PRESCRIPTION MEDICINES: COSTS IN CONTEXT

2015

PhRMA
RESEARCH • PROGRESS • HOPE

Delivering Value

BENEFITS OF MEDICINES TO PATIENTS, THE HEALTH CARE SYSTEM AND THE ECONOMY

Since 2000, biopharmaceutical companies have brought

MORE THAN 500 NEW TREATMENTS AND CURES

to U.S. patients

In the last 100 years, medicines have helped raise average U.S. life expectancy ***from 47 years to 78 years****

5 year cancer survival rates are ***up 39 percent across all cancers*****

Death rates for HIV/AIDS and cancer have fallen ***85 percent and nearly 22 percent since their peaks in 1995 and 1991******

New hepatitis C therapies have cure rates of ***more than 90 percent*******

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*Source: CDC
**Source: American Cancer Society
***Sources: CDC; NCI
****Source: FDA

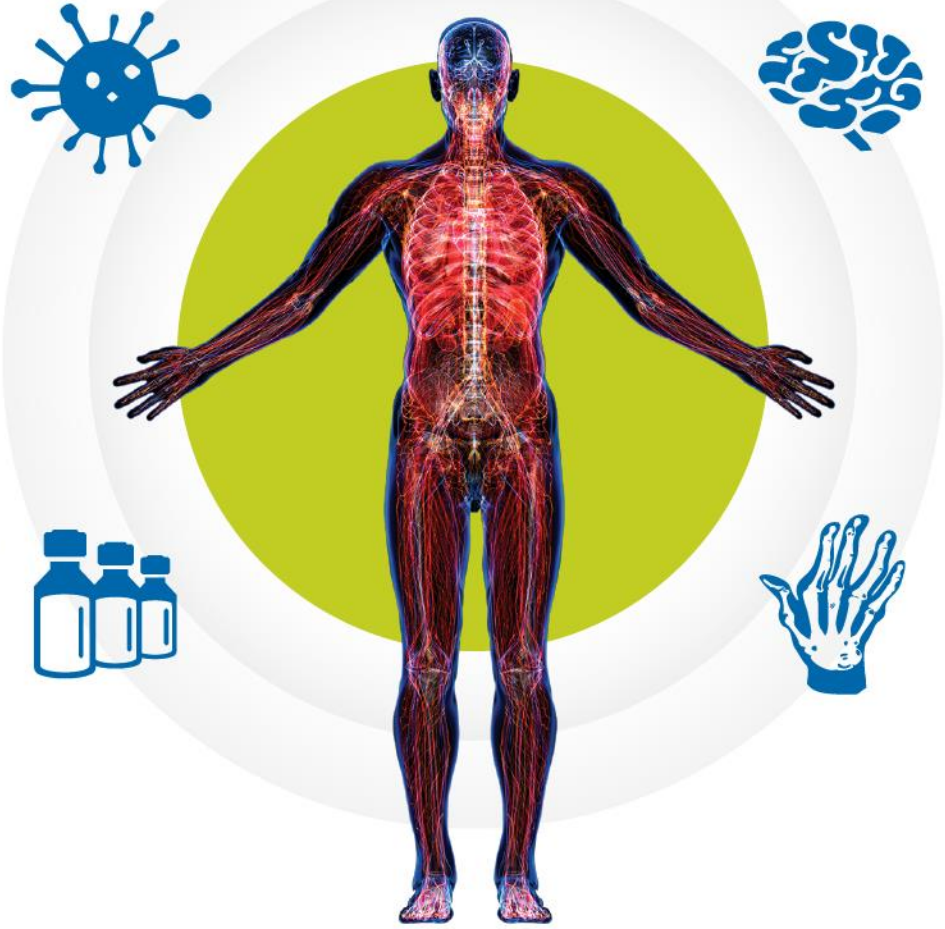
MEDICINES ARE TRANSFORMING THE TREATMENT OF MANY DIFFICULT DISEASES

HIV/AIDS

In the last two decades, advances in treatment have contributed to a more than 80% decline in death rates and transformed the disease from an acute, fatal illness to a chronic condition.

Cancer

New therapies have contributed to a 20% decline in cancer deaths since the 1990s. Today, 2 out of 3 people diagnosed with cancer survive at least 5 years.



Multiple Sclerosis

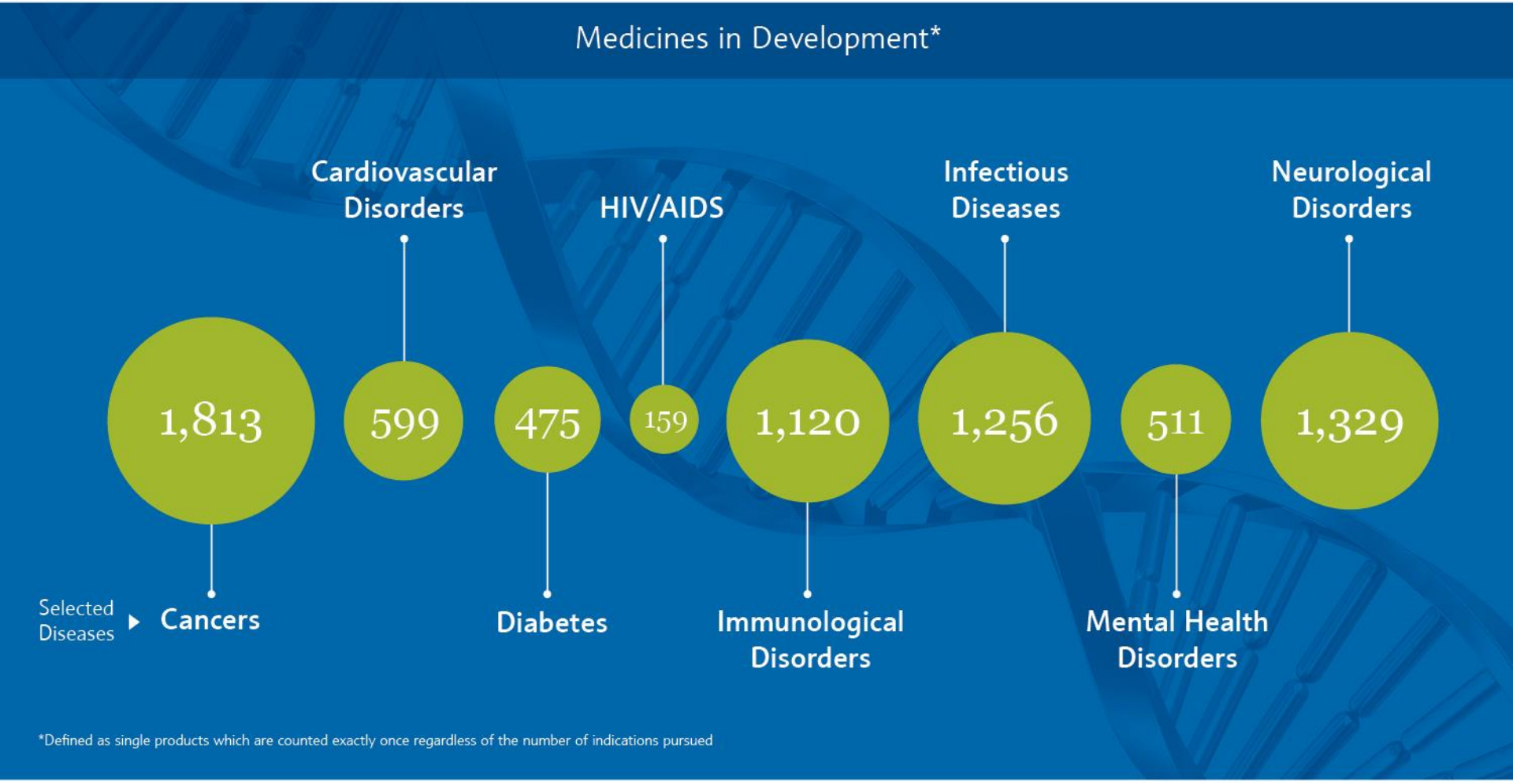
Oral and biologic treatments approved over the past 15 years have dramatically improved outcomes for MS patients, slowing disability progression and offering fewer relapses.

Rheumatoid Arthritis

Therapeutic advances have transformed the RA treatment paradigm over the last 20 years, from focusing on symptom management to now aiming for slowed disease progression and even disease remission.

TODAY MORE THAN 7,000 MEDICINES

are in development around the world



*Defined as single products which are counted exactly once regardless of the number of indications pursued

Source: Adis R&D Insight Database

Value of Medicines:

VALUE TO THE HEALTH CARE SYSTEM

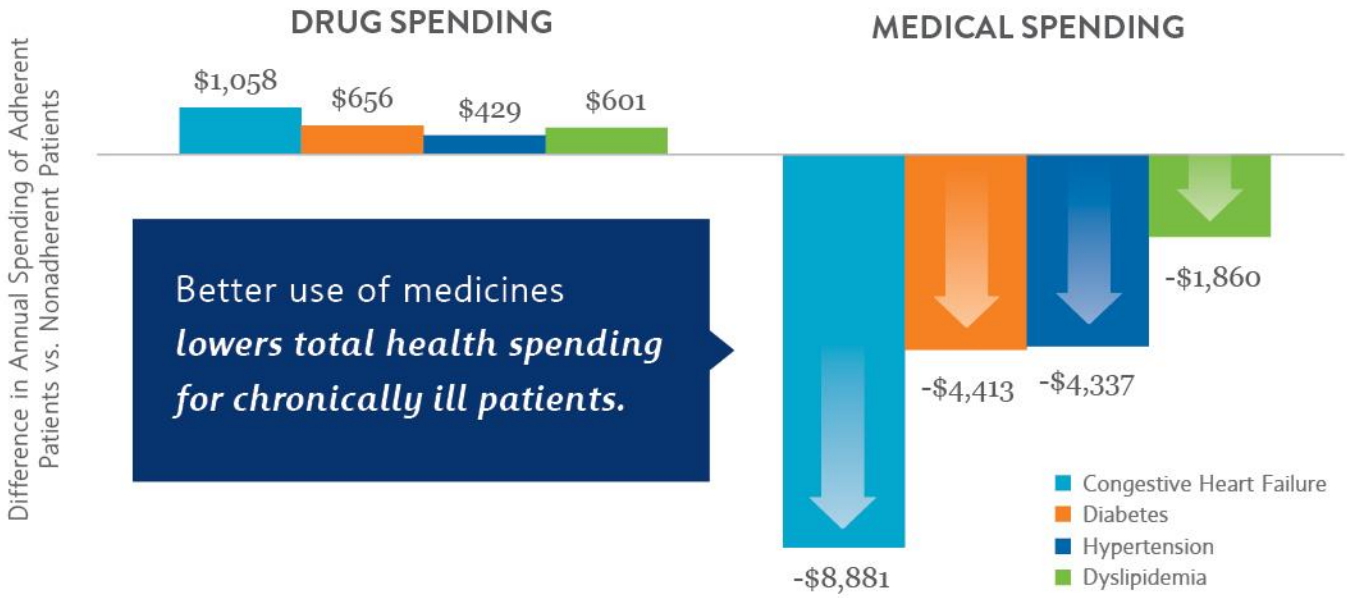
Incentivizing the development of new, innovative medicines is good for patients and society, and helps put our health care system on a more sustainable path.

