

Charting the Course for Change: Industry Update

Doug Long

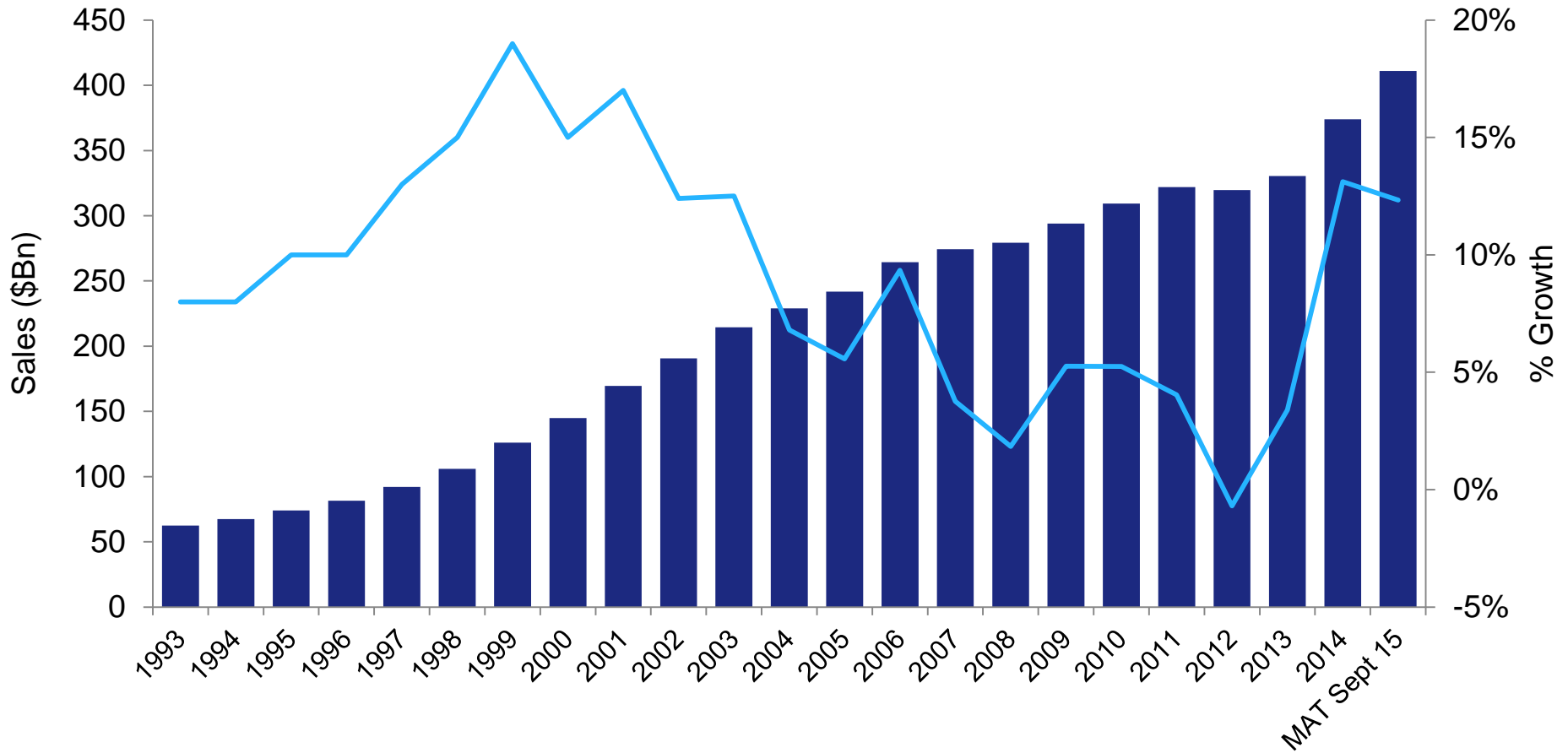
VP Industry Relations IMS Health
MedImpact

March 2016



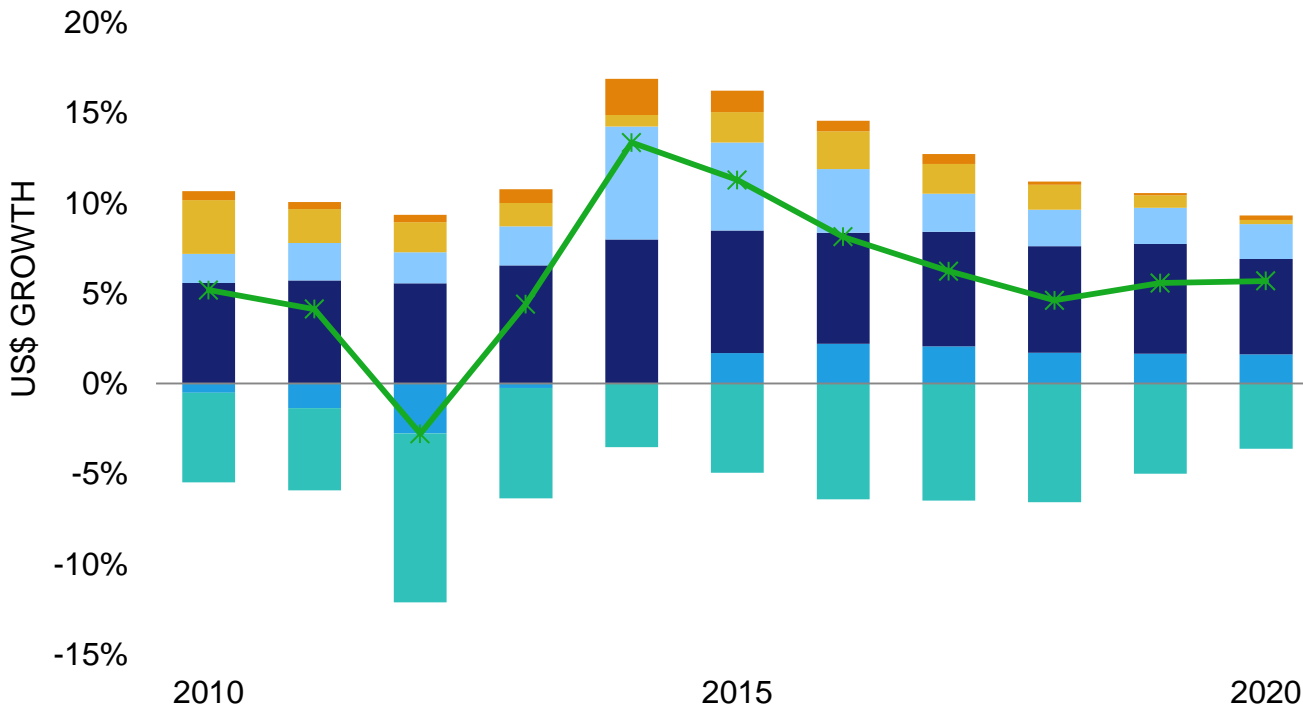
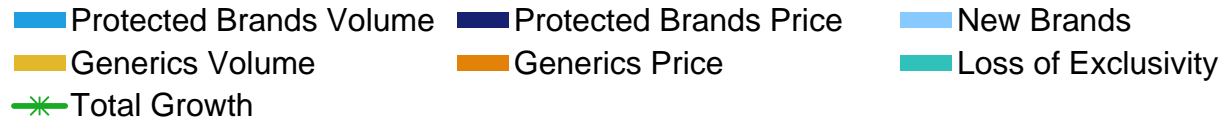
Spending increased 12.3% to \$411Bn in MAT Sept 2015

Growth is 12.2% year to date



Source: IMS Health, National Sales Perspectives, Sept 2015

U.S. Spending Growth, 2010-2020



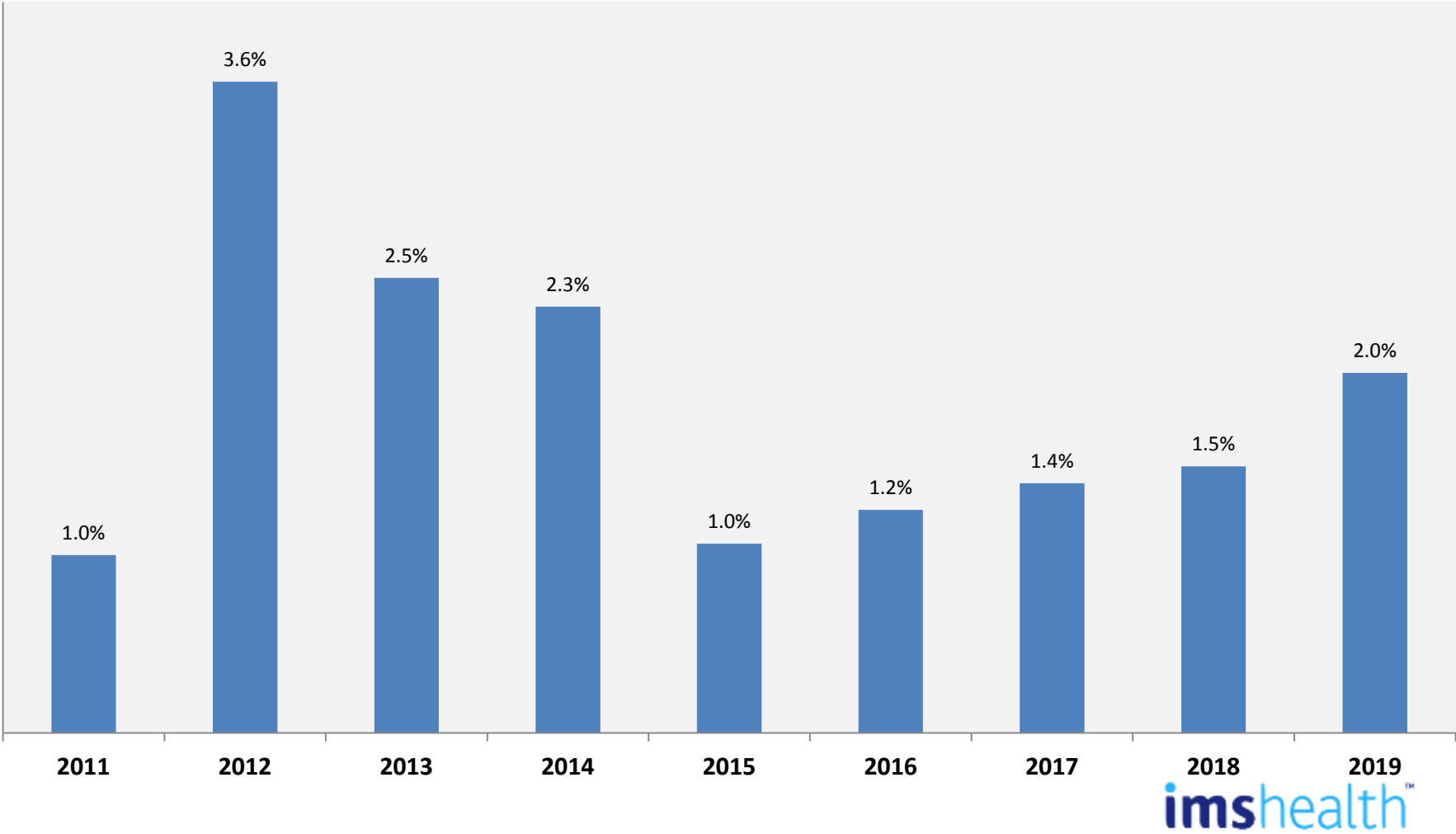
United States

- 2020 Spending: \$560-590Bn
- 2016-20 Growth: +146Bn
- CAGR 2016-20: 5-8%
- Increase over 2015: +34%
- 2020 Brand Share of spending: 67%; unchanged since 2015
- 2020 Specialty Share of spending: 34% + 0.4pts; 34% of increase since 2015

Source: IMS Health Market Prognosis, IMS Institute for Healthcare Informatics, October 2015

