

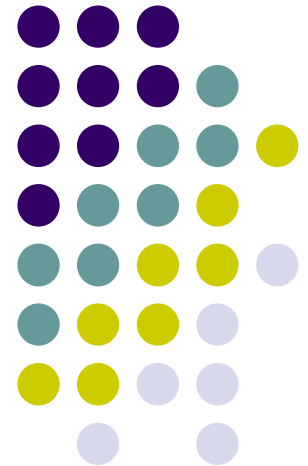
Drug Pricing, Repricing, Rebates, and Patient Access

Jack Hoadley, Ph.D.

Health Policy Institute, Georgetown University

Bipartisan Policy Center

April 13, 2016

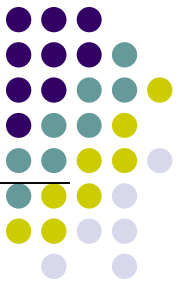


Credits and Notes



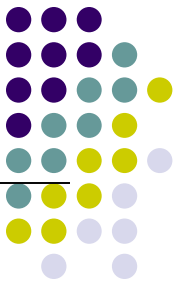
- Some of my drug policy research has been done under contract with the Kaiser Family Foundation
- Find links to full reports:
hpi.georgetown.edu/medicarepartd
- Thanks to Kaiser Family Foundation and the Medicare Payment Advisory Commission for use of their slides

Outline



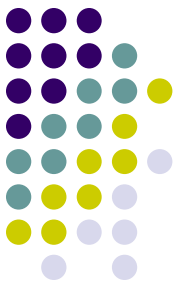
- Background basics
- How are drugs priced?
- Who gets what rebate?
- How are drugs re-priced over time?
- Do payer actions affect patient access
- Looking to the future

Background

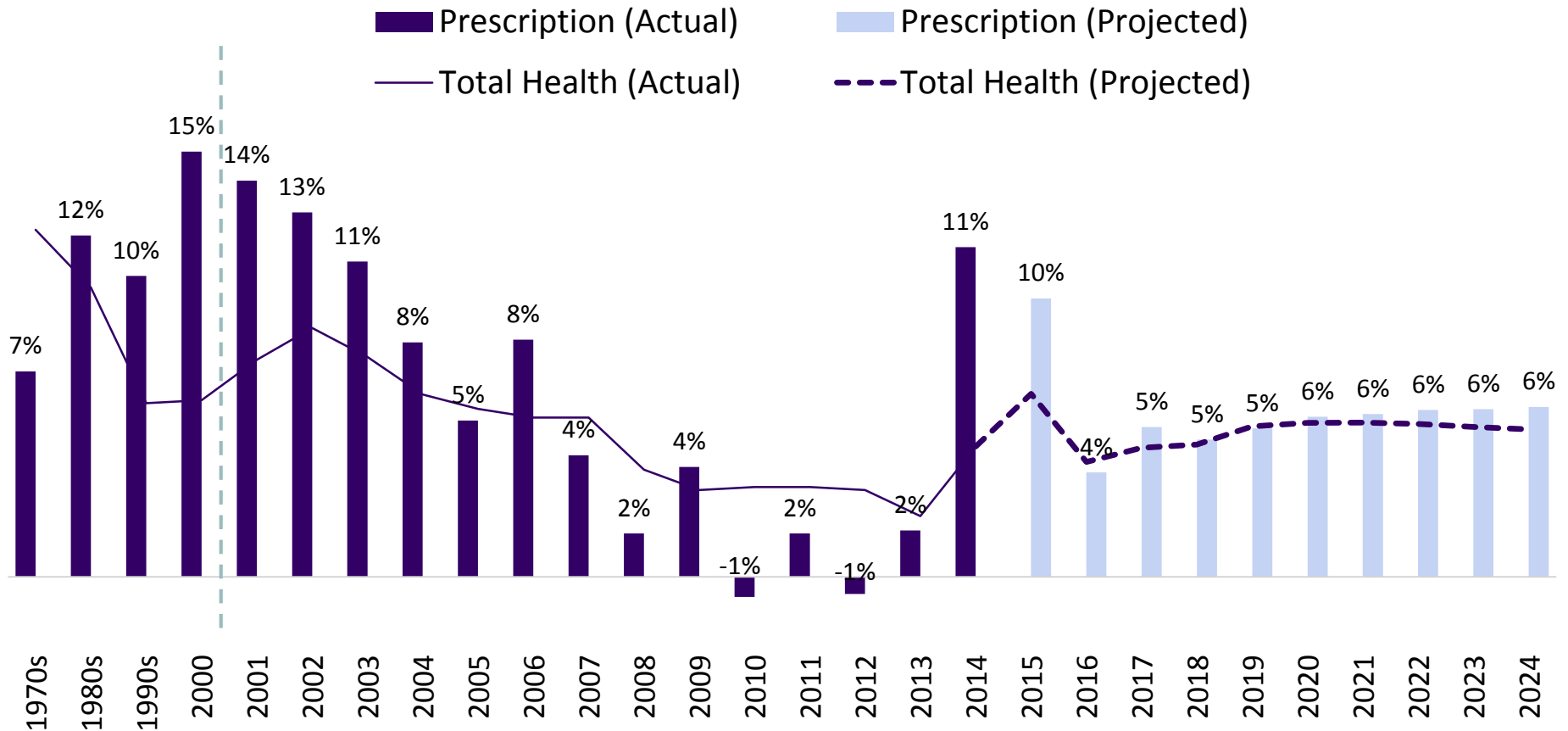


- Drug spending trends
- Brands, generics, and specialty drugs
- Components of the drug supply chain
- Flow of dollars for drug purchases
- Drug pricing terminology and definitions

Drug Spending Growth, 1970s-2024



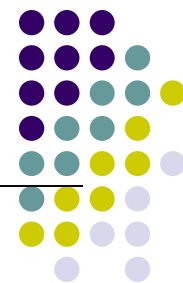
Average annual growth per capita, actual and projected



NOTE: Average annual growth rate of prescription drug spending per capita for 1970's – 1990's; annual change in actual prescription drug spending per capita 2000 – 2014 and projected prescription drug spending per capita 2015 – 2024. 2014 to 2015 percent changes are calculated using 2014 actual and 2015 projected amounts.

SOURCE: Kaiser Family Foundation analysis of National Health Expenditure (NHE) Historical (1960-2014) and Projected (2014-2024) data from Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group (Accessed on December 7, 2015)

Drug Spending as Share of Health

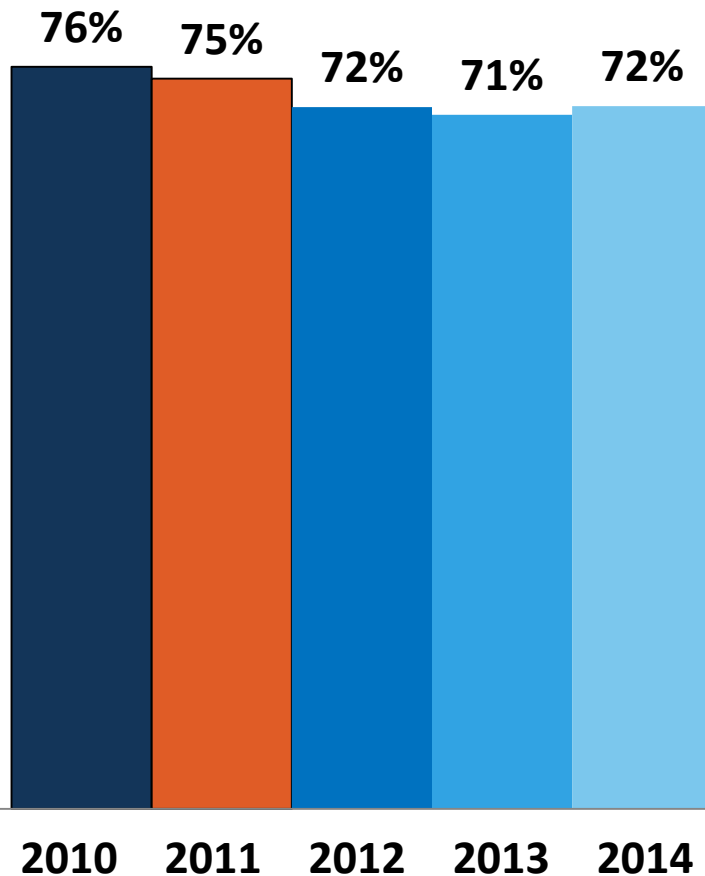


- Retail drug spending = all spending at outlets that directly serve patients
 - 1965-2015: as low as 6% of health spending versus 12% today
- Non-retail drug spending = spending by medical providers for drugs they provide to patients
 - Inpatient hospital, outpatient hospital, physicians' offices, infusion centers
 - 2009-2015: about 4-5% of health spending
- Combined retail and non-retail drug spending:
 - 2015: 17% of spending on personal health services

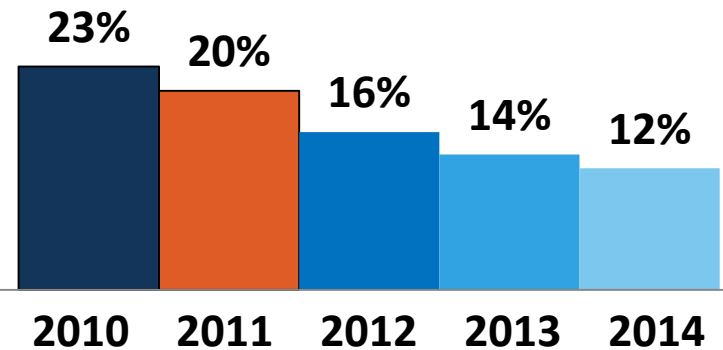
Brand Versus Generic Drugs, 2010-2014



Share of Spending: Brand Drugs



Share of Dispensed Prescriptions: Brand Drugs



1998 brand share of prescriptions = 49%

Specialty versus Traditional Drugs

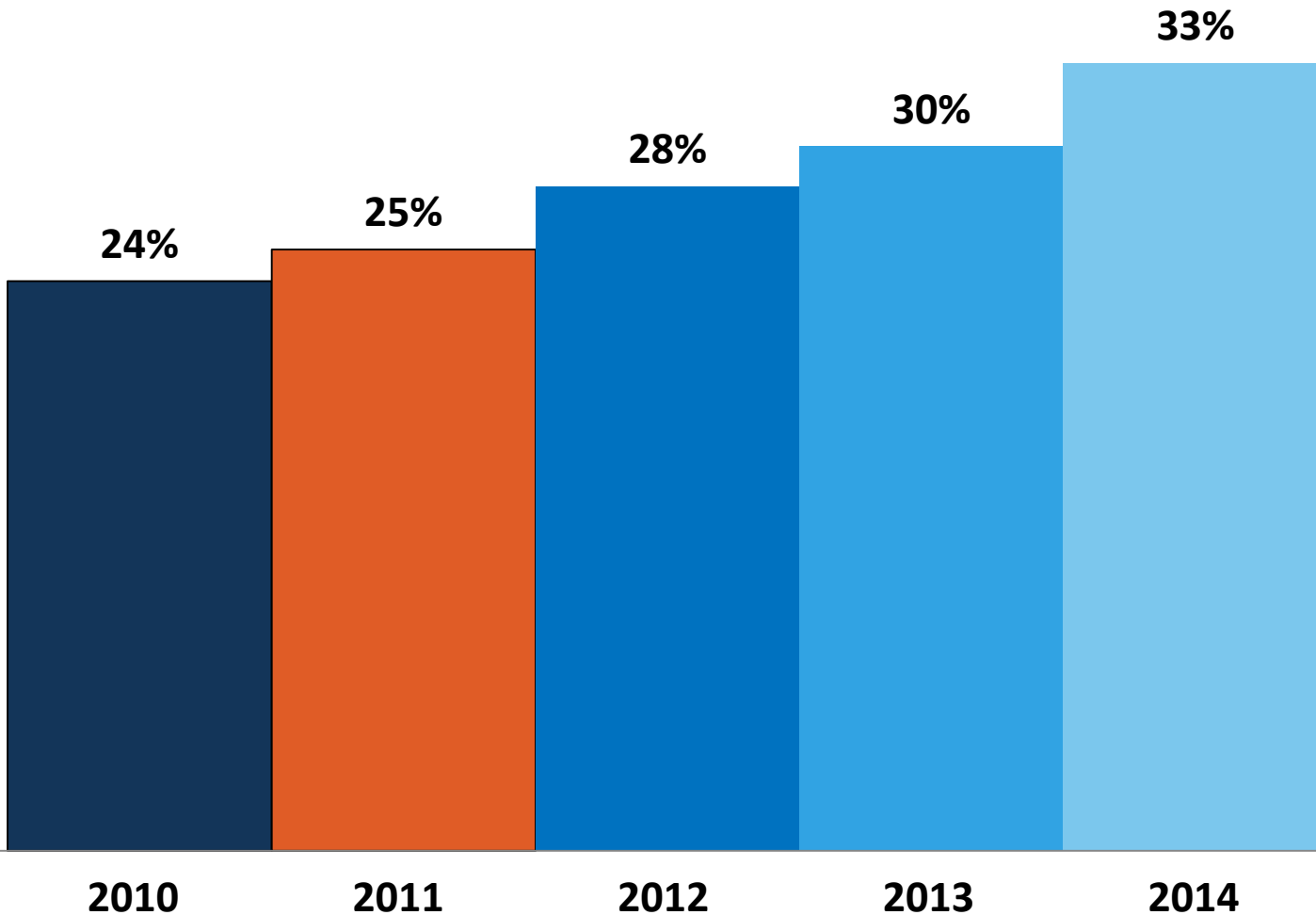


- No universal definition
- Characteristics tend to include:
 - Expensive (at least \$600/month for Part D)
 - Manufactured in living systems (biologicals)
 - Difficult to administer; may be injected or infused
 - Prescribed by specialist physicians
 - May require complex patient follow-up, monitoring
 - Used to treat serious conditions for which few or no alternative therapies available
 - Administered through specialty pharmacies
 - Require special handling (temperature control)

