Why Pick on Bextra?

By ACSH Staff — April 8, 2005

Now that the FDA has pressured Pfizer to remove Bextra from pharmacy shelves, applause rains down from the usual locales: self-styled "consumer advocates," politicos looking for a quick score, and columnists, all patting themselves on the back for "getting" Bextra.

The losers here, also as usual, are those members of the public who benefited (or might have benefited later on) from using this pain-relieving Cox-2 inhibitor.

Bextra was an easy target, especially in these troubled times for the FDA and its still-acting head, Dr. Lester Crawford. It was a member of a tainted class of drugs, the Cox-2s, once industry and clinical favorites, now under widespread assault. It and its cousins, Vioxx and Celebrex, had been granted reprieves from a special panel in February, Bextra by a narrow margin. The concerns were largely over this class of drugs' association with cardiovascular events. The panel, surprisingly and to its credit, overcame these doubts and allowed the drugs to remain on the market, although with stronger warnings (Vioxx had been pulled voluntarily, worldwide, by Merck last September after a study showed a near-doubling of vascular events).

Bextra was the least-prescribed of the three but still had quite a following -- enough users to account for sales of "only" $1.3 billion in 2004! But it also has a unique toxicity: in an extremely small number of users, it caused a severe skin reaction called Stevens-Johnson syndrome, a potential killer. This was the lever used by the FDA to justify its recent advisory -- the equivalent of a ban.

The official FDA advisory letter on Cox-2s (which also mandated labeling changes for the entire NSAID class) notes the inadequate data for Bextra on "cardiovascular safety of long-term use" and "the lack of any demonstrated advantages for Bextra compared with other NSAIDs." Well, the Bextra CV safety data is not so different from the other Cox-2s, and the data on the wide class of NSAIDs is ;well, it's just not there at all, despite thirty-plus years of use. Maybe no one ever thought to do a long-term study on the heart effects of ibuprofen or naproxen -- or more likely, scientists in the pharmaceutical industry saw such studies as a no-win situation for them. Who would conceive of doing a long-term, hugely expensive study that might demonstrate some minor toxicity of a drug in wide clinical use since the 1970s -- such as ibuprofen -- and risk having the new Drug Safety Oversight Board ban it?

So Bextra is gone, joining Vioxx on the pharmaceutical museum shelf. Of course, there is a theoretical possibility that one or both of these drugs, and the unique benefits they hold for many, may someday return. Meanwhile, what about the many thousands of patients who got relief of pain and no untoward effects? Too bad -- they have been regulated out of the picture. Bextra's only a "me-too" drug, after all, and one person in a million may get a skin condition, so out it goes. Activists have advocated, regulators have regulated, and patients will now pay the price. The
choice to use this drug in appropriate populations -- in bygone days, a choice made between doctor and patient -- is no longer to be an option. Someday, regulators and consumers will learn that nothing is risk-free.

Like Vioxx, Bextra may have other benefits of which we will never learn. Vioxx itself, remember, was pulled just after a study demonstrated that it did indeed reduce the incidence of precancerous colon polyps significantly -- but elevated heart risk. At the time of its withdrawal from the market last fall, studies of Vioxx as well as the other Cox-2 drugs suggested they had other anticancer properties as well, possibly reducing the risk of malignancies of a number of sites, including the prostate, lung, bladder, and esophagus. Preliminary studies of Celebrex offered hope it might protect women from breast cancer risk by lowering levels of estrogen receptors. This relatively new class of drugs also showed promise for forestalling the devastating effects of dementia, such as Alzheimer's disease.

Analysts predict that the current withdrawal will redound against the return of Vioxx as well -- although the FDA committee did not so advise in February.

With the imminent creation of an independent FDA drug safety office, it seems likely that whoever is in charge will tend to pull drugs from the market based on ordinary side effects. Will Celebrex -- Pfizer's blockbuster and the only surviving Cox-2 drug in the U.S. -- survive for long? Now is the time for patients who depend on it, as well as scientists who would like to see more benefits discovered, to start getting worried.

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