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 MOTION TO CHALLENGE CONFIDENTIALITY DESIGNATIONS AND FOR RELIEF FROM PRETRIAL ORDER NO. 12 (STIPULATED PROTECTIVE ORDER)

With the Court's permission, the Plaintiffs' Steering Committee (the "PSC") hereby moves to challenge certain confidentiality designations of Defendants Bayer Corporation, Bayer Pharma AG, Janssen Pharmaceuticals, Inc., Janssen Research & Development, LLC, Janssen Ortho, LLC, and Johnson & Johnson (collectively "Defendants") on recently produced documents, and for relief from the Stipulated Protective Order entered as Pretrial Order No. 12 ("Protective Order").

I. INTRODUCTION

As the Court is aware, Xarelto was compared to warfarin in the ROCKET AF trial to determine if Xarelto was a "non-inferior" alternative anticoagulant that could be prescribed for the prevention of ischemic stroke in patients with nonvalvular atrial fibrillation. In the warfarin arm of the study, the INRatio® point-of-care ("POC") device was used to measure the time it takes for a patient's blood to clot, as expressed by INR ("International Normalized Ratio") values. In order to properly administer warfarin therapy, it is critical to measure the INR of each patient and confirm that they are in, and remain in, the therapeutic INR range of 2.0 to 3.0 with a target of 2.5. *See* Exhibit A (Warfarin Label) at 1 ("Risk factors for bleeding include high

intensity of anticoagulation (INR > 4.0) . . . Those at high risk of bleeding may benefit from more frequent INR monitoring, careful dose adjustment to desired INR, and a shorter duration of therapy."); and at 23 ("The dose of warfarin should be adjusted to maintain a target INR of 2.5 (INR range, 2.0 to 3.0) for all treatment durations. These recommendations are supported by the 7th ACCP guidelines."). An excessive INR reading (> 3) increases the risk of bleeding in a warfarin patient and a low INR (< 2) increases the risk of a clot. Defendants were well aware that proper measurement of the INR values in the warfarin arm by the INRatio point-of-care device was critical to assure the safety of the participants, as well as the validity of the study results. *See* Exhibit B (10/17/2007 from Dr. DiBattiste email to C. Nessel, et al stating: "[redacted]") (XARELTO_JANSSEN_07545453) (Filed Under Seal). Yet, the INRatio® device used in the study to monitor INR was the subject of a U.S. Food & Drug Administration ("FDA") Class I recall[1] because of evidence that the system registered INR results that are "clinically significantly lower" than results using standard laboratory methods. *See* Exhibit C (Dec. 5, 2014 Letter from Alere to Healthcare Professionals). In the context of the ROCKET AF study, such erroneously low INR values would cause an increase of the warfarin dose and directly expose a substantial number of warfarin patients to additional undue and otherwise avoidable risk of major bleeding during the trial. The use of the recalled INRatio device calls into question the validity of the ROCKET AF study.

It has been confirmed that the INRatio® PT/INR Monitor devices used in Defendants' ROCKET AF Phase III trial to support approval of Xarelto was defective. As a result, FDA is

[1] Class I recalls involve "situation[s] in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death." 21 C.F.R. § 7.3 (m)(1).

currently conducting a regulatory investigation to determine what Defendants knew or reasonably should have known about the recalled INRatio® device. As recently as January 12, 2016, FDA propounded an information request to Defendants seeking information in their possession on this topic. Exhibit D (1/12/2016 FDA Information Request) (XARELTO_BHCP_07995641) (Filed Under Seal). Alarmingly, however, a review of Defendant Janssen's February 5, 2016, response to FDA reveals a misleading, inaccurate and/or incomplete portrayal of the facts. *See* Exhibit E (2/5/2016 Response to FDA Information Request) (XARELTO_JANSSEN_16397478) (Filed Under Seal).

