Scientist: FDA suppressed imaging safety concerns

March 30 2010, By MATTHEW PERRONE , AP Business Writer

(AP) -- A former Food and Drug Administration scientist said Tuesday his job was eliminated after he raised concerns about the risks of radiation exposure from high-grade medical scanning.

Dr. Julian Nicholas said at a public hearing that he and other FDA staffers "were pressured to change their scientific opinion," after they opposed the approval of a CT scanner for routine colon cancer screening. Nicholas said that he objected to exposing otherwise healthy patients to the cancer risks of radiation.

After FDA officials pushed ahead with plans to clear the device, Nicholas, now a physician at the Scripps Clinic in San Diego, said he and eight other staffers raised their concerns with the division's top director Dr. Jeffrey Shuren last September. The device apparently is still under review.

"Scientific and regulatory review process for medical devices was being distorted by managers who were not following the laws," Nicholas said. A month later Nicholas' position was terminated, he said.

Nicholas does not think there was undue influence by the manufacturer in his ouster, but that his more cautious stance was in opposition to that of FDA higher-ups.

The allegations about suppression of scientific dissent come at an inopportune time for the agency.

The FDA announced an effort to improve scanning safety in February after three California hospitals reported hundreds of acute radiation overdoses last year, with many patients reporting lost hair and skin redness.

Tuesday's meeting was designed to kick off that campaign. The agency is seeking input from physicians and manufacturers on additional safety controls and training to improve CT scanners and other medical imaging devices.

Hundreds of studies have linked certain types of radiation, including the type used in medical imaging, to cancer that can surface decades later.

FDA medical reviewer Dr. Robert Smith, a colleague of Nicholas who also presented at Tuesday's public meeting, said he hoped the FDA would learn a lesson from Nicholas' testimony.

"Science must not be ignored, suppressed or distorted as that endangers the public," Smith told the audience.

Smith, who still works for the agency, supported Nicholas' conclusion that CT scanning for colon cancer should be rejected on safety grounds.

Agency spokesman Dick Thompson said in a statement the FDA's inspector general looked into allegations of retaliation against agency scientists and did not pursue further action or investigation. The agency's policies do not allow staffers to be penalized for expressing scientific views, he added.

"It is not uncommon for scientists, both internal and external to the agency, to disagree on the safety and effectiveness of products under review or on the steps needed to achieve public health goals," said the FDA statement.

Nicholas said, however, he has never been contacted and is still waiting to hear from the FDA's inspector. He stresses that the inspector's jurisdiction is criminal investigations, not allegations of improper conduct.

As a reviewer of medical device applications, Nicholas repeatedly rejected a manufacturers' request to market a CT scanner specifically for colon cancer screening. According to Nicholas, between 1.5 and 2 percent of cancers are caused by CT scanning, and he did not want to see scanning used when a conventional colonoscopy could be used instead.

CT scans provide detailed, three-dimensional images of the body, but at a cost: one CT chest scan carries as much radiation as nearly 400 chest X-rays, according to the FDA.

Nicholas said FDA rules legally barred from naming the manufacturer or discussing the details of its application.

In a June 2009 letter to senior managers, Nicholas stressed that patients should be warned of the radiation risks of CT scanning.

"I hope you understand that the failure to include a warning on the label will mean that patients will undoubtedly develop abdominal cancer and leukemia," Nicholas wrote "It may not happen tomorrow, but yes, sadly it will happen."

Nicholas said he was ridiculed by agency managers for "raising the bugaboo of radiation."

Medical experts are somewhat divided over the usefulness of the so-called virtual colonoscopy, which was designed as a less-invasive alternative to colonoscopy.

The American Cancer Society and the American College of Radiology endorse the procedure for its potential to boost screening for colon cancer, the country's second leading cancer killer.

But some insurers and the government's own Medicare program refuse to pay for the procedure, questioning its effectiveness and the rationale of exposing healthy patients to radiation.

Supporters of the procedure say that virtual colonoscopies use low levels of radiation that don't threaten older patients who get colonoscopies. Radiation exposure that causes cancer accumulates over a lifetime, making younger people the most at-risk population for screening.

"When we look at virtual colonoscopy, the benefits of detecting polyps far outweigh the theoretical risk the low amounts of radiation would have on people of that age," said Dr. Michael Macari of New York University's Langone Medical Center.

CT scans became popular because they offer a quick, relatively cheap way to get an almost surgical view of the body. Doctors are free to use them as they choose, but FDA approval for specific indications allows companies to tout those uses in marketing materials.

The average American's radiation exposure has nearly doubled in the last three decades, largely due to CT tests, according to the FDA.

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