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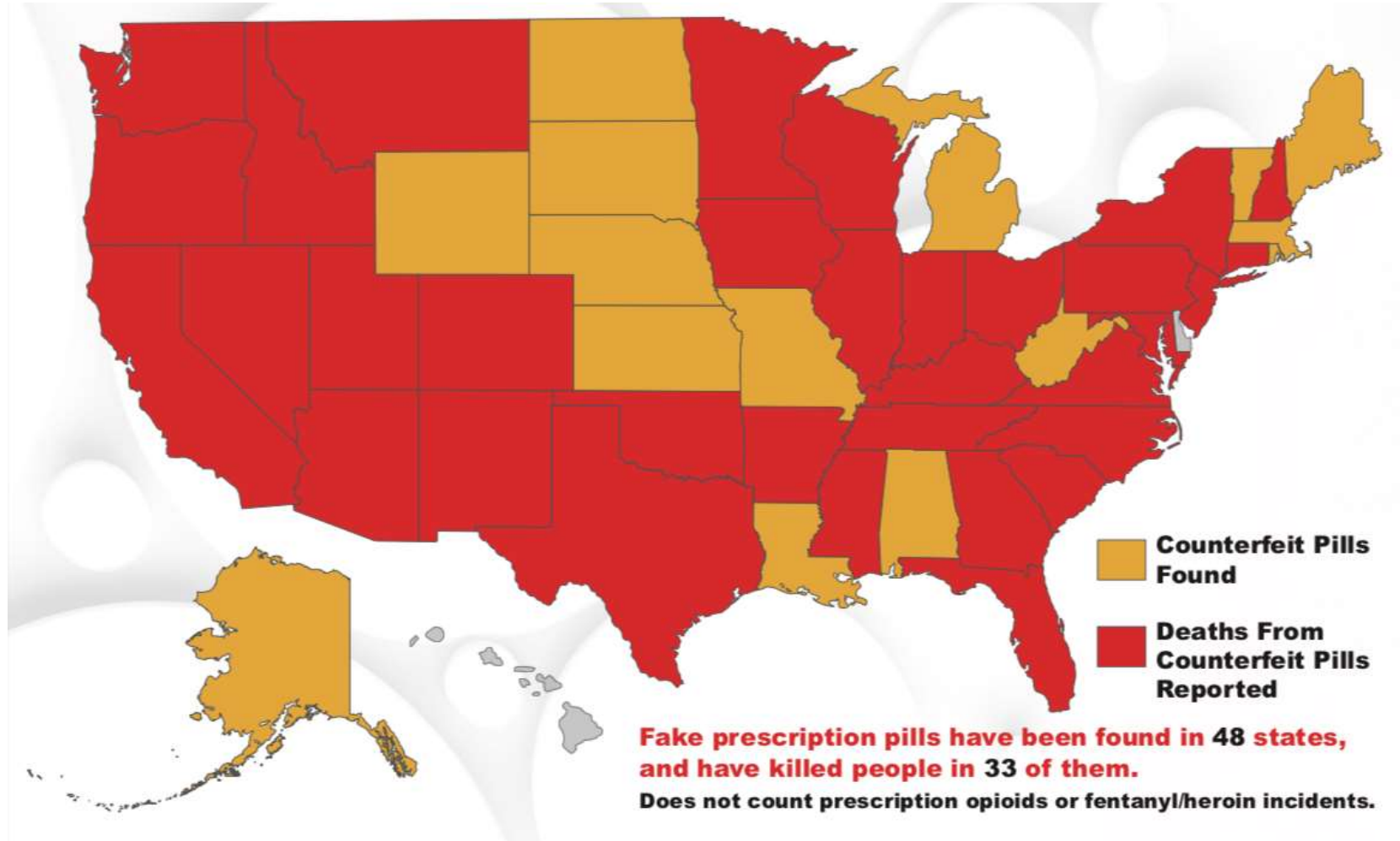
# Prescription Drug Importation in the States

## Right Question, Wrong Solution

NCSL  
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**PRMA**  
RESEARCH • PROGRESS • HOPE

