December 14, 2004

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

Dear Senator Bingaman:

Consumers Union, publisher of *Consumer Reports* Magazine, commends 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 to President Bush asking him to act immediately to nominate a Commissioner to the FDA for this critical post.

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 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 well know, 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.

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 (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 legislation mandating sponsors of clinical trials to 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,

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cc: Members of Senate Finance Committee