U.S. SENATE COMMITTEE ON
Finance
SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN
http://finance.senate.gov

For Immediate Release
Tuesday, November 29, 2005

Grassley seeks correction from the Food and Drug Administration

WASHINGTON — Sen. Chuck Grassley is calling on the Food and Drug Administration to correct its statement of last week that the agency conducted an investigation of one of its own scientists with her knowledge despite evidence to the contrary.

Grassley said that in addition to misrepresenting the fact that its scientist was informed of the investigation before the matter was nearly closed, the FDA denied that its internal investigation was criminal in nature. He said that documents and emails obtained by his staff investigators suggest otherwise. The text of a letter Grassley sent today to the Acting Commissioner of the FDA follows this news release. The attachment to the letter is posted at http://finance.senate.gov.

Earlier this month, Grassley publicly questioned the way that both the FDA and Wyeth Pharmaceuticals had handled the findings of FDA employee Dr. Victoria Hampshire that led to the recall of the heartworm medication ProHeart 6. He asked the drug maker to respond to allegations that the company had launched an investigation to discredit the FDA scientist before the FDA's own internal review was started. The text of Grassley's November 17 letter to Wyeth Pharmaceuticals follows today's letter text below. The attachment to the November 17 letter is posted at http://finance.senate.gov.

November 29, 2005

Dr. Andrew C. von Eschenbach
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 executive branch agencies. As part of the Committee's ongoing review of the Food and Drug Administration (FDA) and events surrounding the investigation of Dr. Victoria Hampshire, V.M.D., I write today seeking a clarification from the FDA regarding facts FDA released to the

press related to this matter.

It has come to my attention that on November 18, a spokesperson for the FDA provided information to a reporter from Reuters regarding the FDA's investigation of Dr. Victoria Hampshire that was factually inaccurate. Specifically, the article quoted the FDA spokesperson stating that "the [FDA] investigation was conducted with Dr. Hampshire's knowledge." Further, the FDA spokesperson went on to add that the FDA investigation of Dr. Hampshire was not a criminal investigation. Information that was obtained by Committee staff through a review of documents and interviews conducted with FDA personnel supports the position that these two statements made by the FDA spokesperson were factually inaccurate and portrayed in a light other than in the way they occurred.

Interviews conducted by Committee staff with Special Agents from the FDA's Office of Internal Affairs, of the Office of Criminal Investigation revealed, among other things, that the FDA internal investigation into Dr. Hampshire was in fact a criminal investigation and that Dr. Hampshire had no knowledge of the internal FDA criminal investigation until it was nearly completed. Documents and emails obtained by the Committee further support both of these facts, and show that the FDA was, at all times, aware of both of these facts. Further, Committee staff has obtained emails that show FDA officials were aware of factual inaccuracies in their November 18 press release.

For example, in an email dated November 18, 2005 Mr. Mark Cohen, the attorney for Dr. Hampshire, sent an email to the FDA Office of Communications stating:

"[T]he press release that the FDA plans to release tonight is inaccurate in one regard: It uses the language that the FDA investigation of her [Dr. Hampshire] was conducted 'With your knowledge…' In fact, Dr. Hampshire was not aware at the time that she was being investigated. We'd ask that you correct this in the press release."

The current inquiry into events surrounding the investigation of Dr. Hampshire remains open and the Committee is continuing to examine various aspects of this matter. While the recent information presented to the media by the FDA did not directly harm the ongoing inquiry, the potential damage that incorrect and misleading statements could cause remains a reality. I strongly encourage the FDA to examine the attached information and correct any factual irregularities that it presented to the media related to the November 18, 2005 article by Reuters. Please 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.

Thank you in advance for your cooperation on this matter. Should you or any of your staff have any questions regarding this matter or the documents in question, please Emilia DiSanto or Nick Podsiadly of my Committee staff at (202) 224-4515.

