IN THE FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
PHILADELPHIA COURT OF COMMON PLEAS
TRIAL DIVISION – CIVIL

IN RE: XARELTO® PRODUCTS LIABILITY LITIGATION ***This Document Relates to All Actions***	**JANUARY TERM 2015,** **NO. 002349**

ORDER

AND NOW, this _____ day of _____ 2018, having reviewed the parties' briefs and Proposed Trial Plans, **IT IS ORDERED** that the Court adopts Plaintiff's Proposed Case Management Order No. 19.

_____
ARNOLD L. NEW, J.

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PHILADELPHIA COURT OF COMMON PLEAS
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IN RE: XARELTO® PRODUCTS LIABILITY LITIGATION ***This Document Relates to All Actions***	**JANUARY TERM 2015,** **NO. 002349**

PLAINTIFFS' RESPONSE TO DEFENDANTS' OBJECTION TO PLAINTIFFS' PROPOSED TRIAL PLAN AND PLAINTIFFS' CROSS-MOTION TO ADOPT PLAINTIFFS' PROPOSED CMO-19

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June 5, 2018

The Honorable Arnold L. New
Court of Common Pleas, Trial Division
City Hall, Room 606
Philadelphia, PA 19107

RE: *In re Xarelto® Products Liability Litigation*, January Term 2015, No. 2349

PLAINTIFFS' RESPONSE TO DEFENDANTS' OBJECTION TO PLAINTIFFS' PROPOSED TRIAL PLAN AND PLAINTIFFS' CROSS-MOTION TO ADOPT PLAINTIFFS' PROPOSED CMO-19

Dear Judge New:

Plaintiffs hereby: (1) respond to Defendants' Objection to Plaintiffs' Proposed Trial Plan and Motion to Adopt Defendants' Proposed CMO 19 ("Motion"), and respectfully request that the Court deny said Motion; and (2) cross-move for the adoption of Plaintiffs' Proposed CMO-19 ("Cross-Motion"). A revised proposed CMO-19 is attached. [1]

I. INTRODUCTION

Defendants' motion is riddled with inaccurate or misleading statements regarding the present status of the Xarelto litigation in an attempt to undermine the soundness of Plaintiffs'

[1] Plaintiff's revised CMO-19 attached to Plaintiff's Cross-Motion slightly modifies Plaintiff's prior version submitted to the Court in light of Defendants' proposed CMO in an effort to "meet in the middle." Specifically, the current version modifies the prior version in the following ways: (1) in Section I.A.3 the language is adjusted to make clear that the death cases being excluded are those where a death was caused by the gastrointestinal bleed; (2) in Section I.B.5, the language is modified to add an additional defense strike to providing a total of three (3) defense strikes; (3) in Section 1.B.11(a), the language is modified to make clear that Plaintiff may request custodial files for three sales personnel from those identified in the defense fact sheet; (4) in Section I.B.12, the language is modified to remove the limitation on depositions pertaining to Plaintiffs' treating physicians; and (5) Section II.3, the language is modified to allow Plaintiff to request two custodial files of sales personnel for cases in the limited discovery pool.

failure-to-warn claims. Notwithstanding Defendants' mistaken rhetoric, as discussed with the Court at the May 16, 2018 Liaison counsel meeting, Plaintiffs are committed to finding a way forward in order to bring finality to this litigation.

While generally speaking the past acts as a prelude to the future, Plaintiffs hope to part with previous trial selections that resulted in cases with unique factual circumstances that have hindered Plaintiffs' ability to present claims representative of the vast majority of atrial fibrillation ("Afib") cases on the Court's docket. These atypical selections forced Plaintiffs to adapt and employ a multitude of varying theories given their unique qualities. Given the un-representativeness of the selections, *e.g.*, the Defendants' selection of a dual antiplatelet therapy patient who was also using Xarelto for Afib, *i.e.*, Daniel Russell, it ill-behooves them to feign surprise that Plaintiffs were improvising at trial, especially in light of the trial court's erroneous and overly restrictive evidentiary rulings addressing proximate causation. Simply put, there have been few cross-cutting issues that can be applied to the overwhelming number of Afib cases, which is reflected in the next two upcoming trials involving DVT/PE indications or brain bleed, which are not representative of most cases on the Court's docket. *Hartman*, of course, is the exception, as that plaintiff had Afib and a GI bleed, which reflects and is representative of the vast majority of cases filed in Pennsylvania. To be clear, the primary failure-to-warn theories presented to the jury in *Hartman* for which the jury returned a favorable verdict, will be those at-play in the trials to be scheduled in 2019 under Plaintiffs' proposed plan, namely, that the Xarelto label failed to warn of the true risk of bleeding: (1) in patients on concomitant aspirin; (2) in the United States; (3) and because of its interpatient variability.

Plaintiffs' proposed CMO-19 should be adopted, because it allows Plaintiffs to select those cases that are the most representative of two-thirds of the docket in Pennsylvania. Plaintiffs

submit that it is these types of cases that are highly representative of the overall docket and should be set for trial next year. It is against this factual context that Plaintiffs' primary failure-to-warn theories will be applied.

