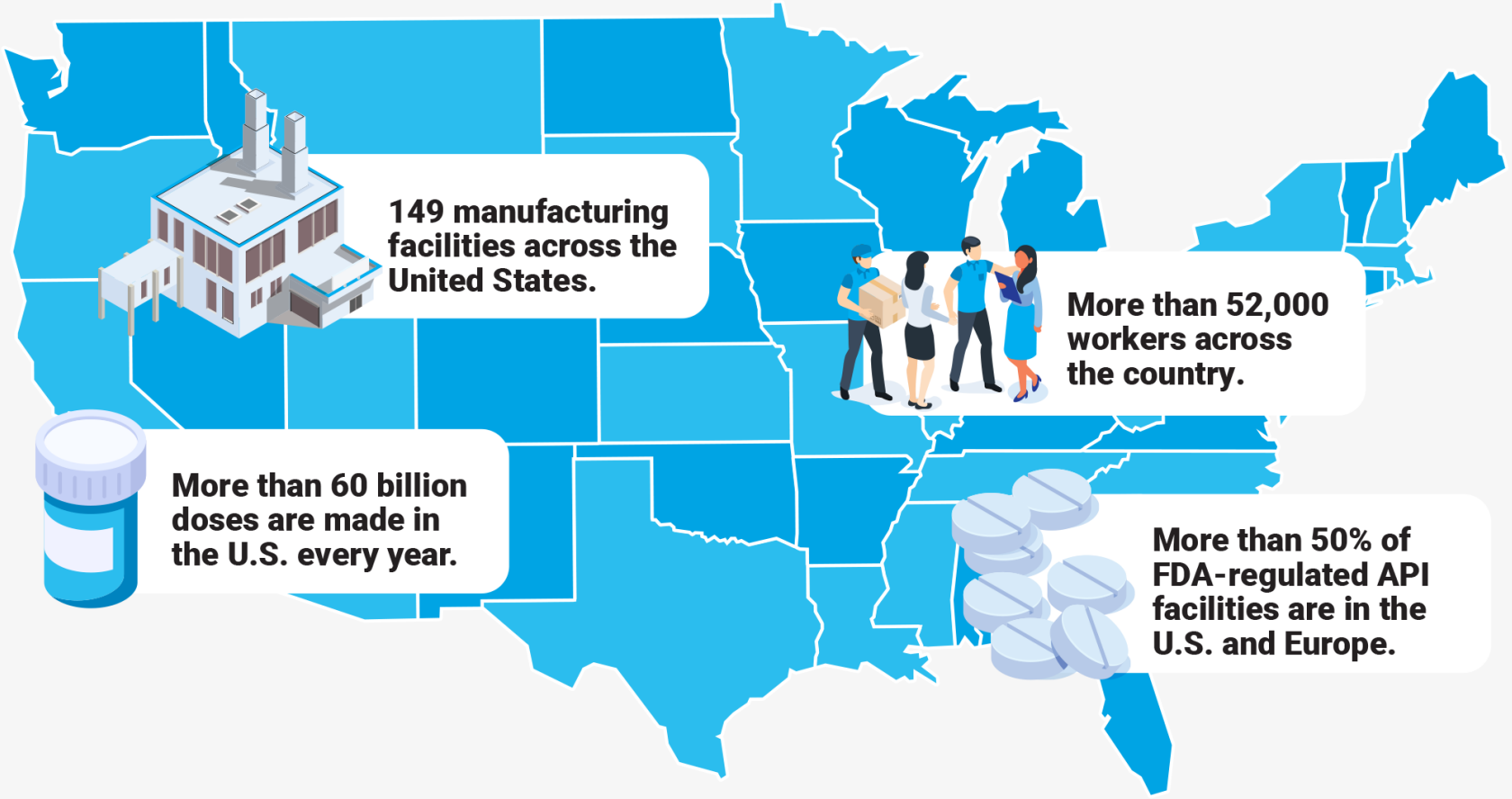
Association for Accessible Medicines

Your Generics & Biosimilars Industry

Driving Prescription Drug Access and Affordability in New Mexico

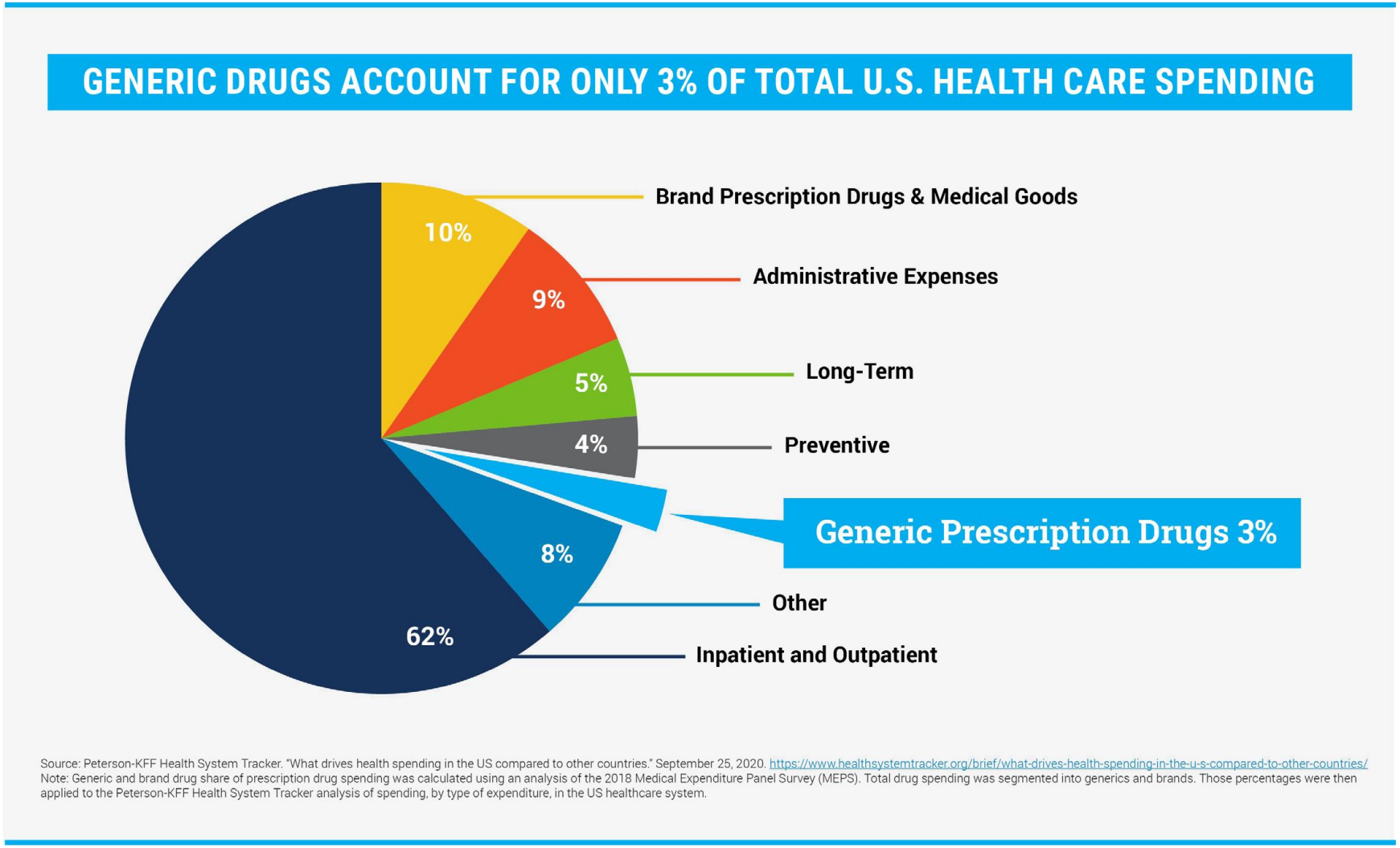
August 10, 2022 | Brett Michelin

Generics Are Manufactured Across the U.S.



