
SETTING THE STAGE:CURRENT ACCESS POLICY CHALLENGES AND INITIATIVES

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Trends in Drug Pricing in US

- Trends in US Drug Pricing
- Potential Drivers & Future Challenges
 - Innovator and Generics Drugs
 - Therapeutic Areas
 - Biologics

Disclosure Statement

I have no financial relationships with proprietary entities that produce health care goods and services

The opinions and information in this presentation are my own and do not necessarily reflect the views and policies of the FDA

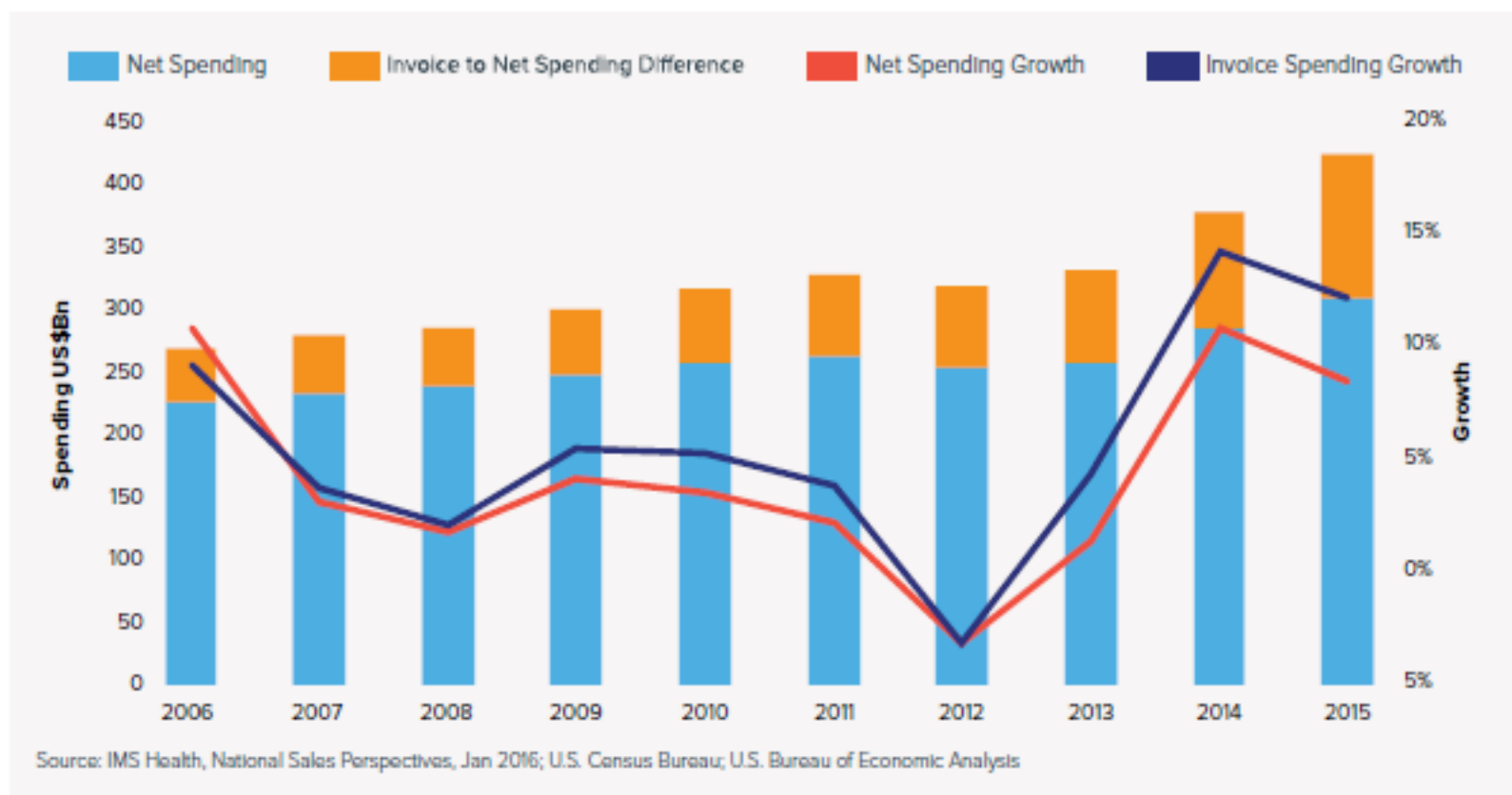
Trends in US Healthcare Spending on Drugs

