

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

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

**DEFENDANTS’ OPPOSITION TO THE PSC’S MOTION
TO CHALLENGE DESIGNATIONS AND
RELIEF FROM PRETRIAL ORDER NO. 12**

I. INTRODUCTION

Disregarding the Court’s Protective Order (“Pre-Trial Order 12”), which was entered with the approval and consent of all parties, the plaintiffs have interjected innuendo, supposition and cherry-picked sound-bites from internal emails and other documents into the public domain, enlisting the aid of favored media outlets, with the hope, seemingly, of bolstering their litigation position. Their success in creating a public spectacle is manifest – within approximately 45 minutes of the filing of the plaintiffs’ motion, the press appeared on the defendants’ doorstep with a list of questions that echo, if not copy, those questions the plaintiffs had asked several days earlier in depositions. The defendants submit that the plaintiffs’ argument that these internal emails are somehow necessary for the U.S. Food and Drug Administration (“FDA”) to further assess the use of the INRatio® Monitoring System (“INRatio® Device”) in the ROCKET AF Trial is meritless. Nonetheless, the defendants have provided to the FDA the emails and documents that are at issue in this motion. Thus, the plaintiffs’ motion is moot. That should be the end of inquiry, and the Court should deny the motion.

The ROCKET AF Trial was a multi-center, randomized, double blind clinical trial comparing Xarelto® to dose-adjusted warfarin in approximately 14,000 patients with non-

valvular atrial fibrillation (“AF”). More than 1,000 sites in more than 40 countries participated in the trial. The results of the trial demonstrated that Xarelto® had an overall favorable efficacy and safety profile when compared to warfarin. Since the 2014 recall of the INRatio® Device, the defendants and, independently, Duke Clinical Research Institute (“DCRI”), which conducted the ROCKET AF Trial, performed a reanalysis of the data. All have confirmed that the original results of the ROCKET AF Trial remain unchanged. The European Medicines Agency (“EMA”) separately conducted a review of the defendants’ reanalysis and concluded that “any incorrect measurements obtained with the defective device would have had only a marginal effect on the study results, and the safety of Xarelto remains unchanged” and noted that “data from other large studies confirmed the comparative safety of the medicine and showed similar rates of bleeding in their warfarin groups.”¹ DCRI reached the same conclusion after conducting “a secondary analysis [after the recall] of the trial findings [which] are consistent with the results from the original trial and do not alter the conclusions of ROCKET AF—rivaroxaban is a reasonable alternative to warfarin and is non-inferior for the prevention of stroke and systemic embolism with less intracranial hemorrhage and fatal bleeding.”²

The plaintiff lawyers’ putative “public interest” motives for bringing this motion are largely a sham. The unstated but primary purpose of this motion has been achieved – the creation of press coverage designed to pressure defendants. Their proposal to interject emails and deposition testimony gleaned from argumentative and leading questions into a scientific review of the ROCKET AF Trial are not significant to an objective evaluation of the results of

¹ http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2016/02/news_detail_002465.jsp&mid=WC0b01ac058004d5c1; *see also* PSC Mot., Ex. F.

² <https://www.dcri.org/research/news/dcri-news-2016/rocket-af-re-analysis-published>.

ROCKET AF Trial. Nevertheless, defendants have provided the entire cherry-picked collection to FDA. For these and the reasons set forth below, the motion should be denied.

II. BACKGROUND

A. Xarelto®

Xarelto® (rivaroxaban) is an FDA-approved prescription medicine that is prescribed to reduce the risk of serious and life-threatening conditions such as stroke, deep vein thrombosis (“DVT”), and pulmonary embolism (“PE”), in certain patients. PSC Mot., Ex. A. Since Xarelto® was first approved in 2011, the FDA has repeatedly assessed and endorsed Xarelto®’s efficacy and safety profile by expanding its approved uses. Xarelto® continues to be extensively studied; more than 275,000 patients will have participated in the rivaroxaban clinical development program, including in clinical trials, independent registries and non-interventional studies. Moreover, post-market observational studies of more than 25,000 patients have confirmed the favorable benefit-risk profile of Xarelto® in patients with atrial fibrillation.³ It is important, as instructed in the package insert that “Premature discontinuation of any oral anticoagulant, including XARELTO, increases the risk of thrombotic events,” and patients should not discontinue this medicine without consulting with a healthcare professional. PSC Mot., Ex. A.

