Division of
Pharmacoepidemiology & Pharmacoeconomics
Department of Medicine, Brigham & Women's Hospital, Harvard Medical School

States and Rising Prescription Drug Costs: Origins and Prospects for Reform

Ameet Sarpatwari, J.D., Ph.D.
Instructor in Medicine, Harvard Medical School
Assistant Director, Program On Regulation, Therapeutics, And Law (PORTAL),
Division of Pharmacoepidemiology and Pharmacoeconomics,
Department of Medicine, Brigham and Women's Hospital
January 10, 2017
asarpatwari@bwh.harvard.edu

Disclosures

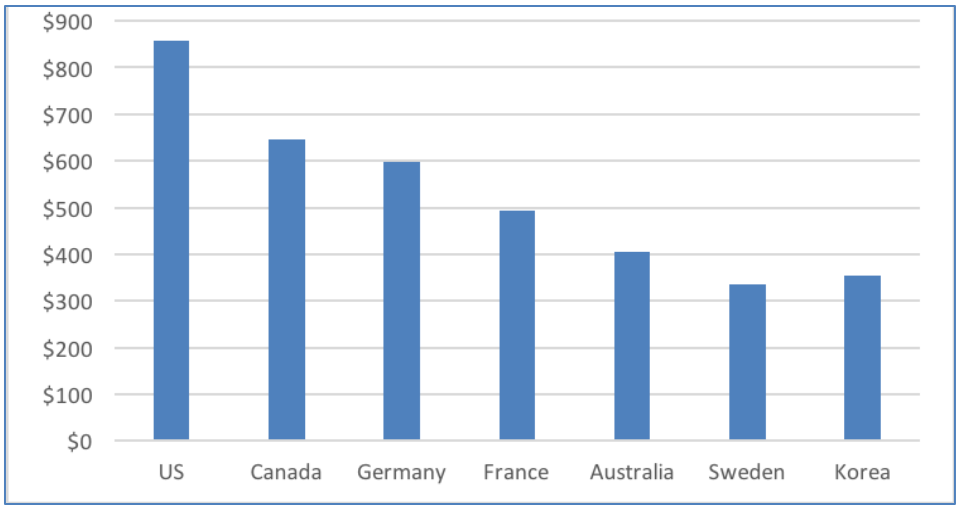
- No one in our Division has personal financial relationships with any pharmaceutical company

- Current research funding: Greenwall Foundation, FDA Office of Generic Drugs, Harvard Program in Therapeutic Science, Laura and John Arnold Foundation

- Current consulting: Leerink, NASHP

Prescription Drug Spending in the US

- Rose 20% between 2013-2015 to $457 billion
  -Wall Street Journal (2015).
  - Outpaced a 6% increase in aggregate healthcare spending
    -Keehan et al., Health Aff (2015).
- Constitutes 19% of employer-based insurance benefits
  -Kaiser Family Foundation (2015).
- International per capita comparisons
  - US: $858
  - Average of 19 industrialized countries: $400



-OECD (2015).

Clinical Consequences of High Drug Costs

- More patients have coverage due to Medicare drug benefit and the ACA, but cost-containment strategies have shifted drug expenses onto patients' shoulders

- Medicaid programs facing higher drug costs have had to cut back on other services or have tightened eligibility requirements

  Barlas. PT (2016).

- 25% of patients in 2015 reported that they or another family member did not fill a prescription in the last year due to cost

  Kaiser Family Foundation (2016).

- Patients prescribed a costly brand-name product rather than a more affordable generic alternative adhere less well, and have worse health outcomes

Shrank et al. Arch Intern Med (2006); Gagne et al. Ann Intern Med (2014).

DoPE BWH

Claim: High Prices Drive Innovation

- …but innovation that leads to transformative new drug products is often performed in academic institutions and supported by public investment such as the NIH

  -Kesselheim et al. Health Aff (2015).

- …but proportion of large pharmaceutical company revenues that goes to R&D is 10%-15%, and much smaller if only innovative product development is considered

  -Kesselheim et al. JAMA (2016).

- …but economic analyses contending that it costs $2.6 billion to develop a new drug have been disputed as inaccurate and inflated

  -Avorn. NEJM (2015).

- …but there is no evidence of an association between R&D costs and prices

  -Kesselheim et al. JAMA (2016).

