Health & Human Services Committee

Monday, January 8, 2024
3:00 PM – 5:00 PM
Morris Hall (17 HOB)

Meeting Packet

Paul Renner
Speaker

Randy Fine
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Health & Human Services Committee

Start Date and Time:	Monday, January 08, 2024 03:00 pm
End Date and Time:	Monday, January 08, 2024 05:00 pm
Location:	Morris Hall (17 HOB)
Duration:	2.00 hrs

Presentations on International Drug Reference Pricing:

Andrew Mulcahy, Ph.D, Senior Policy Researcher, RAND Corporation

Drew Gattine, Senior Policy Fellow, National Academy for State Health Policy

To submit an electronic appearance form, and for information about attending or testifying at a committee meeting, please see the "Visiting the House" tab at www.myfloridahouse.gov.

NOTICE FINALIZED on 12/28/2023 12:35PM by Clenord.Judeline

Andrew Mulcahy, PH.D MPP
Senior Health Economist
Rand Corporation

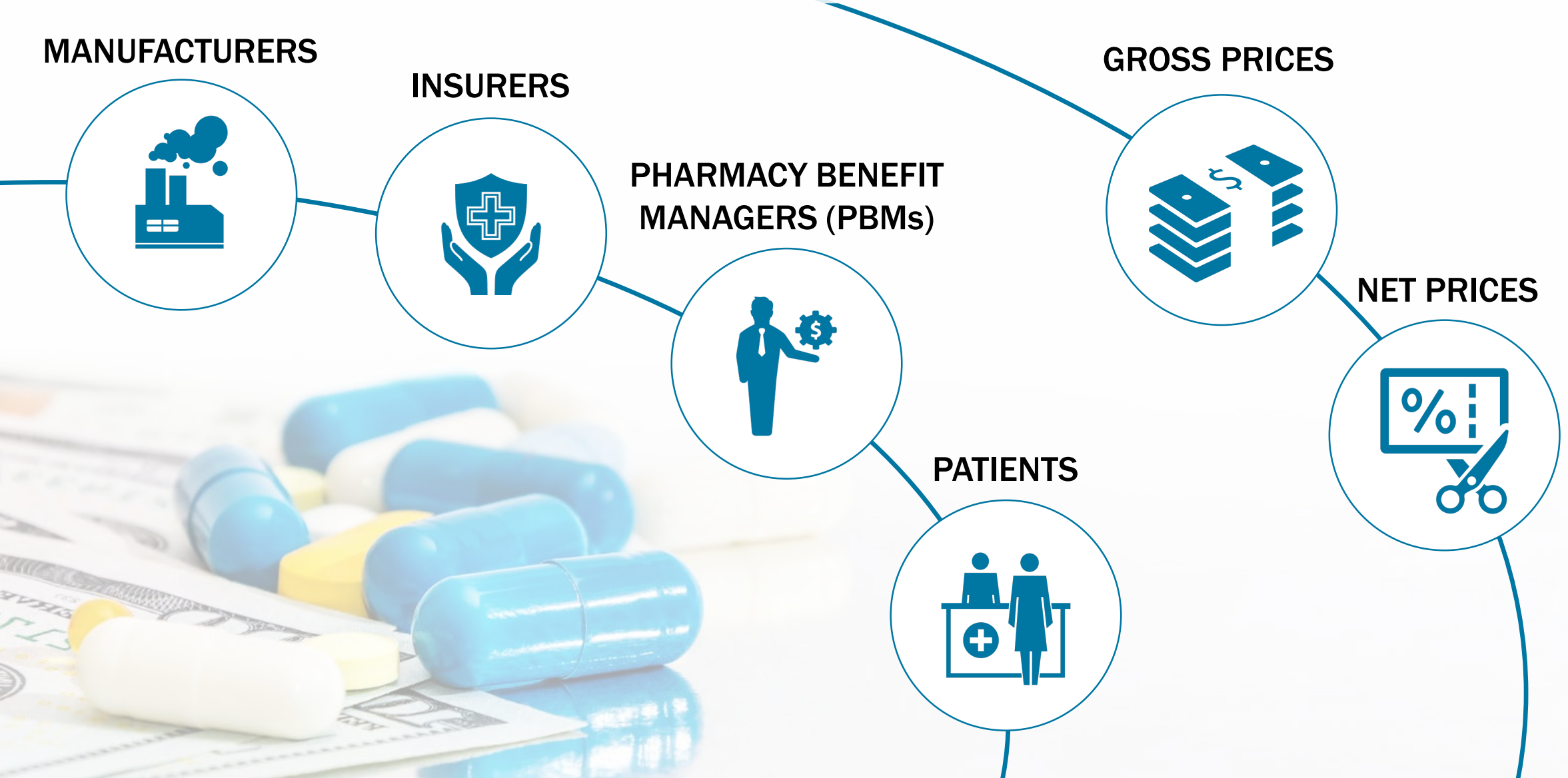
U.S. and International Drug Prices: An Overview

Briefing to the Florida House of Representatives Health and Human Services Committee