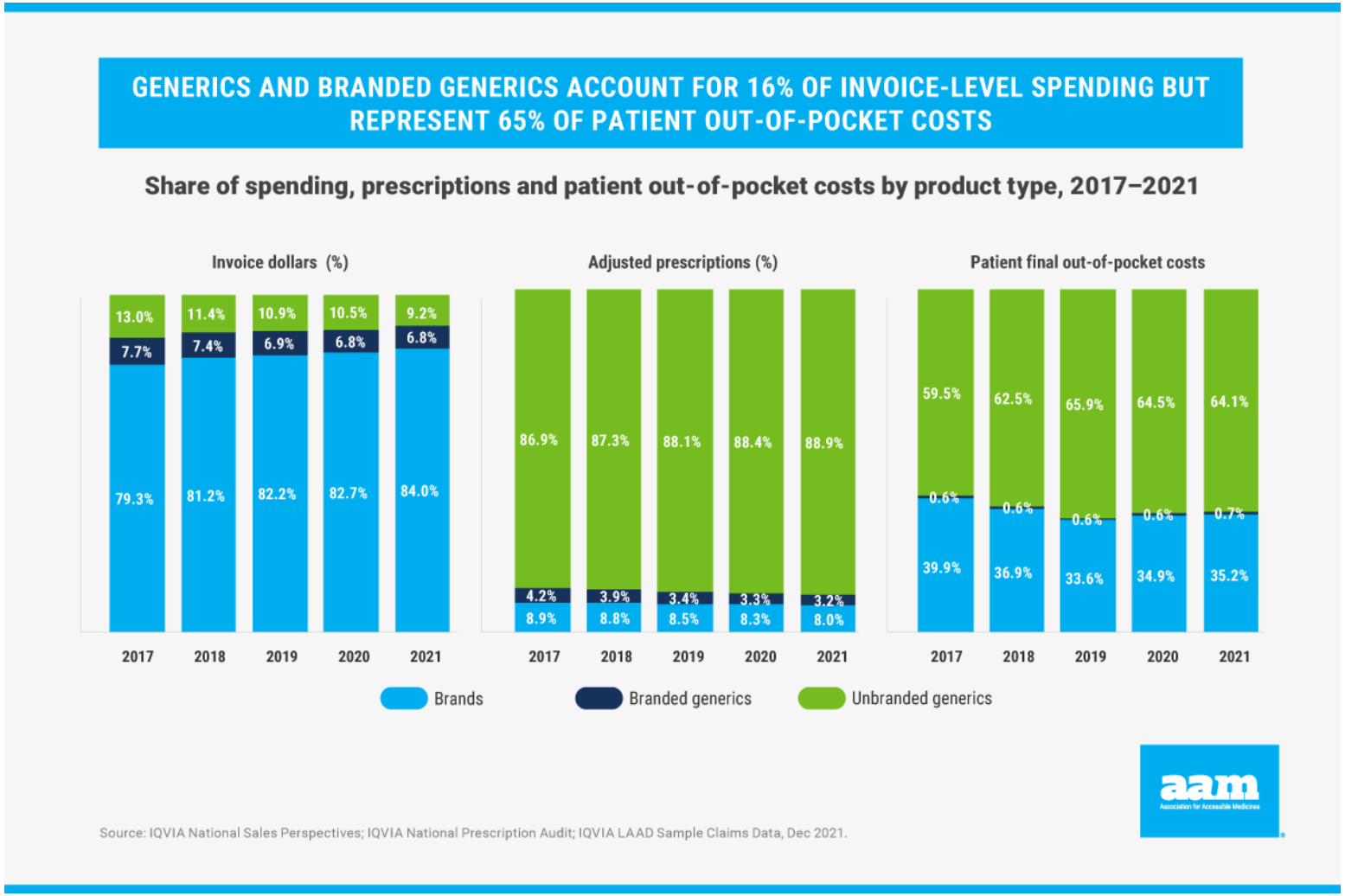
Sources: AAM Member Survey 2020, IBISWorld, Generic Pharmaceutical Manufacturing in the U.S. Employment Statistics 2005–2026

Generics As a Share of U.S. Health Care Spending

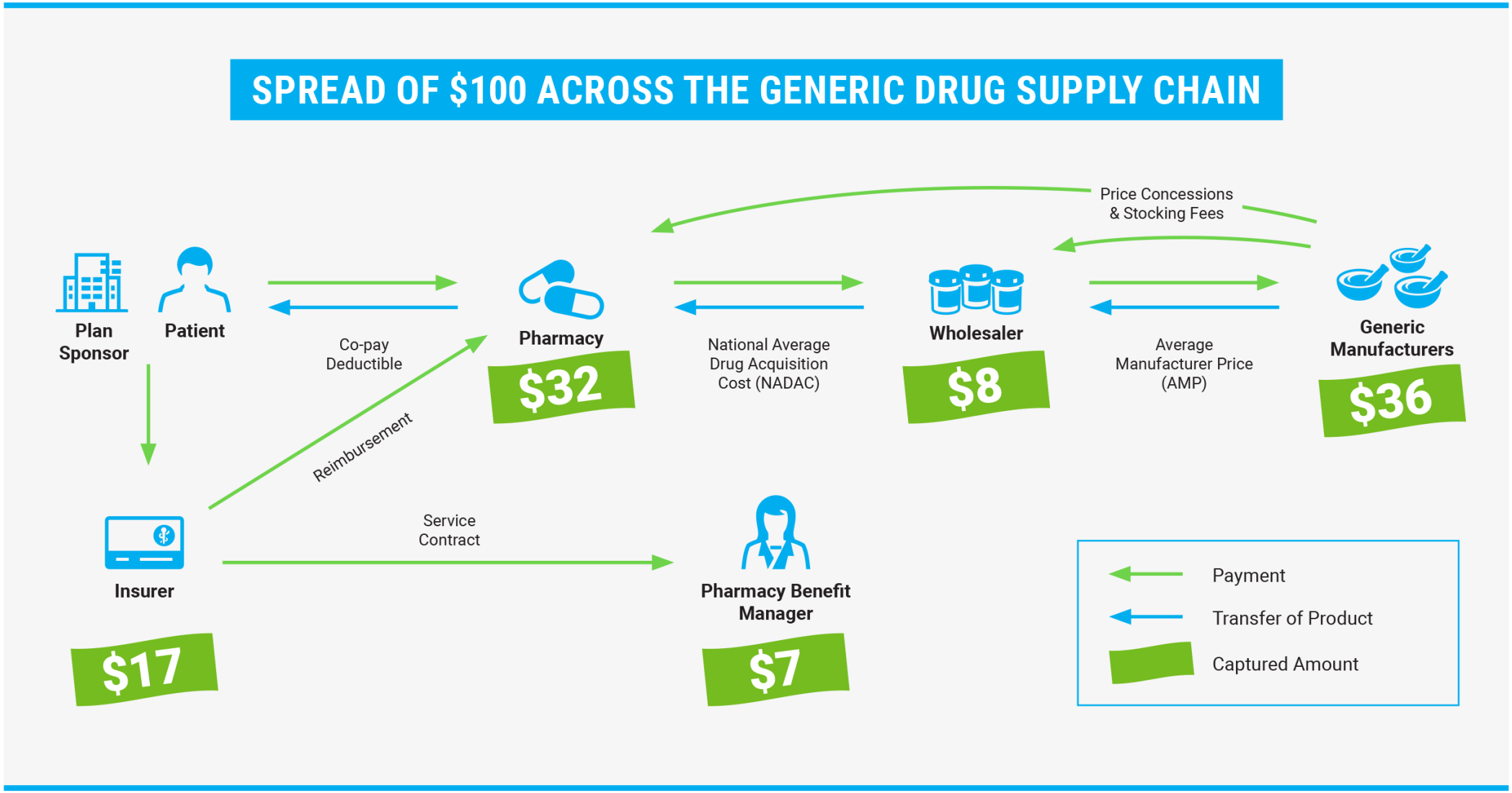


Source: Peterson-KFF Health System Tracker. "What drives health spending in the US compared to other countries." September 25, 2020. https://www.healthsystemtracker.org/brief/what-drives-health-spending-in-the-u-s-compared-to-other-countries/
Note: Generic and brand drug share of prescription drug spending was calculated using an analysis of the 2018 Medical Expenditure Panel Survey (MEPS). Total drug spending was segmented into generics and brands. Those percentages were then applied to the Peterson-KFF Health System Tracker analysis of spending, by type of expenditure, in the US healthcare system.

