



QuintilesIMS™

# PCMA 2017

*The US Pharmaceutical Market:  
Trends, Issues, and Outlook*

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# What's happened in 2016?

## Snapshot of key happenings in the industry

### Market Performance

- ✓ Dollar growth is decelerating
- ✓ TRX growth is improving
- ✓ 90 day scripts are 14% of scripts
- ✓ Below avg. Flu and Allergy Seasons

### Mergers / Alliances

- ✓ *Walgreens and Rite Aid postponed*
- ✓ **Ahold and Delhaize**
- ✓ **Target pharmacies are now CVS** pharmacies
- ✓ **Walmart and McKesson Alliance**
- ✓ Anthem and Cigna- Turned down
- ✓ Aetna and Humana Turned down

### Reimbursement

- ✓ AMP finally arrives
- ✓ **Generic Deflation**
- ✓ DIR fees
- ✓ Pharmacists can prescribe in more places

### Generic Launches

- ✓ Crestor
- ✓ Gleevec
- ✓ Benicar, Tamiflu
- ✓ Seroquel XR, Nuvigil, Asacol

### Regulation

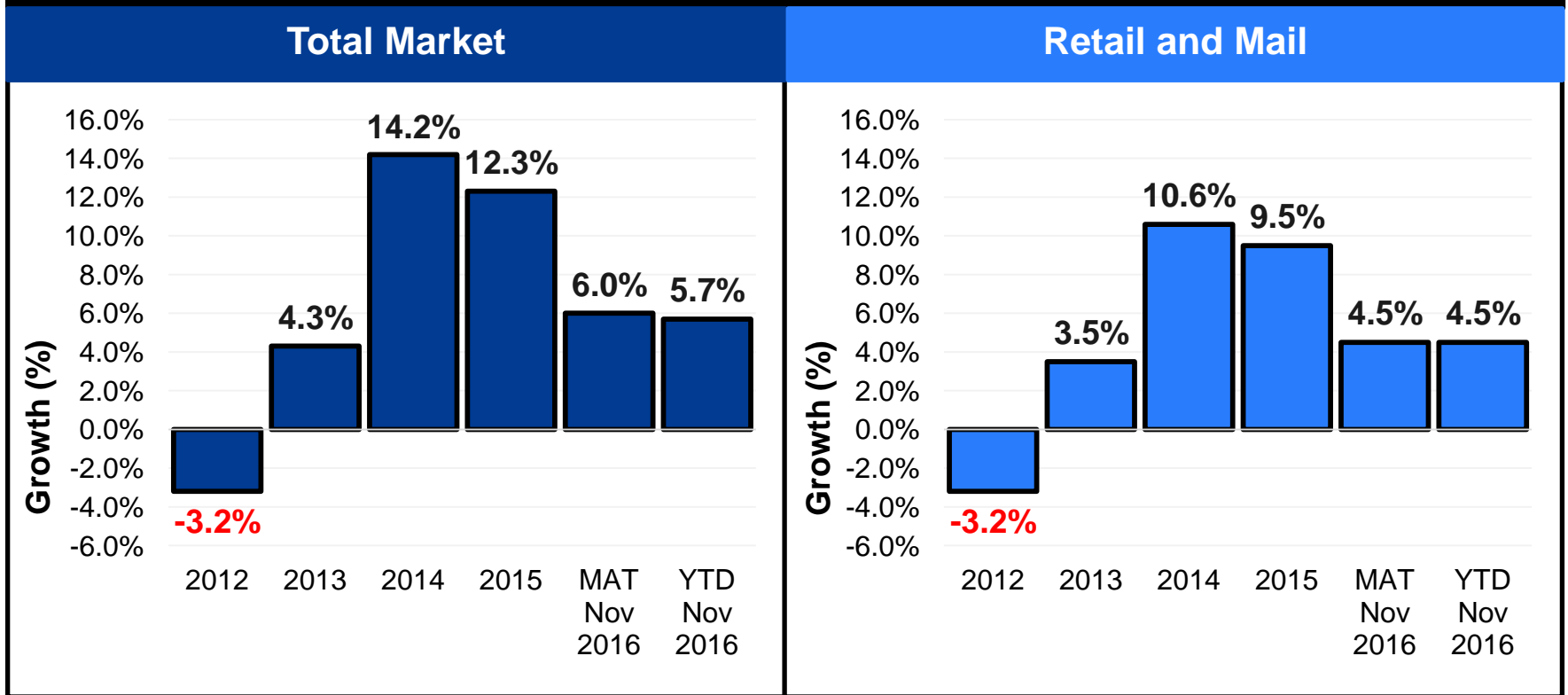
- ✓ New FDA/DEA guidelines on Controlled Substances

### Price / Politics

- ✓ Turing, Valeant and now Epipen
- ✓ 2016 Elections and public anger
- ✓ DOJ investigations

# US market dollar sales growth is decelerating

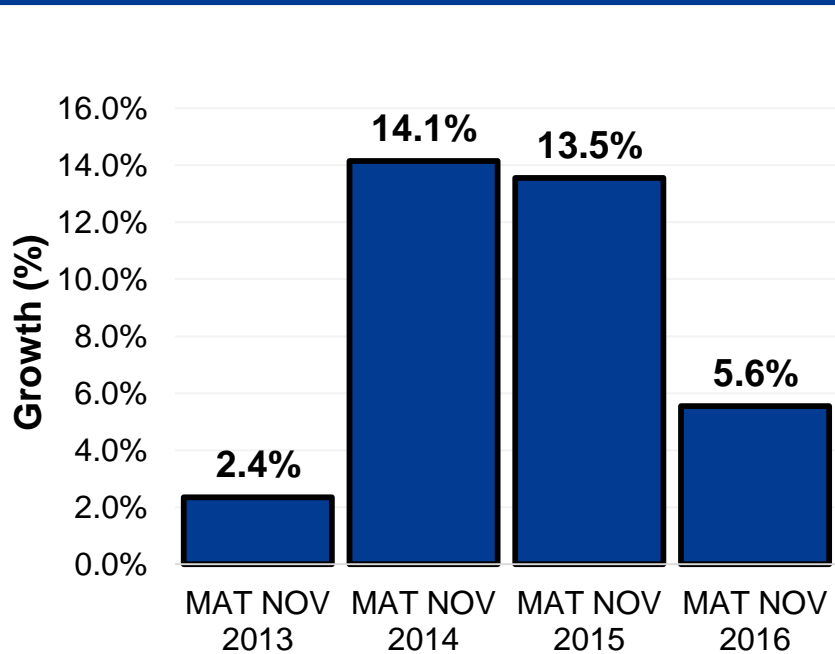
## Growth (%) of Sales



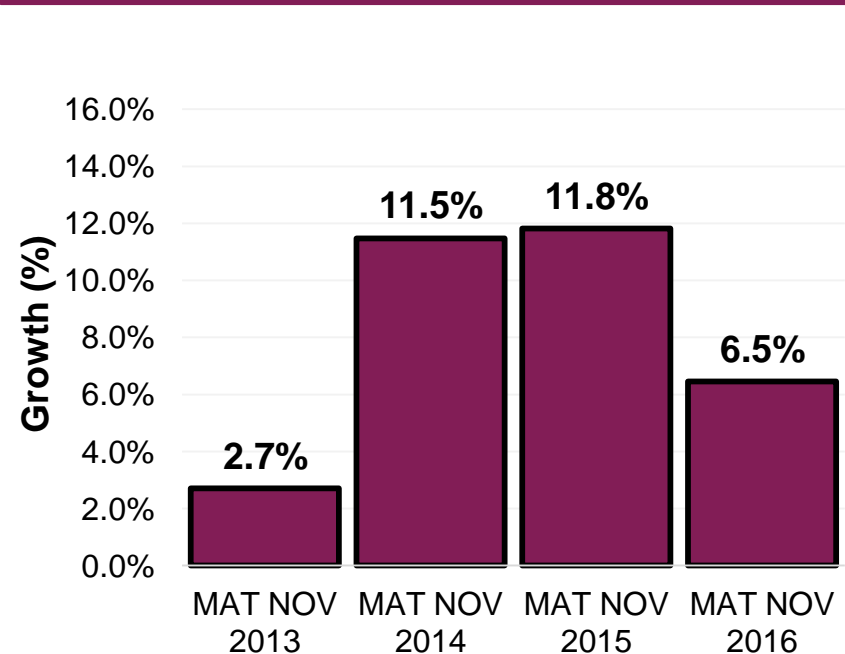
# Year over year market growth is decelerating from 2015 to 2016

## Growth (%) of Sales

### Total Sales (\$) including Hepatitis C



### Total Sales (\$) excluding Hepatitis C



# Causes for spend decline from 2015 to 2016

## 1. Loss of patent exclusivity

### a. 2014

1. Nexium: down ~\$1.9BN

### b. 2015

1. Abilify: down ~\$3.1BN
2. Gleevec: down ~\$1.1BN
3. Namenda: down ~\$700MN

### c. 2016

1. Crestor: down ~\$2.1BN

## 2. Drop in Hep C Sales

- a. ~\$3BN less than 2015

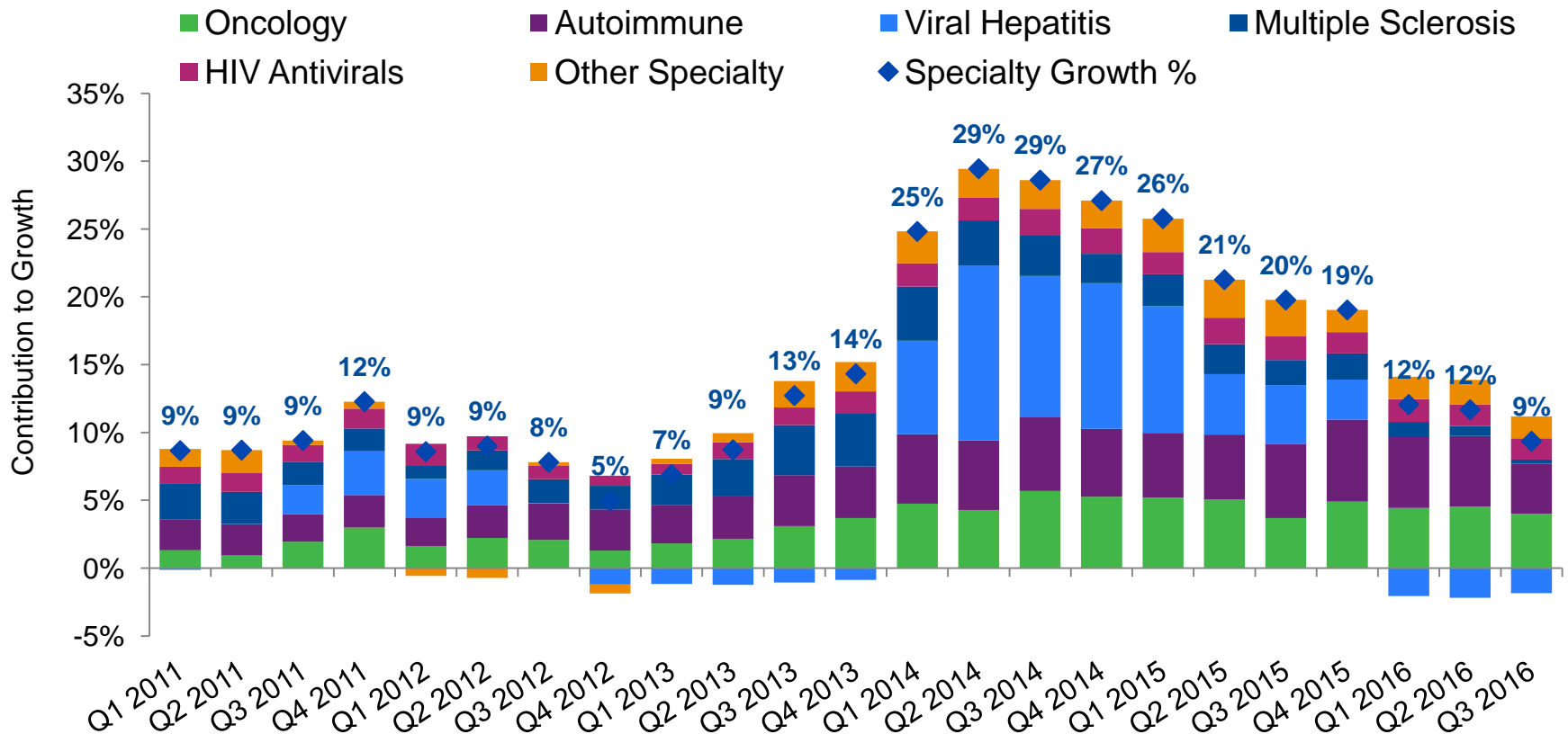
## 3. Drop in Narcotic Sales

- a. ~\$1.6BN less than 2015

# Specialty spending growth is slowing from the record high growth rates reached in 2014-15 with Hep C

Specialty growth would have been 3.5% lower in 2015 without HCV

Contribution to Specialty Spending Growth by Therapy Area



Source: QuintilesIMS, National Sales Perspectives, Sep 2016

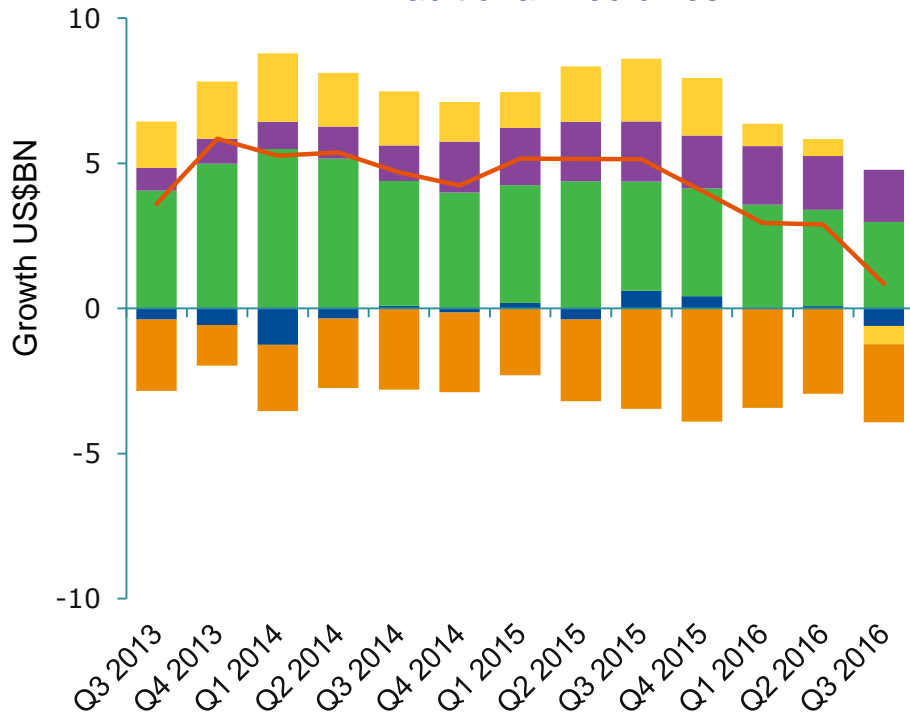
# Spending on specialty medicines increased \$3.7Bn in Q3 2016

