NEHI Network for Excellence in Health Innovation

Policy and Politics of Drug Pricing – A Brief Overview

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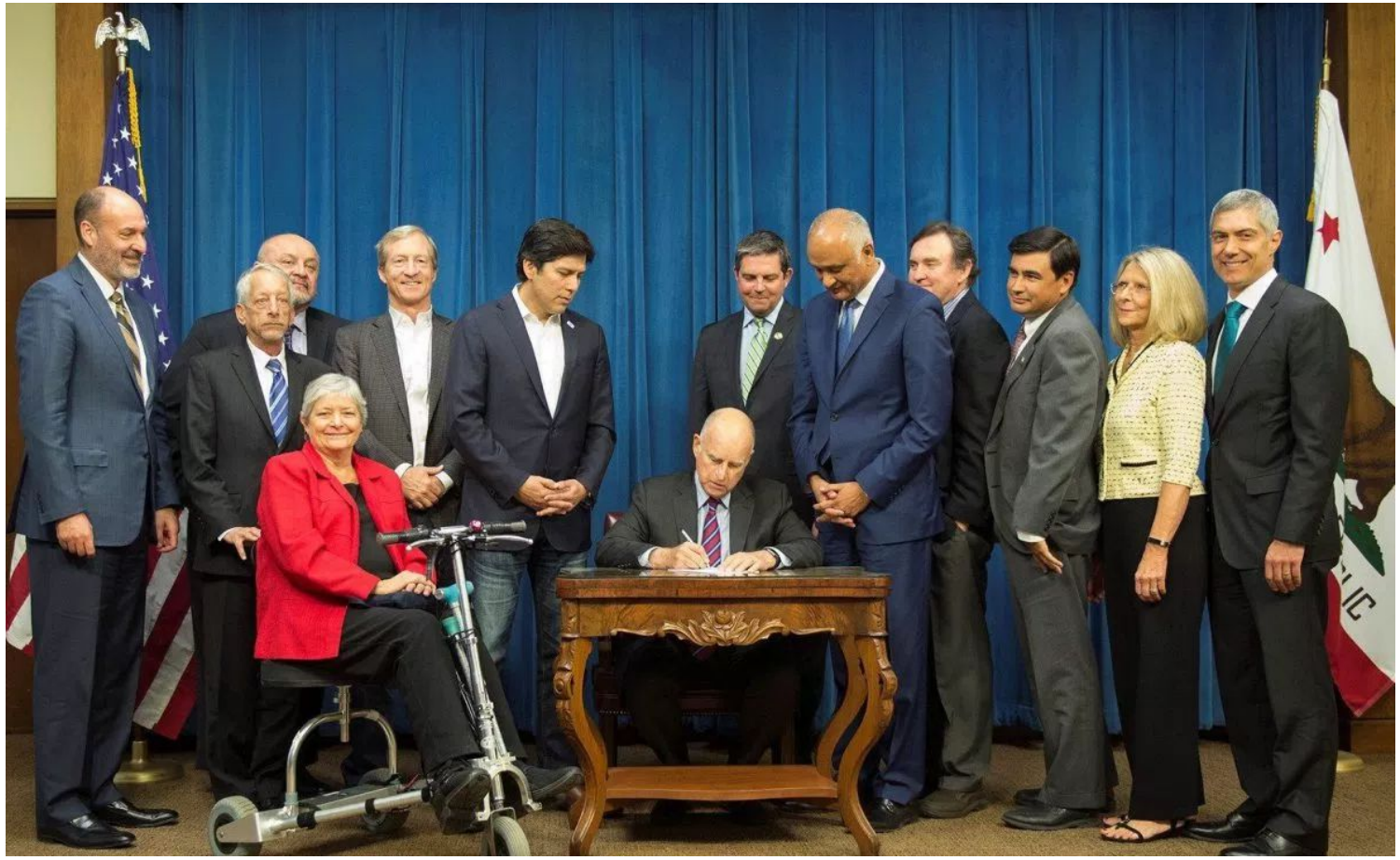
NEHI: Who We Are

- Headquartered in Boston and Washington

- A national nonprofit, nonpartisan organization composed of stakeholders from across al key sectors of health and health care. Our mission is to advance innovations that improve health, enhance the quality of health care, and achieve greater value for the money spent.