Medicines save lives and help patients

AVOID EXPENSIVE HOSPITALIZATIONS AND EMERGENCY ROOM VISITS

THE U.S. HEALTH CARE SYSTEM COULD SAVE $213 BILLION ANNUALLY IF MEDICINES WERE USED PROPERLY*

Adherence to Medicines Lowers Total Health Spending for Chronically Ill Patients**



*Source: IMS Institute for Healthcare Informatics. Avoidable costs in US healthcare: the $200 billion opportunity from using medicines more responsibly.;
**Source: Roebuck MC, et al. Medication adherence leads to lower drug spending. *Health Affairs*. 2011;30(1):-99.

Medicine Use Yields

SIGNIFICANT HEALTH GAINS AND SAVINGS ON OTHER SERVICES

Due to a growing body of evidence, the Congressional Budget Office (CBO) began recognizing reductions in non-drug expenditures associated with increased use of prescription medicines in Medicare.

> "Pharmaceuticals have the effect of improving or maintaining an individual's health...adhering to a drug regimen for a chronic condition such as diabetes or high blood pressure may prevent complications...taking the medication may also avert hospital admissions and thus reduce the use of medical services."
>
> –CONGRESSIONAL BUDGET OFFICE

Researchers also found that gaining Medicare Part D prescription drug coverage was tied to an

8% decrease

IN HOSPITAL ADMISSIONS

for seniors overall, with higher reductions for certain conditions*

*Source: Kaestner R, et al. Effects of prescription drug insurance on hospitalization and mortality: evidence from Medicare Part D. The National Bureau of Economic Research.

The cost of disease could bankrupt the United States health care system,

WITHOUT NEW MEDICINES

Estimated 10-Year Savings to Medicare From Improved Adherence to Congestive Heart Failure Medications, 2013-2022

$22.4 billion

Savings to Medicare if adherence reached recommended levels

$367 billion

The amount America would save in health services by 2050 if we develop a new medicine that delays the onset of Alzheimer's disease by

just five years

Sources: Dall TM et al. The economic impact of Medicare part D on congestive heart failure. *Am J Manag Care.* 2013;19:S97-S100.; Alzheimer's Association

HIV/AIDS:

As Treatment Improved Spending Became Sustainable

1989

The New York Times

September 15, 1989

AIDS Treatment Costs Put at $5 Billion a Year

"We have got to get our act together now because the medical system is going to be crushed in two years."

–Daniel Hoth, director of the division of AIDS at the National Institute for Allergy and Infectious Diseases

"If we don't act now, we will be soon rationing health by queuing," ...

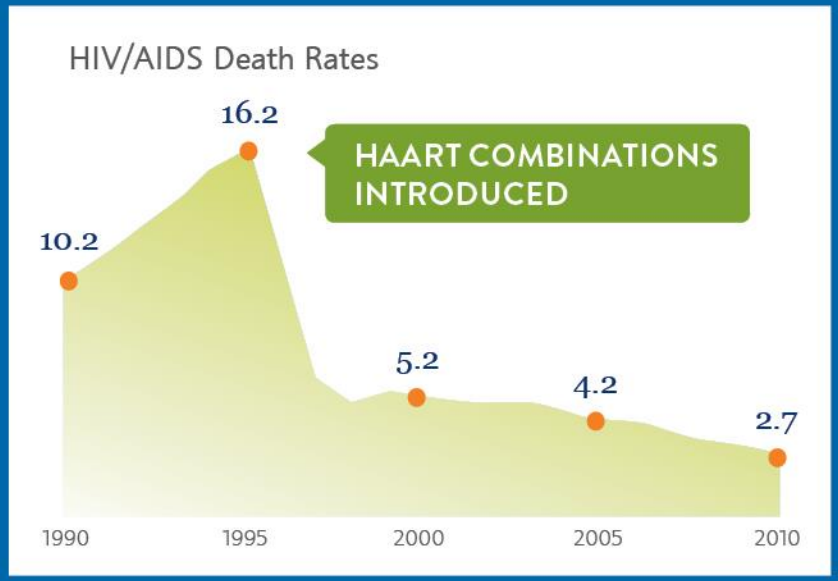
"People will wait longer and longer in the emergency rooms, more people will die, the whole level of care will decrease significantly." He called it "a downward spiral of effects which we cannot afford."

–Dr. Douglas Shenson, Montefiore Medical Center

Today

"WE USED TO THINK HIV COSTS WOULD OVERWHELM US....BUT WE FIGURED IT OUT AND LET DRUG DEVELOPMENT PROGRESS."

– Ira Klein, M.D., M.B.A., FACP, Aetna



Value of Medicines:

ECONOMIC VALUE

The biopharmaceutical industry serves as a foundation of one of the country's most dynamic innovation and business ecosystems.

THE ECONOMIC REACH

of the US Biopharmaceutical Industry

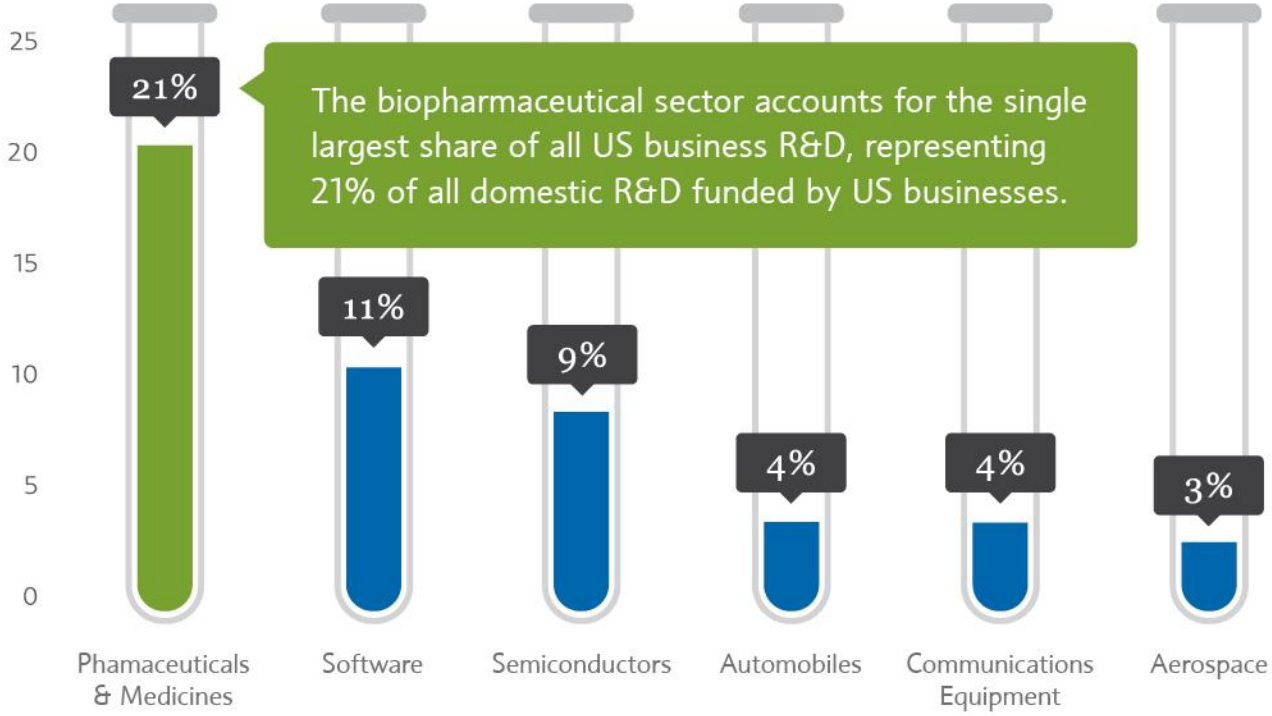
THE BIOPHARMACEUTICAL INDUSTRY SUPPORTED 3.4 MILLION JOBS ACROSS THE US ECONOMY IN 2011.

3,364,000 TOTAL JOBS

The Biopharmaceutical Sector Is the

SINGLE LARGEST FUNDER OF BUSINESS R&D IN THE UNITED STATES

Share of Total US Business R&D by Industry, 2011*



The remaining 48% share of business R&D spending is conducted by other industries including subsectors of the machinery sector, the electrical equipment sector, and the professional, scientific, and technical services sector among others.