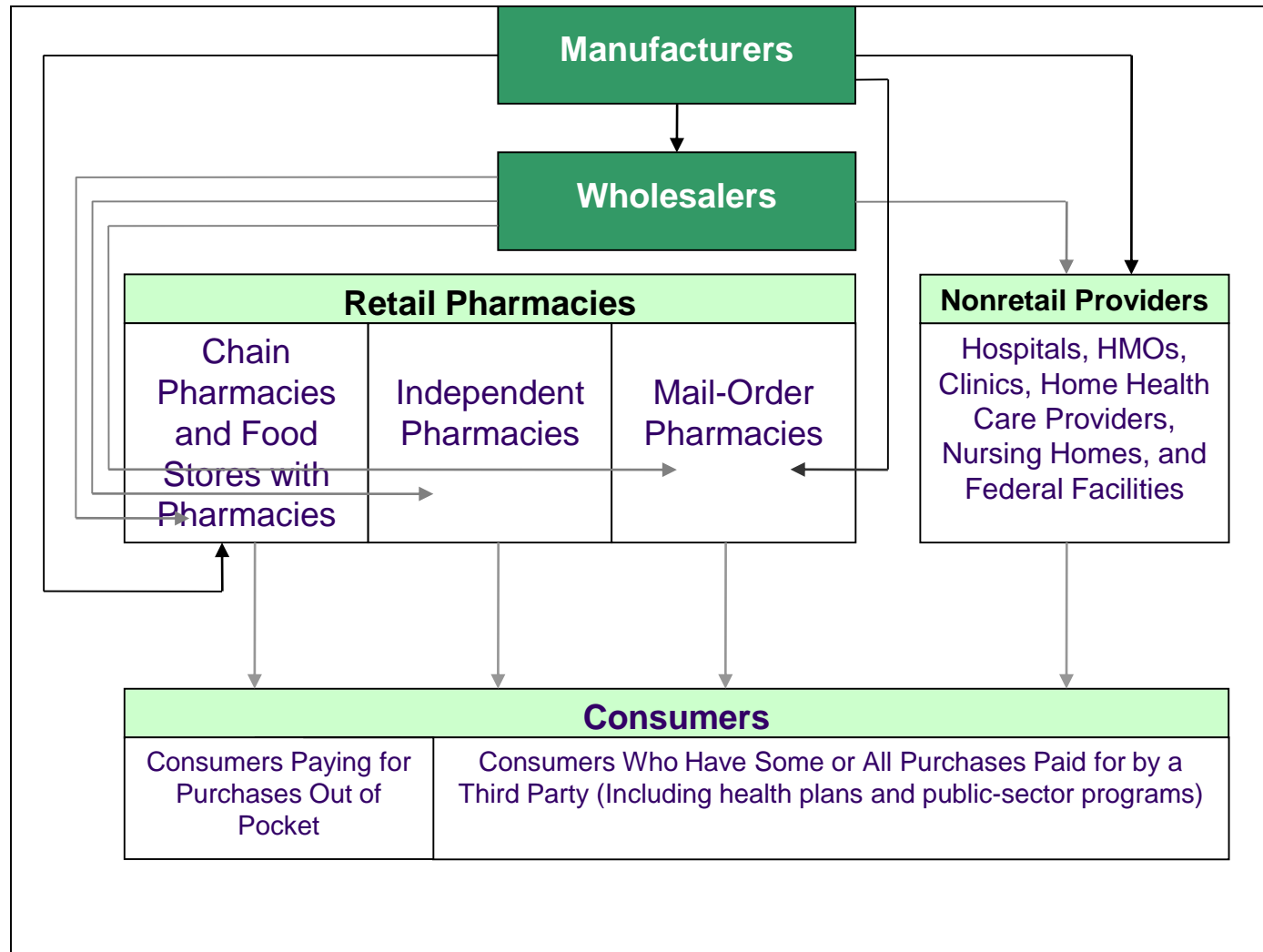
Spending on Specialty Drugs, 2010-2014



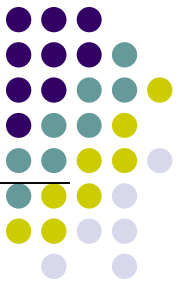
As Share of Total Spending



Supply Chain for Drug Delivery



Supply Chain Functions

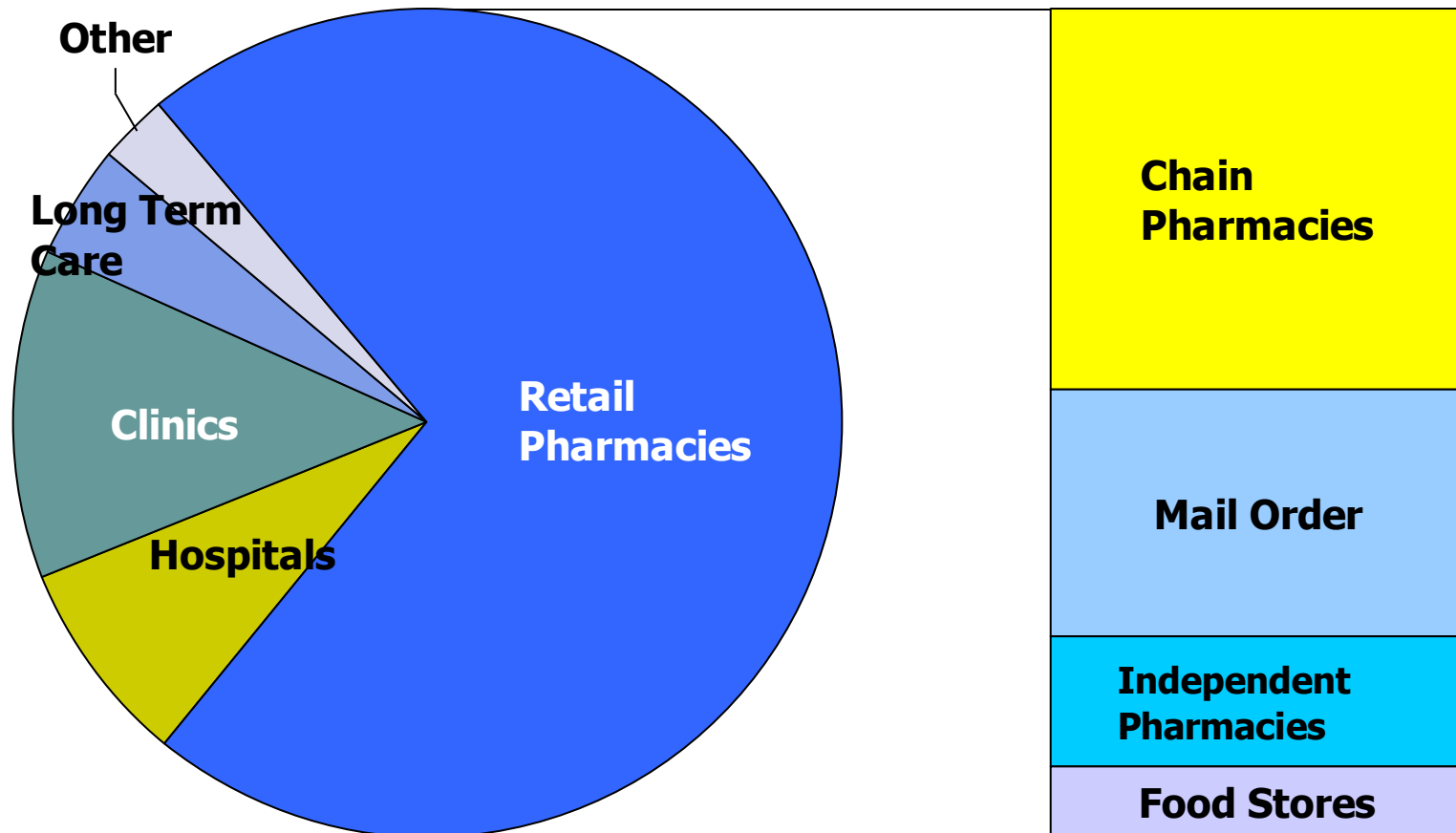


- **Manufacturers**
 - Develop, produce, and market drugs
 - Set list prices as a basis for price negotiations
 - Negotiate rebates and discounts with plans or PBMs
- **Wholesalers**
 - Link manufacturers with outlets that dispense drugs
 - Help smaller pharmacies negotiate with generic manufacturers
- **Pharmacies**
 - Stock drugs and fill prescriptions on demand
 - Negotiate discounts with generic drug manufacturers
- **Pharmacy Benefit Managers (PBMs)**
 - Administer drug benefit for health plan or employer
 - Build pharmacy networks
 - Negotiate rebates with manufacturers

