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FOOD AND DRUG ADMINISTRATION

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



GAO

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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.

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Abbreviations

| | |
|-------|---|
| ACRA | Associate Commissioner for Regulatory Affairs |
| AIMS | Automated Investigative Management System |
| CIR | Case Initiation Report |
| CID | Criminal Investigation Division |
| EPA | Environmental Protection Agency |
| FDA | Food and Drug Administration |
| FDCA | Federal Food, Drug, and Cosmetic Act |
| FTE | full-time equivalent |
| GDP | gross domestic product |
| GPRA | Government Performance and Results Act of 1993 |
| HHS | Department of Health and Human Services |
| OCC | Office of the Chief Counsel |
| OCI | Office of Criminal Investigations |
| OIA | Office of Internal Affairs |
| OIG | Office of Inspector General |
| ORA | Office of Regulatory Affairs |
| ROI | Report of Investigation |
| TIGTA | Treasury Inspector General for Tax Administration |

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United States Government Accountability Office
Washington, DC 20548

January 29, 2010

The Honorable Charles E. Grassley
Ranking Member
Committee on Finance
United States Senate

Dear Senator Grassley:

The Food and Drug Administration (FDA), an agency within the Department of Health and Human Services (HHS), is responsible for protecting public health by regulating products such as prescription and over-the-counter drugs, human and pet food, medical devices, cosmetics, and biological products such as vaccines. The products that FDA regulates account for more than 20 percent of all consumer spending in the United States annually—or approximately \$1 trillion worth of products. Its regulatory activities include taking enforcement actions such as product recalls and investigating allegations of criminal activity involving FDA-regulated products. In response to a generic drug scandal that occurred in the 1980s and increased criminal activity involving various FDA-regulated products, FDA established the Office of Criminal Investigations (OCI) in 1991 to conduct and coordinate criminal investigations for the agency.¹ 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.

While OCI focuses its investigative efforts on companies and individuals external to FDA, another office within FDA—the Office of Internal Affairs (OIA)—conducts internal investigations of allegations of misconduct, criminal activity, or other violations of applicable laws or regulations by FDA employees. FDA established OIA in 1995 after a congressional subcommittee recommended that FDA establish an internal affairs office.²

¹The generic drug scandal in the late 1980s involved several drug companies that falsified study data and bribed several FDA officials to receive quick approval for their generic products. See *Mylan Labs. v. Akzo, N.V.*, 770 F. Supp. 1053, 1057-58 (D.Md. 1991).

²This recommendation was made by the Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce. See Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, U.S. House of Representatives, *Less than the Sum of its Parts: Reforms Needed in the Organization, Management, and Resources of the Food and Drug Administration's Center for Devices and Radiological Health* (Washington, D.C.: May 1993).

While OIA and OCI have different purposes, OIA is organizationally part of OCI.³ You and others have raised concerns about OCI's and OIA's procedures for conducting and coordinating investigations, that these offices are operating without adequate oversight or accountability, and that OCI's funding and staffing for criminal investigations have grown significantly despite limited federal resources to fund other FDA activities. At a congressional hearing in February 2008, on FDA's investigation of a researcher employed outside of FDA accused of fraudulently conducting a clinical study of the drug Ketek, you raised concerns that OCI did not effectively coordinate its investigative work with another FDA unit.⁴ In addition, based on an internal investigation conducted by OIA of an FDA scientist with an alleged conflict of interest, you concluded that certain investigative findings were inaccurate and were not sufficiently reviewed within FDA.⁵ Further, in 2008, concerns about accountability and increases in funding and staffing at a time when resources were limited for other parts of FDA prompted the House Committee on Energy and Commerce to request information about OCI's recent operational and staffing expenses.⁶ Because OIA is part of OCI, its funding and staffing are provided and accounted for with funding and staffing for the rest of OCI.

In light of these concerns, you asked us to conduct a review of FDA's oversight of OCI and OIA investigations, including the investigative policies and procedures each office has in place, and FDA's resources for OCI and OIA investigations. In this report we examine (1) FDA's oversight of OCI investigations, (2) FDA's oversight of OIA investigations, and (3) FDA's funding, staffing, and workload for OCI.

³For the purposes of this report, when we refer to OCI we mean OCI not including OIA, unless indicated otherwise.

⁴Statement of Senator Charles E. Grassley, hearing before the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, House of Representatives, 110th Congress, 2nd session, *Ketek Clinical Study Fraud: What Did Aventis Know?*, February 12, 2008, Serial No. 110-87.

⁵Letter to the Secretary of HHS and FDA Commissioner, February 6, 2008, from Senator Charles E. Grassley, Ranking Member, U.S. Senate, Committee on Finance. See <http://finance.senate.gov/press/Gpress/2008/prg020608.pdf>.

⁶See http://republicans.energycommerce.house.gov/Media/File/News/05-14-08_OCI_Letter.pdf, http://republicans.energycommerce.house.gov/Media/File/News/12.05.08_FDA_OCI_Letter.pdf.

To examine FDA's oversight of OCI investigations of individuals and companies external to FDA, we reviewed FDA documents and interviewed FDA managers and officials from other federal agencies. We reviewed OCI documents describing its internal policies and procedures and compared the policies with the broad components of the investigative process which we identified by reviewing relevant investigative standards and consulting with officials in several federal law enforcement agencies and GAO's Forensic Audits and Special Investigations Unit.⁷ We reviewed FDA organizational charts, position descriptions for OCI managers, and FDA documents describing office reporting requirements, as part of FDA's oversight of OCI investigations. We also examined OCI's policy on conducting office assessments (that is, its procedure for monitoring compliance with investigative policies) and we reviewed reports that were based on the completed office assessments for each of the six OCI field offices as well as OCI's schedule of completed office assessments for OCI's field offices.⁸ We interviewed OCI managers about OCI's investigative process and the individual roles and responsibilities for OCI staff and managers in conducting and coordinating criminal investigations. We also interviewed an Assistant U.S. Attorney from the U.S. Attorney's Office for the Western District of Missouri, about the role of the U.S. Attorney in prosecuting cases based on the investigative work of OCI.⁹ We interviewed an associate commissioner in FDA's Office of Regulatory Affairs (ORA) and OCI headquarters managers about OCI's reporting requirements, how ORA and OCI monitor investigations, and how ORA and OCI assess OCI's performance.¹⁰ To further understand the criminal investigative process, including the management and oversight of investigations, we conducted structured phone interviews with OCI's field supervisors in each of OCI's six field offices. We interviewed budget staff from ORA and OCI to understand the funding allocation process and

⁷We reviewed the President's Council on Integrity and Efficiency Quality Standards for Investigations, and based on this review and discussions with officials from relevant law enforcement agencies, we identified five investigative components: (1) documenting and evaluating allegations/leads; (2) opening an investigation; (3) collecting information; (4) documenting, managing, and tracking investigative data; and (5) case resolution. In 2008, this council became part of the Council of the Inspectors General on Integrity and Efficiency.

⁸The six OCI field offices are located in Chicago, IL; Kansas City, MO; Los Angeles, CA; Miami, FL; New York, NY; and Washington, D.C.

⁹We interviewed this Assistant U.S. Attorney because of his experience working with OCI.

¹⁰The OCI Director reports directly to the Associate Commissioner for Regulatory Affairs in ORA, the office responsible for inspecting all FDA-regulated products.

reporting requirements for OCI's funding. We also interviewed officials who conduct investigations in HHS's Office of Inspector General (OIG), the Environmental Protection Agency Criminal Investigation Division (EPA CID), and the Treasury Inspector General for Tax Administration (TIGTA) on how they measure the performance of their investigative programs and monitor compliance with their investigative policies and procedures.¹¹ We reviewed federal government internal control standards¹² to identify effective management practices for providing oversight, and compared the standards with FDA's management practices for overseeing OCI investigations. We focused on practices to monitor compliance with policies and procedures, measure performance, and report pertinent information to management. Finally, we reviewed OCI's investigative statistics, such as arrests and convictions, from fiscal years 1999 to 2008.

To examine FDA's oversight of OIA's internal investigations of FDA employees, we reviewed FDA documents and interviewed several FDA managers and officials from the HHS OIG. Similar to our examination of OCI, we reviewed documents describing OIA's policies and compared them to the broad components of the investigative process which we identified by reviewing investigative standards and consulting with officials in relevant federal law enforcement agencies. We reviewed FDA organizational charts and the position description for the OIA manager. We interviewed OIA's manager about the roles and responsibilities of the OIA staff and manager, and other FDA managers, in conducting and coordinating its investigations of FDA employees. We also interviewed the OCI Director and the OIA manager about what information OIA reports to FDA management, how OIA monitors compliance with its investigative policies and procedures, and what investigative statistics are collected and maintained. We interviewed HHS OIG officials from the Office of Investigations about the OIG's role in conducting investigations of FDA employees. Similar to our OCI review, we reviewed federal government internal control standards to identify effective management practices for providing oversight, and we compared the standards with FDA's

¹¹We interviewed officials in EPA CID and TIGTA because these agencies have separate criminal investigations offices that function similarly to FDA's OCI. TIGTA also conducts internal affairs investigations. We interviewed HHS OIG officials from the Office of Investigations because the HHS OIG conducts criminal investigations related to FDA-regulated products. These agencies are not the only agencies with criminal investigations offices.

¹²See GAO, *Standards for Internal Control in the Federal Government*, [GAO-AIMD-00-21.3.1](#) (Washington, D.C.: November 1999).

management practices for overseeing OIA investigations. We focused on practices to monitor compliance with policies and procedures and report pertinent information to management.