The plaintiffs’ motion and the resulting press coverage about it is not inconsequential to public safety – but for a different reason than that propounded by Plaintiffs. Patients who discontinue anticoagulant medications without consulting their physicians may be at an increased risk of sustaining a serious adverse event such as a stroke, embolism or death. In a recent report

³ See Tamayo et al., *Characterizing Major Bleeding in Patients With Nonvalvular Atrial Fibrillation: A Pharmacovigilance Study of 27 467 Patients Taking Rivaroxaban*, Clin. Cardiol. 38, 2, 63–68 (2015). There is also significant clinical experience that Xarelto provides substantial benefits to patients in need of anticoagulant medications. See <http://www.ncbi.nlm.nih.gov/pubmed/25588595>.

published in *Heart Rhythmic Case Report*, the author noted that “[b]eginning in 2014, advertising has appeared on television, radio and in print media directed toward patients who may have experienced adverse clinical evidence while on rivaroxaban.”⁴ The article reported on 31 individual patients who “discontinued their anticoagulant without consulting their physician after viewing negative rivaroxaban legal advertising.” *Id.* at 4. Seventy-five percent of these “patients experienced a stroke or a transient neurologic event, 2 patients had persistent residual paralysis,” with some incidents resulting in death. *Id.* The author noted that “[c]ontinued partnership between drug manufacturers, physicians, regulators and patients is necessary to provide sufficient education to ensure that these important medical events do not occur.” *Id.* This article reinforces that sensationalized advertisements and negative media reports to discontinue a course of treatment with an anticoagulant medication may have serious negative consequences for patients.

B. ROCKET AF Trial

The ROCKET AF Trial was a rigorously designed, multi-center, randomized, double-blind trial comparing Xarelto® with dose-adjusted warfarin in approximately 14,000 patients with nonvalvular AF at moderate to high risk for stroke. The trial consisted of more than 1,100 participating sites in more than 40 countries. The primary purpose of the trial was to demonstrate that Xarelto® is non-inferior to dose-adjusted warfarin for the prevention of thromboembolic evidence in subjects with AF, and that Xarelto® was superior in relation to as major and non-major bleeding events. The ROCKET AF Trial was conducted by well-qualified investigators who followed the trial protocol to ensure the validity and accuracy of the study.

⁴ Burton, Paul, et. al., A Medwatch Review of Reported Events in Patients Who Discontinued Rivaroxaban (XARELTO) Therapy in Responses to Legal Advertising, *Heart Rhythm Case Reports* (forthcoming 2016), available at [http://www.heartrhythmcasereports.com/article/S2214-0271\(16\)00014-2/pdf](http://www.heartrhythmcasereports.com/article/S2214-0271(16)00014-2/pdf).

C. The Selection of the Hemosense INRatio® Device

The double-blind nature of the ROCKET AF Trial required investigators to receive INR values in a manner that would preserve the integrity of the study blind, and required that a process be followed to ensure that investigators did not know whether they were treating patients with Xarelto® or warfarin. In establishing the study protocol, the Study's Executive Committee debated the use of a central laboratory, local hospital laboratories or "point-of-care" device to measure blood coagulation. Given the challenges associated with maintaining the integrity of a blind study and the obstacles associated with laboratory testing, including the accuracy of test results, the trial leadership decided that investigators would use a point-of-care device to obtain an INR value.⁵ The use of a point-of-care device removed any need for sample shipment and storage and did not raise concerns related to laboratory results that could result in the unblinding of the study. A point-of-care device, as opposed to a laboratory test, also allowed clinical investigators to make treatment decisions for their patients in real-time while maintaining the study blind.

The Hemosense INRatio® Device was the point-of-care device that was selected for the trial, among several different potential devices that were considered. Among the selection considerations was the desire to have a device that was FDA-cleared, could be used for research purposes, was portable and hand-held and auto-calibrated and could be used with a printer for real-time recordation.

