U.S. SENATE COMMITTEE ON
Finance
SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN
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For Immediate Release
Wednesday, July 19, 2006

Grassley requests investigation of FDA for conspiring against scientist

WASHINGTON — Trying to stop more of the same inside the Food and Drug Administration, Sen. Chuck Grassley is asking a government watchdog to investigate how an FDA employee apparently worked in concert with a pharmaceutical drug maker to try to discredit the FDA scientist who publicized information about the safety risks of the drug Vioxx.

Grassley made his request today of the Inspector General for the Department of Health and Human Services.

Grassley said he based his request on the handwritten notes of a Merck executive about his meeting with a high-level FDA official indicating that the FDA official had suggested sharing the drug-company's critique of Dr. David Graham. Graham was the lead witness at a November 2004 hearing conducted by Grassley about the way the FDA handled Vioxx.

"This evidence makes it look like the FDA hung Dr. Graham out to dry," Grassley said today. "If that's what happened, the message sent to the rank and file is 'we're not with you, we're with the industry.'"

The full text of Grassley's letter to the Inspector General follows here.

July 19, 2006

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

Dear Inspector General Levinson:

The purpose of this letter is to request that the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) conduct an internal investigation relating to attempts to discredit a whistleblower at the Food and Drug Administration (FDA).

Specifically, as Chairman of the Finance Committee (Committee), I am requesting that

you examine whether or not one or more employees of the FDA acted in concert with Merck & Co., Inc. (Merck) to discredit and/or to call into question allegations made by Dr. David Graham, regarding the safety and efficacy of Vioxx, as well as, the relationship between FDA and the pharmaceutical industry.

Unfortunately, I have come to learn that it is not as unusual as one might think for a pharmaceutical company to use its power, influence, and access to discredit "thought leaders" that may present impediments to their agenda. Indeed, during the course of a hearing that I convened on November 18, 2004, entitled, "FDA, Merck, and Vioxx: Putting Patient Safety First?" (Vioxx Hearing) the Committee examined that exact situation.

During the Vioxx Hearing, Dr. Gurkipal Singh provided testimony relating to, among other things, his repeated requests to Merck for more data, including information on high blood pressure and heart failure rates related to Vioxx. Dr. Singh was in a unique position to request this data because, in addition to being an Adjunct Professor of Medicine at Stanford University School of Medicine, he was a consultant to Merck on Vioxx. In pertinent part, Dr. Singh stated the following to describe the efforts that Merck initiated to "put an end" to his repeated inquiries:

When I was unable to obtain this data after multiple requests I added a slide to my presentations that showed a man—representing the missing data—hiding under a blanket. Up until this point in time, Merck had responded to all of my requests promptly and in a scientific fashion. With VIGOR, suddenly it was as if the company had to think what questions to answer, and what answers to give. I persisted with my inquiry, and I was warned that if I continued in this fashion there would be serious consequences for me. I was told that Dr. Louis Sherwood, a Merck senior vice president and a former Chief of Medicine at the medical school had extensive contacts within academia and could make life very difficult for me at Stanford, and outside.

According to the hearing testimony, even after warning Dr. Singh personally, Merck continued contacting Dr. Singh's superiors at Stanford to complain. Fortunately, and according to Dr. Singh, Stanford did not succumb to the pressure tactics used by Merck, believing that the "suppression of scientific discussion was unethical…."

Although the situation experienced by Dr. Singh resolved itself in the best interest of science, and in the best interest of the American people, the importance of this incident cannot and should not be underestimated.

With respect to Dr. Graham, it appears that at least one FDA employee worked in concert with Merck to "get the message out" on Dr. Graham and not in a friendly way. This is based upon hand-written notes dated October 13, and prepared by Dr. Ned Braunstein, the present Senior Director of Merck Research Labs. The notes appear to document a conversation that he had with Dr. Brian Harvey, the current Director of the Division of Gastrointestinal and Coagulation Drug Products and the Deputy Director of the Office of Nonprescription Products at the FDA. Specifically, I am troubled by the contents of Dr. Braunstein's notes, which state, "Brian suggests an official rebuttal on Graham." The notes go on to say "Brian- opportunity to get message out on Graham et al." Immediately thereafter the notes say, "suggests we provide journalists a copy of our critique on Graham."

It is no secret that Dr. Graham was and is a critic of the FDA. However, that does not

mean the FDA should scheme with drug sponsors to discredit its own employees. Moreover, the FDA may disagree with the characterizations made by Dr. Graham, but that does not absolve the FDA of its duty to maintain a clear, bright line between the regulated and the regulator; that is why I am requesting an investigation into this matter. If FDA employees conspired with Merck to discredit Dr. Graham, then HHS and FDA need to ensure that the offending parties are held accountable for their actions and the FDA must ensure that similar attempts to discredit, pressure or intimidate other FDA scientists do not occur in the future.

Moreover, it is important to recognize that not only does Federal law provide individuals who are assisting a congressional investigation protection from retaliation; it also provides fines against those who interfere with a committee inquiry. (See 18 USCS 1505) (partial cite)

In closing, I want to thank you in advance for your prompt review of this important and troubling matter.

Sincerely,

Chuck Grassley
United States Senator
Chairman, Committee on Finance