

What a Vioxx redux might do

An FDA panel said the Merck drug could return. Sales volume may be less, but good; lawsuits could turn either way.

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Call it a pharmaceutical phoenix.

Vioxx, the popular pain pill that Merck & Co. Inc. recalled 4 1/2 months ago, narrowly got a green light Friday from U.S. Food and Drug Administration advisers to go back on sale under tight prescribing rules and marketing limitations.

If the recommendation is approved and Merck brings back its blockbuster drug, some patients may be thrilled and the sagging drug industry may get a boost, medical and industry experts said. Merck stock rose 13 percent Friday.

But Vioxx, much of whose development and marketing was handled at Merck's facilities in Montgomery County, would have a hard time regaining its peak sales level of \$2.5 billion a year, they said.

And legislative and legal battles over Vioxx and other drugs are likely to rage on, and perhaps even intensify.

"If Merck puts it back, we would petition immediately to have it taken off the market," said Sidney Wolfe, director of the advocacy group Public Citizen, which calls Vioxx dangerous.

The prospect of a Vioxx comeback arose during an FDA hearing on the painkillers known as Cox-2 inhibitors - Celebrex, Bextra and Vioxx.

The drugs do not necessarily work better at reducing pain than older drugs, such as ibuprofen, but were designed to cause less gastrointestinal bleeding and fewer ulcers.

However, many independent studies also showed that Cox-2 drugs increase the risk of heart attacks, strokes and kidney problems. Merck voluntarily recalled Vioxx on Sept. 30, based on a company-sponsored study showing an increased risk of heart attack and stroke after 18 months on the drug.

Celebrex and Bextra, both made by Pfizer Inc., remained on the market, although their prescriptions plunged because of safety concerns.

In 2004, Cox-2 inhibitors were used by 50 million people worldwide, with sales topping \$5.3 billion, and were promoted by some of the industry's biggest sales forces and costliest marketing campaigns, according to IMS Health, a prescription tracking firm.

That made Vioxx a symbol. Its recall brought intense scrutiny of the FDA for approving the drugs in the first place, criticism of over-prescribing by physicians, and retrenchment in an industry reliant on blockbuster profits. Analysts predicted more layoffs, mergers and licensing deals.

Against that backdrop, the two FDA advisory panels, meeting jointly in Gaithersburg, Md., agreed that the Cox-2 drugs' benefits outweigh their risks. They had the most faith in Celebrex, were nearly divided on Bextra, and were most skeptical of Vioxx. They voted to let them stay on the market, but urged the FDA to require strict "black box" warnings to limit their use.

Panel recommendations are not binding on FDA officials but carry great weight. FDA officials promised a final decision within weeks.

On Thursday, in anticipation of the recommendation, Peter Kim, chief of Merck Research Labs in West Point, hinted that Merck might relaunch Vioxx if the panels concluded that all Cox-2 inhibitors had similar mechanisms, risks and benefits.

"If the advisory committee and FDA conclude that the benefits of this class outweigh the risks in some patient populations, then we would have to consider the implications of these new data, given the unique benefits Vioxx offers," the company said later in a statement.

Merck declined to comment further Friday, saying only it looked "forward to discussions with the FDA."

But expectations of Vioxx's return quickly swept through the medical community and industry.

"I think, frankly, Merck made a terrible mistake in withdrawing Vioxx," said George Ehrlick, a Philadelphia physician and a former chairman of the FDA arthritis advisory committee that met this week. "There is still a group of people it serves, and they could've restricted the group with better labeling."

A group representing people with psoriasis called for keeping the drugs on the market.

But at least one patient remained skeptical. "I probably won't take it, out of an abundance of caution," said Philadelphia lawyer Mike Ecker, 46, who said he had constant foot pain from damage to his arches.

For Merck and Pfizer, "things will be OK," said Timothy Anderson, an analyst at Prudential Financial Securities.

"Sales will definitely be restricted. These drugs were always overutilized," Anderson said.

David Kramer, chief executive officer of Medical Broadcasting Co. in Philadelphia, which has designed marketing campaigns for pharmaceutical firms including Merck, was more bullish.

"Absolutely, it could regain its blockbuster status," he said. "My advice would be, stay away from advertising, at least initially, because an ad by its own virtue draws the wrong kind of scrutiny."

Kramer said he would advise Merck to focus its relaunch campaign directly on physicians and on the medical organizations that influence their prescribing decisions.

Merck faces at least 575 personal-injury cases over Vioxx, three federal investigations, and a score of investor lawsuits related to its recall decision. Opinions differed on whether relaunching Vioxx would affect those claims.

"It would just make it more difficult for lawyers to argue that Vioxx never should've been approved in the first place," said Ruairi O'Neill, a PNC Advisors analyst.

However, Thomas Kline, a partner at Kline & Specter in Philadelphia, a leading firm in the lawsuits, said rereleasing Vioxx with new patient restrictions could strengthen his cases.

"There is an element of proof here that the labeling was wrong to begin with," Kline said. "The proof is not in the withdrawal of the drug. The proof is in the overwhelming scientific evidence that the drug is bad."