



For Immediate Release

Contact: Craig Orfield  
(202) 224-6770

Monday, May 7, 2007

***SENATE MOVES TOWARD PASSAGE OF BILL TO GIVE FDA  
AUTHORITY, RESOURCES TO ENSURE PATIENT SAFETY***

Washington, D.C. –U.S. Senator Mike Enzi (R-WY), Ranking Member of the Senate Health, Education, Labor and Pensions (HELP) Committee, today said the Senate has taken a bold step to protect American consumers and patients by moving forward on a comprehensive bill to enhance drug safety by providing new resources for post-market surveillance and review of new drugs and medical devices - key improvements to ensure that drugs and devices are safe and effective.

“This bill will establish a system that gives the FDA, through sound science and remarkable innovation, the tools to get drugs to the market quickly and efficiently, especially when lives are on the line and people need new drugs and therapies,” Enzi said. “It gives the FDA new authority to take swift, appropriate, and decisive action to ensure patient safety and protect consumers when new information comes to light to expose unexpected risks.”

“Half of all Americans will take a prescription drug today,” Enzi said. “This bill is critical to restoring peace of mind to Americans who want to be assured that the drugs they purchase to treat illnesses and chronic medical conditions can be relied upon and trusted. I am pleased that the Senate has voted to move forward on this critical legislation.”

The “Food and Drug Administration Revitalization Act” represents over a year of bipartisan discussions and cooperation following the Vioxx incident. It establishes a system of active surveillance for drugs already on the market, and explicitly gives the FDA new authority through Risk Evaluation and Mitigation Strategies (REMS) to respond quickly and appropriately when previously unknown risks arise.

“Right now, the FDA has its hands tied behind its back when it tries to manage the risks of drugs already on the market. This bill will clarify and strengthen the FDA’s authority and give it new tools to take measured and appropriate steps to protect the health and safety of Americans when the agency’s post-market surveillance signals potential dangers from a drug or therapy. Pulling a drug from the market and denying patients who need it shouldn’t be the only tool available to the FDA.”

The Senate approved a cloture vote on a manager's substitute amendment to the bill by an 82-8 count. The Senate can now move toward a vote on final passage of the bill this week.

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