- Spending for drugs continued to increase, >10% in 2015
 - Accounted for 9.9% of total healthcare spending in 2014*

- Source: IMS Institute for Healthcare Informatics imshealth.com

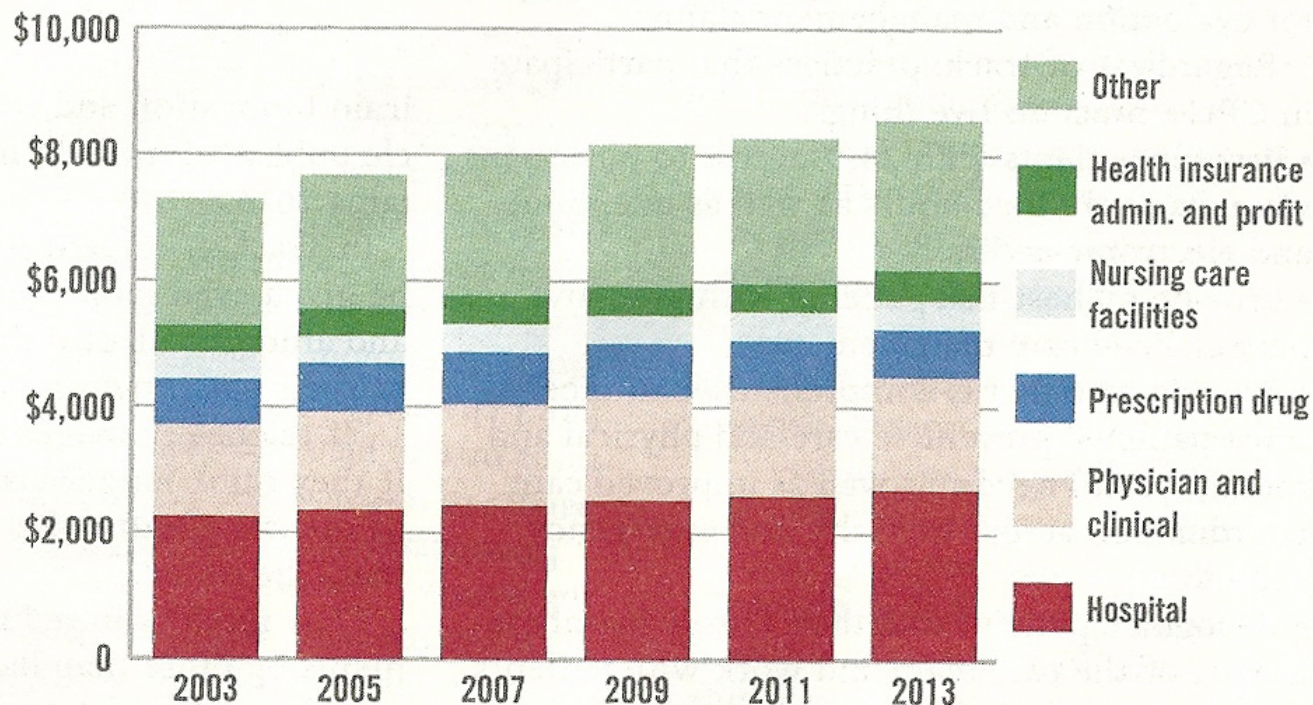
Overall US Healthcare Spending on Drugs

Chart 1: Total Spending on Medicines US\$Bn



Per Capita US Spending on Drugs a Part of Overall Healthcare Costs

Per capita national health spending: Largest components



Frontline Medical News

Notes: Based on data from the Centers for Medicare & Medicaid Services. Adjusted to 2009 \$.