# 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

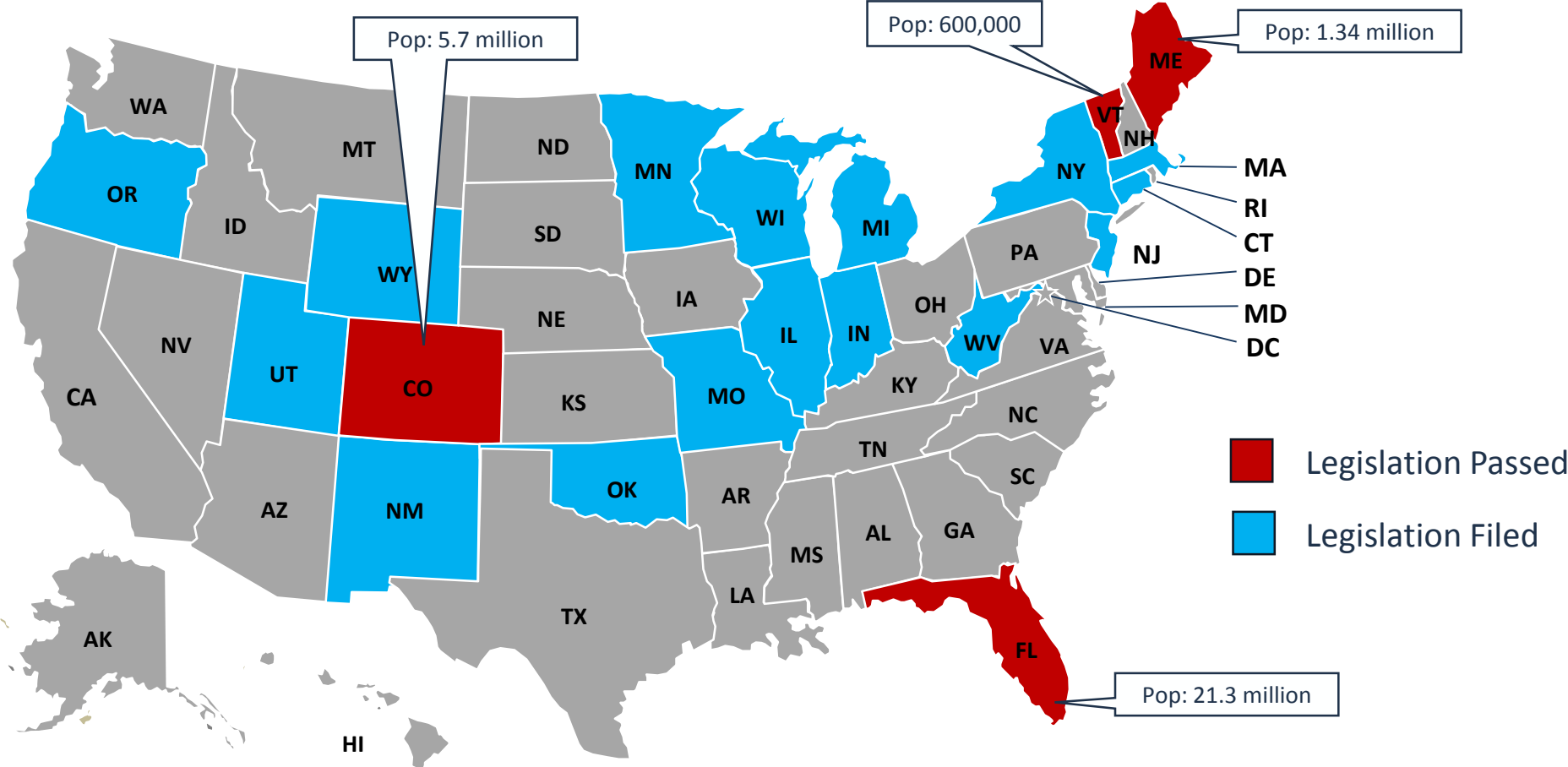
Large Population Difference



37 million



327 million



# 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

# Florida Drug Importation Analysis

How much might it cost the state to implement and administer its program?