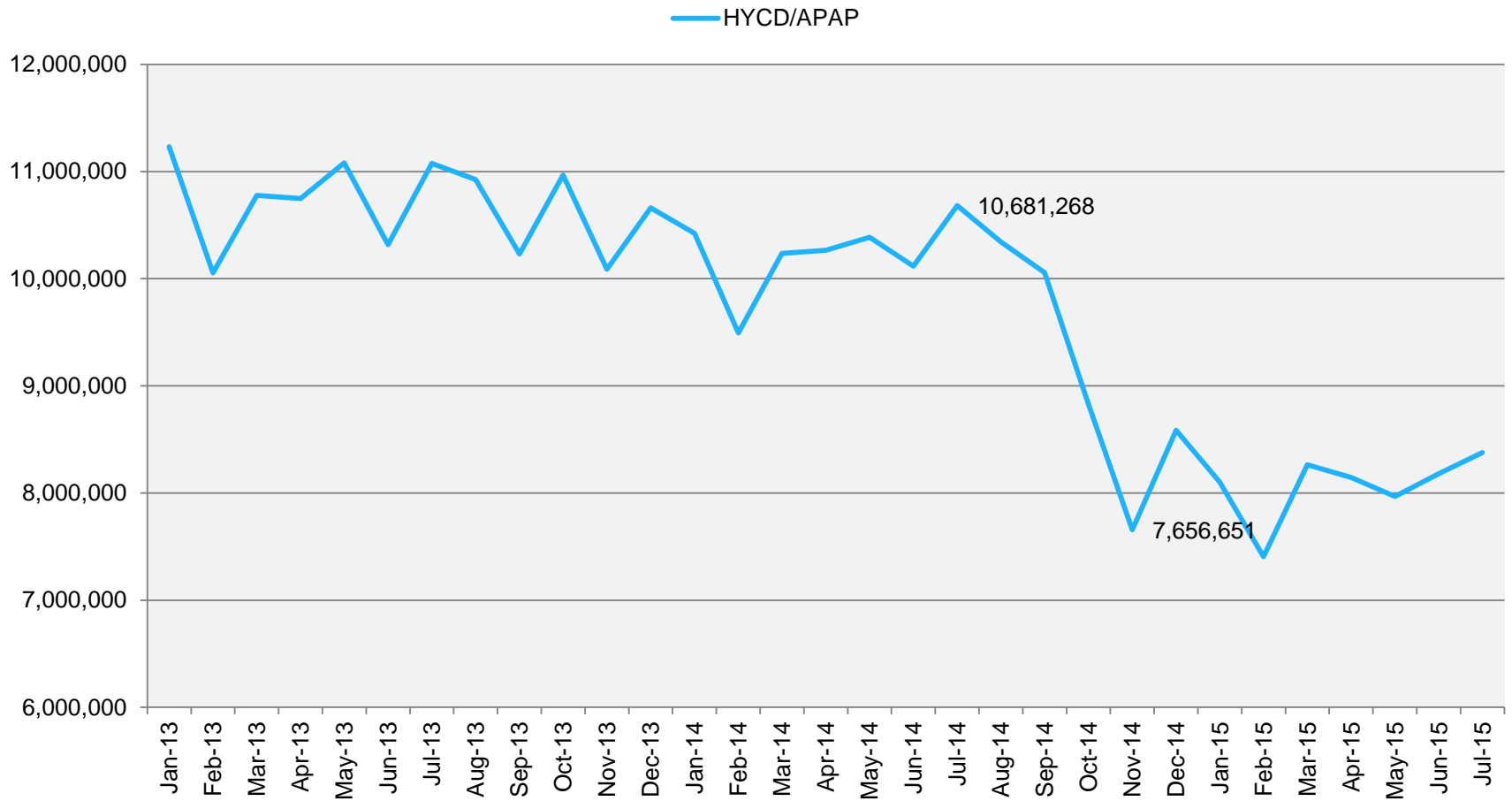
Historic and forecast dispensed prescription growth

Historical Rx growth has been between 1% and 3.5%, (it was much lower during the economic crisis) and is expected to be between 2% and 3% through 2018



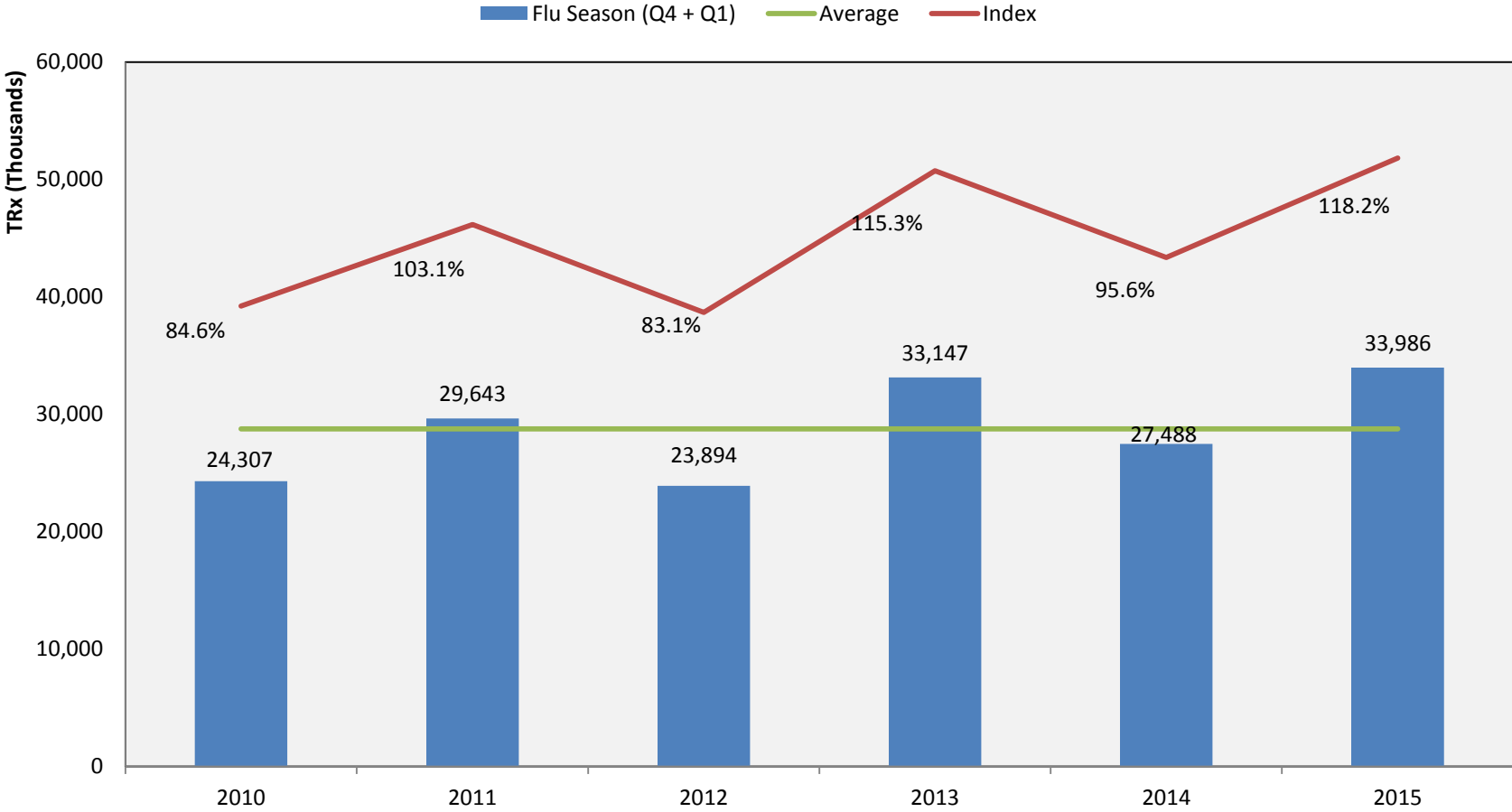
HYCD/APAP fell precipitously after rescheduling

The DEA's August 22, 2014 ruling dramatically affected sales



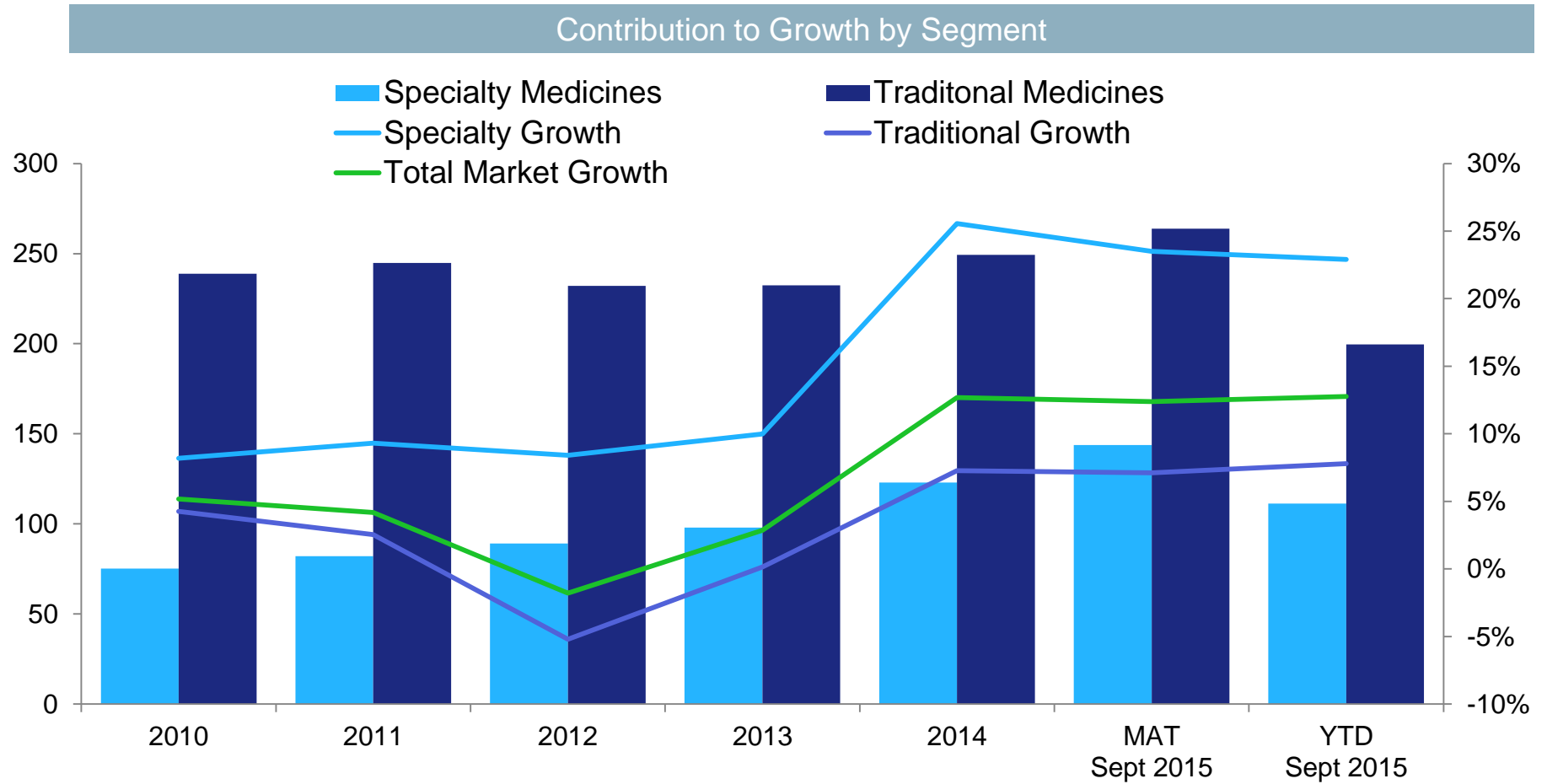
Flu Season Comparisons

2015 flu season shows most TRx in the past 6 years



Specialty sales growth outpaces that of traditional medicines

Specialty growth rate is 23% compared to traditional growth at 8% YTD



Source: IMS Health, National Sales Perspectives, Sept 2015

IMS Health definition of Specialty Products

Medicines that treat specific, complex chronic diseases with the min 4 of the 7 following attributes:

- **Initiated *only* by a specialist**
 - **High expense**
 - **Requires reimbursement assistance**
 - **Generally not oral**
 - **Warrants intensive patient counseling**
 - **Require special handling**
 - **Unique distribution**
- Few prescribers/ centers
 - Low inventory important
 - Processing of pre-approval essential and competitive skill
 - Requires patient training to administer
 - Support to achieve adherence needed
 - Cold chain when needed
 - No need for supplying all pharmacies through all warehouses

Specialty pharmaceuticals differ from common therapies in a variety of aspects

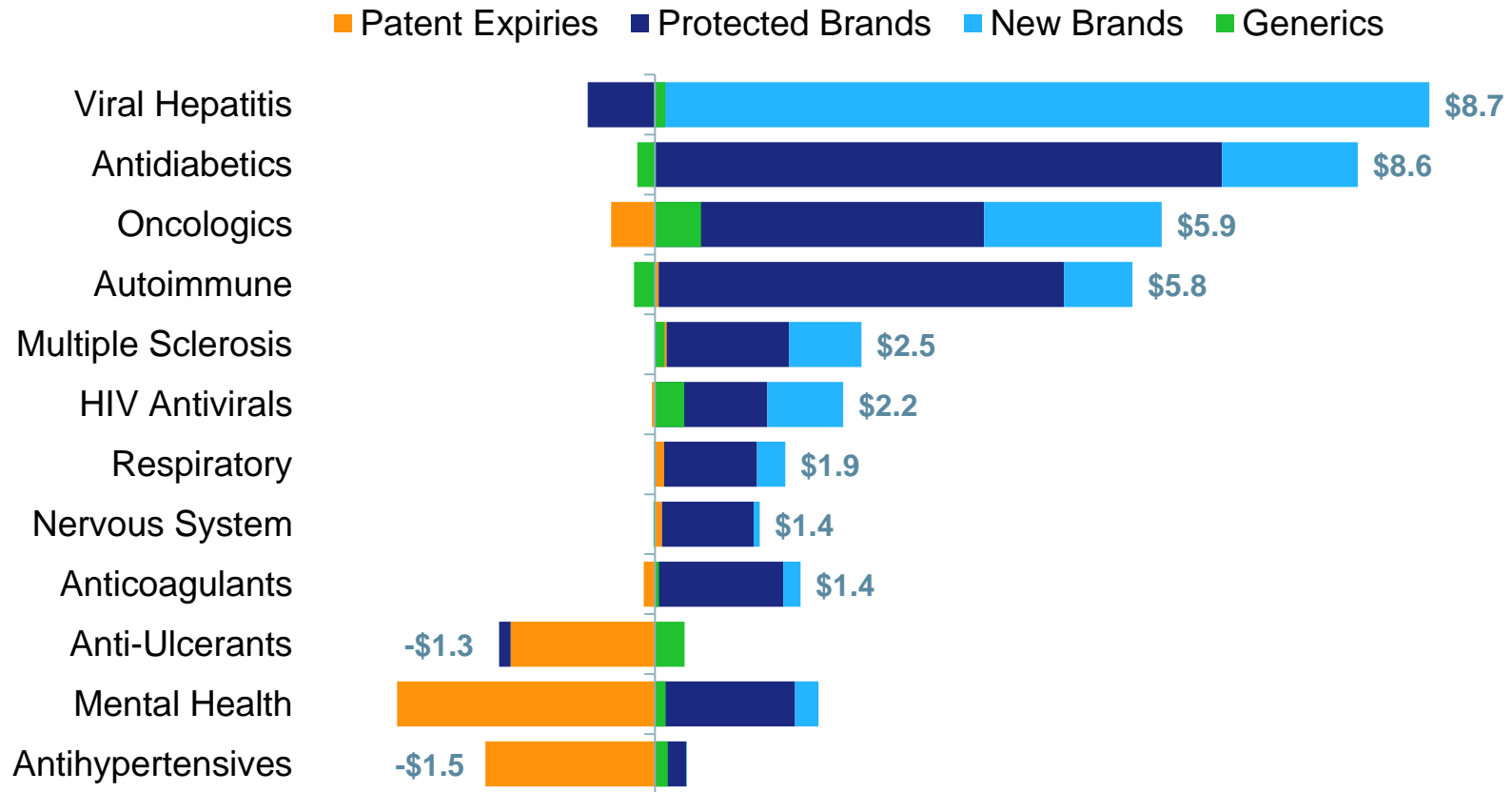
	Common		Specialty	
Type of Condition	Common Acute	Common Chronic	Complex Chronic	Rare Disease
U.S. Patient Population	Millions	Affects >50 million	Affects ~ 2 million	Affects ~ 20K
Duration of Therapy	About 10 days/episode	Ongoing (maintenance)	Lifelong	Lifelong
Cost of Therapy	~ \$100/episode	\$1,000+/year	\$14,000+/year	\$250,000/year
Medication	Anti-infective	Lipitor®	HUMIRA®	Cerezyme®
Indication	Acute bacterial infection	Cholesterol reduction	Rheumatoid arthritis	Gaucher's disease
Handling Requirements	No special requirements	No special requirements	Refrigeration training	Refrigeration/mixing/pumps/central line training