Traditional spending increased only \$848mn in Q3 2016

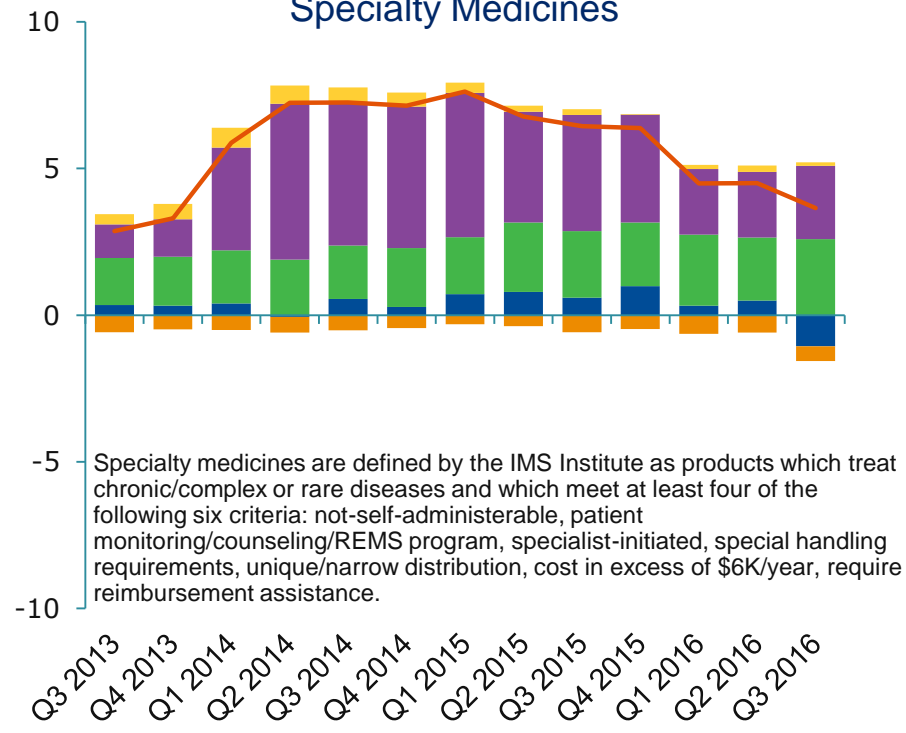
## Traditional and Specialty Spending Growth Dynamics

Protected Brands Volume Protected Brands Price New Brands Generics Patent Expiries Growth

### Traditional Medicines



### Specialty Medicines



Source: QuintilesIMS, National Sales Perspectives, Sep 2016

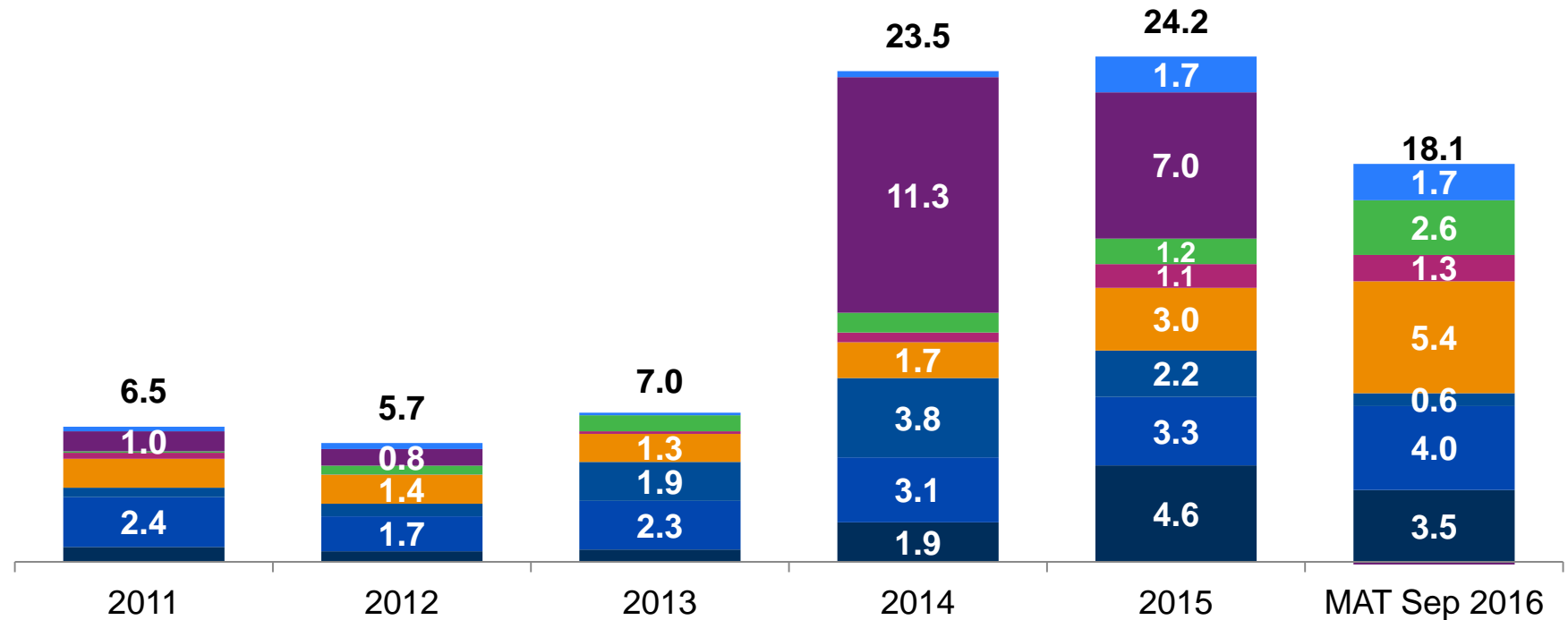


# Spending on brands launched in the last 24 months grew \$18Bn to \$42Bn in sales in the last 12 months

Drivers: Opdivo, Ibrance, Daklinza, Triumeq, Genvoya, Gardasil 9

New Brand Spending Growth (\$BN)

- Diabetes
- Other Traditional
- Multiple Sclerosis
- Oncology
- Autoimmune
- HIV Antivirals
- Viral Hepatitis
- Other Specialty



Source: IMS Health, National Sales Perspectives, Sep 2016

# Sales by Channel – 12 months ending Nov. 2016

Channels	MAT Nov 2016		
	US\$bn	% Market Share	% Growth
<b>Retail</b>	<b>320.8</b>	<b>71.8</b>	<b>5.5</b>
Chain/Mass	136.6	30.6	4.7
Mail service	103.7	23.2	7.8
Independents	49.6	11.1	4.0
Food stores	31.0	6.9	4.6
<b>Institutional</b>	<b>126.1</b>	<b>28.2</b>	<b>7.2</b>
Clinics	62.3	13.9	12.4
Hospitals	37.0	8.3	3.6
Long-term care	16.6	3.7	-0.8
Home health care	3.8	0.9	0.5
HMO	5.1	1.1	6.0
Others	1.3	0.3	10.2
<b>Total</b>	<b>446.9</b>	<b>100.0</b>	<b>6.0</b>

Source: IMS Health, National Sales Perspectives, Mar 2014

# 2016 Therapeutic Area Snapshot

## Non-Discounted Spend (US\$)

## Dispensed Prescriptions (TRx)

Therapeutic Area	Non-Discounted Spend (US\$)			Dispensed Prescriptions (TRx)		
	MAT Nov. 2016 Spend (US\$ BNs)	Δchange in US\$ (US\$ BNs)	Growth (Δ MAT NOV 2015 to MAT NOV 2016)	MAT NOV 2016 Dispensed (TRx MNs)	Δchange in TRx (MNs)	Growth (Δ MAT NOV 2015 to MAT NOV 2016)
DIABETES	\$50.0	\$7.1	16.7%	222.7	12.0	5.7%
ONCOLOGICS	\$41.1	\$6.1	17.4%	19.8	0.7	3.9%
AUTOIMMUNE	\$32.1	\$5.3	19.9%	6.5	-0.3	-3.9%
RESPIRATORY	\$25.7	\$2.1	8.9%	180.5	4.8	2.7%
PAIN	\$19.8	-\$1.1	-5.1%	463.5	-6.6	-1.4%
MULTIPLE SCLEROSIS	\$18.2	\$1.1	6.7%	2.2	-0.1	-2.7%
MENTAL HEALTH	\$17.3	-\$2.7	-13.4%	393.9	18.0	4.8%
HEP C	\$16.0	-\$2.6	-14.1%	0.9	-0.1	-11.9%
LIPID REGULATORS	\$12.5	-\$0.9	-6.4%	263.9	3.3	1.3%
NERVOUS SYSTEM DISORDERS	\$12.4	\$1.3	11.8%	197.9	11.0	5.9%
ANTICOAGULANTS	\$12.1	\$2.2	22.6%	81.4	1.0	1.2%
<b>TOTAL MARKET</b>	<b>\$447.5</b>	<b>\$23.5</b>	<b>5.6%</b>	<b>4,448.2</b>	<b>75.1</b>	<b>1.7%</b>

# Top 10 Molecules by MAT Nov. 2016 Sales (US\$)

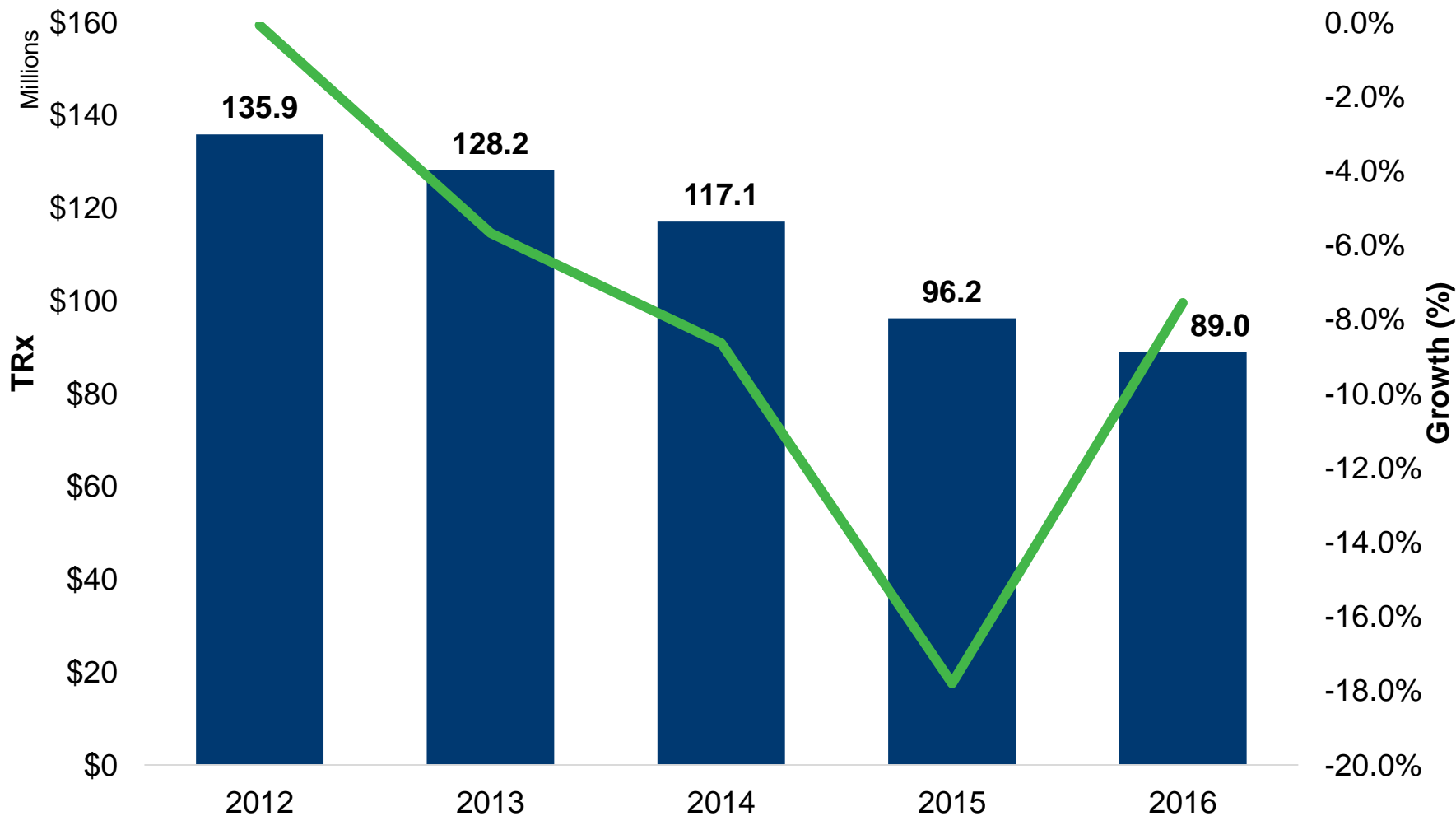
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HUMIRA	12.7	2.8	28.9%	2.6	0.3	12.1%
HARVONI	10.3	-3.9	-27.3%	0.3	-0.1	-32.3%
ENBREL	7.9	0.9	12.5%	1.6	-0.1	-4.7%
LANTUS SOLOSTAR	5.6	-0.1	-2.3%	11.8	0.3	2.6%
REMICADE	5.3	0.4	8.6%	0.1	0.0	9.5%
JANUVIA	4.7	0.6	15.2%	9.7	0.4	4.5%
CRESTOR	4.7	-1.5	-24.8%	13.4	-7.0	-34.3%
ADVAIR DISKUS	4.6	0.0	-1.0%	12.0	-1.2	-9.4%
LYRICA	4.3	0.6	15.3%	10.5	0.2	2.4%
NEULASTA	4.3	0.2	4.5%	0.0	0.0	-7.5%

# Top 11-20 Molecules by MAT Nov. 2016 Sales (US\$)

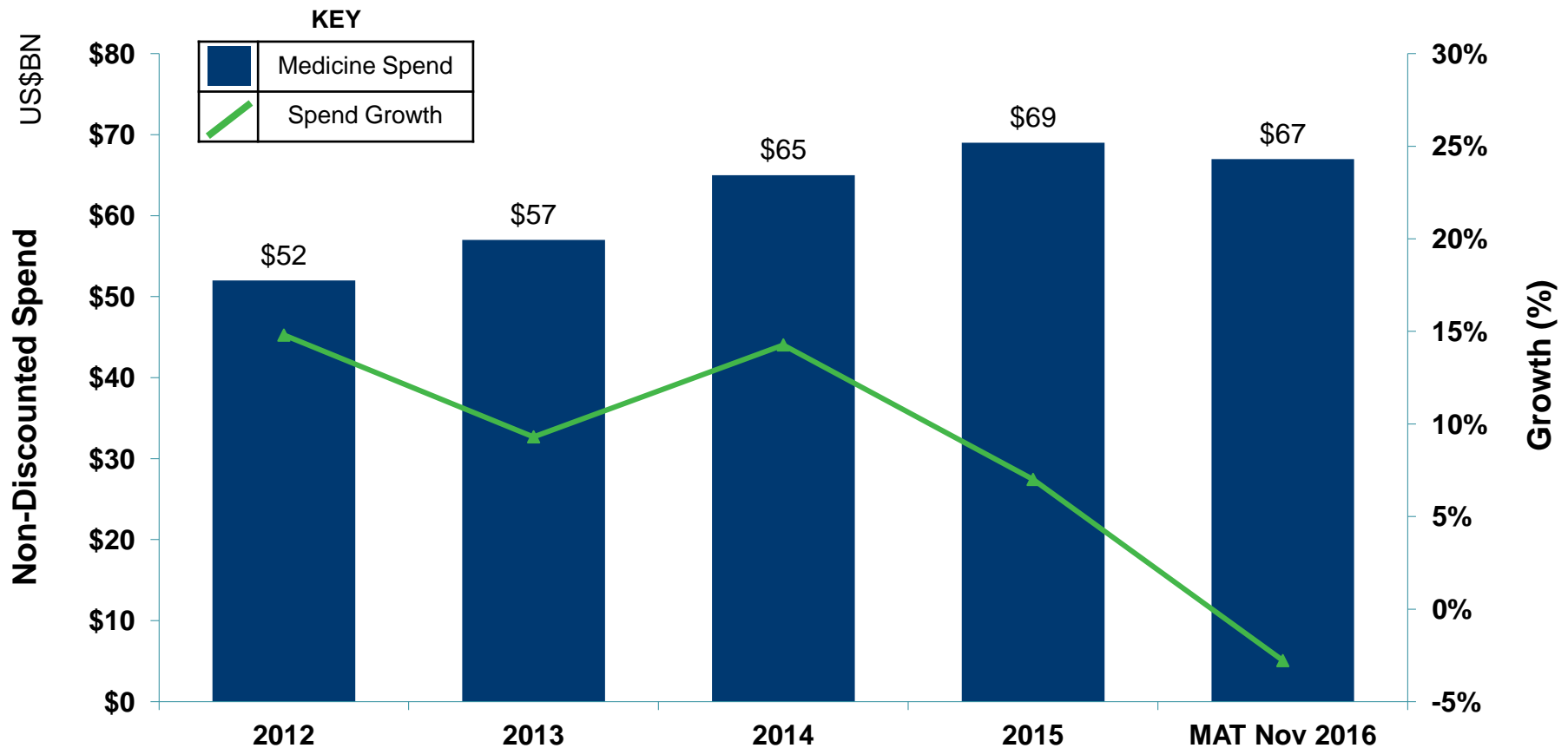
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	MAT Nov. 2016 Spend (US\$ BNs)	Δchange in US\$ (US\$ BNs)	Growth (Δ MAT NOV 2015 to MAT NOV 2016)	MAT NOV 2016 Dispensed (TRx MNs)	Δchange in TRx (MNs)	Growth (Δ MAT NOV 2015 to MAT NOV 2016)
<b>COPAXONE</b>	4.1	-0.3	-6.3%	0.6	0.0	-6.6%
RITUXAN	3.9	0.2	6.2%	0.0	0.0	22.7%
TECFIDERA	3.6	0.2	6.7%	0.5	0.0	-4.4%
XARELTO	3.5	0.7	25.9%	8.4	1.0	13.8%
LANTUS	3.3	-0.5	-12.2%	7.8	-0.9	-10.1%
TRUVADA	3.1	0.4	14.4%	2.0	0.2	10.2%
AVASTIN	3.1	0.0	-1.1%	0.0	0.0	-11.8%
VYVANSE	3.0	0.4	15.5%	11.8	0.8	7.6%
SYMBICORT	3.0	0.3	12.2%	9.8	0.8	9.1%
ELIQUIS	3.0	1.5	99.0%	7.1	3.3	83.5%

