U.S. SENATE COMMITTEE ON
Finance
SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN
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For Immediate Release
Wednesday, Nov. 24, 2004

Grassley Seeks Review by Government Watchdog
Senator Asks About Allegations of FDA Attempts to Discredit Drug Safety Official

WASHINGTON — Sen. Chuck Grassley today asked for an official investigation into whether the Food and Drug Administration has attempted to discredit one of its own drug safety officials who has been critical about agency actions.

"Government whistleblowers are patriotic Americans who stick out their necks for the public good. They deserve rewards, not reprisals," Grassley said.

Grassley has been conducting congressional oversight of the Food and Drug Administration. Last week he held a hearing about agency mismanagement of information about cardiovascular risks with a leading painkiller. The hearing featured testimony from Dr. David J. Graham of the Office of Drug Safety at the FDA. Earlier this year Grassley investigated the reluctance of the FDA to provide information to the public about the increased risk of young people taking anti-depressants.

The text of Grassley's letter of request to the Inspector General for the Department of Health and Human Services follows here. Grassley is chairman of the Senate Committee of Finance. He was a principal sponsor of the 1989 Whistleblower Protection Act.

November 24, 2004

Mr. Daniel R. Levinson
Acting Inspector General
Department of Health and Human Services
Office of Inspector General
330 Independence Ave, SW
Washington, DC 20201

Dear Mr. Levinson:

As Chairman of the U.S. Senate, Committee on Finance (Committee), I request that the Office of Inspector General (OIG), Department of Health and Human Services (HHS) conduct a complete and thorough investigation into the facts, events, persons, policies, regulations and laws

relating to allegations that a number of management level employees at the Food and Drug Administration (FDA) may have acted "to discredit an outspoken agency safety officer who was challenging the FDA's drug safety policies." Specifically, please find attached an article from today's *Washington Post* entitled, "Attempt to Discredit Whistle-Blower Alleged."

The *Washington Post* article raises substantive questions about whether a number of FDA employees "used deceptive practices against [Dr. David] Graham" and whether those employees acted within the spirit and intent of all applicable laws, including, among others, laws governing whistleblowers and prohibited personnel practices. According to the *Washington Post*, the alleged activities involve "managers at the FDA because of their phone numbers and other identifying information." If these allegations indeed have merit, it appears that these activities may have been coordinated by FDA management and may have involved the misuse of government resources, including government property and time.

As Chairman of the Committee, I request that:

A. Members of your staff and staff members of the Committee staff meet in the very near future regarding this matter;
B. The OIG commence an investigation immediately; and
C. The OIG keep my Committee staff informed about developments throughout the course this investigation.

Thank you in advance for having your staff coordinate with my staff no later than December 1, 2004.

Sincerely,

Charles E. Grassley
United States Senator
Chairman, Senate Committee on Finance

The Washington Post
November 24, 2004 Wednesday
Final Edition
SECTION: A Section; A19

HEADLINE: Attempt to Discredit Whistle-Blower Alleged;
Group Says His FDA Colleagues Made Calls

BYLINE: Marc Kaufman, Washington Post Staff Writer

BODY:
Managers at the Food and Drug Administration last month anonymously called a group that protects whistle-blowers in an attempt to discredit an outspoken agency safety officer who was challenging the FDA's drug safety policies, the legal director of the whistle-blower group said yesterday.

Tom Devine of the nonprofit Government Accountability Project (GAP) said the anonymous callers did not identify themselves but he is "100 percent positive" they were managers at the FDA because of their phone numbers and other identifying information. He said he initially took the callers' concerns seriously but later came to see the calls as an effort to smear the whistle-blower, Associate Director David J. Graham of the Office of Drug Safety.

Last week, Graham, a 20-year FDA veteran, said at a Senate hearing that FDA policies have left the American public "virtually defenseless" against the kind of safety problems that led to the abrupt withdrawal in September of the popular arthritis drug Vioxx.

He named five other prescription medications that he said pose serious safety risks that are not being adequately addressed by the FDA.

Although the FDA initially sharply criticized Graham's testimony -- one top official called him "irresponsible" and a practitioner of "junk science" -- the agency yesterday tightened the restrictions on one of the five drugs Graham had criticized, the acne medication Accutane.

In a statement regarding the GAP allegations, the FDA said yesterday that it "acknowledges the right of its employees to raise their concerns to oversight groups."

The agency said that it had no prior knowledge of any employee's contact with the whistle-blower group and that it is working to improve a process for ensuring that internal differences of scientific opinion are fully incorporated into its decision-making. "The agency promotes vigorous debate of the tough scientific questions it confronts every day," the statement said.

The allegation that the FDA used deceptive practices against Graham came two days after the Government Accountability Project agreed to take him on as a client.

