Drug Injury Watch: Possible Blood Level Testing For Eliquis / Xarelto / Pradaxa / Savaysa

(Posted by Tom Lamb at www.DrugInjuryWatch.com on February 4, 2016)

As background, Xarelto (rivaroxaban) belongs to a class of medicines known as the direct oral anticoagulants (DOAC), which also includes Pradaxa (dabigatran), Eliquis (apixaban), and Savaysa (edoxaban). These still relatively new blood thinners have gained popularity in place of warfarin for the prevention of ischemic stroke in non-valvular atrial fibrillation because, as currently approved by the FDA, routine blood monitoring is not required.

According to this *BMJ* medical journal article, "Rivaroxaban: can we trust the evidence?", published on February 3, 2016, a faulty medical device used in the clinical trial leading to the FDA's approval of Xarelto (rivaroxaban) has called those results into question.

But in this letter to the *New England Journal of Medicine (NEJM)*, "Point-of-Care Warfarin Monitoring in the ROCKET AF Trial", also published on February 3, 2016, the medical researchers who conducted that Xarelto clinical trial conclude that the use of this device "did not have any significant clinical effect on the primary efficacy and safety outcomes in the trial."

However, going back to the *BMJ* article, we get this counterpoint:

> In a letter submitted to the *NEJM* (as yet unpublished) and shown to *The BMJ*, former FDA cardiovascular and renal drug reviewer, Thomas Marcinicak, says: “The care for the warfarin control arm patients [in ROCKET-AF] appears to have been compromised.”

The medical device at issue, which was later recalled by the FDA, allegedly is prone to giving falsely low INR readings. In the context of this Xarelto clinical trial, such readings would have prompted higher doses of warfarin being given to participants — resulting in higher bleeding risks for those given that warfarin — making Xarelto seem comparatively safer.

Perhaps the most interesting part of the February 2016 *BMJ* article, "Rivaroxaban: can we trust the evidence?", is a possible unexpected result flowing from this current Xarelto controversy:

> At the end of 2015, both the EMA and the FDA held meetings to discuss the need to measure blood levels of direct oral anticoagulants and adjust the dose accordingly to maximise benefit and minimise harm—despite all the manufacturers claiming that this is not necessary. The meetings were held after The BMJ revealed that Boerhinger Ingelheim, manufacturers of dabigatran, withheld analyses from the regulators that

> showed how many major bleeds could be prevented by monitoring anticoagulant activity and adjusting the dose.
>
> A presentation to EMA last year by Robert Temple, deputy director for clinical science at the FDA's Center for Drug Evaluation and Research, suggests that the FDA believes there is a scientific argument for measuring the blood levels of these drugs and adjusting the dose.

However, the latest on this front is found in the February 16, 2016 *Reuters* news report, "Xarelto trial results reaffirmed despite faulty device":

> Europe's drug regulator said on Friday the defective blood clotting test device used in a key trial for the approval of Bayer's top-selling anti-clotting drug Xarelto did not distort the study's main findings.
>
> "Xarelto can continue to be used as before, in line with the current prescribing information," the European Medicines Agency (EMA) said on its website.

While the EMA has now made its determination, we wait to see what this current Xarelto fiasco leads to in terms of possible action by the FDA and other drug regulators.

[Read this article in full at original source]

Earlier articles by attorney Tom Lamb on the Side Effects Blog:

- Eliquis, Savaysa, And Xarelto Worry Doctors Because No Antidote, Still
- Eliquis Might Be Safer Than Xarelto, But Neither Has Approved Antidote
- Xarelto / Savaysa / Pradaxa / Eliquis: Effect Of Platelet Inhibitors
- No Antidotes For Eliquis, Savaysa, And Xarelto To Stop Acute Bleeding
- New Blood-Thinner Savaysa Has No Antidote To Reverse Acute Bleeding

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Attorney Tom Lamb represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, **Drug Injury Watch** – with live links and readers' Comments.
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