STATE OF WISCONSIN

GOVERNOR'S TASK FORCE ON REDUCING PRESCRIPTION DRUG PRICES

Value of Medicines
July 21, 2020

PhRMA
RESEARCH • PROGRESS • HOPE

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About 4,500 Medicines in Development in the U.S.

Biopharmaceutical researchers are working on new medicines* for many diseases, including:

CANCERS
1,120

HEART DISEASE &STROKE
200

HIV
52

ASTHMA &ALLERGY
130

SKIN DISEASES
328

MENTAL DISORDERS
140

RARE DISEASES
566

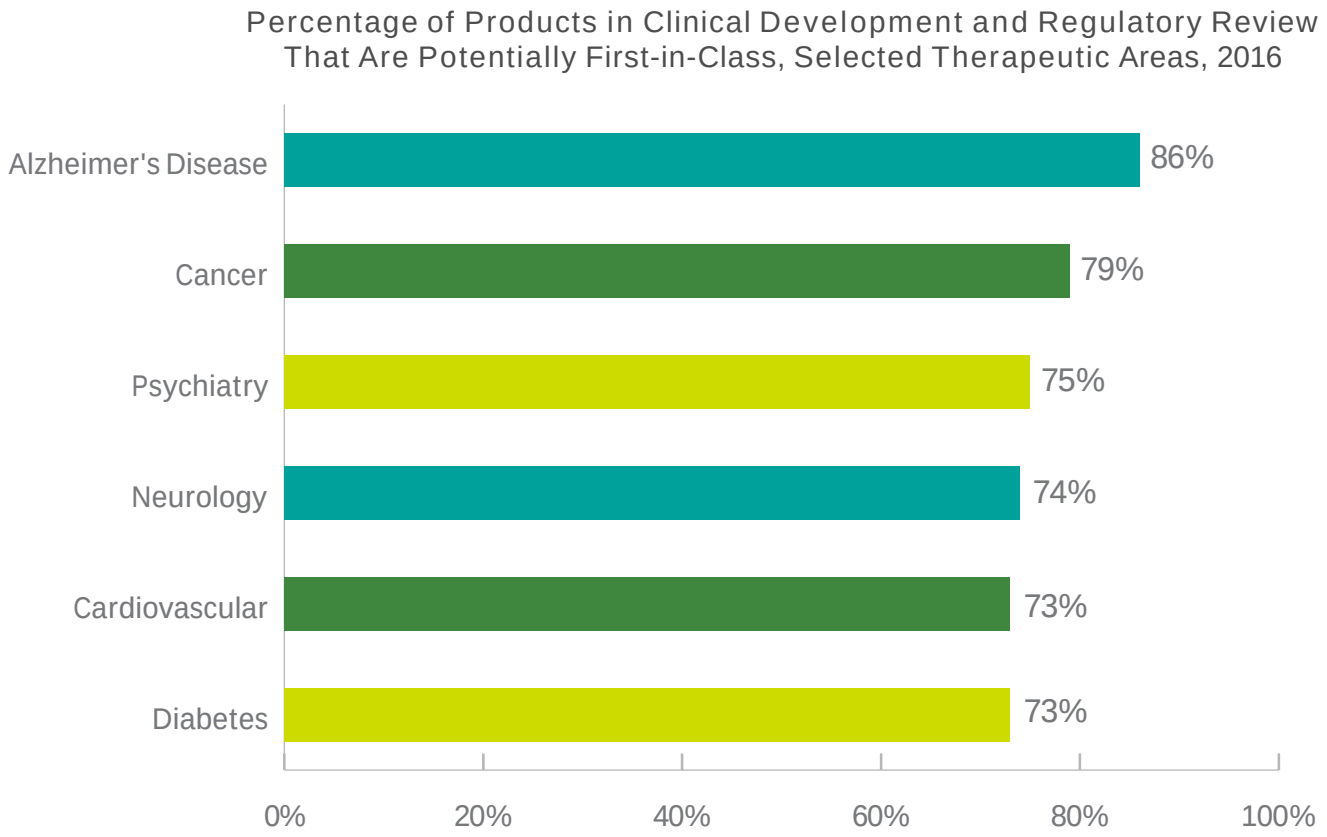
NEUROLOGICAL DISORDERS
537

*Defined as single products that are counted only once regardless of the number of indications pursued

Source: Adis R&D Insight Database[2]

Potential First-in-Class Medicines in the Pipeline

An average of 74% of drugs in the clinical pipeline are potential first-in-class medicines.



Source: Analysis Group[3]

Biopharmaceutical Companies Are Committed to Advancing Personalized Medicine

In recent years, we have seen remarkable advances in targeted therapy, and the R&D pipeline has never been more promising.

MORE THAN **42%**[10] of new medicines approved by the FDA in 2018 were

42%[11] of new medicines IN THE PIPELINE have the potential to be

PERSONALIZED MEDICINES

Sources: Personalized Medicine Coalition[10]; Tufts CSDD[11]

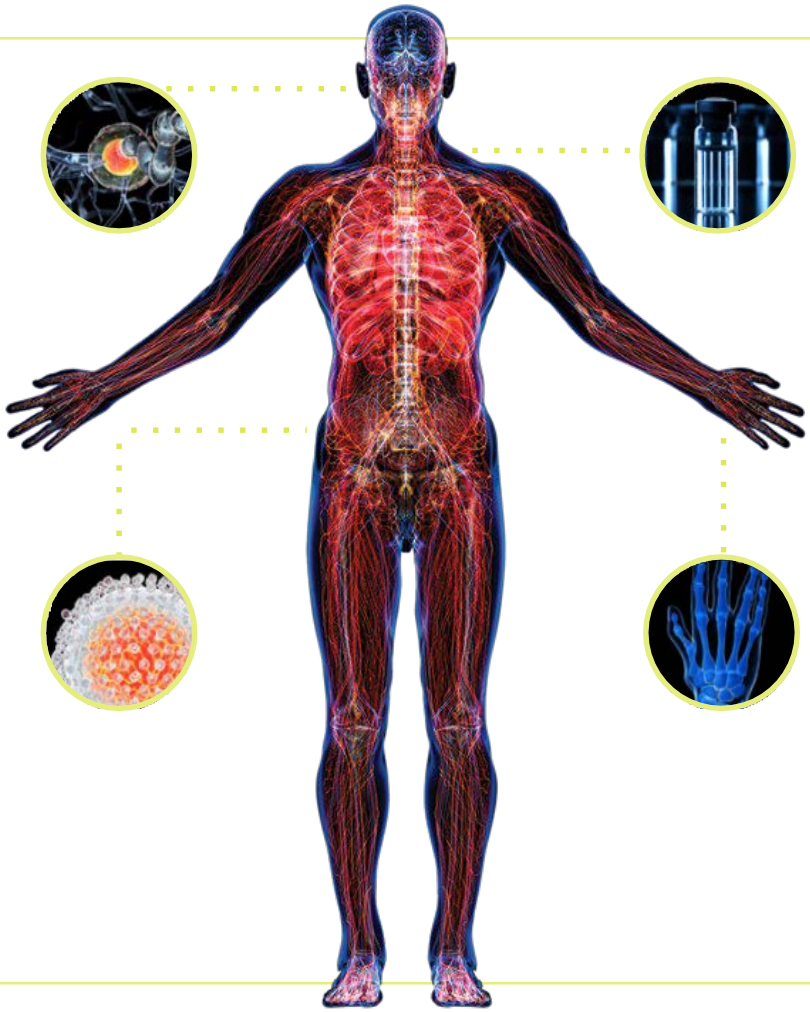
Medicines Are Transforming the Treatment of Many Diseases

Multiple Sclerosis (MS)

Advances in recent years, including convenient oral medicines and the first-ever treatment for progressive MS, offer patients greater opportunity to better manage MS and slow disease progression.[4]

Hepatitis C

Recent therapeutic advances can cure the disease and help patients avoid serious disease complications—including cirrhosis, advanced liver disease, liver cancer, and death.[5]



Cancer

New therapies have contributed to a 26% decline in cancer death rates since the 1990s.[6] The chance a cancer patient will live 5 years or more has increased 41% across all cancers since 1975.[7]

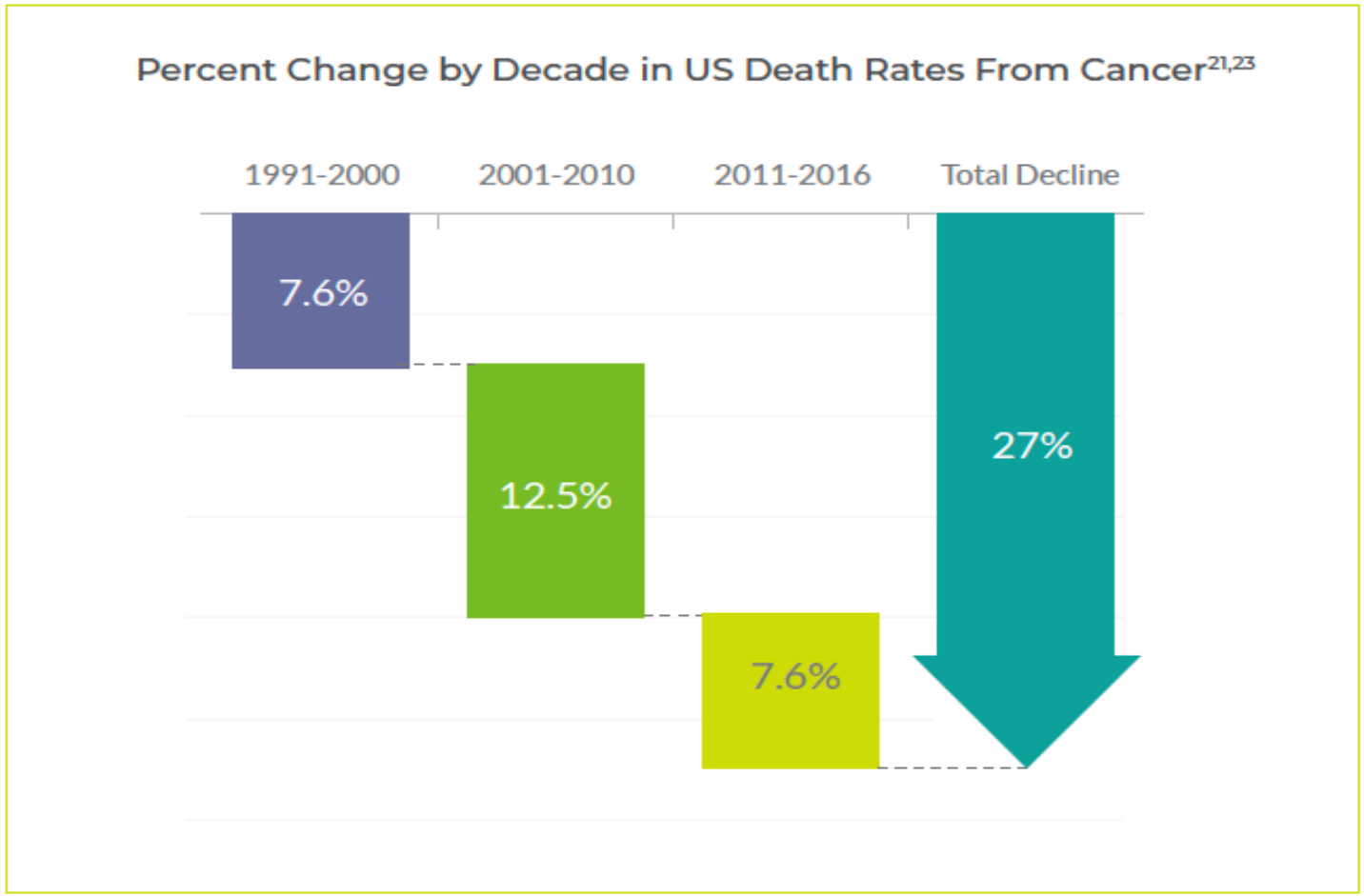
Rheumatoid Arthritis (RA)

Therapeutic advances have transformed the RA treatment paradigm, shifting from a focus on managing symptoms to aiming for slowed disease progression and even disease remission.[8]

Sources: PhRMA[4,5]; Siegel RL et al.[6]; ACS[7]; Boston Healthcare Associates[8]

Cancers: Decline in Death Rates

Since peaking in the 1990s, cancer death rates have declined 27%.[21] Approximately 73% of survival gains in cancer are attributable to new treatments, including medicines.[22]

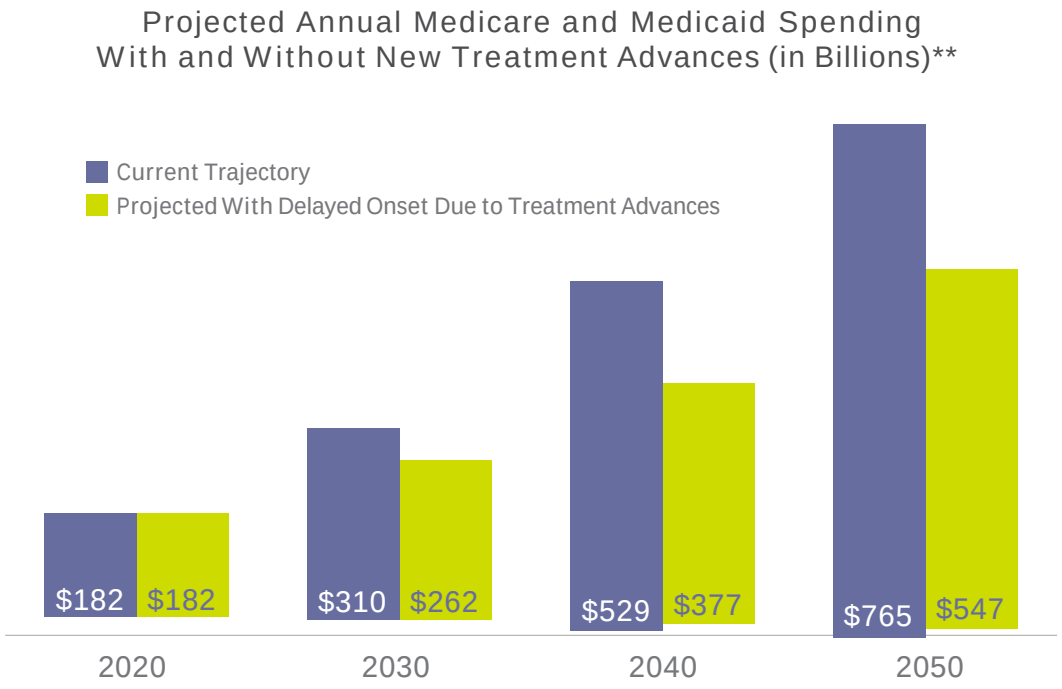


> I think some of the treatments that we have developed over the last half century or so are really starting to pay off and, honestly, [it] seems limitless as to what may pay off in the future."
>
> — William Nelson, MD, PhD, Director, Sidney Kimmel Comprehensive Cancer Center[24]

Sources: Siegel RL et al.[21]; Seabury SA et al.[22]; NCI[23]; Dunellari A[24]

Unmet Need: Future Impact of New Treatments for Alzheimer's Disease

The development of a new treatment that delays the onset of Alzheimer's disease could reduce Medicare and Medicaid spending on patients by $218 billion annually by 2050.*

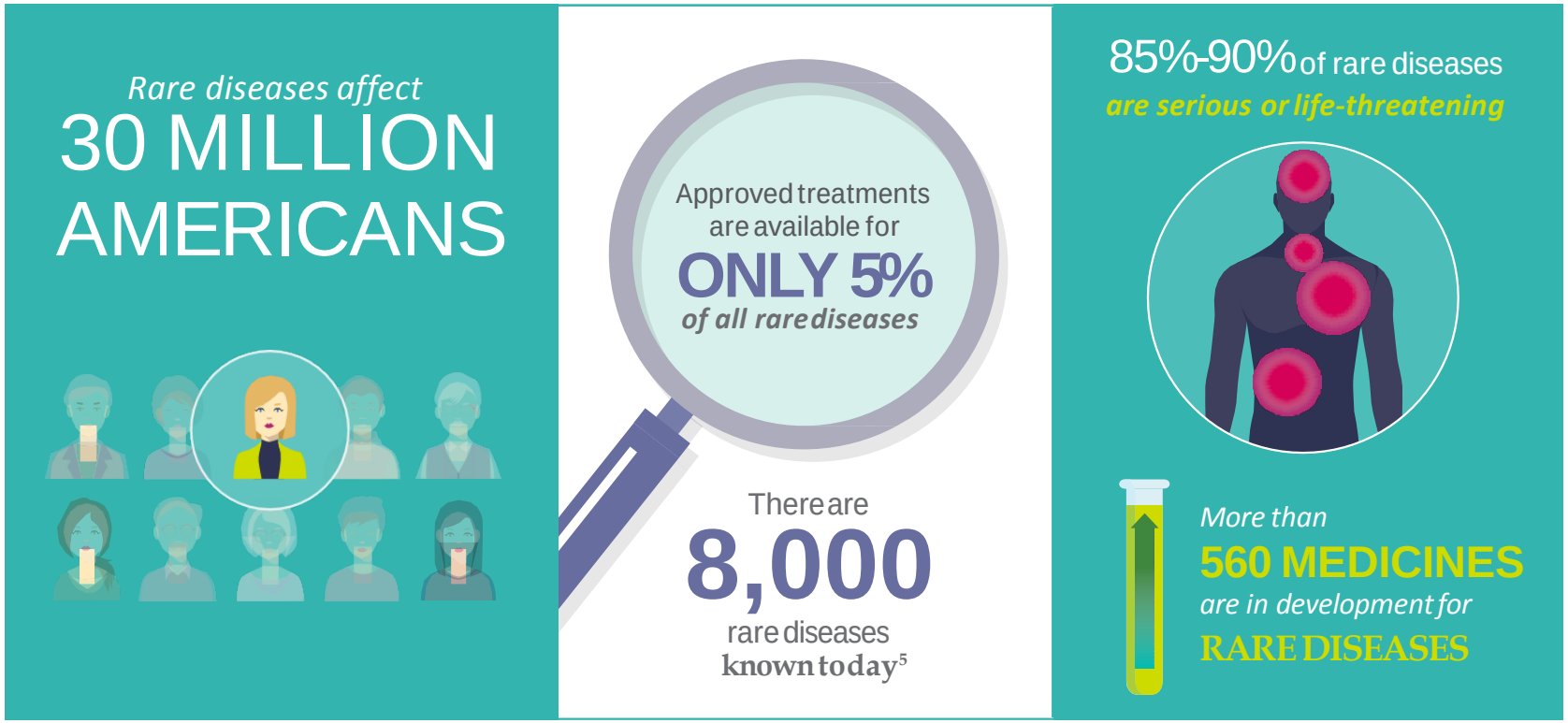


*Assumes research advances that delay the average age of onset of Alzheimer's disease by 5 years beginning in 2025.
**Projected savings to Medicare and Medicaid assume research breakthroughs that slow the progression of Alzheimer's disease. This would dramatically reduce spending for comorbid conditions and expensive nursing home care.

Source: Alzheimer'sAssociation[39]

Harnessing Innovation in Rare Diseases

Since the passage of the Orphan Drug Act in 1983, we have seen tremendous advances in treatments for rare diseases,* with more than 770 orphan drug approvals (compared with fewer than 10 in the decade before passage).[4]



*Rare diseases are defined as conditions for which there are fewer than 200,000 patients diagnosed in the United States.

Sources: FDA[4]; Danese E et al.[5]; PhRMA[6]

Medicines Are Transforming Treatment of Many Rare Diseases

Collectively, rare diseases affect 30 million Americans. Treatments are available for only 5% of rare diseases, but recent advances are providing important new options to many patients for the first time.[9]

Fabry Disease[10]

Fabry disease is a genetic disorder that can cause fat buildup in blood vessels, nerves, and other organs and slowly progress to kidney disease, abnormal heart rhythm, stroke, and early death. The first treatment for adults was approved in 2018 and works by increasing the activity of a deficient enzyme.

Primary Hemophagocytic Lymphohistiocytosis (HLH)[11]

Primary HLH is an inherited and life-threatening immune disorder typically affecting children. The disorder causes damage to various organs, including the liver, brain, and bone marrow. The first treatment specifically for HLH was approved in 2018 for adults and children.

