United States Senate
Committee on Finance

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Ranking Member

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For reporters and editors —
The text of the floor statement made today by Sen. Grassley regarding his introduction of FDA reform and drug safety legislation with Sen. Dodd is below, along with a summary for both bills.

Floor Speech of U.S. Senator Chuck Grassley
Introduction of the Food and Drug Administration Safety Act of 2007 (S.468)
and Fair Access to Clinical Trials Act of 2007 (S.467)
Wednesday, January 31, 2007

Mr. President, I'm pleased to sponsor with Senator Dodd two important bills that are being introduced today, the Food and Drug Administration Safety Act of 2007 and the Fair Access to Clinical Trials Act of 2007. These bills are part of a sustained effort to restore public confidence in the federal government's food and drug safety agency. Enactment of these two bills would provide doctors and patients with more information about the risks and benefits of their medicines and bring about greater transparency and accountability at the Food and Drug Administration.

I began my oversight of the FDA three years ago in response to concerns about the reluctance of the FDA to provide information to the public about the increased suicide risks for young people taking anti-depressants. In November 2004, I chaired a groundbreaking hearing on drug safety, the FDA and Vioxx. That hearing and other critical drug safety concerns that have come to light since then highlight the need for comprehensive and systematic reforms, as well as more stringent oversight of the FDA. Over the past three years it has become increasingly apparent that the FDA has repeatedly failed to protect the public from an industry that focuses all too often on profits, even when those profits come at the expense of John Q. Public.

In 2005, Senator Dodd and I introduced almost identical companion bills to advance serious reform at the FDA. In the two years following the introduction of those bills, however, the Food and Drug Administration failed to take comprehensive and systematic steps toward restoring public confidence in the agency and strengthening public safety.

Yesterday, the FDA released its response to the Institute of Medicine's 2006 Report on drug safety. The two safety bills introduced today are not intended to supplant the plans articulated in FDA's response, but rather to augment those plans and provide the FDA with additional enforcement tools; something they now lack.

In fact, one of our bills is intended to specifically address a serious problem that was also identified by the Institute of Medicine. Dr. Alta Charo, a member of the IOM committee that wrote the report on drug safety, stated to USA Today, "I have to confess I'm disappointed that they [the FDA] ignored one of our most critical recommendations." According to the USA Today article, she was referring to IOM's recommendation that the FDA give more clout to the office that monitors drugs after they go on the market. I agree with Dr. Charo.

The Food and Drug Administration Safety Act of 2007 would establish an independent Center within the Food and Drug Administration - the Center for Postmarket Evaluation and Research for Drugs and Biologics (CPER). The Director of CPER would report directly to the FDA Commissioner, and would be responsible for conducting risk assessment for approved drugs and biological products.

This new center would also be responsible for ensuring the safety and effectiveness of drugs once they are on the market. Unfortunately, what happens now at the FDA is that the office that reviews the safety of drugs is a mere consultant and under the thumb of the office that puts the drugs on the market in the first place. Even more troubling is the fact that those who speak out of line are targeted. This legislation would provide the new Center-CPER-with the independence and authority to promptly identify serious safety risks and take necessary actions to protect the public. At the same time, intra-agency communication is essential in addressing drug safety, so this legislation would encourage communication between CPER and the other centers and offices at the FDA that handle drugs and biological products to do what's best for the consumer-not big Pharma.

The FACT Act of 2007 would expand an existing website, www.clinicaltrials.gov, to create a publicly accessible national data bank of clinical trial information. The data bank would be comprised of a clinical trial registry and a clinical trial results database of all publicly and privately funded clinical trials. This legislation would foster transparency and accountability in health research and development and ensure that the scientific community and the general public have access to basic information about clinical trials. The legislation would also create an environment that would encourage companies to submit clinically important information about their products from the FDA and from the public.

If we have learned anything over the last few years, it is that the FDA is a troubled agency that lost sight of its most important function-to ensure the safety and efficacy of new prescription drugs. Unfortunately, the public has good reason to doubt the FDA's ability to do its job, and experts from all over this country have expressed concern. These two bills will help put FDA back on the path to fulfilling its mission and most importantly put the American consumer first.

Mr. President, in closing, I ask unanimous consent that my statement be printed into the record and coupled with the statement Senator Dodd will file later today regarding the introduction of these important pieces of legislation.

Summary of the Food and Drug Administration Safety Act of 2007

Senator Charles E. Grassley (R-IA), Senator Christopher J. Dodd (D-CT),
Senator Barbara A. Mikulski (D-MD), Senator Jeff Bingaman (D-NM)
January 31, 2007

The Food and Drug Administration Safety Act of 2007 (FDASA) will establish an independent Center within the Food and Drug Administration (FDA) - the Center for Postmarket Evaluation and Research for Drugs and Biologics (CPER). The Director of CPER will report directly to the FDA Commissioner and will be responsible for conducting risk assessment for approved drugs and biological products and ensuring their safety and effectiveness once they are on the market.

FDASA will:

Authorize the Director to require manufacturers to conduct postmarket 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 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 postmarket study requirement, or the product was approved within the last two years.

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 CPER are transparent.

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

Require a report and recommendations to Congress on postmarket surveillance of medical devices.

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

Summary of the Fair Access to Clinical Trials (FACT) ACT
Introduced by Senator Dodd (D-CT), Senator Grassley (R-IA), Senator Wyden (D-OR), Senator Bingaman (D-NM), Senator Durbin (D-IL), Senator Harkin (D-IA)
January 31, 2007

The FACT Act will expand www.clinicaltrials.gov to create a publicly accessible national data bank of clinical trial information comprised of a clinical trial registry and a clinical trial results database. The legislation will 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. The legislation will also prevent companies from withholding clinically important information about their products.

The FACT Act will:

Maintain a clinical trial registry accessible to patients and health care practitioners seeking information related to ongoing clinical trials for serious or life-threatening diseases and conditions;

Establish a clinical trial results database of all publicly and privately funded clinical trial results regardless of outcome that is accessible to the scientific community, health care practitioners, and members of the public;

Require the Food and Drug Administration (FDA) to make internal drug approval and safety reviews publicly available, including documentation of significant differences of opinion and their resolution;

Build on the successful model of www.clinicaltrials.gov, which was established in 1997. The web site will continue to be run by the National Library of Medicine at the National Institutes of Health, with assistance from the FDA;

Apply to clinical trials for drugs, biologics, and medical devices. All trials must be registered in the database in order to obtain approval from a U.S. Institutional Review Board;

Require that foreign trials that are submitted to the FDA as part of a new drug application or a supplemental drug application or are used in advertising to U.S. physicians be posted in the database in a timely manner;

Require that researchers promptly disclose the objectives, eligibility criteria, sources of

funding, and anticipated timeline of clinical trials. The bill's standards will meet all of the minimum criteria for a trial registry set out by the International Committee of Medical Journal Editors on September 8, 2004;

Mandate that the results of clinical trials be available to doctors and patients. Recognizing that the peer review process is the best safeguard for scientific accuracy, the bill provides time for researchers to publish their results. The disclosure of important trial results satisfies the recommendation of the American Medical Association;

Establish strong enforcement mechanisms. The bill will provide for civil monetary penalties of up to $10,000 per day for sponsors who refuse to comply. The bill will also establish penalties for sponsors of a new drug application or a supplemental new drug application for failing to certify that the information they are submitting to the FDA is accurate. Monetary penalties will be earmarked for studies that compare clinical therapies;

Provide authority to audit the completeness and accuracy of the information in the registry; and

Ensure that the Food and Drug Administration has the authority to correct false or misleading statements about the results of clinical trials.