

United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

June 5, 2008

Via Electronic Transmission

Mr. Gene Dodaro
Acting Comptroller General of the United States
Government Accountability Office
Washington, DC 20548

Dear Acting Comptroller General Dodaro:

The Food and Drug Administration (FDA/Agency) established the Office of Criminal Investigations (OCI) in 1992 following the generic drug scandal and in response to growing concern about criminal violations of laws enforced by the FDA, including prescription drug counterfeiting, new drug application fraud, and product tampering. The mission of OCI includes developing, coordinating, and implementing Agency policy related to criminal investigations, investigating potential criminal violations, and making recommendations on referral of cases for further investigation and/or prosecution.

The enforcement of FDA laws is critically important to the safety and security of our country's pharmaceutical products, thus the work of OCI and its Office of Internal Affairs (OIA) must be effective, efficient, and conducted in accordance with, among other things, proper investigative procedures. Over the past year, however, I have received complaints and independently identified concerns regarding the operation and activities of OCI. The complaints were received from various sources alleging that, at times, OCI used improper investigative techniques, including abusive tactics and the collection of false information to incriminate suspects under investigation.

Therefore, I am asking that the GAO review the activities and operations of OCI/OIA to determine, among other things, if the organization is operating effectively and efficiently. In addition, I can make available to the GAO a set of responses submitted by the FDA to follow-up questions posed to Mr. Terrell L. Vermillion, Director of OCI. These questions were prepared by Committee on Finance (Committee) staff subsequent to conducting an interview of Mr. Vermillion related to the Committee's investigation of the antibiotic Ketek. A review of Mr. Vermillion's responses raises a number of serious questions regarding the operation of the OCI/OIA. These questions range from OCI's lack of formal written policies on a number of matters to its decision to perform no follow-up on matters it refers to FDA's respective centers.

Perhaps most troubling to me is the fact that during the course of the investigation into Dr. Victoria Hampshire, Committee staff determined that OIA employees prepared a criminal referral that was riddled with factual errors. This finding merits an in-depth review regarding, among other things, the level of due diligence conducted by OCI/OIA prior to making a criminal referral.

For your review and future reference is a copy of my February 6, 2008 letter to the FDA and the Department of Health and Human Services summarizing the findings of my Dr. Victoria Hampshire investigation which is available at <http://finance.senate.gov/sitepages/grassley.htm>. Please refer specifically to pages 17 and 18.

Additionally, I have become concerned regarding the relationship between OCI/OIA and the Center for Drug Evaluation and Research. FDA said that it is working to improve communications between OCI and the Center for Drug Evaluation and Research and I would like you to examine those efforts.

In addition, I would like GAO to conduct a programmatic review of the operation of OCI/OIA, including but not limited to a review of the investigative standards and techniques used. In addition, I would like GAO to review the process for receiving and acting upon allegations of wrongdoing, the investigative process including the reporting of completed investigations, the case files for investigative evidence, the OCI/OIA budgets and use of FDA funds, and the accomplishments reported by OCI/OIA over the past five years.

Furthermore, I would like you to examine the pay for OCI/OIA agents for FY 2006 and FY 2007. For each agent identified, please be sure to identify the respective:

1. pay grade;
2. salary;
3. overtime;
4. bonuses;
5. awards; and
6. travel expenses.

And for FY 2006 and FY 2007, I would also like to learn the following about practices and expenses at OCI:

1. Number of hours OCI agents logged against each particular case;
2. Amounts paid from central funds for OCI leased office space; and
3. Amount of money OCI has recovered for its budget from sharing in fines or forfeitures. And for each case, please identify:
 - a. Name of the case;
 - b. Amount recovered from each case; and
 - c. Where the asset forfeitures went.

Should you have any questions regarding this request, please do not hesitate to contact Paul Thacker of my staff at (202) 224-4515. All documents responsive to this request should be sent electronically, on a disc, in searchable PDF format to Brian_Downey@finance-rep.senate.gov.

Sincerely,



Charles E. Grassley
Ranking Member