Documents produced in recent discovery in this litigation disclose that Defendants possess substantial evidence indicating that they knew *prior* to the start of the ROCKET AF trial that the INR monitoring device chosen for the trial was prone to malfunction and that risk of error in the INR readings was great. *See, infra,* at 12-13. Indeed, substantial evidence exists that the device did malfunction during the course of the ROCKET AF trial and that Defendants were aware of the malfunctions *during the trial* but did not provide that information to the FDA and other regulators around the world. The FDA's ongoing review of this critical safety issue impacts a majority of the Plaintiffs in this MDL, most of whom were prescribed Xarelto for the atrial fibrillation indication. For that reason, the PSC believes it is important and urgent that a prompt submission be made to FDA of information and documents that, unbeknownst to FDA, exist and are responsive to FDA's January 12, 2016, Information Request. Janssen has improperly failed to disclose to FDA the true and full story told through these documents. Defendants' overly broad confidentiality designations prevent the PSC from disclosing this knowledge with parties outside this litigation—most importantly, FDA. As such, the PSC

challenges the confidentiality designation of the documents identified herein and seeks relief from the Protective Order to allow disclosure.

A. FDA's Investigation and Defendants' Response

An assessment report issued by the European Medicines Agency ("EMA") on February 5, 2016, traces the history of Defendants' acknowledgments of the potential impact of the defective INRatio® device on the ROCKET AF trial results. Exhibit F (2/5/2016 EMA Report).[2] EMA stated that "on September 9, 2015,[3] [Janssen Research & Development, LLC] became aware through a third party that the recall notice of the Alere INRatio® device might be applicable to the HemoSense INRatio® devices used in the ROCKET AF trial program as well."[4] *Id.* at 5. Upon learning of this issue, Defendants informed global health authorities per local regulations. *Id.* at 6. A series of information requests and responses ensued between global regulators—including FDA—and Defendants.

As of February 5, 2016, the following communications between FDA and Defendants relative to this topic had occurred:

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[2] The EMA concluded that "the benefit/risk balance remains unchanged and favorable for treatment with rivaroxaban …" *Id.* at 41. However, like FDA, the EMA was deprived of critically important information that sheds light on the full extent of the impact of this device on the results of ROCKET AF. Further, EMA's conclusion is at odds with defendants own *internal confidential* assessment of the sensitivity analyses, which points out that they are merely "[redacted]" that hold "[redacted]" and "[redacted]" Exhibit G (9/22/2015 Meeting Minutes) (XARELTO_BHCP_07993872) (Filed Under Seal).

[3] This is at odds with documents obtained from Defendant Janssen that make clear that Alla Rhoge – responsible for regulatory affairs pertaining to Xarelto - first became aware of the Alere INRatio recall in December 2014. See Exhibit H (12/10/14 Email) (XARELTO_JANSSEN_14522268)

[4] As explained in the EMA report, when Defendants purchased the devices and testing strips for use in the clinical trial, HemoSense Inc. was the manufacturer. HemoSense Inc. was subsequently purchased by a company now known as Alere. Exhibit F. at 5.

- On September 29, 2015, [redacted]
- On October 15, 2015, [redacted]
- On November 16, 2015, [redacted]
- On December 14, 2015, [redacted]
- On December 21, 2015, [redacted]
- On December 23, 2015, [redacted]
- On January 21, 2016, [redacted]
- On February 1, 2016, [redacted]

Exhibit E (2/5/2016 Response of Defendants to FDA's 1/12/16 Information Request) (Filed Under Seal)

EMA's assessment confirmed that the INRatio devices did indeed malfunction. The report affirmatively states that "data provided on INR values estimated simultaneously on weeks 12 and 24 with the two methods (POC device vs. laboratory testing) indicate that discrepancies of potential clinical relevance were rather frequently observed (approximately in 35% of the estimations)." Exhibit F (2/5/2016 EMA Report) at 21. Even more disturbing information is revealed in Table 1 of the EMA assessment report, which indicates that at week 12, the warfarin patients identified by the central lab as having INR values > 4, were misidentified by the defective POC device 28.5% of the time as being below range (47 patients) or within range (172 patients). *Id.* at 28. Or put another way, 28.5% of the time that a warfarin patient was in need of

a downward dose adjustment[5], the defective device generated a result which would incorrectly encourage the treating physicians to either increase the dose or maintain the current dose.