DoPE BWH

Claim: It's the FDA's Fault

- But the FDA has a tolerant efficacy standard
  - A single trial can be sufficient
    - 1997 FDAMA: Explicitly allowed efficacy proven by "one adequate and well-controlled clinical investigation and confirmatory evidence"
  - Control: single-arm trials sufficient for orphan drugs
  - Outcome: biomarker rather than clinical endpoint

Agent/Indication Characteristic (Indications)	No. (%) [95% CI]						
		Trial Duration		Comparator		End Point	
	≥2 Pivotal Trials[a]	≥6 mo	≥12 mo	Active	Placebo	Clinical Outcome	Clinical Scale
All indications (N = 201)	127 (63.2) [56.5-69.9]	68 (33.8) [27.2-40.4]	17 (8.5) [4.6-12.3]	79 (39.3) [32.5-46.1]	119 (59.2) [52.4-66.0]	73 (36.3) [29.6-43.0]	39 (19.4) [13.9-24.9]

Downing et al., NEJM (2012).

Expedited Review Pathways

- Over half of new molecular entities approved in 2012 qualified for at least one expedited development or review program

2012 NMEs	Orphan	Fast Track	Priority Review	Accelerated Approval
Amyvid			■	
Aubagio				
Belviq				
Bosulif	■			
Choline c-11			■	
Cometriq	■	■	■	
Elelyso	■	■		
Eliquis			■	
Erivedge			■	
Fulyzaq		■	■	
Fycompa				
Gattex	■			
Iclusig	■	■	■	■
Inlyta		■		
Jetrea			■	
Juxtapid	■			
Kalydeco	■	■	■	
Kyprolis	■	■		■
Linzess				
Myrbetriq				
Neutroval				

2012 NMEs	Orphan	Fast Track	Priority Review	Accelerated Approval
Omontys				
Perjeta			■	
Picato				
Prepopik				
Raxibacumab	■	■	■	
Signifor	■			
Sirturo	■	■	■	■
Stendra				
Stivarga		■	■	
Stribild		■		
Surfaxin		■		
Synribo	■			■
Tudorza Pressair				
Voraxaze	■	■	■	
Xeljanz				
Xtandi		■	■	
Zaltrap			■	
Zioptan				