Hereditary Transthyretin-Mediated Amyloidosis (hATTR)[12]

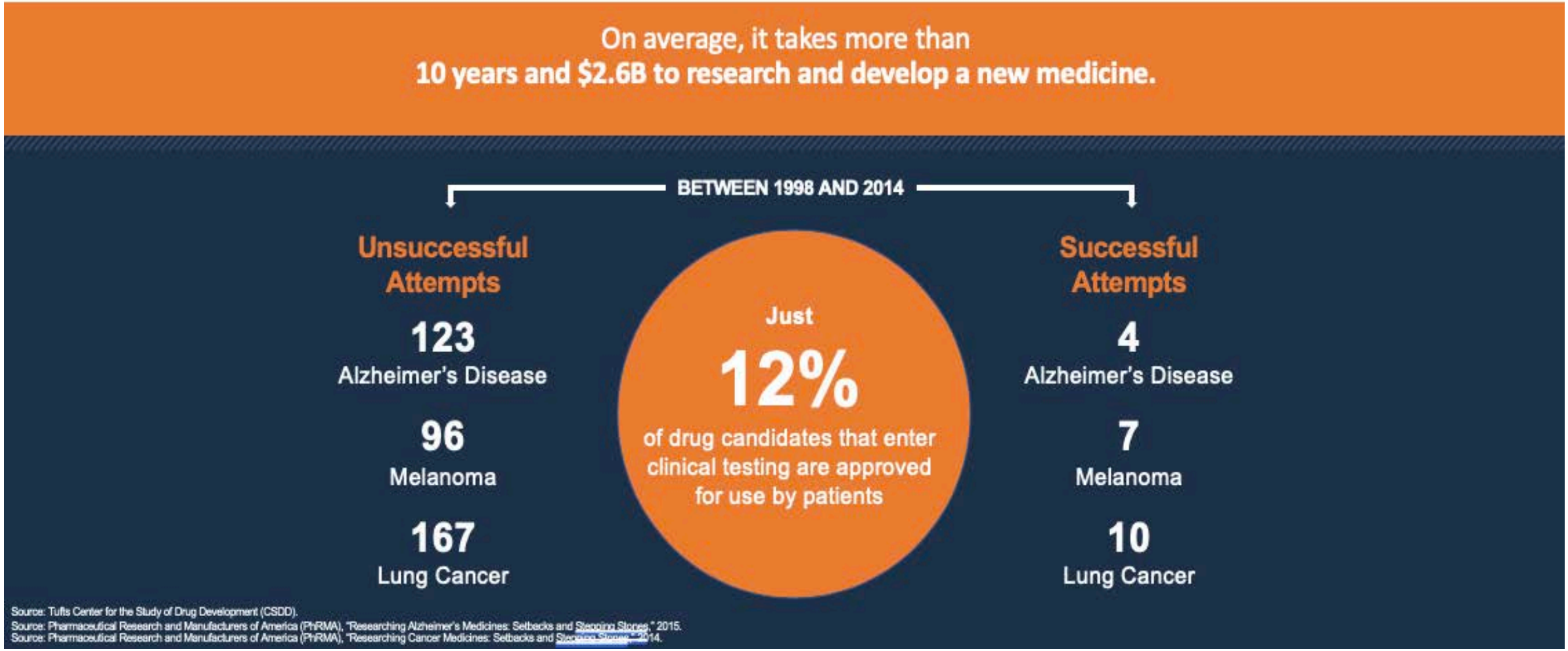
hATTR interferes with the normal functioning of nerves, heart, and other organs and can lead to loss of sensation, pain, or immobility in the limbs. The first treatment for this often fatal genetic disease was approved in 2018 and targets the root cause by interfering with abnormal RNA protein production.

Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)[13]

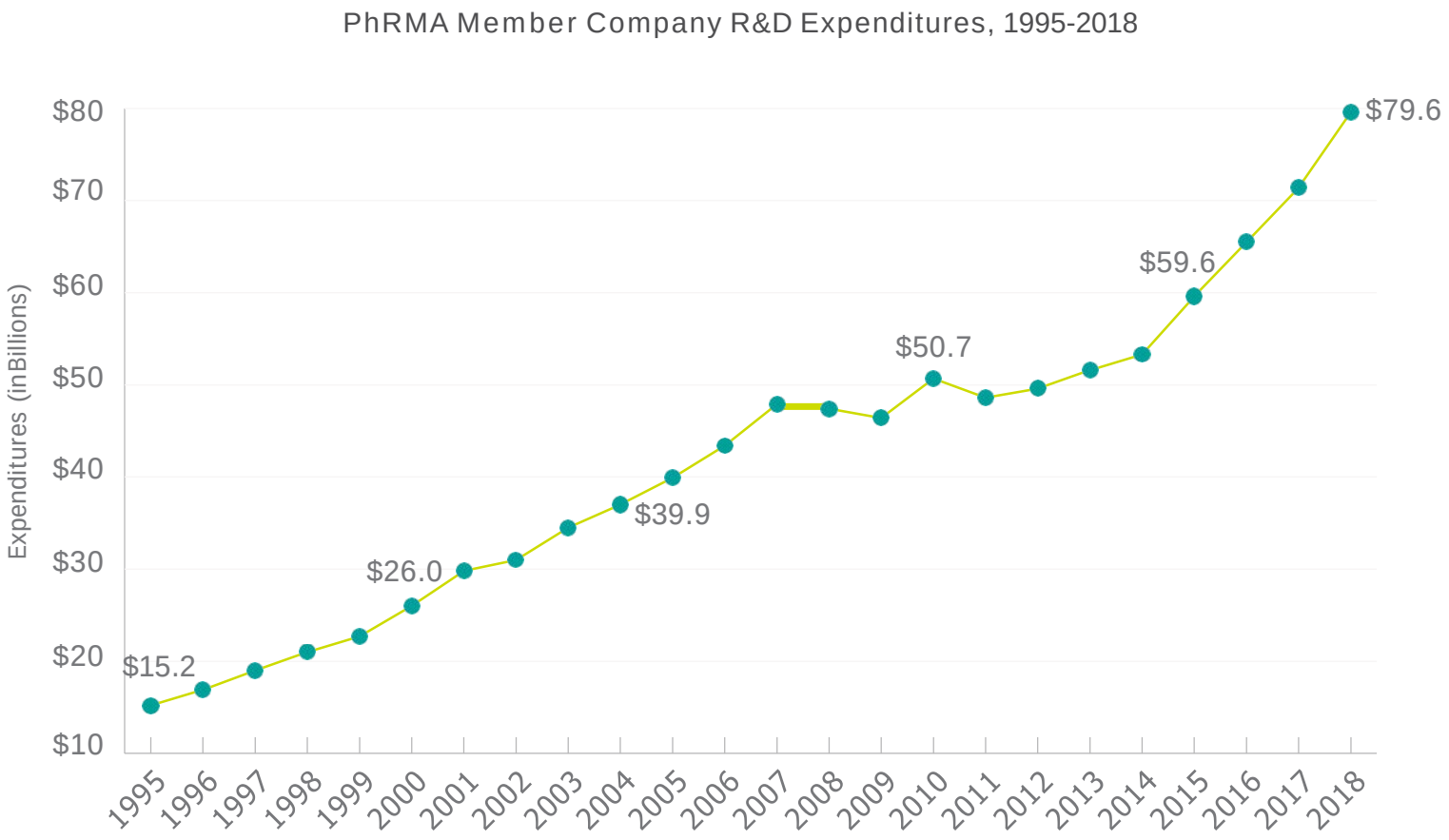
BPDCN is an aggressive blood cancer affecting multiple organs, including the lymph nodes and skin. The first treatment specifically for BPDCN was approved in 2018 for adults and children. Prior to this treatment, intensive chemotherapy and bone marrow transplant had been the standard of care.

Sources: Global Genes[9]; FDA[10-13]

R&D is risky and expensive



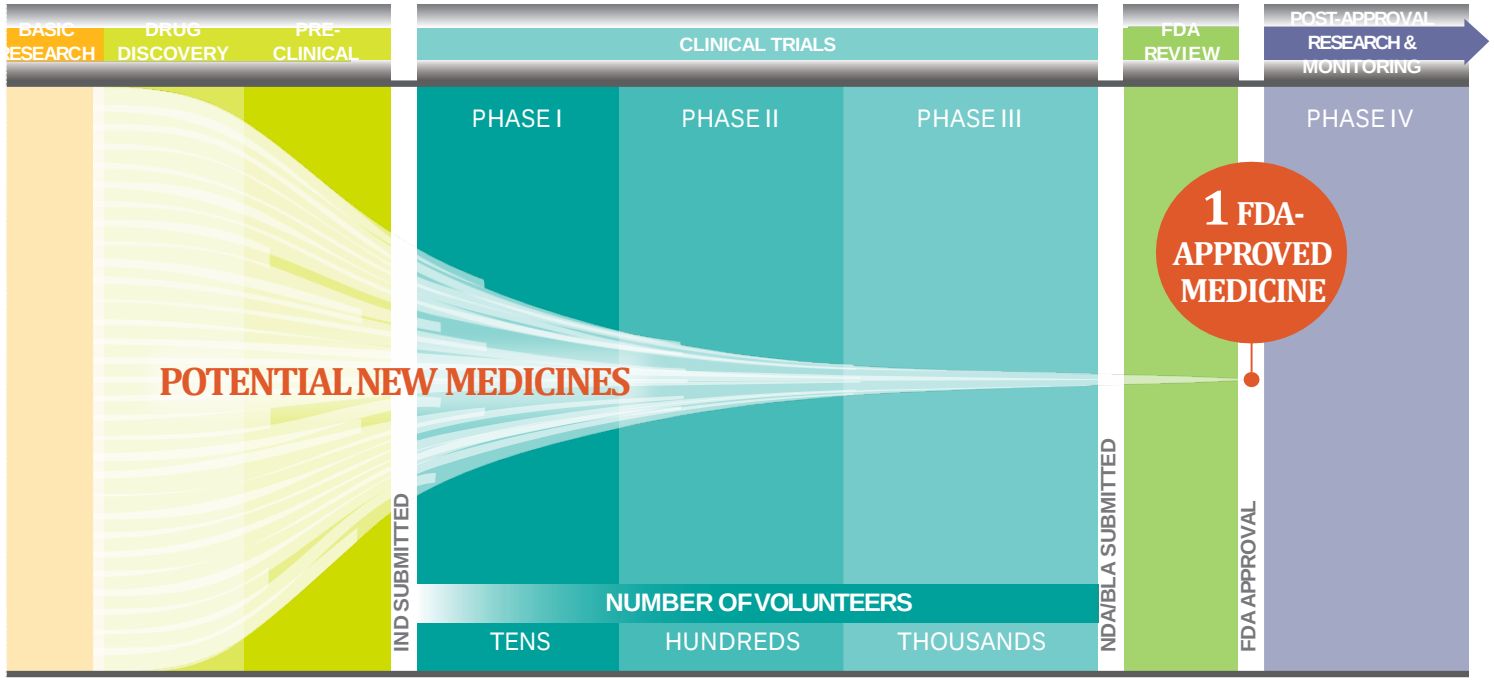
PhRMA Member Company R&D Investment



Source: PhRMA[26]

The R&D Process for New Drugs Is Lengthy and Costly, With High Risk of Failure

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 research & development (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.

Sources: PhRMA adaptation of DiMasi JA et al.; Tufts CSDD[7]; FDA[8]

Wisconsin Clinical Trials

409 Clinical Trials

6,811 Participants

$90.2 Million invested

$237.4 Million in economic impact to WI

Illustrative Pharmaceutical Lifecycle

New pharmaceutical medicines typically face competition after a relatively short time on the market, first from brand competitors, and eventually from generics.

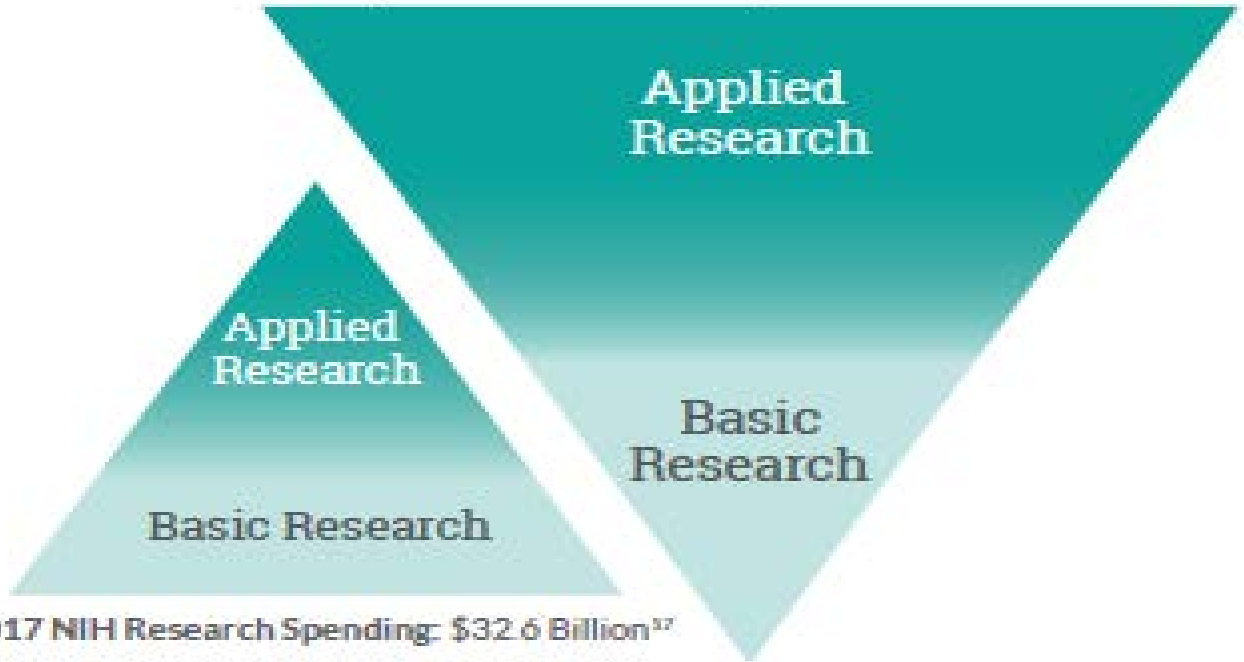
*Brand drug market share generally declines rapidly after generic entry.
**For brand medicines with more than $250 million in annual sales in 2008 dollars, which account for 92% of sales of the brand medicines analyzed

Sources: PhRMA[1]; DiMasi JA et al.[2,3]; Grabowski H et al.[4]

Biopharmaceutical Industry Does the Majority of Research to Translate Basic Science Into New Medicines

While basic science is often initiated in government and academia, it is biopharmaceutical firms that provide the necessary expertise and experience needed to develop new medicines.[16]

2017 Biopharmaceutical Industry R&D Investment: $97 Billion[17]



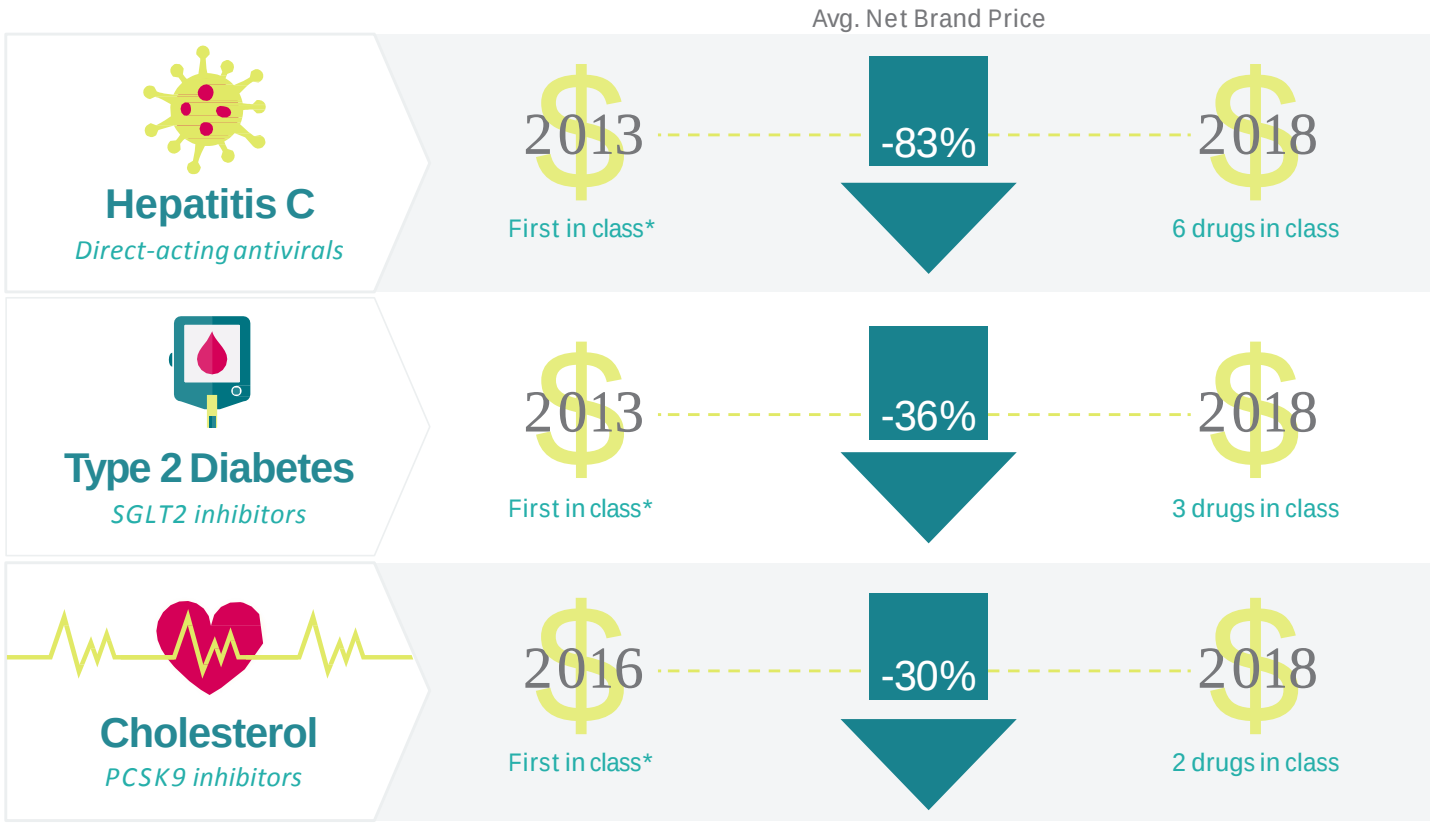
2017 NIH Research Spending: $32.6 Billion[17]

In addition to basic research and biopharmaceutical-related research, NIH supports applied research on medical devices, diagnostics, prevention, and other areas.[18]

Sources: Chakravarthy R et al.[16]; ResearchAmerica[17]; NIH[18]

Brand-to-Brand Competition Drives Savings in U.S. Market-Based System

Payers leverage purchasing power and competition among brand medicines to negotiate substantial discounts on medicines.



*Indicates launch year of the first drug in this pharmacologic class.

