

Pfizer reacts with a Press Release, rather than a warning about strokes and heart attacks.

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Want to know what Pfizer is saying about the article linking its drug Bextra to strokes and heart attacks? Consider that Pfizer is selling \$600,000,000 worth of the drug, and then see what they have to say below.

Pfizer Statement on Bextra(R) (Valdecoxib) Wednesday November 10, 1:55 pm ET

NEW YORK, Nov. 10 /PRNewswire-FirstCall/ — Pfizer Inc said a New York Times article published today draws unsubstantiated conclusions about the cardiovascular safety of its COX-2 medicine Bextra and is based on information that has not been published in a medical journal or subject to independent scientific review. In contrast, the White et al. analysis published earlier this year in the peer-reviewed American Journal of Therapeutics(1) stated that short-and intermediate-term treatment with Bextra was not associated with an increased incidence of thrombotic events relative to nonselective NSAIDs or placebo in osteoarthritis and rheumatoid arthritis patients. This conclusion was based on evaluation of a clinical trials database that includes nearly 8,000 patients treated with Bextra for durations ranging from 6 to 52 weeks.

"Pfizer has shared Bextra clinical results in a timely manner with regulatory authorities both in the United States and worldwide," said Joseph Feczko, MD, Pfizer's president of worldwide development. "In addition, in an October 15 communication, a comprehensive summary of currently available data was provided to healthcare professionals in the United States." This communication included information regarding the White analysis as well as the results of studies in several surgical settings. As previously announced, Pfizer has committed to conducting further studies to confirm the longer-term cardiovascular safety profile of Bextra in patients who require chronic treatment for arthritis with a COX-2-specific inhibitor.

The Food and Drug Administration plans to convene an advisory committee in February 2005 to review the cardiovascular safety of all COX-2 inhibitors. "We look forward to a scientific and reasoned evaluation in this appropriate setting," Dr. Feczko said.

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#### Additional Information on Bextra

Bextra is contraindicated in patients who have demonstrated allergic-type reactions to sulfonamides; in patients with known hypersensitivity to valdecoxib; and in patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or NSAIDs because severe, rarely fatal, anaphylactic-like reactions to NSAIDs are possible in such patients. In rare cases, serious skin reactions can occur. Fatalities due to Stevens–Johnson syndrome and toxic epidermal necrolysis have been reported. If an allergic reaction is suspected or if there are other severe or unusual symptoms while taking Bextra, a patient should call his or her doctor or other healthcare professional immediately.

DISCLOSURE NOTICE: The information contained in this document is as of November 10, 2004.

Pfizer assumes no obligation to update any forward-looking statements contained in this document as a result of new information or future events or developments.

This document contains forward-looking information. A list and description of risks and uncertainties relating to matters discussed in this document can be found in the Company's Annual Report on Form 10–K for the fiscal year ended December 31, 2003, and in its periodic reports on Forms 10–Q and 8–K.

(1) White WB, et al. "Effects of the Cyclooxygenase–2 Specific Inhibitor Valdecoxib Versus Nonsteroidal Antiinflammatory Agents and Placebo on Cardiovascular Thrombotic Events in Patients with Arthritis." *American Journal of Therapeutics*. 2004; 11: 244–250. Number 4.

Michael Monheit, Esquire is the managing attorney for Monheit Law, located in Philadelphia, Pennsylvania Monheit Law, P.C. concentrates its practice in the field of plaintiff personal injury cases on a contingency fee basis. They can be found at <http://www.monheit.com/Bextra>

#### **Forbe's writes, "Forget Bextra"**

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On November 10, 2004, according to Forbes Magazine, "Pfizer was blindsided as The New York Times reported information about a reanalysis of old data that say the drug giant's Bextra, which is similar to Merck's Vioxx, increased the risk of heart attacks and strokes."

However, one has to ask, how much of a blind side could it possibly be, when Pfizer receives that adverse reports from doctors whose patients are having these side effects, such as heart attacks and strokes? Only time will tell how much Pfizer knew before. Looking back a month, Pfizer decided to update its warning. So it appears clear that they saw this coming.

While the link to strokes and heart attacks in all patients may not be clear at this point. It seems that it is only a matter of time. Forbes recommends that the "executives should start thinking about Bextra as a lost cause, partly because it will make it easier for the company to defend Celebrex, which is

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Bextra's chemical cousin and one of Pfizer's best-selling drugs."

Pfizer is sure to be pulled into the mix as the FDA convenes a panel to look at all Cox-2 drugs. This may actually be a boon for Pfizer, who can narrow its focus on how Celebrex may be safer, as it does not take Cox-1 and Cox-2 as far out of balance with each other. It may be better, albeit having a greater risk of ulcers.

The information was released by Dr. Garret FitzGerald, a pharmacologist at the University of Pennsylvania, in a lecture he was giving here at the American Heart Association's annual meeting. However, it is not a detailed study, and only a retrospective looking back at data. Pfizer has already admitted that open heart surgery data showed an increased risk of heart attack and stroke in those patients. Pfizer disclosed information about those studies in increased warning letters approved by the FDA and sent to doctors on Oct. 15.

According to Forbes, "FitzGerald and two colleagues used statistical methods to try to make sure that he wasn't mixing apples and oranges by adding data about patients with arthritis, but he says the risk was certainly driven by the open heart surgery patients. In the first open heart surgery paper, patients were 3.5 times more likely to have heart attacks than those on a sugar pill. In the second, the risk was 2.88 times higher. In the third study, of arthritis patients, the risk was 1.77 times higher, according to slides presented by FitzGerald."

What is needed now is further study. Meanwhile, those injured by this drug will wonder why further study was not done sooner. Pfizer is trying to defend itself, claiming that meta-analysis shows the drug is safe.

FitzGerald calls for better warnings, rather than a withdrawal of the drug. In this way, a doctor can exercise his sound judgment in determining if the risks are worth the medical effectiveness of the drug. Pfizer may need to act fast in putting this warning out, so that patients are given the risks and choices of alternatives.

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