To examine OCI funding,¹³ staffing, and workload, we analyzed data provided by FDA and interviewed OCI officials.¹⁴ To examine OCI funding and staffing, we analyzed aggregate FDA data from fiscal years 1999 to 2008 provided for OCI. We first compared changes in funding in actual terms during this 10-year period with changes in funding after adjusting for inflation. We used the gross domestic product (GDP) price index for nondefense goods and services to adjust for inflation.¹⁵ Second, we identified changes in OCI's staffing during the same time period and we report on staffing resources as the number of full-time equivalent (FTE) staff.¹⁶ To examine changes in OCI's workload, we analyzed OCI data on the number of opened and closed investigations each year from fiscal years 1999 to 2008 as well as the number of ongoing investigations, that is, those that remained open at the end of each fiscal year. OCI investigative workload data came from OCI's Automated Investigative Management System (AIMS), the data system that OCI uses to track and maintain key information about each investigative case. To assess the reliability of FDA data on investigative workload and statistics, funding, and staffing, we reviewed existing information about the data and we interviewed agency officials knowledgeable about the data. We determined that the data were sufficiently reliable for their use in this report.

We performed our performance audit from January 2009 to November 2009 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe

¹³For the purposes of this report, outlays are used to approximate funding. Outlays during a fiscal year may be for payment of obligations incurred in prior years (prior-year obligations) or in the same year. Outlays made during a fiscal year for prior-year obligations are generally made with prior-year appropriations.

¹⁴FDA's funding and staffing for OCI include funding and staffing for OIA.

¹⁵The GDP price index for nondefense goods and services measures the change in the value of nondefense-related goods and services produced by the U.S. economy in a given period.

¹⁶One FTE represents 40 hours of work per week conducted by a federal government employee over the course of 1 year. For the purposes of this report, FTEs reflect filled positions.

that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

FDA has the authority to conduct investigations of alleged criminal activity related to FDA-regulated products, such as the misbranding of those products, and to investigate allegations of misconduct and criminal activity by FDA employees. OCI, the office with responsibility for conducting and coordinating criminal investigations, is located within ORA and has field offices located across the United States. OIA is a distinct office within OCI with responsibility for investigating allegations involving FDA employees. OCI's Director reports to the head of ORA and OIA's manager reports to the OCI Director.

FDA's Authority to Conduct Investigations

The Secretary of HHS has granted FDA the authority to conduct investigations of alleged criminal activity related to FDA-regulated products. Such criminal activity may involve violations of the Federal Food, Drug, and Cosmetic Act (FDCA),¹⁷ the Federal Anti-Tampering Act,¹⁸ and other statutes including provisions of Title 18 of the United States Code.¹⁹ Under this authority, FDA may investigate crimes such as the misbranding of FDA-regulated products, product tampering, and the manufacture and sale of unapproved FDA-regulated products. The Secretary of HHS has also granted FDA the authority to investigate cases involving FDA employees—that is, any allegations of misconduct, criminal activity, or other violations of applicable laws or regulations.

Under the Inspector General Act of 1978, the HHS OIG also has the authority to conduct investigations of FDA-regulated entities and to investigate cases involving FDA employees.²⁰ An HHS OIG official stated that his agency focuses on investigating FDA-regulated entities when HHS programs—such as Medicare and Medicaid—or funds are involved.²¹ In

¹⁷See 21 U.S.C. §§ 301-399a.

¹⁸See 18 U.S.C. § 1365.

¹⁹See 18 U.S.C. §§ 1341 (mail fraud), 2320 (trafficking in counterfeit goods or services).

²⁰See 5 U.S.C. app. 3. However, under the act, Inspectors General may not carry out program operating responsibilities. See 5 U.S.C. app. 3, § 9(a).

²¹For example, in 2007 and 2008, the HHS OIG and OCI worked jointly on investigations involving violations of FDA-related laws that resulted in the submission of false claims for reimbursement by HHS programs.

addition, the HHS OIG has authority for investigating cases involving HHS employees, which includes cases involving FDA employees. This authority supersedes FDA's authority to investigate its employees; HHS OIG can decide to investigate a case independently, jointly with FDA, or decline to investigate a case, which allows FDA to investigate the case independently.

Office of Criminal Investigations' and Office of Internal Affairs' Structure, Staff, and Investigations

In response to evidence of increased criminal activity in FDA-regulated products, OCI was established in 1991 to conduct and coordinate criminal investigations of violations of FDA-related laws.²² OCI's mission includes working with and supporting U.S. Attorneys, who initiate prosecution of OCI cases as well as criminal cases for other investigative agencies.²³ OCI is composed of a headquarters office that has two divisions—Administrative Operations and Investigative Operations—and six field offices (see fig. 1). Each field office covers a geographic region of the United States, made up of several states, and within each field office there are subordinate offices—referred to as resident and domicile offices, also with responsibility for designated geographic areas.²⁴ OCI investigations are primarily conducted in the field offices under the direction of field supervisors, and the headquarters office provides policy, investigative, and administrative support to the field offices.²⁵ The field supervisors report directly to the Special Agents in Charge of the Administrative Operations and Investigative Operations Divisions, who in turn report to the OCI Director.

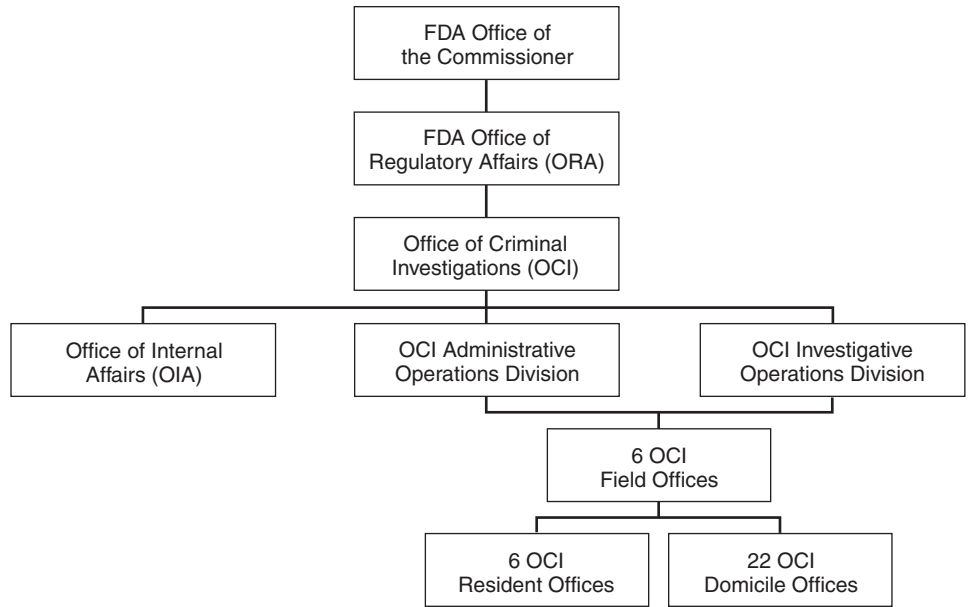
²²The FDA Commissioner delegated FDA's authority to conduct criminal investigations to OCI. See 56 *Fed. Reg.* 67,076.

²³U.S. Attorneys receive most of their criminal referrals from federal investigative agencies. Once a referral is received, U.S. Attorneys decide on the appropriateness of bringing criminal charges and, if deemed appropriate, initiate prosecution.

²⁴Field offices are the largest of the three types of OCI offices and each of the 6 field offices has responsibility for several states. Located within the field office jurisdictions, the 6 resident offices each cover a smaller number of states than each field office. Domicile offices are the smallest of the three types and they also cover smaller jurisdictions than the field offices. For example, some domicile offices cover jurisdictions that are smaller than a state. There are 22 domicile offices and they are usually located within private residences. Resident offices and domicile offices are not evenly distributed across the field offices.

²⁵According to an FDA official, OCI's current priorities include conducting investigations of counterfeit medical products, imports, and food safety.

Figure 1: FDA's Organizational Structure for Conducting Investigations



Source: GAO analysis of FDA organization charts.

OCI's staff includes criminal investigators, forensic and information technology personnel, and other support staff.²⁶ Most of OCI's staff is comprised of criminal investigators—in fiscal year 2008, 180 of the 223 OCI staff were criminal investigators.²⁷ The role of the criminal investigator includes evaluating allegations of criminal activity and determining whether an investigation should be opened within OCI; if an investigation is opened, investigators gather evidence using various investigative techniques, such as electronic surveillance, and document the steps taken in the course of the investigation.²⁸ Criminal investigators often complete their investigations by presenting their cases to local U.S. Attorneys for prosecution.

²⁶Some criminal investigators have polygraph training and also serve as polygraph examiners.

²⁷Criminal investigators are law enforcement officers as defined in 5 U.S.C. § 5541(3).

²⁸Each OCI field office is assigned one or more attorneys from FDA's Office of the Chief Counsel (OCC) to provide legal guidance and prosecutorial support on OCI criminal investigations. OCC is located in FDA's headquarters office.

OCI is located within ORA, the office with primary responsibility for all FDA field activities such as conducting inspections of FDA-regulated products and manufacturers (see fig. 1).²⁹ OCI's Director reports to the head of ORA, the Associate Commissioner for Regulatory Affairs (ACRA).³⁰ OCI is funded as part of ORA and ORA uses OCI's previous year's funding as a baseline for the current year when allocating funding to OCI. In fiscal year 2008, OCI's funding was \$41.3 million.

