Prescription Medicines: Costs in Context

PhRMA
RESEARCH • PROGRESS • HOPE

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1 Prescription Drugs 101

We are in a new era of medicine where breakthrough science is transforming care with innovative treatment approaches...

Then

- Medicines made of chemical compounds
- Medicines treat broad diseases
- Radiation and chemotherapy to treat cancer

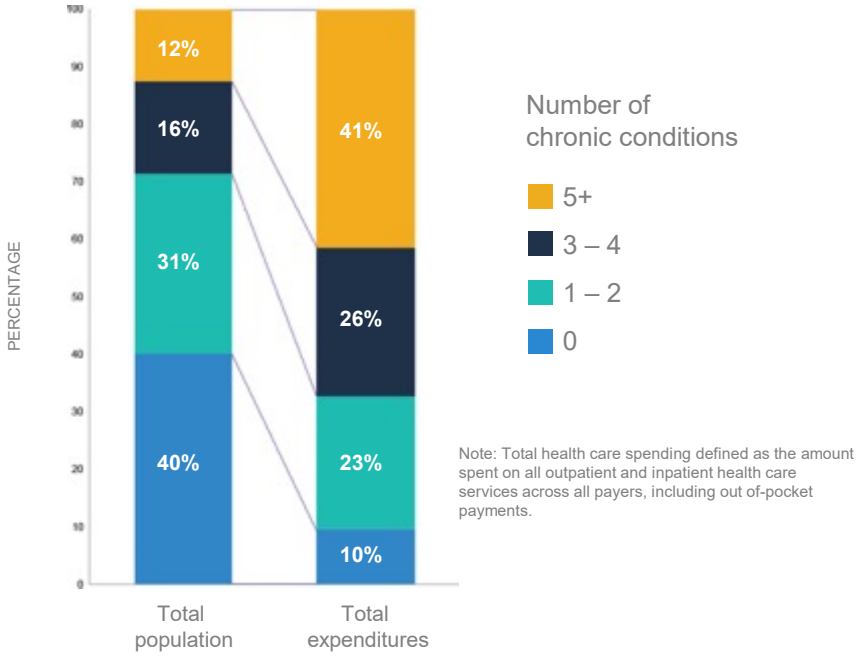
Now

- Medicines made from living cells
- Medicines targeted to specific patient based on genetic makeup
- Immunotherapy that harnesses body's own immune system to fight disease
- CAR T-cell therapy
- CRISPR

…and enabling us to more effectively treat chronic disease, the biggest cost driver.

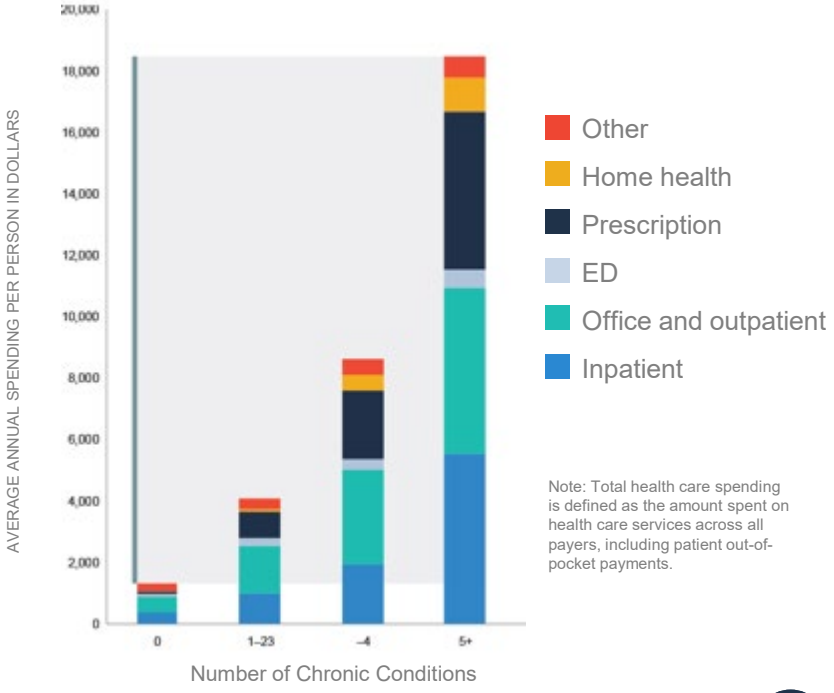
Treating people with one or more chronic condition consumes 90 cents of every dollar spent on health care.

Prevalence and Spending by Number of Chronic Conditions (2014)



Note: Total health care spending defined as the amount spent on all outpatient and inpatient health care services across all payers, including out of-pocket payments.

Health Care Spending by Number of Chronic Conditions (2014)

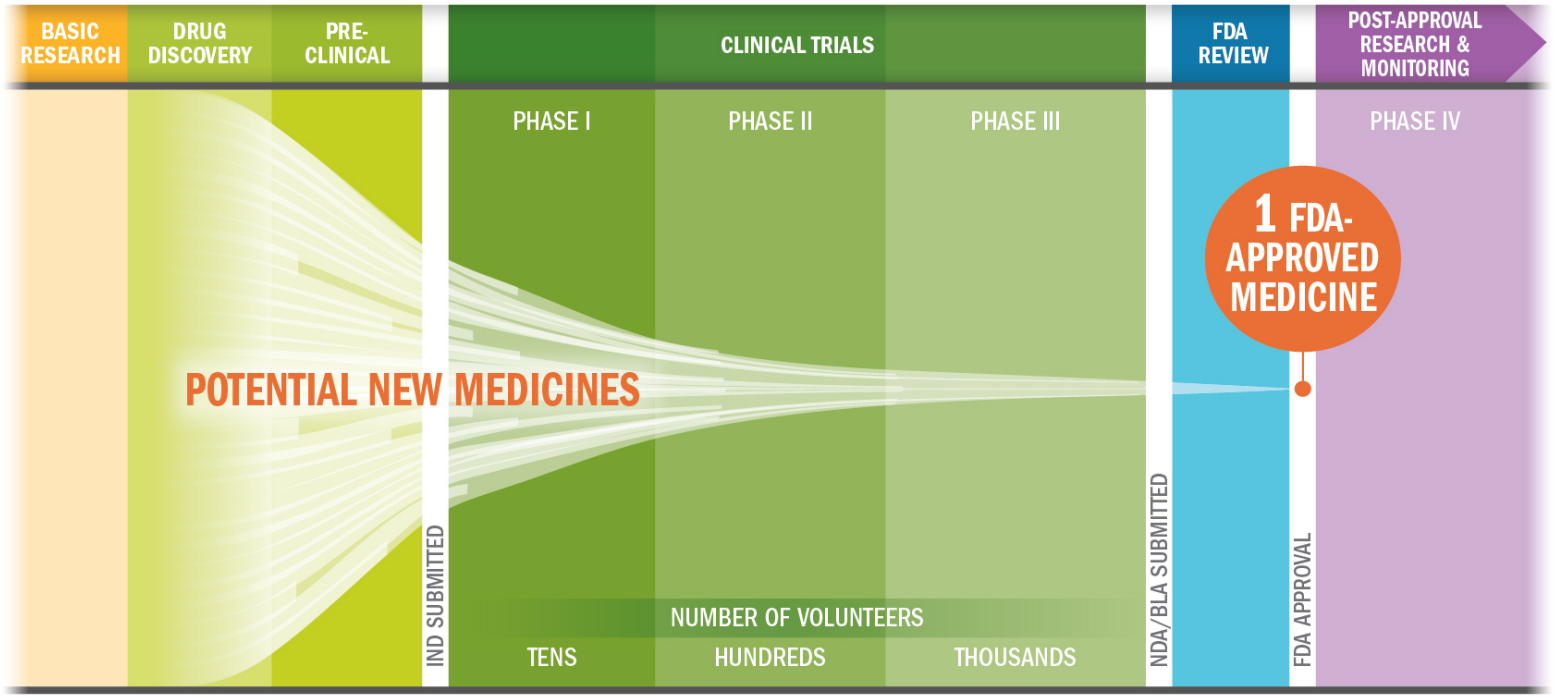


Note: Total health care spending is defined as the amount spent on health care services across all payers, including patient out-of-pocket payments.

Source: RAND Corporation

Biopharmaceutical Research and Development Process

From drug discovery through FDA approval, developing a new medicine on average takes 10 to 15 years and costs $2.6 billion.* Less than 12% of the candidate medicines that make it into phase I clinical trials are approved by
the FDA.

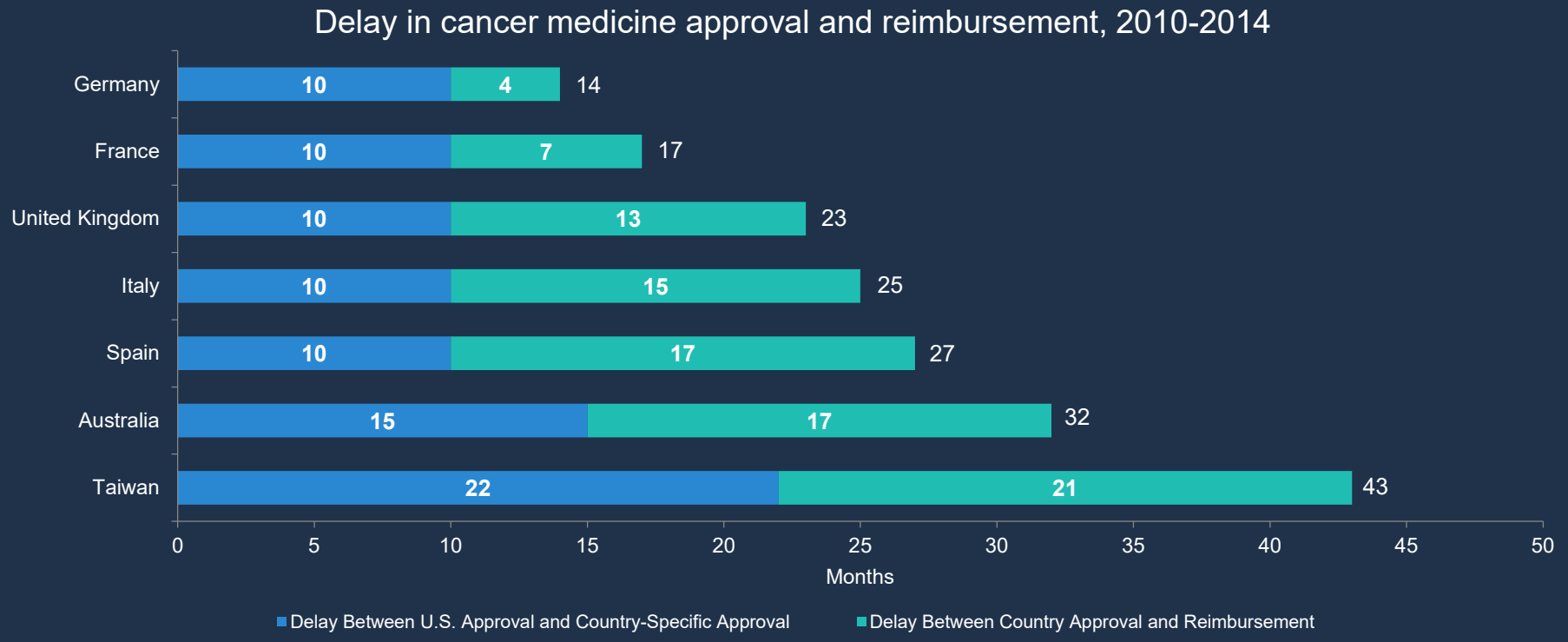


Key: IND: Investigational New Drug Application, NDA: New Drug Application, BLA: Biologics License Application

*The average R&D cost required to bring a new FDA-approved medicine to patients is estimated to be $2.6 billion over the past decade (in 2013 dollars), including the cost of the many potential medicines that do not make it through to FDA approval.

