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Appeals and Shifting Theories of Injury: What's Next for the Xarelto Litigation

The focus of the plaintiffs' theories in the Xarelto trials shifted along with the venue changes, but the plaintiffs are expecting more changes with the upcoming trials in state court.

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After three straight losses in federal court, plaintiffs suing Janssen Pharmaceuticals and Bayer over the blood thinner Xarelto won a hard-fought victory last week with a nearly $28 million verdict. The award breathes new life into the litigation, but with appeals likely and a new class of plaintiffs on the horizon, plaintiffs counsel aren't expected to simply rinse, wash and repeat.

On Dec. 5, after nearly a month of trial, a Philadelphia jury awarded Lynn Hartman $27.8 million over claims that the defendants failed to adequately disclose the risk that patients on Xarelto would suffer a bleed. The case was the first bellwether trial for plaintiffs in state court after three federal juries—two juries in Louisiana and one in Mississippi—found for the drugmakers.

The defendants have promised to appeal. The next trials in Philadelphia are set to take place in March, April, May and June.

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The claims in the federal suits focused more on the theory that the defendants should have told doctors to perform a PT, or prothrombin test, that assesses coagulation levels in a person's blood before prescribing the medication. Hartman highlighted the theory that the company failed to adequately warn about the risks of taking Xarelto with Aspirin, which, according to plaintiffs' counsel, increases the risk of bleed by 93 percent.

Hartman's trial provides a template for cases involving plaintiffs with similar claims involving both Aspirin and Xarelto, but, according to plaintiff liaison counsel Michael Weinkowitz of Levin Sedran & Berman, the next case is likely to focus on the theory that the defendants failed to warn about the dangers of taking Xarelto and Aspirin together with Plavix, which is called dual antiplatelet therapy.

Although some attorneys noted the different standards used in state and federal court for evaluating scientific evidence before allowing it in at trial, attorneys also said the simplicity of the theory outlined in Hartman versus the cases in federal court may have also played a role in the recent win.

Kline & Specter attorney Thomas R. Kline, who is not involved in the Xarelto litigation, but is leading the mass tort program aimed at Risperdal, another Janssen medication, said that, since the plaintiff has the burden off proof, plaintiffs always want to present the simplest theories of liability to the jury.

"From the trial lawyer's perspective, there has to be something to which a juror can relate," he said. "The more direct the claim, and the less attenuated it is, the more likely a jury will say this is something the physician on behalf of the plaintiff should have known."

A statement from Janssen spokeswoman Sarah Freeman said the company stands by its position that Xarelto's labeling has always properly warned about the risks of a bleed.

"We plan to appeal the Hartman verdict and believe we have strong grounds to do so. The verdict contradicts years of scientific data and the U.S. Food and Drug Administration's repeated confirmation of Xarelto's safety and efficacy," she said in an emailed statement.

A spokesman for Bayer also said the company will "vigorously defend" the product, and that Hartman's verdict should be reversed.

"Bayer and Janssen will ask the court to enter judgment in favor of the defendants because the plaintiff failed to prove her case as a matter of law," spokesman Chris Loder said in an emailed statement.

Possible Appeal

With a punitive damages award nearly 15 times larger than the compensatory damages award, the jury was clearly swayed against the defendants. But both Janssen and Bayer have promised to appeal, and some attorneys say the defendants might fare better before an appellate panel.

Duane Morris attorney Alan Klein, who focuses on representing generic drug companies, said it appears the defendants have at least one strong argument on appeal, and that focuses on the learned intermediary doctrine. That principle holds that a drug company's duty to warn only goes as far as the doctor, and it is only the doctor's duty to warn the patient.

In Hartman the defendants noted that her prescribing doctor testified that she stood by her decision to prescribe Xarelto to Hartman and that she continues to prescribe Xarelto.

At trial, Gary Douglas, lead trial attorney for Hartman, said during closing arguments that characterization was misleading, since the prescribing doctor based her decision on a limited amount of information included in the label, and that she said she continues to prescribe the drug now because the label has since been updated with adequate warnings.

The plaintiffs also argued that they further overcame the learned intermediary doctrine because Hartman testified that if the doctor had told her the full extent of the risks, she would not have agreed to take the medication.

However, according to Klein, that approach does not square with the learned intermediary doctrine, and conflates the concepts of the learned intermediary with informed consent.

"Most courts do not add steps two and three to the equation. It stops at the doctor," he said. "As long as the company has told the doctor all they know about the risks of the product, then that's all a drug company has to do."

Loder confirmed that the company will base some of its appellate arguments on failure to overcome the learned intermediary doctrine.

"Prescribers in all four bellwether cases gave similar testimony, resulting in three defense verdicts and one voluntary dismissal with prejudice," Loder wrote.

The lead attorney in the Risperdal mass tort, however, said decisions regarding the learned intermediary are factual determinations by juries, and appellate courts are usually reluctant to overturn a factual determination.

"J&J notoriously complains—not sometimes but every time—that a jury verdict is wrong, and this is one more example, in the face of one more product, in the face of one more verdict, where they are saying that another 12 people got it wrong," Kline said.

More than 18,000 cases are pending in the federal MDL over Xarelto, which makes it the second largest litigation nationwide, second only to the consolidated pelvic mesh litigation. In Philadelphia more than 1,500 Xarelto cases are pending. That number is largely flat from the more than 1,400 in the state court inventory as of summer.

Although the win in Hartman isn't going to bring a swift end to the litigation, everyone agreed the verdict was significant.

"Every first bellwether trial in any jurisdiction is a very significant event, and this win in this jurisdiction where there are a substantial number of cases falls into that category," Kline said.