Michigan Health Policy Committee Briefing

March 8, 2016

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VALUE OF INNOVATION

PhRMA
RESEARCH PROGRESS HOPE

Developing New Treatments and Cures

IS A COMPLEX AND RISKY UNDERTAKING

On average, it takes more than
10 years and $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

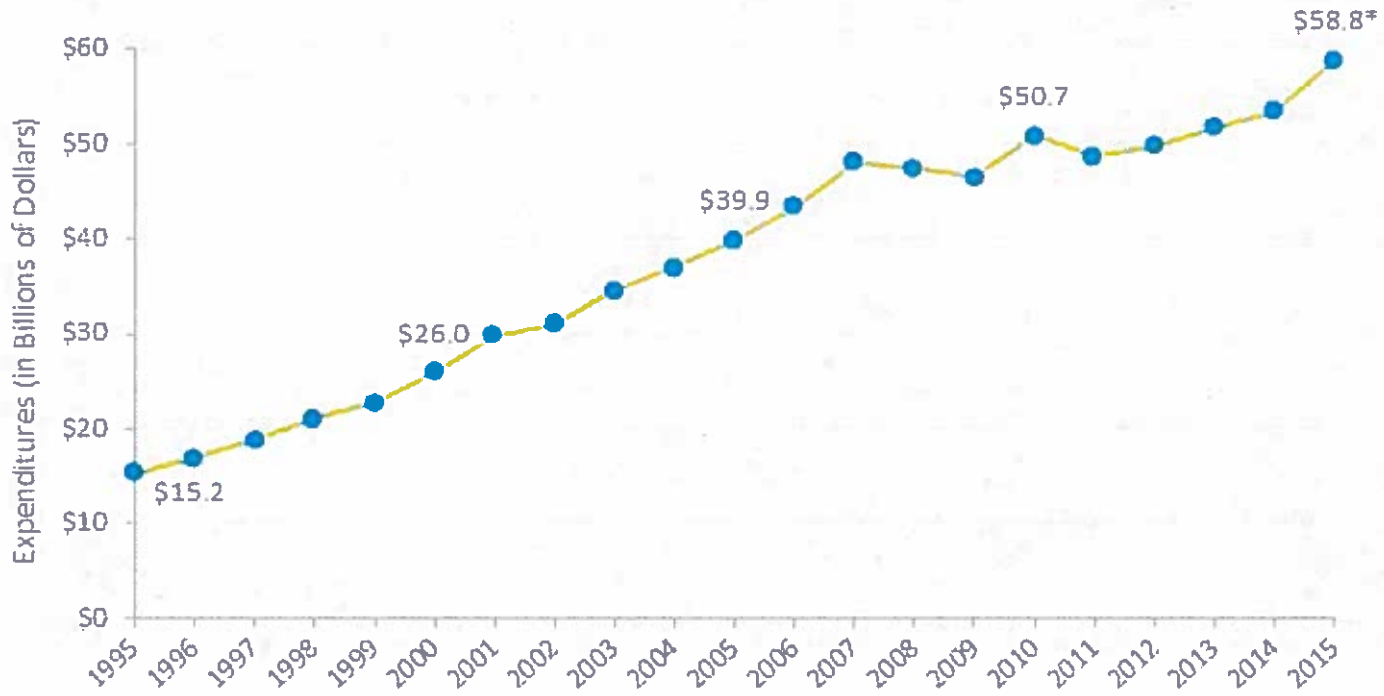
*Source: Tufts Center for the Study of Drug Development (CSDD)
**Source: Pharmaceutical Research and Manufacturers of America (PhRMA), "Researching Alzheimer's Medicines: Setbacks and Stepping Stones," 2015
***Source: Pharmaceutical Research and Manufacturers of America (PhRMA), "Researching Cancer Medicines: Setbacks and Stepping Stones," 2014

PhRMA Member Company R&D Investment

The pharmaceutical industry is one of the most research-intensive industries in the United States. Pharmaceutical firms invest as much as five times more in research and development, relative to their sales, than the average U.S. manufacturing firm.

— Congressional Budget Office (CBO)

PhRMA Member Company R&D Expenditures, 1995-2015



*Estimated fiscal year 2015

Sources: CBO; PhRMA

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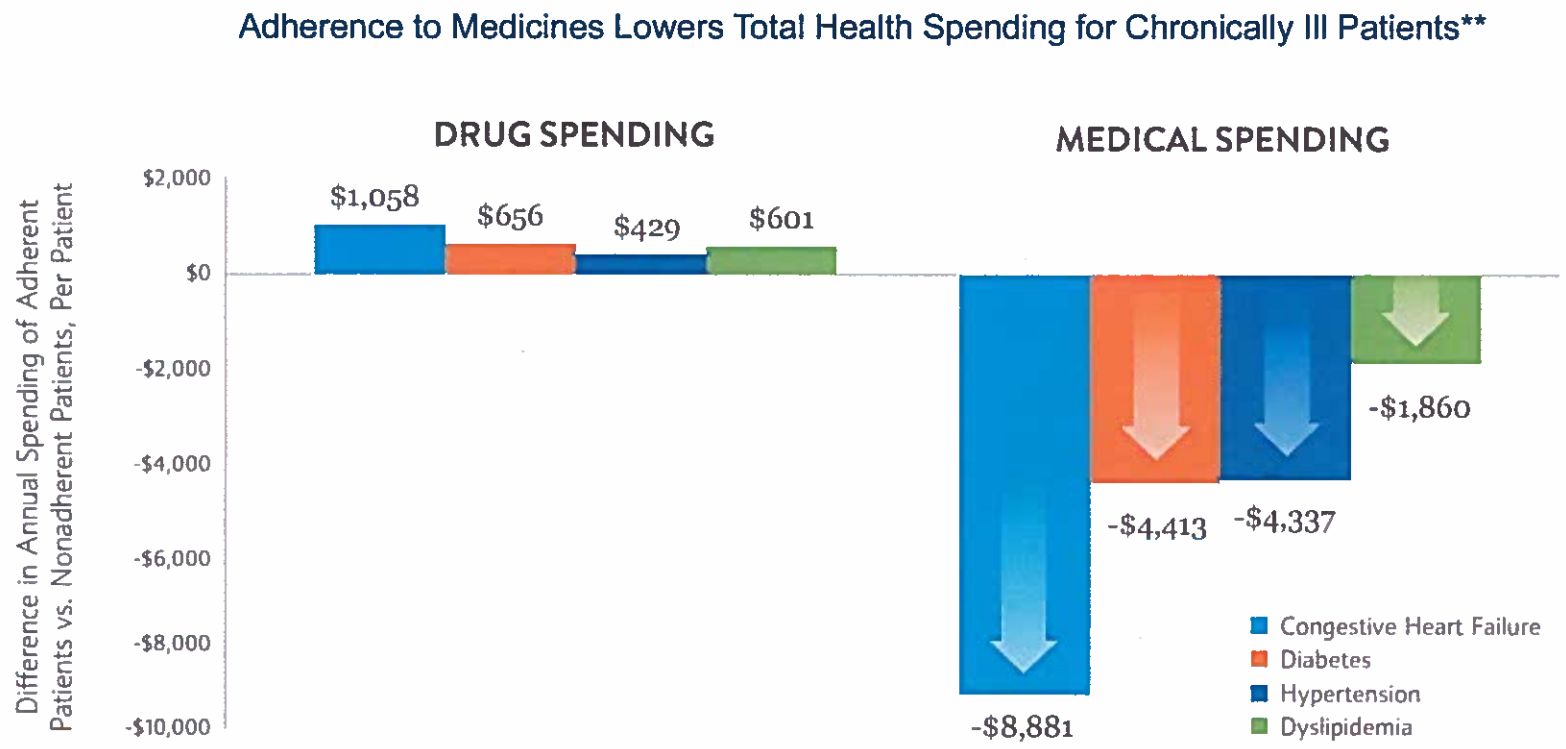
Medicines Help Patients