Source: Agency for Healthcare Research and Quality

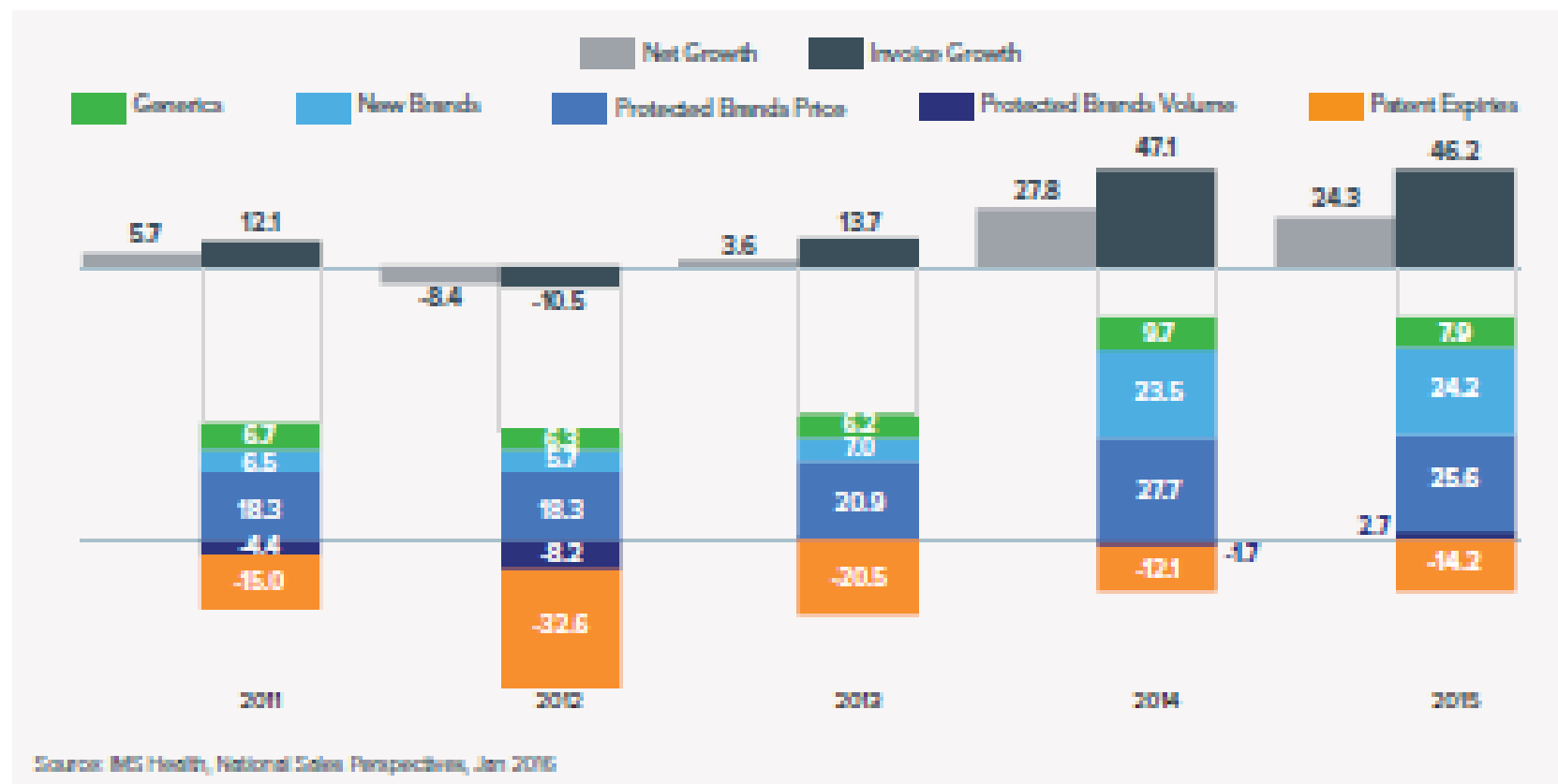
Trends in US Healthcare Spending on Drugs (2)

- Overall, more prices rose for brand name drugs but increases were smaller
- Drivers for price changes differ generic versus brand name
 - Generic drug prices overall were more likely to decline
 - 64% of generics saw price decreases (July 2013 to June 2014)
 - Marked drug price increases (>100%) were more likely for generics than brand name drugs:
 - Occur in a small fraction of overall generics (<10%)
 - Appear less frequent in 2015 vs 2014

