United States Senate

Washington, D.C. 20510

For Immediate Release
Thursday, June 7, 2007

New questions about FDA attempt to denigrate doctor with concerns about drug safety

WASHINGTON — Leading lawmakers today called on the FDA Commissioner to explain the agency's policy on conflicts of interest regarding staff hired directly from pharmaceutical companies that are regulated by the FDA.

They made their inquiry based on the actions of an FDA spokesman, who previously worked for multiple pharmaceutical companies. The FDA employee used agency email to attack the research of an independent scientist. Yesterday, the FDA Commissioner testified that the employee had been formally reprimanded with a letter in his employment file.

The letter is signed by Sens. Chuck Grassley, Max Baucus and Sherrod Brown, as well as Reps. John Dingell and Bart Stupak.

"After all the talk of reform by the FDA commissioner, it's discouraging and alarming to see another situation where you can't tell the difference between the actions of the FDA and those that might come from a drug maker it's regulating," Grassley said.

"The opinions of independent scientists must be valued by the FDA," said Baucus. "Objective, outside advice is essential to protect Medicare and Medicaid patients—and all Americans—from drugs that could turn out to be harmful. I have some serious questions about Mr. Arbesfeld's use of government resources, but I am even more concerned about whether his drug company connections led him, in any way, to seek to unjustly discredit Dr. Nissen. The FDA's ultimate duty is to ensure the safety of the products it regulates, which includes sharing credible, potentially life-saving information from any trustworthy source."

"The FDA should thank doctors who identify potential health risks, not demonize them. Congress is working on legislation to clean up FDA's act, and none too soon," Brown said.

Here is the text of the letter.

June 7, 2007

The Honorable Andrew C. von Eschenbach, M.D.
Commissioner
Food and Drug Administration
Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. von Eschenbach:

On May 24, 2007, Food and Drug Administration (FDA) consultant Douglas Arbesfeld sent an e-mail to journalists entitled "What are St. Steven's feet made of? Clay, perhaps?" The body of the e-mail contained text copied from an online article that criticized a study on Avandia published by Dr. Steven Nissen, chairman of Cardiovascular Medicine at the Cleveland Clinic. The original article that Arbesfeld e-mailed to journalists appeared on a Web site (www.theheart.org). That article has now been corrected to contain a long note of caution from the editor that sections of the article do not "meet the highest standards of journalistic or scientific integrity or credibility."

We are concerned that Mr. Arbesfeld sent this message using his Government e-mail, which carried his FDA signature line and work-related contact information at the bottom. In several news articles on other matters, Mr. Arbesfeld is named as the spokesman for FDA. Given that he has acted in this capacity in the past, this e-mail may have given journalists the impression that the United States Government actively encourages smear campaigns against independent scientists. If so, this is a completely unacceptable use of Government time and equipment.

In the Agency's response to this incident, it stated that Mr. Arbesfeld is a consultant and does not speak on behalf of FDA. Accordingly, this response may leave the media wondering how they should interpret future e-mails from FDA spokesmen and Mr. Arbesfeld, in particular.

The Committee finds it even more troubling that Mr. Arbesfeld may be using his position with FDA to settle old scores with Dr. Nissen. Certainly, Mr. Arbesfeld is familiar with Dr. Nissen, since the two have been on opposing sides of drug safety in the past. On April 26, 2005, the New York Times reported quotes from Dr. Nissen that were critical of Natrecor, a drug manufactured by Johnson & Johnson ("Johnson & Johnson Adds Data on Deaths to Label on Heart Treatment." Stephanie Saul, the New York Times, April 26, 2005). The article also noted that Dr. Nissen cast the only vote against the product when a FDA advisory panel recommended it in 2001. The person featured in the article defending Natrecor was Mr. Arbesfeld, who at the time was Johnson & Johnson's spokesman.

Accordingly, we ask that you answer the following questions related to this matter. In your response, please use the question and answer format, which would have each question below given with the corresponding response:

1. What is the justification for the use of taxpayer dollars for a communications consultant?
2. What is FDA's policy regarding the hiring of consultants/employees who have recently worked for the companies directly regulated by the Agency?
3. How does FDA ensure that consultants such as Mr. Arbesfeld do not have relationships with companies in direct conflict with his role as FDA spokesperson?

4. Is Mr. Arbesfeld currently receiving, or has he received in the last year, income or other remuneration from companies that manufacture, distribute, or market products directly regulated under the Food, Drug, and Cosmetic Act?

5. Does FDA have a policy regarding employees/consultants using their official FDA e-mail accounts to express their personal opinions, which may not be official FDA positions, to members of the press?
6. If there is such a policy as described in question 5, what is that policy?

Please provide your response by no later than June 20, 2007.

Sincerely,

Max Baucus
Chairman
Senate Committee on Finance

John D. Dingell
Chairman
House Committee on Energy and Commerce

Charles E. Grassley
Ranking Member
Senate Committee on Finance

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations
House Committee on Energy and Commerce

Sherrod Brown
United States Senator

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Ed Whitfield, Ranking Member
Subcommittee on Oversight and Investigations

Staff Contacts:
Jill Kozeny, for Sen. Grassley, 202/224-1308
Carol Guthrie, for Sen. Baucus, 202/224-4515
Joanna Kuebler, for Sen. Brown, 202/224-2315