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Dissidents at F.D.A. Complain of Inquiry

By GARDINER HARRIS

Nine dissident scientists at the Food and Drug Administration who say they were forced to approve high-risk medical devices sent a letter to President Obama on Monday stating that agency officials might have made them the targets of a criminal investigation into their complaints.

“It has been brought to our attention that F.D.A. management may have just recently ordered the F.D.A. Office of Criminal Investigations (O.C.I.) to investigate us rather than the managers who have engaged in wrongdoing!” states the letter, which was provided to The New York Times. “It is an outrage that our own agency would step up the retaliation to such a level because we have reported their wrongdoing to the United States Congress.”

Heidi Rebello, an F.D.A. spokeswoman, said she could neither confirm nor deny the existence of a criminal investigation.

The letter is the latest escalation in a highly unusual internal battle that has been simmering for nearly a year within the agency’s device division. The nine scientists have banded together and charged that agency officials have acted illegally and that patients are routinely put at risk from high-risk medical devices that are approved for sale even though manufacturers have never proved that the products are either safe or effective.

The scientists complained in May to Dr. Andrew C. von Eschenbach, who was then the F.D.A. commissioner, and the agency began an internal review that continues. 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, which also continues.

Three weeks ago, the scientists wrote a similar letter to the president-elect’s transition team. And on Monday, the scientists wrote another letter to President Obama.

Confidential agency documents, which include both e-mail messages and medical reviews detailing the internal dispute were provided to The Times.

It can be a crime for agency employees to reveal documents or information considered confidential by companies seeking agency approval for medical products.

Some of the scientists’ claims about the agency’s device approval process were echoed in a report released

two weeks ago by the Government Accountability Office that was also critical of the agency's device center.

Created in 1976, the F.D.A.'s process for approving devices divides the products into three classes and three levels of scrutiny. Tongue depressors, reading glasses, forceps and similar products are called Class I devices and are largely exempt from agency reviews. Mercury thermometers are among Class II devices, and most get quick reviews. Class III devices include pacemakers and replacement heart valves, and Congress mandated that manufacturers of Class III devices must prove through extensive testing that their products are safe and effective.

But the accountability investigators found that the agency still allowed manufacturers of most Class III devices to gain approval without conducting extensive testing. Part of the reason may be that some Class III devices should be reclassified as Class II devices, while other such devices simply should be tested more.

The agency has promised for years to fix its device approval process but cannot say when the fix will be completed.

Critics have long bemoaned the agency's device approval process, which allows most devices to be approved with minimal testing. Manufacturers say the agency is already overly restrictive.

With internal, Congressional and perhaps now criminal investigations swirling about the agency's device division, the controversy regarding device approvals appears only to be worsening. In Monday's letter to Mr. Obama, the nine scientists provided a detailed list of laws that they claim agency officials have violated.

"We are asking for your immediate intervention," the letter to Mr. Obama stated.