

News from the

**U.S. Senate Committee on
Health, Education, Labor and Pensions**

Michael B. Enzi (Wyoming), Chairman



For Immediate Release

Monday, May 22, 2006

Contact: Craig Orfield (Enzi) 202.224.6770

Melissa Wagoner (Kennedy) 202.224.2633

***ENZI, KENNEDY, REQUEST FDA RESPONSE TO GAO RECOMMENDATIONS FOR
IMPROVEMENT TO DRUG SAFETY PROCESS***

Washington, D.C. - Continued refinement of the drug safety decision-making and oversight processes of the Food and Drug Administration (FDA) is essential to better protect and promote the public health, U.S. Senator Mike Enzi (R-Wyo.), Chairman of the Senate Health, Education, Labor and Pensions (HELP) Committee and Senator Edward M. Kennedy (D-Mass.), Ranking Member of the Committee, said today, in a letter to Acting Commissioner Dr. Andrew von Eschenbach, calling on the agency to respond to key improvements recommended in a newly-released Government Accountability Office (GAO) report.

“The GAO has identified critical areas of policy and procedure within FDA that need improvement to keep tabs on drugs once they are approved and allowed on the market,” Enzi said. “It is critical that we maintain public confidence in the FDA’s ability to protect the public health. Senator Kennedy and I are working across party lines to exercise careful and responsible oversight of the FDA, and we plan to introduce comprehensive drug safety legislation soon.”

Senator Kennedy said: “It’s absolutely essential that the FDA remain vigilant in the monitoring of drugs once they’ve been introduced to the market to ensure that Americans are receiving the best possible information about the drugs they’re taking and their adverse effects. The GAO report highlights the critical need for FDA oversight, and

I'm hopeful that Congress will support legislation that will protect Americans and strengthen FDA oversight.”

The GAO report, “Drug Safety: Improvement Needed in FDA’s Postmarket Decision-making and Oversight Process,” released on April 24, identified four major issues with FDA’s processes:

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

The full text of the letter is attached.

###