Implementation & Start Up Costs	\$25 million
Annual Administrative costs	\$2.5
Annual Program Integrity & Enforcement Costs	\$1.5 – 3 million
Estimated Sampling and Testing Costs	\$6.6 - \$27 million
Annual Cost of an Adverse Medical Event	\$50,000 - \$800,000 per event
FL Annual Administrative costs (best case scenario)	\$10.6 million
FL Annual Administrative costs (worst case scenario, assuming an adverse event)	\$33.3 million

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

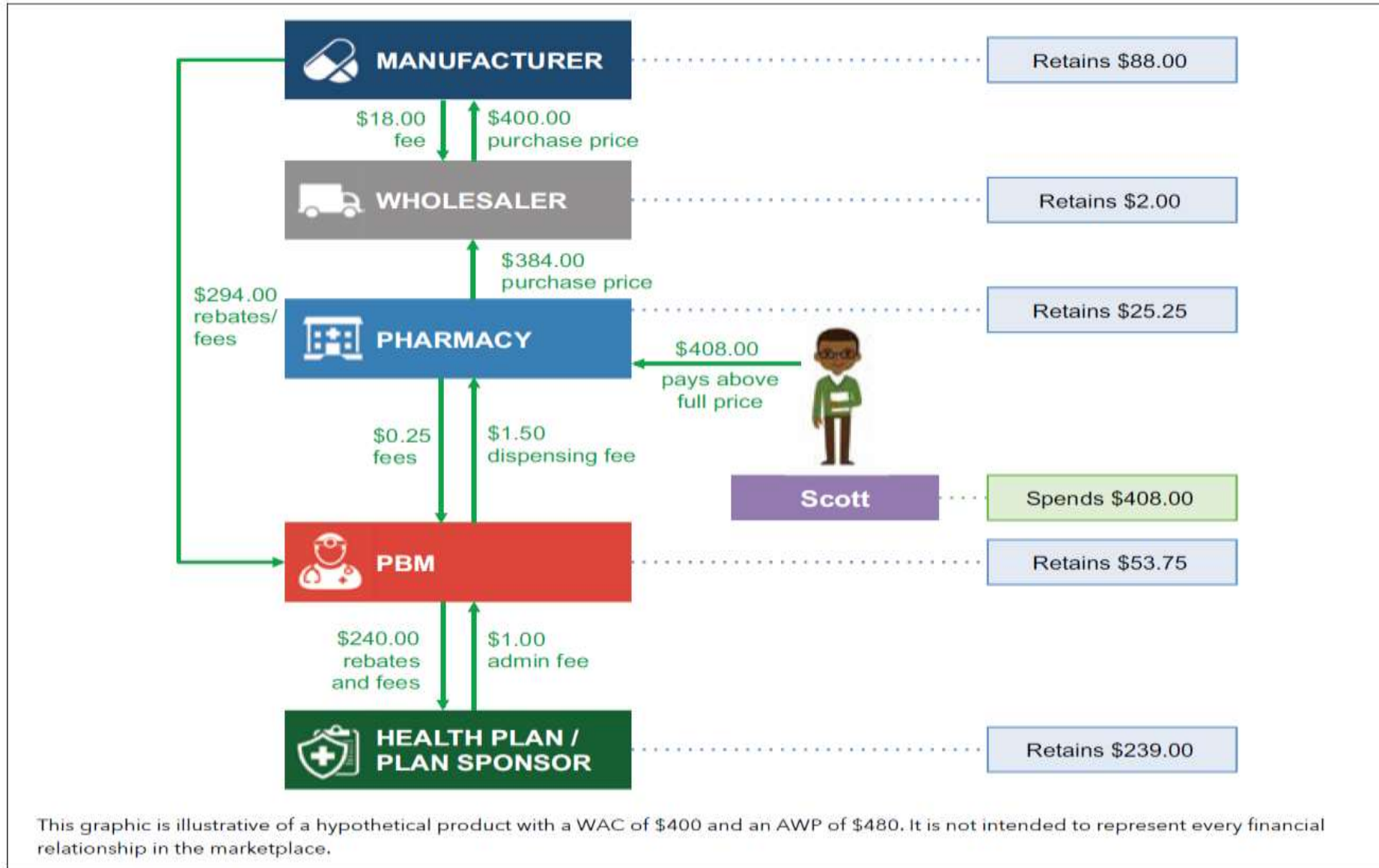


# In the midst of incredible scientific progress, medicine cost growth is declining

		
<p data-bbox="563 672 713 735"><b>1.5%</b></p> <p data-bbox="606 758 670 786">2017</p>  <p data-bbox="563 939 713 1002"><b>0.4%</b></p> <p data-bbox="606 1029 670 1058">2018</p>	<p data-bbox="1200 672 1350 735"><b>3.2%</b></p> <p data-bbox="1243 758 1307 786">2016</p>  <p data-bbox="1200 939 1350 1002"><b>1.9%</b></p> <p data-bbox="1243 1029 1307 1058">2017</p>	<p data-bbox="1849 672 2000 735"><b>3.9%</b></p> <p data-bbox="1893 758 1956 786">2016</p>  <p data-bbox="1849 939 2000 1002"><b>0.6%</b></p> <p data-bbox="1893 1029 1956 1058">2017</p>

