Can Importation Address High Generic Drug Prices?

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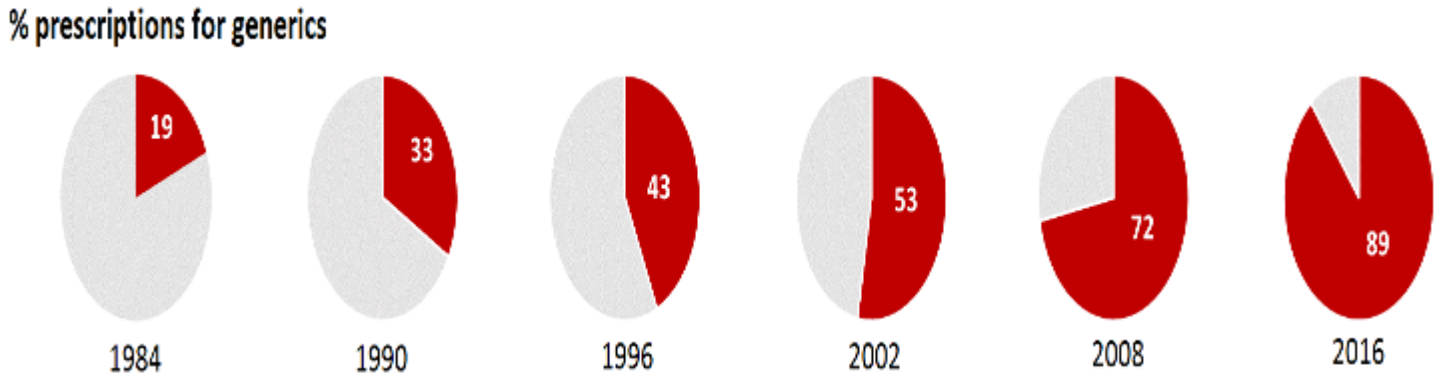
"Reining in Prescription Drug Prices"
The Brookings Institution
May 2, 2017

Overview

- Role of generics in U.S. drug market
- Sources of market failure
- Current strategies to address
- Our proposal
- Empirical analysis
- Benefit/risk assessment

Role of Generics

- 89 percent of the dispensed medications in the United States, but only 27% of overall drug spending
- Estimated savings of $1.68 trillion from 2005-2014



Generic Drug Market

- Small molecule drugs inexpensive to manufacture, interchangeable at the pharmacy level
- Price dependent on number of generic competitors
  - Price declines to 55% of brand-name price when 2 competitors; 33% when 5 competitors, and 13% when 15
- Supply and demand inelastic

Price Hikes on Generics

- Changes in price of >21,000 generic products (2008-15)
  - 400 (2%) increased more than 1,000%
  - 11,393 (54%) remained constant

Price trend of generic drugs, December 2012–July 2015

Drug name	Price per unit ($)				Percentage (%) price increase 2012–2015
	2012	2013	2014	2015	
Tetracycline 500 mg capsule	0.04	0.05	8.50	8.40	18,808
Niacin ER 1,000 mg tablet	0.10	4.80	4.80	4.20	7,673
Captopril 50 mg tablet	0.00	0.80	1.80	1.60	6,863
Clomipramine 25 mg capsule	0.20	8.30	8.30	8.30	3,600
Albuterol sulfate 2 mg tablet	0.10	3.80	3.80	4.00	3,516
Doxycycline hyclate 100 mg tablet	0.10	3.50	2.30	1.90	3,139