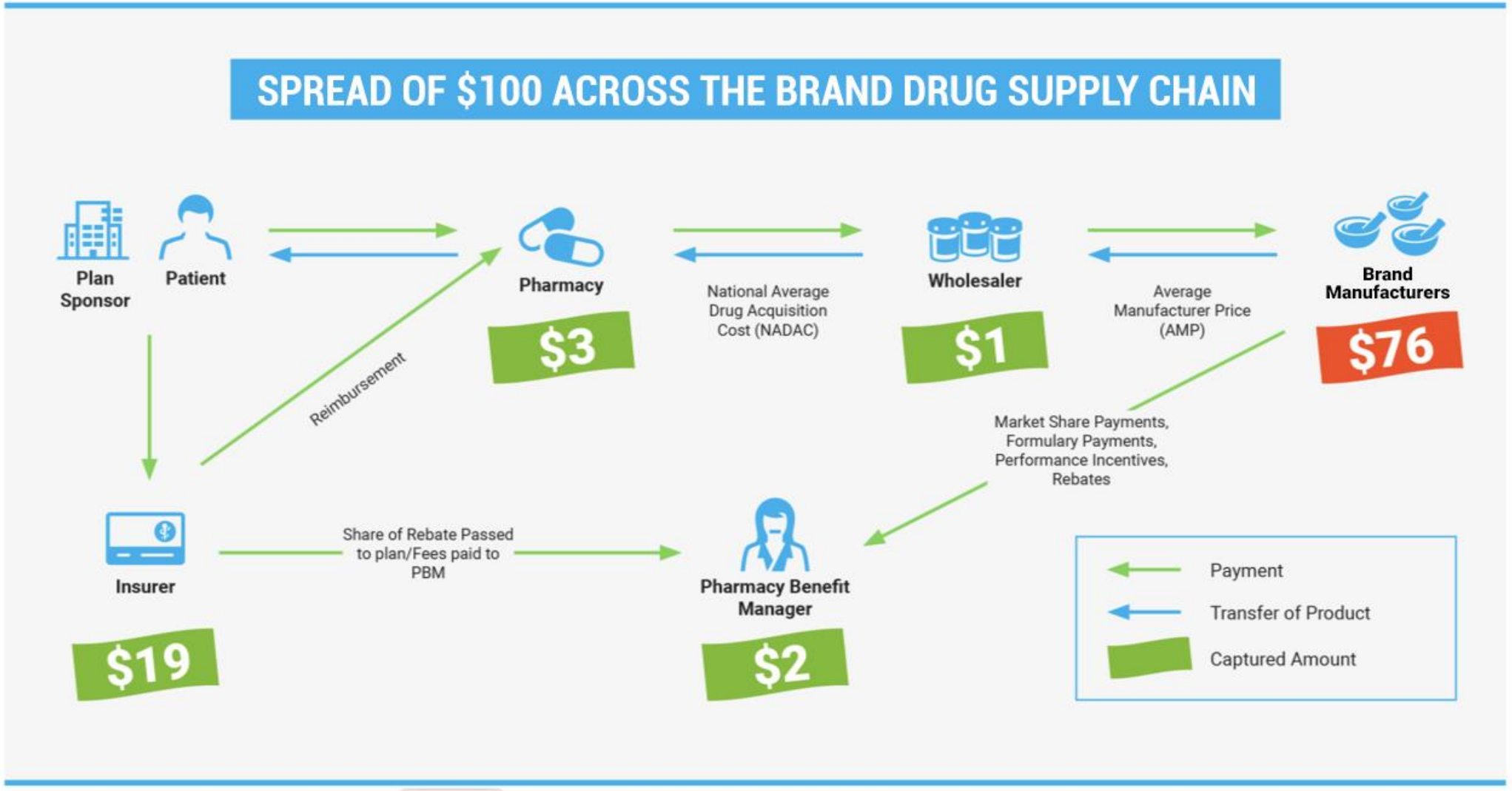
Generics Account For Only 16% Of Total Medicine Purchases but 92% Of All Prescriptions Dispensed and 65% Of Patient Out of Pocket Costs



