



February 15, 2005

Division of Dockets Management  
(HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville, Maryland 20852  
e-comments to <http://www.fda.gov/dockets/ecomments>

Re: Joint Meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee -- Docket No. 2004N-0559 "Overall Benefit to Risk Considerations for COX-2 Selective Nonsteroidal Anti-inflammatory Drugs and Related Agents"

### **Introduction**

These comments are submitted by Consumers Union of U.S., Inc. (CU)<sup>1</sup> to the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee for consideration during their joint meeting (Joint Meeting) scheduled for February 16-18, in Gaithersburg, Maryland.

The Joint Meeting will convene to discuss the overall benefit to risk considerations (including cardiovascular and gastrointestinal safety concerns) for COX-2 selective nonsteroidal anti-inflammatory drugs and related agents. As the Committees consider the safety questions specific to COX-2s, we urge the Committees and the FDA to also address the systemic problems of FDA's drug

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<sup>1</sup>Consumers Union is a nonprofit membership organization chartered in 1936 under the laws of the State of New York to provide consumers with information, education and counsel about good, services, health, and personal finance; and to initiate and cooperate with individual and group efforts to maintain and enhance the quality of life for consumers. Consumers Union's income is solely derived from the sale of *Consumer Reports*, its other publications and from noncommercial contributions, grants and fees. In addition to reports on Consumers Union's own product testing, *Consumer Reports* with approximately 4.5 million paid circulation, regularly, carries articles on health, product safety, marketplace economics and legislative, judicial and regulatory actions which affect consumer welfare. Consumers Union's publications carry no advertising and receive no commercial support.

safety system that have delayed and stifled public availability of drug safety information about NSAIDs, hampered the ability of the agency to take timely action to address public health concerns surrounding them, and suppressed internal voices within the agency who sought to bring safety issues to light.

Our comments focus on these broader public policy concerns that, unless addressed, will continue to threaten public confidence in FDA's ability to fulfill its mission and protect consumers from unreasonably unsafe drug products. We welcome Secretary Leavitt's announcement, on February 15, 2005, that FDA is taking steps to improve public transparency of FDA drug safety information and will create a drug safety oversight board to oversee management of drug safety issues and policies. We look forward to more information on the responsibilities and authorities of that board, how it will differ from current advisory committee functions, and how FDA will decide what information is made available on the Drug Watch web site.

We believe, however, that additional steps must be taken to ensure the safety of drugs for consumers. While some of our recommendations would require Congressional action, a number can be implemented within FDA's existing statutory authority. We urge the Agency and Congress to act quickly to better equip and empower the FDA to address the current crisis in drug safety.

### **Loss of Public Confidence**

To a great extent, the public has lost confidence in the ability and the willingness of FDA to protect consumers from unreasonably dangerous drugs. Recent regulatory failures relating to painkillers (such as COX-2 inhibitors considered during this Joint Meeting) likely resulted in tens of thousands of untimely deaths. Other drug safety concerns such as the dangers of antidepressants taken by children, and other serious drug safety revelations have called into question the ability of the Agency to serve as a swiftly moving, strong and effective guardian of the public health. Some measures needed to improve drug safety and transparency include:

## **1. Strong and Independent Office of Drug Safety**

Consumers need a strong, independent and transparent Office of Drug Safety at FDA that is empowered to vigorously pursue emerging safety concerns and is free of the conflicts and concerns highlighted by Dr. David Graham in his November 18, 2004 testimony before the Senate Finance Committee. The strengthened Office must be given the ability and authority to:

- Operate independently and free of undue influence from staff responsible for the initial approval of new drugs;
- Where safety questions arise, mandate that a company conduct studies seeking to clarify the extent of any unreasonable risks associated with use of the drug both before and after the drug is approved. The Office should have the ability to set both the deadlines, terms and standards for such studies;
- Make determinations, independent of the Office of New Drugs, as to whether a drug poses a significant health risk and demand or take corrective action to minimize unreasonable risks. This authority should include, among other steps: restrictions on distribution; timely labeling changes; and oversight or withdrawal of promotional materials; and marketing campaigns, especially where alternative products exist with a better safety profile;
- Where the Office determines that corrective action is insufficient to protect public health, withdraw the product using expedited processes; and
- Withdraw a product or strongly penalize a company when drug sponsors fail to meet the deadlines and terms for required safety studies.

## **2. Mandatory Clinical Trial Registry and Disclosure of Results**

Congress must give FDA the ability to require that companies register all clinical trials before they begin, and make all trial results publicly available in a usable and accessible format. FDA's current drug trial registry functions

solely to inform the public about the opportunity to participate in some drug trials. It does not provide complete information about *all* ongoing clinical trials, nor does it provide results for *any* clinical trials. Efforts of the pharmaceutical industry to provide for disclosure of drug trial results are voluntary and therefore wholly inadequate.

