



# The US Pharmaceutical Market

Looking back and  
looking ahead!

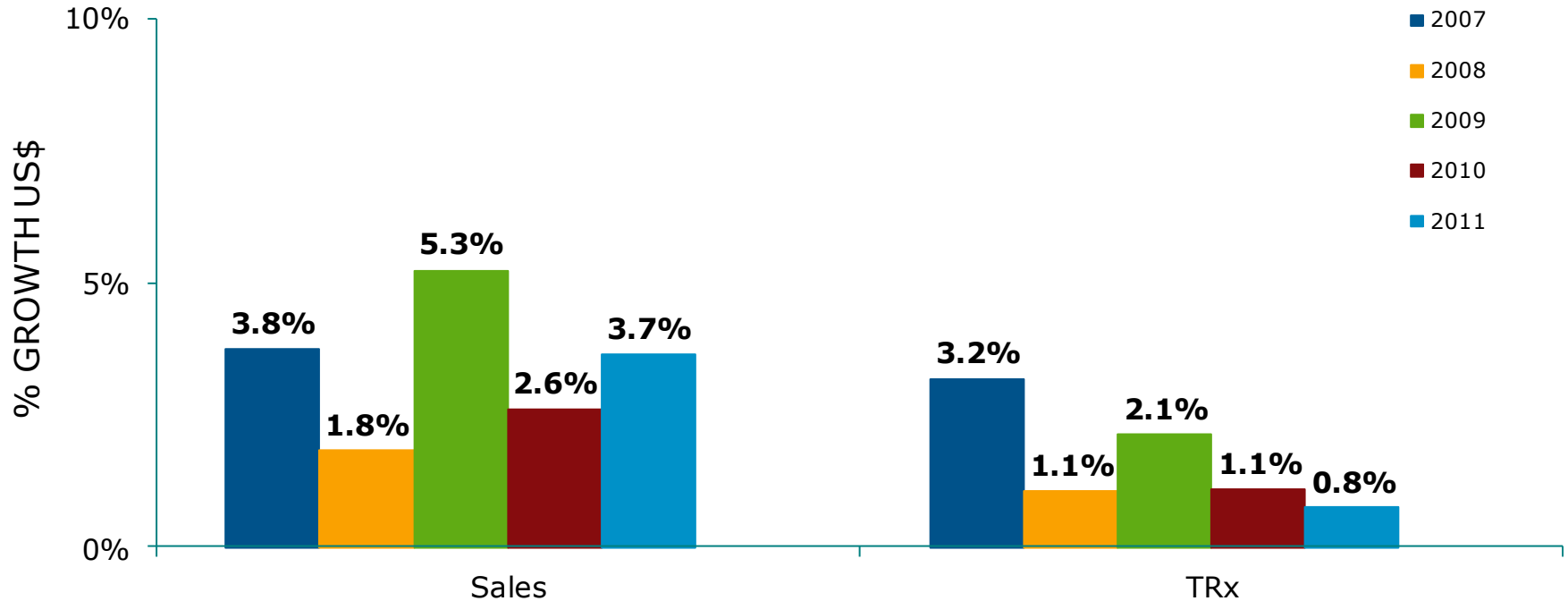
Prepared for FMI  
By Doug Long  
VP Industry Relations  
March 20, 2012

# 2012 Strategic management presentation

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# The total market grew 3.7% in 2011

## % Growth of prescription products Total market



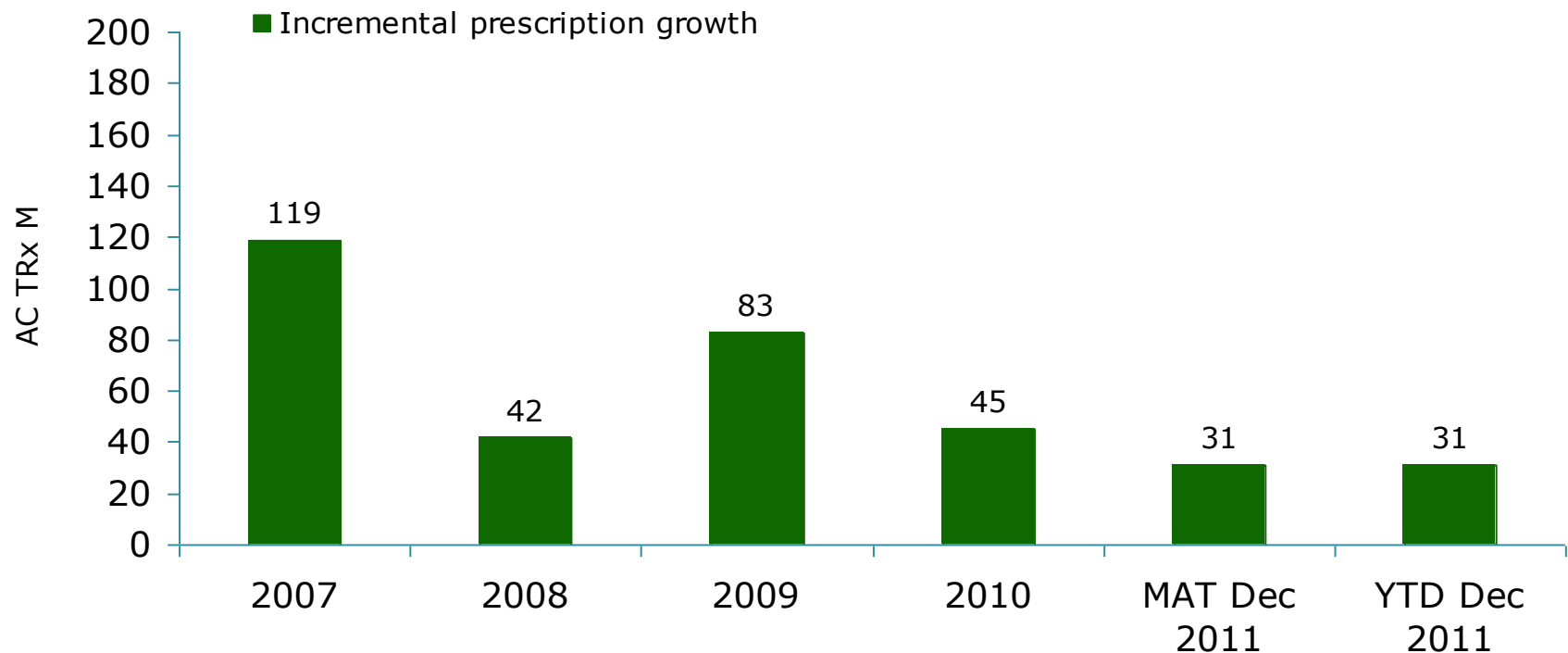
Source: IMS Health, National Sales Perspectives, Dec 2011

IMS Health, National Prescription Audit, Dec 2011

# Reasons for Moderation in the Growth of Drug Expenditures

- Increased cost sharing for consumers
- Economic downturn
- Innovation drought
- Safety concerns for various drugs
- Rx to OTC conversions
- Ongoing introduction of first time generic drugs

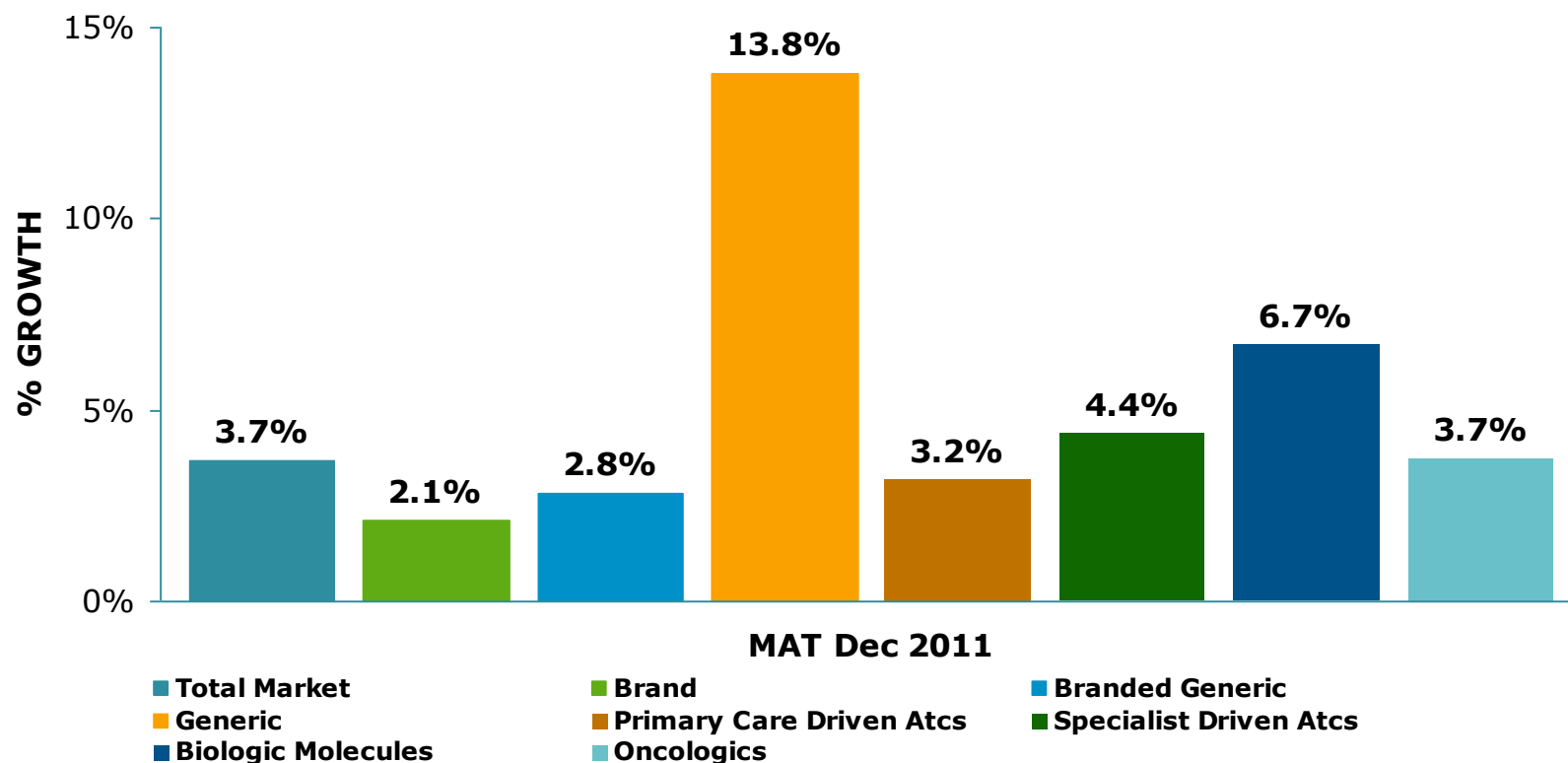
# There were 31 million more TRXs in 2011 than in 2010