Plaintiffs' proposed trial plan in their proposed CMO-19 seeks to identify a dozen representative cases whose trial results can inform the parties and the Court. To this end, Plaintiffs submit that these cases should include Plaintiffs: (1) whose Xarelto use is indicated for the treatment of atrial fibrillation; (2) who suffered a non-fatal gastrointestinal bleeding event; (3) were hospitalized for no more than one week;[2] (4) with or without concomitant aspirin use; (5) and whose prescription(s) of Xarelto pre-date the addition of the United States subgroup bleeding data.[3] These representative Xarelto cases make up the majority of the Pennsylvania docket, and thus trying then will provide the most valuable information in any effort towards finality of this litigation. In their motion, Defendants argue that Plaintiffs already had the opportunity to try precisely this sets of facts and did not prevail;[4] however, this contention ignores the elephant in the room, namely, that the *Hartman* jury did, in fact, find the Xarelto label to be inadequate based on at least one of Plaintiff *Hartman's* failure-to-warn theories, if not more than one.

Moreover, Plaintiffs' proposed plan likewise seeks to promote fairness by adopting a first-in-first-out ("FIFO") trial priority schedule for the 2019 trial cases themselves, and provides defense counsel the opportunity to strike three (3) of Plaintiffs' trial selections. Finally, and

[2] Through this limitation on damages, Plaintiffs have self-policed to ensure that the selected cases do not involve catastrophic-type injuries that are not reflective of the majority of cases.

[3] Defendants have no response to this, except to object and propose a draconian plan that will not help advance the litigation. Yet as noted, Plaintiffs CMO 19, does allow for a complementary FIFO work-up for 30 cases so that Defendants can discover the initially filed cases.

[4] *See* Motion at 5.

importantly, Plaintiffs' proposed plan strikes a balance between the parties competing proposals by allowing the Defendants to depose the Plaintiff and spouses in the first thirty (30) filed cases.[5] This provides the Defendants all the necessary discovery to file certain dispositive motions as is Defendants' articulated desire.[6]

II. ARGUMENT

Thus far, in the two Xarelto trials in Pennsylvania, *Hartman* and *Russell*, four basic failure-to-warn claims were presented to the jury.[7] These included allegations that the Xarelto label's bleeding warning was inadequate as it pertains to: (1) concomitant use of aspirin; (2) use by patients in the United States; (3) interpatient variability; and (4) concomitant use of both Plavix and aspirin ("triple therapy").[8] All except the last pertaining to triple therapy, were presented to the jury in the *Hartman* trial, and the jury returned a verdict in Plaintiff's favor for $27.8 million dollars, and proved that the Xarelto label is indeed inadequate.[9] As such, going forward, the primary claims presented to the jury in *Hartman* trial, for which the jury returned a

[5] *See* generally, Section II.

[6] *See* Defs' Motion at 8. Plaintiffs are also willing to discuss a separate CMO to address discovery and a briefing schedule for cases involving Texas and Michigan Plaintiffs.

[7] Notably, in future trials, Plaintiffs may very well pursue claims of design defect and/or even manufacturing defect assuming admissible expert testimony in support of these theories. There is no obstacle from so doing other than competent expert testimony.

[8] In the MDL trials, Plaintiffs alleged that the Xarelto label failed to instruct doctors to use prothrombin time (PT) testing in order to assess the degree and/or extent of their anticoagulation when using Xarelto. However, bellwether trials are a learning curve, and the three defense verdicts pertaining to this failure-to-warn theory, instructed Plaintiffs' counsel that the addition of a PT instruction may not be the strongest regulatory opinion for Xarelto cases. It is not surprising therefore that other theories would be advanced, and should have been advanced in light of the defense verdicts.

[9] That the trial court entered a judgment notwithstanding the verdict, that does not diminish Plaintiff's victory in having the jury return a verdict which found the label to be willfully inadequate. The JNOV was based on an improper and inconsistent evidentiary ruling regarding the proximate causation testimony of the prescribing doctor.

favorable verdict, and which are applicable to the vast majority of cases in the Pennsylvania docket, will be those at-play in the trials to be scheduled in 2019.

In *Russell* (a defense selection), due to the plaintiff's concomitant medication use, specifically, Plavix and aspirin, a different claim was examined in order to account for the case-specific facts in Mr. Russell's case, which were not present in the *Hartman* case.[10] Because of these case-specific facts pertaining to Mr. Russell, different claims were at play in comparison to the *Hartman* case. In short, it is not a question of a lack of a theory Plaintiffs' part. Rather, it is difference in the case-specific facts in the Pennsylvania cases selected for trial thus far that have rendered the need for a new trial plan, which Plaintiffs respectfully submit should be their proposed plan in CMO-19, which will focus on the failure-to-warn theories presented to the *Hartman* jury, which are applicable to the majority of cases filed in Pennsylvania.

