United States Senate
Committee on Finance

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Grassley works to reform FDA and improve drug safety for American consumers

WASHINGTON — Sen. Chuck Grassley has filed 11 amendments aimed at strengthening the work of the Food and Drug Administration for possible consideration during Senate debate on the FDA Revitalization Act of 2007.

Grassley said that he is particularly focused on improving the FDA's surveillance of pharmaceuticals and other consumer products after they are on the market and giving the public access to information about the results of clinical trials.

"Americans rely more than ever before on prescription drugs, and it's as important as ever that the FDA do its job and do it well," Grassley said. "My amendments to this FDA bill are a way to help improve public safety and respond to well-documented problems. There probably won't be another FDA bill for ten more years, so the stakes are high for this legislation, and we need to get it right. When we vote, every member of Congress needs to ask themselves if they're doing everything possible to improve drug safety."

Last fall, the Institute of Medicine of the National Academies issued a report on its assessment of the nation's drug-safety system. The Institute said the FDA had systemic problems and needed to exercise more vigilance over the life-cycle of drugs and provide more information to the public about drug risks. Grassley said this prestigious review validated concerns expressed by the watchdog community and added considerable muscle to the reform effort. Last spring, the Government Accountability Office issued a separate report that said improvement was needed in the FDA's post-market decision making and oversight process.

Grassley has conducted active oversight of the FDA for the last three years and has put pressure on the drug safety agency to act with more independence and transparency in order to restore public confidence and strengthen public safety. Grassley has called the FDA's relationship with the drug industry "too cozy" and revealed how agency leaders have acted to suppress scientific dissent regarding agency actions and drug-safety recommendations.

In January, Grassley and Sen. Christopher Dodd introduced for the second time two bills to revamp and prioritize the post-market surveillance process within the FDA and to greatly expand public access to information about all clinical trials through a registry and results database. Their bills are S.468, the Food and Drug Administration Safety Act of 2007, and

S.467, the Fair Access to Clinical Trials Act of 2007.

The FDA Revitalization Act on the Senate floor this week is S.1082. It would reauthorize the FDA's user fee authority, which collects money from drug and device companies for review of their products. Here is a listing of the amendments filed by Grassley this week:

Grassley Amendment No. 994 – Establishes a separate, independent Center for Postmarket Evaluation and Research for Drugs and Biologics.

Grassley Amendment No. 995 – Provides for joint decision making between the Office of Surveillance and Epidemiology (OSE) and the Office of New Drugs (OND) with respect to post-market drug safety, including labeling changes requiring additional post-market studies, restrictions on distribution or use of a drug. The joint decision making would give OSE sign-off on actions taken as opposed to their present role of mere consultants to the OND in a post-market environment. The Institute of Medicine report recommended joint authority for OSE and OND, as it noted that OSE lacked the authority to take actions regarding post-marketing safety. This amendment also designates the Director of the Office of Surveillance and Epidemiology as the chief post-market drug safety officer who acts as a liaison between the Office of the Commissioner and FDA employees.

Grassley Amendment No. 996 – Provides for a certification that all clinical trial information related to the safety and efficacy of a drug under review is submitted to the Food and Drug Administration as part of a new drug or supplemental application. This is intended to have drug sponsors affirmatively state that they submitted all the information that they are expected to submit.

Grassley Amendment No. 998 – Provides for the application of stronger civil penalties for violations of approved risk evaluation and mitigation strategies. Presently S. 1082 has penalties that are insignificant for large companies. This amendment is intended to give some added enforcement authority to the FDA.

Grassley Amendment No. 999 – Provides for a certification that all information submitted as part of a new drug or supplemental application is accurate.

Grassley Amendment No. 1000 – Protects the rights of employees of the Food and Drug Administration.

Grassley Amendment No. 1001 – Provides subpoena authority to the Food and Drug Administration.

Grassley Amendment No. 1002 – Requires that the Food and Drug Administration document all communications and contacts with drug sponsors.

Grassley Amendment No. 1003 – Requires electronic submission of information to the Food and Drug Administration.

Grassley Amendment No. 1020 – Grassley Amendment No. 997 was incorporated into this amendment which 1020 broadens what results information would be available to the public once

a drug is on the market. This amendment is intended to close a loophole in S. 1082 by requiring that results from certain trials, regardless of outcome, including some foreign clinical trials, be made available to the public and also included in the trial registry data bank once that data bank is expanded to include results information. Presently, S.1082 would in effect allow sponsors to withhold certain results from the public, including results from foreign clinical trials and negative trials, if such trials are not part of a drug or device application submitted to the FDA. S.1082 requires that regulations on the expansion of the trial registry data bank to include results information be finalized 2½ years after enactment of the Act. But it leaves it open as to what results will ultimately be required to be included in that data bank.