Had clinical trial data regarding NSAIDs been more widely available, it is likely this Joint Meeting to consider the safety of these drugs would have occurred several years ago, saving lives and better protecting public health. Pairing a clinical drug trial registry with mandatory disclosure of trial results would not only create a centralized repository for such information -- making adverse information much more difficult to hide and providing consumers and physicians the information they need -- it would also help hold the FDA and drug sponsors publicly accountable. Consider the experience of Oregon and Washington State: Medicaid program administrators excluded Vioxx from their preferred drug lists a full two years before it was withdrawn from the market precisely because they had access to and analyzed key safety information related to cardiac concerns that allowed them to them to conduct comparative analysis on safety and effectiveness for painkillers. This information should be made more widely available so that state and federal regulators, researchers, consumers and doctors can make more informed health care decisions as FDA waits to act on drug safety.

### **FDA Five-Point Plan to Improve Drug Safety**

On November 5, 2004, the FDA announced that it would strengthen its system for reviewing drug safety by: (1) sponsoring an Institute of Medicine study of the drug safety system (emphasizing the post-market phase); (2) implementing a program for adjudicating differences of professional opinion; (3) appointing a director for the FDA ODS (responsible for overseeing the post-marketing safety program for all drugs); (4) conducting drug safety/risk management consultations (including workshops and advisory Committee meetings to discuss complex drug

safety and risk management issues); and (5) publishing risk management guidances.

While these efforts are positive steps, they provide little in the way of immediate demonstrable structural improvements to address the regulatory shortcomings of FDA highlighted by Congress, public interest groups and the media over the last 12 months. Moreover, reliance on the IOM study will merely delay reform that clearly is needed now to improve the drug safety system and restore public confidence in the Agency. We urge the Arthritis Advisory Committee and The Drug Safety and the Risk Management Advisory Committee to recommend such action independent of the IOM review.

### **Increased Funding of Comparative Effectiveness and Safety Data**

As noted above, consumers need unbiased comparative information in order to make the best decisions in selecting appropriate drug treatments. In order to better inform consumers, the Administration should request and Congress should provide full funding for Section 1013 of the Medicare Modernization Act, which would enable publicly funded study of the relative cost-effectiveness of drugs. Counteracting the ability of companies to increase demand for a product that may be no more effective than a less expensive prescription or over-the-counter drug would greatly benefit the public health. However, without widely available clinical drug trial data, such comparative analysis will be difficult. Though implementation on Section 1013 falls outside the authority of FDA, this Committee can aid implementation of that section by urging greater transparency of clinical trial data for all approved drugs.

In an effort to better inform consumers, Consumers Union recently initiated the Consumer Reports Best Buy Drugs™ project ([www.CRBestBuyDrugs.org](http://www.CRBestBuyDrugs.org)). The mission is to provide consumers and their doctors with information to help guide prescription drug choices—based on effectiveness, a drug's track record, safety and price. The goal of the project is to fill a gap in the public's knowledge about the comparative effectiveness, safety

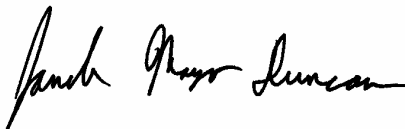
and cost of prescription drugs and especially how drugs to treat a given illness or condition stack up against each other. Armed with the information provided, consumers—in consultation with their doctors—will be better able to choose drugs that best suit their medical needs while taking cost into account. The project gives the public another perspective on the comparative value of prescription drugs—a perspective not driven primarily by pharmaceutical industry marketing and advertising that often emphasizes newer (and more costly) drugs.

### **Conclusion**

Consumers Union commends the Arthritis Advisory Committee and the Drug Safety and the Risk Management Advisory Committee for their work at this important Joint Meeting on COX-2s, and urge them to recommend that FDA take immediate steps to fill any gaps in information remaining at the conclusion of the Joint Meeting required to determine the risks associated with the use of COX-2s – as compared to other products in the NSAID drug class. We strongly urge this Committee to recommend additional regulatory and statutory improvements required to implement the above-described improvements to the transparency of Agency decisions and to address drug safety concerns. We believe that the public availability of all clinical trial results, a strong and independent Office of Drug Safety, and the availability of comparative effectiveness and safety data will dramatically improve FDA’s ability to ensure drug safety and better enable consumers and doctors to make crucial treatment decisions.

For further information, please contact Janell Mayo Duncan or Jeannine Kenney at Consumers Union at 202-462-6262.

Respectfully Submitted,



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