Andrew Mulcahy, PhD MPP
Senior Health Economist, RAND Corporation

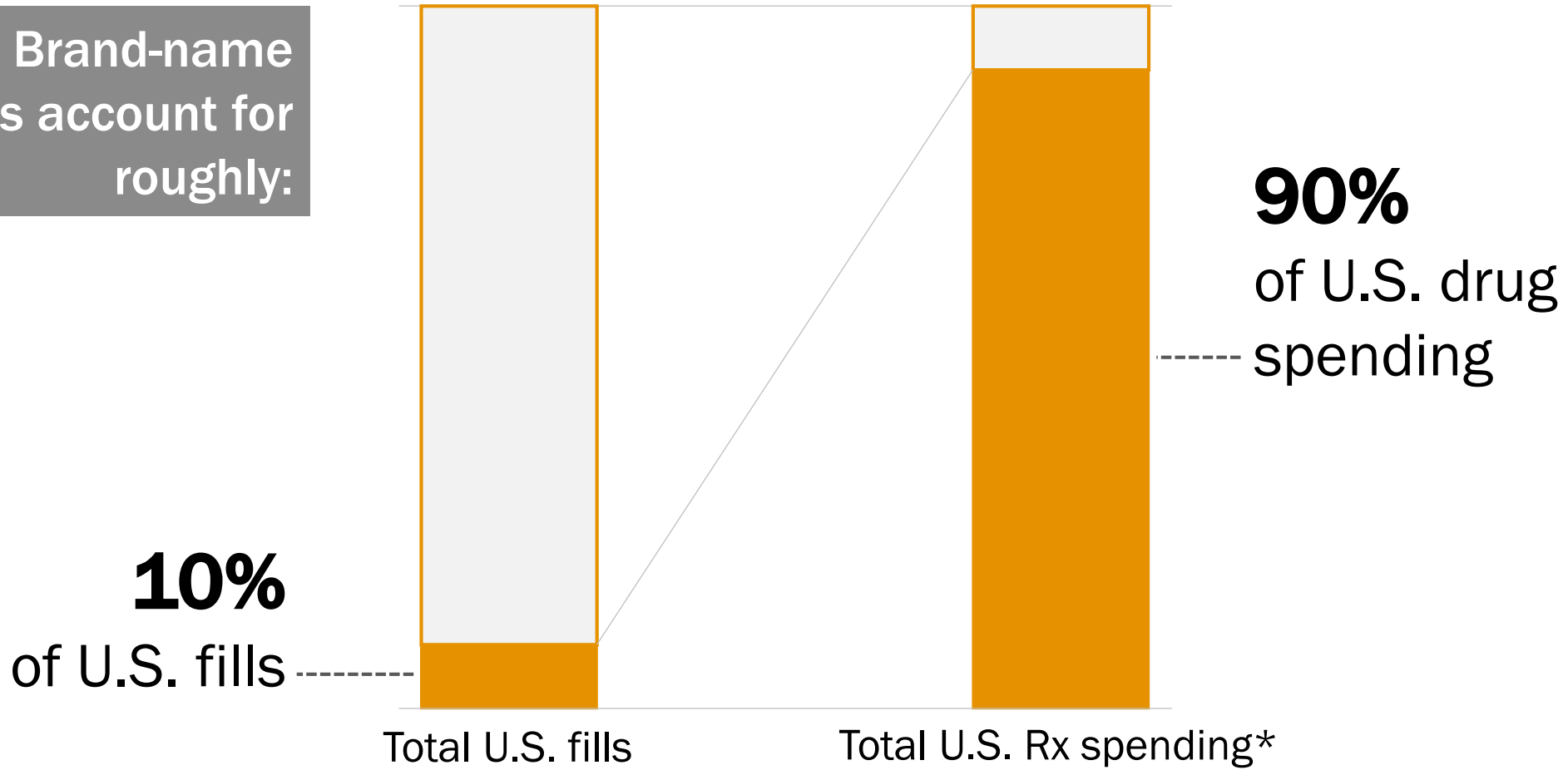
January 8, 2024

For any drug, there are many U.S. “prices”…



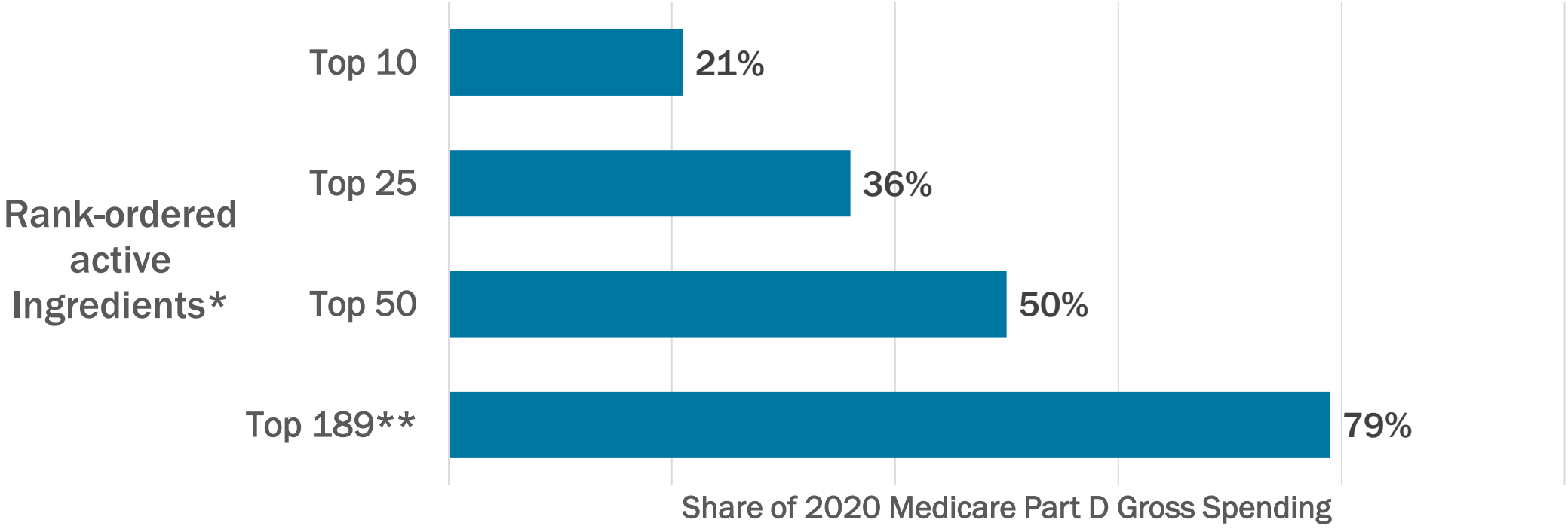
And U.S. prices vary across different types of drugs

U.S. Brand-name drugs account for roughly:



Source: IQVIA 2023
*Spending at manufacturer gross prices

U.S. drug spending is concentrated in just a few drugs



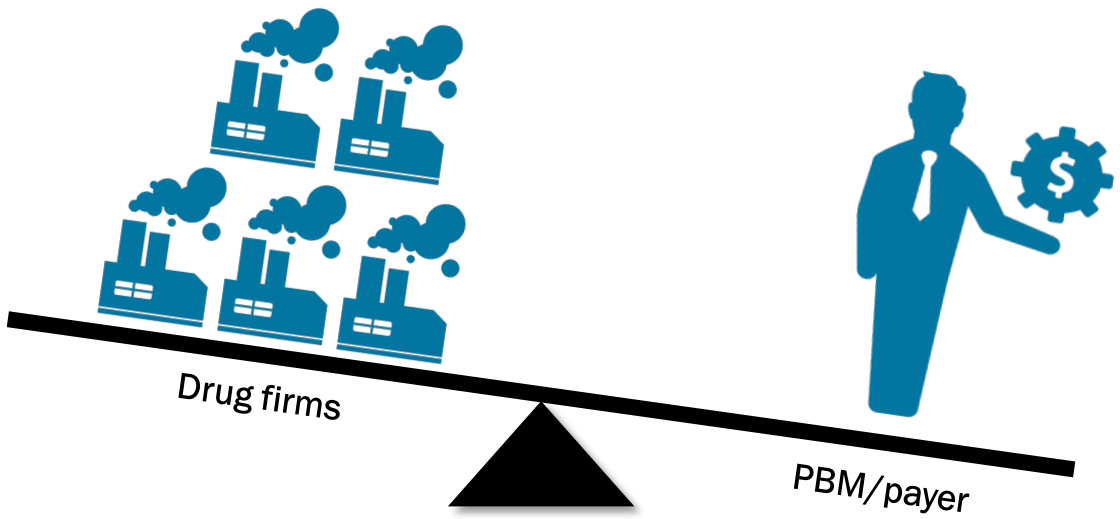
***Of ~1,800 Part D active ingredients**
****Covering all active ingredients with >$200M in payments**

Source: 2020 Part D Dashboard data

U.S. brand-name drugs have high gross ("list") prices and—sometimes—lower net prices