The EMA assessment report further confirms that device malfunctions occurred at a similar frequency and similar degree at week 24, which was the only other time systematic paired samples were collected. Notably, while the results at week 12 and 24 were "similar," the rate of discrepancy was slightly higher at week 24; for example, in the above analysis comparing LAB > 4 to POC < 2 and POC 2 - 3 at week 24, the discrepancies increased to [redacted]%. *See* Exhibit I (Table of Cross Tabulation of Lab INR vs Device Based INR at Week 24 for Warfarin Subjects (XARELTO_BPAG_25624898 at 25624928)) (Filed Under Seal).

FDA was provided this same data on December 14, 2015. Exhibit J (12/14/2015 Submission to FDA) (XARELTO_BHCP_07998728) (Filed Under Seal). Given the alarming rate and degree of discrepancy between the defective device and the central lab data, it is not surprising that FDA launched an investigation into whether there was evidence of the device malfunctioning during the ROCKET AF study.[6] Initial requests for information and submissions

[5] Warfarin dosing guidance indicates that an INR > 4 necessitates a withholding of a dose and/or decrease in total weekly dose. *See, e.g.* ACC/AHA/ESC 2006 Guidelines for the Management of Patients with Atrial Fibrillation, available at http://circ.ahajournals.org/content/114/7/e257 ; American Society of Hematology, 2011 Clinical Practice Guide on Anticoagulant Dosing and Management of Anticoagulant Associated Bleeding Complications in Adults., available at www hematology.org/Clinicians/Guidelines-Quality/Quick-Ref/525.aspx.

[6] A re-analysis of the ROCKET AF data similar to that conducted by Defendants was conducted by Duke Clinical Research Institute (DCRI) and published in the New England Journal of Medicine (Patel et al, Point-of Care Warfarin Monitoring in the ROCKET AF Trial, Feb. 2016, available at http://www.nejm.org/doi/full/10.1056/NEJMc1515842). As part of the peer-review process, DCRI was specifically asked by the NEJM about paired laboratory and POC samples. *See* Exhibit K (XARELTO_BHCP_07998588 at 07998597). (1/11/16 DCRI Letter to NEJM) (Filed Under Seal) Despite being provided this opportunity to respond to the peer-reviewers, Defendants remained silent on this point, thereby misleading the NEJM with respect to the very data on the discrepancies that had already been requested by and provided to two global regulators (FDA and EMA). *See* Exhibit L (2/16/16 Dep. of C. Nessel (Vol. I) at 440:3-18; 443:19-24; 445:6-19; 455:13-20.

by Defendants in the fall of 2015 focused on analyses of the defective device's impact on the clinical trial. In its January 12, 2016, Information Request, however, FDA sought details from Defendants that would shed light on whether evidence of device malfunctioning had surfaced during the trial. FDA's specific requests were as follows:

1. [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted]
7. [redacted]

Exhibit D (1/12/2016 FDA Information Request) (Filed Under Seal).

Discovery in this litigation has exposed the extent to which Janssen failed to respond to FDA in a manner in keeping with the spirit of the requests and the FDA's clear aim to obtain information in Defendants' possession that would demonstrate whether or not the INRatio® devices used during the trial had malfunctioned. Undoubtedly, FDA's goal in its ongoing investigation is to learn what relevant information on device failures exists, who had such information, and when did they have it. Instead Janssen responded with a document and attachments of over 400 pages that *fail* to include *direct* evidence of device malfunctions that the PSC has discovered in document productions, and that fail to provide a complete and accurate description of the roles and responsibilities of individuals with personal knowledge of the malfunctions *specifically* identified in the FDA Information Request. *See* Exhibit E (2/5/2016 Response to FDA Information Request) (Filed Under Seal).