⁵ A point of care device is a device that can be used for treatment at the time that an individual is being treated by the physician. In the context of blood measurements for coagulation, physicians can administer the blood test while the patient is at the doctor's office.

The Executive Committee for the ROCKET AF Trial discussed the use of three different devices, but the INRatio® Device was the only device that satisfied all of the criteria necessary to comport with the study design.

The FDA recalled the INRatio® Device in December 2014. This was more than five years after the ROCKET AF Trial concluded and four years after the results were published in the *New England Journal of Medicine*. Janssen and Bayer learned of the recall in September 2015. Upon learning of the recall, Janssen and Bayer immediately undertook steps to re-evaluate the results of the trial, and also notified regulatory agencies around the world.

D. The Covance Recheck Program

Plaintiffs' motion also makes reference to the "Covance Recheck Program." The Covance Recheck Program was a component of the ROCKET AF Trial that consisted of an unblinded monitor who oversaw an external check and validation process for the INR measurements obtained from the INRatio® Device. The program was instituted in response to questions received from investigators who were accustomed to obtaining measurements from laboratory tests. PSC Mot., Ex. L at 169. The Program was implemented to give assurance, both on the use of the device and the readings, to investigators who had not previously used a point-of-care device. The INRatio® Device readings were confirmed by the unblinded monitor through re-checking the measurements of the point-of-care readings through laboratory test results (Covance). All investigators had access to the program and were notified of the availability of the program in a letter. The unblinded monitor was responsible for consulting with physicians to discuss specific issues, if needed. Of the more than 14,000 patients over three years, there were 142 inquiries from investigators who availed themselves of the recheck program. *Id.* at 219. Most of the time, the values from the INRatio® device and the lab re-check

were consistent. There were just 16 instances identified where the value from the point-of-care device and lab were recorded as inconsistent. Where results were determined to be below or above the target range, the investigators received correspondence reminding them of the importance of achieving a target INR reading.

The role of the unblinded monitor is familiar to regulatory authorities. The EMA's report explains the role of the unblinded monitor as follows:

A monitor unblinded to study data was employed to review INR data and ascertain if subjects were frequently out of range. This monitor could consult with a physician unblinded to study data at DCRI to discuss specific cases, if needed. Occasionally and as a result of these surveillance efforts, specific investigators whose patients were found to be persistently below or above the target range received correspondence reminding them of the importance of achieving the INR target. The monitor unblinded to study data was also available to answer questions about individual INR results, in a blinded fashion, from investigators, through local medical monitors.

PSC Mot, Ex. F at 11.

E. Laboratory Samples Were Taken at Weeks 12 and 24 and Unlocked at the Conclusion of the ROCKET AF Trial

Plaintiffs' motion also references (in a footnote) certain blood sampling. During the ROCKET AF Trial patients underwent laboratory blood measurements at weeks 12 and 24. These results remained locked until the conclusion of the trial in 2010. Those measurements were available to both the EMA and DCRI as part of their reanalysis. The EMA recently assessed the reanalysis comments on these laboratory results:

[O]nly for 2 time points (Week 12 and Week 24) were trial Lab based INR values with a corresponding Device based INR value available. A device performance analysis was performed in this subset of patients at Week 12 and Week 24. It was revealed that there was a linear correlation for the Lab based INR value to the Device based INR value at Week 12 and 24 for the subjects with or without any recall-related time of observation. Using discrepancy specifications adapted from those defined in 2007 ISO 17593, nearly 90% of the Warfarin treated subjects in the ROCKET AF trial showed no discrepancy between the Lab based INR value and Device based INR value at Week 12 or at Week 24.

PSC's Mot., Ex. F at 36. The EMA's report further states:

The MAH would like to reiterate that the initial response (dated 15 October 2015) with the three sensitivity analyses constitutes the most sound assessment of the effect of the Alere correction notice on the ROCKET AF trial and provides the evidence that the results and conclusions from the ROCKET AF trial remain valid.

Id.