CASE 1: High Competition

Close substitute drugs from multiple companies

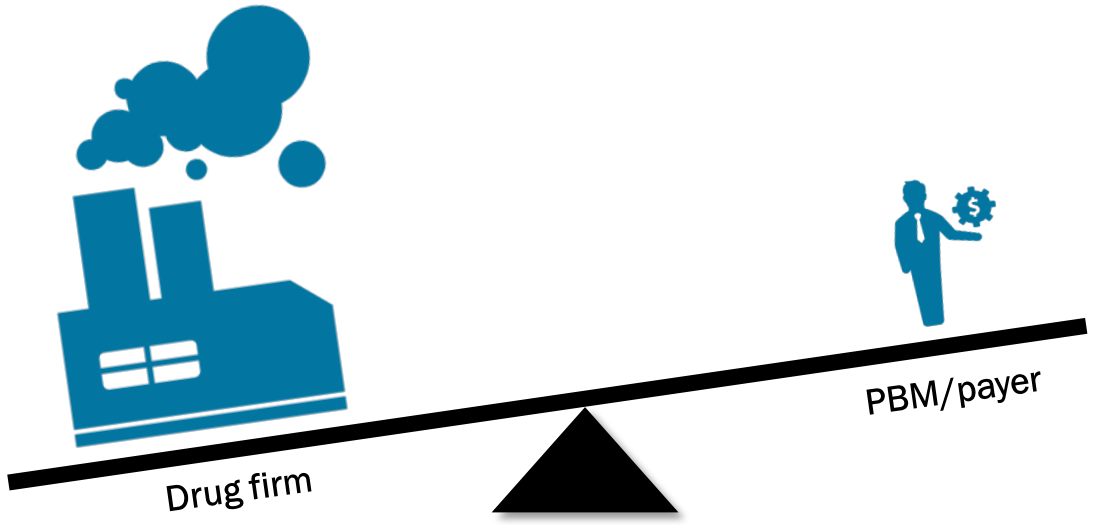


PBMs/payers have more leverage

Big rebate off gross price

CASE 2: Low Competition

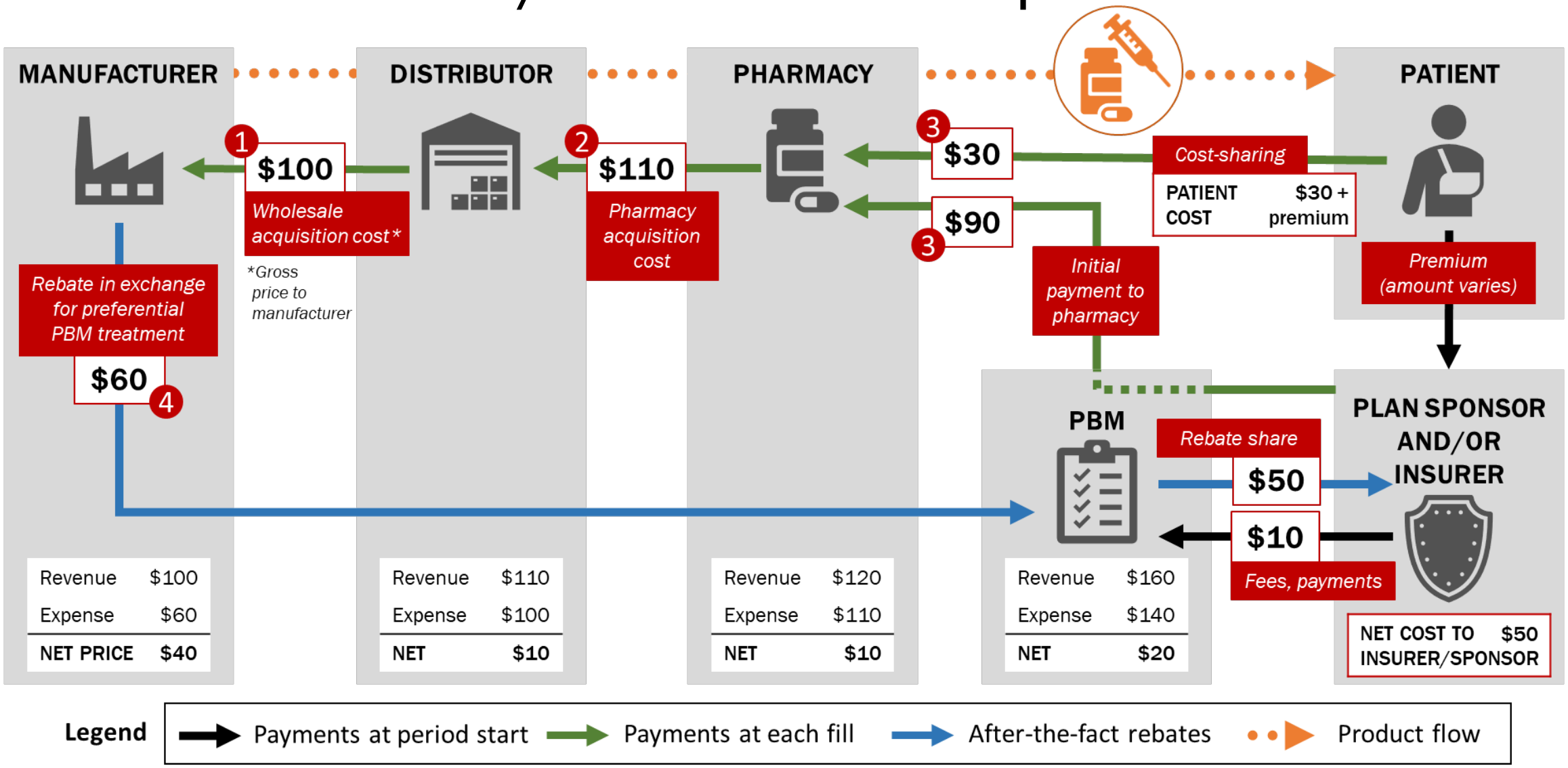
No close substitute drugs



Drug firms have more leverage

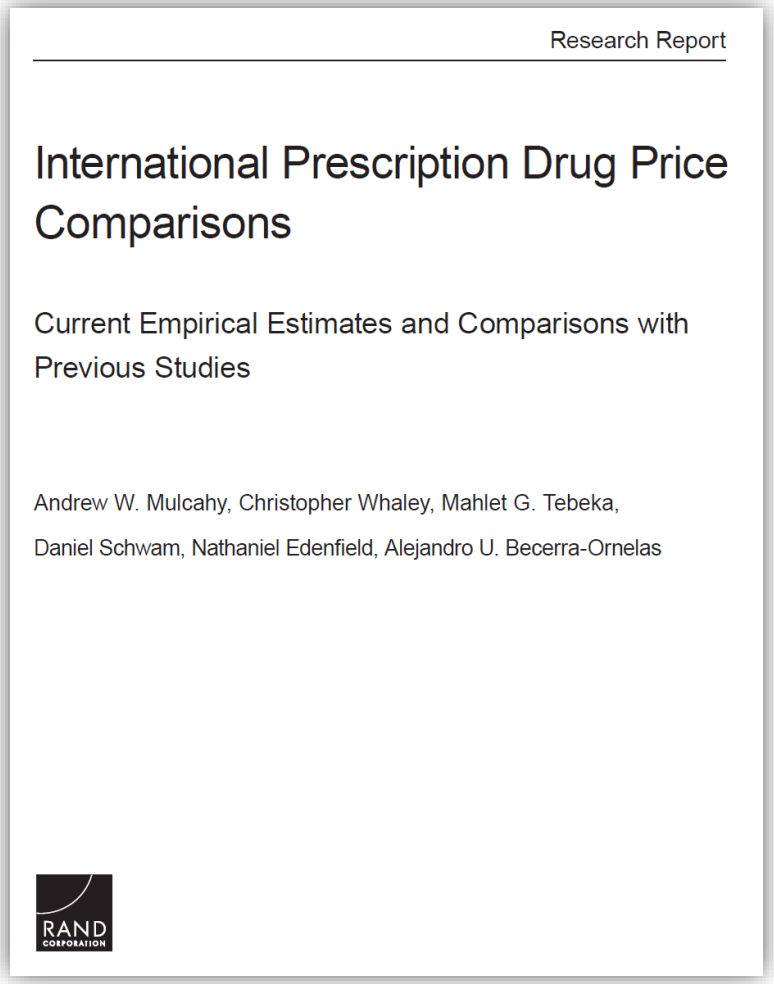
Little/no rebate off gross price

Determining net prices to manufacturers and from PBMs/insurers is complicated



How do U.S. prices compare to those in other countries?

- RAND's peer-reviewed 2021 report to HHS available here
- Our study:
  - Used IQVIA MIDAS data for the United States and 32 higher-income OECD countries
  - Included all drugs sold in each country (brand, generic, biologic, small molecule, etc.)
  - Compared primarily ***manufacturer gross*** prices using price indexes
  - We also compared U.S. ***manufacturer net*** prices (i.e., after rebates)


Research Report

International Prescription Drug Price Comparisons

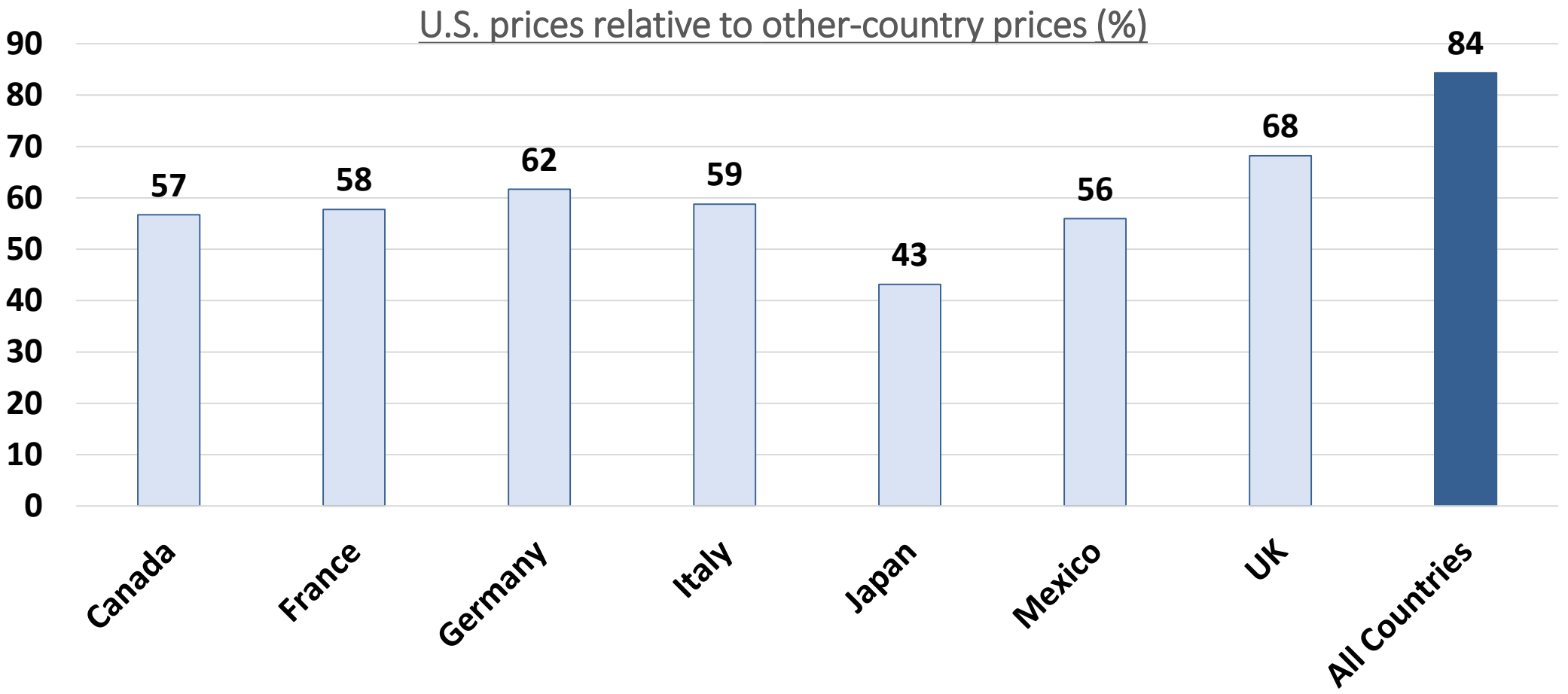
Current Empirical Estimates and Comparisons with Previous Studies

Andrew W. Mulcahy, Christopher Whaley, Mahlet G. Tebeka, Daniel Schwam, Nathaniel Edenfield, Alejandro U. Becerra-Ornelas

RAND CORPORATION

Source: https://www.rand.org/pubs/research_reports/RR2956.html
Note: The U.S. Department of Health and Human Services (HHS), Office of the Assistant Secretary for Planning and Evaluation (ASPE) funded this work. Neither the report nor this briefing reflects the views of HHS.