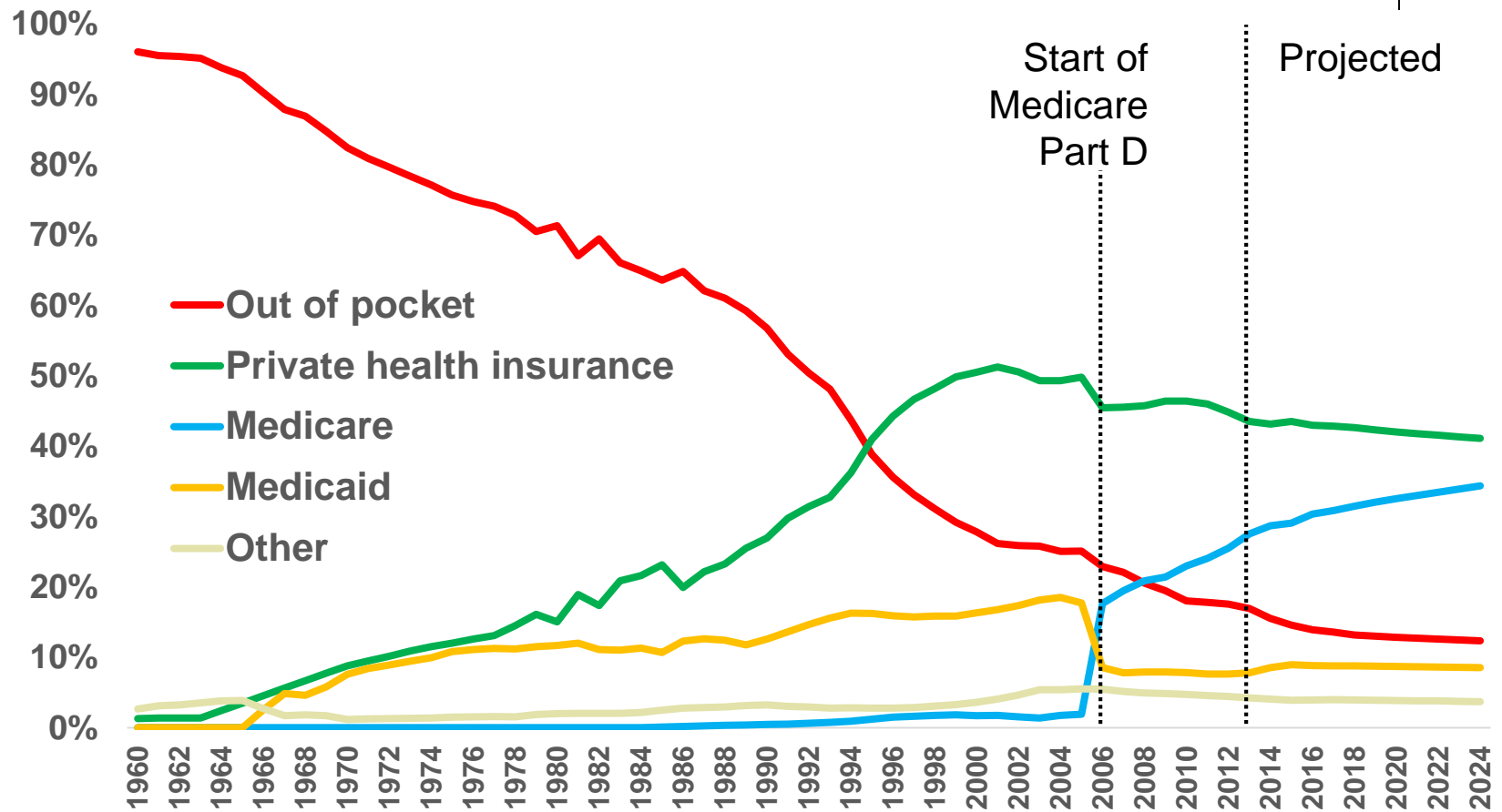
Supply Chain Market Shares



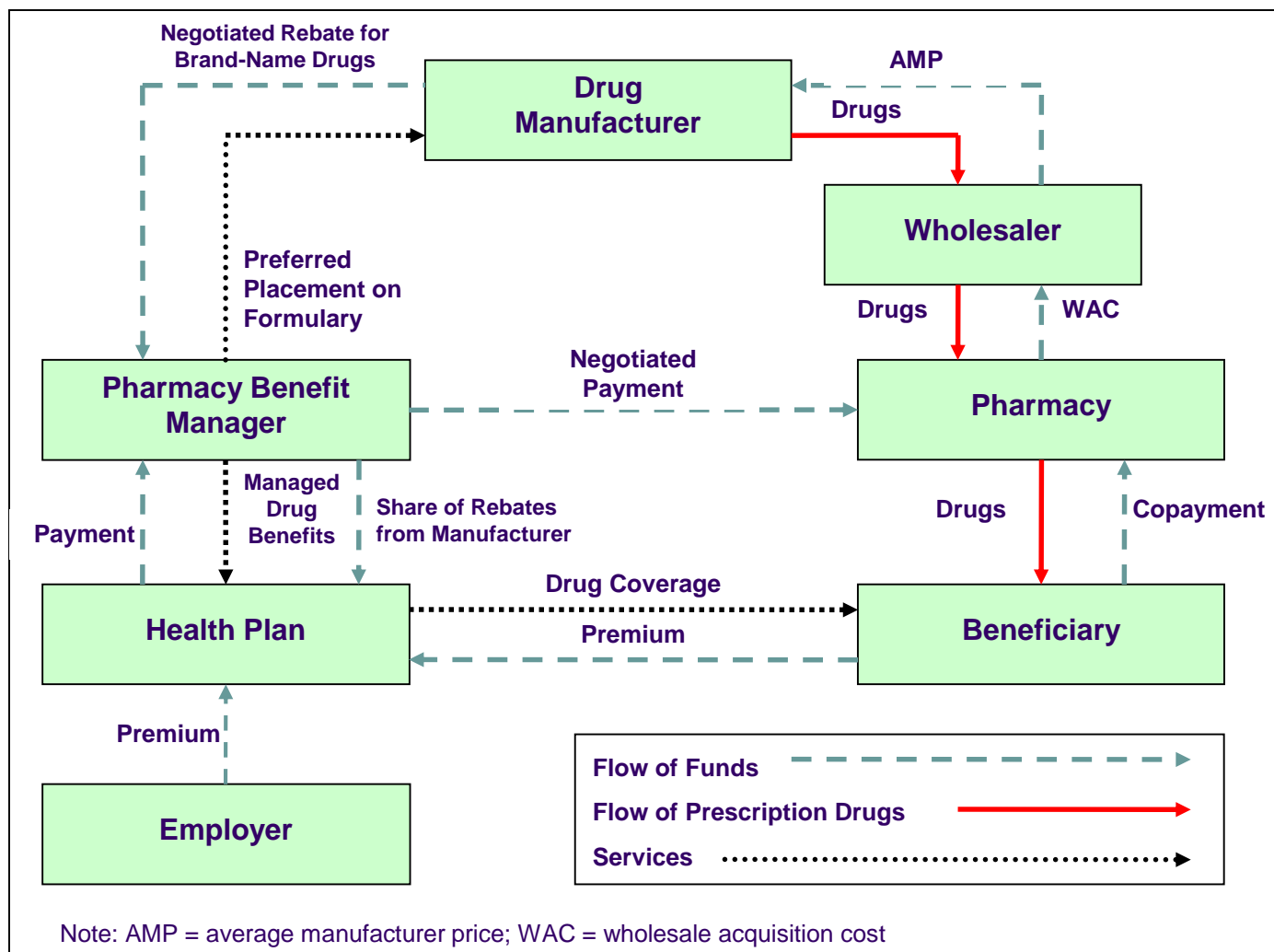
By non-discounted spending, 2014



Drug Spending by Payer, 1960-2024

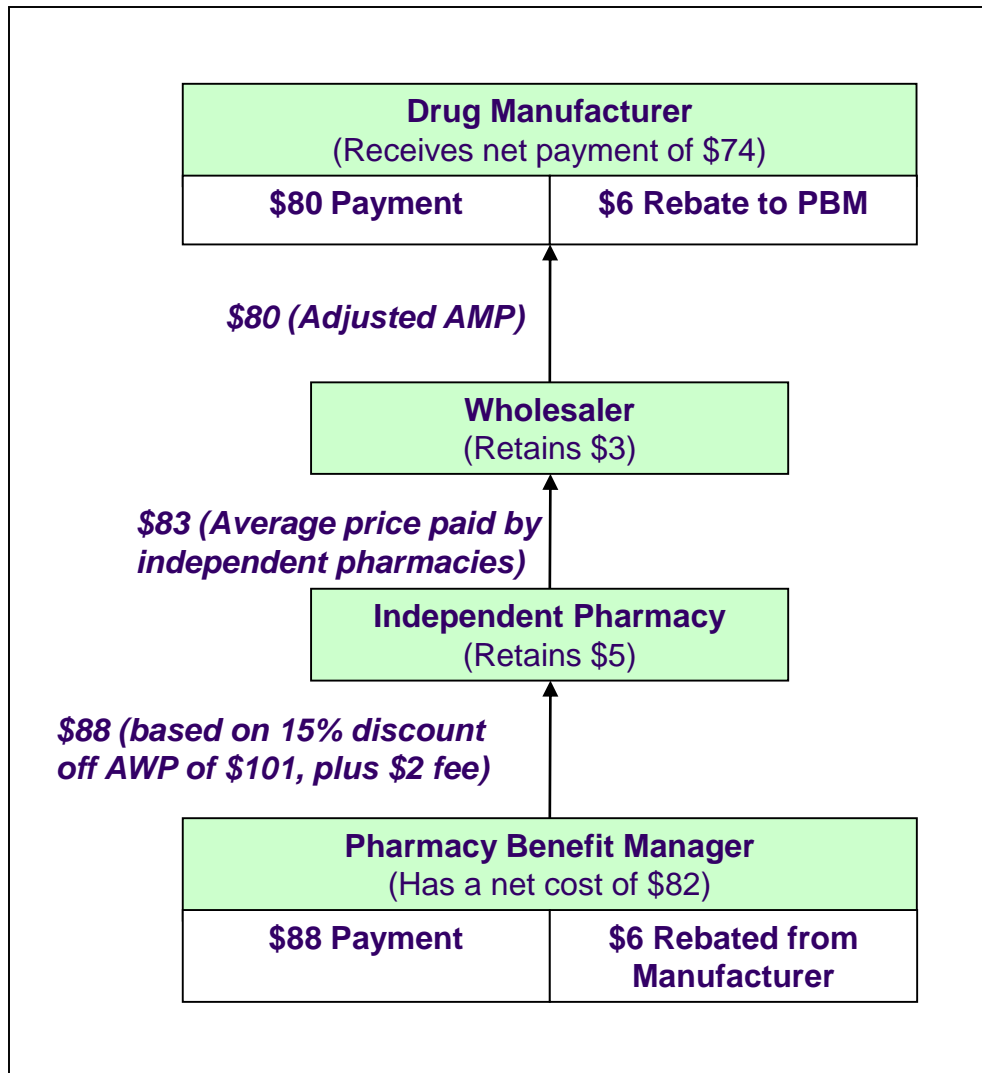


Flow of Funds for a Brand Drug



Source: Congressional Budget Office, Prescription Drug Pricing in the Private Sector, 2007

Pricing for a Brand Drug



How Are Drugs Priced?



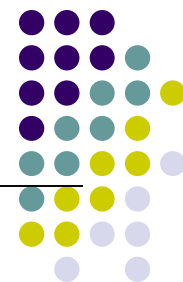
- What is the “price”?
- Pricing rationales
- Factors influencing pricing
- Price variation by payer

What is the Price of a Drug?



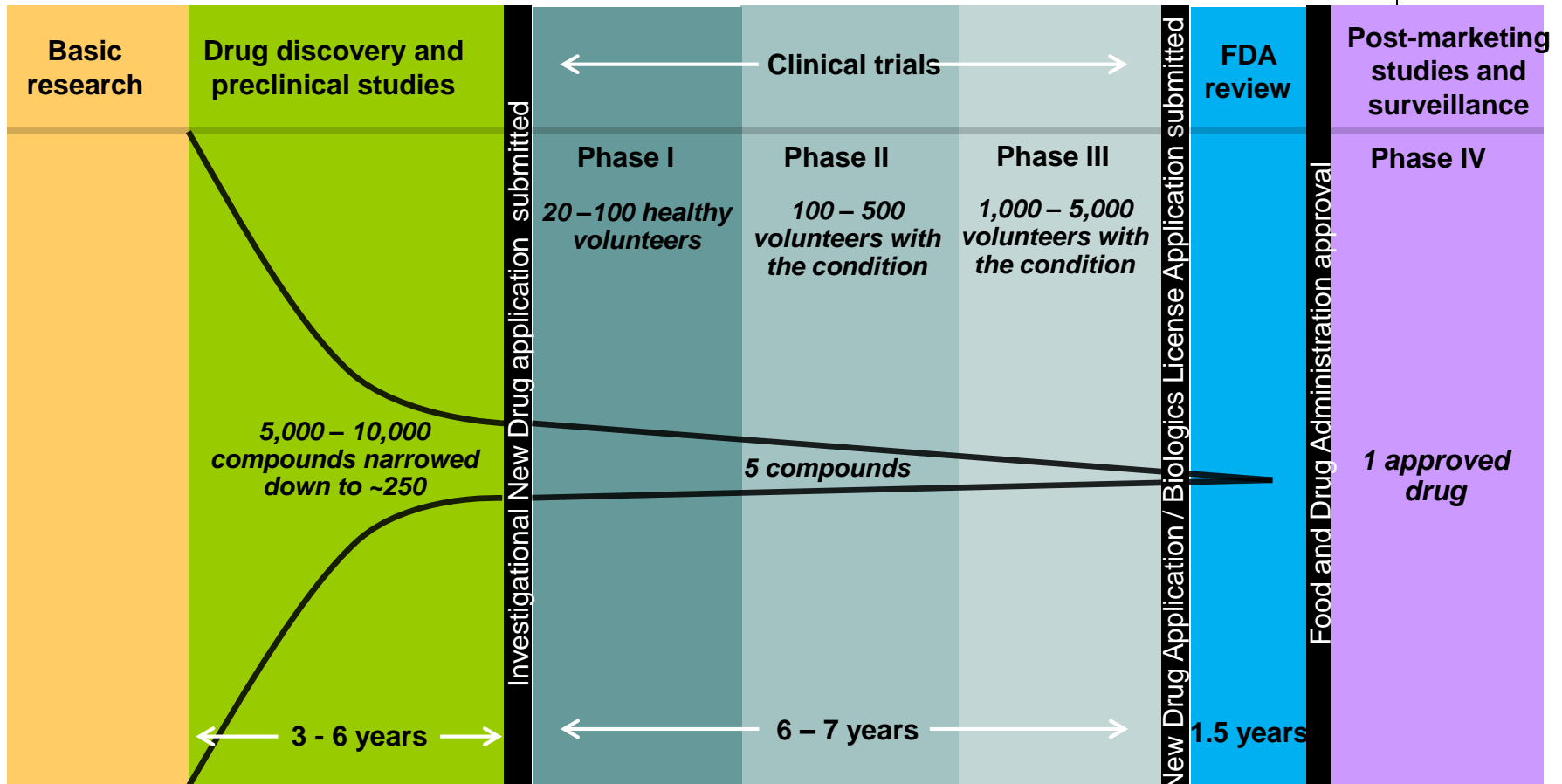
- List prices
 - AWP = average wholesale price, defined as the published list price that wholesalers post for retailers and other providers
 - WAC = wholesale acquisition cost, defined as list prices posted by manufacturers
- Price measures calculated by the government
 - AMP = average manufacturer price, defined as the average of prices actually paid by wholesalers and retailers who buy directly from manufacturers
 - ASP = average sales price, defined as the average price realized by manufacturers for sales to all purchasers net of rebates, discounts, and price concessions
- Discounts
 - Retail discounts = discounts available to large-volume retailers on purchases from wholesalers or manufacturers
 - Manufacturer rebate = amounts paid by manufacturer to health plan or PBM to create a discount price