The plaintiffs' assertion that data about these blood samples were withheld is simply not true – they were provided to the FDA and to the EMA and were in the possession of DCRI. The plaintiffs' motion also refers to a few isolated patients who were seen outside of the trial and had laboratory tests performed for various reasons. In those instances, Janssen evaluated those results as necessary and performed the appropriate follow up. These measurements were not available for the overwhelming vast majority of patients in the trial, and therefore would not be a basis for any reliable assessment of the performance of the INR.

F. Re-Analyses by the Companies and DCRI

Both the defendants and DCRI have conducted thorough reanalyses of the results of the ROCKET AF Trial to ensure the accuracy of the results after the recall of the INRatio® Device. After reviewing the INR measurements and the clinical data as submitted by Bayer, the EMA conducted a robust review of the reanalysis and reiterated that those results “confirm[ed] the positive benefit/risk profile which rivaroxaban provides.” PSC Mot., Ex. F at 18. The EMA concluded that:

[After taking] into consideration that INRatio device was used to assess PT INR values in the trial, [the result] shows little change from the original analysis for rivaroxaban versus warfarin. The effect of potentially discrepant INR readings does not alter the conclusions of the ROCKET AF Trial.

Id.

Similarly, after the recall of the INRatio® Device the Executive Committee of DCRI undertook a rigorous analysis of the ROCKET AF Trial. The DCRI confirmed its original

conclusion that “rivaroxaban is noninferior to warfarin for prevention of stroke and systemic embolism in patients with nonvalvular atrial fibrillation and additional stroke risk factors, and its use is associated with less bleeding.” In particular, the DCRI reported its findings⁶ as follows:

The purpose of the re-analysis was to determine what effect, if any, the possible malfunctioning of the device may have had on the original trial’s conclusions. The device recall occurred in 2014, four years after the trial’s completion.

The results of the re-analysis confirm the original study’s finding that the anticoagulant rivaroxaban is noninferior to warfarin for prevention of stroke and systemic embolism in patients with nonvalvular atrial fibrillation and additional stroke risk factors, and its use is associated with less bleeding. The re-analysis found that any possible malfunction of the device that could have led to lower INR measures than laboratory testing did not have any significant clinical effect on the primary efficacy and safety outcome measures recorded in the ROCKET AF trial. The results among patients with no conditions and among patients with any condition possibly affecting device function were consistent with the results of the overall trial population and with each other.

The re-analysis by the Executive Committee is separate from, and in addition to, the study sponsor’s analysis, which has been provided to U.S. and European regulatory agencies. The results of the Executive Committee’s re-analysis have undergone peer review and statistical review and appear as a research letter in the online edition of the *New England Journal of Medicine*. The Executive Committee has worked diligently to conduct the re-analysis and to get a peer-reviewed research letter into the public domain as quickly as possible and will continue to discuss options for additional analysis of the data, including review and replication by other groups.

G. The FDA’s Inquiry and Documents and Testimony at Issue

On January 12, 2016, Janssen received an Information Request from the FDA seeking information about the recent recall of the INRatio® Device manufactured by Hemosense that was used in the ROCKET AF Trial to monitor the coagulant properties of blood in patients participating in the trial. Janssen responded to the FDA’s request in a 495-page submission

⁶ <https://www.dcri.org/research/news/dcri-news-2016/rocket-af-re-analysis-published>; See also Patel, et al., Point-of-Care Warfarin Monitoring in the ROCKET AF Trial, *N. Engl. J. Med.* 2016; 374:785-788 (February 25, 2015) (<http://www.nejm.org/doi/full/10.1056/NEJMc1515842>)

detailing its use of the INRatio® Device, serious adverse events and other information that was requested. PSC Mot., Ex. E at 109. Janssen's response included:

- (1) A list of Serious Adverse Events ("SAEs") as requested by the FDA in connection with use of the INRatio® Device, as well as Janssen's methodology for identifying particular SAEs that may be of interest to the FDA.
- (2) An explanation of why a point-of-care device such as INRatio® Device was used, including the benefits of allowing investigators to receive "real-time" results to monitor coagulation for on-site treatment, rather than having to wait on lab results that would have required sample shipment and storage. Janssen also explained the various products that were considered and why the INRatio® Device was chosen.
- (3) The models for the serial numbers, part numbers and test strip lot numbers for the INRatio® Devices that were used in the ROCKET AF Trial.
- (4) A detailed explanation of how the INRatio® Device was used in the ROCKET AF Trial and measures taken to ensure that the study remained double-blinded.
- (5) A report explaining the role of an unblinded monitor to evaluate the readings of the INRatio® Device and to take appropriate steps to contact investigators and others when measurements were not consistent with the treatment regimen.
- (7) A detailed explanation of the training on use of the INRatio Device that was provided to investigators who were participating in the ROCKET AF Trial as requested by the FDA.
- (8) A summary of the study protocol that was used to collect laboratory test results and to analyze those results as requested by the FDA.