Generic Drug Supply Chain

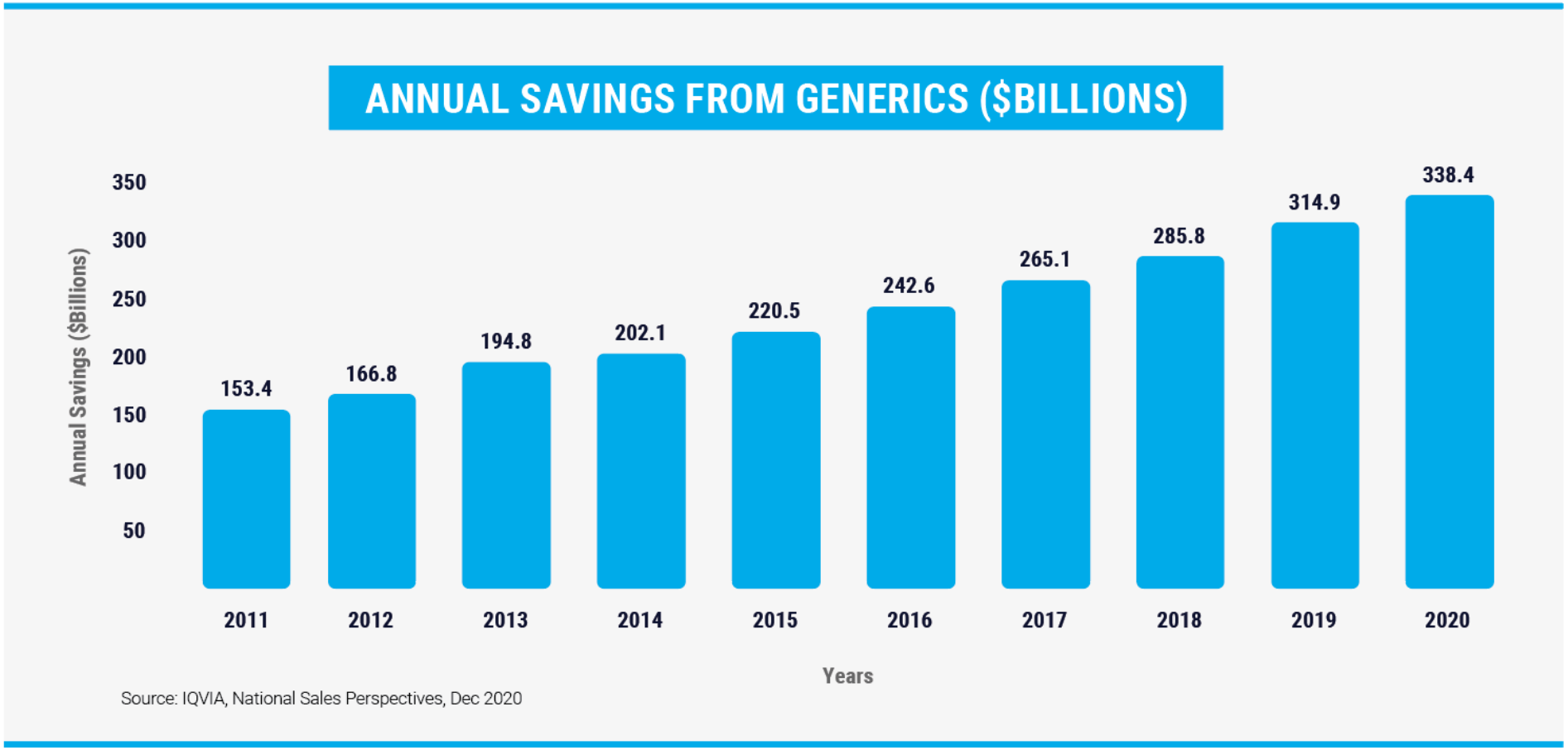


Brand Drug Supply Chain

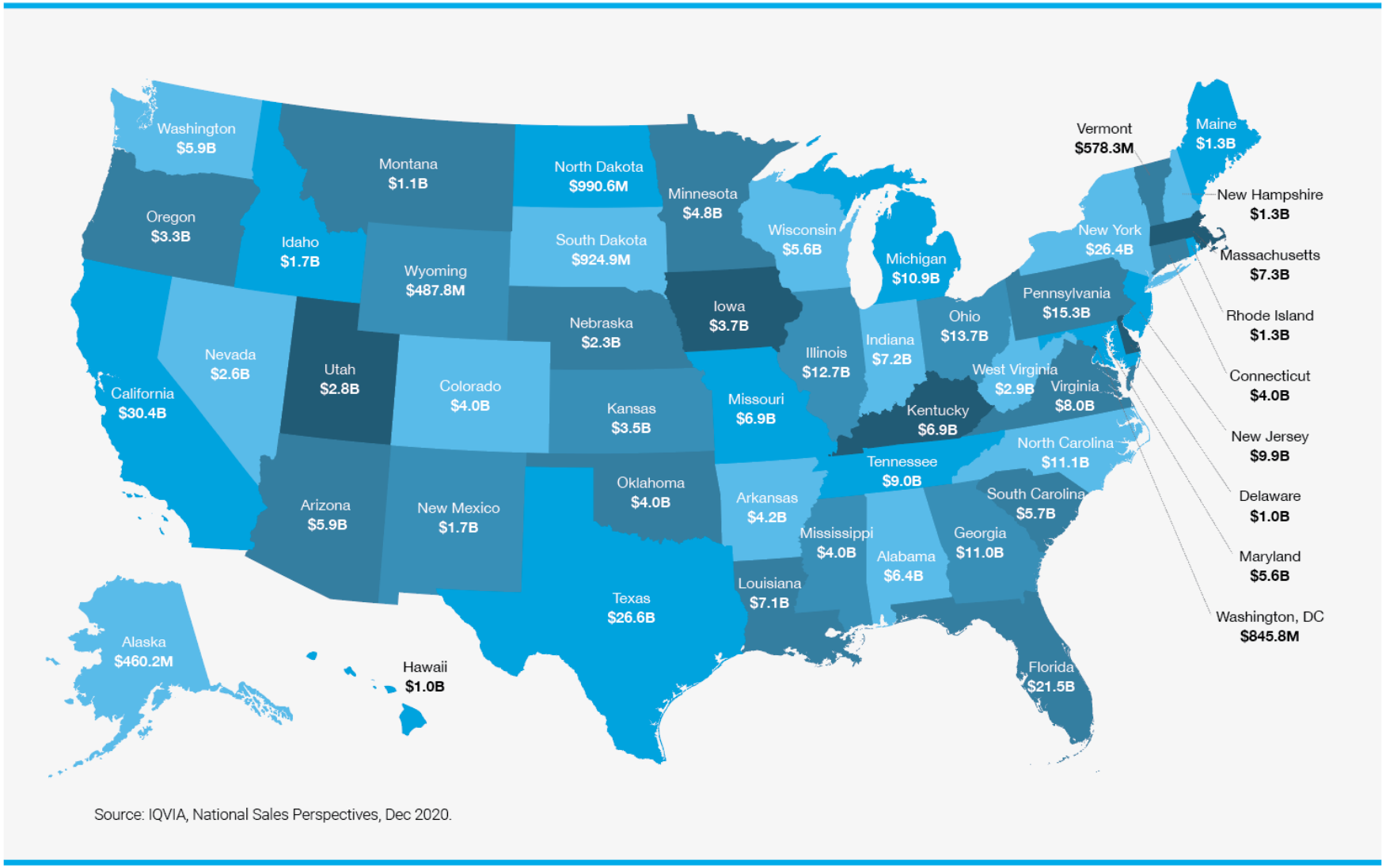


Savings From Generics and Biosimilars Totaled $338 Billion in 2020

GENERIC AND BIOSIMILAR SAVINGS INCREASED BY $23.5 BILLION FROM 2019 TO 2020



Savings From Generic Medicines by State, 2020



Source: IQVIA, National Sales Perspectives, Dec 2020.

GENERIC DRUGS SAVE NEW MEXICANS MILLIONS

In 2020, New Mexico saved $1.7 billion with generic and biosimilar medicines.

Patients win when FDA-approved generics and biosimilars deliver savings on their medicines. Market-based competition drives prices down, but meaningful action is needed to lower brand prescription drug costs while ensuring sustainable competition in the pharmaceutical sector.

SEE HOW THE SAVINGS ADD UP IN NEW MEXICO

Generics and biosimilars save money and increase access for public and private payers alike.

