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FDA Scientists Complain to Obama of "Corruption"

by: Ricardo Alonso-Zaldivar | Visit article original @ The Associated Press

Washington - In an unusually blunt letter, a group of federal scientists is complaining to the Obama transition team of widespread managerial misconduct in a division of the Food and Drug Administration.

"The purpose of this letter is to inform you that the scientific review process for medical devices at the FDA has been corrupted and distorted by current FDA managers, thereby placing the American people at risk," said the letter, dated Wednesday and written on the agency's Center for Devices and Radiological Health letterhead.

The center is responsible for medical devices ranging from stents and breast implants to MRIs and other imaging machinery. The concerns of the nine scientists who wrote to the transition team echo some of the complaints from the FDA's drug review division a few years ago during the safety debacle involving the painkiller Vioxx.

The FDA declined to publicly respond to the letter, but said it is working to address the concerns.

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In their letter the FDA dissidents alleged that agency managers use intimidation to squelch scientific debate, leading to the approval of medical devices whose effectiveness is questionable and which may not be entirely safe.

Political Appointee

"Managers with incompatible, discordant and irrelevant scientific and clinical expertise in devices...have ignored serious safety and effectiveness concerns of FDA experts," the letter said. "Managers have ordered, intimidated and coerced FDA experts to modify scientific evaluations,

conclusions and recommendations in violation of the laws, rules and regulations, and to accept clinical and technical data that is not scientifically valid."

A copy of the letter, with the names of the scientists redacted, was provided to The Associated Press by a congressional official.

"Currently, there is an atmosphere at FDA in which the honest employee fears the dishonest employee, and not the other way around," the scientists wrote.

FDA spokeswoman Judy Leon said in response: "We have been working very closely with members of the transition team and any concerns or questions they have on any issue, we will address directly with the team. Separately, the agency is actively engaged in a process to explore the staff members' concerns and take appropriate action."

Senior Democratic and Republican lawmakers are urging Obama to appoint a commissioner who will shake up the FDA and restore the confidence of its working-level scientists and medical experts. But industry officials fear that approval of new drugs and devices could be delayed by endless scientific disputes - which is the agency's reputation.

The FDA dissidents have previously taken their concerns to Congress and found support from lawmakers in the House.

In the letter the group singled out mammography computer-aided detection devices as an example of a technology that should not have gone forward. The devices were supposed to improve breast cancer detection, but instead studies showed they were associated with false alarms that led to unnecessary breast biopsies.

Since 2006, FDA experts have recommended five times against approving the devices without better clinical evidence, the letter said. In March of last year, a panel of outside advisers supported some of the concerns of the FDA's in-house scientists. Nonetheless, FDA managers overruled the objections and ordered approval.

Top FDA managers "committed the most outrageous misconduct by ordering, coercing and intimidating FDA physicians and scientists to