DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

MAR 23 2007

The Honorable Joe Barton
Ranking Member, House Committee on Energy and Commerce
House of Representatives
Washington, DC 20515

Dear Mr. Barton:

In light of the jurisdiction and important work of the Committee on Energy and Commerce, as well as the keen interest you personally have taken in conflict-of-interest issues over the years, I wanted to take the opportunity to inform you of several initiatives that the Office of Inspector General (OIG) at the Department of Health and Human Services (HHS) has undertaken to further enhance its work in this important area. As evidenced through our body of conflict of interest oversight and investigation work over the past 20 years, OIG has demonstrated its belief that it is vital that Department officials conduct their official duties in a manner that does not result in personal benefit or financial gain. The American public must have confidence that important decisions made by Government officials are based on merit and are free of improper influence through questionable or improper relationships with the industry that they regulate and/or with which they conduct business.

Throughout most of OIG's history, allegations of criminal misconduct—including violations of the criminal ethics statutes—have been investigated in the regional offices of OIG's Office of Investigations (OI). Prior to 2000, OIG found that ethics cases were not typically a priority with United States Attorneys Offices; therefore, those cases that were ultimately prosecuted generally involved only the most egregious conduct or the most senior officials of the Department. A notable example was the investigation and subsequent prosecution of the Department's former Chief of Staff, who was convicted on conflict-of-interest charges in 1987 and served 4 months in prison for using his official position to promote a company of which he was the director.

OIG's ability to attract Department of Justice interest in conflicts cases evolved in 2000, when OIG successfully pursued a major conflict-of-interest case against a former official of the Centers for Disease Control and Prevention (CDC). It was alleged that this official, a former Commissioned Corps officer in charge of CDC's HIV program, had persuaded the agency to fund certain expenses for a clinical trial of an AIDS vaccine that had been developed by a biotech firm with which he was negotiating for future employment. OIG's 2-year investigation resulted in the employee's pleading guilty in February 2002 to violating 18 U.S.C. § 208 and being fined $32,500.

Since 2000, OIG has managed a significant caseload of conflict-of-interest matters. In an effort to streamline the handling of sensitive cases, including criminal conflict-of-interest matters that meet certain criteria, in 2004 OIG established a Special Investigations Unit (SIU) within the OI.[1]

Staffed by five criminal investigators, the SIU is dedicated exclusively to handling sensitive and complex internal investigations of alleged criminal misconduct by HHS employees. The conflict-of-interest caseload of the SIU has increased dramatically since its establishment in 2004; the number of conflict-of-interest cases under investigation tripled between 2005 and 2006.

The efforts of the SIU were critical in a recent high-profile conflict-of-interest case involving the former FDA Commissioner.[2] The FDA investigation focused on the former Commissioner's false reporting that he had sold stock in companies regulated by FDA when in fact he continued to hold shares in those firms. He entered guilty pleas to two criminal charges for false writings and conflict-of-interest. He was recently fined approximately $90,000, received 3 years of supervised probation, and was ordered to perform 50 hours of community service.

In addition, over the past 6 months, the SIU has taken the lead in coordinating a review of potential conflict-of-interest cases within NIH. The review was generated by a written request from the Committee to several large pharmaceutical companies to provide the names of NIH employees with whom the company had consulting or business relationships. The SIU met with officials from the Office of Management Assessment (OMA) at NIH and concluded that potential conflict-of-interest concerns existed with 103 NIH employees. The SIU and OIG ethics attorneys are presently examining these cases to determine whether investigation is warranted.

The SIU has also been instrumental in increasing outreach to the Operating Divisions (OPDIVS) within the Department. On a monthly basis, the Director of SIU meets with representatives from FDA, Office of Criminal Investigations, Office of Internal Affairs,

---

[1] SUI will investigate matters involving the following: (1) employees who are GS-15 or higher; (2) law enforcement officers; (3) allegations involving pornography; and (4) computer intrusions.

[2] OI's Region III also handled a high-profile case involving an NIH senior scientist. The Chief of the Geriatric Psychiatry Branch at NIH was charged on December 4, 2006, with a conflict-of-interest violation relating to his alleged acceptance of $285,000 in consulting fees and additional travel expenses from a drug company without the required disclosure to and approval of NIH officials.

to discuss individual cases and referrals. Similarly, the SIU Director meets quarterly with other Departmental components, such as the NIH Police and the Centers for Medicare & Medicaid Services, to ensure efficient identification and appropriate referrals of conflict-of-interest and related investigations.

OIG has also initiated efforts to improve the referral of conflict-of-interest cases from the OPDIVs to OIG. In October 2006, the SIU developed a referral form entitled "Referral of Potential Criminal Conflict-of-interest or Ethics Violations," a copy of which is enclosed. This new form serves two functions. First, it enables OIG investigators and attorneys to quickly determine whether a potential criminal violation exists and to return noncriminal matters to the OPDIV for timely administrative followup. Second, the requested information will assist OIG in conducting efficient investigations and ensuring that Special Agents have the basic documentation necessary for meaningful and expeditious consultation with the Department of Justice or a local United States Attorney, as required by law.