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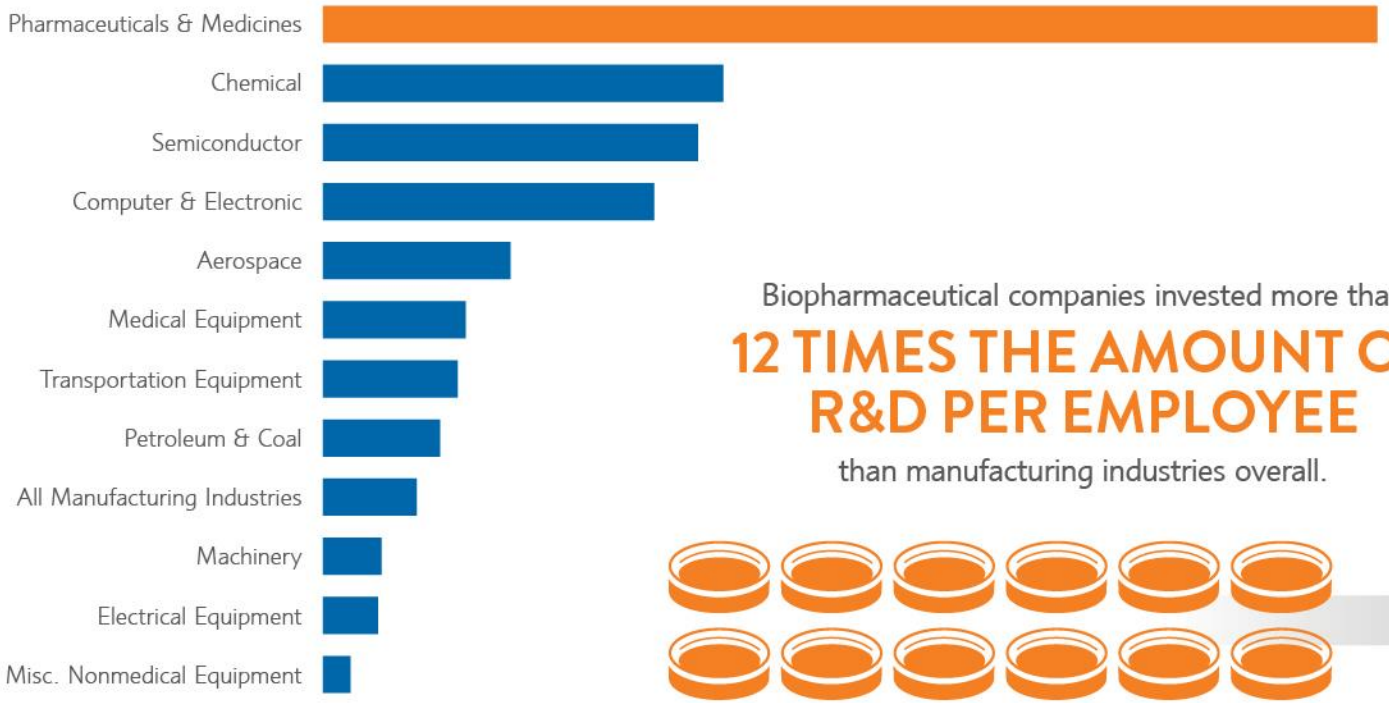
*Source: National Science Foundation

The Biopharmaceutical Sector Is the

MOST R&D INTENSIVE IN THE UNITED STATES

R&D Expenditures per Employee, by Manufacturing Sector and Industry, 2000-2010



Biopharmaceutical companies invested more than

12 TIMES THE AMOUNT OF R&D PER EMPLOYEE

than manufacturing industries overall.

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Source: NDP Analytics

Biopharmaceutical Companies Do the

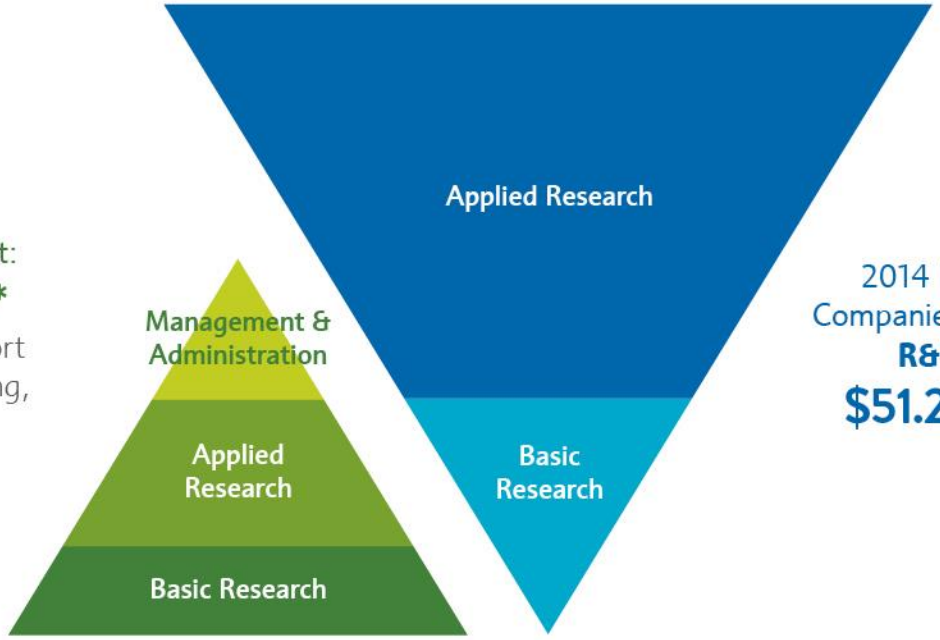
VAST MAJORITY OF RESEARCH TO TRANSLATE BASIC SCIENCE INTO NEW MEDICINES

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

2014 **TOTAL** NIH Budget:

$30.1 BILLION*

includes funding in support of medical devices, training, and other activities



2014 PhRMA Member Companies Biopharmaceutical **R&D** Investment:

$51.2 BILLION**

*Total National Institutes of Health (NIH) spending is for fiscal year 2014. In addition to funding for basic and applied research, the total NIH budget includes funding in support of prevention (eg, suicide prevention), diagnostics and medical devices, superfund activities, training and education (eg, dental), program evaluation, management and support, buildings and facilities, and other activities.
**PhRMA member companies' R&D spending is estimated for calendar year 2014. PhRMA member companies account for the majority of private biopharmaceutical R&D spending. Nonmember company data are not included.

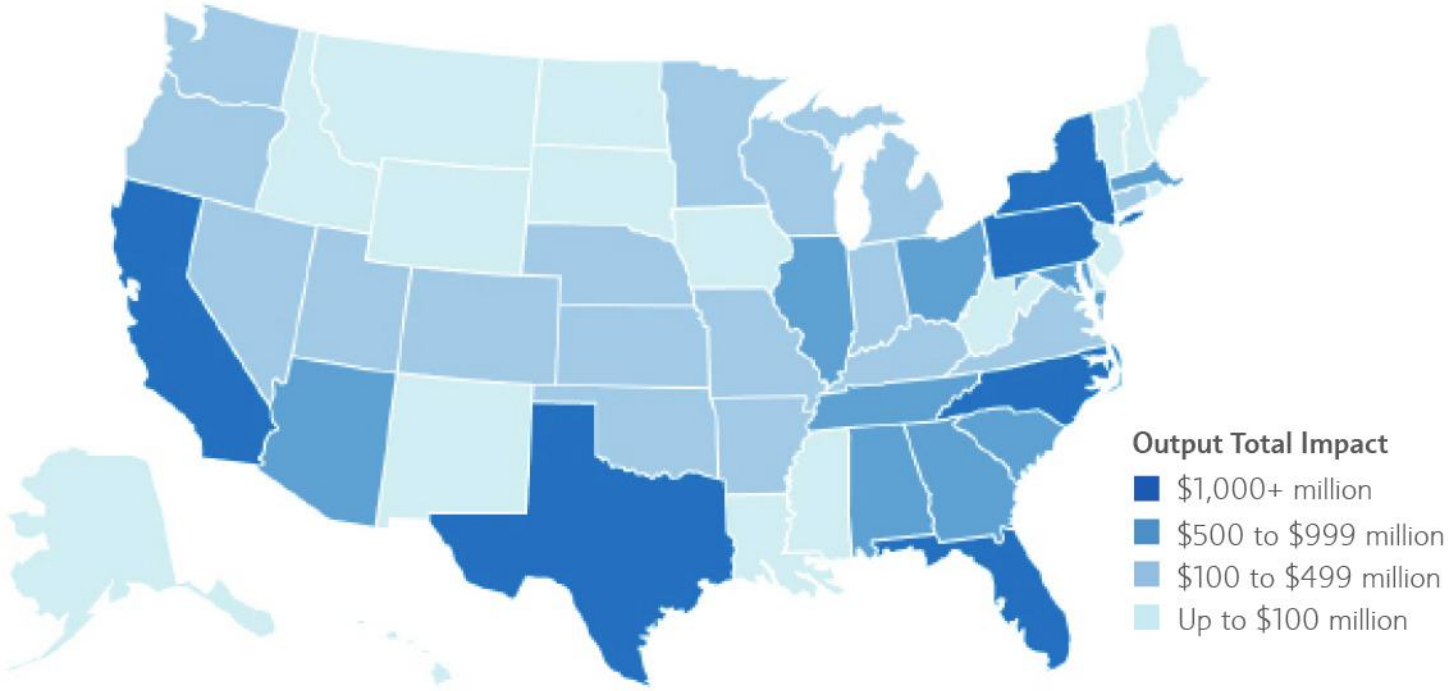
1.Chakravarthy R, et al. Public and private sector contributions to the research & development of the most transformational drugs of the last 25 years. http://csdd.tufts.edu/files/uploads/PubPrivPaper2015.pdf. Boston, Mass.: Tufts Center for the Study of Drug Development; January 2015. Accessed March 2015.
2. Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA annual membership survey. Washington, DC: PhRMA; 2015.
3. National Institutes of Health (NIH), Office of Budget. 2016 budget roll out. http://www.nih.gov/about/director/budgetrequest/fy2016_directorsbudgetrequest_slides.pdf. Bethesda, Md.: NIH; 2015. Accessed March 2015.