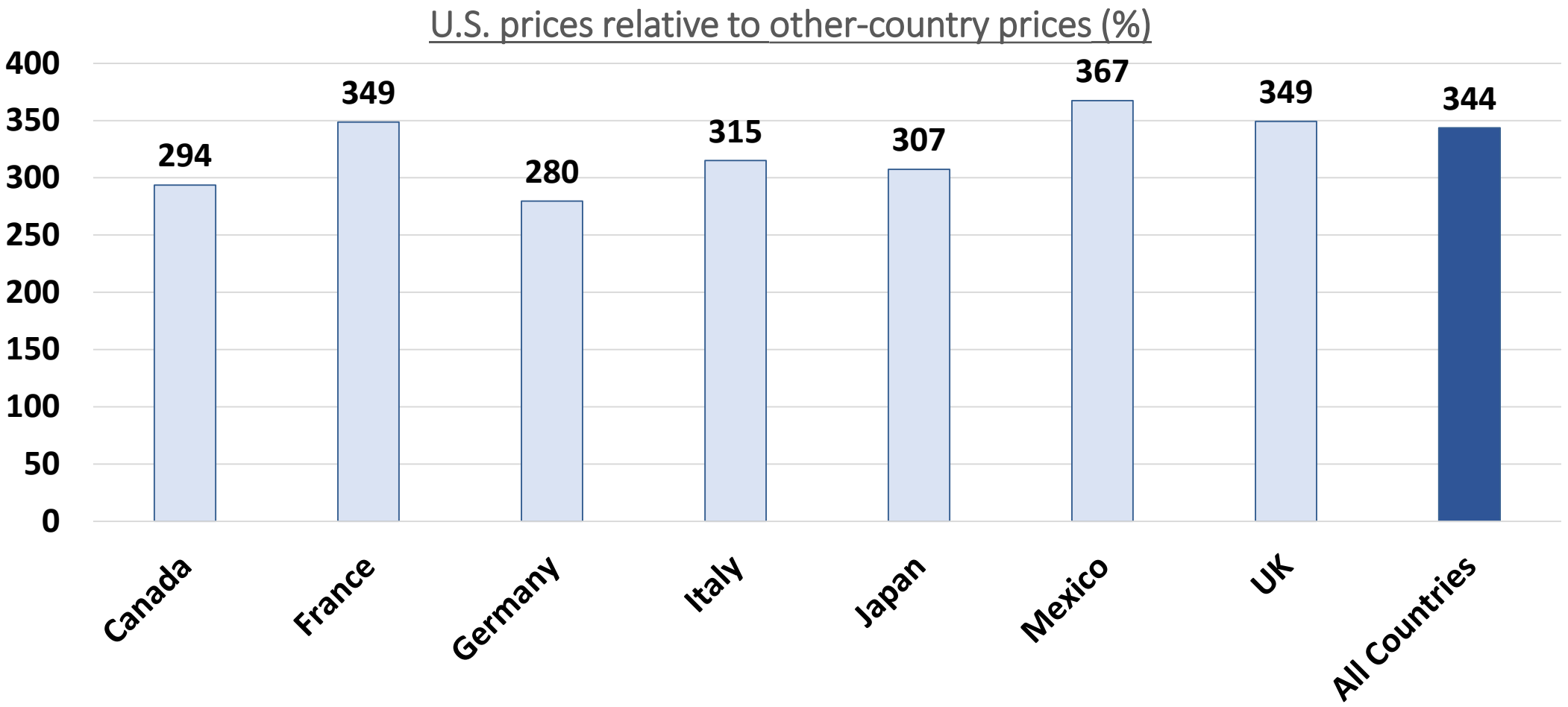
U.S. unbranded generics are cheaper than those in other countries



For example: U.S. generic prices were 57 percent those in Canada

SOURCE: RAND analysis of 2018 IQVIA MIDAS data (run date October 28, 2019). NOTE: "All countries" includes all 32 OECD comparison countries combined weighted by volume. Other-country prices are set to 100. *Excluding all presentations categorized as biologics in MIDAS. Most biosimilars are categorized in MIDAS as branded generics. The "All country" result is significantly higher than the G7 country and Mexico results reported here. Other OECD countries had unbranded generic prices closer to US prices. Only some presentations sold in each country contribute to bilateral comparisons.

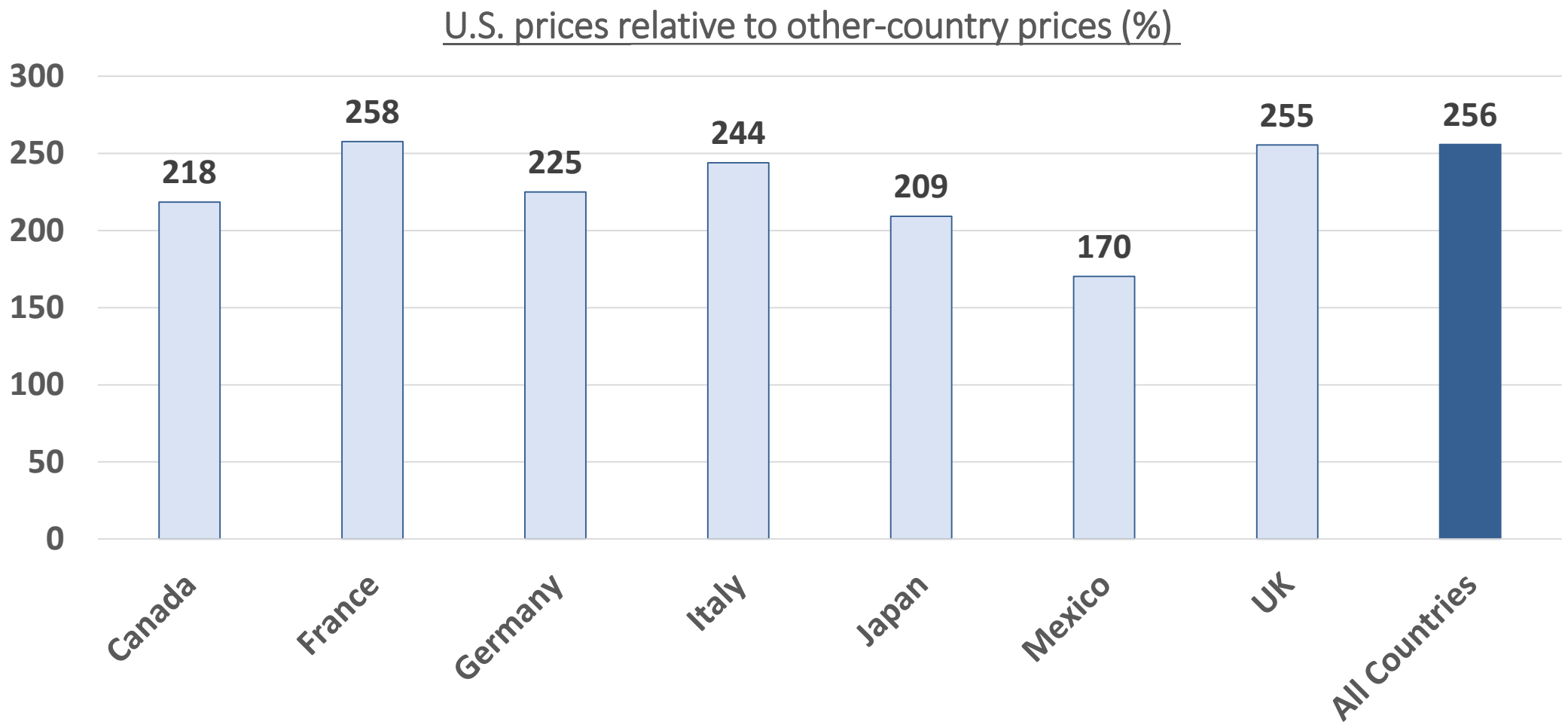
But U.S. brand-name prices are (much) higher



For example: U.S. brand-name drug prices were roughly 3 times (300%) those in Canada

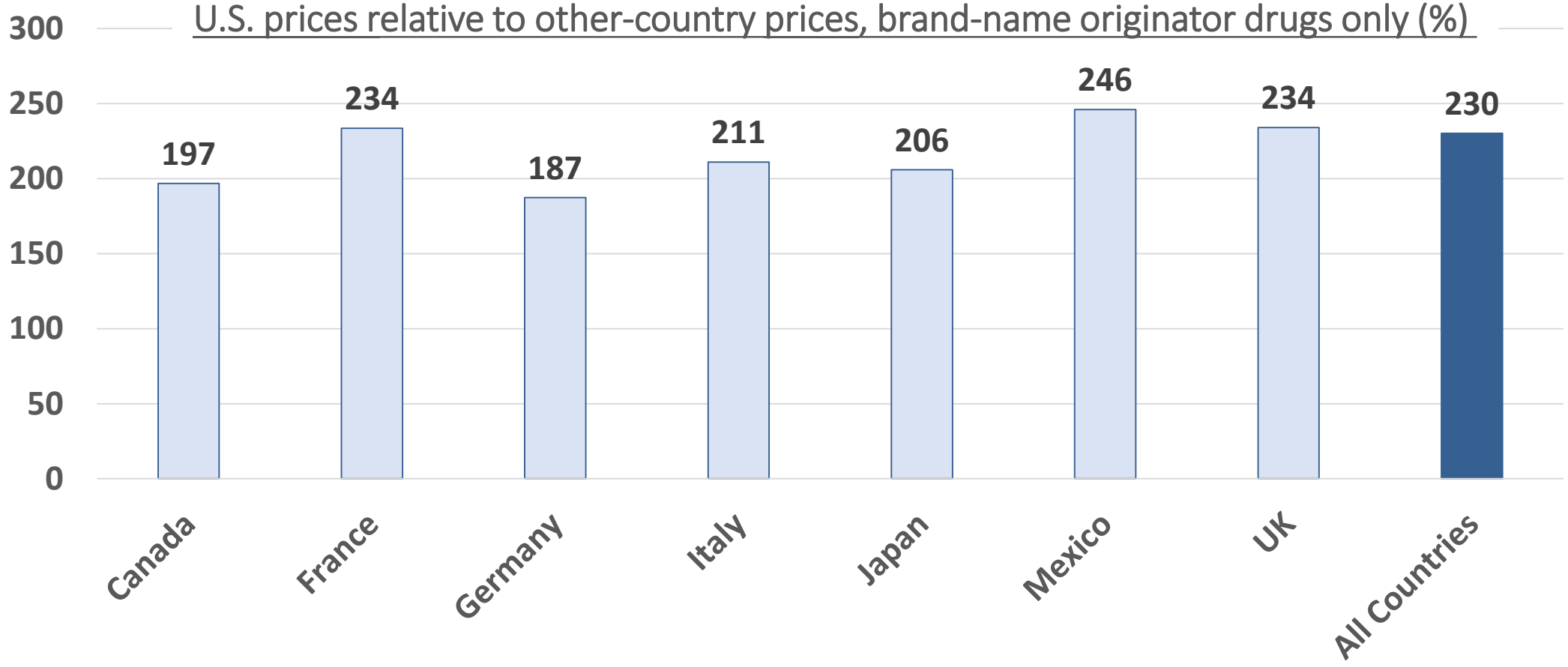
SOURCE: RAND analysis of 2018 IQVIA MIDAS data (run date October 28, 2019). NOTE: "All countries" includes all 32 OECD comparison countries combined weighted by volume. Other-country prices are set to 100. Only some presentations sold in each country contribute to bilateral comparisons.

