

Panacea or Bitter Pill? Prescription Drugs under Health Care Reform



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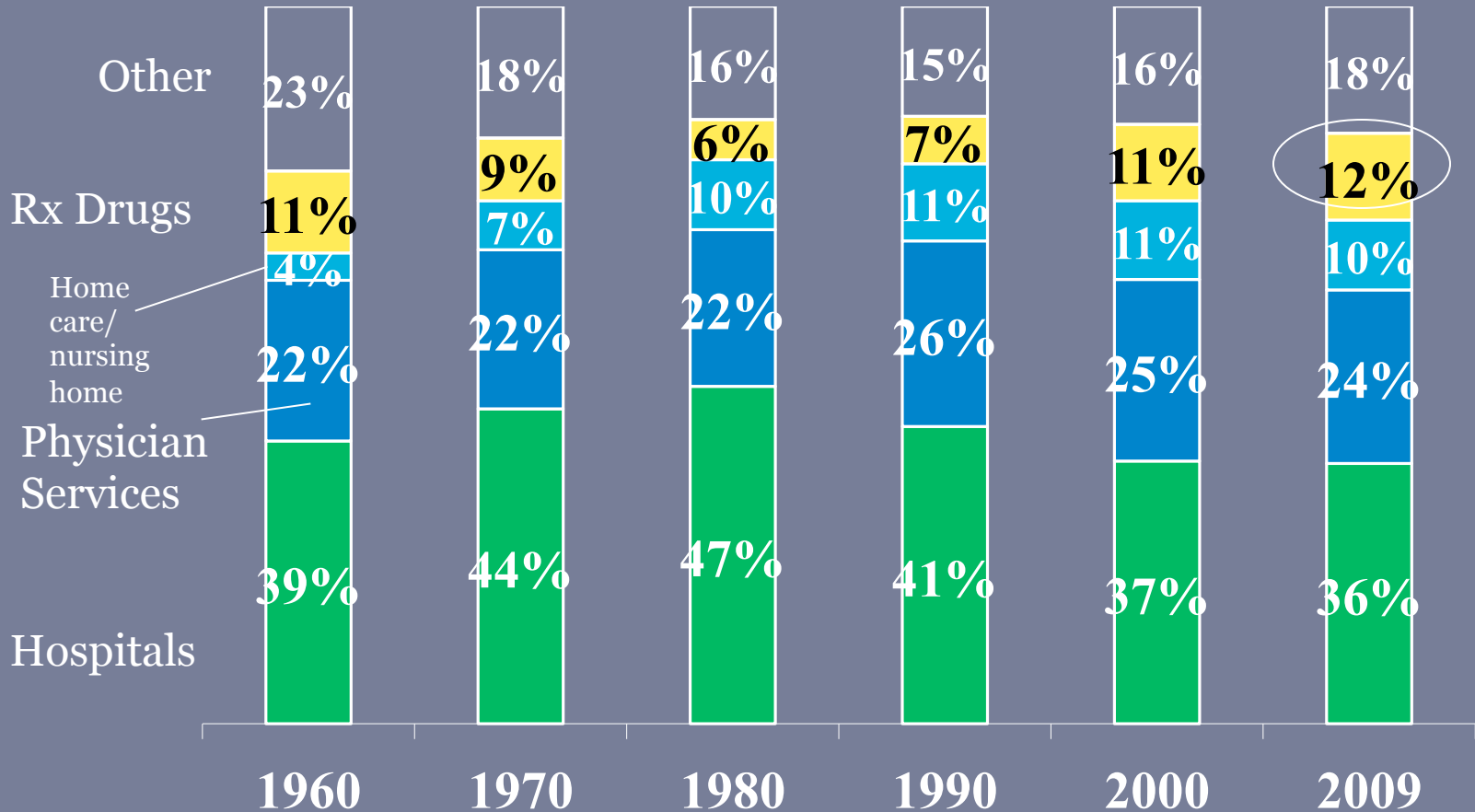
Outline of Talk



- Landscape of US Prescription Medications
 - ✦ Document its importance
 - ✦ What is driving recent slowdown in spending growth?
- Prescription Drug Features in the Affordable Care Act
 - Medicare Part D donut hole and beyond
- The road ahead
 - How might the ACA and existing trends affect prescription markets for consumers and producers?

Importance of Pharmaceutical Sector in U.S. Health Care Spending

12% in 2009

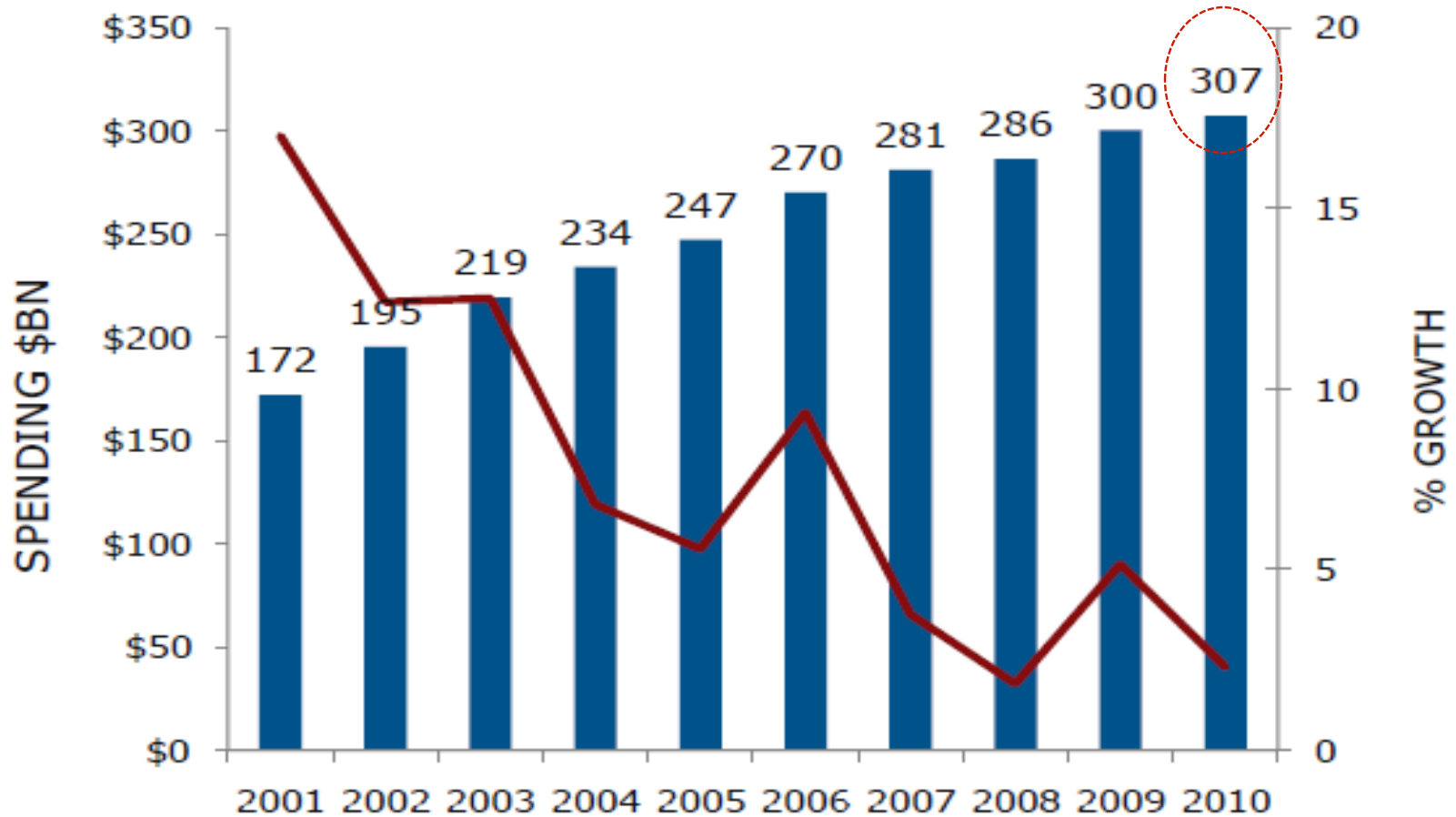


Source: CMS and Martin et al., 2011;

Many graphs courtesy of Prof. Sean Nicholson, Sloan MHA Program, Cornell University

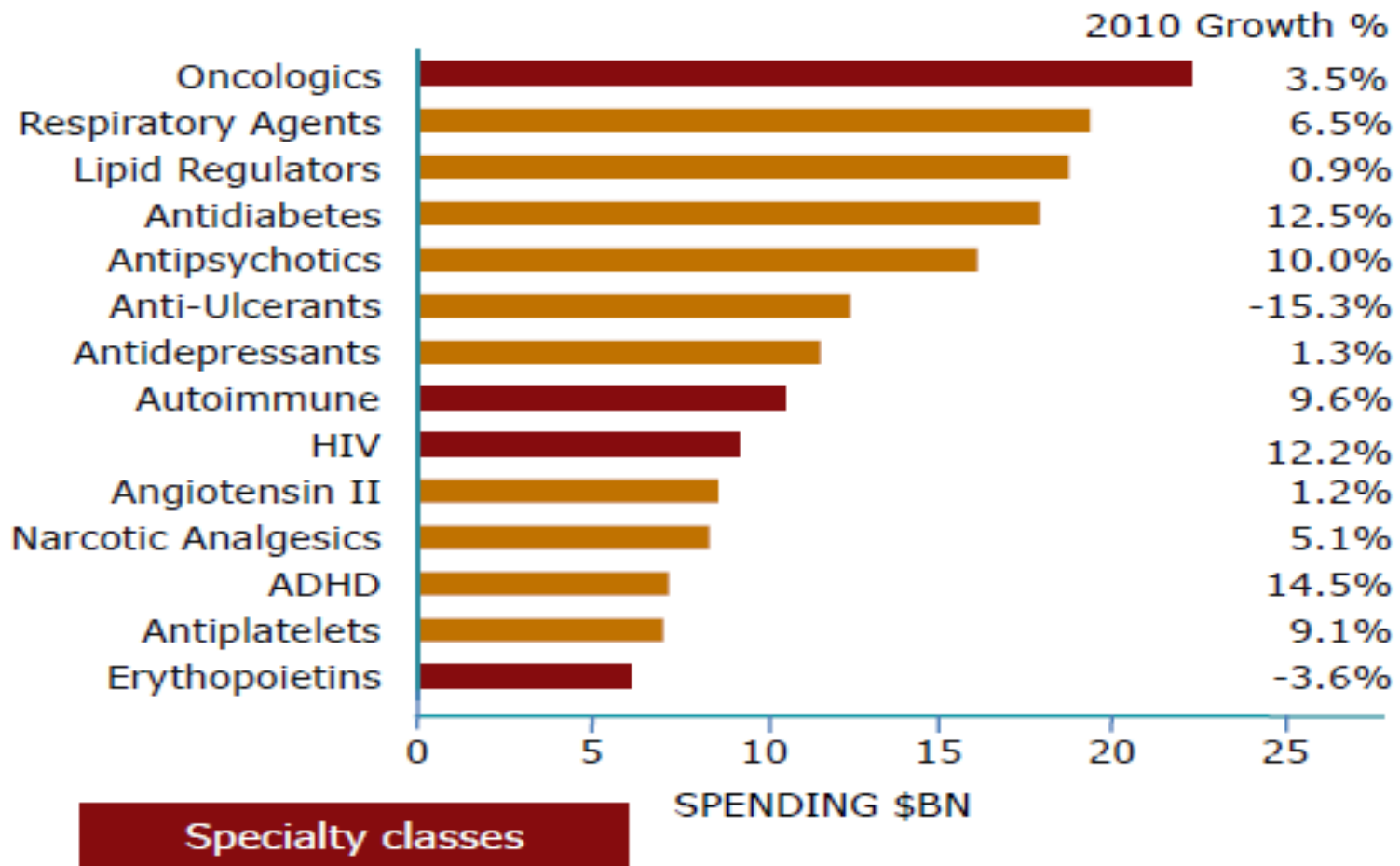
US spent \$307B on prescription drugs in 2010 (IMS Health, 2011)