MEDICARE
$530 MILLION
IN SAVINGS

MEDICAID
$288 MILLION
IN SAVINGS

MEDICARE SAVINGS PER ENROLLEE
$1,679

MEDICAID SAVINGS PER ENROLLEE
$914

Source: IQVIA, National Sales Perspectives, Dec 2020

The Top 10 Medicines of 2020 Saved $99.1 Billion in 2020

THE TOP 10 PRODUCTS REPRESENT 29% OF THE OVERALL SAVINGS IN THE PAST 10 YEARS

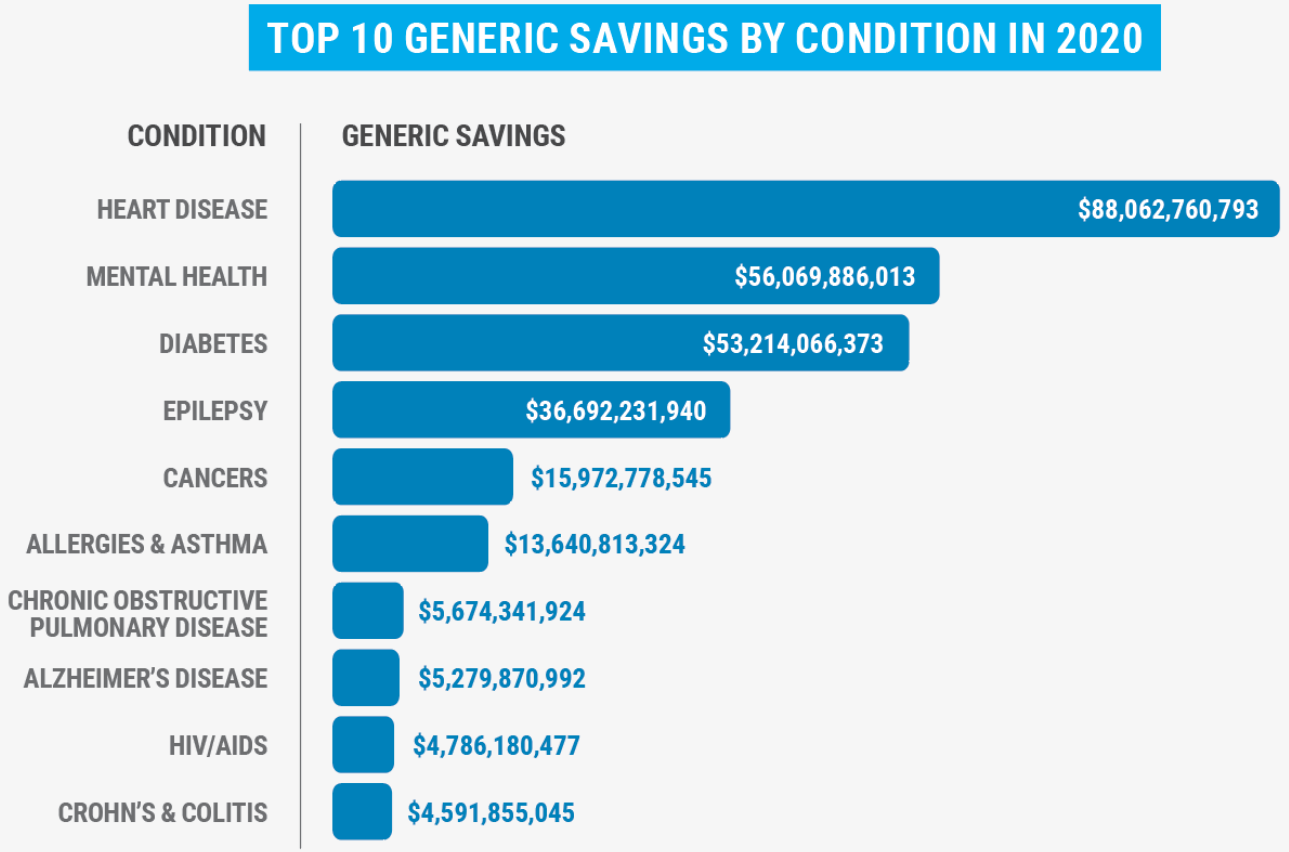
TOP 10 MEDICINES WITH GREATEST SAVINGS IN 2020

Products	Generic Entry Year	Brand Pre-Expiry Price (per unit)	Price of Generic Equivalent 2020 (per unit)	2020 Savings ($Bn)	Percent Savings	2020 Dispensed Rxs (Mn)
Lipitor	2011	$3.29	$0.08	$19.2	98%	5982
Zofran	2006	$21.67	$0.16	$13.9	99%	745
Prilosec	2002	$3.31	$0.06	$12.0	98%	4116
Crestor	2016	$5.78	$0.08	$10.7	99%	1899
Abilify	2015	$21.68	$0.40	$8.9	99%	423
Neurontin	2004	$1.02	$0.07	$7.5	93%	7864
Norvasc	2007	$1.54	$0.02	$7.4	99%	4799
Singulair	2012	$3.74	$0.09	$6.6	98%	1821
Cymbalta	2012	$4.61	$0.21	$6.5	96%	1462
Protonix	2005	$3.63	$0.03	$6.2	98%	2290

Source: IQVIA, National Sales Perspectives, Dec 2020

Savings From Generic Medicines by Primary Patient Condition

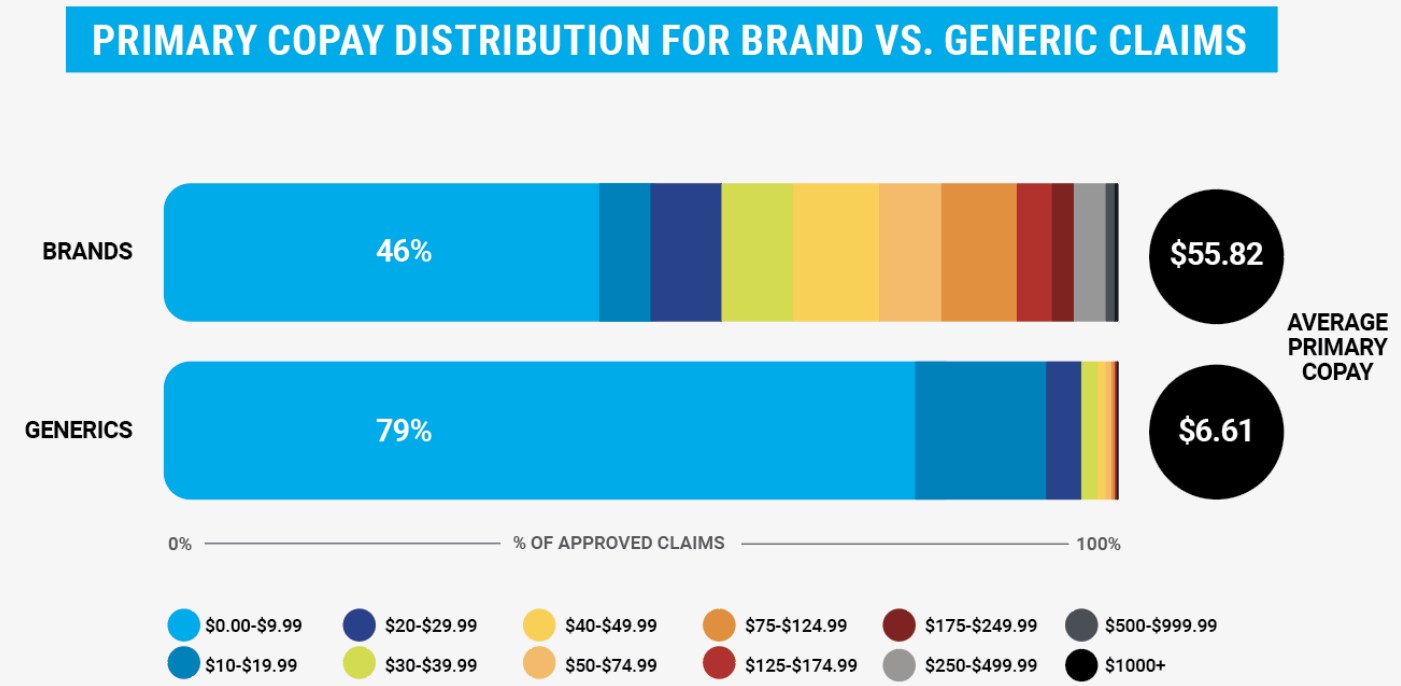
GENERICS SAVED AMERICANS WITH COMMON CONDITIONS BILLIONS



Source: IQVIA, National Sales Perspectives, Dec 2020.