AVOID EXPENSIVE HOSPITAL SERVICES

The U.S. health care system could save $213 billion annually if medicines were used properly*



*Source: IMS Institute for Healthcare Informatics, "Avoidable Costs in U.S. Healthcare: The $200 Billion Opportunity from Using Medicines More Responsibly," June 2013.
**Source: Roebuck M.C., et al. ""Medication adherence leads to lower health care use and costs despite increased drug spending." Health Affairs. 2011;30(1):-99."

VALUE OF COMPETITION

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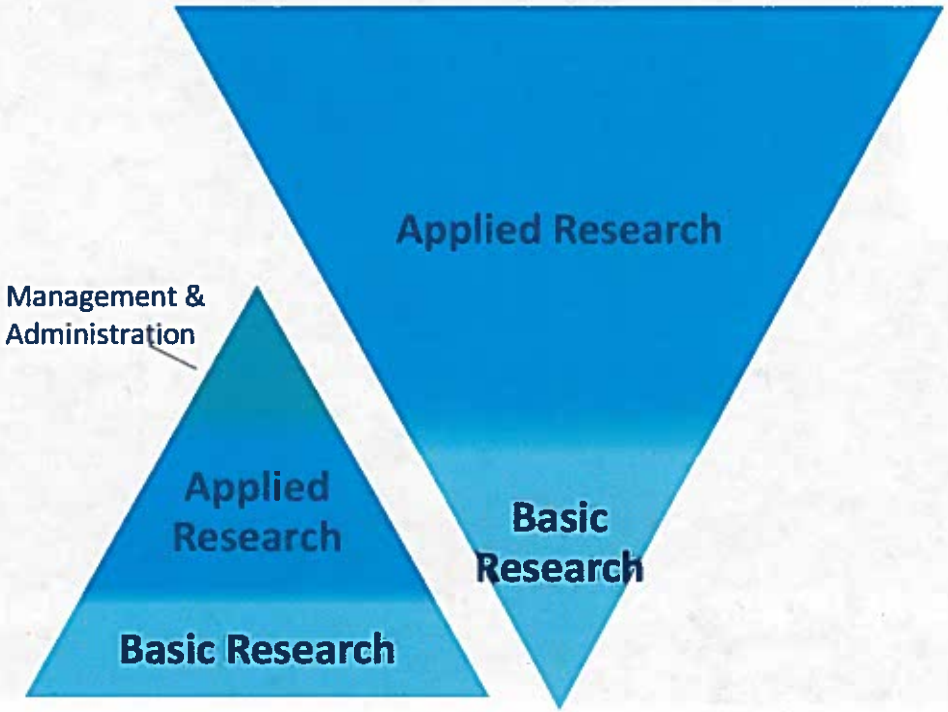
Biopharmaceutical Companies Do the Vast Majority of Research to Translate Basic Science Into New Medicines

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

2015 PhRMA Member Companies
Biopharmaceutical R&D Investment: $58.8 Billion (est.)



2015 TOTAL NIH Budget: $30.3 Billion

In addition to biopharmaceutical R&D, the NIH budget includes funding in support of medical devices, diagnostics, prevention, training, and other activities.

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Sources: Tufts CSDD; PhRMA; NIH

COMPANIES RACE TO BE FIRST TO MARKET

with a New Medicine

Competing brands generally launch within two years.