OIA, which is a distinct office within OCI, was established in 1995 to investigate cases involving FDA employees (see fig. 1).³¹ OIA's manager reports to the OCI Director.³² OIA's investigations are intended to collect evidence to determine the validity of allegations involving FDA employees so that FDA managers can decide whether administrative actions against employees are warranted. In cases where criminal sanctions are warranted, OIA refers cases to U.S. Attorneys or local prosecutors for prosecution.³³ OIA's staff in fiscal year 2008 included seven criminal investigators and two support staff. Two of the seven criminal investigators are supervisors. OIA investigators are usually assigned from OCI although OIA sometimes recruits specifically for OIA investigators.³⁴ OCI's allocation of funding from ORA includes funding for OIA, as well as OCI's other components. OCI then further allocates funding from ORA among its components, including OIA.

According to the OCI Director, OCI prefers to hire experienced criminal investigators from other federal law enforcement agencies because they bring to OCI prior federal law enforcement training, professional contacts, and expertise in several areas, including the use of investigative

²⁹Other FDA field activities include conducting sample analysis of regulated products and reviewing imported products offered for entry into the United States.

³⁰The ACRA is responsible for conducting midyear and end-of-year performance reviews of the OCI Director. The ACRA reports directly to FDA's Office of the Commissioner.

³¹The FDA Commissioner delegated FDA's authority to conduct investigations involving FDA employees to OIA. See 60 *Fed. Reg.* 4417. OIA also has responsibility for investigating, among other things, threats against FDA facilities.

³²The OCI Director is responsible for evaluating the performance of the OIA manager.

³³In addition to notifying HHS OIG about all cases involving criminal allegations, OIA also notifies HHS OIG prior to referring cases for prosecution.

³⁴Throughout this report, we refer to criminal investigators that work in OIA as OIA investigators.

techniques.³⁵ Upon hire, OCI criminal investigators must have completed basic and advanced federal law enforcement training through their previous law enforcement agency and all newly hired OCI criminal investigators attend an OCI-specific training program.³⁶ OCI criminal investigators also receive continuing instruction in areas such as courses on the FDCA and the Anti-Tampering Act, interviewing techniques, and internet investigations. OIA investigators have the same training requirements as OCI criminal investigators because they are generally assigned to OIA from OCI; OIA provides additional training to OIA investigators on internal affairs issues, such as employee rights.

OCI Maintains Policies to Guide Its Investigations but FDA's Oversight of Those Investigations Is Limited

Although OCI has policies to guide its investigations of individuals and companies external to FDA, FDA's oversight of OCI's criminal investigations is limited. As a key element of its oversight, FDA has a process in place that is intended to ensure OCI's compliance with investigative policies and procedures; however, FDA has not ensured that this process is implemented by OCI in accordance with its prescribed time frames. In addition, FDA lacks performance measures that could enhance its oversight of OCI by allowing it to assess OCI's overall success. Although the OCI Director regularly meets with the ORA ACRA, there is no requirement for OCI to report regularly on specific topics to FDA senior-level offices as part of the formal reporting relationship. As a result, FDA relies on the OCI Director to determine which aspects of OCI's operations and investigations are made known to FDA's top management.

OCI Has Policies to Guide Its Investigations

OCI has policies in place to guide its investigations of individuals and companies external to FDA that address each of the five investigative components that we identified by reviewing relevant investigative standards and consulting with several federal law enforcement agency officials (see table 1). OCI's policies generally outline the role of the criminal investigator in the investigative process as well as designate responsibilities for the field supervisors and OCI headquarters

³⁵ According to an OCI official, OCI's 17 criminal investigators that were hired in fiscal year 2008 had an average of 10.2 years of prior federal law enforcement experience, with a range of nearly 3.5 to 21 years of experience. These criminal investigators were hired from several federal law enforcement agencies such as U.S. Secret Service and HHS OIG.

³⁶ OCI criminal investigators attend the OCI-specific training program at the Federal Law Enforcement Training Center, which is the largest single provider of law enforcement training for the federal government.

management.³⁷ The policies also describe the necessary steps for documenting investigative activities, including the review and approval of such activities by field supervisors. For example, for the first component—documenting and evaluating allegations/leads—OCI’s policy on tampering states that criminal investigators and their field supervisors must assess the potential threat to the public health for all tampering allegations, determine what investigative actions are warranted, and report this information to headquarters management within 24 hours of receipt. As an example of an OCI policy addressing collecting information—the third component—when a criminal investigator plans to conduct electronic surveillance of certain telephone communications, the investigator must first obtain written approval from the field supervisor, who in turn is required to forward the approved request to headquarters management for final approval.³⁸

³⁷ Although the role of the U.S. Attorneys’ Offices in the investigative process is not formalized in OCI policy, OCI criminal investigators generally document their interactions with attorneys from the U.S. Attorneys’ Offices during the course of an investigation.

³⁸ Criminal investigators must also comply with applicable laws requiring that they obtain a court order.

Table 1: Description of the Office of Criminal Investigations' Investigative Policies

| Component | Description of the Office of Criminal Investigations' investigative policies |
|--|---|
| Documenting and evaluating allegations/leads | <ul style="list-style-type: none"> Upon receipt of an allegation or lead that requires additional investigation, a Case Initiation Report (CIR) must be filled out by the criminal investigator, approved by his/her field supervisor, and sent to the Office of Criminal Investigations (OCI) headquarters management for review. A CIR must also be completed for preliminary cases, that is, those in which an allegation or lead does not necessarily result in a criminal investigation. |
| Opening an investigation | <ul style="list-style-type: none"> Based upon the information in the CIR, OCI headquarters management must decide if a case needs to be opened. If so, a case number is assigned to the case. |
| Collecting information | <ul style="list-style-type: none"> Certain interviews must be documented, including suspect interviews, key victim/witness interviews, and interviews that disclose complex information. Specific policies guide the use of specialized techniques such as searching e-mail or internet usage, electronic surveillance, confidential informants, and undercover operations. These techniques generally require at least field supervisor approval and often approval by headquarters management. The use of specialized techniques may also require a warrant or court order. Evidence must be documented and catalogued using relevant standards and under the supervision of the investigator's field supervisor and also the field office official responsible for overseeing evidence. |
| Documenting, managing, and tracking investigative data | <ul style="list-style-type: none"> To document and track allegations, OCI requires its criminal investigators to submit a Report of Investigation (ROI) at least every 90 days to document their investigative activities, including activities such as interviews, surveillance, and search warrants. The ROI is required to be reviewed and approved by a field supervisor. Documents central to the investigation (i.e., CIRs, ROIs, Judicial Action Forms, and Subject History Forms) must be entered into AIMS and also sent as hard copies to OCI headquarters once they are approved by a field supervisor. |
| Resolution of the case | <ul style="list-style-type: none"> To resolve a case, OCI requires that its criminal investigators document the outcome of each investigation in a closing ROI, including any legal action taken against subjects that are charged with criminal offenses. Indictments, arrests, and convictions which occur as a result of a criminal investigation must be entered into AIMS. Field supervisors are responsible for making sure all appropriate steps are taken prior to case closure. For example, the destruction of evidence no longer needed must be documented. |

Source: GAO analysis and summary of OCI policies.

Note: We identified the five investigative components by reviewing relevant investigative standards and consulting with several federal law enforcement agency officials.

A Key Element of FDA's Oversight of OCI to Ensure Its Compliance with Investigative Policies Has Not Been Implemented within Established Time Frames

As a key element of its oversight, FDA has had an established process in place to monitor OCI's compliance with investigative policies and procedures since 1996, but FDA has not ensured that this process is implemented by OCI in accordance with its prescribed time frames. As stated in OCI policy, each field office's investigative and administrative procedures are to be evaluated for compliance with OCI policies through the office assessment process at least every 3 years, depending on the availability of resources. The office assessment process, according to OCI policy, is an oversight mechanism to ensure that OCI is in compliance with its policies and procedures. The field office assessment process has four steps that include a self assessment and an onsite visit that is conducted by OIA staff.³⁹ For the self assessment, field office staff are required to analyze compliance with OCI policies in 10 areas of administrative and investigative operations, such as the supervision of criminal investigator activities, and all identified findings of noncompliance must be documented.⁴⁰ For the onsite inspection, OIA staff are to review certain administrative and investigative files to assess compliance with OCI policies and interview criminal investigators, for example about the adequacy of the supervision that they receive. The field supervisor and OCI Director are to be provided a final report, prepared by OIA staff, summarizing the office assessment results. The field supervisor is to work with OCI headquarters and OIA staff to correct any identified areas of noncompliance and the corrective actions are required to be documented. An example of a corrective action based on an office assessment occurred in 2007 when OCI headquarters issued an interim policy to clarify its existing policy on documenting the receipt of evidence.

Of the 24 OCI field office assessments that should have been completed by August 2009—4 for each of the six field offices—only 7, or about

³⁹The four steps are (1) field office self assessment, (2) OCI Headquarters-led onsite visit, (3) OIA-led onsite visit, and (4) return visit by OIA. According to OCI policy, the second step includes a review of the office self assessment and may be omitted, for example, if significant issues of concern are not identified during the field office self assessment. The fourth step—the return visit by OIA—may also be omitted if the field office does not require significant corrective actions.

