The New York Times nytimes.com

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November 18, 2008

F.D.A. Scientists Accuse Agency Officials of Misconduct

By GARDINER HARRIS

WASHINGTON — Top federal health officials engaged in “serious misconduct” by ignoring concerns of scientists at the Food and Drug Administration and approving for sale unsafe or ineffective medical devices, the scientists have written in a letter to Congress.

The House Committee on Energy and Commerce will investigate the accusations, first aired when eight agency scientists wrote a private letter in May to the F.D.A. commissioner, Andrew C. von Eschenbach.

“These allegations are deeply concerning,” said the committee chairman, Representative John D. Dingell, Democrat of Michigan, “and we intend to uncover whether any F.D.A. activity has compromised the health and safety of American consumers.”

Heidi Rebello, an agency spokeswoman, said, “The F.D.A. will respond directly to the committee’s concerns.”

The letter to Congress, dated Oct. 14, is part of a growing chorus of dissent from what had long been a tight-lipped agency. In decades past, scientists rarely disagreed publicly with their agency’s decisions, and any concerns they had about important decisions were whispered among veterans.

But increasing scrutiny of the agency on Capitol Hill has coincided with a growing willingness by some scientists to voice their misgivings. The disputes tend to pit agency managers, who often lean toward approving drugs or devices when the data are equivocal, against agency scientists, who want more certain trial results before allowing the products to be sold.

Medical devices include products like cardiac stents, nerve stimulators to relieve depression, imaging equipment and breast implants. It is not clear from the publicly released information which device approvals the scientists questioned.

The most recent dispute is unusual if only for the number of doctors and scientists who signed their names to the May letter. Previous disagreements involved at most a few agency scientists. Mr. Dingell and Representative Bart Stupak, another Michigan Democrat, released the letter sent to Congress on Oct. 14 but blacked out the scientists’ names and some crucial details the scientists did not want disclosed.

The letter says that the scientists have documentary evidence that senior agency managers “corrupted the scientific review of medical devices” by ordering experts to change their opinions and conclusions in violation of the law.

Dr. von Eschenbach asked William McConagha, the agency’s assistant commissioner for integrity and accountability, to investigate the accusations, the letter states. Mr. McConagha characterized the documentary

evidence supporting the accusations as “compelling” and sufficient to justify disciplinary actions, it says.

Mr. McConagha may have recommended the removal of certain agency managers, Mr. Dingell and Mr. Stupak said.

But a top agency manager, after conducting his own investigation, concluded that the dissidents should “move forward,” and he decided against taking any curative or disciplinary action growing out of the dissidents’ complaints, the letter states. Instead, the letter says, the manager has allowed the dissidents to become victims of reprisals by agency managers.

The letter further says that Congress should consider reforming a process in which, the scientists say, the F.D.A. agrees to approve complex medical devices on the basis of little evidence of effectiveness.

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