Combining across all drugs, U.S. prices are roughly 2.5 times those in other countries



SOURCE: RAND analysis of 2018 IQVIA MIDAS data (run date October 28, 2019). NOTE: "All countries" includes all 32 OECD comparison countries combined weighted by volume. Other-country prices are set to 100. Only some presentations sold in each country contribute to bilateral comparisons.

U.S. manufacturer **net** prices remained more than twice those in other countries



Caveat: We adjusted only U.S. prices downward. Net prices are generally not available in other countries.

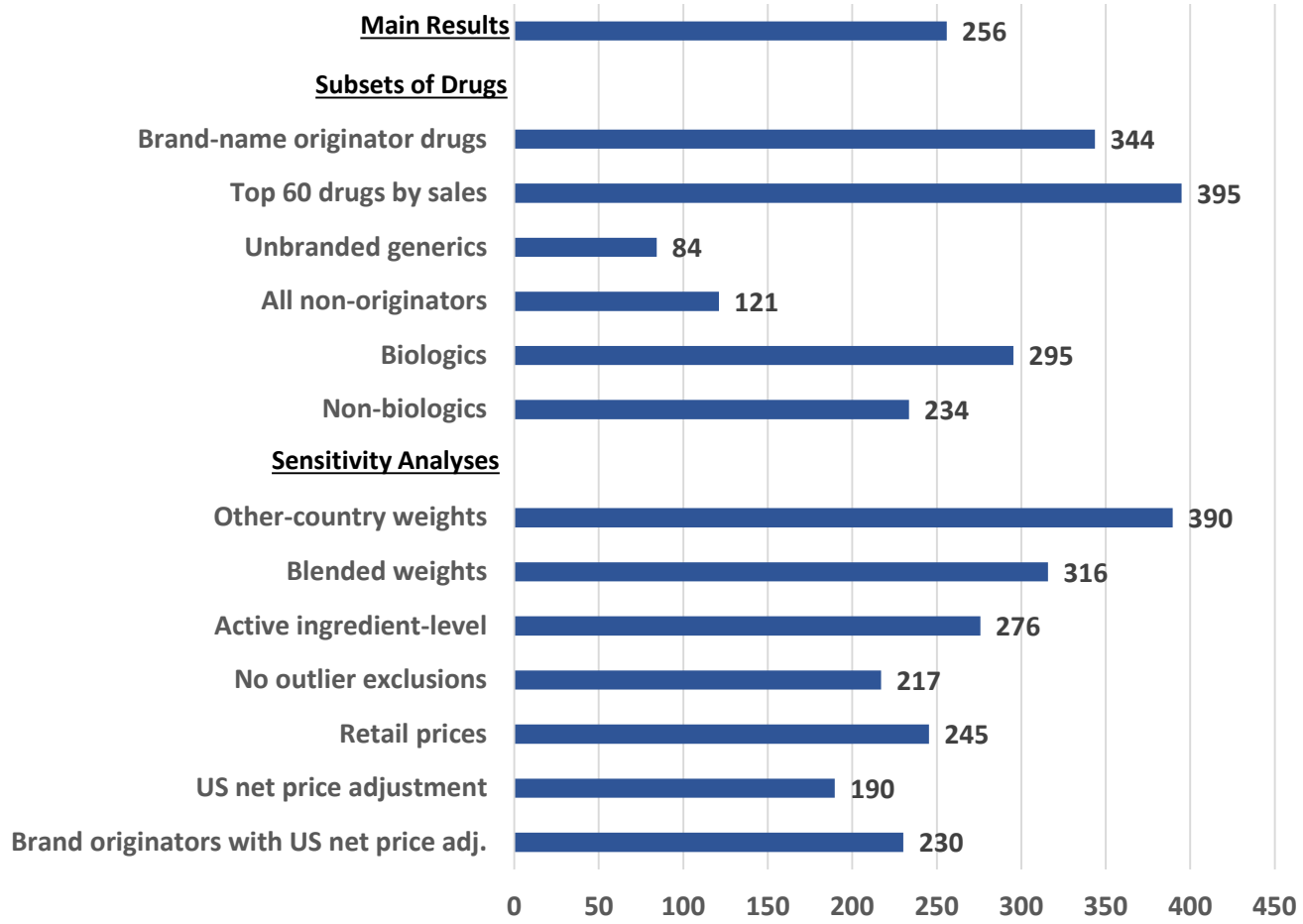
SOURCE: RAND analysis of 2018 IQVIA MIDAS data (run date October 28, 2019). NOTE: "All countries" includes all 32 OECD comparison countries combined weighted by volume. Other-country prices are set to 100.
*Prices in other countries where rebates and other discounts that are not captured in manufacturer sales are not adjusted. As a result, the reported price indexes will understate the gap between US and other-country prices. Only some presentations sold in each country contribute to bilateral comparisons.

Settling on “a price” for analysis or reference pricing involves many implementation decisions

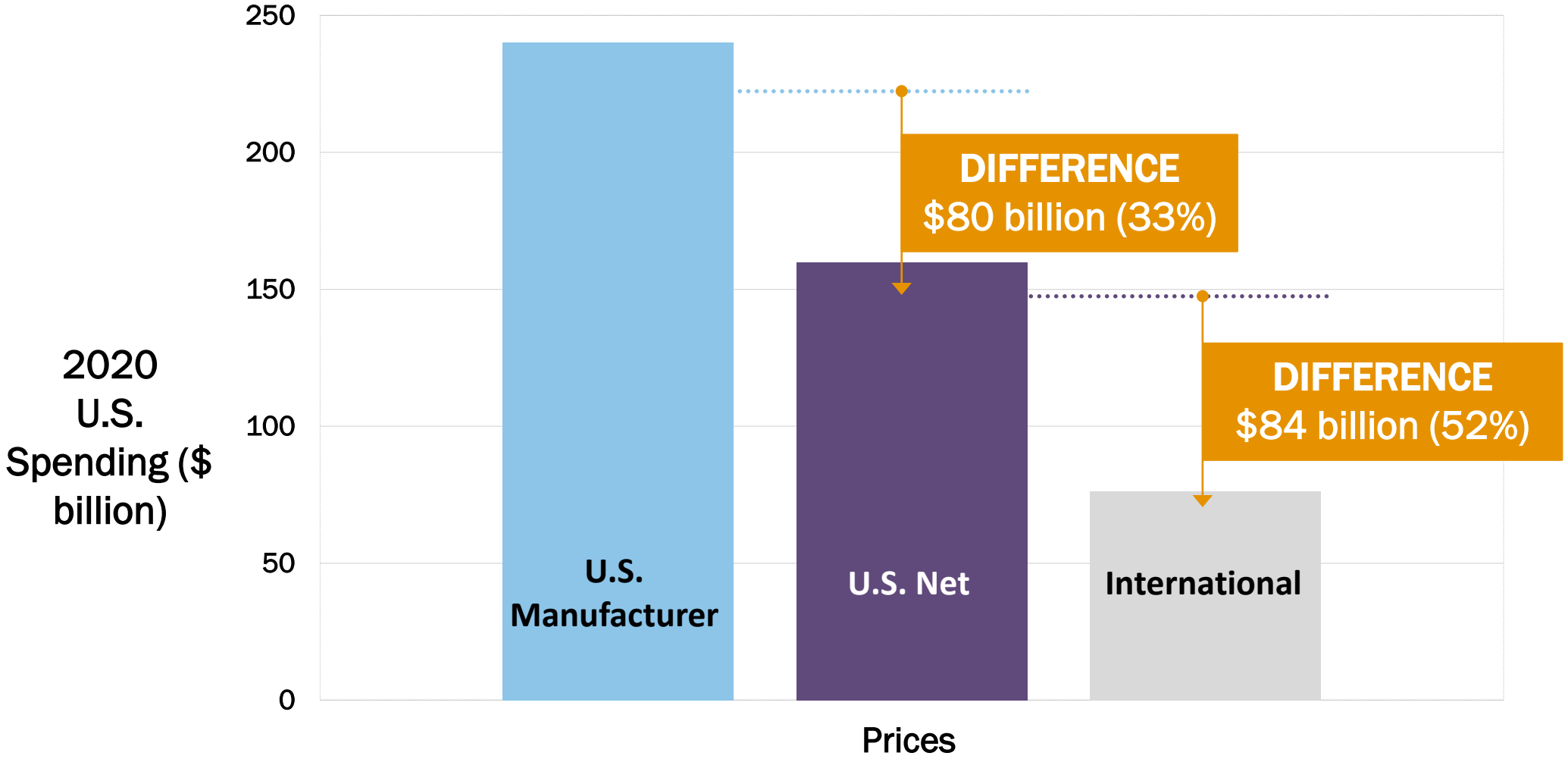
Key decisions

1. Which price to use and from which source?
2. What level of aggregation is appropriate?
3. How are volume and payment/spending amounts calculated?
4. How to address the lack of overlap in drugs sold in different countries?
5. Whether to use the US mix of drugs, other-country mix, or a blend?
6. Whether and how to address outlier drugs that can skew results?