After receiving several referrals utilizing this form, OI has determined that its use results in an improved referral. OIG recently provided the form to the Department's Office of the General Counsel (OGC) for distribution and use throughout the Department.

OIG is also sponsoring a Conflict-of-Interest Summit on May 30, 2007, in Washington, DC. Attendees will include employees from throughout the Inspector General community who are involved in the investigation and oversight of conflict-of-interest issues. In addition, representatives from the Department of Justice, Public Integrity Section, and the Office of Government Ethics will be in attendance. This Summit will provide an opportunity for a robust discussion of conflict-of-interest issues among those Federal agencies with responsibility for Government ethics policy, oversight, and enforcement.

In addition to conducting investigation activities, OIG has devoted resources to conducing audits and evaluations related to ethics enforcement and oversight, including conflict-of-interest issues.

OIG has recently begun a review of the way in which NIH oversees conflict of interest on the part of its grantees. Because the majority of NIH appropriated funds are distributed to NIH grantees who undertake extramural research and these extramural researchers are not covered by the Federal ethics rules that apply to NIH intramural researchers, OIG determined that this project was an important next step in examining NIH conflict of interest. This study will determine the extent to which the NIH oversees grantee institution's financial conflict-of-interest issues.

OIG is also in the very early stages of a review of the operations of the NIH Division of Program Integrity within the OMA, OGC ethics staff located at NIH, and the Ethics Office within the Office of the Director. This study will evaluate the effectiveness of NIH's conflict-of-interest policies, procedures, and internal oversight mechanisms. OIG expects to issue a draft report in early 2008.

With respect to FDA, our FY 2007 work plan includes a study designed to assess the nature of financial interests disclosed by clinical investigators to FDA; the extent to which drug, biologic, and device applicants monitor their clinical investigators for conflicting financial interests; and the extent to which FDA monitors the financial interests disclosed by clinical investigators. Because of resource constraints and the identification of new work determined to be of a higher priority (e.g., the study referenced above), OIG will not be starting this review in FY 2007.

We will keep you and your staff informed as developments warrant. OIG understands the value and importance of its conflict-of-interest oversight role and will continue to focus on this important area. Identical letters have been sent to several other Members of Congress.

Should you have any questions about our ongoing initiatives or prior work, please contact me or your staff may call Claire Barnard, Director of External Affairs, at 202-205-9523.

Sincerely,

Daniel R. Levinson

Daniel R. Levinson
Inspector General

Enclosure

US Department of Health & Human Services
Office of Inspector General
Referral of Potential Criminal Conflict of Interest or Ethics Violations

REFERRING INFORMATION:

Referring Party Name:	Referring OPDIV:
Referring Office Name :	Office Phone:

EMPLOYEE/CONTRACTOR INFORMATION:

Subject Full Legal Name:		Position/Title/Series & Grade:
DOB:	OPDIV/Branch/Agency:	Social Security Number:

ALLEGATION INFORMATION: (Provide brief summary of each violation)

Check ☑ alleged violation(s).

☐ **Violation of Criminal Ethics Statutes**	Description: (Please cite specific statute):
☐ **Criminal Violation of Standards of Ethical Conduct**	Description: (Please cite specific standard):
☐ **Department Policy Violation**	Description (Please cite specific HHS-wide policy):
☐ **OPDIV Policy Violation**	Description (Please cite specific ODPIV policy):
☐ **Other Government Regulation**	Description (Please cite specific regulation):

US Department of Health & Human Services
Office of Inspector General
Referral of Potential Criminal Conflict of Interest or Ethics Violations

Please submit the following documents as applicable or provide a brief explanation of why they are not being submitted.

For the relevant time period.

☐	Position Description
☐	Performance Plan & Evaluation
☐	HHS 520: Request for Approval of Outside Activity
☐	SF278 / SF450: Public Financial Disclosure / Confidential Financial Disclosure report
☐	Copy of OPDIV/Branch/Agency/Institute policy governing violation(s)
☐	Copies of prepared reports/memorandums regarding interviews/meetings with the referred employee/contractor.
☐	Copies of any electronic mail messages or other correspondence relating to this matter
☐	Copy of the incoming allegation
☐	Copies of certificates or other evidence of all relevant ethics and/or conflict of interest training received by employee/contractor

Any Additional Remarks/Information:

Directions: Please complete this form and submit all of the information requested for each person(s) involved in the matter that you are forwarding to OIG for review. Only one (1) employee/contractor per form.

Please submit to:

Director, Special Investigations Unit
DHHS/OIG/OI/SIU
Wilbur J. Cohen Building
330 Independence Avenue, SW
Room # 5409
Washington, DC 20201

The Department's General Administrative Manual (5-10-20) requires that allegations of potential criminal conduct by HHS employees be referred to the OIG. OPDIVS may choose to refer non-criminal violations to the OIG as they deem necessary. In referring such non-criminal conflict of interest or ethics matters, this form may also be utilized.