

# 18<sup>TH</sup> ANNUAL PHARMACEUTICAL AND MEDICAL DEVICE COMPLIANCE CONGRESS


## Office of Inspector General Update

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# AGENDA FOR TODAY

- ▶ Update on recent enforcement activity
  - ▶ Update on recent OIG reports
  - ▶ Lessons/suggestions for consideration
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# RECENT SETTLEMENTS

- ▶ Settlements involved a variety of issues:
  - ▶ Kickback issues
  - ▶ Promotional issues
  - ▶ REMS issues
  - ▶ Medicaid drug rebate program issues
  - ▶ Other issues (OIG authorities)


# FALSE CLAIM ACT SETTLEMENTS

- ▶ Settlements with Pharmaceutical Manufacturers
    - ▶ Aegerion Pharmaceuticals, Inc.
    - ▶ Galena Biopharma Inc.
    - ▶ Novo Nordisk, Inc.
    - ▶ Celegene Corp.
    - ▶ Forest Laboratories LLC and Forest Pharmaceuticals, Inc.
    - ▶ Mylan Inc. and Mylan Specialty L.P.
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# FALSE CLAIMS ACT SETTLEMENTS

- ▶ Settlements involving Medical Devices
    - ▶ Shire Pharmaceuticals, LLC and subsidiaries
    - ▶ Biocompatibles, Inc.
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# CIVIL MONETARY PENALTY SETTLEMENTS

- ▶ Settlements with OIG
    - ▶ Stratus Pharmaceuticals, Inc.
    - ▶ Daiichi Sankyo subsidiaries
    - ▶ Tobii Dynavox, LLC
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# OIG REPORTS

- ▶ Drug pricing issues
  - ▶ “High Price Drugs are Increasing Federal Payments for Medicare Part D Catastrophic Coverage”  
January 2017 (OEI-02-16-00270)
  - ▶ “Calculation of Potential Inflation-Indexed Rebates for Medicare Part B Drugs 2017” - August 2017 (OEI-1-12-17-00180)
  - ▶ “Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2015 Average Sales Prices”  
September 2017 (OEI -03-17-00360)

# OIG REPORTS

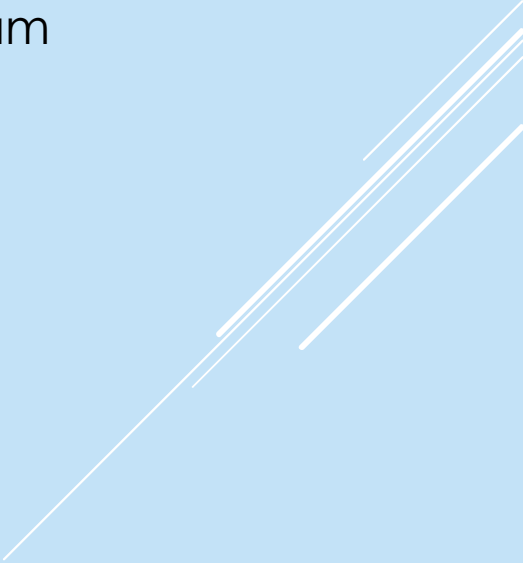
- ▶ Reports relating to the Medicaid drug rebate program
  - ▶ Reviews of States' collection of Medicaid rebates for physician-administered drugs, including drugs dispensed to enrollees of Medicaid managed care organizations
    - ▶ Hawaii, Washington, Nevada, Iowa, Wisconsin, Colorado, Delaware, Virginia, California



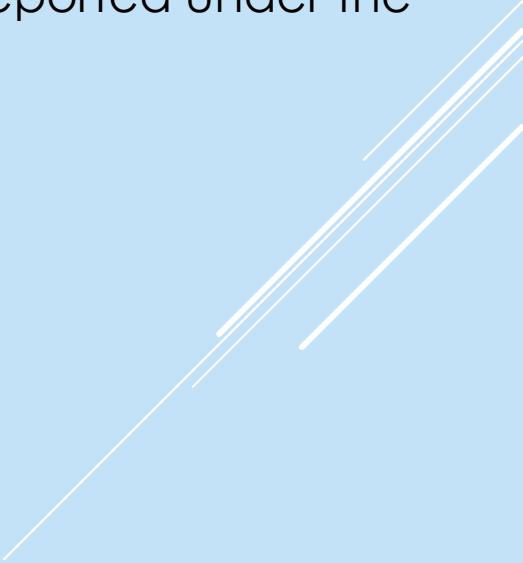
# OIG REPORTS

- ▶ Reports on other Issues
  - ▶ “Drug Supply Chain Security: Wholesalers Exchange Most Tracing Information” – September 2017 (OEI-05-14-00640)
  - ▶ “Shortcomings of Device Claims Data Complicate and Potentially Increase Medicare Costs for Recalled and Prematurely Failed Devices” – September 2017 (A-01-15-00504)