Spending Growth 2001-2010



Source: IMS Health, National Sales Perspectives, Dec 2010

Spending in Leading Therapy Classes



Source: IMS Health, National Sales Perspectives, Dec 2010

Top Selling US Medications 2006-2010

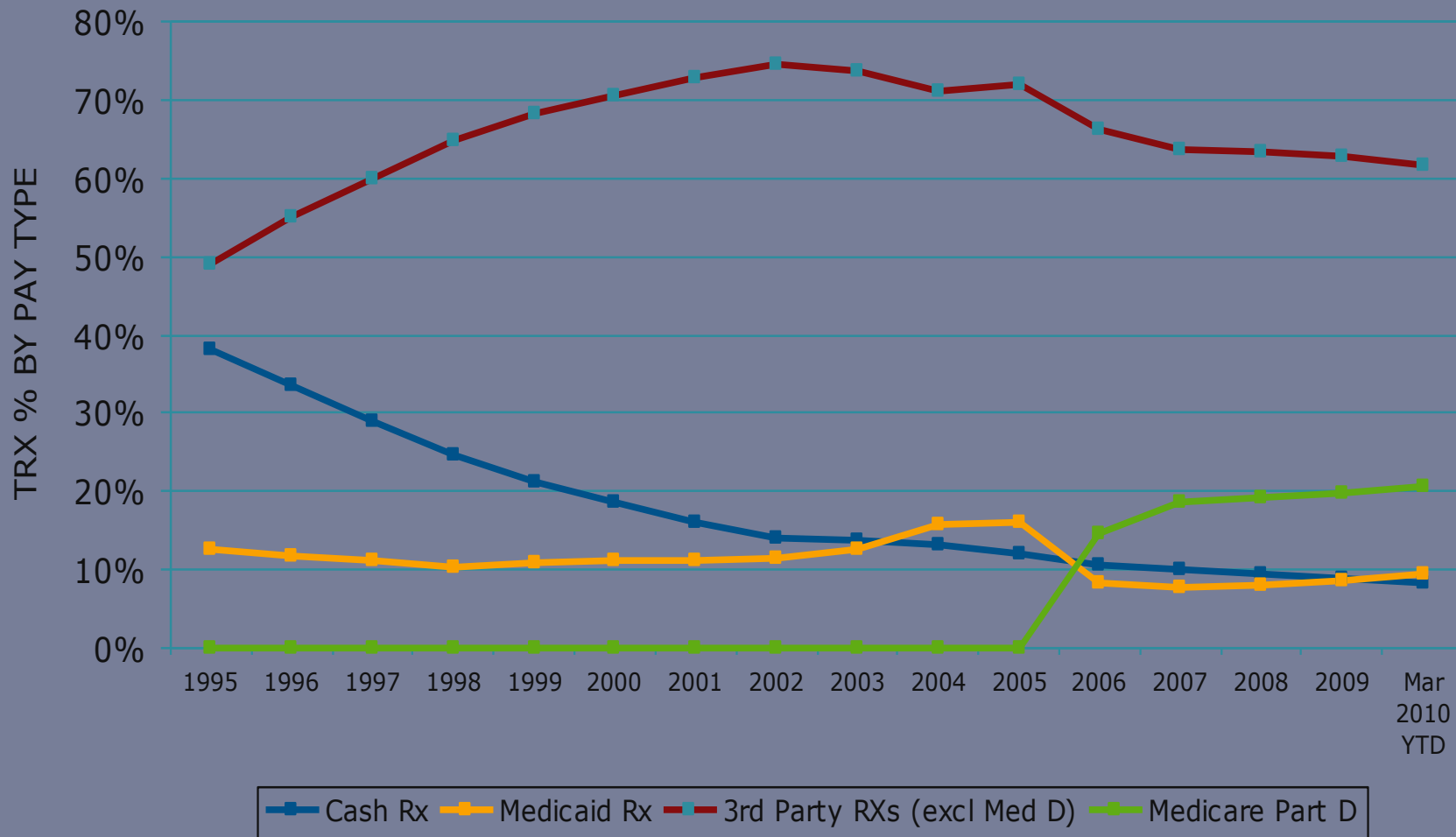
		2010	2009	2008	2007	2006
Total US Prescription Market		307.4	300.3	285.7	280.5	270.3
1	Lipitor ®	7.2	7.6	7.8	8.1	8.6
2	Nexium ®	6.3	6.3	5.9	5.4	5.1
3	Plavix ®	6.1	5.6	4.8	3.9	2.9
4	Advair Diskus ®	4.7	4.7	4.4	4.2	3.9
5	Abilify ®	4.6	4.0	3.0	2.3	1.9
6	Seroquel ®	4.4	4.2	3.8	3.4	3.0
7	Singulair ®	4.1	3.7	3.5	3.4	3.0
8	Crestor ®	3.8	3.0	2.1	1.7	1.3
9	Actos ®	3.5	3.4	3.1	2.9	2.6
10	Epogen ®	3.3	3.2	3.0	3.0	3.2
11	Remicade ®	3.3	3.2	3.0	2.7	2.5
12	Enbrel ®	3.3	3.3	3.1	3.1	3.1
13	Cymbalta ®	3.2	2.8	2.4	1.9	1.2
14	Avastin ®	3.1	3.0	2.5	2.2	1.7
15	Oxycontin ®	3.1	2.9	2.3	1.0	0.8
16	Neulasta ®	3.0	3.0	3.0	3.0	2.8
17	Zyprexa ®	3.0	2.7	2.5	2.4	2.4
18	Humira ®	2.9	2.5	2.1	1.5	1.2
19	Lexapro ®	2.8	2.8	2.7	2.6	2.4
20	Rituxan ®	2.8	2.6	2.4	2.2	2.0

Leading Pharmaceutical Firms Emerging From Mergers & Acquisitions



Prescriptions by Payer Type

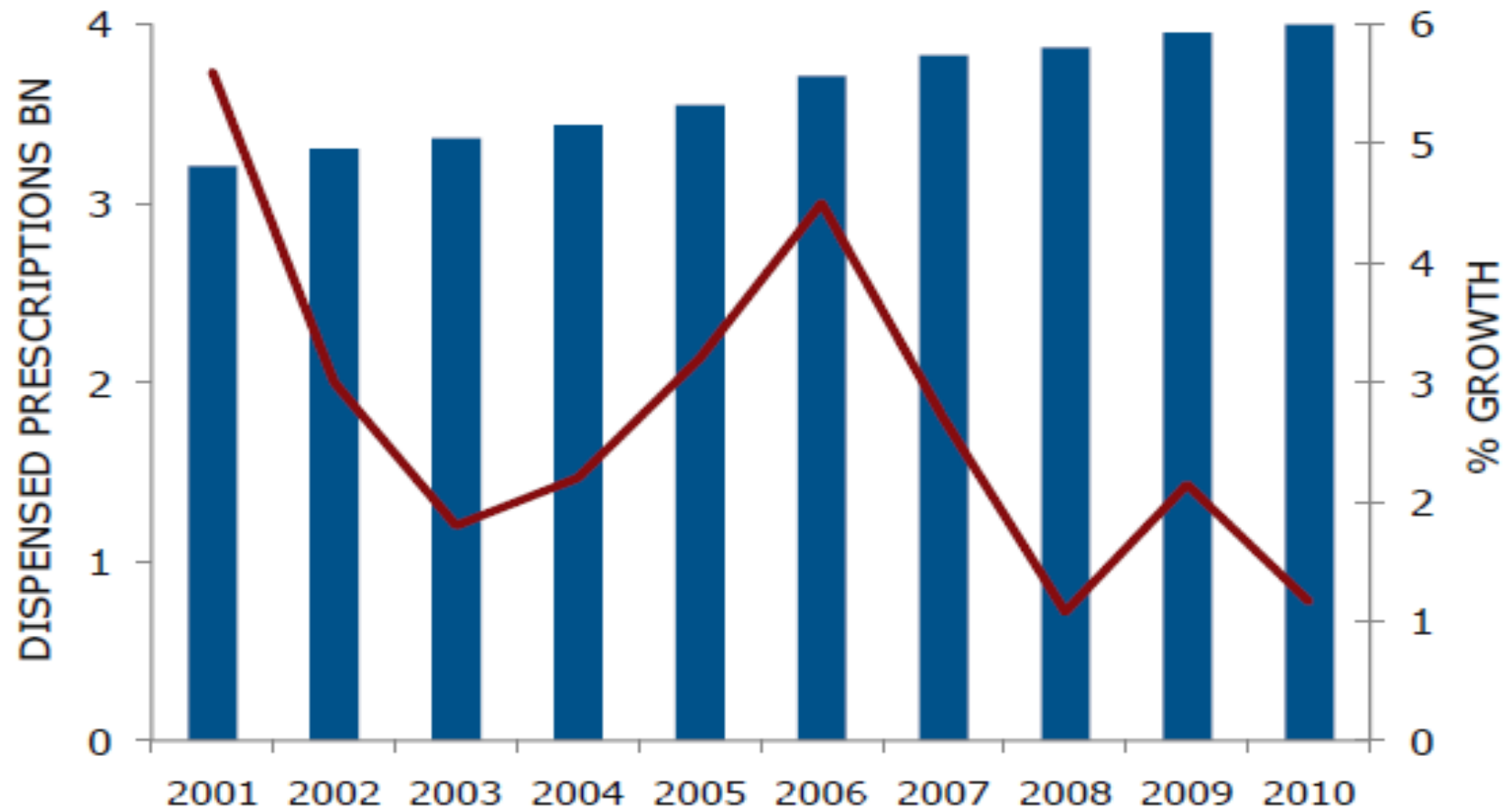
(Private insurance 60% in 2010)



What is driving the recent slow
down in Rx spending growth?