Rationales for Launch Prices



- Lack of transparency
- Cost of research & development
 - Industry estimate: \$2.6 billion for an average drug
 - Source: J. DiMasi et al, Innovation in the pharmaceutical industry: New estimates of R&D costs, Journal of Health Economics May 2016. Tufts Center for the Study of Drug Development
- Savings accrued for the health care system as a result of taking the new drug
- Presence and pricing of competing therapies
- Strategic positioning relative to products on the market or coming soon

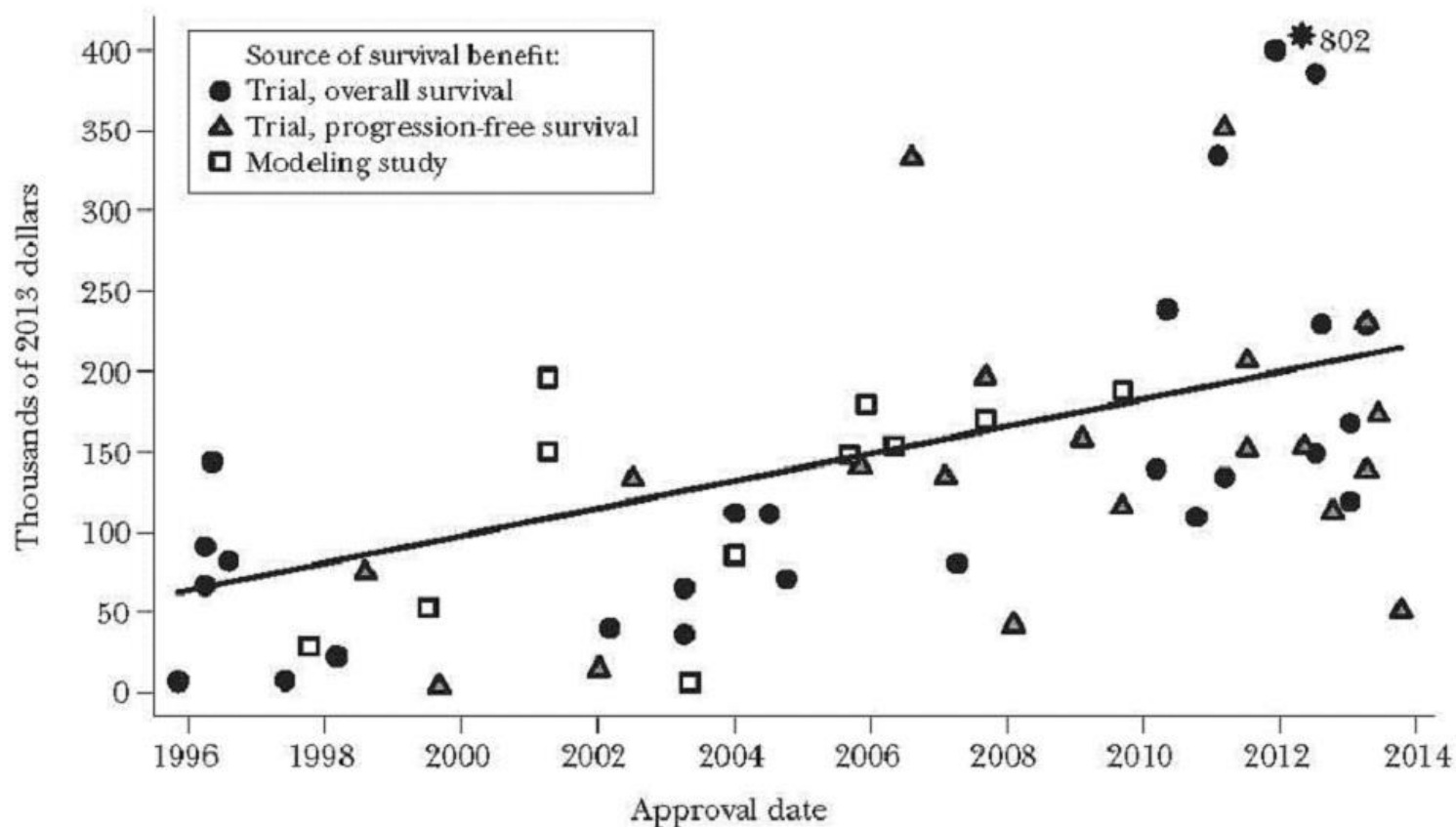
Drug Discovery, Development and Review



Price of Oncology Drugs per Life-Year Gained



Drug Price per Life Year Gained versus Drug Approval Date

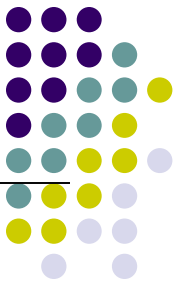


Supply-Side Factors Influencing Prices



- Increasing complexity of biopharmaceuticals
- Emphasis on treatments for small disease populations (e.g., orphan drugs), often with few competing therapies
- Patents and temporary monopolies granted by the government
- Consolidation within biopharmaceutical industry
- Changes in the drug supply chain

Demand-Side Factors Influencing Prices



- Shift from out-of-pocket purchases by consumers to a third-party payment system
- Shift from private to public insurance
- Consolidation in the insurance industry
- Discounts and rebates mandated by law (Medicaid, VA, DOD, 340B program)
- Increased demand as the population ages

Who Gets What Rebate?



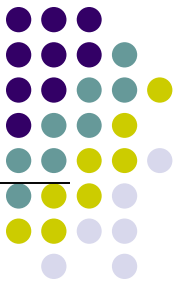
- Factors influencing rebates
- Trends over time
- Public-sector rebates

Factors Influencing Rebates



- Proprietary
- Ability of a payer to grow market share for the manufacturer's drug
- Ability of a payer to move market share
 - Encouraging use of one manufacturer's drug over competing therapies

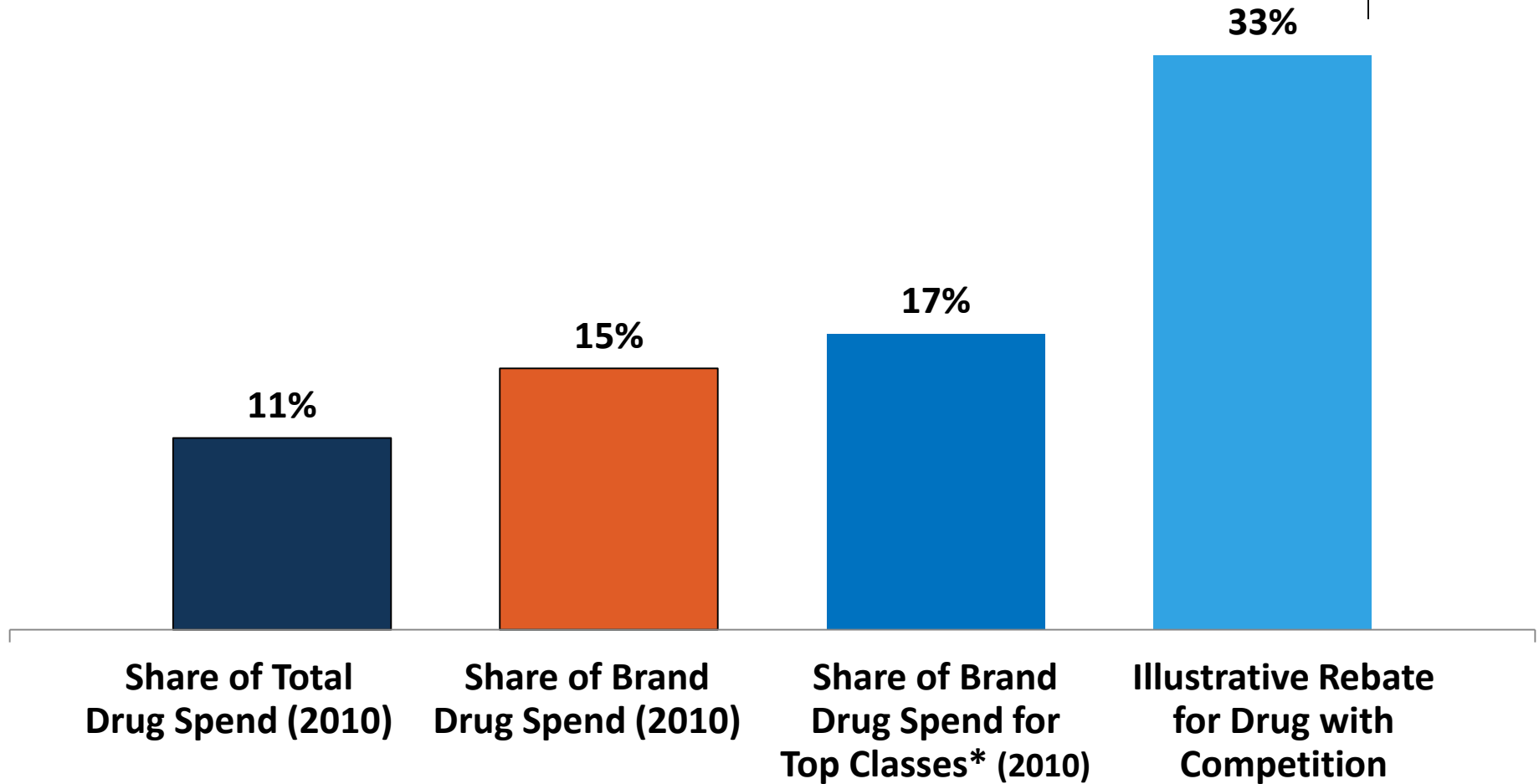
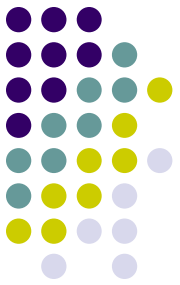
Tools Payers Use in Negotiating Rebates



- Formulary management tools
 - Exclusion of competing drugs from the formulary
 - Preferential tier placement on the formulary, with lower cost sharing for the consumer
 - Utilization management tools, such as prior authorization, for competing drugs
- Other factors
 - Evidence of comparative effectiveness or clinical preferences
 - Access to needed drugs for plan members
 - Marketing considerations

Estimated Rebate Amounts

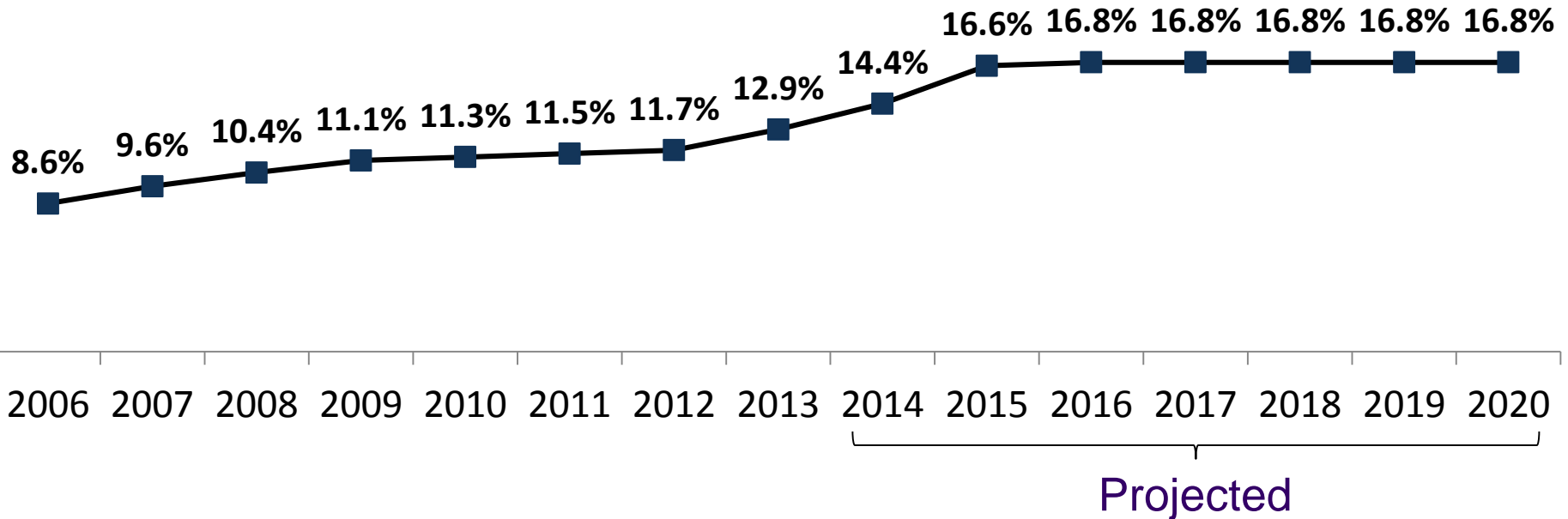
As Percentage of Drug Costs by Category



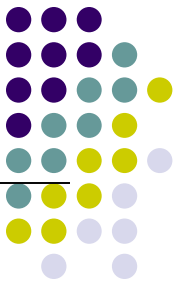
* Refers to the top 53 therapeutic classes of drugs, which accounted for 70 percent of Part D spending in 2010
SOURCE: Adapted from Congressional Budget Office, Competition and the Cost of Medicare's Prescription Drug Program, July 30, 2014