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

Attachment

November 17, 2005

Mr. Robert Essner
Chairman, President, and CEO
North America and Global Business
Wyeth Pharmaceuticals
500 Arcola Road
Collegeville, PA 19426

Dear Mr. Essner:

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 government and companies that do business with the government. Over the past year, the Committee has reviewed various matters relating to the pharmaceutical industry and its relationship with the Food and Drug Administration (FDA). In previous letters to you, the Committee sought your assistance with inquiries into nominal pricing, educational grants, as well as employer sponsored education of the False Claims Act. I write today seeking your continued cooperation with a matter concerning Wyeth Pharmaceuticals (Wyeth) and FDA's Center for Veterinary Medicine (CVM).

Recently, the Committee received allegations regarding Wyeth and events surrounding the recall of the heartworm medication ProHeart 6. Information and documents reviewed by the Committee appear to support allegations that Wyeth investigated an employee of the FDA involved in the safety review of ProHeart 6. It appears that the express purpose of the investigation was to discredit the employee and have the employee reassigned. Further, following the investigation conducted by Wyeth, the FDA initiated an internal criminal investigation into the same FDA employee. The Committee's review of these allegations raises serious questions regarding, among other things, the appropriateness of the actions taken by both the FDA and Wyeth.

Wyeth manufactures and distributes a number of animal health care products through its division Fort Dodge Animal Health (FDAH), including at one time, the heartworm preventative drug called ProHeart 6. Originally approved in 2001 by the FDA, ProHeart 6 was a novel heartworm prevention drug for dogs. It was an injectable sustained-release drug that provided six months of coverage and was administered only by a veterinarian. As part of the FDA's post-market review of ProHeart 6, the FDA assigned Dr. Victoria Hampshire, V.M.D., as the Adverse Drug Event Coordinator, to monitor adverse events sent in by both consumers and veterinarians.

From 2003 to 2005, Dr. Hampshire compiled the results of over 5500 adverse drug event reports (ADEs) related to ProHeart 6, including nearly 500 canine deaths. Responding to the numerous adverse drug reports, Dr. Hampshire urged the FDA to take action on ProHeart 6 in November of 2003. While this initial call to action garnered little attention within the FDA, a subsequent effort by distraught consumers in July 2004 caught the attention of Dr. Sundlof, the Director of CVM. Dr. Hampshire presented this information and subsequently brought the matter to the attention of former Commissioner Dr. Lester Crawford. Dr. Crawford, a veterinarian

himself, agreed with the findings and on September 1, 2004, the FDA organized a meeting with Wyeth to review the adverse event data.

Following the presentation, CVM, the Acting Commissioner and FDA Legal Counsel agreed to recall ProHeart 6 from the market. After two days of negotiating with the FDA, Wyeth voluntarily recalled ProHeart 6 from the market on September 4, 2004.

Shortly after the recall of ProHeart 6, Wyeth sought a review of the recall decision through a meeting of the Veterinary Medicine Advisory Committee (VMAC). The FDA granted the request for a VMAC meeting and scheduled it for January 2005. It appears the timing of the VMAC would have allowed Wyeth a chance to reintroduce ProHeart 6 for the spring heartworm season if the VMAC voted to support its return to the market. In preparation for the VMAC meeting, Dr. Hampshire prepared a presentation regarding the thousands of ADEs received and worked to ensure that the advisory committee would have complete information regarding these events.

Documents obtained and reviewed by the Committee, coupled with interviews conducted by Committee staff, appear to support allegations that Wyeth investigated Dr. Hampshire and presented its findings to Dr. Crawford. Following Wyeth's presentation, Dr. Hampshire was removed from the review of ProHeart 6 and subjected to a criminal investigation by the FDA. FDA Investigators advised Committee staff that the criminal investigation resulted in no action taken against Dr. Hampshire. Furthermore, the FDA recently gave Dr. Hampshire an award for her job performance related to ProHeart 6.