Source: IMS Health, National Prescription Audit, Dec 2011

# Generics and Specialty outperformed the market in 2011

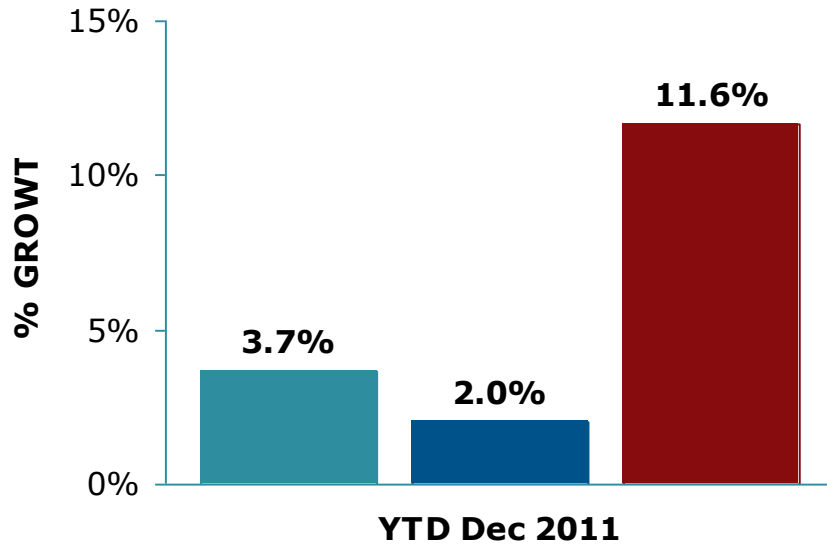
% Growth US\$



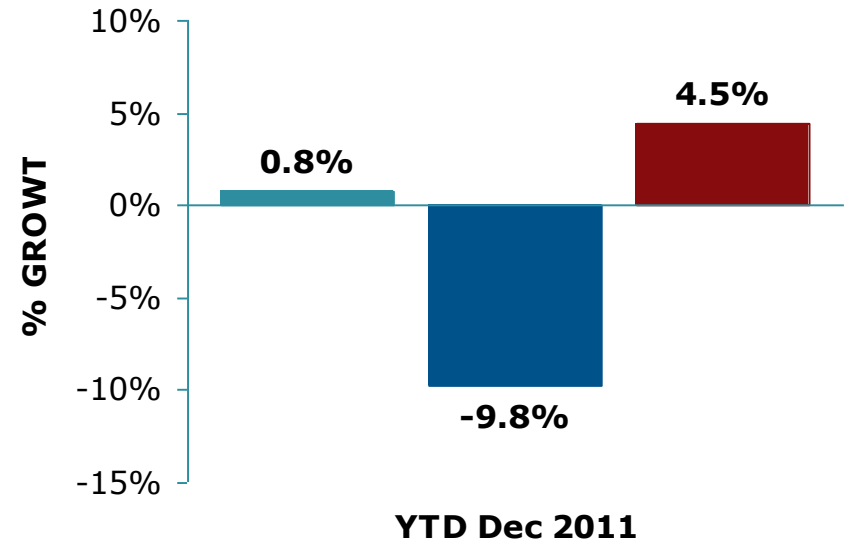
Source: IMS Health, National Sales Perspectives, Dec 2011

# Generics continue to post strong growth

% Growth US\$



% Growth TRx



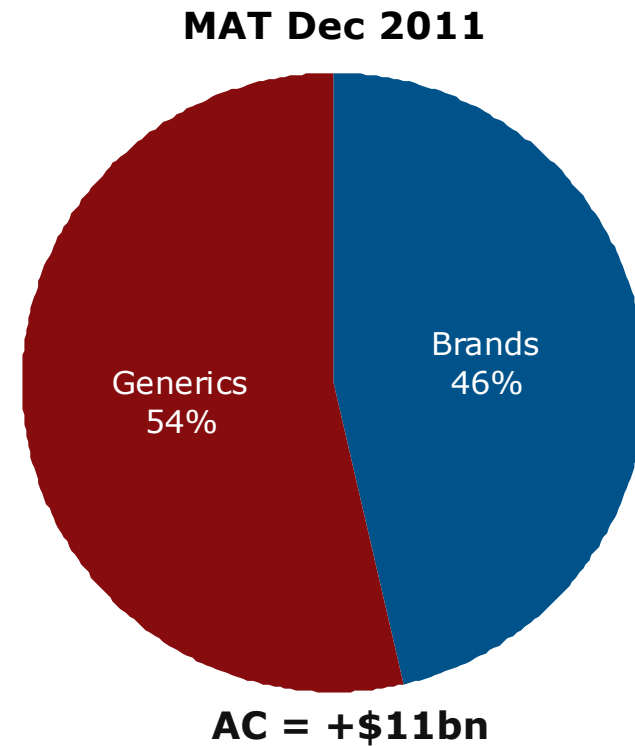
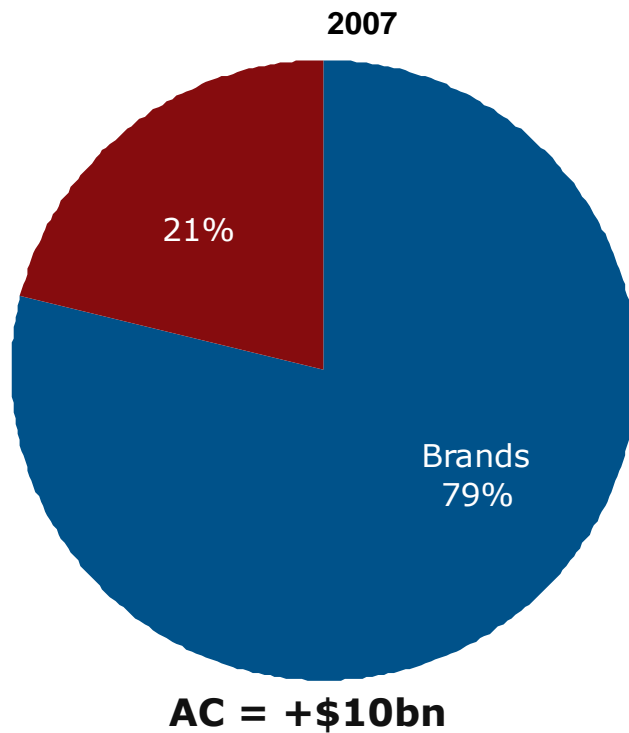
■ Total market ■ Brands ■ Generics

Source: IMS Health, National Sales Perspectives, Branded generics disaggregated, Dec 2011

Source: IMS Health, National Prescription Audit, Branded generics disaggregated, Dec 2011

# Generics account for 54% of the dollar growth in 2011

## % Contribution to growth US\$

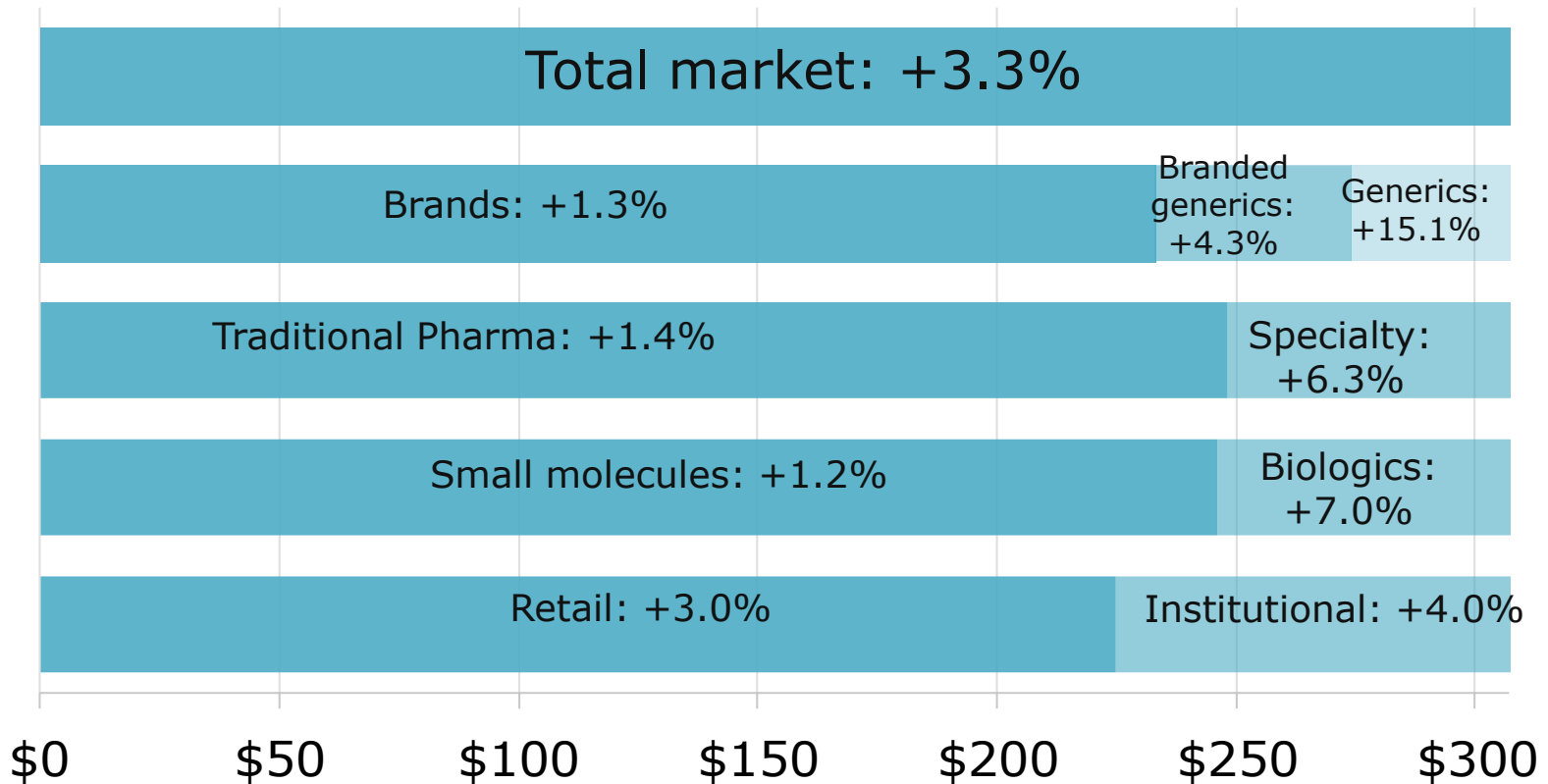


Source: IMS Health, National Sales Perspectives, Branded generics disaggregated, Dec 2011

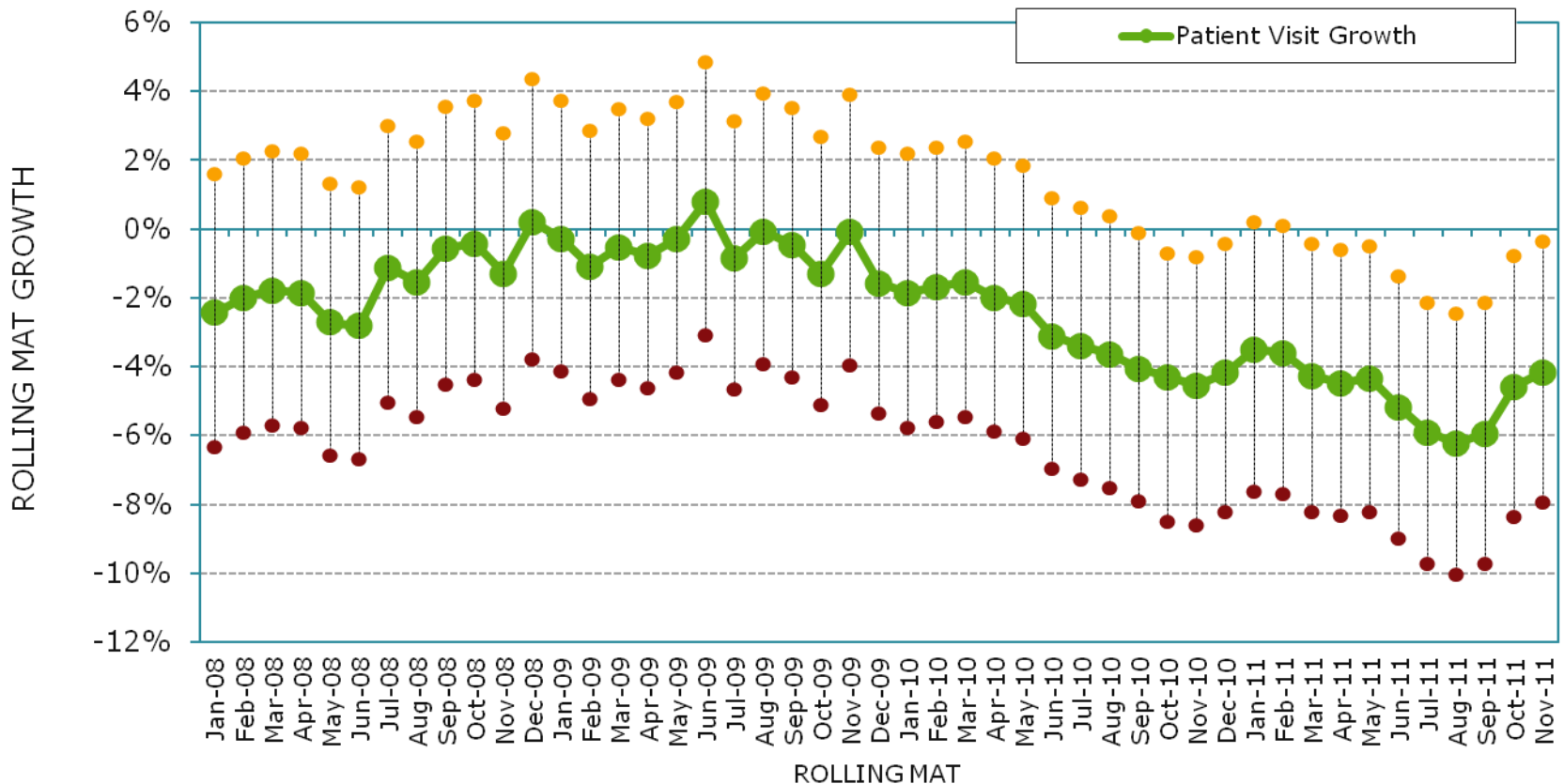


# Spend grew 3.3% but largest segments grew slower or declined

## Spending Growth (MAT Sep 2011)

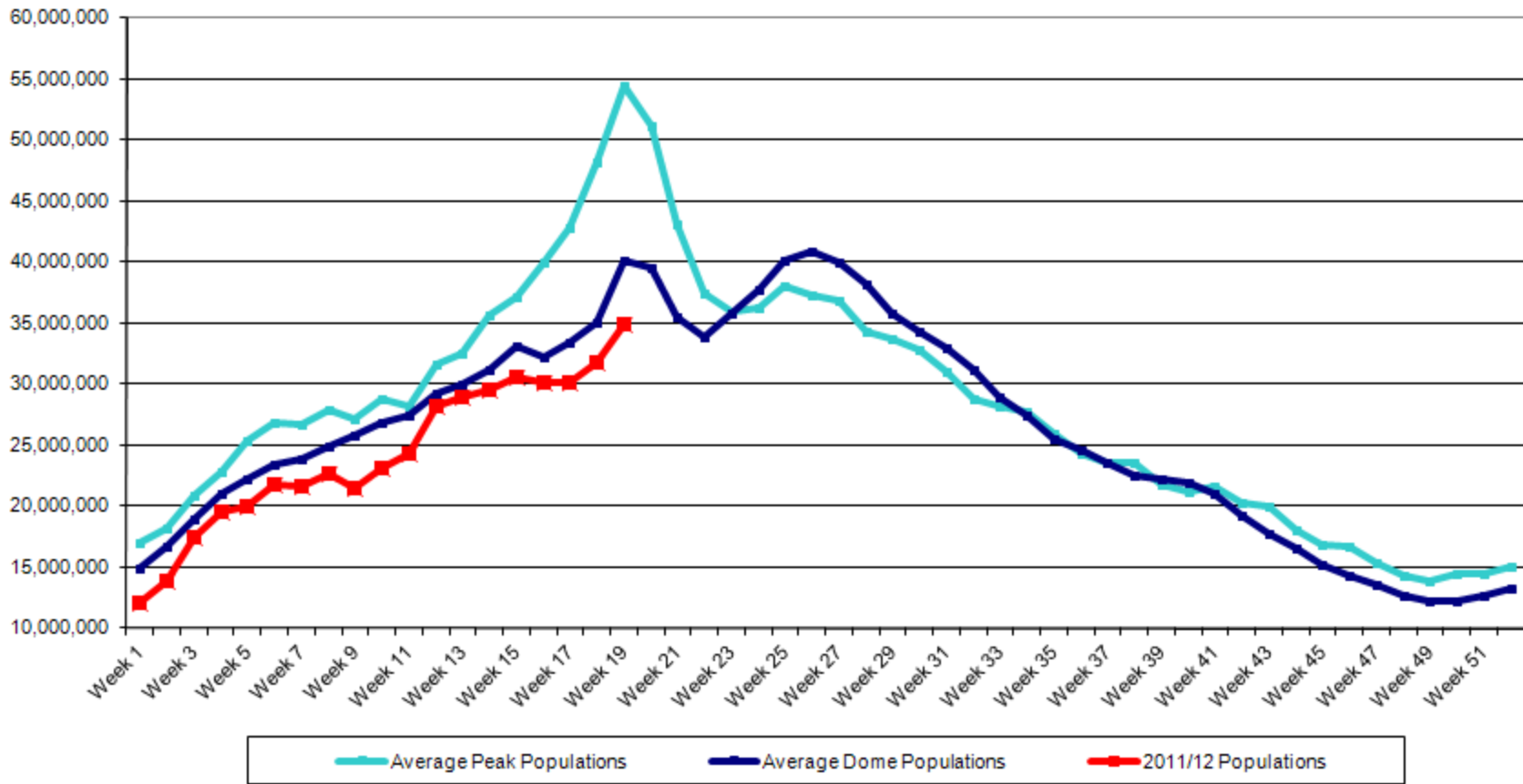


# Patient visits down 4.1% through Nov 2011 but recent periods consistent with expected recovery



Source: IMS Health, National Disease and Therapeutic Index, Nov 2011, 95% confidence interval (+/-3.9%)

## US Respiratory Incidence Level Comparison Average Peak vs. Average Dome Seasons



Peak Seasons: 99/00, 03/04

Dome Seasons: 00/01, 01/02, 02/03, 04/05, 05/06, 06/07, 07/08, 08/09, 09/10, 10/11

# Top 10 Therapy Classes- Absolute Growth

<b>Dollars</b>	<b>AC US\$mn</b>	<b>Total Rx dispensed</b>	<b>AC TRxs mn</b>
<b>Antipsychotics,oth</b>	<b>2039.2</b>	<b>Anti-depressants</b>	<b>9.2</b>
<b>Lipid regulators</b>	<b>1355.8</b>	<b>Codeine &amp; comb</b>	<b>7.4</b>
<b>Analogs of human insulin</b>	<b>1241.3</b>	<b>Synth non-narc analg</b>	<b>6.2</b>
<b>Analeptics</b>	<b>1139.4</b>	<b>Seizure disorders</b>	<b>6.1</b>
<b>Neurological disorders</b>	<b>1137.8</b>	<b>Analeptics</b>	<b>4.1</b>
<b>Antiarth,biol resp mod</b>	<b>962.5</b>	<b>Antiarth,plain</b>	<b>3.4</b>
<b>Hepatitis Antivirals</b>	<b>932.5</b>	<b>Influenza</b>	<b>3.1</b>
<b>Dpp-4 Inhib</b>	<b>792.2</b>	<b>Antinauseant 5HT3 antag</b>	<b>2.5</b>
<b>Platelet Inhibitors</b>	<b>750.8</b>	<b>Calcium blockers</b>	<b>2.4</b>
<b>Platinum coordination</b>	<b>574.1</b>	<b>Dpp-4 Inhib</b>	<b>2.4</b>

Source: IMS Health, National Sales Perspectives, Dec 2011, National Prescription Audit, Dec 2011

# Top 10 Therapy Classes- Absolute declines

<b>Dollars</b>	<b>AC US\$mn</b>	<b>Total Rx dispensed</b>	<b>AC TRxs mn</b>
<b>Antihistamines alone</b>	<b>-475.1</b>	<b>Quinolones, systemic</b>	<b>-1.2</b>
<b>Glitazones</b>	<b>-529.7</b>	<b>Diuretics,loop</b>	<b>-1.4</b>
<b>Herpes Antivirals</b>	<b>-568.1</b>	<b>Hormones,estrogens</b>	<b>-1.4</b>
<b>Anti-depressants</b>	<b>-703.2</b>	<b>Beta blockers</b>	<b>-1.9</b>
<b>Quinolones, systemic</b>	<b>-753.5</b>	<b>Diuretics,comb</b>	<b>-2.0</b>
<b>UT benign prostate</b>	<b>-801.9</b>	<b>Ace inhibitors</b>	<b>-3.7</b>
<b>Erythropoietins</b>	<b>-985.9</b>	<b>Glitazones</b>	<b>-4.0</b>
<b>Angiotensin II antagonists</b>	<b>-1061.8</b>	<b>Osteoclast Inhibitors</b>	<b>-6.6</b>
<b>Alzheimer-type dementia</b>	<b>-1612.8</b>	<b>Antihistamines alone</b>	<b>-9.3</b>
<b>Proton pump inhib</b>	<b>-1850.5</b>	<b>Synth narc,analg</b>	<b>-14.7</b>

Source: IMS Health, National Sales Perspectives, Dec 2011, National Prescription Audit, Dec 2011

# Top 10 Therapy Classes- Dollar basis

Leading classes	MAT Dec 2011		
	US\$m	% Market Share	% Growth
<b>US Industry</b>	<b>319,849</b>	<b>100.0</b>	<b>3.7</b>
<b>1 Lipid regulators</b>	<b>18,624</b>	<b>5.8</b>	<b>7.9</b>
<b>2 Antipsychotics,oth</b>	<b>18,120</b>	<b>5.7</b>	<b>12.7</b>
<b>3 Anti-depressants</b>	<b>10,878</b>	<b>3.4</b>	<b>-6.1</b>
<b>4 Proton pump inhib</b>	<b>9,601</b>	<b>3.0</b>	<b>-16.2</b>
<b>5 Analogs of human insulin</b>	<b>8,762</b>	<b>2.7</b>	<b>16.5</b>
<b>6 Antineo monoclonal antib</b>	<b>8,619</b>	<b>2.7</b>	<b>3.3</b>
<b>7 Antiarth,biol resp mod</b>	<b>7,957</b>	<b>2.5</b>	<b>13.8</b>
<b>8 Analeptics</b>	<b>7,854</b>	<b>2.5</b>	<b>17.0</b>
<b>9 Platelet Inhibitors</b>	<b>7,764</b>	<b>2.4</b>	<b>10.7</b>
<b>10 Angiotensin II antagonists</b>	<b>7,394</b>	<b>2.3</b>	<b>-12.6</b>
<b>Top 10</b>	<b>105,573</b>	<b>33.0</b>	<b>4.1</b>

Source: IMS Health, National Sales Perspectives, Dec 2011

# Top 11-20 Therapy Classes- Dollar basis

Leading classes	MAT Dec 2011		
	US\$m	% Market Share	% Growth
11 Steroid,inhaled bronch	6,061	1.9	3.3
12 GI anti-inflam	5,885	1.8	9.6
13 HIV antiviral combination	5,849	1.8	10.8
14 Erythropoietins	5,110	1.6	-16.2
15 Codeine & comb	4,789	1.5	-8.3
16 Leukotriene agents	4,656	1.5	12.0
17 Immune system adjuncts	4,365	1.4	7.6
18 Immunologic interferons	4,157	1.3	4.6
19 Glitazones	4,100	1.3	-11.4
20 Seizure disorders	4,034	1.3	1.8
<b>Top 20</b>	<b>154,580</b>	<b>48.3</b>	<b>3.0</b>

Source: IMS Health, National Sales Perspectives, Dec 2011

# Top 10 Products- Absolute growth

<b>Dollars</b>	<b>AC US\$mn</b>	<b>Total Rx Dispensed</b>	<b>AC TRxsmn</b>
<b>Eloxatin® (S.A)</b>	<b>952</b>	<b>simvastatin (a6d)</b>	<b>9.5</b>
<b>enoxaparin sod (sdz)</b>	<b>907</b>	<b>furosemide (rox)</b>	<b>7.3</b>
<b>Incivek® (Vre)</b>	<b>838</b>	<b>amoxicillin (sdz)</b>	<b>6.6</b>
<b>methylphenidate er (wts)</b>	<b>771</b>	<b>hycd/apap (qlt)</b>	<b>6.6</b>
<b>Copaxone® (Tvn)</b>	<b>702</b>	<b>lisinopril (wok)</b>	<b>6.3</b>
<b>Crestor® (Azn)</b>	<b>638</b>	<b>omeprazole (rx) (drl)</b>	<b>6.3</b>
<b>Abilify® (Ots)</b>	<b>631</b>	<b>citalopram hbr (am9)</b>	<b>6.2</b>
<b>Plavix® (Bsa)</b>	<b>626</b>	<b>sertraline hcl (cm7)</b>	<b>6</b>
<b>Humira® (Abt)</b>	<b>602</b>	<b>amoxicillin (w-w)</b>	<b>5.3</b>
<b>gamunex-c (gfl)</b>	<b>556</b>	<b>lisinopril (qlt)</b>	<b>5.3</b>

Source: IMS Health, National Sales Perspectives, Dec 2011, National Prescription Audit, Dec 2011



# Top 10 Products- Dollar basis

Products	Company	MAT Dec 2011		
		US\$m	% Market Share	% Growth
<b>US Industry</b>		<b>319,849</b>	<b>100.0</b>	<b>3.7</b>
<b>1 Lipitor®</b>	<b>PFZ</b>	<b>7,664</b>	<b>2.4</b>	<b>5.7</b>
<b>2 Plavix®</b>	<b>BSA</b>	<b>6,765</b>	<b>2.1</b>	<b>10.2</b>
<b>3 Nexium®</b>	<b>AZN</b>	<b>6,151</b>	<b>1.9</b>	<b>-2.7</b>
<b>4 Abilify®</b>	<b>OTS</b>	<b>5,187</b>	<b>1.6</b>	<b>13.9</b>
<b>5 Advair Diskus®</b>	<b>GSK</b>	<b>4,633</b>	<b>1.5</b>	<b>-1.8</b>
<b>6 Seroquel®</b>	<b>AZN</b>	<b>4,630</b>	<b>1.4</b>	<b>6.4</b>
<b>7 Singulair®</b>	<b>MSD</b>	<b>4,588</b>	<b>1.4</b>	<b>12.6</b>
<b>8 Crestor®</b>	<b>AZN</b>	<b>4,401</b>	<b>1.4</b>	<b>17.0</b>
<b>9 Cymbalta®</b>	<b>LLY</b>	<b>3,663</b>	<b>1.1</b>	<b>16.0</b>
<b>10 Humira®</b>	<b>ABT</b>	<b>3,530</b>	<b>1.1</b>	<b>20.5</b>
<b>Top 10</b>		<b>51,211</b>	<b>16.0</b>	<b>8.4</b>

Source: IMS Health, National Sales Perspectives, Dec 2011

# Top 11-20 Products- Dollar basis

Products	Company	MAT Dec 2011		
		US\$m	% Market Share	% Growth
11 Enbrel®	AAI	3,506	1.1	6.5
12 Remicade®	CTO	3,472	1.1	5.1
13 Actos®	TAK	3,435	1.1	-3.0
14 Neulasta®	AAI	3,315	1.0	10.1
15 Rituxan®	GTC	3,005	0.9	8.8
16 Zyprexa®	LLY	2,963	0.9	0.1
17 Copaxone®	TVN	2,955	0.9	31.2
18 Lexapro®	FOR	2,923	0.9	3.9
19 Oxycontin	PUF	2,877	0.9	-6.8
20 Epogen®	AAI	2,770	0.9	-16.7
<b>Top 20</b>		<b>82,433</b>	<b>25.8</b>	<b>6.2</b>

Source: IMS Health, National Sales Perspectives, Dec 2011

# Retail and Mail grew 0.6% on scripts in 2011

Channels	MAT Dec 2011		
	TRxs mn	% Market Share	% Growth
<b>Retail</b>	<b>3,695</b>	<b>91.8</b>	<b>0.6</b>
Chain/Mass	2,212	55.0	1.8
Independents	740	18.4	-1.1
Mail service	260	6.5	-1.7
Food stores	483	12.0	-1.1
<b>Non retail channels</b>	<b>329</b>	<b>8.2</b>	<b>3.1</b>
LTC	329	8.2	3.1
<b>Total</b>	<b>4,024</b>	<b>100.0</b>	<b>0.8</b>

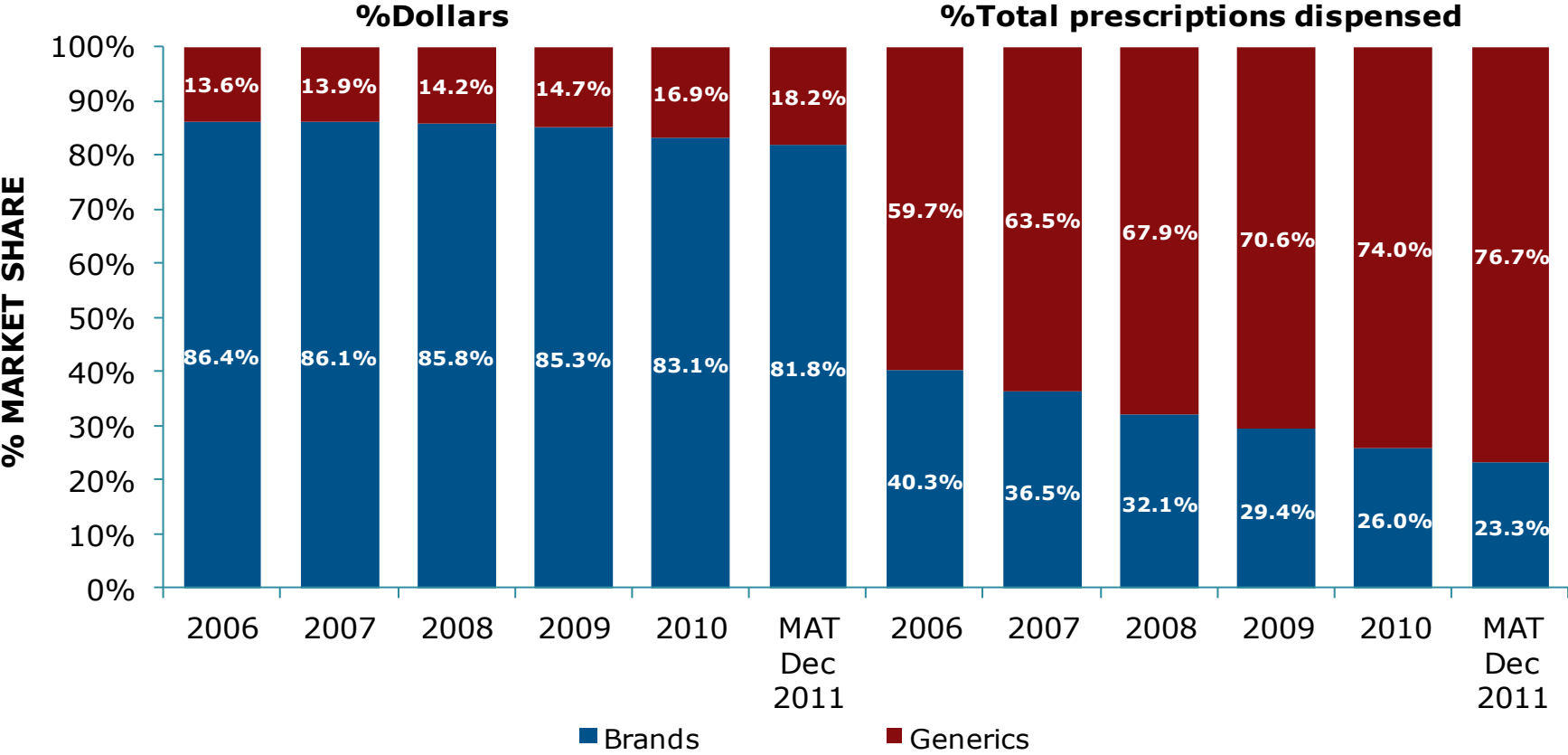
Source: IMS Health, National Prescription Audit, Dec 2011

# Retail grew 3.6% and Institutional 3.7% in 2011

Channels	YTD Dec 2011		
	US\$bn	% Market Share	% Growth
<b>Retail</b>	<b>227.3</b>	<b>71.1</b>	<b>3.6</b>
Chain/Mass	112.5	35.2	4.1
Mail service	55.1	17.2	6.4
Independents	38.1	11.9	0.3
Food stores	21.5	6.7	0.9
<b>Institutional</b>	<b>92.5</b>	<b>28.9</b>	<b>3.7</b>
Clinics	38.4	12.0	4.5
Hospitals	32.4	10.1	1.2
Long-term care	15.2	4.8	3.0
Home health care	2.7	0.9	8.2
HMO	2.7	0.8	27.7
Others	1.0	0.3	0.6
<b>Total</b>	<b>319.8</b>	<b>100.0</b>	<b>3.7</b>