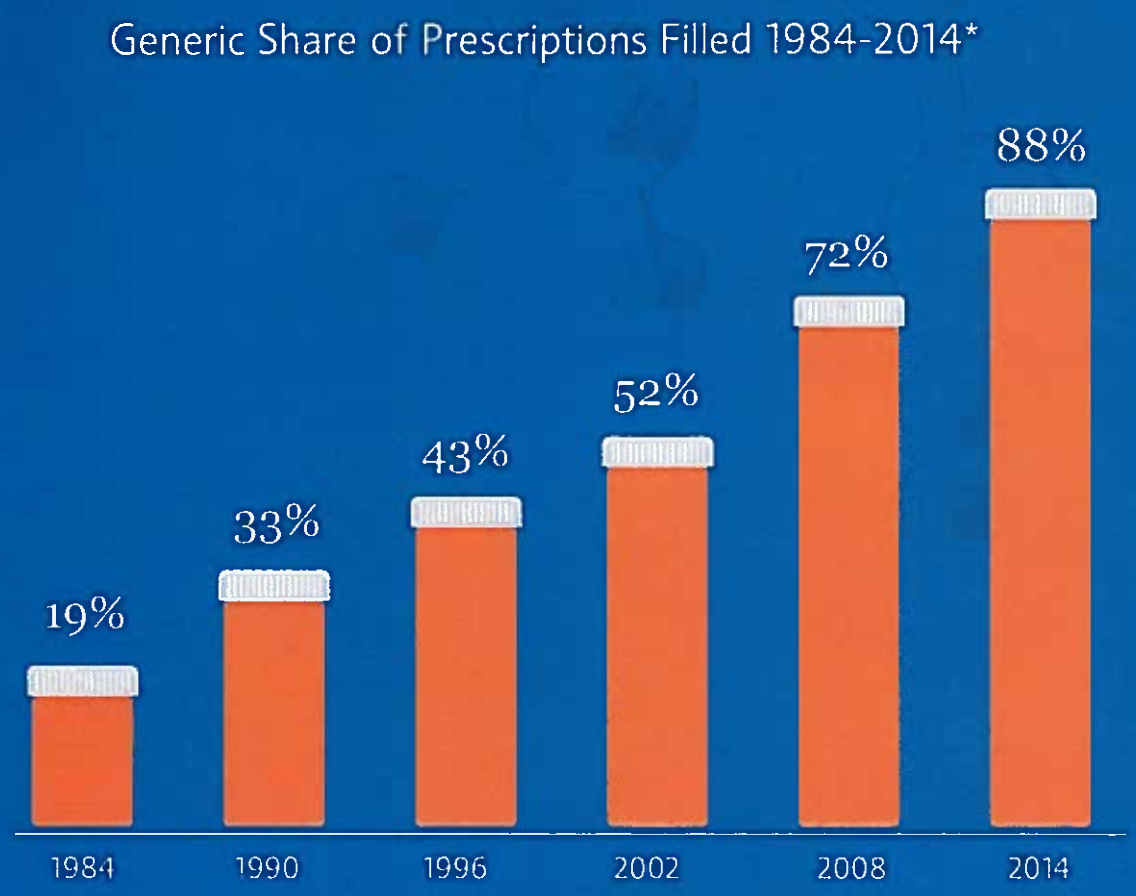
Time Between Approval of First and Second Medicines in a Pharmacologic Class Has Declined Dramatically

BRAND COMPETITION HELPS CONTROL COSTS

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

Nearly 9 Out of Every 10 U.S. Prescriptions

ARE FILLED WITH GENERICS



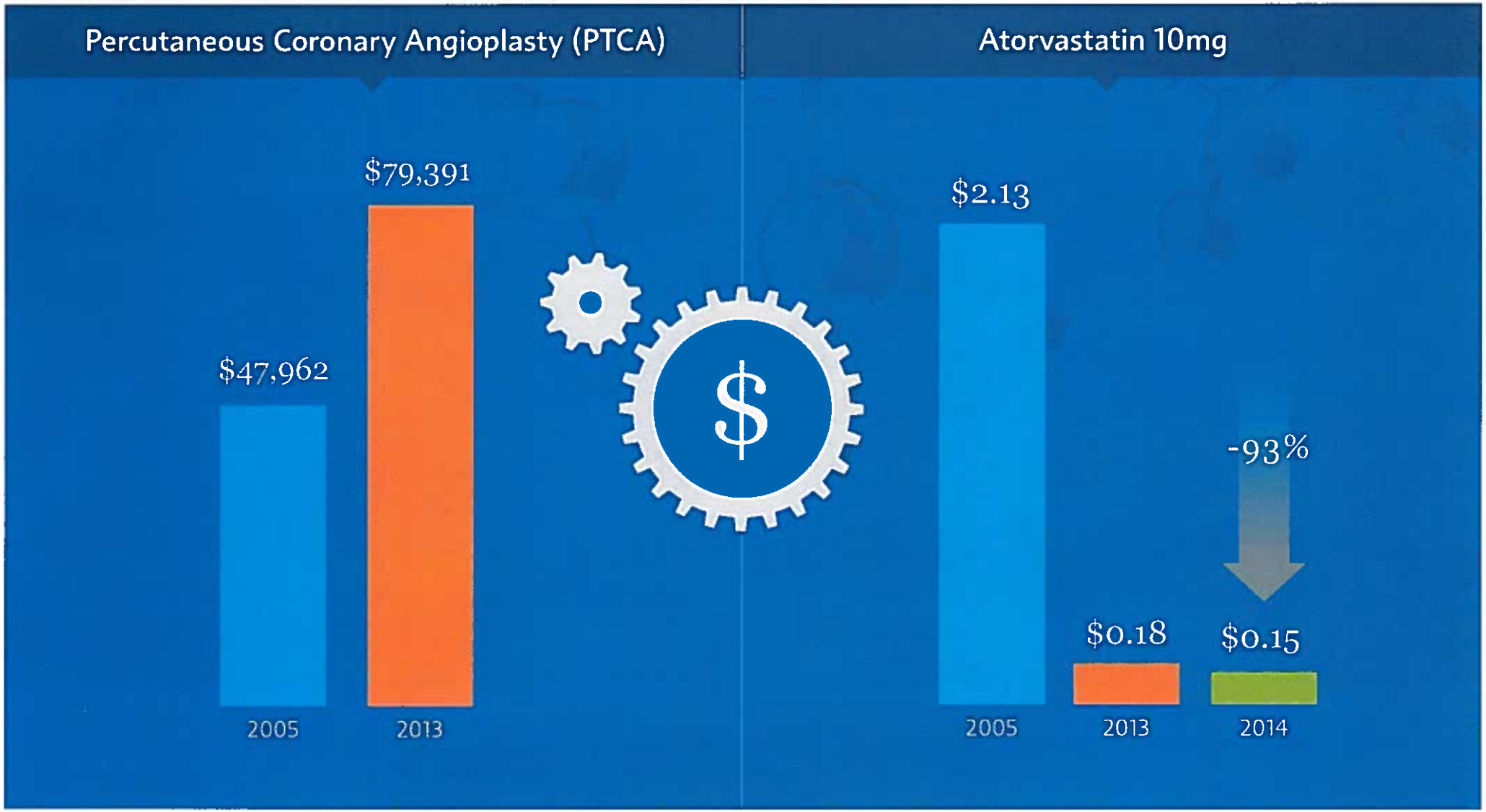
$1.68 TRILLION

10-YEAR SAVINGS (2005-2014)**

*Source: IMS Health.
**Source: Generic Pharmaceutical Association, "Generic Drug Savings in the U.S. Report," 2015.