⁴⁰The 10 areas are (1) personnel and administration, (2) evidence, (3) public affairs and liaison activities, (4) vehicles and safety, (5) training, (6) management and supervision, (7) investigation operations, (8) office space and security, (9) accountable/sensitive property, and (10) financial management.

30 percent, were completed.⁴¹ None of the six field offices has been evaluated within the required 3-year time frame and only one has been evaluated more than 1 time since 1996—the year the office assessment policy was established. Moreover, the most recent assessment for one field office was conducted over 10 years ago—in 1997.⁴² The field supervisor in this office told us in June 2009 that his office had recently begun another assessment.

According to the OCI Director, limited resources and logistical issues have prevented FDA from assessing field office compliance with OCI's investigative policies and procedures every 3 years. The OCI Director stated that scheduling is a key concern given that the assessments require multiple staff to be available to participate, including OCI headquarters and field office staff and OIA staff. OCI's Director also told us that once an assessment has begun, scheduling issues can affect implementation of the assessment. For example, according to a 2007 final office assessment report, an ongoing trial and a mandatory training program prevented OIA staff from interviewing certain field office employees during the OIA-led onsite visit.

FDA Lacks Performance Measures that Could Enhance Its Oversight of OCI

FDA lacks performance measures for OCI that could enhance its oversight of OCI by allowing it to assess OCI's overall success. As part of its performance plan, FDA has long-term goals, such as improving patient and consumer safety, and associated performance measures that the agency uses to assess whether it is meeting its goals.⁴³ However, FDA's current performance plan does not include performance measures related to OCI under any of the agency's long-term goals even though FDA considers OCI's role in enforcing FDA laws and regulations to be essential to the

⁴¹A total of 24 completed assessments is expected because there are six field offices and each should have had 4 assessments completed between 1996—the year OCI's policy was established—and 2008.

⁴²OCI finalized its policy in 1996 and the first office assessment was completed in 1997.

⁴³FDA's other long-term goals are to strengthen FDA for today and tomorrow; increase access to new medical and food products; and improve the quality and safety of manufactured products and the supply chain. For more information about FDA's long-term goals and mission, see Department of Health and Human Services, Food and Drug Administration, *FDA Strategic Action Plan: Charting Our Course for the Future*, Fall 2007. See <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/%20Reports/StrategicActionPlan/UCM061415.pdf>.

agency's mission of protecting public health.⁴⁴ Congress passed the Government Performance and Results Act of 1993 (GPRA) to encourage agencies to focus on the performance and results of their programs, rather than solely on program activities and resources.⁴⁵ The principles of the act include establishing measurable goals and related measures, developing strategies for achieving results, and identifying the resources that will be required to achieve the goals. GPRA requires that federal agencies develop performance measures—indicators that an agency will use to measure its performance against its established goals—and prepare annual performance plans that include a summary of the agency's performance measures.⁴⁶ The act does not require agencies to use these principles for individual programs, but past GAO work⁴⁷ and the experience of leading organizations have demonstrated that the principles are the basic underpinning for performance-based management—a means to strengthen program performance.

OCI has also not established results-oriented goals and measures with which to assess its own performance. OCI's Director said that measuring the performance of FDA's criminal investigative program is a challenge because of the difficulty in isolating the effects of OCI's work from other factors that affect outcomes, but over which OCI has limited control. For example, OCI could conduct a high-quality investigation that does not lead

⁴⁴FDA's fiscal year 2010 congressional budget justification for the agency's field activities (i.e., ORA's program) describes OCI's role to be essential to FDA's overall mission of protecting public health. See Department of Health and Human Services, *Fiscal Year 2010 Food and Drug Administration Justification of Estimates for Appropriations Committees*. See <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/BudgetReports/ucm153374.htm>. In addition, the FDA Commissioner stated in August 2009 that effective enforcement against violations of FDA laws is critical to the agency's public health mission. See FDA Commissioner, "Effective Enforcement and Benefits to Public Health," Food and Drug Law Institute meeting, August 6, 2009. See <http://www.fda.gov/NewsEvents/Speeches/ucm175983.htm>.

⁴⁵Pub. L. No. 103-62, 107 Stat. 285.

⁴⁶Under GPRA, federal agencies are also required to report annually on their progress in achieving their goals.

⁴⁷For example, see GAO, *Managing for Results: Enhancing Agency Use of Performance Information for Management Decision Making*, GAO-05-927 (Washington, D.C.: Sept. 9, 2005); GAO, *Program Evaluation: Studies Helped Agencies Measure or Explain Program Performance*, GAO/GGD-00-204 (Washington, D.C.: Sept. 29, 2000); GAO, *Agency Performance Plans: Examples of Practices That Can Improve Usefulness to Decisionmakers*, GAO/GGD/AIMD-99-69 (Washington, D.C.: Feb. 26, 1999); and GAO, *Managing for Results: Strengthening Regulatory Agencies' Performance Management Practices*, GAO/GGD-00-10 (Washington, D.C.: Oct. 28, 1999).

to a prosecution. Criminal prosecutions that result from investigations have been suggested by some agencies to be a measure that reflects the work of criminal investigative organizations. However, the OCI Director explained that when an OCI case is presented to a U.S. Attorney's Office for a prosecution decision, the U.S. Attorney's Office typically evaluates the case based on a number of factors, including not only the strength and quality of the evidence provided, but also the extent to which the case falls under the office's current investigative and prosecutorial priorities.⁴⁸ Individual U.S. Attorney's Offices may establish their own investigative and prosecutorial priorities based on local crime problems and the needs of the local community. In addition, there may be national prosecution priorities set by the Department of Justice based on a national assessment of crime problems. As an example, an Assistant U.S. Attorney told us that mortgage fraud is a current investigative and prosecutorial priority. He indicated that priorities often affect staffing and resources within a U.S. Attorney's Office and may indirectly affect the ability of the office to proceed on every matter presented for prosecution.⁴⁹

Other federal agencies, however, have established performance measures for their criminal investigative programs despite the challenge of isolating the effects of their agency's investigative work from other factors that might affect a given measure. For example, according to its current strategic plan, the Department of Justice's Drug Enforcement Administration has a performance measure targeting the number of major organizations responsible for distributing drugs in the United States that are dismantled annually.⁵⁰ An EPA official, while acknowledging the challenge in measuring performance for criminal investigative programs, told us that her agency is developing a performance measure addressing

⁴⁸The Assistant U.S. Attorney we interviewed told us that when a criminal investigative agency is interested in pursuing an investigation toward prosecution, the agency typically works with the U.S. Attorney's Office to develop potential investigative strategies which will tend to increase the likelihood of developing admissible evidence necessary to facilitate prosecution.

⁴⁹OCI's Director also told us that measuring the performance of OCI is further complicated by the fact that, unlike other law enforcement agencies, FDA's primary mission is to protect the public health. Therefore, if OCI identifies an activity that could harm the public during a criminal investigation, the agency must warn the public. The OCI Director explained that while making such information public could damage its criminal investigation, the agency's decision is based on serving the agency's primary mission to protect the public health.

⁵⁰This annual performance measure is included in DOJ's Strategic Plan, Fiscal Years 2007-2012. See <http://www.usdoj.gov/jmd/mps/strategic2007-2012/index.html>.

the reduction in repeat environmental crimes among violators. This official added that performance measures help inform and focus the management of EPA's criminal enforcement program. Several agency officials we spoke with acknowledged that the measures their agencies use are not perfect because they do not have complete control over them. However, they stated that their measures provide some indication of whether the agencies are achieving results. Prior GAO work has noted similar challenges in measuring performance in other federal agencies, including those with criminal investigative programs.⁵¹ However, according to a 2004 GAO report, federal managers do not perceive issues such as "difficulty distinguishing between the results produced by the program and results caused by other factors" to be a substantial hindrance to measuring their agencies' performance.⁵²

In the absence of standard performance measures, various FDA managers described somewhat different views on how OCI's performance could best be measured. For example, the OCI Director told us that OCI's performance should be viewed based on FDA's overall mission to protect the public health and how well OCI handles high-priority cases. Furthermore, an FDA document states that OCI's impact on protecting the public health cannot be measured solely by the number of arrests and convictions. In contrast, one OCI field office supervisor told us that he believed legal actions—including the number of annual convictions and arrests that result from OCI investigations—are indicators of how well OCI is performing. The acting ACRA told us that OCI's performance should be assessed based, in part, on the court-ordered fines and restitution that result from OCI investigations. OCI maintains investigative statistics, which include court-ordered fines and restitution, convictions, and arrests and reports certain statistics on its Web site.⁵³ For more information about these statistics and other OCI investigative statistics, see appendix I.

⁵¹For example, see GAO, *Combating Gangs: Better Coordination and Performance Measurement Would Help Clarify Roles of Federal Agencies and Strengthen Assessment of Efforts*, [GAO-09-708](#) (Washington, D.C.: July 24, 2009); and GAO, *Results-Oriented Government: GPRA Has Established a Solid Foundation for Achieving Greater Results*, [GAO-04-38](#) (Washington, D.C.: Mar. 10, 2004).

⁵²See [GAO-04-38](#).

⁵³See HHS, Food and Drug Administration, *The Enforcement Story, Fiscal Year 2008* (Rockville, MD: March 2009), chapter 6: Office of Criminal Investigations. See <http://www.fda.gov/ICECI/CriminalInvestigations/default.htm>.