Trends in Medicare Part D Rebates, 2006-20

As Percentage of Total Drug Costs



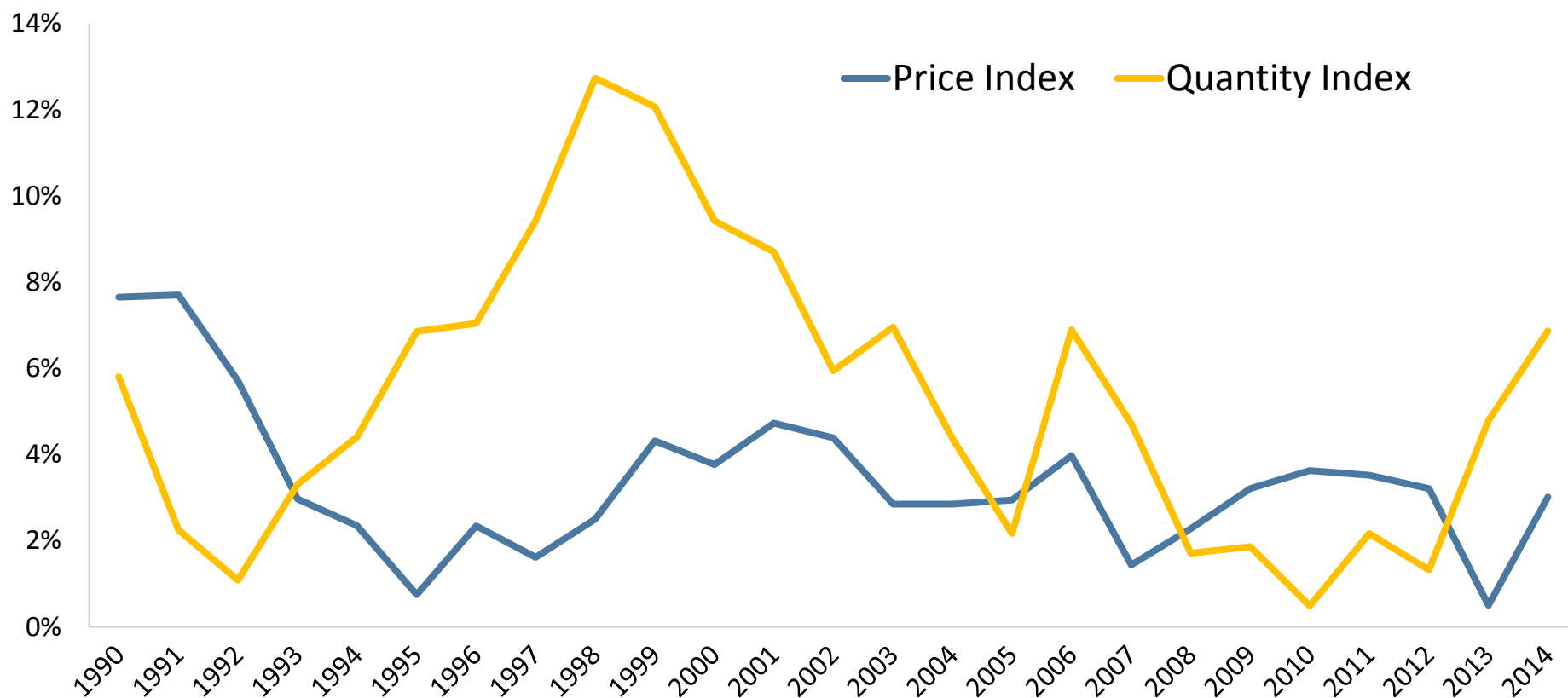
How Are Drugs Re-Priced?



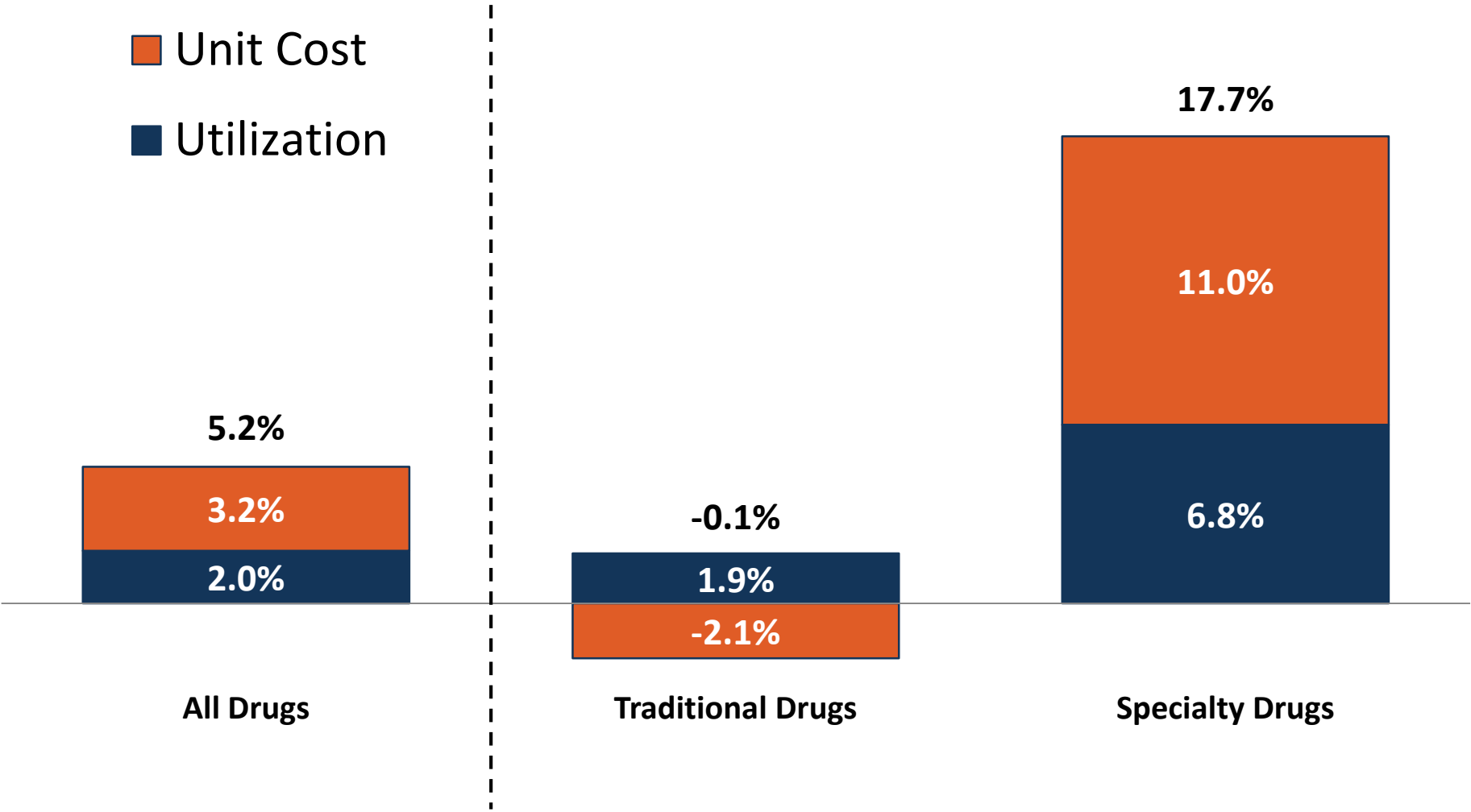
- Interaction of price and utilization
- Price trends over time
- Factors driving price changes for generics
- Impact of generic substitution
- Factors driving price changes for brand drugs, including specialty drugs

Growth in Drug Prices and Utilization

Annual percent change in price and quantity indexes of pharmaceutical and other medical products, index numbers 2009=100

