



For Immediate Release

Contact: Craig Orfield
(202) 224-6770

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***ENZI WELCOMES FDA RESPONSE, CONTINUES PUSH FOR REFORM
LEGISLATION TO ENHANCE DRUG SAFETY***

Washington, D.C. –U.S. Senator Mike Enzi (R-Wyo.), Ranking Member of the Senate Health, Education, Labor and Pensions (HELP) Committee, today welcomed the Food and Drug Administration’s (FDA) response to a report from the Institute of Medicine (IOM) on the U.S. drug safety system. The IOM report echoed Enzi's calls for legislation to give the FDA better tools to protect and promote the public health.

"I am glad that FDA recognizes the need for reform in order to protect the public health and has weighed into this debate," Enzi said. "FDA and the industry have made some good suggestions for improving drug safety in the Prescription Drug User Fee Act (PDUFA) renewal proposal, and we look forward to incorporating that progress into the Enzi-Kennedy drug safety legislation.

"The American people are demanding action to improve drug safety, and we owe it to them to tackle this issue and ensure that the drugs they take are safe and beneficial," Enzi said. "I look forward to reviewing the agency's plans and working closely with the FDA to enact critical drug safety reform."

Senator Enzi said that he plans soon to reintroduce the drug safety bill that he and Senator Ted Kennedy (D-MA) authored last year. The IOM report, released in September 2006, issued recommendations that track many provisions of Enzi-Kennedy bill, including giving FDA the authority to: make label changes, order post-market studies, restrict Direct To Consumer Advertising, and restrict distribution of drugs, based on safety issues.

"Families expect the FDA to 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 said. "The bill that Senator Kennedy and I have written will give the FDA the authority and the tools to fulfill that mission."

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