

POLITICS

US drug agency spied on scientists

Food and Drug Administration monitored five employees, defying promises about whistle-blower protection.

BY MEREDITH WADMAN

Until last week, the US Food and Drug Administration (FDA) had been remaking its image as a transparent organization that was supportive of its scientists, even when they spoke out against its decisions.

Now the agency is on the defensive, after the exposure of a clandestine computer-surveillance operation that tracked every keystroke made by five dissident FDA scientists whom it suspected of leaking confidential internal data to the press. The revelation may damage employees' trust in the FDA, and erode their willingness to challenge the decisions of their bosses, say expert observers. "The mere act of monitoring e-mails can chill scientific discourse at the agency and leave scientists more vulnerable to retaliation," says Michael Halpern, the integrity programme manager at the Union of Concerned Scientists (UCS), an advocacy group based in Cambridge, Massachusetts.

UCS surveys of more than 900 FDA scientists had shown that the proportion who feared retaliation for openly expressing concerns about the agency's work fell from 36% to 26% between 2006 and 2011. In the same period, the proportion who said that their supervisor "stands behind scientists" who put forth controversial views climbed from 38% to 61%. And when the agency issued a scientific-integrity policy in February, "supporting whistle-blower protections" was on a list of key principles. Another principle read, "Allowing FDA staff to communicate their personal scientific or policy views to the public, even when those views differ from official Agency opinions."

Critics say that the surveillance campaign strikes at the very heart of those principles. In addition to monitoring keystrokes, the FDA used software to capture all data stored on the computers and on USB sticks, and all e-mails sent and received on the computers, whether using personal or government accounts. The software also took screenshots at five-second intervals. Writing to FDA commissioner Margaret Hamburg last week, Senator Charles Grassley (Republican, Iowa), who is investigating the surveillance, alleged that the operation had been "explicitly authorized, in writing" by

the FDA's head lawyer. The agency gathered more than 80,000 pages of information during the operation, says *The New York Times*, which first disclosed the extent of the surveillance on 14 July.

The scientists, who worked in the FDA's Center for Devices and Radiological Health in Silver Spring, Maryland, first began to speak out in 2008, telling the US Congress that the agency's process for reviewing medical devices was "corrupted".

An article about a breast-cancer imaging device in *The New York Times* in January 2009 was followed by one in March 2010 that quoted an internal review by one of the scientists. The review cautioned against the FDA's potential approval of a colon-cancer screening device that the scientist believed delivered dangerous levels of radiation (see 'Under surveillance').

The FDA says that the disclosures to the

newspaper were illegal under the Federal Food, Drug, and Cosmetic Act, which prohibits the agency from publicizing data and information submitted by a drug- or device-maker before marketing approval has been granted — even the existence of an application cannot be disclosed. GE Healthcare of Little Chalfont, UK, had applied to have a device approved for routine colon-cancer screening among people without symptoms — a huge and lucrative market. After the 2010 article appeared, the company wrote to the FDA asking it to investigate how, as *The New York Times* had reported, "scores of internal agency documents" concerning its application had been leaked to the newspaper.

In a letter to Grassley on 13 July, the FDA said that it began monitoring the scientists' government-owned computers in April 2010. Erica Jefferson, a spokeswoman for the agency, said that the monitoring "was only intended to identify the source of the unauthorized disclosures, if possible, and to identify any further unauthorized disclosures". By the end of 2011, four of the five scientists had been fired or had not had their contracts renewed. Ewa Czerska, who had been at the agency for 23 years, was dismissed "for unauthorized disclosure of confidential information", the agency wrote in its letter. It did not describe its reasons for terminating the others' employment.

The scientists sued the FDA in January, claiming that the agency had violated their rights to free speech and association, their right to petition Congress and their right to be protected from unreasonable search and seizure. In a revised lawsuit filed last week, they also allege that the monitoring actually began in 2009, and that "the FDA intercepted private e-mails that were composed during non-work hours, from home, on personal networks and non-government computers". Jefferson says that the monitoring was limited to the five employees' government-owned computers; Hamburg declined to be interviewed.

The captured documents include personal communications, among them lawyer-client exchanges, as well as letters to Congress and the government's Office of Special Counsel, which investigates whistle-blower complaints and is meant to protect whistle-blowers from retaliation. "This case is different from any we have seen in the past because of the sweeping and pervasive nature of the surveillance conducted, and because the scientists were using laptop computers both at home and at work for a variety of personal and private purposes," says Alan Butler, a privacy-law expert at the Electronic Privacy Information Center in Washington DC.

"These employees are properly going to members of Congress or the Office of Special Counsel and they are being retaliated against, presumably as a result," says Mark Zaid, a lawyer in Washington DC, who specializes in defending whistle-blowers. "It sends a chilling message." ■ SEE EDITORIAL P.405

UNDER SURVEILLANCE

The US Food and Drug Administration (FDA) monitored employees after they voiced concerns about imaging devices.

28 MARCH 2010 *The New York Times* says that FDA managers suppressed scientists' concerns about radiation risks from routine colon-cancer screening.

16 APRIL 2010 GE Healthcare alleges that confidential proprietary information had been leaked.

22 APRIL 2010 The FDA starts to put spyware on scientists' computers.

JULY 2010–OCTOBER 2011 Four monitored scientists lose jobs.

25 JANUARY 2012 Scientists sue the FDA for violating their civil rights.

14 JULY 2012 *The New York Times* reports that the FDA has amassed more than 80,000 documents during the surveillance campaign.

16 JULY 2012 Senator Charles Grassley calls for investigation.