



Highlights of [GAO-10-221](#), a report to the Ranking Member, Committee on Finance, U.S. Senate

Why GAO Did This Study

The Food and Drug Administration (FDA) is responsible for protecting public health by regulating products such as prescription drugs and vaccines and has the authority to investigate alleged criminal activity related to FDA-regulated products, for example on the sale of counterfeit drugs. Within FDA, the Office of Criminal Investigations (OCI) investigates individuals and companies external to FDA. FDA also has the authority to investigate allegations of FDA employee misconduct and these internal investigations are conducted by the Office of Internal Affairs (OIA), a distinct office within OCI. GAO was asked to examine FDA's (1) oversight of OCI investigations, (2) oversight of OIA investigations, and (3) funding, staffing, and workload for OCI. GAO interviewed agency officials, reviewed FDA documents including those describing its investigative policies, and examined FDA data on OCI resources and workload, from fiscal years 1999 to 2008.

What GAO Recommends

To improve oversight of its investigations, GAO recommends that FDA regularly monitor OCI, and establish a process to monitor OIA for compliance with its investigative policies. GAO also recommends that FDA establish performance measures for OCI to assess whether OCI is achieving its desired results. FDA agreed with GAO's recommendations.

View [GAO-10-221](#) or [key components](#). For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

FOOD AND DRUG ADMINISTRATION

Improved Monitoring and Development of Performance Measures Needed to Strengthen Oversight of Criminal and Misconduct Investigations

What GAO Found

Although OCI maintains policies to guide its investigations, FDA's oversight of OCI's investigations of individuals and companies external to FDA is limited. As a key element of FDA's oversight of OCI, FDA's assessment of OCI's six field offices is intended to ensure compliance with investigative policies; however, the assessments are not being implemented in accordance with prescribed time frames. Of the 24 total office assessments that should have been completed by August 2009, only 7, or about 30 percent, were completed and one office had not been assessed in over 10 years. In addition, FDA lacks performance measures that could enhance the agency's oversight by allowing it to assess OCI's overall success. The OCI Director meets weekly with a senior official in the Office of Regulatory Affairs (ORA), the office in which OCI is located, but OCI is not required to report specific information to ORA or other FDA senior-level offices as part of its formal reporting relationship. As a result, FDA depends on OCI's Director to determine what aspects of OCI's investigations should be communicated to FDA senior managers. According to a senior ORA official, OCI operates more autonomously than other offices within ORA, in part, because of OCI's unique role and expertise within FDA.

Similar to OCI, OIA has policies in place to guide its internal investigations, but FDA's oversight of OIA's investigations of FDA employees is limited. Although the OIA manager meets periodically with OCI's Director, FDA does not have a requirement for OIA to report specific information to OCI or other FDA senior-level offices on its investigative activities or a process in place to routinely monitor OIA's compliance with its investigative policies. The OIA manager told GAO that the number of investigations is such that he is generally involved in all of them, and can therefore review investigative documents before closing cases to assess compliance with investigative policies. The OIA manager told GAO that his review alleviates the need for a process to monitor compliance with OIA's investigative policies. The potential effectiveness of this review is limited because it relies on the OIA manager, who is also responsible for supervising investigations.

FDA's funding and staffing for OCI generally increased annually between fiscal years 1999 and 2008, and OCI's investigative workload also increased over this 10-year period. OCI's funding and staffing include funding and staffing for OIA. OCI's funding, measured by the total funds expended, was about \$19 million in fiscal year 1999 and was over \$41 million in fiscal year 2008, representing an increase of about 73 percent, when adjusted for inflation. Staffing increased by about 40 percent during this period, from about 165 full-time equivalent employees to over 230. The largest increase in funding and staffing was between fiscal years 2002 and 2003. The OCI Director told GAO that this was the result of funding authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 to address potential terrorist threats in connection with FDA-regulated products. Investigative workload also increased from fiscal year 1999 to 2008.