U.S. SENATE COMMITTEE ON
Finance
SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN
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Grassley Co-Sponsors Clinical Trial Registry Legislation

WASHINGTON — Sen. Chuck Grassley today joined Sen. Chris Dodd in introducing legislation that would require drug makers to register clinical trials about prescription medicines.

Grassley said that "by making the clinical trial information publicly available we make the system for ensuring drug safety more transparent and more accountable. That ultimately leads to an even safer system and greater consumer confidence." He said his support for a clinical trials registry stems from the oversight work he conducted during the last year regarding the way the Food and Drug Administration has handled information about drug risks.

Grassley's scrutiny began based on allegations made early in 2004 about an attempt by the federal agency to withhold information about the findings of an FDA scientist who found a possible link between antidepressants and teen suicide. Grassley continued his investigation of the Food and Drug Administration with a hearing in November to explore the FDA's handling of the painkiller Vioxx, which had been pulled from the market due to increased risks for heart attacks and strokes.

Grassley is chairman of the Senate Committee on Finance, which is responsible for Medicare and Medicaid legislation and oversight. Medicaid has spent more than $1 billion on the drug Vioxx, and Medicare is about to cover prescription drugs for the first time. "There's no doubt that the performance of the FDA affects the integrity and effectiveness of these important health care programs," Grassley said.

The bipartisan legislation introduced today is titled the Fair Access to Clinical Trials or FACT Act of 2005. It is similar to a measure championed by Dodd in the last Congress. Changes have been made to maintain clinicaltrials.gov as a registry for patients and physicians seeking information about ongoing clinical trials for serious or life-threatening diseases and to require the Food and Drug Administration to make internal drug approval and safety reviews publicly available.

The text of Grassley's floor statement regarding the new measure follows here. The statement includes a summary of the bill.

Floor Statement of Sen. Chuck Grassley of Iowa

Fair Access to Clinical Trials Act of 2005
February 28, 2005

Mr. President, earlier today S.___ was introduced. I'm pleased to sponsor the Fair Access to Clinical Trials Act of 2005 with Senator Dodd. I'm co-sponsoring this legislation as part of a sustained effort to restore public confidence in the federal government's food and drug safety agency. Enactment of this bill would be a meaningful step toward greater transparency and accountability in clinical trials and the scientific process.

The Food and Drug Administration earned its prized reputation through decades of good work on behalf of the American people. The FDA's drug approval process has long been considered the "Good Housekeeping Seal of Approval." However, the Vioxx disaster and its aftermath have shaken the public's confidence. American consumers demand and deserve assurances that the medicines in their cabinets are safe. The health and safety of the public must be the FDA's first and only concern. Unfortunately, reforms at the FDA are necessary to place that mission front and center once again.

I began my oversight of the FDA last year in response to concerns about the reluctance of the FDA to provide information to the public about the increased suicidal risks for young people taking anti-depressants. Last November, I chaired a groundbreaking hearing on drug safety, the FDA and Vioxx. That hearing and other critical drug safety concerns of the past year highlighted the need for reforms and more stringent oversight of the FDA.

Sometimes congressional scrutiny of agency mismanagement can lead to necessary reforms. Sometimes an agency will act on its own to enhance its credibility. I have been pressing for reforms – both administrative and legislative – to bring about greater responsiveness and transparency at the FDA. The risks and benefits of prescription drugs should be readily available to patients and doctors seeking to make informed decisions

The FACT Act 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 clinical trial results database. 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 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.

The FACT Act will:

1. 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;

2. Establish a clinical trials 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;

3. Require the Food and Drug Administration (FDA) to make internal drug approval and safety reviews publicly available;

4. 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;

5. 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;

6. Require that foreign trials that are submitted to the FDA or used in advertising to U.S. physicians be registered in the database at the time of submission;

7. 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;

8. 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;

9. 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. Monetary penalties will be earmarked for studies that compare clinical therapies;

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

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

Next month I will also introduce legislation to establish an independent office of drug safety in the Food and Drug Administration. Today's legislation is an important step toward reforming the FDA. I urge my colleagues to join me in this effort by cosponsoring this important legislation.