# Rescheduling and other factors are causing a decline of HYCD/APAP scripts year over year

35% lower than the peak or 47 million fewer scripts

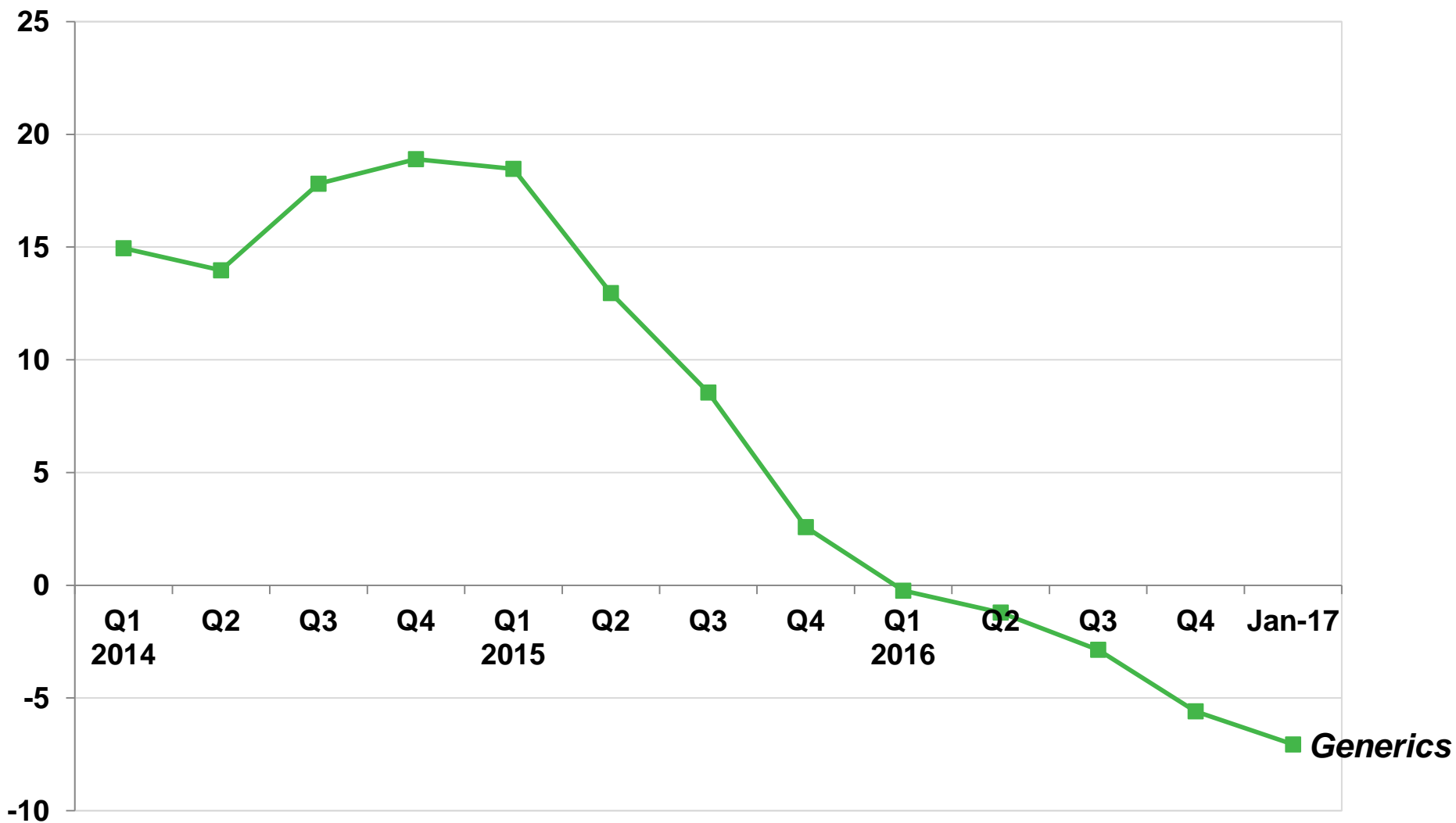


# Non discounted Unbranded Generic sales were \$67 Billion in 2016 but there was negative growth



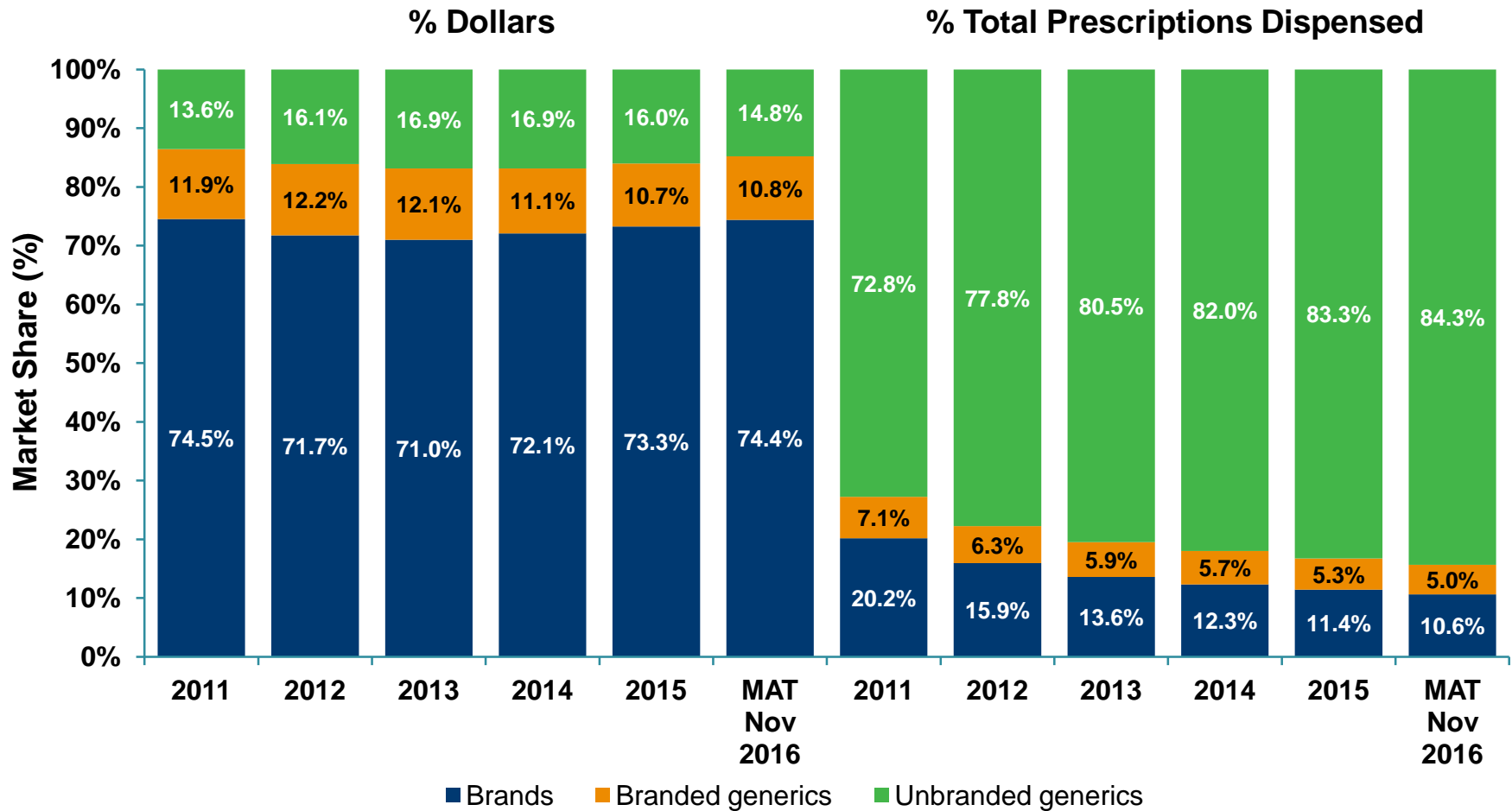
Source: QuintilesIMS, National Sales Perspectives, Nov 2016

# Generics are experiencing Price Deflation since early 2016 according to Barclay's Price Monitor



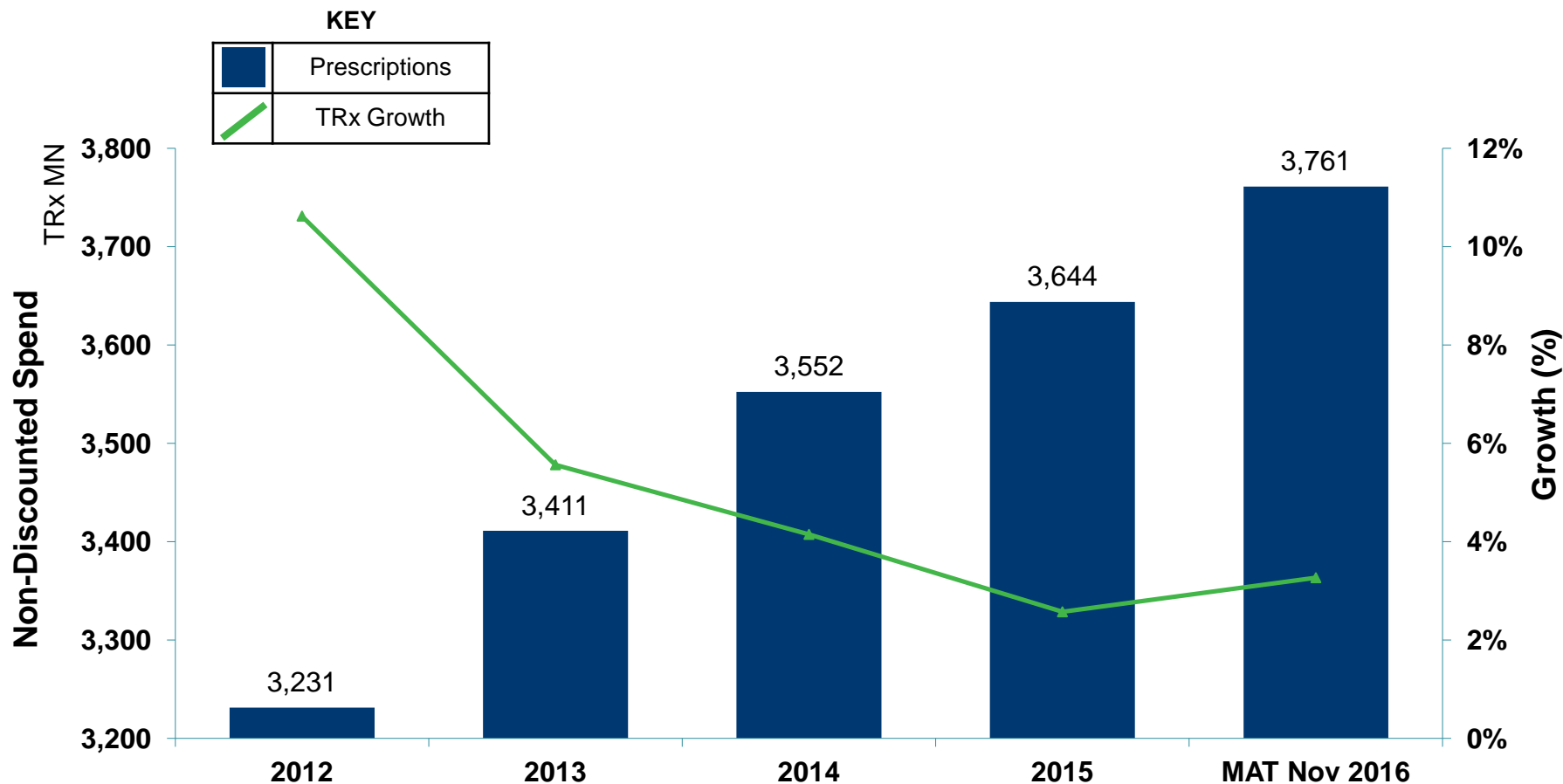


# Unbranded Generics have captured 84.3% of scripts



Source: IMS Health, National Sales Perspectives, Nov 2016, National Prescription Audit, Nov 2016