- Source: IMS Institute for Healthcare Informatics imshealth.com

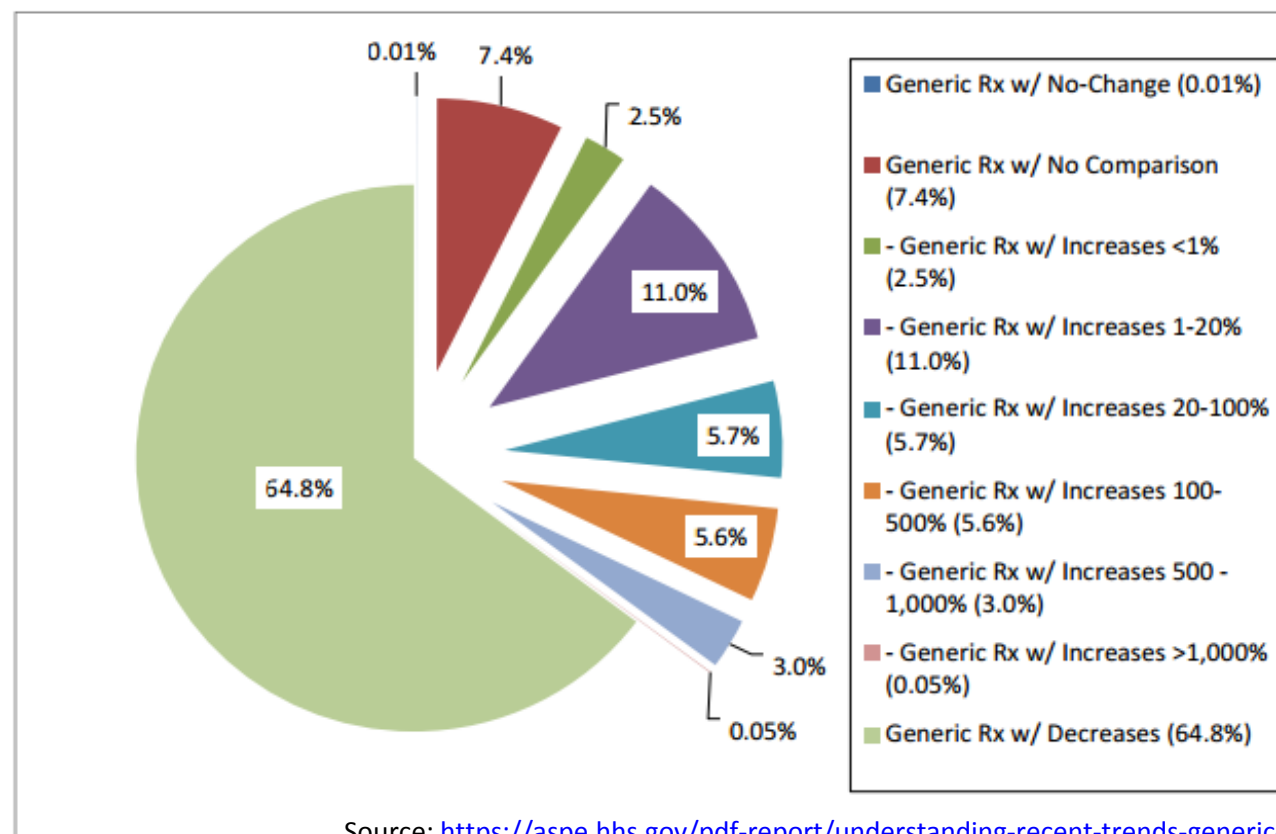
Drivers for Change in Drug Costs: Generic And Brand Name Drugs

Chart 2: Spending Growth and Drivers US\$Bn



Sources of Price Increases in Drug Costs: Changes in Pricing for Generic Products

Figure 1: Percent of Total Medicaid FFS Generic Prescription Expenditures, by Percent of Acquisition Cost Change between July 1, 2013 and June 30, 2014

