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HEALTH

FDA: Consider 'alternative' to Celebrex

Pfizer examining data that show higher risk of heart attack

Friday, December 17, 2004 Posted: 10:19 PM EST (0319 GMT)

WASHINGTON (CNN) -- With a new study that indicates the nation's leading arthritis painkiller could raise the risk of heart attacks, the Food and Drug Administration advised doctors Friday to consider "alternative therapy" to Celebrex.

Earlier Friday, drug giant Pfizer Inc. said it had no plans to pull the painkiller off the market despite the data that showed patients using the drug in a long-term cancer study had increased cardiovascular risks.

The FDA will look at the study results and would then "determine the appropriate regulatory action," the agency said in a news release.

The FDA said it advises doctors to evaluate "alternative therapy. At this time, if physicians determine that continued use is appropriate for individual patients, FDA advises the use of the lowest effective dose of Celebrex."

Celebrex is approved in the United States for treatment of osteoarthritis and pain at doses of 100 milligrams to 200 milligrams a day, or double that for rheumatoid arthritis. It was approved by the FDA in 1998 and has been prescribed to 27 million Americans, according to Pfizer.

Patients in the cancer study were taking 400 milligrams to 800 milligrams of Celebrex daily or placebos, Pfizer said in a news release. Compared with placebo users, the risk of heart trouble was 2.5 times greater for patients taking 200 mg of Celebrex twice daily and 3.4 times greater for those who took 400 mg twice daily.

About 3,600 patients took part in the five-year study, the release said.

Pfizer said a second cancer study that it funded found no problems, and a third is in progress.

Celebrex was expected to generate about



Pfizer said it has no plans to pull the drug from the market.

FACT BOX

Celebrex at a glance

- Approved by the FDA in 1998.
- According to Pfizer, it is "the world's most-prescribed arthritis drug" and has been prescribed to 27 million Americans.
- At least three times since the Vioxx scandal, Pfizer has issued press releases affirming the safety of Celebrex.

Source: www.pfizer.com

VIDEO

A new study shows Celebrex could raise the risk of heart attack. CNN's Allan Chernoff reports.



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- Pfizer Incorporated

\$5 billion in sales for Pfizer next year, or about 9 percent of the company's total revenue, Sena Lund, an analyst for Cathay Financial in New York, had estimated before the announcement Friday.

Pfizer CEO Hank McKinnell told CNN the results from clinical trials were "unexpected," and said the company is taking "immediate steps to fully understand the results and rapidly communicate new information to regulators, physicians and patients around the world."

"We do know from a wealth of other information ... that Celebrex when taken as recommended, at the doses recommended, is safe and effective," he said.

Separately, New York-based Pfizer is facing an investigation by the New York attorney general's office related to Celebrex, a source familiar with the situation told CNN. The source said the probe was not linked to Friday's announcement but rather focused on claims of the effectiveness of the drug.

An official at New York Attorney General Eliot Spitzer's office declined to comment.

The FDA release said another Pfizer painkiller, Bextra, has been shown to increase risks of heart problems after bypass surgery.

Celebrex and Bextra were developed by Pfizer's Pharmacia division, which the company acquired in 2002.

Similar findings doomed Vioxx

The new findings for Celebrex come just over two months after Merck & Co. recalled Vioxx, a similar arthritis drug. A study found Vioxx doubled the incidence of heart attack and stroke among patients taking it longer than 18 months.

Merck is facing hundreds of lawsuits and potentially billions of dollars in damages from Vioxx patients.

At least three times during the revelations about Vioxx's dangers, Pfizer issued statements affirming that Celebrex was safe.

Pfizer has said it has no plans to pull Celebrex from the market.

John Abramson, a physician with Harvard University's medical school and author of "Overdo\$ed America: The Broken Promise of American Medicine," said it was too early to draw conclusions from the study.

"We don't know how serious the risk is," he said.

Abramson said the revelations highlighted the conflict of interest that exists when companies fund safety tests of their own products.

"[Celebrex] wasn't a wonder drug. It was wonder marketing," he said. "We need people with no financial connection to oversee the safety of our drugs."

Abramson recommended that patients taking Celebrex speak with their doctors about alternatives such as Advil.

"I would advise people to talk to their doctor, but understand that giving up Celebrex is not giving up the best drug," he said. "If people want to switch, they can switch to over-the-counter drugs that can probably give them as much relief as Celebrex, but without the complications."

The stock of Pfizer dipped \$3.23, or 11 percent, Friday, to \$25.75 on the New York Stock Exchange. Pfizer is the world's largest drugmaker and a Dow component.

- Merck & Company Incorporated
- National Cancer Institute
- Food and Drug Administration (FDA)

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