

Merck Knew Vioxx Was Unsafe by 2000 - Report

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Nov 15, 2004 - WASHINGTON (Reuters) - Pharmaceutical giant Merck & Co Inc. had evidence by 2000 that its painkiller Vioxx, which was pulled off the market on Sept. 30, was not safe, a heart specialist told CBS News program "60 Minutes" on Sunday.

Dr. Eric Topol, chief of cardiovascular medicine at the Cleveland Clinic, examined all available data about Vioxx and other similar pain relief medications in 2001 for a study published in the Journal of the American Medical Association.

Topol said the company conducted its biggest clinical trial of the drug, widely known as the "Vigor" study, in 1999, which found that Vioxx users had nearly a fivefold increase in heart attacks.

Topol, a well-known cardiovascular researcher, also reviewed an unpublished clinical trial of Vioxx by Merck in 1998 that showed patients who took the drug were six times more likely to have serious cardiovascular events - including heart attacks and strokes - than patients who took another arthritis drug or placebo.

Topol told "60 Minutes" that the two studies showed Vioxx was not safe.

"You've got two trials now. You have essentially lightning striking twice. That's independent replication, that's really serious confirmation," Topol said. "This is unequivocal, this is a serious problem."

Topol's remarks come amid major legal challenges to Merck over Vioxx, fueled in part by class-action lawyers seeking to prove that the drugmaker knew about Vioxx risks but ignored the evidence.

As of Oct. 31, Merck said it has been served or is aware that it has been named as a defendant in about 375 lawsuits, which include some 1,000 plaintiff groups alleging personal injuries resulting from the use of Vioxx.

Merck, which disputes Topol's findings, told "60 Minutes" the 1998 study was too small and not statistically significant enough to be able to draw any conclusions.

In March 2000, results from a clinical trial known as the "Approve" study showed Vioxx doubled the risk of heart attack and strokes in patients who had taken it for over 18 months to prevent recurrence of colon polyps. Merck recalled the drug on Sept. 30 based on data from the trial.

Merck told "60 Minutes" that study provided the first clear evidence that Vioxx was linked to heart attacks and strokes.

Merck executives have said the company acted responsibly by voluntarily withdrawing Vioxx as soon as it had clear evidence the drug was harmful.

About 105 million U.S. prescriptions were written for Vioxx from May 1999 through August 2004, and about 20 million people have used the drug since its 1999 launch, Merck said.

Merck has been subpoenaed by the U.S. Justice Department and the Securities and Exchange Commission has started an informal inquiry concerning the pharmaceutical giant's recalled pain reliever Vioxx.

In an SEC filing, Merck said that it is cooperating with both probes.

Shares of the New Jersey-based drugmaker closed at \$26.45 in Friday trading on the New York Stock Exchange.