The PSC believes that Defendants provided only minimal and hyper-technical responses to the FDA's January 12, 2016 Information Request, and their belief was confirmed in the recent deposition of Dr. Christopher C. Nessel—a Janssen employee and member of the ROCKET AF Executive Committee—who was involved in responding to the request and who has personal knowledge of the extensive evidence within the company that the defective, now recalled, devices malfunctioned during the ROCKET AF trial. In testifying on his understanding of the purpose and intent of FDA's request, he acknowledged that "[redacted]" Exhibit L (2/16/16 Dep. of C. Nessel (Vol. I) at 140:8-141:6) (Filed Under Seal). However, a review of documents produced to the PSC reveals that Defendants withheld from FDA significant information relevant to FDA's investigation. As shown, *infra*, documents produced under the guise of confidentiality

should be provided to FDA so that a full investigation and understanding can be accomplished, with an end toward steps to protect the health and safety of Xarelto users.

B. "Confidential" Documents Revealing the Truth

Numerous documents produced to the PSC in this litigation provide *direct* evidence of INRatio® device malfunctions that were made known to Defendants while the trial was ongoing. These documents, which consist primarily of email chains, demonstrate that on numerous occasions physicians involved in the ROCKET AF trial raised concerns that the devices were providing inaccurate results. Yet, the adverse events discussed in email correspondence produced to the PSC are nowhere to be found in the body of Janssen's February 5, 2016, response to FDA's Information Request or in its attachments. Examples of information responsive to FDA's requests that is contained in produced documents but was *withheld* from FDA by Defendants, include, but are not limited to, the following:

Site ID	Patient ID	Date	Description of Adverse Event
011608	111178	August 2009	[redacted] Exhibit M (XARELTO_JANSSEN_14455639) (Filed Under Seal)
972022	103804	January 2008	[redacted] Exhibit N (XARELTO_JANSSEN_ 07545439) (Filed Under Seal)
	104237	January 2008	[redacted] Exhibit O (XARELTO_JANSSEN_ 14557758) (Filed Under Seal)
044002	105914	June 2008	[redacted] Exhibit P

			(XARELTO_JANSSEN_ 14558085) (Filed Under Seal)
1028		October 2007	[redacted] Exhibit Q (XARELTO_JANSSEN_11444538) (Filed Under Seal)
11008	100997	October 2007	[redacted] Exhibit R (XARELTO_JANSSEN_03933641) (Filed Under Seal)
049008			[redacted] Exhibit S (XARELTO_JANSSEN_14557687) (Filed Under Seal)
	104078	June 2008	[redacted] Exhibit T (XARELTO_JANSSEN_14724821) (Filed Under Seal)
	106080	August 2008	[redacted] Exhibit T (XARELTO_JANSSEN_14724821) (Filed Under Seal)
	110000	October 2008	[redacted] Exhibit T (XARELTO_JANSSEN_14724821) (Filed Under Seal)
	102310	February 2008	[redacted] Exhibit T (XARELTO_JANSSEN_14724821) (Filed Under Seal)
	112483	March 2009	[redacted] Exhibit T (XARELTO_JANSSEN_14724821) (Filed Under Seal)
	108548	January 2009	[redacted] Exhibit T (XARELTO_JANSSEN_14724821) (Filed Under Seal)
	106355	February	[redacted]