Typical Distribution Channel	Retail	Retail and mail service	Specialty pharmacy, infusion clinics, doctor's office, home with advanced clinical services	Specialty pharmacy, infusion clinics, doctor's office, home with advanced clinical services
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Hepatitis, diabetes, oncology drive spending growth

Non-discounted spending on HCV increased by \$8.7Bn in last 12 months

Therapy Class Growth by Segment (\$BN) MAT Sept 2015

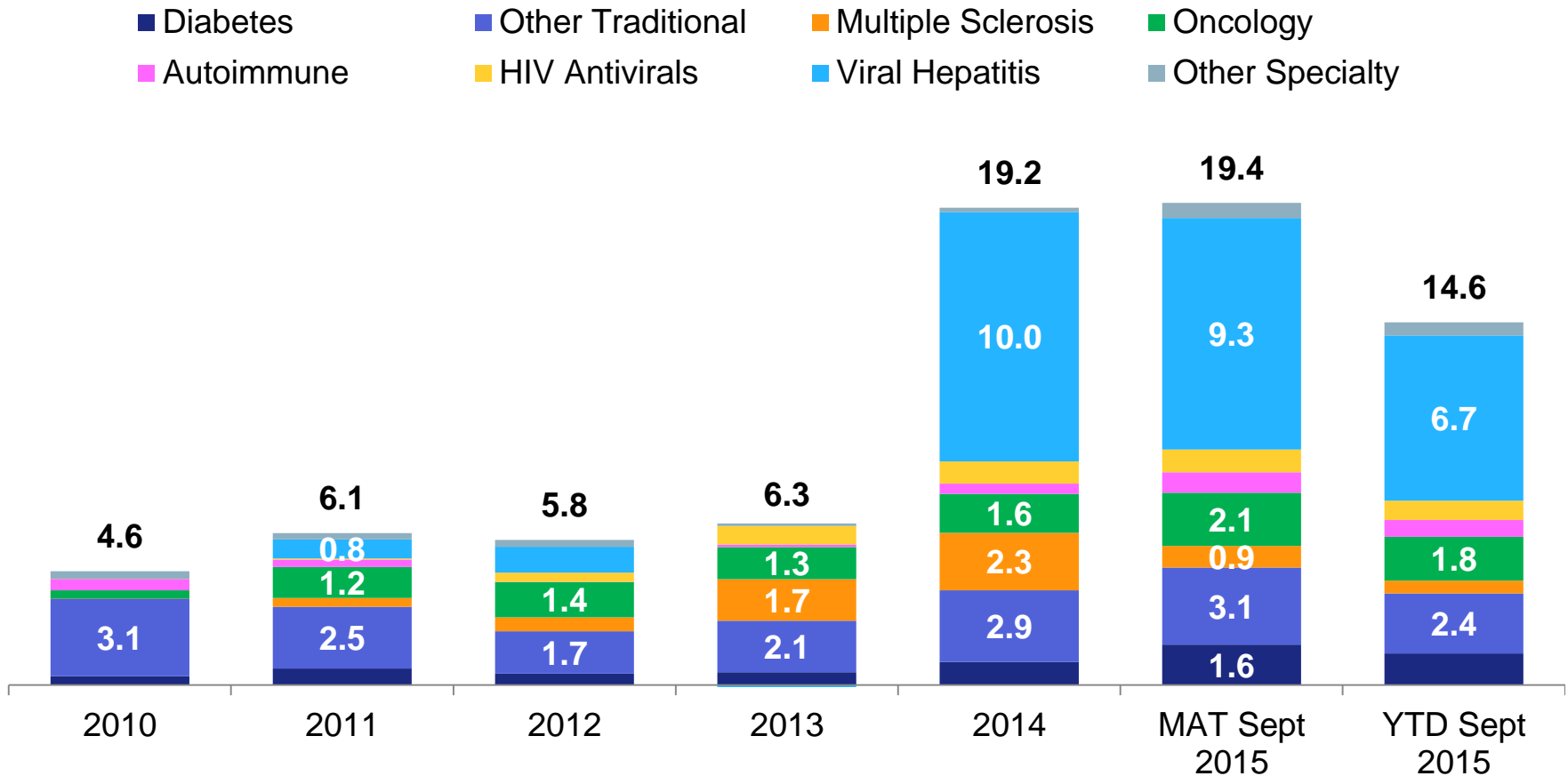


Source: IMS Health, National Sales Perspectives, Sept 2015

New brand spending increased by \$19.4B in last 12 months

Drivers: Harvoni, Triumeq, Viekira, Imbruvica, Tecfidera, Ibrance, Opdivo

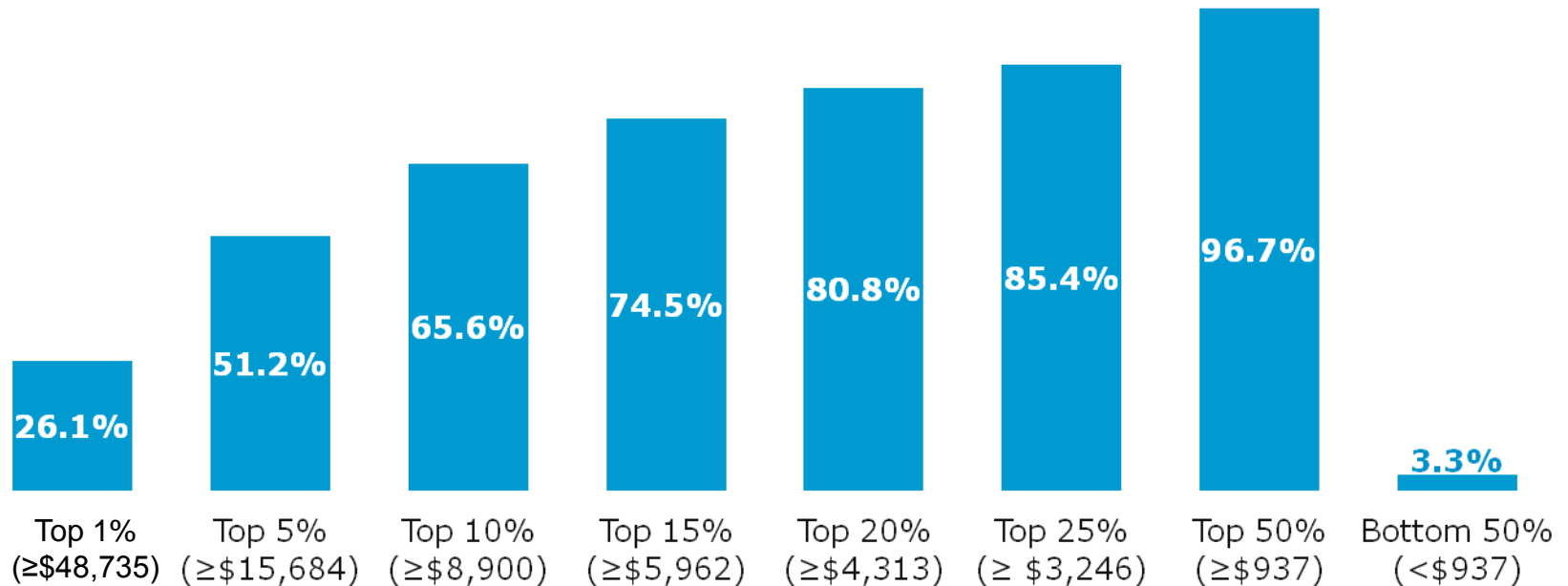
New Brand Spending Growth (\$B)



Source: IMS Health, National Sales Perspectives, Sept 2015

A minority of patients account for the vast majority of healthcare costs

Percent of Health Plan Members Ranked by Healthcare Spending (\$)



Source: IMS PharMetrics, Jun 2012

Costly, high use drugs can drive up spend

	Prevalance	Cost Per Year	Total Cost to Treat
Alzheimers	5.4 million	\$35,000	\$181 Billion
Cancer	14 Million	>\$100,000	\$1.4 Trillion
High Cholesterol	71 Million	>\$14,000	\$994 Billion
Hep C	3.2 Million	<\$50,000	\$160 Billion

Most notable things about 2015

- **Changes at CMS and FDA**
- **Supreme Court upholds Obamacare**
- **Hep C exclusive launches and price wars**
- **Zarxio Biosimilar Neupogen from Sandoz launches**
- **Controlled Substances rescheduled**
- **Generic Nexium finally arrives**
- **Flonase OTC**
- **Abilify, Copaxone and Namenda**
- **Watch for PD1s and PCSK9s**
- **Turing and Valeant**
- **Merger Mania**
 - [Endo & Par](#)
 - [Teva & Actavis](#)
 - [Hikma and Roxane](#)
 - [Lupin and Gavis](#)
 - [Lannett and Kremers Urban](#)
 - [Pfizer & Hospira](#)
 - [Abbvie & Pharma Cyclics](#)
 - [Valeant & Dendreon](#)
 - [Valeant & Salix](#)
 - [Optum and Catamaran](#)
 - [Anthem and Cigna](#)
 - [Aetna and Humana](#)
 - [CVS & Omnicare](#)
 - [CVS buys Target pharmacies](#)
 - [Walgreens and Rite Aid](#)

Specialty Pharmaceuticals growth is 22.1%

Channels	MAT Sep 2015		
	US\$Bn	% Market Share	% Growth
<u>Retail</u>	<u>71.2</u>	<u>62.5</u>	<u>29.0</u>
Chain/Mass	11.2	9.9	15.0
Mail service	49.6	43.5	33.1
Independents	8.7	7.7	30.4
Food stores	1.6	1.4	11.8
<u>Institutional</u>	<u>42.8</u>	<u>37.5</u>	<u>12.0</u>
Clinics	25.6	22.4	11.9
Hospitals	10.7	9.4	7.5
Long-term care	2.3	2.0	17.4
Home health care	2.3	2.1	10.9
HMO	1.4	1.3	49.0
Others	0.4	0.3	24.3
Total	114.0	100.0	22.1

Source: IMS Health, National Sales Perspectives, MAT Sep 2015

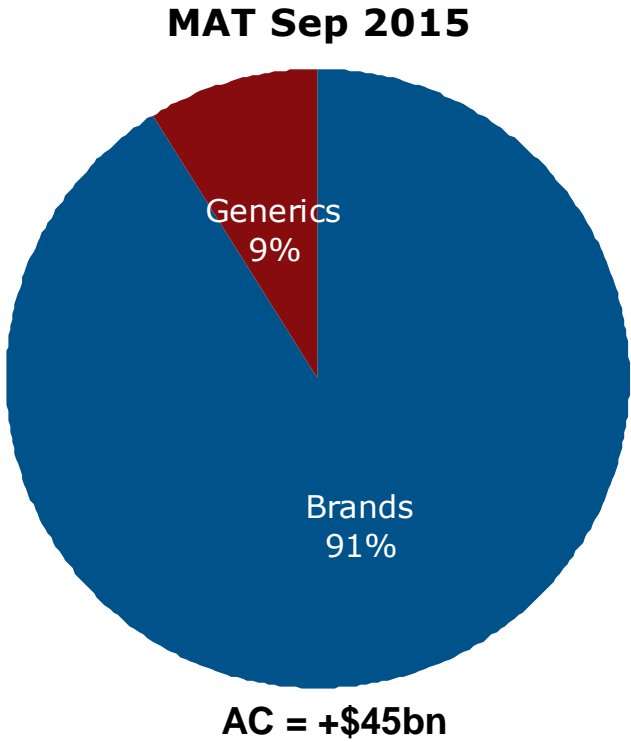
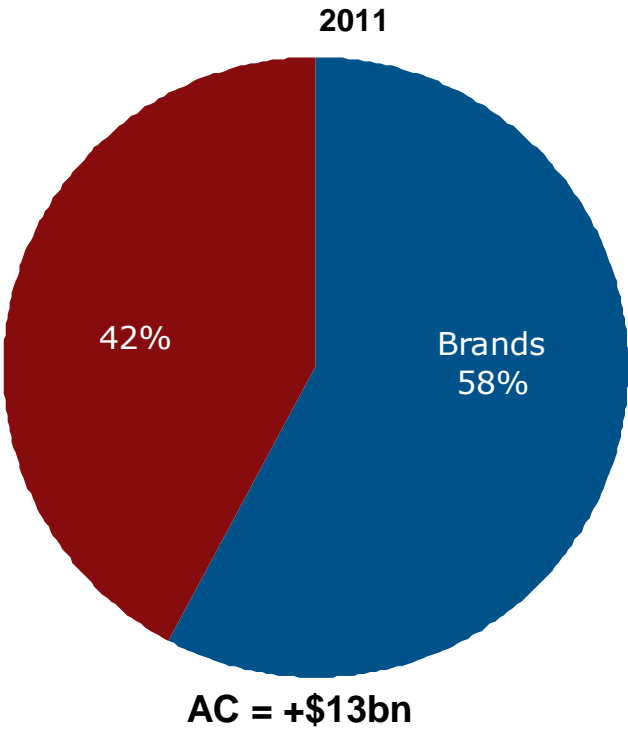
Traditional Pharmaceuticals growth is 9.0%

Channels	MAT Sep 2015		
	US\$Bn	% Market Share	% Growth
Retail	224.4	75.1	7.8
Chain/Mass	119.3	39.9	6.3
Mail service	44.4	14.9	8.4
Independents	37.9	12.7	11.4
Food stores	22.9	7.7	8.6
Institutional	74.3	24.9	12.8
Clinics	29.2	9.8	18.5
Hospitals	25.1	8.4	11.0
Long-term care	14.4	4.8	4.1
Home health care	1.5	0.5	19.9
HMO	3.2	1.1	17.9
Others	0.7	0.3	8.7
Total	298.7	100.0	9.0

Source: IMS Health, National Sales Perspectives, MAT Sep 2015

Generics share of sales growth

% Contribution to growth US\$



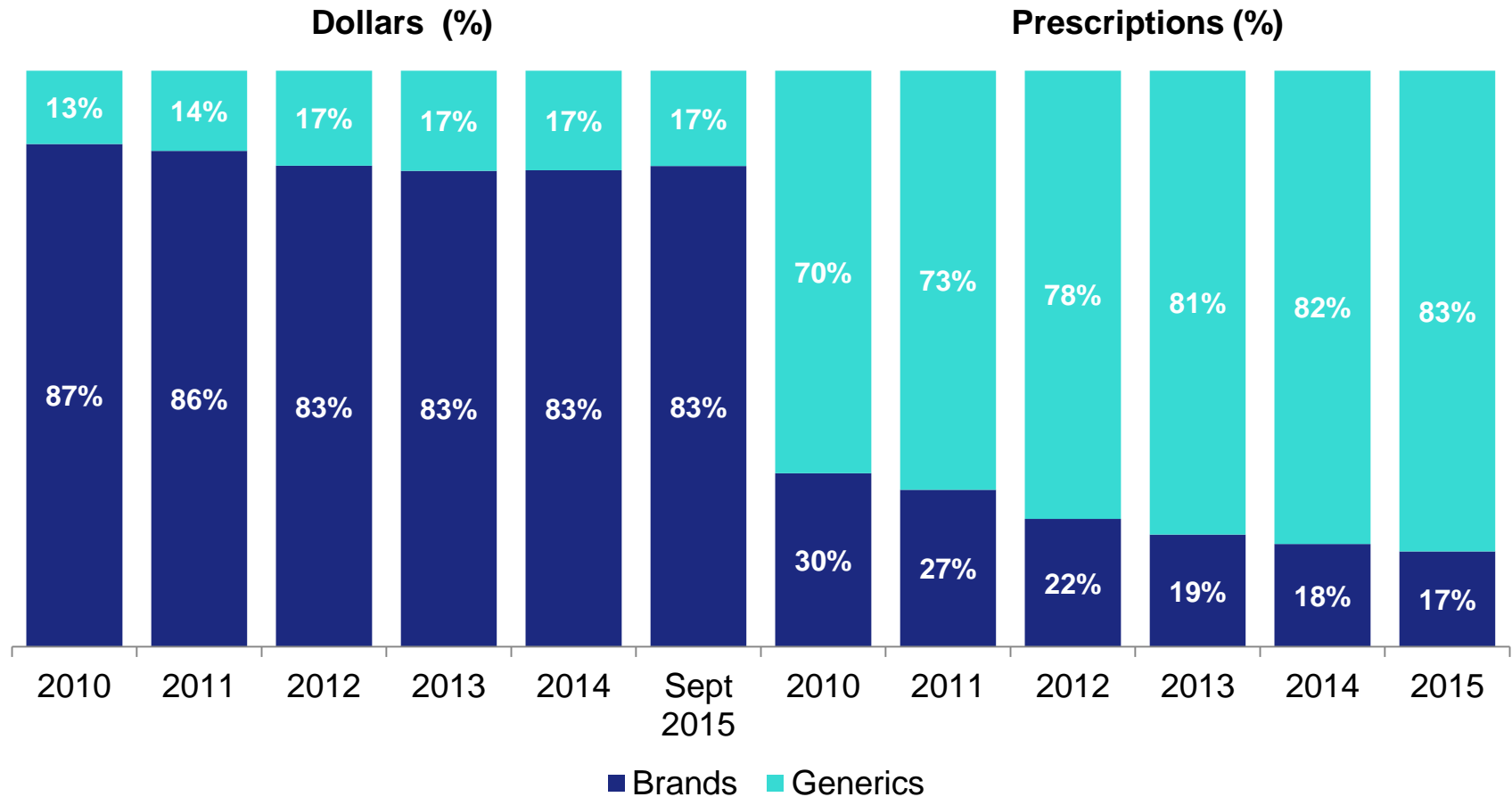
Source: IMS Health, National Sales Perspectives, Branded generics disaggregated, Sep 2015

Notable Generic events in 2015

- Savings from generics reach \$5 billion/week (Nexium and Abilify)
- Teva buys Actavis; will control one-fifth of Gx market
- Mylan-Perrigo deal fails
- First biosimilar is launched
- Glatopa competes with Copaxone
- Congress and DOJ begins deep dive into generic pricing
- Generic price inflation ebbs
- Biosimilars Council is launched
- Signs of GDUFA progress despite growing backlog
- House passes 21st Century Cures
- Industry loses bid to overturn drug take-back ordinance
- Generics become “pay-for” with CPI rebate penalty
- Labeling rule stalled but still coming
- New track-and-trace requirements for supply chain
- Provigil consent decree impacts settlement paradigm

83% of prescriptions are dispensed as generics

Generics account for 17% of spending



Source: IMS Health, National Sales Perspectives, Sept 2015, National Prescription Audit, Dec 2015

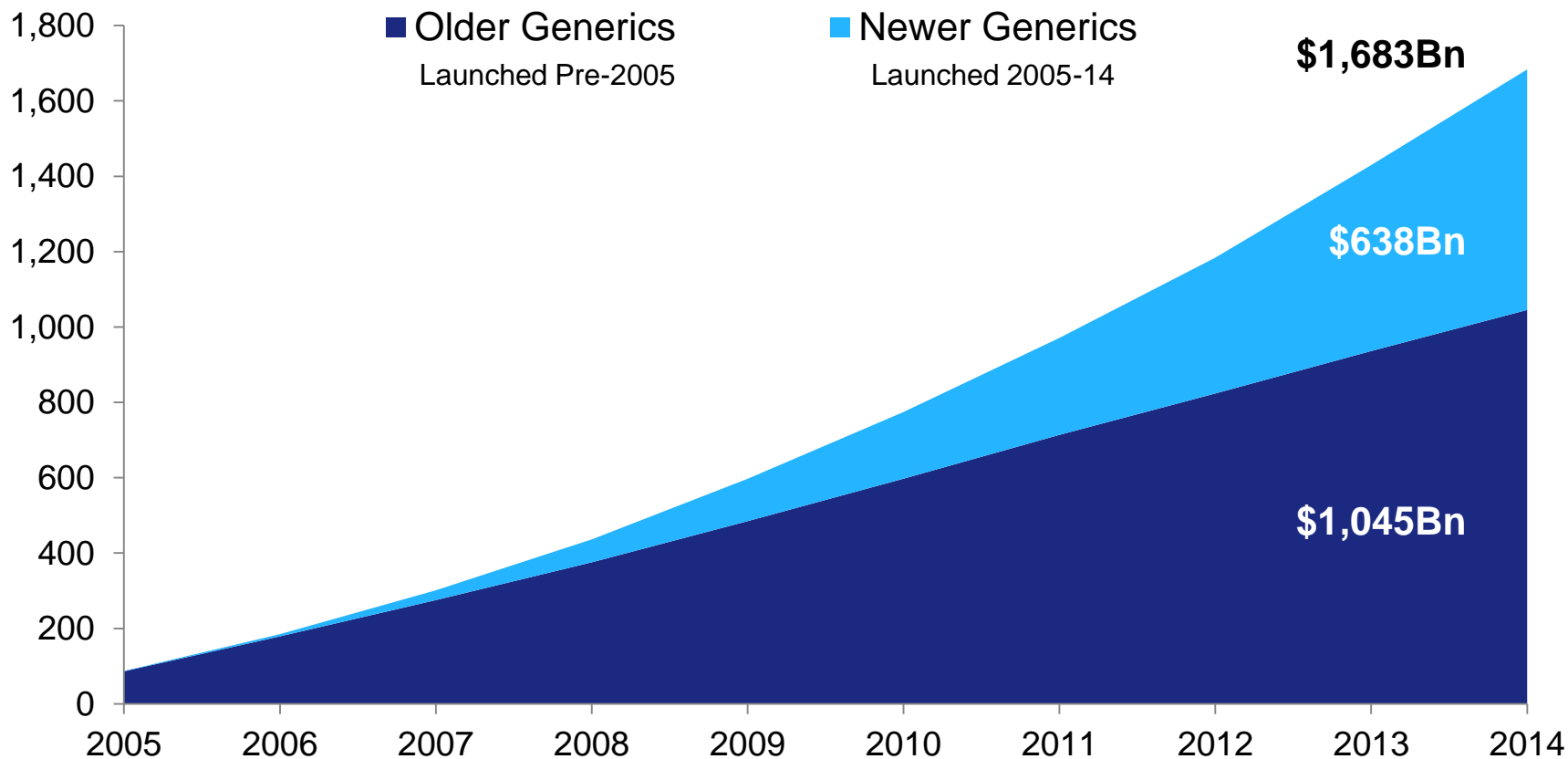
Top Specialty events in 2015!

- HEP C Innovation, PD1s, PCSK9s, & Orphan Drugs and Pricing
- Patient as a Payer
 - Specialty tiers in exchanges
- Growing demand for value driven metrics (CE and RWE)/adoption of guidelines
- Copaxone ® 3X weekly and Copaxone ® generic/Glatopa
- Specialty space gets more crowded with new entrants and more orals are coming
- The first Biosimilar launch
- More Co Pay programs cooperation by payers

The U.S. healthcare system has saved \$1.7 trillion in the last ten years due to the availability of low cost generics

Savings from generics launched 2005-14 total \$638Bn over last 10 years

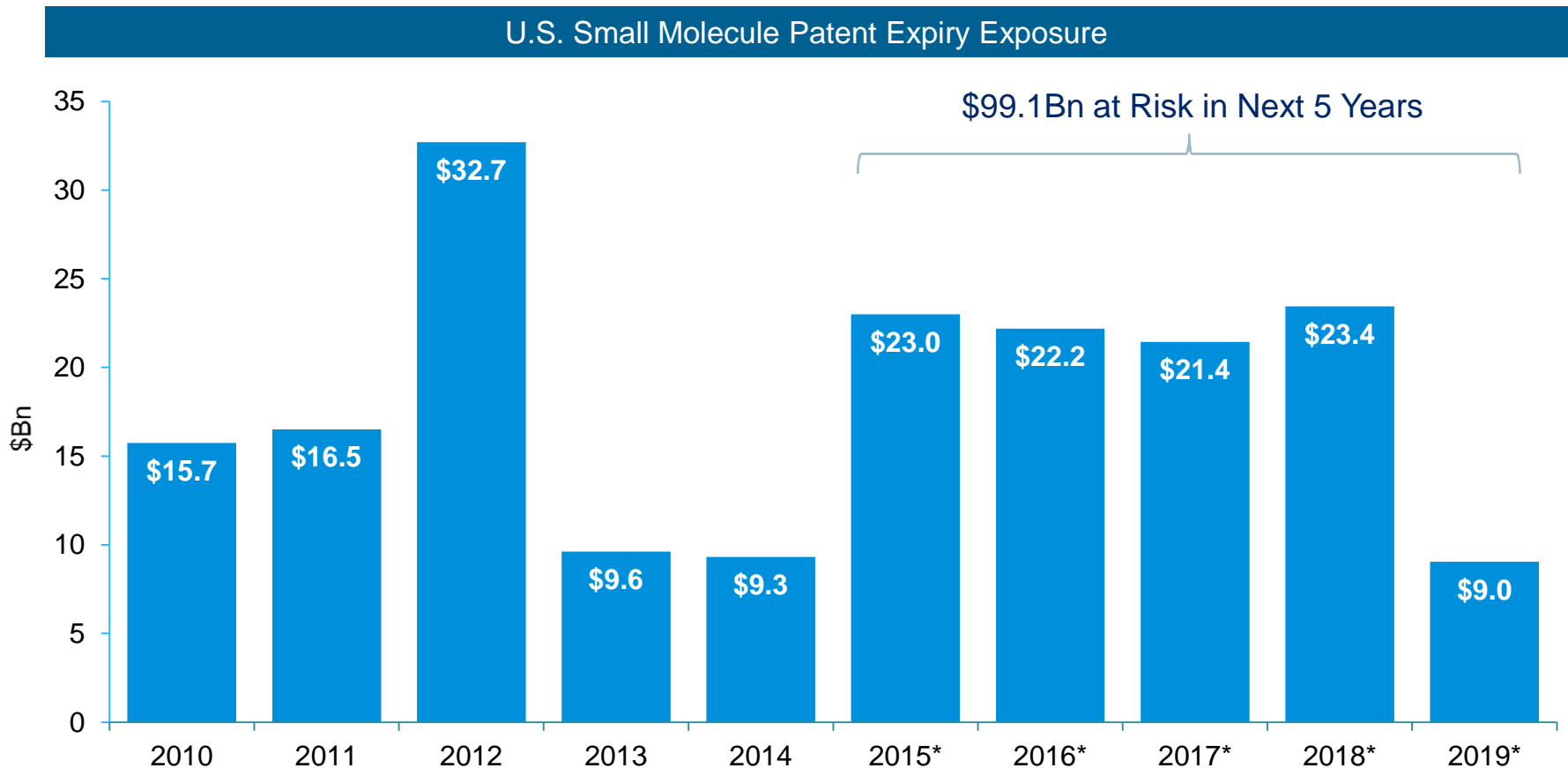
Cumulative Ten Year Savings from Older and Newer Generics (\$Bn)



Source: IMS Health, MIDAS, Q2 2015

Brands facing LOE in the next 5 years are valued at \$99Bn

2015: Abilify, Nexium, Namenda; 2016: Crestor, Gleevec, maybe Advair?

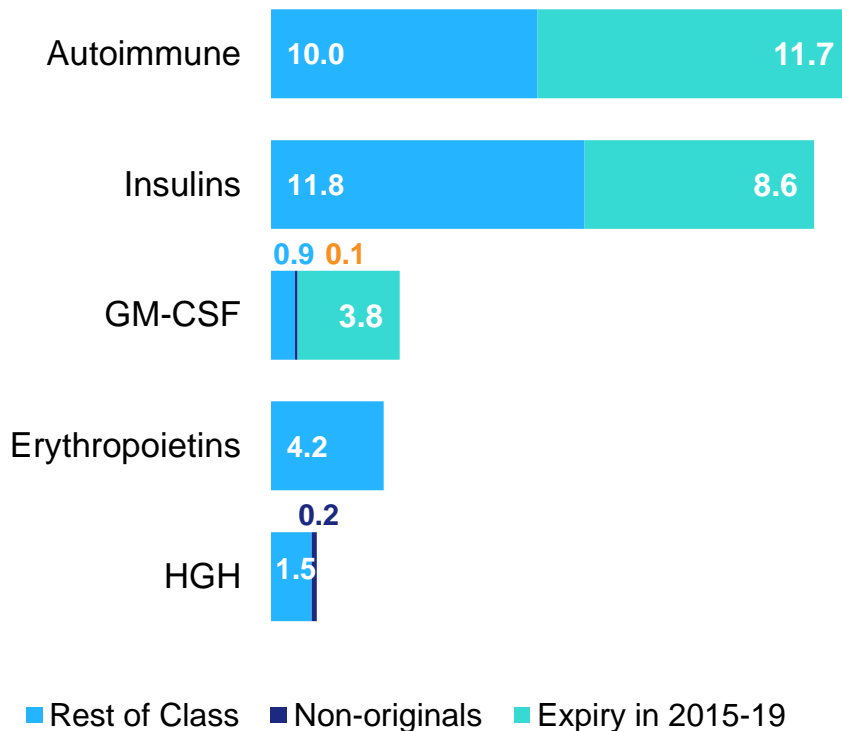


Sales in year prior to expiry used for years 2009-15; sales in MAT Sept 2015 used for years 2016-19

Source: IMS Health, National Sales Perspectives, Sept 2015

The first biosimilar applications were filed in 2014; five years after legislation created the biosimilar pathway

2014 Spending on Biologic Molecules in Classes with Current Non-Original Biologics and Upcoming Losses of Exclusivity (US\$B)



Related events	Expected US Launch
Adalimumab three Phase III trials completed	2015
Infliximab	2018
Insulin glargine tentatively approved pending litigation (2014)	2016
Tbo-filgrastim marketed Dec 2013	2013
Zarxio (filgrastim-sndz) approved in March and launched in Sept 2015	2015
Pegfilgrastim filing accepted	2015
Epogen alfa BLA filed	2015/16

Source: IMS Institute for Healthcare Informatics, Mar 2015; ClinicalTrials.gov; FDA.gov, Mar 2015

US Biosimilars scorecard

1 Biosimilar on the market: Sandoz's Zarxio

7 biosimilars pending at the FDA

Celltrion's Remicade (AdCom 2/9 strong recomendaton)

Apotex's Neulasta (accepted for review Dec 2014)

Apotex's Neupogen (accepted for review Feb 2015)

Sandoz's Enbrel (accepted for review Oct 2015)

Sandoz's Neulasta (accepted for review Nov 2015)

Amgen's Humira (accepted for review Jan 2016)

Pfizer's Epogen received CRL Oct 2015



In contrast to small molecule GX, biosimilar development and marketing pose serious challenges for aspiring players

CLINICAL DEVELOPMENT

Average cost is around **200M\$**, with a significant range of variation (from 40 to 375 M\$) vs. **1 to 4M\$** for a generic drug



REGULATORY AND MARKET ACCESS

Uncertain regulatory framework (aside from Europe), price competition less relevant compared to generics



Biosimilars vs. Generics – a different game?

MANUFACTURING COSTS

Difficulties in rationalizing manufacturing costs due to limited **scale**, at least in the short term



SALES AND MARKETING CAPABILITIES

Need to adopt **expanded** mentality to win stakeholder trust



Reasons for Generic Price Inflation

- **Regulatory/Quality** – with the increased scrutiny from the FDA, manufacturers need to invest more into their quality systems and when a quality / supply issue arises due to 483s, it creates the opportunity to increase prices to recoup part of their investment
- **Customer consolidation** – with the increased purchasing power of the customers, manufacturers need to make up value on products where they can
- **Fewer new product launches** – generic manufacturers make money by launching new products, reducing CGS, M&A activity and raising prices; with fewer launches, it puts more pressure on the “in-line” product portfolio which again is a driver to increase prices

Transformation in Disease Treatments

Innovation drives transformation of disease treatments in 2020

- Use of medicines in 2020 will include 943 New Active Substances introduced in the prior 25 years, new medicines in recent years will be weighted to specialty and biologics
- Patients will have greater access to breakthrough therapies, clusters of innovation around hepatitis C, autoimmune diseases, heart disease, orphan diseases and others by 2020
- Cancer treatments represent the largest category of the 225 new medicines expected to be introduced within the next five years
- Technology will enable changes to treatment protocols, shift patient engagement, accountability and patient-provider interaction accelerating the adoption of behavior changes proven to improve patient adherence to treatments
- By 2020, over 470 drugs will be available to treat orphan diseases for the 7,000 rare diseases with no or limited treatments available
- While global medicine spending on orphan is expected to be 1-2%, it will be as much as 10% in developed markets such as the U.S.

FDA Approval Numbers over the years...

Year	Total Approvals	Specialty	Percentage
2005	19	8	42.1%
2006	20	10	50.0%
2007	18	11	61.1%
2008	26	11	42.3%
2009	28	13	46.4%
2010	22	14	63.6%
2011	32	17	53.1%
2012	40	24	60.0%
2013	29	18	62.1%
2014	50	26	52.0%
as of 9/17/2015	27	15	55.6%
Total	311	167	
Avg. 2005-2014	28.4	15.2	53.5%
Avg. 2010-2015	33	19	57%

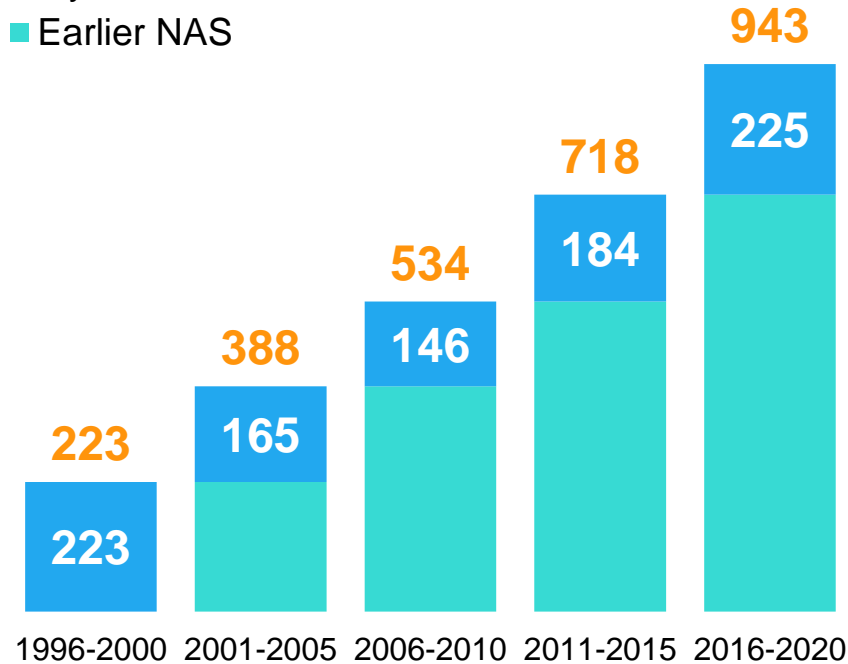
New Molecular Entity US Pipeline

3622 (Filed, Phase I, II, III)
779 orphan drugs

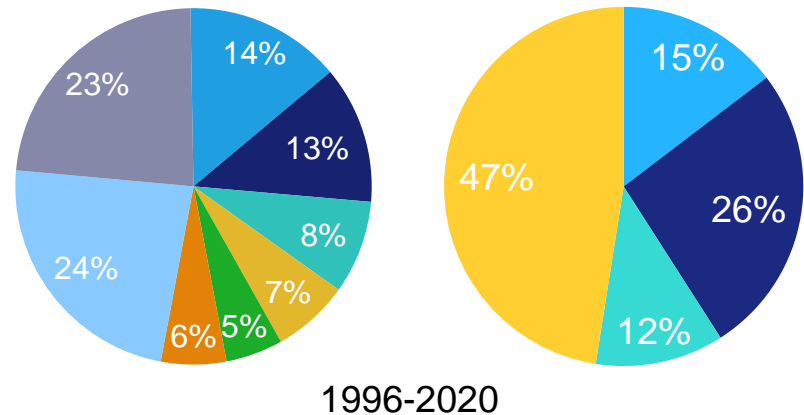
- Oncology & immunology 452 (54%)
- Late phase: Filed & Phase III 250 (32%)
- Route of administration
 - Oral: 30%
 - Injection: 55%
 - Other: 15%

Global New Active Substances (NAS) Available Since 1996

- Cumulative Total Since 1996
- 5 year NAS
- Earlier NAS



- Infection
- Oncology
- Neurology
- Cardiovascular
- Blood & related disorders
- Diabetes
- Orphan
- Others
- Specialty Biologics
- Specialty Small molecules
- Traditional Biologics
- Traditional Small Molecules

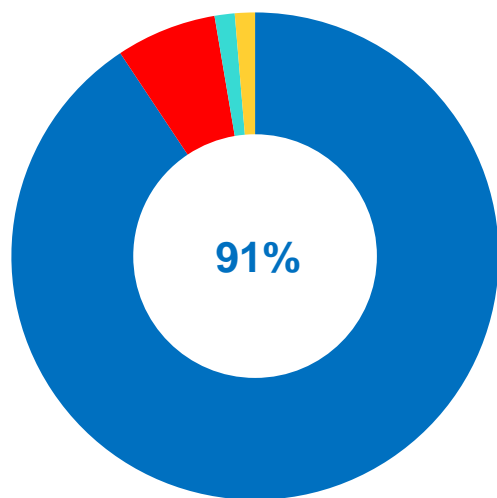


Source: IMS Health, IMS Institute for Healthcare Informatics, October 2015

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 U.S. 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.