Medical Procedures Become More Expensive Over Time,

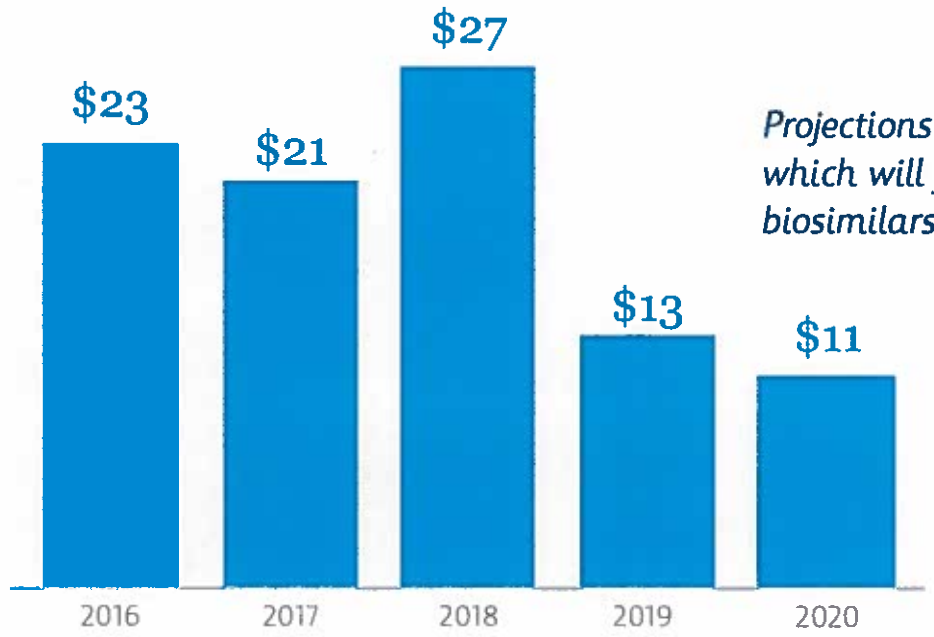
BUT COST CONTAINMENT IS BUILT INTO MEDICINE LIFE CYCLE



Source: Average hospital charges for Atorvastatin 10mg data adapted from HCUP Hospital Charge database 2005 and 2013. IMS National Sales Perspective (NSP) Invoice Price in 2005 (branded Lipitor), 2013 (generic) and 2014 (generic).

$93 BILLION OF U.S. BRAND SALES

are Projected to Face Generic Competition



Projections exclude biologics, which will face competition from biosimilars entering the market.

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.

Source: IMS Institute for Healthcare Informatics, "Global Medicines Use in 2020: Outlook and Implications."

COST IN CONTEXT

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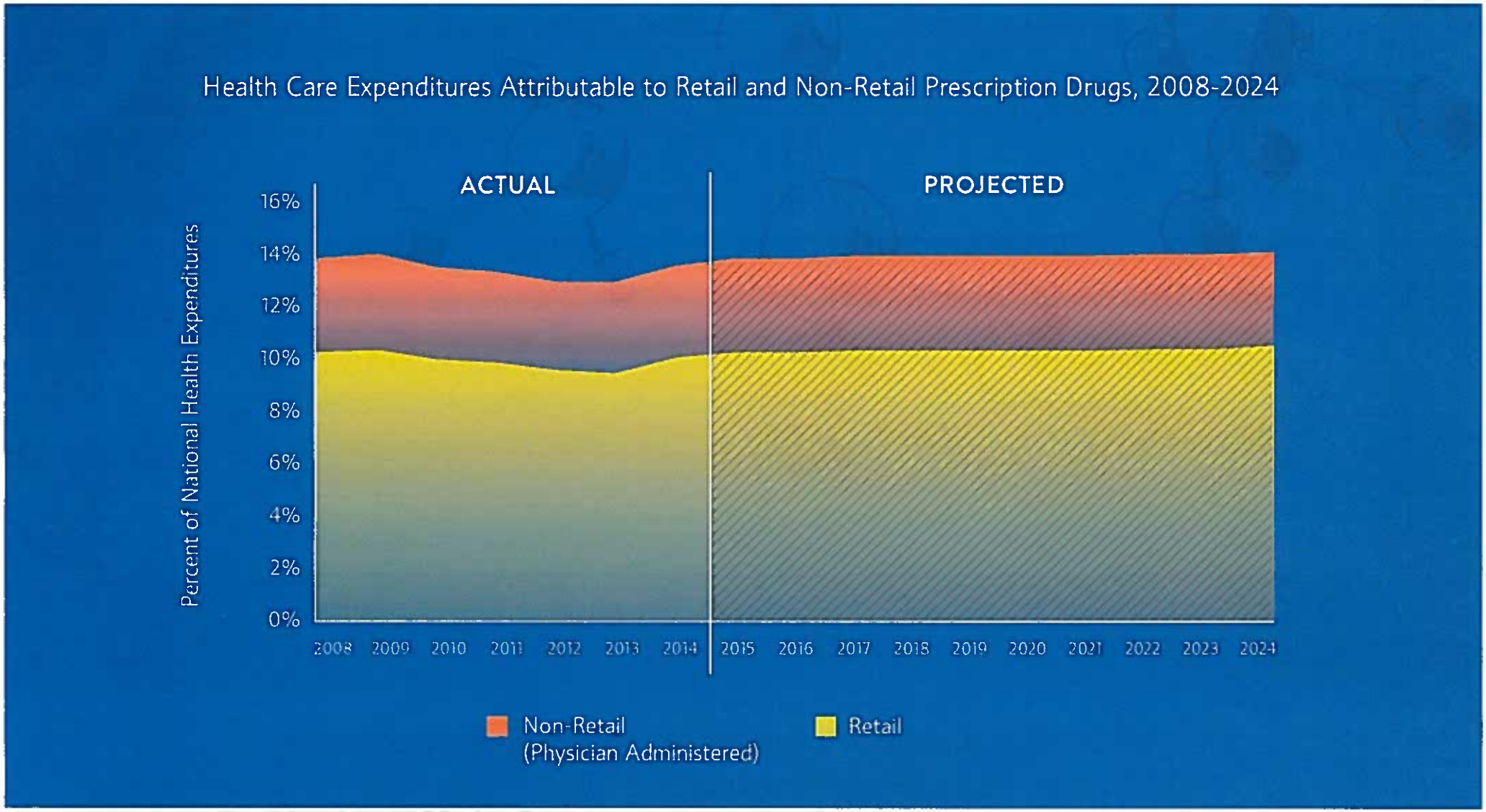
Medicines Account for a