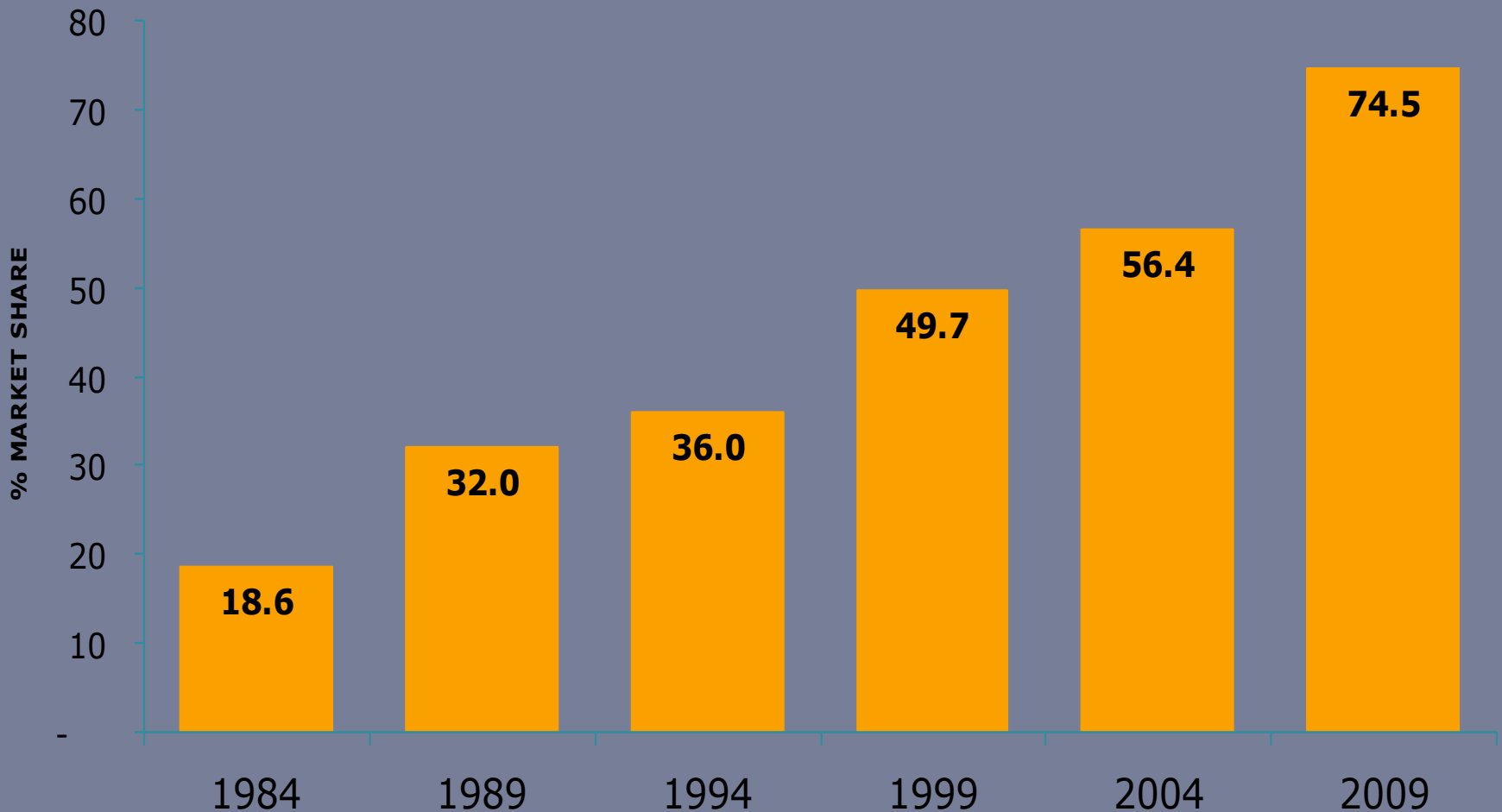
Prescriptions Volume 2001-2010



Source: IMS Health, National Prescription Audit, Dec 2010

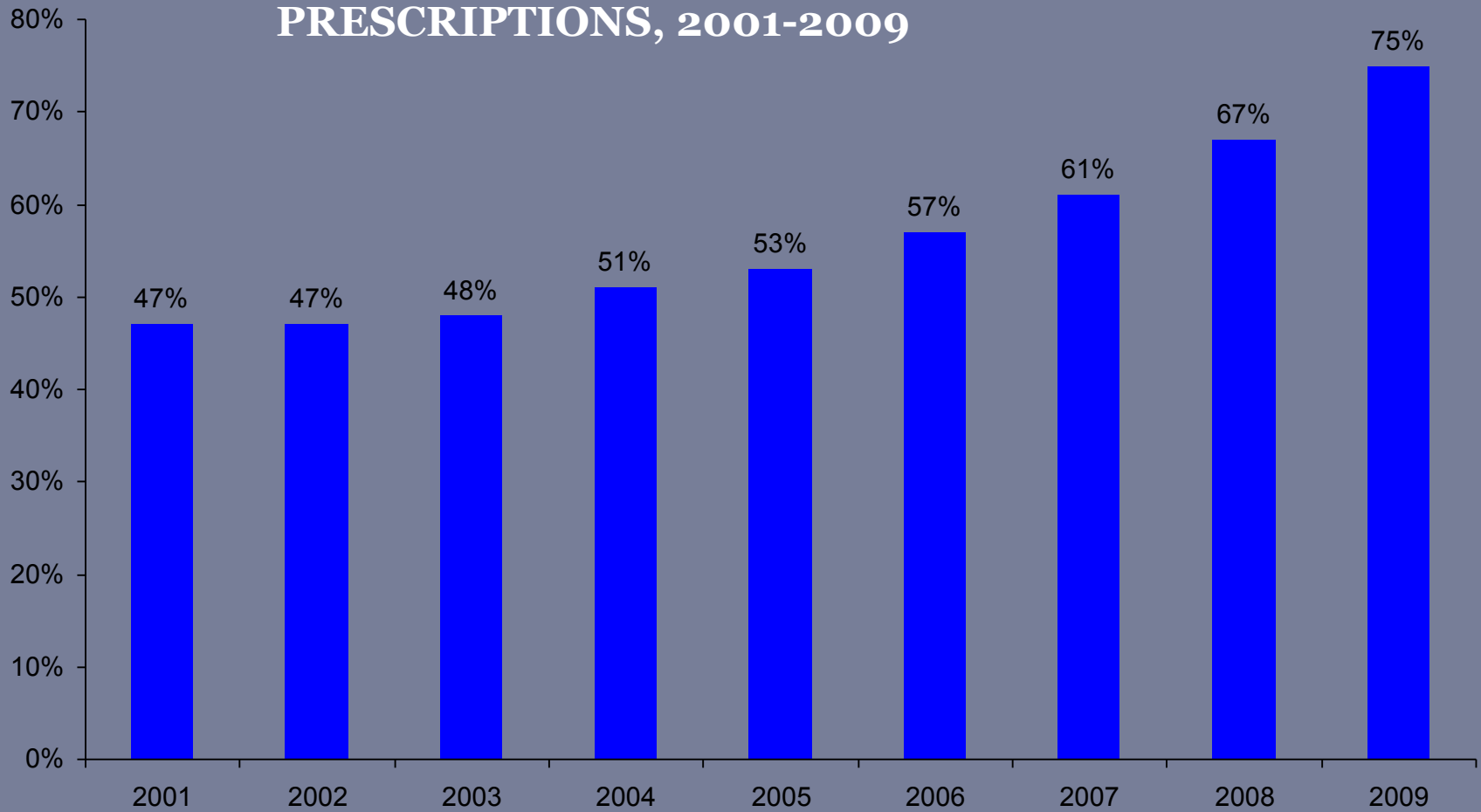
Generic Drugs Now Account for 75% of Prescriptions in the U.S.

GENERIC SHARE OF TOTAL PRESCRIPTIONS, 1984-2009



Sources: For 1984-2004 IMS Health National Prescription Audit archives; for 2005-2009, IMS Health, National Sales Perspectives

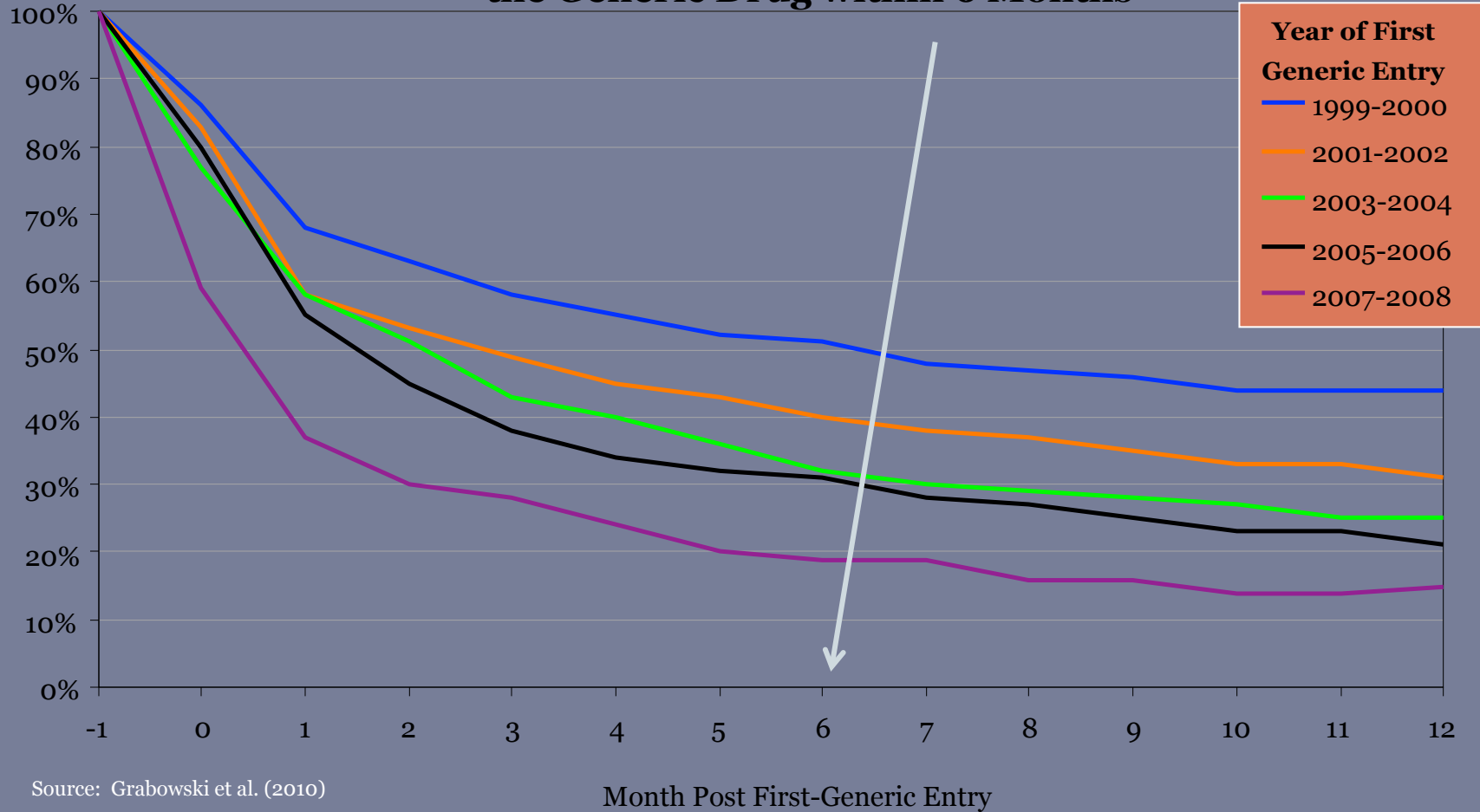
GENERIC SHARE OF TOTAL PRESCRIPTIONS, 2001-2009