Devine said Graham had asked five weeks ago for advice about overcoming his supervisors' opposition to the publication of his critical findings about Vioxx. The anonymous calls followed several weeks later, Devine said.

"The calls came under the guise of being anonymous whistle-blowers," Devine said. "They were clearly working together and shared allegations -- mostly that Dr. Graham's research was unreliable and that there were serious questions of possible scientific misconduct with his study. They said Graham wouldn't address their concerns, and that he was a demagogue and a bully."

Devine said that after several conversations, he persuaded the callers to provide documents to support their accusations, and Devine then challenged Graham based on what was provided.

"It became clear to me that Dr. Graham could reasonably explain any questions about the research, and that the callers were trying to smear him," Devine said. "After that, I called their bluff for more information and that was the end of it. It was all a red herring, and it made me believe Dr. Graham far more."

Devine said that, under his organization's rules, he could not identify the callers because they initially contacted GAP as whistle-blowers themselves. But he said he is certain they were supervisors at the FDA because of the details of the arguments they made and the phone numbers from which they called. In addition, he said that, after identifying the callers to his satisfaction, he referred to them by name during subsequent phone conversations. He said the callers were surprised by his identifications but did not tell him he was wrong.

The allegations follow weeks of bruising criticism of the FDA, which has been accused of being lax on drug safety and was sharply assailed in Congress over its oversight of the British plant that was supposed to produce half of this winter's U.S. supply of flu vaccine. The plant was closed by British health officials because of contamination problems.

The criticism on drug safety issues has led to calls for the creation of a more independent Office of Drug Safety within the FDA, or perhaps outside of it.

Currently, the office is overseen by the Center for Drug Evaluation and Research, which also supervises the Office of New Drugs. To critics of the current setup, the much larger and better-financed Office of New Drugs dominates the safety office, in part because drug reviewers involved in approving a new drug for marketing also play a role in deciding whether the drugs should be withdrawn when safety issues crop up.

In his Senate testimony, Graham said a more independent drug safety office is essential. His position was supported this week by the editors of the Journal of the American Medical Association.

"The drug approval process must be decoupled from the post-marketing safety and surveillance system," the editorial said. "It is unreasonable to expect that the same agency that was responsible for approval of drug licensing and labeling would also be committed to actively seek evidence to prove itself wrong."

The FDA and drug industry officials have generally opposed a more independent safety office, saying it is unnecessary and would serve to de-emphasize the benefits of medications. But the FDA recently asked the congressionally chartered Institute of Medicine to review its drug safety procedures, and top officials said the agency will consider whatever recommendations the institute makes.

Although the drug safety issue involves a number of medications, companies, patients and officials, it has increasingly revolved in recent days around Graham's personality and positions. He has been at the center of the Vioxx controversy and has touched off more heated words and debate with his congressional criticisms of five other drugs, but his impact on drug safety issues goes well beyond those.
During his 20 years in the Office of Drug Safety, he fought passionately to bring about the recall of the diabetes drug Rezulin, the diet pills Fen-Phen and Redux, the cholesterol-lowering drug Baycol, the heartburn remedy Propulsid, and the antihistamine Seldane.

Graham, 50, was trained as a physician at Johns Hopkins and Yale universities and has spent his

entire career at the FDA's drug safety office. A deeply religious Roman Catholic, he has said that his faith serves as a spur to his work. Some see him as a crusading hero, while others believe he unfairly fixates on certain drugs and fails to take into account the patients who are helped by those medications.

His influence has been enormous. In his congressional testimony, Graham said that, in the course of his career, he had recommended that 12 drugs be taken off the market, and that 10 of them were subsequently removed.

The news that Graham had sought whistle-blower assistance and protection -- and that FDA managers had sought to undermine his credibility -- was first reported yesterday in the online edition of BMJ, formerly known as the British Medical Journal.

In that account, Devine said the FDA was "employing a classic law of whistleblower reprisal -- the smokescreen syndrome -- which shifts the spotlight from the message to the messenger. The agency attempted to discredit Dr. Graham rather than provide any scientific evidence contradicting his conclusions."

Graham could not be reached yesterday for comment.

One of the two drugs whose recall Graham has unsuccessfully sought is Accutane, which was approved to treat severe acne but, critics say, is widely prescribed for milder cases. The drug's distribution is restricted to prevent its use by pregnant women because Accutane can cause fetuses to die or develop birth defects. Nonetheless, some women have been getting pregnant while taking the drug.

Under an expanded monitoring program announced by the FDA yesterday, manufacturers will have to keep records of which doctors prescribe the drug, which pharmacies distribute it and which patients take it. Doctors and pharmacies will also have to inform women about the drug's risks, and pharmacists will have to see a signed proof that the patient is not pregnant before they dispense the drug, the FDA said.

In its news release, the agency said the changes stemmed from the recommendations of an advisory panel in February.