Our report describes findings applying different methodological choices, assumptions, and robustness checks

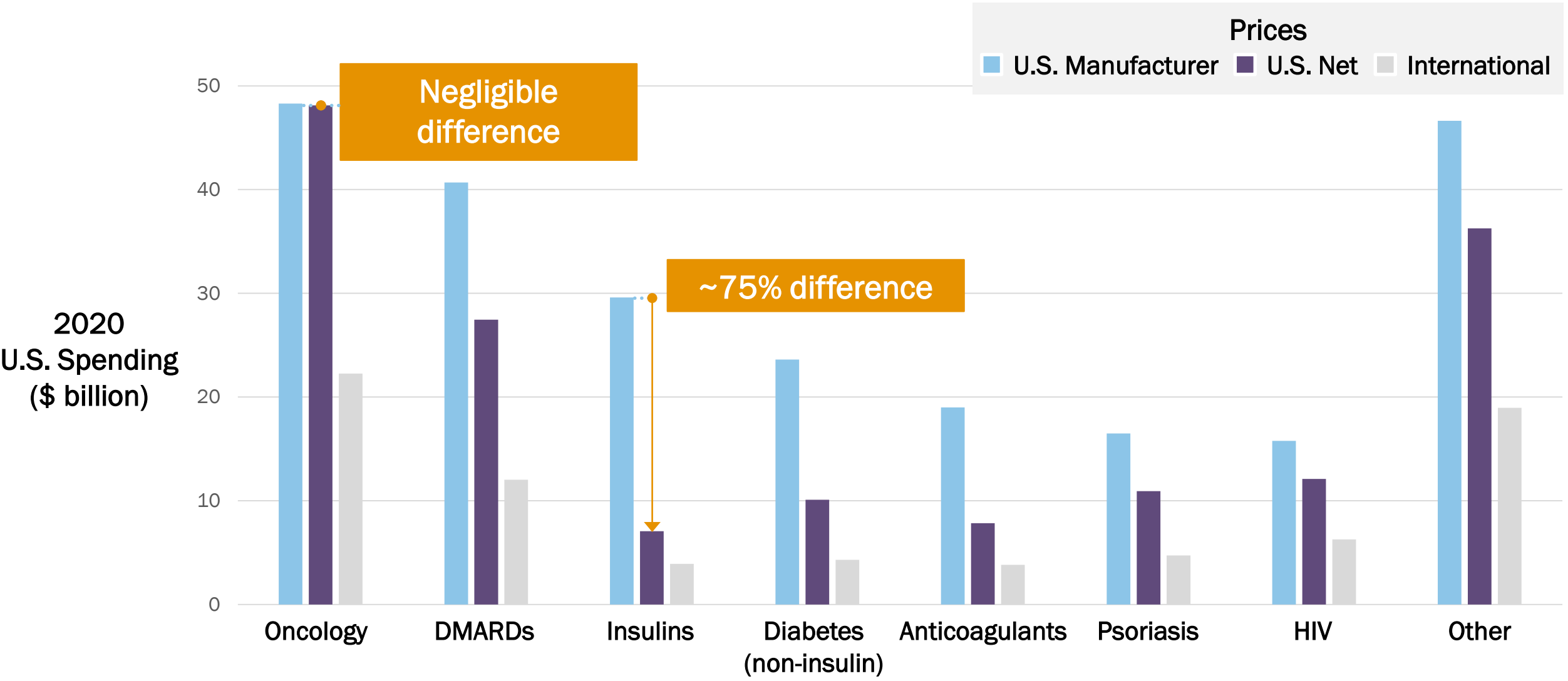


In another study, we found U.S. **net** prices for top drugs by U.S. spending were twice those in other countries



Source: Mulcahy, et al, JAMA (2021).
Note: Study funded by Arnold Ventures.

Gross-to-net ratios varied widely across classes



Source: Mulcahy, et al, JAMA (2021).
Note: Study funded by Arnold Ventures.

Recap of our research findings

The U.S. has lower generic prices than other countries.

But brand-name drugs are more expensive in the U.S.:

- ~3x as expensive at U.S. gross prices
- ~2x at U.S. net prices

A handful of brand name drugs account for much of U.S. spending.

(My own) Closing thoughts

What the U.S. gets for these higher prices is unclear.
All top U.S. drugs by sales are available broadly and relatively quickly
Pharma R&D is increasingly a global endeavor

Fragmented U.S. payers decide–behind closed doors–whether high prices are worth paying (or negotiating down).

Other countries do analysis and conduct checks to ensure prices and benefits align.

International reference pricing and importation in the U.S. leans on this analysis and policy from other countries.

The U.S. needs more, deeper, and transparent discourse on "fair" drug prices anchored on measurable benefits to patients.

RAND CORPORATION

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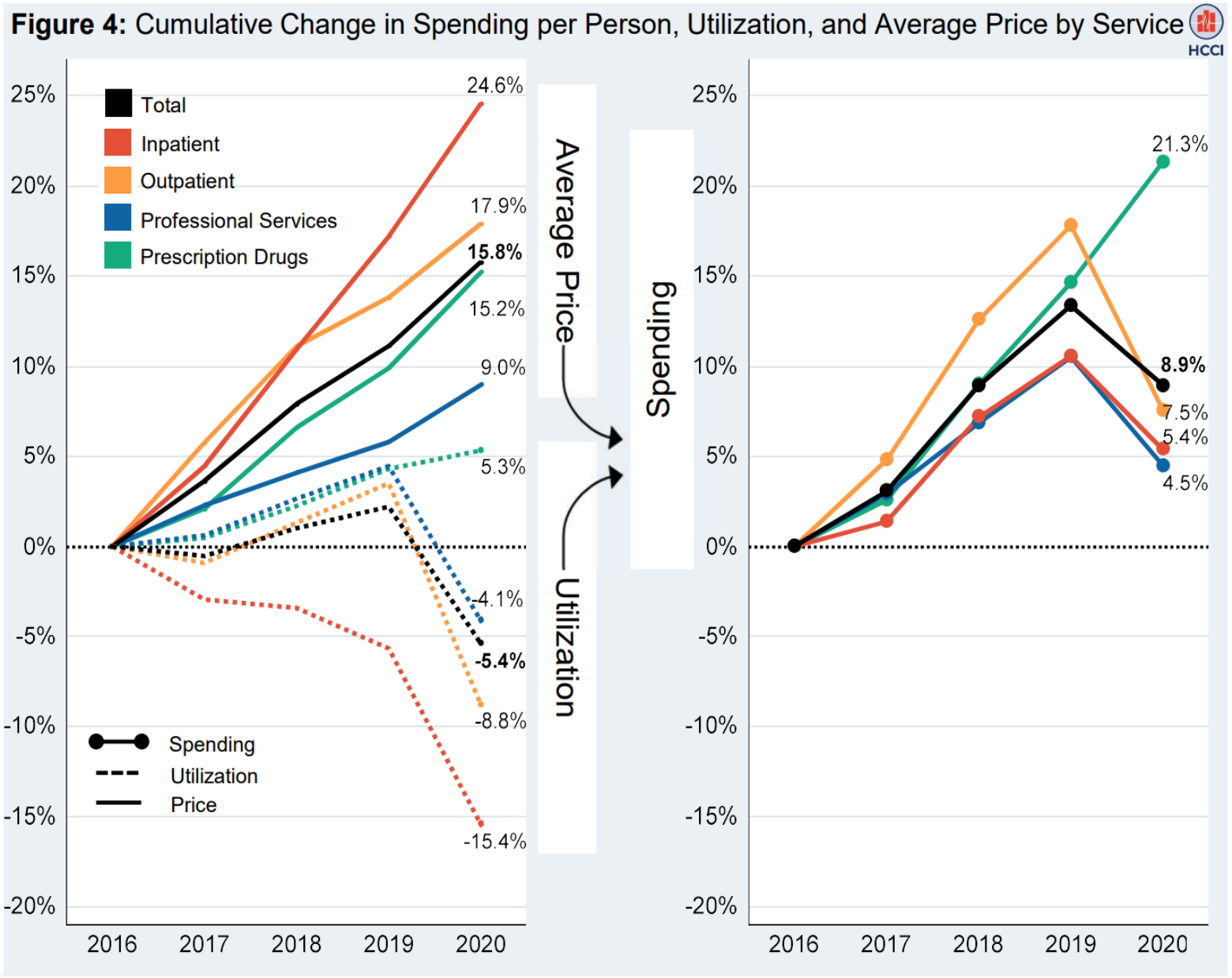
Drew Gattine, Senior Policy Consultant
National Academy for State Health Policy