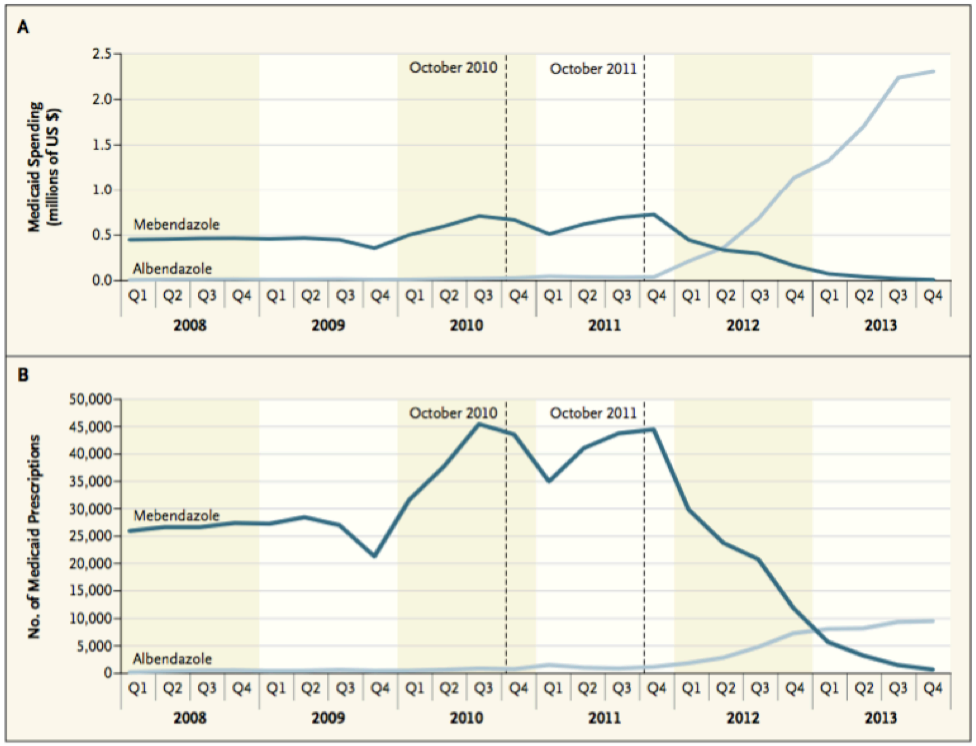
NADAC price as cited in Vega et al., Managed Care, 2016

Reasons for High Generic Drug Prices

- Many reasons, focus on two important ones:

1. Exploiting natural monopolies in niche markets

Albendazole



Medicaid Spending and Prescriptions for Albendazole and Mebendazole, 2008–2013.

