Medical Devices Today

January 15, 2009

CDRH Staffers To Obama: House Cleaning Urgent At Device Center

Full article reprinted from ***"The Gray Sheet"*** - January 12, 2008

Find out how the next FDA commissioner should seek resignations from all current device center managers, a group of CDRH scientists and physicians says in a Jan. 7 1letter to John Podesta, chief of President-elect Barack Obama's transition team.

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Full article reprinted from ***"The Gray Sheet"*** - January 5, 2008

The unnamed center staffers charge CDRH and Office of Device Evaluation managers with coercing and intimidating underlings into modifying scientific evaluations, conclusions and recommendations and failing to "apply even the most fundamental scientific and legal requirements."

The letter calls for the dismantling of ODE into multiple offices headed by rotating leadership as a means to reduce the alleged unchecked corruption.

The letter mirrors an Oct. 14 missive to Rep. John Dingell, D-Mich., that sparked a House Energy and Commerce Committee investigation into CDRH activities (2"The Gray Sheet" Nov. 24, 2008, p. 3).

However, the more recent communication, copied to HHS Secretary-Designate Tom Daschle, Baltimore City Health Department Chief Joshua Sharfstein (who heads Obama's FDA transition activities) and nine members of Congress, goes into even greater detail.

In the case of an April 2008 approval of a computer-aided detection device for mammography, the scientists specifically charge (by title, but not by name) ODE Director Donna-Bea Tillman "and her subordinates" with 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."

The letter also includes a bullet-pointed list of nine "examples of wrongdoing" by the ODE Director, including ordering physicians and scientists to ignore FDA guidance documents and allowing manufacturers to market unapproved devices.

The only one of the bulleted charges tied to a specific product is an allegation that Tillman excluded experts from participating in panel meetings based on manufacturer recommendations. That point includes a citation referencing the Nov. 14, 2008, panel meeting addressing ReGen Biologics' knee repair scaffold (3"The Gray Sheet" Jan. 5, 2009, p. 24).

The CDRH whistleblowers' letter attempts to frame the charges in the language of Obama's presidential campaign - specifically his focus on government transparency and bringing about change "from the bottom up."

"We believe as applied to FDA, this means a complete restructuring of the evaluation and approval process," the agency staffers conclude.

- David Filmore

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