The competitive U.S. market provides patients with access to innovative medicines faster.

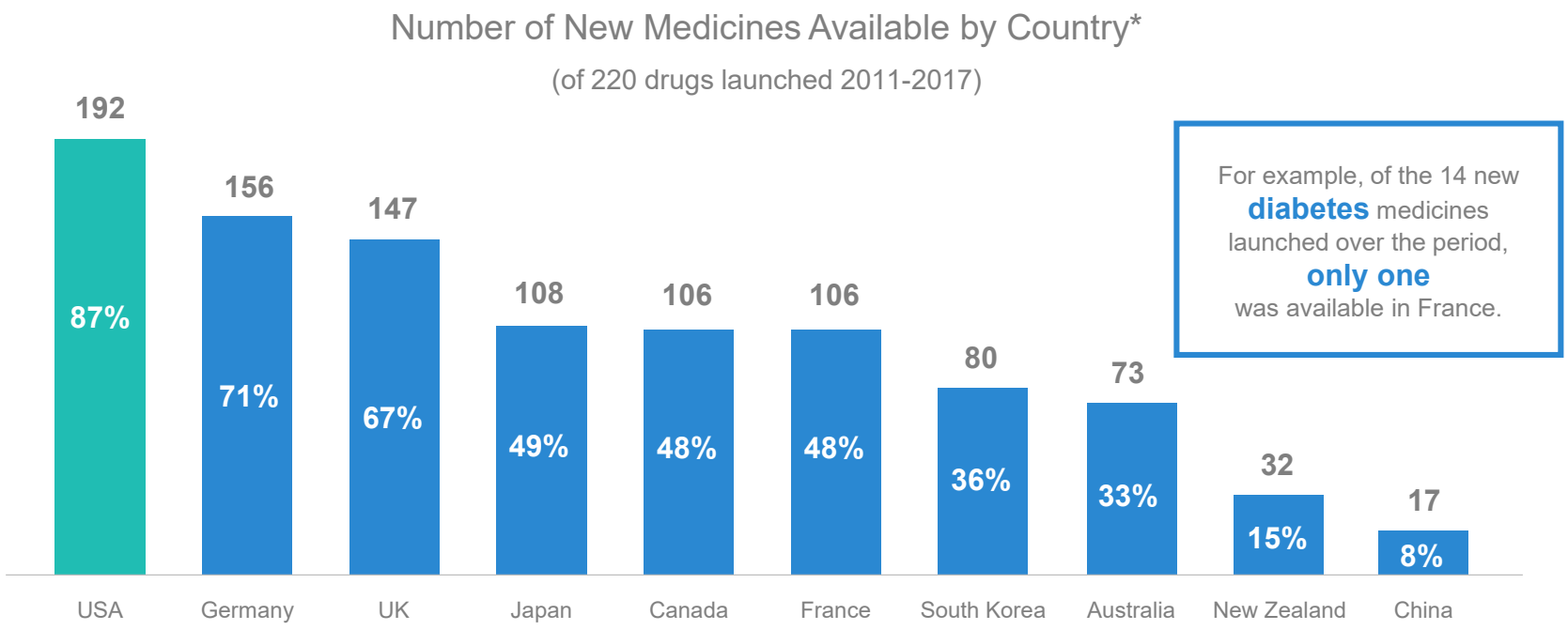
For example, American patients have access to cancer medicines about two years earlier.



Source: PhRMA analysis of IMS Consulting Group "Patient Access to Innovative Oncology Medicines Across Developed Markets." June 2016

More medicines are available to U.S. patients.

Nearly 90% of newly launched medicines from 2011 to 2017 were available in the United States, compared to just two-thirds in the UK, half in Canada and France, and one-third in Australia.



Note: New Molecular Entities (NME) approved by the FDA. European Medicines Agency (EMA) and Japan's Pharmaceuticals and Medical Devices Agency (JPMDA), and launch in any country between 2011-2017
Source: PhRMA analysis of IQVIA Analytics

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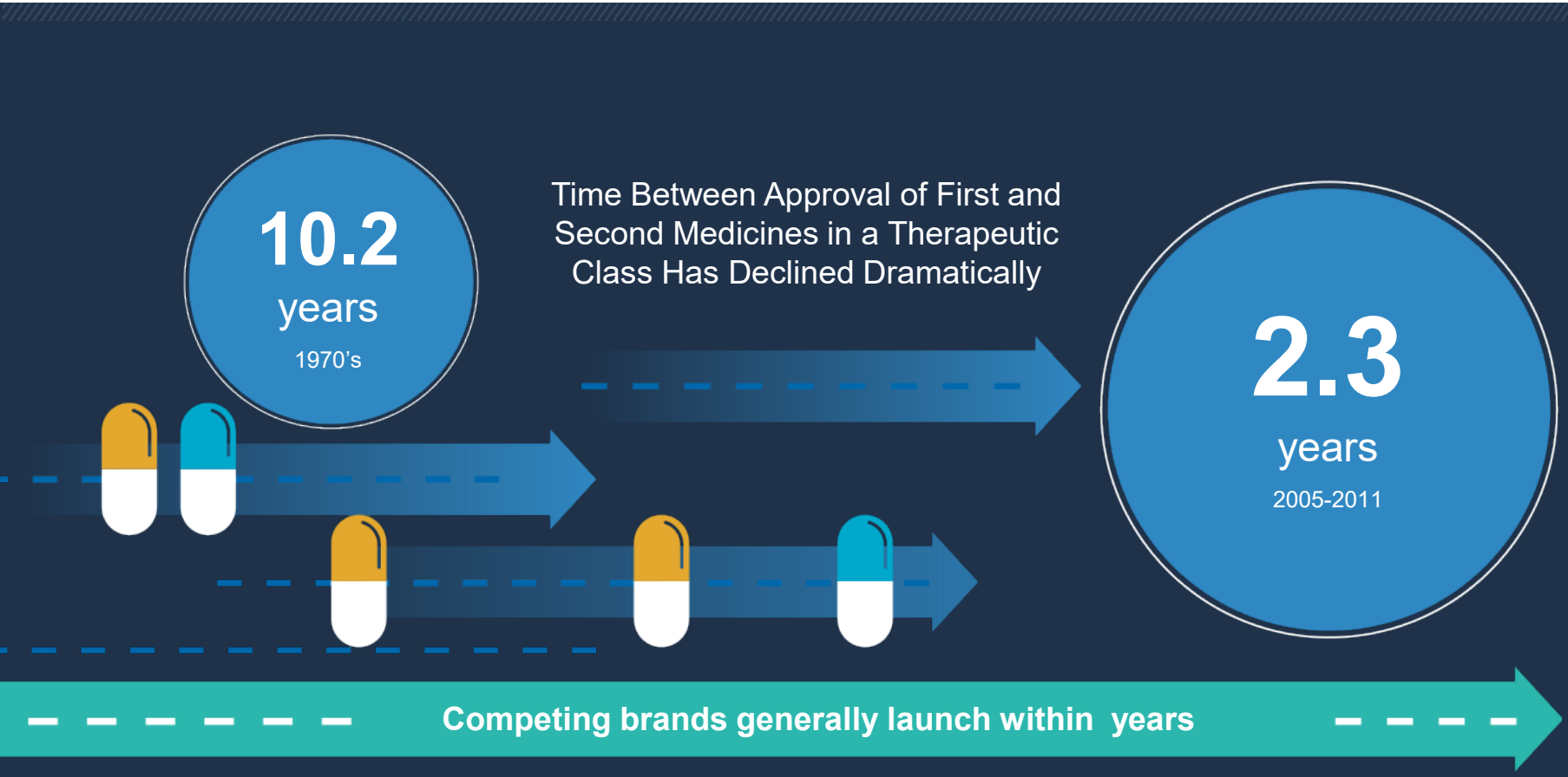
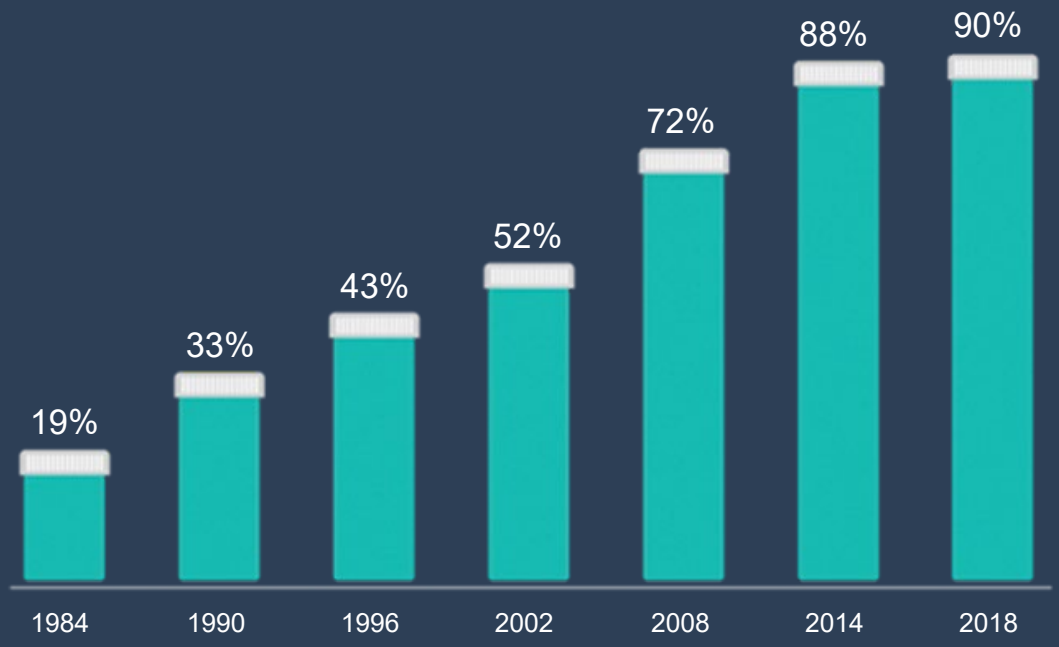
Competition Drives Down Costs

Innovator companies race to be the first to market with a new medicine.



Source: Tufts Center for the Study of Drug Development (CSDD).

90% of all medicines dispensed in the United States are generics.