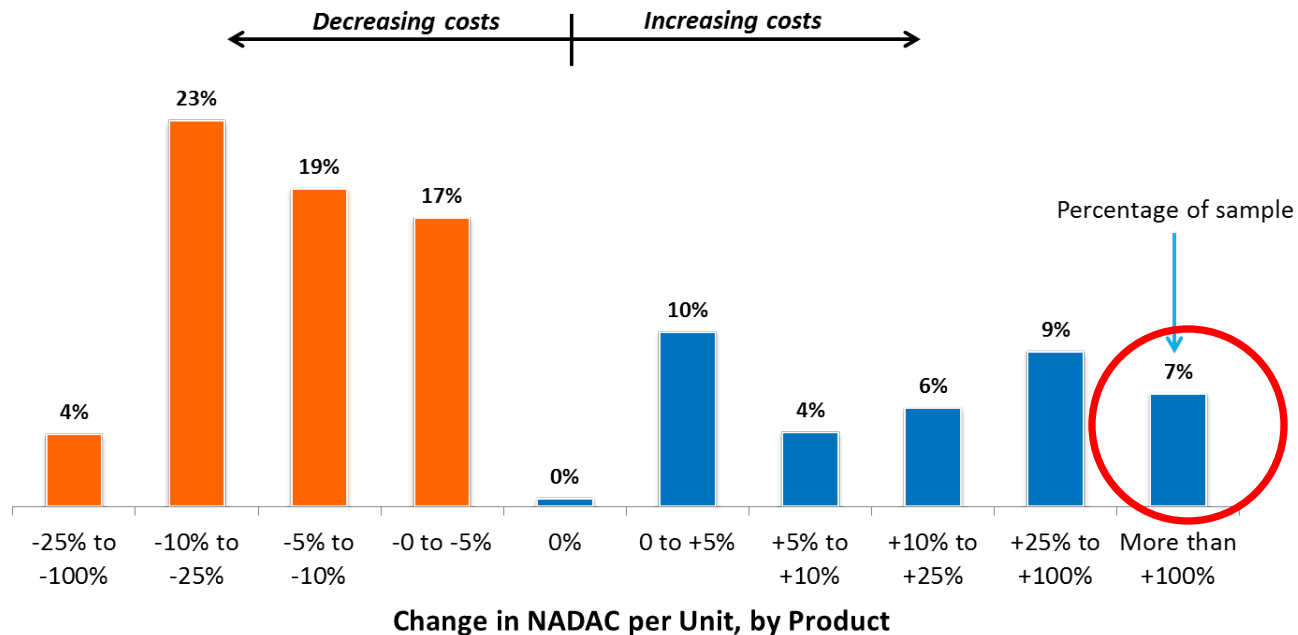


Source: <https://aspe.hhs.gov/pdf-report/understanding-recent-trends-generic-drug-prices>

Changes in Generic Drug Pricing

Generic Drugs, Change in NADAC per Unit, April 2014 vs. April 2015

N=1,796 products



NADAC = National Average Drug Acquisition Cost

Source: Pembroke Consulting analysis of Center for Medicare & Medicaid Services data files

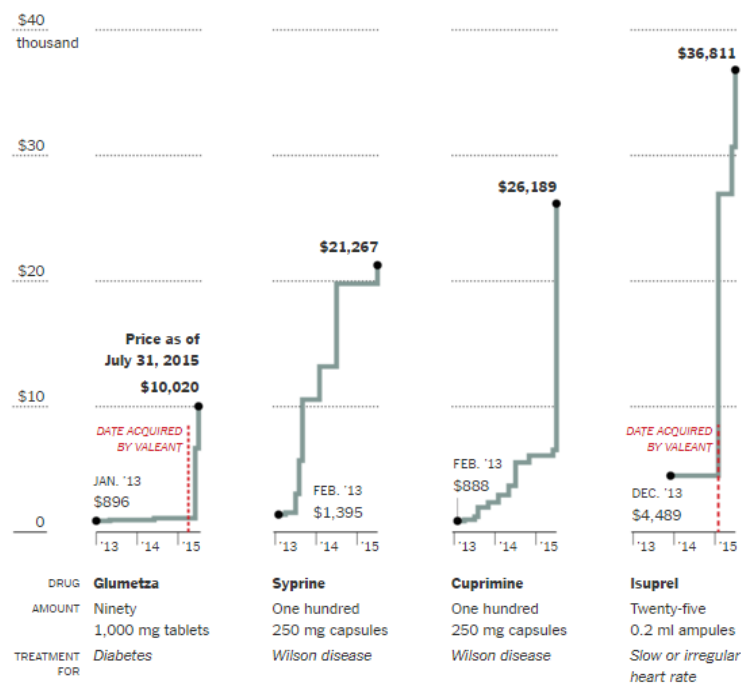
Published on Drug Channels (www.DrugChannels.net) on April 15, 2015.