Industry-Sponsored Clinical Trials Contribute

SIGNIFICANT VALUE TO THE COMMUNITIES IN WHICH THEY ARE LOCATED

In 2013, the biopharmaceutical industry sponsored **6,199 clinical trials** of medicines in the United States, involving a total of **1.1 million volunteer participants** and supporting a total of **$25 billion in economic activity** spread across all 50 states and the District of Columbia.*

Estimated Economic Impact from Industry-Sponsored Clinical Trial Sites Across the United States, 2013

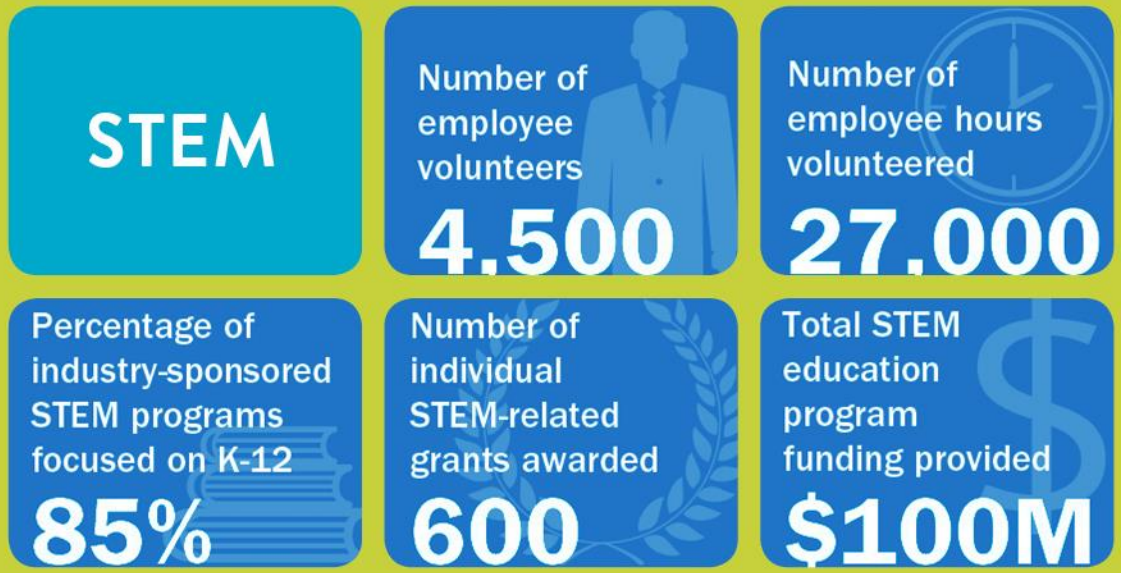


Source: Battelle Technology Partnership Practice

BIOPHARMACEUTICAL INDUSTRY ADVANCING STEM EDUCATION IN THE UNITED STATES

The science, technology, engineering, and mathematics (STEM) workforce accounts for **more than 50% of the nation's sustained economic growth**. From 2008 to 2012, PhRMA member companies and their foundations supported **more than 90 STEM education programs** across the United States, impacting **more than 1.6 million students and 17,500 teachers**.

PhRMA member company and foundation contributions to STEM education in the United States include:



Source: Battelle Technology Partnership Practice

Biopharmaceutical Companies

LEAD CORPORATE GIVING

Biopharmaceutical companies led worldwide corporate giving* in 2013.

NINETY PERCENT OF THESE CONTRIBUTIONS WERE IN THE FORM OF IN-KIND PRODUCT DONATIONS.

Average Corporate Giving by Sector	Total Giving as % of Pre-Tax Profit	Total Giving per Employee
ALL COMPANIES	1.0%	$644
BIOPHARMACEUTICALS	**19.4%**	**$24,453**
ENERGY	0.8%	$2,912
UTILITIES	1.2%	$1,092
INFORMATION TECHNOLOGY	1.1%	$666
CONSUMER STAPLES	1.1%	$608
INDUSTRIALS	0.8%	$244

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Source: Committee Encouraging Corporate Philanthropy

Putting Prescription Drug Spending in Context

RX COSTS HISTORICALLY AND GOING FORWARD

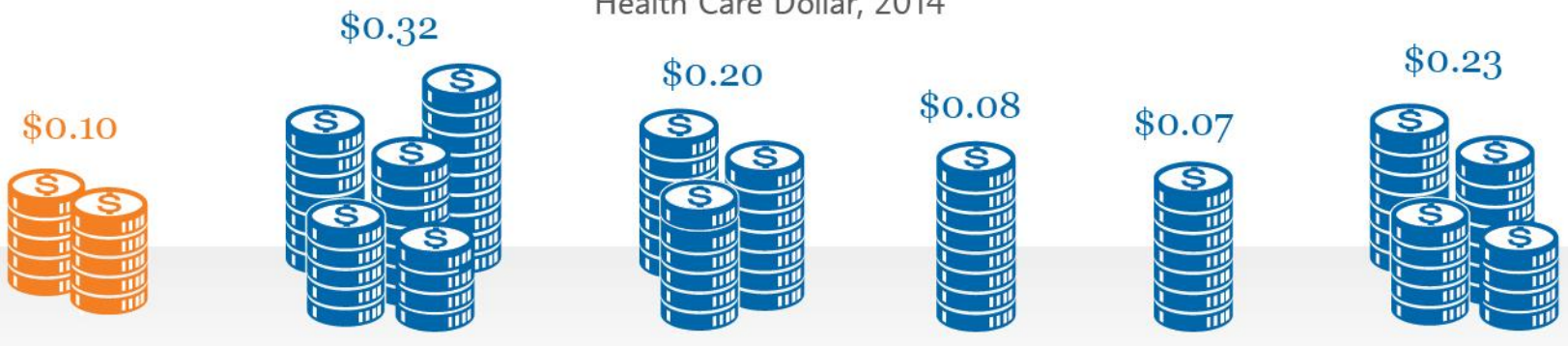
Spending on retail prescription medicines is

THE SAME PERCENTAGE OF HEALTH CARE SPENDING TODAY AS IN 1960 – 10%

Retail spending on prescription medicines is

A SMALL SHARE OF TOTAL U.S. HEALTH CARE SPENDING

Health Care Dollar, 2014



Prescription medicines today account for just 10 PERCENT OF HEALTH CARE SPENDING

*Other includes dental, home health, and other professional services as well as durable medical equipment costs.

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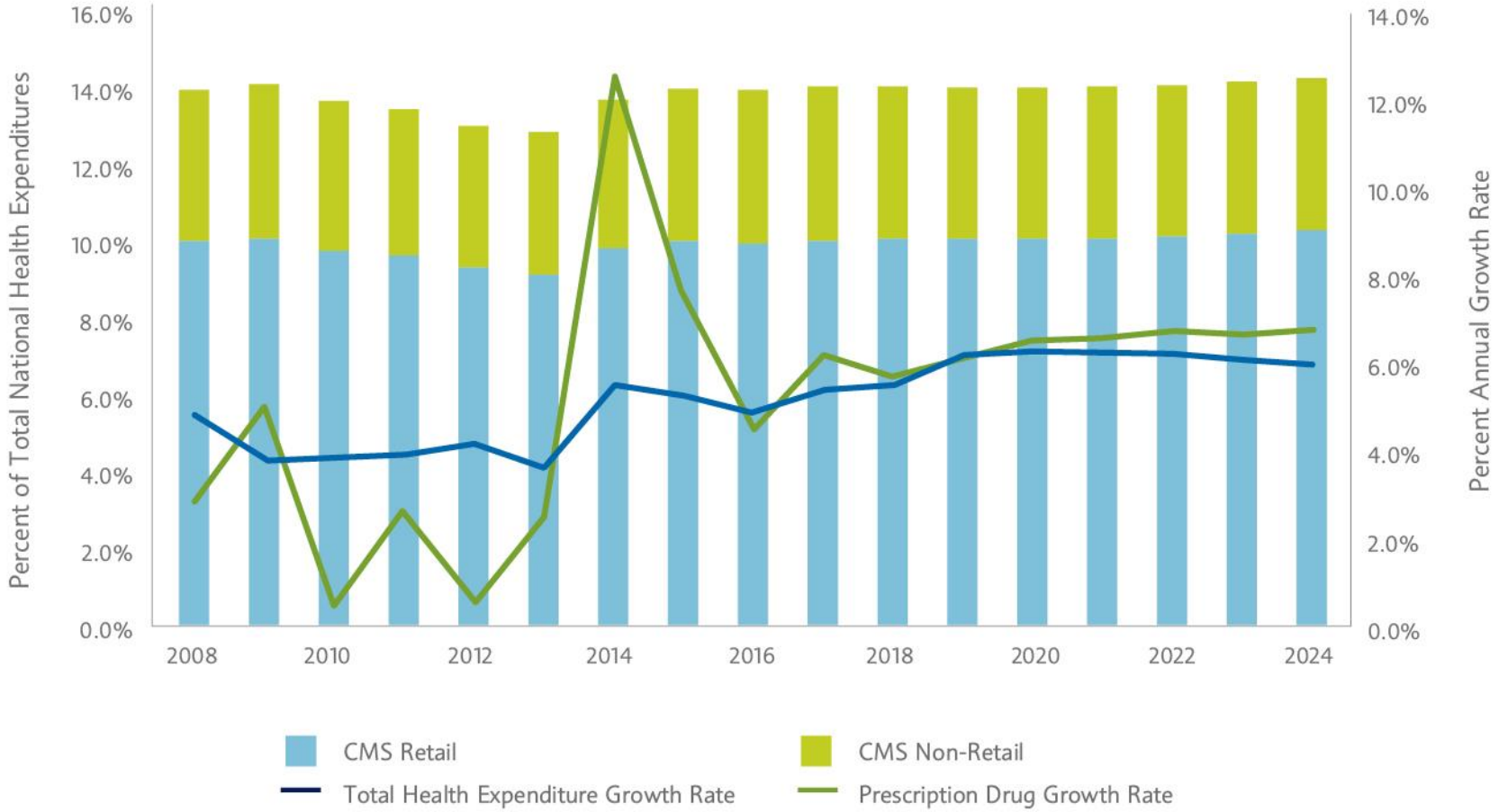
Source: PhRMA analysis based of CMS data. National health expenditures by type of service and source of funds, CY 1960-2013.