Action at the State Level



State Action

Policy aimed at several different, if interrelated sets of issues

- Overall drug spending trend
- Generics and Off-patent drugs
- Branded and novel/new-to-market drugs

State Action: Overall Drug Spending Trend

Issue: Drug Spending Trends in Excess of Benchmark(s)

Remedies (proposed or enacted):

- **Transparency Mandates**
  - Public reporting on major drivers of drug spend (Vermont, California, others)
    - "Top Ten Lists"
  - Early warning" (pre-launch) reports on budget impact of new-to-market drugs (pending proposal in Massachusetts)
- **Discounts & rebates piggybacked on federal health programs** (Ohio referendum)
- **Medicaid drug spending cap (New York)**
- **Expanded utilization management**
  - Commercial insurers
  - Medicaid (New York 2017, also see Massachusetts waiver request)
- **Other: Bans on co-pay coupons, multi-state group purchasing , etc.**

Transparency and Public Reporting

- Proliferation of transparency/reporting requirements

- Will states consolidate efforts?

Institute for Clinical and Economic Review Announces New $13.9 Million Grant from the Laura and John Arnold Foundation

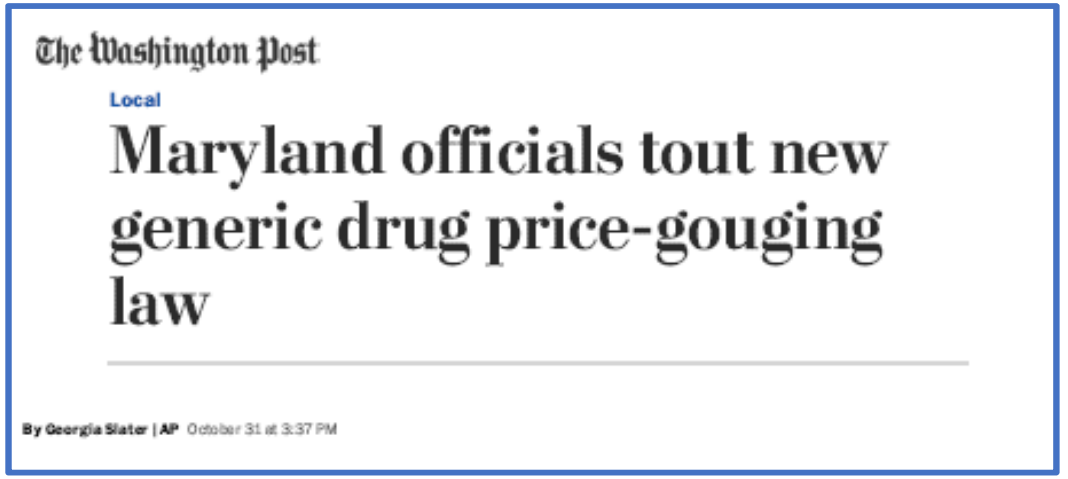
–Expanded funding enables ICER value assessments for all newly approved medicines in the U.S.–

October 31, 2017

State Action: Generics and Off-Patent Drugs

Issues:

- Monopolistic pricing (e.g. Shkreli)
- Unanticipated price increases
- Repeated, frequent price increases


The Washington Post

Local

Maryland officials tout new generic drug price-gouging law

By Georgia Slater | AP October 31 at 3:37 PM

Remedies (proposed or enacted)

- Litigation against “unconscionable” price increases (Maryland)
- Value assessment to support supplemental rebate demands (New York)
- Public hearings (“blame and shame”)

State Action: Novel, New-to-Market Drugs

Issues:

- Launch price
- Real World effectiveness
- Unanticipated and/or repeated price increases
  - e.g. “shadow pricing”

Harvard Pilgrim chief says he dreads costs of new million-dollar treatments

Oct 3, 2017, 4:15pm EDT

Boston Business Journal 10/3/17

Remedies (proposed or enacted)

