



Consumer Federation of America

December 22, 2004

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

Dear Senator Bingaman:

Consumers Union, publisher of *Consumer Reports* Magazine, U.S. Public Interest 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 to restore public confidence the 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 to President Bush today asking him to find a new leader as soon as possible for this critical FDA post.

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.” 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 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 Office of Drug Safety (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.

Furthermore, we strongly support Senator Grassley's June request of the General Accounting Office to investigate the FDA Office of New Drug Approval (OND) and 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.

We believe that both the National Academy and GAO 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