

Statement from Margaret Hamburg, FDA Commissioner, July 17 2012

Over the past few days, a handful of stories, first appearing in The New York Times, were written regarding the agency's monitoring of the computers of five CDRH employees.

I want to reinforce that the FDA's greatest strength is our people. I value the expertise, professionalism and dedication each of you brings to this agency every day. There is no greater mission than that with which we are charged – protecting the public health. I have great confidence in FDA's leadership and employees, and we have worked hard to foster a culture where differing opinions on scientific data, regulatory issues and product approvals may be expressed freely. In addition, employees have avenues available to them to voice their concerns both inside and outside the organization without disclosing proprietary information that is protected by law from unauthorized disclosures. I want to reiterate the FDA's commitment to protecting the rights of whistleblowers who are doing a service by bringing public safety concerns to the forefront. It is only in working together with the highest levels of professionalism and ethics that we will continue to achieve our mission.

Regarding the recent news stories, I want to stress that the FDA's ability to fulfill our mission of protecting and promoting public health necessarily relies upon our ability to protect confidential information. Protecting such information in our possession allows us to work with industry and other stakeholders to ensure the quality of FDA-regulated products and the integrity of FDA-decision-making.

In 2010, the agency initiated monitoring limited to the government-owned computers of five CDRH employees. The impetus for the monitoring was a March 2010 New York Times article and a letter from GE Healthcare that indicated a pattern of unauthorized disclosures of confidential information related to pending medical device applications and submissions over the course of more than a year.

The intent of the monitoring was to determine whether confidential commercial information had been inappropriately released and to stop any further unauthorized disclosures, since any such disclosures are a violation of the law.

Although the FDA, as with other federal agencies, has the discretion to conduct appropriate monitoring of government computers, we do so only in very limited circumstances. We do not take lightly the decision to monitor government computers.

I hope this note offers a bit more context to the situation. We will continue to update you as best we can. Please be assured that your work and your opinions are appreciated.

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs