



The U.S Pharmaceutical Market:

Looking back and
looking ahead!

SLA

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April 20, 2015

2014 Strategic management presentation

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Most notable things about 2014

- **Double Digit Dollar sales growth is back**
- **TRXs slow start but recovered nicely**
- **Generic Diovan® finally appears and Nexium® OTC is here but no Nexium® and Copaxone®**
- **Some Generic Concerta® generics pulled**
- **FTF Nexium® pulled**
- **Generic price inflation**
- **90 day scripts approach 10% of TRXs**
- **Full Line to Specialty Distribution**
- **Controlled substances TRXs still going down**
- **Zohydro® approval**
- **DEA still on the rampage**
- **Track and Trace legislation passed**
- **HYCD products rescheduled**
- **Affordable Health Care Act delays but 8 million signed up? Now 9.5??**
- **More Limited networks and private exchanges**
- **Medicaid Expansion**
- **340B**
- **Highest Healthcare Spending increases since 1980**
- **Generic labeling rules**
- **Tax Inversion**
- **Global Purchasing Alliances**
- **Solvaldi®**

Most notable things about 2015

- **Tavenner out**
- **Hamburg out**
- **Uhl is in**
- **Supreme Court King vs. Burwell**
- **Hep C exclusive launches and price wars**
- **FDA approves Biosimilar Neupogen from Sandoz**
- **Generic Nexium finally arrives**
- **Flonase OTC**
- **Watch for PD1s and PCSK9s**
- **Mergers**
 - **Abbvie & Pharma Cyclics,**
 - **Mylan & Perrigo**
 - **Pfizer & Hospira**
 - **Valeant & Dendreon**
 - **Valeant & Salix**
 - **Optum and Catamaran**

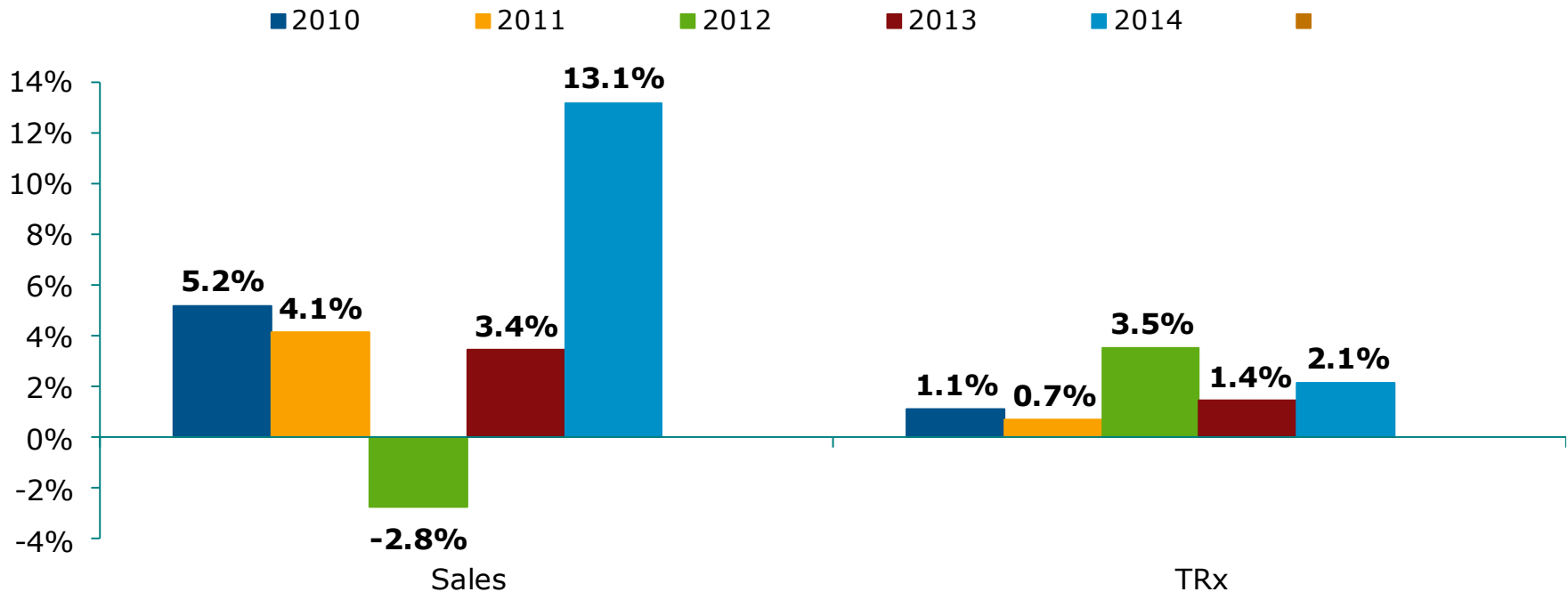
Overview of Macro-changes to U.S. healthcare

The current and future state of the healthcare system

- Healthcare costs rising, drug spend on the rebound
- Specialty, niche and orphan drugs are a key driver
- Traditional therapies post-patent cliff and shifting cost burdens are driving changes across the system
- Changing structure of payment and delivery is focused on improving outcomes and lowering costs

US Market Sales and Dispensed Prescription growth

% Growth of sales and prescription of products Total market



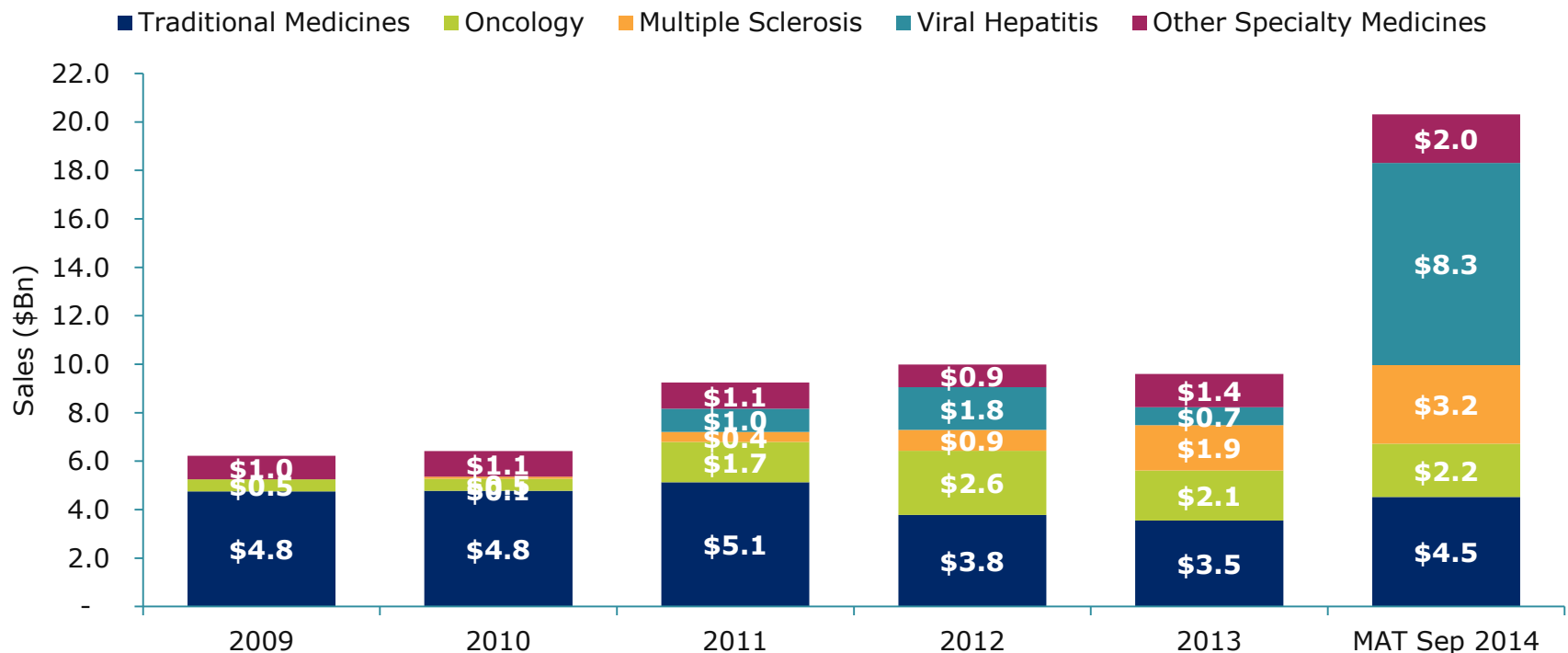
Source: IMS Health, National Sales Perspectives, Dec 2014

IMS Health, National Prescription Audit, Dec 2014

New brand spending has shifted to specialty

Sovaldi, Tecfidera, Olysio launched in last 24 months

New Brand Spending (\$Bn)



Source: IMS Health, National Sales Perspectives, Sept 2014

Recent most successful launches are mostly specialist and for focused patient populations



J&J commercialised 5 of them; Sovaldi the biggest perhaps ever

Achieving >\$1.0bn with a launch in the 5 year period 2008 - FY2013



Xarelto (Bayer/J&J)
Launch Sept 2008
(\$2.124 bn, FY 2013)



Eylea (Bayer/Regeneron)
Launch Dec 2011
(\$1.851bn, FY 2013)



Invega Sustenna (J&J)
Launch August 2009
(\$1.248bn, FY 2013)

- ✓ **All launched into areas of high need:**
- ✓ Specialty Products dominate



Victoza (Novo Nordisk)
Launch June 2009
(\$2.071bn, FY 2013)



Zytiga (J&J)
Launch May 2011
(\$1.698bn, FY 2013)



Prolia/Xgeva (Amgen/GSK)
Launch May 2010
(\$1.763bn, FY 2013)



Tecfidera (Biogen Idec)
Launch April 2013
(\$0.91bn, FY 2013)
(\$1.44Bn, MAT Mar 2014)



Gilenya (Novartis)
Launch Sept 2010
(\$1.934bn, FY2013)



Stelara (J&J)
Launch Jan 2009
(\$1.504bn, FY 2013)



Incivek/Incivo (Vertex/J&J)
Launch May 2011
(\$0.983bn, FY2013)



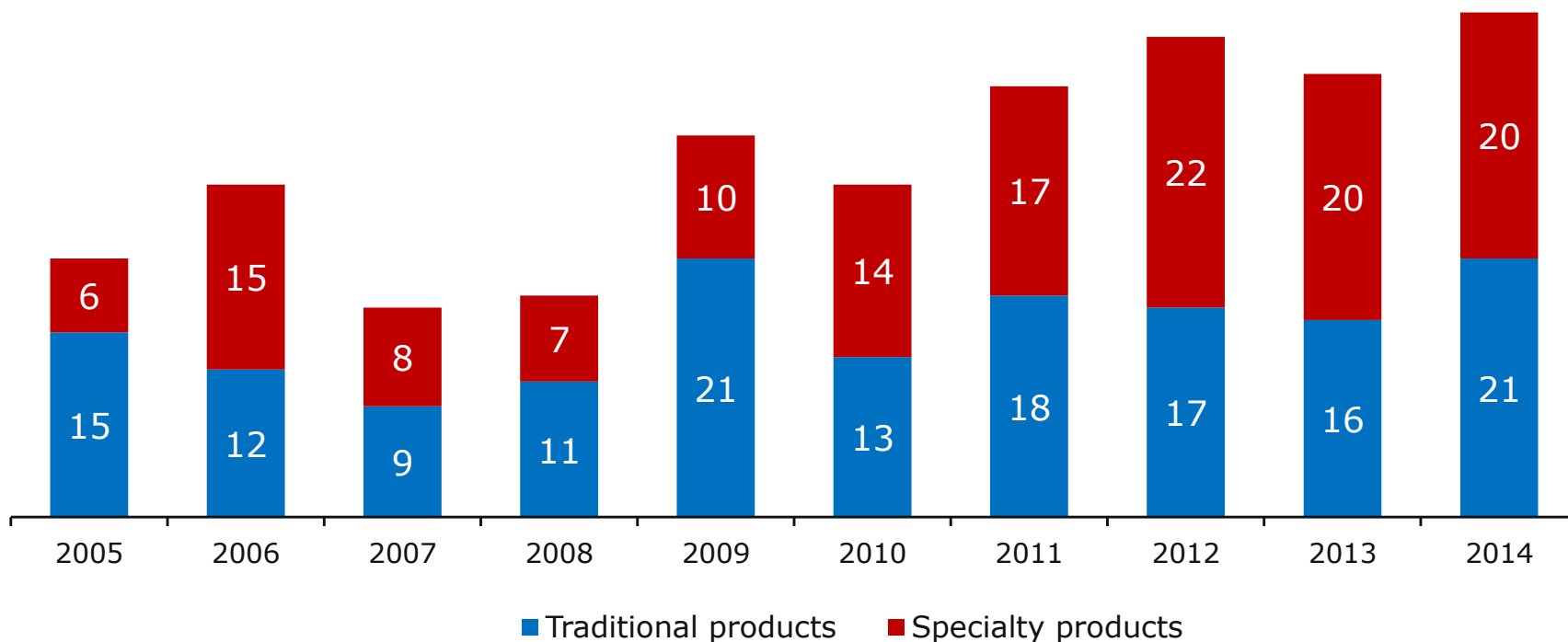
Sovaldi (Gilead)
Launch Dec 2013
(\$2.27bn, Q1 2014*)

Source: Company reported information. IMS Health Dec 2013, first word and IMS analysis

Specialty drugs hold a sizeable share of new molecular entity launches

52% of NMEs in the past 5 years are specialty, up from 40% 2005-09

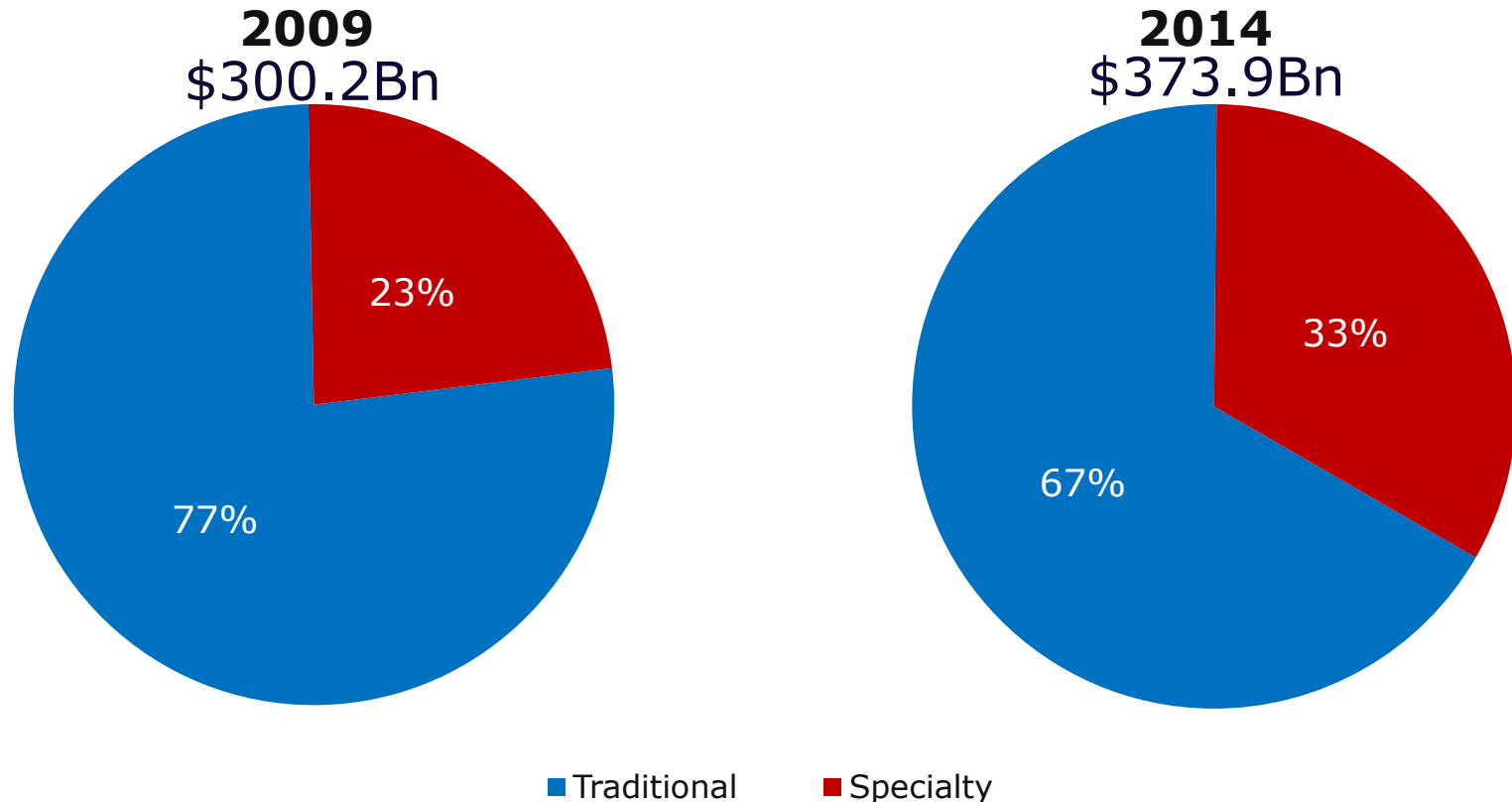
New Molecular Entities Launched in the US, 2002-2014



Source: FDA, IMS Institute for Healthcare Informatics, Jan 2015

Specialty now account for one third of spending up from 23% five years ago

Specialty growth coincided with the traditional “patent cliff”

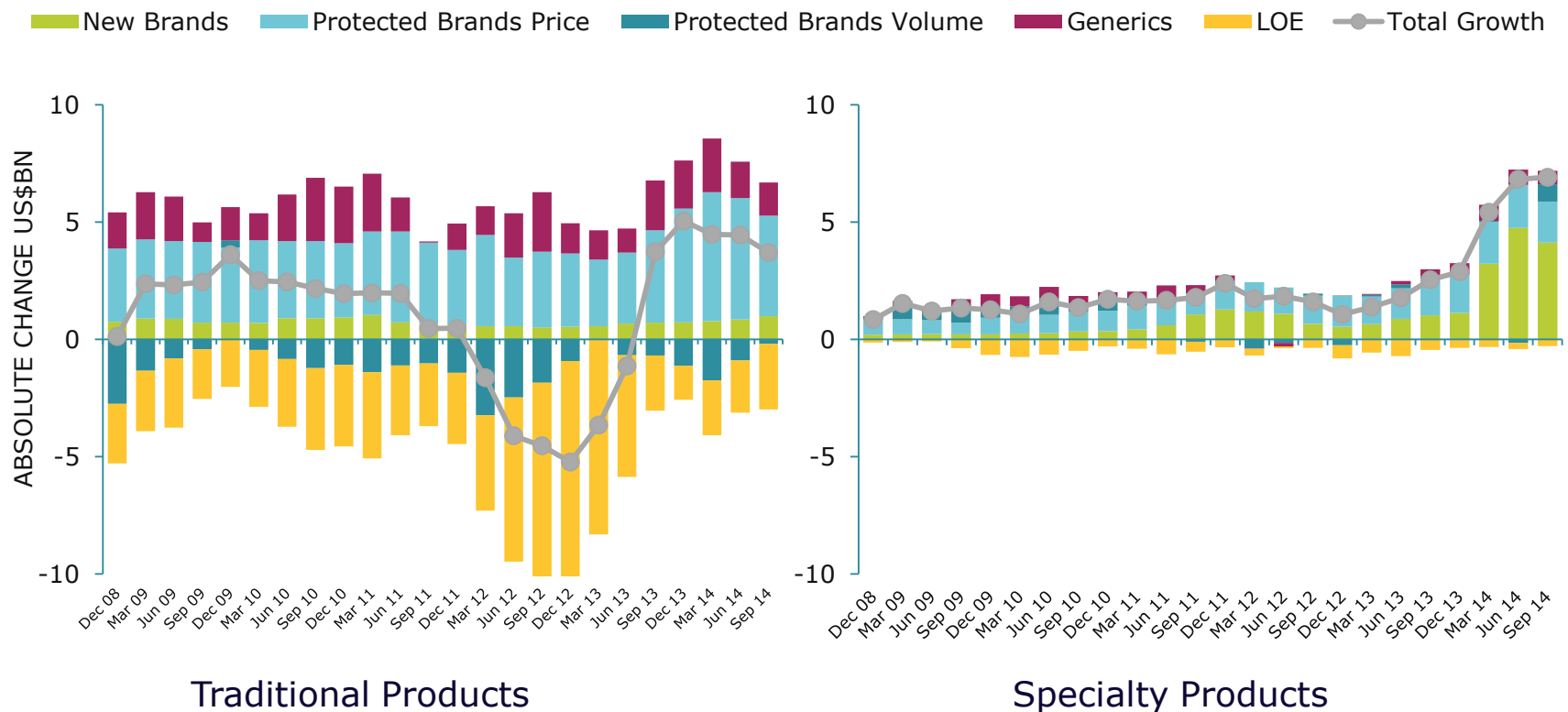


Source: IMS Health, National Sales Perspectives, Dec 2014

Spending growth is being driven primarily by innovation, which is mostly specialty

Price increases for protected brands and expiry dynamics also contribute

Traditional and Specialty Spending Growth Dynamics

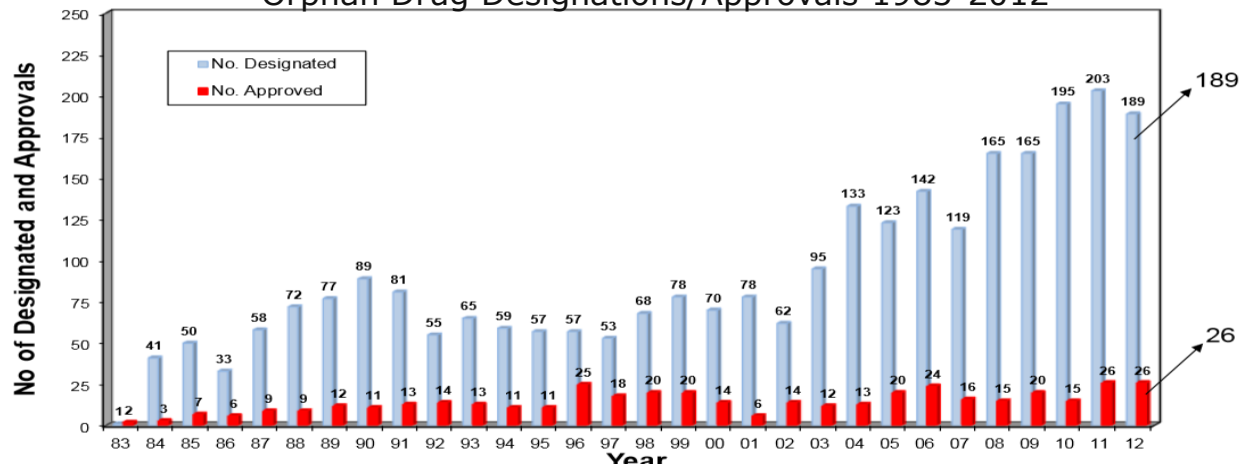


Source: IMS Health, National Sales Perspectives, Sep 2014

Orphan drugs are a significant driver of innovation and more can be expected in the future

- The United States (US) Orphan Drug Act (ODA) of 1983 established incentives for the development of drugs that treat rare or orphan diseases. Approximately 25-30M Americans, or 8-10% of the US population have one
- Total orphan drug expenditures represented 4.8-8.9% of total US drug expenditures, in 2007-2013.
- Despite the clinical value of orphan drugs, payer sensitivity to orphan drugs is increasing due to the perceived potential impact on payers' drug budgets.

Orphan Drug Designations/Approvals 1983-2012



Approx Total # Designation requests submitted through 2012 = > 3900

Approx Total # of Designations through 2012 = > 2700

Approx Total # of approvals of orphan designated products through 2012 = > 420

¹ Handfield R, Feldstein J. Insurance companies' perspectives on the orphan drug pipeline. *Am Health Drug Benefits*. 2013 Nov;6(9):589-98.

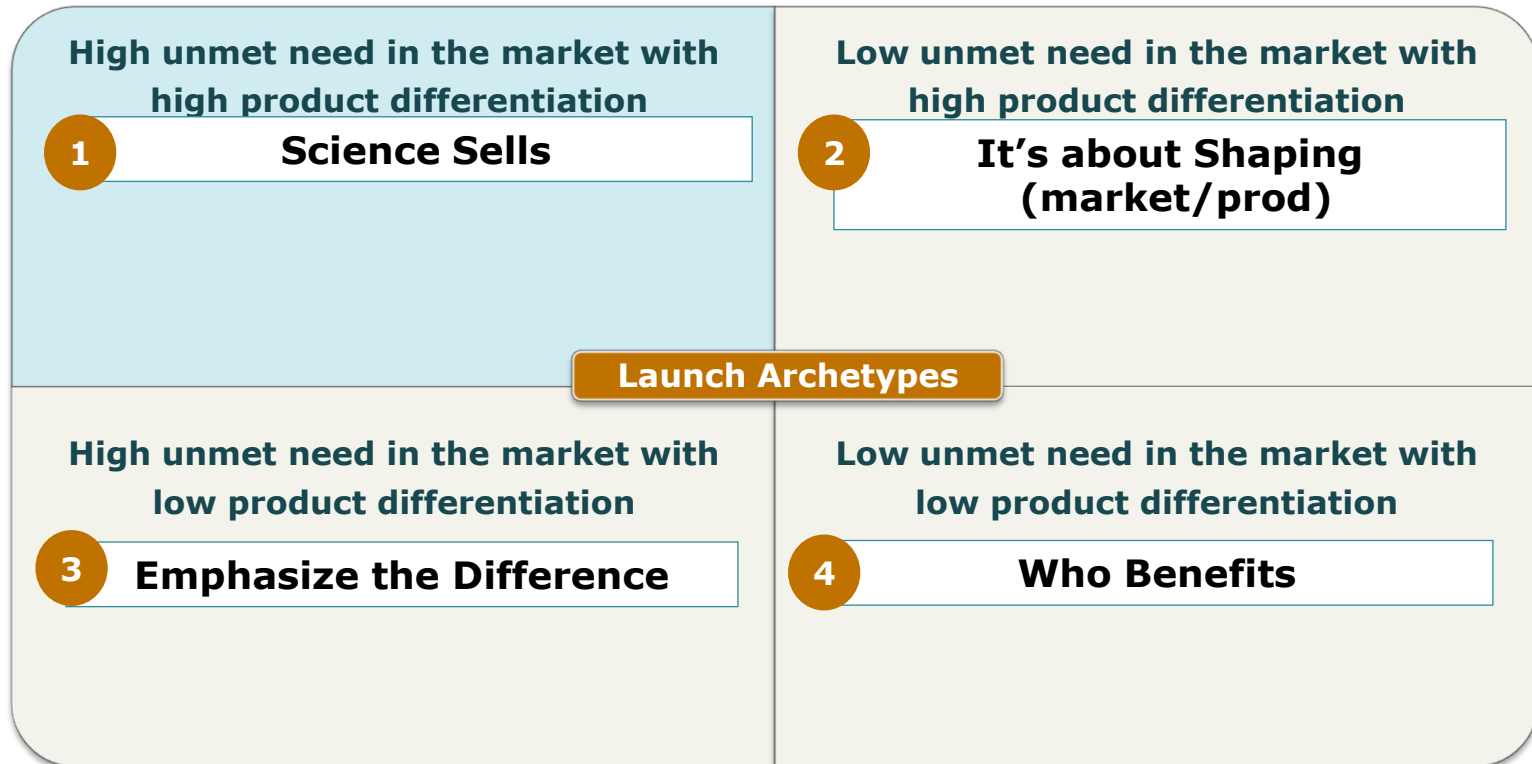
Chart Source: **The Budget Impact of Orphan Drugs in the US: A 2007-2013 MIDAS Sales Data Analysis** Victoria Divino^{1*}, Mitch Dekoven, MHSA^{1*}, Weiying Wang, MPH^{2*}, Michael Kleinrock, MA^{1*}, R. Donald Harvey, PharmD³, Rolin L. Wade, RPh, MS^{1*} and Satyin Kaura, MSci, MBA^{4*}

¹IMS Health, Fairfax, VA; ²MKTXS, Raritan, NJ; ³Winship Cancer Institute, Emory University, Atlanta, GA; ⁴Celgene, Summit, NJ

"Rare Diseases and FDA" Perspectives from the Office of Orphan Products Development (OOPD)" Presented by Katherine Needleman, MS, PhD, RAC, Director, Orphan Products Grants Program FDA/OOPD at the IRDiRC Conference, April 16 & 17, 2013 ¹

Launch success depends on a clear alignment of a product's value to the stakeholder's needs

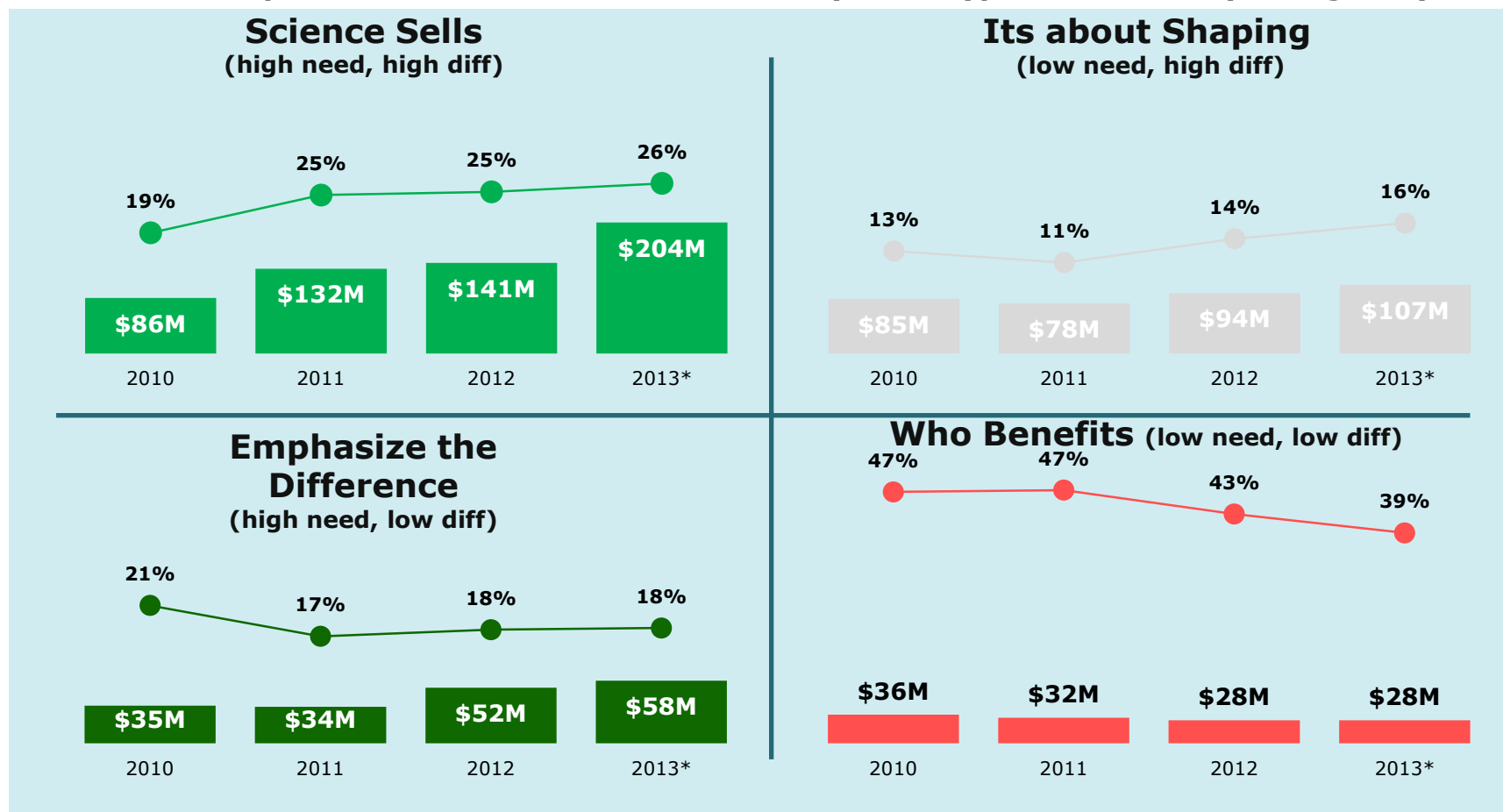
Success is not limited to and doesn't look like the top 2-3 launches



1. Can Launch Archetypes provide insight into a product's opportunity for success?
2. Are investment levels different for each archetype?
3. Does Managed Care treat these archetypes similarly?

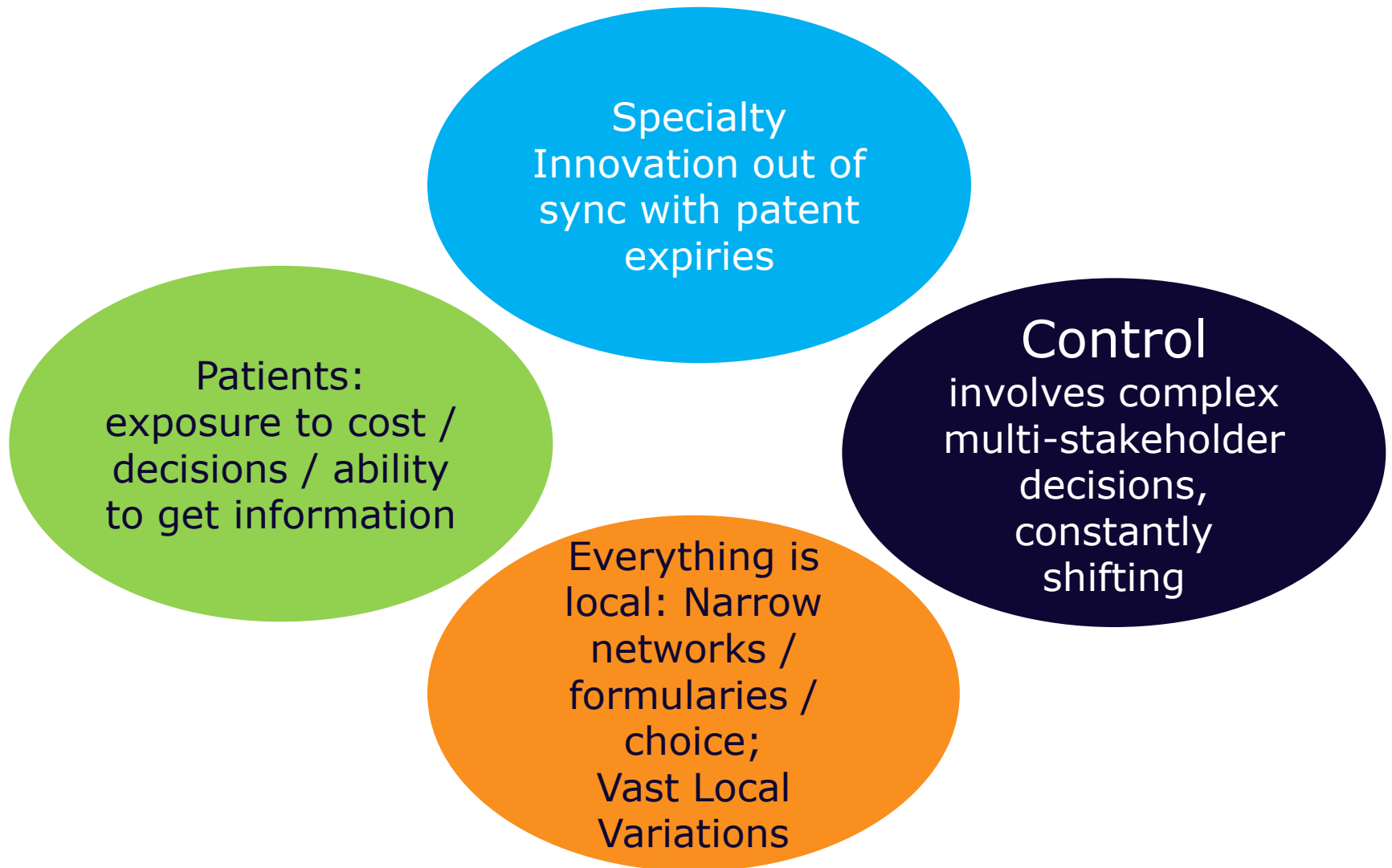
Recent launch performance is improving industry-wide

First Year Sales per Launch & Percent of Launches by Archetype, 2010-2013 (Rolling 4YR)



Sources: IMS Custom PLD; Thought Leadership

Changes in the healthcare environment share common interconnected themes



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
- Generic Price Inflation
- Formularies and exclusive launches
- Rising Oncology costs

- **Generic Manufacturers**

- Purchasing Alliances
- Portfolio Optimization
- Brand 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

Largest absolute Dollar sales gains and losses by leading therapy classes, (2014)

Dollars	AC \$ Gained	Total Rx dispensed	AC \$ Lost
Viral Hepatitis Products	10535.4	Anti-migraine	-165.2
Analogues of human insulin	4976.1	Immunologic interferons	-222.2
Antiarth,biol resp mod	2990.7	Hormones,androgens	-252.1
Antipsychotics,oth	2199.4	Antihyperlipidemic agt	-549.2
Neurological disorders	2158.0	Heparins	-552.5
Anticoagulants, Other	1445.5	Non-barb,oth	-555.1
HIV antiviral combination	1333.9	Tetracyclines	-581.7
Antineo monoclonal antib	1304.3	Angiotensin II antagonists	-665.1
Tyrosine kinase inhibitor	1268.0	Proton pump inhib	-834.5
Dpp-4 Inhib	1247.7	Anti-depressants	-2474.4

Source: IMS Health, National Sales Perspectives, Dec 2014, National Prescription Audit, Dec 2014

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Source: IMS Health, National Sales Perspectives, Dec 2014, National Prescription Audit, Dec 2014

Sales of leading therapy classes

Leading classes	MAT Dec 2014		
	US\$m	% Market Share	% Growth
US Industry	373,858	100.0	13.1
1 Analogs of human insulin	18,876	5.0	35.8
2 Antiarth,biol resp mod	14,805	4.0	25.3
3 Antipsychotics,oth	14,375	3.8	18.1
4 Lipid regulators	12,905	3.5	4.5
5 Viral Hepatitis Products	11,901	3.2	771.6
6 Antineo monoclonal antib	10,930	2.9	13.6
7 HIV antiviral combination	8,786	2.4	17.9
8 Proton pump inhib	8,703	2.3	-8.7
9 Analeptics	8,318	2.2	-0.3
10 Steroid,inhaled bronch	8,148	2.2	8.3
Top 10	117,747	31.5	25.1

Source: IMS Health, National Sales Perspectives, Dec 2014

Sales of 11-20 therapy classes

Leading classes	MAT Dec 2014		
	US\$m	% Market Share	% Growth
11 Neurological disorders	8,141	2.2	36.1
12 GI anti-inflam	8,014	2.1	13.3
13 Dpp-4 Inhib	6,470	1.7	23.9
14 Anti-depressants	6,458	1.7	-27.7
15 Angiotensin II antagonists	5,768	1.5	-10.3
16 Tyrosine kinase inhibitor	5,537	1.5	29.7
17 Codeine & comb	5,263	1.4	7.7
18 Seizure disorders	5,247	1.4	13.4
19 Immunologic interferons	4,843	1.3	-4.4
20 Immune system adjuncts	4,816	1.3	4.7
Top 20	178,304	47.7	17.9

Source: IMS Health, National Sales Perspectives, Dec 2014

Largest absolute dollar sales gains and losses by leading products, (2014)

Dollars	AC \$ Gains	Total Rx Dispensed	AC \$ Lost
Sovaldi® (Gs-)	7782	enoxaparin sod (win)	-183
Olysio® (Jan)	1957	Nexium® (Azn)	-251
Tecfidera® (Bge)	1675	Namenda® (Atv)	-280
Humira® (Av1)	1658	Advair Diskus® (Gsk)	-371
Harvoni® (Gs-)	1546	methylphenidate er (Atv)	-438
Lantus Solostar® (S.A)	1348	Lovaza® (Gsk)	-494
Abilify® (Ots)	1291	Lunesta® (S8r)	-513
Xarelto® (Jan)	1052	Diovan® (Nvr)	-734
Lantus® (S.A)	814	Lidoderm® (End)	-799
Enbrel® (Aai)	796	Cymbalta® (Lly)	-4916

Source: IMS Health, National Sales Perspectives, Dec 2014, National Prescription Audit, Dec 2014

Sales of leading products

ProductsCompany		MAT Dec 2014		
		US\$m	% Market Share	% Growth
US Industry		373,858	100.0	13.1
1	Sovaldi®GS-	7,853	2.1	10910.4
2	Abilify®OTS	7,838	2.1	19.7
3	Humira®AV1	7,222	1.9	29.8
4	Nexium®AZN	5,931	1.6	-4.1
5	Crestor®AZN	5,848	1.6	8.8
6	Enbrel®AAI	5,506	1.5	16.9
7	Advair Diskus®GSK	4,813	1.3	-7.2
8	Remicade®JAN	4,502	1.2	9.5
9	Lantus Solostar®S.A	4,468	1.2	43.2
10	Copaxone®TVN	3,881	1.0	4.6
Top 10		57,863	15.5	29.8

Source: IMS Health, National Sales Perspectives, Dec 2014

Sales of 11-20 products

Products	Company	MAT Dec 2014		
		US\$mn	% Market Share	% Growth
11 Neulasta®	AAI	3,831	1.0	6.9
12 Rituxan®	GTC	3,473	0.9	5.0
13 Januvia®	MSD	3,464	0.9	20.6
14 Lantus®	S.A	3,402	0.9	31.5
15 Spiriva Handihaler®	B.I	3,329	0.9	9.7
16 Lyrica®	PFZ	3,087	0.8	25.8
17 Atripla®	BMG	2,962	0.8	2.4
18 Avastin®	GTC	2,888	0.8	6.7
19 Tecfidera®	BGE	2,580	0.7	185.0
20 Truvada®	GS-	2,502	0.7	10.7
Top 20		89,381	23.9	25.6

Source: IMS Health, National Sales Perspectives, Dec 2014

What do we mean by specialty pharmaceuticals?

IMS has an industry standard definition-must have 4 or more

Medicines that treat specific, complex chronic diseases with the following attributes:

- **Initiated *only* by a specialist**
 - **High expense**
 - **Requires reimbursement assistance**
 - **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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Top US Specialty events of 2014

- Hep C
- Orphan Drugs
- FDA's first Biosimilar actions
- Tremendous pressure on Pharmaceutical budgets

Top Specialty events to watch for!

- **HEP C Innovation 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?**
- **Specialty space gets more crowded with new entrants and more orals are coming**
- **The first Biosimilar launch**
- **Co Pay programs cooperation by payers**
- **Possible 340B changes**
- **Gene Therapies & Orphan drugs price discussions**

Top specialty companies – MAT Nov 2014

		Sales (\$MN)	Share	Growth
	U.S. Specialty Market	116,257	100.0%	25.1%
1	Gilead Sciences	16,416	14.1%	136.0%
2	Amgen	15,084	13.0%	10.6%
3	Genentech	13,040	11.2%	6.1%
4	Johnson & Johnson	11,844	10.2%	37.7%
5	Abbvie	8,423	7.2%	22.5%
6	Novartis	6,878	5.9%	12.5%
7	Biogen Idec	6,002	5.2%	66.1%
8	Teva	5,361	4.6%	10.9%
9	Bristol-Myers Squibb	4,054	3.5%	9.4%
10	Lilly	2,810	2.4%	7.2%
	Top 10	89,911	77.3%	29.8%

Source: IMS Health, National Sales Perspectives, Nov 2014

Sales of leading corps

Leading corporations	MAT Dec 2014		
	US\$m	% Market Share	% Growth
US Industry	373,858	100.0	13.1
1 Novartis (incl Sandoz)	19,486	5.2	3.0
2 AstraZeneca	19,485	5.2	7.2
3 Johnson & Johnson	19,088	5.1	37.1
4 Gilead Sciences	18,387	4.9	140.9
5 Pfizer (incl Greenstone)	18,050	4.8	6.7
6 Roche (incl Genentech)	17,737	4.7	6.9
7 Merck & Co	17,584	4.7	8.4
8 Teva	17,471	4.7	14.0
9 Amgen Corporation	16,398	4.4	10.9
10 Sanofi Aventis	14,602	3.9	19.9
Top 10	178,289	47.7	18.3

Source: IMS Health, National Sales Perspectives, Dec 2014

Sales of 11-20 corps

Leading corporations	MAT Dec 2014		
	US\$m	% Market Share	% Growth
11 Actavis US	13,775	3.7	-2.4
12 Abbvie Inc	12,622	3.4	4.7
13 GlaxoSmithKline	12,166	3.3	-4.5
14 Lilly	11,816	3.2	-22.8
15 Novo Nordisk	10,417	2.8	26.4
16 Mylan Labs, Inc.	8,742	2.3	10.3
17 Boehringer Ingelheim	8,256	2.2	6.9
18 Otsuka America Ph	8,212	2.2	21.0
19 Biogen Idec Corp	6,134	1.6	59.0
20 Shire US Corp	5,025	1.3	18.6
Top 20	275,454	73.7	13.1

Source: IMS Health, National Sales Perspectives, Dec 2014

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

Dollars	AC US\$BN	TRx	AC TRx mn
Gilead Sciences	10.8	Novartis (incl Sandoz)	34.6
Johnson & Johnson	5.2	Endo Pharma Inc.	26.2
Sanofi Aventis	2.4	Legacy Pharma Pkg	14.5
Biogen Idec Corp	2.3	Zydus Pharma	14.4
Novo Nordisk	2.2	Accord Healthcare	13.8
Teva	2.1	Apotex Corp	13.5
Amgen Corporation	1.6	Lupin Pharma	13.5
Merck & Co	1.4	Camber Pharma	12.4
Otsuka America Ph	1.4	Amneal Inc	11.6
Astrazeneca	1.3	Aurobindo Pharma	10.5

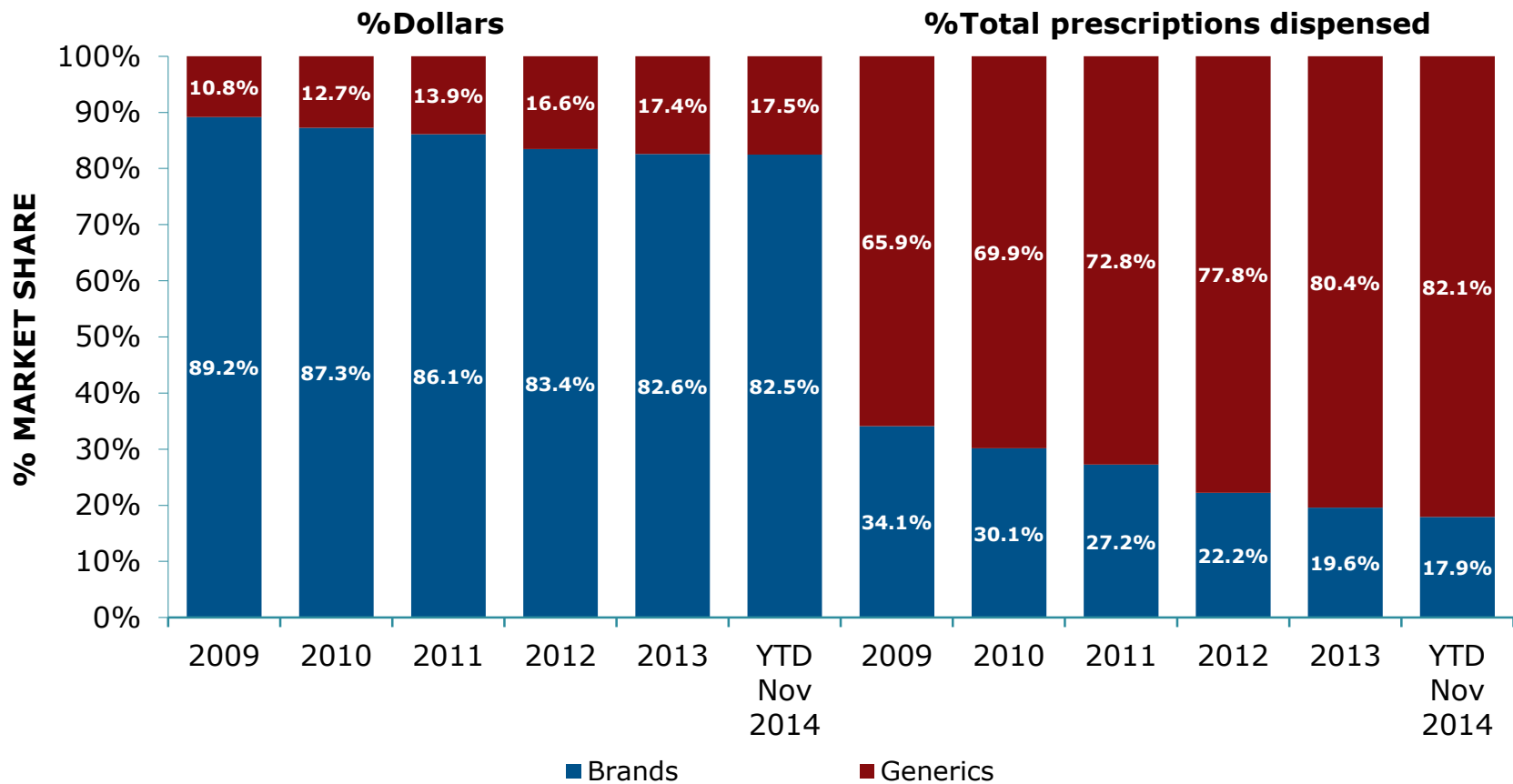
Source: IMS Health, National Sales Perspectives, Dec 2014, National Prescription Audit, Dec 2014

Fastest growth rates by leading corporations, Sales & TRx (2014)

Dollars	% Growth	TRx
Pharma Cyclics, Inc	>999	Bluepoint Labs
Citron Pharma , Llc	796	Citron Pharma , Llc
Horizon Pharma	235	Macleods Pharma
Gilead Sciences	141	Blu Pharma
Insys Therapeutics	124	Sancilio
Cadence Pharma	121	Virtus Pharma
Torrent Pharma	99	Unichem Pharma Usa
Rhodes Pharma	77	Solco Healthcare
Heritage Pharma	61	Accord Healthcare
Lundbeck Inc	60	Kvk-Tech

Source: IMS Health, National Sales Perspectives, Dec 2014, National Prescription Audit, Dec 2014

Sales and TRx share brands and generics (5yrs w/ YTD)



Source: IMS Health, National Sales Perspectives, Nov 2014, National Prescription Audit, Nov 2014, Branded generics disaggregated

Reasons for Generic Price Inflation

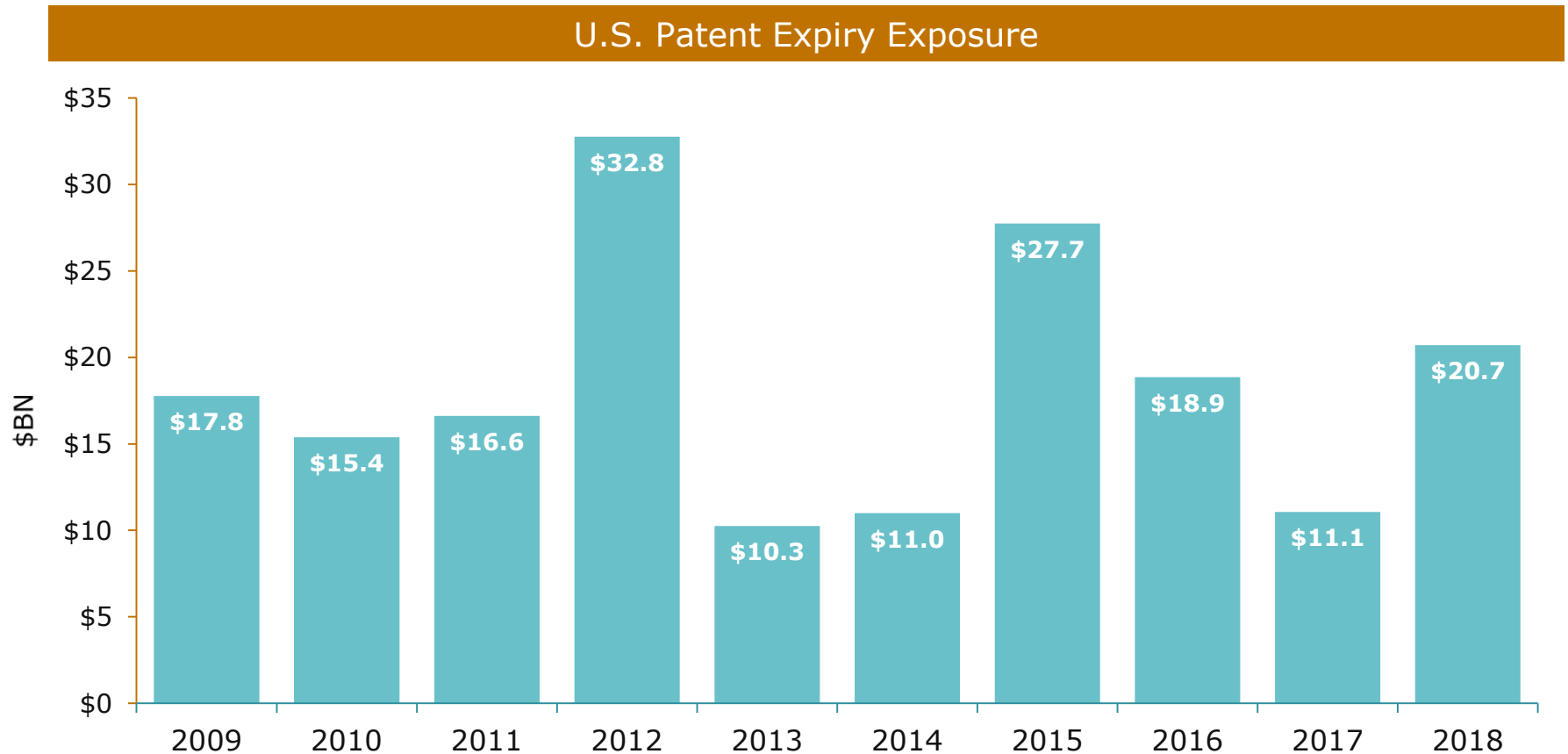
- **Regulatory/Quality** – with the increased scrutiny from the FDA, manufacturers need to invest more into their quality systems and when a quality / supply issue arises due to 483s, it creates the opportunity to increase prices to recoup part of their investment
- **Customer consolidation** – with 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

Top US Generic events of 2014

- Hep C
- Generic Price Inflation
- Patent Expiries
 - the ones that didn't happen and the ones that did
- FDA's first Biosimilar actions
- FDA raising the bar
 - Indian company inspections ramped up
 - Forced withdrawal of Concerta generic competitors
- Global purchasing alliances expanding
- More mergers
- Rx to OTC

Products facing LOE in the next 4 years are valued at \$78.4Bn

Nexium, Abilify and Namenda face generic competition in 2015



Sales from year-prior to expiry for years 2009-14; sales in MAT Sep 2014 used for years 2015-18

Source: IMS Health, Dec 2014

Biologicals future loss of exclusivity

Twelve compounds will present a US\$ 73 billion opportunity by 2020



EU expiry date	US expiry date
2018	2016
2015	2028 (extended)
2014	2018
2014	2015
Expired	2018
2019	2019
Expired	Expired
2015	2016
2014	2019
2017	2014
2015	2015
2016	2016

Not considered existing biosimilars such as Epoetin Alfa expired in EU, but still patent protected in the US

Source: IMS MIDAS, 09/2013, IMS Patent focus

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



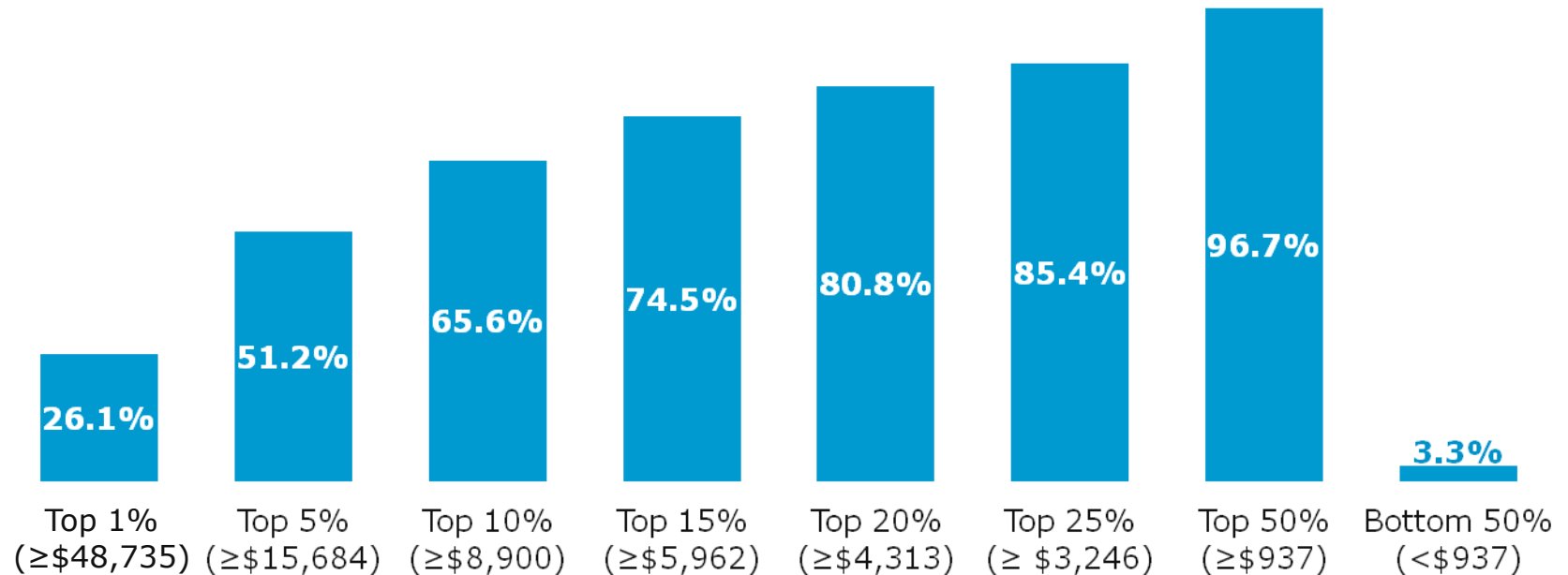
SALES AND MARKETING CAPABILITIES

Need to adopt a branded mentality to win stakeholder trust



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

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%

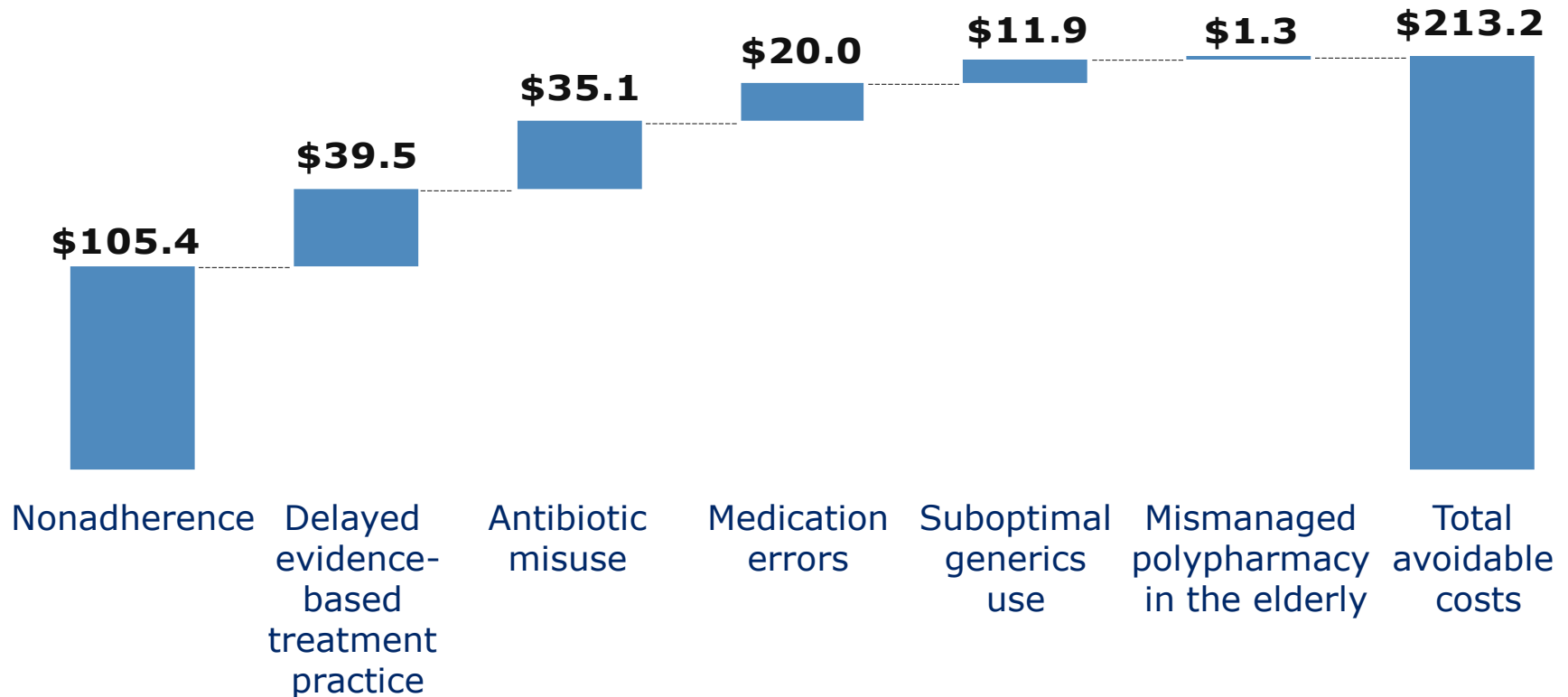
Prescriptions not taken as directed⁵ drive \$260B in additional care costs⁴

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

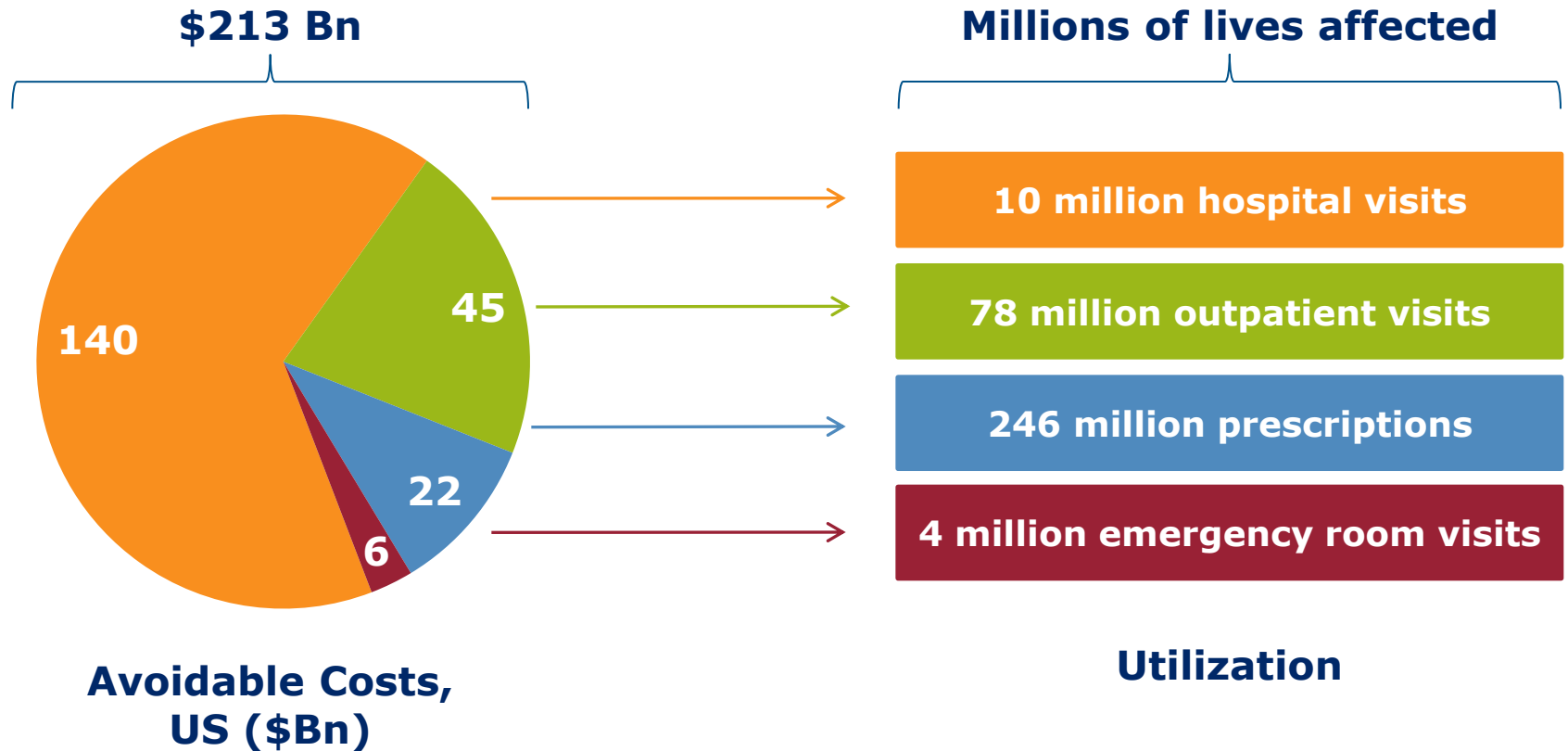
The economic stakes are high for the healthcare system

Estimated avoidable costs by lever (\$Bn), 2012



Source: Avoidable Costs in U.S. Healthcare Study by IMS Institute of HealthCare Informatics

The financial costs are caused by avoidable use of healthcare services by patients



Source: Avoidable Costs in U.S. Healthcare Study

Focus of study was limited to six areas

Medicine access and pricing were not addressed

Medication nonadherence

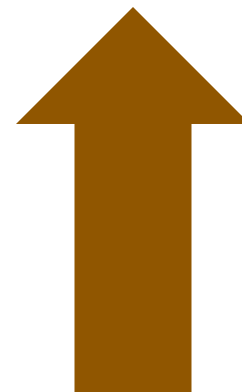
Delayed evidence-based
treatment

Antibiotic misuse

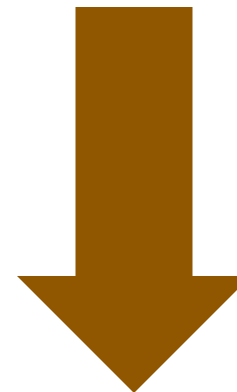
Medication errors

Suboptimal generics use

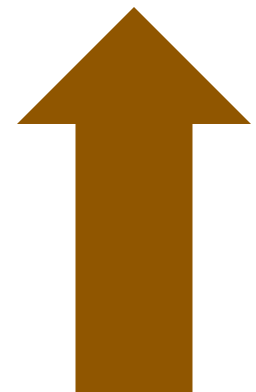
Mismanaged polypharmacy



Improvement
in health
outcomes



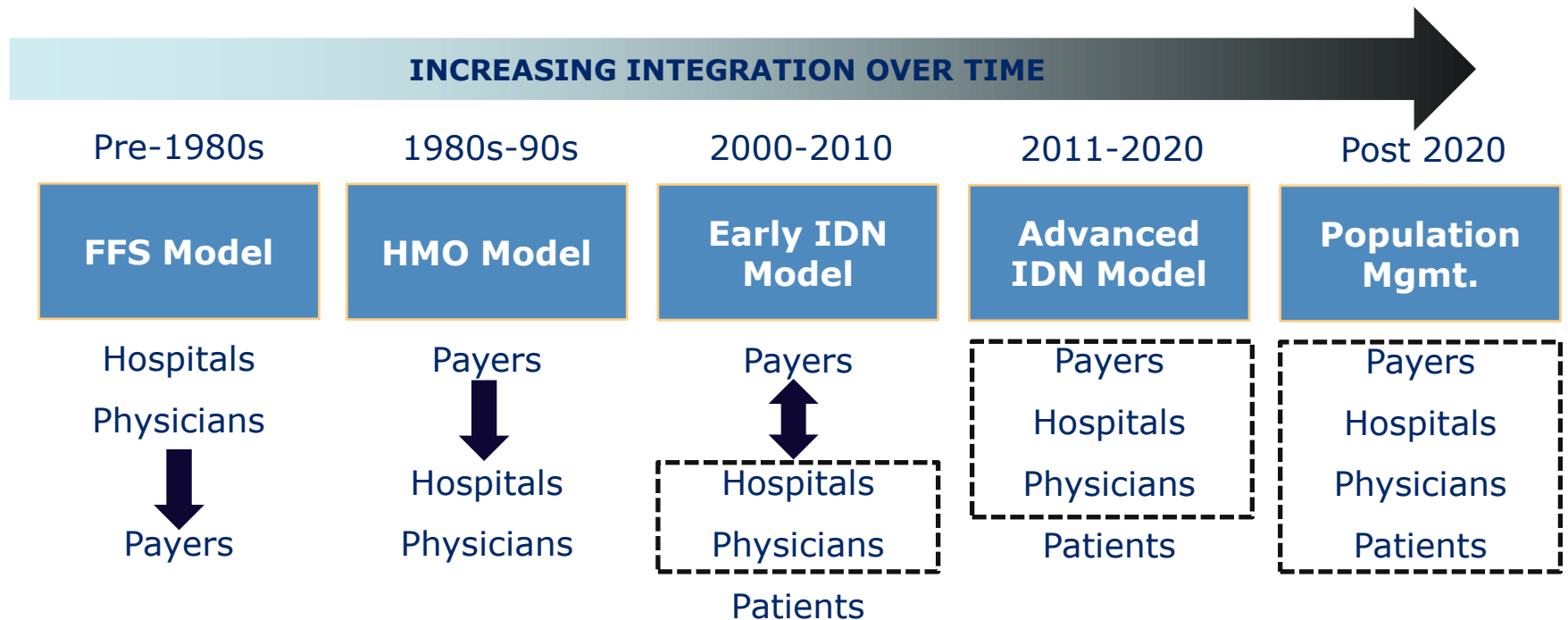
Decline in
healthcare
costs



Increase in
medicines
value

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

Tomorrow's models will be built on alignment and cooperation

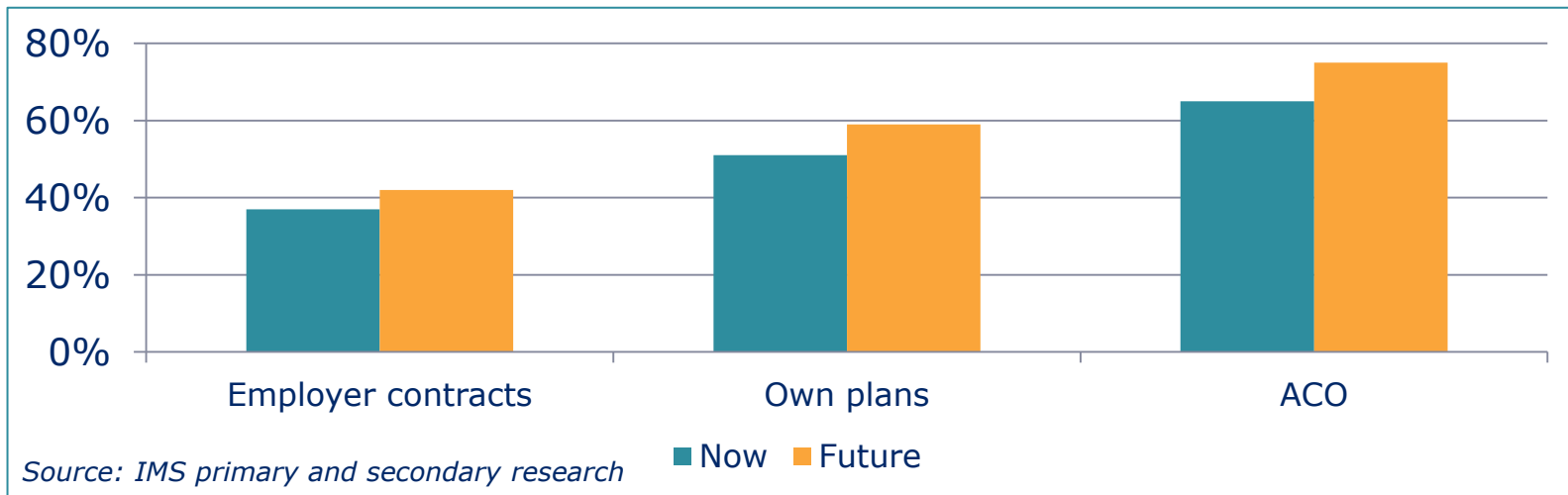


Lines are blurring between care delivery and health insurance through vertical integration

- **2/3 of health networks are part of ACOs**
- **1/2 own or operate their own insurance plans**
- **1/3 have direct contracts with employers**

"Ascension Health (largest non-profit IDN) is in talks to acquire an unnamed insurance company that operates in 18 states...a significant escalation in the brewing shift among hospital operators toward the business of selling health plans."

Source: Modern Healthcare, 05/22/14



Aetna plans to cover nearly 60% of US population
ACO deals in the pipeline to achieve 10% savings
ACOs today estimated to cover 15-20% of Americans

Health networks focus first on managing chronic disease and their targeted therapy areas continue to expand

Key focus today

- Diabetes
- Stroke
- Cardiovascular disease
- Hip replacement
- Congestive heart failure



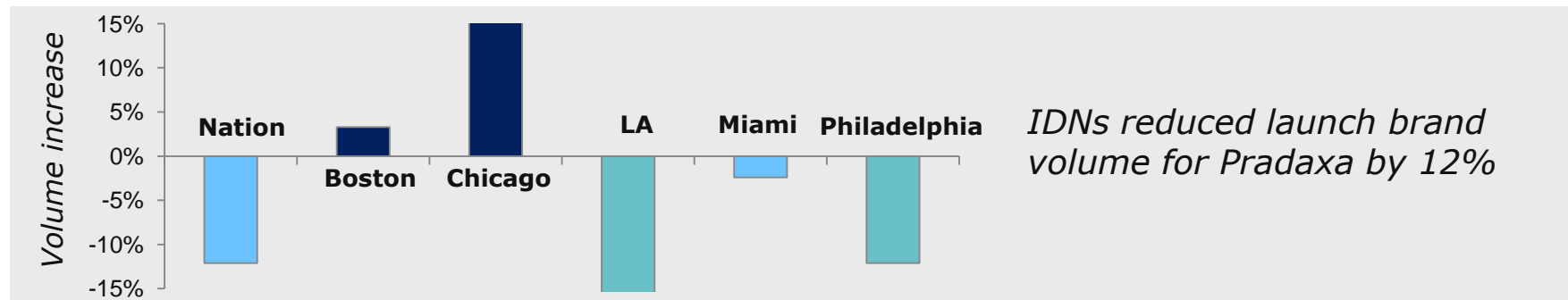
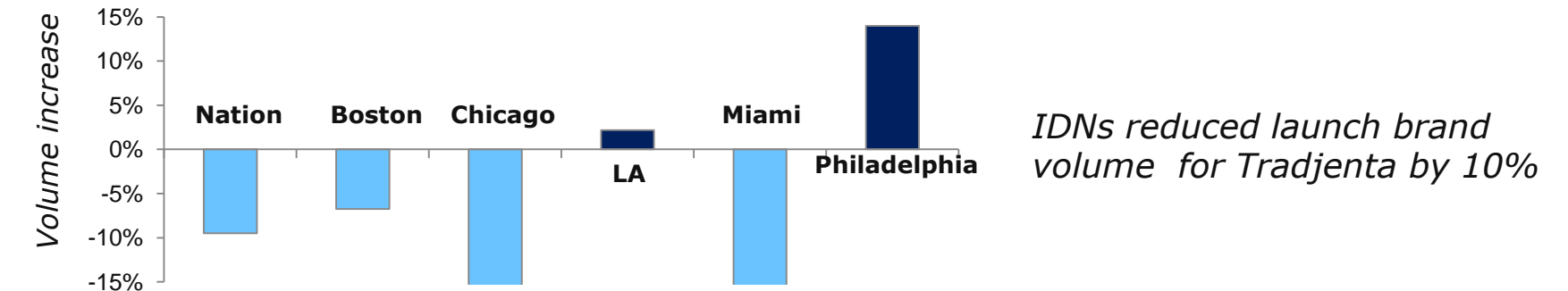
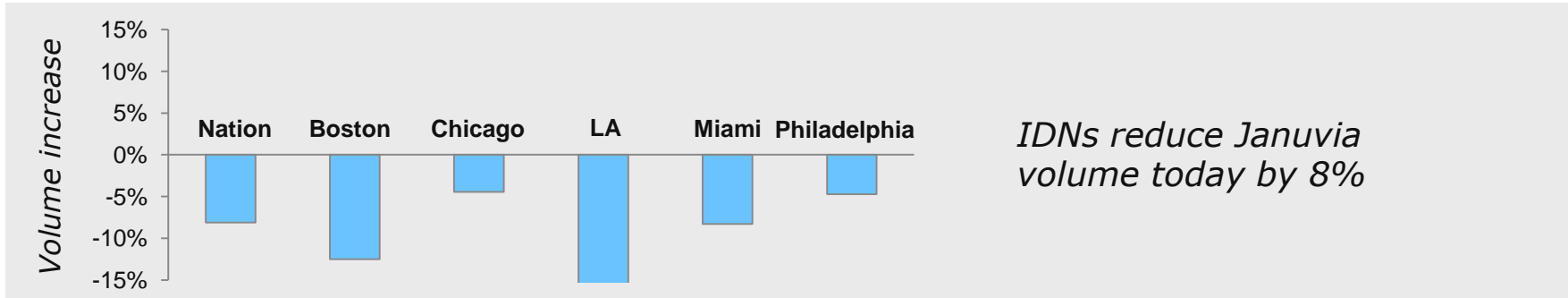
Coming up

- Depression
- Alzheimer's
- Parkinson's
- COPD
- Pain
- Arthritis
- Bariatric
- Oncology

Source: IMS primary and secondary research

- PCPs and specialists driven to coordinate treatment decisions through a team approach (pharmacists, NPs, social workers etc)
- Practice emerging of paying physicians bonus (even 20%) on patient outcomes

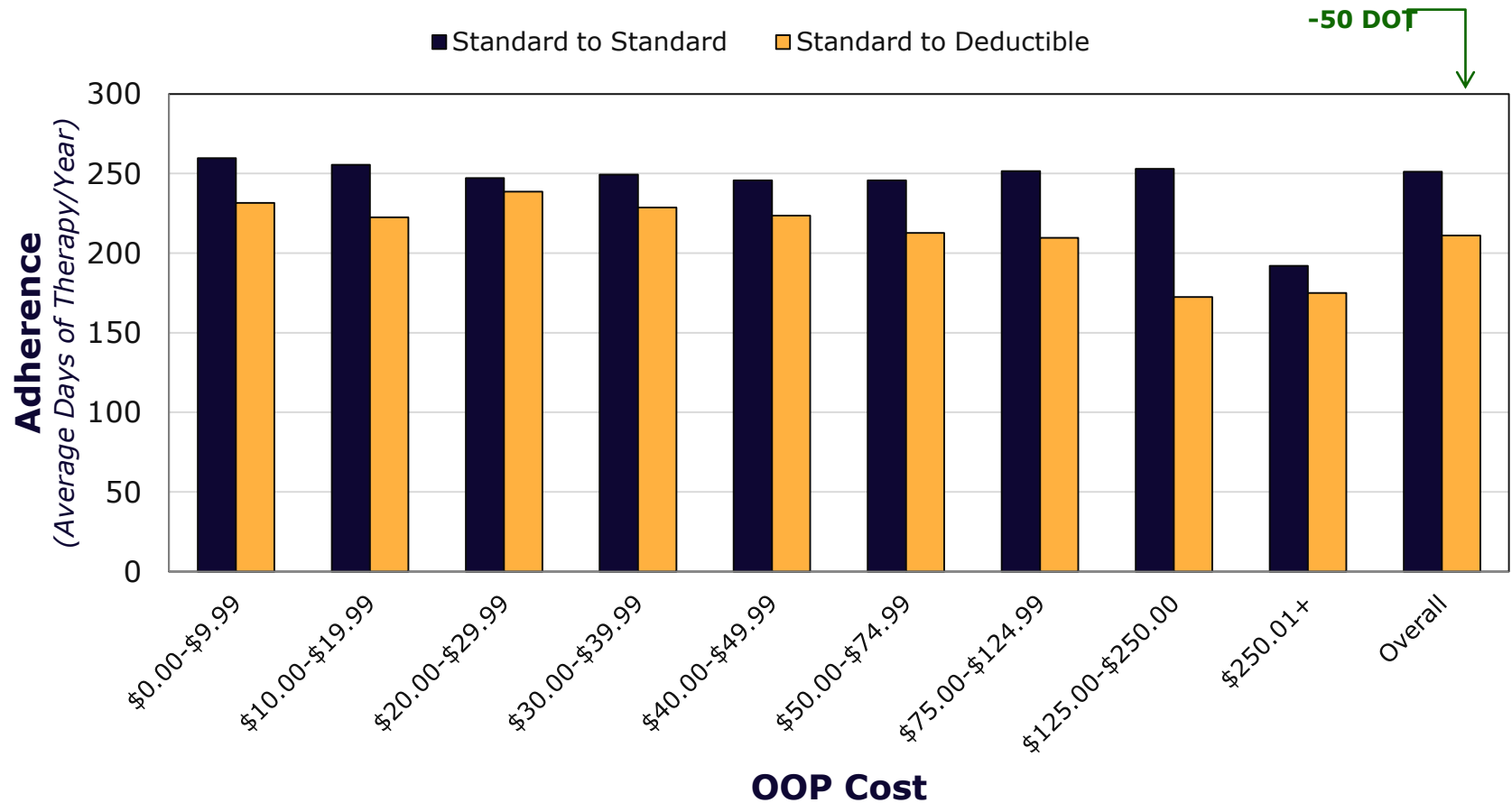
IDNs are organized corporatized care providers that drive care protocols and treatment choices locally



High Deductibles have a proven negative effect on patient adherence

Average Continuing Adherence by Co-Pay and HDHP Grouping

(Continuing Patients, DPP4s, 2013)



Source: IMS Formulary Impact Analyzer (January 2011-December 2014); IMS Health Analysis

Patients now use the internet to seek healthcare information before they talk to their doctor

Typical patient on-line journey



Source: IMS Health European Thought Leadership

The need is urgent for actionable use of evidence-based approaches to drive better outcomes

Potential RWE partnerships / examples

Evidence of Value & Outcomes

Customer need: As IDNs/ payers take on risk, they are looking to improve patient outcomes and move to value based model

Opportunity: Since customers are still in the initial phase of employing **specialty (oncology) metrics**, it poses an opportunity to collaborate on creating patients outcome data

Align metrics on payment/ outcomes incentives

Customer need: Evolving payment models incentivize IDN/ payer to align on novel metrics (e.g. quality, outcomes)

Opportunity: There is an opportunity to identify progressive customers in the evolving phase and help them implement payment metrics to leverage the relation for **specialty metrics in the future**

Identify & partner on high risk populations

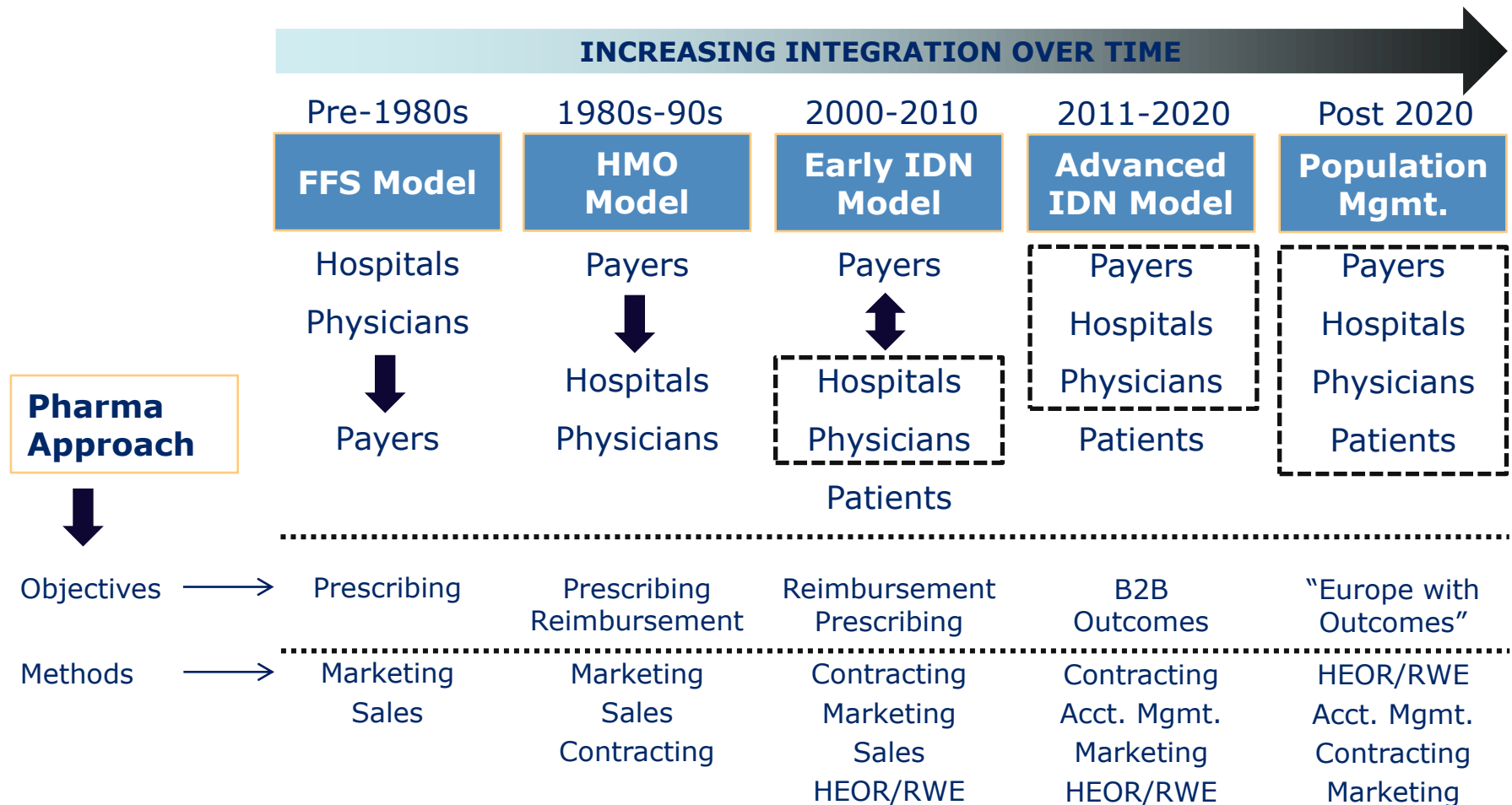
Customer need: With increased integrated clinical and financial risk, customers will look to identify high risk populations via predictive modeling, to create solutions/ protocols