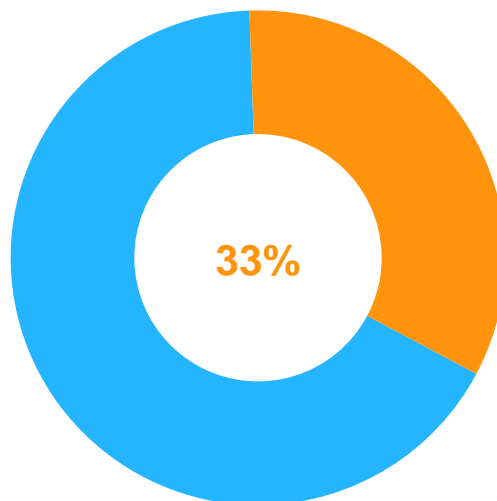
Novel Active Substances (NAS) for Cancer by Mechanism, Targeting Type and Patient Population

2016-2020 Oncologic NAS by Mechanism



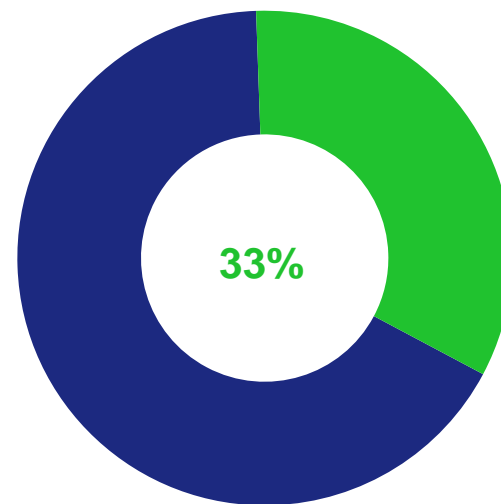
- Targeted
- Cytotoxics
- Hormonals
- Radiopharmaceuticals

2016-2020 Oncologic NAS by Type of Targeting



- No Biomarker
- Biomarker

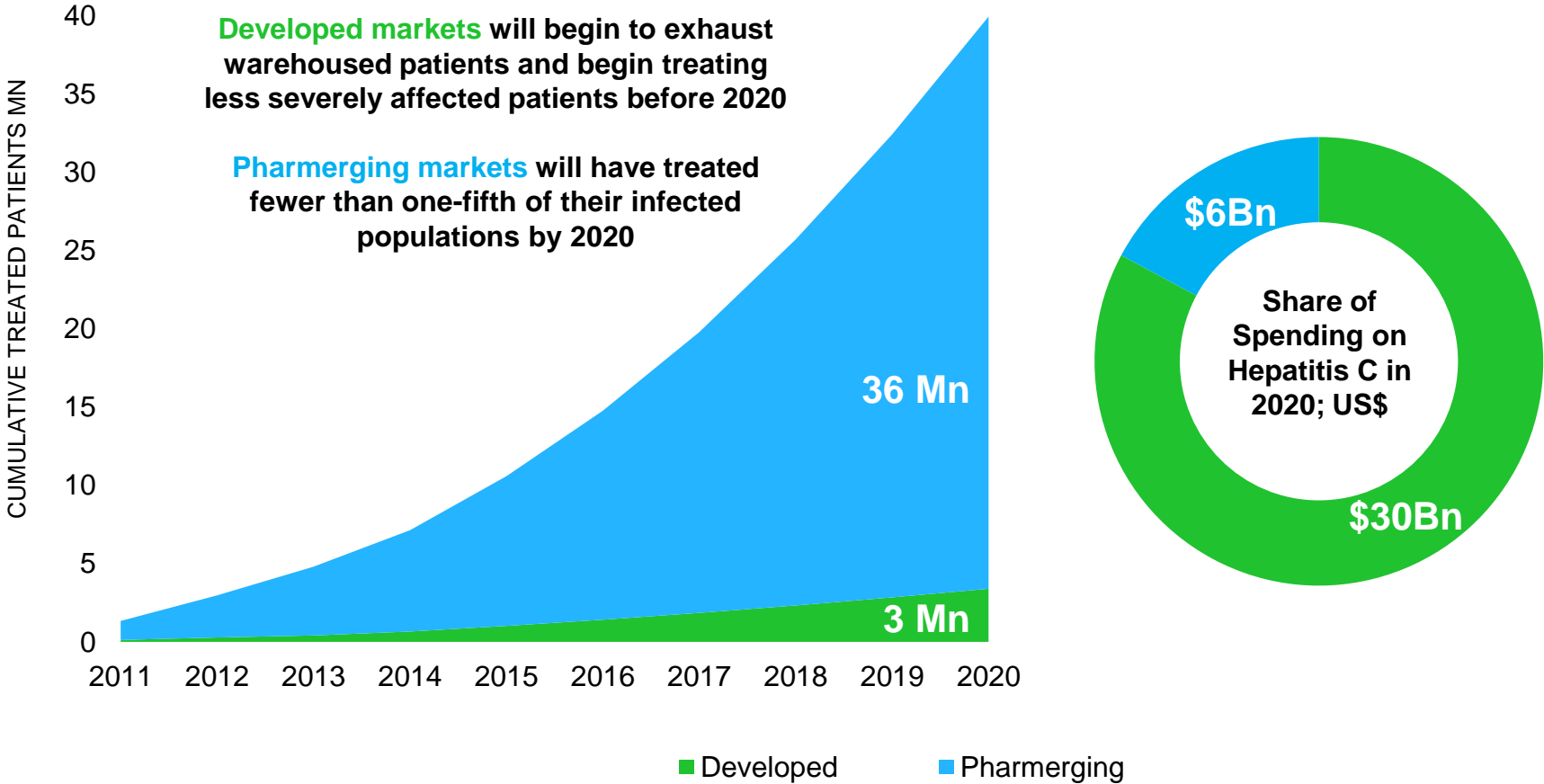
2016-2020 Oncologic NAS by Patient Population



- Non-Orphan
- Orphan

Source: IMS Health Market Prognosis, IMS Institute for Healthcare Informatics, October 2015









Global Estimated Treated Patients and Spending on Viral Hepatitis through 2020; Estimated 180 Million Infected



Source: IMS Health Market Prognosis, IMS Institute for Healthcare Informatics, October 2015

Hepatitis, diabetes, autoimmune are fastest growing classes

Spending increased in 7 of the top 10 therapy areas

Rank	MAT Sept 2015	Sales (\$Bn)	Share (%)	Growth (%)	2011-15 CAGR
	Total U.S. Market	411.0	100.0	12.3	5.7
1	 Antidiabetes	39.1	9.5	28.9	16.9
2	 Oncology	37.4	9.1	18.2	10.8
3	 Autoimmune	28.0	6.8	27.3	20.9
4	 Respiratory	23.5	5.7	9.4	3.7
5	 Mental Health	21.8	5.3	-8.0	-6.6
6	Pain	20.0	4.9	-1.0	2.7
7	 Viral Hepatitis	17.7	4.3	90.0	76.4
8	 Multiple Sclerosis	16.6	4.0	17.6	23.6
9	HIV Antivirals	16.0	3.9	16.0	12.0
10	 Lipid Regulators	13.5	3.3	-3.3	-7.2
	Top 10	233.5	56.8	16.5	8.7

Source: IMS Health, National Sales Perspectives, Sept 2015

Sales of anti-ulcerants fell 13.6% following the Nexium expiry

Top twenty therapy classes represent 79% of total spending

Rank	MAT Sept 2015	Sales (\$Bn)	Share (%)	Growth (%)	2011-15 CAGR	
11	▼ 1	Antihypertensives	10.8	2.6	-12.7	-7.4
12	▲ 2	Nervous System	10.7	2.6	15.8	8.8
13	▼ 2	ADHD	10.6	2.6	6.3	7.1
14	▲ 1	Dermatologicals	10.5	2.6	14.4	11.1
15	▲ 2	Anticoagulants	9.4	2.3	16.7	-4.9
16		Antibacterials	8.4	2.0	-5.3	-4.1
17	▼ 5	Anti-Ulcerants	8.2	2.0	-13.6	-8.2
18		Vaccines excl flu	8.1	2.0	25.3	12.4
19	▲ 1	Other Cardiovasculars	7.1	1.7	15.8	15.7
20	▲ 2	GI Products	6.7	1.6	23.3	15.2
Top 20		324.0	78.8	13.4	6.4	

Source: IMS Health, National Sales Perspectives, Sept 2015

Medicines to treat chronic diseases drive script growth

Prescriptions for diabetes meds rose 5.1% in the last 12 months

Rank	MAT Sept 2015	TRx (Mn)	Share (%)	Growth (%)
	Total U.S. Market	4,363	100.0	1.5
1	Antihypertensives	705	16.2	0.1
2	Mental Health	545	12.5	2.1
3	Pain	471	10.8	-3.0
4	Antibacterials	271	6.2	2.6
5	Lipid Regulators	261	6.0	-1.1
6	Antidiabetes	209	4.8	5.1
7	Nervous System Disorders	186	4.3	5.6
8	Respiratory	175	4.0	4.9
9	Anti-Ulcerants	172	3.9	1.2
10	Antithyroid	133	3.0	1.5
	Top 10	3,127	71.7	1.1

Source: IMS Health, National Prescription Audit, Sept 2015

The 10 most commonly dispensed medicines of 2015

MAT Dec 2015

Rank	MAT Dec 2015	TRx	Share (%)	Growth (%)
	Total U.S. Market	4,368	100.0	1.0
1	levothyroxine	121	2.8	0.6
2	lisinopril	106	2.4	2.0
3	acetaminophen-hydrocodone	97	2.2	-18.3
4	atorvastatin	93	2.1	15.2
5	metoprolol	86	2.0	1.0
6	amlodipine	82	1.9	4.1
7	metformin	80	1.8	4.5
8	omeprazole	77	1.8	2.3
9	albuterol	70	1.6	4.0
10	simvastatin	66	1.5	-9.7
	Top 10	877	20.1	-0.2

Source: IMS Health, National Prescription Audit, Dec 2015

Sales of leading products

Products	Company	MAT Sep 2015		
		US\$m	% Market Share	% Growth
US Industry		411,049	100.0	12.3
1 Harvoni®	GS-	12,841	3.1	
2 Humira®	AV1	9,279	2.3	36.0
3 Enbrel®	AAI	6,333	1.5	14.0
4 Crestor®	AZN	6,248	1.5	7.8
5 Abilify®	OTS	5,912	1.4	-21.6
6 Lantus Solostar®	S.A	5,215	1.3	24.8
7 Remicade®	JAN	4,801	1.2	7.5
8 Advair Diskus®	GSK	4,800	1.2	-3.1
9 Copaxone®	TVN	4,388	1.1	12.8
10 Nexium®	AZN	4,102	1.0	-33.2
Top 10		63,918	15.6	29.5

Source: IMS Health, National Sales Perspectives, Sep 2015

Sales of 11-20 products

Products	Company	MAT Sep 2015		
		US\$m	% Market Share	% Growth
11 Neulasta®	AAI	4,056	1.0	7.5
12 Januvia®	MSD	3,952	1.0	19.7
13 Lantus®	S.A	3,708	0.9	14.7
14 Lyrica®	PFZ	3,629	0.9	23.0
15 Rituxan®	GTC	3,610	0.9	5.7
16 Sovaldi®	GS-	3,416	0.8	-49.1
17 Spiriva Handihaler®	B.I	3,416	0.8	3.8
18 Tecfidera®	BGE	3,378	0.8	33.0
19 Avastin®	GTC	3,084	0.8	8.7
20 Atripla®	BMG	2,998	0.7	1.7
Top 20		99,167	24.1	17.6

Source: IMS Health, National Sales Perspectives, Sep 2015

Largest absolute growth by leading products, Sales & TRx (MAT)

Dollars	AC US\$mn	Total Rx Dispensed	AC TRxsmn
Harvoni® (Gs-)	12841	atorvastatin ca (atx)	9.1
Humira® (Av1)	2458	lisinopril (lu.)	6.7
Levemir Flextouch® (N-N)	2326	lisinopril (a6d)	6.7
Prevnar 13® (Pfz)	1273	amoxicillin (tev)	6.4
Lantus Solostar® (S.A)	1038	levothyroxine (sdz)	6.3
Invokana® (Jan)	965	fluticasone prop (atx)	5.9
Tecfidera® (Bge)	839	furosemide (myn)	5.5
esomeprazole mag (tev)	818	lorazepam (atv)	5.4
Eliquis® (Bmp)	812	atorvastatin ca (myn)	5.1
Xarelto® (Jan)	792	gabapentin (cm7)	4.8

Source: IMS Health, National Sales Perspectives, Sep 2015, National Prescription Audit, Sep 2015

Largest absolute growth by leading corporations, Sales & TRx (MAT)

Dollars	AC US\$BN	TRx	AC TRx mn
Gilead Sciences,In	11.2	Accord Healthcare	23.7
Abbvie Inc	2.7	Apotex Corp	15.3
Novo Nordisk	2.5	Torrent Pharma	13.4
Sanofi Aventis	2.5	Lupin Pharma	13.2
Johnson & Johnson	2.4	Aurobindo Pharma	11.7
Merck & Co	2	Glenmark Pharma	9.2
Teva	2	Camber Pharma	8.6
Amgen Corporation	1.7	Unidentified	7.8
Valeant Corp	1.6	Bluepoint Labs	7.6
Biogen Idec Corp	1.5	Solco Healthcare	7.5

Source: IMS Health, National Sales Perspectives, Sep 2015, National Prescription Audit, Sep 2015

Sales of leading corps

Leading corporations	MAT Sep 2015		
	US\$m	% Market Share	% Growth
US Industry	411,049	100.0	12.3
1 Gilead Sciences	26,557	6.5	73.2
2 Johnson & Johnson	20,557	5.0	13.1
3 Merck & Co	20,478	5.0	10.7
4 Novartis (incl Sandoz)	20,073	4.9	-2.2
5 Astrazeneca	19,291	4.7	-1.7
6 Teva	19,120	4.7	11.5
7 Pfizer (incl Greenstone)	18,969	4.6	6.1
8 Amgen Corporation	18,045	4.4	10.7
9 Genentech	17,752	4.3	4.8
10 Allergan, Inc	16,791	4.1	1.1
Top 10	197,634	48.1	11.6

Source: IMS Health, National Sales Perspectives, Sep 2015

The top 10- post mergers (MAT Sept 2015)

Top 10 Dollars is 61.9%

Top 10 TRX is 64.4%

	Company	Dollar Share
1	Teva/Actavis	21.6
2	Mylan	10.6
3	Sandoz	7.5
4	Endo/Par	6.1
5	Sun	3.7
6	Dr. Reddy's	2.6
7	Hospira	2.5
8	Lupin	2.4
9	Apotex	2.2
10	Greenstone	2.2

	Company	TRX Share
1	Teva/Actavis	18.9
2	Mylan	9.2
3	Sandoz	7.2
4	Endo/Par	6.2
5	Lupin	5.6
6	Amneal	4.1
7	Sun	3.4
8	Zydus	3.3
9	Aurobindo	3.3
10	Apotex	2.9

Cost Containment Opportunities

Readmissions

20%

1 in 5 Medicare FFS patients readmit within 30 days of discharge¹

21K
AMI
readmissions

13.4% or 21,000 AMI Medicare admissions readmit within 15 days, at a cost of \$136M²