Information available to the Committee appears to support allegations that Wyeth's efforts to discredit Dr. Hampshire were not limited to the FDA. More specifically, it appears that Wyeth's efforts to reintroduce ProHeart 6 to the market included a Wyeth sales representative presenting information to the veterinary community in an apparent effort to discredit Dr. Hampshire. Attached is a two-page letter from a veterinarian and former commissioned officer in the United States Public Health Service. According to the letter, a Wyeth sales representative in Alabama stated that Dr. Victoria Hampshire was the sole reason for the recall of ProHeart 6. Further, the Wyeth representative stated that Wyeth investigated Dr. Hampshire and said that she pursued the withdrawal of ProHeart 6 for personal financial gain. Finally, the Wyeth representative added that once "[Dr. Hampshire] was taken care of" the number of adverse event reports being submitted for ProHeart 6 dropped significantly.

As Chairman of the Committee, I request that Wyeth provide the following records and information to the Committee:

(1) State how Wyeth concluded that Dr. Hampshire had an "apparent conflict of interest." In complying with this request, describe in detail the actions taken by Wyeth, including but not limited to whether or not Wyeth subsidized, either directly or indirectly, an investigation of Dr. Hampshire. Additionally, provide copies of all communications, documents, and records related to Wyeth's conclusion that Dr. Hampshire had an "apparent conflict of interest," including but not limited to, payments associated with one or more investigation(s) of Dr. Hampshire.

(2) Identify all individual(s) and/or agent(s) (including full name, title, and contact information) employed by and/or associated with Wyeth, either directly or indirectly, who were involved in any way with an investigation(s) of Dr. Hampshire. In the event that any individual(s) and/or

agent(s) is/are no longer associated with Wyeth, identify that individual(s) and/or agent(s) as well.

(3) Identify all individual(s) and/or agent(s) (including full name, title, and contact information) employed by and/or associated with Wyeth, either directly or indirectly, who were involved in any way with the research supporting and the preparation of the Power Point presentation entitled, "ProHeart 6 Apparent Conflict of Interest," dated November 19, 2004. In the event that any individual(s) and/or agent(s) is/are no longer associated with Wyeth, identify that individual(s) and/or agent(s) as well.

(4) Provide copies of all documents and records, including but not limited to communications and email, related to the Wyeth Power Point presentation entitled, "ProHeart 6 Apparent Conflict of Interest," dated November 19, 2004.

(5) State whether or not Wyeth provided notice to the FDA that it was initiating or conducting a private investigation into an FDA employee? If so, provide the name(s) of any individual at the FDA who received notice prior to the initiation of the investigation. Provide copies of all records, including but not limited to communications and emails between Wyeth and the FDA related to the investigation of Dr. Hampshire.

(6) How many times has Wyeth investigated an FDA employee(s) and/or presented information to the FDA related to an FDA employee's apparent conflict of interest? Additionally, describe in detail the facts associated with each investigation and/or presentation.

(7) Provide complete contact information for Mr. Clint "C.T." Newsum, Vice President for Wyeth Pharmaceuticals. Additionally, please make Mr. Newsum available for an interview with my staff to take place no later than December 23, 2005.

(8) Provide complete contact information for Mr. Glen Kimmorely, a Senior Territory Manager for Fort Dodge Animal Health, a division of Wyeth Pharmaceuticals. Additionally, please make Mr. Kimmorely available for an interview with my staff to take place no later than December 23, 2005.

(9) Provide complete contact information for Mr. Tom O'Hare of Copiague, New York. Identify the relationship Mr. O'Hare has with Wyeth Pharmaceuticals, including but not limited to, any financial relationship. State whether or not Wyeth is able to make Mr. O'Hare available for an interview, and if so, please make Mr. O'Hare available for an interview with my staff to take place no later than December 23, 2005.

Thank you in advance for providing the name and contact information, including an email address, for a person who will act as the point of contact for Wyeth Pharmaceuticals during the Committee's review by November 22, 2005, unless it is available sooner. All requests for communications, documents, records and written responses to questions should be received no later than December 16, 2005. In cooperating with the Committee's review, no documents, records, data or information related to these matters shall be destroyed, modified, removed or otherwise made inaccessible to the Committee.

Sincerely,
Charles E. Grassley

United States Senator
Chairman, Committee on Finance

Attachment