Projected Total Spending on

RETAIL AND NON-RETAIL BRAND & GENERIC MEDICINES AND PHARMACY COSTS, THROUGH 2024



Source: Altarum Institute and 2014 CMS National Health Expenditures Report

TO PUT SPENDING ON MEDICINES IN PERSPECTIVE

Private insurers spent nearly as much on medicines as on administrative costs in 2013 and the U.S. will spend $13.5 trillion on hospital care over the next decade

That's more than three times the total spending on prescription medicines

HEALTH CARE SPENDING

MEDICINE SPENDING

HOSPITAL CARE SPENDING

Source: PhRMA analysis based of CMS data. National health expenditures by type of service and source of funds, CY 1960-2013.

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HEALTH CARE SPENDING

MEDICINE SPENDING

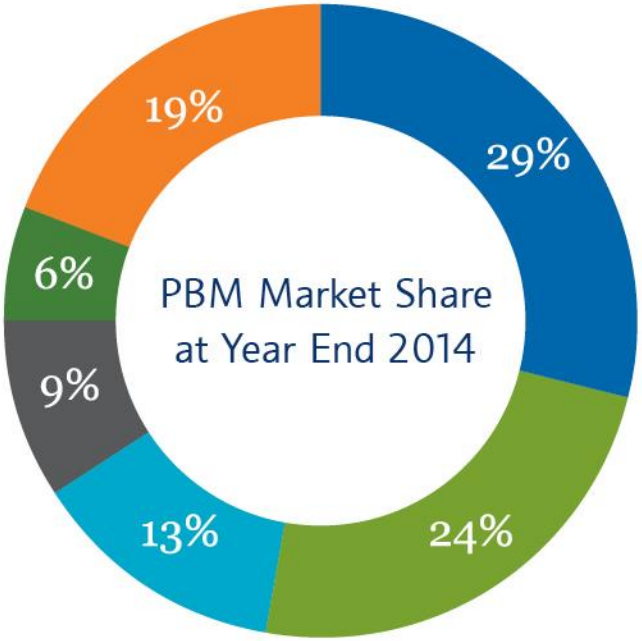
HOSPITAL CARE SPENDING

Source: PhRMA analysis based of CMS data. National health expenditures by type of service and source of funds, CY 1960-2013.

POWERFUL PURCHASERS NEGOTIATE ON BEHALF OF PATIENTS

Negotiating power is increasingly concentrated among fewer benefit managers, with the

TOP FIVE PBMS INCREASING THEIR MARKET SHARE TO OVER 80%.



PBMs
TOP 5 MARKET SHARE 81%

- Express Scripts, Inc.
- CVS Caremark
- OptumRx
- Catamaran Corporation
- Prime Therapeutics Inc.
- All Else

*OptumRx and Catamaran Corp. will merge to UnitedHealth Group in fall of 2015
Sources: Drug Channel Institute Study Jan. 2015
IMS Institute for Healthcare Informatics Health Study: 2014

CASE STUDY

Manufacturer-payer hepatitis C negotiations

What Payers Claimed Would Happen

"What they have done with this particular drug will break the country.... It will make pharmacy benefits no longer sustainable. Companies just aren't going to be able to handle paying for this drug."

–EXPRESS SCRIPTS (APRIL 2014)

"This pricing, which Gilead attempts to justify as the cost of medical advancement, will have a tsunami effect across our entire health care system."

–AMERICA'S HEALTH INSURANCE PLANS (JULY 2014)

What Actually Happened

"The price is sufficiently low that we can go to our clients and say that they can treat every patient with hepatitis C."

–EXPRESS SCRIPTS (JANUARY 2015)

"We are receiving market-leading rates from both companies. Neither company wanted to be left off the formulary."

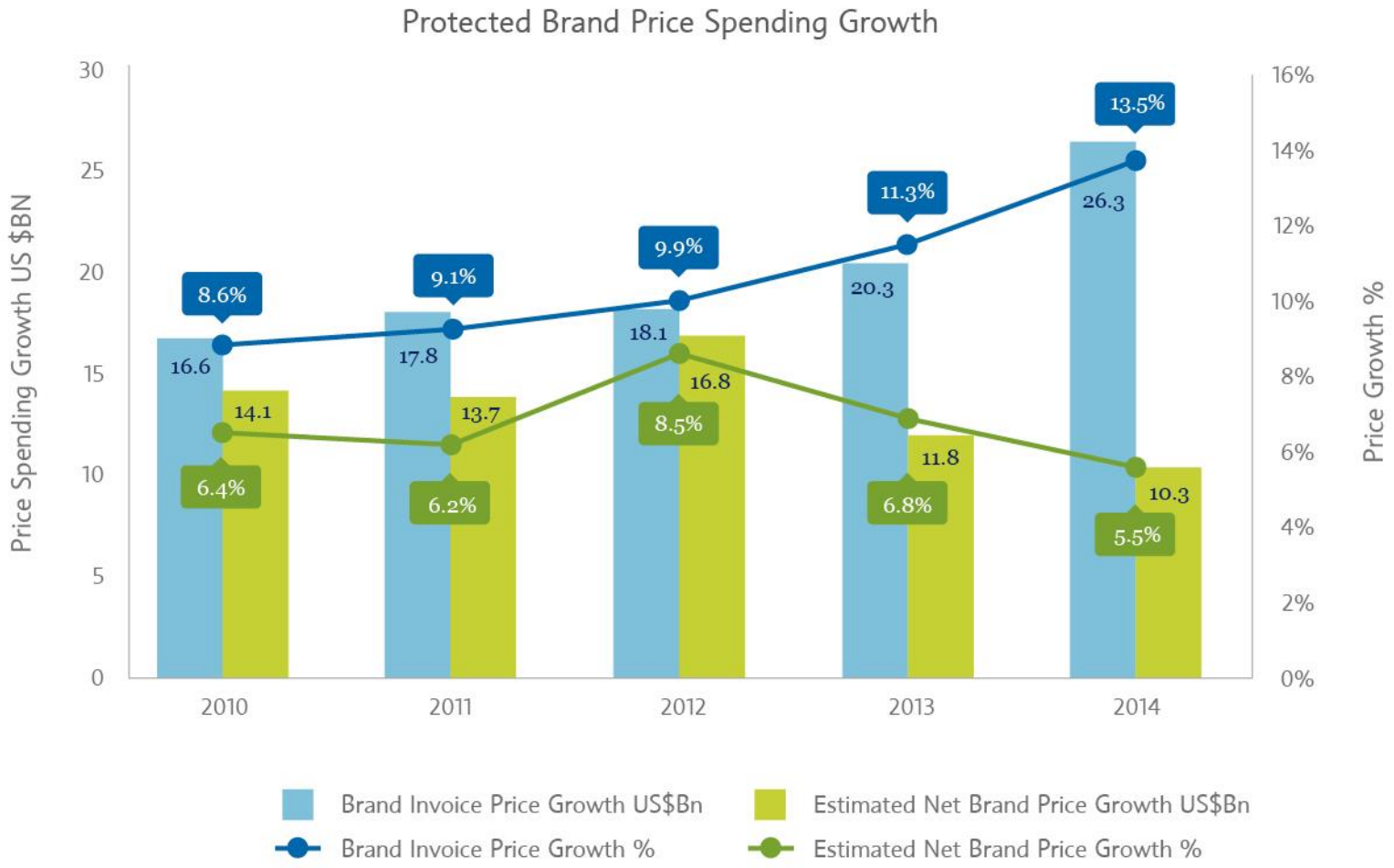
–PRIME THERAPEUTICS (JANUARY 2015)

"Competitive market forces and hard-nosed bargaining" make 'tremendously effective' new hepatitis C medicines not just more accessible to ailing patients – but also offer good value to the U.S. health care system."

–THE NEW YORK TIMES EDITORIAL BOARD (SEPTEMBER 2015)

