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**ENZI: DRUG APPROVAL SYSTEM MUST BE RE-EVALUATED; RESPONSE MUST NOT SLOW LIFE-SAVING DRUGS, THERAPIES**

Washington, D.C. - U.S. Senator Mike Enzi (R-WY), Chairman of the Senate Health, Education, Labor and Pensions Committee (HELP Committee) today said it is time to re-evaluate the Food and Drug Administration's (FDA) organization and process for approving drugs, but cautioned "we should not try to reinvent the wheel and develop a system that aims for an impossible standard of zero risk."

"We must not sacrifice safety to speed drugs to market," Enzi said. "However, we must weigh benefits and risks on the same scale. As patients, every time we take a drug, we take a risk, so we should not overreact to recent events. Attempting to achieve a zero safety risk, would block millions from benefiting from life saving drugs and therapies."

Convening the first of two hearings on the FDA Tuesday, Enzi focused today's hearing on examining how the agency makes decisions about new drugs and on reviewing the recent controversies regarding the approval process.

"It is essential that the public be confident that the FDA will approve new drugs only if they are safe, effective, and that the known benefits outweigh the known risks if those drugs are used as intended," he said.

Through the hearings, Enzi said the Committee will bring out the facts behind the recent controversies over arthritis drugs in the so-called Cox-2 inhibitor class and will assess whether the FDA's current system worked as intended or broke down - either in the initial approval stage or the post market monitoring of the drugs.

Although Enzi acknowledged that great advances in the drug approval process have been made over the past dozen years, following passage of "The Prescription Drug User Fee Act," and the "Food and Drug Administration Modernization Act," he said he is committed to determining whether the FDA and the drug industry can continue their efforts to reduce drug development time without compromising safety.

Outlining his objectives for the FDA's role, Enzi maintained the public must be able to trust that the FDA will:

- approve a new drug only if it is safe, effective, and the known benefits of the drug outweigh the known risks if used as intended;
- ensure that companies are communicating the benefits and risks of their drugs to patients and physicians in a clear and consistent manner; and

- keep tabs on the drugs on the market to ensure continued safety, and to take appropriate action if new information demonstrates new risks that were not apparent when a drug was initially approved.

Enzi has scheduled a second hearing on Thursday, March 3 to examine steps the FDA is taking to address public concerns about the safety of prescription medications. The hearing also will evaluate the FDA's ability to handle the challenges it will face meeting its mission in the future.