

# National Pharma Audioconference

## Bristol-Myers Squibb 2007 Settlement

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# Overview

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- Key elements
- Investigative Approach
- Relator Issues
- State Process
- Corporate Integrity Agreement

# Civil Settlement Agreement

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- Extensive Alleged “Covered Conduct” Released
  - Apothecon payments to retailers and wholesalers
    - Former generic subsidiary
    - Divested in December 2000
  - AWP allegations (23 drugs)
  - Payments to consultants (31 drugs)
  - FDA promotion allegations (Abilify)
  - Best Price reporting allegations (Kaiser private label)

# Civil Settlement Agreement

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- No admission of liability
- \$499 million
  - Announced \$515 million includes agreed to interest (4.5% per annum) from the date of agreement in principle
  - ~\$181 million allocated to states (plus accumulated interest)
- Abilify FDCA release

# Resolution of Multiple Issues

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- Working toward a “global” resolution
- What can be accomplished in today’s complex enforcement world
- Advantages and disadvantages of a “global” approach
- Keeping an eye on collateral aspects
  - States
  - Private civil litigation

# Philosophy and Approach

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- Establish credibility
  - Open and regular communication
  - Complete responses to government concerns
  - Facing facts
- Prompt and complete voluntary disclosure of potential issues
- Cooperation directed toward a genuine understanding of the issues
- Development of sophisticated financial analysis to guide resolution
- Active engagement on the facts, the medicine and the law

# Key Role of Compliance

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- Important demonstration of corporate mindset
- Corrective actions prior to awareness of investigative interest
  - Discontinued certain programs
  - Developed new policies and procedures
  - Intensive implementation training
  - Efforts to address potential promotional concerns
- Best-in-class compliance program
  - Involvement of compliance with investigative process
- Open and active engagement

# Relator Issues

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- Eight (8) known related *qui tam* actions
- Many actions include overlapping allegations
- Certain actions filed subsequent to BMS's voluntary disclosure
- Scope of Relators' release
- Fees



# State Process

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- State share of Medicaid recovery (~ \$181 million)
  - State sign-off required to resolve those claims
  - If not resolved, money reverts to BMS
- Coordination with assigned NAMFCU Team
  - Negotiation of state settlement agreement
  - Roll-out to states
- Overlapping AG AWP litigation

# Corporate Integrity Agreement

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- Required element of resolution
- Evolving OIG expectations
- Importance of having an effective compliance program in place
  - Pre-existing compliance structure
  - Pre-existing policies and procedures
  - Pre-existing extensive training program

# Corporate Integrity Agreement

- Recognition of BMS internal monitoring capabilities
  - Internal review of records reflecting the content of detailing sessions, medical information requests, IME, and grants
  - BMS-run Field Force Monitoring Program
  - Contemplation that BMS's internal audit work will substitute for certain required IRO transaction reviews
- Only one Medicaid Drug Pricing Systems Review required
- Clear map of IRO responsibility

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