Source: IMS Health, National Sales Perspectives, Dec 2011

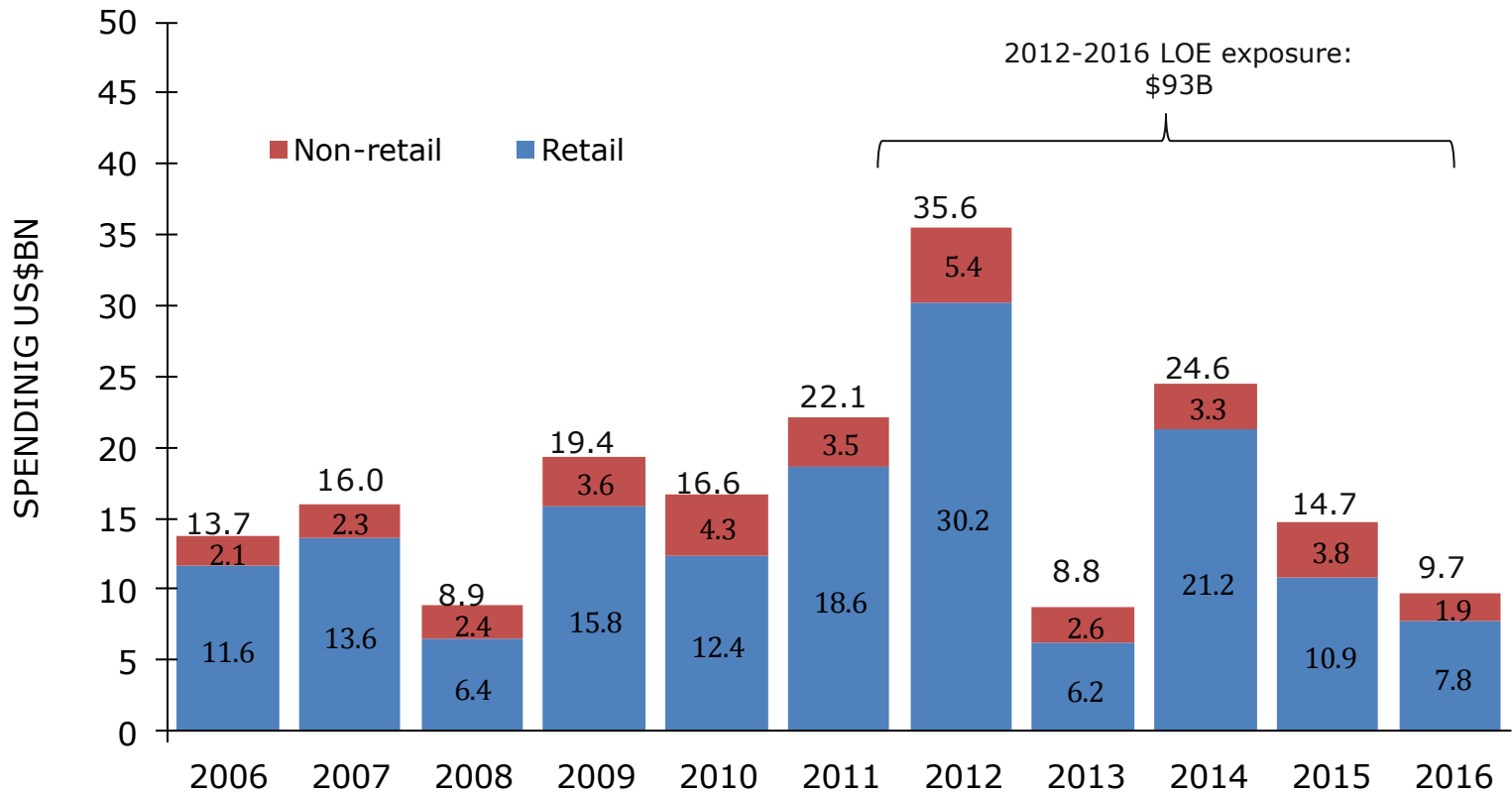
# Generics have reached an all-time high share



Source: IMS Health, National Sales Perspectives, Dec 2011, National Prescription Audit, Dec 2011, Branded generics disaggregated

# \$93B exposed to generic competition by 2016, ~80% from retail

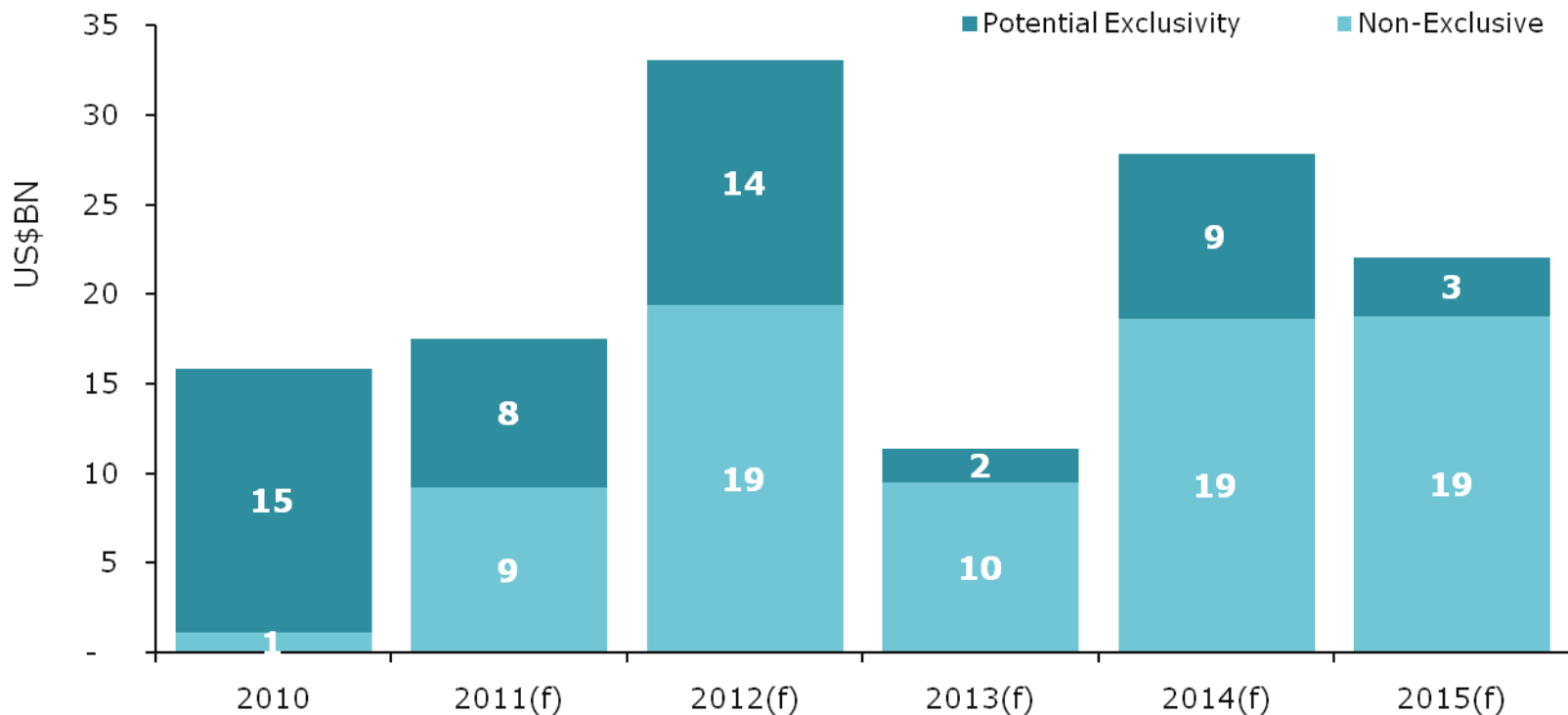
## Value of products at risk 2006-2016, MAT Sep 2011 (US\$B)



Source: IMS Health, MIDAS, Market Segmentation, Sep 2011; For 2006-2011 spending in year prior to expiry shown; For 2012-16 MAT Sep 2011 values are shown and are not projected to reflect expected future sales

# Expiries in 2010 were largely exclusive; potential exclusivities to trend down through 2015

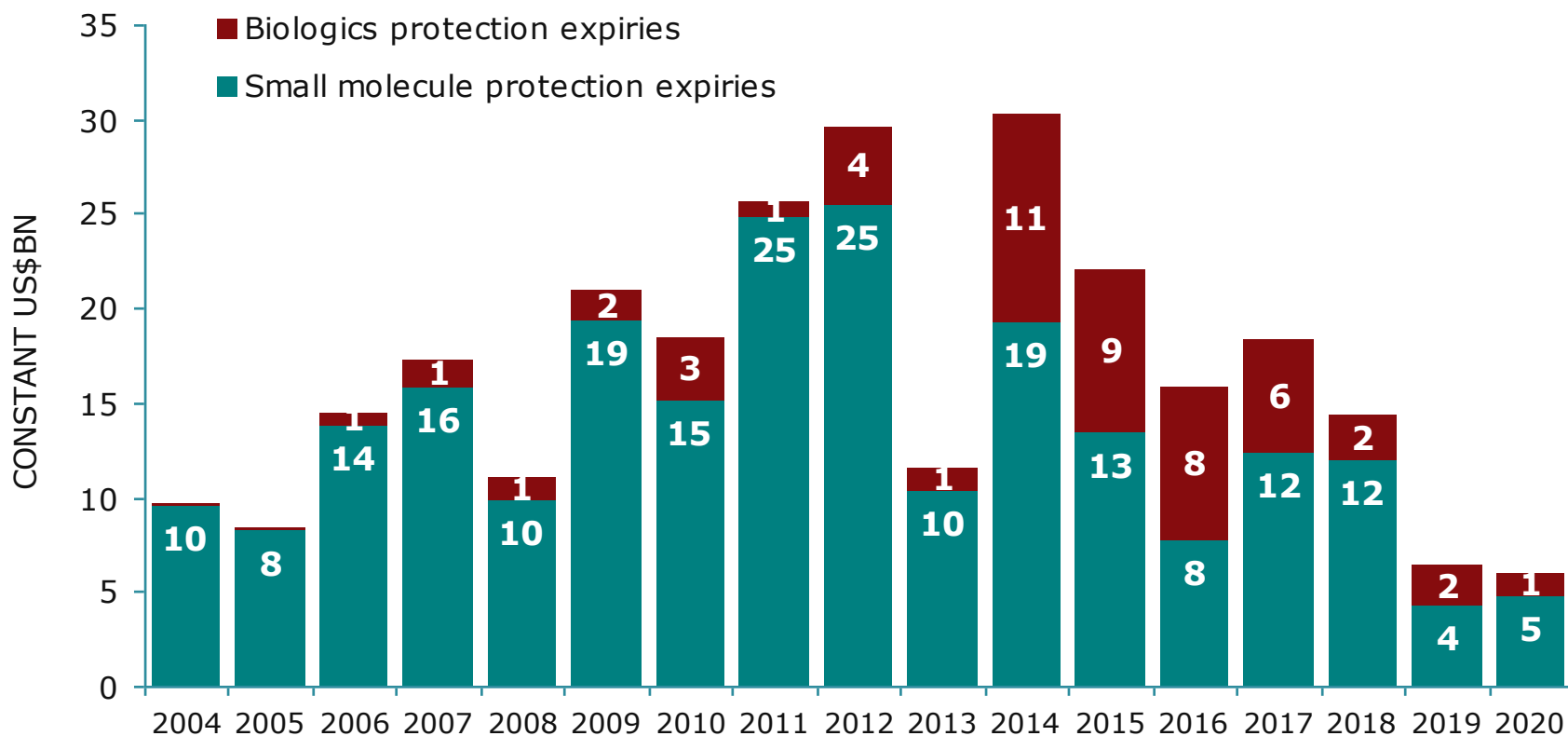
## US Protection Expiry Exposure And Market Exclusivity Potential 2010-2015



Source: IMS Institute for Healthcare Informatics, Aug 2011. Sales from prior years included.