# Americans filled 3.8 Billion Unbranded prescriptions in 2016

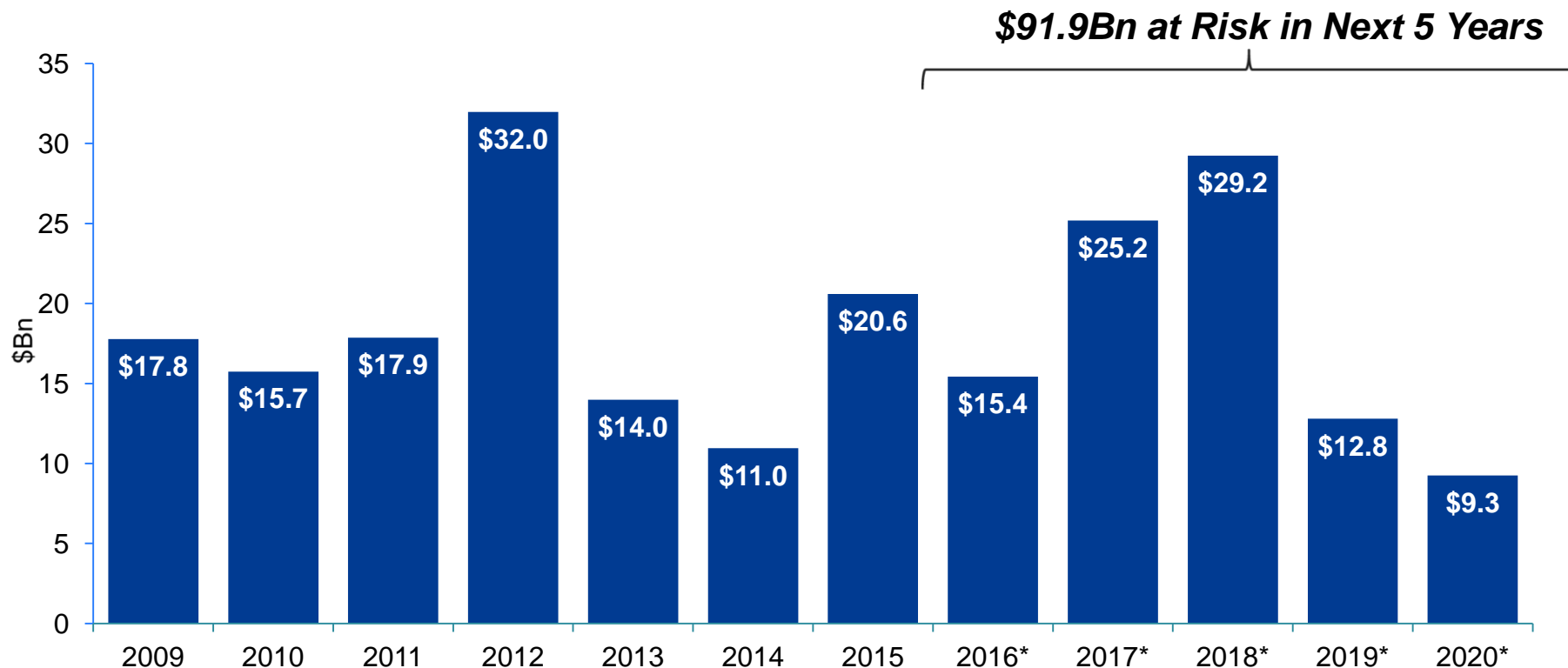


Source: QuintilesIMS, National Prescription Audit, Nov 2016

# Small Molecule Brands facing LOE in the next 5 years are valued at \$91.9Bn

Biggest 2016 expiries: Crestor, Gleevec, Benicar, Zytiga

U.S. Small Molecule Patent Expiry Exposure



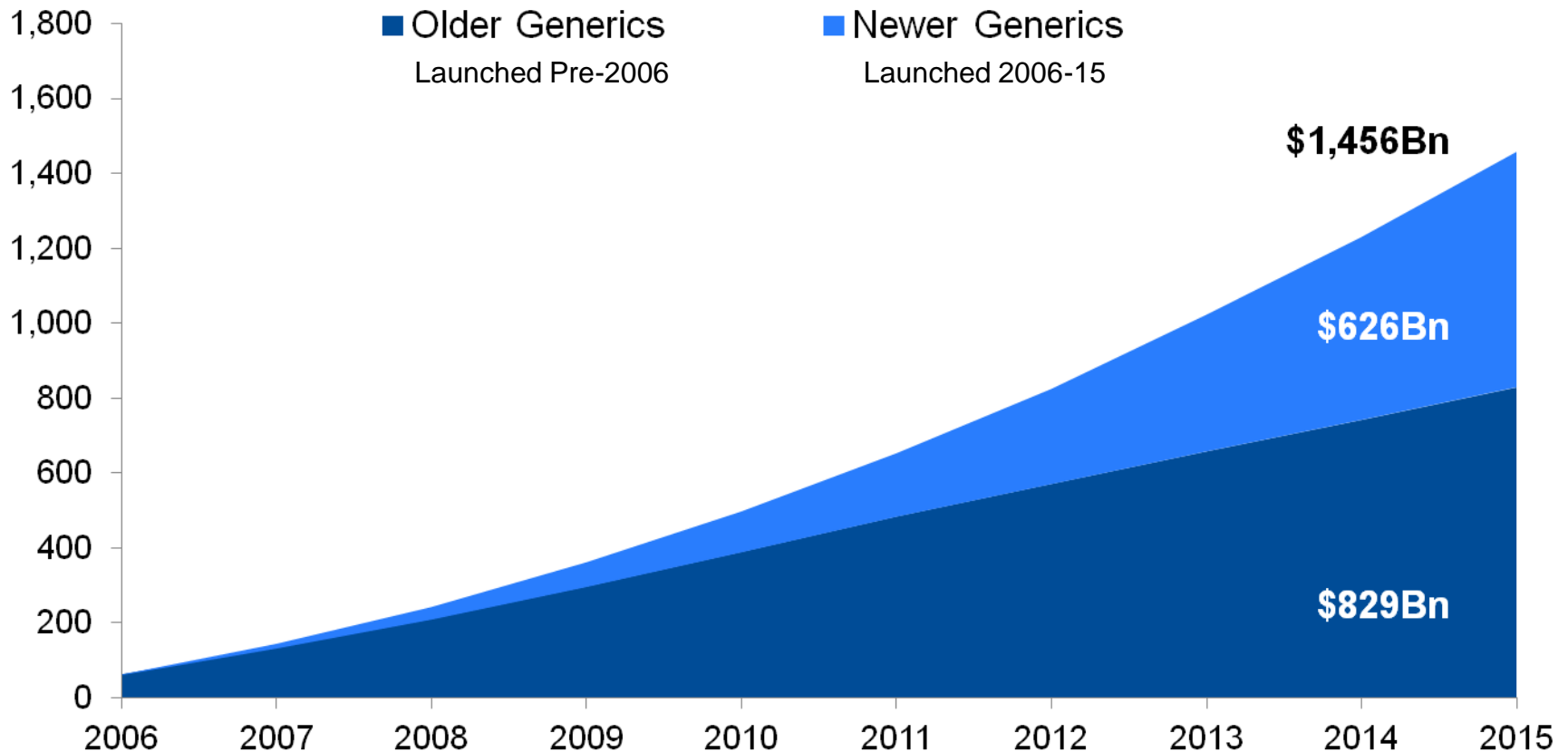
\*Sales in year prior to expiry used for years 2009-16; sales in MAT Sep 2016 used for years 2017-20

Source: IMS Health, National Sales Perspectives, Sep 2016

# The U.S. healthcare system has saved \$1.46 trillion in the last ten years due to the availability of low cost generics

Savings from generics launched 2006-15 total \$626Bn over last 10 years

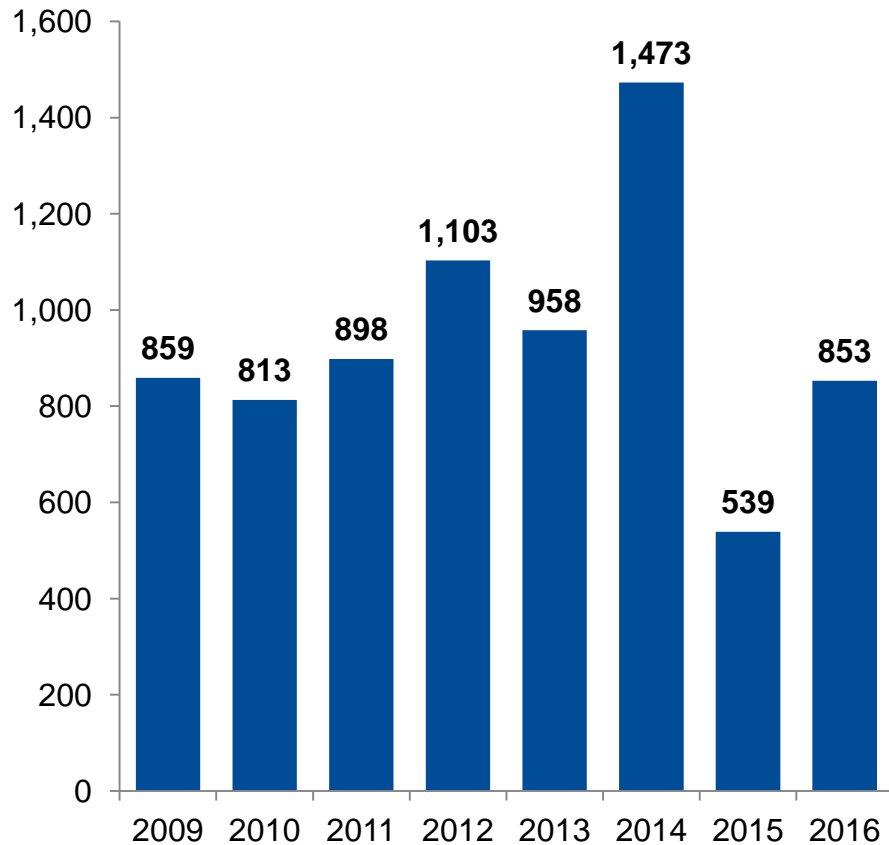
Cumulative Ten Year Savings from Older and Newer Generics (\$Bn)



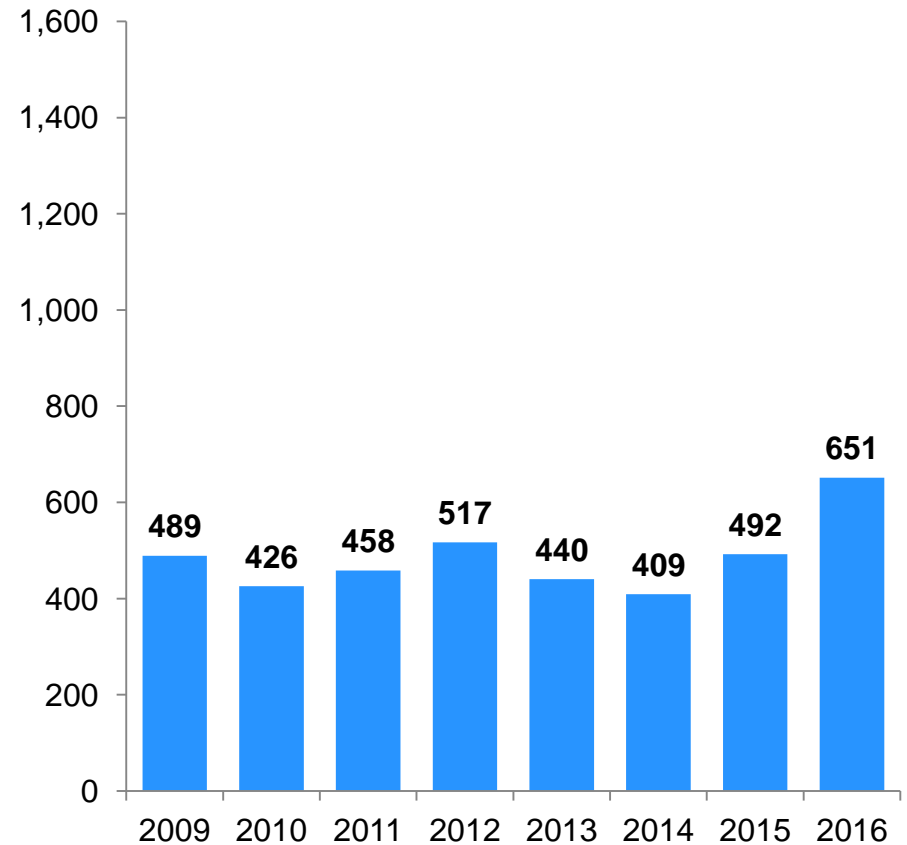
# 2016 was a record year for ANDA Approvals

*FDA Fiscal Year Basis*

## Received



## Approved



Source: FDA, 2016

# 4 Trends of Generics

According to Randall Stanicky- Royal Bank of Canada

- **Acceleration in OGD's generic ANDA approval times**
- **Consortium bid pressures are building**
- **Competition from India is increasing**
- **There are more hurdles to raising prices**

## Median Approval times

FY 2010	19.5 months
FY 2011	16.4 months
FY 2012	20.1 months
FY 2013	24.2 months
FY 2014	21.6 months
FY 2015	14.8 Months

# Many key biologics losing protection by 2020



Top 10 biologics total \$79Bn sales globally

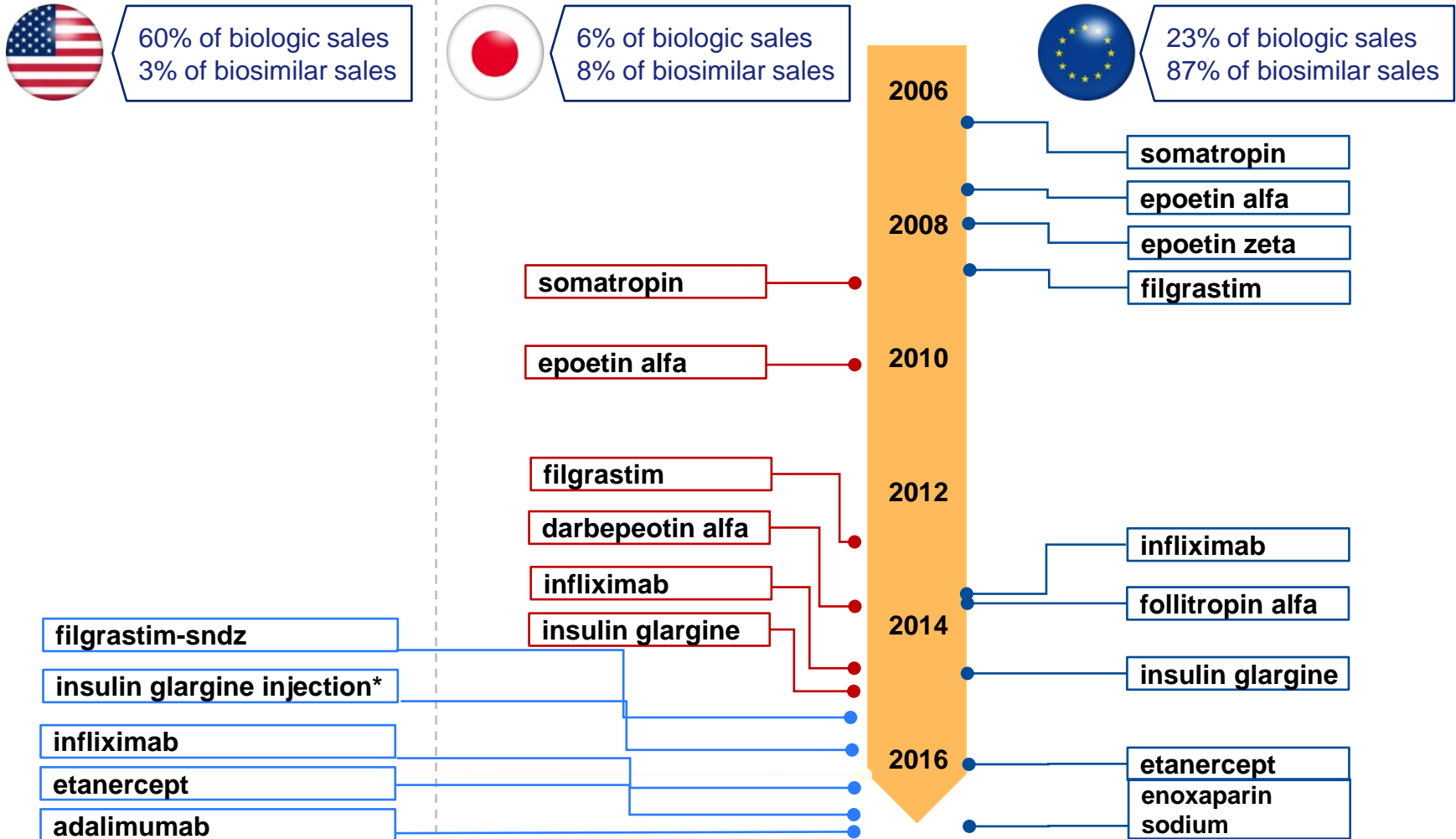
Global Top 10 Biologics sales by region		US expiry date	EU expiry date	
66%	34%	Adalimumab (Humira)	2016	2018
77%	23%	Insulin Glargine (Lantus)	Expired	Expired
66%	34%	Etanercept (Enbrel)	2028 (extended)	Expired
57%	43%	Infliximab (Remicade)	2018	Expired
55%	45%	Rituximab (Mabthera)	2018	Expired
48%	52%	Bevacizumab (Avastin)	2020	2019
41%	59%	Trastuzumab (Herceptin)	2019	Expired
78%	22%	Insulin Aspart (Novorapid)	Expired	Expired
84%	16%	Glatiramer Acetate (Copaxone)	Expired	2017
84%	16%	Pegfilgrastim (Neulasta)	2015	2017