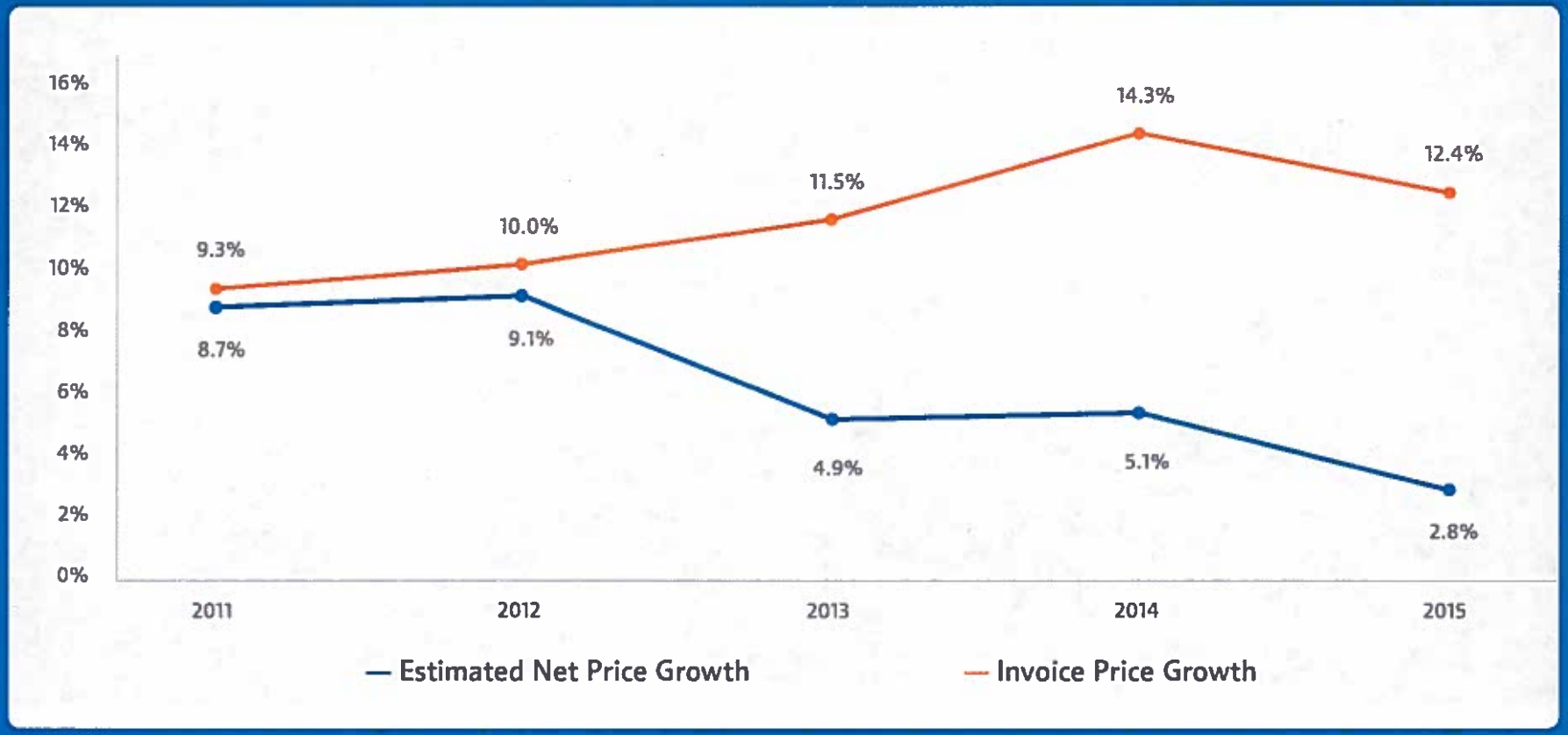
STABLE SHARE OF HEALTH CARE SPENDING



Source: Altarum Institute, "A Ten Year Projection of the Prescription Drug Share of National Health Expenditures Including Non-Retail," August 2015.

BRAND MEDICINE NET PRICE GROWTH SLOWED IN 2015

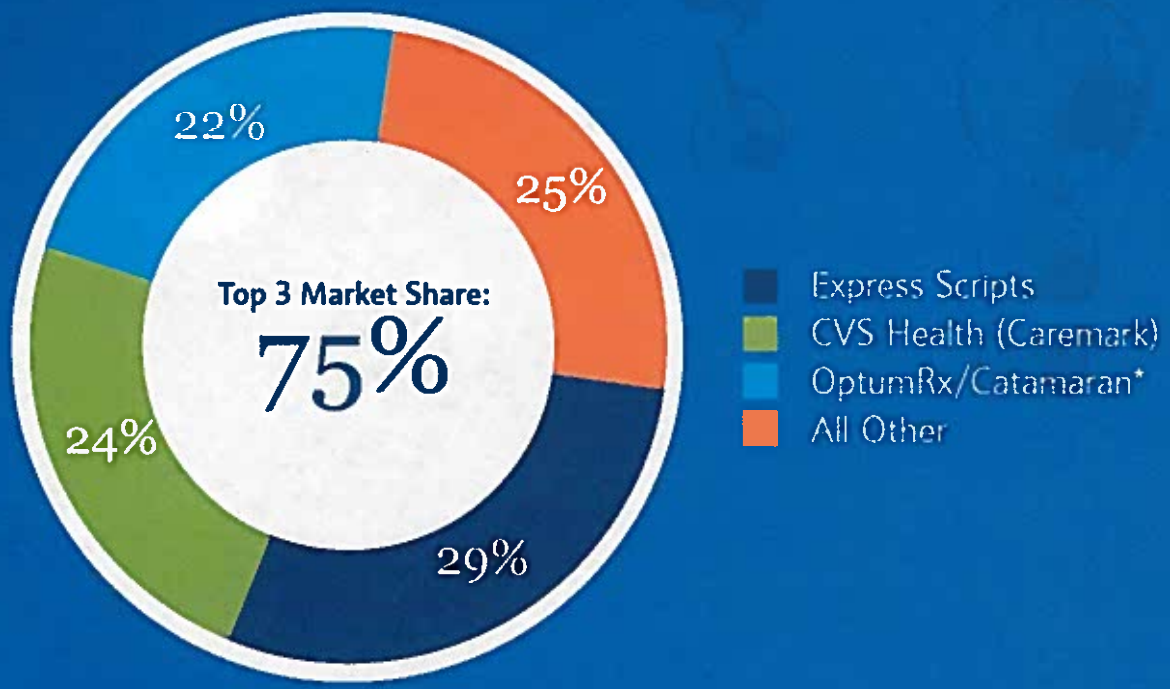
as Discounts, Rebates Negotiated by Payers Rose Sharply



