

## Litigator of the Week: A Compassionate—But Effective—Product Liability Defense

When Boehringer Ingelheim was hit with a new wave of suits over its blood thinner Pradaxa, it changed course and decided to fight, tapping Butler Snow's Rod Richmond Sr. and Covington & Burling's Phyllis Jones

By Robert Storace

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Four years ago, Boehringer Ingelheim agreed to pay roughly \$650 million to settle claims that its blood thinner Pradaxa caused excessive bleeding. But when the pharmaceutical giant was hit with a new wave of Pradaxa suits, Boehringer changed course. This time, it decided to go to court and fight.

The company turned to Covington & Burling's Phyllis Jones, who has racked up a series of wins on behalf of drug companies facing product liability suits, including Eli Lilly and Co.

Along with colleague Paul Schmidt, Jones secured the first victory for Connecticut-based Boehringer on March 23. On Monday, she and Butler Snow's Rod Richmond Sr. notched another win for the defense before a Connecticut state court jury in Hartford.

Jones and Richmond, who had worked together once before, have differing lawyering styles.

Jones describes herself as more laid-back, mellow and to the point while Richmond sees himself as a frank conversationalist with jurors. But both had the same objective: Show the jury they were compassionate about 72-year-old Ohio resident Mary Lou Anne Gallam, who suffered severe bleeding after taking Pradaxa—but also tell the story of the medication, which the Food and Drug Administration approved in 2010 as an anticoagulant used to prevent strokes.



Orlando R. Richmond, Sr.

The two experienced litigators did so by focusing on the rigorous approval needed to get the drug on the market.

"The FDA had very closely evaluated and reviewed Pradaxa before approving it in the U.S.," Jones said. "That included not only the standard FDA review,

but also there was an advisory committee where the agency brings in external experts to evaluate the application.”

The question at the time, Jones said, was whether or not the drug should be approved for stroke prevention in patients who have atrial fibrillation. The six-person Hartford jury was made aware that the panel of external experts “shared the view that the FDA reached, and that is the medicine would be an important contributor for doctors treating atrial fibrillation,” she said.

The plaintiffs attorneys’ core argument during the six-week trial was that the labeling on the drug was not sufficient. They argued the medicine could cause serious and potentially fatal bleeding. The plaintiff in the first case died, but Gallam recovered.

The strategy to combat the labeling argument, Richmond said, was straightforward: Bring on defense experts to detail the labeling procedures and strongly cross-examine the plaintiff’s medical experts.

“All of the witnesses, on both sides, said the warning label regarding bleeding was strong,” said Richmond, who cross-examined the plaintiff’s regulatory/pharmacology expert, presented the defense expert cardiologist and delivered the hour-long closing arguments. He said the jury’s verdict form unanimously showed his team won the labeling argument.

“They ruled for the defense on the warning label and on the issue of causation, they said there was no negligence on the part of the company that caused the plaintiff’s injury.”

Richmond added that showing understanding, compassion and care for Gallam was front and center.

“It’s always important for us to be sympathetic to anyone who has suffered any injury, and that sympathy is sincere.” Richmond said. “The plaintiff is

a wonderful person and a very nice lady. While we know jurors have natural human emotions that we will not be able to eliminate, at the same time, we need to marshal the relevant facts for the jury’s consideration.”

Richmond said he doesn’t believe that Pradaxa had anything to do with Gallam’s condition, pointing to significant evidence of a pre-existing condition

“She had an abnormality in her colon that began bleeding,” Richmond said. When she went to the hospital, doctors repaired the colon abnormality. “In terms of timing, though, the bleeding event occurred after she had been on Pradaxa for 2 1/2 years. This was not caused by Pradaxa,” he said.

Both attorneys said they had no role in the company prior to a \$650 million settlement in May 2014. That settlement, in which Boehringer denied any wrongdoing and said was undertaken to avoid lengthy litigation, resolved roughly 4,000 state and federal cases.

Since that time, the company has been hit with an additional 2,500 lawsuits, most filed in Connecticut. The \$650 million settlement did not cover future lawsuits, Jones said, because “that settlement was of a particular grouping of cases that has nothing to do with future cases.”

On Monday, plaintiffs announced that they are giving up on a similar case that was set for trial in early June in California.

“It’s often the case when a new medicine is on the market that there is more attention paid to it. You do not see as many lawsuits with older drugs,” Jones said.

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