		2010	Exhibit T (XARELTO_JANSSEN_14724821 (Filed Under Seal)
	108508	April 2009	[redacted] Exhibit T (XARELTO_JANSSEN_14724821) (Filed Under Seal)
	105466	May 2009	"[redacted]" Exhibit T (XARELTO_JANSSEN_14724821) (Filed Under Seal)
	112708	May 2009	"[redacted]" Exhibit T (XARELTO_JANSSEN_14724821) (Filed Under Seal)
	100688	February 2009	"[redacted]" Exhibit T (XARELTO_JANSSEN_14724821) (Filed Under Seal)

In fact, the number of concerns that arose about the accuracy and reliability of the device, from the outset of the clinical trial and beyond, led Defendants to create a special program, known as "[redacted]" to investigate suspected instances of INRatio® device malfunctions. Exhibit L (2/16/16 Dep. of C. Nessel (Vol. I) at169:4-170:9) (Filed Under Seal). Surprisingly, this program and its results were not even mentioned by Janssen in its February 5, 2016, response to FDA. *See* Exhibit E (2/5/2016 Response to FDA Information Request) (Filed Under Seal). Janssen's omission is especially troubling in light of the fact that Request No. 5 of FDA's January 12, 2016, Information Request specifically asks Janssen to elaborate "[redacted]" Exhibit D (1/12/2016 FDA Information Request) (Filed Under Seal). In response, Janssen identifies Mr. "[redacted]" as the "[redacted]" but make no mention whatsoever of his role in investigating suspected instances of device malfunction nor the results of his investigations through the [redacted] program. *See* Exhibit E (2/5/2016 Response to FDA Information

Request) (Filed Under Seal); *see also* Exhibit L (2/16/16 Dep. of C. Nessel (Vol. I) at 173:18-174:5) (Filed Under Seal).[7]

Further evidence of Janssen intentionally misleading the FDA is indicated by their response to FDA Request Number 6, through which FDA seeks information about how those who used the INRatio® devices at the point-of-care sites were trained. In their February 5, 2016 response, Janssen provided FDA with a slide deck entitled the "[redacted]" as an example of material shared with personnel involved in the trial. Exhibit E (2/5/2016 Response to FDA Information Request, Attachment 12) (Filed Under Seal). However, in an absolutely brazen attempt to intentionally mislead the FDA about the problems the company was aware of with respect to the device, Janssen inexplicably removed slides directly relevant to the issue at hand that they had created internally. The omitted slides include, but are not limited to: 1) a slide referencing literature stating that "[redacted]" 2) a slide that references Defendants' own experience in the ROCKET AF trial as related in the literature; 3) a slide that indicates that [redacted]% of the time, the INRatio® device misidentifies hyper-therapeutic levels as hypo-therapeutic or therapeutic levels; 4) a slide that cites a peer-reviewed article reporting "[redacted]" and 5) a slide referencing the [redacted] quality control program, the existence of which was hidden from the FDA in its entirety. Compare *Id.* (Attachment 12

[7] Counsel for Defendants who have attended recent depositions where this evidence has been presented also have knowledge that their clients have withheld these documents from global regulators. While all counsel must zealously represent their clients, defense counsel now armed with this knowledge (and who have designated all such evidence as "confidential," are in the untenable position of aiding the Defendants in withholding this information from regulators and the medical community.

XARELTO_JANSSEN_16397907-16397924) with Exhibit U (XARELTO_JANSSEN_13531745 and attached slides) (Filed Under Seal).[8]

Documents produced in the recent discovery in this litigation disclose that Defendants possess substantial evidence indicating that they knew even *prior* to the start of the ROCKET AF trial that the INR monitoring device chosen for the trial was prone to malfunction and that risk of error in the INR readings was great. *See, e.g.,* Exhibit V (1/22/2007 email re: Other Warning Letter to HemoSense (XARELTO_JANSSEN_04962074-77) (Filed Under Seal)); Exhibit W (1/11/2007 email chain re: FDA Warning Letter (XARELTO_JANSSEN_04962095-101) (Filed Under Seal)).