# Long term LOE exposure

Value of products at risk 2004-2020

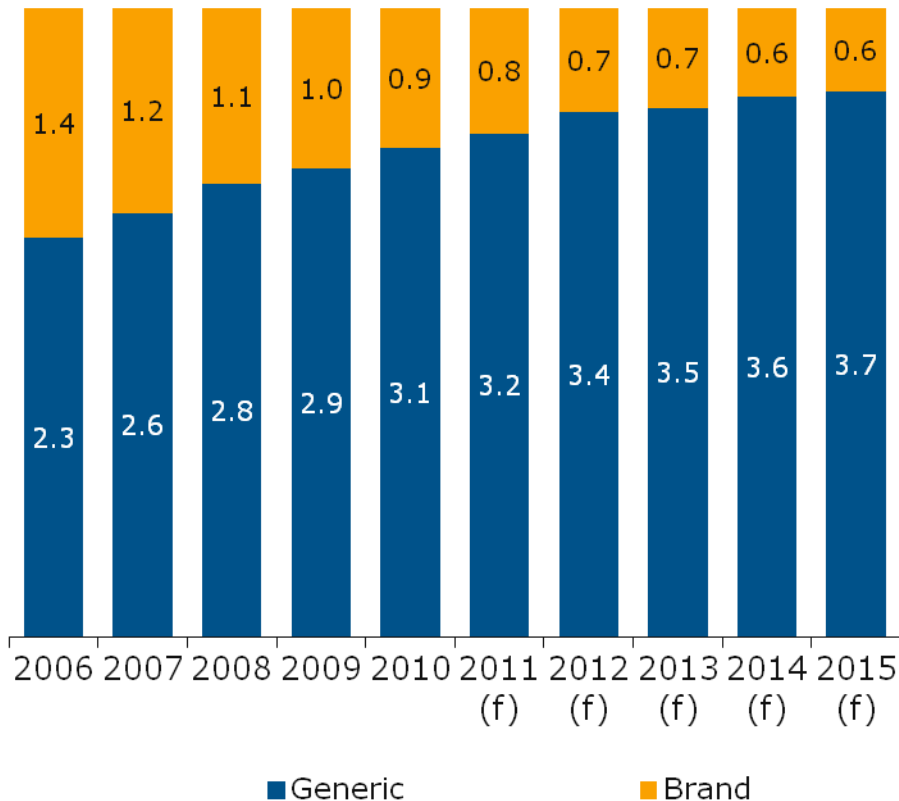


Source: IMS Health, MIDAS, Market Segmentation, Jun 2010

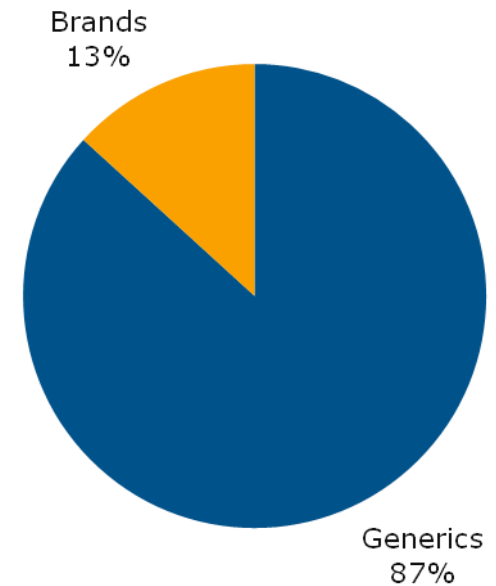


# Prescriptions to become more generic through 2015 with generic share reaching 87%

**TRX Volume BN (Retail, Mail & Long Term Care)**



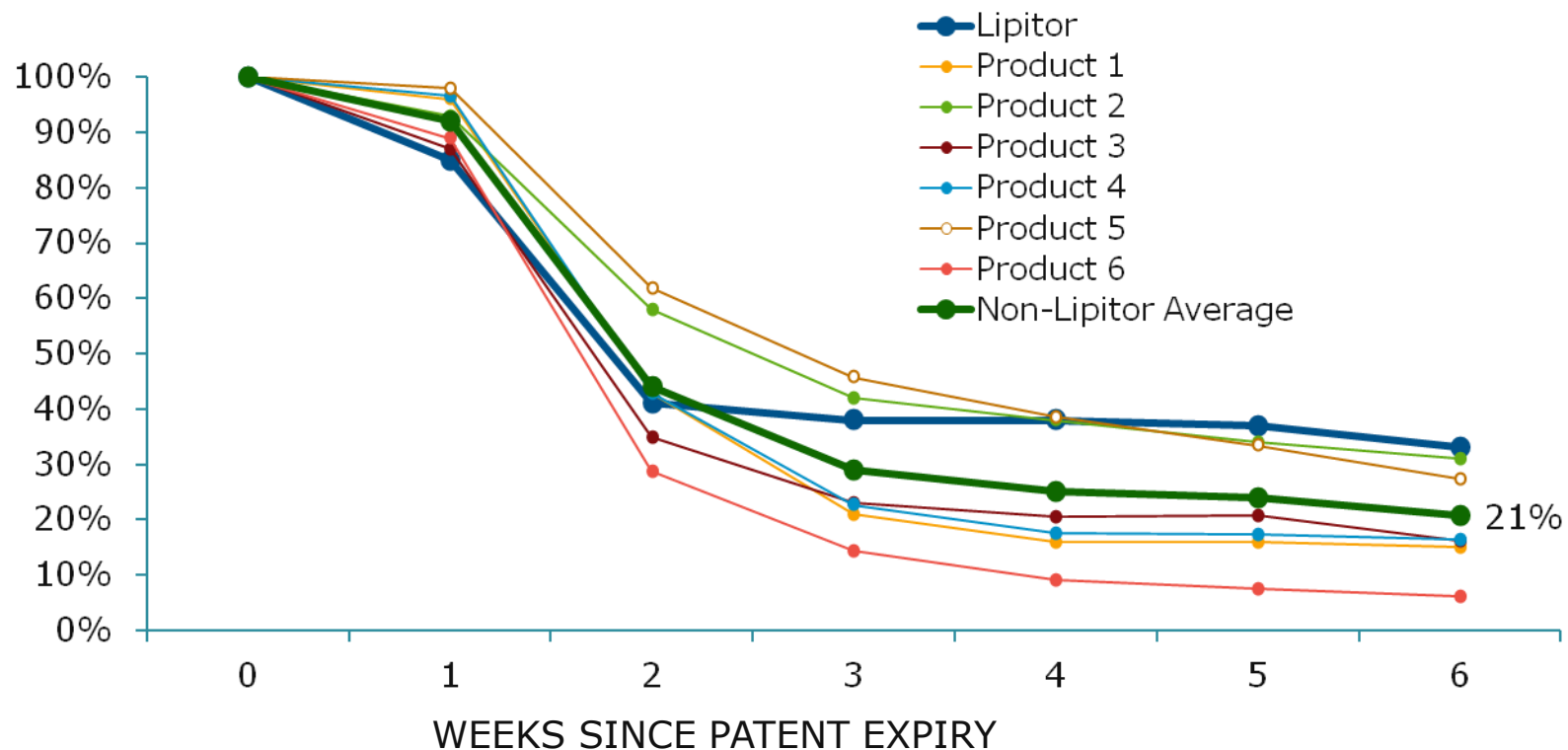
**2015 Market Share, TRX**



Source: IMS Institute for Healthcare Informatics, 2011

# 2011 expiries continue pattern of rapid brand erosion

## Brand Prescription Share of Molecule Post-Expiry (Top Expiries 2010/2011)



Source: IMS National Prescription Audit Weekly, January 6, 2012

# FDA Approval Highlights- 2011

## Highlights

35 new drugs

2<sup>nd</sup> highest total over the last decade

2 new Hepatitis C drugs

A new drug for late stage prostate cancer

1<sup>st</sup> new drug for Hodgkin's lymphoma in 30 years

1<sup>st</sup> new drug for Lupus in 50 years

7 of the new drugs provide major advances in cancer treatment

Almost 50% were significant advances over existing treatments for heart attack, stroke, and kidney transplant rejection

10 were indicated for orphan diseases, which frequently lack any therapy

2 drugs (1 for melanoma and 1 for lung cancer) represent breakthroughs in personalized medicine

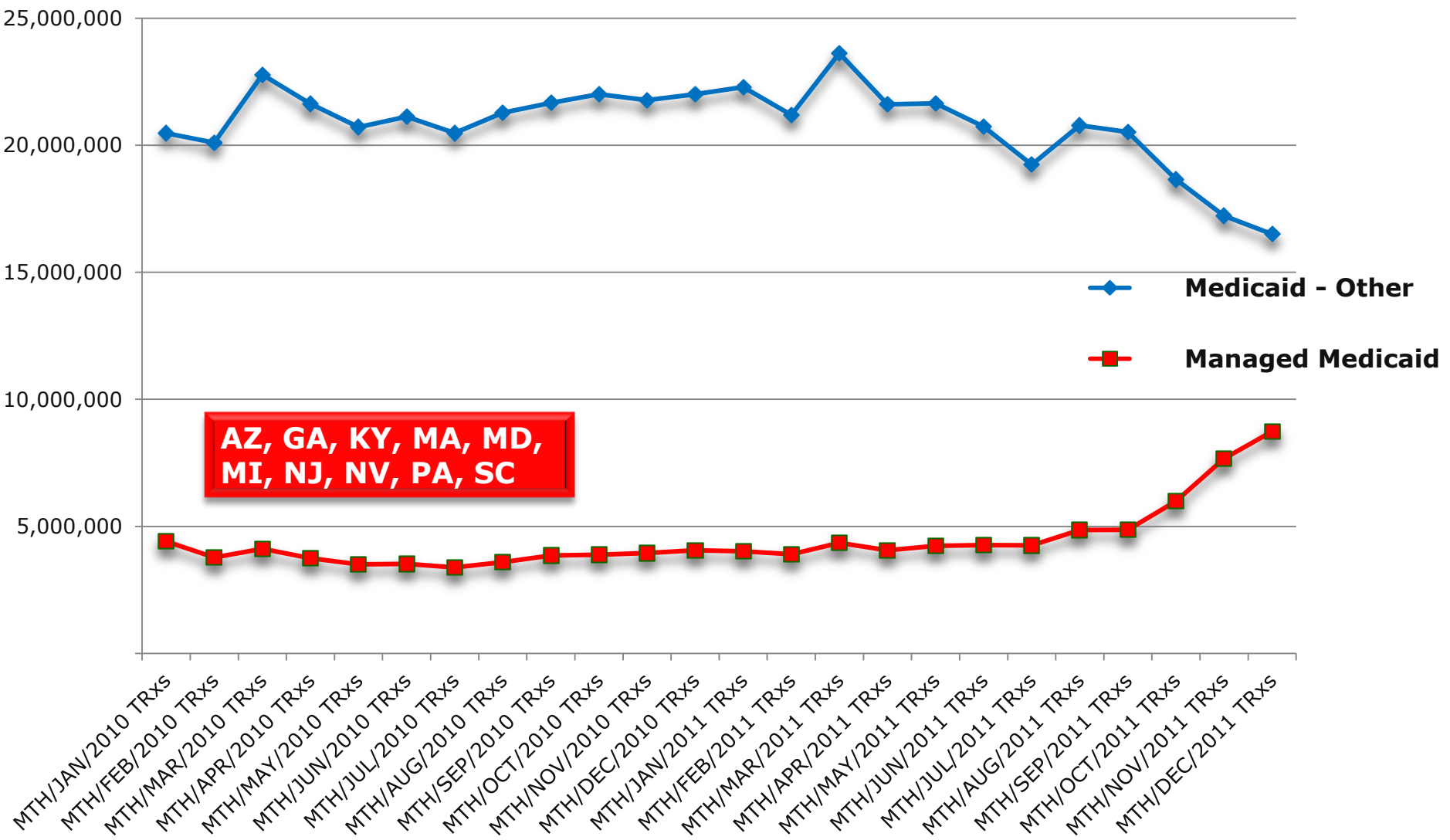
# Recent and future novel therapies do address unmet patient needs