The plaintiffs' motion goes well beyond the FDA's specific inquiries and alleges that Janssen should have produced virtually every email and document relating to a blood measurement taken during the ROCKET AF Trial. Rather than focus on the specific issues raised by the FDA in the context of evaluating any effect of the recall on the ROCKET AF Trial, the PSC's allegations focus on *the plaintiffs'* theories of purported wrongdoing that *the plaintiffs* are pursuing as part of the litigation. The categories of documents identified by the PSC consist of (1) deposition testimony of Dr. Christopher Nessel, and (2) emails from various individuals

who were following study protocol to ensure the safety of patients and the integrity of the study.

The documents identified in the PSC's Motion include the following:

- Communications to and from the FDA concerning the INRatio® Device and emails regarding these communications. (Ex. E and Z). The FDA is already aware of its own communications with Janssen.
- Emails discussing the INR results of particular patients and the plan to investigate the results. (Exs. B, I, M, O, Q, R). Regulatory authorities are aware that individuals were treated outside the clinical study and may have had laboratory test results performed for reasons unrelated to the study that were reported to study monitors.
- Emails related to communications between the FDA and Hemosense (Ex. V and W). The FDA is already aware of its own communications with Hemosense.
- An email about the re-analysis of the ROCKET AF Trial (Ex. G). Both EMA and DCRI have performed a re-analysis and published the results.
- Correspondence about an investigator applying the INRatio® Device reading improperly (Ex. S) and other documents about ensuring accuracy and training related to use of the INRatio Device. (Ex. U, X, Y, BB). Regulatory authorities are already aware of the training program and the role of the unblinded monitor.
- An email dated October 29, 2007 discussing the role of the unblinded monitor and proposal to educate investigators on the use of the INRatio® Device (Ex. CC). The EMA reported on the role of the unblinded monitor in its report on the re-analysis of the ROCKET AF Trial.
- The transcript of the February 16 and 17, 2016 of Dr. Christopher Nessel, Vice President and Franchise Medical Leader, Cardiovascular Medicine, of Janssen.

The FDA already has the vast majority of what is contained in Exhibits E, V, W, and Z, which includes regulatory documents. 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. Therefore this motion is now moot.

H. The Protective Order

Pre-Trial Order No. 12 was entered with the consent of both sides in the litigation. It allows parties to designate "Protected Documents" and "Protected Information" in order to

“facilitate prompt discovery and the preparation for trial” without the need to litigate the confidentiality of documents before trial. PTO 12, ¶ 1. Materials that are subject to PTO 12 include documents or information that “may reveal trade secrets, manufacturing processes, proprietary design, drug formulation, drug development, sequencing, chemical stability and characteristics, analytical methods used in manufacturing, quality control processes, CMC information exchanged with the FDA and not the subject of a patent, source and specification for drug components and raw materials, manufacturing plans...” and other information. PTO 12, ¶ 7.

Pre-Trial Order 12 establishes a clear mechanism for challenging the designation of a document as confidential. In particular, the party seeking to challenge the designation of a “Protected Document” is required to notify the designating party who then has fourteen days to respond. If the parties cannot reach an agreement, the designating party has thirty days to file and serve a motion for protective order, unless the court orders otherwise. PTO 13, ¶ 13. Pending a court determination, no document or information designated as “Protected” shall be disseminated. PTO 12 also provides that if an administrative agency subpoenas “Protected Information” the person receiving the subpoena must notify the designating party and in “no event shall ‘Protected Information’” be produced before the expiration of fifteen business days after notice to counsel for the designating party unless required to do so by the order seeking the documents.” PTO 12, ¶ 28.