Based, in part, upon evidence of the potential for malfunctions in the ROCKET AF trial, numerous individuals, including members of the ROCKET AF executive committee, expressed concern over the accuracy and reliability of the INRatio® device and specifically called on Defendants to validate the device and/or implement study-wide routine quality control procedures. *See, e.g.,* Exhibit X (2/12/2007 email containing concerns of ROCKET AF executive committee (XARELTO_JANSSEN_13402553)) (Filed Under Seal); Exhibit Y (12/7/2006 email evidencing concerns expressed by investigator (XARELTO_JANSSEN_13403496)) (Filed Under Seal). Sadly, both the concerns and the

[8] This isn't the first time the Defendants have improperly withheld INRatio performance characteristic data from the FDA. In a March 14, 2011, Information Request, the FDA specifically sought [redacted] See Exhibit Z (March 14, 2011 Email from FDA's Alison Blaus to Janssen's Alla Rhoge) (XARELTO_JANSSEN_04932509) (Filed Under Seal) However, in what can now only be described as a pattern and practice of deceit, the Defendants failed to provide the FDA with the data obtained through the secretive [redacted] program as well as their analyses of paired (POC and Lab) samples collected at weeks 12 and 24 – both of which confirmed the performance of the device, as used in ROCKET, was unacceptably poor. See Exhibit AA (March 17, 2011, Janssen's Response to FDA Information Request) (XARELTO_BPAG_06620987) (Filed Under Seal)

recommendations to address them were rejected. *See, e.g.,* Exhibit BB (12/6/2007 email rejecting ROCKET AF executive committee members' concerns and recommendation to "[redacted]" (XARELTO_JANSSEN_13598946)) (Filed Under Seal); see *also* Exhibit CC (10/29/2007 email with meeting minutes describing concern expressed by DCRI and ultimate rejection of routine quality control procedures (XARELTO_JANSSEN_04961856-858)) (Filed Under Seal). As shown, *supra*, as the clinical trial proceeded, the errors and malfunctions that had been feared actually did occur. Yet, the extent of the failures and malfunctions has yet to be revealed to the agencies investigating the impact of the defective INRatio® device on the ROCKET AF trial.

In summary, the documents described above contain information that Janssen failed to disclose to FDA despite the fact that the information is highly relevant to FDA's ongoing investigation into the INRatio® device recall and its impact on the integrity ROCKET AF clinical trial. Defendants' omission of this obviously responsive information from their February 5, 2016, response to FDA's January 12, 2016, Information Request must be addressed to assure that FDA has the information necessary to ascertain the truth about what Defendants knew, and when they knew, about INRatio® device malfunctions. As shown, the documents at issue should not be afforded protection under the Protection Order entered in this litigation.

II. LEGAL ARGUMENT

The Protective Order governing discovery in this MDL provides that a party may designate documents produced in the course of discovery as "PROTECTED INFORMATION" if the documents fall within the categories of information protected under Fed.R.Civ.P. 26(c)(1)(G), which includes "trade secret or other confidential research, development, or commercial information." Pretrial Order No. 12, ¶ 6; Fed.R. Civ.P. 26(c)(1)(G). Additionally,

the Protective Order provides for designation as " 'PROTECTED INFORMATION – HIGHLY PROTECTED' any document or information which, if potentially disclosed to a competitor or the general public, could result in a substantial business harm." Pretrial Order No. 12, ¶ 7. A third designation, "HIGHLY PROTECTED INFORMATION – DEFENDANT RESTRICTED/SUBJECT TO PROTECTIVE ORDER," adds protection from disclosure to a co-defendant. *Id.* The documents at issue herein were produced by Defendants with one of these confidentiality designations.

The PSC seeks relief from the bar to disclosure of these documents on the grounds that the documents contain information that is relevant to a critical public health and safety concern. Indeed, the documents inform the issues at the heart of FDA's investigation into the impact of the defective INRatio® device on the ROCKET AF clinical trial. Hence, they do not deserve protection. *See 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).

