

ONE HUNDRED THIRTEENTH CONGRESS
Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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WASHINGTON, DC 20515-6115

Majority (202) 225-2927
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December 9, 2013

The Honorable Margaret A. Hamburg, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

Dear Dr. Hamburg:

Pursuant to Rules X and XI of the U.S House of Representatives, the Committee on Energy and Commerce is investigating the October 15, 2013 cybersecurity breach, or hacking, of the Food and Drug Administration's (FDA) online submission system, and FDA management issues related to this incident.

According to information FDA provided to the media, on October 15, 2013, FDA's online submission system, the electronic submissions gateway historically managed by the Center for Biologics Research and Evaluation (CBER), was breached by an unauthorized user. While the online submission system is managed by CBER, its reach is much broader than that division and includes all medical product information for FDA, including information for drug and medical device products. In addition, the gateway supports receipt of Adverse Event Reporting System (AERS) reports and attachments. The security breach exposed the names, details, phone numbers, email addresses and passwords of 14,000 accounts, around 5,000 of which are active. The FDA advised the 5,000 active users on October 18, 2013 to change their passwords and keep an eye on their credit reports in case the hackers have stolen their identity. However, the FDA did not notify members of industry about the breach until approximately 5:30 p.m. on November 8, 2013 (late Friday afternoon leading into the Veterans Day weekend), about the same time that FDA made the announcement about the security breach. The security breach of FDA's gateway system not only compromised the security of personal identifiable information, but also compromised the protection of confidential business information and medical privacy information of patients enrolled in clinical trials. The nature of FDA's notification to active account holders – for example, advising the change of passwords – suggests that FDA may not have encrypted passwords and other information.

To determine the circumstances of the security breach, and the adequacy of corrective actions at the FDA, please provide the following by December 23, 2013:

1. Identification of current or former contractors and/or subcontractors with knowledge about the security breach, and how they came to have that knowledge.
2. Details on the nature of the information stolen or at risk because of the security breach.
3. Details on the FDA's notification to the parties whose information was affected by the breach, including the dates, and the categories (i.e., FDA employees, former FDA employees, companies, patients in clinical trials). Please include copies of the different types of notification.
4. Details on the corrective actions taken by FDA or by entities under the direction of FDA in response to the security breach, including but not limited to the Incident Response Plan (IRP).
5. An explanation of how FDA determined that 14,000 accounts were affected by the breach, and how FDA knows that the breach was limited to 14,000 accounts.
6. An explanation of how the FDA information security system came to be compromised by this security breach, and how the weakness(es) in the system was addressed by FDA. In particular, FDA needs to explain whether this security breach occurred because certain security protocols and/or guidelines were not followed.
7. For the time period beginning January 1, 2010, all minutes of operations management meetings held by any group of FDA officials under the auspices of the Office of FDA Commissioner in which the issue of cybersecurity at FDA was discussed.
8. All documents related to the October 15, 2013 security breach.
9. All documents related to the selection of the contractor responsible for security of the online submission system or electronic submissions gateway.
10. All documents from Margaret Hamburg, Walter Harris, Lisa Barclay, John Taylor, and Karen Midthun related to the October 15, 2013 security breach. These individuals are immediately advised to preserve and prevent the destruction of existing documents related to the October 15, 2013 security breach.
11. All security control assessments of the FDA electronic submissions gateway since January 1, 2010.

FDA's information technology expenditures and overhead account for about 12 percent of the total FDA budget, a "significant investment" according to the agency. It is very troubling that such a security breach could have occurred, particularly given the resources invested. Such a breach is viewed with sufficient gravity that Federal law and regulations subject private sector entities to several legal requirements for breach notification to affected individuals. FDA is only covered by an OMB memorandum on breach notification policy. It is essential to the fulfillment of FDA's mission that regulated industry and patients have confidence in the security of sensitive information they submit to the FDA. To restore public confidence in the FDA's information security, we request that you immediately obtain a third-party audit from a qualified expert to assess and ensure the adequacy of FDA's corrective actions taken in response to this incident. We ask that you respond by December 19, 2013 on whether you will seek such an audit, and if not, why not.

Letter to the Honorable Margaret A. Hamburg, M.D.

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An attachment to this letter provides additional information about how to respond to the Committee's request. If you have any questions regarding this request, please contact Alan Slobodin or Carl Anderson with the Committee staff at (202) 225-2927.

Sincerely,



Fred Upton
Chairman



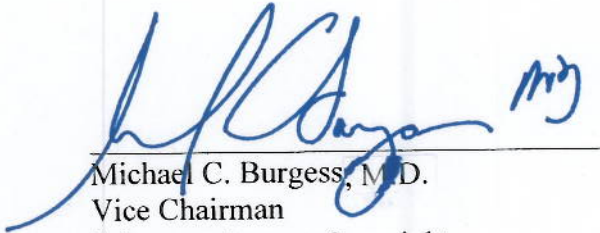
Tim Murphy
Chairman
Subcommittee on Oversight and Investigations



Joe Barton
Chairman Emeritus



Marsha Blackburn
Vice Chairman



Michael C. Burgess, M.D.
Vice Chairman
Subcommittee on Oversight
and Investigations

Attachment

cc: The Honorable Henry A. Waxman, Ranking Member

The Honorable Diana DeGette, Ranking Member
Subcommittee on Oversight and Investigations