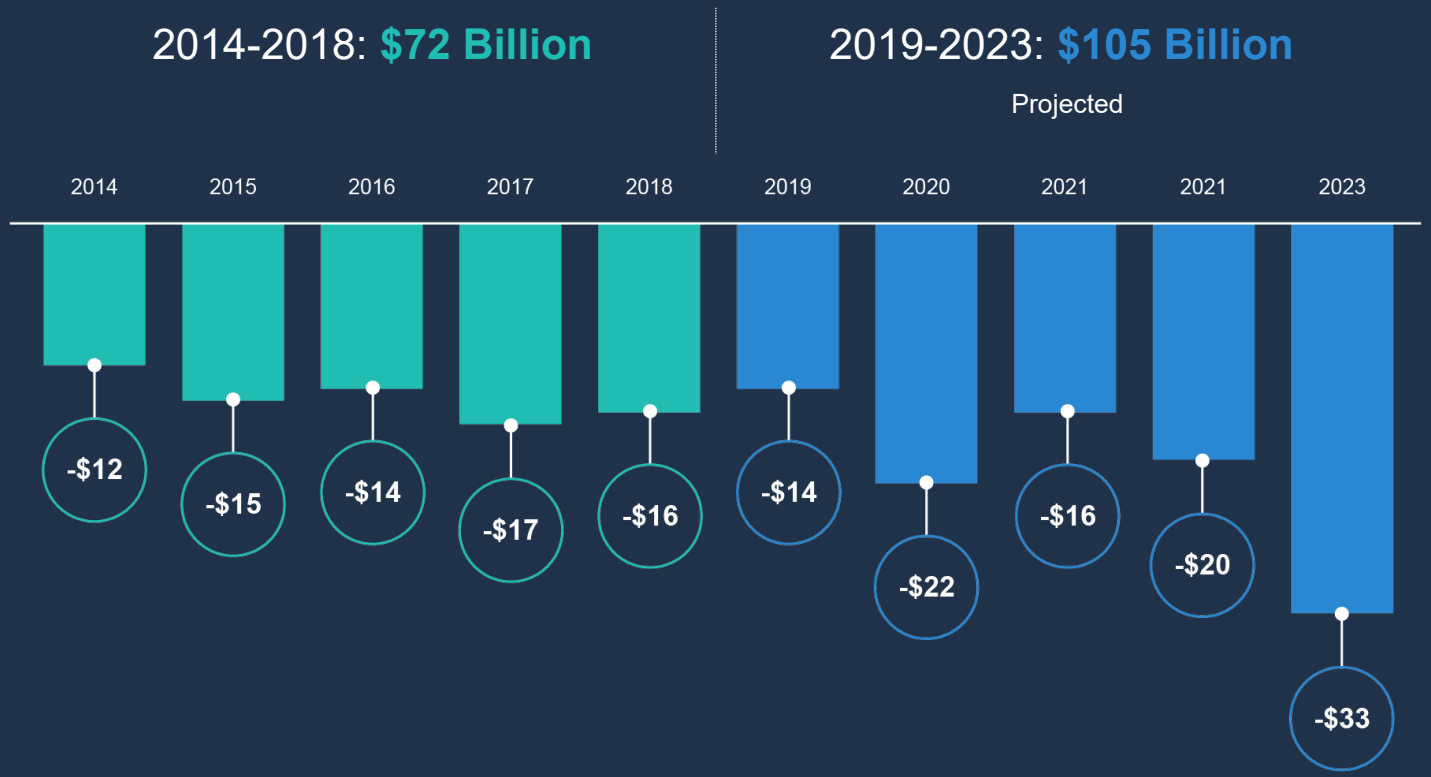


$1.79 trillion

10-year savings (2008-2017)

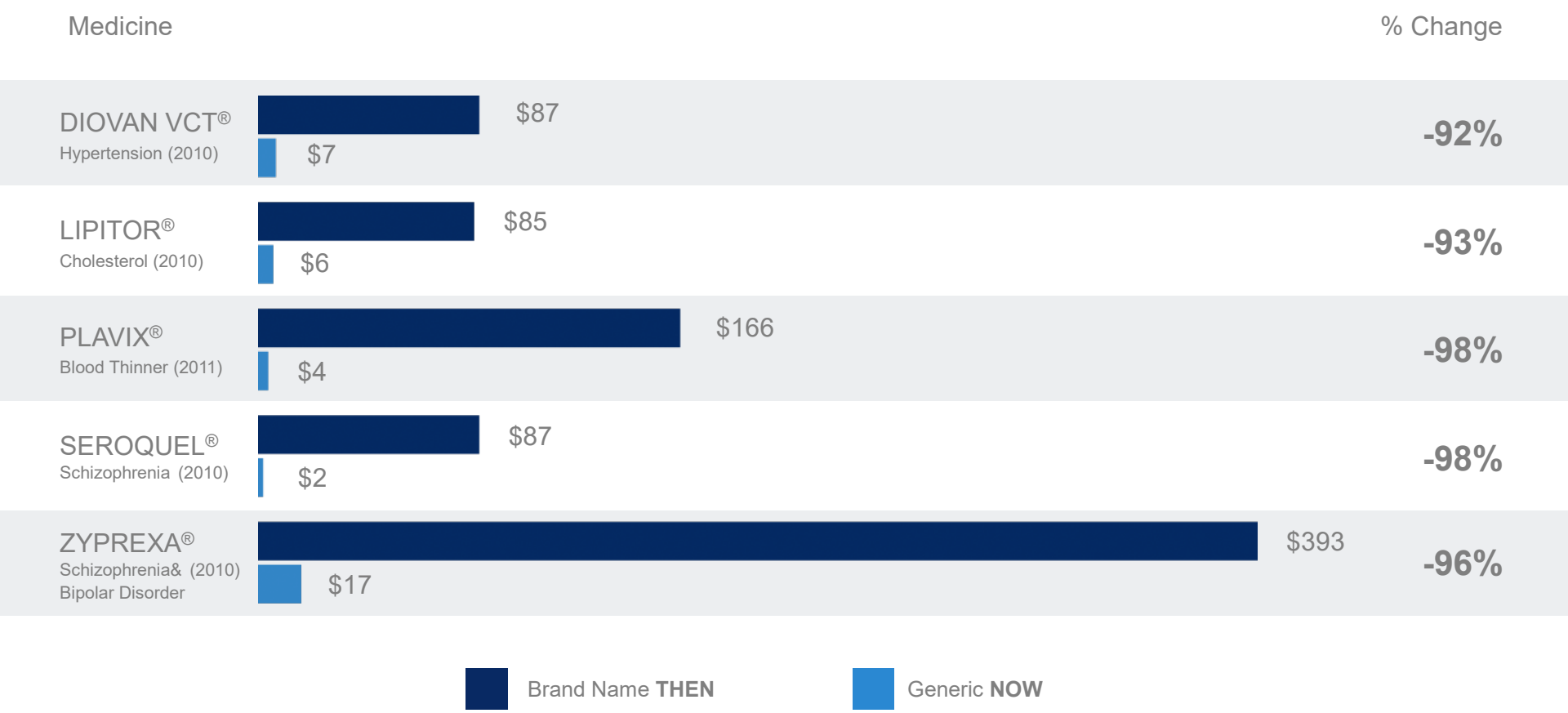
Source: IMS Health. Drug Channels Institute, March 2019.
Source: Generic Pharmaceutical Association, "Generic Drug Savings in the U.S. Report," 2018.

Competition from generics and biosimilars is expected to reduce U.S. brand sales by $105 billion from 2019 to 2023.



Source: IQVIA. January 2019.

Generics cost a fraction of the price of the initial brand medicine.



Note: Figures represent the average annual price for 30 pills of the most commonly dispensed form and strength. "Then" price represents the average price in the year prior to generic entry. "Now" price represents the average price in December 2017.
Source: IQVIA Institute for Human Data Science analysis for PhRMA. May 2018.

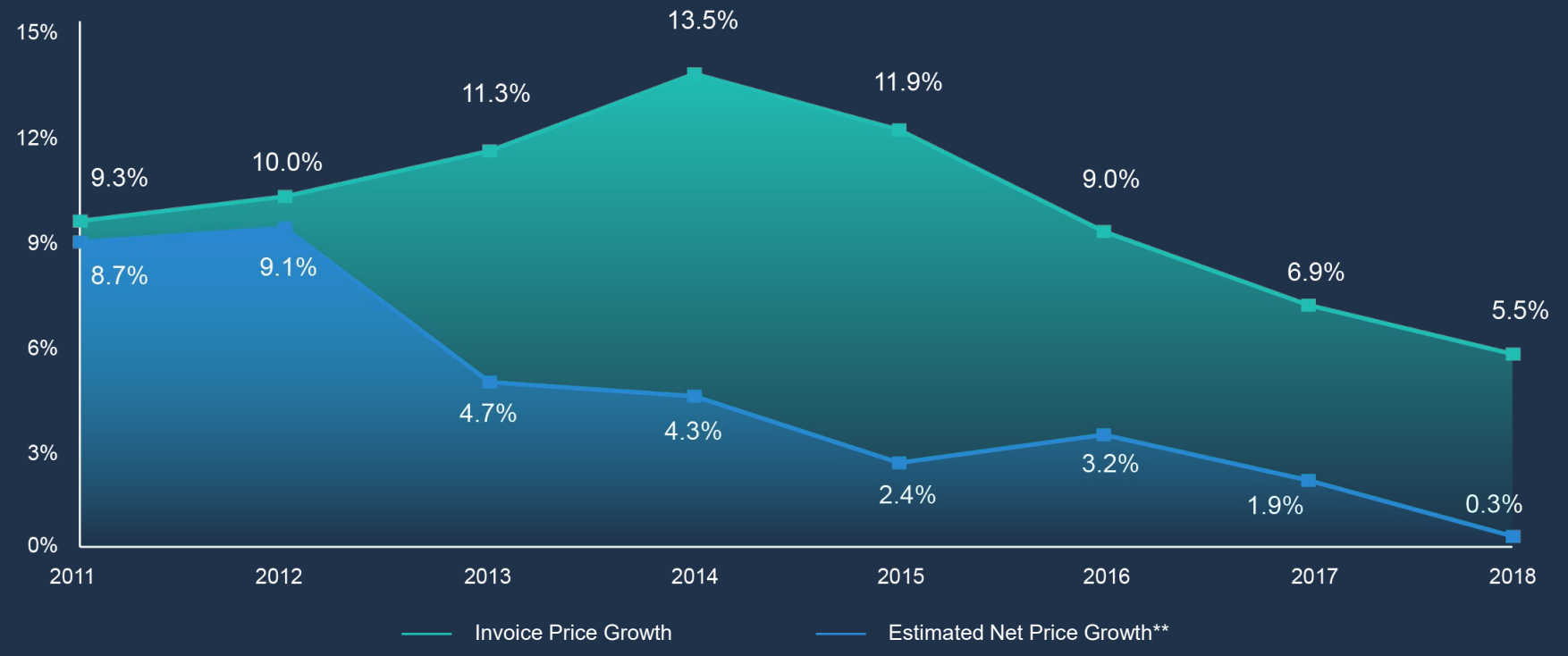
Costs in Context

In the midst of this incredible progress, medicine cost growth is declining.

