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For Immediate Release

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Obama Administration Should Re-Open Investigation of FDA Wrongdoing After Inspector General Office Rejected Whistleblower Complaints

The Department of Health and Human Services' Office of the Inspector General (OIG) overlooked serious wrongdoing within the Food and Drug Administration (FDA), rejecting whistleblower complaints that the agency allows unsafe medical devices onto the market, the Project On Government Oversight (POGO) [said today in a letter](http://www.pogo.org/pogo-files/letters/public-health/ph-fda-20110112.html) (<http://www.pogo.org/pogo-files/letters/public-health/ph-fda-20110112.html>) to Secretary of Health and Human Services Kathleen Sebelius.

POGO Executive Director Danielle Brian and staff scientist Ned Feder, M.D., urged Sebelius to open a new investigation into misconduct within the FDA's Center for Devices and Radiological Health (CDRH). A 2009 OIG investigation was inadequate because it focused solely on possible criminal violations, while turning a blind eye to non-criminal misconduct and retaliation, including violations of federal regulations. Brian and Feder met with Deputy Inspector General for Investigations Gerry Roy in July to discuss the unchecked managerial misconduct within the FDA's devices center. Roy's follow-up inquiry was cursory at best, as he apparently looked at little or no new evidence and failed to interview any of the 10 FDA whistleblowers.

"We believe it is almost certain that managers in the devices center have committed serious violations of FDA regulations," Brian said. "Secretary Sebelius can help restore credibility to the medical devices center by doing what the FDA and Inspector General have failed to do—put the health of the American public first and thoroughly investigate the allegations of mismanagement and wrongdoing."

The problems within the CDRH brought to light by the whistleblowers are well documented and include several instances of unsafe medical devices being approved for marketing, including a pediatric feeding tube which caused deaths that could easily have been avoided. Furthermore, in October, the FDA took the rare step of revoking the FDA's approval of a medical device used in the repair of knee injuries after it was revealed that the device sold by a New Jersey company had won approval, in part, because of political pressure from members of the New Jersey congressional delegation.

"A failure of leadership in the FDA and the Office of Inspector General continues to put the health and safety of countless patients at risk," Feder said. "It is inexcusable that Mr. Roy could close the book on these serious allegations without interviewing a single whistleblower."

Founded in 1981, the Project On Government Oversight (POGO) is a nonpartisan independent watchdog that champions good government reforms. POGO's investigations into corruption, misconduct, and conflicts of interest achieve a more effective, accountable, open, and ethical federal government.

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