U.S. SENATE COMMITTEE ON
Finance
SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN
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For Immediate Release
Tuesday, Oct. 31, 2006

Grassley Continues to Press FDA on Handling of Hampshire Case

WASHINGTON – Sen. Chuck Grassley, chairman of the Committee on Finance, continues to press the federal Food and Drug Administration for details of how the agency handled an internal investigation of one of its scientists, Dr. Victoria Hampshire. Grassley also wants to know how the agency interacted with a pharmaceutical company that actively discredited Hampshire for her work cataloging adverse events for a product the company produced. Documents and information obtained by the committee show that the then-FDA commissioner and chief counsel held a private meeting with the manufacturer at which no notes or minutes were taken. This meeting took place shortly before the FDA removed Hampshire as a presenter at its advisory meeting for the company's product.

In a new letter, Grassley says the agency responded to some of his requests for information on the case but some responses require clarification, and the agency failed to respond at all to still other requests. The text of his Oct. 25, 2006, letter to the agency follows. The enclosures and another relevant document are attached.

October 25, 2006

Via Electronic Transmission
Original via USPS Mail
Andrew C. von Eschenbach, M.D.
Acting Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Acting Commissioner von Eschenbach:

As a senior member of the United States Senate and as Chairman of the Committee on Finance (Committee), it is my duty under the Constitution to conduct oversight into the actions of the executive branch, including the activities at the Food and Drug Administration (FDA). Last year, I wrote to you regarding the troubling allegations I received related to a pharmaceutical company conducting a private investigation into Dr. Victoria Hampshire, an FDA employee and commissioned officer in the Public Health Service. This investigation was conducted with the purpose of discrediting Dr. Hampshire because of her work cataloging adverse events for a product

the company produced, information which ultimately led to the product's removal from the market.

Two additional follow-up letters were sent to you regarding this matter and seeking access to witnesses, documents, and information. While some of my requests have been met, others remain outstanding or were addressed in a manner that requires further clarification.

First and foremost, I asked some time ago, that FDA "examine the attached information and correct any factual irregularities that [FDA] presented to the media."[1] Further, I asked that FDA, "inform me immediately when this is done and in the event a decision is made not to correct these factual irregularities, please explain why FDA decided not to do so."[2] In light of the already lengthy delay, I again request an immediate response from FDA regarding this outstanding matter.

Secondly, I want to address the responses to my letter of April 18, 2006. FDA previously provided a number of documents related to the internal investigation of Dr. Hampshire and also provided information regarding contacts between the Office of the Commissioner and Wyeth Pharmaceuticals (Wyeth) and its subsidiary division, Fort Dodge Animal Health (FDAH). I am concerned about FDA's response regarding the contacts between Wyeth/FDAH and the Office of the Commissioner. Specifically, I am concerned about FDA's failure to provide in its response any detail other than a one page document denoting a meeting in 2004, between representatives of Wyeth/FDAH and then-FDA Commissioner Lester Crawford and then-FDA Chief Counsel Daniel Troy.

FDA regulations provide that, "an official transcript, recording, or memorandum summarizing the substance of any meeting described in this section will be prepared by a representative of FDA when the agency determines that such documentation will be useful."[3] Based upon the lack of notes, transcripts, recording, or other written detail, it appears that FDA made a determination that any such documentation of the meeting between Dr. Crawford, Mr. Troy, and representatives of Wyeth/FDAH would not be useful. Therefore, I ask that FDA respond to the following requests:

(1) Provide the date that the document was provided to the Committee and included in FDA's June 7, 2006, response was originally prepared.

(2) Provide all documents related to the scheduling of the meeting with Wyeth/FDAH and the Office of the Commissioner, including, but not limited to, electronic calendars, emails, and handwritten notes.

(3) State who made the decision not to create an official transcript, recording, memorandum, or other written documentation of the purpose and events occurring at the November 19, 2004, meeting and provide the basis for not memorializing the meeting.

(4) Provide a list of all meetings between representatives of Wyeth/FDAH and the Office of the Commissioner between November 2004 and present. In complying with this request, please provide the date of the meeting, the parties in attendance, and the topics of discussion.

Third, it has come to my attention recently that individuals within the FDA's Office of Surveillance and Compliance received inquiries from Wyeth/FDAH regarding ProHeart 6, the animal drug that was removed from the market and ultimately led to the investigation of Dr. Hampshire. Among the inquiries was a request from Wyeth/FDAH to meet with staff from the Center for Veterinary Medicine (CVM) regarding new information on ProHeart 6. It is my understanding that this meeting was to be "low-key and cordial."[4] As this meeting was scheduled to occur in August, I request that

you provide the official transcript, recording, or memorandum summarizing the substance of the meeting. Further, I ask that you provide all communications between FDA and Wyeth/FDAH regarding Dr. Hampshire that may have occurred between April 18, 2006, and the date of this letter.

Thank you in advance for providing the requested records and information by no later than October 31, 2006. In complying with this request, please respond by repeating the enumerated request, followed by the accompanying response; attach and identify all responsive records and communications by the enumerated request(s) to which they are responsive.

Sincerely,

Charles E. Grassley
Chairman

Enclosures

[1] See Attachment 1.
[2] *Id*.
[3] 21 CFR § 10.65 (2006).
[4] See Attachment 2.