Generic Copays Are About 8.5 Times More Affordable Than Brands

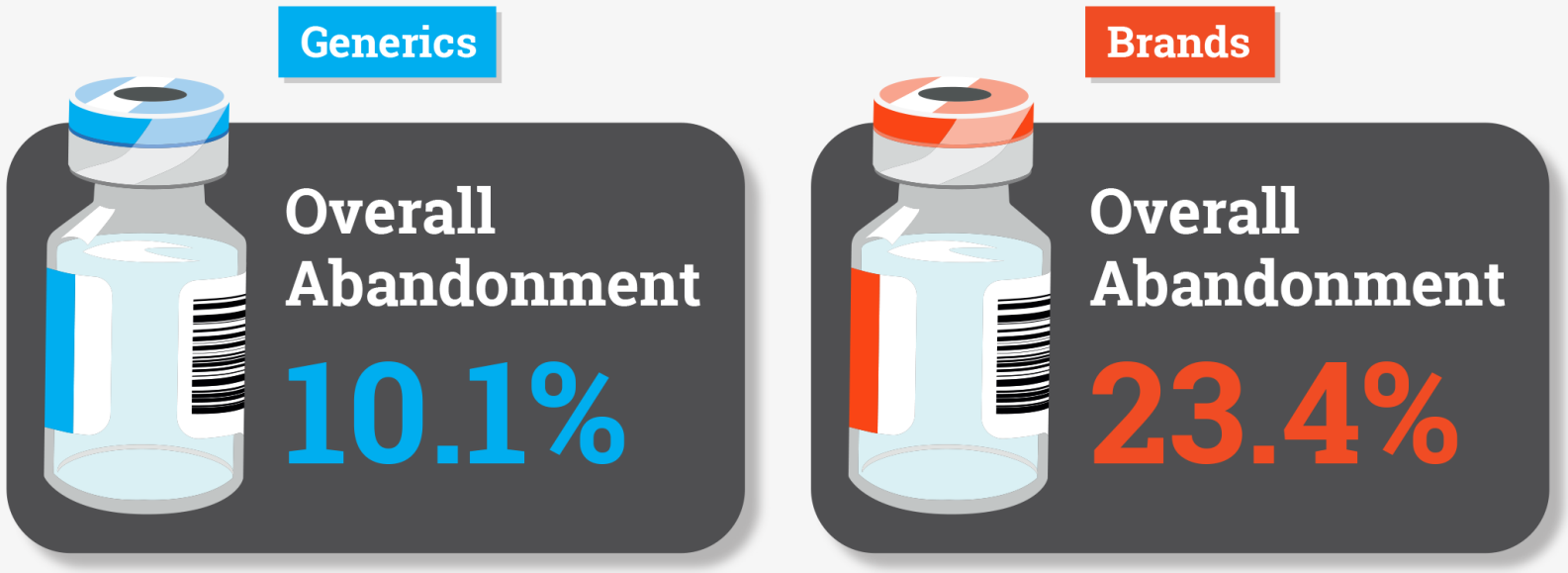
93% OF GENERIC COPAYS ARE BELOW $20, COMPARED TO ONLY 51% OF BRANDS



Note: Includes commercial, Medicare Part D and Medicaid channels; Limited to standard market baskets.
Source: IQVIA LAAD dataset; US Market Access Strategy Consulting analysis.

Abandoned Prescriptions: Health Consequences

PATIENTS ARE MORE LIKELY TO ABANDON COSTLY BRAND PRESCRIPTIONS



Source: IQVIA 2018

Biosimilars Market Overview

37
approved

22
marketed

Projected savings through 2025
$133 Billion

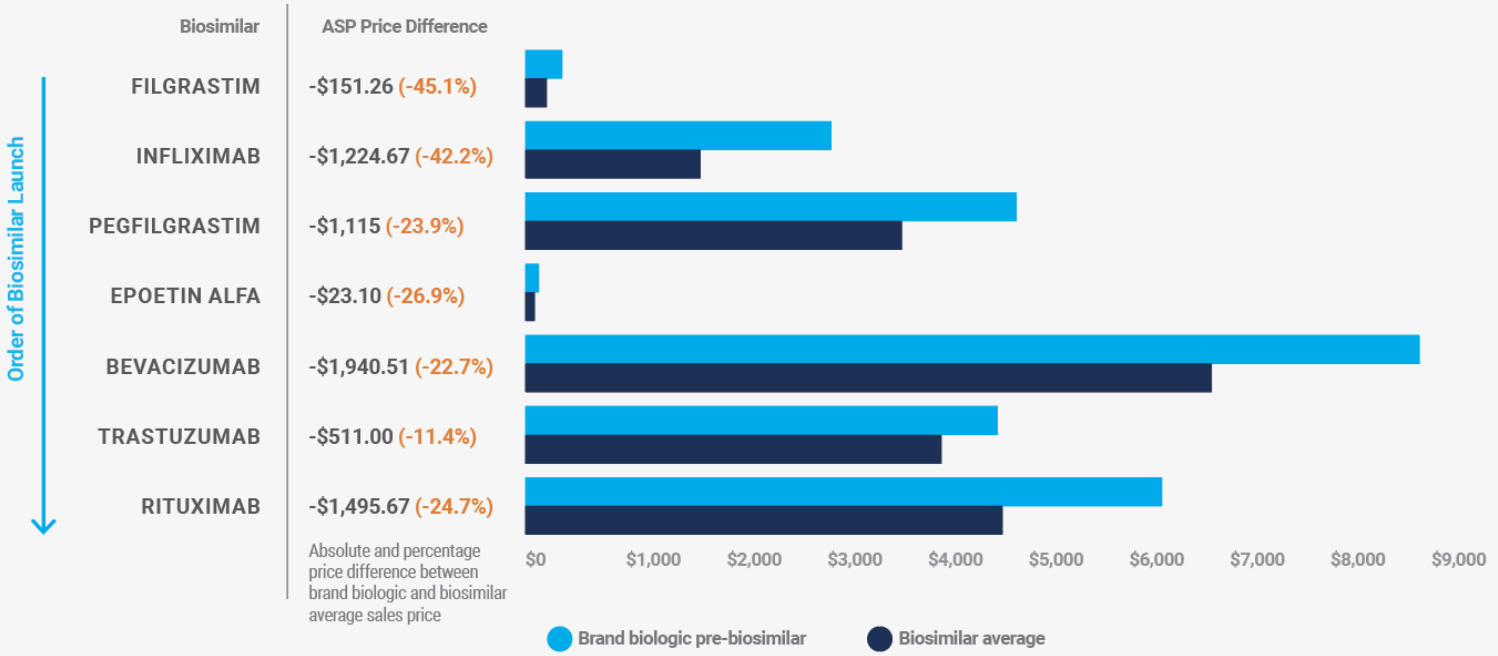
Biosimilars have been used in more than **121 million days** of patient therapy and have resulted in almost **10 million incremental days** of therapy.

Approval / Marketing data as of August 2022. Source: U.S. FDA.
Patient day data developed by Biosimilars Council with IQVIA

