

Office of Inspector General Update

**15th Annual Pharmaceutical Regulatory and
Compliance Congress and Best Practices Forum
November 3, 2014**

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Agenda for Today

- Three main topics:
 - Update on OIG enforcement activity
 - Update on OIG reports and bulletins
 - Lessons/suggestions for consideration

Agenda for Today

- Enforcement Activity:
 - Global resolutions (civil and criminal)
 - False Claims Act civil settlements
 - Criminal matters



False Claim Act and Global Settlements

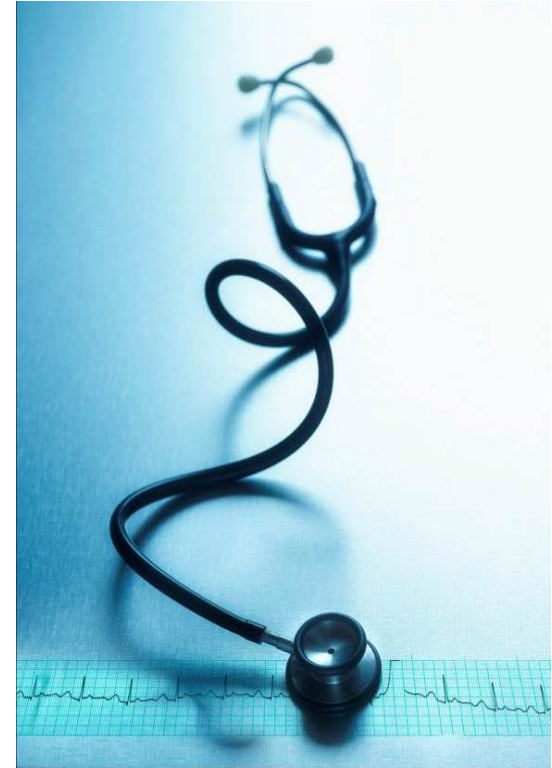
- Settlements addressed a variety of issues:
 - Off-label/ improper promotion
 - Kickback issues
 - “Other” issues
 - Billing issues
 - Shipping issues
 - Unapproved foreign drug issues

False Claim Act and Global Settlements

- Global resolutions:
 - Johnson & Johnson
 - \$2.2 billion, Nov. 2013
 - Endo Pharmaceuticals and Endo Health Solutions
 - \$192.7 million, Feb. 2014

False Claim Act and Global Settlements

- Improper promotion cases:
 - Shire Pharmaceuticals
 - Sept. 2014
 - Astellas Pharma USA
 - April 2014
 - Genzyme Corp.
 - Dec. 2013



False Claim Act and Global Settlements

- Kickback- related cases :
 - Teva Pharmaceuticals USA, Inc. and IVAX LLC – March 2014
 - Abbott Laboratories – December 2013
 - Biomet Companies – October 2014
 - Medtronic, Inc. - May 2014
 - CareFusion, Corp. – January 2014

False Claim Act and Global Settlements

- Cases with “other” issues:
 - McKesson Corp. – Aug. 2014
 - Shipping/distribution issues
 - EndoGastric Solutions Inc. – Feb. 2014
 - Billing issues
 - Cases involving unapproved foreign drugs

OIG Reports

- Reports relating to Medicare drug reimbursement:
 - “Comparing Average Sales Prices and Average Manufacturer Prices for Medicare Part B Drugs: An Overview of 2012” – March 2014 (OEI-03-13-00570)
 - “Limitations in Manufacturer Reporting of Average Sales Price Data for Part B Drugs” – July 2014 (OEI-12-13-00040)

OIG Reports

- Reports relating to Medicare drug reimbursement:
 - “Compounded Drugs under Medicare Part B: Payment and Oversight” – April 2014 (OEI-03-13-00270)
 - “Update: Medicare Payments for End Stage Renal Disease Drugs” – March 2014 (OEI-03-12-00550)

OIG Reports

- Reports relating to the Medicaid Drug Rebate Program:
 - Reviews of the collection of Medicaid rebates for physician-administered drugs – DC, NE, MD, OR, ID
 - “Average Manufacturer Price Determinations by Selected Drug Manufacturers Generally Were Consistent with Federal Requirements”
– June 2014 (A-06-13-00014)

OIG Reports

- Reports relating to the Medicaid Drug Rebate Program:
 - “Medicaid Drug Rebate Dispute Resolution Could Be Improved” – Aug. 2014 (OEI-05-11-00580)

OIG Reports

- Other reports of interest:
 - “Contract Pharmacy Arrangements in the 340B Program” – Feb. 2014
(OEI-05-13-00431)
 - “Drug Compendia Publishers Maintain Transparent Processes for Evaluating Anticancer Drug Therapies and Identifying Potential Conflicts” – Oct. 2014
(OEI-07-13-00220)

OIG Reports and Bulletins

- New and Noteworthy:
 - “Manufacturer Safeguards May Not Prevent Copayment Coupon Use for Part D Drugs” – Sept. 2014 (OEI-05-12-00540)
 - Special Advisory Bulletin: Pharmaceutical Manufacture Copayment Coupons – Sept. 2014
 - Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs – May 2014



Lessons/Suggestions

- Kickbacks are an issue
 - Think about kickback risks associated with financial relationships



Lessons/Suggestions

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

Lessons/Suggestions

- Continue to Monitor:
 - Promotional activities
 - Drug price reporting activities
 - Medicaid rebate issues



Lessons/Suggestions

- Lessons from recent CIAs:
 - Top-level involvement in compliance is necessary/important
 - Financial incentives for individuals need scrutiny

Lessons/Suggestions

- Lessons from recent CIAs:
 - Risk assessment and mitigation programs are important
 - Meaningful monitoring is essential
- Compliance programs should continually evolve

Lessons/Suggestions

- Key question: Is your compliance program effective?