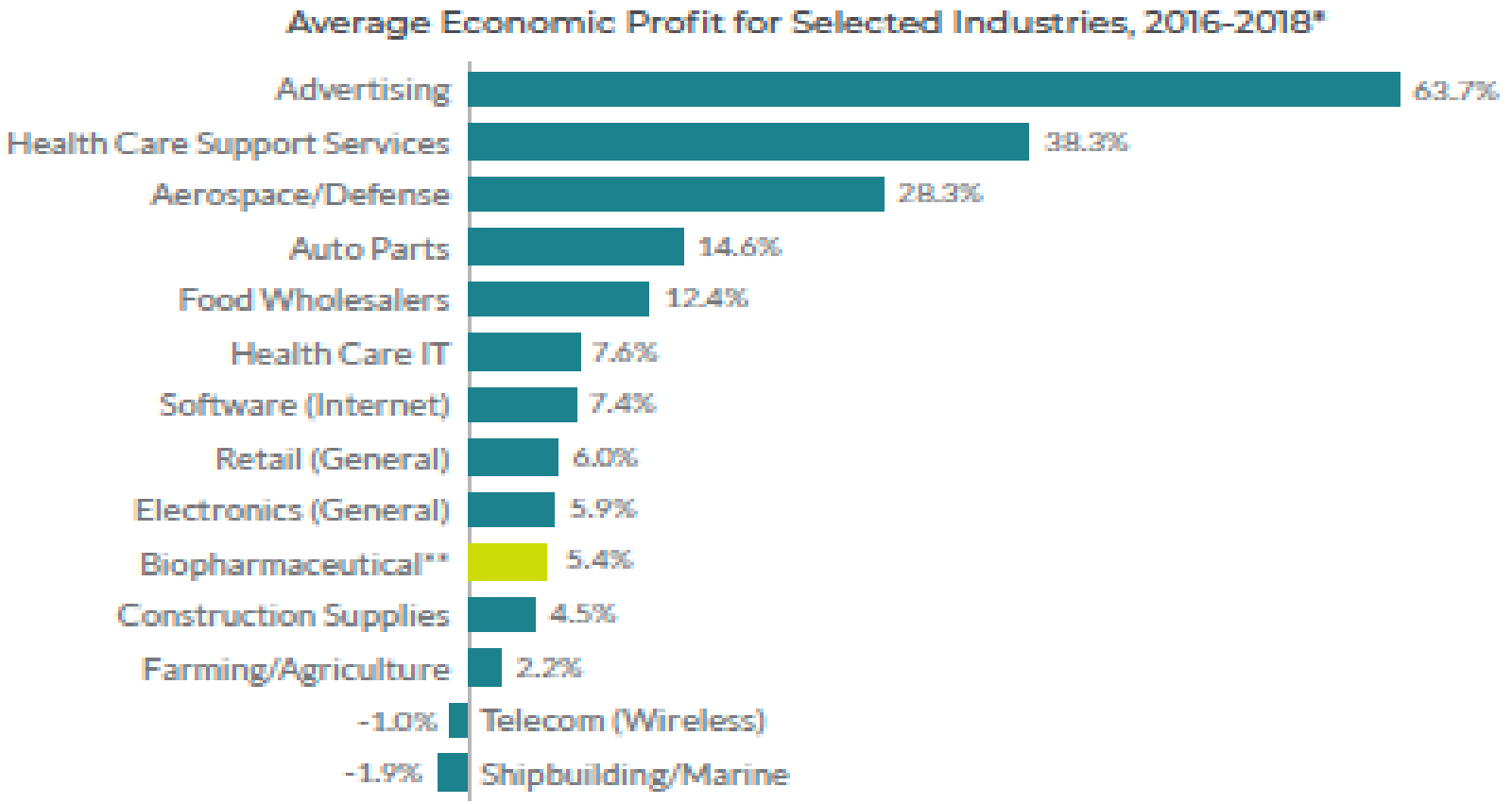
Source: PhRMA analysis of SSR health data[16]

Patent Cliff: Competition from generics and biosimilars is expected to reduce U.S. brand sales by $95 billion from 2019 to 2023…

Source: IQVIA January 2019

Biopharmaceutical Profits Are in Line With Those of Other Industries

Adjusted for the significant risk and capital investments required to develop medicines, biopharmaceutical industry profits are average among industries.



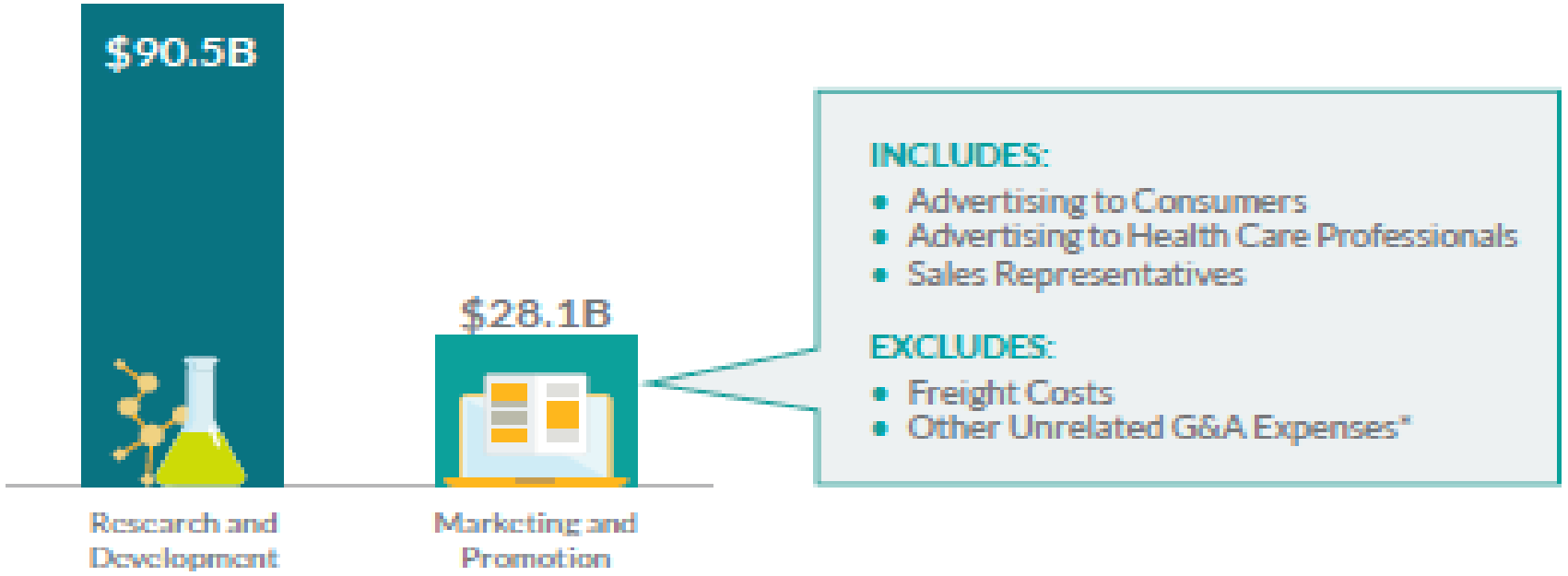
*Economic profits are accounting profits minus capital expenses.
**Represents the weighted average of pharmaceuticals (8.2%) and biotechnology (2.2%), which are listed as separate industries in the source data.

Source: Adapted from Bates White**

Biopharmaceutical Company Marketing and Promotion Spending in Context

Use of inflated estimates of marketing and promotion spending has created the false impression that the biopharmaceutical industry spends more on marketing than on R&D. More precise estimates show the opposite to be true.

Select US Biopharmaceutical Industry Expenses, 2016



*Indicates general and administrative (G&A) expenses unrelated to marketing and promotion, such as finance and office staffs, rent, utilities, and supplies. Some have inaccurately used sales and G&A expenses as a proxy for industry marketing and promotion expenses.

Sources: Schwartz L et al.[31]; Research!America[32]

Cycle of Reinvestment: Biopharmaceutical Companies use today's revenues, to invest in tomorrow's treatments and cures.

Invested about

$90 Billion

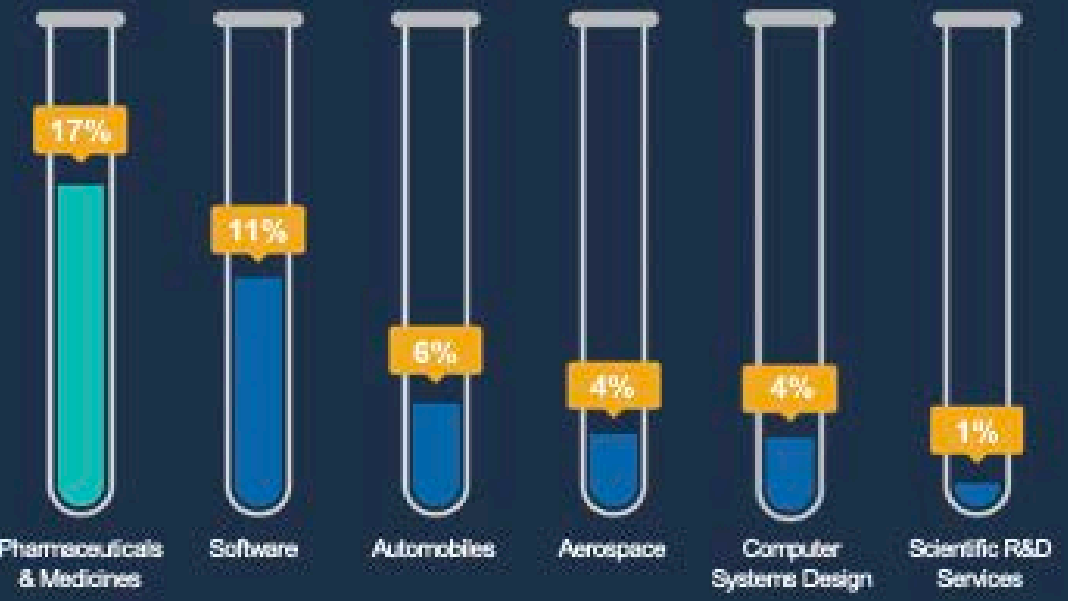
in R&D in 2016

And

20%

of revenues are reinvested into R&D

Industry invests 17% of all domestic research and development funded by U.S. businesses

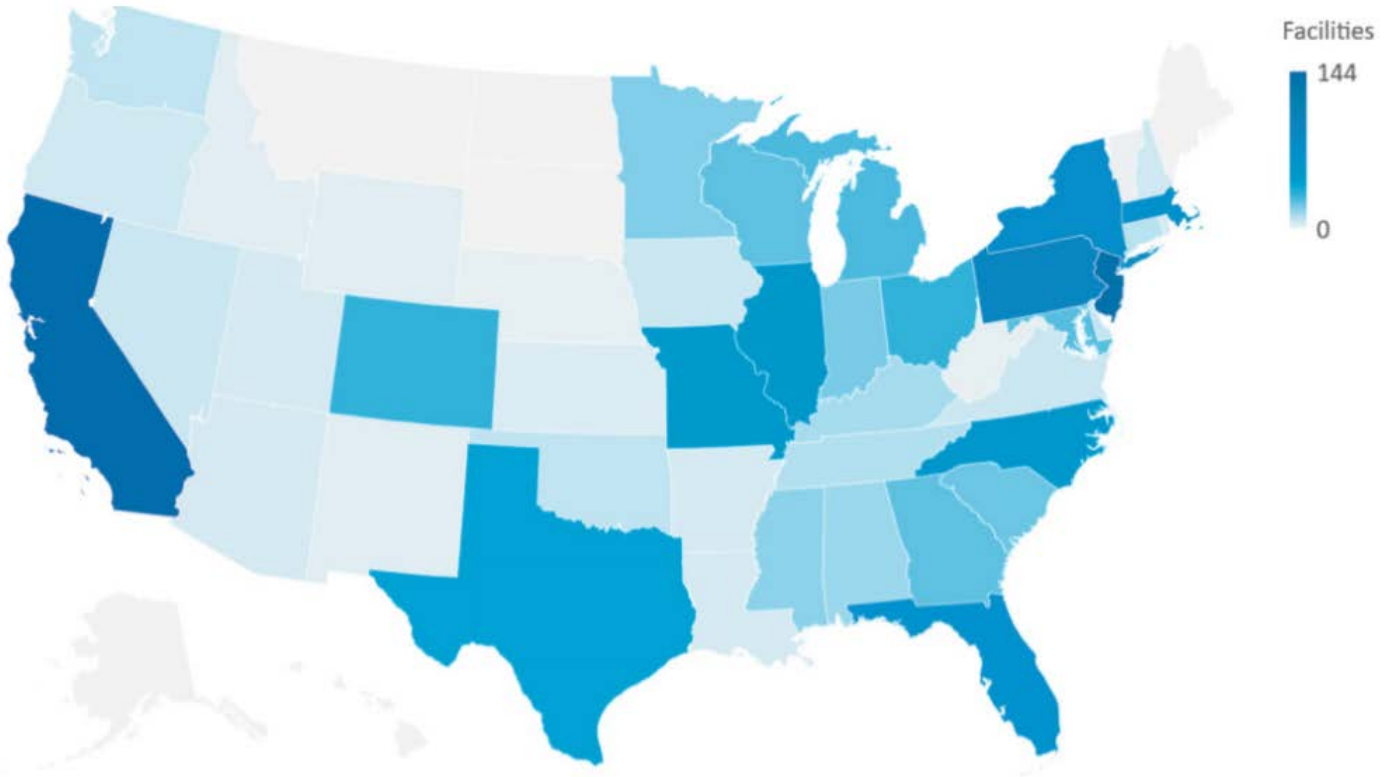


NOTE: The remaining 57% share of business R&D spending is conducted by other industries, including subsectors of the machinery sector, the computer and electronics products sector, and the electrical equipment, appliance, and components sector.
Source: Research! America report and PhRMA analysis of National Science Foundation data.

Our Diverse Manufacturing Supply Chain Includes a Significant Presence in the United States

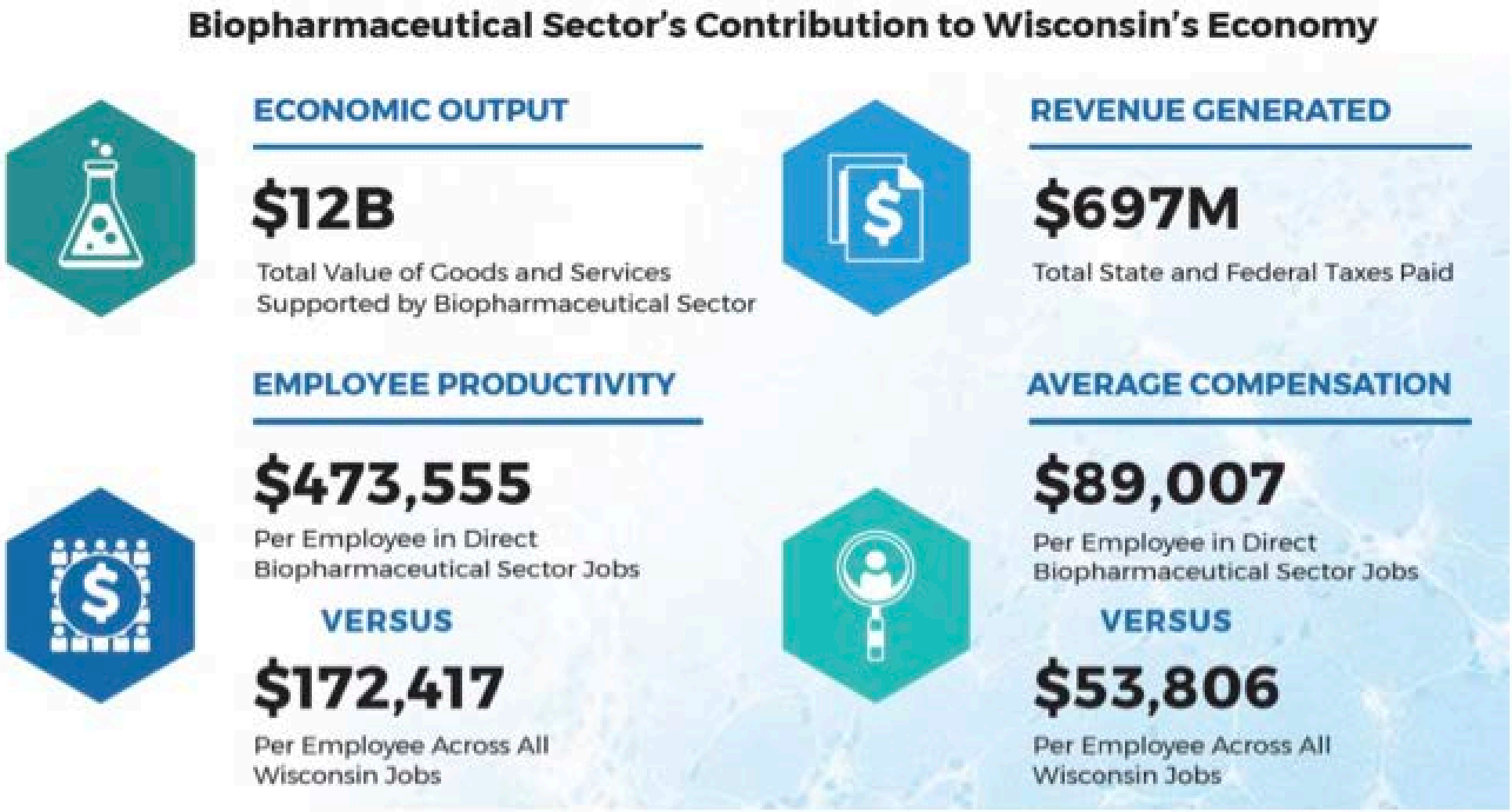
The biopharmaceutical industry:

- Has more than 1,300 U.S. facilities involved in the production of human-use medicines located in 45 U.S. states and Puerto Rico compared to fewer than 150 generic manufacturing facilities
- Directly employs nearly 120,000 employees specifically at manufacturing facilities and 811,000 Americans in total
- Supports more than 4 million U.S. jobs across the economy



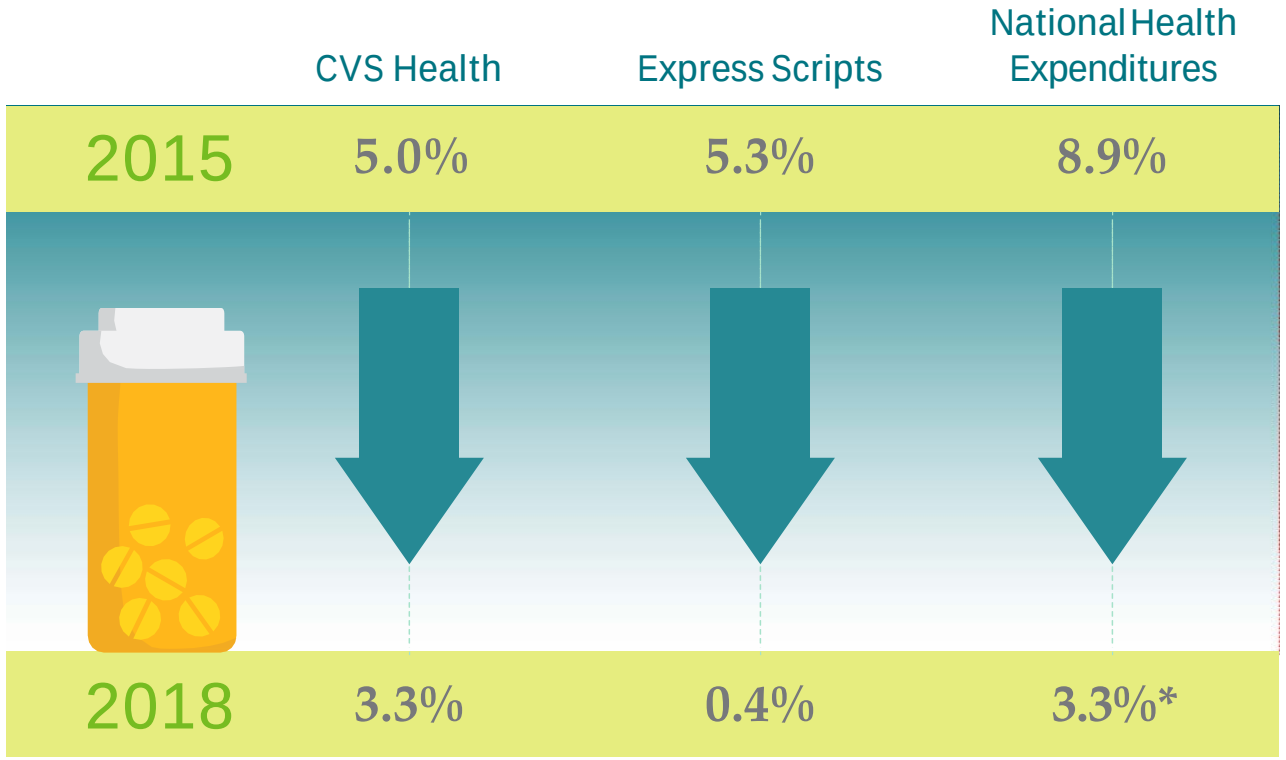
Source: NDP Analytics; for PhRMA. Analysis of the U.S. Food and Drug Administration's Drug Establishments Current Registration Site. April 2018

