

# Office of Inspector General Update

**16th Annual Pharmaceutical Regulatory and  
Compliance Congress and Best Practices Forum  
October 21, 2015**

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Office of Counsel to the Inspector General**

# Agenda for Today

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

# Issues in Recent Settlements

- Settlements addressed a variety of areas:
  - Kickback issues
  - Marketing issues
  - Other issues:
    - Medicaid drug rebate program issues
    - Unapproved foreign drug issues
  - Late reporting of drug pricing information

# False Claim Act Settlements

- Kickback settlements:
  - Daiichi Sankyo, Inc.
  - AstraZeneca LP
  - Medco Health Solutions Inc.
  - PharMerica Corp.
- Marketing settlement:
  - Inspire Pharmaceuticals, Inc.

# False Claim Act Settlements

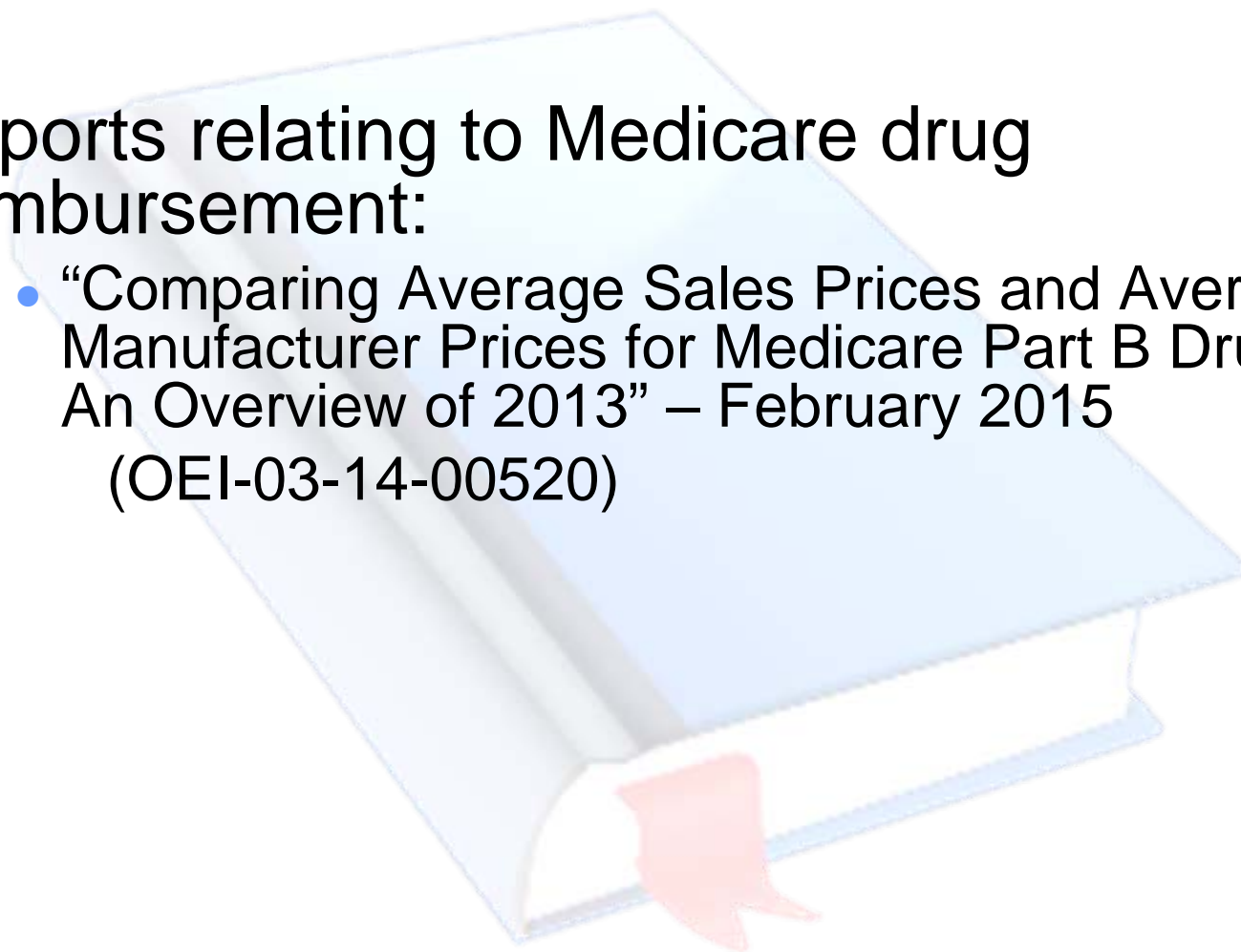
- Cases with “other” issues:
  - Cases involving the Medicaid drug rebate program
    - AstraZenca LP
    - Cephalon Inc.
  - Cases involving unapproved foreign drugs