Coordination of Care

\$300_B

Treating 60% of high-cost chronic condition patients yields \$300B in savings over 10 years³

\$62_B

1.1% of global total health expenditure or 62B worldwide, can be avoided with timely treatment⁴

Pharmacy

\$500_B

8% of total health expenditure = \$500B globally can be avoided with optimized use of medicines⁴

50%

Prescriptions not taken as directed⁵ drive \$260B in additional care costs⁴

Sources:

1. Jencks SF, Williams MV, Coleman EA. Rehospitalizations among Patients in the Medicare Fee-for-Service Program. *New England Journal of Med.* 2009;360(14):1418-28
2. MedPAC. Report to Congress: Promoting Greater Efficiency in Medicare, Oct 2008
3. David Blumenthal, MD. "More focus on high-cost patients could save \$300B," *Healthcare Finance News*, Apr. 2012
4. IMS Institute, *Advancing the Responsible Uses of Medicines*, October 2012
5. Lars Osterberg and Terrence Blaschke, "Adherence to Medication," *New England Journal of Medicine*, 2005

The focus of study was limited to six areas where there is opportunity to increase the value of medicines

Medicine access and pricing were not addressed

Medication nonadherence

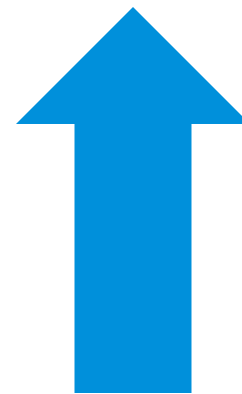
Delayed evidence-based treatment

Antibiotic misuse

Medication errors

Suboptimal generics use

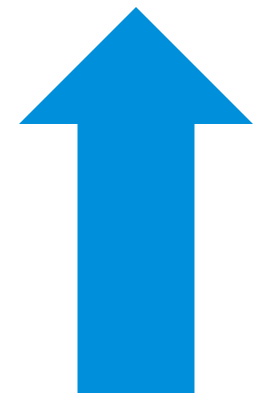
Mismanaged polypharmacy



Improvement in health outcomes



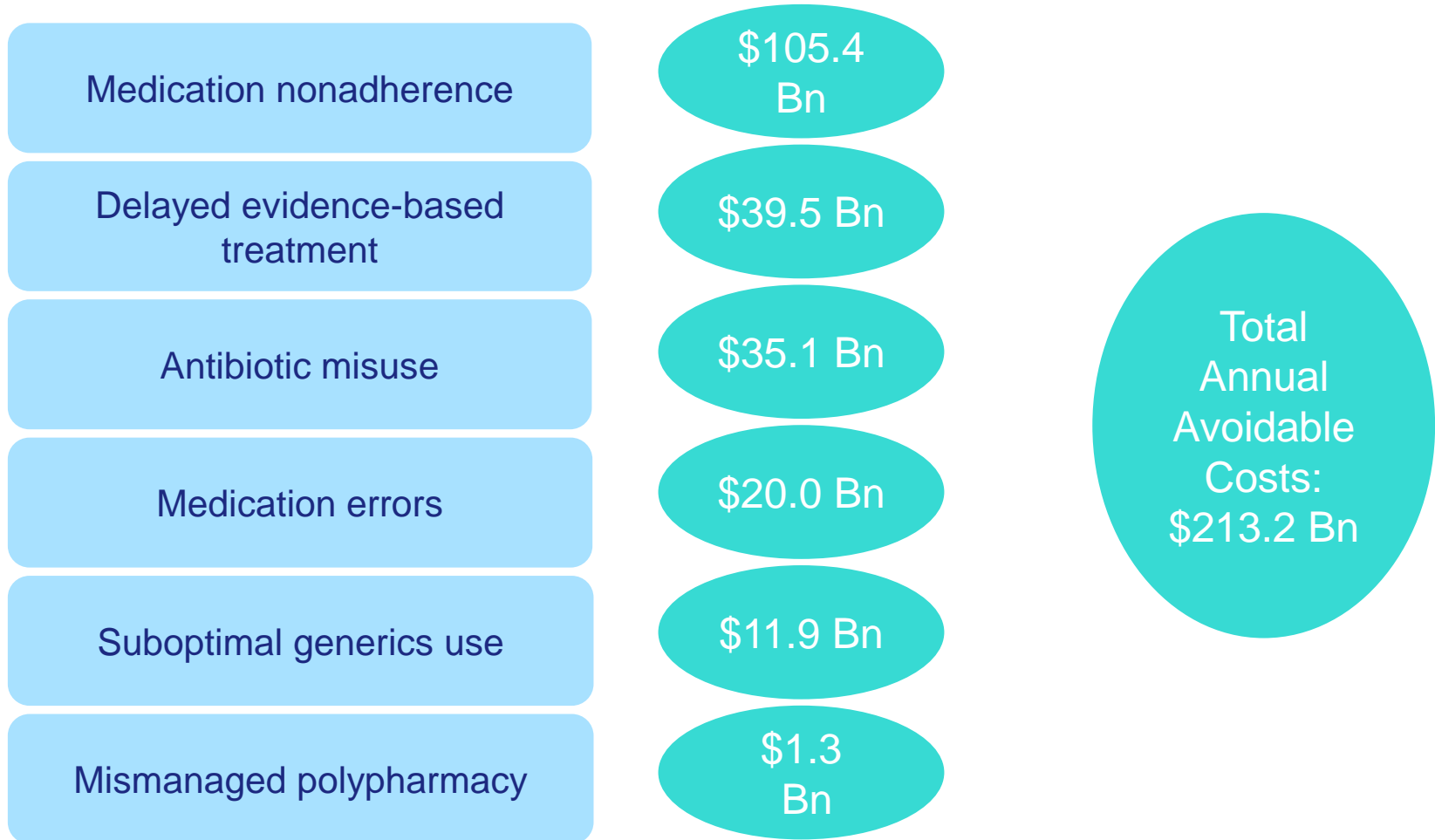
Decline in healthcare costs



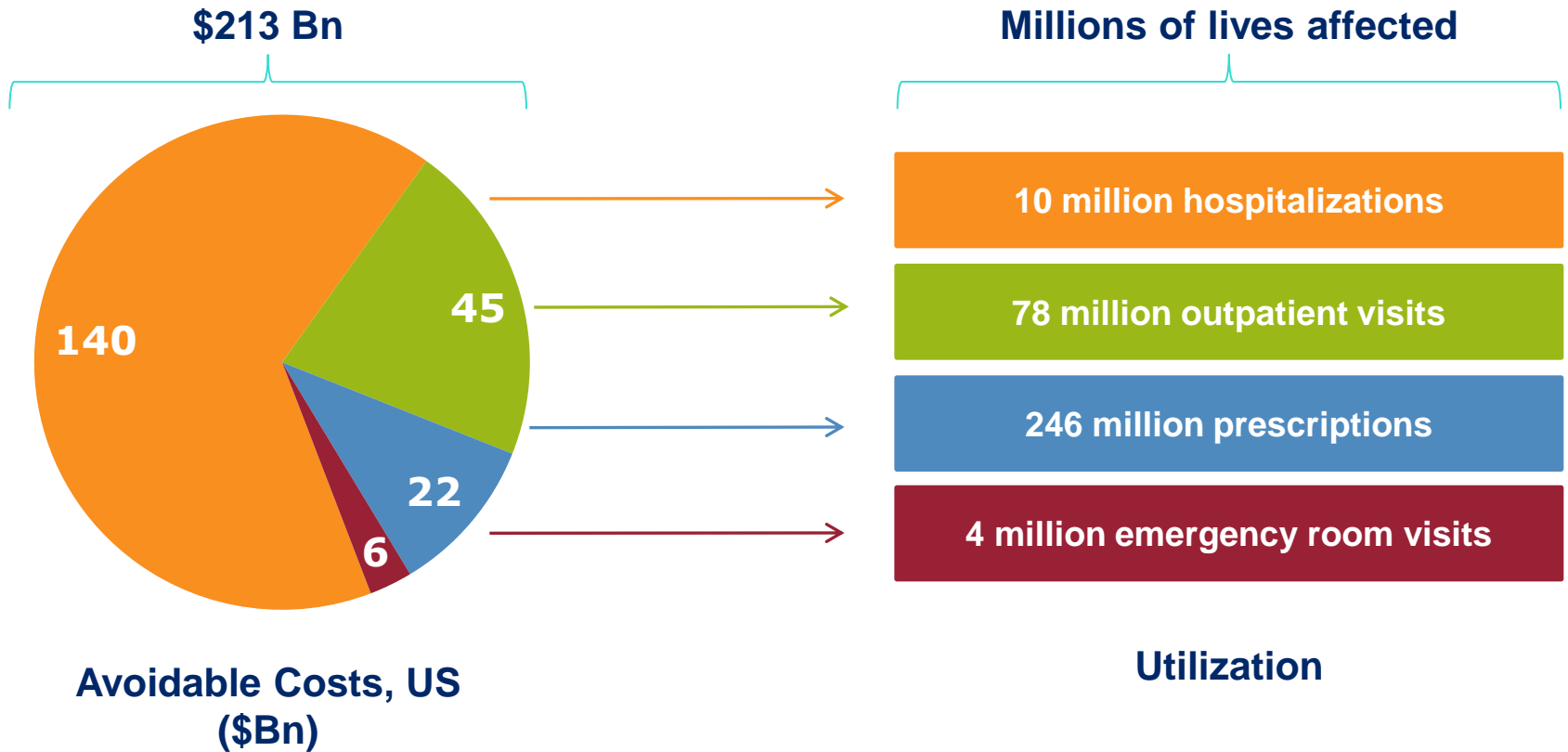
Increase in medicines value

Annual avoidable costs were estimated for each of the six areas

Annual Avoidable Costs (2012)



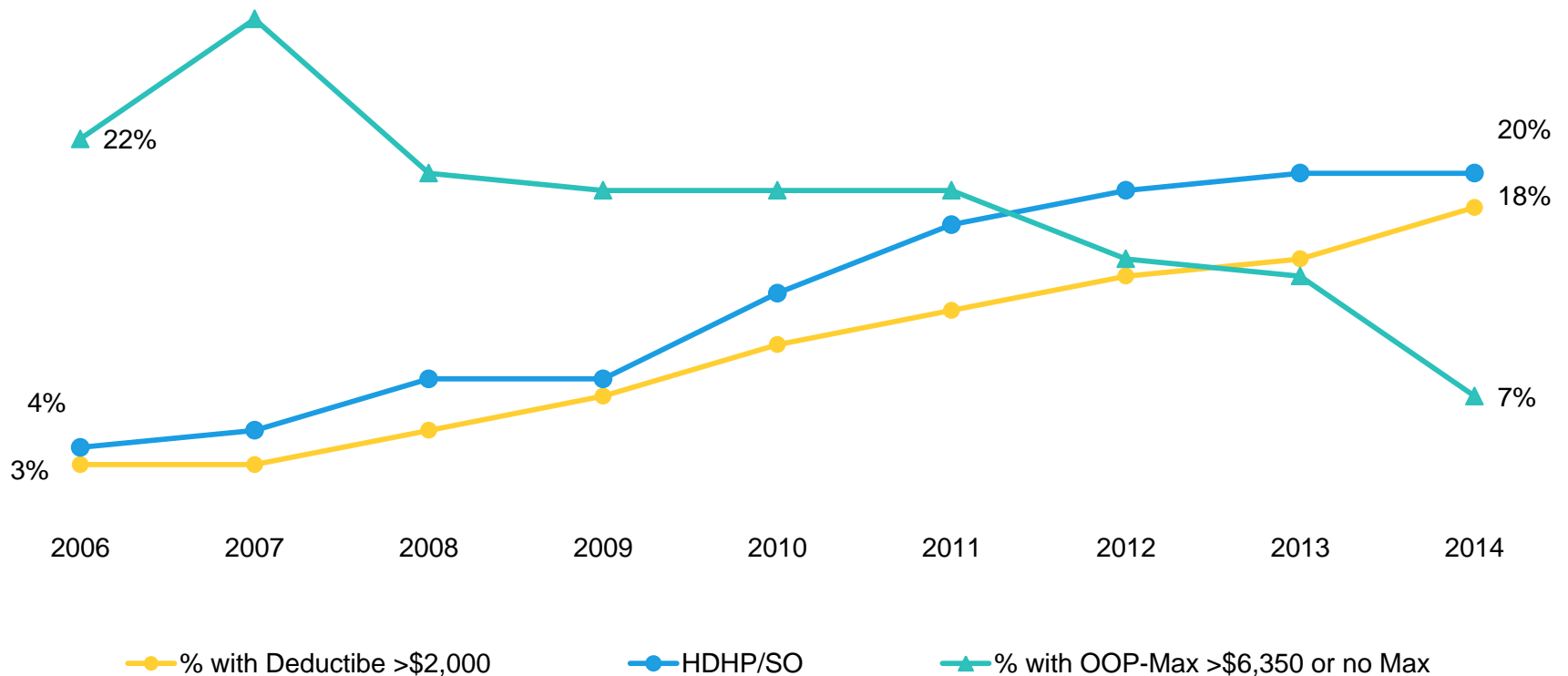
These costs represent avoidable healthcare services utilized by millions of patients



Source: Avoidable Costs in U.S. Healthcare Study

Insurance coverage has been shifting to higher deductibles and to capping out-of-pocket costs over the past decade