- Voluntary, pre-approval value assessment (e.g. Dupixent, Regeneron/Sanofi)
- Mandatory value assessment (e.g. New York Medicaid drug utilization board)
- Value-based contracting/Value-based arrangements

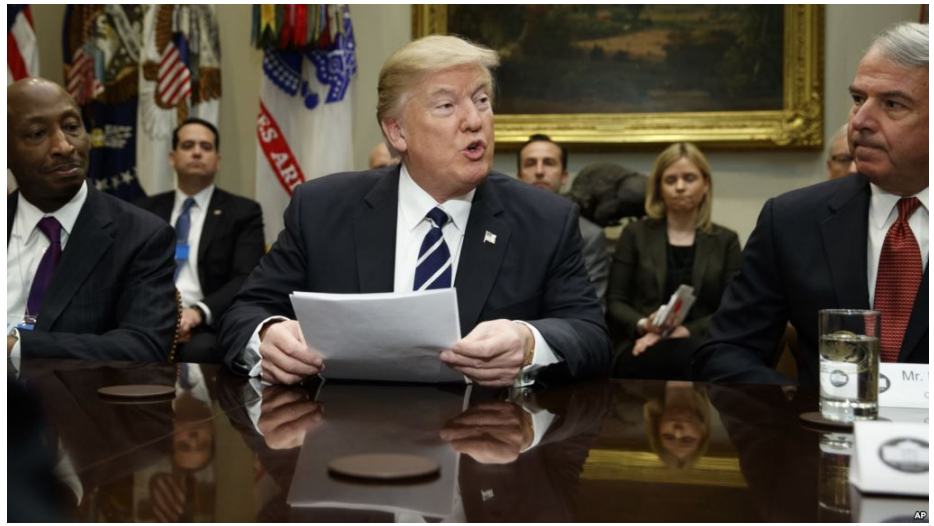
Congressional Action

- **Pending legislation**
  - Direct negotiation of drug prices by Medicare Part D (Franken, Sanders, Welch, et al)
  - Re-importation (Sanders et al)
  - Expedited FDA approvals for generics (Collins)
  - Advance notice of price increases (McCain, et al)
  - PBM rebate transparency reporting (Wyden et al)

- **Senate Health, Education, Labor and Pensions (HELP) Committee hearings**
  - Planned hearing (#3) on impending report from National Academy of Medicine (Norman Augustine panel, “Ensuring Patient Access to Affordable Drug Therapies”)

Trump Administration

- Presidential executive order?
- FDA
  - Accelerated action on approval of generics



CMS

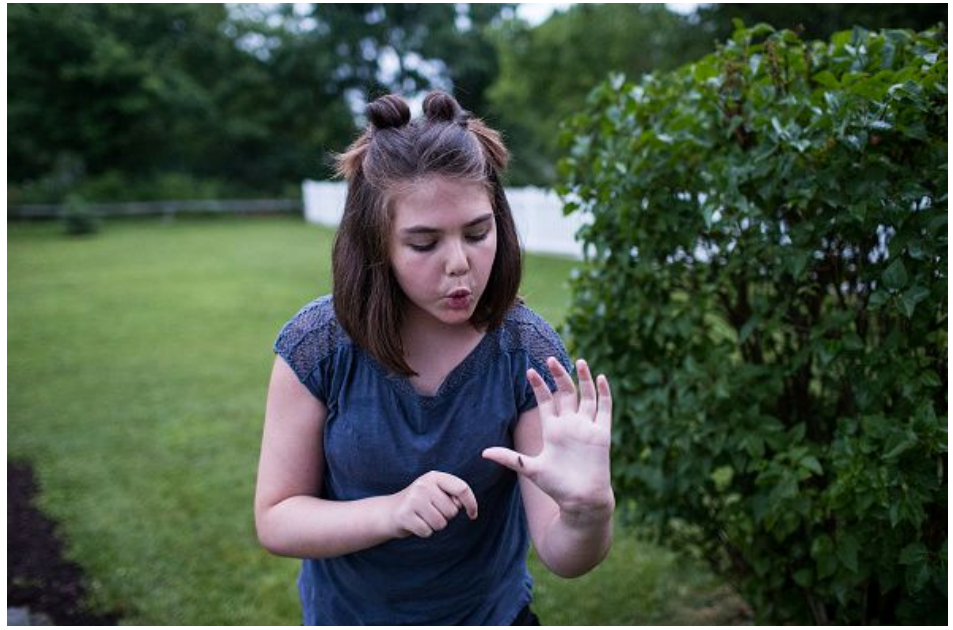
- **340B Program:**
  - Cut provider charges on drugs purchased under 340B, “lower(ing)… patient out of pocket cost.” (November 1)

