

United States Senate

Washington, DC 20510

FOR IMMEDIATE RELEASE

Thursday, August 3, 2006

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ENZI, KENNEDY INTRODUCE DRUG SAFETY LEGISLATION TO ENSURE BETTER SAFEGUARDS FOR MILLIONS TAKING PRESCRIPTION DRUGS

Washington, D.C. - U.S. Senator Mike Enzi (R-WY), Chairman of the Senate Health, Education, Labor and Pensions (HELP) Committee, along with the Committee's Ranking Member, Senator Edward Kennedy (D-MA), today introduced a bill to require drug makers to engage in better safety planning before a drug is approved for release to the public while improving the FDA's response to risks identified after a drug is on the market.

"Our bill, the Enhancing Drug Safety and Innovation Act, will raise the bar to ensure that drug safety is not an afterthought, but an integral part of the process from the very beginning," Enzi said. "It requires drug makers to engage in better safety planning before a drug is approved for release to the public, and will improve both the understanding of and response to risks that arise after a drug is on the market."

"FDA needs better authorities and more resources to monitor and manage drug safety after drug approval," said Kennedy, "and this bill gives FDA both."

"This bipartisan bill is designed to provide better, flexible, adaptive, and rapid safeguards to protect the millions of Americans who take prescription drugs daily," Enzi added.

Enzi and Kennedy have spent months developing the proposal in hopes of restoring public confidence in the FDA's review process to weigh the benefits and risks of prescription drugs.

"The bill will also require disclosure of the results of clinical trials involving drugs," added Kennedy, "which will help patients and their health care providers make better informed decisions about treatment."

The Senators said the bill, which reflects the comments and input of dozens of stakeholders, including the FDA, patient and consumer groups, industry trade associations, individual companies, and scientific experts, will:

- Integrate safety issues and the approval process by requiring earlier and more focused consideration of safety issues;
- Establish a flexible planning mechanism to obtain the necessary safety information about each unique new drug or indication;
- Permit adaptation of the safety plan in response to new information; and,
- Bring fairness, timeliness and finality to the dispute resolution process.

“As Chairman of the HELP Committee, I am deeply grateful for the cooperation and support of Senator Kennedy, as well as the dozens of stakeholders, who have worked tirelessly to make this bill a reality,” Enzi concluded.

Other key provisions of the bill:

- Establishing a collaboration among the FDA, academic research institutions, and the biomedical research industry to improve the process of drug development and evaluation, and advance the FDA's Critical Path Initiative;
- Establishing a publicly available database of clinical trials to help enhance patient enrollment in clinical trials of drugs, provide a mechanism to track subsequent progress of trials, and ensure that the results of trials are made public, and that patients, doctors, and pharmacists have the most up-to-date information;
- Making improvements to the FDA's process of screening advisory committee members for financial conflicts of interest to ensure that these committees provide independent expert advice, and to bolster the credibility of the product review process.

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