U.S. SENATE COMMITTEE ON
Finance
SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN
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For Immediate Release
Wednesday, June 8, 2005

Grassley Continues Push for Transparency, Accountability and Independence at FDA

WASHINGTON — Sen. Chuck Grassley is questioning the make-up of the new drug and safety board set up by the Food and Drug Administration to provide independent review of FDA-approved medicines.

In a letter sent to the acting commissioner of the nation's drug safety agency, Grassley asked for assurances that the board could act in an unbiased way given its composition and said the deliberations of the panel should be more transparent in order to improve accountability at the Food and Drug Administration.

Grassley has conducted oversight of the Food and Drug Administration since early last year based on concerns about how the agency resisted making public information about suicide risks for teenagers using antidepressants and cardiovascular risks associated with the painkiller Vioxx. Grassley is chairman of the Senate Committee on Finance, which is oversees the Medicare and Medicaid programs. Medicaid has spent more than $1 billion on Vioxx. Medicare will offer a new prescription drug benefit beginning in January. Grassley has advocated administrative and legislative reforms to make the Food and Drug Administration's work more transparent.

In April, Grassley and Sen. Christopher Dodd introduce a bill (S.930) to set up an new, independent Center inside the Food and Drug Administration to review drugs and biological products once they are on the market. In February, Dodd and Dodd and Grassley introduced a separate bill (S.470) to make clinical trial results publicly available to researchers, doctors and consumers. Both pieces of legislation have been endorsed by consumer and health groups including the Center for Medical Consumers, the Consumer Federation of America, Consumers Union, the National Women's Health Network, Public Citizen, and the U.S. Public Interest Research Group.

The text of Grassley's letter regarding the FDA's new Drug Safety Oversight Board follows here.

June 6, 2005

Lester M. Crawford, D.V.M., Ph.D.
Acting Commissioner
U.S. Food and Drug Administration

5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Crawford:

On May 18, 2005, the Food and Drug Administration (FDA) announced the members of its new Drug Safety Oversight Board (DSB). According to the FDA's policies and procedures manual for the DSB, one of the purposes of this board is to provide independent oversight and advice to the director of the Center for Drug Evaluation and Research (CDER) regarding drug safety issues.

The new board, however, is established within CDER and has no authority to pull a drug from the market if it determines that the drug is harmful to patients. Of particular concern to me is the makeup of the DSB. The FDA states that the DSB will "enhance the independence of internal deliberations and decisions regarding risk/benefit analyses and consumer safety." But, I do not believe that this is the case for several reasons. First, a majority of the DSB members are senior managers within CDER, the center responsible for drug approvals. In fact, CDER officials hold 11 out of a total of 15 voting positions on the DSB. Even more interesting regarding the make-up of the board is the fact that only three of the 11 DSB CDER officials come from organizational subunits not directly involved in the review of new drug applications. Moreover, two of these three originally came from the Office of New Drugs, which is charged with getting new drugs on the market in the first place. So, what we have here is nothing more than the status quo. My question to you, Dr. Crawford, is: Where are the people responsible for post-marketing surveillance who have allegiances only to post-marketing safety and the public's well-being and not to the drugs that they helped put on the market in the first place?

In addition, according to FDA Week (May 20, 2005), the FDA announced in early May that the deliberations of the DSB will be private, unlike decisions that are made by FDA's advisory committees. It is surprising to me that the FDA has chosen to make DSB deliberations private at a time when the agency should be making every effort to improve transparency and accountability.

As Chairman of the Committee on Finance, I request that the FDA explain in detail how it will ensure that the DSB is truly independent and objective. In addition, please describe in detail any actions the FDA will take to assure the public that decisions made by the DSB will be unbiased.

I look forward to hearing from you regarding the issues and concerns set forth in this letter and would appreciate a response to my inquiries no later than July 1, 2005.

Sincerely,
Charles E. Grassley
Chairman