- **Alternative payment models**
  - Outcomes-based pricing for Kymriah, Novartis CAR-T therapy; indication-based pricing for 2nd Kymriah indication likely (August 30)
  - Announced intention to work with manufacturers on alternative payment models for highly innovative, high-cost drugs

- **CMMI:**
  - Alternative contract models a priority for “new directions” ; RFI comments due 11/20

Value-based Arrangements and the Drug Price Debate

- **Objective:**
  - Enable timely access to therapy for patients, while
  - Hedging or sharing the financial risk of patients' failure to respond or achieve agreed-upon outcomes



Pros and Cons

For payers-

- Pro: pay for results seen in Real World utilization, especially with therapies emerging from accelerated or expedited reviews
- Con : operationally complex, few precedents or templates, volume discounts may still make more sense

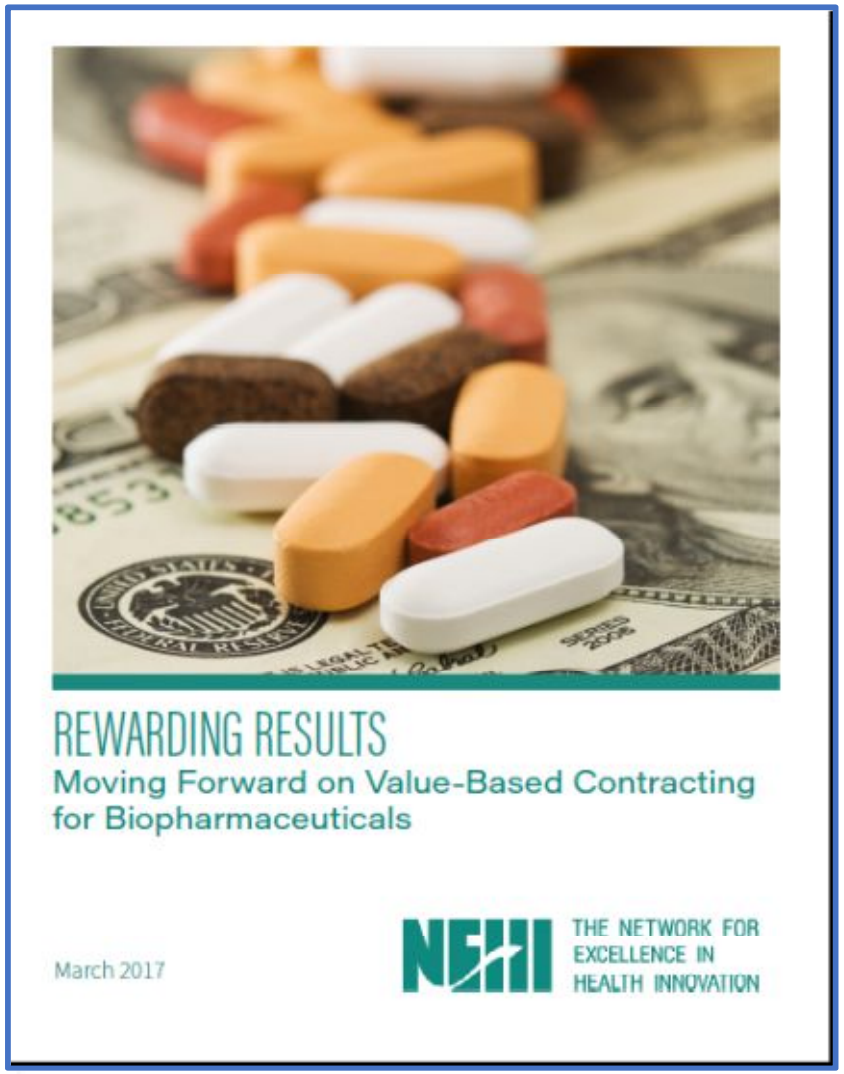
For manufacturers:

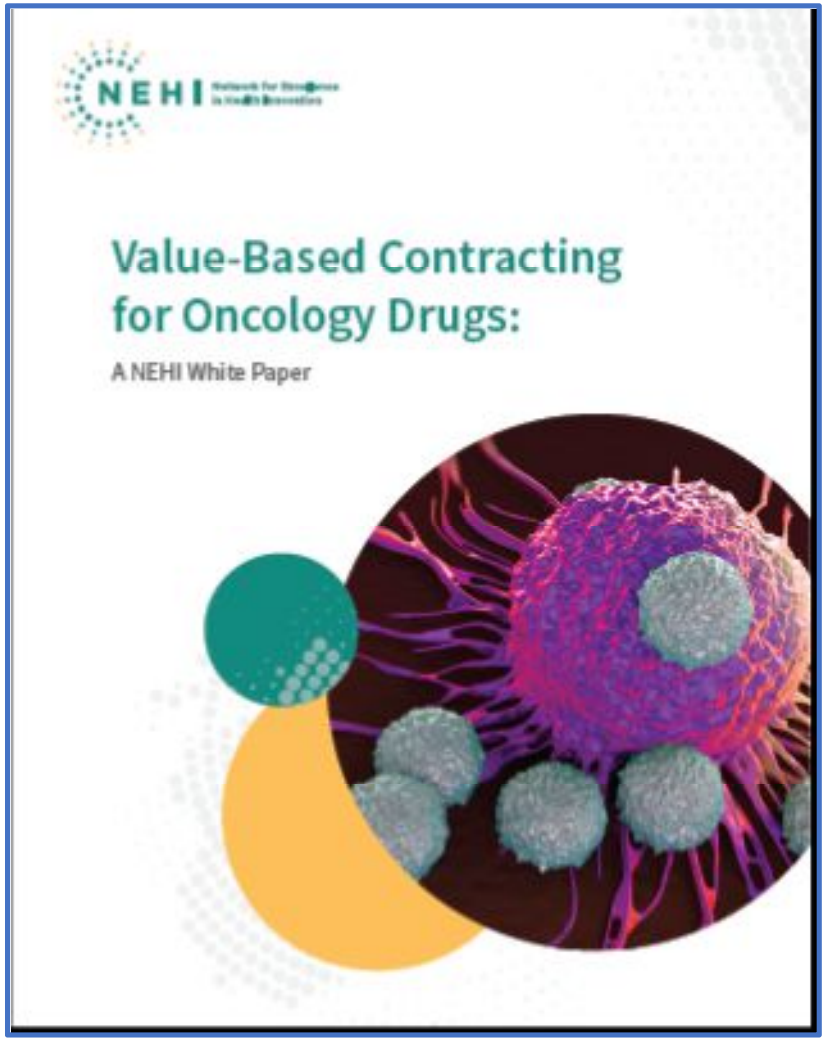
- Pro: Get new therapy onto formulary and in use more quickly
- Con: operationally complex, few precedents or templates, volume discounts may still make more sense

Policy Barriers

- **Federal health program drug price reporting and rebate obligations**
  - Example: does a patient's failure on a drug with a "money back guarantee" generate a Best Price of $0 ?
- **Anti-Kickback Statute enforcement**
  - When does the exchange of data, analysis, and other services in a value-based contract represent an illegal inducement?
- **FDA-regulated communication among manufacturers and payers**
  - Does pending FDA guidance fully address appropriate exchange of information, pre and post-approval?

Value-based Contracts and the Drug Price Debate





Thank You

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