Source: IMS health

Generic Entry Has Caused Brands to Lose a Larger Percentage Sales and to Lose Sales More Quickly in Recent Years

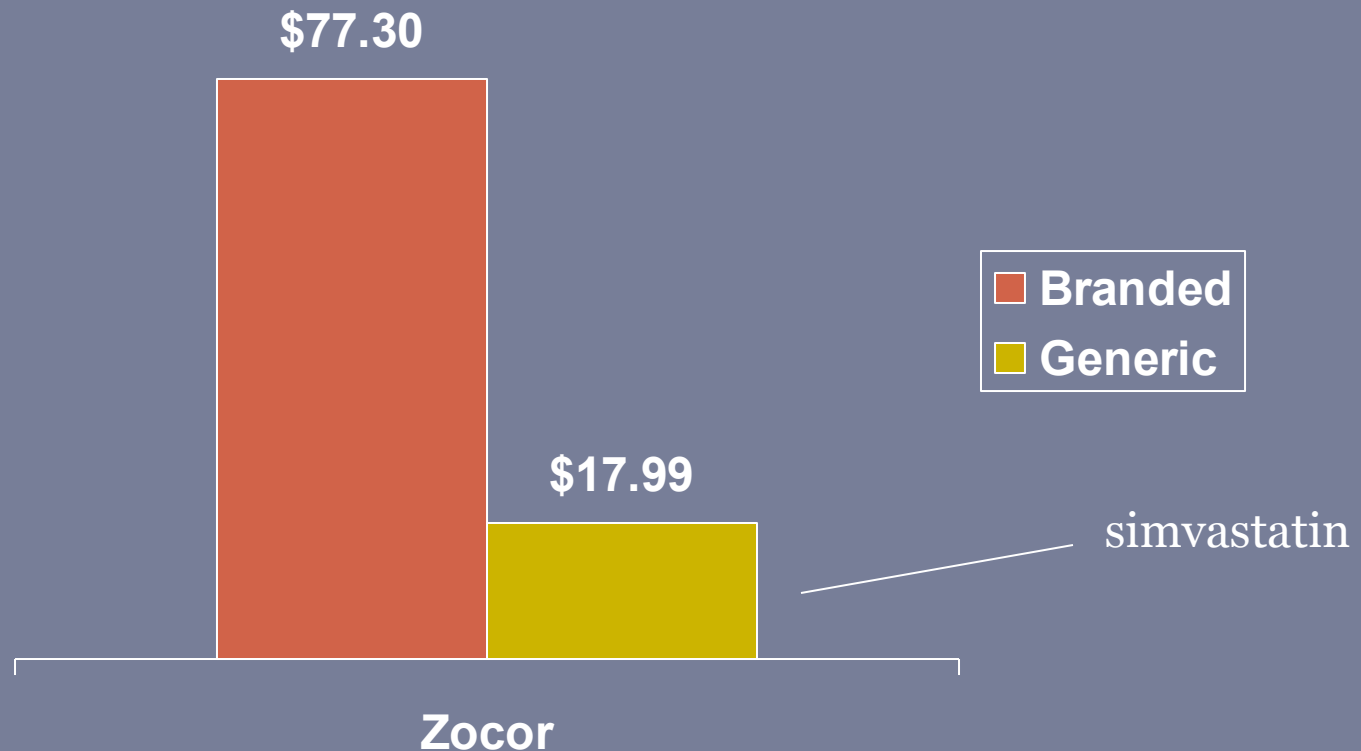
Once a Patent Expires, 80% of Patients Shift to the Generic Drug within 6 Months



Source: Grabowski et al. (2010)

Generic Drugs Are Much Less Expensive Than the Branded (formerly patent-protected) Drug

Price per 30 pack of 5 mg pills



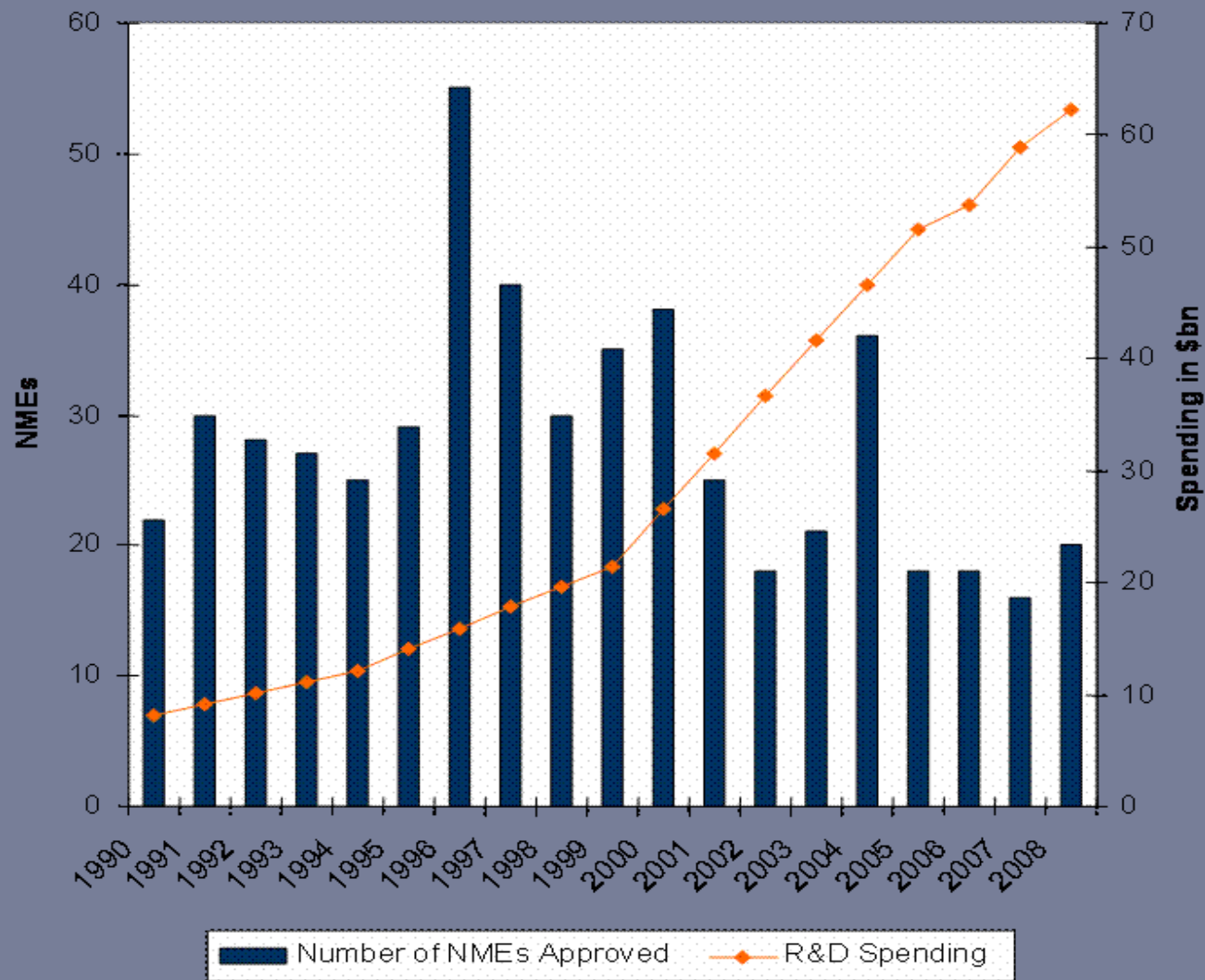
Source: drugstore.com, prices as of 11/11/11

Patent Expiry of Many Popular Drugs

Class	Expired before 2006	Expired 2006-2010	Expiring 2011-2015	Protected Beyond 2015
Lipid Regulators	None	Zocor (6/2006), Pravachol (4/2006)	Lipitor (11/2011)	Crestor (7/2016), Zetia (4/2017), Vytorin (4/2017)
Ace Inhibitors	Vasotec (2/2000), Zestril (6/2002), Accupril (4/2003)	Lotrel (4/2007)	Tarka (2/2015)	None
Calcium Channel Blockers	Sular (11/1998), Cardizem, Others	Norvasc (3/2007)	None	None
Beta Blockers	Brevibloc (12/2003)	Toprol-XL (7/2007), Coreg (9/2007)	Bystolic (12/2012)	Coreg CR (4/2016)
Proton Pump Inhibitors	Prilosec (11/2002)	Prevacid (11/2009)	Nexium (11/2014), Aciphex (5/2013)	Dexilant (12/2020)
Thyroid Hormone	Synthroid (Branded Generic), Others	None	None	None
Angiotensin II	None	Cozaar/Hyzaar (2/2010)	Diovan (9/2012), Avapro (3/2012)	Benicar (10/2016)
Codeine & Combinations	Percocet, Others	None	Oxycontin (4/2013)	None
Antidepressants	Prozac (8/2001)	Zoloft (6/2006), Effexor XR (6/2010)	Cymbalta (7/2014), Lexapro (3/2012)	Pristiq (2/2022)
Seizure Disorders	None	Lamictal (1/2009), Topamax (3/2009), Depakote ER (6/2009)	Keppra XR (9/2011)	Lyrica (12/2018)

Source: [http://www.imshealth.com/deployedfiles/ims/Global/Content/Insights/IMS%20Institute%](http://www.imshealth.com/deployedfiles/ims/Global/Content/Insights/IMS%20Institute%20Patent%20Expiry%20of%20Many%20Popular%20Drugs.pdf)

R&D Spending & NME Approvals



Approvals:

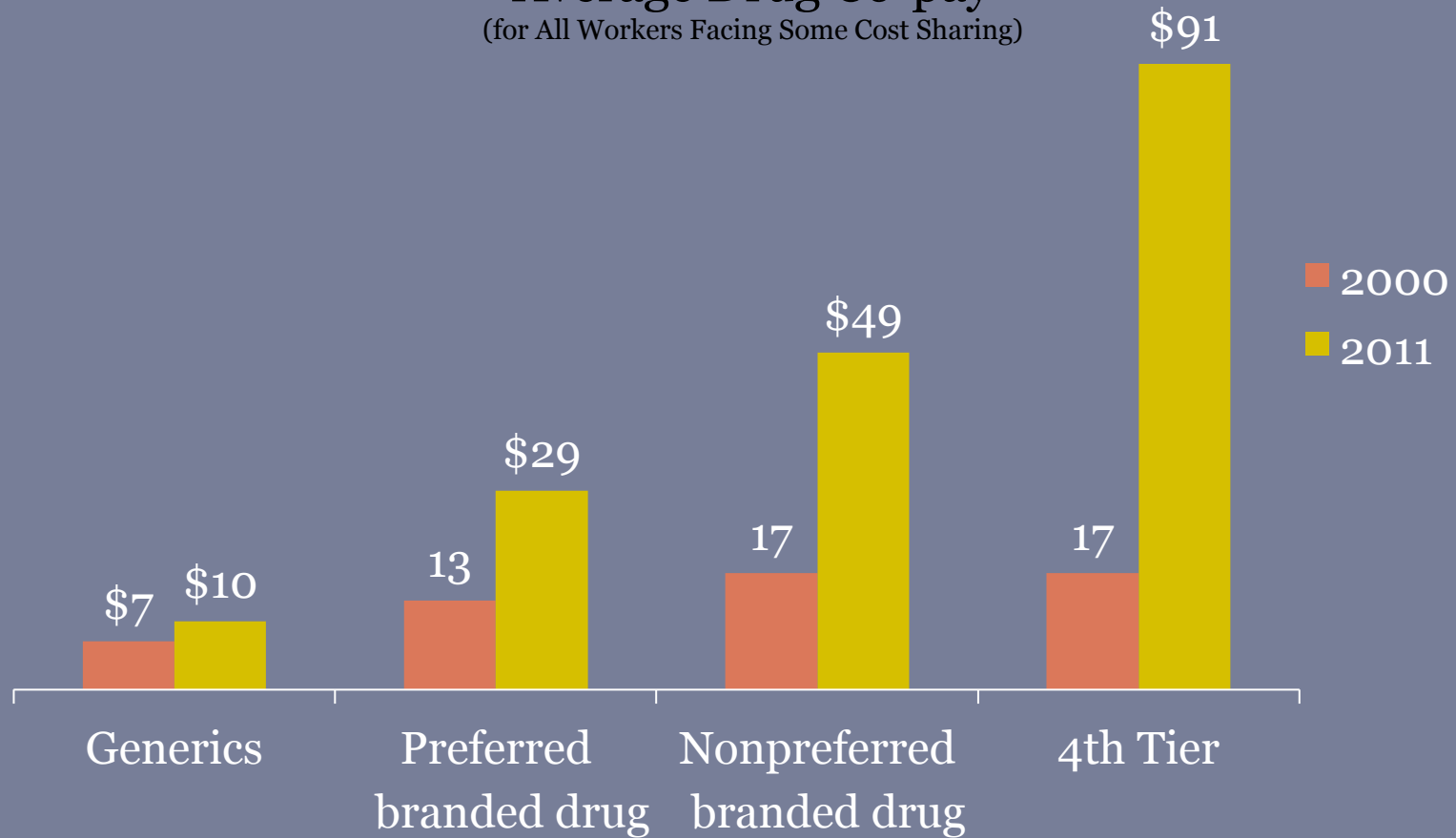
2009: 25

2010: 21

(3 are biologics)

Health Insurers Have Shifted Costs to Patients

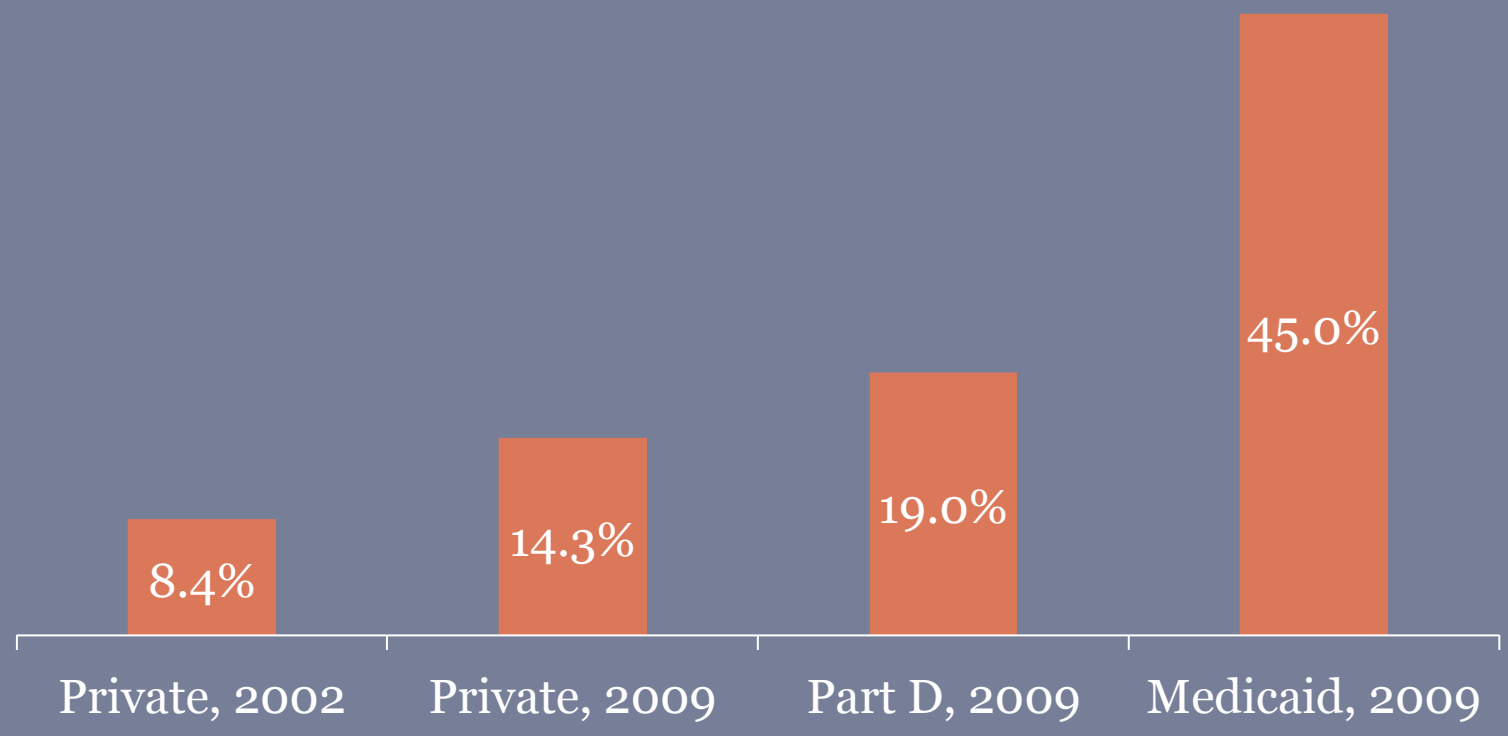
Average Drug Co-pay
(for All Workers Facing Some Cost Sharing)



Source: The Kaiser Family Foundation, Employer Health Benefits 2011 Annual Survey.

Health Plans/PBMs Receive Discounts/ Rebates Due to Formulary Design

Average Percentage Cost Savings

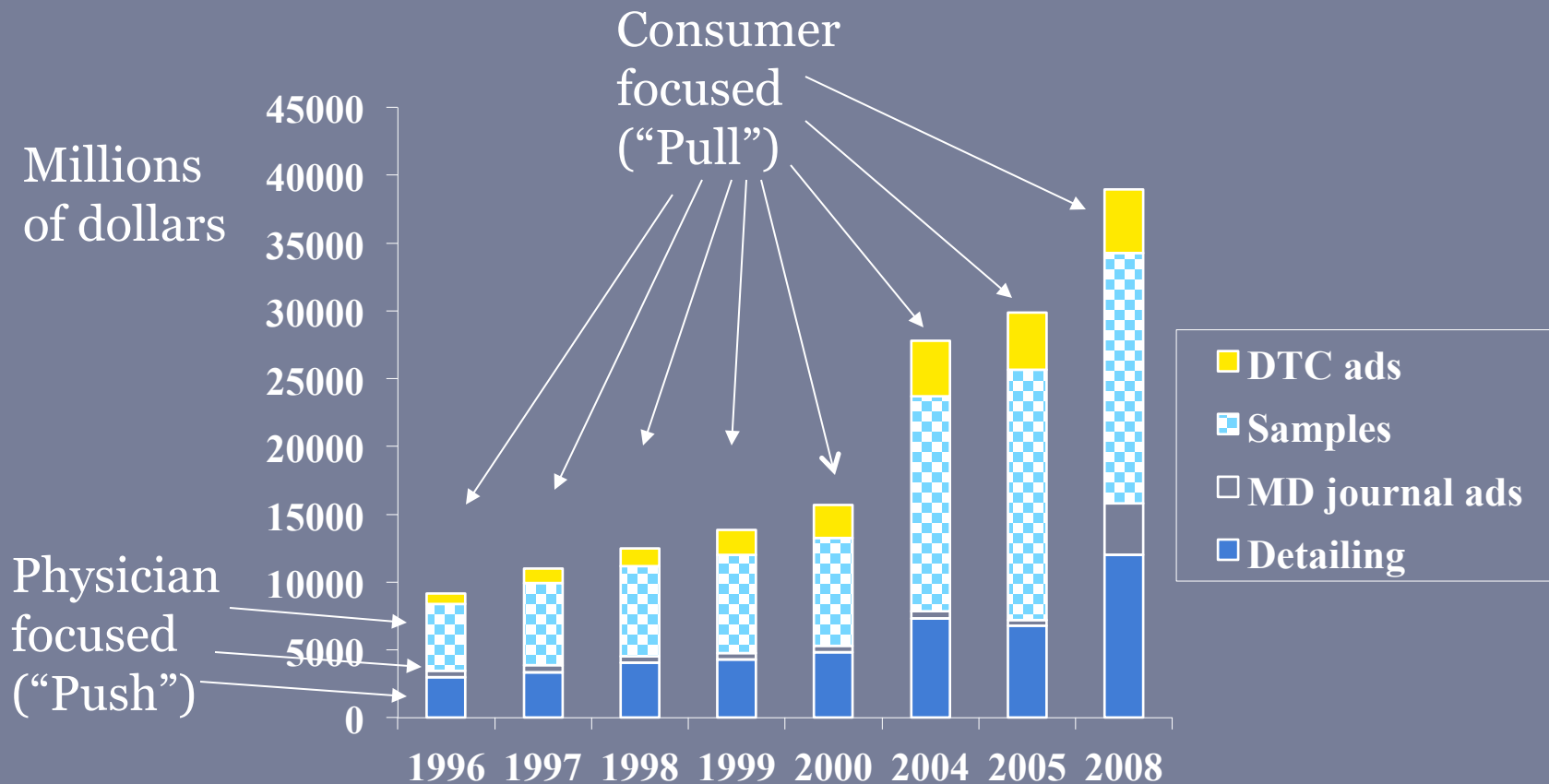


Source: Sector & Sovereign Research; Office of Inspector General, August 2011.