Economic Impact of Pharmaceutical Industry in WI



Pharmacy Benefit Managers (PBMs) and Government Actuaries Report Slowing Growth in Medicine Spending

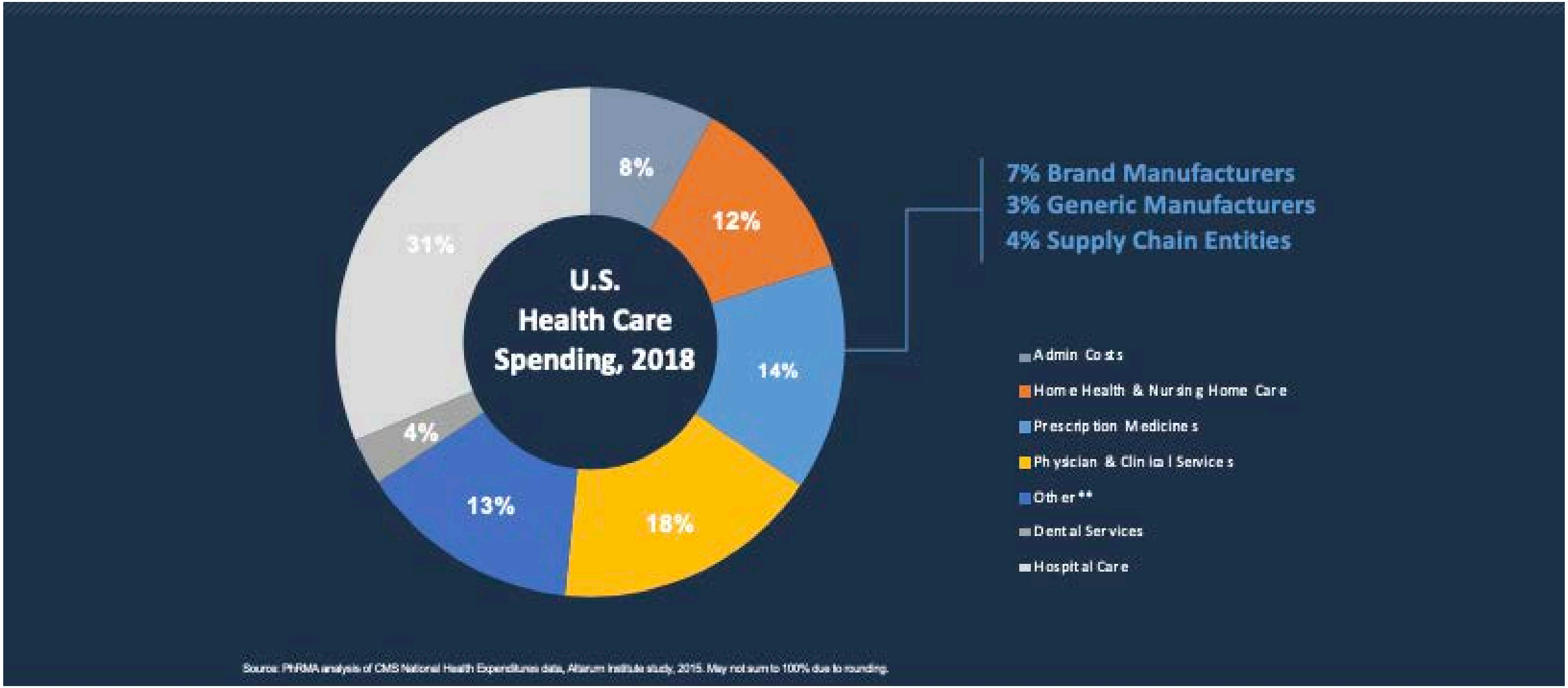
Annual Growth in Net Retail Prescription Medicine Spending



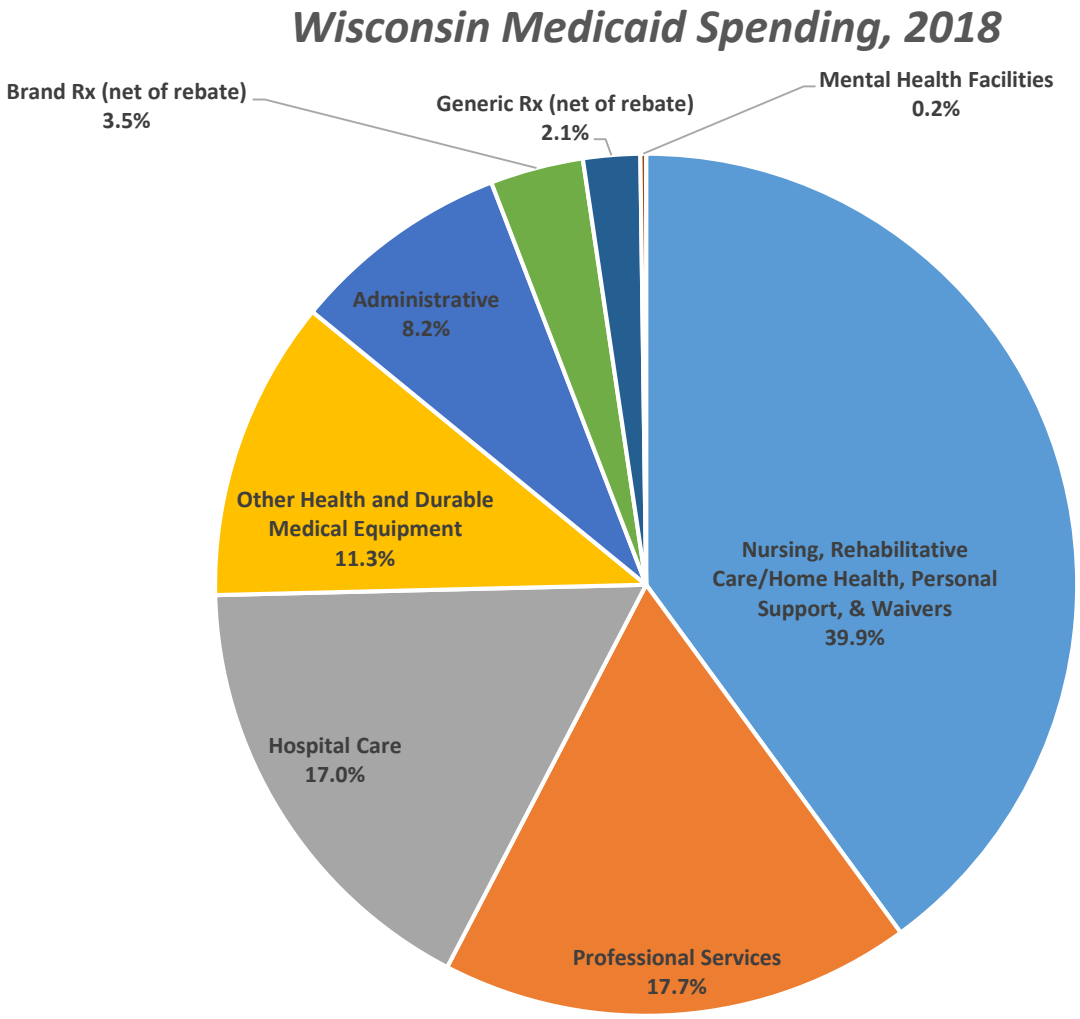
*Projected

Sources: CVS Health[16,17]; Express Scripts[18,19]; CMS[20,21]

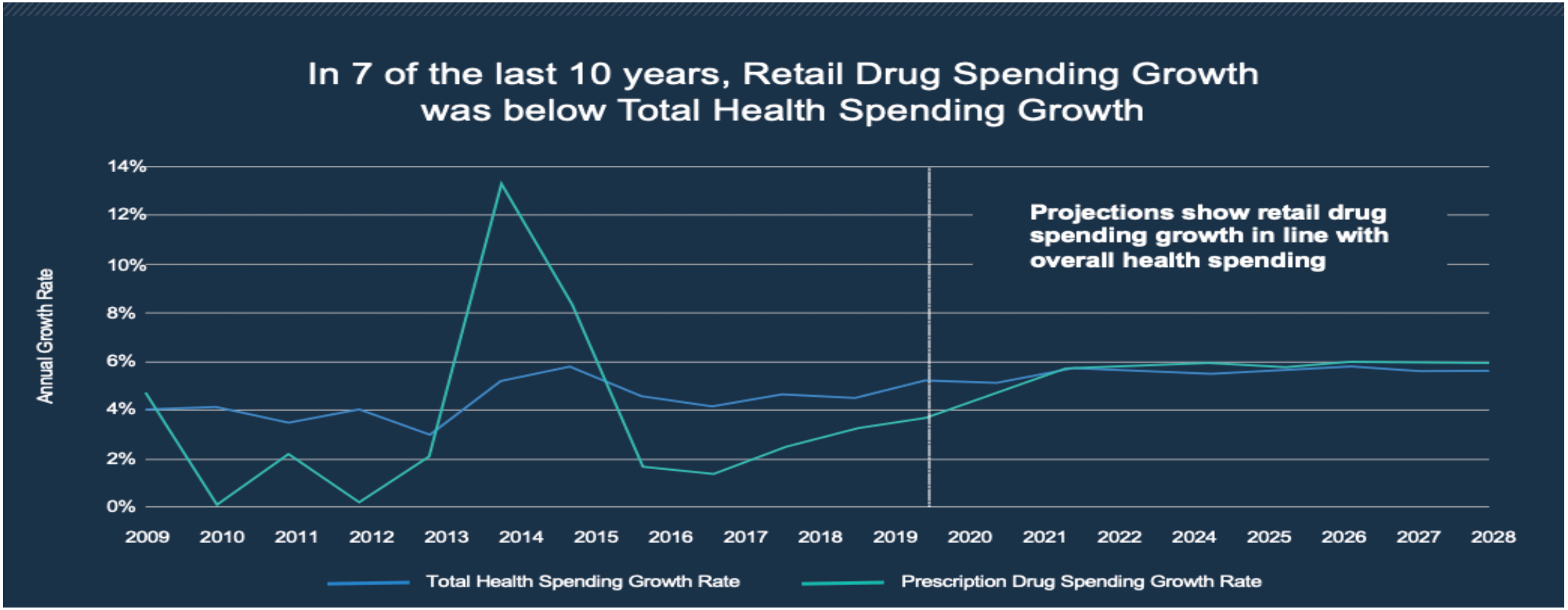
Spending on Retail and Physician-administered Medicines Represents Just 14% of Health Care Spending



Brand Drugs *Only* 3.5% of WI Medicaid Spend

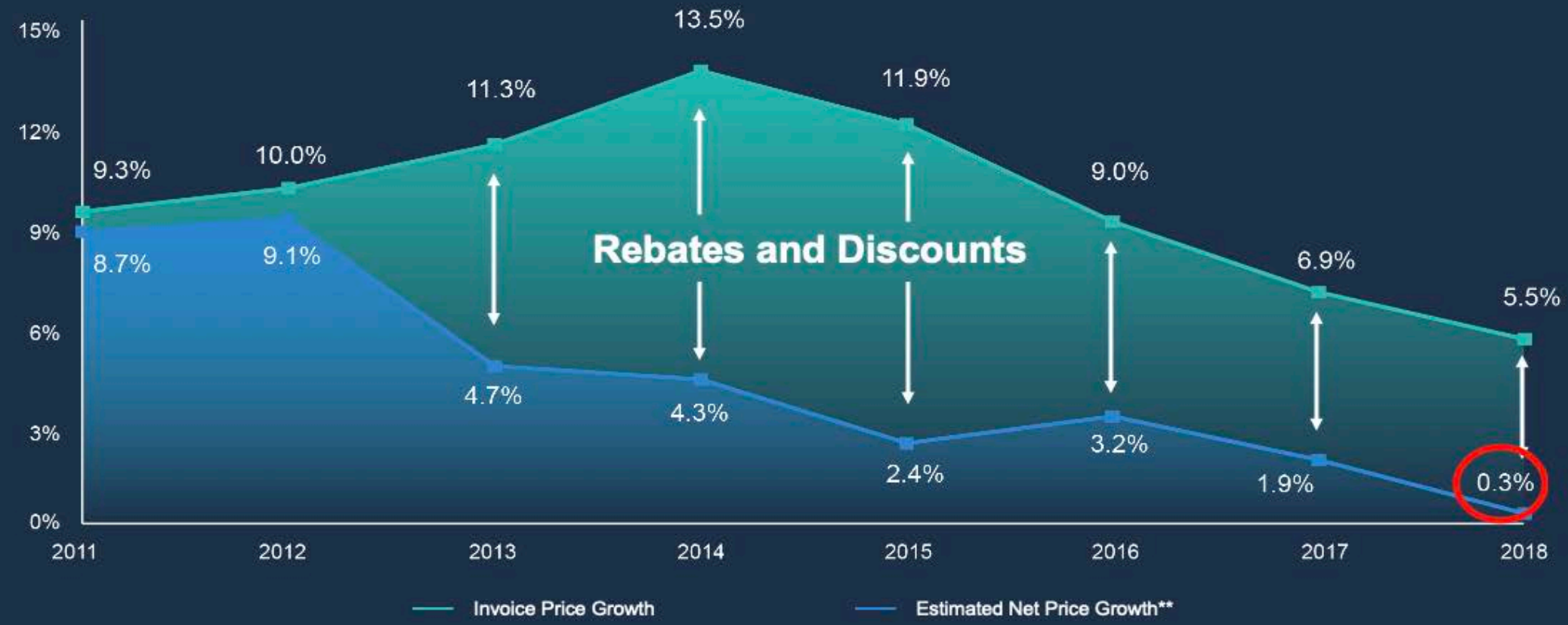


Medicine Spending is Projected to Grow in Line with Health Care Spending Through Next Decade



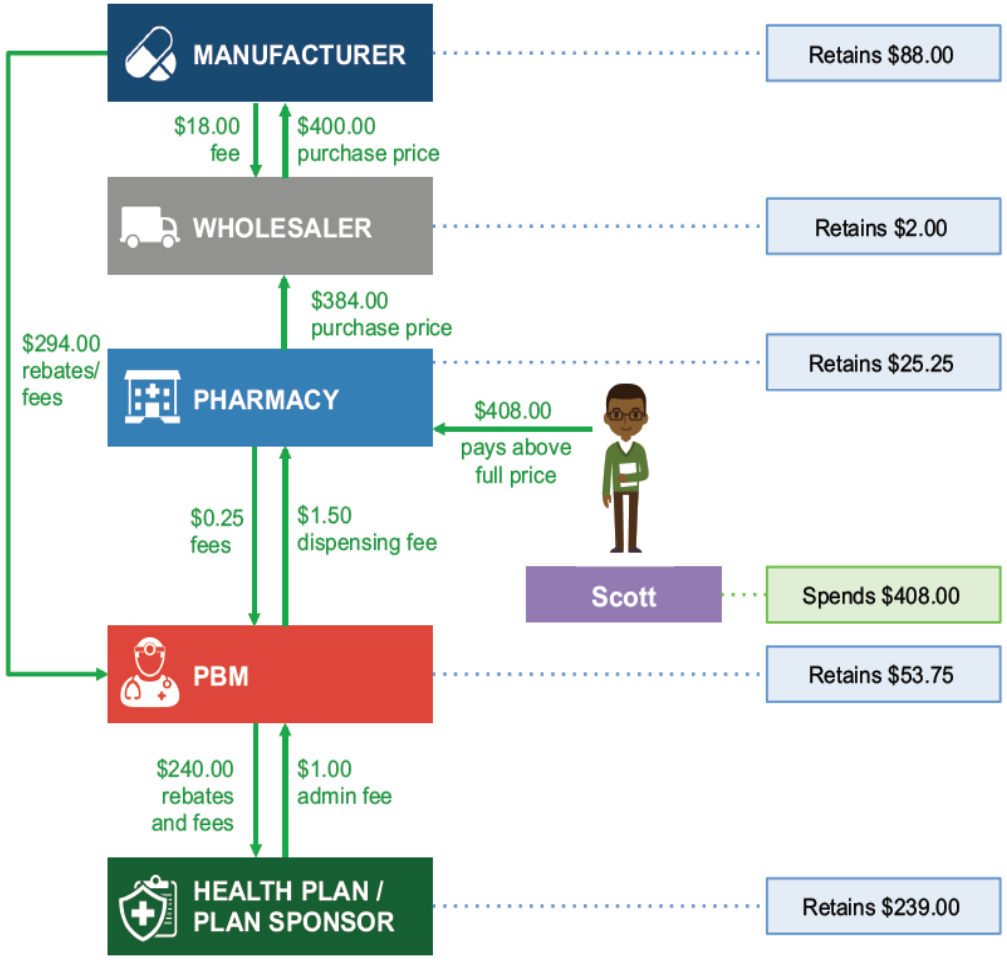
Note: Total retail sales include brand medicines and genSource: CMS National Health Expenditures Rep

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.

Flow of Payment for a $400 Insulin



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.

- Since Scott hasn't reached his deductible, his insurer does not cover any of his costs
- Scott pays more than the list price of his medicine
- The PBM and health plan pay nothing, and actually earn $292.75 on this prescription
- Due to industry consolidation, the PBM, health plan, and even the pharmacy are often part of the same parent company

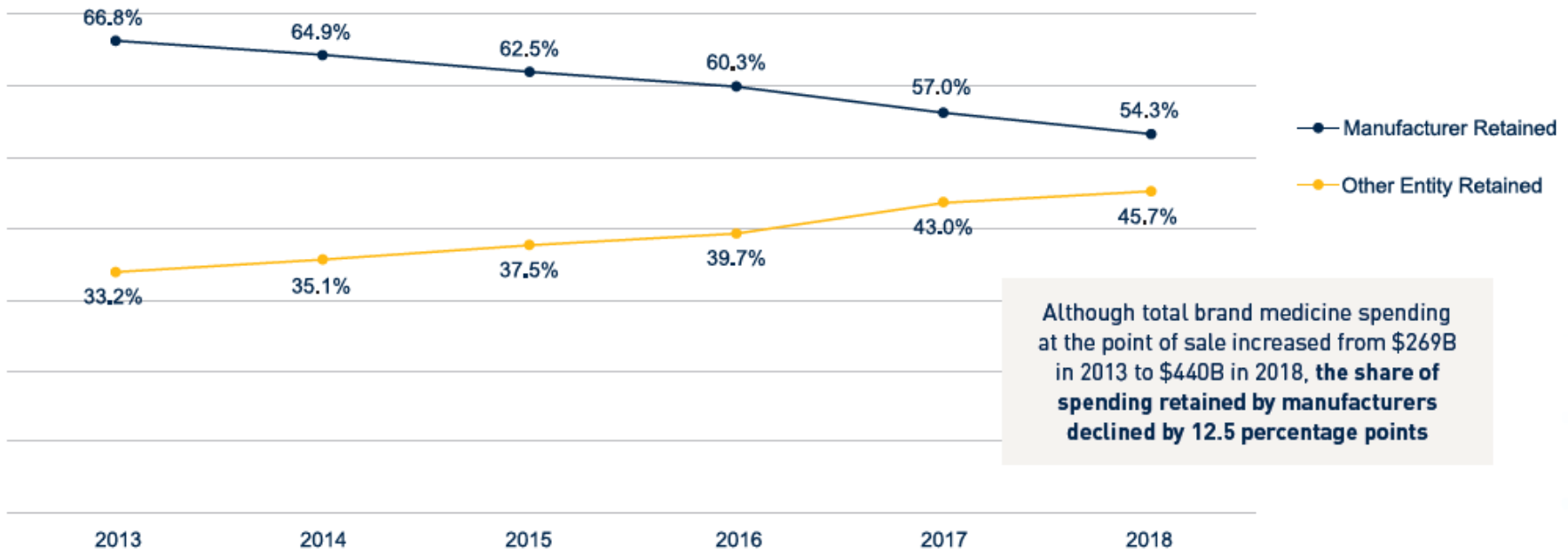
Assumptions:

- $400 list price per prescription
- 65% base rebate
- Patient pays full undiscounted price of medicine

Manufacturers are retaining an increasingly smaller share of total spending on brand prescription medicines

FIGURE 1

Percentage of Total Point of Sale Brand Medicine Spending Retained by Manufacturers and Other Entities, 2013-2018

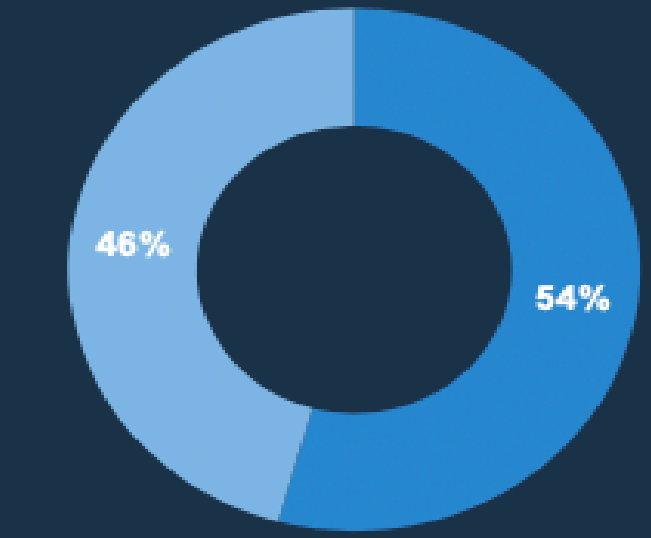


Although total brand medicine spending at the point of sale increased from $269B in 2013 to $440B in 2018, **the share of spending retained by manufacturers declined by 12.5 percentage points**

"A common misconception of the pharmaceutical industry is that manufacturers retain the vast majority of drug spending."