Recent Pronounced Generic Drug Price Changes

For Prescription Drugs, Some Astronomical Price Increases

Valeant Pharmaceuticals has made a business of buying prescription drugs and raising their prices when possible. Now some members of Congress are demanding information from the company about price increases on two heart drugs, one of which is Isuprel. Some examples of price increases in Valeant's drugs over the last several years:

List prices for some of Valeant's prescription drugs



Note: The rights to Syprine, Cuprimine and Demser were acquired by Valeant in 2010.

Source: AB Bernstein

Source:

<http://www.nytimes.com/2015/10/05/business/valeants-drug-price-strategy-enriches-it-but-infuriates-patients-and-lawmakers.html>

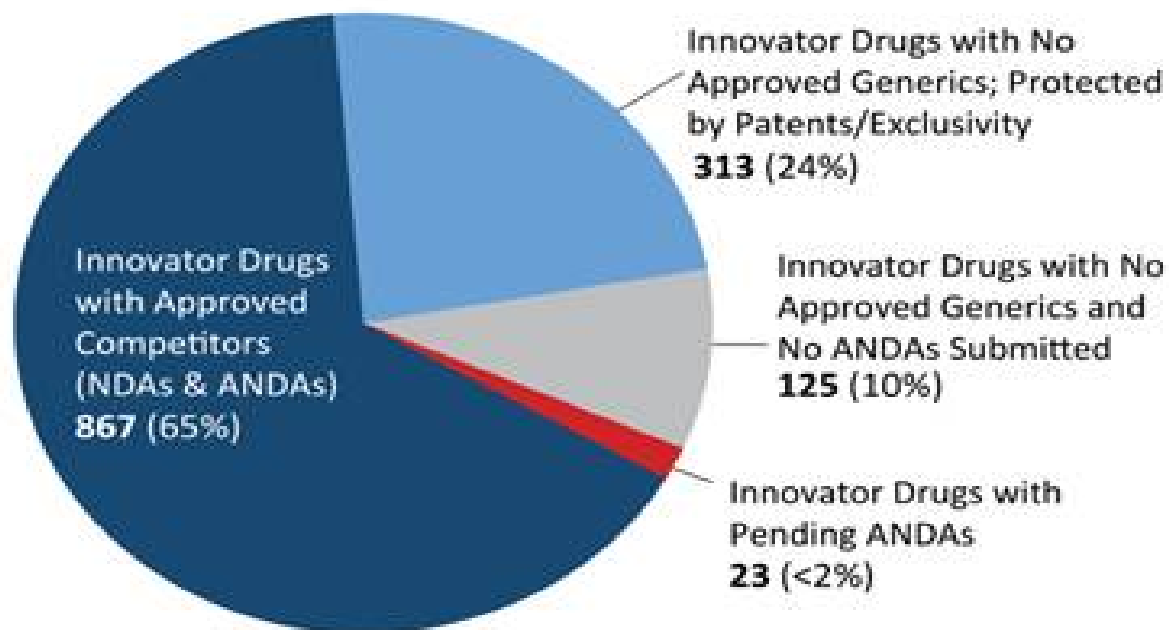
Trends in US Healthcare Spending on Drugs (3)

- Central Theme: Role of Competition in Drug Pricing
 - Generics
 - Brand Name S
 - Biosimilars