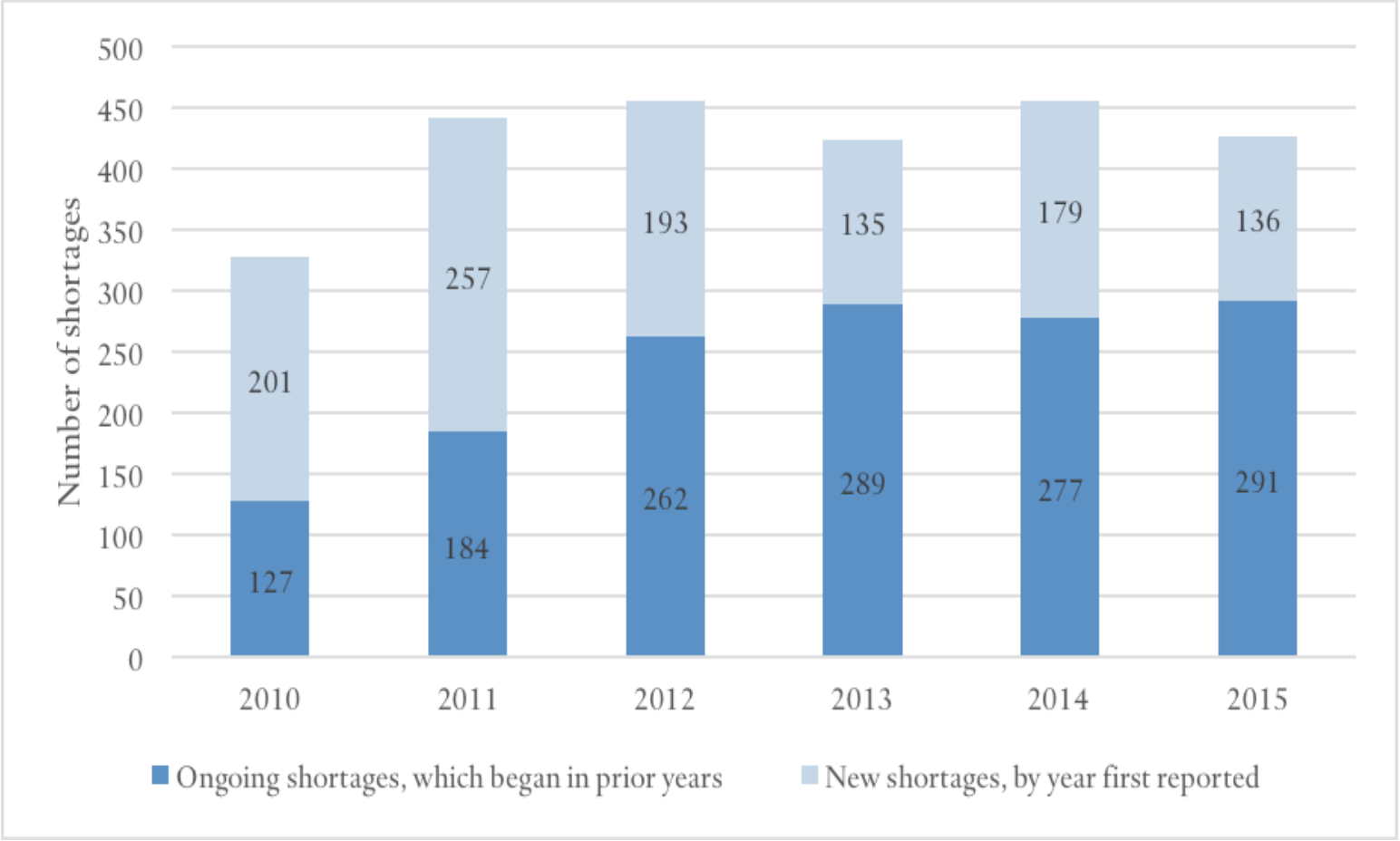
Alpern Stauffer Kesselheim, NEJM, 2015

Reasons for High Generic Drug Prices

- Many reasons, focus on two important ones:

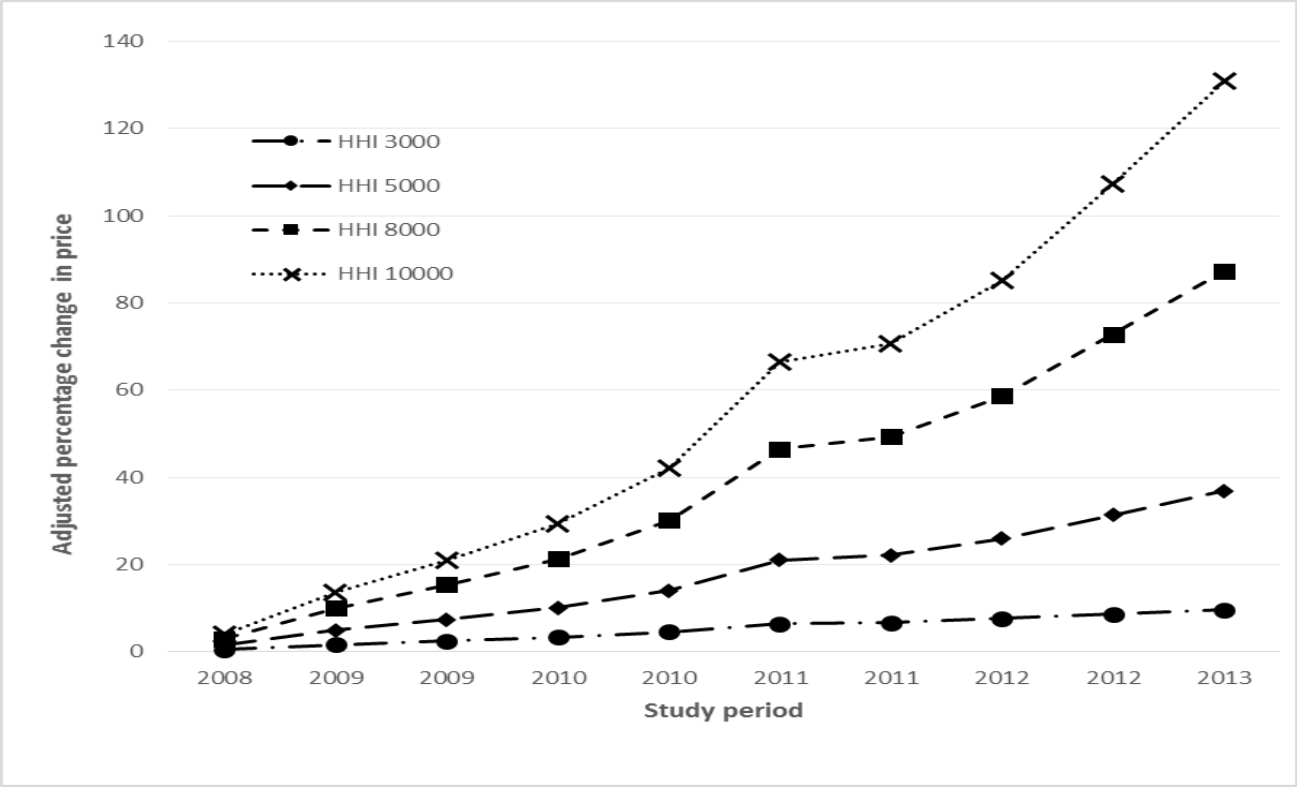
1. Exploiting natural monopolies in niche markets
2. Consolidation/mergers, exits from market

Number of U.S. Drug Shortages



U.S. Government Accountability Office, *Drug Shortages: Certain Factors Are Strongly Associated with This Persistent Public Health Challenge*, GAO-16-595 (Washington, DC, 2016)

