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IN RE: XARELTO® LITIGATION	**PHILADELPHIA COUNTY COURT OF COMMON PLEAS TRIAL DIVISION**
This document relates to all actions	**JANUARY TERM, 2015**
	NO. 2349

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

TYPE OF LITIGATION:	**IN RE: XARELTO® PRODUCTS LIABILITY LITIGATION, January Term 2015, No. 02349**
NAME OF OPPOSING COUNSEL:	**Michael M. Weinkowitz, Esquire** **Levin Sedran & Berman** **Daniel N. Gallucci, Esquire** **NastLaw LLC** **Laura Feldman, Esquire** **Feldman & Pinto** ***Plaintiffs' Liaison Counsel***
FILING DATE:	**June 5, 2018**
RESPONSE DATE:	**June 18, 2018**

IN RE: XARELTO® LITIGATION	**PHILADELPHIA COUNTY** **COURT OF COMMON PLEAS** **TRIAL DIVISION**
This document relates to all actions	**JANUARY TERM, 2015** **NO. 2349**

ORDER

AND NOW, this ____ day of _____ 2018, upon consideration of Defendants' Objection to Plaintiffs' Proposed Trial Plan and Motion to Adopt Defendants' Proposed CMO 19, and any response thereto, it is hereby **ORDERED**, **ADJUDGED** and **DECREED** that the Defendants' Motion is **GRANTED**, Plaintiffs' Proposed Trial Plan is rejected and Defendants' CMO 19, as attached hereto, is entered.[1]

BY THE COURT:

_____

J.

[1] The Parties are instructed to meet and confer to set appropriate dates required by CMO 19.

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June 5, 2018

Via Electronic Filing and Hand Delivery

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

Re: *In re Xarelto® Litigation*, January Term 2015, No. 2349

Dear Judge New:

Defendants (1) object to Plaintiffs' proposed trial workup plan discussed at the May 16, 2018 Case Management Conference (now styled by Plaintiffs as "Proposed Case Management Order 19"), and (2) propose an alternative plan (Defendants' proposed Case Management Order 19, attached hereto). Instead of Plaintiffs' plan that would allow them nearly unfettered discretion to unilaterally pick whatever cases they want for trial, the Court should adopt Defendants' plan, which provides a data-driven and fairer approach to selection for the workup pool and trial (that still allows for the trial of cases that Plaintiffs argue should be tried next), and also addresses the growing problem of improvidently filed claims that are crowding the docket (through a manageable process of initial workup, followed by motion practice).

* * *

Plaintiffs' proposal, and Defendants' response and counter-proposal, must be assessed against the background of this litigation and how it has unfolded, both in this Court and in the MDL.

This is a litigation in search of a theory. Nothing triggered it: There was no label change or clinical trial safety signal, or a market withdrawal. Plaintiffs have no "signature injury"—they allege bleeding, a potential side effect that is inherent with use of *any* anticoagulant. And this is not a case where the plaintiffs allege that a pharmaceutical company failed to warn about the adverse event that they claim to have experienced. Because the very therapeutic properties that make anticoagulants so important to public health also can—necessarily—cause patients to bleed, *every* anticoagulation medication has a warning label that explicitly and unequivocally warns of the risk of bleeding. Xarelto is no different—its label is replete with warnings (indeed, it mentions "bleeding" more than 70 times) that use of Xarelto may increase the "risk of bleeding," including "serious or fatal bleeding." The risk of bleeding associated with anticoagulants is universally known and accepted in the medical community. Unsurprisingly, *all* of the independent, prescribing physicians who have testified in the Xarelto trials to date have acknowledged that they were well aware of the risk of bleeding associated with anticoagulants, including Xarelto.[1]

Plaintiffs have cast about for a theory that "works." In light of the Xarelto label's clear and extensive warnings, Plaintiffs have concocted speculative, alternative theories, which have morphed in various directions from day one—and continue to change at every turn, even during the course of trial. Plaintiffs' original complaint focused on the absence of a reversal agent for Xarelto, Defendants' purported failures to adequately "test" Xarelto before bringing it to market, and the lack of a "black-box" warning about the risk of "excessive bleeding." None of these theories ever made it to trial. Recognizing that these theories were meritless, in their experts'

[1] For that reason, it is unsurprising that similar claims against the makers of the other NOACs, Pradaxa and Eliquis, have likewise failed, either through threshold motion practice or at trial.

reports, Plaintiffs pivoted to an entirely new theory that was not even pleaded in their complaint—namely, that Xarelto's label failed to instruct doctors to conduct prothrombin time (PT) testing.[2] After three federal juries unanimously rejected that theory, Plaintiffs in Philadelphia used their PT theory to overcome summary judgment in the *Hartman* case, but then abandoned the PT theory at trial in favor of new theories that also were never pleaded.

