

INTERNATIONAL BUSINESS

\$650 Million to Settle Blood Thinner Lawsuits

By KATIE THOMAS MAY 28, 2014

The German drug maker Boehringer Ingelheim has agreed to pay \$650 million to settle thousands of lawsuits involving its blood thinner Pradaxa, the company said Wednesday.

The settlement will most likely resolve most of the 4,000 cases in state and federal courts filed by patients and their families who claimed that Boehringer failed to properly warn them that the drug, which is used to prevent blood clots, caused serious and sometimes fatal bleeding that could not easily be reversed. The first case was set to go to trial in September.

In a statement, the company said that it stood behind the safety and efficacy of Pradaxa and continued to believe that the lawsuits lacked merit, but that settling the case allowed the company to move on. "Time and again, the benefits and safety of Pradaxa have been confirmed," said Desiree RallsMorrison, senior vice president and general counsel of Boehringer Ingelheim USA.

Ned McWilliams, a lawyer in Pensacola, Fla., who represented some plaintiffs, said he was pleased with the agreement. "We believed from the very beginning that the company had no defense to the claims in this case," he said. "The fact that Boehringer Ingelheim has agreed to compensate thousands of victims hundreds of millions of dollars prior to expert disclosure or trial is telling in this regard."

Pradaxa, which was approved in 2010, was the first in a new group of blood thinners intended to replace an older treatment, warfarin, that required patients to submit to frequent blood tests and adhere to a strict diet. One of Pradaxa's main selling points was its convenience because it did not require any tests or dietary restrictions.

But after it arrived on the market, emergency department doctors and trauma surgeons became alarmed because patients using the drug were arriving with life-threatening bleeding that did not always respond to standard treatments. Pradaxa does not have an antidote to stop bleeding when it occurs, although Boehringer is developing one.

Pradaxa has been prescribed to 850,000 patients in the United States. It has been linked to more than 1,000 deaths, according to the Institute for Safe Medication Practices, which tracks drug safety. The company has stood by the drug's safety profile, and follow-up studies by the Food and Drug Administration have also concluded that the drug's benefits outweigh its risks.

Lawyers for the patients, however, claimed that the company misled patients and their doctors about Pradaxa's risks and about its advantages over warfarin.

Company documents, made public earlier this year by the judge overseeing most of the lawsuits, showed that Boehringer employees argued for revising — and even quashing — an internal research paper because they feared it would lead some to conclude that patients on Pradaxa would benefit from taking blood tests. That could undercut a major selling point of the drug, the employees warned.

Pradaxa has sales of more than \$2 billion in the United States, according to the research firm IMS Health.

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