ONE HUNDRED TWELFTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515–6143

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http://oversight.house.gov

February 9, 2012

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

Dear Commissioner Hamburg:

Documents published in the *Washington Post* show that over the course of two years, the Food and Drug Administration (FDA) secretly monitored the personal e-mail accounts of a group of employees known as the "FDA Nine."[1] The FDA Nine consisted of scientists and doctors who raised concerns – first to FDA management and then to President Obama's transition team and Congress – about the effectiveness of FDA's process for approving medical devices. The first documented interception of an e-mail occurred in January 2009, shortly after a group of FDA scientists and doctors wrote the transition team and began communicating their concerns to Congress.

The act of monitoring an employee's personal e-mail account is a violation of privacy and can only be justified in cases where the employee is reasonably suspected of serious wrongdoing. In this case, the employees monitored by FDA managers had done nothing wrong. In fact, it appears that FDA targeted these employees for surveillance because they talked to Congress, including staff from the Committee on Oversight and Government Reform. Interference with an employee's right to provide information to Congress is unlawful and will not be tolerated.[2]

The appearance of wrongdoing by FDA managers is heightened because the agency used the intelligence it gathered to build a case to retaliate against the FDA Nine. The *Washington Post* reported that the FDA relied on the information it gleaned through secret surveillance to fire, harass, or pass over for promotion at least six individuals who communicated with Congress.[3] Those personnel actions are now the subject of a lawsuit filed against the FDA in U.S. District Court. According to the *Washington Post*:

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[1] Ellen Nakashima and Lisa Rein, *FDA staffers sue agency over surveillance of personal e-mail*, WASH. POST, Jan. 29, 2012.

[2] 5 U.S.C. §7211 provides in pertinent part: "The right of employees, individually or collectively, to petition Congress or a Member of Congress, or to furnish information to either House of Congress, or to a committee or Member thereof, may not be interfered with or denied."

[3] *Id.*

> Information garnered this way eventually contributed to the harassment or dismissal of all six of the FDA employees, the suit alleges. All had worked in an office responsible for reviewing devices for cancer screening and other purposes.
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> Copies of the e-mails show that, starting in January 2009, the FDA intercepted communications with congressional staffers and draft versions of whistleblower complaints complete with editing notes in the margins. The agency also took electronic snapshots of the computer desktops of the FDA employees and reviewed documents they saved on the hard drives of their government computers.
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> [One of] the six employees who filed the suit was fired in November after a negative performance review; an internal FDA letter obtained in separate litigation quoted managers saying they did not "trust" him. Of the other five scientists and doctors, the suit says two did not have their contracts renewed, two suffered harassment and were passed over for promotions, and one was fired.[4]

In 2009, the Office of Legal Counsel in the Department of Justice issued an opinion that a government agency may monitor employees' computers in pursuit of a lawful purpose.[5] In this case, the FDA's purpose was not lawful – FDA was not investigating wrongdoing or tracing a security breach. In fact, FDA's purpose appears to have been unlawful because retaliation against a whistleblower is illegal.

Additionally, federal law prohibits managers from initiating a personnel action against an employee in response to protected whistleblowing by that employee.[6] As you know, communicating with Congress is a protected form of whistleblowing. Treating such communications in any other way would have a chilling effect on the willingness of federal employees to report waste, fraud and abuse.

Monitoring an employee's personal e-mail rises to such a level of invasiveness that the burden to justify doing so clearly falls on the FDA. So that I may better understand how and why FDA managers decided to monitor the personal e-mail accounts of individuals who communicated with Congress, please provide responses to the following:

1. Identify the individual(s) responsible for deciding to initiate monitoring of the personal e-mail accounts of the FDA Nine.

2. Identify each employee who was the subject of any form of surveillance, including, but not limited to, screen captures and e-mail monitoring.

3. State the date on which surveillance started for each employee identified above.

4. For any individual no longer employed by FDA whose e-mail was monitored, please explain the circumstances of departure from the agency, including relevant dates.

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[4] *Id.*

[5] *See* Memorandum for Fred F. Fielding, Counsel to the President, from Steven G. Bradbury, Principal Deputy Ass't Att'y General, Office of Legal Counsel, U.S. Dep't of Justice, *Re: Legal Issues Relating to the Testing, Use, and Deployment of an Intrusion-Detection System (EINSTEIN 2.0) to Protect Unclassified Computer Networks in the Executive Branch* (Jan. 9, 2009).

[6] 5 U.S.C. §2302(b)(8).

5. Explain the extent of the agency's surveillance of the FDA Nine, including a description of the methods for and frequency of any surveillance.

6. State the purpose of the agency's surveillance of the FDA Nine.

7. Explain the legal justification relied on by FDA to initiate surveillance of the FDA Nine.

Additionally, please provide the following documents:

1. Documents referring or relating to the FDA Nine collectively or individually, including, but not limited to, all communications to or from Gregory Campbell, Dr. Jeffrey Shuren, Ruth McKee, Ralph Tyler, or Dr. Joshua Sharfstein.

2. Documents created or obtained as a result of e-mail monitoring since January 1, 2009, including but not limited to all documents in the file named "FDA 9."

3. Guidance from the Office of the General Counsel referring or relating to monitoring employee e-mail accounts.

4. Guidance from the Office of the Inspector General referring or relating to monitoring employee e-mail accounts.

The Committee on Oversight and Government Reform is the principal oversight committee of the House of Representatives and may at "any time" investigate "any matter" as set forth in House Rule X.