OCI Is Not Required to Report Specific Information to FDA Management

OCI is not required to report specific information to ORA or other FDA senior-level offices as part of its formal reporting relationship. While the OCI Director meets regularly with the ORA ACRA, there is no formal reporting requirement—that is, FDA does not have a protocol establishing what information is to be reported, the time frame for the information to be communicated, and the format in which the information is reported—between OCI and FDA management.⁵⁴ The OCI Director told us that he meets weekly with the ORA ACRA to discuss any pertinent issues that arise, such as OCI’s active investigations, funding, or personnel. The OCI Director also advises the ORA ACRA about results of the field office assessments. The OCI Director told us that he meets on an as-needed basis with the Office of the Commissioner, for example to brief the Commissioner on a case involving an indictment. None of the meetings between the OCI Director and the ORA ACRA or Office of the Commissioner are documented, for example with meeting minutes or agendas. According to the acting ACRA, OCI is not required to report any specific information to ORA, for example, about OCI’s investigative activities, performance, use of funding, or monitoring activities. The lack of a requirement for OCI to report regularly on specific topics to FDA senior-level offices means that FDA has relied largely on the OCI Director to determine which aspects of OCI’s operations and investigations are made known to FDA’s top management. This management approach could place ORA, and other FDA senior-level offices, in a reactive rather than leadership position with respect to overseeing OCI and the criminal investigative work OCI manages. Moreover, the ACRA noted that, compared to other units within ORA, he has less of a ‘chain-of-command’ relationship with OCI, and that OCI operates more autonomously than other offices within ORA, in part, because of its unique role and expertise within FDA. FDA and OCI officials said that they believe the existing processes for the reporting of information are adequate for their needs. We were unable to assess the adequacy of OCI’s current reports to ORA and the Office of the Commissioner due to the lack of meeting documentation.

⁵⁴GAO’s *Standards for Internal Control in the Federal Government* do not include specific guidelines for how information should be reported to management. Instead, the standards state that information should be recorded and communicated to management in a form and within a time frame that enables them to carry out their oversight responsibilities. See [GAO-AIMD-00-21.3.1](#).

FDA's Oversight of OIA Investigations Is Limited

Similar to OCI, OIA has policies in place to guide its internal investigations of FDA employees but FDA's oversight of OIA investigations is limited. FDA does not have formal arrangements in place to oversee OIA investigations, such as a requirement for OIA to report regularly on its investigative activities to FDA management⁵⁵ or a process to regularly monitor OIA's compliance with its investigative policies.

OIA Has Policies to Guide Its Investigations

OIA has policies in place to guide its internal investigations of FDA employees and the policies address each of the five investigative components we identified. As described earlier, we reviewed relevant investigative standards and consulted with officials in several federal law enforcement agencies to identify these components (see table 2).⁵⁶ The policies outline the responsibilities of the OIA investigators and the OIA manager in the investigative process including investigative activities where supervisory review and approval must be documented. As an example of an OIA policy that addresses the first component—documenting and evaluating allegations/leads—an OIA investigator is required to complete a case initiation form when a complaint about an FDA employee is received. The OIA manager is then to review and approve the form, which includes information about the type of alleged employee misconduct and the source of the allegation. As another example, OIA's policies on interviews address the third component—collecting information—by outlining the rights of government employees during an interview.⁵⁷ For instance, for criminal allegations, an employee has a right to have a lawyer present during a custodial interview and to refuse to answer questions that could be self-incriminating. For cases without criminal allegations, an employee may have the right to have a union representative present during an interview but may be compelled to answer questions or face termination. OIA policy states that compelling an employee to answer questions must be approved by the OIA manager prior to initiating the interview.

⁵⁵The OIA manager shares information about the initiation of OIA investigations with the OCI Director.

⁵⁶The investigative components are the same as those identified for OCI's criminal investigations.

⁵⁷These rights have been recognized by federal courts and are also applicable at other federal agencies.

Table 2: Description of the Office of Internal Affairs' Investigative Policies

| Component | Description of the Office of Internal Affairs' investigative policies |
|--|---|
| Documenting and evaluating allegations/leads | <ul style="list-style-type: none"> Investigators in the Office of Internal Affairs (OIA) who receive a complaint must complete a Case Initiation Report (CIR) Form which must be submitted to the OIA manager for evaluation and approval. OIA investigators must notify the HHS OIG upon receipt of allegations with the reasonable potential for criminal charges or an otherwise sensitive case. HHS OIG's decision to accept the case, work the case jointly with OIA, or refer the case back to OIA must be documented in the investigative file and also in a report of investigation (ROI). |
| Opening an investigation | <ul style="list-style-type: none"> Upon receipt of a CIR, the OIA manager must determine whether an investigation should be initiated. If so, a case will be opened and the case will be assigned to an OIA investigator. |
| Collecting information | <ul style="list-style-type: none"> When collecting information for a case, OIA investigators must follow relevant policies for initiating and conducting interviews. According to the OIA manager, OIA generally follows OCI's policies when using relevant specialized techniques to collect information, such as searching e-mail or internet usage, since it does not have separate guidelines for these techniques. |
| Documenting, managing, and tracking investigative data | <ul style="list-style-type: none"> OIA requires its investigators to document their investigative activities in an ROI at least every 90 days, including activities such as interviews, record of internet usage, or pending administrative actions taken against an employee. However, an ROI must be submitted within 10 days of any significant development in a case, such as an employee termination or resignation. All ROIs must be reviewed and approved by the OIA manager. |
| Resolution of the case | <ul style="list-style-type: none"> To resolve a case, OIA must refer its investigative findings to the FDA manager responsible for determining what, if any, administrative action is necessary, ranging from a verbal reprimand to termination of employment. Each OIA investigator will prepare the relevant documents for referral to FDA management, in consultation with the OIA manager. OIA requests that the appropriate FDA manager inform the office within 30 days about the details of any proposed administrative actions taken, based upon OIA's investigation. Copies of the investigative findings must also be sent to FDA's unit responsible for employee relations. For cases that involve legal actions, OIA must document in the ROI information such as alleged criminal violations, related evidence of these violations, and a listing of witnesses and their testimony. |

Source: GAO analysis and summary of OIA policies.

Note: We identified investigative components by reviewing relevant investigative standards and consulting with several federal law enforcement agency officials.

FDA Conducts No Formal Oversight of OIA

Although the OIA manager said he meets periodically with the OCI Director to discuss administrative issues such as hiring, FDA does not conduct formal oversight of OIA with a requirement for it to report regularly on its investigative activities or with a process to routinely monitor OIA's compliance with its investigative policies.⁵⁸ According to OCI and OIA officials, OIA is not required to formally report information to OCI or other senior-level FDA offices, for example, about OIA's investigative activities or its use of funding. The OIA manager said that he meets only when needed with the OCI Director and that these meetings focus primarily on administrative issues such as hiring or training; the OIA manager also stated that he has minimal discussion with the OCI Director regarding ongoing OIA investigations.⁵⁹ However, the OIA manager told us that he briefs the OCI Director about high-profile or otherwise significant investigations. While there is no requirement for formal reports, the OIA manager does share all case initiation reports for OIA investigations with the OCI Director. OIA does not have a formal oversight process in place for its management to monitor compliance with its investigative policies. According to the OIA manager, the office's small size and low number of investigations alleviate the need for a formal monitoring process because he is involved to some extent in all ongoing OIA investigations.⁶⁰ That is, the OIA manager told us that his involvement, which includes a review of each OIA investigation's documentation prior to closure, helps to ensure that OIA investigations are being conducted in accordance with OIA policies. However, relevant internal control standards state that the separation of duties and responsibilities is important for an effective monitoring strategy.⁶¹ OIA does not maintain a separation of duties as the

⁵⁸GAO's *Standards for Internal Control in the Federal Government* do not include specific guidelines for how information should be reported to management. Instead, the standards state that information should be recorded and communicated to management in a form and within a time frame that enables them to carry out their oversight responsibilities. See [GAO-AIMD-00-21.3.1](#).

⁵⁹As of January 2010, the OCI Director and OIA manager had begun holding regular monthly meetings to discuss OIA issues.

⁶⁰OIA's staff in fiscal year 2008 included seven criminal investigators. At the end of fiscal year 2008, OIA closed 85 investigations and had 18 ongoing cases. In comparison, OCI closed 418 investigations and had 1087 ongoing cases at the end of fiscal year 2008.

⁶¹According to GAO's internal control standards, the separation of duties and responsibilities helps deter fraud and organizations should examine their ongoing monitoring procedures by, among other things, assessing the appropriateness of their organizational structure and supervision. See GAO, *Internal Control Standards: Internal Control Management and Evaluation Tool*, [GAO-01-1008G](#) (Washington, D.C.: August 2001).

OIA manager is directly involved in the supervision of ongoing OIA investigations and is also responsible for the review of OIA cases, which is the office's mechanism for ensuring compliance with its investigative policies. The potential effectiveness of OIA's monitoring process is limited by relying on the OIA manager—rather than an external reviewer who is not involved in ongoing investigations—to assess the office's compliance and to correct any identified deficiencies.

