

November 29, 2004

VIA FACSIMILE: (301) 827-1960  
ORIGINAL BY U.S. MAIL

Mr. Lester M. Crawford, D.V.M., Ph.D.  
Acting Commissioner  
U.S. Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Dear Dr. Crawford:

As Chairman of the Committee on Finance (Committee), I have made it clear to you that I expect that Dr. David Graham's rights as a federal employee will be fully respected by the Food and Drug Administration (FDA). Last Wednesday, November 24, 2004, I requested that the Office of Inspector General (OIG), Department of Health and Human Services conduct a complete and thorough investigation into the facts, events, persons, policies, regulations and laws relating to allegations that a number of management level employees at the FDA may have acted "to discredit an outspoken agency safety officer who was challenging the FDA's drug safety policies." I referred to the attached article from the *Washington Post* entitled, "Attempt to Discredit Whistle-Blower Alleged."

To reiterate my own expectations, in a letter dated October 7, 2004, I stated, "I sincerely hope that no allegations of retaliation or other prohibited personnel practices arise from anything relating to this Committee's inquiry." On November 18, 2004, in my opening comments at the Committee's hearing related to Vioxx, I stated:

Before the testimony begins, I want to respond to comments issued last night by the Food and Drug Administration's Acting Administrator, Dr. Crawford, about Dr. Graham, our first witness. News reports today say that the FDA is calling him "a maverick who did not follow agency protocols." . . . [T]he clarifications provided last night by Dr. Crawford appear intended to intimidate a witness on the eve of a hearing. . . . Dr. Crawford knows there's a problem and would better serve the FDA by spending time on the problem, rather than going after congressional witnesses who helped identify the problem in the first place.

In addition, I also stated to Dr. Sandra Kweder at the hearing: "I'd like to reiterate what I have repeatedly stated in writing and have verbally communicated to your agency, namely that this Committee takes its responsibility to protect witnesses and particularly government witnesses very seriously, and that holds particularly true for Dr. Graham."

The article in the *Washington Post* raises substantive questions about whether a number of FDA employees “used deceptive practices against [Dr. David] Graham” and whether those employees acted within the spirit and intent of all applicable laws, including, among others, laws governing whistleblowers and prohibited personnel practices. As Chairman of the Committee, I request that the FDA cooperate fully with the OIG’s investigation. Further, I request that you advise all FDA employees about this investigation and notify them that all records and documents relating in any manner whatsoever to this investigation, either directly or indirectly, must be preserved immediately.

I understand that retaliatory action against dissident employees can come under many guises. Therefore, I also request that you address allegations that administrative action may be taken against Dr. Graham, including that he may be terminated or transferred against his wishes to a job other than conducting scientific research. Please advise me whether there is any truth to these allegations and, if so, explain what actions are being taken to transfer Dr. Graham from his present position and duties at FDA.

Beyond that, I request that you address another matter that remains outstanding. On at least 6 separate occasions—3 by letter and 3 in meetings with FDA staff—I have requested that FDA employees be advised that they may come to Congress and speak freely without fear of reprisal. Do you believe that FDA employees are free to speak to members of Congress without advising FDA’s Office of Legislation? If so, when are you going to act on this request?

Thank you in advance for having your staff coordinate with my staff about these outstanding matters by no later than December 1, 2004. Any questions or concerns should be directed to Emilia DiSanto or Dan Donovan at (202) 224-4515. All formal correspondence should be sent via facsimile to (202) 228-2131 and original by U.S. mail. Please do not hesitate to contact me if you have any concerns.

Sincerely,

Charles E. Grassley  
Chairman