Pharmaceutical
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Mini Summit IX: Pricing Update

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Agenda

- Congressional Pricing Investigations
- Substantive Congressional Initiatives
- Recent Federal Regulatory Action
- State Pricing Laws
- Where the Administration May Go on Drug Pricing
- Non-FCA Pricing Civil Litigation

Congressional Pricing Investigations

- Turing / Valeant: old but not forgotten
- ARIAD Pharma investigation
- Mylan investigation
- Insulin pricing investigation
- Multiple sclerosis drug pricing investigation

Substantive Congressional Initiatives

- Oversight of 340B
  - In three recent hearings, members of the House Energy & Commerce Subcommittee on Oversight and Investigations indicated bipartisan support for increased oversight of the 340B program
    - Lack of program requirement specificity in the 340B statute
    - Lack of HRSA authority to promulgate regulations
    - Lack of HRSA resources to provide oversight
    - Lack of transparency into covered entity activities/charitable spend
    - Support for the contribution covered entities make to the public health
    - Concern about the rapid growth of the program and the incentives driving that growth

Recent Federal Regulatory Action

- Medicare final rule reducing Part B reimbursement from ASP+6% to ASP-22.5% for 340B drugs
- January 5, 2017 340B final rule delayed until next July; will likely be rewritten
- 340B “mega-guidance” withdrawn
- MDRP expansion to territories put off until 2020

State Pricing Laws

- California Drug Cost Transparency Law
- Maryland Generics Price Gouging Law
- Louisiana WAC Reporting Requirement
- Nevada Diabetes Drug Price Transparency Law
- Vermont Drug Price Transparency Law
- New York Medicaid Price Control Measures

- Ohio Price Cap Initiative: on the ballot *today*

Where the Administration May Go on Drug Pricing

- Unreleased draft executive order
- FDA and competition
- International trade solutions
- The Sanders / Warren effect
- Measures related to the opioid emergency

Non-FCA Pricing Civil Litigation

- Ipsen “new drug” litigation against CMS
- *Streck 2*

John Shakow

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John Shakow is a nationally-recognized expert in all aspects of drug pricing and price reporting. He has counseled pharmaceutical and biotechnology clients on their rights and obligations under the Medicaid, Medicare, Federal Supply Schedule, 340B and TRICARE programs for almost twenty years. John regularly advises manufacturers on the spectrum of regulatory, commercial and litigation matters relating to pricing and government payor programs. He has extensive experience helping clients resolve commercial, strategic, organizational and other legal challenges while maintaining the integrity of their government pricing compliance efforts.

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