Grassley: FDA legislation now better protects whistleblowers, charts path to posting of clinical trials.

Senate proposal also targets counterfeit drugs and requires electronic import records

WASHINGTON – Senators late yesterday agreed to add two provisions sponsored by Senator Chuck Grassley to legislation that will renew user fee agreements that fund the Food and Drug Administration.

The first addition is a whistleblower reform he authored based on congressional oversight of the FDA. The second is a plan to see that clinical trial results are posted when the National Institutes of Health issues regulations, as it was called upon to do in a law enacted five years ago.

Grassley said more should be done to protect FDA whistleblowers, but the part of his reform proposal that's now been made part of the Senate FDA bill would expand protections for uniformed employees of the Public Health Service. Earlier this year, Grassley was contacted by FDA whistleblowers after they were negatively targeted by FDA officials for communicating with his office about concerns regarding the FDA. The FDA read messages on the employees' personal email accounts to learn about the communication.

"The situation was egregious for a number of reasons, including the fact that the FDA went after an employee who wasn't covered by the Whistleblower Protection Act," Grassley said. "Whistleblowers identify fraud, waste and abuse, often when no one else will, and risk their professional careers to do so. Those inside the federal government should feel comfortable expressing opinions both inside agencies and to those of us in Congress."

Grassley's proposal to push the National Institutes of Health to publish regulations on clinical trials as was required in the reauthorization of user fees five years ago will require a study by the Government Accountability Office two years after the regulations are final in order to make certain the posting of clinical trial results occurs as intended.

"The goal is to give patients, researchers and health care professionals access to valuable information that could help to build understanding of the efficacy and safety of drugs and medical devices," Grassley said.

Grassley's clinical trials provisions are supported by the Union of Concerned Scientists, the Consumer Federation of America, U.S. PIRG, Public Citizen, and NRC for Women & Families.

Separately, the overall FDA bill, the Prescription Drug User Fee Act, contains legislation authored by Grassley and Senator Patrick Leahy to increase penalties for counterfeiting drug products. It also contains legislative language that will heighten the scrutiny of imported drugs through electronic records. This language comes from legislation Grassley previously co-authored with the late Senator Ted Kennedy.

Grassley also offered an amendment to the FDA bill with Senator Kohl and Senator Blumenthal to try to combat excessive use of antipsychotics in nursing homes. "Our effort would empower nursing home residents and their loved ones in decision-making about what drugs are prescribed for them," he said.

Otherwise, Grassley said he had hoped the 2012 reauthorization of the Prescription Drug User Fee Act would give the FDA its own subpoena authority so that it no longer would need to navigate a cumbersome process at the Department of Justice. He said the FDA also should be given the FDA authority to destroy unsafe products that are refused admission to the United States.

In response to consumers, the drug industry and the FDA, Congress first enacted the Prescription Drug User Fee Act in 1992 to try to speed up the drug approval process. The fees raise supplement federal appropriations instead of replacing them.

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