Given the urgent health and safety implications, the PSC chose to address its challenge to designation of the documents as protected through this motion rather than through the provisions in paragraph 13 of the Protective Order. *See* Pretrial Order No. 12, ¶ 13; *see also* Pretrial Order No. 12, ¶ 34 (allowing application to the Court for modification of the Order upon good cause shown). The Protective Order's challenge process would be unlikely to result in a satisfactory resolution and, therefore, would only serve to unnecessarily delay the presentment of this pressing matter to the Court. All the while, the FDA would be proceeding with its investigation without full disclosure of information responsive to its Information Request and relevant to its critical health and safety concerns.

This Court has recognized that "'[a]s a general proposition, pre-trial discovery must take place in the [sic] public unless compelling reasons exist for denying public access to the proceedings.'" *The Louisiana Coca-Cola Company, et al*, Civ. A. No. 86-80, 1986 WL 14781, *1 (E.D. La. Dec. 19, 1986) (also observing that "the abstract virtues of sunlight [serve] as a disinfectant"); *see also Citizens First Nat. Bank v. Cincinnati Ins. Co.*, 178 F.3d 943, 946 (7th Cir. 1999) (noting "[m]ost cases endorse a presumption of public access to discovery materials") (citations omitted). The case law also establishes that the Court, and not the parties, ultimately decides whether documents are subject to protection. *Id.* at 945 ("The judge is the primary representative of the public interest in the judicial process and is duty-bound therefore to review any request to seal the record (or part of it)"); *Camilotes v. Resurrection Healthcare*, No. 10-C-366, 2012 WL 2192168, *4 (N.D Ill Jun 14, 2012) ("The timing provisions in the Protective Order do not override the Court's obligation to determine whether good cause exists to seal documents, or portions thereof, from the public record.") (citations omitted).

In balancing the factors a court must consider in determining whether confidentiality is warranted, public health and safety is a prominent concern. *Pansy*, 23 F.3d at 787 ("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) (upholding district court's modification of protective order to allow disclosure of documents to a third party on grounds that the right of public access "was especially strong in this case because of the important public health concerns surrounding the documents in question."). Here, without doubt, public health and safety must override any right of Defendants to protection of the documents at issue.

There can be no dispute that "[t]his Court retains the authority to modify or lift confidentiality orders that it previously entered." *Holland v. Summit Autonomous, Inc.*, No. CIV.A. 00-2313, 2001 WL 930879, *2 (E.D. La. Aug. 14, 2001), citing *Pansy,* 23 F.3d at 784. Such relief is warranted here. Certainly, in the PSC's agreement to entry of the Protective Order and in the Court's approval of the Order, it was never contemplated that overly broad designations would be used to hide health and safety information from the FDA and the public. This point alone justifies lifting the protections from disclosure as to these documents. Further support is found, however, in the fact that the documents are not even covered by the categories afforded. *See Appalachicola Riverkeeper v. Taylor Energy Co., LLC.*, 309 F.R.D. 381, 389-390 (E.D. La. 2015) (ruling that documents summarizing and providing the chronology and facts of events, or constituting investigatory "scientific research," do not fall within the parameters of protection established under Fed.R.Civ.P. 26(c) and the Protective Order).

The PSC has shown there is good cause to lift the Protective Order and allow disclosure of the documents and information discussed herein. When considering designations under a blanket Protective Order, as is the case here, the burden is on the party seeking to protect the documents from disclosure to establish a "good faith" basis for finding that the documents "contain trade secrets or other confidential commercial information" entitled to protection. *See Taylor*, 309 F.R.D. at 387. As in *Taylor*, the Defendants here cannot meet their burden to establish the documents and information are entitled to protected status. *Id.* at 389-390

As shown, *supra*, Defendants are in possession of documents describing events that reveal knowledge withheld from FDA of INRatio® device malfunctions occurring during the ROCKET AF clinical trial. Defendants' investigations of the malfunctions, and research through the [redacted] program on how the defective device was performing during the trial, have

obvious relevance to the FDA's investigation into what Defendants knew, or should have known, about the device failures. Yet, Janssen failed to provide this information to FDA, despite it being responsive to FDA's January 12, 2016, Information Request. Given that there are serious health and safety risks at stake, and that the documents do not fall squarely within the parameters warranting protection under the Protective Order, the PSC respectfully requests that the Court grant its motion and allow disclosure of the documents and information.

