



For Immediate Release

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ENZI SUPPORTS BILL TO GIVE FDA AUTHORITY, RESOURCES TO ENSURE PATIENT SAFETY, SAYS MORE WORK IS NEEDED

Washington, D.C. –U.S. Senator Mike Enzi (R-WY), Ranking Member of the Senate Health, Education, Labor and Pensions (HELP) Committee, today announced an important first step toward protecting American consumers and patients as the HELP Committee approved a comprehensive bill to enhance drug safety, provide key resources to review new drugs and medical devices, and ensure that drugs and devices for children are safe and effective.

Enzi added that the bill, the “Food and Drug Administration Revitalization Act,” is by no means a finished product, and said that he will continue to work with colleagues on both sides of the aisle to improve the bill as it moves to the Senate floor in order to best protect the health and safety of all Americans. The bill was approved by a vote of 15-5.

“As today’s debate demonstrated, there are legitimate concerns about the potential unintended consequences of this bill and the amendments that were offered,” Enzi said. “I look forward to working with the Members of the HELP Committee in the coming weeks to address the concerns outlined in their amendments, and I am confident that we can work together in a bipartisan manner to strike the right chord for patient safety.”

The “Food and Drug Administration Revitalization Act,” S. 1082, establishes a system of active surveillance for drugs already on the market through Risk Evaluation and Mitigation Strategies (REMS). The bill explicitly gives the FDA new authority to measure the risks of drugs on the market and to respond quickly and appropriately when previously unknown risks arise.

“Many people are asking, ‘Why REMS? Why now?’” Enzi said. “The answer is easy. 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 authority of the Food and Drug Administration (FDA) touches the lives of all Americans – from infants to the elderly, animals that provide the food and fiber for living, and even our pets,” Enzi said. “We need to restore peace of mind for Americans who are buying drugs for themselves and their children.”

“Like everyone else, when I purchase a product for myself, my children, or my grandchildren, I want assurance that the product is safe and beneficial,” Enzi said. “Safety must be at the forefront of every decision the FDA makes during the life of a drug, so that Moms and Dads are able to trust that the products at the pharmacy counter are safe and effective.”

“Imagine 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. Imagine also a system that 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. We can make this a reality.”

The full text of Senator Enzi’s statement is available at <http://help.senate.gov>.

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The Food and Drug Administration Revitalization Act Summary

Title I — Prescription Drug User Fees

Title I codifies the user fee agreement reached by drug and biotech industries with the FDA. It establishes an overall amount for user fees of nearly \$393 million for 2008 (which will be adjusted upward based on 2007 workload). It includes the expansion of use of drug user fees by nearly \$30 million for post-approval drug safety programs.

Title I also includes the FDA-industry proposal to create a voluntary user fee program under which drug companies can submit direct-to-consumer television advertisements to the agency for review before they are distributed.

Title II — Drug Safety

Subtitle A—Risk Evaluation and Mitigation Strategies

This subtitle establishes a system of routine active surveillance for postmarket drug safety through a public-private partnership. The partnership will aggregate data from Federal and private health databases containing information for at least 100,000,000 covered lives and support the analysis of utilization and safety data from these databases. The establishment of this system will be supported with up to \$30 million in appropriations.

Given the ability of this active surveillance system to identify and assess drug risks, most drugs and biologics will not need anything further than this system and the drug label to appropriately manage risk. However, some drugs and biologics will need additional tools to manage serious risks, and these products will be approved with risk evaluation and mitigation strategies (REMS). Sponsors would propose a REMS and FDA would approve it after structured negotiations, if necessary. The REMS will be reviewed at 18 months and three years, as well as in labeling supplements and when FDA requests a review.

Additional Elements of a REMS — For those drugs that have a REMS, the REMS will always include the FDA-approved professional labeling and a timetable for periodic assessment of the REMS.

When more is needed, a REMS may include tools to assess, communicate about, or manage risks. The bill contains clear standards detailing the appropriate application of each tool. These standards ensure that new FDA authorities are applied narrowly, and only as necessary.

A REMS would be assessed in response to new information about a serious risk, and could be modified, including by reducing the stringency of elements, in response to new information.

Compliance — Civil money penalties would apply for violation of an element of a REMS.

Resources — Increased drug user fees would be used to review REMS and for FDA's general drug safety surveillance. This subtitle increases user fee revenue by \$50 million over the agreement between industry and the FDA to fund drug safety activities.

Subtitle B—Reagan-Udall Foundation for the Food and Drug Administration

Subtitle B establishes a foundation to lead collaborations amongst the FDA, academic research institutions, and industry directed to supporting the FDA's mission.

