FDA Scientists Describe Corruption to Obama Transition Team

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(NaturalNews) A group of federal scientists has sent a letter to President-elect Obama's transition team describing serious managerial misconduct within a division of the Food and Drug Administration (FDA). The letter was dated last week and was written on FDA Center for Devices and Radiological Health letterhead.
"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," the letter states.

The Center for Devices and Radiological Health is the division responsible for oversight of medical devices like stents, breast implants, and medical imaging machinery. The scientists who were involved in sending the letter are in agreement with earlier complaints from the FDA's drug review division that involved the painkiller Vioxx years ago.
The letter includes allegations about FDA managers using intimidation tactics designed to hide scientific debate. This concealment led to the approval of medical devices that have questionable effectiveness and safety.

The letter also highlighted mammography computer-aided detection devices as an example of a technology that should never have been approved. These devices were supposed to improve the detection of breast cancer but instead they have been associated with false positive results that led to unneeded breast biopsies.
Five times FDA experts recommended against approving these devices without having better clinical evidence, according to the letter. In March of 2008 a panel of outside advisers concurred with some of the concerns of the FDA's in-house scientists. Despite these expert concerns, however, FDA managers overruled the objections and ordered approval.
The letter states that top FDA managers "committed the most outrageous misconduct by ordering, coercing and intimidating FDA physicians and scientists to recommend approval, and then retaliating when the physicians and scientists refused to go along."

Various Quotes from the Letter:

"Managers with incompatible, discordant and irrelevant scientific and clinical expertise in devices...have ignored serious safety and effectiveness concerns of FDA experts."

"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."

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

A copy of the letter was provided to The Associated Press by a congressional official.

In response to the letter, the FDA responded:

"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."

Lawmakers are encouraging Obama to appoint a commissioner to look closely at the FDA. Industry officials have concerns about such an inspection contributing to delays in the approval of new drugs and devices due to lengthened scientific disputes.

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