OIG Reports $20.97 Billion in Savings and Recoveries in FY 2009

In its Semiannual Report to Congress, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) today announced significant audit, investigation, and evaluation accomplishments for the second half of fiscal year (FY) 2009 (April 1, 2009-September 30, 2009) and for FY 2009 in total. OIG reported savings and expected recoveries of $20.97 billion for all of FY 2009.

Specifically, OIG’s $20.97 billion in savings and expected recoveries includes $16.48 billion in implemented recommendations to put funds to better use, $4 billion in investigative receivables, and $492 million in audit receivables.

"We continue to make significant progress in our fight against fraud, waste, and abuse in HHS programs, particularly Medicaid and Medicare," said Inspector General Daniel R. Levinson. "We’re doing this by leveraging our audit, legal, evaluation, and investigative tools, as well as employing the latest in data analysis technology. But the results we’ve achieved are due primarily to the hard work of our professional staff and effective collaboration with our government partners. We will remain aggressive in our mission to protect the integrity of these vital programs."

Additionally, in FY 2009, OIG excluded 2,556 individuals and organizations from participation in Federal health care programs. OIG also reported 671 criminal actions against individuals or organizations that engaged in crimes against HHS programs and 394 civil actions, including False Claims Act and unjust enrichment suits filed in Federal district court, Civil Monetary Penalties Law (CMPL) settlements, and administrative recoveries related to provider self-disclosure matters.

Significant OIG accomplishments during the semiannual reporting period include the following:

**Medicare Fraud Strike Force Operations Lead to Sentencing of Seven Miami-Area Residents in Medicare Infusion Fraud Scheme**

Seven employees of a Miami infusion clinic were ordered to pay $19.8 million in restitution and sentenced to prison terms ranging from 37 to 97 months. In their guilty pleas, the individuals admitted to activities including manipulating patients’ blood samples to generate false medical records, ordering and administering medications to treat conditions that were falsely documented with fraudulent test results, and billing Medicare for services that were medically unnecessary or never provided.
This operation was conducted by the Medicare Fraud Strike Force, a key component of the joint HHS-Department of Justice Health Care Fraud Prevention and Enforcement Action Team, known as HEAT. During the reporting period, Medicare Fraud Strike Force investigations resulted in the filing of charges against 138 individuals or entities, 44 convictions, and $40.7 million in investigative receivables.

State and Local Pandemic Influenza Preparedness

During this semiannual period, we issued two reports related to States’ and localities’ pandemic influenza preparedness. Our key findings include the following:

■ In one review we found that although the majority of selected localities had begun planning to distribute and dispense vaccines and antiviral drugs, more needs to be done to improve localities’ ability to respond to an influenza pandemic. Specifically, in their preparedness plans, selected localities had not addressed most of the vaccine and antiviral drug distribution and dispensing preparedness items identified in HHS guidance. Further, although all of the selected localities conducted exercises related to vaccine and antiviral drug distribution and dispensing, most did not create after-action reports and improvement plans for these exercises. (OEI-04-08-00260)

■ In a second review, we found that although selected States and localities are making progress in preparing for a medical surge, they need to do more to improve their ability to respond to an influenza pandemic. Specifically, fewer than half of the selected localities had started to recruit the medical volunteers required to respond to a medical surge, and none of the States reviewed had implemented electronic systems to manage volunteers. Moreover, although all of the selected localities had acquired limited medical equipment for a pandemic, only three of the five States had electronic systems to track beds and equipment. Also, most of the selected localities had not identified guidelines for altering triage, admission, and patient care during a pandemic. (OEI-02-08-00210)

Pfizer Inc. Enters Into Settlement for Marketing and Promotion Practices

Pfizer Inc. entered into a $1 billion civil False Claims Act settlement with the United States in connection with Pfizer's marketing and promotion practices associated with the anti-inflammatory drug Bextra and several other drugs. The settlement agreement is part of a global criminal, civil, and administrative settlement with Pfizer and its subsidiary, Pharmacia & Upjohn Company, Inc., which also includes a comprehensive 5-year corporate integrity agreement (CIA) between Pfizer and OIG.

[NOTE TO EDITORS: Pfizer and Pharmacia & Upjohn agreed to pay a total of $2.3 billion in this case, the largest health care fraud settlement in history, to resolve both the civil and criminal liability arising from the illegal promotion of certain pharmaceutical products. The criminal portion of the settlement is not included in this semiannual report because it became effective after September 30, 2009.]

Medicaid Personal Care Claims Made by Providers in New York City

We estimated that New York State improperly claimed $275.3 million in Federal Medicaid reimbursement for some personal care claims submitted by providers in New York City during calendar years 2004 through 2006. The improper claims occurred because the State did not adequately monitor New York City’s personal care services program for compliance with
Federal and State requirements. We recommended that the State refund $275.3 million, work with the Centers for Medicare & Medicaid Services to resolve two Consumer Directed Personal Assistance Program (CDPAP) claims, improve its monitoring of New York City’s personal care services program, and promulgate specific regulations related to CDPAP claims. The State disagreed with our first recommendation and with several of our findings. (A-02-07-01054)

**Barriers to the Food and Drug Administration’s Response to Food Emergencies**

In two reviews, we addressed the Food and Drug Administration’s (FDA) responsibilities for overseeing the safety of food in both the human and pet food supply.

- In one review, OIG found that in the event of a food emergency, FDA would likely have difficulty tracing food products through the food supply chain. We were able to trace only 5 of the 40 products reviewed through each stage of the food supply chain. For 31 of the 40 products, we could identify the facilities that likely handled the products, and for the remaining 4 products, we could not identify the facilities. Furthermore, 59 percent of the facilities reviewed did not meet FDA’s requirements to maintain records about their sources, recipients, and transporters, and 25 percent were not aware of these requirements.

We recommended, among other things, that FDA consider seeking additional statutory authority to strengthen its lot-specific information requirements and to request facilities’ records at any time. We also recommended that FDA work with the industry to develop needed guidance and that FDA address issues related to mixing raw food products from a large number of farms. FDA agreed to consider these recommendations. (OEI-02-06-00210)

- In the second review, we found that FDA did not have statutory authority to require pet food manufacturers or importers to initiate recalls of contaminated food or to assess penalties for recall violations. Furthermore, FDA’s existing regulations were issued as nonbinding recall guidance for firms. We found that FDA’s lack of authority, coupled with its sometimes lax adherence to its recall guidance and internal procedures, limited FDA’s ability to ensure that contaminated pet food was promptly removed from retailers’ shelves. Our report contained detailed recommendations for strengthening FDA’s recall authority and improving its monitoring of recalls. FDA agreed or agreed in principle with all of our recommendations. (A-01-07-01503)

**Nursing Home Executive Agrees to Permanent Exclusion**

The President and Chairman of the Board of Pleasant Care Corporation (Pleasant Care), Emmanuel Bernabe, agreed to be permanently excluded from Federal health care programs following an investigation of substandard care at nursing homes formerly operated by Pleasant Care. OIG alleged that Bernabe, through his management and oversight of Pleasant Care, caused services to be furnished to Pleasant Care residents that substantially departed from the professional standard of care. For example, Pleasant Care failed to maintain adequate staffing levels, properly administer medication, provide adequate hydration and nutrition, and prevent accidents.