Collaborative research projects will be selected that are designed to bolster R & D productivity, provide new tools for improving safety in regulated product evaluation, and in the long term make regulated product development and safety more predictable and manageable. The Foundation will be financially supported by industry and philanthropic donated funds.

Subtitle C—Clinical Trials

To enhance patient enrollment and provide a mechanism to track subsequent progress of trials, the data bank at ClinicalTrials.gov will be expanded to include all phase II and later trials, and to include devices. Currently, only clinical trials of drugs for serious and life threatening conditions are required to register in the data bank.

In addition, to ensure that results of trials are made public, and that patients and providers have the most up-to-date information, results information would be added to this database. Information would be added only after the product in question has been approved or cleared for marketing. Results information would first come from existing FDA and NIH documents, as well as peer-reviewed scientific publications. A negotiated rulemaking process would be used to determine when and how to add results information not captured under those conditions.

Subtitle D—Conflicts of Interest

Subtitle D requires disclosure of conflicts of interest of advisory committee members prior to an advisory committee meeting, and greater efforts by FDA to identify and recruit members of advisory committees.

Title III—Medical Device User Fees

Title III is reflective of the agreement between FDA and industry regarding the total list of issues within their agreement from the time of the publication of the Federal Register notice. Given that some of the submitted language does not track the intent of the agreement, we expect to provide further improvements to the language at a later date. Those improvements will be agreed to by both FDA and industry.

Per the agreement between FDA and industry, it establishes an overall amount of \$287 M of user fees over five years, with \$48 M in 2008. This is coupled with a fixed 8.5% annual increase (with no other adjustors) and a further reduction of fees for small business.

Title III also includes the FDA-industry proposal on third party inspection improvements to ensure that the program works more efficiently and clarifying that entities can register and list electronically.

Title IV – Pediatric Medical Products

Subtitle A – Best Pharmaceuticals for Children

Subtitle A would reauthorize the Best Pharmaceuticals for Children Act and improve its provisions in order to make it more effective at ensuring that drugs for children are safe for pediatric populations. BPCA generally provides six months of additional exclusivity to drug manufactures to encourage the determination of safety and efficacy of drugs in pediatric populations. The bill contains an incentive of three months of additional exclusivity if US sales of the active moiety by the innovator and its affiliates exceed \$1 billion annually at the time written request for study is issued. The bill is a five-year authorization and will expire in 2012. No PDUFA funds can be used for BPCA studies. The Secretary may send declined requests for study to the NIH Foundation if funds are available.

Subtitle B – Pediatric Research Improvement

Subtitle B would reauthorize the Pediatric Research Equity Act and improve its provisions in order to make it more effective at ensuring that drugs for children are safe for pediatric populations.

In order to improve coordination with the pediatric exclusivity provisions of the *Best Pharmaceuticals for Children Act (BPCA)*, PRIA would consolidate an internal FDA committee to review all issues of pediatric-related labeling and assessments. Doing so ensures that a drug that falls under PRIA or BPCA is reviewed not only by experts for that particular drug, but experts with pediatric expertise. PRIA will sunset in tandem with BPCA in 2012. If a company chooses not to pursue pediatric exclusivity for an already marketed drug under the *Best Pharmaceuticals for Children Act*, and no study is performed through NIH, then the Secretary has the authority to require the submission of pediatric data for such drug. PRIA streamlines this process and helps get essential pediatric data for important drugs, while preserving the ability of companies to meet and discuss testing with the agency.

The bill would require two reports – one from the Institute of Medicine and one from the GAO – that would allow us to have better data on the number and ways in which the pediatric rule is used, and evaluate its contributions to ensuring overall pediatric drug safety.

Subtitle C - Pediatric Medical Devices

Subtitle C modifies the existing humanitarian device exemption (HDE) for medical devices to allow profit for HDE-approved devices specifically designed to meet a

pediatric need. Maintains existing requirement that a humanitarian use device is limited to one that treats and diagnoses diseases or conditions that affect fewer than 4,000 individuals in the U.S. per year. No profit will be allowed for a device used in more than 4,000 individuals. The HDE exemption expansion sunsets in 2013 and a GAO report assessing the HDE exemption expansion and its impact on patients and manufacturers is required.

The FDA's Office of Pediatric Therapeutics will acquire enhanced authority to collaborate with NIH, AHRQ, and subject matter experts in order to assess pediatric device R&D needs.

Demonstration grants, with tracked results, will be established for non-profit consortia to promote pediatric device development, manufacture and distribution. The bill grants explicit authority to the FDA's Pediatric Advisory Committee to monitor pediatric devices and make recommendations for improving their availability and safety. This approach incorporates several recommendations of the Institute of Medicine including improving the postmarket surveillance of medical devices used in children and expanding public access to postmarket studies of pediatric medical devices.

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