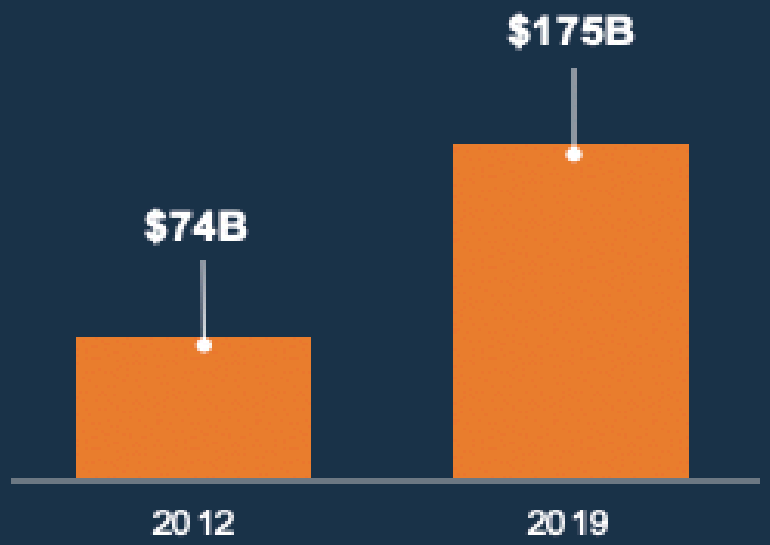
Nearly Half of Spending on Brand Medicines Goes to Entities Other Than the Manufacturers Who Developed Them

Percent of Total Spending on Brand Medicines Received by Manufacturers and Other Entities, 2018



Source: Berkeley Research Group, 2020.

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



Source: Drug Channels Institute, March 2020.

Potential Solution: Share the savings – Pass rebates directly onto the patient at the pharmacy counter.

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

Out-of-pocket Costs for the Sickest Continue to Soar Despite a Dramatic Slowdown in Medicine Prices and Spending

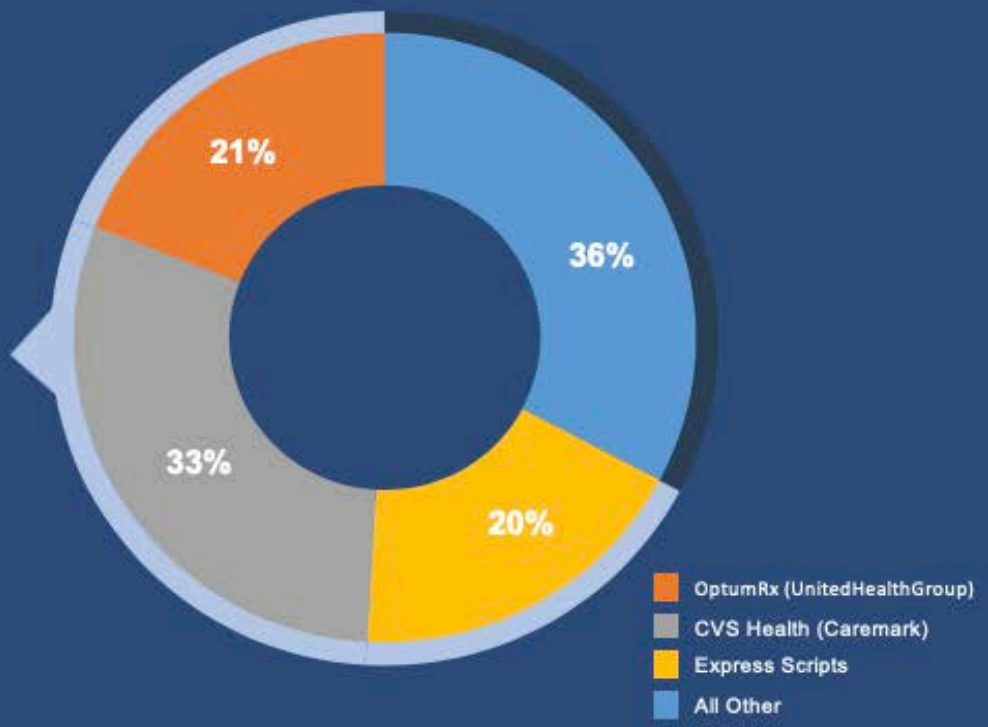
Brand Medicine Prices	Retail Medicine Spending
IMS Health & Quintiles are now IQVIA™	CMS CENTERS FOR MEDICARE & MEDICAID SERVICES
0.3%	**2.5%**
2018	2018

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:

74%



Source: Drug Channels Institute, March 2020.

Insurers determine:

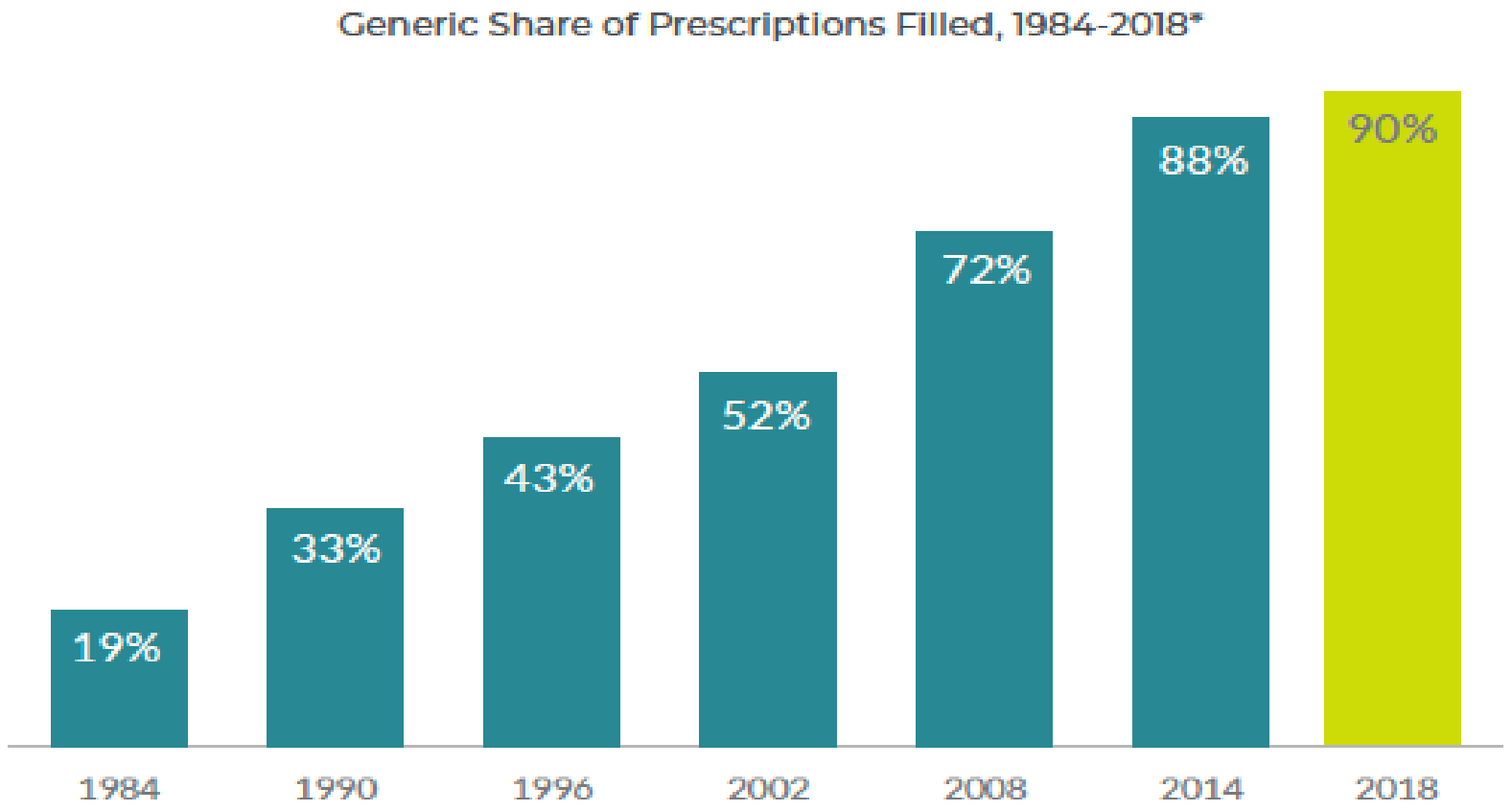
FORMULARY
if a medicine is covered

TIER PLACEMENT
patient cost sharing

ACCESSIBILITY
utilization management through prior authorization or fail first

PROVIDER INCENTIVES
preferred treatment guidelines and pathways

Nine out of Every Ten US Prescriptions Are Filled With Generics

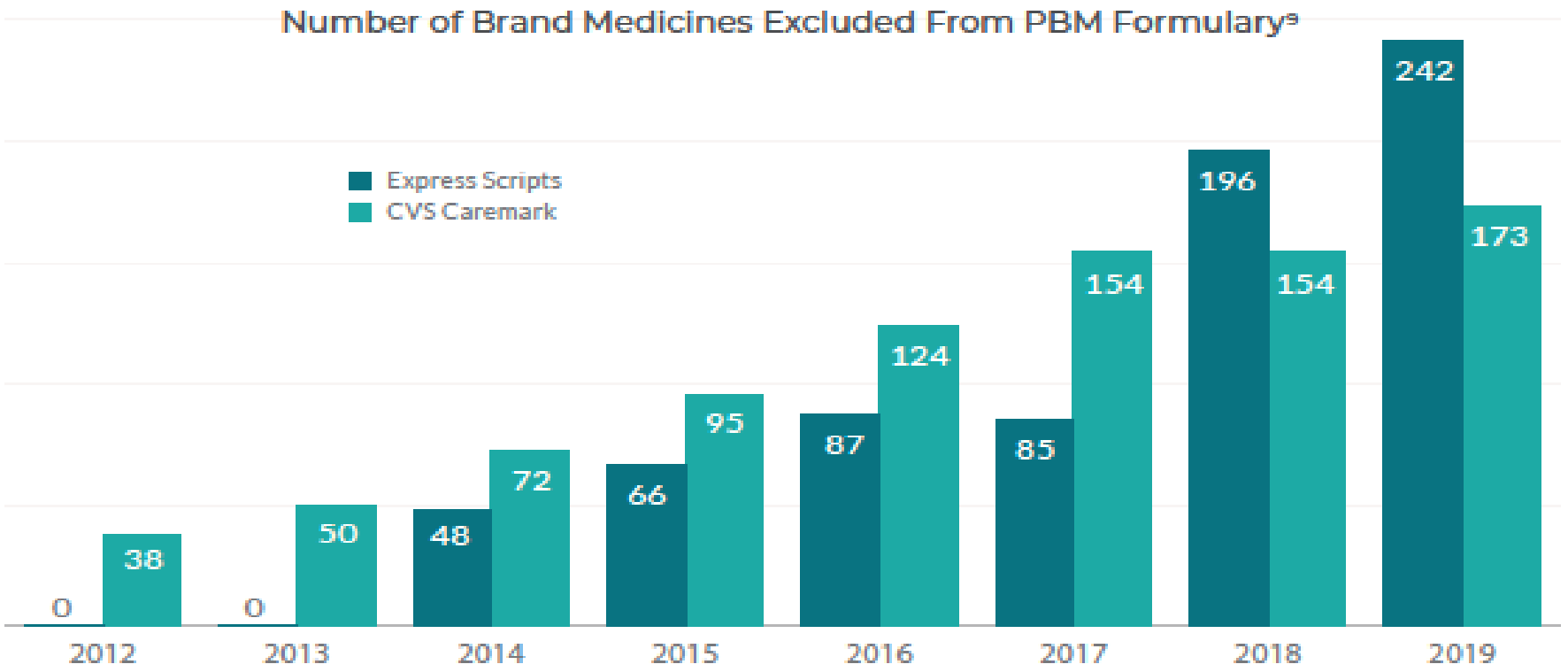


*Generic share includes generics and branded generics. "Other" category from IMS National Prescription Audit™ not included in calculation.

Sources: IQVIA Institute[28]; Drug Channels Institute[27]

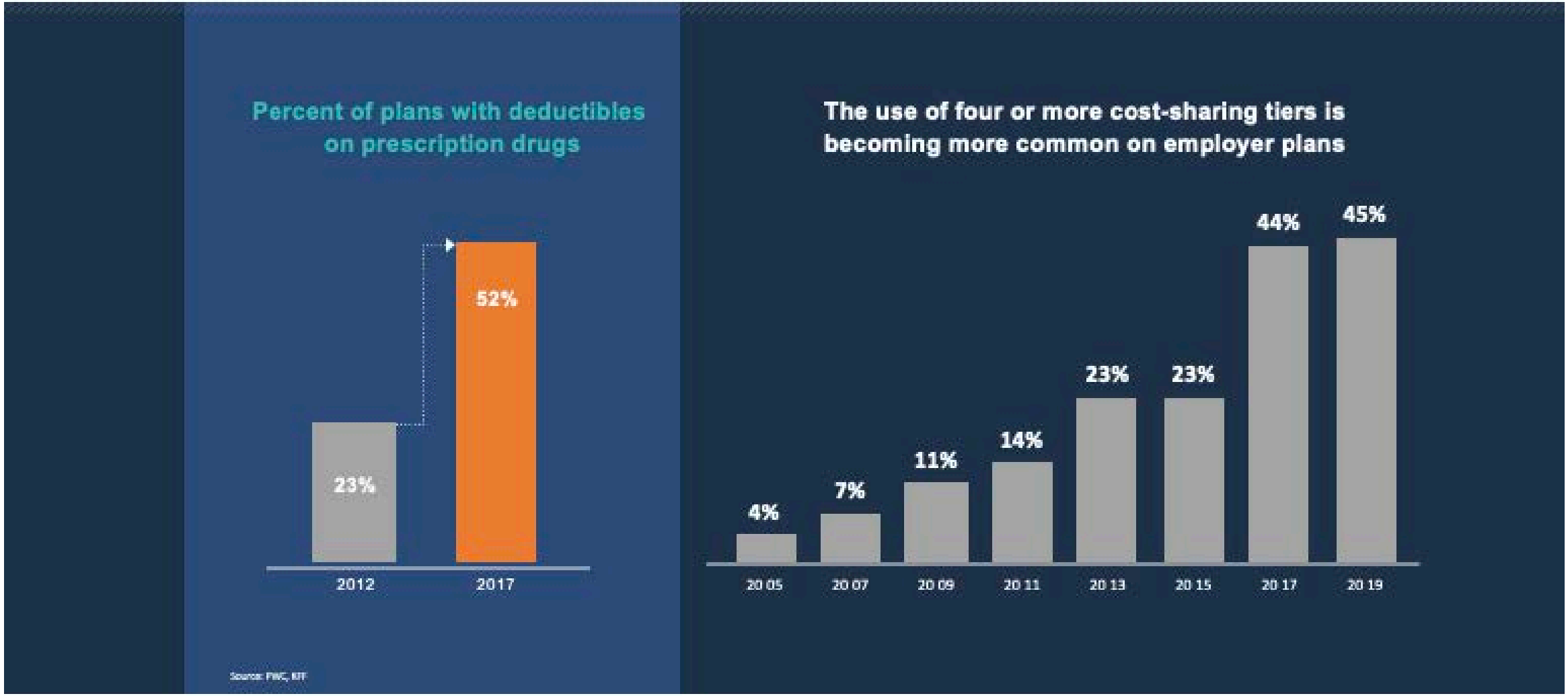
Number of Brand Medicines Excluded From PBM Formularies Has Increased Over Time

When a medicine is excluded from a pharmacy benefit manager's (PBM's) formulary, patients cannot access it without paying the list price. This can interrupt the continuity of a patient's treatment as well as their doctor's ability to make prescribing decisions that best meet their patients' needs.[8]



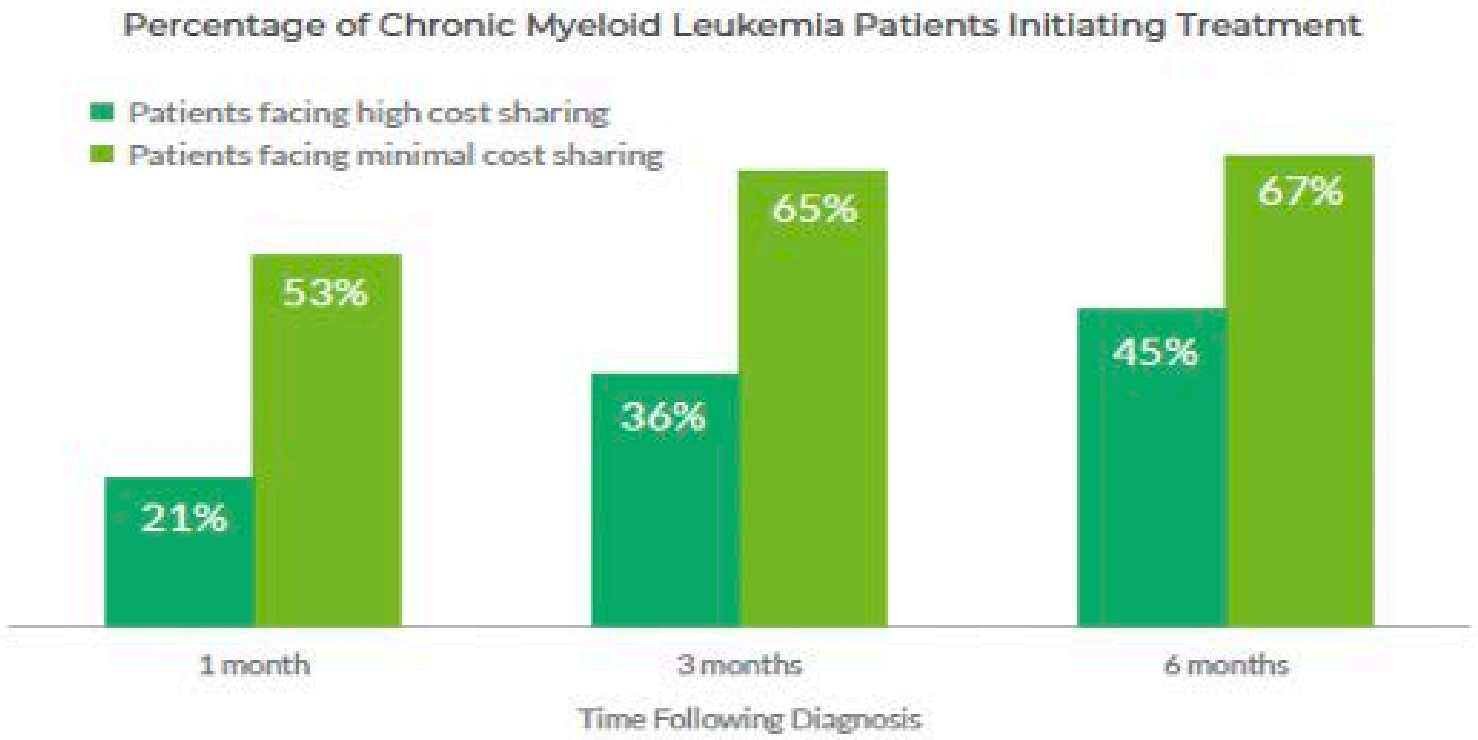
Sources: Tufts CSDD[8]; Drug Channels Institute[9]

Patients Face Rising Out-of-Pocket Costs for Medicines and Other Barriers to Care



Patients Facing High Cost Sharing Commonly Do Not Initiate Treatment

Chronic myeloid leukemia patients facing high out-of-pocket costs for medicines on a specialty tier are less likely to initiate drug therapy than patients receiving a cost sharing subsidy, and these patients take twice as long to initiate treatment.