Biosimilars Are Less Expensive Than Their Reference Brand Biologic

BIOSIMILAR COMPETITION HAS BEEN STABLE AND PROVIDES CONSISTENT SAVINGS

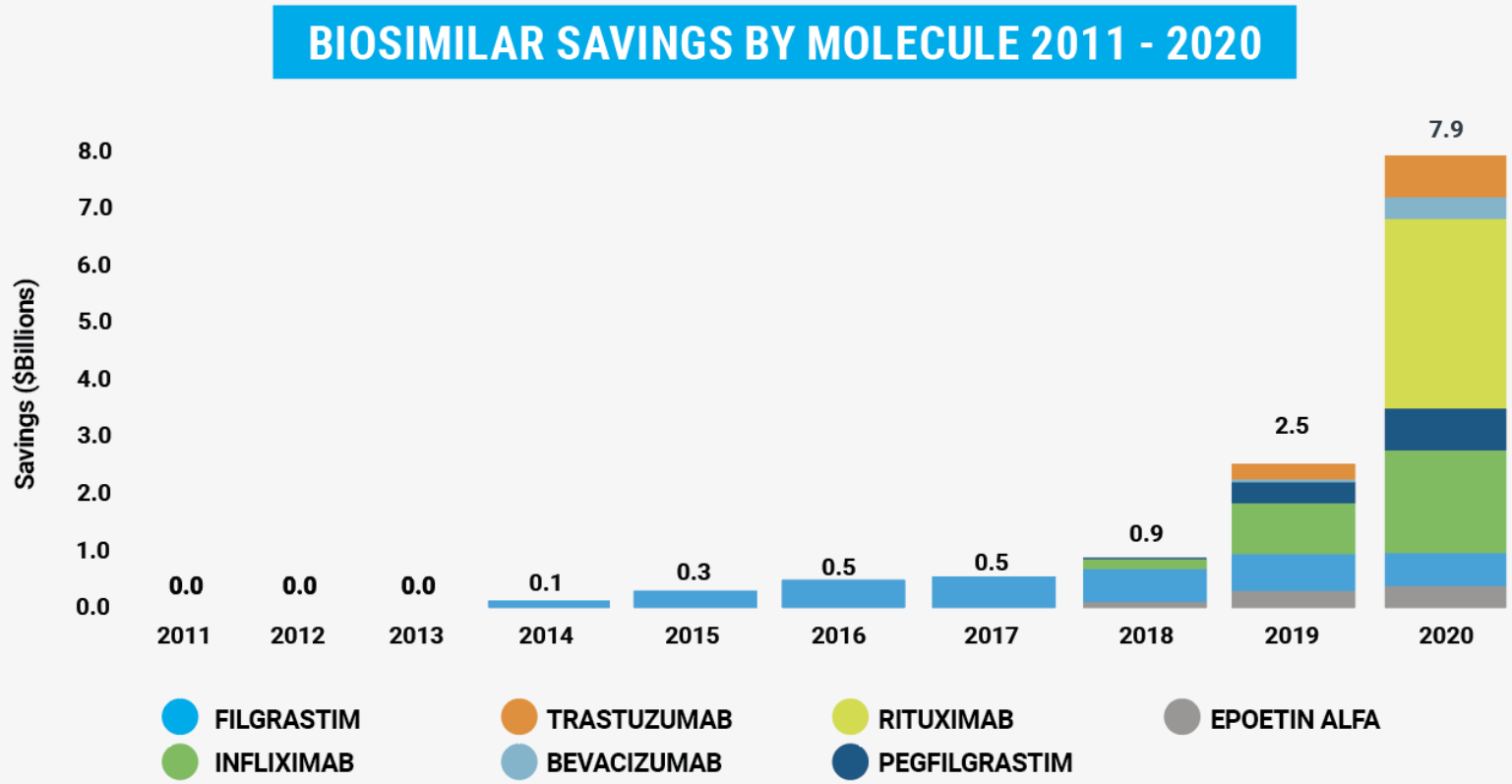
ORIGINATOR AND MEAN BIOSIMILAR AVERAGE SALES PRICE, JULY 2020



Source: IQVIA Institute (October 2020) "Biosimilars in the United States 2020-2024; Competition Savings and Sustainability."

Biosimilar Savings Totaled $7.9 Billion in 2020

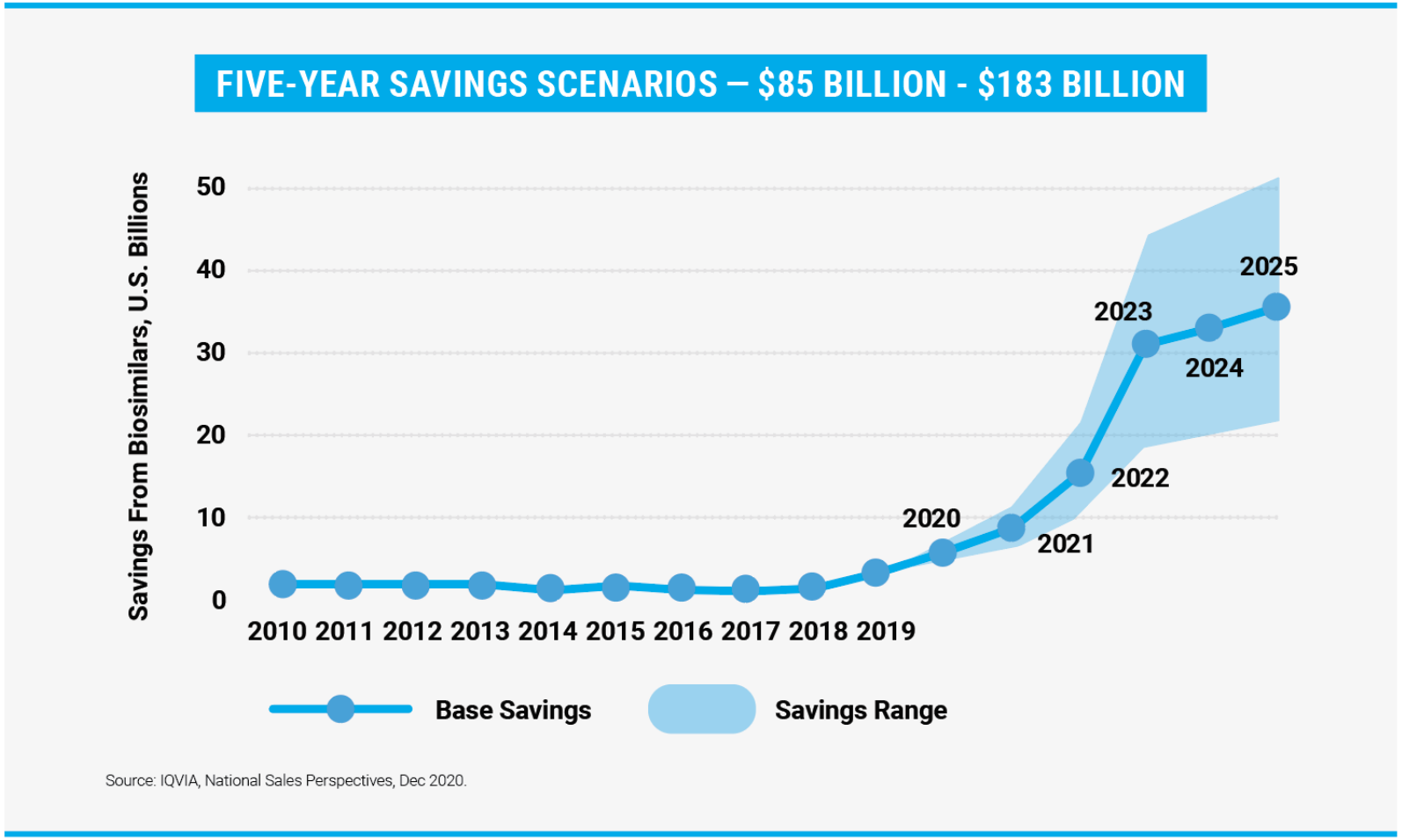
SAVINGS FROM BIOSIMILAR USE MORE THAN TRIPLED FROM 2019



Source: IQVIA, National Sales Perspectives, Dec 2020

Biosimilars Projected to Save $133 Billion by 2025

SAVINGS WILL DEPEND ON APPROPRIATE POLICIES TO SUPPORT ADOPTION



AAM's Prescription for State Savings

Prescription for State Savings

Preserve Patient Access to Generics and Biosimilars

- State proposals often negatively impact generic and biosimilar manufacturers through one-size-fits-all policies or with onerous requirements that threaten continued patient savings.

Combat Misinformation, Promote the Use of Biosimilars

- States could make available and distribute FDA's biosimilar materials, conduct studies on the savings to patients and payers derived from these new treatments, and help raise awareness about the use of biosimilar medicines.

