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January 11, 2005

Lester M. Crawford, D.V.M, Ph.D
Acting Commissioner
US Food and Drug Administration
U.S. Department of Health and Human Services
Parklawn Building
5600 Fishers Lane, Room 15-47
Rockville, MD 20857

Dear Dr. Crawford:

Following the recall of Vioxx and the concerns that have been raised over the safety of other COX-2 inhibitors and nonsteroidal anti-inflammatory pain medications (NSAIDS), many patients are confused and trying to figure out what pain medications are safe for them to take. I believe that it is very important for the FDA to quickly provide some guidance for physicians and consumers regarding the risks and benefits of these drugs. I am writing to ask for your help in examining the available information about the risks and benefits of these drugs.

In December, after concerns were raised regarding the drug Celebrex, researchers turned to a large, ongoing three-year-old National Institutes of Health (NIH) study which designed to evaluate whether Celebrex and naproxen could help delay the onset of Alzheimer's disease. This review uncovered the potential problem with naproxen. If this analysis had never been conducted, we would still be in the dark with regard to the risks of naproxen.

Therefore, if a review is not currently underway, I respectfully request that you immediately launch a comprehensive review of all government sponsored studies that could possibly provide some insight into the safety and effectiveness of COX-2 inhibitors and NSAIDS that have been conducted or are ongoing at any of federal agencies including the FDA, the Departments of Health and Human Services (HHS), Veterans Affairs, and Department of Defense. After conducting this review, I would urge the Secretary to release the data and provide the public with clear guidance on the use of such drugs for pain management in the light of the possible risks associated with these drugs.

I also request your assistance in providing answers to the following questions:

1. How many federally supported studies that examine COX-2 inhibitors and/or NSAIDs for any purpose have been conducted or are ongoing at any of federal agency, including the Department Health and Human Services (HHS), Veterans Affairs, and the Department of Defense. Please provide a list of these studies.
2. Other than the Alzheimer's study, has any of this research been reviewed in light of the recent concerns raised about the safety of these drugs? If so, how many? If not, why?

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Have attempts been made to compare results across studies? How do the methodologies compare across studies?

3. Have these reviews yielded any valuable information that could provide consumers and health care professionals with further guidance as to how to evaluate the risks and the benefits of these medications?
4. If a review across federal agencies has not been conducted, what mechanisms/resources are available to implement such a review of studies across federal agencies?
5. Have the advisory committees on Drug Safety and Risk Management or Arthritis Drugs made any recommendations regarding the recent concerns raised regarding these drugs? If so, what did they recommend? If not, are they planning on meeting to discuss these concerns and provide recommendations? If so, when are they planning on meeting? If not, why not?
6. What other actions is the FDA taking to examine the safety and effectiveness of all Cox-1 and Cox-2 inhibitors and NSAIDs?
7. When and how does the FDA plan to issue guidance to consumers and health care professionals regarding these drugs?
8. In a recent letter (December 22, 2004) to you, I suggested redesigning a portion of the FDA website and renaming it "sideeffects.gov." Such a site would be an excellent place to provide user friendly information on these medications as well as guidance on how to manage pain in light of recent concerns. What plans does the FDA have to launch an education campaign to inform consumers about side effects information available on its website or make other changes in the website to make it more accessible to consumers (such as those suggested in my letter of December 22nd)?

Thank you for your attention to this important issue. If you have any questions regarding this request, please do not hesitate to contact Ms. Katharine Reinhalter or Mr. Jeffrey Duncan on my staff at 202-225-2836. I look forward to your prompt reply.

Sincerely,

Edward J. Markey

Edward J. Markey
Member of Congress