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In F.D.A. Files, Claims of Leniency and a Rush to Approve Medical Devices

By GARDINER HARRIS

CORRECTION APPENDED

An official at the Food and Drug Administration overruled front-line agency scientists and approved the sale of an imaging device for breast cancer after receiving a phone call from a Connecticut congressman, according to internal agency documents.

The legislator's call and its effect on what is supposed to be a science-based approval process is only one of many of accusations in a trove of documents regarding disputes within the agency's office of device evaluation.

Nine agency scientists complained in May to Andrew C. von Eschenbach, the F.D.A. commissioner, and the agency began an internal review. Dissatisfied with the pace and results of that review, the scientists wrote a letter to Congress in October pleading for an investigation, and the House Committee on Energy and Commerce announced in November that it would begin one. Last week, the scientists wrote a similar letter to President-elect Barack Obama's transition team.

Agency documents that are part of the internal investigation, including e-mail messages, were provided to The New York Times. Details of the investigations have not previously been made public.

The documents show that front-line agency scientists, like many outside critics of the agency, believe that F.D.A. managers have become too lenient with the industry. In medical reviews and e-mail messages, the scientists criticize the process by which many medical devices gain approval without extensive testing. And in e-mail correspondence, they contend that an agency supervisor improperly forced them to alter reviews of the breast imaging device and others.

William McConagha, the agency's assistant commissioner for integrity and accountability, said he was continuing to investigate the scientists' claims. Mr. McConagha said that Dr. von Eschenbach had offered to meet with the nine scientists before Friday, his last day in office.

"We in the Office of Commissioner are extremely concerned about allegations like this," Mr. McConagha said.

In the documents, Representative Christopher Shays, a Connecticut Republican who lost re-election in November, is described as having called an agency supervisor a year ago to express concern about the fate of a computer device that is supposed to help radiologists detect breast tumors.

The device, the iCAD SecondLook Digital Computer-Aided Detection System for Mammography, is used with screening equipment made by Fujifilm Medical Systems.

Fujifilm Medical is based in Stamford, Conn., the heart of Mr. Shays's former district. In the documents, Mr. Shays is referred to as "Congressman Fuji."

"I am the Fuji congressman because I represented that district," Mr. Shays said in an interview Friday.

Mr. Shays said he had called the agency supervisor only to demand that the agency make a final decision, not that it approve the product.

He scoffed at suggestions in the documents that his call led the supervisor to overrule scientists and approve the device. "That would be idiotic for someone to approve something they don't think should be approved," he said.

A spokeswoman for Fujifilm Medical, Courtney A. Kraemer, said the company had called its "local Congressional offices to ask them to help us get clarification on the F.D.A. process."

The dissenting scientists protested, according to the internal documents, that "iCAD never tested the device by the intended users (i.e. radiologists) under the intended conditions of use. This is the most basic and fundamental requirement of all F.D.A. submissions."

An internal review said the risks of the iCAD device include missed cancers, "unnecessary biopsy or even surgery (by placing false positive marks) and unnecessary additional radiation."

Ken Ferry, iCAD's chief executive, said, "We have done all the appropriate testing to get the product approved."

Mr. Ferry said that F.D.A. scientists were increasingly asking for more rigorous testing of devices, and that his company complied with those demands.

Diana Zuckerman, president of the National Research Center for Women and Families, said the Bush administration had "finally made the device approval process so meaningless that it's intolerable to the scientists who work there." Ms. Zucker, a longtime critic of the agency's

device approval process, particularly as it relates to breast implants, added, "Virtually everything gets approved, no matter what."

The F.D.A. has a three-tiered approval process for medical devices that, depending on their newness or complexity, requires varying amounts of proof.

A growing chorus of critics contends that the agency requires few devices to complete the most rigorous of these reviews and instead allows most devices to be cleared with minimal oversight. In 2007, 41 devices went through the most rigorous process, compared with 3,052 that had abbreviated reviews.

According to internal documents, some scientists in the agency's device division seem to agree with these critics. One extensive memorandum argued that F.D.A. managers had encouraged agency reviewers to use the abbreviated process even to approve devices that are so complex or novel that extensive clinical trials should be required.

For instance, Shina Systems, an Israeli company, applied for approval for AngioCt, a device that combines CT images with X-rays to help guide cardiac surgeons during angioplasty and stenting procedures. The company sought an abbreviated review, according to the documents.

An F.D.A. reviewer said the company should conduct a clinical trial to prove that the device works since it is novel and risky.

"Should the images be misleading," Dr. Brian Lewis, an agency cardiologist, wrote in a memorandum, "F.D.A. could expect immediate misguidance of catheters and possibly puncture of coronary vessels or overaggressive, inappropriate or inadequate stent or balloon use."

Nonetheless, an F.D.A. supervisor -- after meeting with Shina representatives -- pressed scientists to consider allowing an abbreviated review, according to the documents. The agency's decision on the device is pending, according to the documents.

Dr. John Smith, a lawyer for Shina, wrote in an e-mail message that he would not comment on "ongoing regulatory matters."