Opportunity: Collaborate on initiatives to identify high risk patient population, to ensure access to protocols in the future esp. for **markets like HCV, Heart Failure, COPD, and many hard to treat mental health conditions**

Source: IMS Consulting Group

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

Tomorrow's models will be built on alignment and cooperation



Thoughts for 2015 and beyond

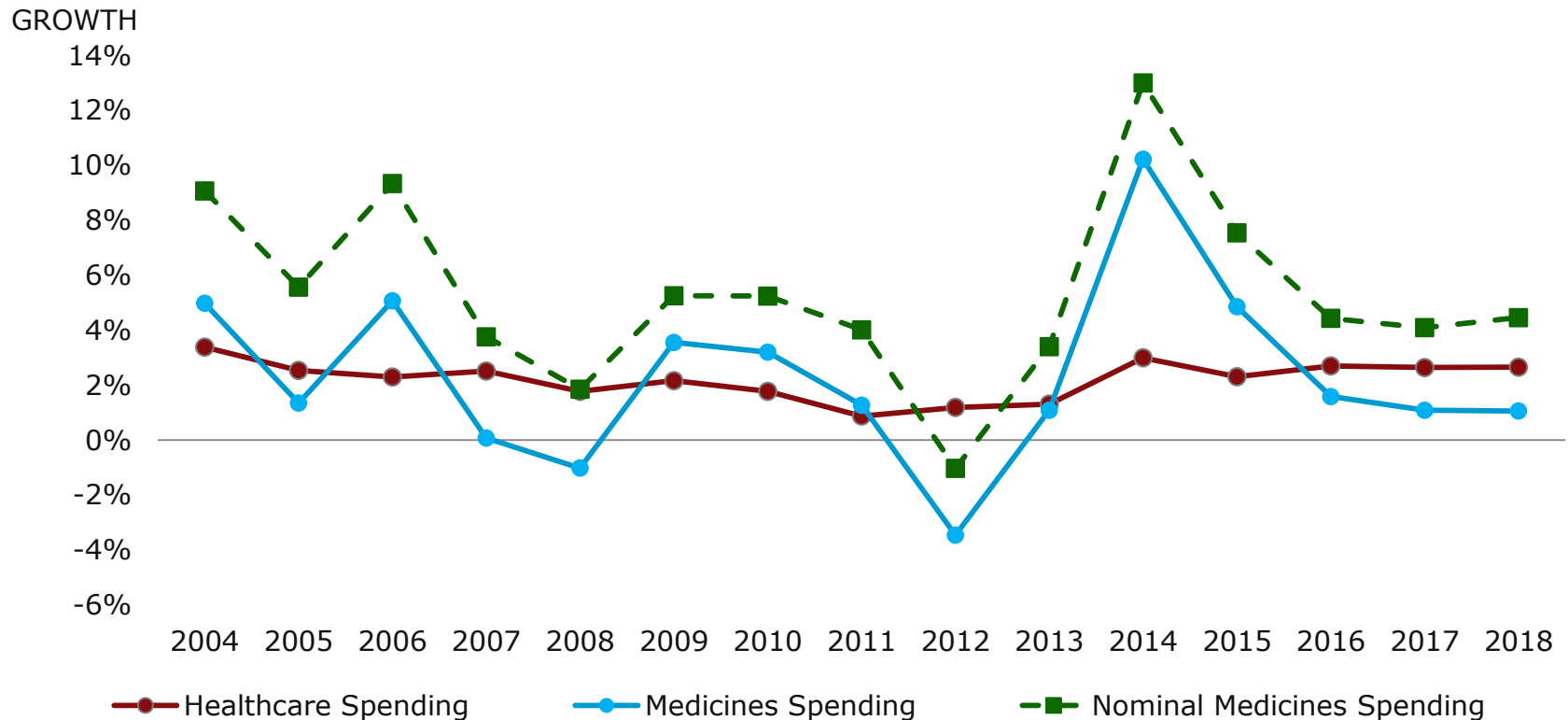
US market evolution at a turning point.

- Increasing numbers of specialty drugs will drive spending upwards and put greater pressure on demonstration of value
- When stakeholders work together they can achieve improved outcomes at lower costs, but is pharma a target in this effort?
- Exposure to costs and access to information is changing everything for payer/providers, for patients and for doctors
- Change is complicated and progress is uneven across the country ... adapting to change means “Everything is Local”

Medicine spending often portrayed as driving up healthcare costs, especially so with 2014 spending growth of 13%

Medicine spending below Healthcare spending growth for 5 of the last 10 years and 3 of the next five

Real Per Capita Spending Growth 2004-2018

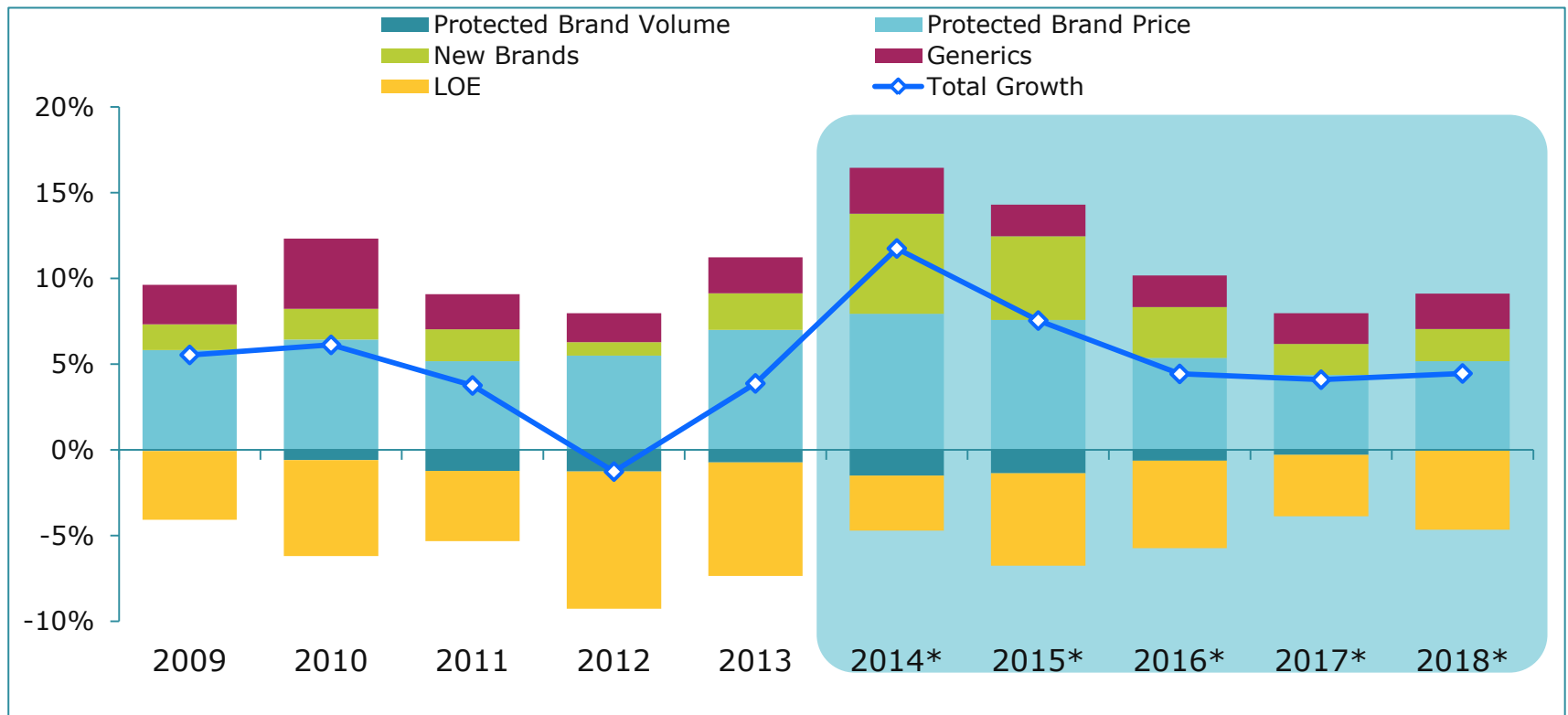


Source: CMS National Health Expenditures Sep 2014; IMS Health, National Sales Perspectives, Dec 2014; U.S. Census Bureau July 2014; Economic Intelligence Unit Sep 2014; IMS Market Prognosis Sep 2014

Growth will moderate over the forecast period

Near-term is driven by less expiry impact, innovation and pricing

U.S. Market Growth by Segment



Source: IMS Health, Market Prognosis, Oct 2014

The Big 5 to watch for

- The HEP C market and other innovation
- Generic Price Inflation
- First Biosimilar Launch
- Supply Chain
- Regulation and Reimbursement Issues

Visit www.TheIMSInstitute.org for additional insights

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FOR
HEALTHCARE INFORMATICS

April 2015

Medicines Use and Spending Shifts

A Review of the Use of Medicines
in the U.S. in 2014



HEALTHCARE COSTS AND SPENDING ON MEDICINES

Spending on medicines increased 13.1% in 2014, the highest level since 2001 when spending growth reached 17.0%

Medicine Spending & Growth 1995-2014



- Real per capita spending was \$995 in 2014 and has nearly tripled since 1995 when it was \$339, both measured in 2005 dollars.
- Higher spending growth between 1997 and 2003 reflected the period when the largest number of blockbuster drugs launched and were increasingly used by millions of Americans.
- Lower levels of growth in spending between 2002 and 2013 were due to lower volume growth, increased use of generics, loss of patent protection for major branded products and reduced spending on new drugs.
- The sharp increase in spending in 2014 was driven by new brands, lower impact from patent expiries and increases in the list prices of branded medicines.

Chart notes:

Measures total value of pharmaceutical spending, including generics, branded products, biologics, small-molecules, retail and non-retail channels. Value measured at Trade Price – the price paid to wholesalers or manufacturers by retail and non-retail pharmacies and excluding off-invoice discounts and rebates that lower net prices received by manufacturers. Real Per Capita adjustments based on data from U.S. Census Bureau and U.S. Bureau of Economic Analysis.

Medicines Use and Spending Shifts. Report by the IMS Institute for Healthcare Informatics.

Page 4

HEALTHCARE COSTS AND SPENDING ON MEDICINES

- 2014 Total Drug Spending \$373.9Bn, up 13.1%
- Growth driven by innovation, less expiry impact and pricing dynamics
- Pricing growth offset by discounts and rebates
- Specialty medicines reach one-third of medicine spending
- Innovation in hepatitis C, cancer, multiple sclerosis and diabetes drove spending growth

TRANSFORMATIONS IN DISEASE TREATMENT

- 42 New Active Substances launched in 2014 up from 36 in 2013
- Hepatitis C, multiple sclerosis and oncology see major advances
- The drug R&D pipeline has shifted to specialty medicines over the past decade
- 10 Breakthrough Therapies launched, and FDA incentives have helped spur a surge in infectious disease drug development
- 18 orphan drugs launched in 2014 up from 17 in 2013, the two highest years ever
- The first biosimilars were filed in 2014 and approvals began in 2015

CHANGES IN THE DEMAND AND PAYMENT FOR MEDICINE

- Insurance coverage expansion is having a measurable impact as millions have new insurance coverage
- Office visits and hospital utilization declined while prescription demand increased driven by Medicaid expansion
- Hospital networks are increasingly concentrated but networks prefer different treatments
- Changing patient share of costs through insurance design and coupons impacts behavior, care and outcomes

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