The Drug Importation Debate: An Economic Perspective

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Effects of Legalizing Drug Importation are Highly Uncertain

- US legislative proposals differ
  - Countries included, conditions
  - Enforcement measures

- Uncertain responses of
  - Manufacturers
  - Wholesalers
  - Governments in exporting countries

- What is clear: Legalizing importation => massive wholesaler involvement and system-wide adjustments

- Current savings to individual consumers on individual drugs overstate system-wide savings
Importation from Canada + EU, with No Radical New Enforcement Rules

- Focus here on economic effects, but safety issues are major

- Aggregate savings to US consumers will be smaller than revenue loss to manufacturers

- Key issues
  - Mismatch of products
  - Supply restrictions – launched products
  - Foreign price increases or non-launch - new products
  - Intermediaries capture much of the savings
1. Mismatch of Compounds and Presentations Reduces Potential for Importation
Sample = Top 249 molecules, by US Unit Volume

2. Manufacturer Supply Restrictions to Exporting Countries

♦ Some manufacturers restrict supply to Canada to volume needed for Canada
  – Supply restrictions are common in EU, and legal so far
  – Provided manufacturer acts unilaterally and without market dominance
    (*Bayer Adalat* case)

♦ How much of limited supply will wholesalers/pharmacies export?
  – Some shortages reported in Canada

♦ Even if 20% of EU + Canada volume is shipped to US, would only fill 20-30% of US volume
  – And only for matching drugs

♦ Illegal sourcing from other countries, channeled through authorized export countries, could pose significant safety risk
### US Dominates Global Sales: Due to Volume and Price

<table>
<thead>
<tr>
<th>World Audited Market</th>
<th>2003</th>
<th>% Growth Constant $</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>US$ Bill</td>
<td>% Share</td>
</tr>
<tr>
<td>Latin America</td>
<td>$17.4</td>
<td>3.7%</td>
</tr>
<tr>
<td>Asia/Africa/Australia</td>
<td>$33.8</td>
<td>7.2%</td>
</tr>
<tr>
<td>Japan</td>
<td>$52.4</td>
<td>11.2%</td>
</tr>
<tr>
<td>Europe (All)</td>
<td>$134.5</td>
<td>28.8%</td>
</tr>
<tr>
<td>North America</td>
<td>$229.5</td>
<td>49.1%</td>
</tr>
<tr>
<td>Worldwide</td>
<td>$467.9</td>
<td>100.0%</td>
</tr>
<tr>
<td>10 Key Markets</td>
<td>$389.2</td>
<td>83.2%</td>
</tr>
<tr>
<td>EU (15)</td>
<td>$116.3</td>
<td>24.9%</td>
</tr>
</tbody>
</table>

Source: IMS Health Incorporated
Per Capita Unit Volume, By Molecule Age Since Global Launch. Relative to U.S. (US = 100)

Note: UK consumption upward biased by a few respiratory products.
3. Some Decline in Foreign-US Price Differentials:
(a) Manufacturers May Try to Raise Foreign Prices
---But Resistance is Likely

♦ Health policy is social insurance and fiscal policy: designed to stabilize health spending and drug spending as a percent of GDP
  – Price/reimbursement controls built in to insurance systems

♦ Foreign drug prices already roughly in line with income in industrialized countries (Danzon and Furukawa, *HA* 2003)
Price Indexes for Comprehensive Sample: Leading 249 Compounds, by Volume, US 1999

Note: United States equals 100%.
Price Indexes Relative to Per Capita Income Differentials (1999)

Note: United States equals 100%.
Control Policies Ex-US Will Constrain Significant Price Increases Abroad

- Health expenditures (including pharmaceuticals) constrained to growth of GDP
- Controls on prices and volumes
- Increased consumer cost-sharing
- Generic and therapeutic referencing=> prices of old products constrain new product prices
- Cost-effectiveness review prior to reimbursement
(b) Delay and Non-launch of New Drugs ex-US if Low Prices

- Manufacturers will rationally weigh foreign revenues vs. loss of US revenues if must accept a lower price to launch abroad.

- Price differential sufficient to induce importation will vary by product, potential sales volume, importer costs of repackaging etc.

- Countries that are unwilling/unable to pay prices close to US levels may see fewer/delayed new product launches.

