Help for Arthritics?

By ACSH Staff — December 8, 2006

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There are two new COX-2 inhibitors on the market in Europe and many other regions, offering possible help against both arthritis and cancer but not in the United States: Novartis' Prexige and Merck's Arcoxia. Will our drug agency fairly evaluate them on the standard benefits and risks scale?

Ever since the recall of the arthritis drug Vioxx three years ago, clinicians, public health experts and patients have been left to wonder if the specter of Vioxx will forever haunt this entire class of potentially beneficial drugs.

Vioxx was removed from the market because of an increased risk of cardiovascular side effects. Even so, many clinicians believe that it should still have a place in the formulary. It still would if it had been prescribed only to its real target group: active arthritics with known gastric intolerance to the older arthritis drugs, the NSAIDs, and with no elevated risk of heart problems. Not only would such patients likely benefit, but Vioxx, as well as other members of the COX-2 class, have been shown to have protective effects against colorectal cancer.

Until the Vioxx debacle, the drugs in the COX-2 inhibitor category -- Pfizer's Celebrex and Bextra, in addition to Vioxx -- were thought by researchers and clinicians to be highly beneficial therapies. They were developed to provide pain relief and anti-arthritis effects with less stomach toxicity than their older cousins, the NSAIDs. The prevention of cancer was discovered serendipitously during post-marketing surveillance -- the same system of oversight that detected the increased heart risk, ironically.

In September 2004, Merck acknowledged the adverse cardiovascular effects of Vioxx detected in their own trial and pulled the drug under pressure, inciting a firestorm of litigation and criticism of Big Pharma and the FDA. Self-styled consumer advocates, Congressmen and even insiders at the FDA blasted the "lax oversight" which had allowed Vioxx on the market.

Now Merck is testing the COX-2 waters again. Its Arcoxia has been available worldwide for some time, but the application it first submitted to the FDA in 2003 has been on hold ever since. A newly released study shows that the drug is relatively safe for the stomach and has no excess cardiovascular risk. These data came from a study involving over 34,000 patients and were reported by researchers from the Harvard Medical School. Merck expects the FDA to have its re-evaluation completed by April 2007.

The Swiss company Novartis recently received EU approval to market Prexige. A new study showed that this drug was associated with far fewer gastrointestinal side effects than two older NSAIDs, ibuprofen and naproxen. And, as with Arcoxia, there was no increase in cardiovascular
adverse effects. The FDA will also get to consider Prexige early in 2007, according to Novartis.

Doctors and patients will be keeping close track of the FDA deliberations on these drugs. Will the new members of the suspect COX-2 class get a fair hearing from the chronically risk-averse FDA? Experience has shown that the FDA is not immune to unscientific pressures. In the case of the COX-2 drugs, trying to avoid all risk is, in fact, a bigger risk than allowing them on the market. The newer COX-2’s have been shown to be as effective as, and safer than, the older arthritis drugs. The scientists at the FDA know that all drugs have risks. As a former practicing rheumatologist, I can bear witness to the suffering caused by arthritis, and I hope the regulators see fit to allow patients access to new treatment options and do not hesitate because of baggage from "the Vioxx taint."

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