Can Importation Address High Generic Drug Prices?

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“Reining in Prescription Drug Prices”
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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

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

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


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

![Bar chart showing the number of drug shortages from 2010 to 2015. The chart indicates a decline in the number of shortages over the years.]

Association between US Market Consolidation and Generic Price Changes

Dave Kesselheim Fox Hartzema, *Annals of Internal Medicine*, under review
Enacted/\textit{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

<table>
<thead>
<tr>
<th>Prong 1:</th>
<th>Pass GDUFA Reauthorization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prong 2:</td>
<td>Single Window Multi-Country Generic Drug Application Pathway</td>
</tr>
<tr>
<td>Prong 3:</td>
<td>Reciprocal Drug Approval Pathway</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Category</th>
<th>Number of Drugs</th>
<th>0 generic competitors</th>
<th>1 generic competitors</th>
<th>2 generic competitors</th>
<th>3 generic competitors</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S. Drugs with insufficient generic competition</td>
<td>69* (69)</td>
<td>35 (35)</td>
<td>13 (13)</td>
<td>7 (7)</td>
<td>14 (14)</td>
</tr>
<tr>
<td>U.S. generic drugs with insufficient competition made by at least one different manufacturer approved outside the U.S.**</td>
<td>44</td>
<td>18 (18)</td>
<td>10 (10)</td>
<td>5 (5)</td>
<td>11 (11)</td>
</tr>
<tr>
<td>U.S. Drugs with insufficient competition made by at least one different manufacturer approved outside the U.S.**</td>
<td>22</td>
<td>7 (7)</td>
<td>5 (5)</td>
<td>4 (4)</td>
<td>6 (6)</td>
</tr>
<tr>
<td>Other regulators</td>
<td>37</td>
<td>17 (17)</td>
<td>7 (7)</td>
<td>3 (3)</td>
<td>10 (10)</td>
</tr>
<tr>
<td>Could reach sufficient competition (defined as 4 or more different manufacturers) with foreign regulator-approved sources of that drug**</td>
<td>23</td>
<td>6 (6)</td>
<td>2 (2)</td>
<td>4 (4)</td>
<td>11 (11)</td>
</tr>
<tr>
<td>EMA or HealthCanada</td>
<td>11</td>
<td>3 (3)</td>
<td>0 (0)</td>
<td>2 (2)</td>
<td>6 (6)</td>
</tr>
<tr>
<td>Other regulators</td>
<td>15</td>
<td>3 (3)</td>
<td>0 (0)</td>
<td>2 (2)</td>
<td>10 (10)</td>
</tr>
</tbody>
</table>
## 2015 Medicare Part D Spending on Drugs w/ Insufficient US Competition

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

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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