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FDA Scientists Ask Obama to Restructure Drug Agency

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WASHINGTON -- A group of scientists at the U.S. Food and Drug Administration on Wednesday sent a letter to President-elect Barack Obama's transition team pleading with him to restructure the agency, saying managers have ordered, intimidated and coerced scientists to manipulate data in violation of the law.

The nine scientists, whose names have been provided to the transition team and to some members of Congress, say the FDA is a "fundamentally broken" agency and describe it as place where honest employees committed to integrity can't act without fear of reprisal.

"There is an atmosphere at FDA in which the honest employee fears the dishonest employee," according to the letter, addressed to John Podesta, head of Mr. Obama's transition team.

The letter will likely increase pressure on Tom Daschle, Mr. Obama's choice to head the Department of Health and Human Services, to make sweeping changes at the agency.

The scientists' main concerns are with the agency's scientific review process for medical devices, which they characterize as having been "corrupted and distorted by current FDA managers, thereby placing the American people at risk."

They sent a similar letter in October to the powerful House Energy and Commerce Committee, but the latest one provides more detailed allegations about problems at the agency, such as the threat of disciplinary action against scientists who dissent from management.

The FDA has been working "very closely" with Mr. Obama's transition team and will address any issues or concerns the team presents, said agency spokeswoman Judy Leon. She said the agency is "actively engaged in a process to explore the staff members' concerns and take appropriate action."

The group says they have taken their concerns to the head of the FDA, Commissioner Andrew von Eschenbach, and his assistant commissioner for accountability and integrity, attorney Bill McConagha. The scientists say no one has been held accountable, and say some of the problematic managers have

been promoted and rewarded.

The Energy and Commerce Committee's Democratic and Republican leaders sent a letter to von Eschenbach in November, saying it had "received compelling evidence of serious wrongdoing" at the agency. The members wrote that they were told McConagha had found the FDA doctors' evidence compelling, and that their findings supported removal of certain managers in the device division.

The agency has been under fire from both parties in both Houses of Congress as being too close to industry. Several leading politicians, including Sen. Chuck Grassley have complained that FDA leaders often ignore or suppress their own scientists' opinions on safety issues involving drugs and devices.

Those concerns were also aired in a report by the National Academy of Sciences' Institute of Medicine in 2006. FDA leaders, including drug division chief Janet Woodcock, have said they are working to improve the culture at the FDA, and are listening to dissent from their experts and doctors.

In addition to Mr. Daschle, the letter was sent to the doctor leading the transition team's assessment of problems at the FDA, Joshua Sharfstein, and to nine members of Congress including Sen. Edward Kennedy who chairs the Health Committee.

Members of the transition team weren't available to discuss the letter or whether they intend to address it publicly.

The scientists appear to hope that their concerns will pressure Mr. Daschle to quickly change leadership at the FDA. Von Eschenbach has said he is planning to step down on Jan. 20, the date of Mr. Obama's inauguration.

Indeed, the group said Mr. Daschle has recognized in his book, Critical: What We Can Do About the Health-Care Crisis, that the 1998 approval of some mammography computer-aided detection devices is an example of the breakdown of the independent scientific review process at the FDA.

The group says the FDA approved such devices without clinical evidence showing they were effective in detecting breast cancer. Since 2006, FDA physicians and scientists have recommended five times that these devices not be approved without valid scientific and clinical evidence.

The group said there needs to be a complete restructuring of the evaluation and approval process, and that Mr. Obama needs to sign new legislation giving protection to government employees who speak out against corruption.

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