FDA's Funding and Staffing for OCI Investigations and OCI Investigative Workload Have Increased

FDA's funding and staffing for OCI investigations and OCI's investigative workload have increased between fiscal years 1999 and 2008. OCI's funding grew by about 73 percent when adjusted for inflation and OCI's staffing also increased by about 40 percent. Similarly, OCI's investigative workload—the number of opened, closed, and active investigations—increased over this 10-year period.⁶²

OCI Funding and Staffing Increased from Fiscal Years 1999 to 2008

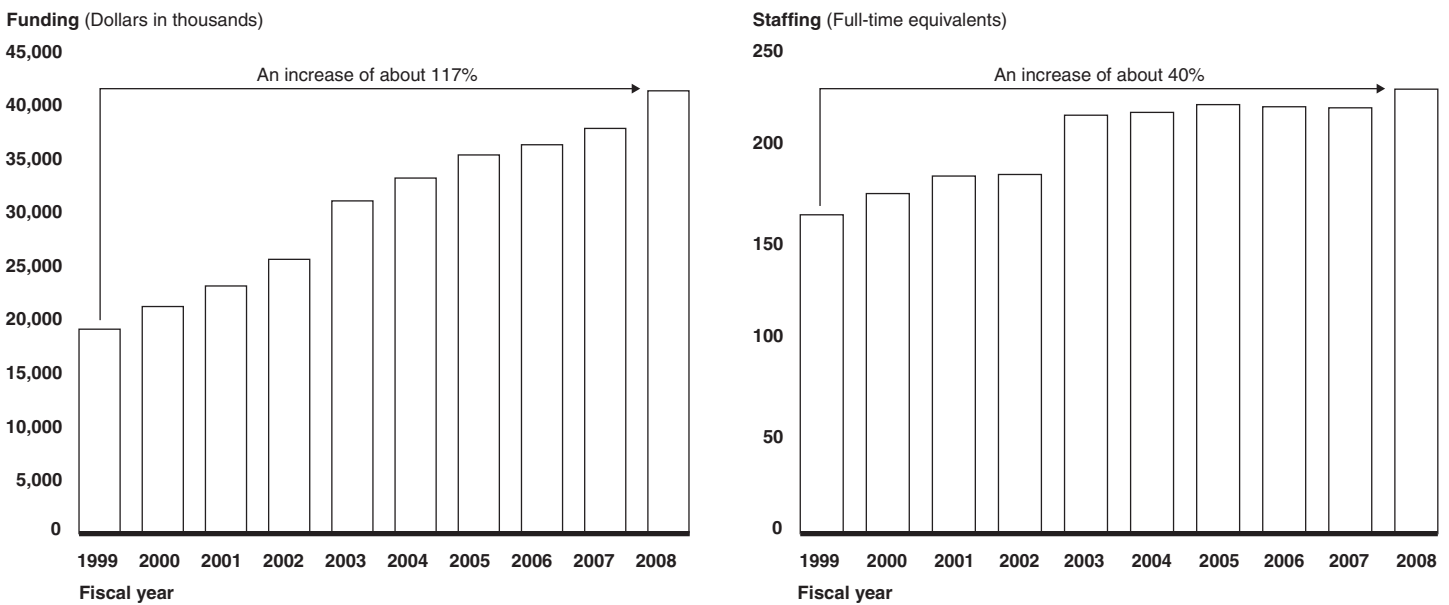
FDA's funding and staffing for OCI investigations increased from fiscal years 1999 through 2008. OCI's funding and staffing include funding and staffing for OIA.⁶³ OCI funding covers staff and operational expenses such as salaries, travel, and rent. Criminal investigator salaries comprise the largest component. In fiscal year 1999, OCI funding was about \$19 million. By fiscal year 2008, funding had increased to over \$41 million (see fig. 2). When adjusted for inflation, funding increased by about 73 percent over this 10-year period and in actual terms, the funding increased by about 117 percent (see app. II for inflation adjustments). OCI staffing has also grown—in fiscal year 1999 OCI had about 165 FTEs and staffing had increased to over 230 FTEs by fiscal year 2008, representing about a 40 percent increase. The largest increase in OCI's funding and staffing occurred between fiscal years 2002 and 2003; according to OCI's Director,

⁶²The number of active investigations includes cases that are ongoing at the end of a fiscal year regardless of when they were opened.

⁶³From fiscal years 1999 to 2002, OCI funding was used for OIA's staffing expenses, such as salary and benefits, because OIA agents were assigned from OCI. However, OCI funding was not used for OIA's operational expenses during this time because OIA was located within the Commissioner's Office. Funding for OIA's operational expenses constituted a small portion of OCI's overall funding between fiscal years 2003 and 2008; for instance, in fiscal year 2008, OIA's operational expenses accounted for less than 1 percent of OCI's overall funding.

this increase was the result of funding authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002,⁶⁴ which provided OCI additional resources to address potential terrorist threats in connection with FDA-regulated products.

Figure 2: Office of Criminal Investigations' Funding and Staffing Growth (Fiscal Years 1999 to 2008)



Source: GAO analysis of FDA data.

Note: Outlays are used to approximate funding. Outlays during a fiscal year may be for payment of obligations incurred in prior years (prior-year obligations) or in the same year. Outlays made during a fiscal year for prior-year obligations are generally made with prior-year appropriations. OCI's funding and staffing include funding and staffing for OIA.

⁶⁴Pub. L. No. 107-188, 116 Stat. 594.

OCI's Investigative Workload Increased from Fiscal Years 1999 to 2008

OCI's investigative workload—the number of opened, closed, and active investigations each year—generally increased annually from fiscal years 1999 to 2008.⁶⁵ The number of investigations that OCI opened each year generally increased. This number increased by 27 percent from fiscal year 1999 to 2008, from 370 to 471. OCI opened the largest number of investigations in fiscal year 2005—513 cases (see table 3). The number of closed investigations each year also generally increased during this time. It increased by 108 percent, from 201 to 418, and the number of cases that OCI's criminal investigators actively worked at the end of a fiscal year increased by 66 percent, from 655 to 1087, from fiscal year 1999 to 2008. OCI's workload data for cases opened in fiscal year 2008 show that most involved investigations of misbranded products, unapproved products, and product tampering.

Table 3: Office of Criminal Investigations' Investigative Workload Growth (Fiscal Years 1999 to 2008)

| Fiscal year | Opened investigations | Closed investigations | Active/ongoing investigations |
|---------------------------------|-----------------------|-----------------------|-------------------------------|
| 1999 | 370 | 201 | 655 |
| 2000 | 327 | 270 | 712 |
| 2001 | 334 | 291 | 755 |
| 2002 | 319 | 309 | 765 |
| 2003 | 394 | 326 | 833 |
| 2004 | 443 | 351 | 925 |
| 2005 | 513 | 401 | 1037 |
| 2006 | 390 | 420 | 1007 |
| 2007 | 425 | 398 | 1034 |
| 2008 | 471 | 418 | 1087 |
| Change from 1999 to 2008 | 27.3% | 108.0% | 66.0% |

Source: FDA data.

⁶⁵These numbers do not include OIA's workload. We also examined OIA's workload—the number of opened, closed, and active investigations each year—between fiscal years 1999 and 2008. OIA's workload remained fairly consistent over this 10-year period. On average, OIA opened about 97 investigations and closed about 99 investigations each year. The average number of active investigations between fiscal years 1999 and 2008 was about 27 each year.

Conclusions

Although OCI and OIA have policies that govern how they conduct investigations, FDA's oversight of these investigations has been limited. FDA has established a process to ensure compliance with OCI's policies, but it does not routinely carry out this process as only about 30 percent of the OCI field office assessments have been completed. OIA's process to ensure compliance depends on its manager rather than an external reviewer, that is, someone who is not directly involved in ongoing investigations. Without a review process and consistent implementation, FDA management cannot have reasonable assurance that OCI and OIA investigative policies and procedures are routinely followed and that deficiencies are promptly resolved when identified. This is particularly important because OCI does work that is different from much of the rest of FDA.

FDA management cannot determine whether OCI's criminal investigative program is achieving its goals—a key element of accountability—because OCI has not developed performance measures. Because FDA managers have somewhat different perspectives on how best to assess the performance of OCI's criminal investigative program, it is unclear how OCI and other FDA managers with oversight responsibility can strategically manage OCI's criminal investigative program to ensure that it is operating successfully. Assessing program results is especially important given that OCI appears to operate more autonomously than other units within FDA's regulatory office.

Recommendations for Executive Action

We recommend that the Secretary of HHS take the following three actions:

- To ensure OCI's compliance with investigative policies, instruct the Commissioner of FDA to have regular assessments of OCI's field offices conducted in accordance with its existing policy.
- To ensure OIA's compliance with investigative policies, instruct the Commissioner of FDA to establish a review procedure for the assessment of OIA's compliance with its investigative policies.
- To assess whether OCI's criminal investigative program is achieving its desired results, instruct the Commissioner of FDA to establish performance measures and assess program results against them.

Agency Comments and Our Evaluation

We provided a draft of this report to HHS for comment and received a written response, which is included in this report as appendix III. In its comments, HHS agreed with our three recommendations and described its planned steps to implement them. HHS also provided technical comments, which we incorporated as appropriate.

In its written comments, HHS described a new FDA internal committee to address OCI, the interaction between the OCI Director and ORA ACRA, and the interaction between the OCI Director and OIA manager. In August, 2009, the FDA Commissioner established an internal review committee—which includes representation from OCI and the Office of the Commissioner—to develop recommendations to improve FDA’s enforcement efforts and enhance the coordination, communication, and strategic alignment between OCI and other FDA components, such as ORA. In its comments, HHS stated that the agency believes better coordination and communication between OCI and others in ORA would improve the effectiveness of FDA’s overall regulatory and enforcement efforts, which includes the criminal investigative work of OCI. While the internal review committee has submitted its recommendations to the FDA Commissioner for consideration, they have not been implemented.

