United States Senate
COMMITTEE ON THE JUDICIARY
WASHINGTON, DC 20510–6275

July 16, 2012

The Honorable Margaret A. Hamburg
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD, 20993

Dear Commissioner Hamburg:

I am writing to express my disappointment and disbelief with the way the Food and Drug Administration (FDA) has retaliated against whistleblowers who expressed concern to Members of Congress and the Office of Special Counsel (OSC) regarding safety concerns about medical products. The FDA's actions represent serious impediments to the right of agency employees to make protected disclosures about waste, fraud, abuse, mismanagement, or public safety to Congress and the OSC.

Continued stonewalling and secrecy about the spying on these employees' protected disclosures is unacceptable. I originally wrote to you on January 31, 2012, regarding this incident. Six months later I have finally received a response.[1] Unfortunately, the response is incomplete and misleading. If you will recall, in June, you and I had a personal phone conversation regarding this matter in which you gave me your word that FDA would fully cooperate with my investigation. The FDA's reply fails to measure up to your pledge of cooperation.

Repeatedly over the last six months, FDA refused to provide any meaningful information about the progress of drafting its reply to my January letter, saying only that it was being worked on and that there was a "good story" to tell regarding the spying on employees. FDA staff claimed it needed additional time to ensure that the response was as accurate and complete as possible. However, in FDA's July 13, 2012, response FDA claims it is "still identifying and gathering evidence with respect to these issues [of who authorized the spying of all the whistleblowers email accounts]."[2] It is simply not credible that FDA went to such great lengths over the course of two years to monitor employees personal email accounts, then spent six

[1] July 13, 2012 FDA letter to Senator Grassley
[2] July 13, 2012 FDA letter to Senator Grassley

months crafting a reply to my questions about it, and yet still cannot identify who authorized the spying.

In fact, according to information provided to my office, spying on these employees was explicitly authorized, in writing, by the General Counsel's Office. Please provide the name of the official at FDA who asked the General Counsel's Office to look into this matter and please provide the memo drafted by the General Counsel immediately.

According to FDA's July 13, 2012, response:

> The impetus for the monitoring was not any communication to Congress. Rather, the impetus for monitoring was the March 2010 *Times* article and the receipt of the GE Healthcare letter just prior to the initiation of monitoring, which indicated that the preceding pattern of similar unauthorized disclosure of confidential information from other pending medical device applications and submissions was continuing unabated.[3]

However, a "scoping document" that FDA drafted specifically targeted future communications with Congressional offices for interception.[4] This "scoping document" alleges FDA whistleblowers were "supplying internal documents and information to external sources."[5] The FDA document identifies "multiple Gmail contacts with Jack Mitchell (aging.senate.gov) – emails include attachments with significant amount of documents including those self-redacted. View ALL instances of the above noted in order by date" and "multiple Gmail contacts with Joan Kleinman (District Director for Rep. Chris Van Hollen) – Emails include attachments with significant amount of documents including those self-redacted. View ALL instances above noted in order by date."[6]

The "scoping document" goes on to list "Possible Collaboration Issue" in which it states "Emails among Actors indicating a collaborative plan to produce a document defamatory to HHS/FDA that will be passed to Joan Kleinman, leaked to the press on Chris Van Hollen's letterhead and returned to Van Hollen's Office."[7] The "Ancillary Actors" identified by FDA include Jack Mitchell with Senate Special Committee on Aging, Joan Kleinman with Congressman Chris Van Hollen, and Congressman Chris Van Hollen himself.[8] Moreover, screen shots the FDA took of those employees accessing their personal email accounts included email correspondence from not only my Senate Finance Committee staff at the time, but also from Congressman John Dingell's Energy and Commerce Committee staff.[9]

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[3] July 13, 2012 FDA letter to Senator Grassley
[4] FDA Scoping Document
[5] FDA Scoping Document
[6] *Id.*
[7] *Id.*
[8] *Id.*
[9] FDA screen shots to Senator Charles Grassley and FDA screen shot to Congressman John Dingell

FDA withheld this "scoping document" from its reply to me on Friday, July 13, 2012. However, perhaps what is even more astonishing is that this document was apparently posted inadvertently on a public internet site, along with thousands of pages of confidential communications captured between whistleblowers, their attorneys, Congress, and the OSC. These documents were obtained by and reported on yesterday by the *New York Times*. FDA has apparently contracted with a firm, Quality Associates, to archive and manage documents. A massive collection of documents provided to Quality Associates were publicly available on the Internet for the entire world to see until late Friday afternoon after the company was contacted and asked for comment. This blatant disregard for privacy and careless treatment of internal agency documents goes against the very core of what FDA claimed in its most recent letter to my office: "This review must respect the rights of individual employees as well as protected governmental legal prerogatives."[10] It seems to me that FDA has failed catastrophically in protecting both its own employees' personal information and that of the companies which they oversee.

