

ONE HUNDRED FOURTEENTH CONGRESS
Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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WASHINGTON, DC 20515-6115

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September 20, 2016

Dr. Robert M. Califf
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

Dear Dr. Califf:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee on Energy and Commerce is examining management concerns with the FDA Office of Criminal Investigations (OCI). The Committee has had a longstanding interest in the management and operations of the FDA OCI since OCI was administratively established in 1991.

The FDA's OCI is located within the FDA's Office of Regulatory Affairs, which is headquartered in Rockville, Maryland and staffed by approximately 260 full time employees. OCI is comprised of OCI headquarters, the Office of Internal Affairs (OIA), six field offices (functioning as regional hubs), and several Resident and Domicile Offices associated as satellites with one of the field offices. The OCI is charged with conducting and coordinating criminal investigations for the FDA. OCI has investigated a wide variety of criminal activities including the manufacture and sale of counterfeit drugs, the illegal marketing of drugs, and the contamination of pet food.

Two independent reports, one from the Government Accountability Office (GAO) in 2010¹ and one from the Department of Health and Human Services Office of Inspector General (HHS-OIG) in 2012,² have identified OCI management issues and made recommendations for improvements. The GAO report on FDA OCI found that the FDA maintained limited oversight of the investigations conducted by OCI and lacked sufficient performance measures. The GAO report also raised concerns about the OIA, a component of FDA OCI comprised of OCI detailees, responsible for conducting internal allegations of misconduct by FDA employees.

¹ GAO, *Improved Monitoring and Development of Performance Measures Needed to Strengthen Oversight of Criminal and Misconduct Investigations*, GAO-10-221, (January 29, 2010).

² HHS-OIG, *Report on the Investigative Operations of the Office of Criminal Investigations for the Food and Drug Administration*, (May 2012).

Issues regarding the functions of the OIA office were again raised in an inspection conducted by the HHS-OIG. Specifically, HHS-OIG reported that OIA utilized criminal law enforcement agents for conducting non-criminal investigations that were mostly administrative in nature or resulted in administrative action. HHS-OIG concluded that the work performed by OIA did not substantiate a need for the office.

The 2012 HHS-OIG inspection also reported tension existed between FDA OCI field offices and OCI headquarters. Interviews with OCI special agents indicated that the OCI field offices lacked the discretion to decide when to open a case. In addition, special agents expressed frustration over OCI headquarters failing to approve requests to initiate cases that address certain local food and drug concerns, and indicated a lack of clarity on investigative priorities making it difficult for field agents to know which case initiation reports will be approved. This issue with opening cases is a particular concern given the urgency and impact on FDA's important public health mission with time-sensitive potential OCI cases, such as product tampering. The 2012 HHS-OIG inspection also found that OCI headquarters was not able to provide signed approvals authorizing Domicile Office locations, and recommended that OCI create a procedure for authorizing a Domicile Office.

A recent change with OCI headquarters also raises questions about the current management model for the OCI. The Director of FDA OCI who came to the FDA from the U.S. Attorney's office in Miami, Florida about one year ago has relocated his permanent duty station to the OCI field office in Miami. The FDA's Office of Regulatory Affairs apparently supported the relocation in view of the global regulatory and law enforcement landscape, believing that this relocation will help address the need to enhance communication, collaboration, and specialization across field operations, and to move away from old, geography-based models. More information is needed to understand the basis for this new management model, and whether this will improve efficiency, OCI operations, and morale.

This recent development, coupled with previous findings, raise several concerns with FDA OCI's management and possible morale concerns with the Field Offices. In order to follow-up on the past GAO and HHS-OIG inspections, and to continue oversight into FDA OCI, please provide the Committee with the following information by October 12, 2016:

1. Did the FDA implement the GAO's recommendation performance measures for the OCI's criminal investigative program and assess program results against them? If so, what are the performance measures and what were the results? Did the results show whether the OCI's criminal investigative program is achieving its results?
2. How has FDA addressed the concerns about case initiation procedures at OCI?
3. What is FDA's existing policy for conducting regular assessments of OCI's field offices? What regular assessments has FDA conducted of OCI's field offices since January 1, 2012? What field offices were assessed? What subjects were covered by the assessments? Who conducted the assessments? What is involved in the assessment process?

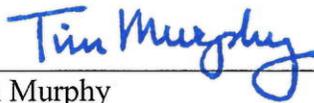
4. Did the FDA implement the GAOs' recommendation to establish a review procedure for the assessment of the Office of Internal Affairs' compliance with its investigative policies? If so, what actions were taken?
5. Has FDA established a procedure for authorizing Domicile Offices? If so, please provide documentation stating the procedure.
6. What is the justification for allowing the Director of FDA OCI to have a duty station and work at the OCI Miami Field Office? Provide all applicable documentation to support this arrangement, including agency telework agreements, OCI Domicile Office location approval from OCI Headquarters, and official duty station paperwork. Please also provide any internal assessments used to justify the management model of the OCI Director working from the Miami field office with headquarters staff remaining at the Rockville, Maryland headquarters.
7. FDA has stated to the Committee that "OCI, as part of FDA, has an overriding responsibility to protect the public health and safety, which is often jeopardized by crimes involving FDA-regulated products. In OCI investigations, protection of the public health is paramount, even at the expense of the criminal investigation, if necessary." How do the OCI's case initiation procedures reflect these values? What is the process for OCI to open a criminal case? How many average days does it take to open a criminal case? Does OCI have any expediting procedures for opening cases when there is a public health exigency such as product tampering?
8. For fiscal years 2012 –2015, please provide number of arrests, number of convictions, number of new investigations opened, and amounts of recoveries.
9. Please provide the number of current FTEs for FDA OCI and OIA.
10. Please provide a copy of OCI's performance plan and/or work plan for FY 2016.
11. The 2012 HHS-OIG inspection report stated that senior employees within various FDA centers indicated the need for a system to track cases referred to OCI by the centers. It was reported that this would assist the centers in staying informed of trends in the industry and assist FDA in its mission to protect public health. Has the FDA established a system to enable the centers to identify which products and product types are currently under investigation? If so, please describe this system and when it was established.

If you have any questions regarding this request, please contact Alan Slobodin with the majority committee staff at (202) 225-2927.

Sincerely,



Fred Upton
Chairman



Tim Murphy
Chairman
Subcommittee on Oversight and Investigations