HHS also described in its written comments the interaction between the OCI Director and the ORA ACRA. HHS stated that the OCI Director reports directly to the ACRA and that the OCI Director meets weekly with the ACRA to discuss, among other things, OCI investigations. All of this information was included in our draft report. HHS also stated that the OCI Director and ACRA meet on an ad hoc basis as requested by either party and frequently communicate to discuss emerging activities. Further, HHS stated that the OCI Director attends regular ORA meetings. In our review of FDA’s oversight of OCI, we focused on OCI’s reporting of information within FDA. As we stated in the report, although the OCI Director communicates regularly with the ACRA, OCI is not required to report specific information to ORA or other FDA senior-level offices as part of its formal reporting relationship. HHS further stated that the types of regular interactions between the ACRA and OCI Director are generally the same as those between the ACRA and other ORA senior-level staff. Assessing the reporting relationships of FDA offices other than OCI was beyond the scope of our work. HHS commented that the ACRA conducts midyear and end-of-year performance reviews of the OCI Director. We added this information to the report.

In its written comments, HHS also described the interaction between the OCI Director and OIA manager. HHS stated that the OCI Director and OIA manager communicate about certain investigations, such as those that are high profile, and that the OIA manager reports directly to the OCI Director. This information was already included in our draft report. HHS stated that the OIA manager participates in all OCI management meetings and that the OCI Director and OIA manager recently initiated a regular monthly meeting to discuss OIA issues. HHS also noted that the OCI Director evaluates the performance of the OIA manager. We added information to the report on the recently initiated monthly meetings and also noted in the report that the OIA manager's performance is evaluated by the OCI Director.

HHS agreed with our three recommendations to strengthen its oversight of criminal and other investigations and described the steps it would take to implement them. Specifically, HHS stated that in order to ensure OCI's compliance with its investigative policies, ORA and OCI will allocate additional resources to comply with the time frames established in OCI's existing policy for conducting regular assessments of OCI's field offices. To ensure OIA's compliance with its investigative policies, OCI is developing a new written policy for conducting regularly scheduled assessments of OIA. Finally, HHS stated that OCI is developing performance measures to determine the extent to which OCI is achieving its desired results, as part of a new FDA-wide initiative.

As we agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the Commissioner of FDA and appropriate congressional committees. The report also will be available at no charge on the GAO Web site at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or crossem@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix IV.

Sincerely yours,

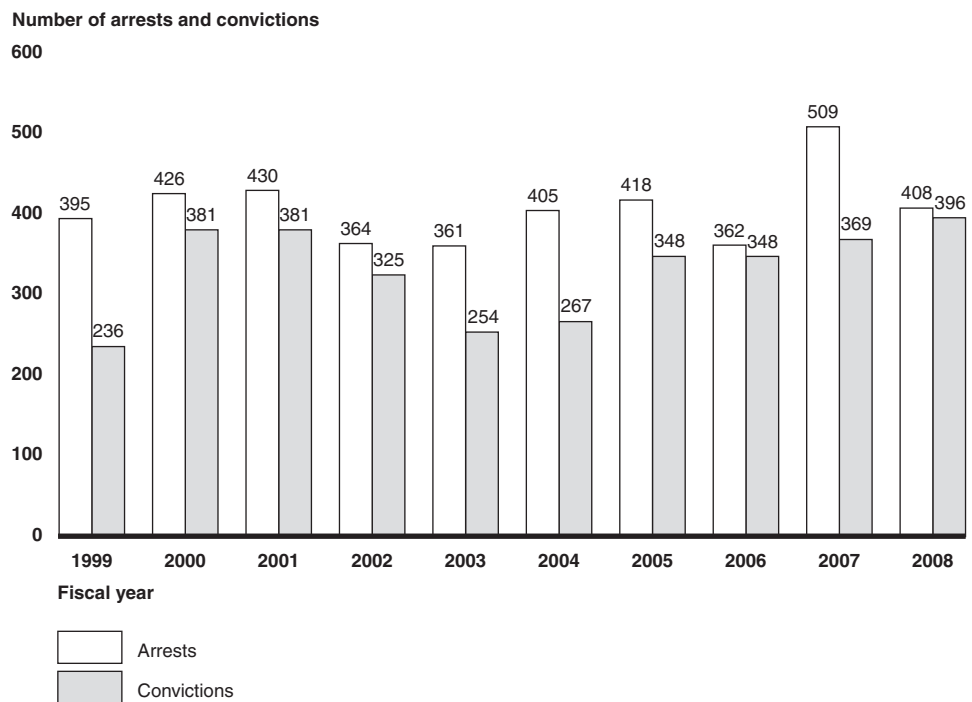
A handwritten signature in black ink that reads "Marcia Crosse". The signature is written in a cursive style with a long horizontal flourish at the end.

Marcia Crosse
Director, Health Care

Appendix I: Statistics from Investigations Involving the Office of Criminal Investigations

Figures 3 and 4 provide information on the statistics that the Office of Criminal Investigations (OCI) maintains about its investigations, which include arrests, convictions, fines and restitution, and assets forfeited/seized, since fiscal year 1999.

Figure 3: Number of Arrests and Convictions from Investigations Involving the Office of Criminal Investigations (Fiscal Years 1999 to 2008)



Source: FDA data.

OCI maintains statistics on the number of arrests and convictions resulting from both investigations it conducts independently and with other federal law enforcement agencies.¹ As shown in figure 3, the number of arrests and convictions has fluctuated somewhat since fiscal year 1999. The number of arrests ranged from 361 in fiscal year 2003 to 509 in fiscal year 2007. Over the 10-year period, the number of convictions has similarly

¹Statistics on arrests and convictions are maintained in OCI's Automated Investigative Management System (AIMS). According to Food and Drug Administration (FDA) officials, statistics on arrests and convictions for investigations that OCI worked independently are not easily or reliably retrievable in AIMS.

fluctuated, from a low of 236 convictions in fiscal year 1999 to a high of 396 in fiscal year 2008.

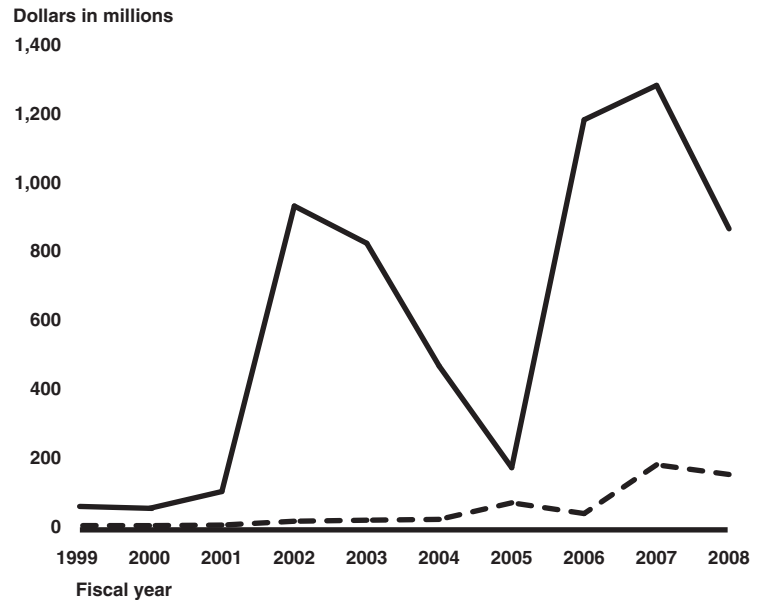
OCI also maintains statistics on the total amount of fines and restitution and assets forfeited or seized resulting from both investigations it conducts independently and with other federal law enforcement agencies.² Individuals convicted of a federal crime can be ordered by the court at sentencing to pay a fine or restitution and forfeited assets include seized and forfeited property such as cash, businesses, and real estate.³ While the total amount of court-ordered fines and restitution has fluctuated widely from year to year, since fiscal year 2001 the amount has exceeded the fiscal year 1999 level of \$56.5 million and the highest level—about \$1.3 billion—was in fiscal year 2007 (see fig. 4). The total amount of assets forfeited has generally increased from a low of \$ 0.7 million in fiscal year 2000 to a high of \$177.5 million in fiscal year 2007.

²Statistics on fines and restitution are included in AIMS. According to FDA officials, statistics on fines and restitution for investigations that OCI worked independently are not easily or reliably retrievable in AIMS. OCI accesses statistics on assets forfeited/seized from the Department of Justice Consolidated Asset Tracking System.

³Most criminal fine payments go to the Crime Victims Fund, which is used for grants to support victim assistance programs. See 42 U.S.C. § 10601. OCI participates in the Department of Justice Asset Forfeiture Program, which is intended to deter criminal activity by depriving criminals of property used or acquired through illegal activities. Most forfeiture proceeds are used to fund law enforcement activities. See 28 U.S.C. § 524 (c).

**Appendix I: Statistics from Investigations
Involving the Office of Criminal
Investigations**

Figure 4: Total Amount of Court-Ordered Fines and Restitution and Assets Forfeited/Seized from Investigations Involving the Office of Criminal Investigations (Fiscal Years 1999 to 2008)



| | | | | | | | | | | |
|-------------------------------|------|------|------|-------|-------|-------|-------|---------|---------|-------|
| — Fines/restitution | 56.5 | 50.8 | 99.8 | 929.4 | 821.1 | 464.1 | 169.1 | 1,180.0 | 1,280.0 | 863.2 |
| - - - Assets forfeited/seized | 0.9 | 0.7 | 2.3 | 13.5 | 16.5 | 18.9 | 67.0 | 35.8 | 177.5 | 149.3 |

Source: FDA data.