EXPRESS SCRIPTS®	CVSHealth®	IMS Health & Quintiles are now IQVIA™
5.3%	5.0%	8.5%
2015	2015	2015
↓	↓	↓
0.4%	3.3%	4.5%
2018	2018	2018

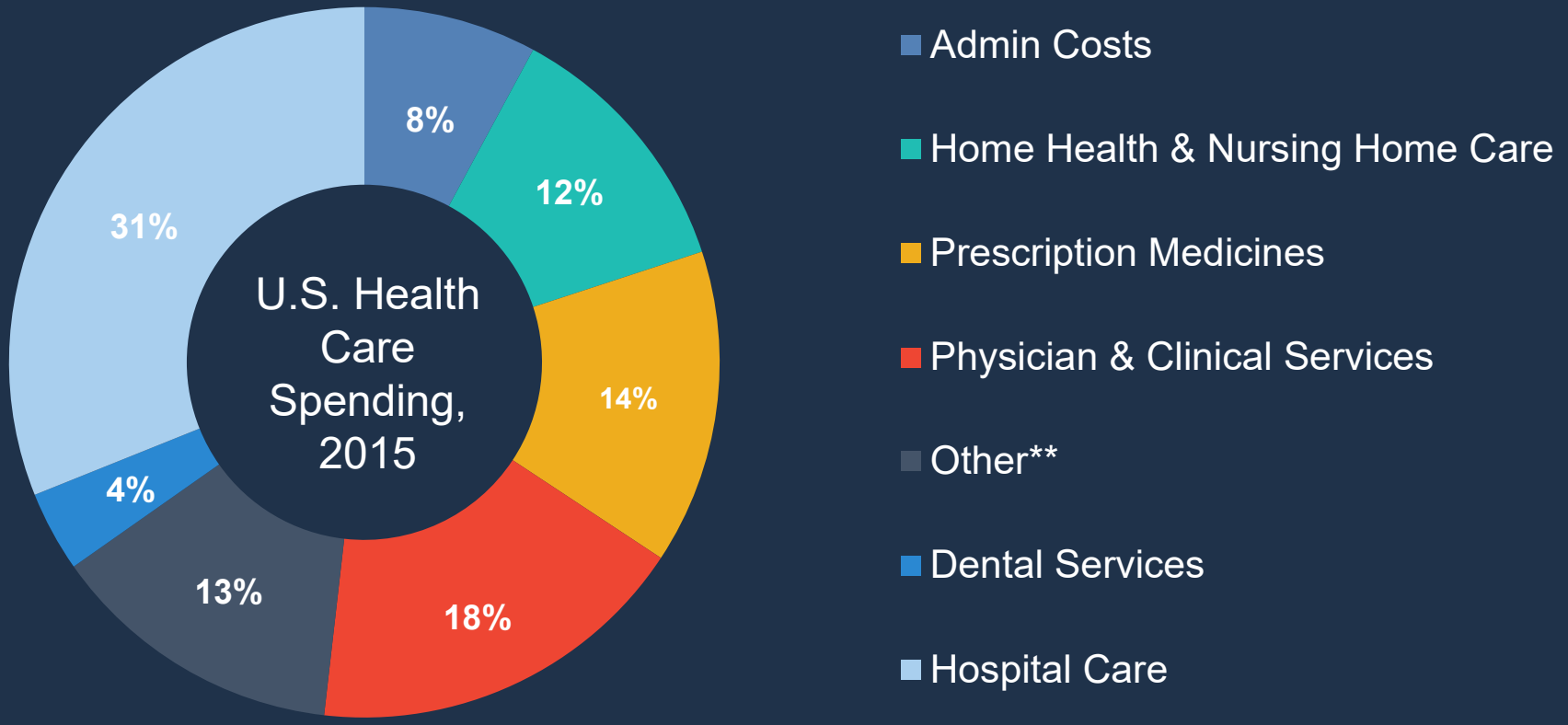
Note: IQVIA data is reflective of retail and physician-administered medicine spending.

In fact, after discounts and rebates, brand medicine prices grew just 0.3% in 2018.



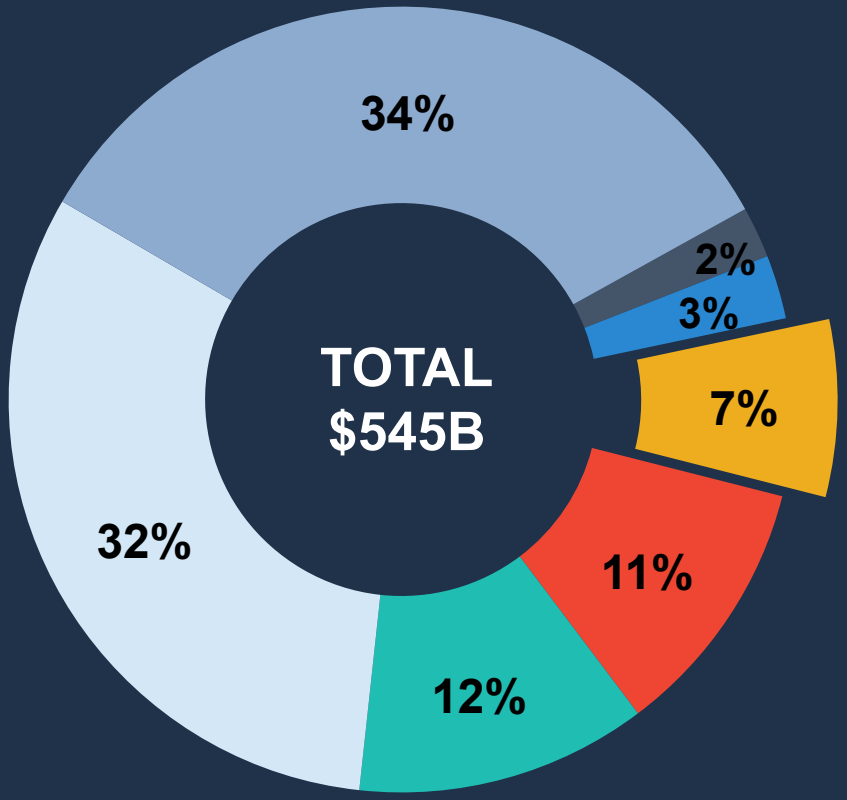
Source: IQVIA, January 2019.
*Includes protected brand medicines only (ie, brand medicines without generic versions available in the year indicated).
**Net price growth reflects impact of off-invoice rebates and discounts provided by manufacturers.

Spending on retail and physician-administered medicines continues to represent just 14% of spending…



Source: PhRMA analysis of CMS National Health Expenditures data, Altarum Institute study and Berkley Research Group study.
**Supply chain entities- stakeholders involved in bringing medicines from manufacturer to patient, including wholesalers, pharmacies, PBMs and healthcare provider locations.

…and a small share of total Medicaid spending…

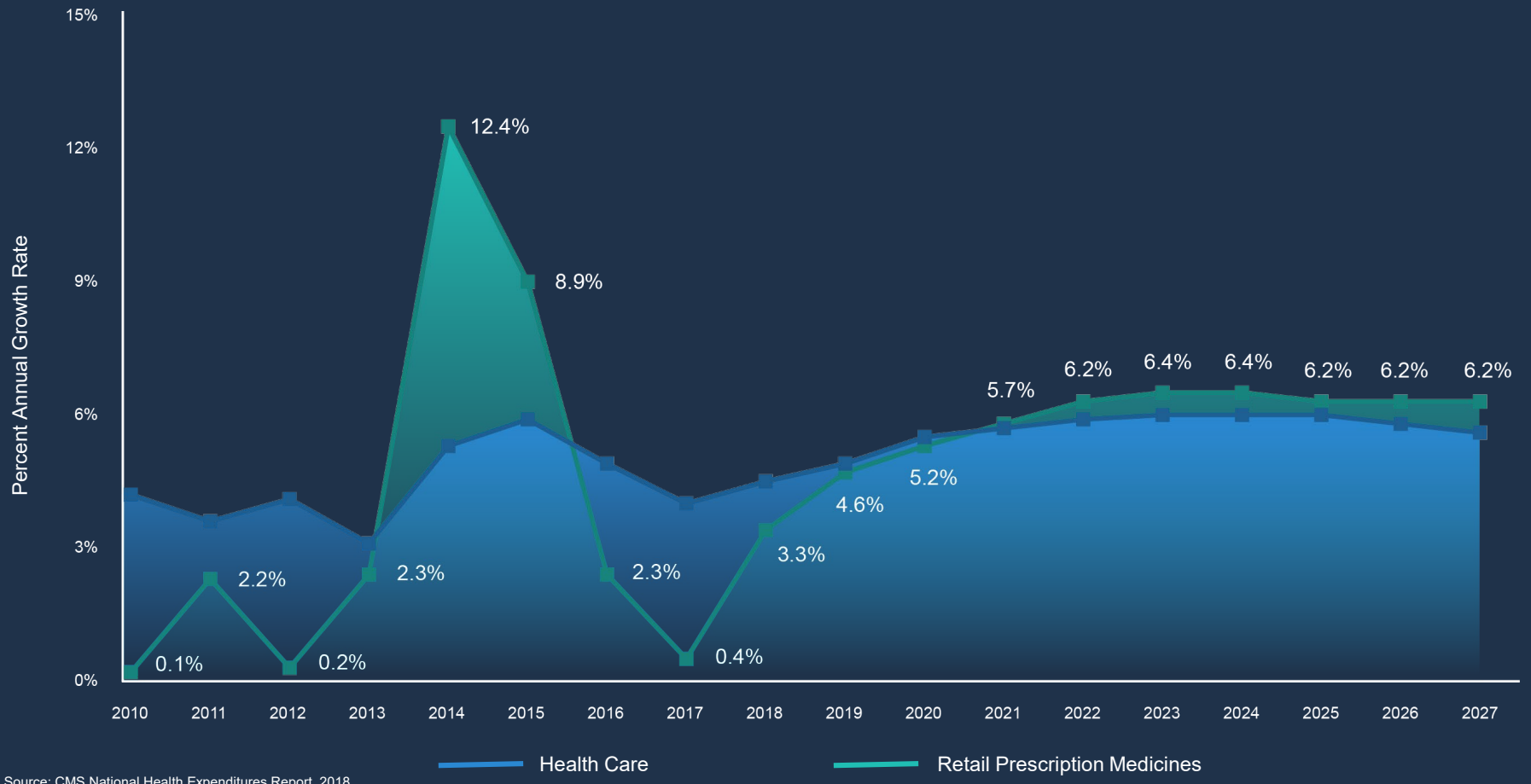


- Dental Services
- Other
- Prescription Medicines
- Government Administrative Costs
- Physician and Clinical Services
- Home Health and Nursing Home Care
- Hospital Care

Note: Prescription drug data is net of rebates and includes both retail and non-retail drugs. Data used were predominantly derived from CMS 64 reports. Pre-rebate expenditures were tabulated using FY2015 CMS State Drug Utilization data files and CMS brand/generic indicators for each NDC.