Prescription Drug Affordability: International Referencing

Florida House of Representatives – Health and Human Services Committee

Drew Gattine, Senior Policy Consultant, NASHP Center for Drug Pricing

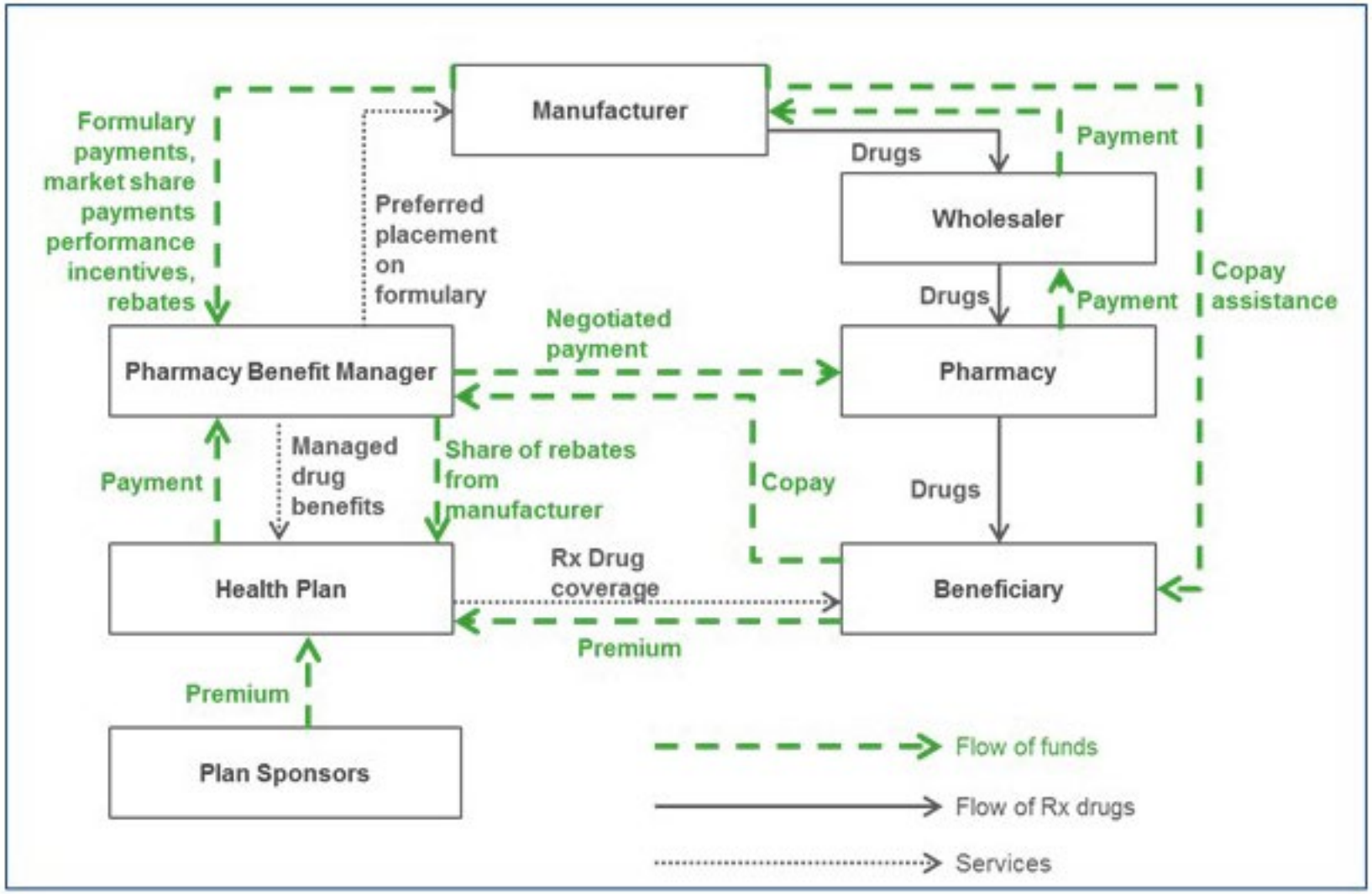
January 8, 2023



Spending on Prescription Drugs Is Increasing Faster than Other Medical Service Sectors

Source: Health Care Cost Institute (2020)

Flow of Products, Funds and Services



Source: Flow of Money Through the Pharmaceutical Distribution System, USC Leonard D. Schaeffer Center for Health Policy and Economics

50 State Legislative Landscape

Enacted Drug Pricing Laws, 2017-2023									
Year	2017	2018	2019	2020	2021	2022	2023	Total	In # of states
Number of States Enacting Laws	13	28	38	19	24	20	29	**50**	
Total Laws Enacted	17	45	65	43	54	33	53	**310**	**50**
Affordability Review	1	0	3	0	2	2	5	**13**	**9**
Consumer Cost Sharing	1	0	4	13	13	8	10	**49**	**28**
Pharmacy Benefit Manager	7	32	34	21	24	18	22	**158**	**50**
Study	0	1	6	1	2	2	0	**12**	**9**
Transparency	3	4	7	4	7	2	6	**33**	**22**
Volume Purchasing	0	0	2	0	1	0	0	**3**	**3**
Wholesale Importation from Canada	0	1	4	2	1	1	2	**11**	**7**
Other	5	7	5	2	4	0	8	**31**	**22**

Since 2017, legislation to address prescription drug costs has been ***enacted*** in all 50 states.

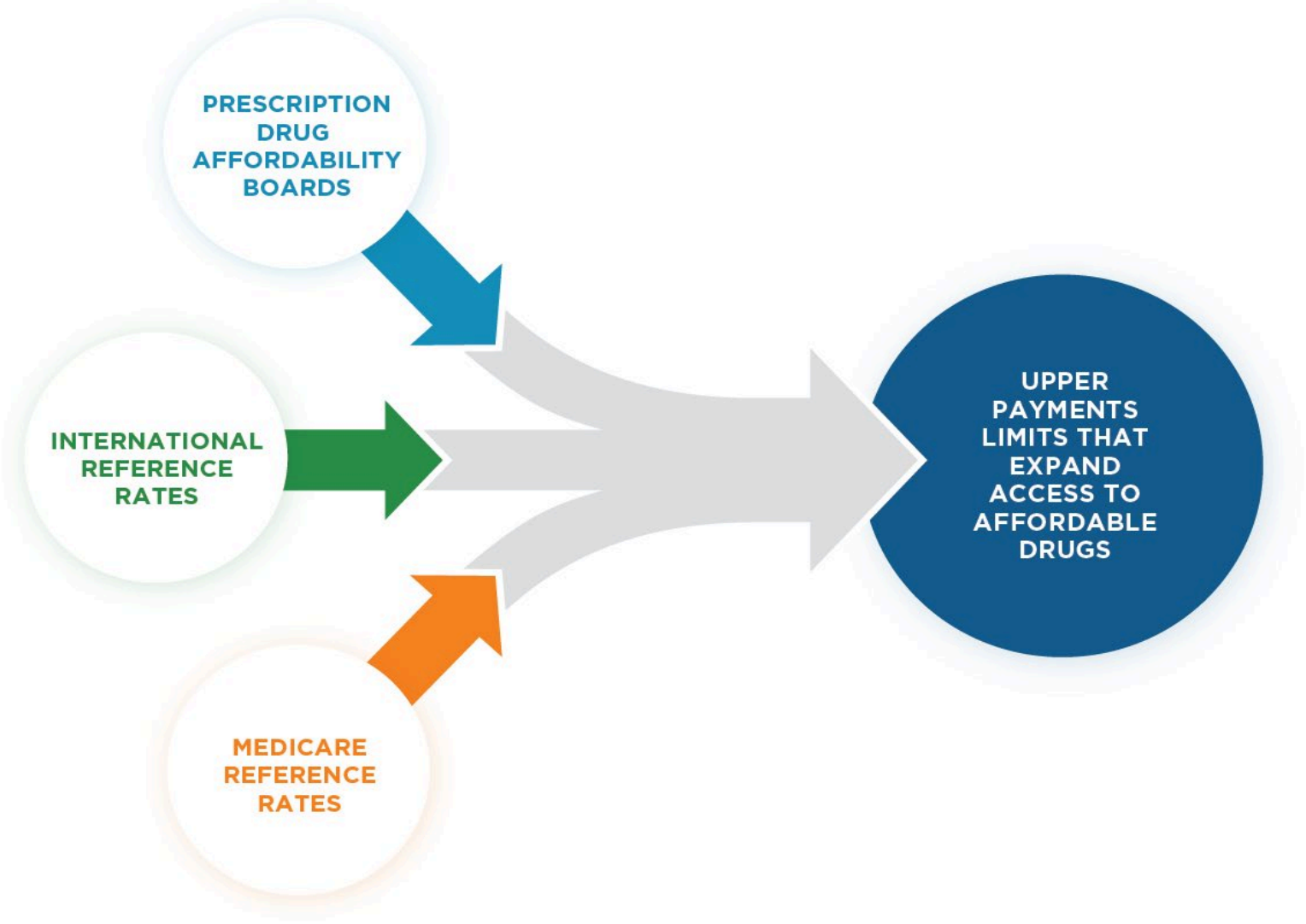
There have been more than 300 laws enacted.