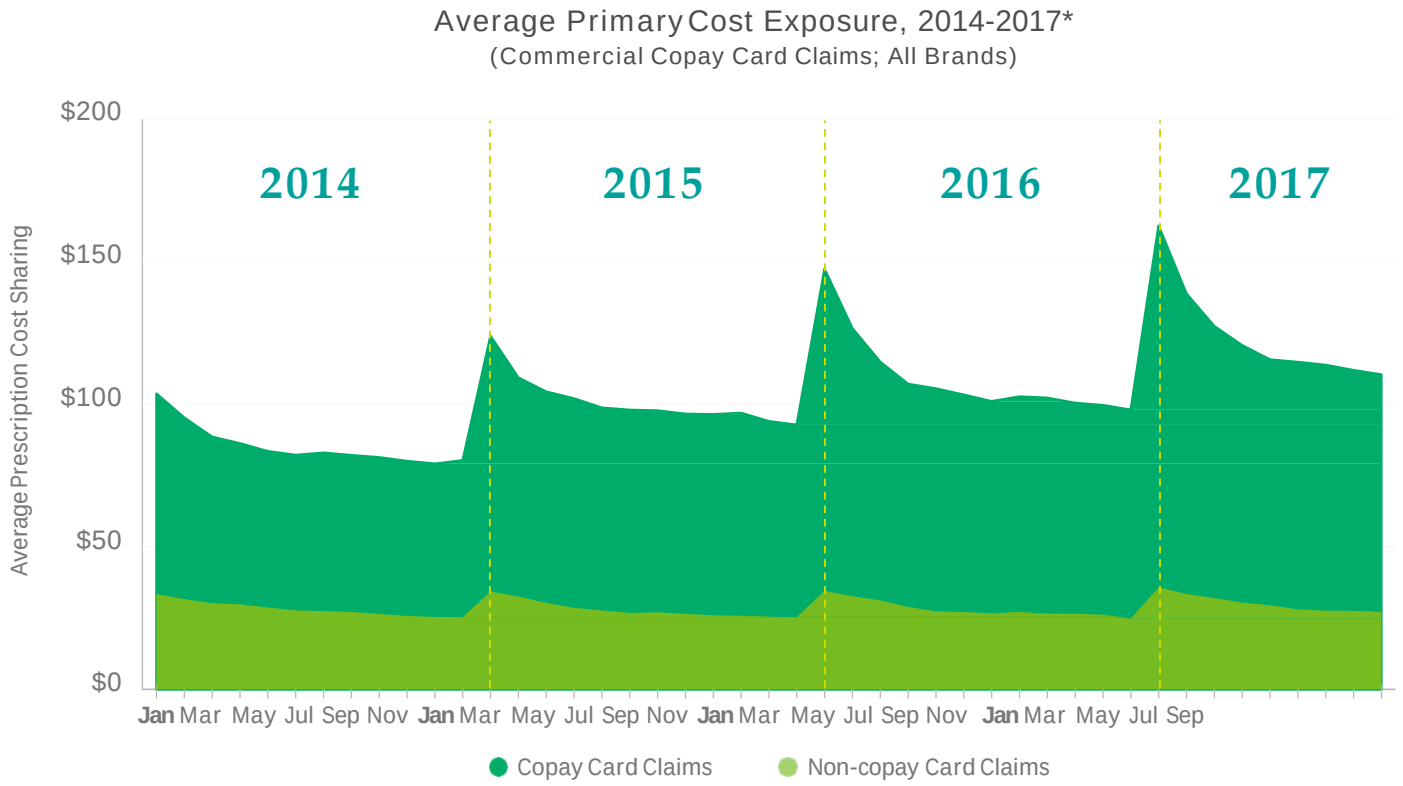
Source: Doshi JA et al.[7]

Policies so that *"Patients Pay Less"*

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

Without Coupons, Patients Would 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]

Manufacturer Cost Sharing Assistance Can Help Ease Patients' Out-of-Pocket Costs

In 2017, just **0.4%**
of commercial claims were filled with a coupon for a **brand medicine** that had a generic equivalent.

Programs that do not count manufacturer cost sharing assistance toward a patient's deductible or out-of-pocket maximum hurt the sickest patients, leaving them vulnerable to unexpected out-of-pocket costs as high as **several thousands of dollars** to continue taking their medicine.

Source: IQVIA[15]

Accumulator Adjustment Program (AAP) Ban

- **Manufacturer cost-sharing assistance** is used by patients enrolled in commercial plans to help them pay their out-of-pocket medicine costs. This assistance can help patients afford their prescribed medicines and stay adherent to them.

- **Accumulator adjustment programs (AAPs)** are used by insurers to exclude the value of cost-sharing assistance from patient cost-sharing requirements, including deductibles and out-of-pocket maximums. Excluding this assistance can lead to patients abandoning their medicines due to large surprise costs.

- **AAP bans** can be passed by states to require state-regulated health plans and issuers to count cost-sharing assistance toward patient cost-sharing requirements. Four states have passed such bans (AZ, IL, VA, WV).

Accumulator Adjustment Program (AAP) Ban

- AAP bans would help patients by requiring manufacturer cost-sharing assistance to count. These bans **do not undermine insurers' ability to control costs**. Health plans and issuers are still able to manage costs through utilization management restrictions, such as prior authorization, among other tools.

- HHS's 2021 Notice of Benefit and Payment Parameters (NBPP) gives group health plans and health insurance issuers the flexibility to operate AAPs but **allows states to pass AAP bans for state-regulated insurance markets**.

- HHS suggests that there may be a conflict between manufacturer cost-sharing assistance counting towards high-deductible health plan enrollees' deductibles and IRS rules on health savings accounts, but IRS has not confirmed HHS's interpretation. Even if HHS's interpretation were correct, the conflict would not impact patients unless they are enrolled in HSA-paired HDHPs.

Value-Based Contracts Deliver Results for Patients

Value-based contracts have the potential to benefit patients and the health care system by improving patient outcomes, reducing medical costs, and reducing the costs of medicines.

Outcomes-Based Contracts are associated with **28% lower patient copayments.**

Value-Based Contracts could generate more than **$12 Billion** if they reduced the diabetes burden in the United States by only 5%.

> We've been able to get the best of both worlds. The insurer gets competitive guaranteed discounts on prescriptions, and the manufacturer is aligned and accountable when something doesn't work."
>
> — Chris Bradbury, Cigna[40]

Sources: PhRMA[39]; Hopkins JS et al.[40]

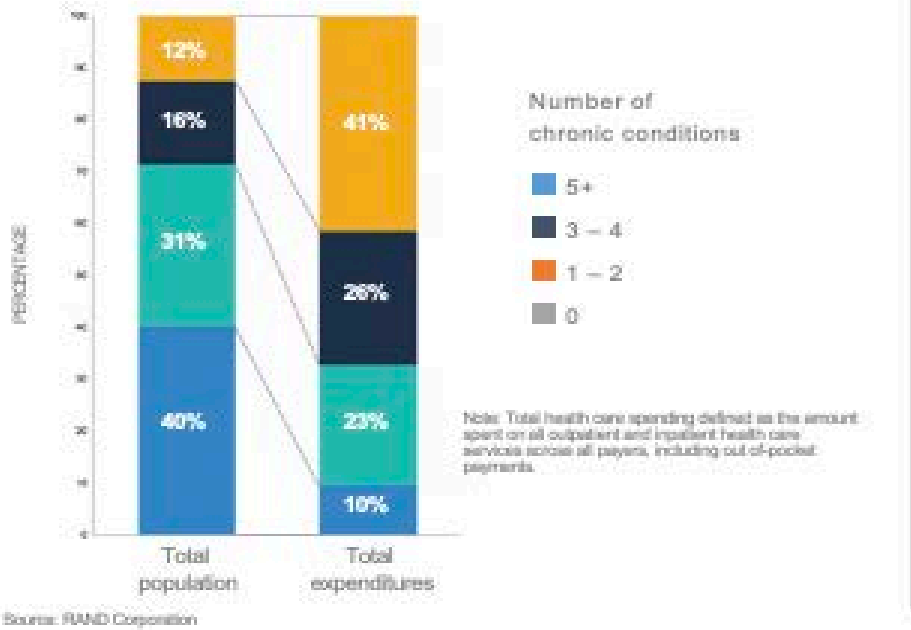
PhRMA Value Assessment Principles

- **Describe a sound process** that is open and transparent, with opportunity for input and a strong role for patients and physicians.
- **Support patient-centered care** by considering patient preferences and heterogeneity, appropriately communicating results, and avoiding misuse.
- **Deliver reliable, relevant information** by using rigorous, transparent methods that rely on the full range of evidence and prioritize longer-term and broader outcomes.
- **Value continued scientific and medical progress** by accounting for personalized medicine, the step-wise nature of progress, and the inherent value of innovation.
- **Take a system-wide perspective** on value by examining the full range of tests, treatments, care management approaches and health care services.

Impact of Chronic Disease on Wisconsin

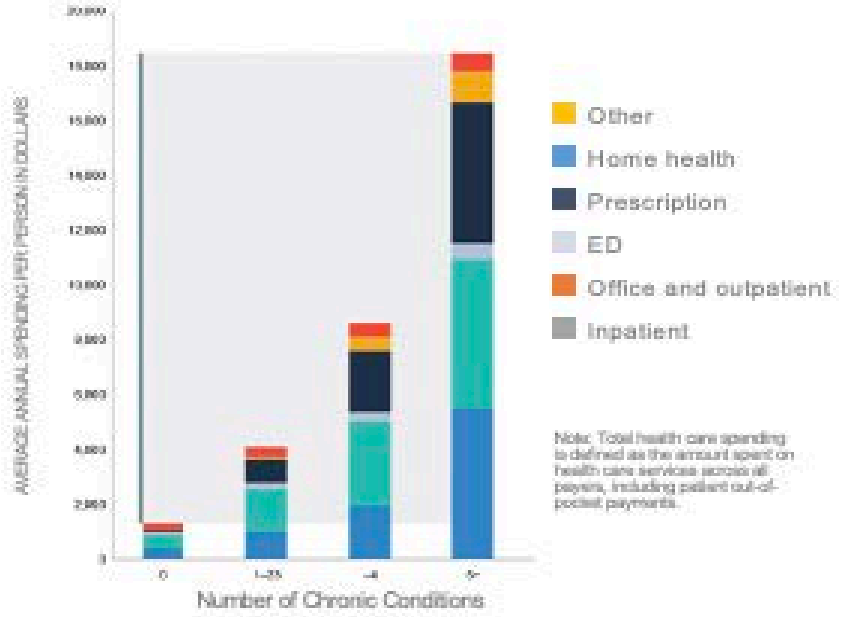
Treating people with one or more chronic condition consumes 90 cents of every dollar spent on health care.

Prevalence and Spending by Number of Chronic Conditions (2014)



Source: RAND Corporation

Health Care Spending by Number of Chronic Conditions (2014)



Impact of Chronic Disease on Wisconsin

Projected total cost of chronic disease 2016-2030 in Wisconsin **$768 BILLION**

In 2015, 3.4 million people in Wisconsin had at least 1 chronic disease, 1.3 million had 2 or more chronic diseases.

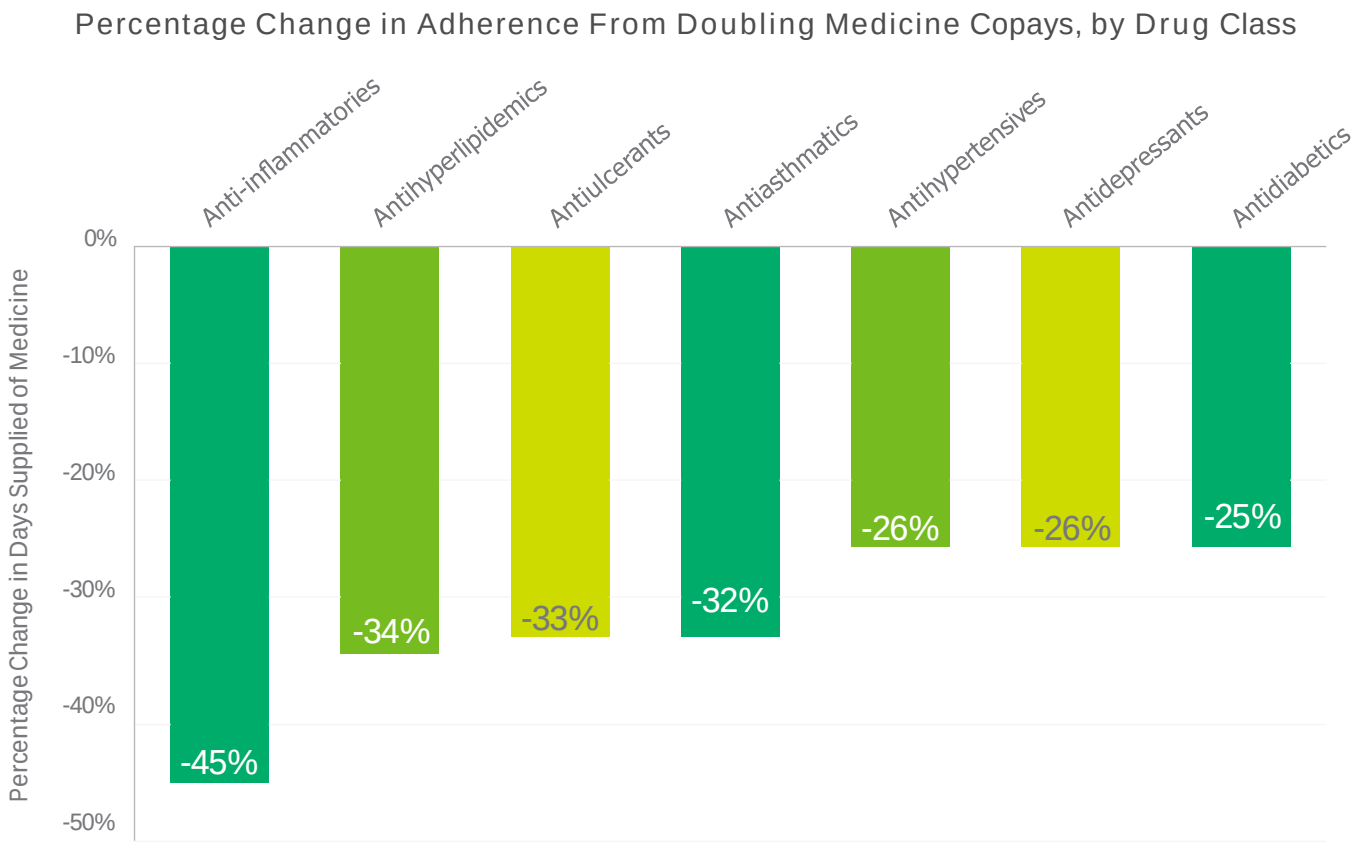
Chronic diseases could cost Wisconsin $37.2 billion in medical costs and an extra $13.9 billion annually in lost employee productivity (average per year 2016-2030).

Medical breakthroughs can and will transform lives and save health care costs over the next 15 years in Wisconsin and across the United States.

	Wisconsin	U.S.
Prevented Cases of Chronic Disease	3.4 Million	169 Million
Total Cost Avoided	$124 Billion	$6 Trillion
Lives Saved	429 Thousand	16 Million

High Cost Sharing Reduces Adherence

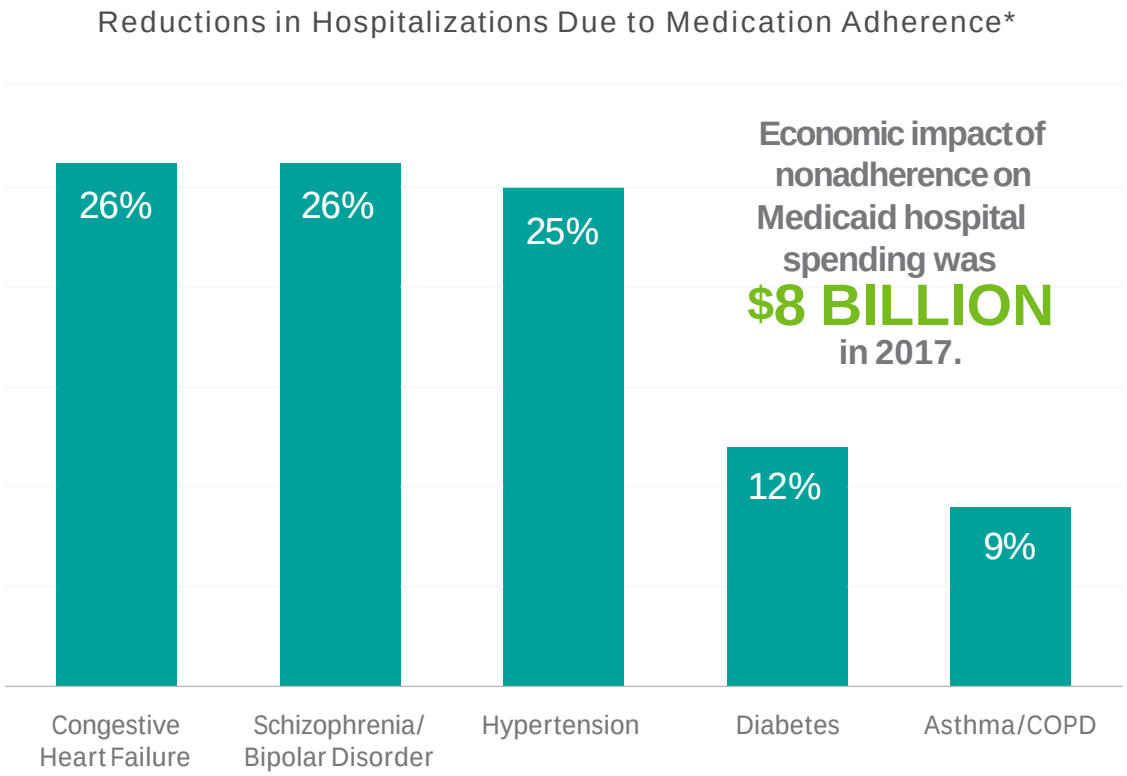
RAND researchers found that doubling copays reduced patients' adherence to prescribed medicines by 25%-45% and increased emergency room visits and hospitalizations.



Source: Goldman DP et al.[8]

Better Adherence Generates Savings in Medicaid

Optimal adherence to medicines for a range of chronic conditions leads to reductions in hospitalizations for many patients enrolled in Medicaid.