Invoiced Prices Increased in 2014,

BUT WERE OFFSET BY REBATES AND OTHER PRICE CONCESSIONS

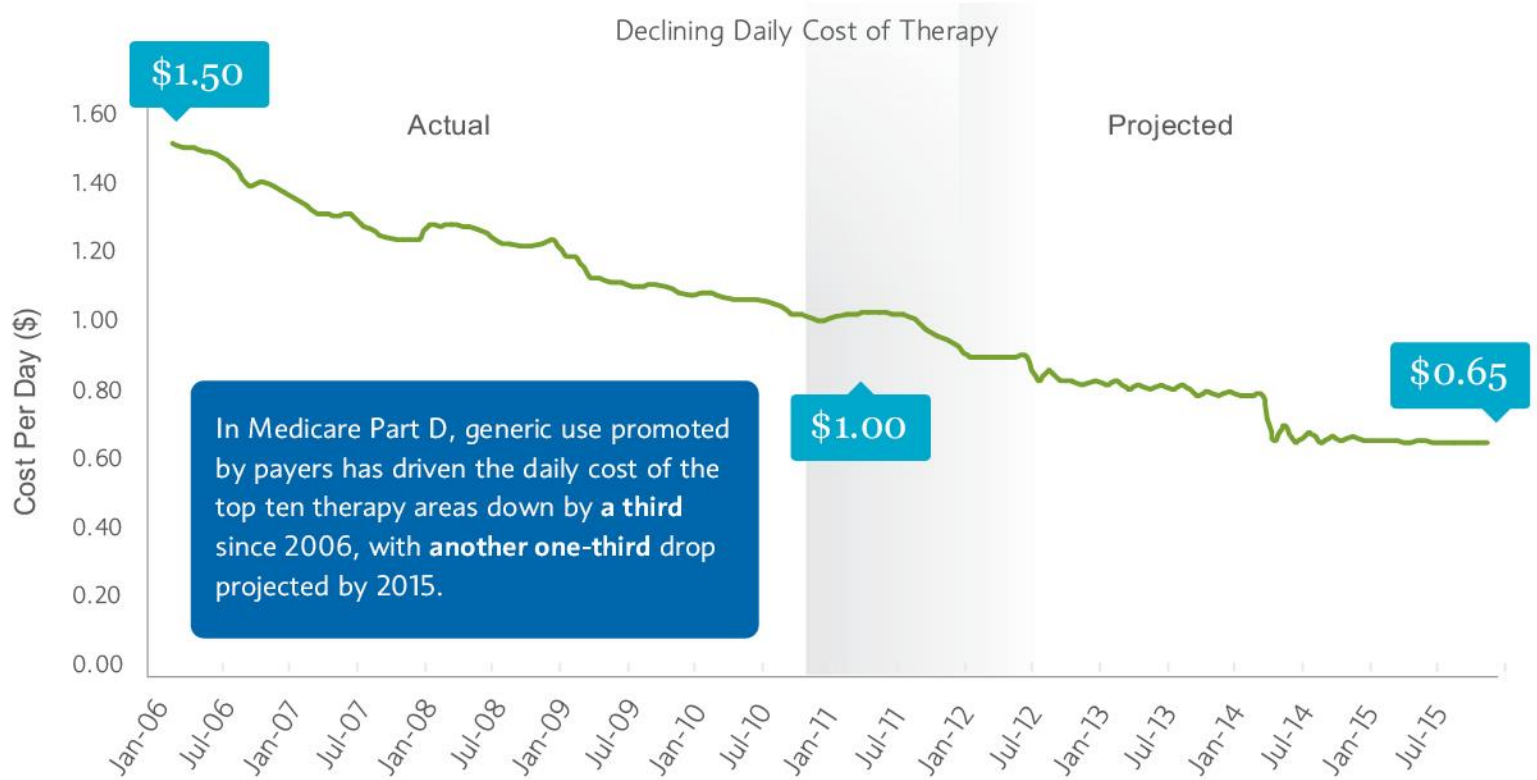


Source: IMS Health, National Sales Perspectives, Dec 2014

The U.S. System Promotes Innovation and Affordability through

THE PRESCRIPTION DRUG LIFE CYCLE

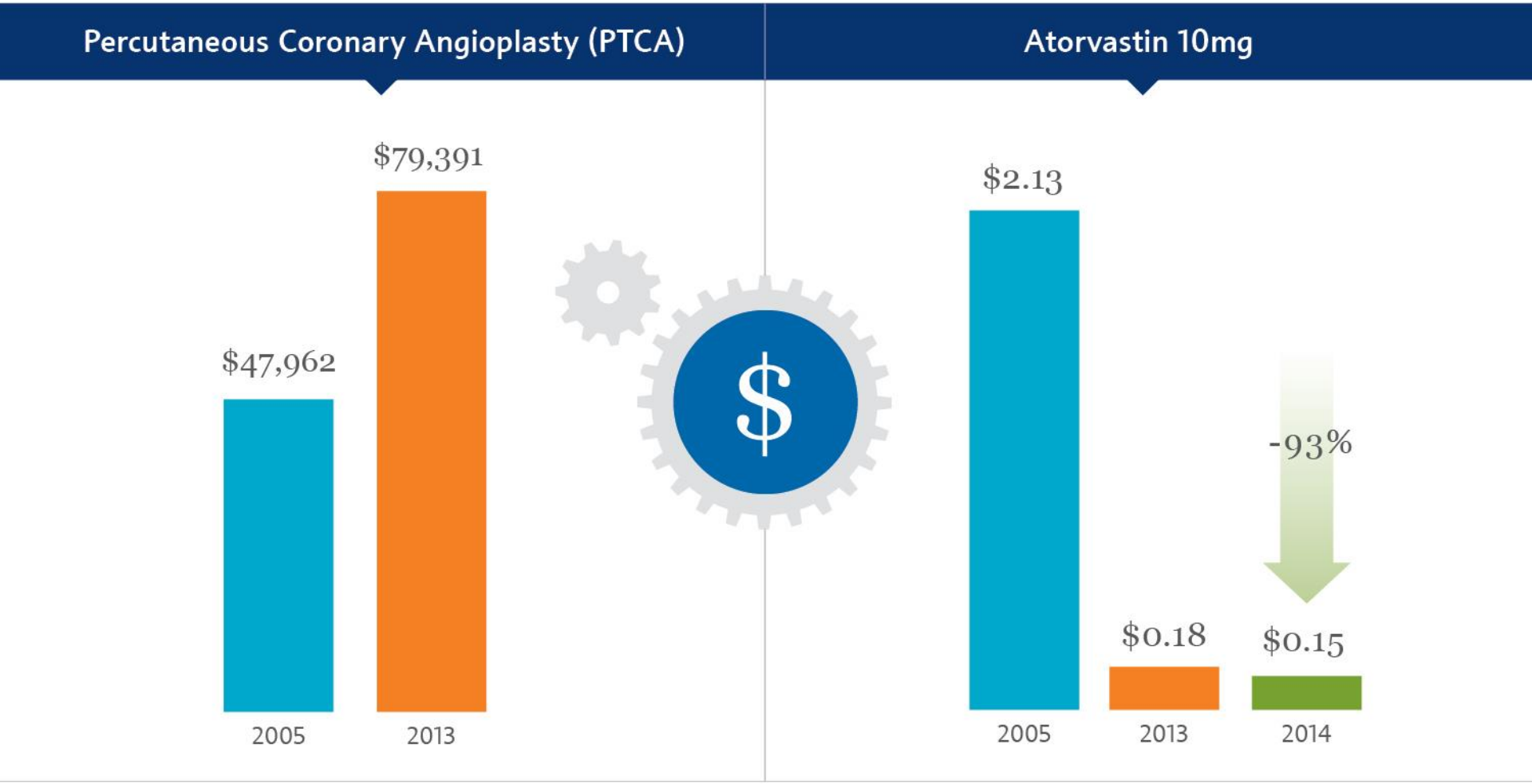
In the U.S. system, innovator pharmaceutical companies produce medical advances, leading to improved health for patients and, over time, generic copies that consumers use at low cost for many years.



Source: Kleinrock M. Daily cost of Medicare Part D. December 2013. IMS Institute for Healthcare Informatics.

Cost of Medical Procedures Continue to Rise, but

COST CONTAINMENT IS BUILT INTO DRUG PRICING LIFE CYCLE



Data adapted from: HCUP Hospital Charge database 2005 and 2013, average Hospital Charges Atorvastatin 10mg – IMS National Sales Perspective (NSP) Invoice price in 2005 (branded Lipitor), 2013 (generic), and 2014 (generic)

Example

THEN & NOW

How Prescription Drug Prices Fall Significantly Over Time

Biopharmaceutical companies invest in pioneering research to bring new treatments to patients, and over time those medicines become available as lower-cost generic copies.

MEDICINE		BRAND NAME THEN	VS.	GENERIC NOW	% CHANGE
DIOVAN HCT® *Hypertension*	2010	$87		$13	-85%
LIPITOR® *Cholesterol*	2010	$85		$4	-95%
PLAVIX® *Blood Thinner*	2011	$166		$5	-97%
SEROQUEL® *Schizophrenia*	2010	$87		$3	-97%
ZYPREXA® *Schizophrenia & Bipolar Disorder*	2010	$393		$8	-98%

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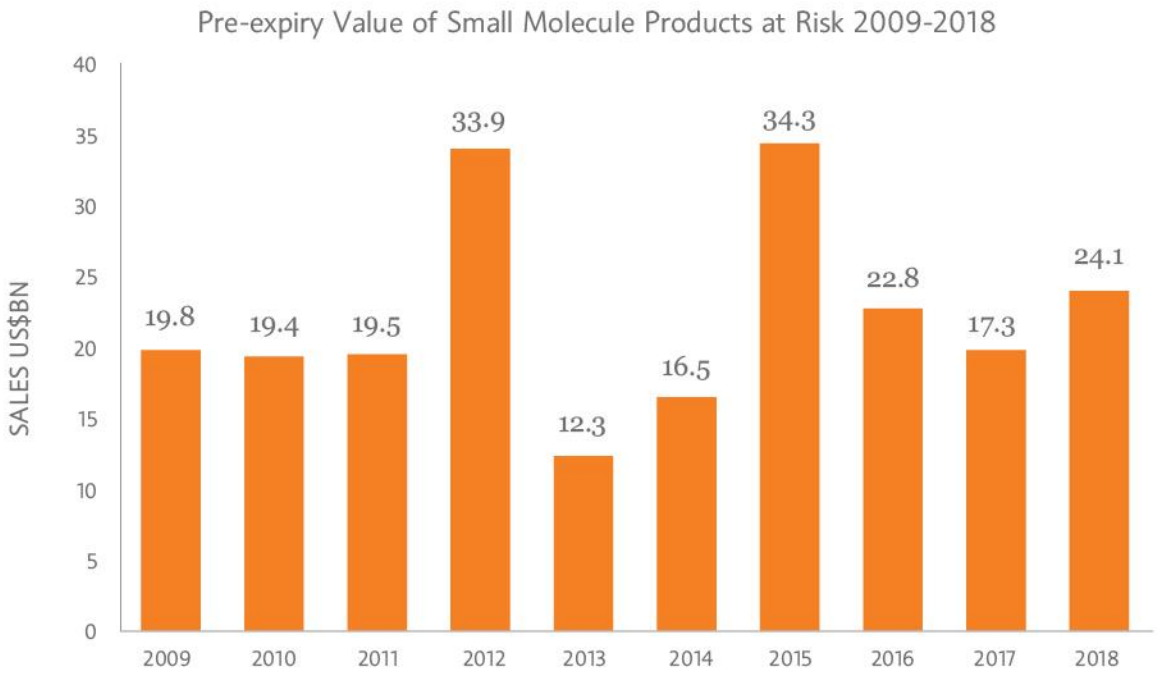
Figures represent the average annual price for 30 pills of the most commonly dispensed form and strength.
"Then" price represents the average price in the year prior to generic entry. "Now" price represents the average price in CY 2014.
Source: IMS analysis for PhRMA, May 2015

$115 Billion of U.S. Brand Sales Projected to

FACE GENERIC COMPETITION FROM 2014 TO 2018

Similar exposure in coming years to the $105Bn loss in 2009-13 (the "patent cliff") underscores continuing cost containment in the pharmaceutical sector



Estimates exclude additional impact of biosimilars entering the market; analysts estimate nearly 3/4 of biologic expenditures are at-risk due to loss of exclusivity before 2017

Notes: Pre-expiry sales of products are calculated for products losing exclusivity (LOE) in each year, the sales in the prior year for each product are aggregated to represent the collective industry exposure to LOE. Loss of exclusivity does not indicate generic market entry. Small molecule losses of exclusivity only.