0 5 10 15 20 Sales 2015 US\$

US Sales Non US

# Three regions make up 88% of global biologic sales and 98% of biosimilar sales\*

## US, Japan, Europe Biosimilar molecule approvals to date





# Europe has paved the way for biosimilar development

- As of the end of 2016, the EMA has approved **23 biosimilars (8 molecules)**
- 2016 marks **the tenth anniversary** of the launch of the first biosimilar in Europe and Medicines for Europe claims:
  - Across Europe, nearly **90% of doctors now know what Biosimilar medicines are and nearly 60% have already prescribed them**
  - Since the first biosimilar medicine was launched in 2006, EU-approved biosimilars have generated more than **400 million patient days of positive clinical experience**
  - Between 2006 and 2014, **biosimilar medicines have increased patient access by 44% overall within in the EU-5 countries\*<sup>^</sup>**



\* France, Germany, Italy, Spain, United Kingdom



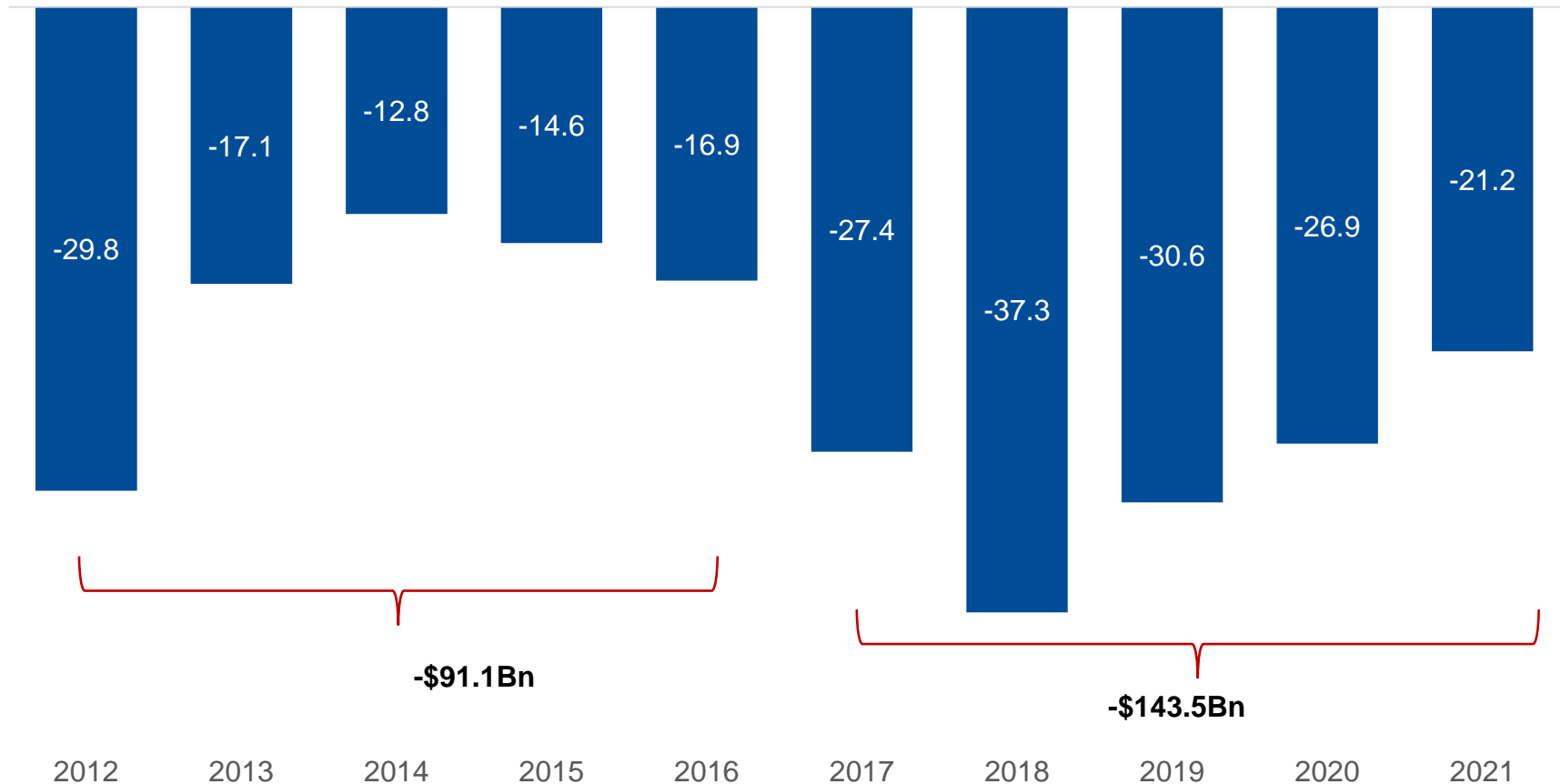
# The FDA is catching up...

- It took longer for US FDA to formulate its guidance for biosimilar development and some guidance's are still being developed
- As of 2016, the FDA:
  - Approved four biosimilars: filgrastim, infliximab, etanercept and adalimumab
  - Also approved extrapolation of data submitted for all other licensed indications of the originator (in most cases)
  - Increased internal resources to handle the volume of biosimilar applications
- Canada, Australia, Japan and South Korea are demonstrating a similar commitment to introducing biosimilars recognizing the significant benefits of making important biologic therapies more affordable and thereby increasing patient access within their populations

# Learnings from IMS Health 2016 “The Impact of Biosimilar Competition” report in Europe

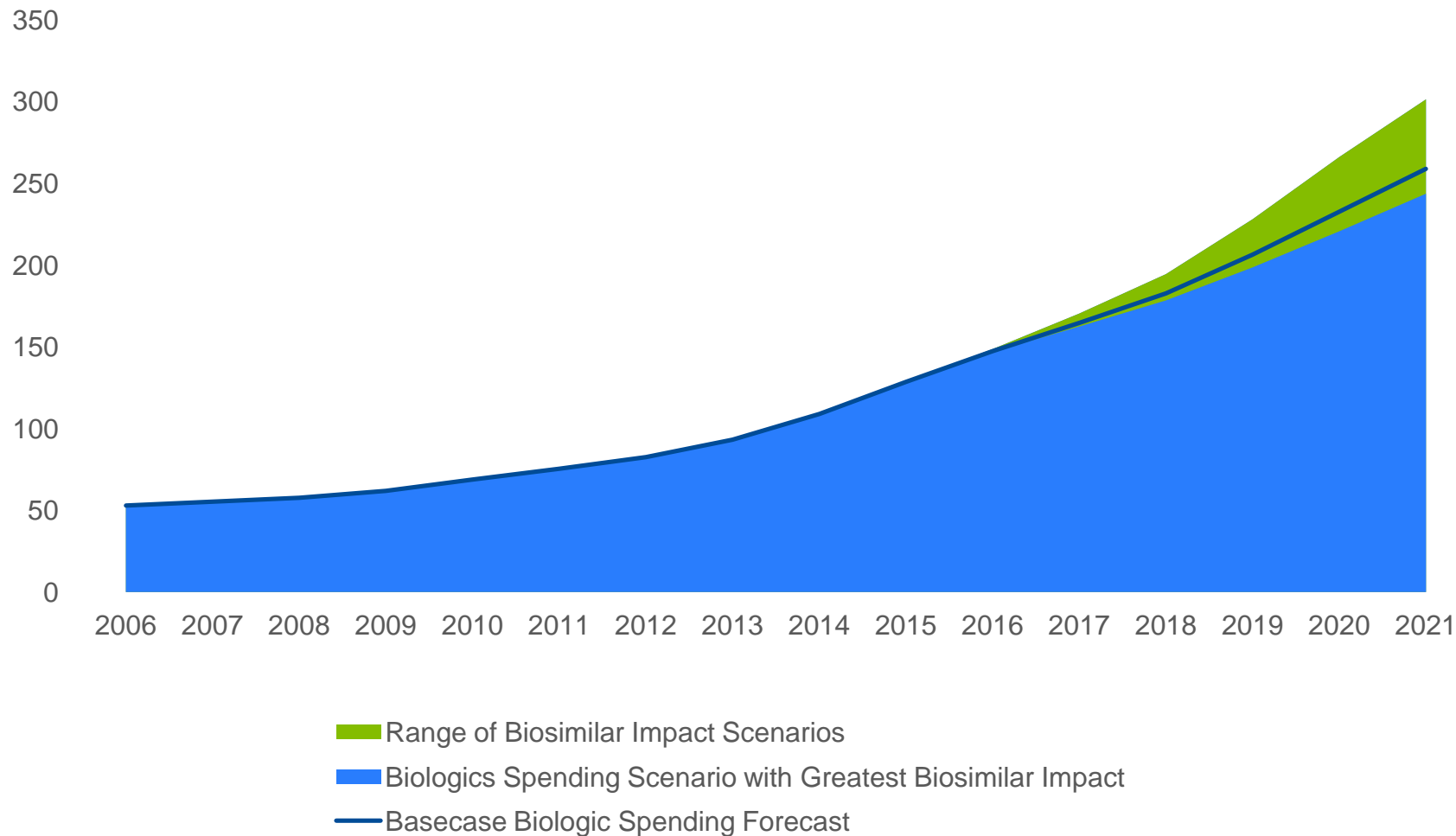
- Competition drives down the price
  - > In order to achieve long-term savings, there should be a competition with multiple players
- The correlation between biosimilars MS and price reduction is weak
  - > High savings can be achieved even if the market share is low
- Competition can also influence the originator’s behaviour
  - > Originators are launching innovative long-acting/pegylated products without a price premium versus the short-acting. This changes the treatment paradigm and therefore usage patterns.
- Lower prices has the most impact on usage in countries with low initial usage
  - > There are significant increases in consumption for countries with low starting volumes
- The product profile differences can explain differences in impact on the KPIs

# Impact of U.S. losses of exclusivity on expected to be 58% greater in next five years including biosimilars



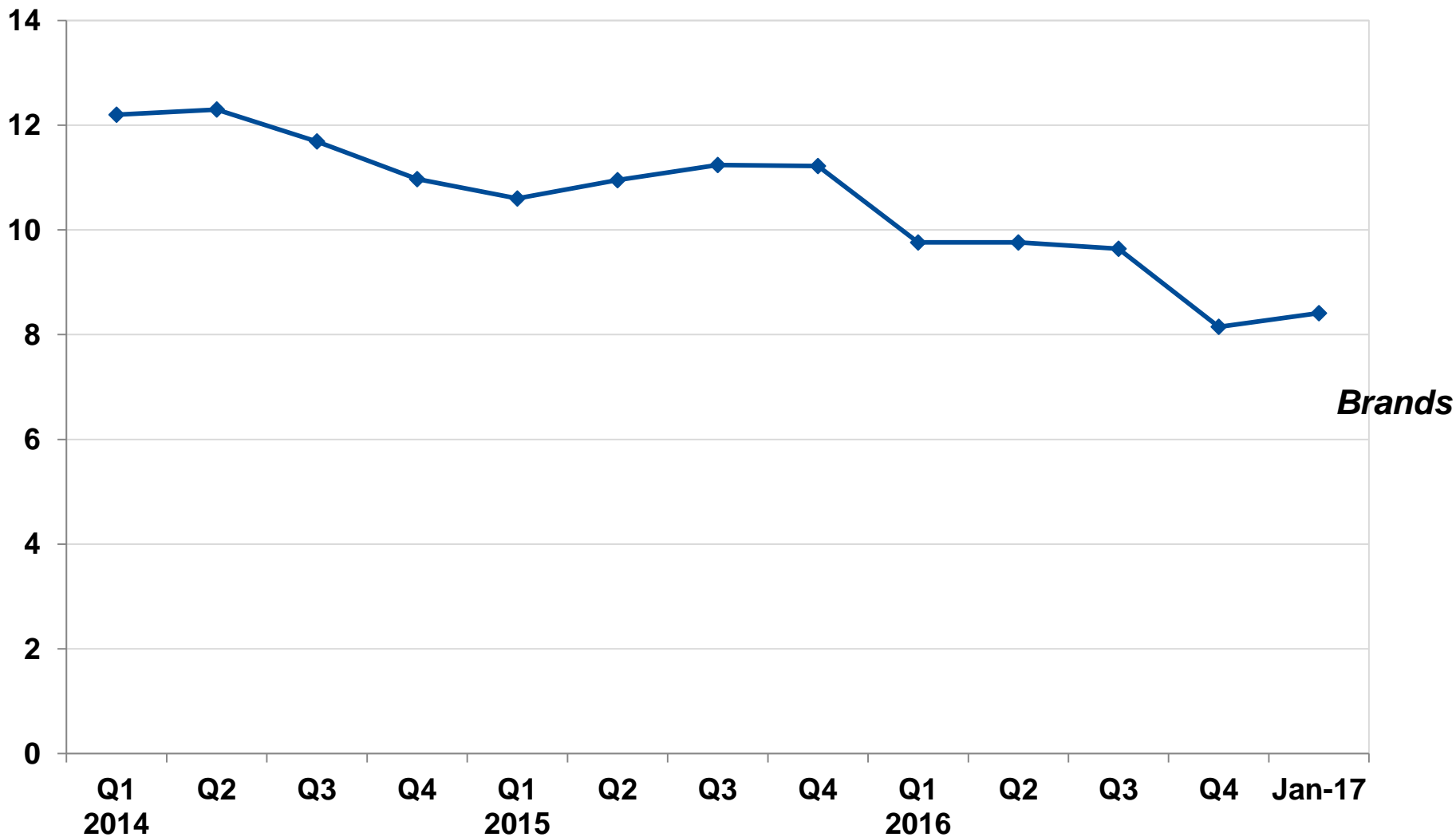
Source: IMS Market Prognosis, Sept 2016; QuintilesIMS Institute, Oct 2016

