United States Senate

Washington, D.C. 20510

FOR IMMEDIATE RELEASE
April 27, 2005

Contact: Jill Kozeny (Grassley)
202-224-1308
Sean Oblack (Dodd)
202-224-5372

Grassley, Dodd Expand Effort to Improve Drug Safety System

WASHINGTON - Seeking to enhance the nation's drug safety monitoring system, Sens. Chuck Grassley (R-IA) and Chris Dodd (D-CT) today introduced legislation to set up a new, independent Center inside the Food and Drug Administration (FDA) to review drugs and biological products once they are on the market.

The bipartisan bill would establish the Center for Post-market Drug Evaluation and Research (CPDER) by transferring the FDA's existing office of drug safety into the Center and establishing new authority for post-market review. The director of the CPDER would report directly to the FDA Commissioner.

Grassley and Dodd said the legislation is aimed at the conflicts of interest that today cloud the ability of the FDA to assess the risks of drugs once they're on the market, and take action when a risk is identified.

"The bill addresses the fact that office of new drugs carries too much sway over the FDA's drug-safety apparatus. Today drug makers have the ability to negotiate with the FDA officials who approved their drugs to begin with when the FDA considers corrective action," Grassley said. "By creating a Center for post-market review, this legislation puts American consumers where they belong at the FDA, and that's front and center."

"Just as patients have regular check ups with their doctor - and not just one - when it comes to their health, there needs to be an on-going independent review of previously approved drugs," said Dodd. "This measure will save patients' lives, help restore consumer confidence in the safety of prescription drugs, and ensure that the words 'FDA Approved' continue to be the gold standard for safety and quality."

The Food and Drug Administration Safety Act of 2005 (FDASA) would:

Authorize the director to require manufacturers to conduct post-market clinical or observational studies if there are questions about the safety or efficacy of a drug or biological product.

Authorize the director to determine whether an approved drug or licensed biological

product may present an unreasonable risk to the health of patients or the general public given the known benefits.

Authorize the director to take corrective action if a drug or biological product presents an unreasonable risk to patients or the general public, including the authority to make changes to the label or approved indication, place restrictions on product distribution, require physician and consumer education, and require the use of other risk management tools.

Allow the director to withdraw approval of a drug or biological product if necessary to protect the public health.

Require submission of advertising prior to dissemination and require certain advertising disclosures related to risks and benefits to patients if one or more of the three following conditions is met: the director has determined that the product may present an unreasonable risk to patients, the product is the subject of an outstanding post-market study requirement, or the product was approved within the last two years.

Establish strong enforcement mechanisms, including civil monetary penalties, for those who fail to comply.

Ensure that the director benefits from all appropriate resources, including consultation with the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER), and makes all decisions based on a risk-benefit analysis.

Ensure that all findings and decisions made by CPDER are transparent.

Require a report and recommendations to Congress on post-market surveillance of medical devices.

Authorize graduated appropriations totaling $500 million over five years to ensure that CPDER has the resources to accomplish its goals.

Currently, post-market review of drugs is conducted by the FDA's Office of Drug Safety (ODS) within the Center for Drug Evaluation and Research (CDER). The existing drug safety office does not have the authority, for example, to require post-market studies once a drug is on the market. In addition, the ODS resides within CDER, which is responsible for approving new drugs. The role of the drug safety office is primarily consultative to the new drugs office, making the office of drug safety effectively subservient to the new drugs office.

"It's very important that the FDA continue to approve new life-saving and life-enhancing drugs as quickly as possible," Grassley said. "At the same time, the FDA needs to focus on reviewing those products after they're on the market. Valuable new information can be gained and new risks are sometimes identified once a drug is used by millions of people. Our initiative to establish this independent drug safety office is part of our effort to restore balance at the Food and Drug Administration. We need the FDA to be a vigilant watch dog."

"This legislation will allow the FDA to act quickly and decisively to uncover safety problems and act to mitigate the risk to patients," said Dodd. "When we are talking about drugs that are already on the market and in widespread use, any delay can put millions of patients in harm's way."

The legislation introduced today also requires the Secretary of Health and Human Services to report to Congress on deficiencies in and recommendations for post-market surveillance of medical devices.

In February, Dodd and Grassley introduced a separate bill, S.470, the Fair Access to Clinical Trials Act, or FACT Act, to make clinical trial results publicly available to researchers, doctors and consumers.

Both pieces of legislation have been endorsed by consumer and health groups including the Center for Medical Consumers, the Consumer Federation of America, Consumers Union, the National Women's Health Network, Public Citizen, and the U.S. Public Interest Research Group.

During the last year, Grassley has conducted oversight of the FDA based on concerns about how the agency resisted making public information about suicide risks associated with the pediatric use of antidepressants and cardiovascular risks associated with the painkiller Vioxx. Grassley is chairman of the Senate Committee on Finance, which is oversees the Medicare and Medicaid programs. Medicaid spent more than $1 billion on Vioxx before it was pulled from the market last September. Medicare will offer a new prescription drug benefit beginning in January. Grassley has advocated administrative and legislative reforms to make the FDA's work more transparent.

Dodd is a senior member of the Senate Committee on Health, Education, Labor and Pensions, which is responsible for overseeing the FDA. He has worked throughout his career to ensure that drugs are safe and effective for all Americans, including children.

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