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## United States Senate

COMMITTEE ON HEALTH, EDUCATION,  
LABOR, AND PENSIONS

WASHINGTON, DC 20510-6300

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<http://help.senate.gov>

May 22, 2006

Dr. Andrew C. von Eschenbach  
Acting Commissioner  
U.S. Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Dear Dr. von Eschenbach:

We write today regarding the March 31st Government Accountability Office report "Drug Safety: Improvement Needed in FDA's Postmarket Decision-making and Oversight Process." This report is especially timely, since work is now beginning on the reauthorization of the Prescription Drug User Fee Act.

As you may know, we are developing legislation to improve the agency's regulation of drug safety after drugs have been approved. It is significant, however, that GAO has suggested changes in FDA's internal culture, procedures, and communications that the agency could implement without the need for legislation.

The report identified four major issues involving FDA processes:

1. A lack of clear and effective procedures for making decisions about post-market safety issues, and following up on those decisions.
2. A lack of procedural criteria for determining when to take a safety action and what that action should be.
3. Certain aspects of the role of the Office of Drug Safety are unclear, and insufficient communication between that office and the Office of New Drugs has sometimes hindered decision-making.
4. The Office of Drug Safety does not track information about ongoing safety issues, including the recommendations they make and what action, if any, is taken on those recommendations.

We recognize that the FDA has taken a number of steps in the past 18 months to improve its internal procedures on drug safety, and we commend those efforts. We believe that continued refinement of the internal workings of the agency is consistent

with your mission and has the potential to translate into better protection and promotion of the public health.

We respectfully request that you provide us with your assessment of GAO's recommendations, and what, if any, steps the agency plans to take to address them. If the agency has already begun to implement changes that will address the GAO's concerns, we request that you identify those initiatives and explain how they address the concerns. If you believe that the GAO's concerns are unwarranted, please explain why.

We ask that you respond by June 8. We also ask that you keep us informed on an ongoing basis of the agency's progress in this needed effort. Thank you for your consideration, and we look forward to your response.

Sincerely,



Michael B. Enzi  
Chairman



Edward M. Kennedy  
Ranking Member