- Source: IMS Institute for Healthcare Informatics imshealth.com

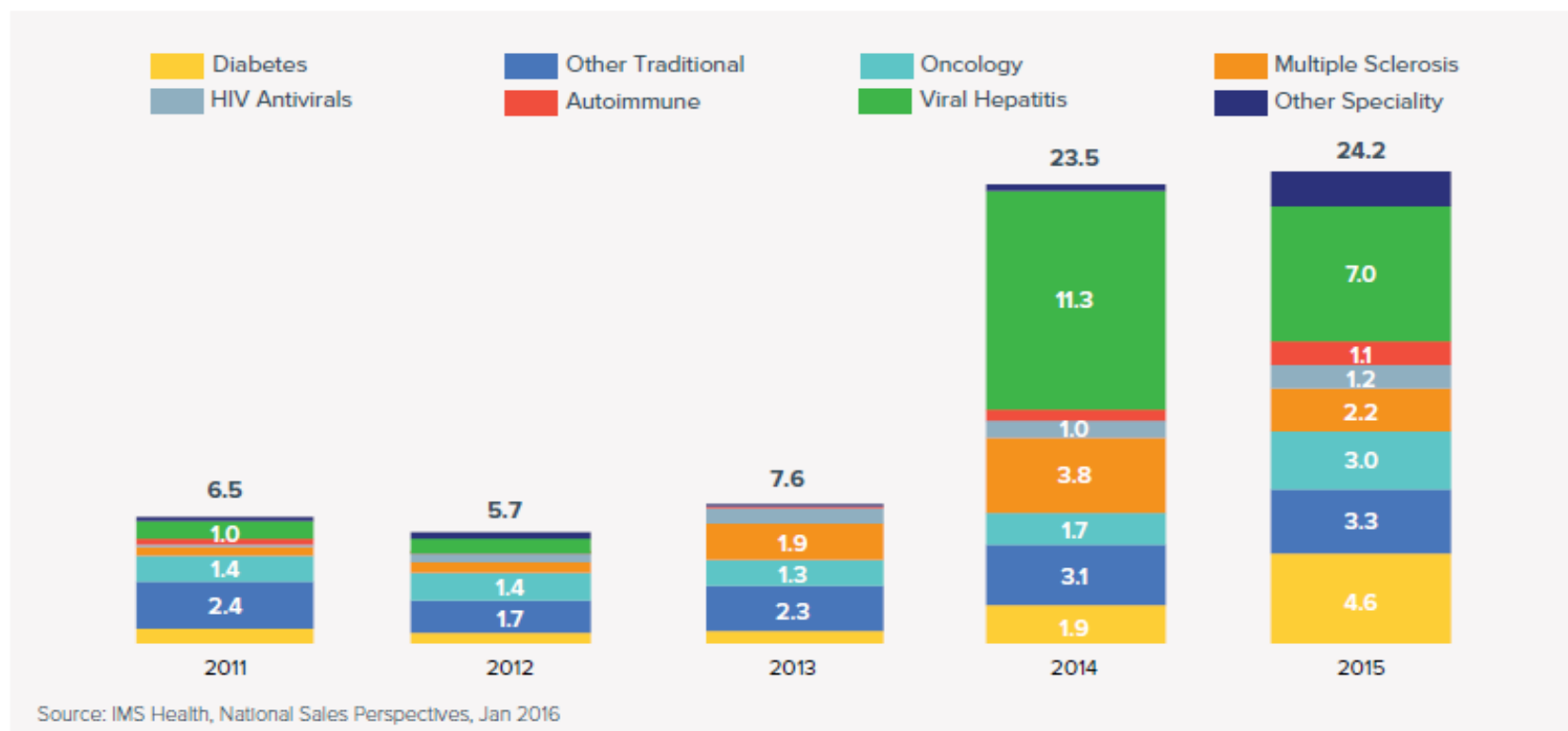
Price Increases for Generics : The Role of Competition