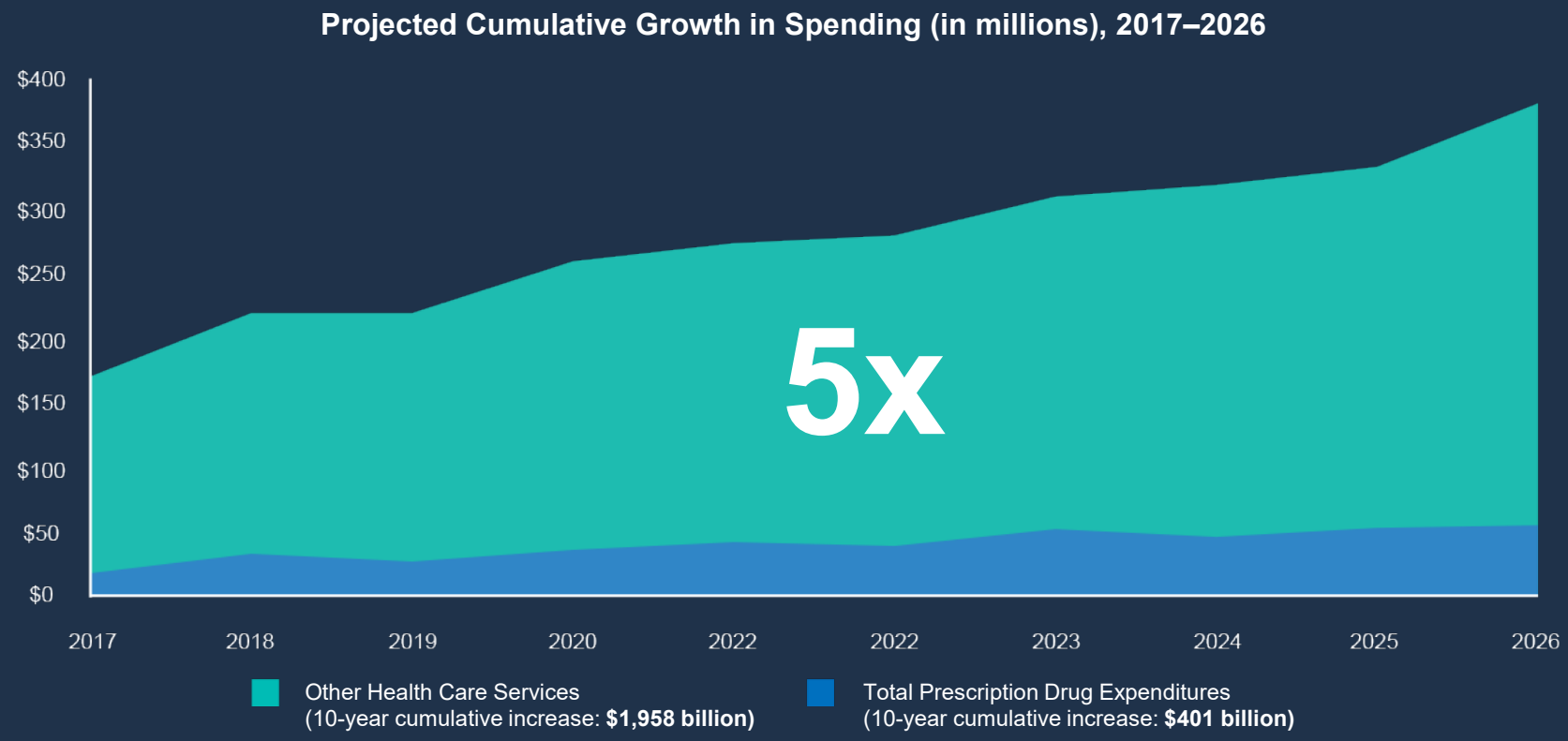
Source: CMS National Health Expenditure Data and Altarum Institute.

…and is projected to grow in line with health care spending through next decade.



Source: CMS National Health Expenditures Report, 2018.
Note: Total retail sales include brand medicines and generics.

At the same time, growth in other health care services will be 5 times total medicine spending growth through next decade.



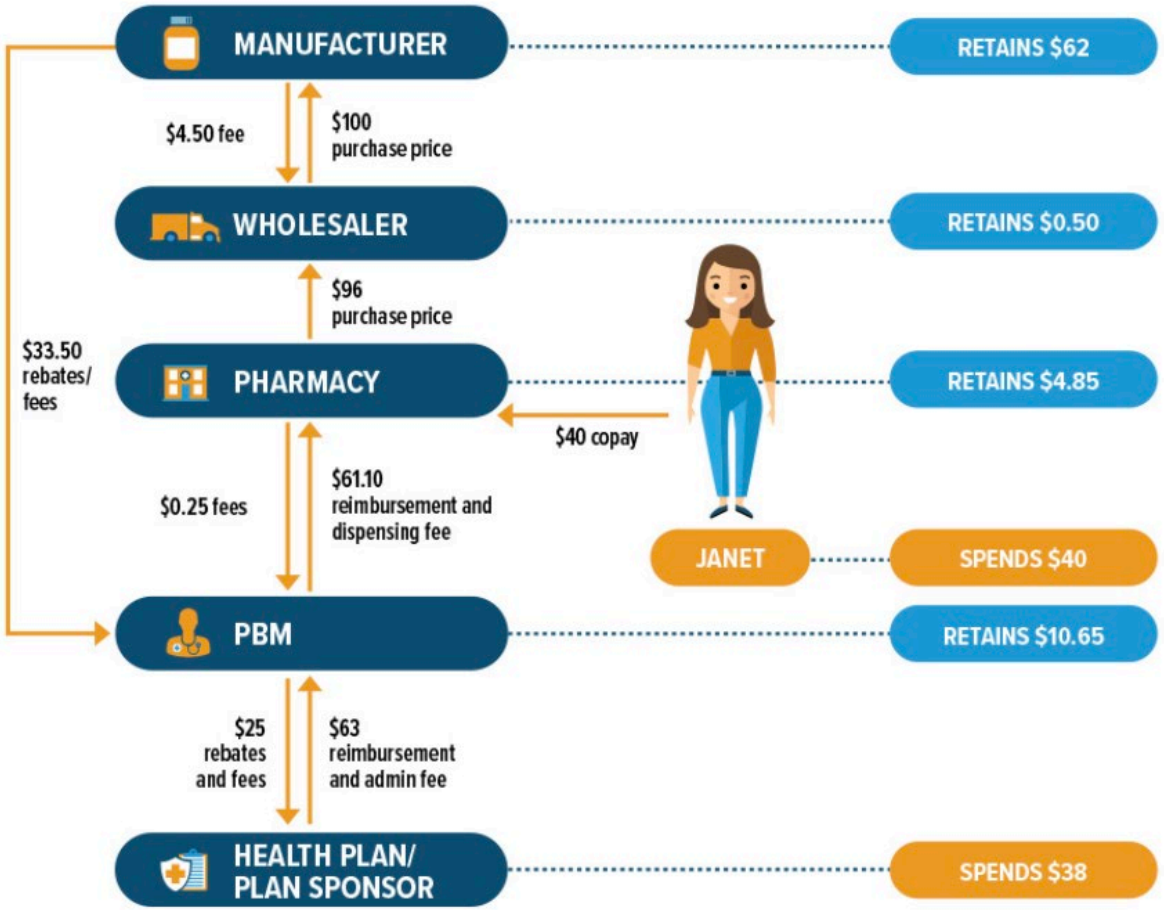
Source: CMS National Health Expenditures Report, 2018.
Note: Total retail sales include brand medicines and generics.

The Pharmaceutical Supply Chain: Follow the Dollar

Understanding How the Pharmaceutical Distribution and Payment System Shapes the Prices of Brand Medicines

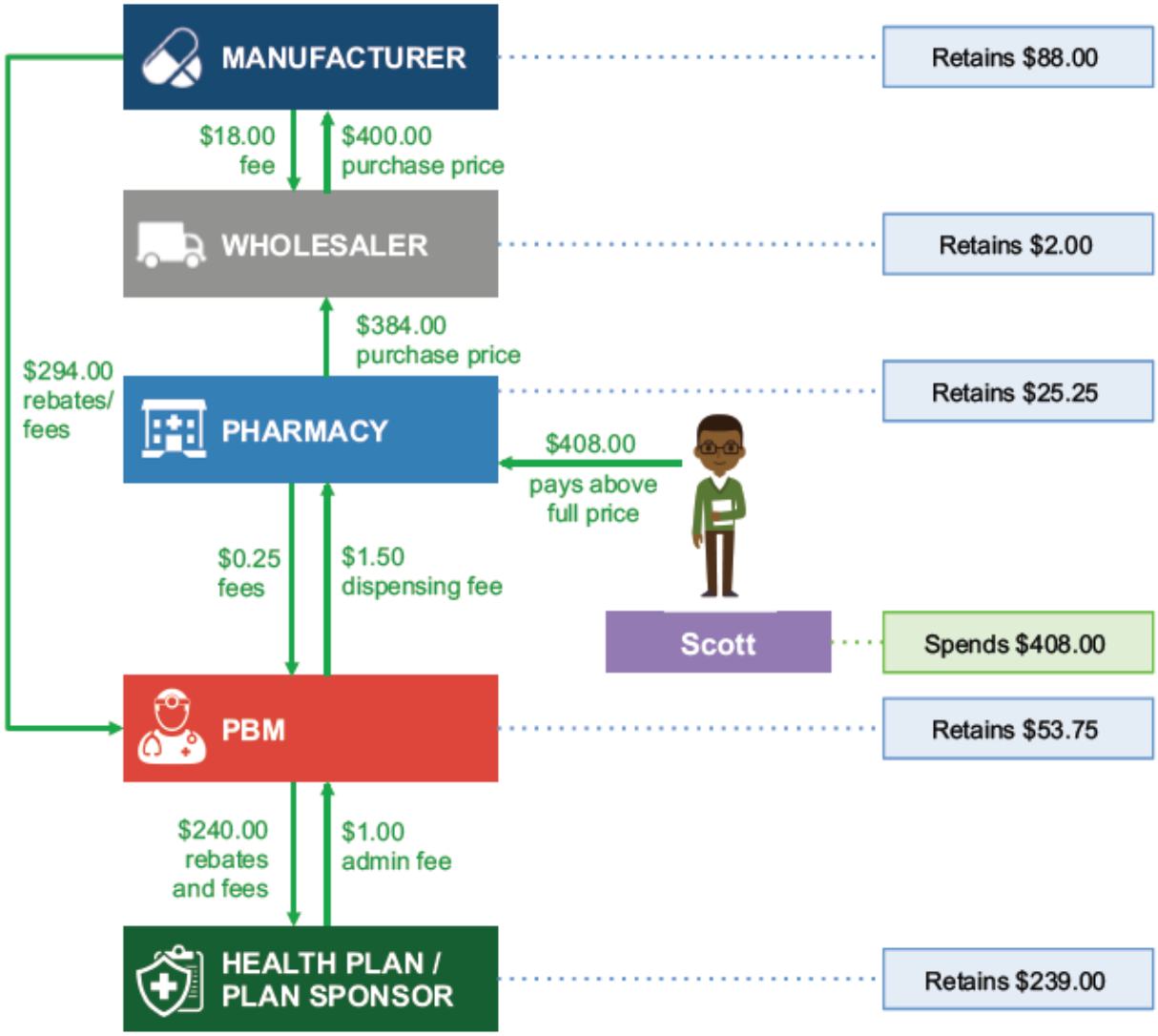
Flow of Payment for a $100 Blood Pressure Medicine
(Patient Pays a Copayment)

- This graphic is illustrative of a hypothetical product with a WAC of $100 and an AWP of $120, and where the health plan receives a rebate from the manufacturer that reduces list price by 25%.
- It is not intended to represent every financial relationship in the marketplace.



