
**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL
OFFICE OF INVESTIGATIONS
INVESTIGATIVE MEMORANDUM**

**October 14, 2010
Unknown FDA Employees
Rockville, Maryland
FDA-Internal Program / Standards of Conduct Violations
H-08-20505-3**

This is a supplemental closing investigative memorandum (IM).

Allegations of Administrative Misconduct

On or about August 2, 2010 HHS-OIG-SIB conducted a special inquiry to assess and review allegations of possible administrative misconduct by FDA/CDRH Management related to the approval of medical devices. Information provided by the complainants can be grouped into two categories:

- 1) Allegations that FDA management violated 21 CFR Part 10.70—Documentation of significant decisions in administrative file; and,
- 2) Allegations that FDA Management retaliated against complainants.

After reviewing the case file and all reports and evidence contained therein, the findings of fact are the following;

- 1) There is no evidence of material violations of 21 CFR Part 10.70, other relevant rules or regulations by FDA/CDRH management.
- 2) There is no evidence of retaliation by FDA/CDRH management against complainants.

Independent Assessments of the Safety and Effectiveness of the 510(k) Process

In response to concerns raised by complainants, FDA management contracted a private firm to conduct a performance audit. A final report on the organizational assessment of CDRH was issued on June 4, 2010. The report issued by ICF, International favorably assessed FDA's mechanisms and abilities for settling disagreements of scientific opinion and made recommendations for further improvements to the established process. FDA management has begun to implement several of these recommendations with the goal of improving communication and transparency between management and review staff.

FDA has also commissioned the National Academy of Sciences' Institute of Medicine (IOM) to review the 510(k) clearance process for medical devices. The IOM committee's report, expected in mid-2011, will answer two principal questions:

This memorandum is the property of the Office of Investigations and is loaned to your agency; it and its contents may not be reproduced without written permission. The memorandum is FOR OFFICIAL USE ONLY and its disclosure to unauthorized persons is prohibited. Public availability shall be determined under 5 U.S.C. 552.

- 1) Does the current 510(k) process optimally protect patients and promote innovation in support of public health?
- 2) If not, what legislative, regulatory or administrative changes are recommended to optimally achieve the goals of the 510(k) process?

Additionally, the OIG's Office of Evaluations and Inspections has begun an examination of FDA's internal controls and quality review process for the 510(k) device approval process (OEI-04-10-00480), as well as an examination of CDRH's Policies for Resolving Scientific Disputes (OEI-01-10-00470).

Other Matters

(b)(6)(7)(c) was contacted for an interview; however, (b)(6)(7)(c) counsel have been non-responsive to the request.

This case is closed.

Elton E. Malone
Special Agent in Charge
Special Investigations Branch