- Will non-launch lead to retaliation? compulsory licensing?
Countries with Lower Prices have Fewer Launches, Longer Launch Lags (Danzon, Wang and Wang, *Health Economics* 2005)

- We estimated the effects of expected price (lagged price of competitor products) on launch delay, controlling for market size, per capita income, etc.

- Sample: launch of 85 NCEs launched in 1994-1999

- 14 EU countries, plus Australia, Canada, Czech, Japan, Mexico, New Zealand, Norway, Poland, S. Africa, Switzerland, and USA

- IMS data on prices and volumes
Findings

- Countries with lower prices have longer launch lags and fewer launches
  
- EU countries that are major PI exporters have longer delays, controlling for expected price and volume
Kaplan-Meier estimates of cumulative launch probability for selected countries
Countries with a significantly longer delays/fewer launches, relative to UK, controlling for price and volume
c. US Price Pressure from Medicare will Narrow Differentials

- Medicare Modernization Act (MMA) to deliver drug benefit through private prescription drug plans (PDPs)

- Each PDP must have at least 2 drugs in each class
  - Classes defined for Medicare by US Pharmacopeia

- Broad definition of classes => older drugs and generics compete with new, on-patent drugs

- Discounts for formulary access could be large in crowded therapeutic classes

- PDPs may demand same discounts for their private plans
4. Middlemen will Capture Some of Any Savings from Importation

♦ If only a fraction of US demand can be sourced abroad, who will capture the savings?
  – Pharmacy chains and GPOs that buy direct
  – PBMs may “clawback” average pharmacy savings
    • AWP – X% - z%

♦ Cash-paying customers are unlikely to benefit

♦ EU experience confirms that middlemen capture much of the savings from parallel trade
Pricing Options When Markets Are Linked by Importation and Regulatory Referencing

1. **Uniform Pricing in Interconnected Markets**
   - Single price is a weighted average of “best” country-specific prices if prices could differ
   - US market dominates determination of best single price
     - Delay or non-launch in countries that cannot pay target price

**Evidence**
- 1990s Pricing within bands in EU + Non-launch in low-price countries
Single List Price with Confidential Discounts to Purchasers: The US PBM Model

- Selling to wholesalers at one price eliminates arbitrage potential of importation/parallel trade

- Rebates can be directed to payers, by-passing wholesalers/distributors, to achieve ex-post price differentials

- Regulatory referencing is not feasible if rebates/differentials are confidential

- Rebate recipients have strong incentives not to “leak”

- Rebates can target subgroups e.g. purchasers for poor in LDCs
  - Public hospitals and clinics, NGOs etc.
Implementing Confidential Rebates

♦ Examples
  – US PBMs negotiate confidential discounts in return for increased market share
    • High control formularies get bigger discounts, more elastic
  – Rebates to East Germany after reunification
  – UNICEF procurement of vaccines: supply prices are not published

♦ Confidentiality encourages competitive discounting, benefits consumers
Least Bad and Worst Case Importation Scenarios

**Least Bad:**
- Modest importation risk =&gt; price and launch strategies are more complex
- Some narrowing of price differentials due to Medicare pressure in US + attempts to raise prices ex-US
- Lags and non-launch =&gt; lower company revenues, loss of access abroad
- Minimal savings to US consumers

**Worst Case:**
- US constrains manufacturer ability to limit foreign supply
  - Anti-trust suits and/or legislation
- US requires registration of foreign formulations
- Foreign countries apply compulsory licensing if
  - High prices
  - Non-launch
The Global Social Welfare Perspective: Differential Pricing Increases Social Welfare, Compared to Uniform Pricing

1. Greater Use of Existing Drugs (Static Efficiency)
   - Low-income markets can only afford drugs at low prices

2. Efficient incentives for R&D (Dynamic Efficiency)
   - Differential pricing is the most efficient, practical way to pay for R&D
   - Lower revenue, less R&D with uniform pricing

3. Equity
   - Pricing related to income is equitable, by most criteria

=> Importation that undermines differential pricing is bad public policy
Conclusions

♦ Likely increased pressure on prices: US and ex-US
  – Importation only one factor

♦ Drug importation in the US would likely reduce industry sales and profits, with little savings to US consumers
  – System-wide effects far less than drug-specific savings to individual consumers

♦ Costs of enforcing safety will further reduce potential savings

♦ Other measures to constrain drug prices could be more effective and less harmful to US consumers, foreign consumers and drug manufacturers