## Selected Product Launches 2009-2013

Disease area	Launched	Upcoming
<b>Arrhythmia</b>	Brinavess™ (vernakalant) Multaq® (dronedarone)	
<b>Autoimmune</b>	Simponi® (golimumab) Stelara™ (ustekinumab)	tofacitinib (JAK inhibitor)
<b>Diabetes</b>	Nesina® (alogliptin, DPPIV) Onglyza™ (saxagliptin, DPPIV) Victoza® (liraglutide, GLP-1) Bydureon™ (exenatide, GLP-1)	canagliflozin (SGLT2) dapagliflozin (SGLT2) lixisenatide (GLP-1) Tadjenta™ (linagliptin, DPPIV)
<b>Hepatitis C</b>	Victrelis™ (boceprevir, NS3-4A PI) Incivek® (telaprevir, NS3-4A PI)	
<b>Lupus</b>	Benlysta® (belimumab)	
<b>Melanoma</b>	Yervoy™ (ipilimumab)	vemurafenib
<b>Multiple sclerosis</b>	Ampyra® (fampiridine, oral) Gilenya® (fingolimod, oral)	laquinimod (oral) ocrelizumab teriflunomide (oral)
<b>Osteoporosis</b>	Prolia® (denosumab)	
<b>Thrombosis/ Acute coronary syndrome</b>	Brilique™ (ticagrelor, P2T), Effient® (prasugrel, Xa) Pradaxa® (dabigatran etexilate, Xa)	Eliquis® (apixaban, Xa)
<b>Prostate cancer</b>	Firmagon® (degarelix) Jevtana® (cabazitaxel) Provenge® (sipuleucel-T) Zytiga™ (abiraterone acetate)	

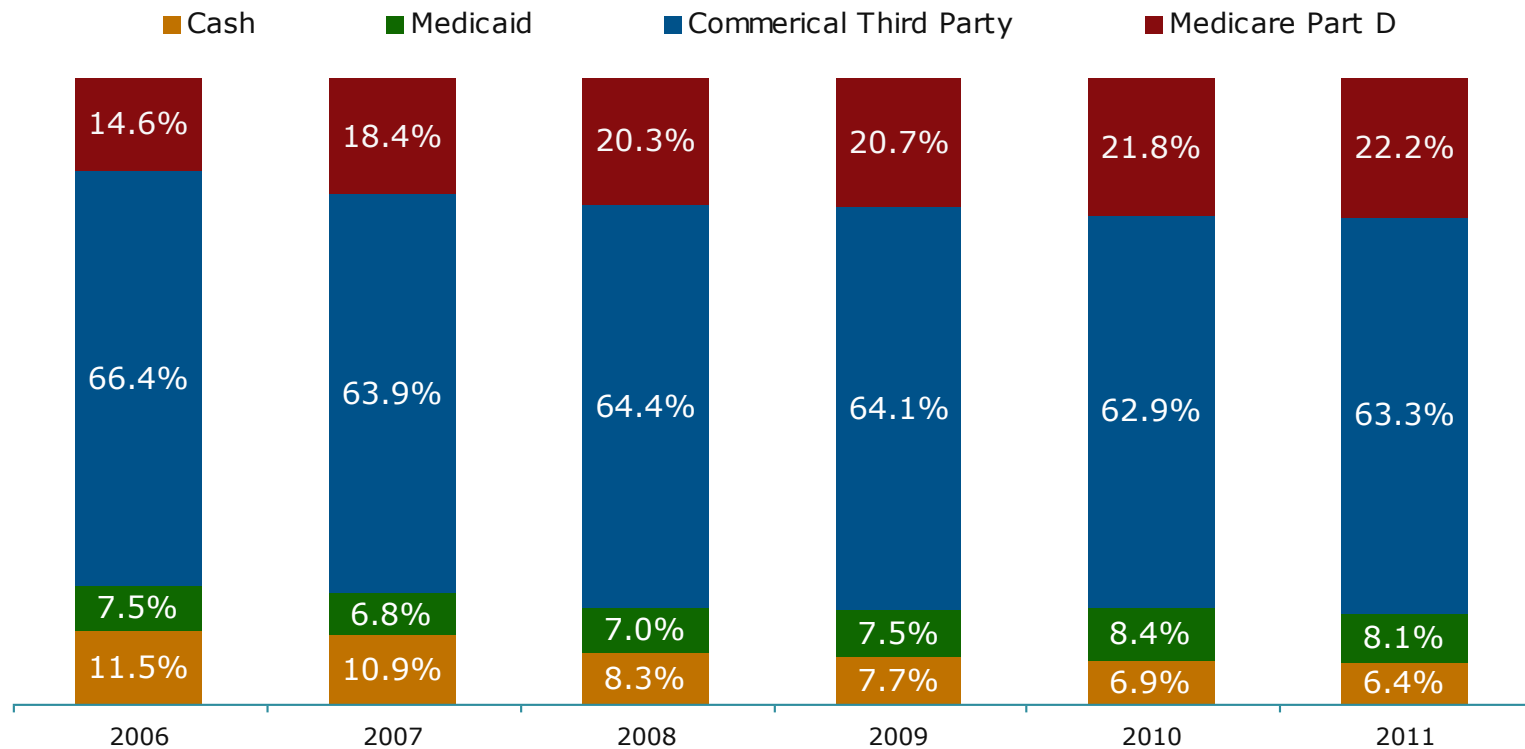
Source: IMS Ins

# FFS Medicaid vs Managed Medicaid



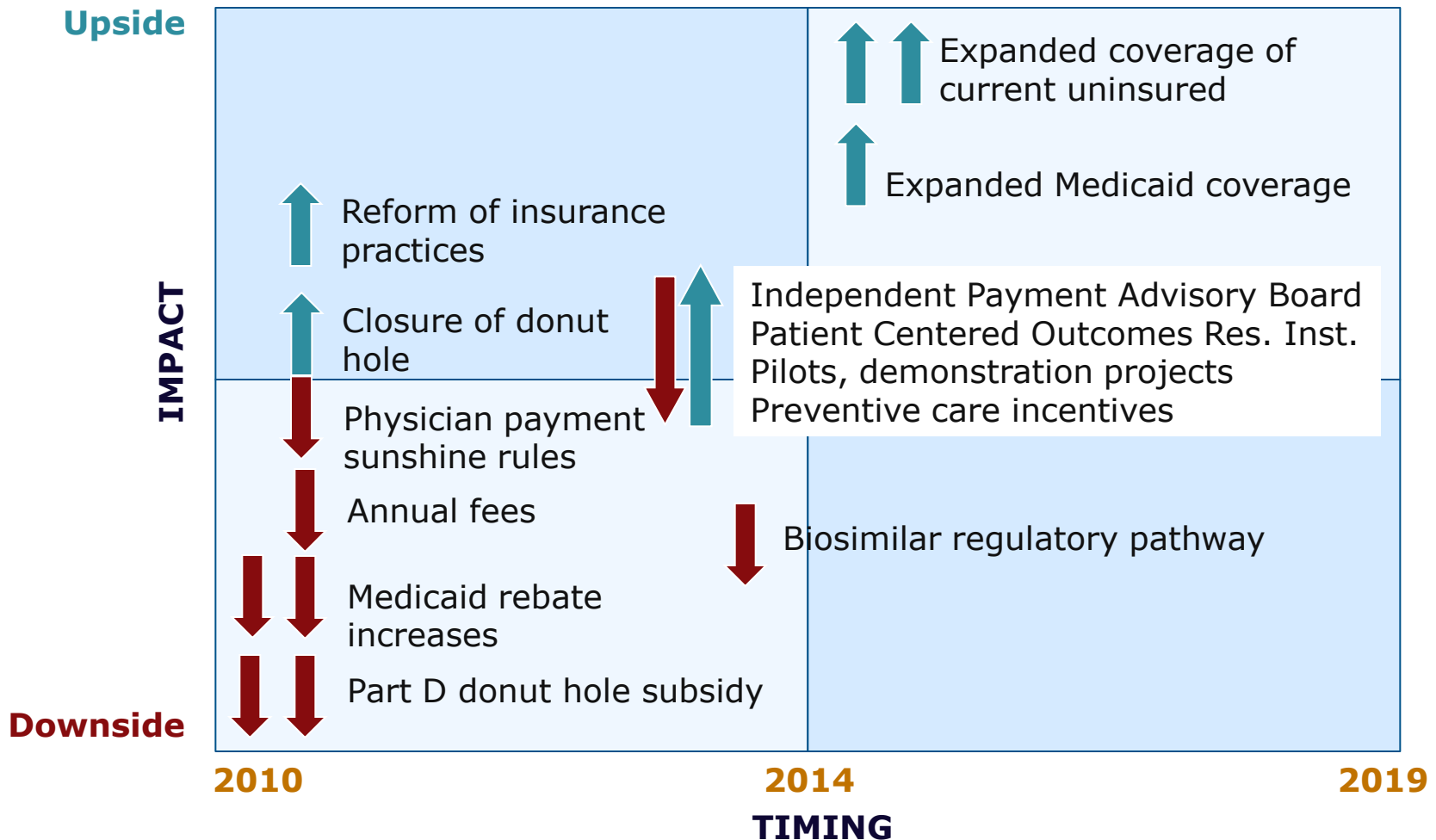
# Commercial Third Party and Medicare Part D gained share in 2011

## Retail (excluding Mail) Dispensed Prescriptions by Payment Type



Source: IMS Health, National Prescription Audit, Dec 2011 ; Note Includes only retail pharmacies

