Feds dismiss misconduct claims at FDA device unit

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(AP) -- For the second time this year, federal inspectors have dismissed allegations by Food and Drug Administration scientists who say they were pressured and harassed by their managers into approving medical devices against their judgment.

The office of inspector general for the Department of Health and Human Services, which oversees the FDA, concluded there is "no evidence of retaliation" against the employees, according to a one-page memo obtained by The Associated Press. The memo, dated Oct. 14, concludes "this case is closed."

The inspector general reached a similar finding in February, but agreed to reopen the investigation at the request of federal lawmakers and advocacy groups. Those groups complained that the previous investigation was too narrow and did not look into allegations of misconduct that fell short of criminal violations.

A spokesman for the inspector general declined to comment beyond the memorandum.

Nine current and former FDA medical device reviewers have alleged since 2008 that agency managers improperly overruled their opinions 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.

The FDA scientists pointed to multiple occasions in which managers overruled their decisions without properly documenting the reason, as required by FDA regulations. At least three of the whistleblowers have left the agency in the last year, saying their contracts were terminated after they sent letters of complaint to Congress, the administration and other outside groups.

One of those whistleblowers, Dr. Julian Nicholas, said he has never been interviewed by the inspector general's office. Nicholas, an Oxford-trained intestinal specialist, said that his contract as a medical reviewer was terminated after he repeatedly opposed approving a CT scanner for routine colon cancer screening. Nicholas said that he objected to exposing otherwise healthy patients to the cancer risks of routine radiation scans.

"It's hard for me to believe this was a bona fide investigation when they haven't even contacted the people who reported these violations," said Nicholas, now a practicing gastroenterologist at the Scripps Clinic in San Diego. "Such a huge amount of money is at stake and so many people are affected, that for the (office of inspector general) not to conduct a credible investigation is criminal in itself."

FDA's device leadership shared the results of the latest investigation with employees last week, according to a Nov. 5 e-mail obtained by The Associated Press.

The e-mail was written by Dr. Jeffrey Shuren, head of the FDA's Center for Devices and Radiological Health, to members of his staff. In it he said the investigation found no evidence of retaliation against the scientists who complained nor of "material violation of rules with respect to documenting significant decisions."

Shuren pointed out in his e-mail that the FDA hired a private contractor last spring to review the device unit's structure and make recommendations for improving relations between scientists and management. The contractor recommended changes in internal communications and training opportunities, Shuren said.