Association between US Market Consolidation and Generic Price Changes



Dave Kesselheim Fox Hartzema, Annals of Internal Medicine, under review

Enacted/*Proposed* Strategies

- GDUFA
  - *Fee waiver for priority drugs*
- Accelerated review of generics for "sole-source" products
  - *Priority Review Vouchers for generic manufacturers*
  - *Accelerated review for trusted manufacturers*
- *Long-term government contracts for niche products*
- *Non-profit generic drug manufacturers*
- *Waive Medicare non-interference provision for multisource drugs*
- *Temporary importation*

Goals of Our Proposal

1. Sustainably reduce U.S. generic drug costs & improve patient access to safe & effective medicines
2. Be able to attract bipartisan support
3. Feasible
4. Does not undercut FDA's role in ensuring quality, safety, and efficacy of medicines used in the United States

Our Proposal

Prong 1: Pass GDUFA Reauthorization

Prong 2: Single Window Multi-Country Generic Drug Application Pathway

Prong 3: Reciprocal Drug Approval Pathway

Single Window

- Common e-application to apply simultaneously to US and other designated stringent NRAs
- Initially limit to a few countries (i.e., Canada & EU) but can be expanded over time
- Builds on existing foundation in U.S.-Canada Common Electronic Submissions Gateway Project (CESG) & ICH
- Precedent: EU Centralized Procedure

Reciprocal Drug Approval Pathway

- Approval based on assessment of other NRA, but final decision still with FDA (e.g. labeling)
- Limited to drug with inadequate generic competition; complex generics excluded at first
- Initially limit to a few countries (i.e., Canada & EU) but can be expanded over time
- Procedure based in part on model of ICAO
- Builds on International Generic Drug Regulators Pilot
- Precedent: EU decentralized procedure

Potential Sources of International Competition

Category	Number of Drugs	0 generic competitors	1 generic competitors	2 generic competitors	3 generic competitors
U.S. Drugs with insufficient generic competition	**69***	**35**	**13**	**7**	**14**
U.S. generic drugs with insufficient competition made by at least one different manufacturer approved outside the U.S.**	**44**	**18**	**10**	**5**	**11**
EMA or HealthCanada	22	7	5	4	6
Other regulators	37	17	7	3	10
Could reach sufficient competition (defined as 4 or more different manufacturers) with foreign regulator-approved sources of that drug**	**23**	**6**	**2**	**4**	**11**
EMA or HealthCanada	11	3	0	2	6
Other regulators	15	3	0	2	10

2015 Medicare Part D Spending on Drugs w/Insufficient US Competition

Median amount per drug (Total amount)	All studied drugs	0 generic competitors	1 generic competitor	2 generic competitors	3 generic competitors
U.S. generic drugs with insufficient competition made by at least one different manufacturer approved outside the USA*	$8,593 ($2,386,756)	$5,711 ($1,625,872)	$11,562 ($107,346)	$9,164 ($312,322)	$7,302 ($441,215)
EMA or HealthCanada	$7,948 ($914,887)	$4,268 ($177,725)	$8,593 ($43,542)	$9,237 ($309,533)	$17,663 ($384,086)
Other regulators	$4,426 ($1,975,700)	$4,989 ($1,460,406)	$4,493 ($68,664)	$2,789 ($12,717)	$13,725 ($433,912)
Could reach sufficient competition (defined as 4 or more manufacturers) with foreign regulator-approved sources of that drug	$7,302 ($1,876,708)	$87,803 ($1,408,606)	$2,430 ($4,860)	$5,976 ($22,028)	$7,302 ($441,215)
EMA or HealthCanada	$9,237 ($568,087)	$82,763 ($165,526)	0	$9,237 ($18,474)	$17,663 ($384,086)
Other regulators	$7,249 ($1,680,545)	$621,540 ($1,243,079)	0	$1,777 ($3,554)	$13,725 ($433,912)

Amounts are listed in thousands

Takeaways

- Could improve sustainable supply & price competition, and has potential to generate significant cost savings
- Particularly true for drugs that have no generic version or only one generic version approved in the United States
- Restricting to EU and Canada would reduce, but not eliminate benefits of reciprocal drug approval
- Strategy not sufficient on its own to address price and supply challenges with all generic medicines in US

Benefits of Proposal

- Limitation to generics reduces safety risk of reciprocal approval
- Maintains role of FDA so less chance of a regulatory race to bottom
- Should not require significant legislative changes to implement
- May help FDA comply with Pres. Trump's 2-for-1 EO
- Competition-based & should be able to attract broad-based political support

Risks of Proposal

- Prices of generic drugs tend to be higher in other developed country markets than in United States
- Long-term consequences of internationalizing the generic drug market are unclear
- Greater demands on already scarce resources at the FDA

Thank you!

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