Drug Advertising Trends



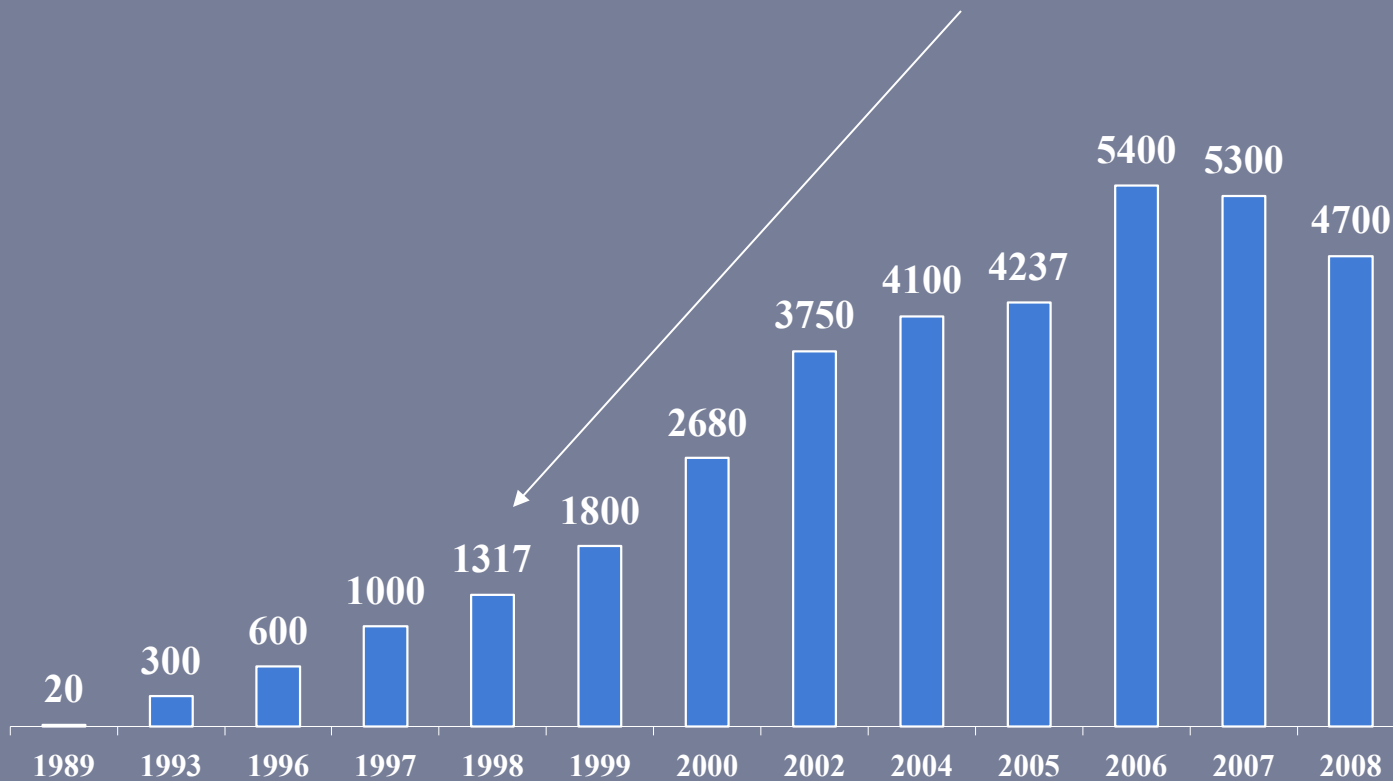
Most Marketing is Focused on Physicians, Not Patients



Growth of DTC Advertising Has Slowed Down

Pharmaceutical Direct-to-Consumer Advertising (\$ million)

FDA: rules of advertising changed

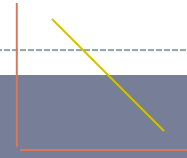


Source: IMS Health; Lehman Brothers; Rosenthal et al., June 2003, "Demand Effects of Recent Changes in Prescription Drug Promotion". TNS Media Intelligence.

Prescription Drug Features in the Affordable Care Act



Impact of Insurance Expansions on Prescription Drug Use

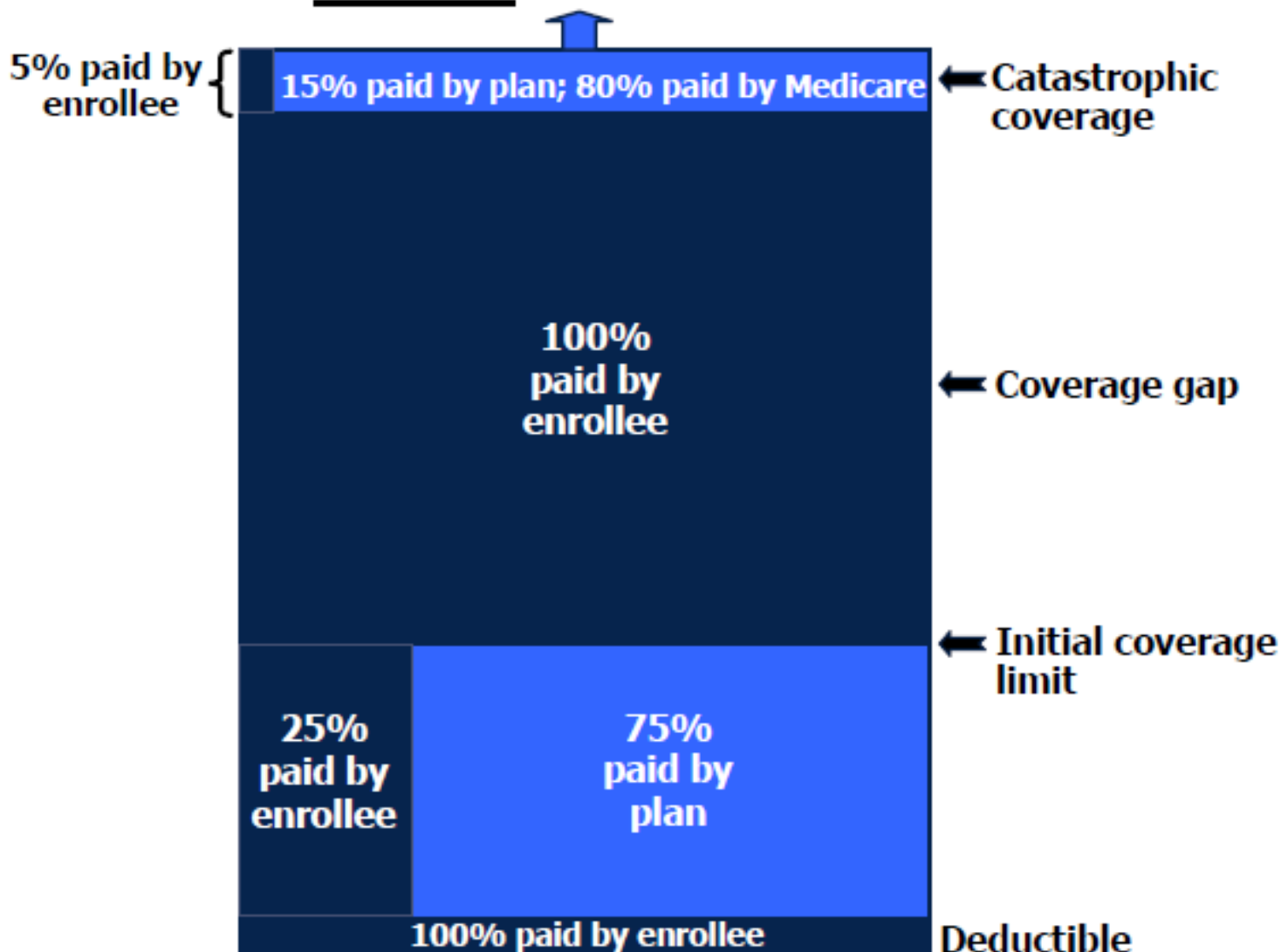


- 32 million will be newly insured by ACA
 - Research evidence shows prescription drugs relatively price inelastic, but more elastic for those with lower incomes (Simonsen, Skipper, and Skipper, 2010)
- Expansion of Medicaid would increase use among a large population of currently uninsured
 - 16 (+/-?) Million more insured under Medicaid (CBO 2009, Sommers and Swartz 2011)
 - ✦ Medicaid represents 1/2 of all newly insured by law
- But note earlier slide; heavy discounts to Medicaid purchases through rebates
 - Under ACA, Medicaid rebates percent increased to 23.1, and extend to Medicaid managed care, effective 2010

Closing of the Donut Hole



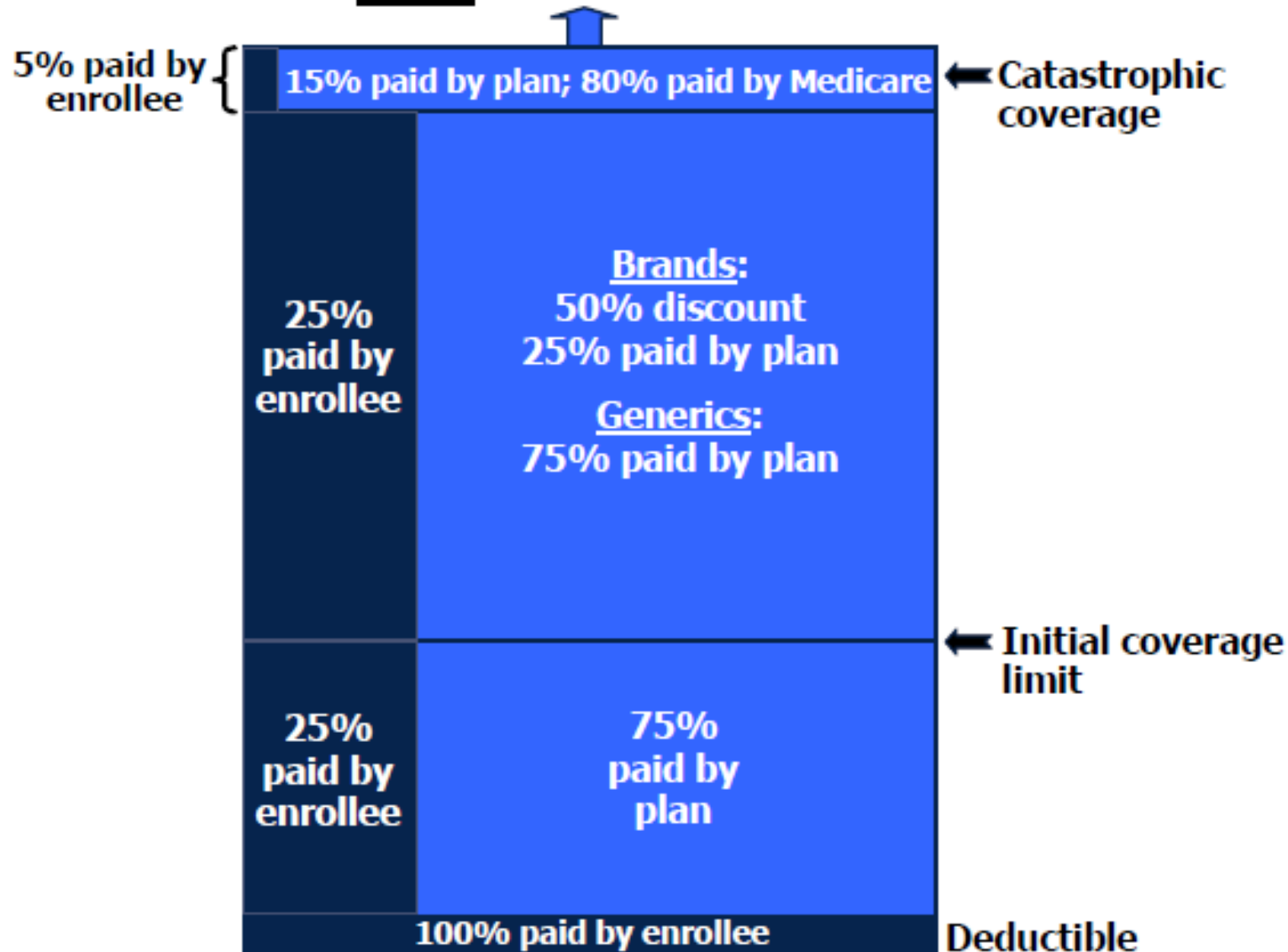
Exhibit 1
Standard Medicare Prescription Drug Benefit, 2020
Without Health Reform



SOURCE: Kaiser Family Foundation illustration of standard Medicare drug benefit in 2020 without health reform legislation. <http://www.kff.org/healthreform/upload/8059.pdf>

Exhibit 2

Standard Medicare Prescription Drug Benefit, 2020 *With Health Reform*



SOURCE: Kaiser Family Foundation illustration of standard Medicare drug benefit for 2020 under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010.

