Pfizer Takes Painkiller Bextra Off Market

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By LAURAN NEERGAARD, AP Medical Writer

WASHINGTON - The blockbuster painkiller Bextra was yanked off the market Thursday, and the government ordered that 19 other popular prescription competitors — from Celebrex to Mobic to high-dose naproxen — carry tough new warnings that they, too, may increase the risk of heart attacks and strokes.

The warnings encompass an entire class of anti-inflammatory medicines called NSAIDs that are the backbone of U.S. pain treatment, not just newer versions of the painkillers initially suspected when the heart concerns made headlines last fall.

The warnings — in black boxes, the strongest the Food and Drug Administration can order — are likely to cause confusion because they won't tell patients and doctors which of these prescription drugs is a safer choice.

In addition, the FDA will make over-the-counter NSAIDs, or nonsteroidal anti-inflammatory drugs, such as ibuprofen, naproxen and ketoprofen bear stronger reminders to take only low doses for a few days at a time to avoid the same risks of high-dose, long-term use.

Worried patients immediately began calling doctors and pain groups to ask what drug they should take. The FDA advised patients to ask which painkiller is best suited to their personal health risks, and then take the lowest dose possible.

There simply isn't enough research yet to rank which drug will pose...
fewer heart problems, said FDA drug chief Dr. Steven Galson. "A lot of the data conflicts," he said.

The FDA is asking painkiller manufacturers to sift through their research to help figure that out.

"Let me emphasize now, this announcement is unlikely to be the last word you'll hear on these drugs," Galson said.

The saga began last September when Merck & Co. voluntarily pulled its pain reliever Vioxx off the market after a study showed long-term use doubled patients' risk of heart attacks and strokes. Pfizer Inc.'s Bextra and Celebrex are similar drugs, a subset of NSAIDs known as cox-2 inhibitors, and studies show they also can raise cardiovascular risks, although apparently to a smaller degree than Vioxx.

Pfizer reluctantly suspended Bextra sales in the United States and European Union on Thursday, at the request of the FDA and its European counterparts. The FDA said that in addition to the cardiac concern, Bextra appears to cause rare but serious skin conditions — some fatal — more often than do other NSAIDs, making the drug too risky to remain on the market.

Pfizer's Celebrex still can sell, the FDA announced Thursday.

But it and all other prescription NSAIDs must carry a major warning on the label that long-term use may cause serious cardiovascular side effects or gastrointestinal bleeding. No one who recently underwent heart bypass surgery should use prescription-strength NSAIDs, the warning stresses.

Also, patients are to receive a special pamphlet with every NSAID prescription filled that spells out the warnings in consumer-friendly language.

Thursday's move was a blow to Pfizer, which said it "respectfully disagrees" with the FDA that the drug, which had sales of $1.3 billion last year, is too risky. Pfizer pledged additional research on Bextra's heart risks and said it would try to bring back the drug.

Use of cox-2 inhibitors skyrocketed, particularly by people with arthritis and other chronic pain, when they hit the market in the late 1990s because of claims that they were easier on patients' stomachs than traditional painkillers. The FDA cautioned that those claims were never proven.

Celebrex, with sales of $3.3 billion last year, remains the nation's last cox-2 inhibitor on sale.

It should be prescribed only for patients not helped by other painkillers, or who are at particularly high risk for stomach problems, said Vanderbilt University pharmacologist Dr. Alastair Wood, who advises the FDA on drug safety.

For chronic pain, such as arthritis, Wood recommends starting patients on the NSAID naproxen, along with a stomach-protecting drug if necessary.

There are studies that show naproxen poses far fewer heart risks than Celebrex or the other now-defunct cox-2 inhibitors, said Dr. Sidney
Wolfe of the consumer advocacy group Public Citizen. He called the FDA’s decision to put the same warning on every NSAID “incredibly reckless.”

These painkillers are "still very good drugs," stressed Dr. Thalia Segal of the New York University Pain Center. But, "we're not supposed to take them for life anymore."

Instead, she advises looking for non-pill therapies where possible. Lidocaine pain patches, for example, help knee arthritis, as does losing weight, she said. Acupuncture, heat or massage helps various forms of pain.

On the Net:

Food and Drug Administration:
http://www.fda.gov/cder/drug/infopage/cox2/default.htm

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