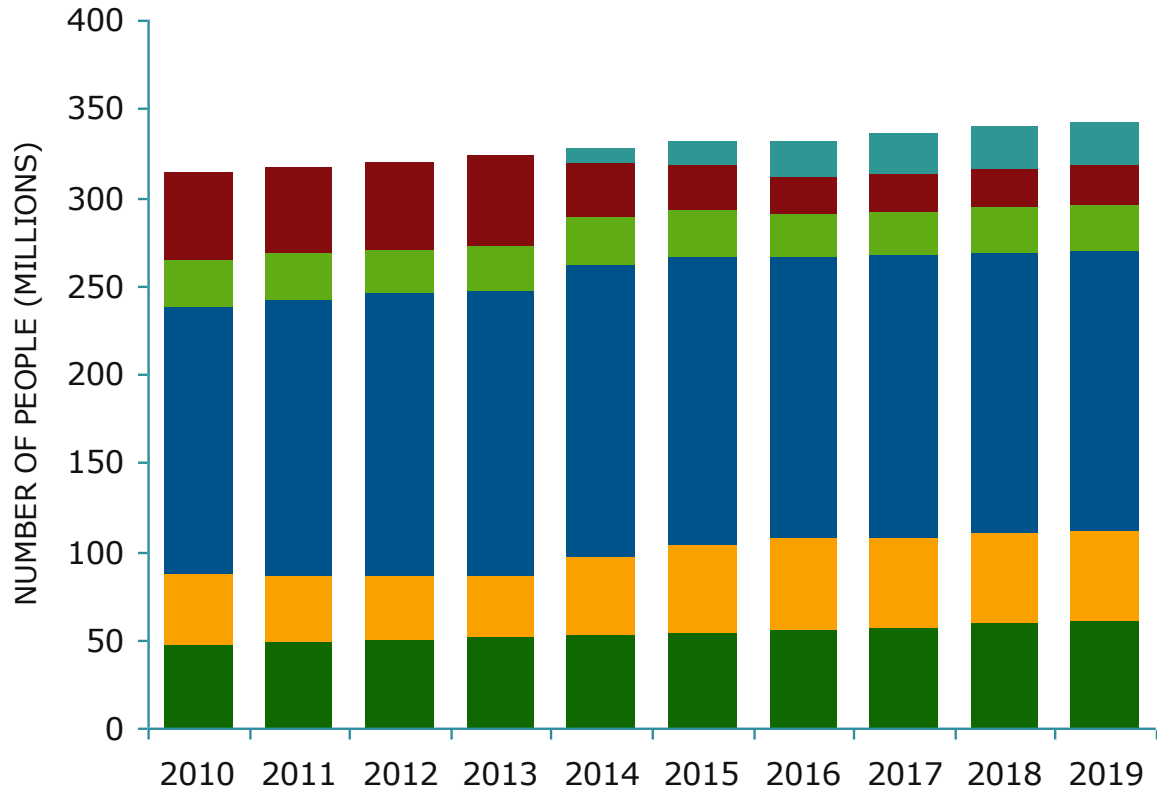
# The most certain impacts are negative in the short term but more positive or uncertain longer term





# 25-30mn people will get coverage under reform but questions remain about how they will use it

## COVERAGE AFTER REFORM



## Impact on 2019 (mn)

	Vs. no-reform	Vs. 2010
Exchanges	+24	+24
Uninsured	-32	-27
Nongroup/Other	-5	-2
Employer	-4	+8
Medicaid/CHIP	+16	+11
Medicare	0	+14

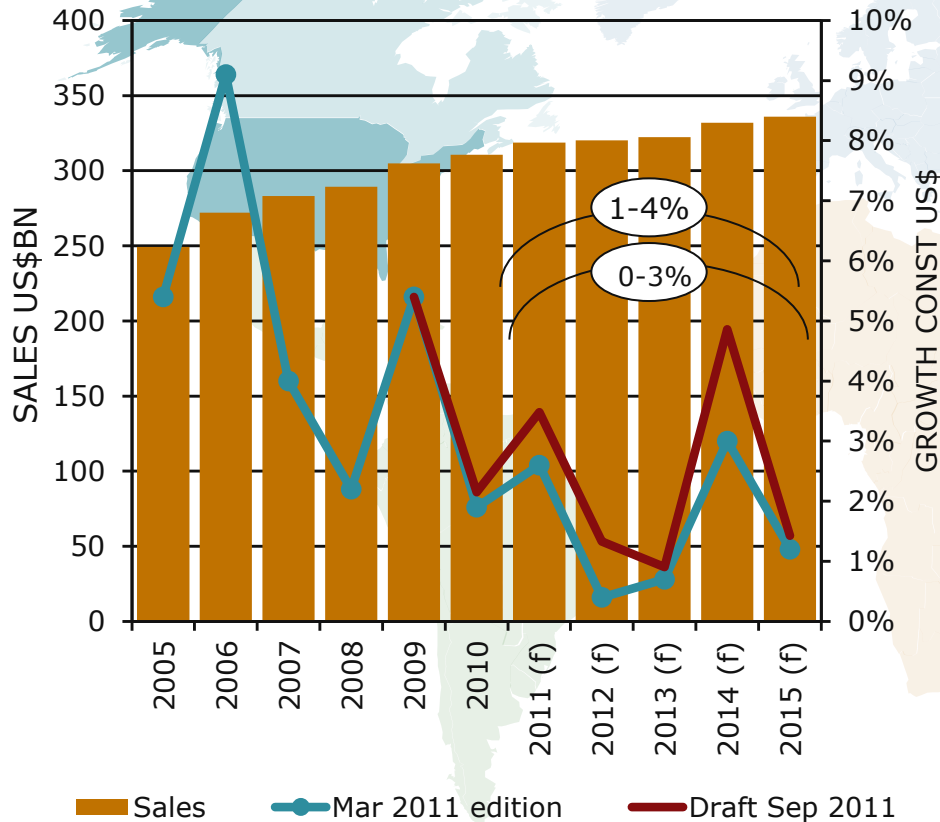
Source: CMS, CBO Healthcare Reform Reconciliation Bill Analysis, Mar 2010





# US forecast to 2015 up slightly; 2011 slightly ahead of prior forecast, HC reform impact up slightly

## Sales and growth forecast



### Key drivers of changes to 2010/11

- Reduced role of brands in therapy areas where high quality generics are available
- Impact of 2010 expiries deeper than expected on brands but generic price discounts were not fully realized

### Key drivers of changes 2012-14

- HC reform incremental demand in 2014 1.9% impact up from 1.5% in prior edition
- Timing of patent expiries shifts; peak impact years now 2012 to 13
- New product contribution improving, but market overall continues to be hampered by the cumulative effects of lower levels of innovation entering 2006-10

Source: IMS Health Market Prognosis Mar 2011 and draft Sep 2011



# What's in for Pharmaceuticals?

- Slower market growth
- Generics & Patent Cliff
- Specialty is growing but at a slower pace
- RX to OTC
- Private label OTC
- Chain & Mass, Mail service, Clinics, & LTC
- Medicaid & Medicare Part D
- Cough, Cold and Flu
- Price Increases
- REMS
- Drug Shortages
- Specialty Innovation
- S&D



# What's out and what's ahead for Pharmaceuticals???

## What's Out?

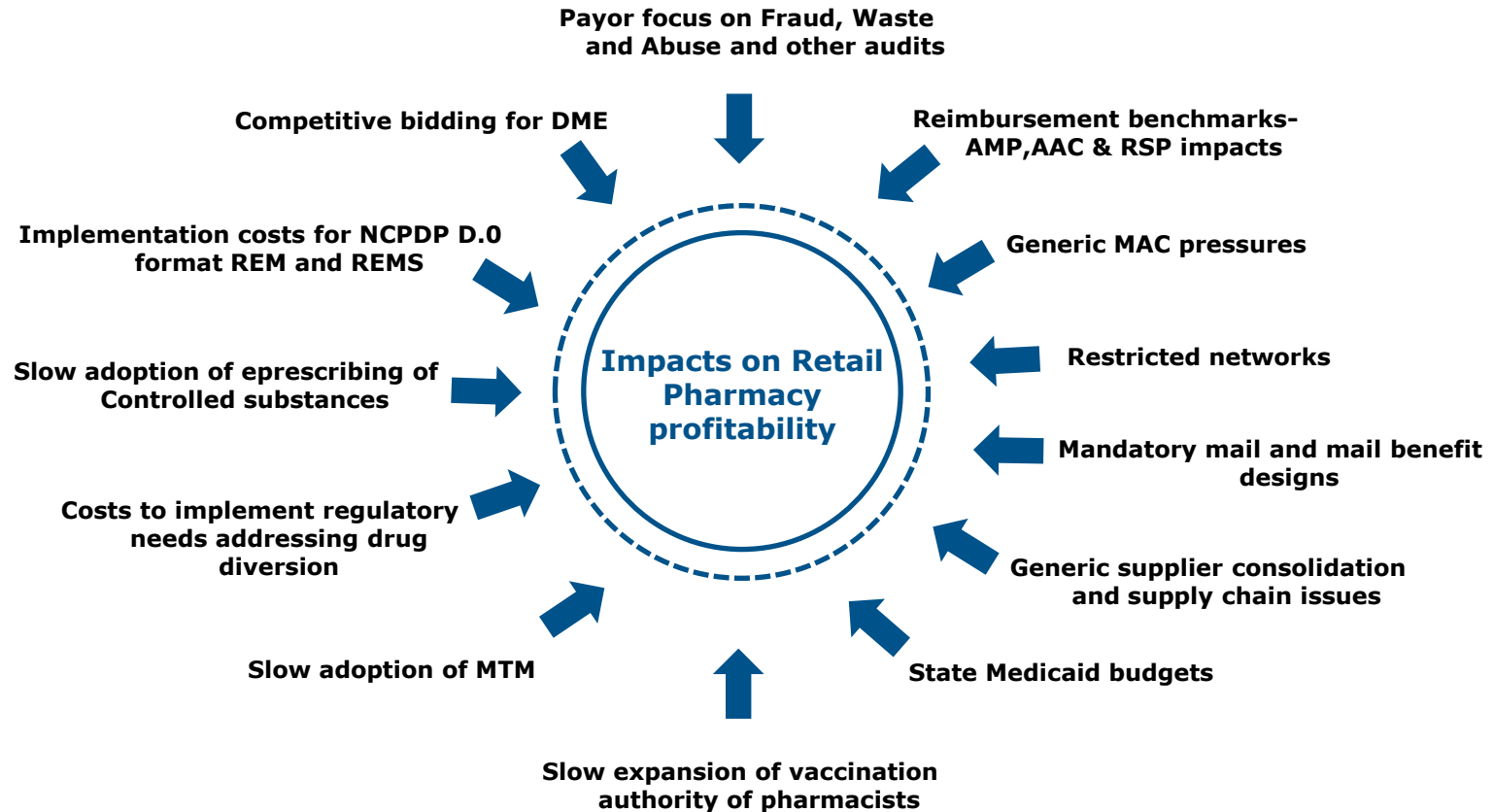
- Brand growth
- Primary Care Innovation
- R&D
- Office visits
- Elective surgery
- Adherence???

## What's Ahead?

- Government
  - Medicaid
  - Medicare Part D
  - Health Care reform
  - Generic User fees
  - Generic approval backlogs
  - More FDA inspections
  - AMP
  - Biosimilar Pathway
  - REMS
  - Patent Settlements
  - [DEA enforcement](#)



# Impacts on retail pharmacy profitability



# Longer-term upsides to pharma growth are possible

**Growing share of healthcare budget for pharmacotherapy**

**Expanded patient access to healthcare**

**Accelerated uptake of healthcare information technology**

**Greater clinical evidence of drug efficacy**

**Increased diagnosis of asymptomatic conditions**

**Emergence of new therapeutic platforms**

**Improved compliance and persistency rates**

**Aging population and economic development**



# The US Pharmaceutical Market

Looking back and  
looking ahead!

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