# U.S. biologic spending without biosimilars would grow at 14-17%; as low as 9-12% in greatest impact scenario



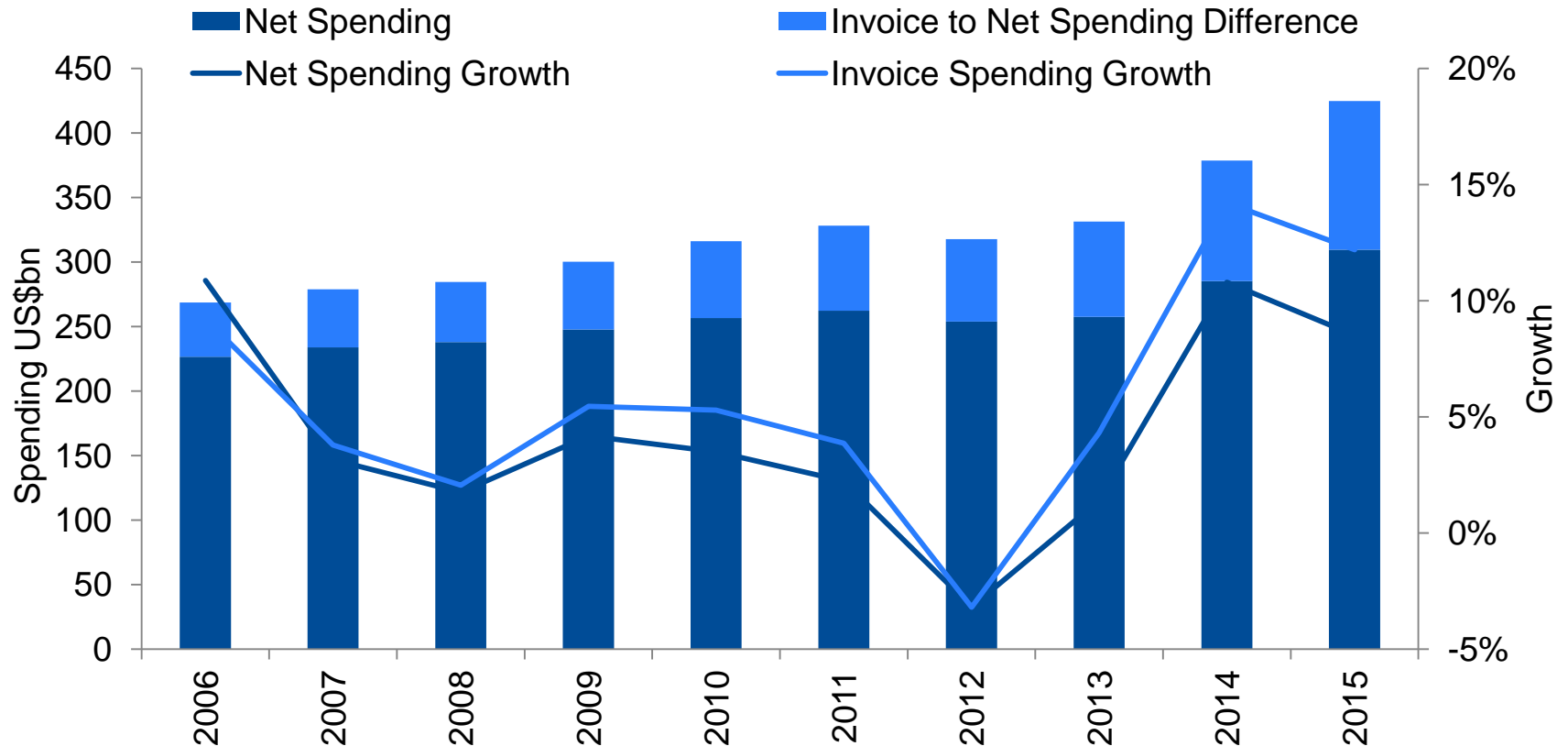
Source: QuintilesIMS Institute, Oct 2016

# Brands have less Price Inflation since early 2016 according to the Barclay's Price Monitor



# Spending on medicines in 2015 increased 8.5% on a net price basis to \$309.5bn and 12.2% to \$424.8bn on an invoice basis

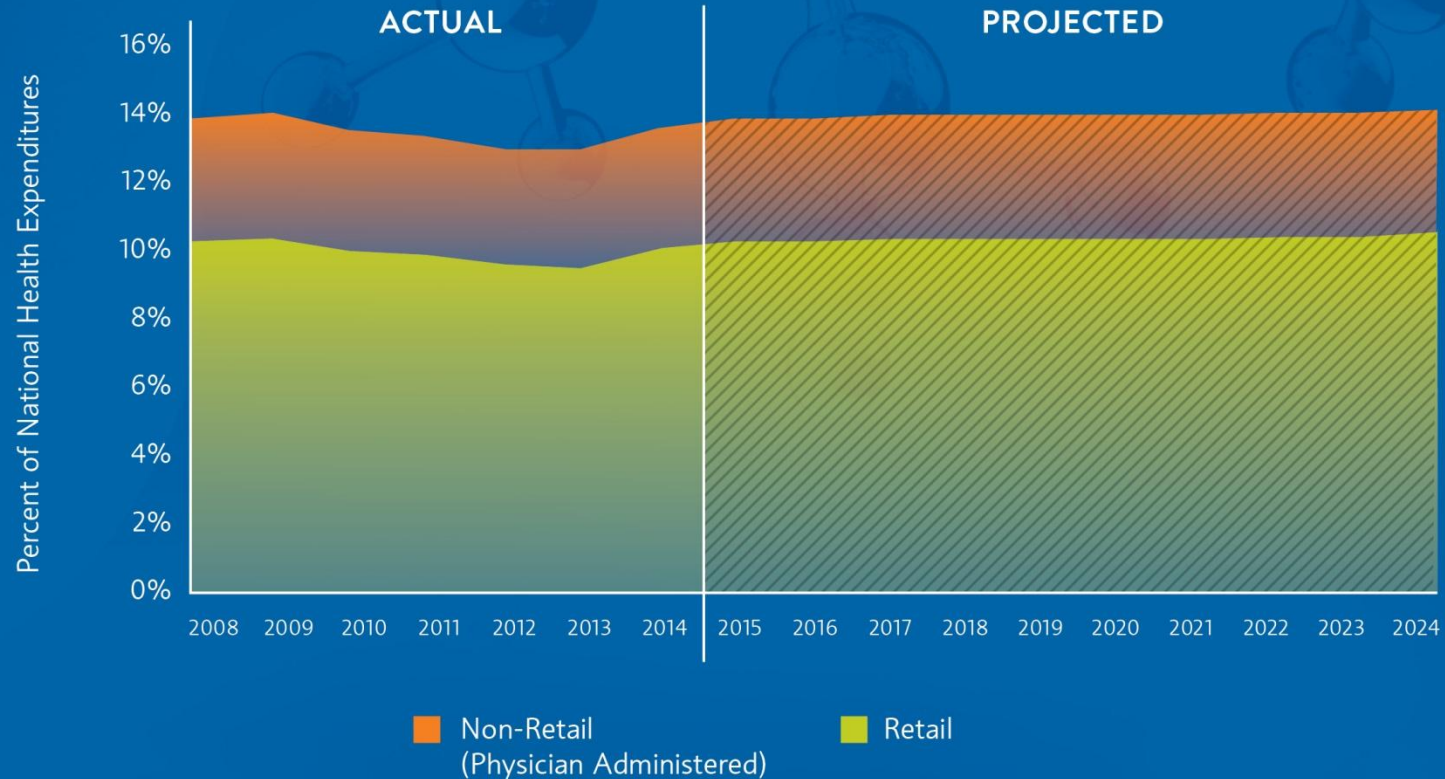
Total Spending on Medicines US\$bn



Source: US Census Bureau; US Bureau of Economic Analysis; IMS Health, National Sales Perspectives, Jan 2016

# Medicines Account for a **STABLE SHARE OF HEALTH CARE SPENDING**

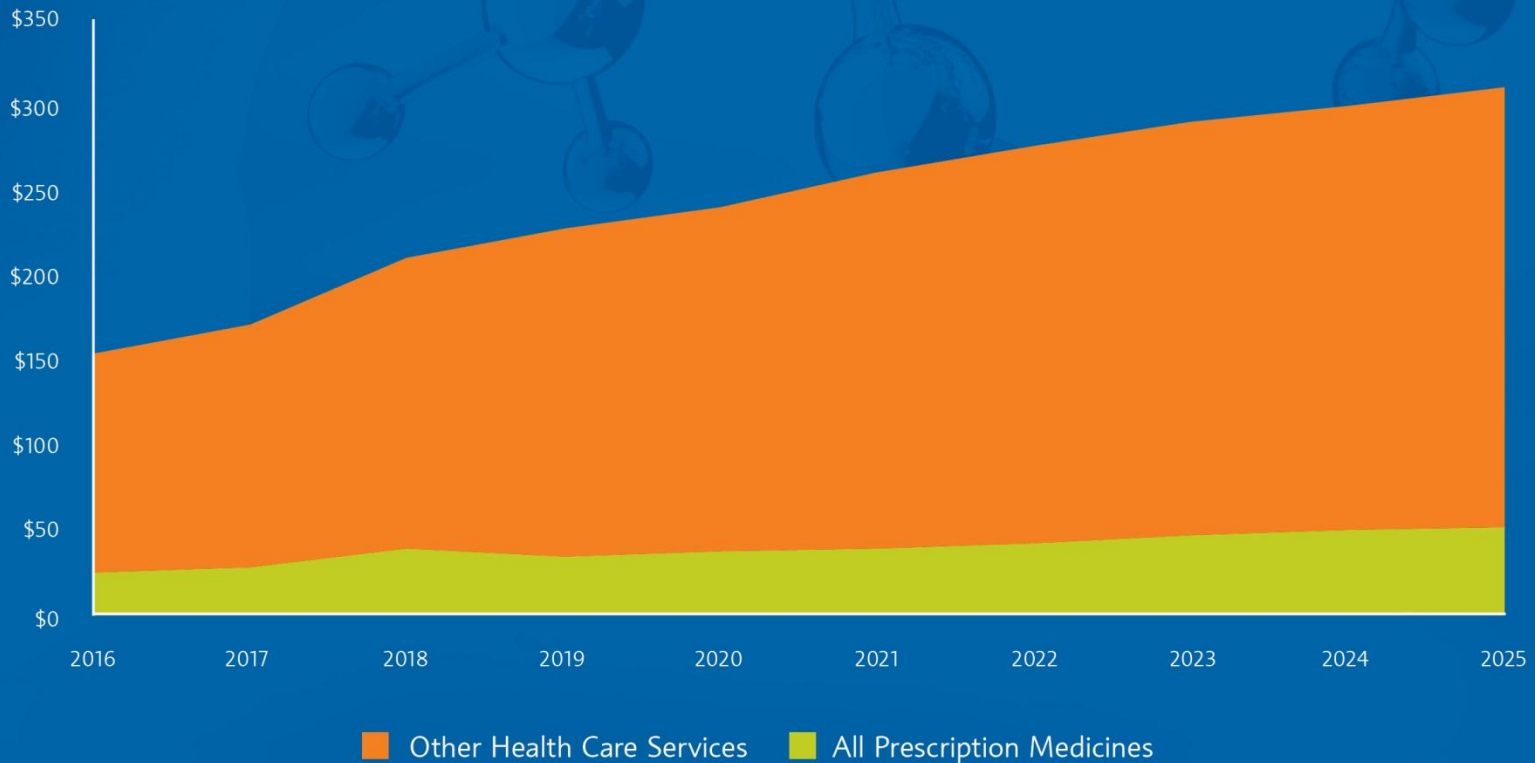
Health Care Expenditures Attributable to Retail and Non-Retail Prescription Drugs, 2008-2024





# GROWTH IN OTHER HEALTH CARE SERVICES WILL BE FIVE TIMES *Total Medicine Spending Growth Through Next Decade*

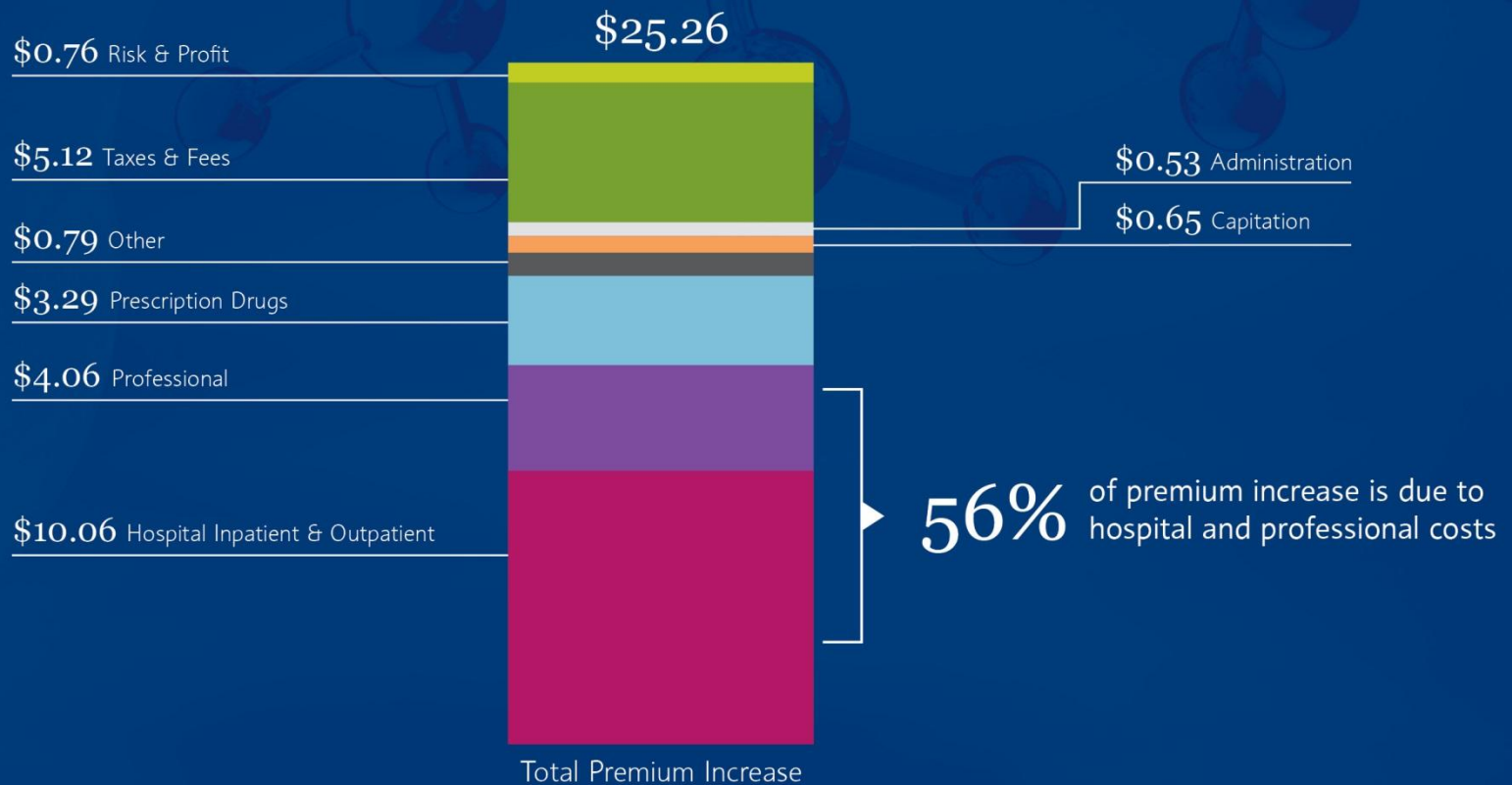
Projected Annual Growth in Spending (\$ Billions)