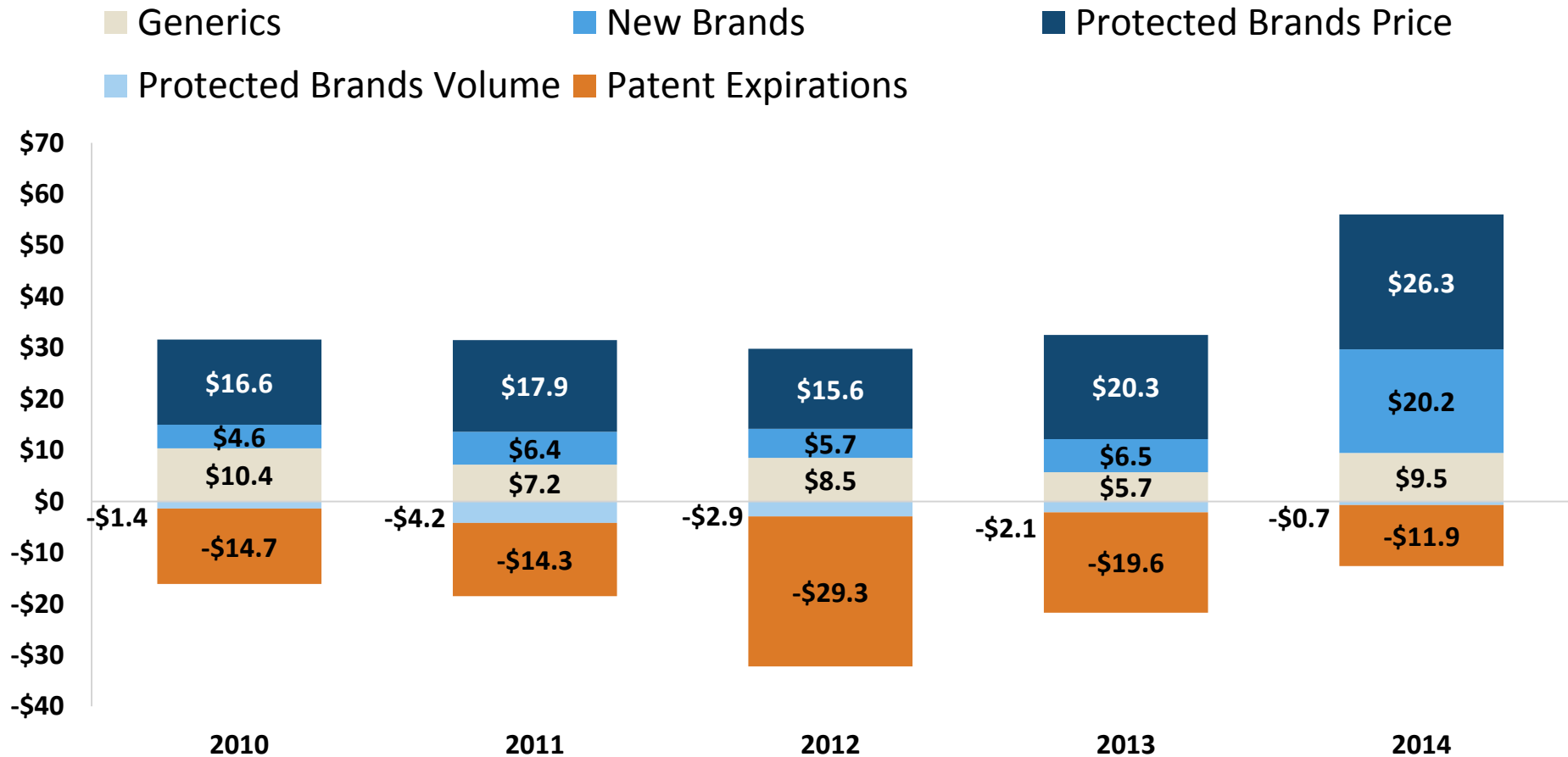


Components of Drug Spending Trend, All Payers, 2015 versus 2014



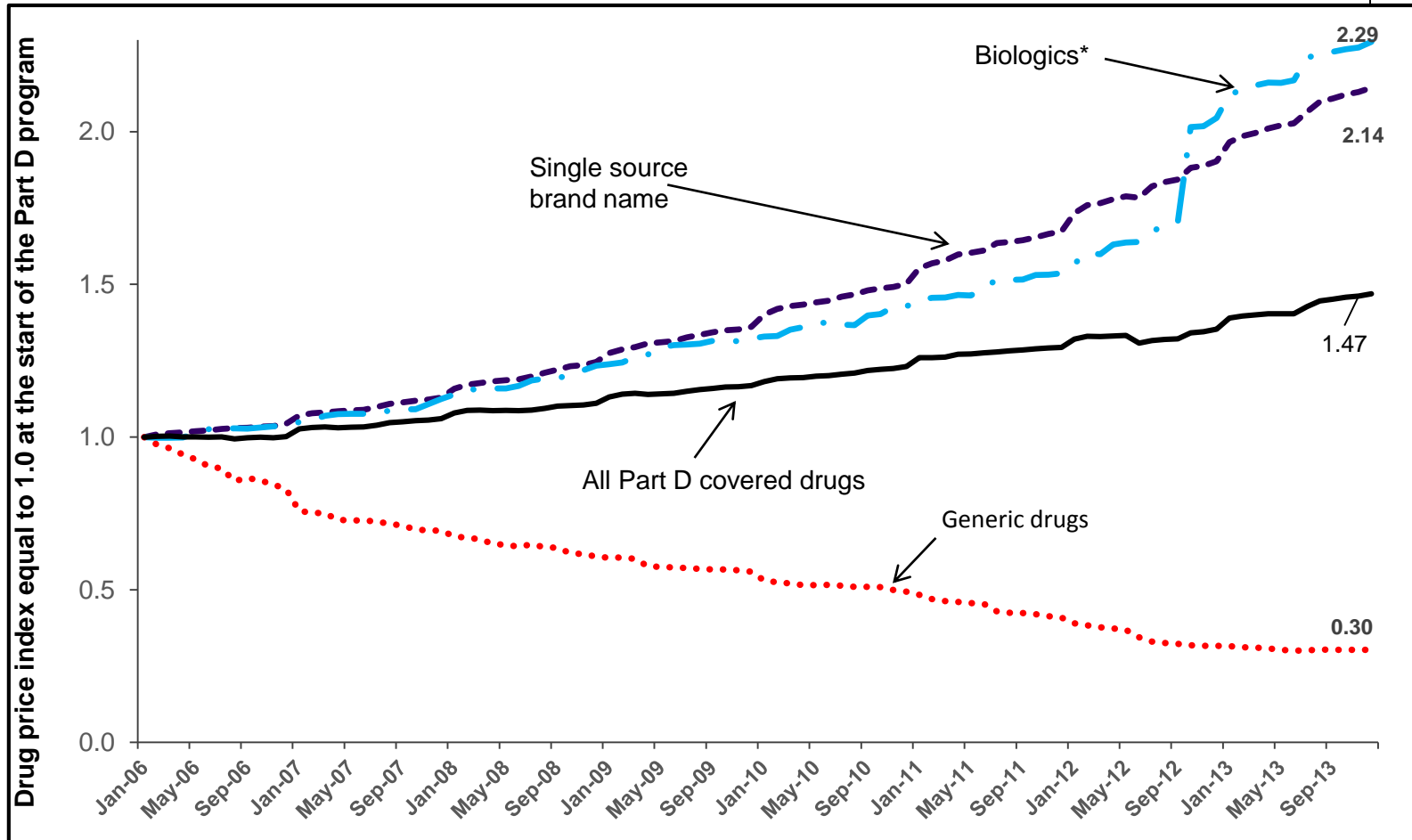
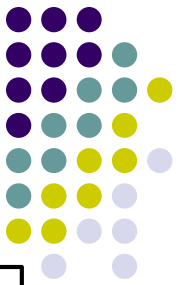
Components of Drug Spending Growth, 2010-2014

Contribution to growth in drug spending, by spending growth drivers, in billions, 2010 -2014



Source: IMS Institute for Healthcare Informatics. Medicines Use and Spending Shifts: A Review of the Use of Medicines in the U.S. in 2014.

Medicare Part D Drug Price Trends, by Brand-Generic-Biological Status, 2006-2013

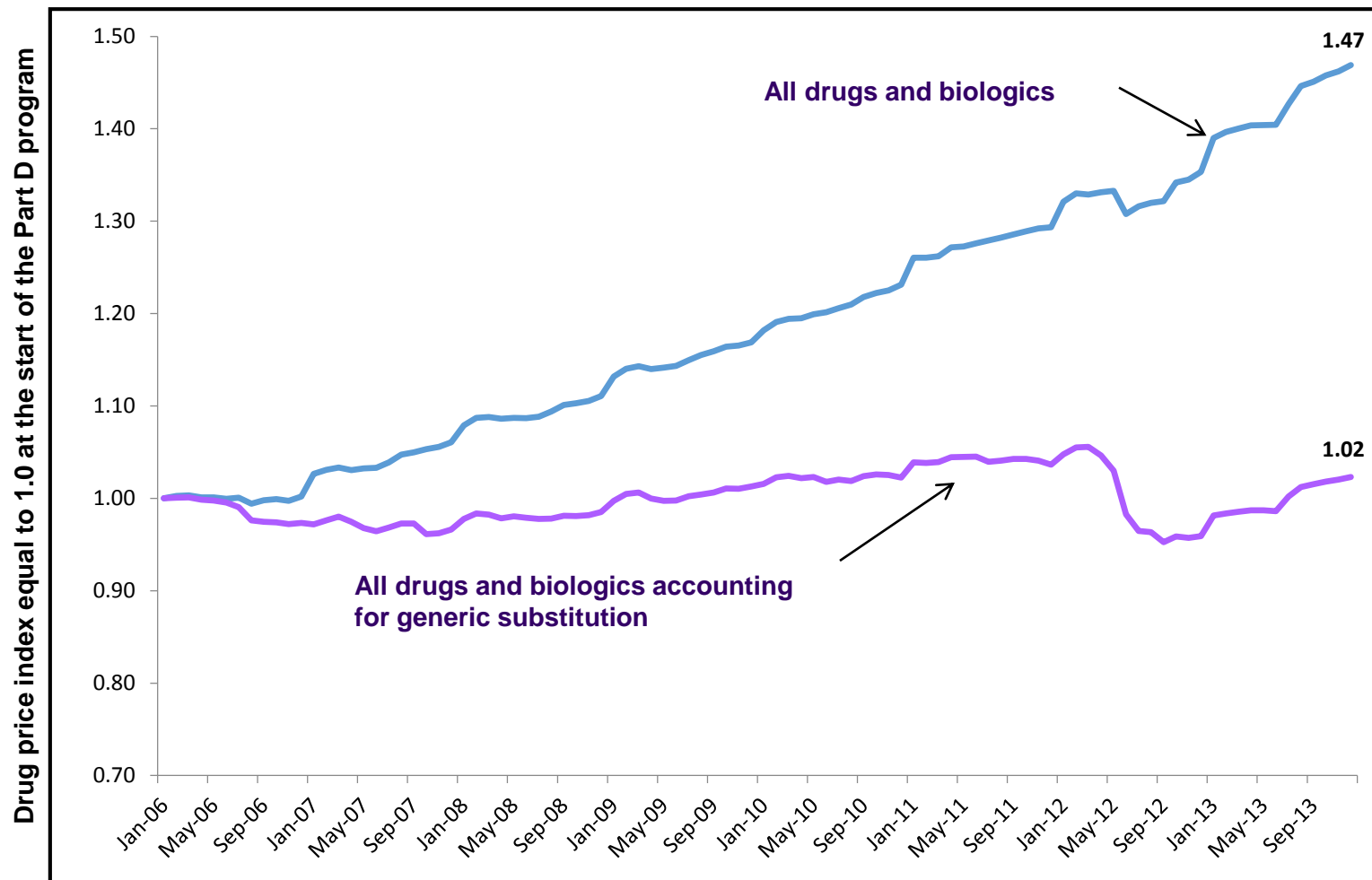


NOTE: Chain-weighted Fisher price indexes.

* The shift in biologics price index in October 2012 is due in part to a change in how prescription quantities were reported for Avonex.

SOURCE: Adapted from MedPAC, Report to the Congress: Medicare Payment Policy, March 2016, Figure 13-8 (Acumen LLC analysis for MedPAC)

Part D Drug Price Trends, with Effects of Generic Substitution, 2006-2013



NOTE: Chain-weighted Fisher price indexes.

SOURCE: Adapted from MedPAC, Report to the Congress: Medicare Payment Policy, March 2016, Figure 13-7 (Acumen LLC analysis for MedPAC)

Factor Driving Generic Price Changes

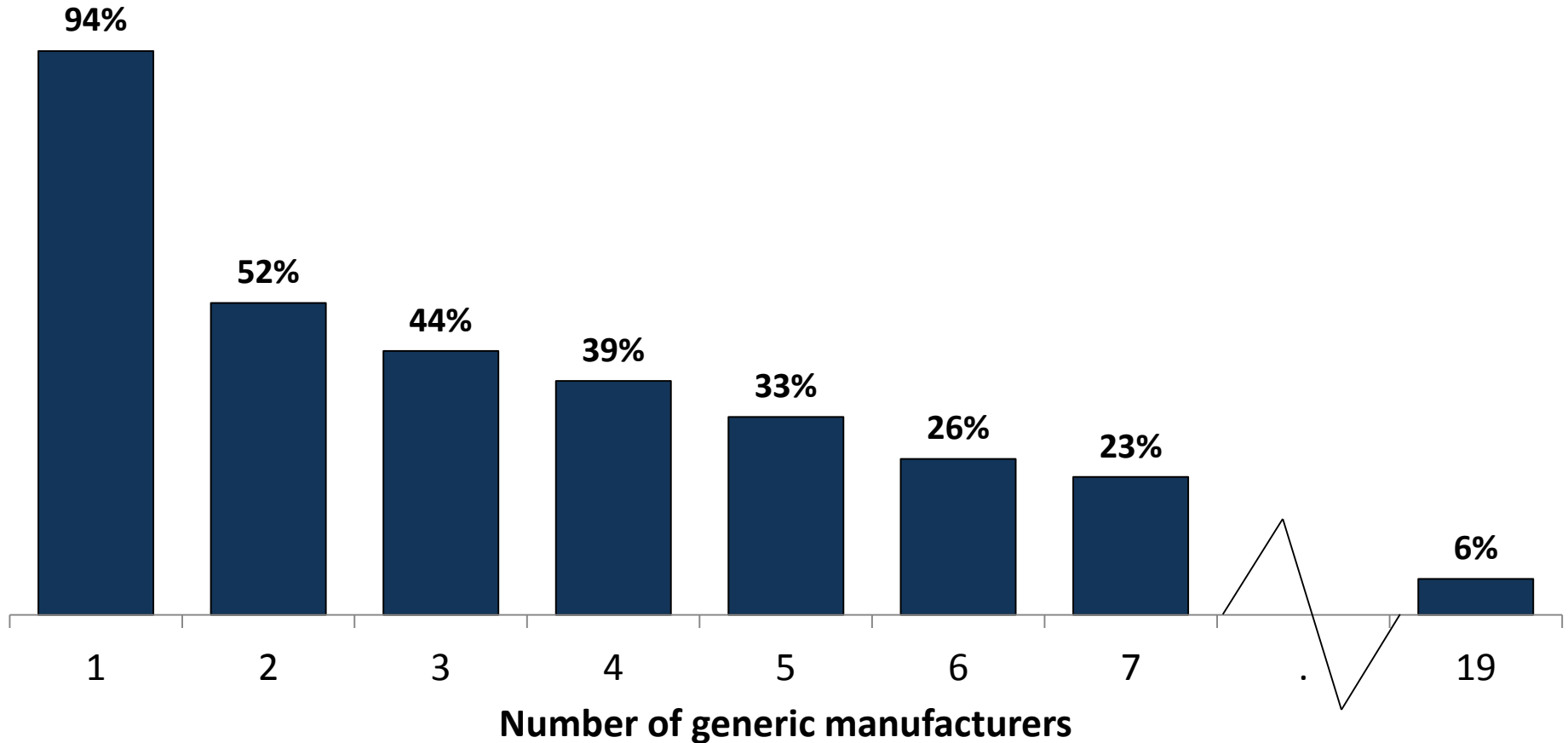


- Number of generic manufacturers in market
- Timing of generic approvals
- Special circumstances
 - Markets with limited entry of generics
 - Mergers and acquisitions, resulting in market concentration
 - Shortages resulting from permanent or temporary market exit
 - Special cases of new patents or market exclusivity (e.g., asthma drugs)