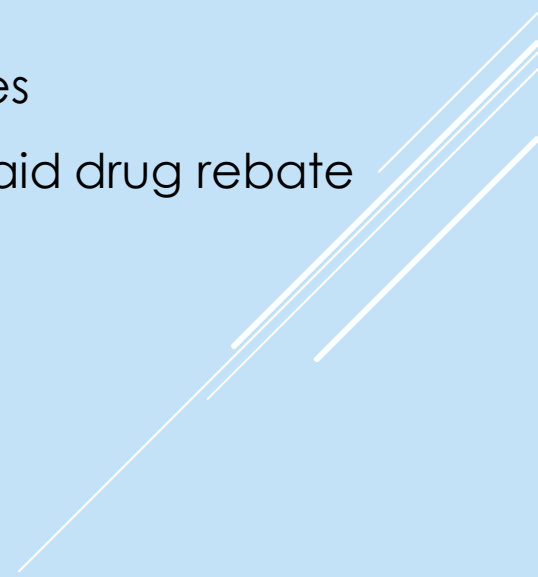
# OIG FY 2017 WORK PLAN

- ▶ Planned work includes several items relating to the Medicaid drug rebate program:
    - ▶ Drug classification Issues
    - ▶ Manufacturers' use of reasonable assumptions
    - ▶ FDA approval status of drugs covered under the Medicaid drug rebate program
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# OIG FY 2017 WORK PLAN

- ▶ Other planned work includes:
    - ▶ Review of specialty drug coverage and reimbursement under Medicaid
    - ▶ Review of FDA oversight of REMS to address prescription opioid abuse
    - ▶ Review of financial interests reported under the Open Payments Program
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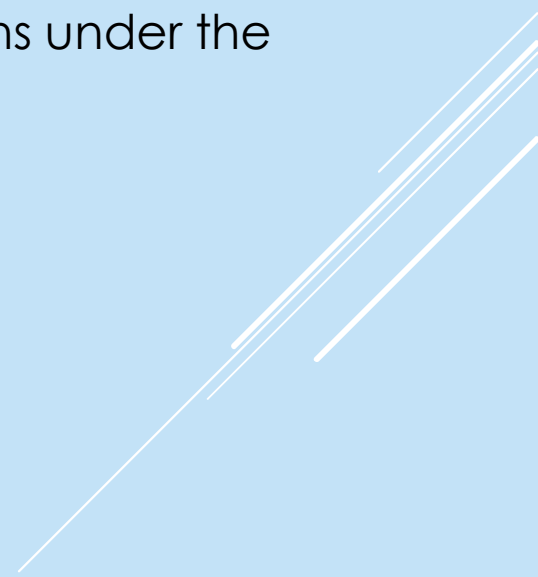
# LESSONS/SUGGESTIONS

- ▶ Think broadly about compliance risk areas – established and emerging
    - ▶ Risks under the Federal anti-kickback statute
    - ▶ Risks associated with failure to comply with REMS obligations
    - ▶ Risks associated with HIPAA issues
    - ▶ Risks associated with the Medicaid drug rebate program
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# LESSONS/SUGGESTIONS

- ▶ Maintain a focus on kickback issues
  - ▶ Kickbacks are a continued area of focus in cases
  - ▶ Think broadly about arrangements with a variety of individuals and entities
  - ▶ Risk areas to watch:
    - ▶ Arrangements with health care providers
    - ▶ Arrangements involving patient assistance programs
    - ▶ Arrangements with other entities in a position to purchase, order, arrange for, or recommend a product

# LESSONS/SUGGESTIONS

- ▶ Other risk areas
    - ▶ Failure to comply with REMS requirements
    - ▶ Conspiracy to violate HIPAA requirements
    - ▶ Failure to comply with obligations under the Medicaid drug rebate program
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# LESSONS/SUGGESTIONS

- ▶ Effective compliance programs remain the goal
  - ▶ Compliance programs should be tailored to address risk areas
  - ▶ Compliance program must continuously evolve
    - ▶ Importance of risk assessment and mitigation
  - ▶ Compliance programs must involve meaningful monitoring

QUESTIONS?

