



Update from the Office of Inspector General

20th Annual Pharmaceutical and Medical Device Compliance Congress

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November 6, 2019





Agenda for Today

- Update on recent enforcement activity
- Update on recent OIG reports and future work
- Compliance lessons and suggestions





Recent Resolutions

- Large number of resolutions - global and civil settlements
- Resolutions involved a variety of issues:
 - Kickback issues
 - Promotional issues
 - Product issues
 - Competitive issues





Opioid-Related Matters

- Matters involving opioid-related issues
 - Reckitt Benckiser Group plc - \$1.4 billion resolution
 - Insys Therapeutics - \$225 million resolution
 - Criminal convictions of founder and former executives
 - Indictment of Indivior Inc.
 - Pending matter





April 2019 Appalachian Region Opioid Takedown

- 60 defendants, including 53 medical professionals
- 11 federal districts
- Over 24,000 opioid patients affected, over 32 million opioid pills prescribed
- Conduct involved illegal prescribing and distribution of opioids and other drugs





Copayment-Related Matters

- Settlements involving copay assistance programs
(Some of these matters also involved other issues)

Astellas Pharma US, Inc.

Amgen Inc.

US WorldMeds LLC

Jazz Pharmaceuticals plc

Chronic Disease Fund, Inc.

Lundbeck LLC

Alexion Pharmaceuticals, Inc.

Actelion Pharmaceuticals US, Inc.

Insys Therapeutics

Patient Assistance Network Foundation





False Claim Act Settlements

Settlements involving other types of kickback issues

- Speaker program issues
- Patient registry issues
- Practice and market development support
- Other issues (e.g., meals and entertainment)





Price-Fixing Matter

Resolution with Heritage Pharmaceuticals

- FCA settlement - \$7 million
- Deferred prosecution agreement with DOJ Antitrust Division
- Alleged scheme to fix prices and allocate customers





Medical Device Matters

- Resolutions involving medical device issues
 - ACell Inc. - \$15 million global resolution
 - Avalign Technologies, Inc.- \$9.5 million settlement
 - Carefusion Corporation - \$3.3 million settlement





OIG Reports

- **Reports on Drug Pricing/Reimbursement Issues**
 - “Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2017 Average Sales Prices” August 2019 (OEI -03-19-00260)
 - “Rebates for Brand-Name Drugs in Part D Substantially Reduced the Growth in Spending from 2011 to 2015” September 2019 (OEI-03-19-00010)





OIG Reports

- **Reports Relating to the Medicaid Drug Rebate Program**
 - “Reasonable Assumptions in Manufacturer Reporting of AMPs and Best Prices” September 2019 (OEI-12-17-00130)
 - “One Percent of Drugs with Medicaid Reimbursement Were Not FDA-Approved” May 2019 (OEI-03-17-00120)





OIG Reports

- **Reports Relating to the Medicaid Drug Rebate Program**
 - “Medicaid Could Save Hundreds of Millions by Excluding Authorized Generic Drug Transactions to Secondary Manufacturers from Brand Name Drugs’ Average Manufacturer Price Calculations” April 2019 (OEI-06-18-04002)
 - Reviews of States’ collection of Medicaid rebates for physician-administered drugs, including drugs dispensed to enrollees of Medicaid managed care organizations
 - Reviews for: Texas, New Jersey, and Indiana





OIG Reports

- **Reports on Other Issues**

- “The Food and Drug Administration’s Policies and Procedures Should Better Address Postmarket Cybersecurity Risk to Medical Devices” October 2018 (A-18-16-30530)
- “The National Institutes of Health Has Limited Policies, Procedures, and Controls in Place for Helping to Ensure that Institutions Report All Sources of Research Support, Financial Interests, and Affiliations” September 2019 (A-03-19-03003)





OIG Reports

- **OIG Work Relating to Opioid Issues**

- Identifying opportunities to improve the efficiency and effectiveness of HHS programs
- Identifying and holding accountable those engaged in fraud
- Empowering and collaborating with partners through data sharing and education
- <https://oig.hhs.gov/reports-and-publications/featured-topics/opioids/>





OIG FY 2019 Work Plan

- **Ongoing work relating to Medicaid drug issues:**
 - Specialty drug coverage and reimbursement in Medicaid
 - Accuracy of drug manufacturers' quarterly pricing data
 - Utilization and pricing trends for naloxone in Medicaid





OIG FY 2019 Work Plan

- **Other planned work includes:**
 - Assessment of the FDA's postmarket surveillance of medical devices
 - Drug traceability test
 - FDA oversight of risk evaluation and mitigation strategies to address prescription opioid abuse





Lessons/Suggestions

- Think broadly about compliance risk areas – established and emerging
 - Risks associated with product promotion, especially for products with a high risk profile
 - Risks involved associated with failure to comply with Federal Food, Drug, and Cosmetic Act requirements





Lessons/Suggestions

- Think broadly about kickback-related compliance risks – established and emerging
 - Risks associated with patient assistance program arrangements
 - Risks associated with pricing-related activities





Lessons/Suggestions

- Think broadly about kickback-related compliance risks – established and emerging
 - Risks associated with speaker programs
 - Risks associated with other arrangements and interactions with health care providers





Lessons/Suggestions

- High level support for, and commitment to, compliance is critical
- Examples of enforcement actions against individuals
- Importance of individual accountability
 - Board, management, employees





Lessons/Suggestions

- Compliance programs should be comprehensive and tailored
 - All business units should be included
 - Compliance programs should be tailored to address the organization's specific risk areas
 - Meaningful monitoring is a must
 - Compliance programs must continuously evolve





Lessons/Suggestions

Key question: Is your compliance program effective?





In Closing . . .

- Thank you
- Questions?