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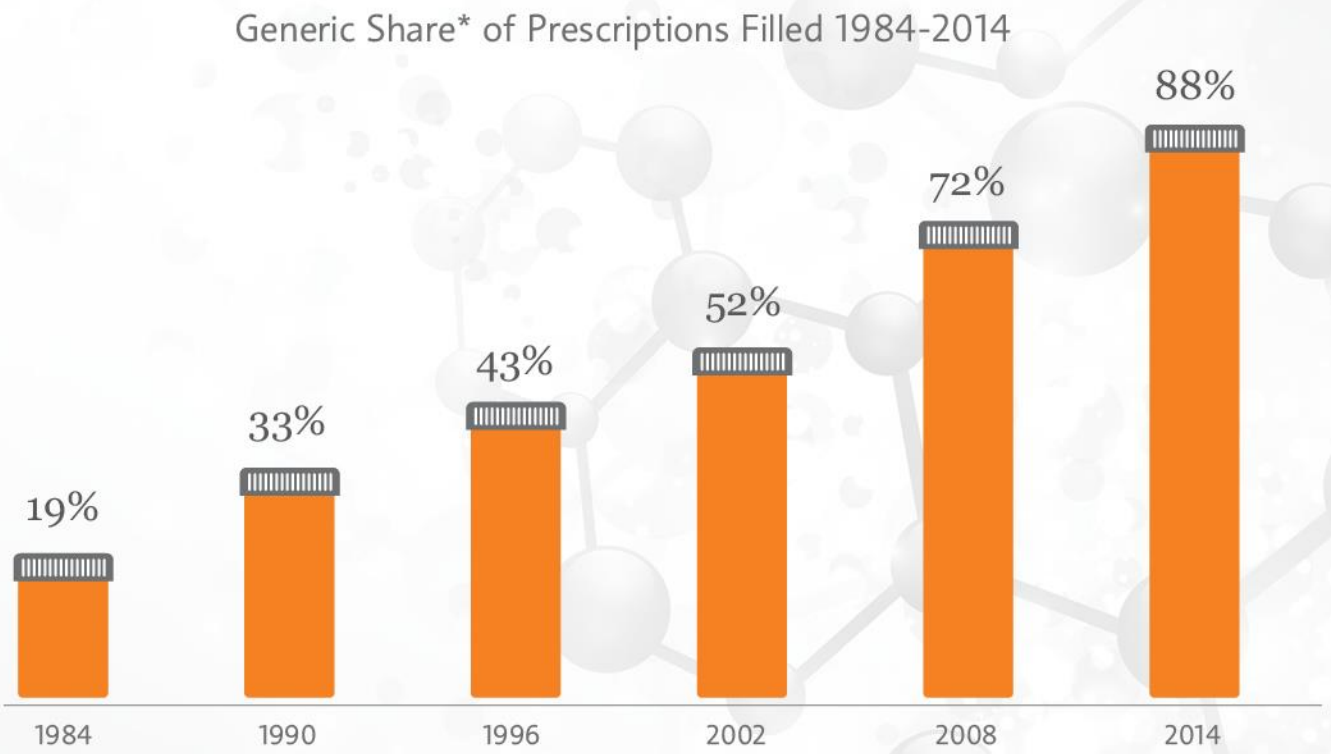
Source: IMS MIDAS, Market Prognosis, Sep 2014

Nearly 9 Out of Every 10 US Prescriptions

ARE FILLED WITH GENERICS

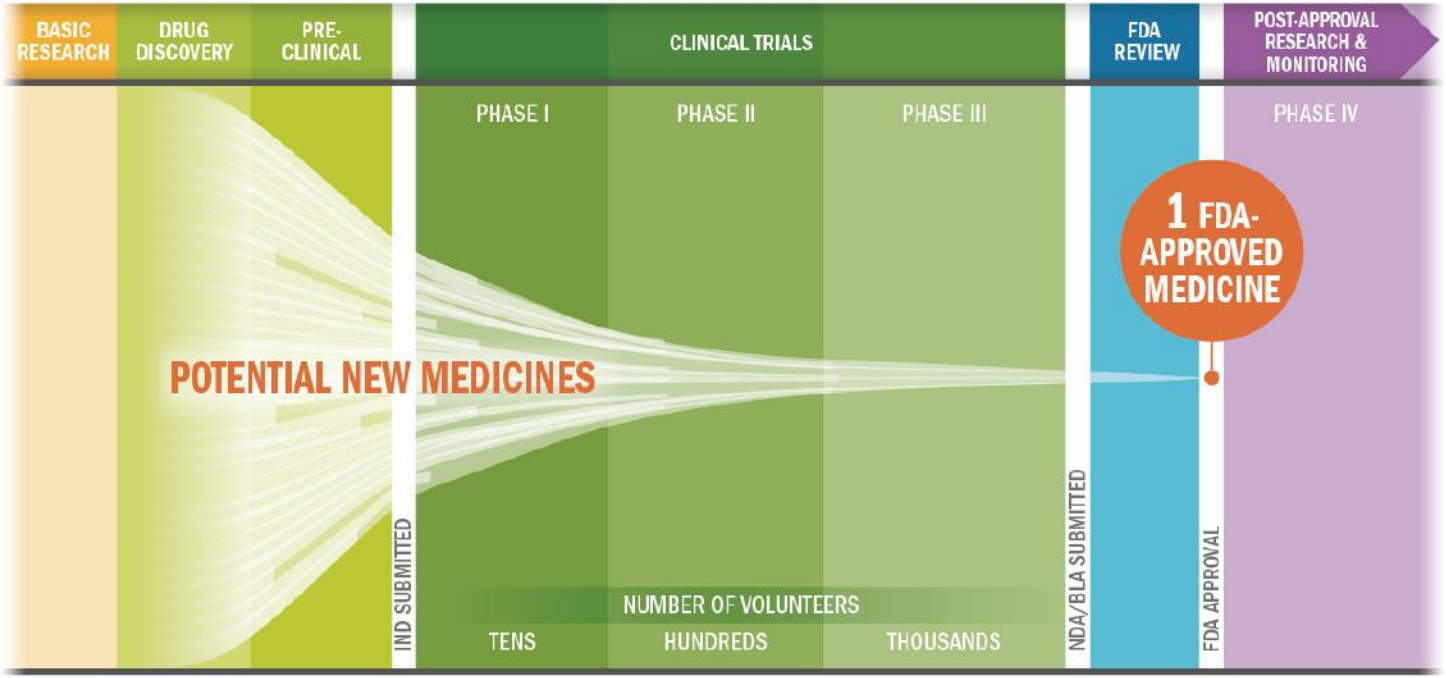


Source: IMS Health

RECOGNIZING CHALLENGES & CHANGES IN THE MARKETPLACE

THE BIOPHARMACEUTICAL RESEARCH AND DEVELOPMENT PROCESS

From drug discovery through FDA approval, developing a new medicine on average takes at least 10 years and costs between $2.6 billion. Less than 12% of the candidate medicines that make it into phase I clinical trials will be 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.

Medicines offer great hope, but developing

NEW TREATMENTS AND CURES IS CHALLENGING

On average, it takes more than

10 YEARS AND MORE THAN $2.6B TO RESEARCH AND DEVELOP A NEW MEDICINE*

BETWEEN 1998 AND 2014**

UNSUCCESSFUL ATTEMPTS

123
ALZHEIMER'S DISEASE

96
MELANOMA

167
LUNG CANCER

JUST

12%

of drug candidates that enter clinical testing are approved for use by patients*

SUCCESSFUL ATTEMPTS

4
ALZHEIMER'S DISEASE

7
MELANOMA

10
LUNG CANCER

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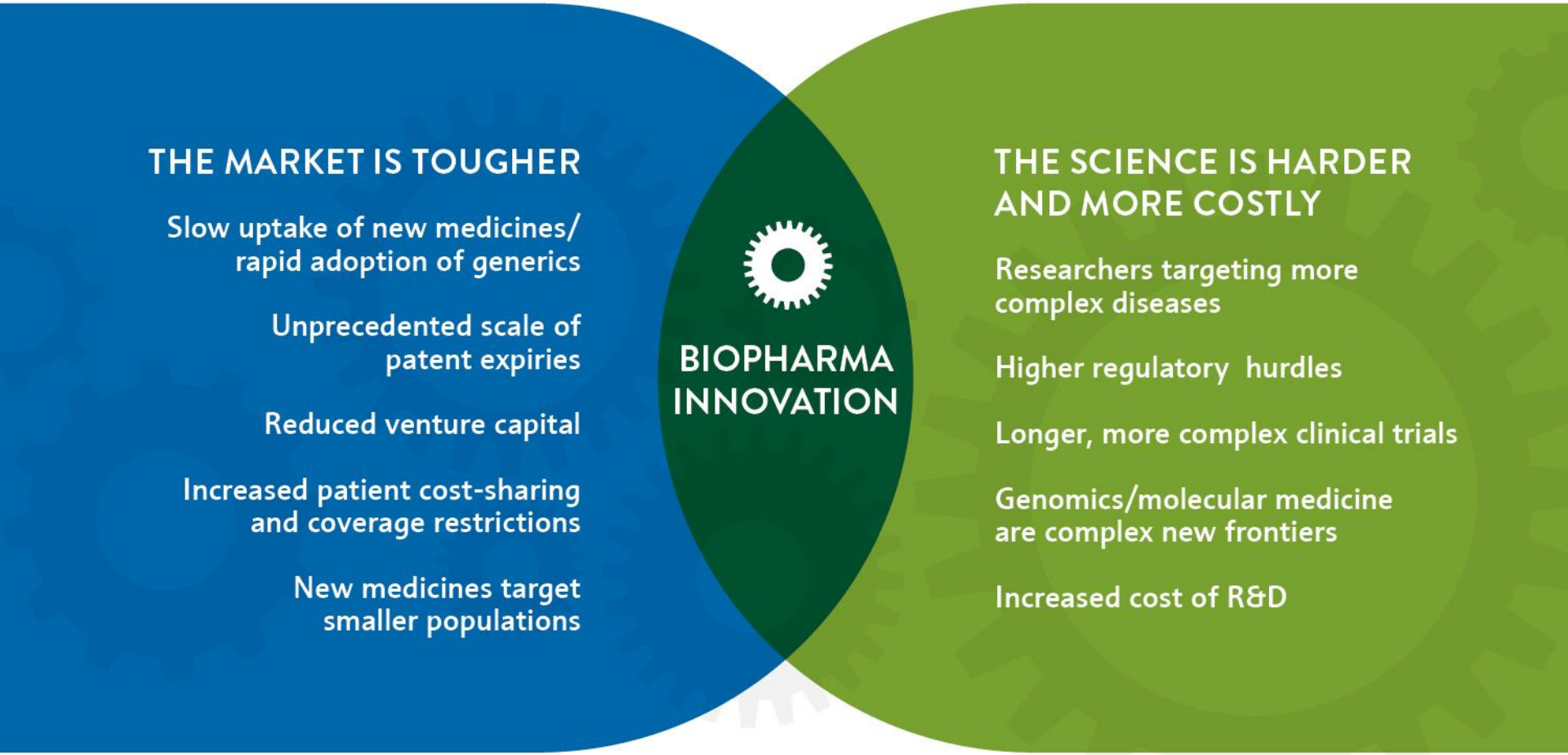
*Source: Tufts Center for the Study of Drug Development (CSDD)
**Source: PhRMA