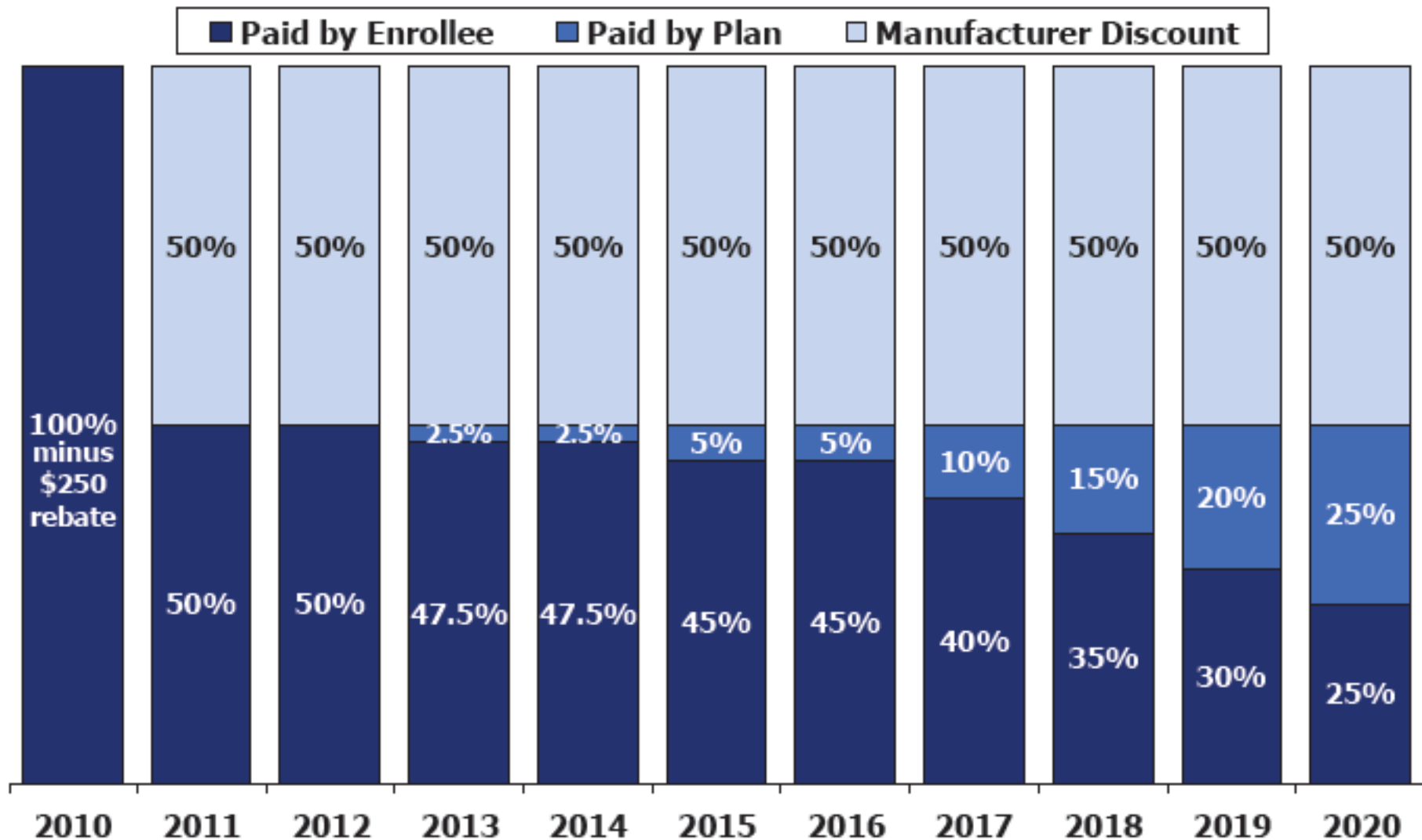
Closing of the Donut-hole (continued)



- 2007, 3.4 Million Part D enrollees (14%) affected by this coverage gap
 - Some plans covered the gap, but sparse and expensive
- Under reform, the exposure to high costs in coverage gap reduced gradually
 - 2010: \$250 checks (mailed starting June; 3.8M people total)
 - 2011-2012: 50% discount on brand name
 - 2013: Add a government subsidy gradually
 - 2020: 25% copay by patient (for generics too)
 - ✦ For generics, 7% incremental changes a year from 2012 until 2020

Exhibit 3

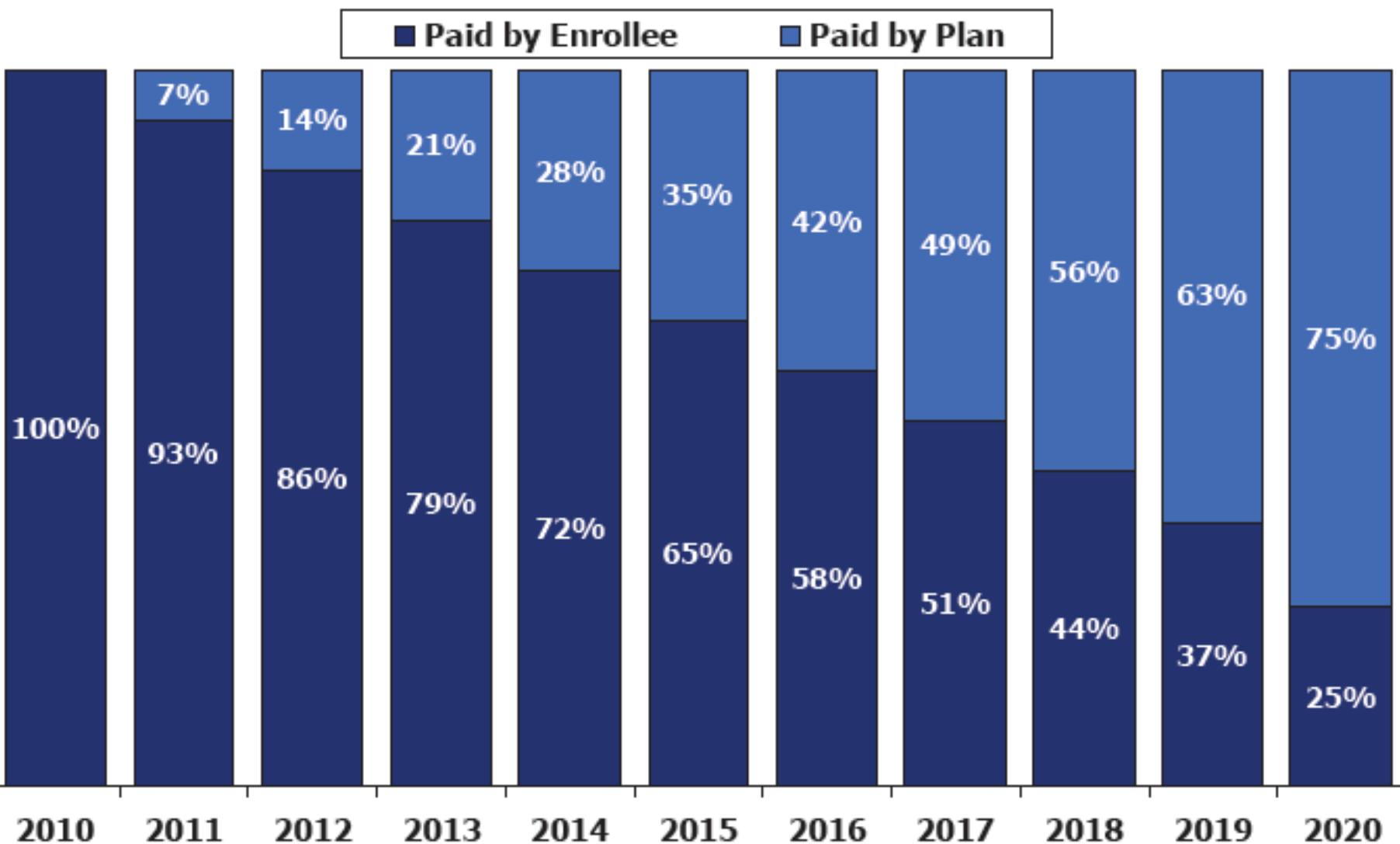
Cost Sharing for Brand-Name Drugs in the Medicare Part D Coverage Gap, 2010-2020



SOURCE: Kaiser Family Foundation analysis of the standard Medicare drug benefit under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010.

Exhibit 4

Cost Sharing for Generic Drugs in the Medicare Part D Coverage Gap, 2010-2020



SOURCE: Kaiser Family Foundation analysis of the standard Medicare drug benefit under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010.

Other Part D changes in the ACA



- Eliminate the tax deduction for employers who receive Medicare Part D retiree drug subsidy payments.(Effective January 1, 2013)
 - AT&T claims this will cost them \$1 Billion
- Reduce Med Ad plans (what does this imply for optimal design of part D formularies, incentives to internalize hospital costs)

Prevention and Prescription Drugs



- U.S. Preventive Services Task Force & Institute of Medicine Report
 - Eliminating copays on drugs, or screenings that may lead to use of drugs
 - ✦ Affects Medicare (starting 2011), Medicaid (starting 2010/2013), and private insurance (starting 2010)
 - ✦ Does not affect all private plans right away due to ‘grandfather’ clause
- Specific classes to watch:
 - Smoking cessation drugs
 - Prescription contraceptives

These provisions will become well known



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**In 2012, your
prescription
birth control
will be totally
free! Under
the Affordable
Care Act,
insurance
companies
will be
required to
foot the bill.
P. 184**

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Pharmaceutical Industry Fees



- Impose new annual fees on the pharmaceutical manufacturing sector, according to the following schedule:
- \$2.8 billion in 2012-2013;
- \$3.0 billion in 2014-2016;
- \$4.0 billion in 2017;
- \$4.1 billion in 2018; and
- \$2.8 billion in 2019 and later.