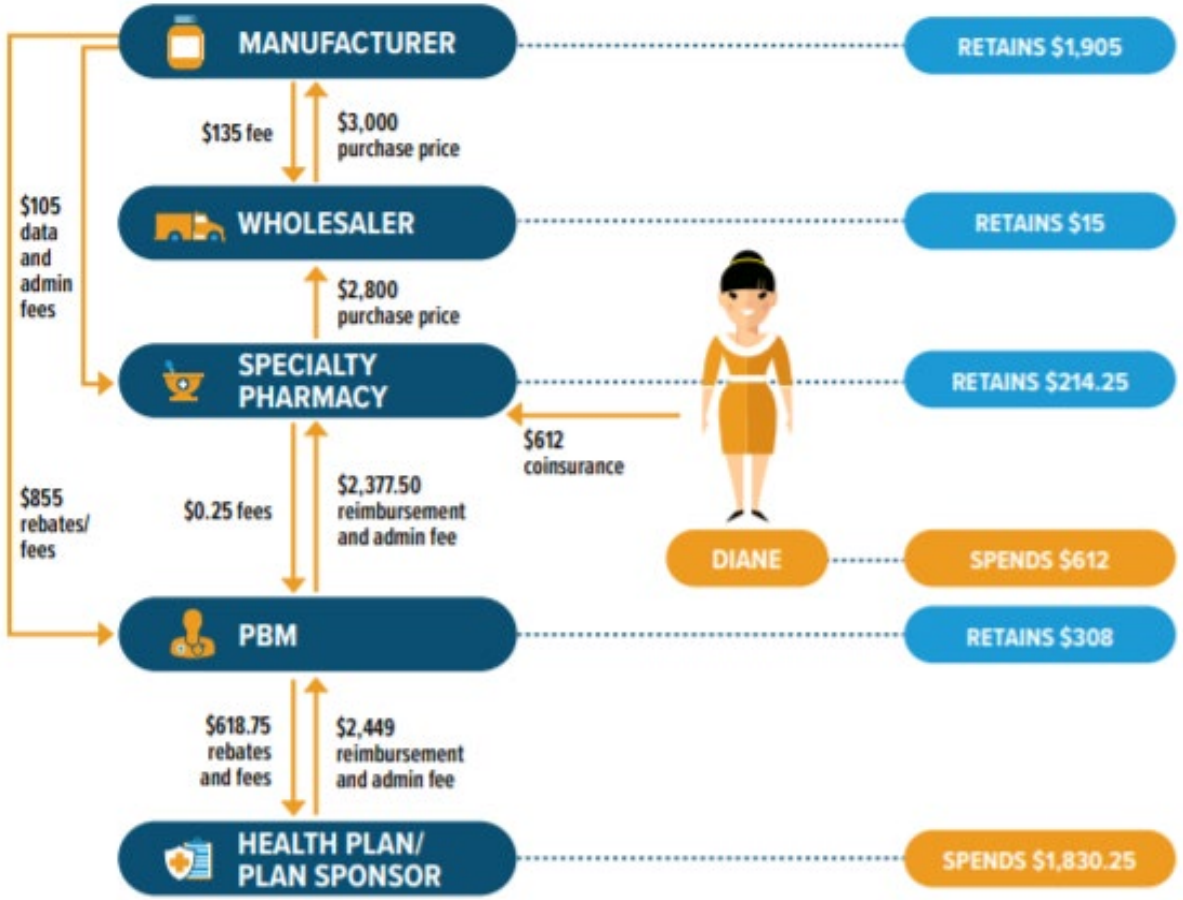
Flow of Payment for a $400 Insulin (Patient Is In Deductible Phase)

- This graphic is illustrative of a hypothetical product with a WAC of $400 and an AWP of $480, and where the health plan receives a rebate from the manufacturer that reduces list price by 65%.
- It is not intended to represent every financial relationship in the marketplace.



Flow of payment for a $3,000 HIV Medicine (Patient Pays Coinsurance)

- This graphic is illustrative of a hypothetical product with a WAC of $3,000 and an AWP of $3,600where the health plan receives a rebate from the manufacturer that reduces list price by 20%.
- It is not intended to represent every financial relationship in the marketplace.
- The amount of payment does not add up to $3,000 due to markups and discounts as a medicine is distributed.



Follow the Dollar: How the Supply Chain Shapes Brand-Name Medicine Prices

- Robust commercial market negotiations between PBMs and biopharmaceutical companies have resulted in substantial rebates, discounts and fees paid to supply chain entities. These price concessions have continued to increase despite a slowdown in brand-name drug list price growth.

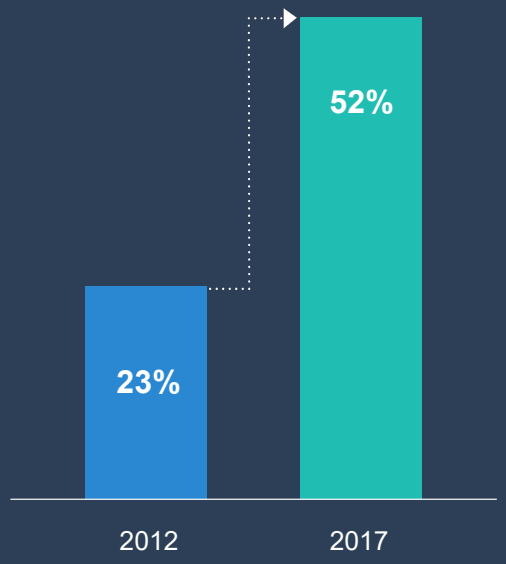
- In some cases, patient cost-sharing may exceed the price the health plan actually pays for a medicine. When this occurs, cost-sharing payments in excess of the medicine's cost are retained by health plans and PBMs—not by biopharmaceutical companies.

- Some industry observers and government agencies have questioned whether insurers and PBMs are more focused on the size of rebates than on achieving the lowest possible costs and best outcomes for patients.

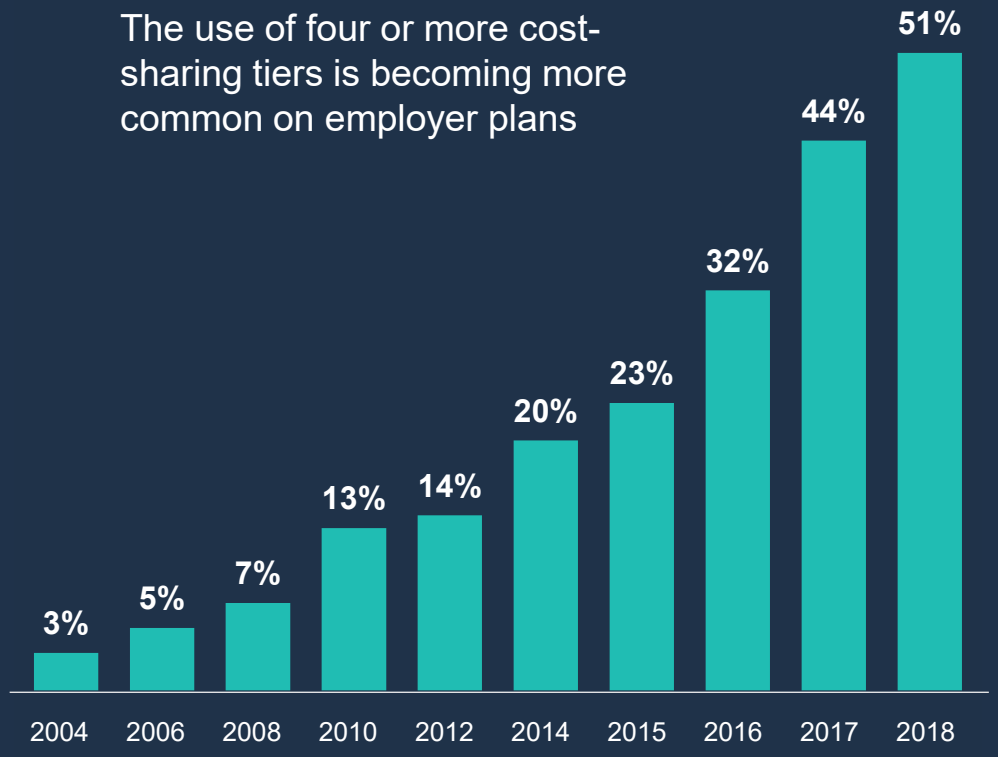
- The current system needs to evolve to better reward results and ensure patients more directly benefit from the significant price negotiations.

Patients in the United States are facing rising out-of-pocket costs and other barriers to care.

Percent of plans with deductibles on prescription drugs



The use of four or more cost-sharing tiers is becoming more common on employer plans



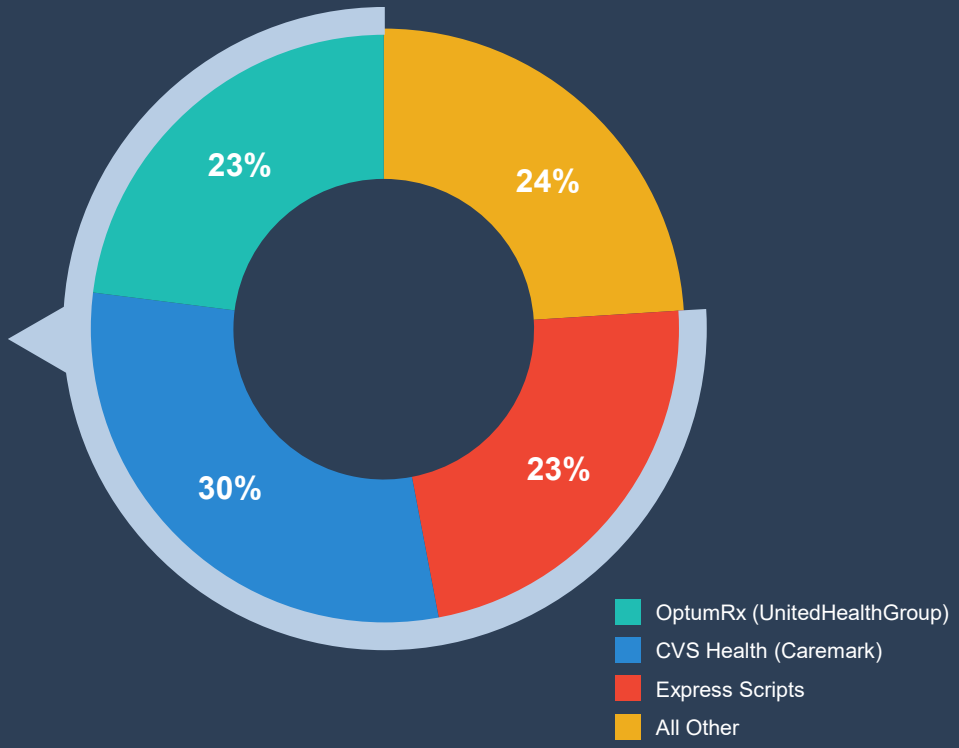
Source: PWC, KFF

Insurers and PBMs have a lot of leverage to hold down medicine costs.

Negotiating power is increasingly concentrated among fewer pharmacy benefit managers (PBMs).