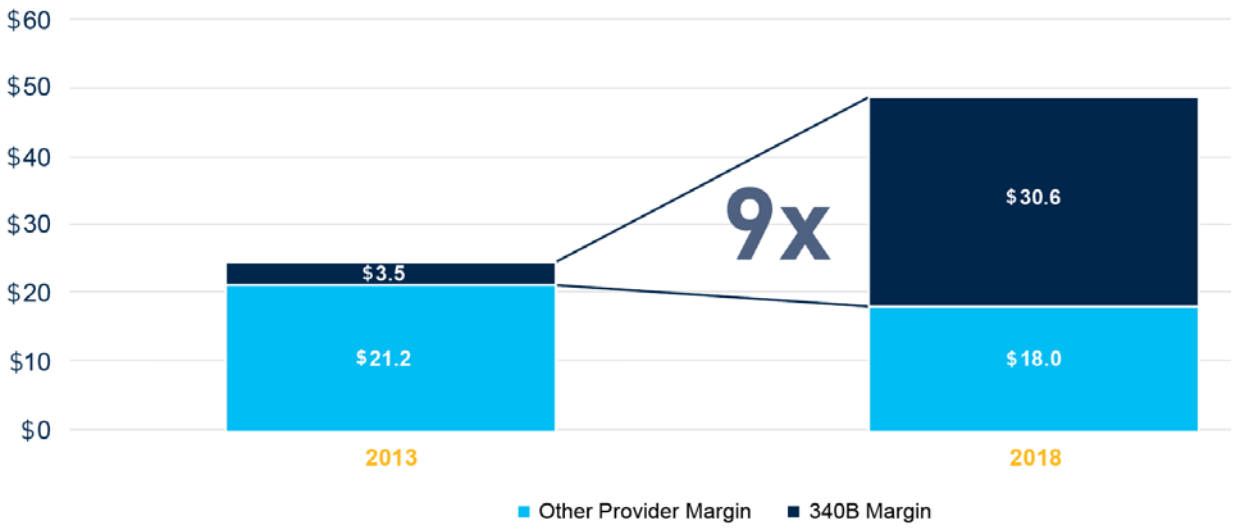


*Results apply to Medicaid populations that are not blind or disabled.

Source: Roebuck M C et al.[12]

340B Program Further Distorts Supply Chain

340B Profits Represent a Growing Share of Provider and Pharmacy Margins



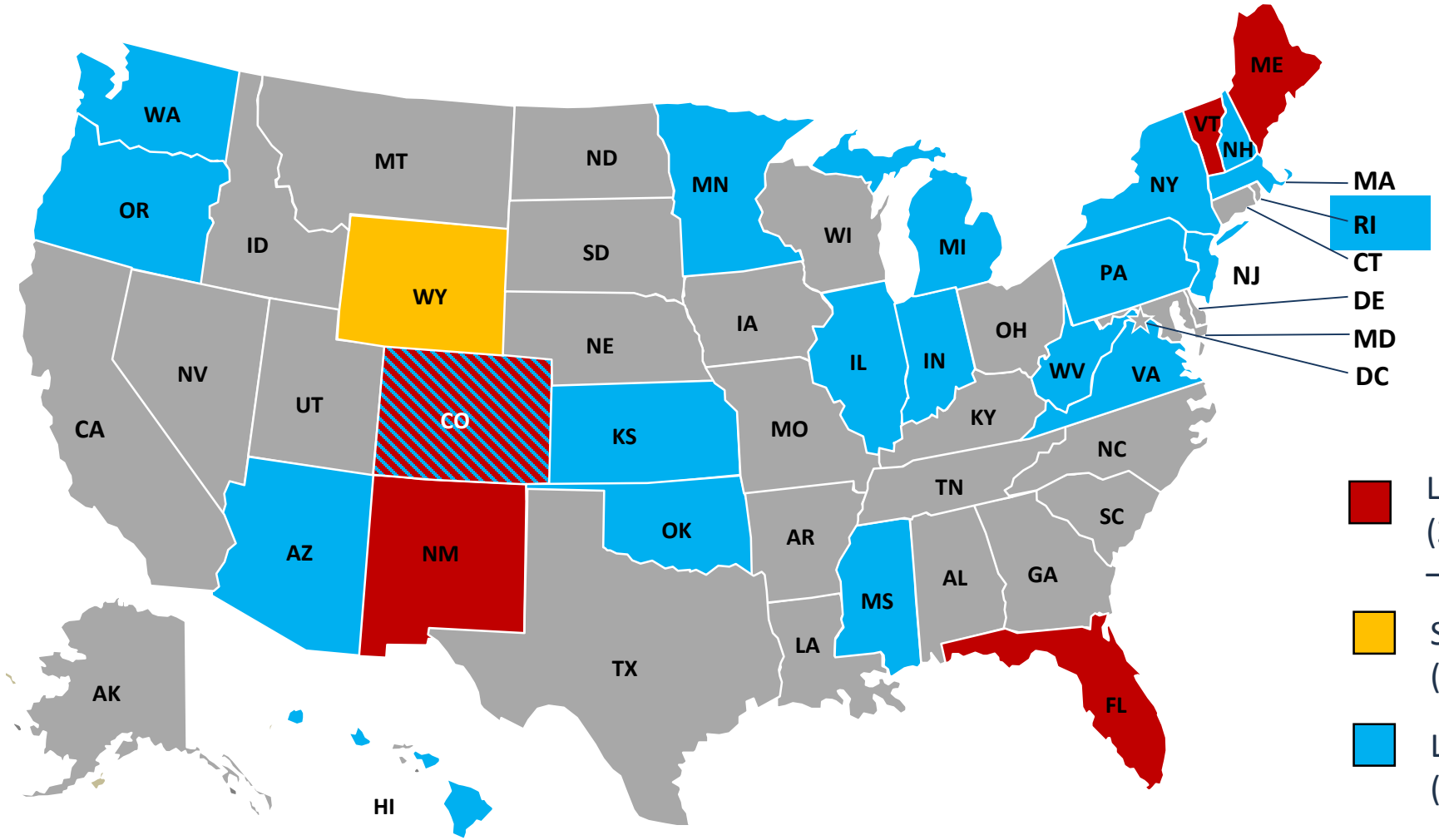
"Unprecedented expansion in the 340B Drug Discount program during this period… was the primary driver of this growth."

Berkeley Research Group. Revisiting the Pharmaceutical Supply Chain: 2013 – 2018.

- 340B discounted purchases were $29.9 billion in 2019*
  - 8% of the total U.S. pharmaceutical market
  - 14% of total U.S. branded outpatient drug sales
- Expansion in 340B program benefits for-profit entities without any guaranteed benefit to patients
- Ways the 340B program distorts supply chain incentives and increases costs:
  - Large 340B discounts create incentives for hospitals to drive up treatment costs
  - Evidence suggests the 340B program shifts care to more expensive and less convenient settings for patients*
- Updated program standards for how 340B discounts are properly applied are necessary to ensure that it continues to serves the needs of safety net providers and patients without creating incentives that contribute to higher costs for the overall health care system

*Drug Channels: https://www.drugchannels.net/2020/06/new-hrsa-data-340b-program-reached-299.html

2020 State Drug Importation Legislative Activity



State Importation Programs Cannot Guarantee Consumer Safety

- The U.S. has one of the most secure supply chains in the world. There is no way to guarantee the safety or integrity of drugs coming from other countries. Importation programs undermine this system.

- Canadian authorities have said they cannot and will not guarantee the safety of medicines imported to the U.S. through Canada.

- In its Comments on the federal Food and Drug Administration's (FDA) Proposed Rule, the Government of Canada expressed concern that any state program could exacerbate Canada's problem with drug shortages and stated that the country will take whatever steps necessary to protect its drug supply for use by its citizens.

- Key stakeholder groups have publicly expressed concern with the safety of importation, including, a Former FDA Commissioners' letter to Congress opposing importation. Others expressing concern are the National Association of Chain Drug Stores, the American Pharmacists Association, the National Sheriffs' Association, and the Western States Sheriffs' Association.

State and Individual Savings Unlikely

- Extensive state resources are required for the implementation and administration of an importation program.
    - Administrative costs; costs of repackaging and re-labeling; law enforcement costs; costs associated with public and stakeholder training and education.

- In public comments to the FDA, states that have passed importation, expressed concern with the ability to recoup state costs, provide significant savings, achieve appropriate levels of access, and operate efficiently under the parameters outlined in the notice of proposed rulemaking (NPRM).

- The Colorado Joint Budget Committee approved the Department of Health Care Policy and Financing's FY 2020-21 recommendation to delay of the implementation of Colorado's Canadian importation program in light of budget concerns.

- The Congressional Budget Office (CBO) estimates a mere 1% reduction in drug spending under importation, and there is not guarantee patients would see any of the potential savings.

Trump Administration Importation Plan

- **Pathway 1:** State demonstration projects under the authority of the Federal Food, Drug, and Cosmetic Act Section 804 to allow importation of drugs from Canada.

- **Pathway 2:** Manufacturers permitted to import versions of FDA-approved drug products that they sell in foreign countries under a new National Drug Code.

- December 2019: FDA issued NPRM and draft guidance on Pathway 1 and 2 respectively; No final rule or guidance to date.

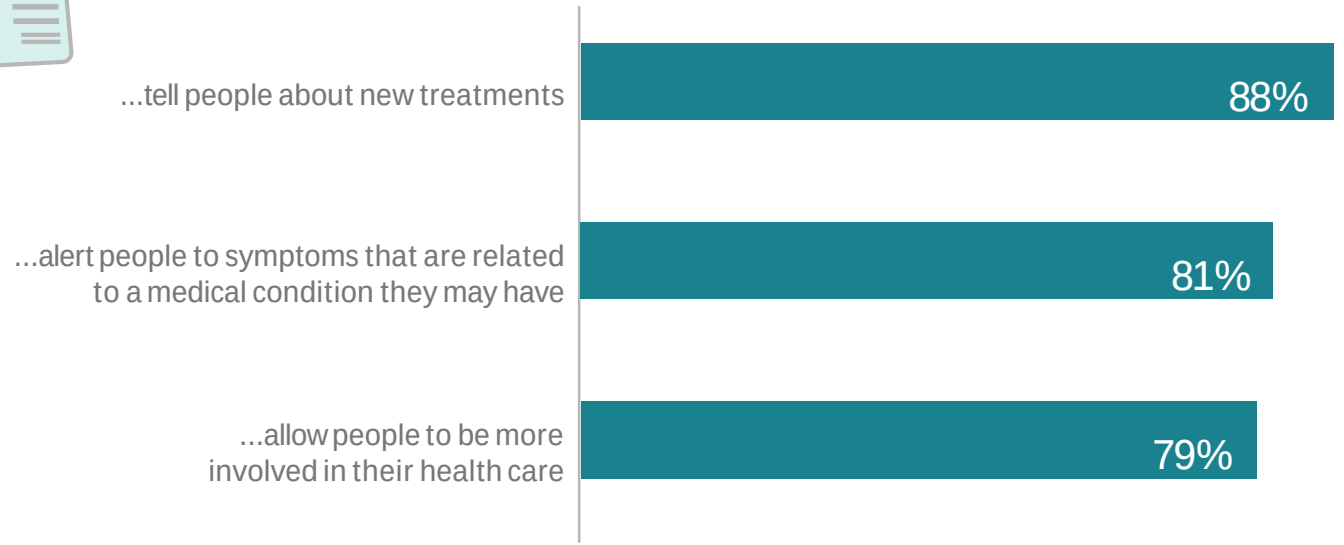
- State Program Approval: VT, CO, FL, ME, and NM have either submitted, or are in the process of submitting, importation plans to HHS; No federal responses to date.

Direct-to-Consumer Advertising Increases Awareness of Conditions and Treatments

A recent survey of consumers demonstrated the positive contribution of direct-to-consumer (DTC) advertising to patients' knowledge.

How strongly do you agree or disagree with each statement?
Percentage who AGREE with each statement
(Survey of consumers, n=1564, April 2017)

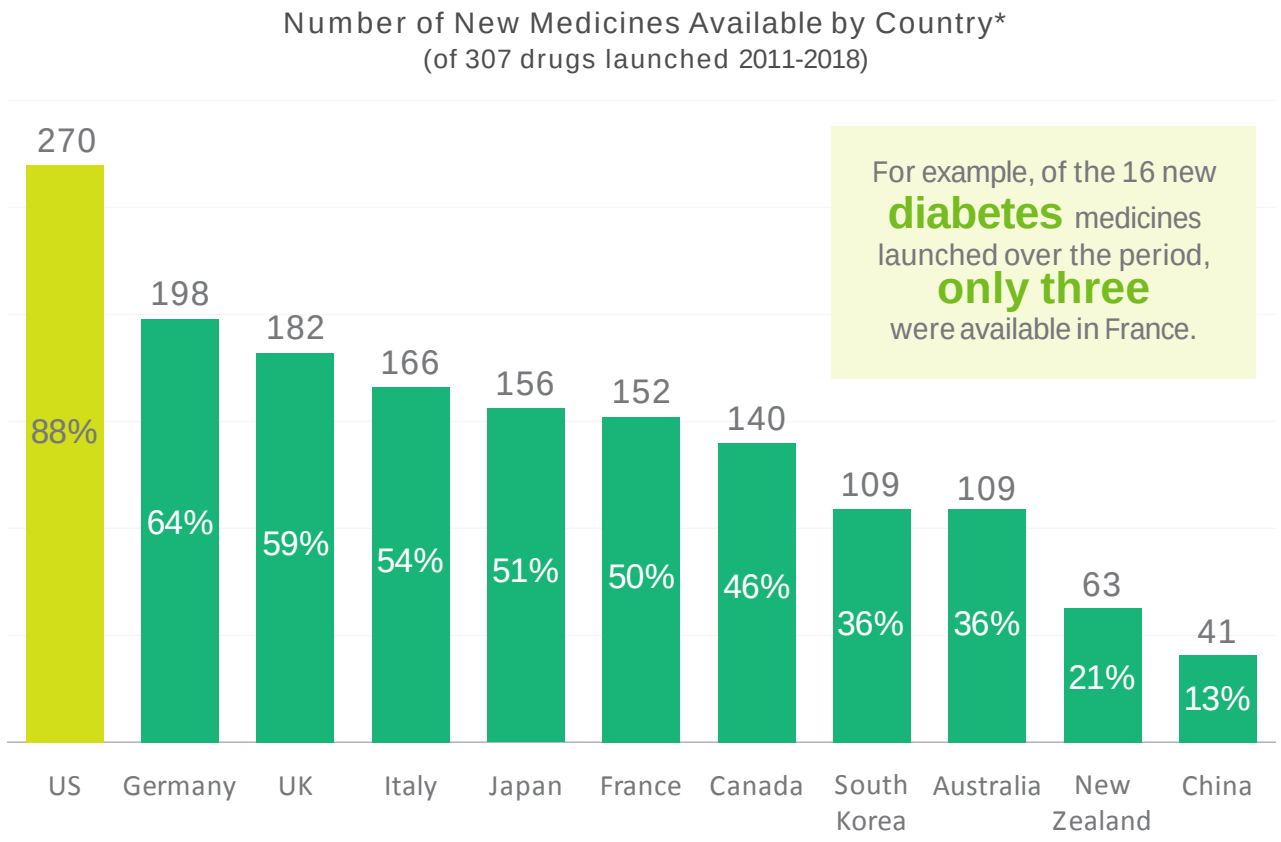
DTC ads



Source: Princeton Survey Research Associates International[27]

More Medicines Are Available to U.S. Patients than International Counterparts

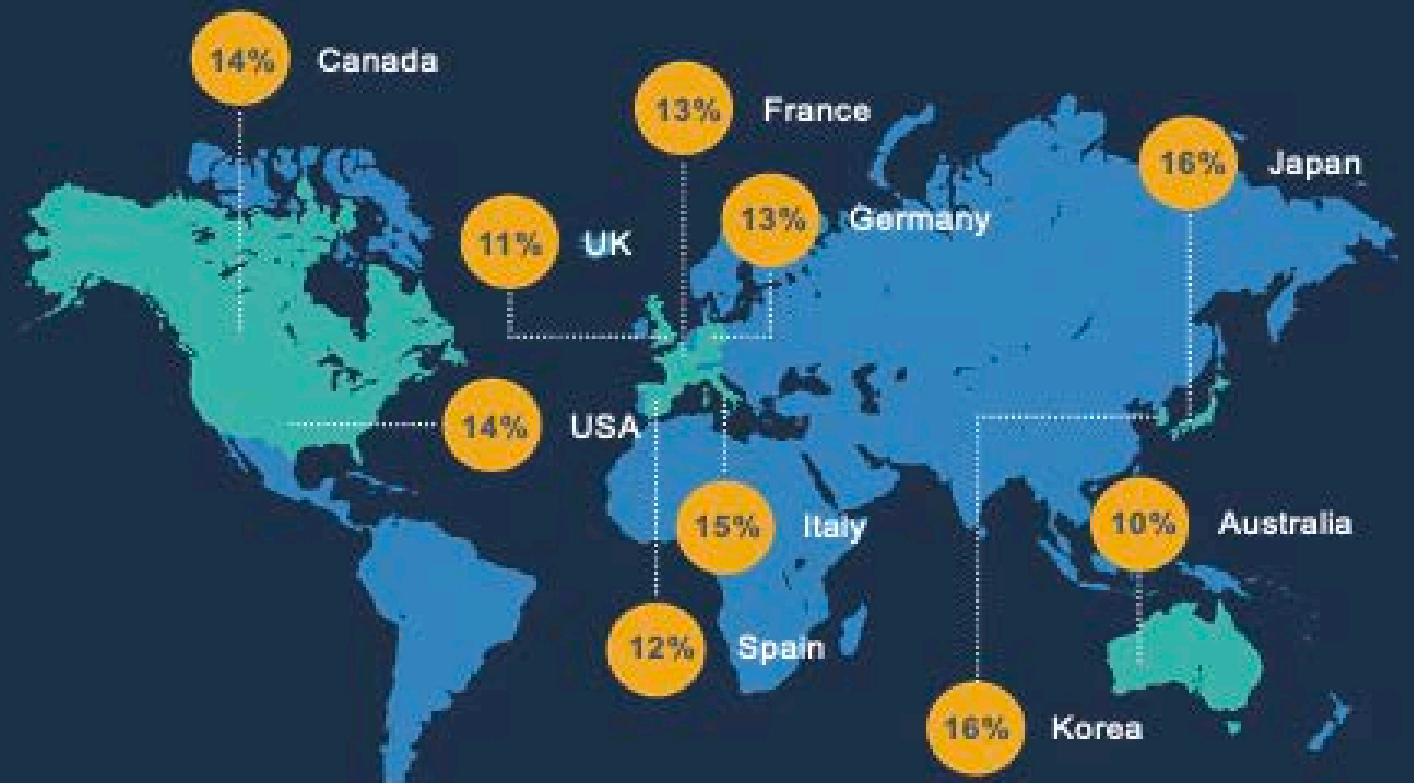
Nearly 90% of newly launched medicines from 2011 to 2018 were available in the United States, compared to just two-thirds in Germany, half in France, and even less in Canada and Australia.



*New Molecular Entities (NMEs) approved by the FDA, European Medicines Agency (EMA), and/or Japan's Pharmaceuticals and Medical Devices Agency (PMDA), and launched in any country between 2011 and 2018.

