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Grassley, Dodd Seek Bold Reforms to Improve Drug Safety System

WASHINGTON - Renewing their commitment to ensuring FDA-approved drugs are safe once on the market, Sens. Chris Dodd (D-CT) and Chuck Grassley (R-IA) are reintroducing legislation to revamp and prioritize the post-market surveillance process within the Food and Drug Administration and to greatly expand public access to information about clinical trials regardless of the outcome of those trials through a clinical trials registry and results database.

Their initiatives are packaged in two bills that will be introduced this week: the Food and Drug Administration Safety Act of 2007 and the Fair Access to Clinical Trials (FACT) Act of 2007. Grassley and Dodd authored nearly identical bills in the last Congress in the aftermath of the Vioxx and antidepressant use in children scandals.

"Both of these bills fill voids in our public health system that I believe need immediate attention," said Dodd. "Every day, doctors and researchers discover important findings in clinical trials. The FACT Act will help bring these to light, and in doing so, provide consumers, health care professionals, and the FDA with a more complete picture of the safety and effectiveness of drugs, biologics and medical devices so that they are able to make more informed decisions. Additionally, the FDA Safety Act will bring a new level of priority and independence to the postmarket surveillance of drugs. A crisis of confidence in the FDA currently exists. If we are to restore public confidence in the words 'FDA Approved,' we must ensure that the men and women who diligently monitor drugs on the market have the resources, the independence, and the authority to do their jobs effectively."

"A mountain of evidence has amassed about the need to improve the way the FDA operates," said Grassley, who is Ranking Member of the Senate Committee on Finance. "Congress will act on FDA-related legislation this year, and meaningful structural reforms to the agency need to be a part of what Congress does with regard to drug safety. Consumers shouldn't have to think twice about what's in their medicine cabinets. The FDA needs to be more transparent, more accountable and more forthcoming with information for the public."

The Food and Drug Administration Safety Act would enhance the FDA's drug-safety monitoring system by setting up a new and independent center within the FDA called the Center for Postmarket Evaluation and Research for Drugs and Biologics (CPER) which would be responsible for monitoring the safety of drugs and biologics once they are on the market, in consultation with other existing Centers at the FDA, and would have the authority to take corrective action if a drug or biologic presents a risk to patients. For example, the Center Director can require manufacturers to conduct post-market clinical or observational studies if there are questions about the safety or efficacy of a drug or biologic once it is already on the

market. Under the bill, CPER would report directly to the FDA Commissioner.

Grassley and Dodd said the legislation is aimed to change the status quo at the FDA. Sens. Barbara Mikulski (D-MD) and Jeff Bingaman (D-NM) are also cosponsors of this legislation.

"The bill addresses the fact that the office approving new drugs carries too much sway over the FDA's drug-safety apparatus. Today drug makers have the ability to negotiate with the same FDA officials who approved their drugs in the first place, when and if the FDA considers corrective action," Grassley said

The FACT Act is based on legislation authored by Senator Dodd dating back to 2003. It would expand www.clinicaltrials.gov to create a publicly-accessible national data bank of clinical trial information comprised of a clinical trial registry and a database of clinical trial results. The legislation would foster transparency and accountability in health-related intervention research and development and ensure that the scientific community and the general public have access to basic information about clinical trials. Importantly, the FACT Act would maintain and improve clinicaltrials.gov as a registry for patients and physicians seeking information about ongoing clinical trials for serious or life-threatening diseases and conditions. The legislation would also prevent companies from withholding clinically important information about their products.

"Consumers shouldn't be left in the dark when it comes to the medicines they are taking," said Dodd. "This measure will help to shine a bright light on information related to clinical trials."

Bingaman and Sen. Ron Wyden (D-OR) are also cosponsors of the FACT Act.

Dodd is a Senior Member of the Senate Committee on Health, Education, Labor, and Pensions (HELP), which is responsible for overseeing the FDA. He is the Chairman of the HELP Subcommittee on Education and Early Childhood Development. Dodd has worked throughout his career to ensure that drugs are safe and effective for all Americans, including children.

Grassley has conducted aggressive oversight of the FDA for three years and has put pressure on the drug-safety agency to act with more independence and transparency than it now demonstrates in order to restore public confidence and strengthen public safety. He has called the FDA's relationship with the drug industry "too cozy" and criticized the way that agency leaders have acted to suppress scientific dissent regarding agency actions and drug-safety recommendations.

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