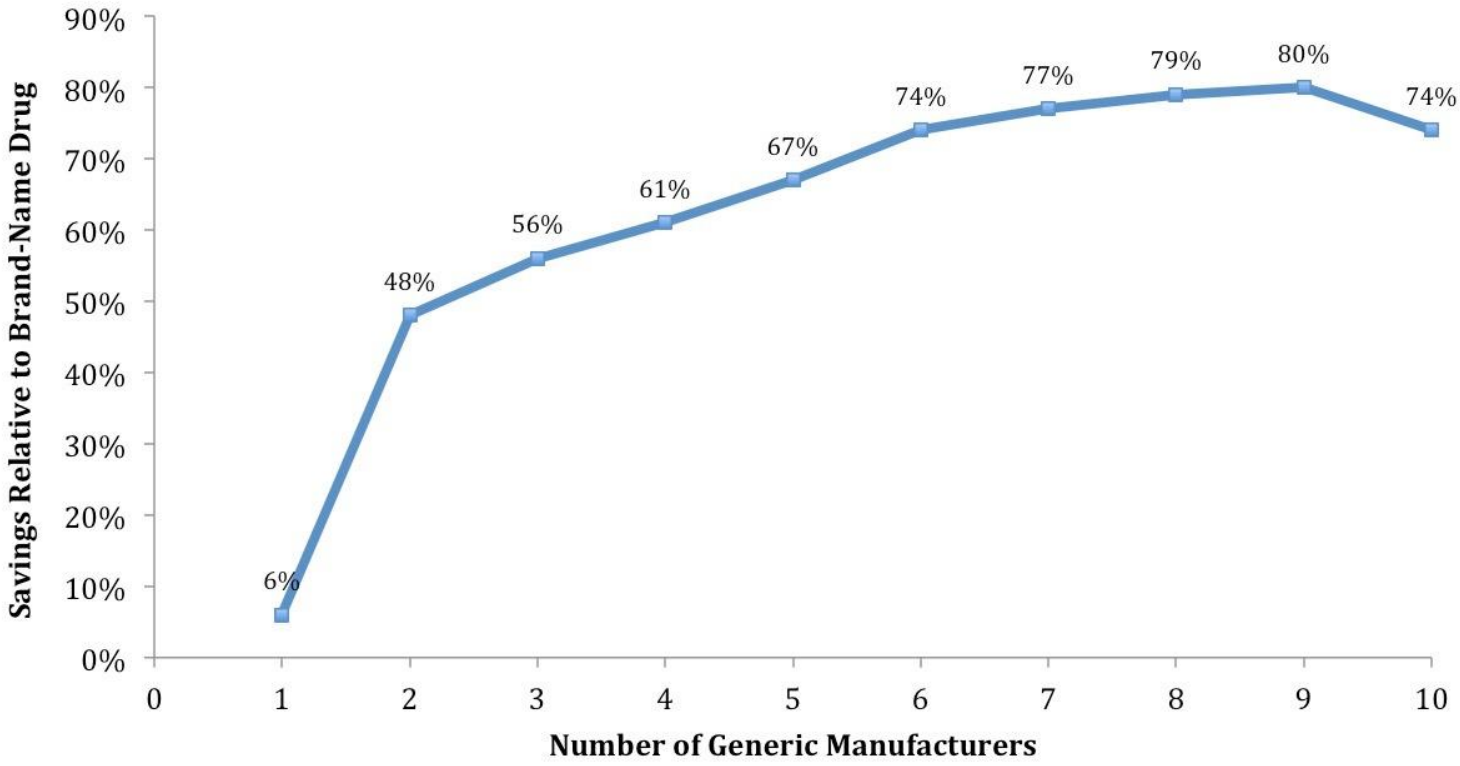
DoPE BWH

Real Explanation

We are seeing surging drug costs because we allow pharmaceutical companies to charge whatever the market will bear, and at the same time permit strategies that undercut competition or hinder payors' abilities to provide counterweights that might reduce high prices.

What Competition Matters?

- The only type of competition that consistently and substantially lowers prescription drug prices occurs from the availability of generic drugs, which emerge after the exclusivity period ends



FDA (2005).

Barriers to Timely Generic Drug Entry

- Delays
  - Secondary patents with or without “product hops”
  - Settlements with patent challengers
  - Restricted distribution pathways
- Insufficient regulatory attention
  - Unused pathway for interchangeable biologics
  - Long regulatory approval times for generic drugs
- Ill-advised government programs
  - Colchicine for gout
  - CFC-free inhalers

DoPE BWH

Negotiating Restrictions: Government Payors

- FDA: no authority to regulate drug prices
- Medicare (40M) cannot negotiate drug prices
  - 2006 Medicare Modernization Act
    - HHS Secretary cannot
      - "interfere with the negotiations"
      - "institute a price structure"
    - Limits on formulary adjustments
- Medicaid (60M) must generally cover all FDA approved drugs
  - Pays acquisition costs, gets rebate
  - Individual states may negotiate supplemental rebates
- VA negotiates directly with manufacturers
  - Prices 40% below those paid by Medicare Part D plans
  - VA price excluded from Medicaid rebate calculation

DoPE BWH

Possible Federal Solutions and Realities

- Prominent ideas
  - Patent reform
    - Changes in reviewing policies for novelty and non-obviousness
  - Government patent use and march-in rights
    - Problem: no indication of willingness to exercise
  - Price review and setting
    - [Wait for laughter]
  - Authorizing CMS to negotiate Medicare Part D drug prices
    - Problem: also require greater latitude to make formulary choices

- States will be the engine for reform
  - "If the federal government doesn't tackle drug pricing fast enough, participants agreed, state governments would."

Politico Working Group (2016).

NASHP Pharmacy Costs Work Group

- **Pharmacy Costs Work Group**
  - Bipartisan group of state leaders from governors' staffs, state legislators; Medicaid, public employee health insurance, and state-based insurance programs; offices of attorneys general, comptrollers' offices; and corrections departments
  - Observations
    - Shifting business climate

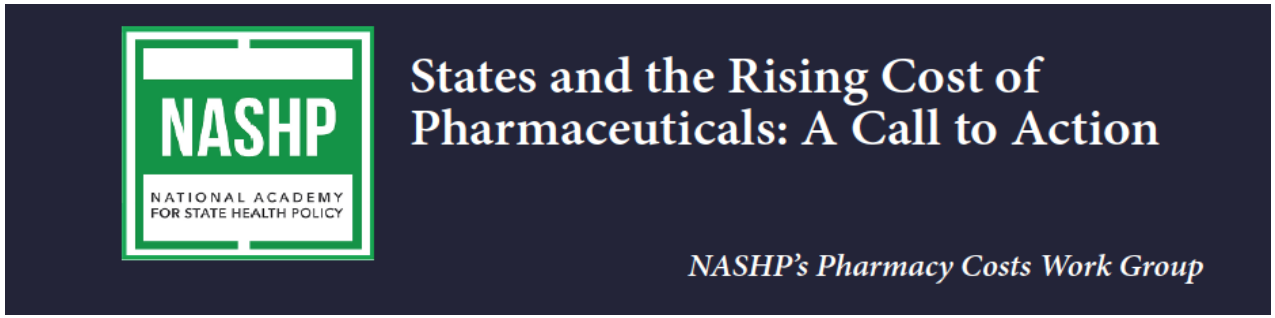
Rising cost of bringing therapeutic innovations to market	Growing speed of scientific advances which create more branded competition	Barriers to successful market entry and launch	Unprecedented levels of generic competition in most therapeutic classes

