

Office of Inspector General Update

**14th Annual Pharmaceutical Regulatory and
Compliance Congress and Best Practices Forum
October 28, 2013**

**Mary E. Riordan, Senior Counsel
Office of Counsel to the Inspector General**

Agenda for Today

- Three main topics:
 - Update on OIG enforcement activity
 - Update on OIG reports
 - Lessons/Suggestions for the future

Agenda for Today

- Enforcement Activity:
 - False Claims Act civil settlements
 - Global resolutions (civil and criminal)
 - OIG administrative actions
 - Affirmative actions
 - Derivative exclusion actions

False Claim Act and Global Settlements

- Recent settlements with drug and device companies addressed:
 - Off-label/ improper promotion
 - Kickback issues
 - Price reporting issues
 - “Other” issues

False Claim Act and Global Settlements

- Off-label/improper promotion case examples:
 - Wyeth/Pfizer – July 2013
 - ISTA Pharmaceuticals – May 2013
 - Par Pharmaceutical – March 2013
 - Amgen – Dec. 2012
 - Boehringer Ingelheim – Oct. 2012

False Claim Act and Global Settlements

- Kickback case examples:
 - Amgen – July 2013 and April 2013
 - Mallinckrodt – July 2013
 - Int'l Nephrology Network- Dec. 2012
 - Victory Pharma – Dec. 2012
 - Blackstone Medical – Nov. 2012
 - Sanofi U.S. companies – Dec. 2012
 - TransS1 – July 2013
 - C.R. Bard – May 2013

False Claim Act and Global Settlements

- Drug price reporting allegations were included in:
 - Amgen settlement – Dec. 2012
 - Sanofi settlement – Dec. 2012

False Claim Act and Global Settlements

- Cases with “other” types of allegations:
 - Guidant/Boston Scientific – Oct. 2013
 - Ranbaxy – May 2013
 - Healthpoint – Dec. 2012

OIG Enforcement Activity

- Affirmative cases
 - Exclusion case – Thomas Valentine
 - CMP case – Paul Lux, M.D.
- Derivative exclusion cases
 - W. Scott Harkonen, M.D.
 - Former executives of Purdue Frederick

Recent OIG Reports

- **Drug reimbursement/expenditure reports:**
 - “Medicare Could Collect Billions if Pharmaceutical Manufacturers Were Required to Pay Rebates for Part B Drugs” – Sept. 2013 (OEI-12-12-00260)
 - “Medicaid Drug Pricing in State Maximum Allowable Cost Programs” – Aug. 2013 (OEI-03-11-00640)
 - “Comparison of Average Sales Prices and Average Manufacturer Prices: An Overview of 2011” – Jan. 2013 (OEI 03-12-00670)
 - “Oklahoma Complied with Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs” – Sept. 2013 (A-06-12-00059)
 - “Least Costly Alternative Policies: Impact on Prostate Cancer Drugs Covered under Medicare Part B” – Nov. 2012 (OEI-12-12-00210)

Recent OIG Reports

- Reports relating to FDA/medical device issues:
 - “FDA’s Clearance of Medical Devices through the 510(k) Process” – Sept. 2013 (OEI-04-10-00480)
 - “FDA Lacks Comprehensive Data to Determine Whether Risk Evaluation and Mitigation Strategies Improve Drug Safety” – Feb. 2013 (OEI-04-11-00510)

Recent OIG Reports

- Issues in the news recently:
 - “Spinal Devices Supplied by Physician-Owned Distributors: Overview of Prevalence and Use” – Oct. 2013 (OEI-01-11-00660)

Lessons/Suggestions

- Lessons from law enforcement activities
 - Think about kickback risks – why?
 - Relatively large number of recent settlements involving kickback issues
 - Multi-source focus on the issue
 - Sunshine reporting begins soon

Lessons/Suggestions

- Lessons from law enforcement activities
 - Reassess kickback risks in:
 - Payments to HCPs for entertainment, travel, meals
 - Common types of arrangements with HCPs (e.g., speaker programs, consulting arrangements)
 - Financial arrangements with purchasers and recommenders

Lessons/Suggestions

- Lessons from law enforcement activities
 - Promotional activities need continued scrutiny
 - What types of messages are being conveyed about products?
 - Research and publication activities are important
 - Communications with FDA are important
 - Drug price reporting and Medicaid rebate issues need continued scrutiny

Lessons/Suggestions

- Lessons from recent CIAs:
 - Financial incentives for individuals are a continued focus
 - Executive recoupment programs
 - Incentive compensation for sales representatives

Lessons/Suggestions

- **Lessons from recent CIAs:**
 - Risk assessment/mitigation programs are recommended
 - Recent CIAs require risk assessment/mitigation programs, but allow variability in implementation
 - Meaningful monitoring is essential
 - Flexibility in CIA monitoring requirements
 - Goal = maximize the value of monitoring/auditing