Please provide the documents and information requested as soon as possible, but by no later than noon on February 21, 2012. When producing documents to the Committee, please deliver production sets to the Majority Staff in Room 2157 of the Rayburn House Office Building and the Minority Staff in Room 2471 of the Rayburn House Office Building. The Committee prefers, if possible, to receive all documents in electronic format. An attachment to this letter provides additional information about responding to the Committee's request.

If you have any questions about this request, please contact Jonathan Skladany of the Committee Staff at (202) 225-5074. Thank you for your attention to this matter.

Sincerely,

Darrell Issa
Chairman

cc: The Honorable Elijah E. Cummings, Ranking Minority Member
Committee on Oversight and Government Reform

Attachment

DARRELL E. ISSA, CALIFORNIA
CHAIRMAN

ELIJAH E. CUMMINGS, MARYLAND
RANKING MINORITY MEMBER

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Responding to Committee Document Requests

1. In complying with this request, you should 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. You should also produce documents that you have a legal right to obtain, that you have a right to copy or to which you have access, as well as documents that you have placed in the temporary possession, custody, or control of any third party. Requested records, documents, data or information should not be destroyed, modified, removed, transferred or otherwise made inaccessible to the Committee.

2. In the event that any entity, organization or individual denoted in this request has been, or is also known by any other name than that herein denoted, the request shall be read also to include that alternative identification.

3. The Committee's preference is to receive documents in electronic form (i.e., CD, memory stick, or thumb drive) in lieu of paper productions.

4. Documents produced in electronic format should also be organized, identified, and indexed electronically.

5. Electronic document productions should be prepared according to the following standards:

   (a) The production should consist of single page Tagged Image File ("TIF"), files accompanied by a Concordance-format load file, an Opticon reference file, and a file defining the fields and character lengths of the load file.

   (b) Document numbers in the load file should match document Bates numbers and TIF file names.

   (c) If the production is completed through a series of multiple partial productions, field names and file order in all load files should match.

6. Documents produced to the Committee should include an index describing the contents of the production. To the extent more than one CD, hard drive, memory stick, thumb drive, box or folder is produced, each CD, hard drive, memory stick, thumb drive, box or folder should contain an index describing its contents.

7. Documents produced in response to this request shall be produced together with copies of file labels, dividers or identifying markers with which they were associated when they were requested.

8. When you produce documents, you should identify the paragraph in the Committee's request to which the documents respond.

9. It shall not be a basis for refusal to produce documents that any other person or entity also possesses non-identical or identical copies of the same documents.

10. If any of the requested information is only reasonably available in machine-readable form (such as on a computer server, hard drive, or computer backup tape), you should consult with the Committee staff to determine the appropriate format in which to produce the information.

11. If compliance with the request cannot be made in full, compliance shall be made to the extent possible and shall include an explanation of why full compliance is not possible.

12. In the event that a document is withheld on the basis of privilege, provide a privilege log containing the following information concerning any such document: (a) the privilege asserted; (b) the type of document; (c) the general subject matter; (d) the date, author and addressee; and (e) the relationship of the author and addressee to each other.

13. 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 under which the document ceased to be in your possession, custody, or control.

14. If a date or other descriptive detail set forth in this request referring to a document is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, you should produce all documents which would be responsive as if the date or other descriptive detail were correct.

15. The time period covered by this request is included in the attached request. To the extent a time period is not specified, produce relevant documents from January 1, 2009 to the present.

16. This request is continuing in nature and applies to any newly-discovered information. Any record, document, compilation of data or information, not produced because it has not been located or discovered by the return date, shall be produced immediately upon subsequent location or discovery.

17. All documents shall be Bates-stamped sequentially and produced sequentially.

18. Two sets of documents shall be delivered, one set to the Majority Staff and one set to the Minority Staff. When documents are produced to the Committee, production sets shall be delivered to the Majority Staff in Room 2157of the Rayburn House Office Building and the Minority Staff in Room 2471of the Rayburn House Office Building.

19. Upon completion of the document production, you should submit a written certification, signed by you or your counsel, stating that: (1) a diligent search has been completed of all documents in your possession, custody, or control which reasonably could contain responsive documents; and (2) all documents located during the search that are responsive have been produced to the Committee.

Definitions

1. 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, expense reports, books, manuals, instructions, financial reports, working papers, records, notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, inter-office 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, disks, 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, disk, videotape or otherwise. 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.

2. The term "communication" means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether in a meeting, by telephone, facsimile, email, regular mail, telexes, releases, or otherwise.

3. The terms "and" and "or" shall be construed broadly and either conjunctively or disjunctively to bring within the scope of this request any information which might

otherwise be construed to be outside its scope. The singular includes plural number, and vice versa. The masculine includes the feminine and neuter genders.

4. The terms "person" or "persons" mean natural persons, firms, partnerships, associations, corporations, subsidiaries, divisions, departments, joint ventures, proprietorships, syndicates, or other legal, business or government entities, and all subsidiaries, affiliates, divisions, departments, branches, or other units thereof.

5. The term "identify," when used in a question about individuals, means to provide the following information: (a) the individual's complete name and title; and (b) the individual's business address and phone number.

6. The term "referring or relating," with respect to any given subject, means anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with or is pertinent to that subject in any manner whatsoever.