

11th Circ. Backs Bayer In Birth Control Stroke Suit

By **Mike Curley**

Law360 (December 22, 2020, 4:46 PM EST) -- The Eleventh Circuit shot down an appeal by a couple who alleged Bayer Healthcare Pharmaceuticals Inc. didn't give enough warning that its birth control pills could lead to stroke, saying Tuesday their case is doomed by testimony from their physician that a different warning wouldn't have changed his decision to prescribe the drug.

While calling the case "tragic," the panel found that under Georgia law, which Karen Leigh Hubbard, Michael L. Hubbard and Bayer agreed applied, a drug company's duty to warn extends only to the prescribing physician, not to the user.

In the course of the case, Hubbard's physician, Dr. Lawrence Rowley, testified that he was well aware of the risks the drug carried and that even if he had been more thoroughly informed about those risks, he considered his prescription "appropriate."

"Though the Hubbards have suffered greatly, the law plainly entitles Bayer to summary judgment," the panel wrote.

The case stems from a "catastrophic" stroke that Georgia resident Karen Hubbard suffered in October 2012, about 10 months after she had been prescribed Beyaz, one of three oral contraceptives that Bayer markets. She had been taking the other two varieties since 2001, according to the order.

Between October 2011 and April 2012, the U.S. Food and Drug Administration had been studying the risk of blood clots associated with oral contraceptives, and its findings led Bayer to revise the warning labels for Beyaz to report that it carried a higher risk of blood clots, which can cause strokes, than some other contraceptives.

The Hubbards sued Bayer, alleging that it did not do enough to warn about the increased risk of blood clots, but Bayer was awarded summary judgment, with a Georgia district court finding that under the learned intermediary doctrine in Georgia law, Bayer only had a duty to warn the physician, and Rowley's testimony clearly showed that he would not have changed his decision to prescribe the drug with updated labeling.

The Hubbards appealed, arguing that Rowley's testimony was not so definitive, but the Eleventh Circuit panel was unpersuaded.

During his deposition, Rowley told the court that he still considered his prescription of Beyaz to Hubbard

"appropriate" and that he did not consider the updated label to be significant enough to change his prescribing practices for patients already on Beyaz or similar pills, as Hubbard was, the panel wrote.

In addition, Rowley testified that Hubbard had been on Bayer's contraceptive pills for a decade without issue, and it's his standard practice to continue prescribing a particular birth control pill if a patient has been taking it or a similar medication for an extended period without problems, which was the case with Hubbard.

Rowley further told the court that he considered Beyaz to be the same medication as Hubbard's previous prescription, with the only difference being a supplement that does not affect the risk of blood clots, according to the opinion.

Although the Hubbards pointed out that after the label change Rowley prescribed Beyaz less often, the panel wrote that while Rowley began telling patients of the slightly higher risk, that was a change in communication that does not show that he changed his own decision-making on whether to prescribe the drug.

The panel added that Rowley testified that his office would have told Hubbard about the possibility of increased risk of blood clots at the time.

The panel also rejected the Hubbards' argument that Georgia law presumes that an inadequate warning is a proximate cause of a failure-to-warn injury, saying precedent holds that the burden of proof is on the plaintiff, and there is no case law holding any such presumption.

Even if there were such a presumption, the panel wrote, Bayer has supplied ample evidence to overcome it.

David F. Walbert of Parks Chesin & Walbert PC, who represents the Hubbards, called the decision "awful," saying it does not accurately reflect the record of the case and ignores or argues away evidence that should have been proof against summary judgment.

"Judge [Stanley] Marcus writes about the so-called 'unambiguous' testimony of the treating physician, but he gets to that position only by ignoring the other testimony of the treating physician to the contrary," Walbert told Law360 on Tuesday.

Representatives for Bayer could not immediately be reached for comment Tuesday.

U.S. Circuit Judges Stanley Marcus and Britt C. Grant and U.S. District Judge Annemarie Axon of the Northern District of Alabama, sitting by designation, sat on the panel for the Eleventh Circuit.

Bayer is represented by Kaspar J. Stoffelmayr and Katherine M. Swift of Bartlit Beck LLP and Carol P. Michel of Weinberg Wheeler Hudgins Gunn & Dial LLC.

The Hubbards are represented by David F. Walbert and Jennifer K. Coalson of Parks Chesin & Walbert PC, John W. Sherrod of Sherrod & Bernard, Leila H. Watson of Cory Watson PC, and Douglas B. Turnbull of Turnbull Law Firm PC.

The case is Hubbard et al. v. Bayer Healthcare Pharmaceuticals Inc. et al., case number 19-13087, in the U.S. Court of Appeals for the Eleventh Circuit.

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