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United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

KOLAN DAVIS, STAFF DIRECTOR AND CHIEF COUNSEL
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November 30, 2005

Via Electronic Transmission
Original via USPS Mail

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 contact Emilia DiSanto or Nick Podsiadly of my Committee staff at (202) 224-4515.

Sincerely,



Charles E. Grassley
United States Senator

Attachment

From: Hampshire, Victoria'

Sent: Wednesday, November 23, 2005 9:55 AM

To:

Subject: The mailings on Friday clarifying to FDA Press that I did not know I was being investigated, their response and my response thanking them.

Zawisza, Julie"

To:

Subject: Re: Press statement on Victoria Hampshiire

Date: Sun, 20 Nov 2005 09:29:03 -0500

Top of Form 1

Bottom of Form 1

Done and my pleasure.

Sent from my BlackBerry Wireless Handheld

-----Original Message-----

From: victoria hampshire

To: Zawisza, Julie

'Mark Cohen'

CC:

Sent: Sat Nov 19 21:44:12 2005

Subject: RE: Press statement on Victoria Hampshire

Dear Julie and Mark:

Thank you very much for working on this. My husband and I have been rushed in a previous engagement traveling to We were either in flight or driving through rather remote parts of and have only just returned to the hotel where the internet is very slow.

Julie: I very much appreciate FDA's kind words and willingness to correct the statement on such short notice.

Tory

"Zawisza, Julie"

wrote:

I am happy to correct this and thanks for letting me know.

Julie Zawisza

cell:

-----Original Message-----

From: Mark Cohen

Sent: Friday, November 18, 2005 3:09 PM

To: julie

Cc:

Subject: Press statement on Victoria Hampshire

Dear Ms. Zawisza:

I write on behalf of Victoria Hampshire, who we represent at the Government Accountability Project. Ms. Hampshire is concerned that the press statement that FDA plans to release tonight is inaccurate in one regard: It uses the language that the FDA investigation of her 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.

Sincerely,

Mark P. Cohen, Esq.
Government Accountability Project
Food and Drug Safety Director