Even those new theories that Plaintiffs have pursued—*i.e.*, that the label lacks U.S. subgroup data, data on concomitant aspirin use, and "triple therapy" data[3]—have been rejected after complete trials on the merits. All of this shapeshifting (including during the middle of trial) has led to numerous inefficiencies, including almost monthly amendments to expert reports, calls for additional discovery that should have been completed long ago, and two amendments to the master complaint. Yet in the face of all of this, Plaintiffs continue to file 400–600 cases *per month*, when they have no viable liability theory. It's a never-ending cycle that needs to be stopped.

This Court (like Judge Fallon in the MDL) set up a bellwether process, which is supposed to give the parties an idea of representative cases. Indeed, that's the purpose of bellwether trials. *See* Eldon E. Fallon, *Bellwether Trials in Multidistrict Litigation*, 82 TUL. L. REV. 2323 (2008). The goal of the bellwether process is not, and should not be, to fast-forward certain cases for trial and ignore what the majority of the docket looks like. At the outset of the initial bellwether process, Defendants cautioned that Plaintiffs' proposed bellwether process would not lead to representative results because it would allow Plaintiffs to cherry-pick the cases

[2] Indeed, in their Master Complaint, Plaintiffs alleged *just the opposite*—that Xarelto's label was inadequate because it "failed to provide adequate warning that it is difficult or impossible to assess the degree and/or extent of anticoagulation in patients taking Xarelto." Pls.' Master Compl. ¶ 76(g); Pls.' 1st Am. Master Compl. ¶ 77(g); Pls.' 2d Am. Master Compl. ¶ 89(h).

[3] Plaintiffs have been quoted in the press as reporting that as much as 25% of the docket is made up of triple-therapy cases, but Plaintiffs recently stated that the true percentage of triple-therapy cases is closer to 6%.

that they wanted to pursue and systematically dismiss any cases that they did not want to pursue. Over Defendants' objection, the Court adopted the bellwether process embodied in CMO 11. The Court established three work-up pools, divided by type of injury and particular use of Xarelto, for a total of 24 cases to be worked up through "core discovery." Plaintiffs and Defendants were permitted to unilaterally select an equal number of cases for inclusion in that pool, with a smaller number of cases added by random selection. After replacements to the pool, 32 different cases have been part of the initial discovery pool. The parties were then permitted to each strike seven cases from the pool, for a trial pool of 10 cases.

Plaintiffs handpicked the first case that went to trial in Philadelphia (*Hartman*), and the second Philadelphia trial (*Russell*) was selected for the original discovery pool by Plaintiffs.[4]

Plaintiffs skewed the bellwether process by systematically dismissing non-plaintiff-selected cases. The bellwether process played out just as Defendants predicted and further skewed the process in Plaintiffs' favor. Plaintiffs dismissed more than half of the bellwether pool cases that were worked up (14 of the 26 cases), and dismissed 10 of the 13 defense picks in the discovery pool. There was a similar story for Defendants' trial picks: Plaintiffs dismissed two of the three. They also dismissed six of the nine randomly selected discovery pool cases. And the same pattern is being repeated in the newest MDL work-up pool that Judge Fallon established less than two months ago—of the 200 cases that Defendants selected for inclusion in the pool, Plaintiffs already have dismissed (or plan to dismiss) 52 of them.[5]

[4] In the MDL, the parties tried three bellwether cases. All were included in the initial work-up pool at Plaintiffs' selection, and all three trials ended in unanimous jury verdicts that the Xarelto label adequately warns of the risks. Plaintiffs dismissed the only defense-selected workup-pool case that was set for trial in the MDL.

[5] There have been a total of 80 dismissals (or planned dismissals) from among the 600 cases in the newly established MDL work-up pool. In addition to the host of dismissals of the defense-selected cases, the MDL plaintiffs have dismissed or plan to dismiss 25 of the 200 random-selection cases and 3 of the 200 plaintiff-selected cases.

The Court has suggested that this pattern will continue if the Defendants are allowed to pick cases for inclusion in the workup pool. That is correct—but it is not a valid justification for dispensing with defense picks entirely. Allowing Defendants to select cases for the pool is essential to the bellwether process as a matter of fundamental fairness. To the extent that bellwether pool selection is the only way to shine a spotlight on the fact that a host of cases that do not even pass an initial factual or legal threshold are being parked in the PCCP docket, that alone is a reason to continue with defense picks. Those cases must be exposed to sunlight and continue to be weeded out. Plaintiffs' persistent efforts to stack the deck in their favor should not be further rewarded, either in this Court or the MDL.