Source: IMS Institute for Healthcare Informatics, National Sales Perspectives, March 2016.

Payers Have Significant Leverage to Negotiate Rebates and Discounts

PBM Market Share, by Total Equivalent Prescriptions



NOTE: OptumRx and Catamaran merged in 2015. Their 2014 shares are shown combined.

Insurers and PBMs 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

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Distribution and Financial Flow

FOR RETAIL BRAND DRUGS

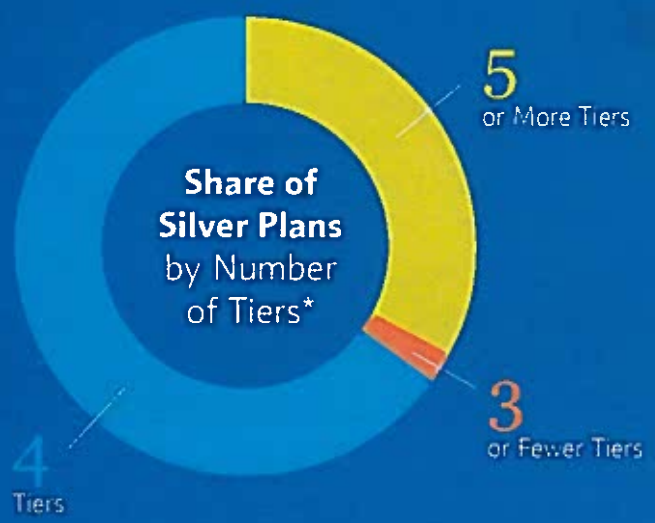
Source: Adapted from Pembroke Consulting

Medicines are Increasingly Put in the

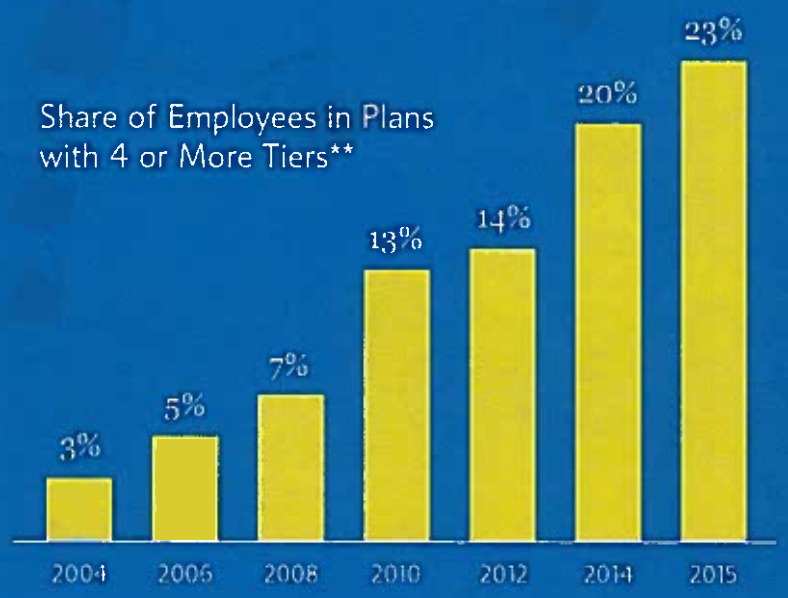
HIGHEST-COST TIER BY INSURANCE COMPANIES

THE USE OF 4 OR MORE COST SHARING TIERS...

normal for plans in health insurance exchange plans



becoming more common on employer plans



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

NOTE: 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.

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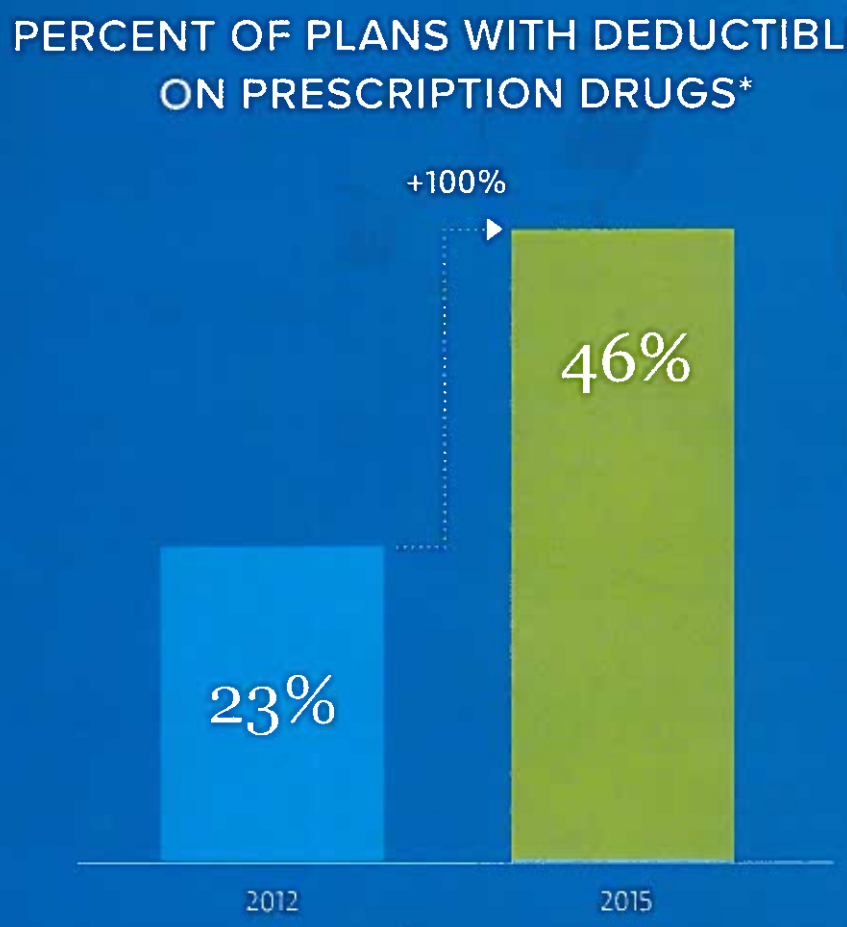
*Source: Avalere Health PlanScape®, a proprietary analysis of exchange plan features, December 2015.
**Source: Kaiser Family Foundation/Health Research & Educational Trust, Employer Health Benefits: 2015 Annual Survey.