Ensure Coverage of Cost-Effective Biosimilar Medicines

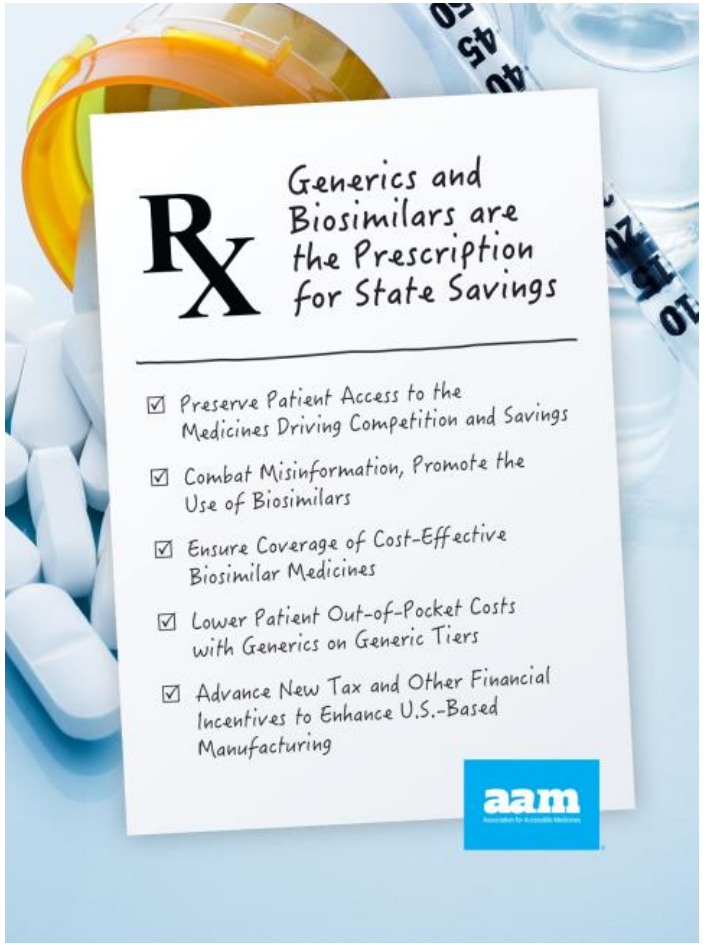
- States could take steps to encourage the coverage and use of biosimilar medicines by addressing payer and provider barriers.

Lower Patient OOP Costs with Generics on Generic Tiers

- Ensuring coverage of newly available generic medicines and proper formulary tier coverage would reduce patient cost-sharing.

Advance Incentives for U.S.-Based Manufacturing

- State-based tax incentives and economic development grants could be provided to support domestic manufacturing and help ensure patients have access to a secure and consistent supply of critical medicines.



#Rx4STATESAVINGS

Prioritizing Biosimilars through Formulary Design

Biosimilar vs Interchangeable is not relevant for formulary regulations. The distinction is only meaningful at the pharmacy counter and is not an indication of superior quality.

Biosimilars

FDA-Approval

- Highly similar to the reference product and does not have clinically meaningful differences

Administration

- Prescribed and administered by a physician or other health care provider

Interchangeable Biosimilars

FDA-Approval

- Biosimilar
- Per FDA's requirements, may have undergone additional studies about the effects of switching between biosimilar and reference

Administration

- Typically dispensed by a pharmacist
- Subject to state law, a pharmacist may substitute an interchangeable biosimilar instead of the reference without the prescribing physician's approval

Price Transparency & Affordability Board Proposals Mistakenly Target Generics

EXAMPLES ARE OFTEN MISLEADING

Generic Prozac® Increased 667%

- Brand Increased from $476 to $811
- 36 Generics Available
- Average of $28 (down from $34)

Generic Vidaza® Doubled in Price

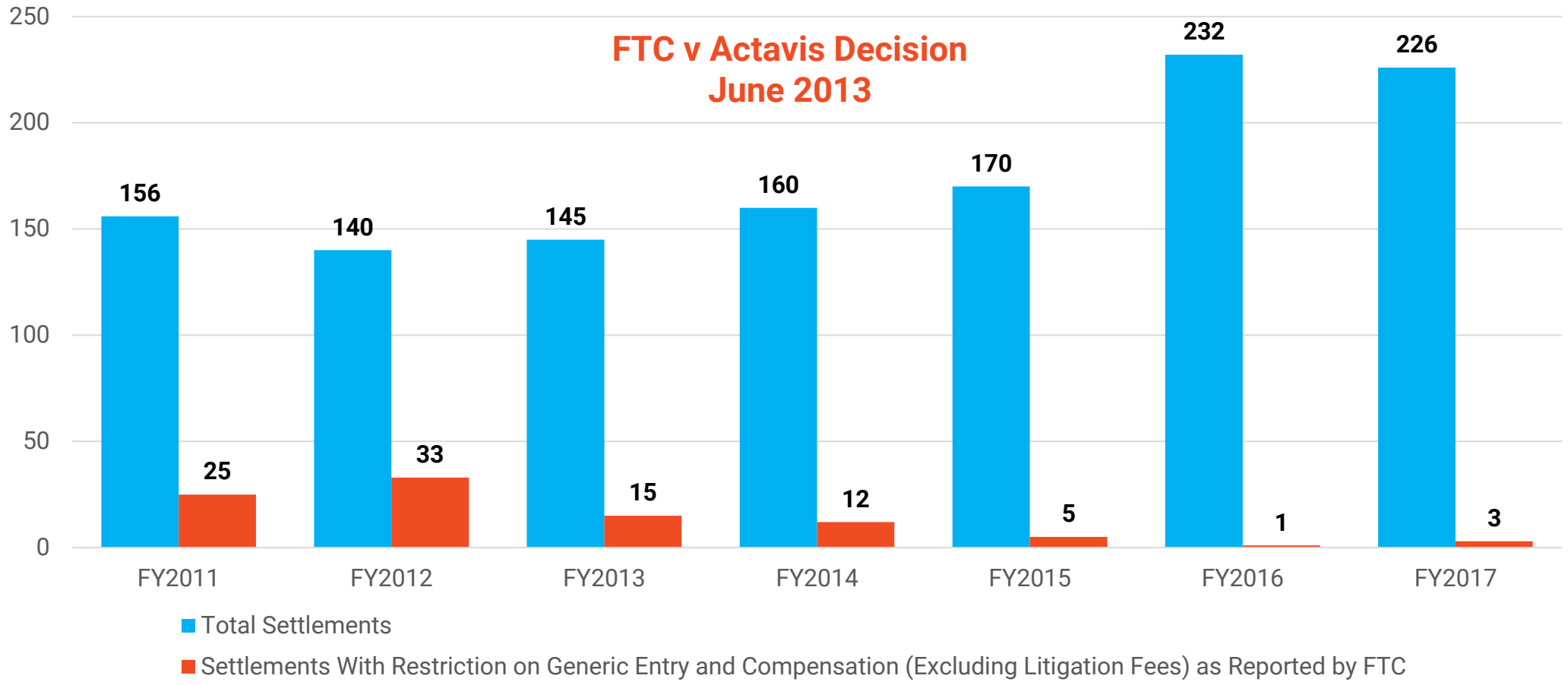
- Brand Price $585
- 14 Generics Available
- Range of $368 to $79

AAM Position

Exempt Medicines with <= $100 WAC for a 30-day Supply

Patent Settlements Promote a Competitive Market

FTC Reports Dramatic Decline in Reverse-Payment Agreements Following Actavis Decision



Source Notes: The bar chart reflects data included in FTC's annual staff report on patent settlement agreements. The most recent report released in December 2020 is for FY2017 and includes the number of patent settlement agreements with restrictions on entry and compensation above $7.5 million. The data displayed is provided for illustrative purposes only and does not reflect how AAM would characterize the agreements in question.