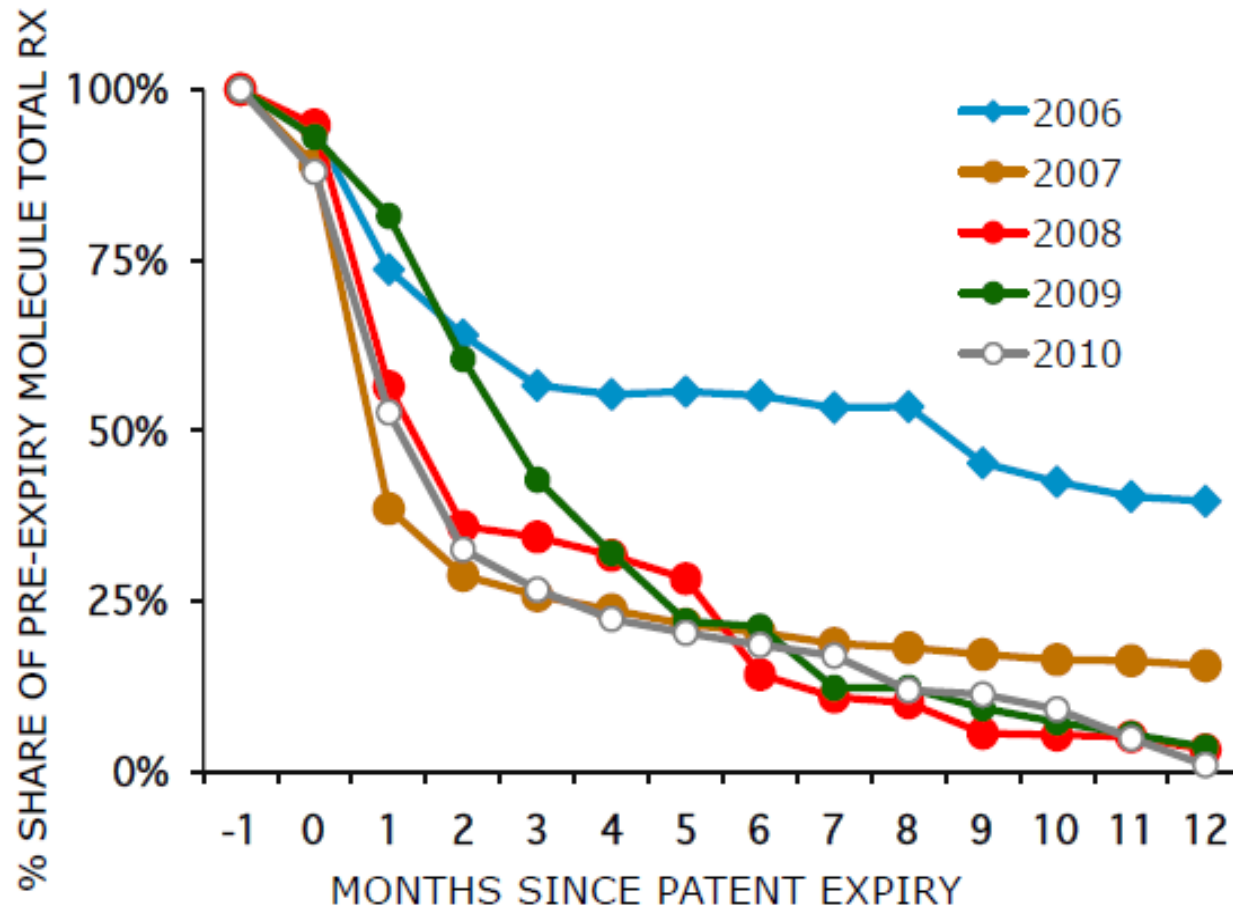
Prices Relative to Number of Generic Entries



Average relative price per dose



Brand Share After Patent Expiration



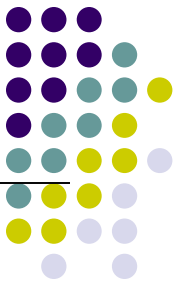
SOURCE: IMS Health, National Prescription Audit, February 2011, used from “The Use of Medicines in the United States: Review of 2010,” IMS Institute for Healthcare Informatics.

Factors Driving Generic Substitution



- Traditional Drugs
 - Automatic substitution by pharmacists with patient consent, based on state laws
- Biosimilars
 - Estimates of lower prices: 20% to 40% (CBO, European experience)
 - FDA policies on interchangeability
 - State laws on substitution of biosimilars
 - Consumer and prescriber acceptance
 - Public and private insurance rules

Factors Driving Brand Price Changes



- Introduction of competing therapies
- Other changes in competitive environment
- Negotiations with PBMs on behalf of plans and employers
- Stage in patent protection cycle

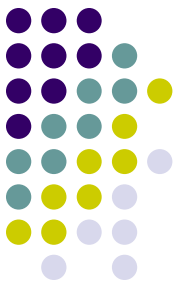
Price Increases, Diabetes Drugs, 2010-2015



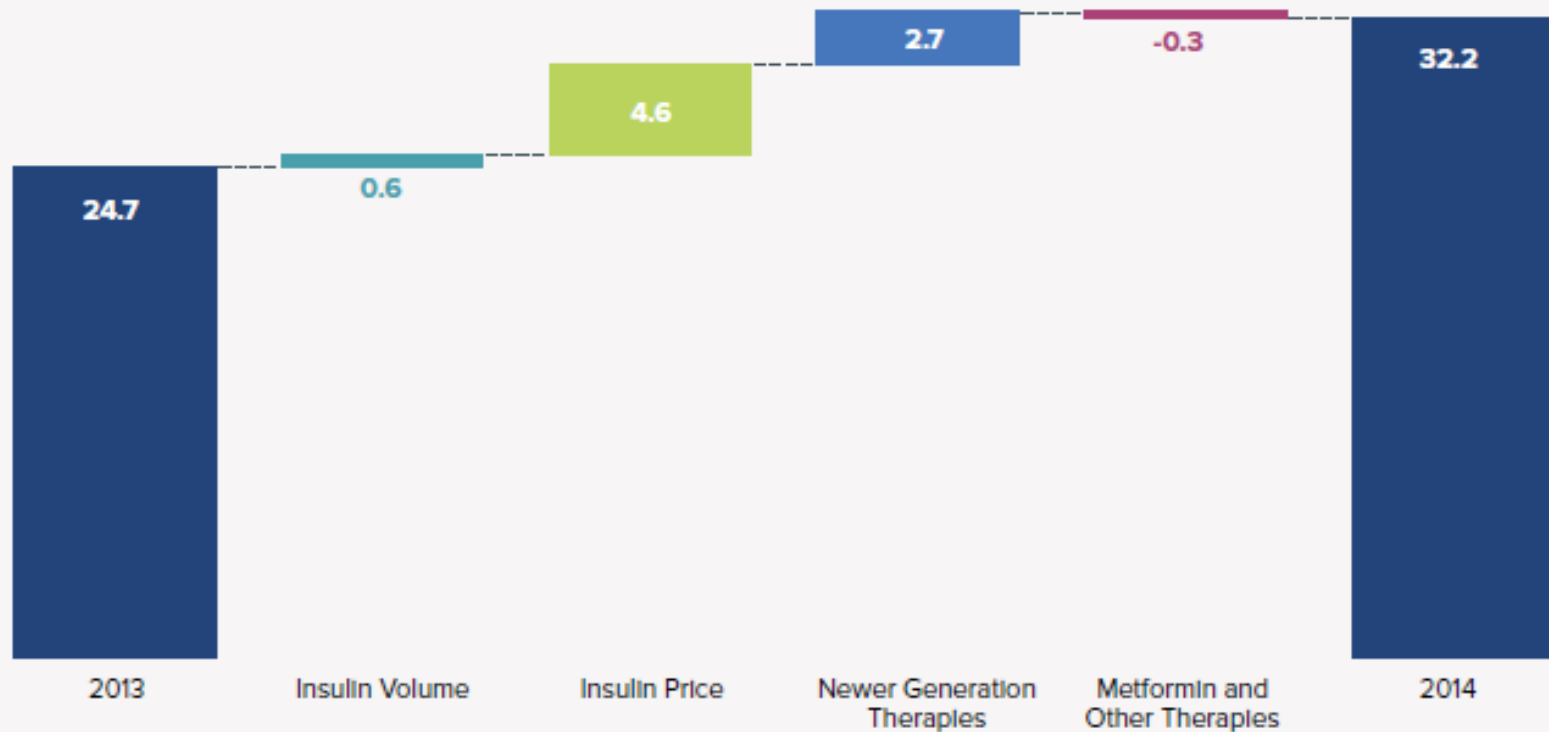
Source: Alliance of Community Health Plans, from *Medi-Span® Price Rx®*.

Note: Figures reflect wholesale acquisition cost. Price modifications will alter the values reflected above.