The Generic Drug Picture



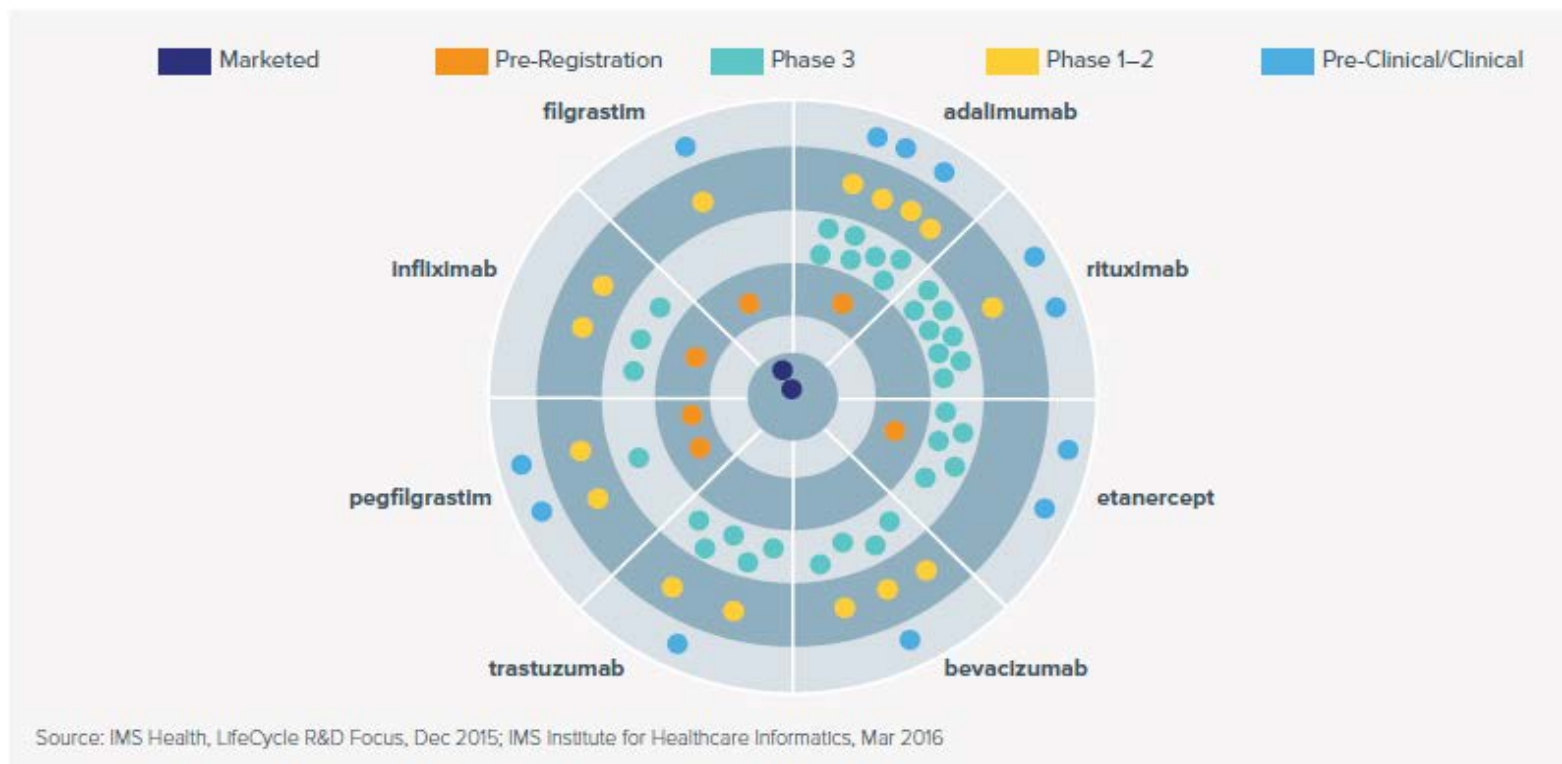
Future of Changes in Brand Name Drug Costs: Effect of Competition and Therapeutic Area

Chart 5: New Brand Spending Growth US\$Bn



Future of Drug Pricing and Competition: Biosimilars

Chart 19: U.S. Biosimilar Pipeline for Biologics with the Greatest Number of Biosimilar Candidates



Summary: Trends in US Drug Pricing

- Drug prices continue to rise, reflecting overall increases in healthcare costs
- Generic and brand name drugs have different trends, perhaps reflecting different drivers of pricing

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