Now, after losing all five MDL and Pennsylvania bellwether cases that have gone to trial, Plaintiffs say that they haven't gotten to "try their best case." That simply is untrue. The first two trials involved the very facts that Plaintiffs *now* say they want (AFib patients who experienced gastrointestinal bleeds). Moreover, Plaintiffs pursued in those two trials the liability theories that they *now* claim are their "best"—in the plaintiff-selected *Hartman* trial, U.S. subgroup and the combined use of Xarelto and aspirin; in the *Russell* trial, "triple therapy" (the combined use of Xarelto, aspirin and Plavix). Yet Plaintiffs did not prevail in either case. The trials exposed the fundamental flaw in this litigation—four juries have validated the adequacy of Xarelto's warning label and, in the fifth case, Judge Erdos concluded that there was insufficient proof that a different warning would have led to a different prescription.

Now Plaintiffs are telling the Court that they should be allowed even greater leeway to manipulate the process. Plaintiffs want a foolproof do-over—no more random selection of cases or defense picks. Instead, they want to be able to comb through the entire inventory of 1600+

cases and unilaterally select the ones they want to go to trial, presumably after having one-sided discussions with the prescribing and treating physicians to encourage favorable testimony. In reality, Plaintiffs' plan is simply a request that they should be given the best possible chance to win a trial and that they need to be able to tilt the scales as much as necessary to do so. That is fundamentally unfair—and certainly not representative. Defendants shouldn't be forced to try cases until Plaintiffs win some, but that's exactly the upshot of their proposal. Allowing Plaintiffs to hand select 12 cases (*i.e.*, less than 1% of the cases filed in Philadelphia) would prove only that Plaintiffs have gamed the system.

Plaintiffs' proposal—and their opposition to Defendants' proposal to use objective criteria to select a manageable number of cases for initial work-up before Plaintiffs' trial selection—betrays their complete lack of confidence in "the other 99%" of their cases. Defendants' proposed plan is more even-handed than Plaintiffs' proposal. In Proposed CMO 19, Defendants propose a phase two trial pool that focuses on the facts that Plaintiffs now think are most important (plaintiffs who used Xarelto to prevent strokes incident to their AFib and who experienced a non-fatal GI bleed), but that is broader in scope—*i.e.*, the first 200 filed cases that meet those facts, where the plaintiff has (1) completed the core case information from section 1 of the Plaintiff Fact Sheet ("PFS"), and (2) produced records showing Xarelto use and an alleged injury. Based on Defendants' analysis of the Brown Greer data, this pool of cases also would represent an equitable cross-section of Plaintiffs' firms.[6] Once selected for the pool, each plaintiff would be required to have a complete PFS or be listed for dismissal.

[6] To limit over-representation by any one Plaintiffs' firm in the pool, Defendants' plan includes a cap that no one firm may have more than 20 cases in the pool. But based on Defendants' current analysis, only two firms have more than 14 cases in the first 200 filed eligible trial pool cases.

The cases selected for inclusion in the pool would proceed on two tracks. For the first track—*i.e.*, the 2019 Trial Pool—Defendants have made the compromise offer, in light of the Court's comments at the last case management conference, that Plaintiffs could select 24 cases to work-up for trial, subject to defense strikes and Court review. That proposal (for Plaintiffs to make all the trial selections) is a good-faith compromise in exchange for a broader, fairer overall process than Plaintiffs' one-sided plan. Under Defendants' plan, Plaintiffs would be required, at the time of selection, to disclose their causes of action and, for a failure-to-warn claim, the precise theory of liability and language that they contend should have been included in Xarelto's label in order to avoid the inefficient demands for new expert reports and additional discovery that have plagued the bellwether process to date. Plaintiffs have objected to this provision—evidently because they want to continue to shift their theories in the next phase of this litigation, just as they have up to this point—but, as Defendants have explained, it is both inefficient and inequitable to allow Plaintiffs to continue to change their theories as each case develops (through case-specific discovery and even into trial). After a set of initial discovery, Defendants would be permitted to strike 12 of the 24 cases and any non-representative cases—*e.g.*, cases with periods of hospitalization outside of the median for all cases or plaintiffs whose age is outside of the median for all cases. The remaining cases would be scheduled for trial at 60-day intervals.

Plaintiffs' proposal also seeks to inappropriately limit the number of doctors who may be deposed. Plaintiffs contemplate depositions of "the healthcare provider(s) who prescribed Xarelto to the Plaintiff" and "one physician who provided the care related to Plaintiff's alleged injuries." Pls.' Proposal ¶ 12. Defendants should be permitted to depose any of Plaintiffs' physicians. Similarly, Plaintiffs' proposal also seeks to perpetuate unfairness by providing that they question

all prescribers first in all cases. Defendants' proposed Order rebalances the playing field to ensure that no party is able to gain unfair tactical advantage. Plaintiffs object to this even-handed procedure.

