

READERS REACT

Is FDA playing politics with pain pills?



CHRISTOPHER A. WILLS
THE ORTHOPEDIC SURGEON IN ORANGE SENT A VERSION OF THIS LETTER TO THE DIRECTOR OF THE FOOD AND DRUG ADMINISTRATION

I was extremely upset to hear about the latest recommendation of the Food and Drug Administration regarding the withdrawal of Bextra from the market.

I am a practicing orthopedic surgeon and my grandfather, Dr. Theodore Klumpp, was once head of the pharmaceutical portion of the FDA. I have extensive experience over 25 years with the use of anti-inflammatory medications in my patients, including Vioxx, Bextra and Celebrex. I think it is appalling that the FDA has taken the action it has.

In many cases for our arthritic patients, anti-inflammatory medications are the difference between functioning with a fairly normal life-style and not being able to function at all.

I think the FDA, in a somewhat knee-jerk type of political response, is losing sight of the overall benefits when evaluating these medications with regard to their risks.



BLOOMBERG

The FDA has forced the painkiller drug Bextra off the market.

While it is undeniable that these medications have risks and need to be used in an educated and reasonable fashion, it is absolutely wrong to have pulled Bextra off the market based on the scientific data available.

Based on my review of the available data and on extensive clinical practice, I agree that Vioxx is the riskiest of the COX 2 anti-inflammatory medications and should be used only sparingly and only when the

benefits are worth the risks.

Reasonable physicians, however, are perfectly capable of making these benefit-to-risk decisions. To limit our ability to make these decisions based on the available risk data is unreasonable. Bextra, which has a far safer profile, is also far more effective in my clinical experience.

When you weigh the increase in function that our patients have against the known risks of Bextra when it is used properly, the benefits clearly outweigh the risks for many patients.

My analogy for the current actions at the FDA would be for the FAA to ban all airline travel in order to deal with the real and significant problem of passenger aircraft crashes. Such a ban would effectively solve the problem of passenger aircraft crashes. Unfortunately, the net effect of the policy would be to shift these passengers into other modes of transportation, such as personal automobiles, trains

and buses, which, as we know, have a far higher incidence of fatal crashes. The effect of such a policy would be to eliminate all airline fatalities, which the FAA could point out is very good.

Unfortunately, we would have 10 to 20 times that many fatalities as the passengers shifted to other modes of transportation.

It is reasonable to expect that trained physicians can make appropriate medical decisions when weighing risks versus benefits of medications such as the COX 2 anti-inflammatories.

This whole current FDA process of analysis of COX 2 anti-inflammatory medications has a very strong smell of political pressure and media hype. These decisions should not be based on those concerns.

The individual medical decisions as to whether or not to use these drugs should be left up to the physicians - with education from the FDA.