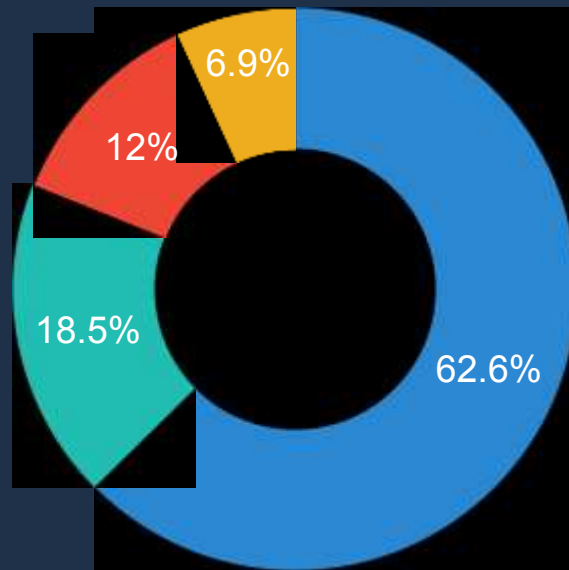


## Flow of Payment for a \$400 Insulin (Patient Is in Deductible Phase)



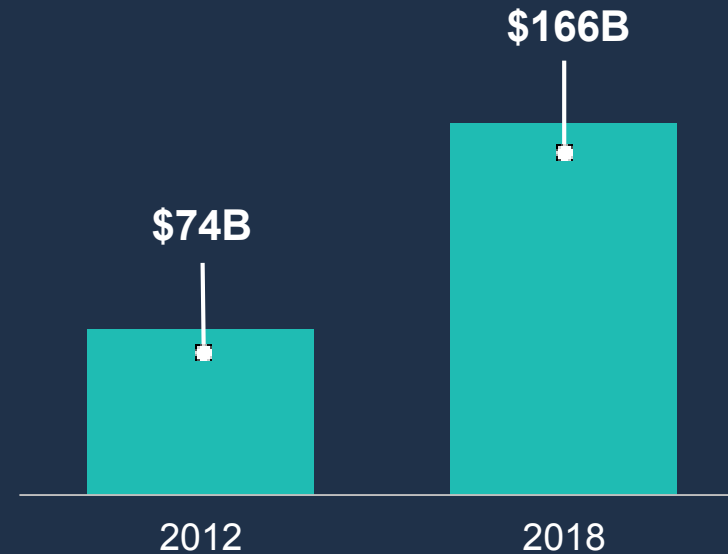
In fact, more than 1/3 of the list price is rebated back to payers, the government and other stakeholders in the supply chain.

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



- Brand Companies
- Market Access Rebates and Discounts
- Statutory Rebates and Fees
- Supply Chain Entities

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



## Share the Savings: Premium Impact Analysis

### Annual Cost Impact to Patients in Integrated Deductible Plans

State	Colorado	Michigan	Ohio	New Hampshire	Nevada	South Carolina	Washington
Average Maximum Savings	\$2,190	\$1,740	\$1,900	\$1,740	\$1,820	\$2,360	\$1,800
Average savings for patients with diabetes	\$590	\$510	\$700	\$610	\$600	\$820	\$570
Average savings for patients with asthma	\$270	\$210	\$260	\$220	\$230	\$300	\$220
Premium Increase for Modeled Plan	\$49.71 (1%)	\$45.72 (1%)	\$65.87 (1.4%)	\$43.98 (1%)	\$51.10 (1.2%)	\$80.07 (1.4%)	\$71.73 (1.6%)

# Policies so that *“Patients Pay Less”*

Share the Savings

Make Coupons Count

Offer Lower Cost Sharing  
Options

Cover Medicines from Day  
One

# Thank You!

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