The PSC followed *none* of these procedures here. Going forward the protective order process should be honored, and further, the case should be prepared for trial, with trial being the time to put the documents in the public domain in context.

III. ARGUMENT

A. Janssen's Ongoing Cooperation with the FDA Concerning the Recall of the INRatio® Should Not Be Driven by Allegations of the PSC

Requests like this – to prematurely disseminate pretrial discovery to federal regulatory agencies and the public at large – have been rejected by other MDL Courts and should be rejected by this Court. See, e.g., *In re: Yasmin and Yaz (Drospirenone) Marketing, Sales Practices and Products Liability Litigation* (MDL 2100), 2011 U.S. Dist. LEXIS 130610 (S.D. Ill. Nov. 10, 2011)(citing *Seattle Times*, 467 U.S. 20); *In re Denture Cream Prods. Liab. Litig.* 2013 U.S. Dist. LEXIS 8114 (S.D. Fla. Jan. 18, 2013). In rejecting a similar request by Plaintiffs' counsel to submit pre-trial discovery to the FDA, the court in *In re Denture Cream* emphasized that “there has been no assertion that the FDA is incapable of seeking the production of documents at issue . . .” 2013 U.S. Dist. LEXIS 8114, at 53. Other courts have made the same observation and concluded that “[i]t is not the role of courts to evaluate or enforce the degree to which manufacturers comply with FDA regulations” or inquiries. *In re Incretin Mimetics Prods. Liab. Litig.*, Case No. 12md2452, 2014 WL 4987877, *3 (S.D. Cal. 2014). Efforts similar to those pursued by the PSC in this case “erode the FDA’s role in pharmaceutical regulation. . .” *Id.* at *4.

Courts defer to the FDA’s regulatory power and recognize that litigation-driven positions only detract from the FDA’s role and responsibilities to serve as an independent regulatory authority and to act in the best interest of the public. As one court noted, “[t]he judiciary and its litigants are neither the appropriate people nor the appropriate forum for evaluations of compliance with FDA” reporting requirements or inquiries. *Id.* at *3; see also *Wilson v. Wyeth*, 3:07-CV-00378-R, 2008 WL 4696995 at * 6 (W.D.Ky.) (“It is the proper role of the FDA, not the

Court to determine whether Defendants have failed to comply with FDA reporting requirements.”).

These decisions illustrate the impropriety of the plaintiffs’ motion. The plaintiffs’ argument is based on an overly broad reading of the FDA’s inquiry, followed by an assertion that Janssen did not submit to the FDA what *the PSC* thought Janssen should have submitted. In calling into question the adequacy of Janssen’s response, the plaintiffs ignore that many of the documents were generated by the FDA itself. In any event, the plaintiffs now seek to intrude into the regulatory process to inject a litigation bias, which the U.S. Supreme Court condemned in *Buckman v. Plaintiffs’ Legal Committee* (2000) 531 U.S. 341, 350. As exemplified in *Buckman*,

[The PSC’s assertions] would . . . cause applicants [seeking approval of medications] to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court. Applicants would then have an incentive to submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA’s evaluation of an application.

Id. at 351.

The plaintiffs’ strategy undermines the very principles upon which the FDA undertakes an independent review of data and other information relevant to its inquiry. It is not the role of the PSC to treat patients or decide whether documents or deposition testimony should be provided to the FDA in response to ongoing communications about the recall of a medical device manufactured by a third party. The FDA is fully aware of the recall and that Alere’s (Hemosense) device was used to monitor blood coagulation during the ROCKET AF Trial. Accusations that information from emails handpicked by the plaintiffs would impact the results of the data analyzed for the ROCKET AF Trial and that has been provided to the FDA has no

support and indeed is contrary to the scientific conclusions of the EMA and DCRI. Accordingly, the motion, even if not now moot, should be denied.

