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First Bellwether Trial in Xarelto MDL Ends in Defense Verdict

NEW ORLEANS — The first bellwether trial in the Xarelto federal multidistrict litigation has ended with a defense verdict in favor of defendants Janssen Pharmaceuticals Inc., Janssen Research & Development LLC, Janssen Ortho LLC, Johnson & Johnson, Bayer Pharma AG, and Bayer Healthcare Pharmaceuticals Inc., HarrisMartin Publishing is reporting.

In a verdict reached moments ago, the U.S. District Court for the Eastern District of Louisiana jury found defendants did not fail to adequately warn plaintiff Joseph Boudreaux's prescribing doctor and, as such, the failure-to-warn claims are barred by the learned intermediary doctrine.

Boudreaux, 74, of Lockport, La., alleged he developed symptoms of gastrointestinal bleeding less than 30 days after he began taking Xarelto in 2014, requiring hospitalization, numerous blood transfusions and other interventions.

Boudreaux maintained that Xarelto is unreasonably dangerous due to inadequate warnings provided by the six defendants.

Judge Eldon Fallon presided over the trial, which began on April 24.

In his claim, brought under the Louisiana Product Liability Act, Boudreaux alleged Xarelto's label should have warned his doctor that Neoplastin PT tests can be used to identify plaintiffs with high risk of bleeding.

Xarelto is marketed as a one-size-fits-all anticoagulant. Patients take one 20-milligram dose of the drug once a day and do not need to undergo routine monitoring. Boudreaux contended that because each person processes and metabolizes Xarelto at a highly individualized rate, each patient's reaction to the drug is decidedly variable, causing some patients to experience major bleeding events.

Boudreaux said defendants should have designed a Xarelto-specific Anti-Factor Xa assay so doctors could monitor Xarelto's anticoagulation effect on each patient. Because defendants have not designed and marketed an antidote to counteract a major bleeding event; and in the absence of a Xarelto-specific Anti-Factor Xa assay, Xarelto's label should have warned doctors about the availability of the Neoplastin PT test to measure patients' anticoagulation, Boudreaux alleged.

On April 24, the parties agreed that the only LPLA claim asserted and reserved by plaintiff is his claim that Xarelto is unreasonably dangerous because of inadequate warning. As such, Judge Fallon dismissed with prejudice plaintiff's remaining LPLA claims.

Earlier in April, Judge Fallon denied defendants' motions for partial summary judgment, rejecting their argument that Boudreaux's claim is preempted because its based on the same information that the Food and Drug Administration considered and rejected for inclusion in Xarelto's label.

The drug makers argued there is clear evidence that the FDA would have rejected (and did reject) the labeling changes plaintiff proposes.

Plaintiff countered, however, that under Wyeth v. Levine, drug makers have the responsibility to draft adequate warnings — not the Food and Drug Administration — and they are responsible for updating them as new evidence comes to light.

Further, defendants failed to provide sufficient evidence that the FDA would have rejected a label change, plaintiff averred. To prove that the FDA would reject a label update, there must be clear evidence that the FDA would rescind defendants' change to the label, plaintiff asserted, and in the instant case there is no such evidence.

Judge Fallon concluded that questions of fact exist as to whether defendants could have utilized the Changes Being Effected process to update their label after they became aware of the number of its consumers claiming they experienced a major bleeding event while taking Xarelto.

"Defendants bear the responsibility for their label and may have been able to include U.S.-specific data at the outset or after post-market data was released showing high instances of bleeding," the judge explained.

Boudreaux is represented by Andy Birchfield of Beasley Allen Crow Methvin Portis & Miles in Mobile, Ala., Brian Barr of Levin Papantonio in Pensacola, Fla., Mekel Alvarez of Dugan Law Firm in New Orleans and Morris Bart III and Daniel Snellings of Morris Bart LLC in New Orleans.

Counsel for Janssen are John Olinde and Peter J. Rotolo III of Chaffe McCall in New Orleans and Kim Moore and Meera Sossamon of Irwin Fritchie Urquhart & Moore in New Orleans.

In re Xarelto (Rivaroxaban) Products Liability Litigation, MDL No. 14-2592; Boudreaux v. Janssen Research & Development, et al., No. 2:14-2720 (E.D. La.)

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