Prescription Drug Importation in the States
Right Question, Wrong Solution

NCSL
Sharon Lamberton, MS, RN
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Deadly Fake Pills Found in 48 49 States

As of Sep. 2019
State Importation: Right Question, Wrong Solution

No Additional Risk to Public Health

Significant Cost Savings to American Consumer
U.S. Drug Importation Proposals Proliferating

Large Population Difference

37 million

327 million

Legislation Passed

Legislation Filed

Population:
- 600,000
- 21.3 million
- 5.7 million
- 1.34 million
- 37 million
- 327 million

Map showing states with legislation passed and those with legislation filed.
Safe Importation Action Plan

- Safe Importation Action Plan

- Under Pathway 1, a Notice of Proposed Rulemaking ("NPRM") would rely on the authority in the Federal Food, Drug, and Cosmetic Act ("FD&C Act") section 804 to authorize demonstration projects to allow importation of drugs from Canada. The NPRM would include conditions to ensure the importation poses no additional risk to the public’s health and safety and that it will achieve significant cost savings to the American consumer.

- Under Pathway 2, manufacturers could import versions of FDA-approved drug products that they sell in foreign countries that are the same as the U.S. versions. Under this pathway, manufacturers would use a new National Drug Code (NDC) for those products, potentially allowing them to offer a lower price than what their current distribution contracts require.

- Currently under review at OMB
How much might it cost the state to implement and administer its program?

<table>
<thead>
<tr>
<th>Description</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implementation &amp; Start Up Costs</td>
<td>$25 million</td>
</tr>
<tr>
<td>Annual Administrative costs</td>
<td>$2.5</td>
</tr>
<tr>
<td>Annual Program Integrity &amp; Enforcement Costs</td>
<td>$1.5 – 3 million</td>
</tr>
<tr>
<td>Estimated Sampling and Testing Costs</td>
<td>$6.6 - $27 million</td>
</tr>
<tr>
<td>Annual Cost of an Adverse Medical Event</td>
<td>$50,000 - $800,000 per event</td>
</tr>
<tr>
<td>FL Annual Administrative costs (best case scenario)</td>
<td>$10.6 million</td>
</tr>
<tr>
<td>FL Annual Administrative costs (worst case scenario, assuming an adverse event)</td>
<td>$33.3 million</td>
</tr>
</tbody>
</table>

While PhRMA provided funding for the analysis, the findings are those of Leavitt Partners. PhRMA did not influence the results, other than providing the baseline list of medications for consideration.
Risks and Costs of State-Run Importation Programs May Outweigh Potential Benefits

**Initial costs**
- Program design and certification
- Technology and infrastructure to track drugs and keep records

**Recurring costs**
- Maintaining medical product safety based on FDA standards

**Potential legal costs**
- Lawsuits associated with mishandling of medicines

**Law enforcement**
- Additional policing to ensure imported drugs are not sold out-of-state

**Repackaging & relabeling**
- Canadian standards differ from FDA requirements

**Reporting to the FDA**
- Fulfilling compliance requirements and reporting standards
Unanswered Questions: State Implementation

• State costs
• From Canada or through Canada
• Medicaid savings
• Track and Trace compliance
• HHS Rulemaking
• Patient choice and transparency
• Canadian to U.S. price comparison
• Supply chain interest
• Liability
State Importation: Right Question, Wrong Solution

Opposition from Regulators and Supply Chain Entities

“Drug importation as a ‘gimmick’ and that ‘the last thing we need is open borders for unsafe drugs to flow through.’” – HHS Secretary Azar

“Canada does not support actions that could adversely affect the supply of prescription drugs in Canada and potentially raise costs of prescription drugs for Canadians.” – Health Canada Officials
In the midst of incredible scientific progress, medicine cost growth is declining

<table>
<thead>
<tr>
<th>EXPRESS SCRIPTS®</th>
<th>CVS Health</th>
<th>IMS Health &amp; Quintiles are now IQVIA®</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.5% 2017</td>
<td>3.2% 2016</td>
<td>3.9% 2016</td>
</tr>
<tr>
<td>0.4% 2018</td>
<td>1.9% 2017</td>
<td>0.6% 2017</td>
</tr>
</tbody>
</table>
Flow of Payment for a $400 Insulin
(Patient Is in Deductible Phase)

This graphic is illustrative of a hypothetical product with a WAC of $400 and an AWP of $480. It is not intended to represent every financial relationship in the marketplace.
In fact, more than 1/3 of the list price is rebated back to payers, the government and other stakeholders in the supply chain.

**Brand companies retain just 63% of list price spending on medicines**

- Brand Companies: 62.6%
- Market Access Rebates and Discounts: 18.5%
- Statutory Rebates and Fees: 12%
- Supply Chain Entities: 6.9%

**Rebates, discounts, fees and other price concessions have more than doubled since 2012**

- 2012: $74B
- 2018: $166B

Source: Berkeley Research Group; Fein AJ; Drug Channels Institute
# Share the Savings: Premium Impact Analysis

## Annual Cost Impact to Patients in Integrated Deductible Plans

<table>
<thead>
<tr>
<th>State</th>
<th>Colorado</th>
<th>Michigan</th>
<th>Ohio</th>
<th>New Hampshire</th>
<th>Nevada</th>
<th>South Carolina</th>
<th>Washington</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average Maximum Savings</td>
<td>$2,190</td>
<td>$1,740</td>
<td>$1,900</td>
<td>$1,740</td>
<td>$1,820</td>
<td>$2,360</td>
<td>$1,800</td>
</tr>
<tr>
<td>Average savings for patients with diabetes</td>
<td>$590</td>
<td>$510</td>
<td>$700</td>
<td>$610</td>
<td>$600</td>
<td>$820</td>
<td>$570</td>
</tr>
<tr>
<td>Average savings for patients with asthma</td>
<td>$270</td>
<td>$210</td>
<td>$260</td>
<td>$220</td>
<td>$230</td>
<td>$300</td>
<td>$220</td>
</tr>
<tr>
<td>Premium Increase for Modeled Plan</td>
<td>$49.71 (1%)</td>
<td>$45.72 (1%)</td>
<td>$65.87 (1.4%)</td>
<td>$43.98 (1%)</td>
<td>$51.10 (1.2%)</td>
<td>$80.07 (1.4%)</td>
<td>$71.73 (1.6%)</td>
</tr>
</tbody>
</table>
Policies so that “Patients Pay Less”

- Share the Savings
- Make Coupons Count
- Offer Lower Cost Sharing Options
- Cover Medicines from Day One
Thank You!

Sharon Lamberton, MS, RN
slamberton@phrma.org