B. The Documents and Deposition Testimony Should Be Limited to Use by Counsel and the Parties to this Litigation

Federal Rule of Civil Procedure 26(c)(1) permits a court, for good cause shown, to curtail improper dissemination of documents and information. A court may preclude, limit or restrict the dissemination of “trade secrets or other confidential research, development, or commercial information not be revealed or be revealed only in a designated way.” In ascertaining whether good cause exists to protect certain information, courts “balance the party’s interest in obtaining access against the other party’s interest in keeping the information confidential.” *In re Denture Cream*, 2013 U.S. Dist. LEXIS 8114, at *39-40. “Rule 26(c) confers broad discretion on the trial court to decide when a protective order is appropriate and what degree of protection is required.” *Pena v. Casteel*, 2016 U.S. Dist. LEXIS 24125 (W.D. La. Feb. 26, 2016) (citing *Seattle Times*, 467 U.S. 20); *see also Cazaubon v. MR Precious Metals, LLC*, 2015 U.S. Dist. LEXIS 104923 (E.D. La. Aug. 17, 2015); *In re Swift Energy, Co.*, No. 13-5552, 2015 WL 1281043, at *3 (E.D. La. Mar. 20, 2015).

This Court entered PTO 12 to limit use of “Protected Documents” to the parties and counsel to this litigation. Pursuant to PTO 12, the PSC already has access to the documents and information in question that they now claim should be shared more broadly. These materials include deposition testimony and numerous emails regarding FDA communications and assessments of isolated INRatio® readings for a small group of individual patients that were part of the ROCKET AF Trial. There is good cause to maintain the “Protected” status of these documents. Because these documents and the deposition testimony consist entirely of study investigators, and other qualified individuals, assessing blood coagulation measurements and

treatment regimens involving Xarelto® and warfarin that are of a highly technical nature and would require expert analysis to interpret, there is a substantial risk that the emails and deposition testimony will be misconstrued, misinterpreted and taken out of context and potentially cause confusion, if disclosed broadly to the public or otherwise.⁷

Good cause also exists where an “order protects the rights of the parties to be free from a negative media campaign that poses the potential result of trying the suit in the public before a jury of the parties’ peers has the opportunity to weigh the evidence and to arrive at an appropriate and open judicial remedy.” *Pamlab, L.L.C. v. Broostone Pharm., LLC*, 2010 U.S. Dist. LEXIS 120303, at * 5 (E.D. La. Oct. 22, 2010). The plaintiffs’ motion has already (as intended) resulted in negative media attention to try this case in the public domain, which increases the likelihood that patients may discontinue treatment, with potential serious health consequences. Limiting use of the “Protected Documents” to this litigation also will allow the FDA to undertake an independent review – without the PSC’s litigation-driven motives – of any impact of the 2014 INRatio® Device recall on the ROCKET AF Trial.

C. There Is No First Amendment Right to Disseminate Materials Produced During Pre-Trial Discovery

The Supreme Court decision in *Seattle Times v. Rhinehart*, 467 U.S. 20, 34 (1984), confirmed that there is no legally protected First Amendment right to disseminate documents produced during the course of discovery. The rationale behind the Court’s decision underscored

⁷ These “Protected Documents” and emails relating to the conduct of the ROCKET AF Trial also qualify as confidential information pertaining to research and development. *See, e.g., Star Scientific, Inc. v. Star Tobacco & Pharm., Inc.*, 204 F.R.D. 410, 416 (S.D. Ind. 2001) (finding that “information relating to how [a party] process[es] their product, its research and development” is protected); *Containment Techs Group, Inc. v. Am. Soc’y of Health Sys. Pharmacists*, No. 07-997, 2008 WL 4545310, at *1-2 (S.D. Ind. Oct. 10, 2008) (finding protected documents because party spent significant time and money pertaining to research and development).

the fundamental problems and policy concerns associated with public dissemination of discovery material before trial or dispositive motion practice. A litigant does not have “an unrestrained right to disseminate information that has been obtained through pretrial discovery” and “pretrial depositions and interrogatories are not components of a civil trial. Such proceedings are conducted in private. . .” 467 U.S. at 30, 33. As a result, “restraints . . . on discovery, but not yet admitted, information are not a restriction on a traditionally public source of information.” *Id.* at 33. “[P]retrial discovery by depositions and interrogatories has a significant potential for abuse” (*id.* at 34) and “[a]n order prohibiting dissemination of discovered information before trial is not the kind of classic prior restraint that requires exacting First Amendment scrutiny.” *id.* at 25.