# Civil Monetary Penalty Settlements

- Drug price reporting settlements:
  - Ascend Laboratories, LLC
  - B.F. Ascher & Company, Inc.
  - Seton Pharmaceuticals
  - Sandoz, Inc.

# OIG Reports

- Reports relating to Medicare drug reimbursement:
  - “Comparing Average Sales Prices and Average Manufacturer Prices for Medicare Part B Drugs: An Overview of 2013” – February 2015  
(OEI-03-14-00520)



# OIG Reports

- Reports relating to Medicare/Medicaid drug rebate issues:
  - “Medicaid Rebate for Brand-Name Drugs Exceeded Part D Rebates by a Substantial Margin” – April 2015 (OEI-03-13-00650)
  - “States’ Collection of Rebates for Drugs Paid through Medicaid Managed Care Organizations Has Improved” – Sept. 2015 (OEI-05-14-00431)



# OIG Reports

- Reports relating to the Medicaid Drug Rebate Program:
  - Reviews of the collection of Medicaid rebates for physician-administered drugs – KS, IA, TX, MO, OR, LA
  - “States’ Collection of Offset and Supplemental Medicaid Rebates”
    - Dec. 2014 (OEI-03-12-00520)

# OIG Reports

- Other reports of interest:
  - “FDA Has Made Progress on Oversight and Inspections of Manufacturers of Generic Drugs” – May 2015  
(OEI-01-13-00600)
  - “Second-Generation Antipsychotic Drug Use Among Medicaid-Enrolled Children: Quality-of-Care Concerns” – Mar. 2015  
(OEI-07-12-00320)

# OIG Guidance

- New and Noteworthy:
  - “Practical Guidance for Health Care Governing Boards on Compliance Oversight”
    - April 2015



# OIG FY 2015 Work Plan

- Planned work includes:
  - Medicare Part B issues
  - Medicaid Part D issues
  - Medicaid drug rebate program issues
  - Medicaid DUR/opioid drug issues
  - FDA post-marketing study issues
  - 340B program duplicate discount issues

# Lessons/Suggestions

- Kickback concerns continue
  - Think about kickback risks associated with financial relationships
  - Think “Open Payments”



# Lessons/Suggestions

- Identify financial relationships that could implicate kickback risks.
  - Examine relationships with potential prescribers, purchasers, recommenders
- What controls are in place?
- Are the controls meaningful and effective?

# Lessons/Suggestions

- In today's environment:
  - Individual accountability is under fresh scrutiny
  - Think about ways to enhance accountability of individuals
    - Compliance must be a shared responsibility
    - Certifications
    - Rewards/discipline relating to compliance

# Lessons/Suggestions

- Effective compliance programs are vital
  - Basic elements are a given
  - Meaningful monitoring is essential
  - Risk assessment and mitigation programs are important
  - Compliance programs must continuously evolve



# Lessons/Suggestions

- Key question: Is your compliance program effective?