Additionally, despite this massive spying campaign, repeated investigations by Health and Human Services Office of Inspector General did not substantiate FDA's accusations about leaks of confidential information to the press. Yet, FDA continued to retaliate against these employees and spy on their personal emails. FDA's "scoping document" lists a "possible future concern" as "Gmail correspondence indicating that Julian Nicholas has reapplied to CDRH and is being considered for a promotion. View ALL instances of the above noted in order by date."[11] Julian Nicholas was later terminated.

I have reminded FDA in the past that interfering with a Congressional inquiry is against the law, that denying or interfering with employees' rights to furnish information to Congress is also against the law, and that federal officials who deny or interfere with employees' rights to furnish information to Congress are not entitled to have their salaries paid by taxpayers' dollars.[12] It is evident from the documents I have obtained that FDA did in fact target communications with Congress for monitoring and then took adverse personnel actions against FDA whistleblowers who were communicating with Congress. As such, I will be handing over these documents not only to OSC, the Department of Health and Human Services Office of Inspector General, but also to the Department of Justice for further investigation into any wrongdoing, including possible violations of whistleblower protection statutes and the Stored Communications Act. FDA's misconduct cannot be ignored.

To help us better understand the circumstances surrounding this issue; please provide the answers to the following by July 27, 2012:

[10] July 13, 2012 FDA letter to Senator Grassley
[11] FDA Scoping Document
[12] January 31, 2012 letter to FDA

1. Please provide the name of the official at FDA who asked the General Counsel's Office to look into spying on FDA whistleblowers.
2. Please provide the memo from the General Counsel's Office and make the author of the memo available for an interview with my staff.
3. Why is FDA unable to identify who authorized the spying even after six months of gathering information in response to my initial request?
4. How do you reconcile the claim in FDA's reply that "the impetus for the monitoring was not any communication to Congress" with the evidence from the scoping document that Congressional communications were specifically targeted for interception and with the evidence showing that Congressional communications were then, in fact, intercepted?
5. FDA's reply indicated that "all keystrokes performed on the government-issued computer" were collected. Yet FDA also claims to be unaware of "any information that suggests that Agency personnel collected passwords for individuals' personal email accounts."
    a. It has been represented to my office that *de minimis* access to personal email accounts from government-issued computers is allowed under FDA policy. Is that correct? Please provide a copy of the policy.
    b. The warning cited in footnote 2 of FDA's reply does not specifically notify the employee that keystrokes, and thus passwords for personal email accounts, will be captured. Were employees ever notified that accessing their personal email accounts from a government-issued computer would result in the password being captured by FDA?
    c. The FDA's reply asserts that the "forensic engineer principally involved in the computer monitoring" indicated that FDA did not use or take any action related to personal passwords captured by the monitoring. Please identify this engineer and make him or her available to for an interview with my staff. Also please identify each FDA employee or contractor who had access to the captured personal passwords and make them available for interviews as well.
6. Please provide FDA's contract with Quality Associates.
7. How long has FDA been working with Quality Associates?
8. How much has FDA paid Quality Associates?
9. How many documents does Quality Associates have access to?
10. In addition to the intercepted whistleblower communications, what other types of documents did FDA entrust to Quality Associates?
11. How many of these documents were on Quality Associates' publically available internet site?
12. How long were these documents available on Quality Associates' publically available internet site?

13. When does FDA plan on providing the additional information and documents requested in my original letter on January 31, 2012?

Thank you for your attention to this matter. Should you have any comments or questions, please do not hesitate to contact Erika Smith with my Committee staff at (202) 224-5225.

Sincerely,

Charles E. Grassley
Ranking Member
Committee on the Judiciary

Cc: The Honorable Patrick Leahy, Chairman, Senate Committee on the Judiciary

Cc: The Honorable Herb Kohl, Chairman, Senate Special Committee on Aging

Cc: The Honorable Tom Harkin, Chairman, Senate Health, Education, Labor and Pensions Committee

Cc: The Honorable Chris Van Hollen

Cc: The Honorable John Dingell