III. CONCLUSION

For the reasons set forth above, the PSC's motion should be granted.

Respectfully submitted,

/s/ Leonard A. Davis

Leonard A. Davis, Esq. (Bar No. 14190)
HERMAN, HERMAN & KATZ, LLC
820 O'Keefe Avenue
New Orleans, LA 70113
PH: (504) 581-4892
FAX: (504) 561-6024
Email: ldavis@hhklawfirm.com

Gerald E. Meunier (Bar No. 9471)
GAINSBURGH BENJAMIN DAVID MEUNIER & WARSHAUER, LLC
2800 Energy Centre, 1100 Poydras Street
New Orleans, LA 70163-2800
PH: (504) 522-2304
FAX: (504) 528-9973
Email: gmeunier@gainsben.com

Plaintiffs' Liaison Counsel

PLAINTIFFS' STEERING COMMITTEE

Andy D. Birchfield, Jr. (Co-Lead Counsel)
234 Commerce Street
Post Office Box 4160
Montgomery, Alabama 36103-4160
Phone: (334) 269-2343
Fax: (334) 954-7555
Email: Andy.Birchfield@BeasleyAllen.com

Bradley D. Honnold
11150 Overbrook Rd., Ste. 200
Leawood, KS 66211
Phone: (913) 266-2300
Fax: (913) 266-2366
Email: bhonnold@bflawfirm.com

Brian H. Barr (Co-Lead Counsel)
316 Baylen Street, Suite 600
Pensacola, FL 32502
Phone: (850) 435-7045
Fax: (850) 436-6044
Email: bbarr@levinlaw.com

Frederick Longer
510 Walnut Street, Suite 500
Philadelphia, PA 19106
Phone: (215) 592-1500
Fax: (215-592-4663
Email: flonger@lfsblaw.com

Russell T. Abney
2100 RiverEdge Parkway,
Suite 720
Atlanta, Georgia 30328
Email: rabney@lawyerworks.com

Jeffrey S. Grand
550 Broad Street, Suite 920
Newark, NJ 07102
Phone: (973) 639-9100
Fax: (973) 639-9393
Email: jgrand@seegerweiss.com

Dr. Mark Alan Hoffman
1650 Market Street, Suite 3450
Philadelphia, PA 19103
Phone: (215) 574-2000
Fax: (215) 574-3080
Email: mhoffman@rossfellercasey.com

Roger C. Denton
100 S. 4th Street
St. Louis, MO 63102
Phone: (314) 621-6115
Email: rdenton@uselaws.com

Michael Goetz
201 N. Franklin St., 7th Floor
Tampa, FL 33602
Phone: (813) 221-6581
Fax: (813) 222-4737
Email: MGoetz@ForThePeople.com

Dianne M. Nast
1101 Market Street, Suite 2801
Philadelphia, Pennsylvania 19107
Phone: (215) 923-9300
Email: dnast@nastlaw.com

Neil D. Overholtz
17 E. Main Street , Suite 200
Pensacola, Florida 32501
Phone: (850) 916-7450
Fax: (850) 916-7449
Email: noverholtz@awkolaw.com

Ellen Relkin
700 Broadway
New York, New York 10003
Phone: (212) 558-5500
Fax: (212) 344-5461
Email: Erelkin@weitzlux.com

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on February 22, 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
LEONARD A. DAVIS