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RAPID ADVANCES IN SCIENCE, DRUG DEVELOPMENT, DEMAND CHANGE TO FDA'S REVIEW PROCESS, ENZI SAYS

Washington, D.C. - Saying science is "racing far ahead of the current regulatory regime" maintained by the Food and Drug Administration (FDA), U.S. Senator Mike Enzi (R-WY), Chairman of the Senate Health, Education, Labor and Pensions Committee (HELP Committee) today said Congress needs to encourage new methods and resources to improve and streamline the nation's drug approval and post market regulatory process.

"We need new and better ways to predict the safety and efficacy of new drugs before they enter widespread use," Enzi said. "But we don't want to return to the days of drug lag, when desperate Americans waited for drugs that were available for months or even years in Europe."

"When we take action to address the current shortcomings in our drug approval system, we will act through the HELP Committee in a bipartisan fashion," he added.

In the second of two hearings on FDA approval procedures and drug safety, Enzi focused today's hearing on steps needed to reduce the chance of new controversies, similar to those surrounding arthritis drugs in the so-called Cox-2 inhibitor class.

Enzi maintained that the rapid increase in funding for biomedical research that Congress provided over the last decade has led to an explosion of basic scientific knowledge and the promise of "an avalanche of new therapies." However, even the earliest stages of resulting drug innovations are placing intense new demands on the FDA's regulatory process.

"Despite the remarkable increase in scientific know how, many life-threatening diseases and conditions still lack effective treatment," he added. "We will need to match our investment in biomedical research through the National Institutes of Health (NIH) with new thinking, new methods, and new resources to improve and streamline the regulatory process at the FDA to keep pace with the promise of ongoing biomedical research."

As an example of the need to streamline the drug approval process, Enzi noted that one-third of all drugs fail during pre-clinical or clinical trials due to the toxic nature of the compounds being tested. In fact most of the tools sanctioned by the FDA to test the toxicity of new drugs are decades old.

"If we were better able to predict these failures before trials even began, we could both improve drug safety and save billions of dollars spent on research and development that leads nowhere," he added.

During Tuesday's hearing, Enzi said it is time to re-evaluate the FDA's 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."