Share of Commercial Plans with a

PRESCRIPTION DRUG DEDUCTIBLE IS INCREASING



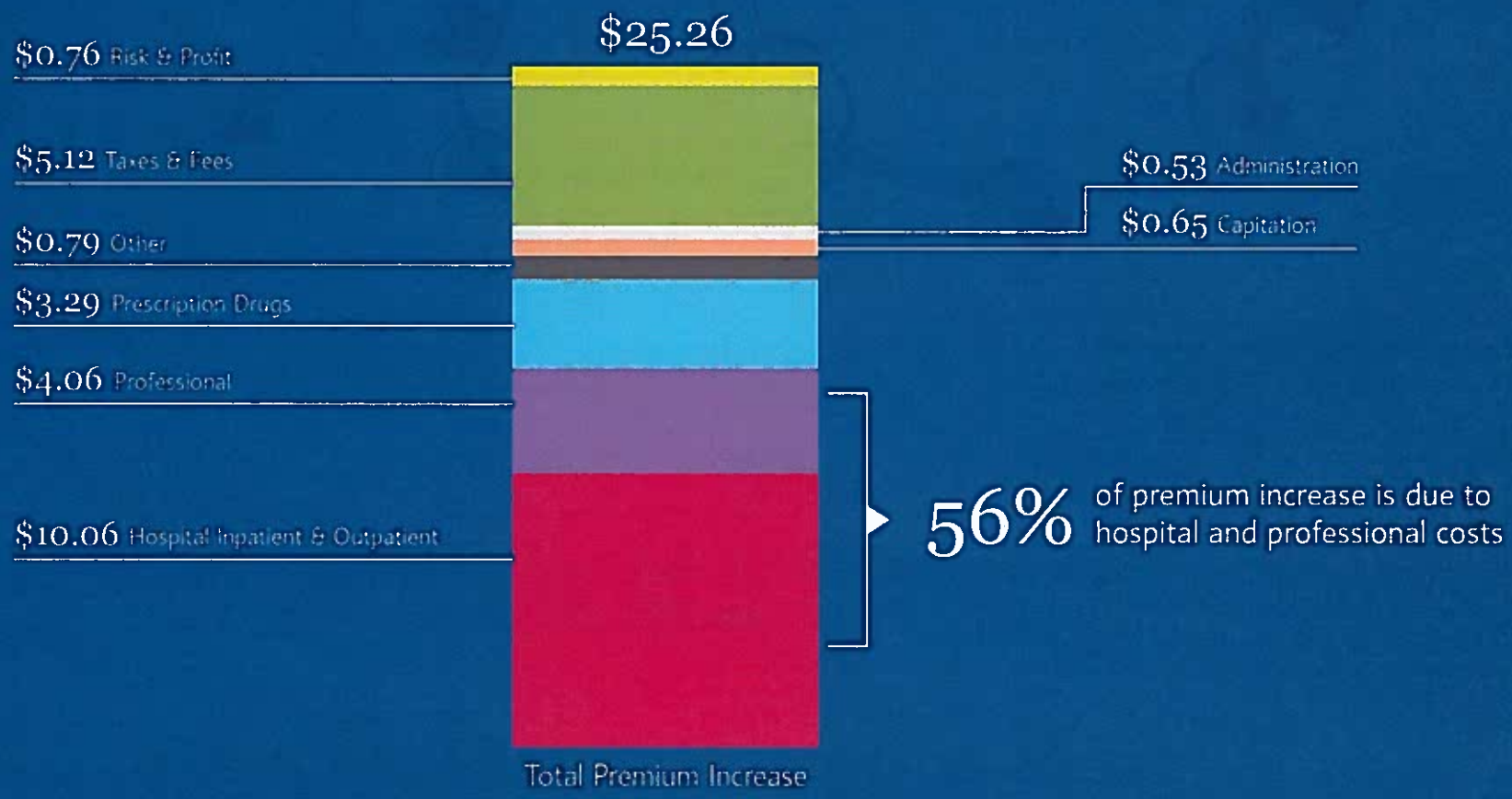
*Cost sharing for patients is shifting from copayment to less predictable deductibles***

*Source: IMS Health, Emergence and Impact of Pharmacy Deductibles, September 2015.

Insurers' Data Show

MEDICINES ARE NOT MAIN DRIVER OF PREMIUM INCREASES

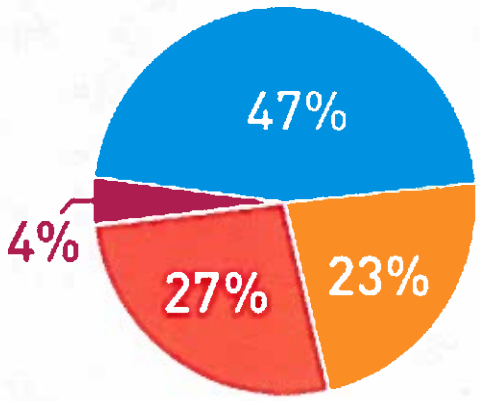
Average Dollar Increase in Monthly Premium by Category, 2016 Individual and Small Group Plans



Source: Avalere Health.