Top 3 Market Share:

76%



Source: Drug Channels Institute, March 2019.

Insurers determine:

FORMULARY
if a medicine is covered

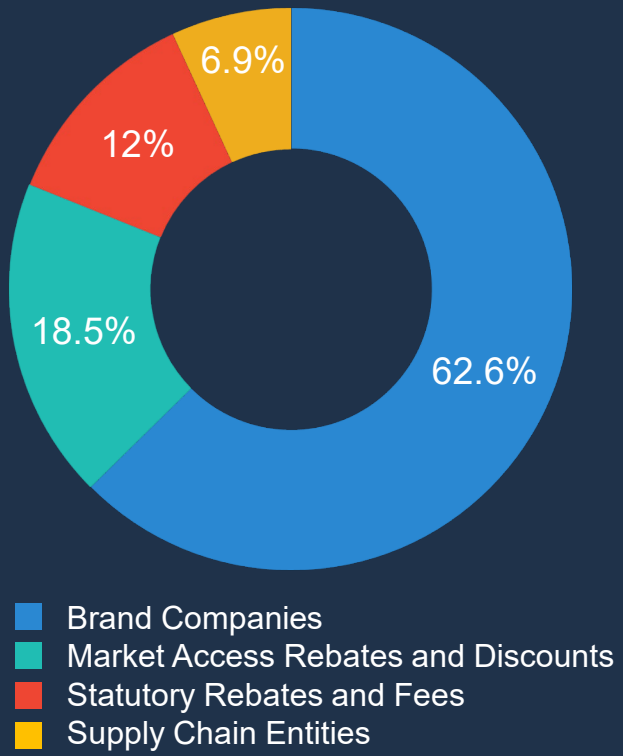
TIER PLACEMENT
patient cost sharing

ACCESSIBILITY
utilization management through prior authorization or fail first

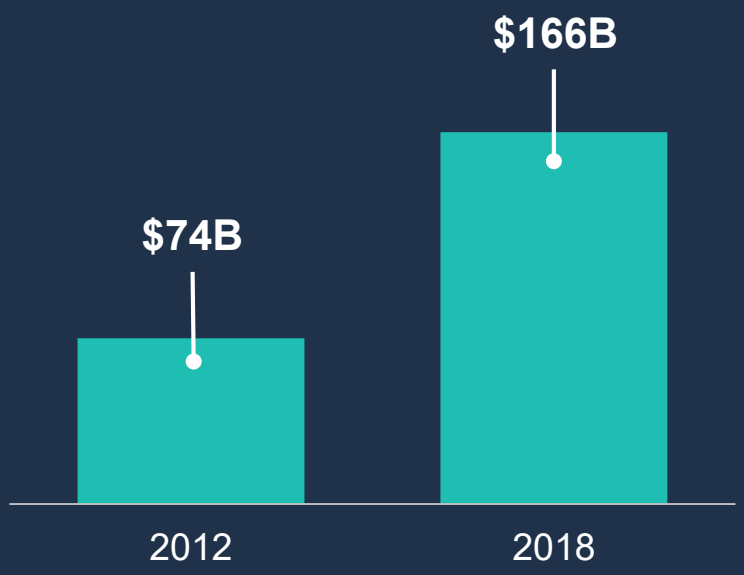
PROVIDER INCENTIVES
preferred treatment guidelines and pathways

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



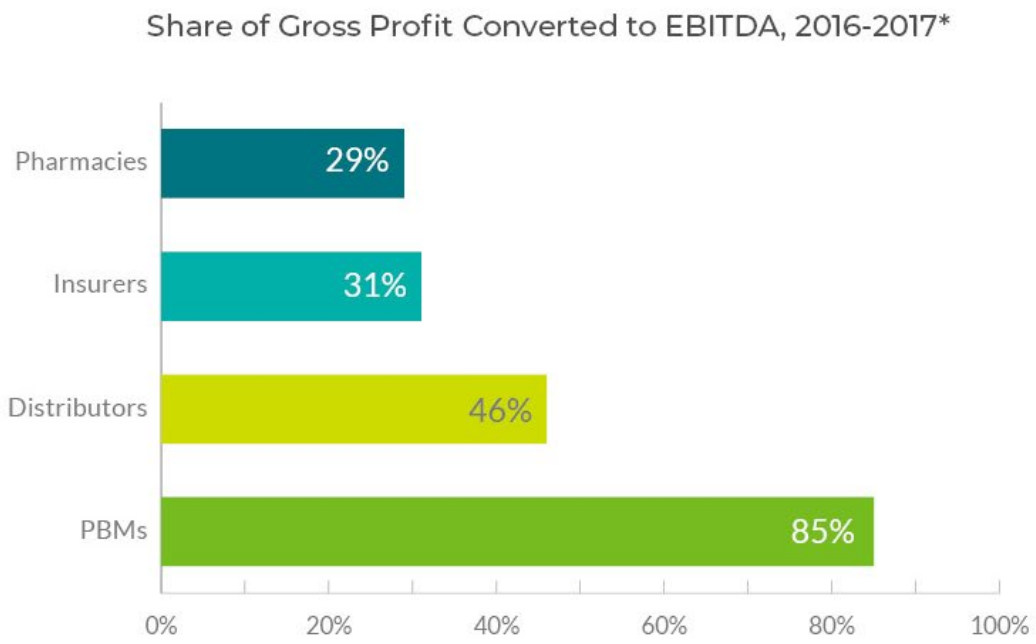
Rebates, discounts, fees and other price concessions have more than doubled since 2012



Source: Berkeley Research Group. Fein AJ; Drug Channels Institute

PBM Profit Margins Are Well Above Others in the Drug Distribution and Supply Chain

Pharmacy benefits managers (PBMs) do not take possession of the medicines they manage, keeping their spending on fixed assets and other expenses very low.



> Analysts at Bernstein tried to get a better picture of how profitable these companies are by excluding the cost of the drugs that are included in their revenue...By this analysis, pharmacy-benefit managers are exceptionally profitable."
>
> — Charley Grant, Wall Street Journal[22]

*Calculated as EBITDA (Earnings Before Interest, Taxes, Depreciation, and Amortization) margin divided by gross margin

Sources: Bernstein Research[21]; *Wall Street Journal*[22]

Fortune 500 Rankings - 2019

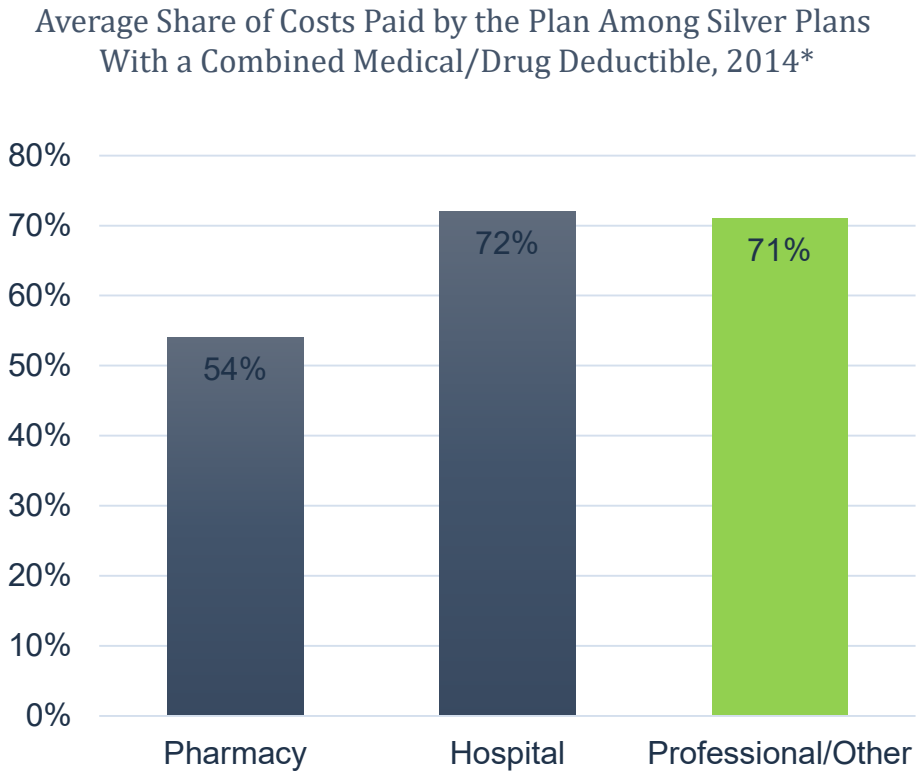
6	UnitedHealth Group	$226,247.0	12.5%	$11,986.0	13.5%	$152,221.0	$237,255.5
8	CVS Health	$194,579.0	5.3%	$-594.0	-109.0%	$196,456.0	$69,951.6
17	Walgreens Boots Alliance	$131,537.0	11.3%	$5,024.0	23.2%	$68,124.0	$59,691.7
33	Anthem	$92,105.0	2.3%	$3,750.0	-2.4%	$71,571.0	$73,826.6
37	Johnson & Johnson	$81,581.0	6.7%	$15,297.0	1076.7%	$152,954.0	$372,228.9
61	Pfizer	$53,647.0	2.1%	$11,153.0	-47.7%	$159,422.0	$235,785.1

Source: Fortune 500 2019

Access & Affordability

Subjecting Prescription Drugs to a Combined Deductible Results in Disproportionately High Patient Cost Sharing

When drug coverage is subjected to a large combined (medical and drug) deductible, on average, patients pay a higher share of their drug costs compared with their other health care services costs.

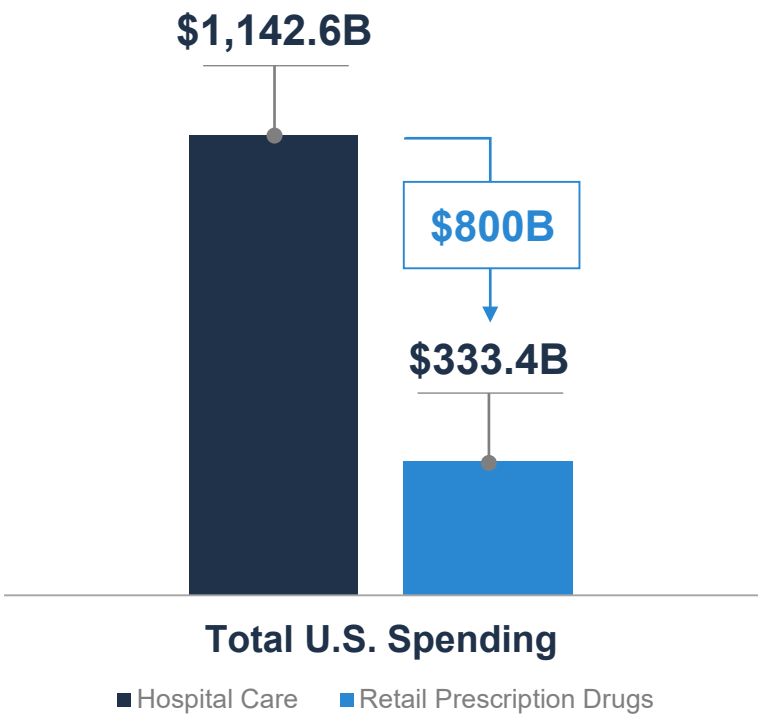


*Silver plans accounted for a majority of Health Insurance Exchange enrollment, and combined deductibles were the most common type of deductible arrangement among these plans. A deductible is the amount patients must pay annually with their own money (out of pocket) before a health plan will pay for any expenses. The figure shows the actuarial value for each service category listed (ie, the percentage of covered costs paid by the plan).

