U.S. SENATE COMMITTEE ON
Finance
SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN
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For Immediate Release
Thursday, Dec. 9, 2004

Grassley questions the FDA about Bextra following new warnings from drug maker

WASHINGTON — Sen. Chuck Grassley is asking the Food and Drug Administration to describe how it has evaluated the risks associated with the painkiller Bextra and made decisions about the agency's regulatory response. Grassley's request for information follows the announcement today by the drug maker that doctors will be warned about Bextra's cardiovascular risk and be given stronger cautions about the drug's possible effect on the skin.

The lead witness at an oversight hearing held in November by Grassley warned of problems with Bextra and four other drugs on the market today, about which Grassley said he will also ask the FDA for information. The hearing last month of the Senate Committee on Finance featured the testimony of Dr. David J. Graham, an FDA physician scientist specializing in pharmacoepidemiology. The panel examined the actions of the Food and Drug Administration before another painkiller, Vioxx, was pulled from the world market in September by its drug maker. Grassley is chairman of the Senate committee.

The senator said today that his letter to the acting administrator of the Food and Drug Administration is part of what will be a sustained effort to restore greater public confidence in the federal government's food and drug safety agency. "When the FDA approves a drug, you should be able to bank on it," he said. "If a drug isn't safe, you should know the FDA will take it off the market."

In addition to questioning the Food and Drug Administration about Bextra, Grassley said he will ask Bextra's maker, Pfizer Inc. for information about its decision to make the labeling changes and its communication with the FDA about the drug's cardiovascular risks.

In conjunction with his oversight work, Grassley is pressing for reforms – both legislative and administrative – to bring about greater responsiveness and transparency at the Food and Drug Administration. The senator said he will introduce legislation early next year to establish an independent office of drug safety in the Food and Drug Administration. "The office that reviews the safety of drugs that are already on the market should not in any way be under the thumb of the office that put the drugs on the market in the first place, which is what we have today as a practical matter." Grassley said he is also looking at legislation to establish a clinical trial registry for drug companies to make more information available to the public regarding pharmaceutical drugs on the market.

In addition, Grassley has called on the FDA to initiative administrative changes that make the agency more transparent. "The FDA has earned its good reputation with decades of good work. Congressional scrutiny of the mismanagement that we know about can lead to necessary reforms and help the FDA keep its good reputation. The FDA can also take actions on its own to enhance its own credibility."

Grassley began his oversight of the Food and Drug Administration earlier this year in response to concerns about the reluctance of the agency to provide information to the public about the increased suicidal risks for young people taking anti-depressants. Grassley has worked in the Senate over the last two decades to bring about good government reforms in a number of federal agencies.

The text of his letter to the FDA commissioner follows.

December 9, 2004

VIA FACSIMILE: (301) 827-1960
ORIGINAL BY U.S. MAIL
Mr. 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:

The United States Senate, Committee on Finance (Committee) has been conducting oversight of the Food and Drug Administration (FDA) since last spring. Over these past months, many problems, concerns, and new drug safety controversies have been brought to light.

On Thursday, November 18, 2004, the Committee held a hearing entitled, “FDA, Merck and Vioxx: Putting Patient Safety First?” At the hearing, Dr. David Graham testified that the problems associated with the worldwide withdrawal of Vioxx were symptomatic of systemic problems within FDA. Among other concerns, Dr. Graham stated that there were a number of drugs on the market that needed to be looked at seriously, including a drug manufactured by Pfizer Inc. and marketed under the brand name Bextra. As chairman of the Committee, I request the following information from the FDA related to Bextra, in accordance with attached general definitions.

1. Provide the Committee with a copy of the administrative file and related documents on labeling changes related to cardiovascular risk and Bextra.

2. Provide all documents relating to communications between the FDA and Pfizer, including but not limited to emails, teleconference minutes, and meeting notes on labeling changes related to

cardiovascular risk and Bextra.

3. Provide the Committee with a briefing for each of the following drugs: Meridia, Crestor, Accutane, Bextra and Serevent. Please make the lead medical review officer for each drug available to attend the briefing as well.

Thank you in advance for having your staff coordinate with my staff about this letter by no later than the close of business on December 13, 2004. Please provide the requested documents by January 3, 2005, unless they are available sooner.

Sincerely,

Charles E. Grassley
Chairman