Other ACA Features Relevant for Rx



- FDA approval of generic biologics: patent exclusivity to 12 years
- Exclude OTC through HRA, HSA MSA. (Effective January 1, 2011)
- Reduced subsidies to medical spenders—
 - Limits FSA
 - Limit the itemized deduction for unreimbursed medical expenses

Effect of e-Prescribing on Physicians' Medicare Fee

Year	Physician e-Prescribes	Physician Does Not e-Prescribe
2009	+2%	0%
2010	+2%	0%
2011-2012	+1%	-1%
2013 (and beyond)	+0.5%	-2%

What Did Not Happen in the ACA to Rx





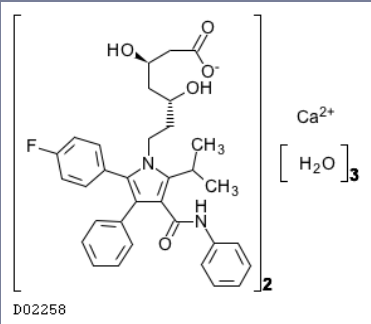
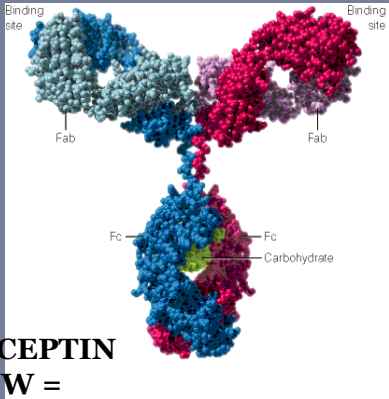
- No use of government administered prices in Part D
 - Proposals to require or allow Medicare to negotiate drug prices with manufacturers have been considered but not adopted
- Independent Payment Advisory Board prohibited from changing beneficiary premium percent in Part D, and from reducing LIS subsidies

What Aspects of Sector to Watch?

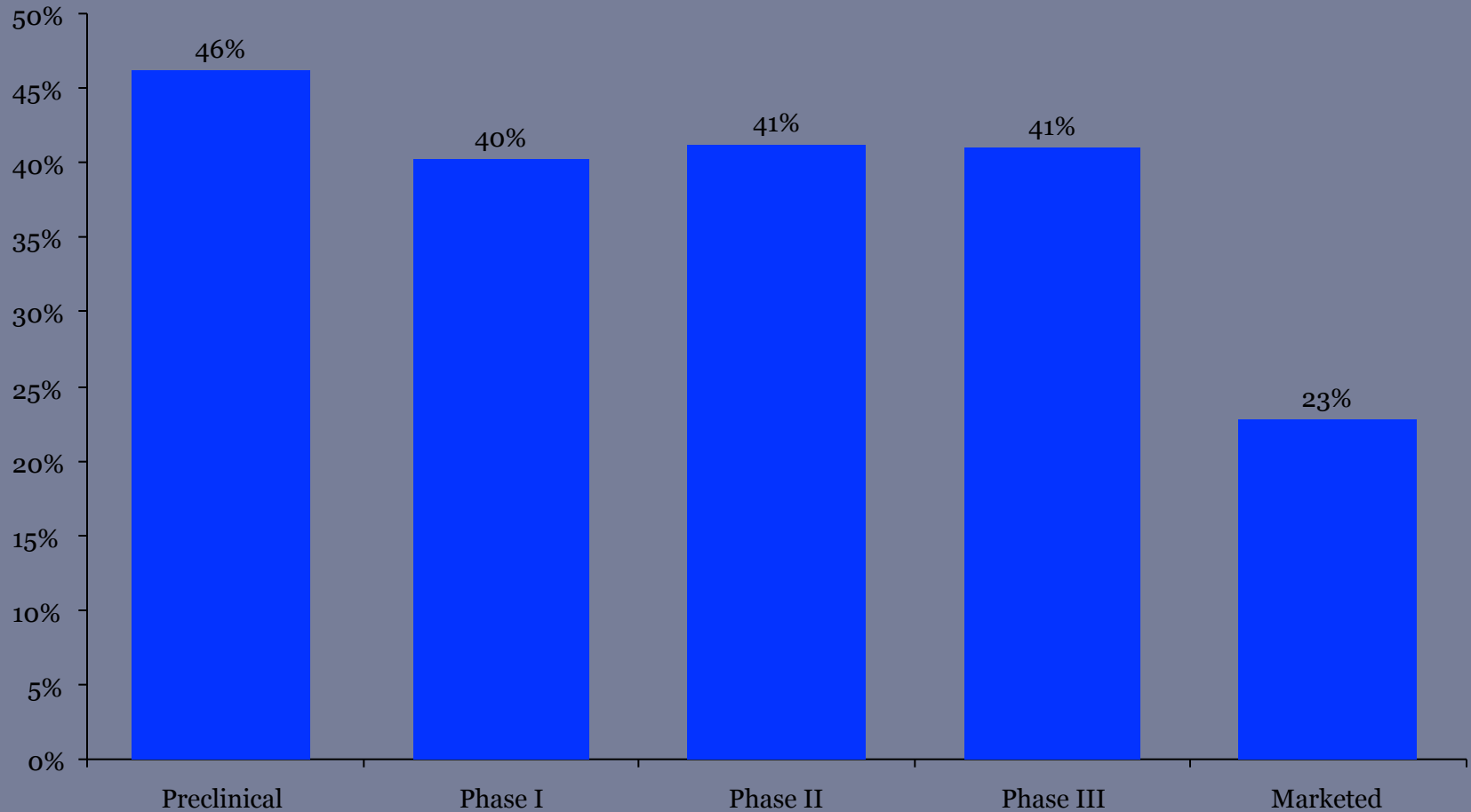


- New drug development, technology adoption reactions to new coverage
- Advertising strategies aimed at more of the newly covered populations
- Pricing—how much of the Rx sector taxes will be passed on?
- Use of new drugs, formulary design of Part D once donuthole closes

Pharmaceuticals vs. Biologics

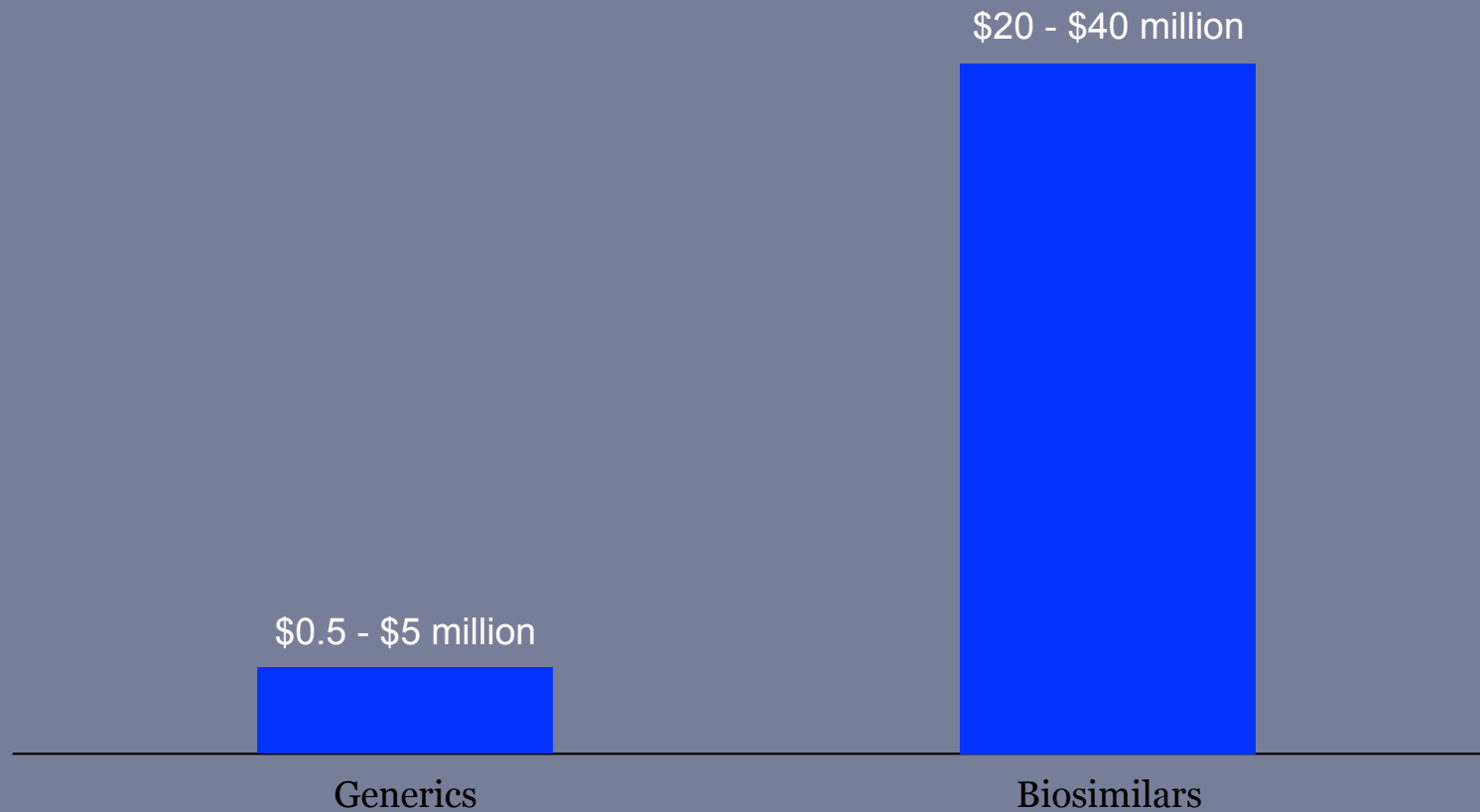
	Pharmaceuticals	Biologics
Size (MW)	Small (<1000)	Large (>10,000)
Source	Chemical synthesis	Cultures of living cells
Form	Generally oral solids 	Often injected or infused 
Reimbursement	Pharmacy benefit	Often medical benefit
Generic Law	1984 Hatch-Waxman	Biologics Price Competition and Innovation Act of 2010
Example	<p>Lipitor (anti-cholesterol)</p>  <p>D02258</p> <p>LIPITOR MW = 558.64</p>	<p>Herceptin (breast cancer)</p>  <p>HERCEPTIN MW = 185,000</p>

Biologic Drugs Make Up a Large Percentage of the Drug Pipeline



Source: Mark Trusheim, Murray L. Aitken, and Ernst R. Berndt, "Characterizing Markets for Biopharmaceutical Innovations: Do Biologics Differ From Small Molecules?" NBER Working Paper 16014, May 2010.

Biosimilars May Be More Than an Order of Magnitude Higher Than for Generics



Source: Company interviews and presentations: Oldham, 2005; Schafer, 2005..

Conclusions



- Prescription drug spending growth slowed
 - Generic use, patent expiry, lack of new blockbuster entry, slowdown of DTCA, increase of copays
- Affordable Care Act
 - Newly insured, Medicare donut-hole, prevention drugs copay reductions, Medicaid prescription drug rebates
- Directions for the future
 - New drug development, generic competition, market for biologics