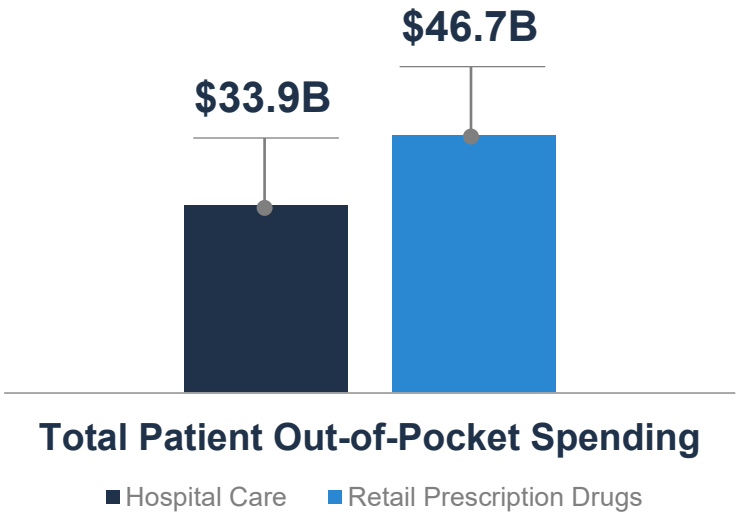
Source: Milliman, Inc.

Patients face higher out-of-pocket costs at the pharmacy counter even though total spending on hospital care is far higher.

Hospital spending is much higher than prescription drug spending.



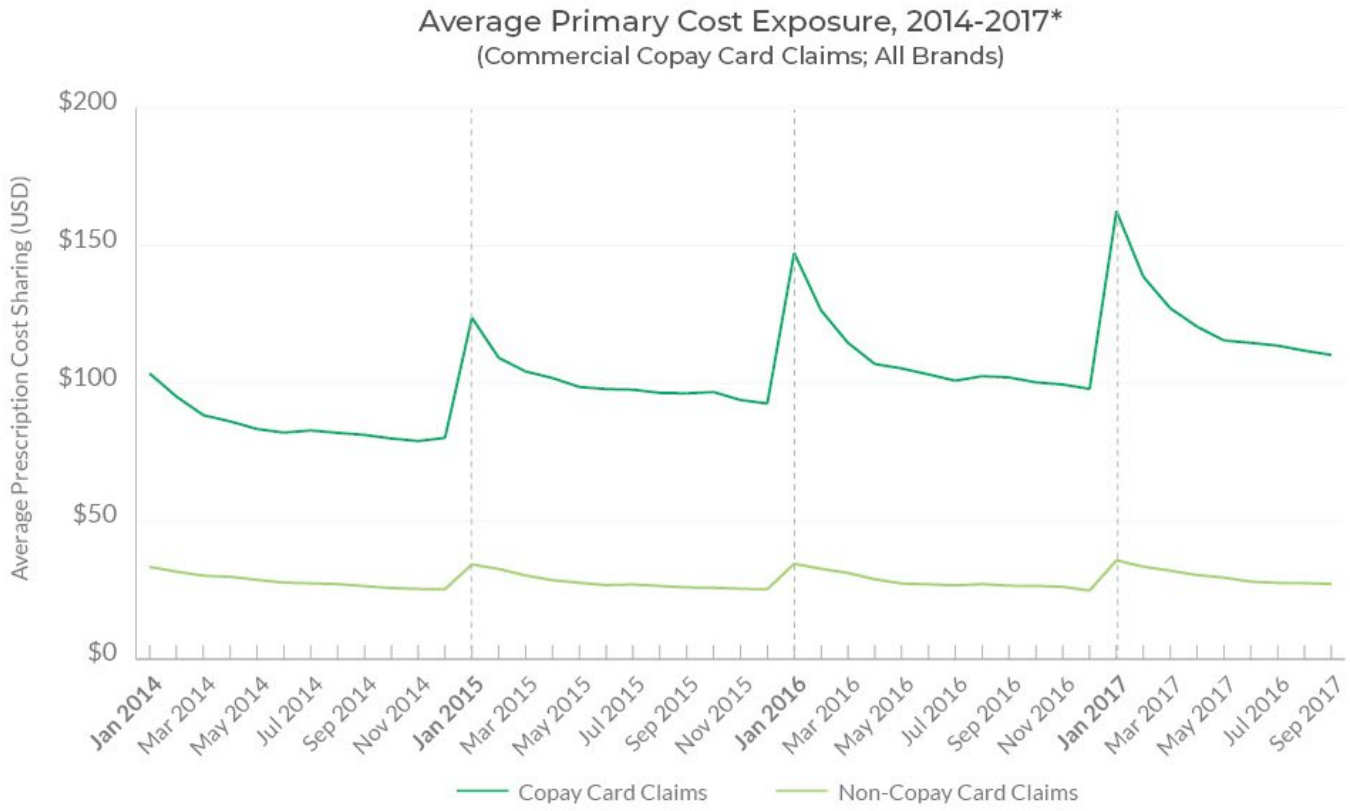
Yet patients pay more out-of-pocket for medicines than for hospital care.



Source: Drug Channels Institute analysis of National Health Expenditure Accounts, Office of the Actuary in the Centers for Medicare & Medicaid Services, December 2018. Outpatient prescription drug figures exclude inpatient prescription drug spending within hospitals and nearly all provider-administered outpatient drugs. Figures in billions.

Patients Who Use Coupons Face Higher Average Out-of-Pocket Costs Per Prescription

Each January, patients in the commercial market with deductibles face steep increases in out-of-pocket costs for brand drugs.



*Averages are calculated among paid claims where a copay card is used as the secondary payer and normalized to 30 days.

Source: IQVIA[14]

2020 NBPP on Coupon Use

- The U.S. Centers for Medicare & Medicaid Services (CMS) released the HHS Notice of Benefit and Payment Parameters for 2020 final rule (Payment Notice) on April 18, 2019. 84 Fed. Reg. 17454 (published Apr. 25, 2019). The Payment Notice finalized regulations, at 45 CFR § 156.130(h), that include provisions on drug manufacturer coupons.
- For plan years 2020 and beyond, insurers filing ACA-compliant major medical products for the individual, small group, and large group markets must apply the value of drug manufacturer coupons toward an enrollee's annual maximum out of pocket limit (MOOP) for brand medications where there is no medically appropriate generic equivalent available. An enrollee may use an exceptions or appeals process to receive a brand drug when the generic equivalent is not available or medically appropriate. Such insurers are not required to apply the value of drug manufacturer coupons toward an enrollee's MOOP in situations where a generic equivalent medication is available and medically appropriate.

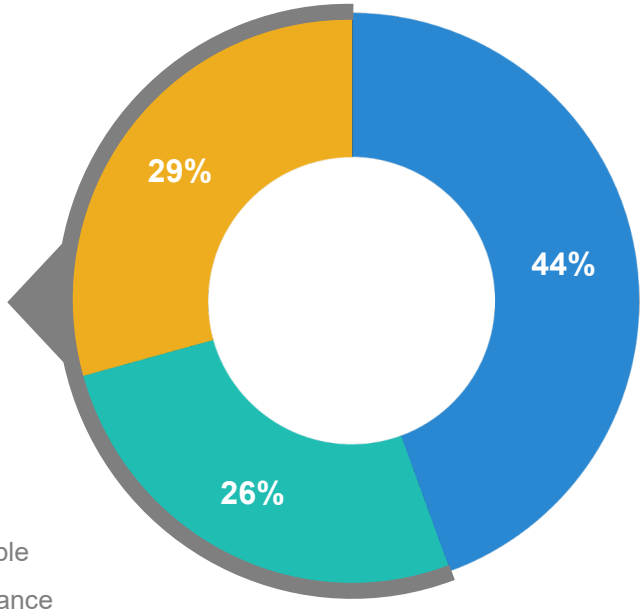
2020 NBPP on Coupon Use – cont'd

- CMS explains in a press release about the 2020 Payment Notice: "Drug companies can offer consumers coupons to incentivize them to purchase the company's brand name drugs even when an appropriate, less-expensive generic medication is available. This rule allows issuers to stop applying the value of these coupons towards an enrollee's maximum-out-of-pocket costs in situations where a generic medication is available and medically appropriate, in order to encourage generic use and result in lower drug spending."
- Additionally, three states – VA, WV, and AZ – have enacted legislation banning accumulator adjustment programs in full or in situations similar to those in the Payment Notice. A fourth state – IL – has passed legislation and is awaiting the Governor's signature.

Too often negotiated savings do not make their way to patients.

More than half of commercially insured patients' out-of-pocket spending for brand medicines is based on the full list price

55%



Cost sharing for nearly 1 in 5 brand prescriptions is based on list price

Source: IQVIA. May 2018.

Sharing negotiated discounts with patients would increase premiums about 1%.

Certain commercially insured patients could save $145 to more than $800 annually.

Change in Plan Costs with Shared Rebates

	PLAN TYPE		
	Traditional PPO	Copay HDHP*	Coinsurance HDHP
Net Plan Per Member Per Month Spend	$433.91	$374.41	$372.89
Change in Plan Costs $	$0.82	$2.62	$3.84
Change in Plan Costs %	0.2%	0.7%	1.0%

NOTE: Plan cost includes medical and pharmacy claims
*HDHP = High-deductible health plan

Collectively, these market-based reforms can make medicines more affordable and accessible.

MODERNIZE THE DRUG DISCOVERY AND DEVELOPMENT PROCESS

- Modernize the FDA to keep pace with scientific discovery and increase efficiency of generic approvals
- Promote and incentivize generic competition.

PROMOTE VALUE-DRIVEN HEALTH CARE

- Remove barriers restricting information companies can share with insurers.
- Reform regulations discouraging companies from offering discounts tied to outcomes.
- Modify Medicaid best price requirements.

EMPOWER CONSUMERS AND LOWER OUT-OF-POCKET COSTS

- Provide patients with access to negotiated rebates.
- Address affordability challenges in the deductible.
- Make more information on health care out-of-pocket costs and quality available to patients.

ADDRESS MARKET DISTORTIONS

- Address burdensome regulations that distort programs like the 340B Drug Pricing program.

IMPROVE TRADE AGREEMENTS

- Enforce existing trade agreements.
- Ensure new trade agreements recognize value of innovative medicines.

Key Takeaways

- After accounting for discounts and rebates, brand medicine **average net price increased just 1.9%** in 2017.

- In 2016, biopharmaceutical companies paid out **$127 billion in rebates and discounts to government and private payers**, but these rebates and discounts were typically not shared with patients at the pharmacy counter.

- **90% of all prescriptions filled in 2016 were generics**, up from 80% in 2011. Projections are that $140 billion of U.S brand sales will face competition from generics of biosimilars between 2017 and 2021. **There is no similar type of cost containment for other health care services.**

Thank You!

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