Brand biopharmaceutical companies realize less than half of total net prescription medicine spending

SHARE OF 2015 NET DRUG EXPENDITURES REALIZED BY MANUFACTURER AND NON-MANUFACTURER STAKEHOLDERS



*Includes any retrospective rebates and fees not shared with the end payer.

	Net Expenditures	
	$ (Billions)	%
MANUFACTURERS		
Brand Manufacturers	$218.6	47%
Generic Manufacturers	$107.6	23%
NON-MANFACTURER STAKEHOLDERS		
Supply Chain Entities	$125.3	27%
Other Retrospective Rebates and Fees	$17.5	4%
Total†	$469.0	100%

†Components may not sum to total due to rounding

Source: Berkley Research Group

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Brand manufacturers realize 63% of gross brand prescription medicine spending

GROSS BRANDED DRUG EXPENDITURES BY COMPONENT (IN BILLIONS)				
TYPE OF COMPONENT	COMPONENT	2013	2014	2015
Initial Gross Drug Expenditures[1]		**$264.9**	**$306.3**	**$349.1**
Statutory Rebates and Fees	Medicaid Drug Rebate Program[2]	$19.1	$23.0	$28.3
	Part D Coverage Gap Discounts	$4.2	$5.1	$5.8
	TRICARE Rebates & Federal Supply Schedule Discounts	$3.5	$4.6	$4.7
	Excise Fee[3]	$2.8	$3.0	$3.0
Market Access Rebates and Discounts	Negotiated Health Plan and PBM Rebates and Fees[4]	$33.2	$43.5	$57.7
	Patient Cost Sharing Assistance	$4.2	$5.4	$6.9
Supply Chain Entities	Pharmacy/Provider Margin[5]	$17.5	$18.5	$20.4
	Wholesaler Margin[6]	$2.3	$2.7	$3.1
	GPO Administrative Fees	$0.6	$0.6	$0.7
Net Amount Realized by Brand Manufacturer ($)		$177.5	$199.9	$218.6
Net Amount Realized by Brand Manufacturer (%)		67.0%	65.3%	62.6%

Source: Berkley Research Group

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VALUE OF THE INDUSTRY

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Biopharmaceutical Sector Supports High Quality Jobs in Michigan

Biopharmaceutical Sector Supported Jobs in Michigan

27,616	+	119,802	=	147,418
Direct Sector Jobs		Other Jobs Supported by the Sector		Total Jobs Supported by the Biopharmaceutical Sector in Michigan

Types of Direct Biopharmaceutical Sector Jobs in Michigan

16%	Life Physical and Social Science	9%	Business and Financial Operations
14%	Office and Administrative Support	7%	Sales and Related
12%	Production	7%	Computer and Mathematical
12%	Management	4%	Transportation and Material Moving
9%	Architecture and Engineering	9%	Other*

Source: TEConomy Partners, The Economic Impact of the Biopharmaceutical Industry: U.S. and State Estimates, Report prepared for PhRMA, May 2018.

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Biopharmaceutical Sector Wages and Benefits

Taxes Paid by Workers in Jobs Supported by Biopharmaceutical Sector in Michigan

Federal Taxes Paid	$1.6B
State Taxes Paid	$209.2M
Total Taxes Paid	$1.8B

Average Compensation per Employee in Michigan

$99,665
Per Employee in Direct Jobs with the Biopharmaceutical Sector

$52,629
Per Employee in All Michigan Jobs

The biopharmaceutical sector's economic output represents the value of the goods and services produced by the sector. In 2014, the biopharmaceutical sector directly generated **$14.5B in economic output** in Michigan and **supported another $20.1B** through the sector's vendors and suppliers and through the economic activity of its workforce.

Biopharmaceutical Sector Output in Michigan

Direct Economic Output:	$14.5B
Indirect Economic Output	$20.1B
Total Output Supported by Biopharmaceutical Sector	$34.6B

Economic Output per Employee in Michigan

$524,040
Per Employee in Direct Biopharmaceutical Sector Jobs

$175,388
Per Employee in All Michigan Job Sectors

*Other occupations include areas such as Installation, Maintenance, & Repair, Healthcare Practitioners, Arts, Design, & Media, and Building & Grounds Maintenance, among others.

Source: TEConomy Partners, The Economic Impact of the Biopharmaceutical Industry: U.S. and State Estimates. Report prepared for PhRMA, May 2016.

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Biopharmaceutical Industry Sponsored Clinical Trails and the Impact on Michigan's Economy

23,600

Number Of Clinical Trial Participants

$191.7 million

Amount Invested In Clinical Trials

$488.2 million

Total Economic Impact Of Clinical Trial Investments

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Patient Assistance Programs Help Patients Access Needed Medicines

Despite more Americans having insurance, many are facing high cost sharing that puts their ability to stay on a needed therapy at risk. Patient assistance programs sponsored by US biopharmaceutical companies are one option to help patients maintain access to needed medicines.

Since 2005, the Partnership for Prescription Assistance (PPA) has helped connect

NEARLY 10 MILLION uninsured or underinsured patients

to assistance programs that may provide medicines they need for free or nearly free.

WHAT PPA OFFERS

- Single point of access to information on **more than 475 public and private patient assistance programs—including nearly 200 programs offered by biopharmaceutical companies**
- A database of nearly 10,000 free or low-cost health care clinics across the country

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Pragmatic Solutions

to Address Cost Concerns

MODERNIZE THE DRUG DISCOVERY AND DEVELOPMENT PROCESS

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

PROMOTE VALUE-DRIVEN HEALTH CARE

- Address barriers to paying for value, develop patient-centered value assessment tools and support appropriate use of medicines

ENGAGE AND EMPOWER CONSUMERS

- Make quality and cost information public to aid in decisions and enforce common-sense rules that prevent discrimination against vulnerable patients

ADDRESS MARKET DISTORTIONS

- Improve risk adjustment models and reform market distorting programs like the 340B Drug Pricing program

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QUESTIONS?

THANK YOU

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