Appendix II: OCI Funding, Fiscal Years 1999 to 2008

Table 4: Food and Drug Administration Funding for the Office of Criminal Investigations, Actual and Inflation Adjusted to Fiscal Year 1999 Dollars (Fiscal Years 1999 to 2008)

| Fiscal year | Actual | Inflation adjusted |
|---------------------------------|---------------|---------------------------|
| 1999 | \$19,073,471 | \$19,073,471 |
| 2000 | 21,187,301 | 20,767,081 |
| 2001 | 23,104,835 | 22,124,445 |
| 2002 | 25,589,446 | 24,043,631 |
| 2003 | 31,040,799 | 28,587,184 |
| 2004 | 33,172,169 | 29,775,353 |
| 2005 | 35,328,057 | 30,725,678 |
| 2006 | 36,279,224 | 30,518,403 |
| 2007 | 37,802,938 | 30,952,200 |
| 2008 | 41,309,714 | 33,037,480 |
| Change from 1999 to 2008 | 116.6% | 73.2% |

Source: GAO analysis of FDA data.

Note: Outlays are used to approximate funding. Outlays during a fiscal year may be for payment of obligations incurred in prior years (prior-year obligations) or in the same year. Outlays made during a fiscal year for prior-year obligations are generally made with prior-year appropriations. The Office of Criminal Investigations' funding and staffing include funding and staffing for the Office of Internal Affairs.

Appendix III: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

JAN 7 2010

Marcia Crosse
Director, Health Care
U.S. Government Accountability Office
441 G Street N.W.
Washington, DC 20548

Dear Ms. Crosse:

Enclosed are comments on the U.S. Government Accountability Office's (GAO) report entitled: "Food and Drug Administration: Improved Monitoring and Development of Performance Measures Needed to Strengthen Oversight of Criminal and Misconduct Investigations" (GAO-10-221).

The Department appreciates the opportunity to review this report before its publication.

Sincerely,

A handwritten signature in black ink, appearing to read "Andrea Palm", written over a horizontal line.

Andrea Palm
Acting Assistant Secretary for Legislation

Enclosure

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: "FOOD AND DRUG ADMINISTRATION: IMPROVED MONITORING AND DEVELOPMENT OF PERFORMANCE MEASURES NEEDED TO STRENGTHEN OVERSIGHT OF CRIMINAL AND MISCONDUCT INVESTIGATIONS" (GAO-10-221)

The Office of Criminal Investigations (OCI) was established in 1992 to provide the Food and Drug Administration (FDA) with a specialized unit to conduct and coordinate criminal investigations of the Federal Food, Drug, and Cosmetic Act and other related laws. OCI is comprised primarily of Special Agents, many of whom have extensive prior Federal law enforcement experience and established professional contacts. Among the crimes OCI agents investigate are counterfeit, unapproved or illegally diverted drugs; product tampering and substitution; fraudulent health treatments; illegal off-label promotion; and fraud in product approval applications and clinical trials.

OCI has been successful in its declared mission "to conduct and coordinate investigations of suspected criminal violations ... and to collect evidence to support successful prosecutions." From 1992 until the end of fiscal year 2009, OCI obtained 4,392 convictions that resulted in the imposition of \$9.89 billion in fines and restitution and forfeited assets worth over \$1 billion.

Commissioner's OCI/Center Coordination and Alignment Review Committee

OCI has achieved a great deal of success during its relatively brief history; however, FDA Commissioner Dr. Margaret A. Hamburg believes that there are important opportunities for OCI and the Centers to enhance information sharing and develop strategic priorities to maximize public health impact and deterrence. In addition, Dr. Hamburg believes that there are opportunities to increase communication and coordination between the Office of Regulatory Affairs (ORA) district offices and OCI field offices, as well as between the Centers and OCI, which would improve enforcement efforts and enhance the effectiveness of each of these organizations.

Consequently, as we discussed during the Exit Conference, Dr. Hamburg created an internal FDA Committee in August 2009, which includes representation from interested FDA stakeholders, including the Centers, OCI, Office of the Chief Counsel (OCC), and the Office of the Commissioner. The Commissioner directed the Committee to examine opportunities and develop recommendations to enhance coordination, communication, and strategic alignment between OCI and other agency components. Dr. Hamburg specifically identified the following potential areas for enhanced coordination based, in part, on her conversations with OCI leadership and FDA's Center Directors:

- Development of shared strategic priorities based on a public health assessment of where patients and consumers are at greatest risk;
- Center and ORA Headquarters and field (district office) referral of potential cases based on evidence of suspected fraud or other criminal conduct;

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- OCI identification of areas where regulatory action or public health communication could prevent or minimize harm associated with products or activities that are ongoing; and
- OCI identification of critical information that could affect regulatory decision making.

The Committee and its working groups have met regularly throughout the fall, and have developed recommendations for the Commissioner's consideration. In addition, the Committee and its working groups have drafted Standard Operating Procedures and policy statements that will help facilitate the implementation of the Committee's recommendations. The Committee's findings and recommendations were presented to the Commissioner, and once implemented, they will improve FDA's enforcement efforts and enhance the coordination, communication, and strategic alignment between ORA, OCI, and the Centers.

OCI Interaction with Associate Commissioner for Regulatory Affairs (ACRA) and Office of Internal Affairs (OIA)

The OCI Director reports directly to the ACRA. The OCI Director has a regularly scheduled in-person one-on-one with the ACRA each week to exchange topical information related to OCI's/OIA's operational needs, initiatives, activities and upcoming actions. During these sessions, as with other senior ORA executives, there is an opportunity for a free exchange of issues and concerns as well as a discussion about ongoing initiatives and investigations within OCI/OIA. There are routine discussions about major agency initiatives as they may relate to OCI investigations or potential investigations. In addition to this weekly meeting, ad hoc meetings are also held between the OCI Director and the ACRA as requested by either party. Lastly the OCI Director and ACRA frequently communicate through email and phone calls regarding OCI emerging activities in which the ACRA or Commissioner may have an interest. The Director also attends the ORA weekly conference call with the ORA Headquarters and field staff as well as key ORA management conferences throughout the year. This process has been followed since the inception of OCI with each ACRA and has been effective for the needs and expectations of both OCI and ORA management. Generally, the interactions between the ACRA and the OCI Director are the same as the regular interactions that the ACRA has with other ORA senior executives.

There is also a face to face performance review at mid-year and end-of-year between the OCI Director and the ACRA where the SES plan elements are discussed and documented.

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: "FOOD AND DRUG ADMINISTRATION: IMPROVED MONITORING AND DEVELOPMENT OF PERFORMANCE MEASURES NEEDED TO STRENGTHEN OVERSIGHT OF CRIMINAL AND MISCONDUCT INVESTIGATIONS" (GAO-10-221)

The OCI Director receives all OIA case initiation reports for review and input. The OIA Special Agent in Charge (SAIC) confers with the Director on certain cases and matters which may be high profile or involve noteworthy issues. The Director and the OIA SAIC recently initiated a regular monthly meeting to discuss OIA issues. The OIA SAIC is a direct report to the Director of OCI and as such is rated based on the SAIC's established performance plan. The OIA SAIC participates in all OCI management meetings.

Responses to GAO Recommendations:

To ensure OCI's compliance with investigative policies, have regular assessments of OCI's field offices conducted in accordance with its existing policy

FDA Response

OCI acknowledges that limited resources and logistical issues have prevented it from complying with its existing policy to conduct regular assessments of its field offices. OCI will ensure compliance with its investigative policies and conduct assessments of its field offices in accordance with the schedule established in its current office assessment procedures. ORA and OCI will allocate additional resources to ensure that OCI has sufficient manpower to conduct regular assessments that comply with the timeframes in OCI's internal policy. The first round of assessments will begin in 2010.

To ensure OIA's compliance with investigative policies, establish a review procedure for the assessment of OIA's compliance with its investigative policies

FDA Response

OCI is developing a new written policy to conduct regularly scheduled assessments of OIA's compliance with its investigative policies.

To assess whether OCI's criminal investigative program is achieving its desired results, establish performance measures and assess program results against them

FDA Response

We agree with GAO's recommendation and are working to develop meaningful performance measures to determine the extent to which OCI is achieving its desired results. OCI is developing program performance measures as part of a new FDA-wide initiative called FDA-TRACK. This initiative is focused on developing meaningful measures at the program office level and tracking those measures on a monthly basis. The measures and results will be reviewed with FDA's senior leadership on a quarterly basis to assess how well each program office is progressing towards achieving its desired

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PERFORMANCE MEASURES NEEDED TO STRENGTHEN OVERSIGHT OF
CRIMINAL AND MISCONDUCT INVESTIGATIONS" (GAO-10-221)**

goals. FDA-TRACK is currently being piloted and is scheduled for a public roll-out in the spring of 2010.

We believe that OCI's participation in FDA-TRACK, coupled with strategic program reviews and targeted process improvements, will significantly improve OCI's ability to measure its performance and demonstrate achievement of its desired results.

Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact

Marcia Crosse, (202) 512-7114 or crossem@gao.gov

Acknowledgments

In addition to the contact named above, Thomas Conahan, Assistant Director; Pamela Dooley; Cathy Hamann; Thomas Han; Jennel Harvey; Eagan Kemp; and Lisa Motley made key contributions to this report.

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