

December 22, 2004

Senator Grassley  
Chairman  
Senate Finance Committee  
United States Senate  
Washington, D.C. 20510

Dear Mr. Chairman:

Consumers Union, publisher of *Consumer Reports* Magazine, U.S. Public Interest Research Group and the Consumer Federation of America commend the Senate Finance Committee for its recent work uncovering FDA delays in acting against potentially dangerous prescription drugs – most notably Vioxx – despite growing evidence of unreasonable safety risks. These failures have raised concerns about FDA's willingness and ability to fulfill its mandate to protect the American people from drugs with unreasonable risks.

This agency has lacked a Senate-confirmed head for almost of two-thirds of the current Administration's tenure. We believe that FDA must redouble its efforts on safety, and that it must have strong and determined leadership to reach this goal. We, therefore, strongly support your call, cited in an article in the December 19, 2004 *Washington Post*, "FDA's Reliance on Unconfirmed Chiefs is Faulted," stressing the need for stronger, permanent leadership at the Food and Drug Administration. We urge you to call upon President Bush asking him to act immediately to nominate a Commissioner to the FDA for this critical post.

Furthermore, we strongly support your June request of the General Accounting Office to investigate the FDA Office of New Drug Approval (OND) and the Office of Drug Safety (ODS) to determine whether ODS is improperly suppressing staff concerns about drug safety. We agree that it is critical that systemic failings at FDA be identified so that they can be addressed. We urge the Committee to seek completion of the study by GAO as soon as possible.

As you know, at the November 18, 2004 Finance Committee hearing, Dr. David Graham – the FDA employee who battled internally to have Vioxx pulled from the market – courageously detailed systemic problems at the agency, and concluded "that the FDA, as currently configured, is incapable of protecting America against another Vioxx." In addition, during the hearing Dr. Graham named five more drugs that should be examined to determine if they should remain on the market. Dr. Graham's concerns have been confirmed by the recently released results of a 2002 survey conducted by the HHS Inspector General's Office of FDA scientists indicating that almost one fifth of those surveyed said they had been pressured to approve a drug despite concerns about safety, effectiveness or quality.

As an implicit recognition of the agency's shortcomings, on November 5, 2004, the FDA announced that it will 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.

We believe that both the GAO and the National Academy studies may yield important insight as to changes needed at FDA to ensure that early warning signs about drug safety are investigated and the public adequately protected. To further protect consumers, we strongly support the creation of a vigorous and independent office of drug safety, and legislation mandating sponsors of clinical trials register their studies in a central repository and make the trial results public. A public clinical trial registry will make adverse information much more difficult to hide, and would give consumers and physicians the information they need as they make important decisions about health care.

We look forward to working with you and other members to make certain that the FDA effectively ensures prescription drug safety for consumers.

Sincerely,

Janell Mayo Duncan  
Legislative and Regulatory Counsel  
Consumers Union

Travis Plunkett  
Legislative Director  
Consumer Federation of America

Lindsey Johnson  
Consumer Advocate  
US Public Interest Research Group

cc: Members of Senate Finance Committee