Since *Seattle Times*, courts have consistently held that, upon issuance of a valid protective order under FRCP 26(c), a litigant has no right to disseminate protected information obtained through pre-trial discovery. *See, e.g., Reyes v. Freeberry*, 141 Fed.Appx. 49, 51 (3d Cir. 2005) (“When a civil litigant obtains discovery pursuant to a valid protective order, the litigant has no First Amendment right to disclose the information”); *U.S. v. Microsoft Corp.*, 165 F.3d 952, 959-60 (D.D.C. 1999) (“[T]he good cause standard of Rule 26(c) comports with the first amendment not fortuitously but precisely because it takes into account all relevant interests, including those protected by the first amendment.”); *Cippollone v. Liggett Group, Inc.*, 785 F.2d 1108, 1119 (3d Cir. 1986) (“*Seattle Times* prohibits a court considering a protective order from concerning itself with first amendment considerations”); *In re Denture Cream*, 2013 U.S. Dist. LEXIS 8114 (“[T]he common-law right of access to judicial proceedings does not apply to discovery materials, “as these materials are neither public documents nor judicial records.”); *In re: Yasmin*, 2011 U.S. Dist. LEXIS 130610 (*citing Seattle Times*, 467 U.S. 20) (“Litigants do not

have an unfettered First Amendment right to disseminate documents obtained through the discovery process.”).

Courts have similarly rejected First Amendment challenges to protective orders where a party demonstrates “good cause” to limit dissemination of materials obtained through discovery. *See In re Zyprexa Injunction*, 474 F.Supp.2d 385, 423 (E.D.N.Y. 2007) (protective order restricting dissemination of confidential materials produced during discovery did not violate parties’ First Amendment rights); *In re Alexander Grant & Co. Litig.*, 820 F.2d 352, 355 (11th Cir. 1987) (First Amendment did not entitle publisher and journalist to access confidential materials produced in discovery where protective order was issued upon showing good cause); *Pamlab, L.L.C.*, 2010 WL 4363879, at *4 (rejecting plaintiff’s request to remove confidential designation from defendant’s discovery responses in reliance on *Seattle Times*); *Philips v. General Motors Corp.*, 307 F.3d 1206 (9th Cir. 2002) (Discovery materials submitted to a court in connection with a “non-dispositive motion, the usual presumption of the public’s right of access is rebutted...”); *Kamakana v. City and County of Honolulu*, 447 F.3d 1172, 1179 (9th Cir. 2006).

The plaintiffs’ request to disclose pre-trial discovery to the FDA and outside of this litigation is not based on a legally protected right, and their assertion that they intend to share documents and deposition testimony with the FDA does not change the analysis. The right to petition the government for grievances is not unlimited and does not include use of protected information obtained through pretrial discovery. *Wagner v. City of Holyoke*, 241 F.Supp.2d 78, 103 (D. Mass. 2003). As noted in *Seattle Times*, a plaintiff is free to petition the government and may support that petition with information that is not subject to protection or with any other information gathered outside the discovery process. *Seattle Times*, 467 U.S. at 33. (“[T]he party

may disseminate the identical information . . . gained through means independent of the court's processes").

The First Amendment right to disseminate discovery is not triggered until a dispositive motion or trial, at a time when there is a fair opportunity for both sides to put the evidence into context and to argue the merits under the Federal Rules of Evidence. Sound judicial policy and fundamental fairness dictate that the PSC not be permitted to selectively pick and choose the documents and deposition testimony for disclosure to the FDA or otherwise. Nor should Janssen, or Bayer, have to defend this case in the media by responding to the PSC's attempts to misconstrue the testimony and emails.

The significant interests in limiting the use of the pre-trial discovery materials to this litigation clearly outweigh the PSC's purported desire to disseminate these documents. This Court should allow Janssen to continue its dialogue with the FDA and provide supplemental information relating to its use of the INRatio® Device during the ROCKET AF Trial. Accordingly, the PSC's Motion should be denied.

IV. CONCLUSION

For these and the foregoing reasons, the PSC's Motion should be denied.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on March 8, 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.

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