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

Floor Statement of U.S. Senator Chuck Grassley of Iowa

One-Year Anniversary of the Finance Committee's Hearing on the FDA and Vioxx

Thursday, November 17, 2005

Mr. President, I rise today on the anniversary of the hearing on the worldwide withdrawal of Vioxx, the blockbuster drug that became a blockbuster disaster. As chairman of the Committee on Finance, I called for this hearing a year ago. The Vioxx hearing turned the spotlight on a troubled agency in denial. The type of problems exposed during the hearing have proven to be not isolated but systemic.

Over the past year, my Committee staff have investigated allegations coming from within and without the agency. Brave whistleblowers – such as Doctors Andrew Mosholder, David Graham and others – have come forward to expose the too cozy relationship between the agency and the drug industry. I can tell you today that problems exist not only within the Center for drugs, but extend to the Centers for devices, biologics and even to veterinary medicines. I am concerned and every other member of this Senate should also be concerned.

To further illustrate this problem, I am sending today a letter to another drug company that appears too cozy with the Food and Drug Administration. Last year, just two days after the Vioxx hearing, the drug company Wyeth met with former Commissioner Crawford. Why did Wyeth's CEO want to talk with the Commissioner? Because Wyeth recently had to remove one of its most profitable veterinary drugs from the market.

So what did Wyeth do? They launched an investigation of an FDA employee, Dr. Victoria Hampshire. You see, it was Dr. Hampshire who concluded that Wyeth's drug was killing hundreds of dogs. I have in my hand what Wyeth presented to former Commissioner Crawford. It's a 29-page power point with 10 pages of back up materials, dated November 19, 2004. It's marked "confidential" and says "ProHeart 6 Apparent Conflict of Interest."

In summary, it alleges that Dr. Hampshire had personal and financial conflicts of interest. Dr. Hampshire approached my Committee staff because she was scared and felt unfairly targeted by Wyeth and her agency for simply doing her job. Last week, the FDA briefed my Committee investigators on this matter. It turns out that Wyeth succeeded in having Dr. Hampshire removed from reviewing its drug. Dr. Hampshire's hard work and dedication to science and drug safety placed a bulls eye on her reputation and career. Without her knowledge, the FDA also launched a criminal investigation against her.

This sordid story is still unraveling. But I can say that no action was taken against Dr. Hampshire and, after the investigation closed, the FDA rewarded her for her work on Wyeth's drug, which remains off the market. Unfortunately for Dr. Hampshire, Wyeth's efforts to discredit her did not end at the FDA. At least one Wyeth sales representative attempted to discredit Dr. Hampshire in the Veterinary community. Fortunately for Dr. Hampshire, the sales

person's comments about Wyeth's investigation of her and her alleged conflicts of interest were made to a former colleague of Dr. Hampshire. My letter to Wyeth today seeks information and documents related to Wyeth's investigation of Dr. Hampshire and the salesperson's comments.

So a year later, we are still uncovering the cozy relationship between the agency and the drug industry. Dr. Hampshire's sad story is further proof that the FDA needs a permanent Commissioner who can restore order and respect for independence. The Food and Drug Administration cannot serve the American people and the interests of the drug industry at the same time.

A year ago today, Dr. Graham created a firestorm when he said at the Vioxx hearing, "I can tell you right now, there are at least five drugs on the market today that I think need to be looked at quite seriously to see whether or not they belong there...". Dr. Graham identified those five drugs – Accutane, Bextra, Crestor, Meridia and Serevent – when asked by my distinguished colleague, Sen. Bingaman. Some roundly criticized Dr. Graham's testimony as inflammatory.

Today, it is noteworthy that the agency has taken regulatory action or action is pending on four out five of the named drugs. Less than a week after the hearing, the Food and Drug Administration announced it was strengthening its plan to reduce the risk of birth defects associated with Accutane. Then in August, the agency issued a public health advisory to help make sure females do not become pregnant while taking this medicine and to release more information about depression and suicidal thoughts associated with the drug.

A month after the hearing, the Food and Drug Administration issued a public health advisory for Bextra. The agency announced it changed Bextra's label to provide consumers with upgraded warnings about possible heart and blood clotting problems. Ultimately, the agency asked Pfizer to voluntarily remove Bextra from the market in April. Less than four months after Dr. Graham's testimony, Crestor was subject to a public health advisory too as part of the agency's efforts to notify the public of potentially significant emerging safety data. Crestor's label was changed to highlight important information on the safe use of Crestor. Eight months after the hearing, the Food and Drug Administration convened an Advisory Committee meeting related to the safety of Serevent and other asthma drugs. The Advisory Committee recommended strengthening the labels for Serevent too, but the agency has yet to act. Only one drug – MERIDIA – has not been the subject of any action by the FDA.