Source: PhRMA analysis of IQVIA Analytics Link and FDA, EMA, and PMDA data[1]

Medicine Spending in the United States is In Line with Spending Around the World

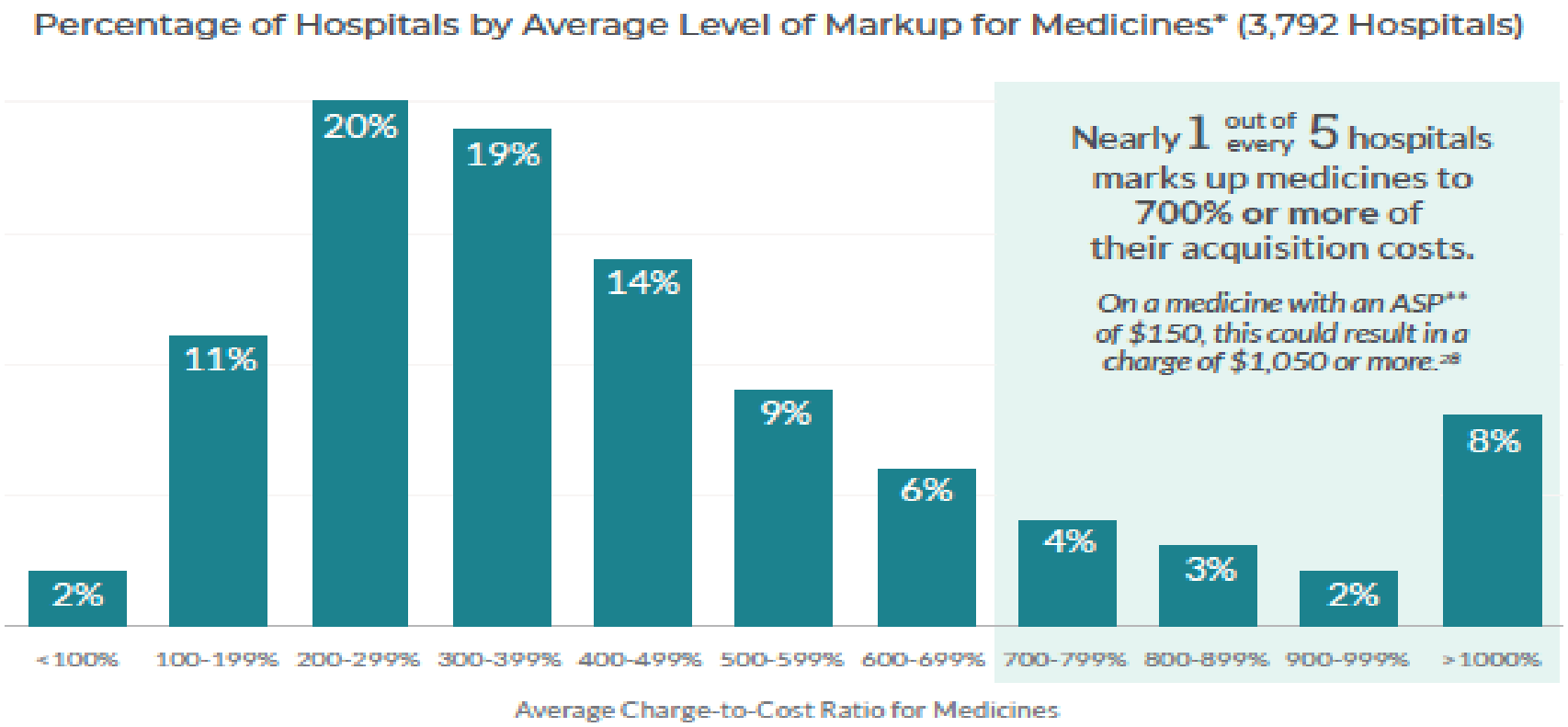


Prescription Medicines as a Percentage of Total Health Care Spending

Note: Total health care spending includes hospital care, physician and clinical services, home health and nursing home care, government administration and net cost of private health insurance, dental, home health and other professional services as well as durable medical equipment.
Source: OECD Health Statistics Database (accessed February 2016); Altarum Institute, 2015. A ten-year projection of the prescription drug share of national health expenditures including non-retail.

Hospitals Mark Up Medicines in the Outpatient Setting, Driving Up Costs to Patients and the Health System

Hospitals mark up medicine prices, on average, nearly 500%. The amount hospitals receive after negotiations with commercial payers is, on average, more than 250% what they paid to acquire the medicine.[27]



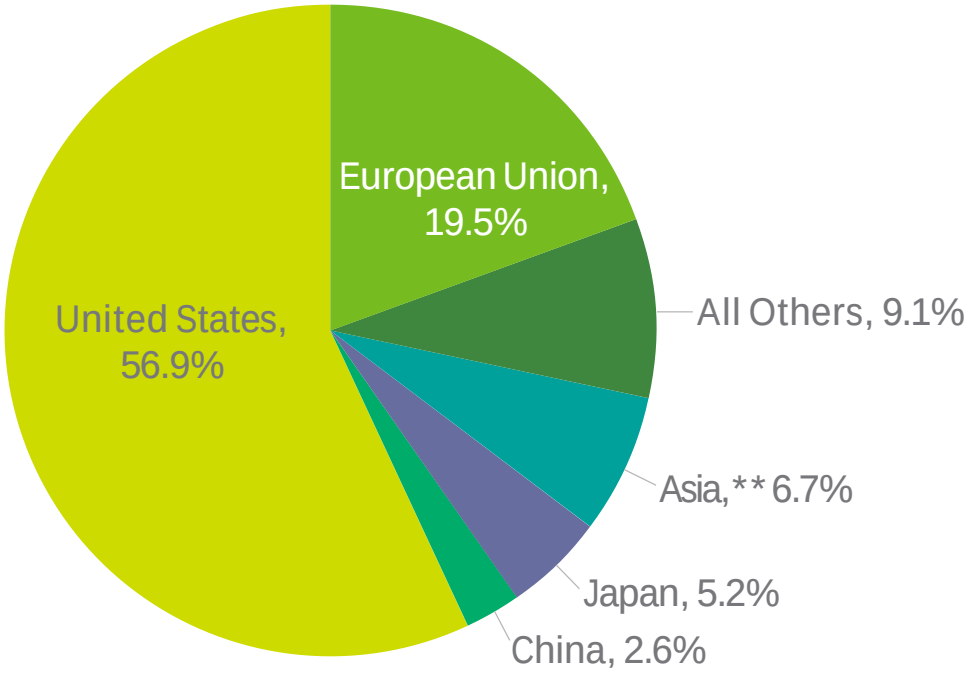
*Percentages in chart may not add up to 100% due to rounding.
**ASP: Average Sales Price

Sources: The Moran Company[27,28]

The U.S. Leads in Biopharmaceutical Intellectual Property

More than half of the intellectual property related to new medicines was created in the United States.

US Patents Granted in Pharmaceuticals
by Region/Country of Inventor, 2016*



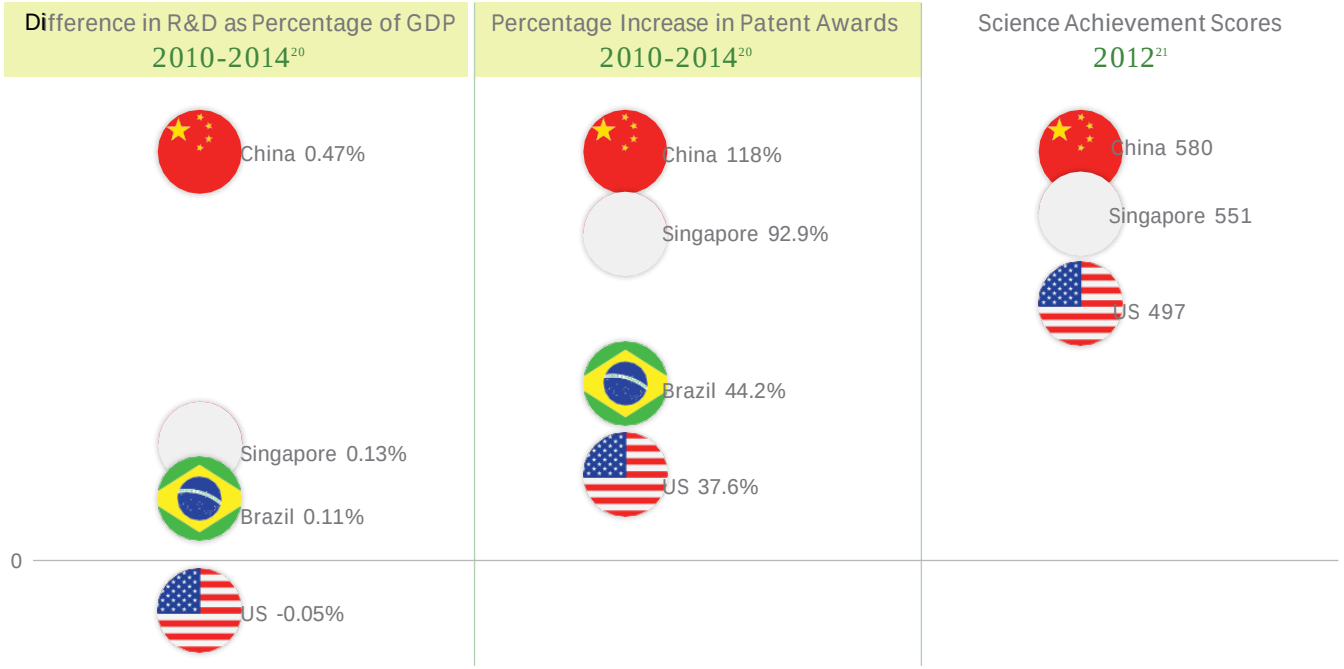
*Percentages may not add up to 100% due to rounding.
**Asia includes India, Malaysia, South Korea, and others.

Source: PhRMA analysis of National Science Foundation data[13]

Other Nations Are Challenging U.S. Leadership in Biopharmaceutical Innovation

Emerging economies are exceeding US performance on key measures related to a robust biopharmaceutical environment.

> The United States is now facing increasing competition to attract and grow a biopharmaceutical presence, not just from developed countries, but also from emerging nations, such as Brazil, China, and Singapore, that are laying the groundwork for future growth."
>
> — TEConomy Partners[20]



Sources: TEConomy Partners[20,21]

Factors Contributing to the Industry's Response

Armed with experience garnered from previous outbreaks and a vast storehouse of knowledge about infectious diseases like influenza, malaria and HIV, researchers are working to develop and deliver diagnostics, treatments and vaccines to save lives and restore the rhythms of daily life for billions of people.

Developing Treatments and Vaccines to Fight COVID-19

There are **1228 clinical trials under way across the globe** for vaccinations and treatments.

Data as of 6/19/2020

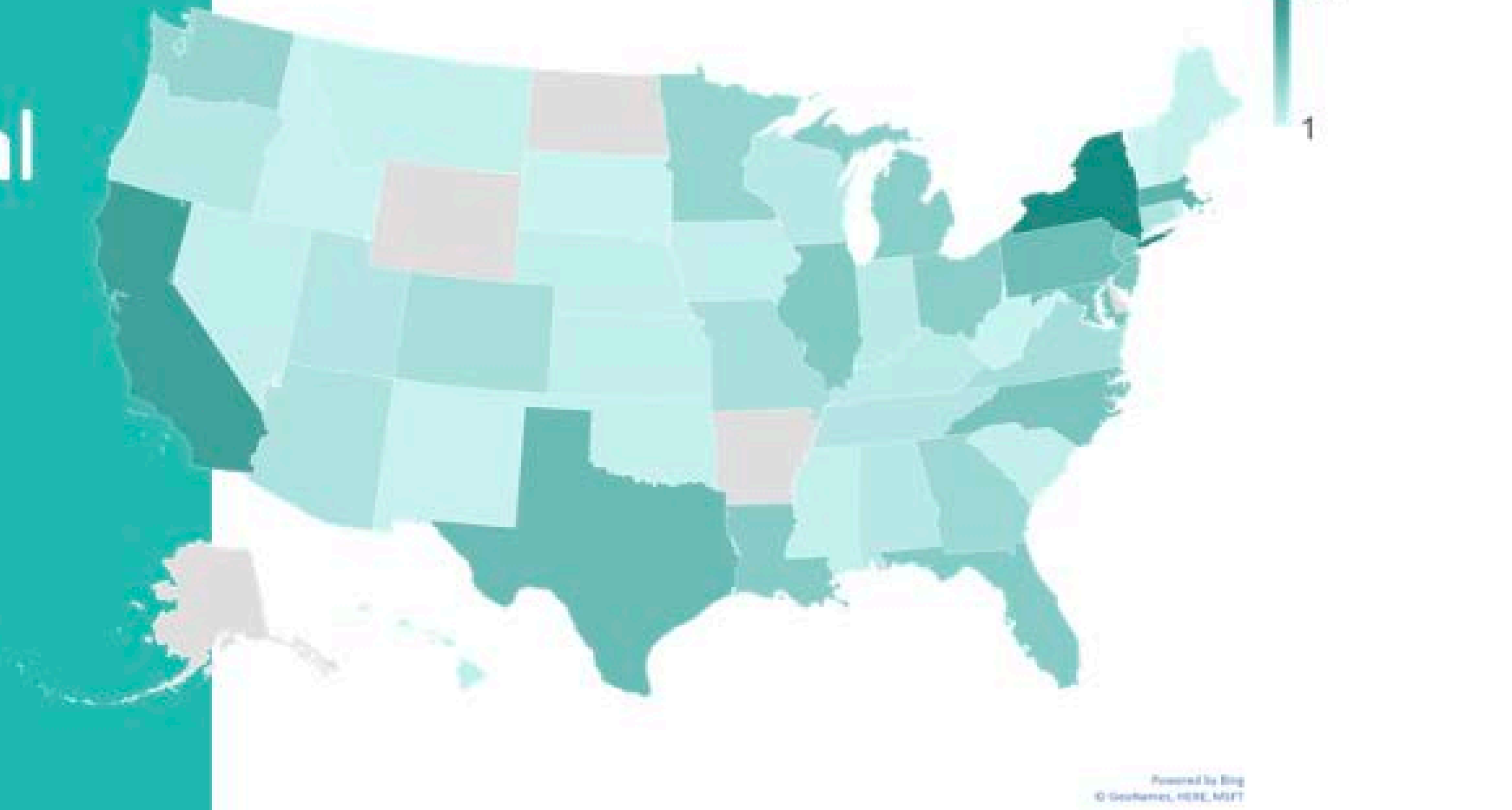
Source: World Health Organization International Clinical Trials Registry Platform (ICTRP)

U.S. Clinical Trials of Investigational Therapies

There are 265 clinical trials investigating therapeutics in 45 states and Washington, D.C.

75 of the 265 clinical trials are being conducted in more than one state

Data as of 6/15/2020



Source: World Health Organization International Clinical Trials Registry Platform (ICTRP)

Diverse, Robust Supply Chains Have Been a Long-Term Priority for the Innovative Biopharmaceutical Industry

Setting up the manufacturing supply chain for a medicine begins years before that medicine is approved for use by patients

Carefully built, robust global supply chains help ensure patients in the United States and around the world have ongoing access to medicines

Building a new biopharmaceutical manufacturing facility can cost between $1 and $2 billion and take 5 to 10 years before it is operational

Companies invest significantly in the design and ongoing maintenance and modernization of manufacturing facilities and their quality systems to help avert disruptions

Facts About the Pharmaceutical Supply Chain

Myth: Changes can quickly be made to supply chains. Moving all manufacturing to the United States would be easy.

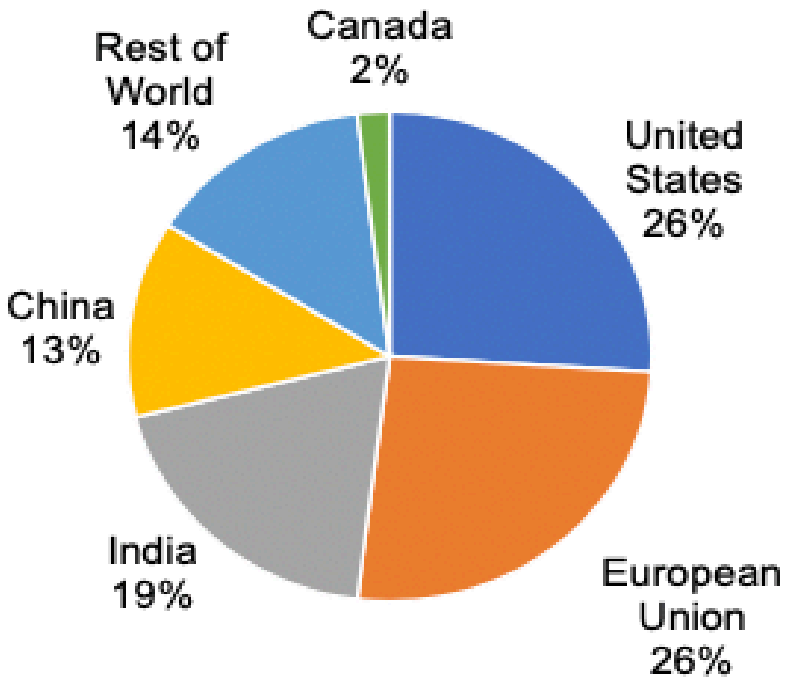
- Biopharmaceutical manufacturers must begin setting up the manufacturing supply chain for a medicine years before that medicine is approved for use by patients so changes can't be made quickly.

- Moving all manufacturing to the US would be detrimental to the supply chain because geographic diversity is essential, especially in time of pandemic or natural disaster.

- The US is not overly reliant on any 1 country for APIs.

The APIs Used in Medicines Come From a Diverse Supply Chain

Only 13% of API Manufacturing Facilities Are Located in China



Claims the United States is Highly Reliant on China for API Are Inaccurate

- FDA determined there are **only three medicines** on the WHO Essential Medicines list whose API manufacturers are solely based in China
- FDA has identified **only 20 medicines**[1] that solely source their API or medicine from China, and none of these have been deemed critical medicines
- The FDA is **not aware of any** cellular or gene therapies that are made in China for the U.S. market

Source: FDA, "COVID-19 and Beyond: Oversight of the FDA's Foreign Drug Manufacturing Inspection Process," June 2, 2020. https://www.fda.gov/news-events/congressional-testimony/covid-19-and-beyond-oversight-fdas-foreign-drug-manufacturing-inspection-process-06022020

MAT Can Help Patients Learn More About Their Medicine Costs

PhRMA member companies are committed to helping patients make more informed health care decisions by providing more transparency about medicine costs. Through MAT.org, we share links to member company websites that include:

List Price of a Medicine

Average Estimated or Typical Patient Out-of-pocket Costs

Other Context About Potential Cost of the Medicine

Each member company has individually and independently determined the content of any cost information provided on their websites.

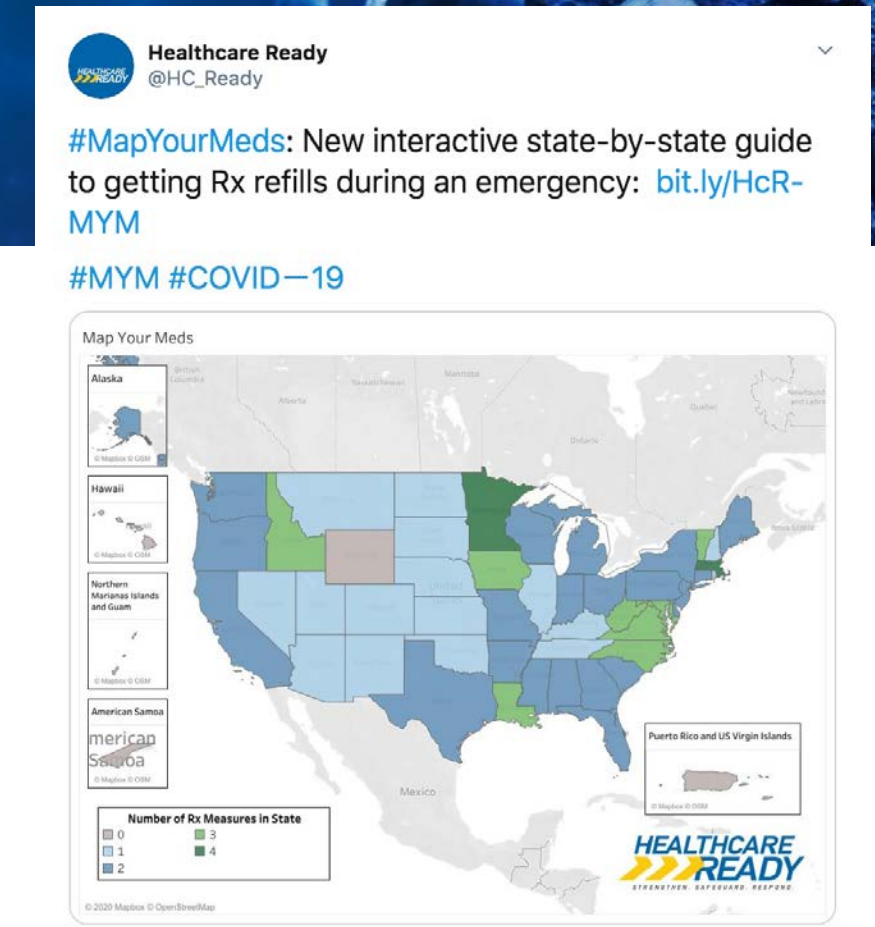
Healthcare Ready Programs for Constituents

Healthcare Ready Resources

RX OPEN: Provides access to open and closed pharmacies in a disaster-stricken area.

RX ON THE RUN: Personalized wallet card to document prescriptions and other important medical information.

COVID-19 Resource Hub: Resources for individuals and patients including state-level insurance emergency orders on prescription refills and telehealth coverage policies for COVID-19, and relevant pandemic business continuity resources.



QUESTIONS AND ANSWERS

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