# Despite birth control's warning update, stroke victim can't sue Bayer - 11th Circ

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(Reuters) - A lawsuit against Bayer Healthcare Pharmaceuticals Inc by a woman who suffered a stroke while taking the company's oral contraceptive Beyaz and her husband is barred by the learned intermediary doctrine, a federal appeals court has ruled.

A unanimous panel of the 11th U.S. Circuit Court of Appeals on Tuesday affirmed a lower court's summary judgment against plaintiffs Karen and Michael Hubbard, finding that their claims failed because Karen Hubbard's doctor would have prescribed Beyaz even if he had received additional warning about the drug.

"Though the Hubbards have suffered greatly, the law plainly entitles Bayer to summary judgment," Circuit Judge Stanley Marcus wrote in the opinion.

David Walbert of Parks, Chesin & Walbert, a lawyer for the Hubbards, called the decision "atrocious" and said the court had ignored key parts of the doctor's testimony. He said he is discussing next steps with his clients.

Bayer, which is represented by Katherine Swift of Bartlit Beck, did not immediately respond to requests for comment.

Karen Hubbard suffered a stroke in October 2012, resulting in brain damage, paralysis and profound loss of cognitive functioning, according to the opinion. She had been taking Beyaz since 2011, and similar Bayer birth control products since 2001.

In 2014, the Hubbards filed a lawsuit against Bayer in the Southern District of Illinois, later transferred to the Northern District of Georgia, accusing the company of failing to warn of Beyaz's risk. They noted that in 2011, when Karen Hubbard received her prescription, the product's label carried only a general warning of possible stroke risk. In 2012, the label was updated with a warning that the product, which contains drospirenone, a synthetic version of the female hormone progesterone, increased stroke risk by up to three times.

U.S. District Judge William Ray last year granted summary judgment to Bayer, saying that testimony from Karen Hubbard's prescribing physician, Lawrence Rowley, showed he would not have made a

different decision if the label had contained additional warnings.

The Hubbards appealed.

Marcus, in affirming the lower court decision, noted that the case was controlled by Georgia's learned intermediary doctrine, which holds that drugmakers' duty to warn is to doctors, not patients.

Under that doctrine, he said, the Hubbards would have to prove that Rowley would have made a different decision but for Bayer's failure to warn. He agreed with Ray that they could not, pointing out that the doctor testified he still considered his prescription in 2011 appropriate.

"Moreover, Dr. Rowley's testimony indicates that he already knew in December 2011 what he considered to be substantially the same risk information later included in the 2012 Beyaz label," Marcus wrote. "The causal chain is therefore broken, and the Hubbards cannot establish proximate cause."

Marcus rejected the Hubbards' argument that the label update was significant because Rowley testified that he changed his counseling to patients somewhat in light of the new label. The doctor's testimony did not suggest that the change in counseling went along with any change in prescribing practices, the judge wrote.

Marcus was joined by Circuit Judge Britt Grant and U.S. District Judge Annemarie Carney Axon of the Northern District of Alabama, sitting by designation.

The case is Hubbard et al v. Bayer Healthcare Pharmaceuticals Inc, 11th U.S. Circuit Court of Appeals, No. 19-13087.

For the Hubbards: David Walbert of Parks, Chesin & Walbert

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