    - Reliance on high launch prices and price increases
  - Objective: toolkit of possible state actions
    - No-one size fits all approach

NASHP Pharmacy Costs Work Group Members

Susan Barrett *Executive Director* Green Mountain Care Board, VT	**Kevin Lembo** *Comptroller* State of Connecticut
Burl Beasley *Clinical Pharmacist* Oklahoma Health Care Authority	**Wendy Kelley** Director Arkansas Department of Corrections
Robert Crittenden *Senior Policy Advisor to the Governor* State of Washington	**Heather Korbulic** *Executive Director* Silver State Insurance Exchange, NV
Rebekah Gee *Secretary, Dept. of Health and Hospitals* State of Louisiana	**Eileen Mallow** Deputy Director Wisconsin Department of Employee Trust Funds
James DeBenedetti *Director, Plan Management Division* Covered California	**John McCarthy** *Medicaid Director* State of Ohio
Richard Gottfried *Chair, Committee on Health* New York State Assembly	**Janet Mills** *Attorney General* State of Maine
Emily Hancock *Clinical Pharmacist* Dept. of Social and Family Services, IN	**David Seltz** *Executive Director* Massachusetts Health Policy Commission
Stuart Hudson *Deputy Director of Healthcare and Fiscal Operations* Ohio Department of Corrections	**Norman Thurston** *Representative, 64th District* Utah State Legislature
Nathan Johnson *Chief Policy Officer* Washington State Health Care Authority	**Rebecca Pasternik-Ikard** *State Medicaid Chief Operating Officer* Oklahoma Health Care Authority

Possible State Solutions



http://nashp.org/states-rising-cost-pharmaceuticals-call-action/

1. Leverage **transparency laws** to create accountability
2. Create a **public utility model** for in-state drug prices
3. **Bulk purchase and distribute** high-priced, broadly-indicated, drugs that protect the public's health
4. Utilize state unfair trade and **consumer protection laws**
5. Seek the ability to **re-import drugs** from Canada

Possible State Solutions Cont'd

6. Pursue **Medicaid waivers** to promote greater purchasing flexibility
7. Create a **State Pharmacy Benefits Manager (PBM)**
8. Pursue **return on investment (ROI) pricing and forward financing**
9. Ensure state participation in **Medicare Part D as Employer Group Waiver Plans**
10. Protect consumers against **misleading marketing**
11. State pension funds assume **active shareholder role** to influence pharmaceutical company actions

Transparency

State Initiatives to Control Medication Costs — Can Transparency Legislation Help?

-Sarpatwari et al. NEJM (2017).

- Past bill focus: research and development costs for high-priced drugs
  - Vermont: An Act Related to Prescription Drugs
  - Challenges
    - Shift away from value-based pricing
    - Leverage
- Scope for utility: information needed for better decision-making
  - Sources of high drug costs
    - Drug manufacturers vs. PBMs
  - Savings passed on by 340(b) programs
  - Utilization of drug coupons
- NASHP model legislation

Public Utility Model

- Prescription drugs = critical goods

- Drug price review board
  - Review drugs with high launch prices or price increases
    - Conduct open hearings
    - Collect data from drug manufacturers
    - Commission studies
  - Approve, reject, tax, or set

- Legal questions
  - Reasonable rate of return
  - Scope of federal patent preemption
    - BIO v. District of Columbia (Fed. Cir. 2007)

Bulk Purchasing

- Central contracting for essential public health drugs
  - Hepatitis-C treatments
  - Epinephrine

- Benefit to manufacturers: predictability and volume

- Models
  - Vaccines for Children
    - Medicaid-recipient, uninsured, or underinsured
    - CDC purchased, freely available

