The Competition Prescription
A Market-Based Plan for Making Medicines Affordable

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U.S. PHARMA SPENDING FAR EXCEEDS PEER NATIONS

Annual per-capita drug spending, 2014 (US$ purchasing power parity-adjusted)

Source: OECD, QuintilesIMS, FREOPP analysis
U.S. LEADS THE WORLD IN GENERIC DRUG UTILIZATION

Market share by prescription volume of unbranded generics, 2014

Source: QuintilesIMS, FREOPP analysis
BRANDED SPENDING IS EXPLODING; GENERICS DECLINING

Annual U.S. invoice sales (billions)

<table>
<thead>
<tr>
<th>Year</th>
<th>Generics (branded)</th>
<th>Generics (unbranded)</th>
<th>Patented brands</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>$39</td>
<td>$52</td>
<td>$228</td>
</tr>
<tr>
<td>2013</td>
<td>$29</td>
<td>$55</td>
<td>$236</td>
</tr>
<tr>
<td>2014</td>
<td>$30</td>
<td>$47</td>
<td>$272</td>
</tr>
<tr>
<td>2015</td>
<td>$33</td>
<td>$51</td>
<td>$310</td>
</tr>
<tr>
<td>2016</td>
<td>$36</td>
<td>$50</td>
<td>$334</td>
</tr>
</tbody>
</table>

Source: QuintilesIMS, FREOPP analysis
UNDERSTANDING NET PRICING VS. LIST PRICING

• Pharmaceutical manufacturers point out that list prices don’t reflect the net revenue they actually receive
  • **List price**: wholesale acquisition cost (WAC); rarely paid in practice
  • **Invoice price**: prices after discounts to bulk purchasers (wholesalers / distributors); **16%** lower than list price on average
  • **Net price**: prices after rebates to pharmacy benefit managers and co-pay assistance payments to consumers; **33%** lower than invoice price on average

• But: Net prices don’t reflect the actual cost to consumers
  • Not all of the rebate is passed down to consumers in the form of lower premiums
  • Co-pay assistance leads to **higher premiums**, by encouraging utilization of high-priced drugs and evading cost controls
NET PRICES UNDERESTIMATE REAL CONSUMER COSTS

Per-capita drug spending, 2014 (US$ purchasing power parity-adjusted)

United States
- Net: $899
- Net to Consumers: $251
- Invoice: $177
- List: $327

OECD Median
- Net: $489

Source: OECD, QuintilesIMS, FREOPP analysis
NET PRICES UNDERESTIMATE REAL CONSUMER COSTS

Per-capita drug spending, 2014 (US$ purchasing power parity-adjusted)

United States

OECD Median

Source: OECD, QuintilesIMS, FREOPP analysis
THE U.S. IS NOT A FREE MARKET FOR PRESCRIPTION DRUGS

- Third party purchase of third party insurance
- Legal monopolies (innovative patents)
- Medicare, Obamacare coverage mandates
- Insurer antitrust regulations (unlevel playing field)
- FDA drug development mandates (cost of R&D)
- Artificial monopolies for off-patent drugs
  - Orphan drugs, drugs that predate FDA, delivery devices, REMS
- Competitive barriers for biosimilar drugs
- Bias against “me-too” and clinically equivalent drugs
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ORPHAN DRUG SPENDING IS DEVOURING THE BUDGET

U.S. spending on orphan drugs, 2015 actual vs. 2020 estimated (Billions)

2015

$318B

$107B

Non-orphan drugs
Orphan drugs

2020E

$379B

$176B

Source: American Journal of Clinical Oncology, QuintilesIMS, FREOPP analysis
CONGRESS & FDA HAVE CREATED ARTIFICIAL MONOPOLIES

- Stacked 7-year monopolies for off-patent orphan drugs
- FDA has awarded monopolies for old drugs with new clinical trials
- Lack of FDA pathway for generics with complex delivery
  - E.g. EpiPen (injector), Advair (inhaler), transdermal patches
- Use of FDA risk evaluation & mitigation strategies as barriers to competition (e.g. thalidomide for multiple myeloma)

**Biosimilars face greater barriers than traditional generics**

- H-W: 5 years of exclusivity for off-patent drugs; BPCI: 12 years
- H-W: automatic therapeutic substitution at pharmacy; BPCI: not automatic (state rules vary)
REMOVING FEDERAL BARRIERS TO PHARMA COMPETITION

- Minimize FDA barriers to competition for small molecules
  - Limit stacking orphan drug designations; sunset Unapproved Drugs Initiative; new pathway for generics requiring delivery devices; standardize REMS protocols
- Make biosimilar pathway look more like Hatch-Waxman
- Create Fast Track authority for disease areas with 1-2 available drugs
- Minimize federal drug coverage mandates (Medicare, Medicaid, ACA)
- Migrate Medicare A/B drug coverage into Part D
- Antitrust safe harbors for insurers
- REINS Act for FDA (Congress up-or-down vote for $100MM regs)
- A patient-centered, consumer-driven health care system
THE COMPETITION PRESCRIPTION

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Avik S. A. Roy

The Foundation for Research on Equal Opportunity