Merck Study Finds A Vioxx Risk After Use Ended

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Merck & Co. released new data from a critical Vioxx study that suggests patients remained at risk of a heart attack or stroke during the first year after they stopped taking the painkiller.

In a follow-up analysis of the 2,587-patient study called Approve that led the company to pull the drug from the market in September 2004, Merck officials said patients who took the drug during a three-year trial were 1.64 times as likely to have a heart attack or stroke during a subsequent year when they weren't taking it, compared with those who had been on a placebo.

The findings for the fourth year alone weren't statistically significant, the company said, meaning that they could be due to chance. But the company said among 44 patients who suffered what it termed a confirmed thrombotic cardiovascular event, 28 had taken Vioxx during the three-year study, while 16 had been on placebo.

On a conference call with reporters and analysts, Peter Kim, president of Merck Research Laboratories, said the full four-year data confirmed a statistically significant 1.74 times higher risk of heart attacks and strokes for the Vioxx patients, compared with patients in the placebo group. After the first three years of the study, patients who had taken Vioxx were 1.92 times as likely to suffer such an event.

Ken Frazier, Merck's general counsel, said the new data wouldn't change Merck's litigation strategy, which has been to fight each lawsuit on a case-by-case basis. The Whitehouse Station, N.J., company faces roughly 11,500 suits over Vioxx, which an estimated 20 million Americans took during the 4½ years the drug was on the market. Of the six cases that have gone to trial, Merck has won three and lost three.

Because not all patients completed the full study, Merck also provided statistics for 1,721 patients who could be tracked for the full four years. Of those patients, 15 who had taken Vioxx and nine who had taken a placebo had a heart attack or stroke during the follow-up fourth year, when none of the patients were on the drug. That suggests those Vioxx patients were 1.85 times as likely as those on placebo to suffer either event -- a finding that didn't achieve statistical significance.

"You have to look at the big picture," said Steven Nissen, acting chief of cardiovascular medicine at the Cleveland Clinic, who said he has seen the data. "The big picture is that the hazard stays the same."

Plaintiffs' lawyers said that the new data further confirmed Vioxx's dangers. "The important fact is that the cumulative scientific evidence established that the risk is there," said Thomas R. Kline, a key player in the litigation.