  - Naloxone
    - State agency (*e.g.*, Attorney General's Office)
    - Trust funded by fees from participating groups

Consumer Protection: Unfair Trade Practices

- Nebulous definition: immoral, unfair, causing substantial harm

- Predatory pricing
  - Forcing patients to forgo treatment altogether or partially
  - *E.g.*, pyrimethamine (Daraprim)

- Case study: sofosbuvir (Sovaldi)
  - Massachusetts
    - Chapter 93A Section 2
    - Attorney General Healey: threat to sue
    - Skepticism: "I think she looses in Massachusetts and any court in the country." –Prof. Erik Gordon
    - Result: negotiated rebate for MassHealth

Consumer Protection: Antitrust Enforcement

- Pay-for-delay
  - Agreement to delay generic entry in return for compensation
  - 2010 FTC estimate: $3.5 billion in forgone savings annually

- FTC vs. Actavis (2013)
  - Pay-for-delay can violate antitrust law
  - Practical effect
    - Elimination of cash payments
    - Persistence of alternative arrangements
      - *E.g.*, agreement not to market authorized generic

- Possible lever: state antitrust law

State as Re-Importer and PBM

- Re-importation
  - HHS Secretary may authorize but has never done so
  - New landscape?
    - Data Quality and Security Act
    - Presidential campaign

- PBM
  - Uniform formularies for all state programs
    - Consideration: population heterogeneity
  - Possible benefits
    - Increased purchasing power
    - Elimination of profit extraction by commercial PBMS

Drug Coupons

- Generally reduce out-of-pocket but not third-party costs
- Widespread use
  - 2009: 86 programs
  - 2012: 525 programs
- Limitations
  - Often: time-limited, restricted eligibility
  - Steers patients away from lower-cost generics
    - Study: Drugs first facing generic competition 2007-2010
      - Increased spending $700 million
      - By reducing sales of bioequivalent generics

-Dafny et al. NBER (2016).

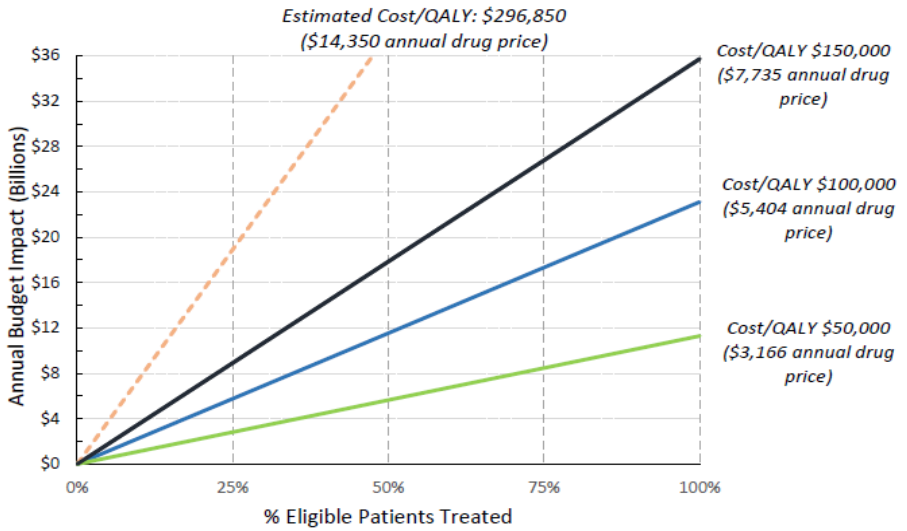
- Possible actions: consumer protection measures
  - Prominent eligibility criteria, expiration dates, and warnings
  - Set eligibility and duration floors

ROI Pricing and Forward Financing

- Value-based pricing coupled with long-term payment plan
  - Mechanism to avoid systemic shocks

- Types
  - Outcomes-based
    - *E.g.*, sacubitril/valsartan (Entresto) and hospital admissions
  - Indication-specific

- Challenges
  - Value determination
  - Risk allocation
  - Data collection
  - Medicaid restrictions



-ICER (2015).

Additional Possibilities

- Re-evaluate use of free samples, and “DAW” prescriptions
- Promote value-based prescribing
  - Point-of-care reminders
  - Academic detailing
    - Provision of non-commercial, non-product-driven, evidence-based information related to common clinical problems provided by well-trained clinicians
      - Comparative benefit, risk, and cost-effectiveness
    - Supported by a state, public health agency, or a non-profit health care system interested in improving clinical outcomes

Thank you!

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