DESPITE GREAT PROGRESS, CHALLENGES LOOM

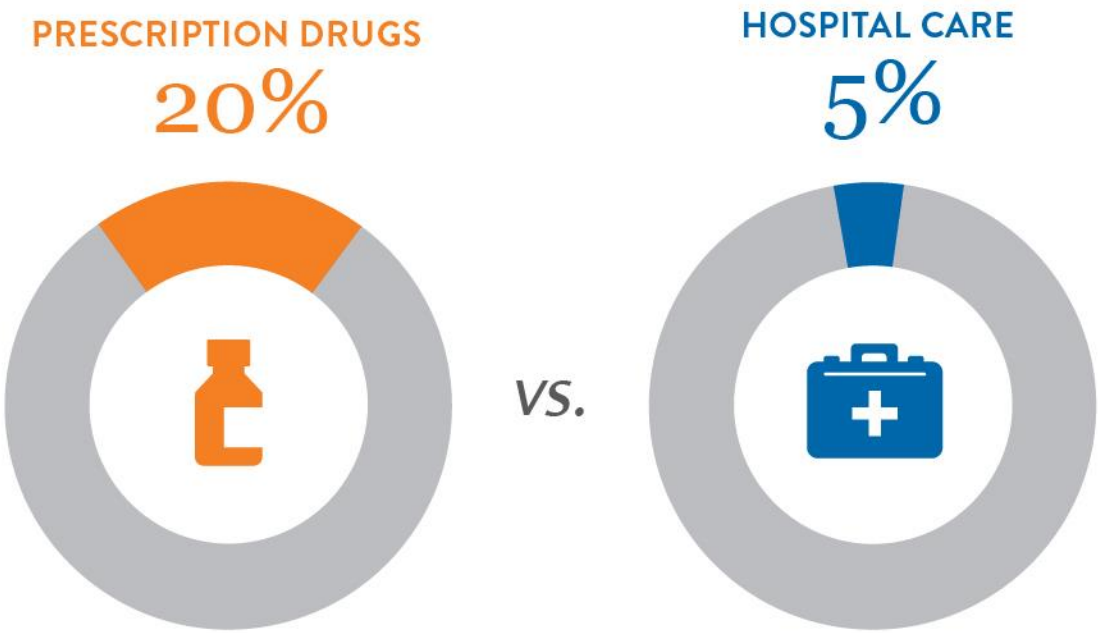


MEDICINES ARE OFTEN SINGLED OUT BY INSURERS

for high cost sharing and restrictions on access

On average, patients pay out of pocket nearly

20 PERCENT OF THEIR TOTAL PRESCRIPTION DRUG COSTS COMPARED TO 5 PERCENT OF HOSPITAL CARE COSTS*

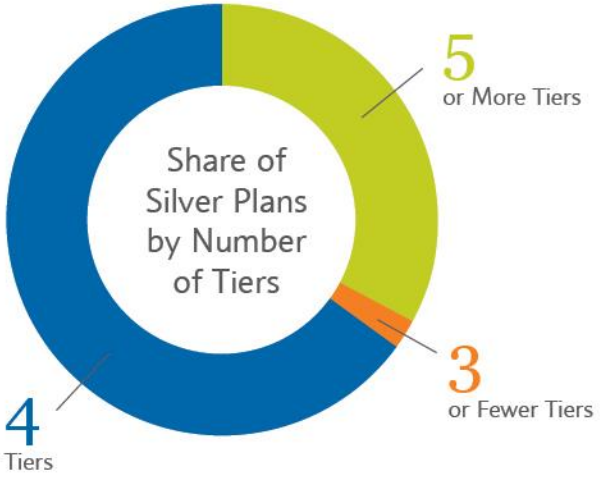


*Includes brand and generic

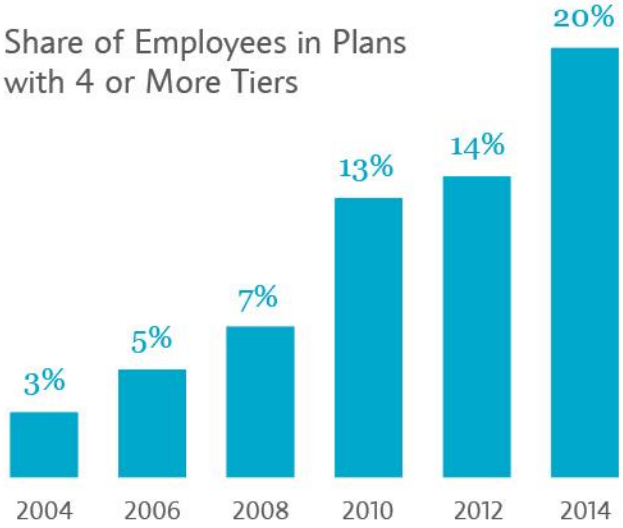
Source: PhRMA analysis based on Medical Expenditure Panel Survey (MEPS)

THE USE OF 4 OR MORE COST-SHARING TIERS*

...is the norm for plans in Health Insurance Exchanges



...and is becoming more common in employer plans



Beyond high cost sharing, barriers to access include insurer practices like prior authorization and step therapy.

*Silver Plans account for a majority of Health Insurance Exchange enrollment. "Tiers" refer to the different levels of cost sharing that plans require patients to pay for different groupings of medicines.

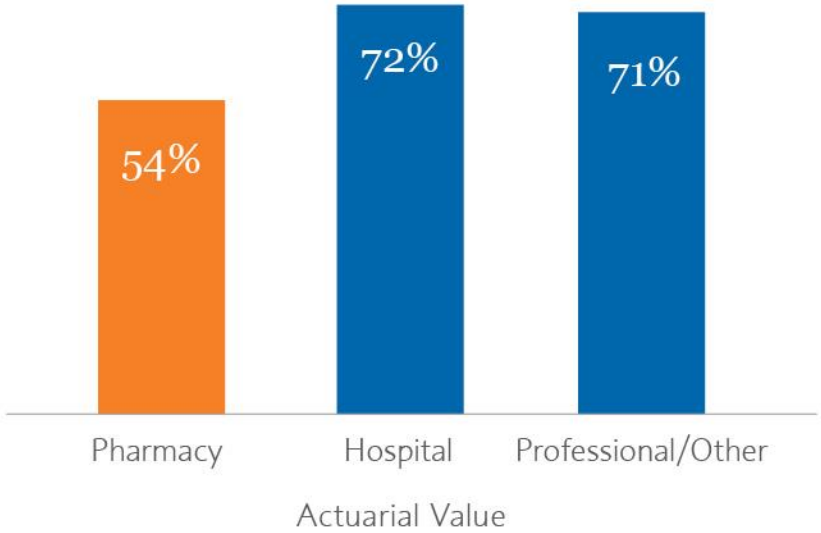
Sources: Avalere PlanScape© Database; Kaiser Family Foundation/Health Research & Educational Trust. Employer health benefits: 2014 annual survey. September 2014, 166.

Subjecting Prescription Drugs to a Combined Deductible Results in

DISPROPORTIONATELY HIGH COST SHARING

An analysis of the most common type of exchange plans under the Affordable Care Act found that drug coverage was generally less generous than for other covered services—primarily because plans subjected drug spending to a large deductible.

Average Share of Costs Paid by the Plan,
Among Silver Plans in 2014 with a Combined Medical/Drug Deductible*



*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. Figure shows the actuarial value for each service category listed, ie, the percentage of covered costs paid by the plan.

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Source: Milliman, Inc

RAPID CHANGE IN THE MARKET FOR MEDICINES

NEW TOOLS ARE BEING DEVELOPED TO CONTROL COSTS AND DRIVE VALUE

VALUE-BASED INSURANCE DESIGN	AGGRESSIVE NEGOTIATION OVER REBATES, DISCOUNTS	ACCOUNTABLE CARE ORGANIZATIONS
CLINICAL PATHWAYS	PROVIDERS AT RISK FOR RX COSTS	BUNDLED PAYMENTS

Medicines are Part of the Solution...

AND MORE CAN BE DONE TOGETHER

COST CONTAINMENT	PAY FOR VALUE	SOLUTIONS
Look at all health care costs, reduce administrative costs and waste, replicate effective cost-containment practices.	Support evidence-based care and empowered patients and providers, backed by sound research and strong quality measures.	Avoid blanket policies that chill investment, and collaborate to find new approaches.