For the second track—*i.e.*, the 2020 Trial Pool—Defendants would select cases for limited discovery (a plaintiff deposition and a prescriber/treater deposition) as necessary for certain dispositive motions. Those motions would target threshold issues to pare improvidently filed claims from the docket—*e.g.*, cases with likely statute-of-limitation issues, cases involving less than two days hospitalization, cases with post-injury Xarelto use, cases from states that preclude pharmaceutical claims as a matter of law, etc. After motion practice, both Plaintiffs and Defendants would select 12 cases each for additional work-ups, both sides would then each have six strikes, and the remaining cases would be scheduled for trial in in 60-day intervals. Plaintiffs apparently agree with the need for an additional pool of cases beyond another set of trials, but their proposal (1) expands beyond the fact pattern that they now contend is their "best" (AFib with GI bleeding), (2) fails to account for cases with non-compliant plaintiff fact sheets, (3) limits discovery too narrowly by only accounting for depositions of plaintiffs, and (4) adds inefficiencies (like defendant fact sheet and sales representative custodial file productions) in light of the numerous expected dismissals.

Plaintiffs' opposition to any proposal that involves a broad-based work-up of cases is striking—and is proof positive that Plaintiffs don't want to try representative cases. It's clear that Plaintiffs just want the Court to tilt the system in a direction that will improve their odds of somehow persuading a jury to rule in their favor.

Which brings us back to the beginning—this litigation-in-search-of-a-theory cries out for a more exacting selection process. There is a reason that Plaintiffs are concerned about working up more than 1% of the inventory and cases other than the ones that they handpick. Beyond their global problem that Xarelto's label is in fact adequate and the alleged injuries are inherently part of any anticoagulant's risk-benefit balance, Plaintiffs have experiential knowledge of the facts that Defendants see in the individual-case data—among just the first 200 filed cases, 29 have likely statute-of-limitation issues; 46 involve de minimis injury; 6 experienced a bleeding event far after they stopped taking Xarelto; and at least 10 involve state law that bars any cause of action in a case involving an FDA-approved prescription medication.[7] Plaintiffs know that these cases are not worth litigating. Those cases were filed and parked in this Court simply in the hope that there would be some future payday.

The solution to easing the pressure on this Court's docket is not to allow Plaintiffs to cherry pick trial cases. The trial selection process must be more objective and representative of the cases that have been filed. But beyond scheduling additional trials, something more bold and creative is needed to lop off the frivolous claims that were destined to be dismissed and are clogging this Court's docket, and to stop the constant flow of cases that Plaintiffs are parking in the MDL and in this Court, with no reasonable expectation they'll be required to do anything.

Defendants' plan gives the Court a workable solution. Plaintiffs get trials of cases that they argue should be tried next: AFib cases where plaintiffs experienced gastrointestinal bleeds.

[7] Similar threshold issues are present in the newly established MDL work-up pool: among the 600 cases in wave 1, 7 have been dropped by agreement based on the pool criteria; 80 have been (or will soon be) voluntarily dismissed; and based on reviews completed to date, 133 have failed to provide an amended plaintiff fact sheet, as required in the MDL order (with another 154 having failed to provide a *compliant* amended plaintiff fact sheet). In all, at this point, of the 600 cases in wave 1 of the most recent MDL work up pool, only 170 cases (*i.e.*, less than one-third of the pool) are currently qualified to be worked up.

ECKERT SEAMANS
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And Defendants get the much-needed opportunity to excise numerous facially invalid cases from the docket through a manageable process of initial workup.

Respectfully submitted,

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IN RE: XARELTO® LITIGATION	PHILADELPHIA COUNTY COURT OF COMMON PLEAS TRIAL DIVISION
This document relates to all actions	JANUARY TERM, 2015 NO. 2349

ATTORNEY CERTIFICATION OF GOOD FAITH

The undersigned counsel for movant hereby certifies and attests that:

☑ a. He has had the contacts described below with opposing counsel or unrepresented party regarding the matter contained in the foregoing motion in an effort to resolve the specific dispute(s) at issue and, further, that despite all counsel's good faith attempts to resolve the dispute(s), counsel have been unable to do so.

The parties discussed their competing proposals at the May 16, 2018 status conference and have exchanged draft proposals. As of filing, we have been unable to reach agreement.

Dated: June 8, 2018

CERTIFIED TO THE COURT BY:

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing Defendants' Objection to Plaintiffs' Proposed CMO 11(e) and Motion to Adopt Defendants' Proposed CMO 19 was served by email on June 5, 2018, and served via the Court's Electronic Filing System, on the following counsel of record:

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