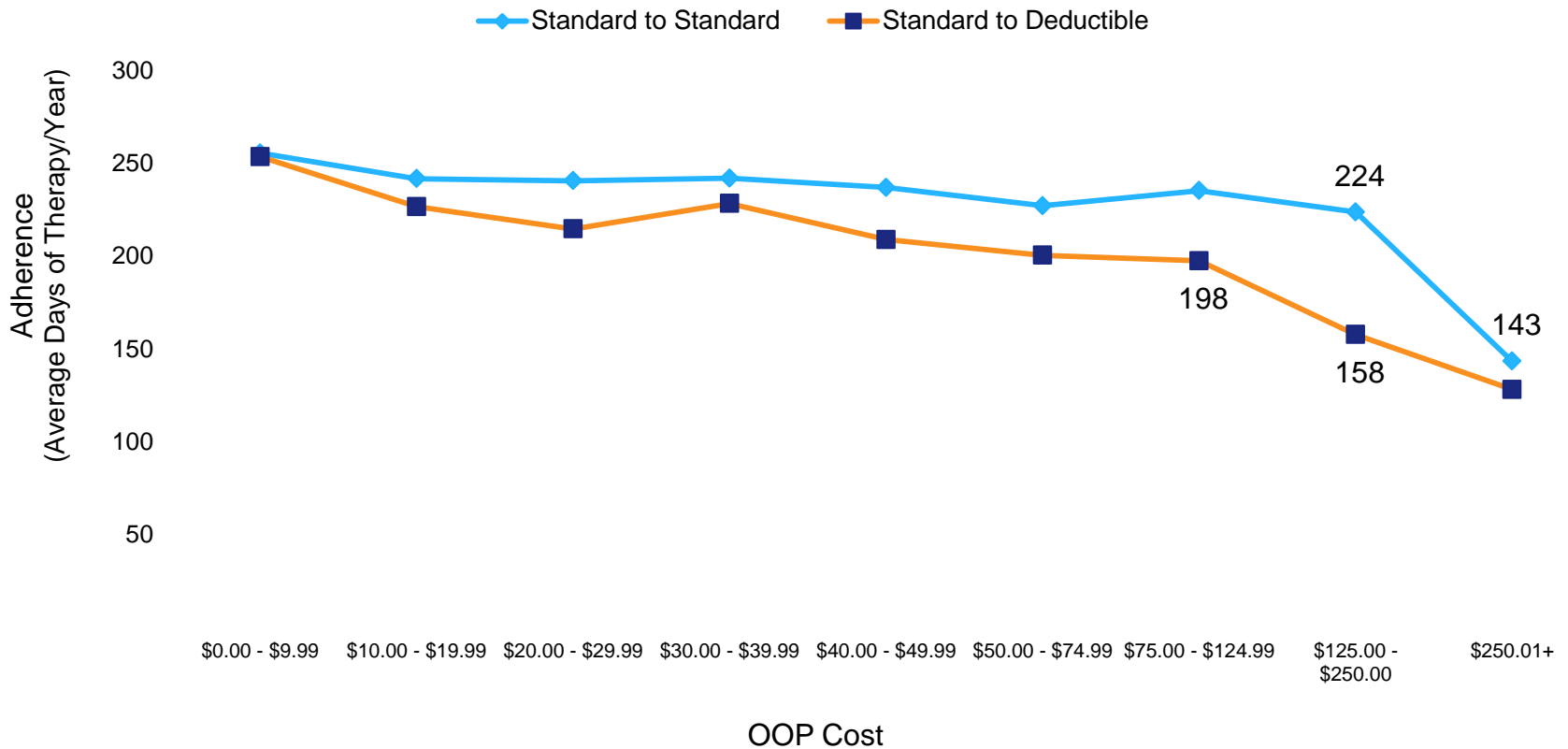
Percentage of Employer-Based Insurance 2006-2014



Source: Kaiser Family Foundation, Kaiser Employer Health Benefits: 2014 Annual Survey, Jan 2015

Deductibles have had a proven negative effect on patient adherence particularly when out-of-pocket costs are over \$125 per prescription

Average Continuing Adherence for Patients Changing Insurance Type (DPP-IVs)



Source: IMS Health, Formulary Impact Analyzer, Dec 2014, IMS Health Analysis

Top Specialty events to watch for in 2016!

- Politics
- CMS rules on Part B Reimbursement
- HEP C Innovation, PD1s, PCSK9, & Orphan Drugs and Pricing
- Patient is a Payer
- Growing demand for value driven metrics (CE and RWE)/adoption of guidelines
- Specialty space gets more crowded with new entrants and more orals are coming
- More Biosimilar launches
- More Co Pay programs cooperation by payers
- Possible 340B changes
- Gene Therapies & Orphan drugs price discussions

What to look out for in 2016 in Generics

- The very significant AMP final rule from CMS came out in January
- GDUFA II / BsUFA II negotiations should be completed and the package sent to Congress to reauthorize the program
- What happens to the Gx backlog?
- FDA said it will release final guidance for industry on approval standards for generic versions of tamper-resistant opioids
- Patent reform and IPR likely could be big issues in Congress
- Does Generic inflation stay down?
- FDA should release guidance on biosimilar interchangeability and maybe final guidance on naming
- Teva/Actavis merger consummated and what else?
- Impact of Global Purchasing alliances
- Crestor, Gleevec, Benicar, Zytiga patent expiries
- Advair Diskus?
- More Biosimilars to come
- What will Senate do with 21st Century Cures?

What are people thinking about?

- **Pharmacies**

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

- **Wholesalers**

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

- **Payers**

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

- **Generic Manufacturers**

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

- **Brand/Specialty Manufacturers**

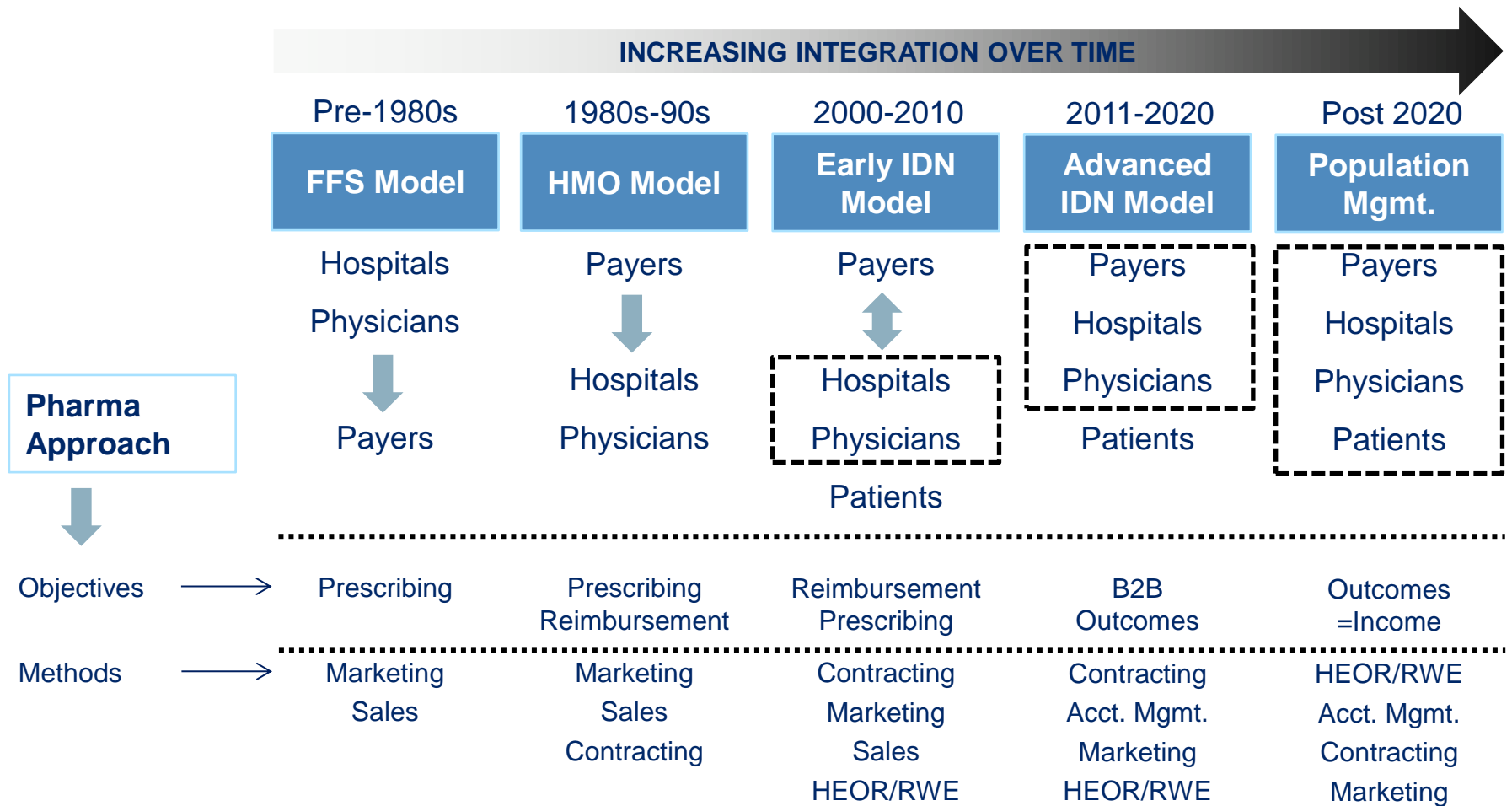
- Price backlash
- Becoming more specialized
- Oral Specialty
- Orphan Drugs
- Tax Inversion

- **Consumers**

- Rising costs
- Specialty Tiers
- Losing Insurance

It may seem like we've been here before ...

Tomorrow's models will be built on alignment and cooperation

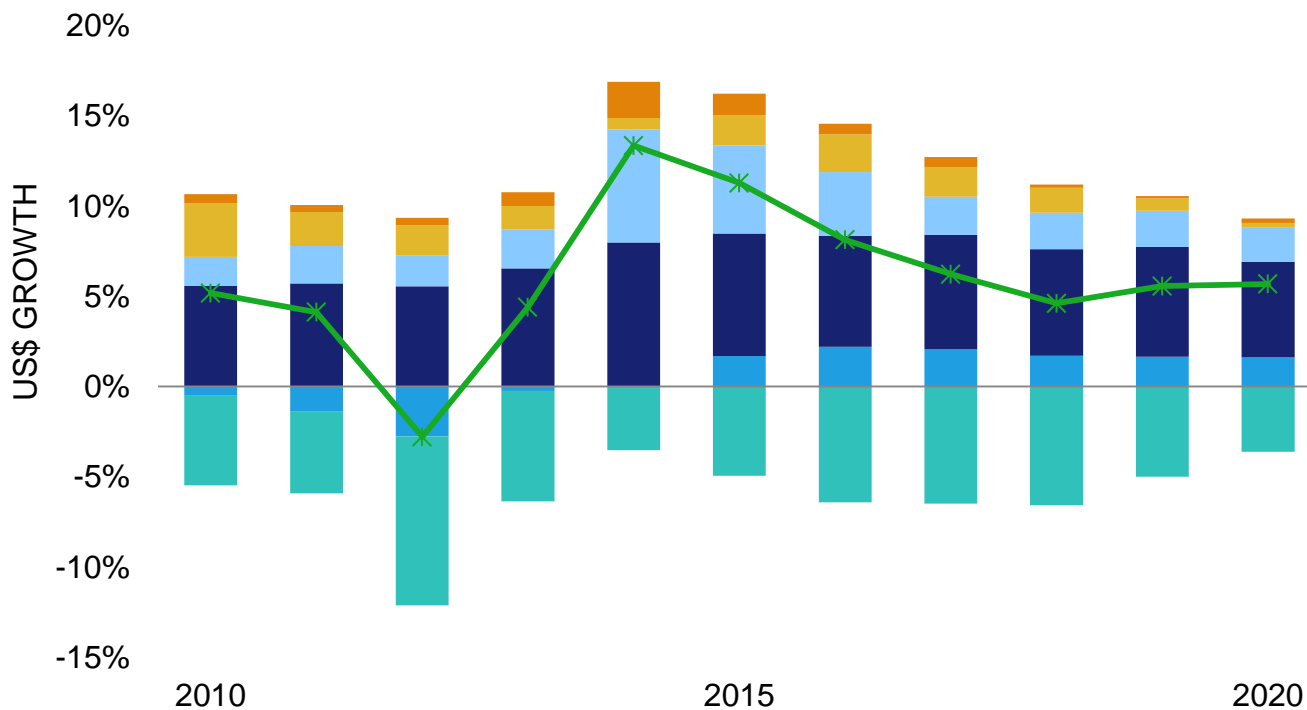


Closing thoughts

- Specialty spending is on the rise and will continue to rise thru 2020
 - 35% of dollars and 1-2% of prescriptions
 - Fastest growing areas are Hep C, Oncology, Diabetes and Orphan Drugs
 - The new Hep C drugs are our first specialty cures!
 - Innovation and more patients treated are the major drivers of the this trend.
- Near term payer focus is on Hep C, PCSK9s, PD1s, and Orphan Drugs.
- Clusters of innovation around hepatitis C, autoimmune diseases, heart disease, orphan diseases and others by 2020
- Management Tools: (Right Patient, Right Drug, & Right Setting)
 - Generics
 - Biosimilars
 - Appropriate patient populations
 - Exclusive Contracts and more price negotiations
 - Appropriate use of Medicines will save money

U.S. Spending Growth, 2010-2020

■ Protected Brands Volume ■ Protected Brands Price ■ New Brands
■ Generics Volume ■ Generics Price ■ Loss of Exclusivity
✱ Total Growth



United States

- 2020 Spending: \$560-590Bn
- 2016-20 Growth: +146Bn
- CAGR 2016-20: 5-8%
- Increase over 2015: +34%
- 2020 Brand Share of spending: 67%; unchanged since 2015
- 2020 Specialty Share of spending: 34% + 0.4pts; 34% of increase since 2015

Source: IMS Health Market Prognosis, IMS Institute for Healthcare Informatics, October 2015

Thank you

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