*Insurers' Data Show*

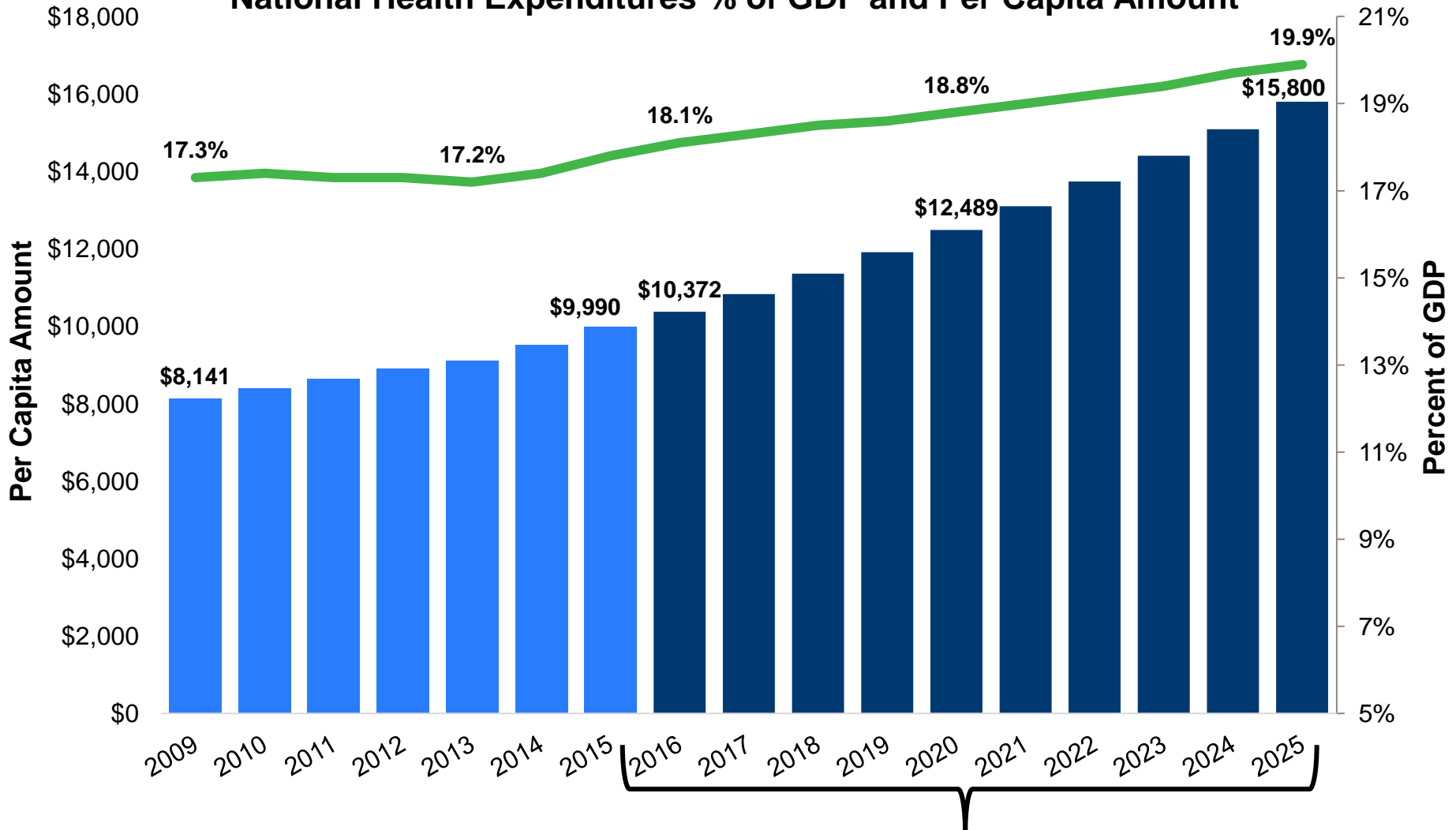
# MEDICINES ARE NOT MAIN DRIVER OF PREMIUM INCREASES

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



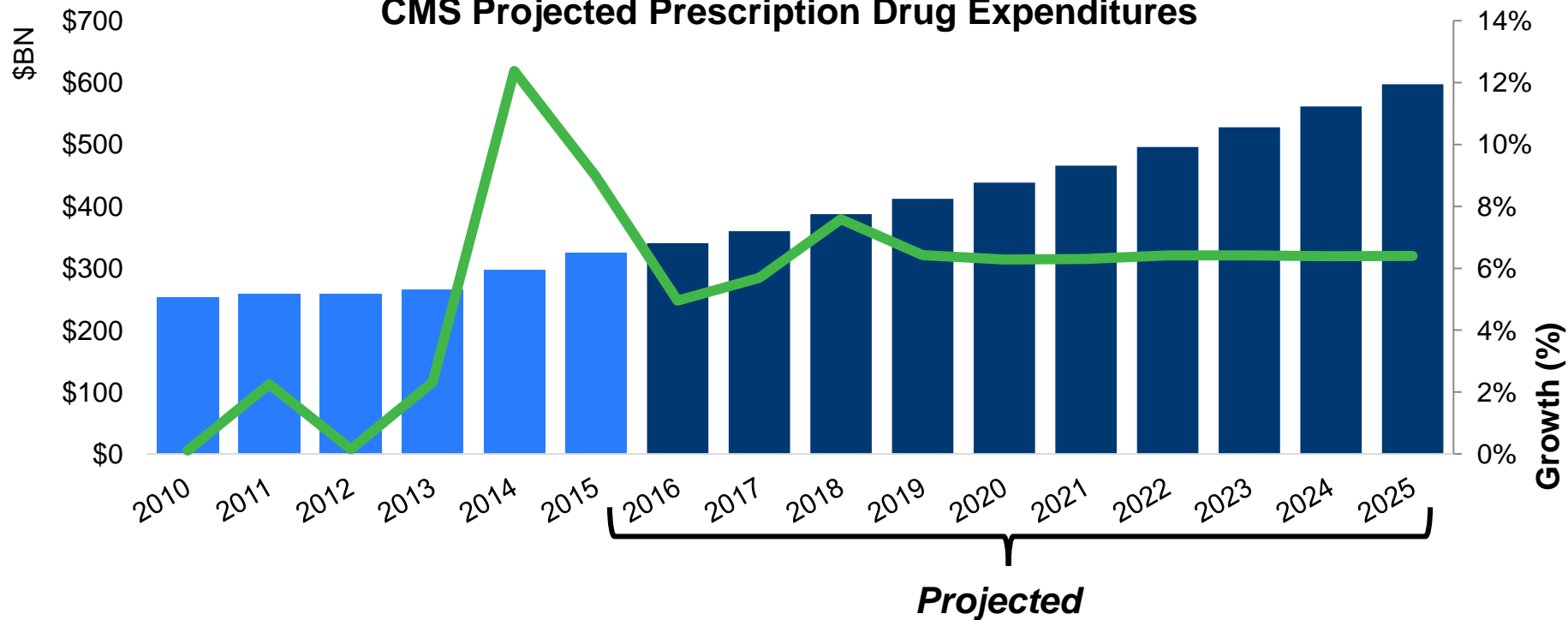
# National Health Expenditures will account for ~20% of US Gross Domestic Product spend by 2025

National Health Expenditures % of GDP and Per Capita Amount



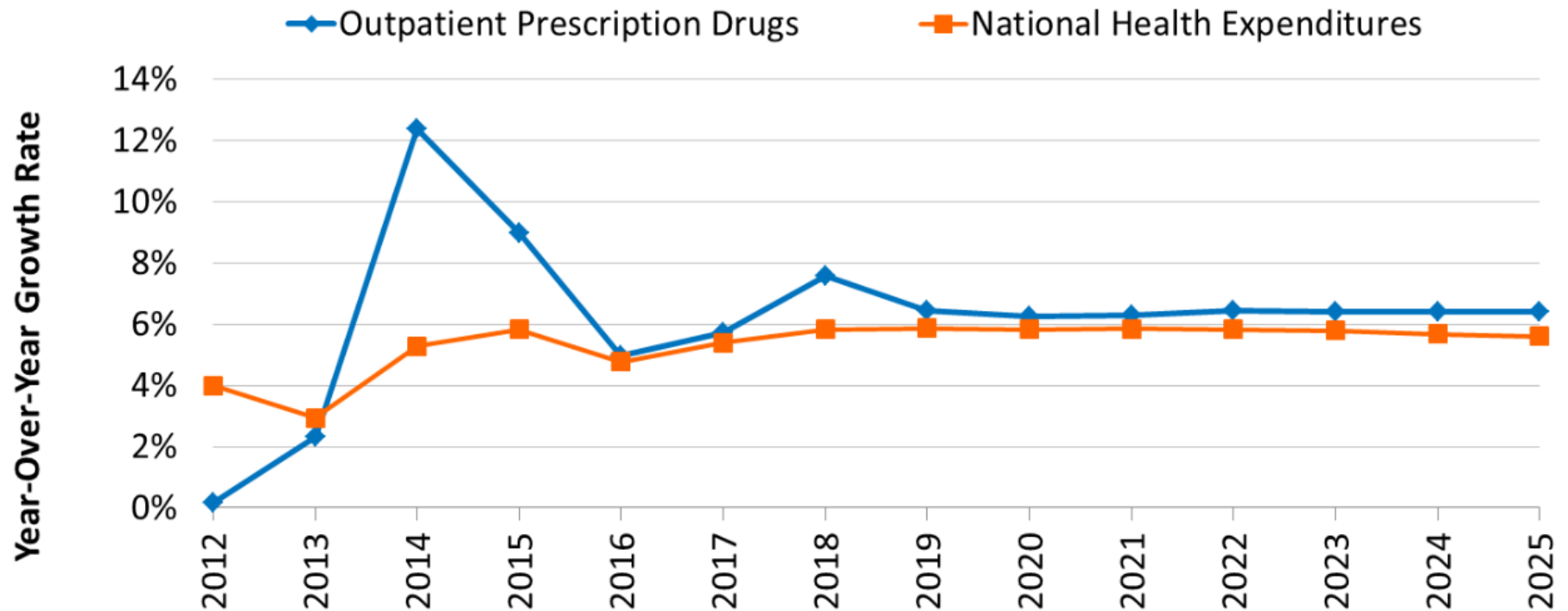
# Prescription Drug spend may reach \$597.1BN by 2025 and contribute ~11% to total national health expenditures

## CMS Projected Prescription Drug Expenditures



Prescription Drug Expenditure Share	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
% of National Health Expenditures	9.7%	9.6%	9.3%	9.2%	9.8%	10.1%	10.1%	10.2%	10.3%	10.4%	10.4%	10.5%	10.5%	10.6%	10.7%	10.8%
% of Personal Health Care Expenditures	11.5%	11.4%	11.0%	10.9%	11.6%	11.9%	11.9%	12.0%	12.2%	12.2%	12.3%	12.3%	12.4%	12.5%	12.6%	12.7%

# Projected Growth Rates in National Health and Outpatient Prescription Drug Expenditures, 2012-2025

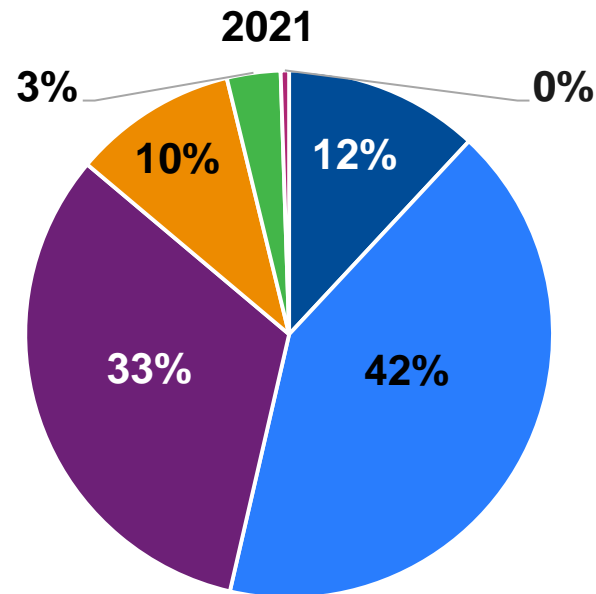
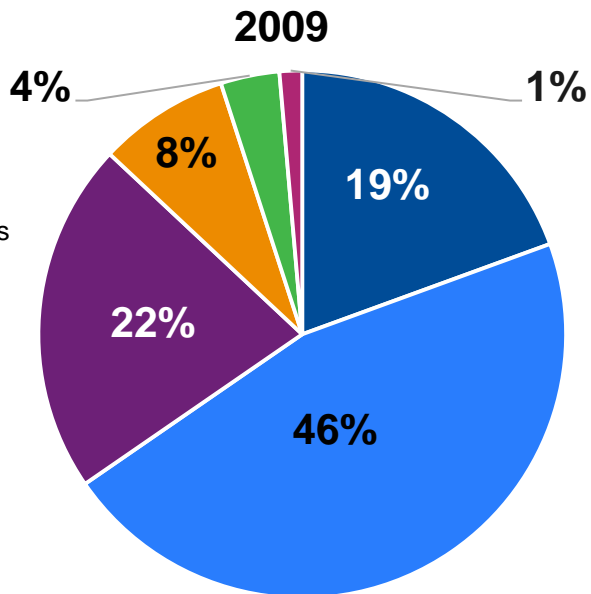
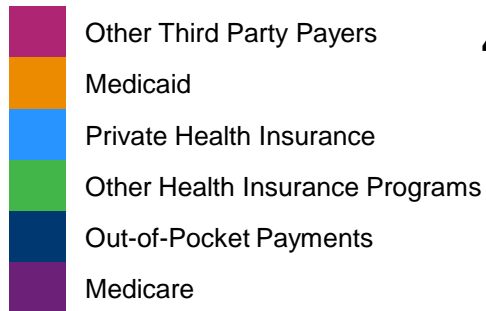


First projected year is 2016.

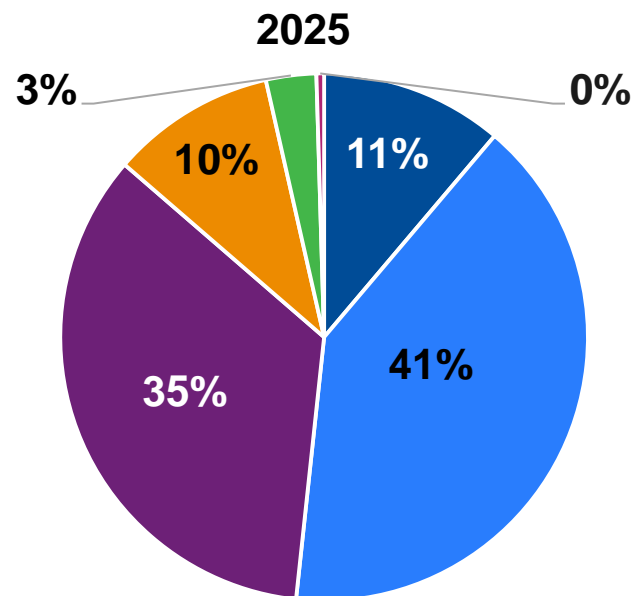
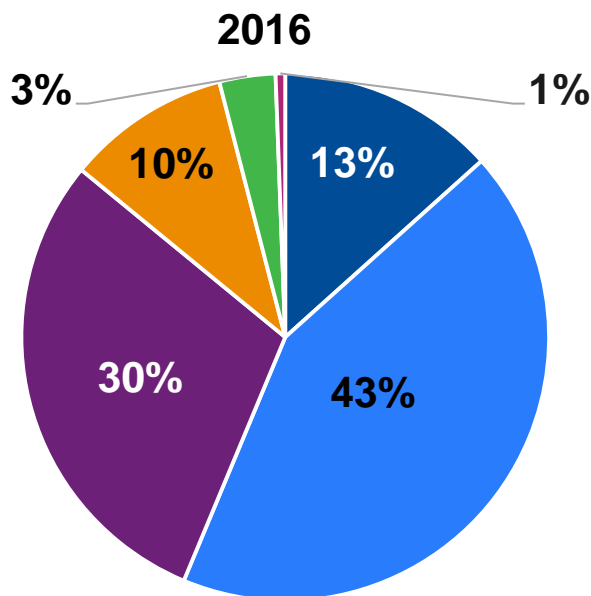
Source: Pembroke Consulting analysis of National Health Expenditure Accounts, Office of the Actuary in the Centers for Medicare & Medicaid Services, February 2017.

Published on Drug Channels ([www.DrugChannels.net](http://www.DrugChannels.net)) on March 3, 2017.