Defendants likewise conflate the concepts of "signature injury," "label changes," and the general knowledge within the medical community concerning bleeding associated with anticoagulants as being somehow synonymous with Plaintiffs' alleged inability to prove their failure-to-warn claims.[11] Initially, the concept of a "signature injury" simply has nothing to do with Plaintiffs' claims concerning the adequacy of a label. This was similarly true in the Yaz/Yasmin litigation where the injury was blood clots (PE, DVT and Strokes). Pointing this out is a red-herring with no relevance. *Second,* although state law may vary on this point, the majority of states permit failure to warn claims predicated on whether a label ***sufficiently***

[10] Notably, Mrs. Hartman did not have a PT test done at the time of her admission for her GI bleed. Thus, while Plaintiff submits that had she decided to, she could have gone to the jury on this theory, and had sufficient expert testimony to do, Plaintiff made strategic trial decisions to not present the theory to the jury. This is precisely what trial lawyers do, consider law and facts and present them to the jury in the light most favorable to their client. Counsel in *Hartman* clearly determined that did not include presenting a PT theory to the jury.

[11] *See* Defs' Motion at 2.

conveys a particular risk even where a particular risk is conveyed to some degree in the product label.[12] *Finally*, again, Plaintiffs' claims do not require a label change in order to be viable. The viability of state tort-law claims are separate and apart from the FDA regulatory scheme governing label changes, and further, represents the *floor*, not the ceiling with respect to label adequacy.

Notwithstanding this point regarding labeling, it is also patently inaccurate to state that there is no label change in this case. Specifically, there was a label change regarding Plaintiffs' regulatory opinions concerning the addition of the U.S. subgroup data. In fact, in *Hartman*, Plaintiff presented specific evidence that the Xarelto label was updated to include the U.S. subgroup bleeding data in September 2015 at the request of the Food and Drug Administration. In short, Defendants' motion simply conflates multiple legal concepts in an effort to undermine the soundness of Plaintiffs' claims. It does not, however, change the fact that Plaintiffs are entitled to present multiple competent claims, which going forward, Plaintiffs suspect will be those presented to the *Hartman* jury and which have nearly global applicability.

Going forward, Plaintiffs submit that the focus of the litigation should be to ensure that representative trials occur. This will maximize the lessons to both sides. If the trials are successful, as the *Hartman* case was, that will be telling, and if they are lost, that too will be telling.

[12] On this point, Defendants' statement that claims against similar makers of other novel oral anticoagulants have failed, is not accurate. In the *Pradaxa* litigation, which was pending before the Honorable David Herndon of the United States District Court for the Southern District of Illinois, over 4,000 Pradaxa cases settled. Indeed, the Pradaxa settlement, in contrast to the litigation approach here, saved those Defendants hundreds of millions of dollars. All of the cases settled but for a tiny pocket of cases that remain in state court. By contrast, the defendants here are content with trying to advance theories to prevent representative cases from getting to trial and to obfuscate facts, rather than implement trial plans that address two-thirds of the cases on the docket.

To this end, Plaintiffs' proposed plan accomplishes precisely this goal while also promoting fairness to both sides by implementing a FIFO trial-priority schedule (namely the trial cases that are ultimately selected, after Defendants exercise their strikes, are tried in FIFO order). Therefore, Plaintiffs who have waited the longest for their trial will be the first to have their day in Court. Moreover, Plaintiffs' plan will ensure that neither party will be selecting either the "best" or the "worst" cases to be amongst the first tried.[13] Finally, and critically important to the notion of fairness (lacking from Defendants' proposal), is that Plaintiffs' proposal allows the Court to, in essence, "split the baby" by giving the Defendants' the ability to obtain discovery on the initially filed cases, which Defendants can then use to support any dispositive motions they may wish to file. This is precisely the relief sought by Defendants' in their motion. Plaintiffs' proposed plan allows for this discovery to be conducted in tandem with the trial selection plan.

III. CONCLUSION

For the reasons set forth above, Plaintiff's Cross-Motion should be granted and Plaintiffs' Proposed CMO-19 entered by the Court.

Respectfully submitted,

Michael M. Weinkowitz
Daniel N. Gallucci
Laura A. Feldman

[13] For example, fatal GI-Bleeds and any cases with more than 7-day hospitalizations are excluded, which excludes strong cases with lengthier hospitalizations.

ATTORNEY CERTIFICATION OF GOOD FAITH

Pursuant to Pa.R.C.P. 208.2(e), the undersigned counsel for movant hereby certifies and attests that opposing counsel has been contacted in an effort to resolve the specific dispute at issue, and despite discussions with opposing counsel in Plaintiff counsel's good faith attempts to resolve the dispute, counsel has been unable to do so.

CERTIFIED TO THE COURT BY:

MICHAEL M. WEINKOWITZ

Date: June 5, 2018

CERTIFICATION OF SERVICE

I hereby certify that on June 5, 2018, a true and correct copy of the foregoing *Plaintiffs' Response to Defendants' Objections to Plaintiffs' Proposed Trial Plan and Plaintiffs' Cross Motion to Adopt Plaintiffs' Proposed CMO 19* was caused to be served on counsel of record through the Court's electronic filing system, with courtesy copies by email, addressed as follows:

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