Menu of NASHP Policy Tools to Address High Prescription Drug Costs

Policy Approach	Tools
1. Transparency	• Reporting by drug manufacturers, wholesalers, PBMs, and health plans on prescription drug prices, spending and rebates*
2. Active state purchasing	• Wholesale Canadian Importation (requires FDA approval)* • Stronger PBM contracting* • Pooled Purchasing (e.g. ArrayRx Solutions) • Direct negotiation for high-cost drugs (Medicaid) • Outcomes-based contracting (Medicaid)
3. Limit Price Increases	• Prohibiting Price Gouging* • Penalizing Unsupported Price Increases (UPIs)*
4. Set Upper Payment Limits	• Prescription Drug Affordability Boards (PDABs)* • International Reference Rates* • Medicare Reference Rates (Nov. 2022)*

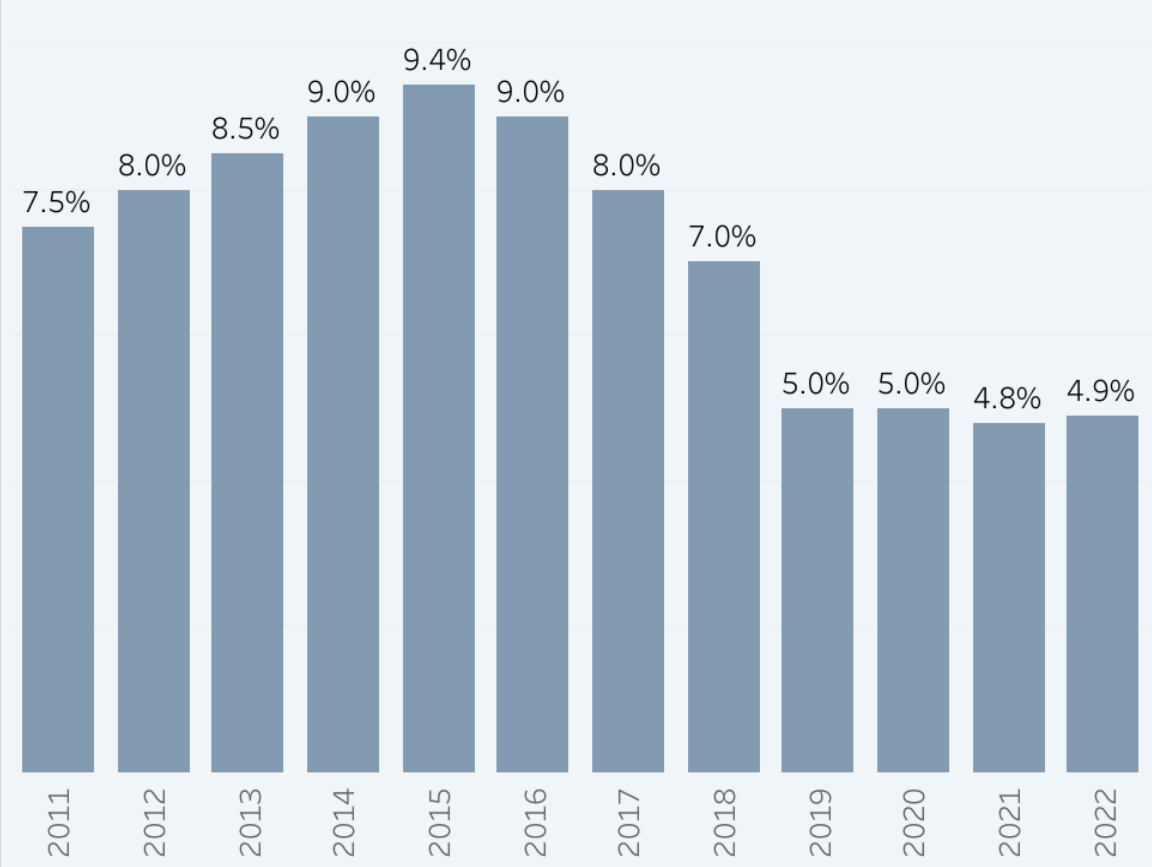
*NASHP model available at www.nashp.org

NASHP Model Legislation for Setting Upper Payment Limits for Costly Drugs

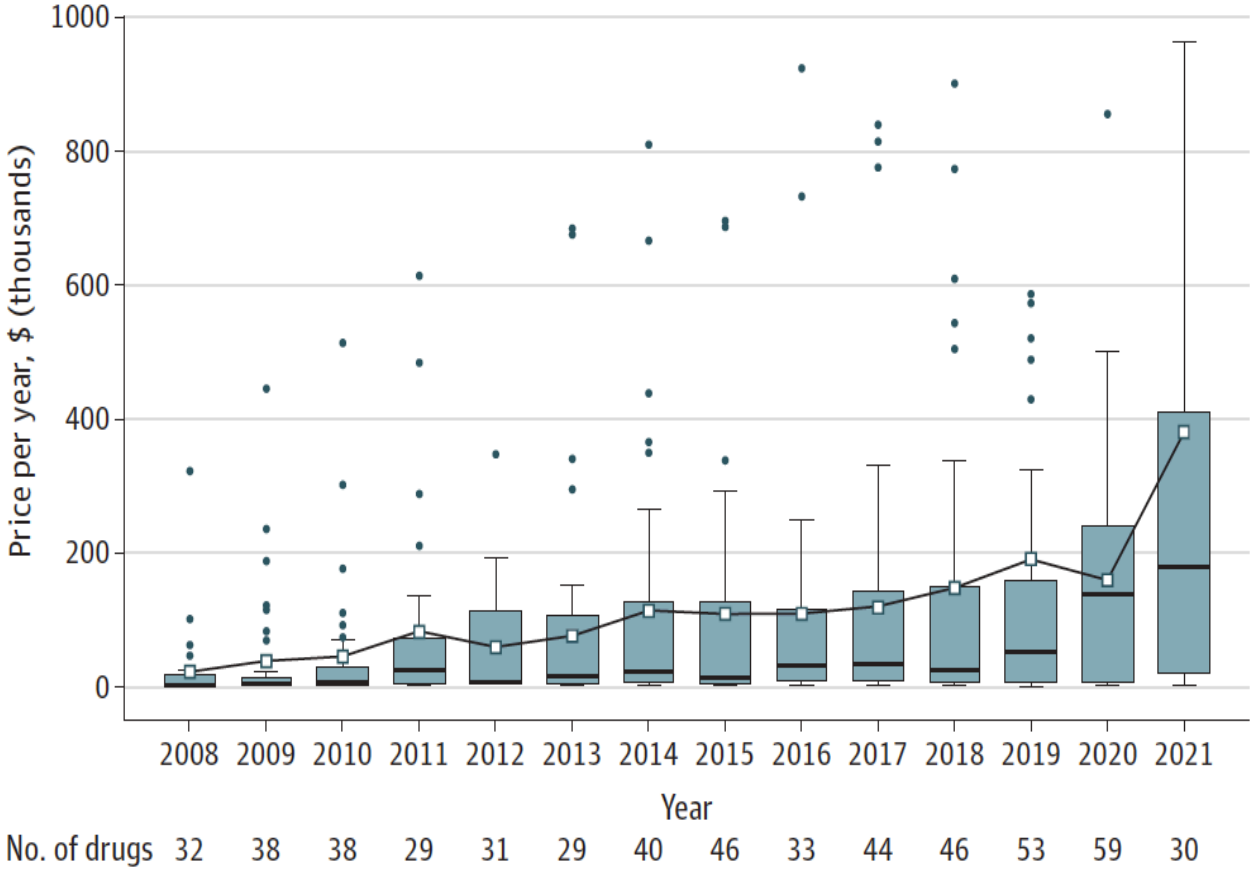


Price Increases Moderate, Launch Prices Rise

Median Percentage WAC Increase on Brand-name Drugs



Average Launch Prices Increased by 20% per year



NASHP International Reference Rates Model Legislation

Why Reference to Canadian Prices?

- Foreign countries pay a fraction of what Americans pay for prescription drugs
- International prices offer a fair, easy-to-implement approach to rate setting
- Canadian prices are publicly available and the methodology is transparent
- The Canadian pricing system looks at the prices in other countries to determine reasonableness

How Referencing Works:

- State identifies the costliest drugs and crosswalks to Canadian prices for the four largest provinces
- Reference price becomes the upper payment limit for payers (ERISA plans can opt in)
- Savings are calculated and reported, and **savings must be used to offset the costs for consumers**

Examples of Canadian Rates

Drug Name & Dosage	US Price (NADAC)	Canadian Reference Rate	Price Difference	Savings off US prices
Humira (40mg/.8) (arthritis, psoriasis, Crohn's)	$3,121.27	$794.10	$2,327.17	75%
Eliquis (2.5mg tablet) (blood clots)	$8.47	$1.60	$6.87	82%
Biktarvy (50-200-25 mg tablet) (HIV)	$115.81	$39.22	$76.59	66%
Stelara (90 mg/ml syringe) (arthritis, psoriasis, Crohn's)	$24,599.06	$4,465.58	$20,133.48	82%
Dupixent (200mg/1.14ml syringe) (atopic dermatitis, asthma, chronic rhinosinitus with nasal polyps)	$1,530.50	$978.70	$551.80	36%
Xarelto (10mg tablet) (nonvalvular atrial fibrillation, deep vein thrombosis, pulmonary embolism, DVT prophylaxis)	$16.53	$2.84	$13.69	83%
Trulicity (1.5mg/0.5ml) (type 2 diabetes)	$425.67	$42.07	$383.60	90%
Average discounts based on top selling drugs of 2022				**73%**

International Referencing – Potential Savings

- States have evaluated the possible savings from implementing international referencing
- **Oklahoma** – The legislature's fiscal office estimated potential annual savings of $52 million for the 25 drugs with the top overall spend for state employees and retirees
- **North Dakota** – Referencing the top 25 drugs would save an estimated $21 million for state employees and retirees
- **Maine** – The All-Payer Claims Database calculated potential savings of $146.7 million for 72 high-cost drugs in 2022 and $123M for 65 NDCs in 2023

UPLs: Key Legal Issues

Patent Preemption	UPLs don't set prices

ERISA Preemption	ERISA-regulated plans may opt-in to UPLs

Dormant Commerce Clause	UPLs regulate in-state transactions only