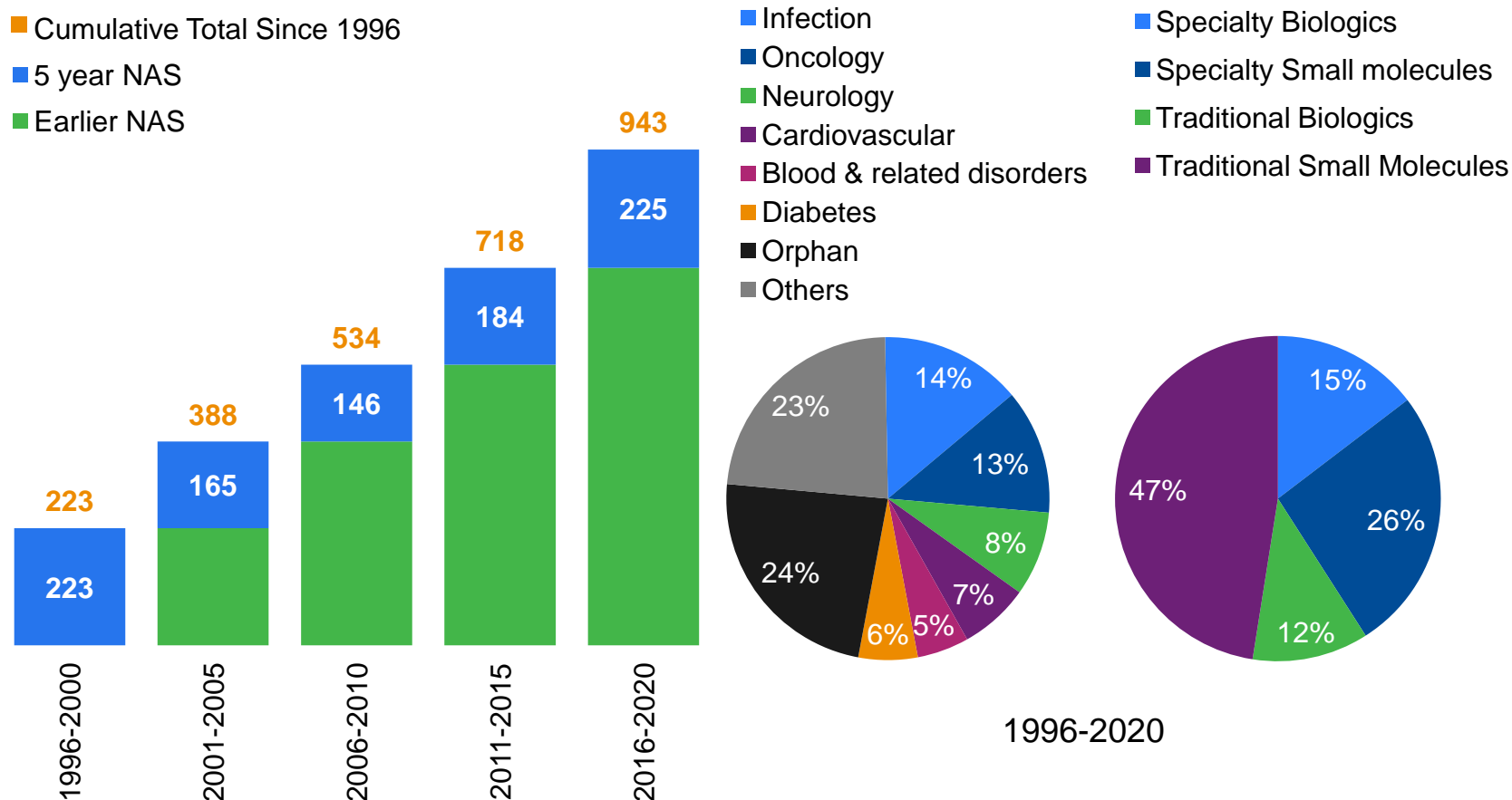
# Share of Prescription Drug Expenditure by Source of Fund



**Medicare funding is projected to increase from 30% in 2016 to 35% by 2025**



# Global New Active Substances (NAS) Available Since 1996



Note: Disease categories based on therapy areas and expected launches 2016-20. Orphan drugs are those to treat small populations with rare diseases, and are defined separately by US FDA and the European Medicines Agency (EMA). Any medicine with an orphan designation for an approved use within the first year after global launch are categorized as Orphan. Half of designated orphan indications are granted more than a year after original approval.  
 Source: IMS Health, IMS Institute for Healthcare Informatics, October 2015

# Top 2016 Launches

Product	Class	Manufacturer	2016 Sales (US\$)	Months on Market	Average Monthly Sales
<b>EPCLUSA</b>	HEPATITIS C	GILEAD			
<b>ZEPATIER</b>	HEPATITIS C	MERCK			
<b>BENDEKA</b>	ALKYLATING AGENTS	TEVA			
<b>ODEFSEY</b>	HIV ANTIVIRALS	GILEAD			
<b>DESCOVY</b>	HIV ANTIVIRALS	GILEAD			
<b>TECENTRIQ</b>	ANTINEOPLASTICS,MISC	GENENTECH			
<b>TALTZ</b>	IMMUNOMODULATORS	LILLY			
<b>XELJANZ XR</b>	ANTIARTHR,SYSTEMIC	PFIZER			
<b>XIIDRA</b>	OPHTH ANTI-INFLAM	SHIRE			
<b>BASAGLAR</b>	DIABETES THERAPY, INSULINS	LILLY			

Source: QuintilesIMS, National Sales Perspectives, Dec 2016



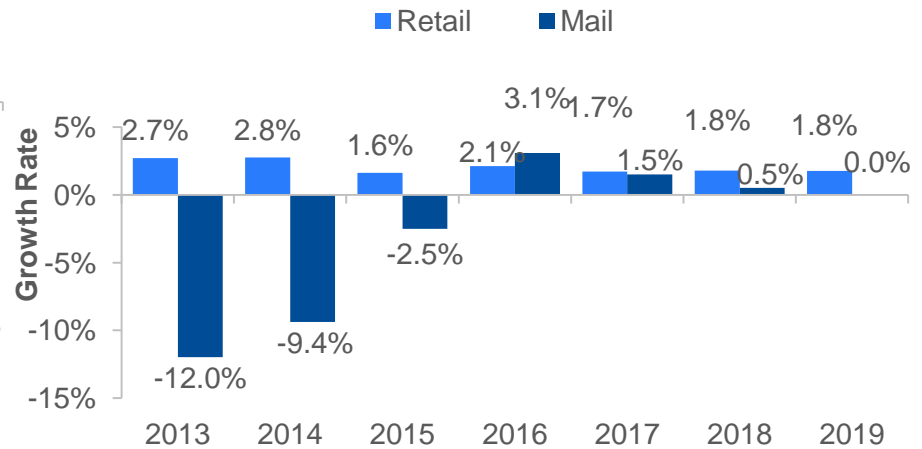
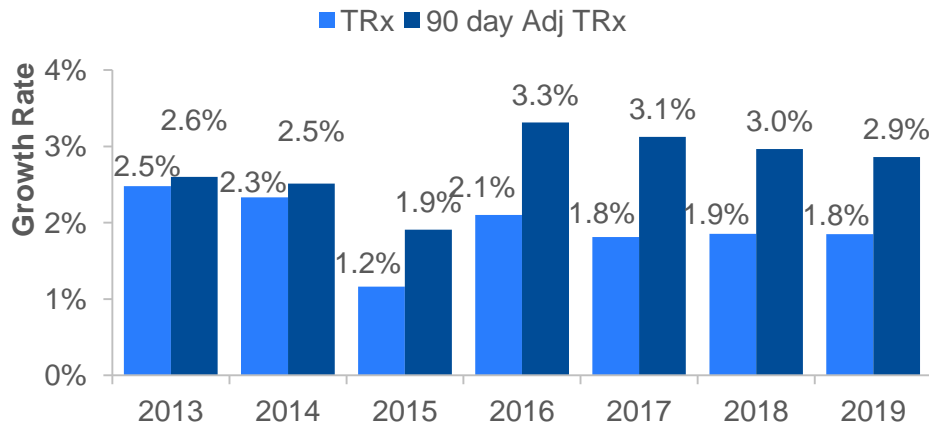
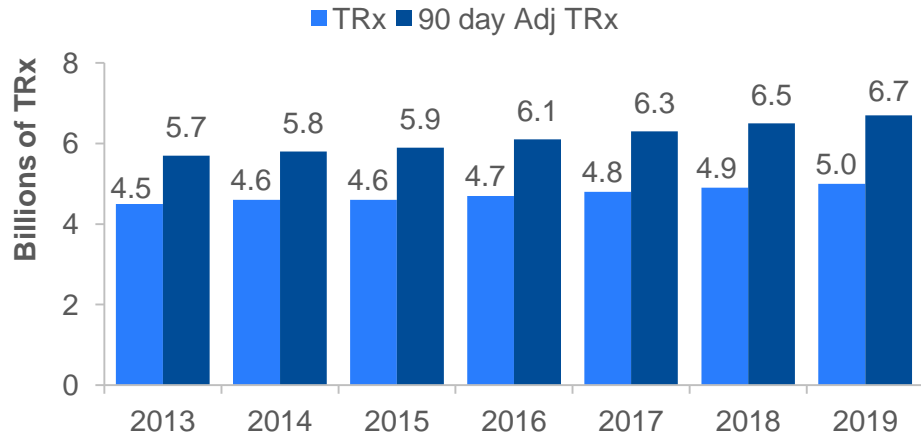
# Top 10 Potential Launches in 2017

*According to Fierce Pharma*

RK	Name	Company	Disease	2022 \$ EST
1	Ocrevus	Roche	MS	4.1
2	Dupixent	Sanofi & Regeneron	Atopic Dermatitis	4.1
3	Semaglutide	Novo Nordisk	Diabetes	2.2
4	Durualumab	Astra Zeneca	Cancer Immunotherapy	1.9
5	Niraparib	Tegaro	Ovarian Cancer	1.9
6	Baricitinib	Lilly & Incyte	RA	1.8
7	LEE011	Novartis	Breast Cancer	1.6
8	KTE-C19	Kite	Non Hodgkins Lymphoma	1.4
9	Ingressa	Neurocrine BS	Tardiva dyskinesia	1.3
10	Spinraza	Biogen	Spinal Muscular Atrophy	1.3

# Executive Summary

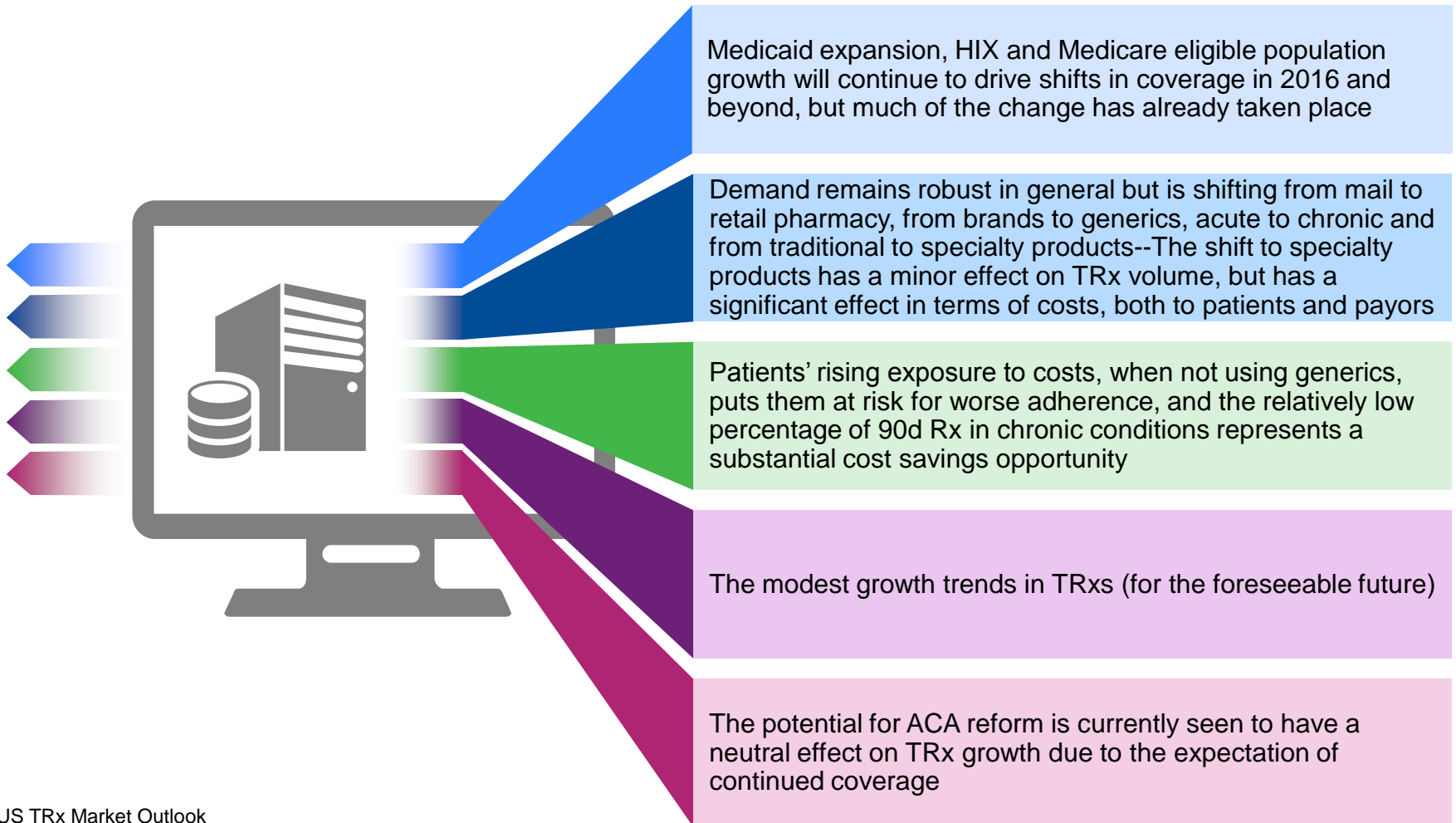
TRxs are forecast to grow slightly less than 2% per year through 2019



# Forecast Summary

- **Class of Trade:** Chain TRx growth of >2% is expected to exceed market growth (<2.0%)
- **Rx Length:** 90 day prescriptions continue to outpace market growth and capture share
- **Rx Length by Class of Trade:** 90 day TRxs are growing rapidly across all classes of trade; share growth of 90 day Rxs is greatest in Chains
- **Method of Payment:** Growth of Medicaid / Medicare D continues to outpace other payment categories driven by ACA and aging population; potential decline in Medicaid due to presidential outcome
- **Brand and Generic:** Brand growth rates are expected to climb as generics reach saturation
- **Acute and Chronic Therapies:** Chronic therapies continue to dominate the market and are expected to continue growing faster than acute therapies
- **Specialty and Traditional:** Specialty areas continue to grow but do not outpace traditional therapies; MS and oncologics are most dominant specialty category
- **Age Group:** Aging population (age 50+) continues to have an increasing demand for TRxs

# Thoughts for 2016 and Beyond



# What are People Thinking About?

## Pharmacies

- Reimbursement
- Controlled Substances abuse
- Access to Specialty Drugs
- Purchasing Alliances
- Track and Trace

## Generic Manufacturers

- Purchasing Alliances
- Price increase backlash
- Portfolio Optimization
- Brand /niche drugs
- Proposed labeling changes
- Tax Inversion

## Wholesalers

- Purchasing Alliances
- Controlled Substances abuse
- Access to Specialty Drugs
- Generic Price Deflation
- Track and Trace

## Brand/Specialty Manufacturers

- *Price backlash*
- *Becoming more specialized*
- *Oral Specialty*
- *Orphan Drugs*
- *Tax Inversion*

## Payers

- Exploding costs of Specialty Drugs
- Rising Oncology costs
- Formularies blocks and exclusive launches

## Consumers

- Rising costs
- Specialty Tiers
- Losing Insurance



QuintilesIMS™

# PCMA 2017

*The US Pharmaceutical Market:  
Trends, Issues, and Outlook*

Doug Long  
VP Industry Relations  
QuintilesIMS