American consumers are the beneficiaries of these actions. I don't know if the agency would have acted without Dr. Graham's testimony. But I know from experience that sunlight is the best disinfectant. The scrutiny of the last 12 months is just the kind of medicine the Food and Drug Administration needed. Things have not turned around overnight.

Reforming this agency is a long-haul task for those of us in Congress committed to oversight, reform and improvement. The Vioxx investigation and hearing, as well as other investigations, prompted me to co-sponsor two FDA reform bills this year. Senator Dodd and I introduced the Fair Access to Clinical Trials Act in February and the Food and Drug Administration Safety Act of 2005 in April. These bills represent part of a sustained effort to restore public confidence in the federal government's food and drug safety agency. A number of you have co-sponsored these bills with us and I urge everyone to consider them again today.

Enactment of these bills will be another meaningful step toward greater accountability and transparency for the Food and Drug Administration. And if enacted they would provide the agency with some much-needed authorities to ensure the safety and efficacy of drugs. One big opportunity that absolutely cannot be missed right now is appointment of a new, full-time

commissioner who is committed to reform. This leader must recognize the problems of a culture that's become too cozy with the industry. Then that leader must be tough enough to make necessary changes happen. Mr. President, the FDA has to do a top-notch job on ensuring the safety of the products it regulates. And where the FDA lacks the tools and resources to do so, Congress has to step in and help.

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

Attachment

GENERAL INSTRUCTIONS

1. Please note that, for purposes of responding to this document request, the terms "document" and "record" should be interpreted in accordance with the general definitions attached to this letter.

2. In complying with this document request, produce all responsive documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, and representatives acting on your behalf. In addition, produce documents that you have a legal right to obtain, documents that you have a right to copy or have access to, and documents that you have placed in the temporary possession, custody, or control of any third party.

3. No documents, records, data or information requested by the Committee shall be destroyed, modified, removed or otherwise made inaccessible to the Committee.

4. If the document request cannot be complied with in full, it shall be complied with to the extent possible, which shall include an explanation of why full compliance is not possible.

5. In complying with this document request, respond to each enumerated request by repeating the enumerated request and identifying the responsive document(s).

6. Each document produced shall be produced in a form that renders the document susceptible of copying.

7. If any document responsive to this request was, but no longer is, in your possession, custody, or control, identify the document (stating its date, author, subject and recipients) and explain the circumstances by which the document ceased to be in your possession, or control.

8. This request is continuing in nature. Any document, record, compilation of data or information, not produced because it has not been located or discovered by the return date, shall be produced immediately upon location or discovery subsequent thereto.

GENERAL DEFINITIONS

1. The term "Wyeth" means Wyeth Pharmaceuticals, its corporation, its board of directors, or one or more of its divisions, subsidiaries or affiliates, or related entities, including, but not limited to, Fort Dodge Animal Health.

2. The term "document" means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to the following: memoranda, reports, statistical or analytical reports, books, manuals, instructions, financial reports, working papers, records notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, interoffice and intra office communications, electronic mail (E-mail), contracts, cables, notations of any type of conversation, telephone call, meeting or other communication, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto), and graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, microfiche, microfilm, videotape, recordings and motion pictures), and electronic, mechanical, and electric records or representations of any kind (including, without limitation, tapes, cassettes, discs, and recordings) and other written, printed, typed, or other graphic or recorded matter of any kind or nature,

however produced or reproduced, and whether preserved in writing, film, tape, disc, or videotape. A document bearing any notation not a part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.

3. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.

4. The terms "relate," "related," "relating," or "regarding" as to any given subject means anything that discusses, concerns, reflects, constitutes, contains, embodies, identifies, deals with, or is any manner whatsoever pertinent to that subject, including but not limited to documents concerning the preparation of other documents.

5. The terms "and" and "or" shall be construed broadly and either conjunctively or disjunctively to bring within the scope of this document request any information which might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa to bring within the scope of this document request any information which might otherwise be construed to be outside its scope.

6. The term "communication" means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, written, electronic, by document or otherwise, and whether face to face, in a meeting, by telephone, mail, telexes, discussions, releases, personal delivery, or otherwise. Documents that typically reflect a "communication" include handwritten notes, telephone memoranda slips, daily appointment books and diaries, bills, checks, correspondence and memoranda, and includes all drafts of such documents.