

17TH ANNUAL PHARMACEUTICAL AND MEDICAL DEVICE COMPLIANCE CONGRESS

Office of Inspector General Update

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Office of Counsel to the Inspector General

October 19, 2016

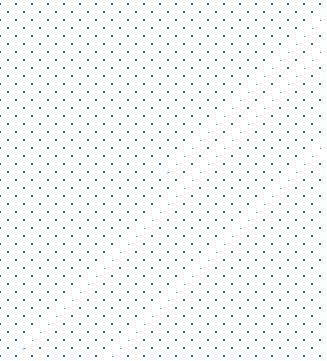
AGENDA FOR TODAY

- ▶ Update on recent enforcement activity
- ▶ Update on OIG reports and other publications
- ▶ Lessons/suggestions for consideration

ISSUES IN RECENT SETTLEMENTS

- ▶ Settlements addressed a variety of areas:
 - ▶ Kickback issues
 - ▶ Marketing and sales issues
 - ▶ Medicaid drug rebate program issues
 - ▶ Drug price reporting issues

FALSE CLAIM ACT SETTLEMENTS

- ▶ Kickback-related settlements
 - ▶ Salix Pharmaceuticals, Inc.
 - ▶ Olympus Corporation of the Americas
 - ▶ Novartis Pharmaceuticals
 - ▶ Warner Chilcott
 - ▶ Omnicare, Inc.
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FALSE CLAIM ACT SETTLEMENTS

- ▶ Settlements involving sales and marketing issues
 - ▶ Acclarent, Inc.
 - ▶ Genentech Inc. and OSI Pharmaceuticals LLC
 - ▶ Paradigm Spine
 - ▶ Qualitest Pharmaceuticals
- ▶ Settlement involving Medicaid drug rebate issues
 - ▶ Wyeth/Pfizer
- ▶ Settlements involving other issues
 - ▶ Imported and compounded drugs

CIVIL MONETARY PENALTY SETTLEMENTS

- ▶ Drug Price Reporting CMP Settlements
 - ▶ Nephron Pharmaceuticals Corporation
 - ▶ Cipher Pharmaceuticals US, LLC
 - ▶ Coloplast Corp.

OIG REPORTS

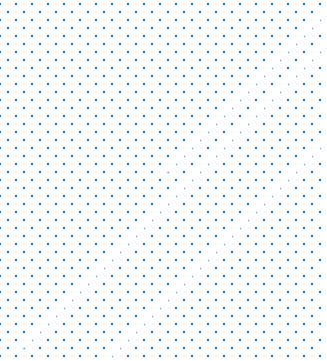
- ▶ Drug pricing issues
 - ▶ “Average Manufacturer Prices Increased Faster Than Inflation for Many Generic Drugs” – December 2015 (A-06-15-00030)

- ▶ 340B program issues
 - ▶ “Part B Payment for 340B Purchased Drugs” - Nov. 2015 (OEI-12-14-00030)
 - ▶ “State Efforts to Exclude 340B drugs from Medicaid Managed Care Rebates” – June 2016 (OEI-05-14-00430)

OIG REPORTS

- ▶ Reports relating to the Medicaid Drug Rebate Program
 - ▶ Reviews of the collection of Medicaid rebates for physician-administered drugs – KS, UT, WY, SD, MT, CA
- ▶ Other issues
 - “FDA Is Issuing More Postmarketing Requirements, but Challenges with Oversight Persist – July 2016 (OEI-01-14-00390)

OIG FY 2016 WORK PLAN

- ▶ Planned work includes
 - ▶ Medicare Part B drug pricing review
 - ▶ Reviews of price increases for Medicare Part D covered drugs
 - ▶ Medicaid drug rebate-related reviews
 - ▶ 340B drug pricing program review
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NEW AND NOTEWORTHY

- ▶ April 2016 – Criteria for implementing permissive exclusion under Section 1128(b)(7) of the SSA
 - ▶ Supersedes and replaces prior 1997 notice
 - ▶ Reflects lessons learned from OIG's experience
 - ▶ Reflects widespread development of compliance programs
 - ▶ Under the new criteria, OIG uses a risk spectrum to evaluate whether to pursue exclusion.

LESSONS/SUGGESTIONS

- ▶ Maintain a focus on kickback issues
 - ▶ A continued area of focus in cases/settlements
 - ▶ Open Payments database
 - ▶ Think broadly – payments and transfers of value
 - ▶ Risk areas from recent cases:
 - ▶ Speaker programs
 - ▶ Arrangements with specialty pharmacies
 - ▶ Equipment loans, free equipment

LESSONS/SUGGESTIONS

- ▶ Importance of individual accountability
 - ▶ Law enforcement focus on responsible individuals
 - ▶ Think about accountability in compliance
 - ▶ Certifications from Boards of Directors
 - ▶ Management certifications
 - ▶ Compliance as a component of employee evaluations
 - ▶ Disciplinary action for compliance failures

LESSONS/SUGGESTIONS

- ▶ Effective compliance programs remain the goal
 - ▶ Basic compliance program elements are expected
 - ▶ Modifications in recent CIAs
 - ▶ Compliance programs/CIAs should be tailored to address risk areas
 - ▶ Compliance program must continuously evolve
 - ▶ Importance of risk assessment and mitigation

QUESTIONS?

