Feds Reopen Probe Into Medical Scanner Approvals

Matthew Perrone, AP Health Writer

WASHINGTON (AP) — Federal inspectors have reopened an investigation into complaints by Food and Drug Administration scientists who say they were pressured by their managers to approve high-tech medical scanners that could pose harm to patients.

The lead inspector overseeing the matter told The Associated Press on Tuesday that the inquiry into the allegations, which were dismissed in February, is being revisited to look at manager misconduct.

"The original intent of the investigation was to look at criminal matters and our agents did that," said Gerald Roy, deputy inspector general for investigations in the Department of Health and Human Services. "But I point toward broader issues that really compelled me to take a second look at this and reopen it from an administrative perspective."

The HHS office of inspector general, which oversees the FDA, closed the case in February after finding there was "no violation of law."

But the whistleblowers have repeatedly stressed that their grievances involve mismanagement and violations of regulations — which don't fall under criminal law.

Nine FDA medical device reviewers alleged in 2008 that agency management overruled their opinions without supporting evidence and tried to intimidate them when they went public with their concerns.

At issue are CT scanners, MRI machines and other medical devices that use radiation to detect or treat diseases. Many of the devices allow lifelike pictures of the human anatomy, but carry a higher risk from radiation than older scans such as X-rays.

In recent years, hundreds of radiation overdoses have been reported with imaging devices used by hospitals across the country. The whistleblowers say these problems underscore the concerns they raised about such devices.

The new probe comes after prodding from lawmakers and nonprofit watchdog groups, including the Project for Government Oversight. In a letter to the inspector general Tuesday, the group calls the previous investigation a "sham."

"If these allegations are true, the FDA is failing in its primary mission of keeping

people safe," said Danielle Brian, the group's executive director.

An agency spokeswoman said she could not immediately provide comment Tuesday.

Since the FDA whistleblowers went public with their concerns — in letters to Congress and the Obama administration in 2008 and 2009 — at least two scientists have been let go and another has quit after alleged intimidation.

Interviews with the staffers and internal e-mails obtained by The Associated Press provide new details of alleged mismanagement in the FDA's device division.

Central to the scientists' complaints is an FDA pathway to approval that allows speedy clearance if a device appears comparable to others already on the market.

Former FDA reviewer Dr. Gamal Akabani repeatedly recommended against clearing radiation-emitting devices used to treat cancer under the accelerated system, saying the devices needed to undergo actual testing to prove their safety and effectiveness. Between 2007 and 2008, Akabani said he was frequently pressured by supervisors to change his opinion, he said in an interview with The Associated Press.

In the final incident, Akabani's manager asked about the health of his wife, who has cancer, and his son, who was born severely handicapped. According to Akabani, the manager suggested his job — and health insurance for his family — would be safe as long as he cooperated with his supervisors.

"It shook me to the core because I realized that he was coercing me," said Akabani, who resigned from the FDA and currently teaches nuclear physics at Texas A&M University.

Akabani and other whistleblowers say a key problem at the agency is that managers — who have often spent decades in government — have far less expertise and up-to-date training than the medical reviewers they oversee. Akabani was recruited to the FDA after a decade in the radiology department at Duke University Medical Center.

The whistleblowers also point out that FDA managers are evaluated, in part, on their ability to get speedy reviews of devices, causing them to pressure and sometimes overrule scientists who slow down the process.

In another case of alleged retaliation, an Oxford-trained medical specialist's contract was not renewed after he repeatedly opposed approving a CT scanner for routine colon cancer screening. Dr. Julian Nicholas said that he objected to exposing otherwise healthy patients to the cancer risks of radiation. He says he was ridiculed by agency managers for "raising the bugaboo of radiation."

"They conspired against me because I refused to change my expert medical opinion to conform with their desired regulatory outcome," Nicholas wrote in an e-mail to

FDA Commissioner Margaret Hamburg after his termination late last year.

Both Akabani and Nicholas say they were never contacted by the office of inspector general, which they say makes the inspectors' original report flawed and incomplete.

The inspector general's office issued a memo to FDA leadership in February when it concluded there had been no criminal violations.

The whistleblowers complain that FDA officials have used the four-page memo to try to dissuade members of Congress from looking into their allegations.

Robert Smith, a former radiology division reviewer who left the agency in July, said FDA leadership assured the whistleblowers that the investigation would be comprehensive.

"It was the FDA's responsibility to make sure the investigation they requested was properly conducted and reported," Smith said, "And it was the responsibility of the inspector general to conduct a legitimate investigation — which they know they did not."

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