Components of Diabetes Spending Growth, 2013-2014



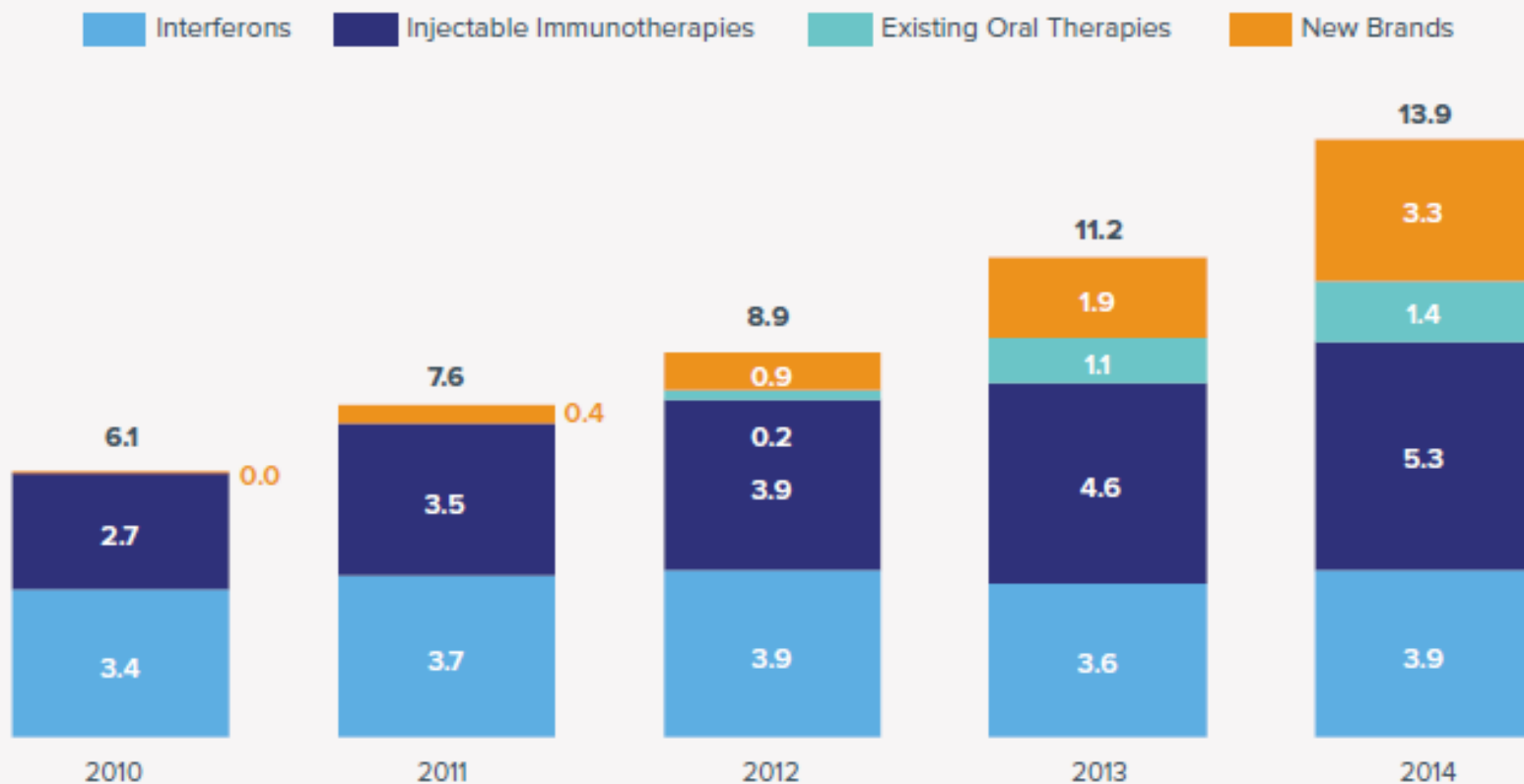
In billions of dollars



Source: IMS Health, National Sales Perspectives, Dec 2014

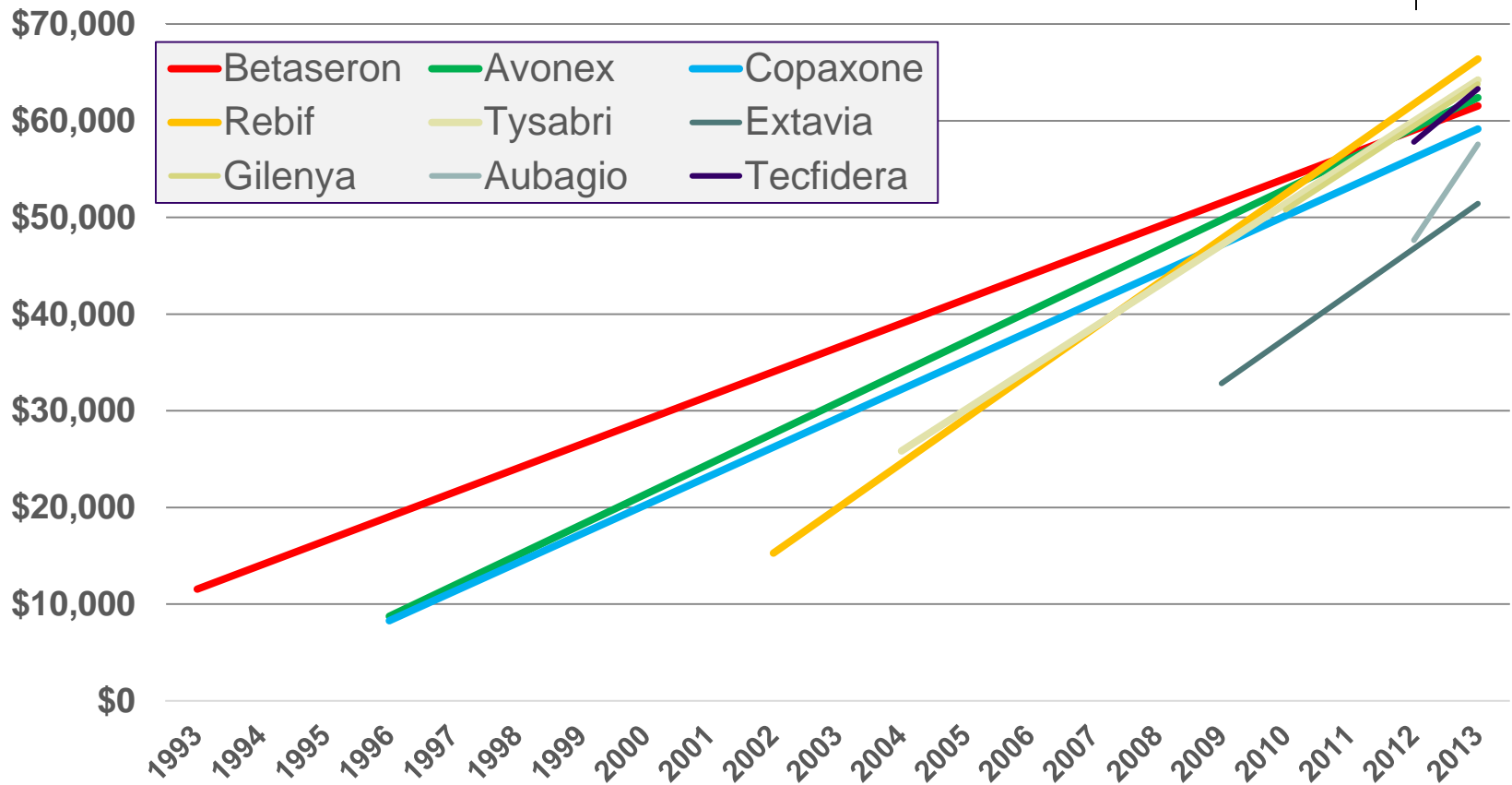
Changes in MS Drug Spending, 2010-2014

In billions of dollars

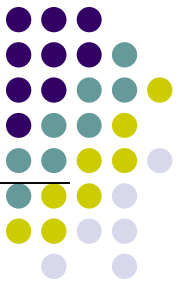


Source: IMS Health, National Sales Perspectives, Dec 2014

MS Drug Prices from FDA Approval Date



Do Payer Actions Affect Patient Access?



- Utilization management
 - Decisions by payers to raise or lower access barriers (e.g., PA criteria) in concordance with price negotiations (e.g., new hepatitis C drugs)
- Impact of price changes on the cost to consumers
 - Varying use of coinsurance versus copay
- Impact of closed and open formularies on consumers
- Effectiveness of appeals and exceptions

Express Scripts Plan Management Strategies



Average annual increase in per-member per-year spending, 2014-2015, compared to overall U.S. trend of 5.2%

12.9%



Unmanaged Plans

5.6%



Managed Plans

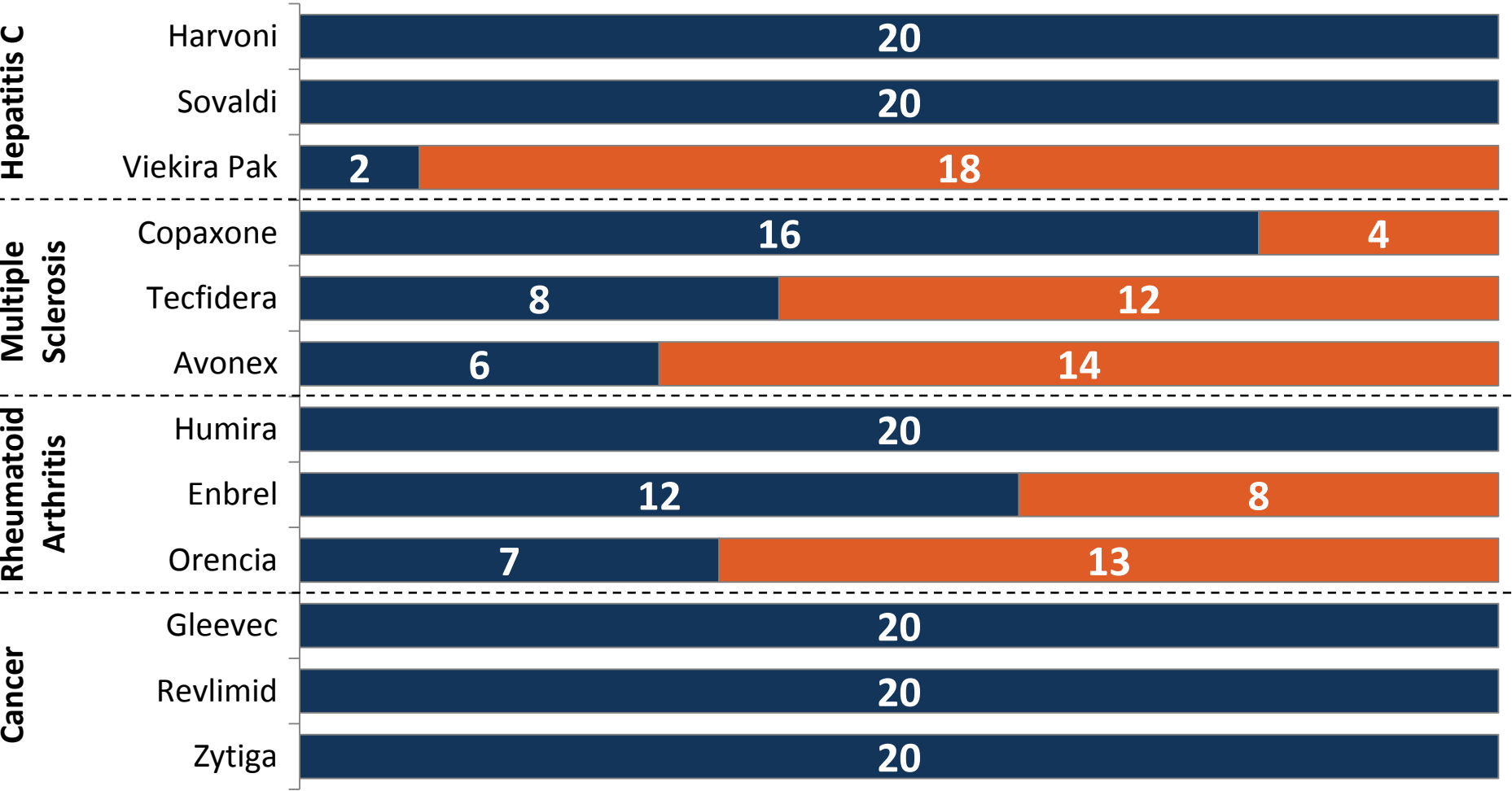
3.3%



Tightly Managed Plans

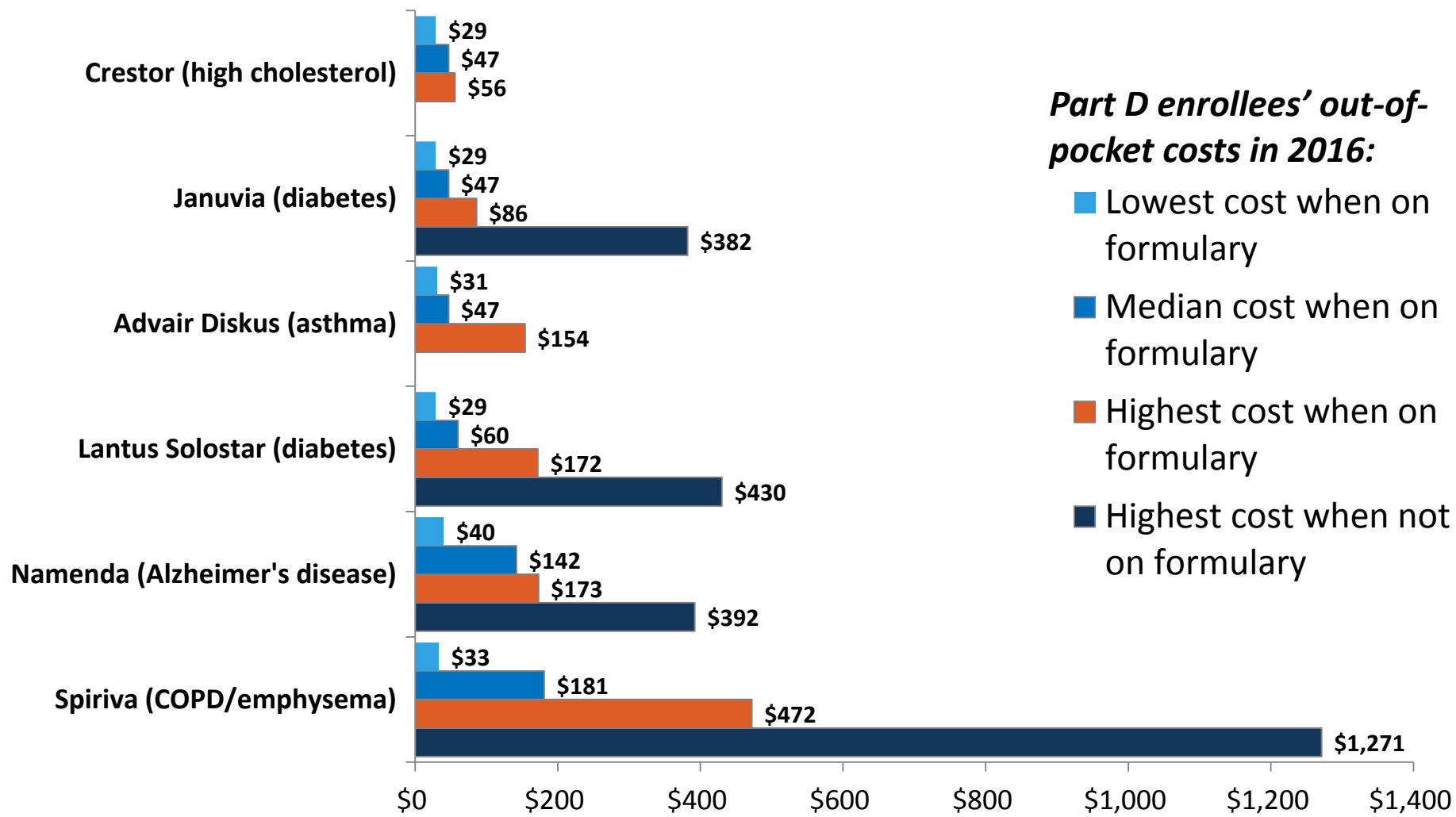
Formulary Coverage of Specialty Drugs Varies Across Medicare Part D Plans, 2016

■ Plans listing drug on formulary in 2016 ■ Plans not listing drug on formulary in 2016



NOTE: Analysis includes 20 national and near-national stand-alone prescription drug plans in Baltimore, MD (zip code 21201).
SOURCE: Georgetown/Kaiser Family Foundation analysis of 2016 Medicare Plan Finder data.

Difference Between the Lowest and Highest Out-of-Pocket Monthly Cost, Brand Drugs, Medicare Part D, 2016



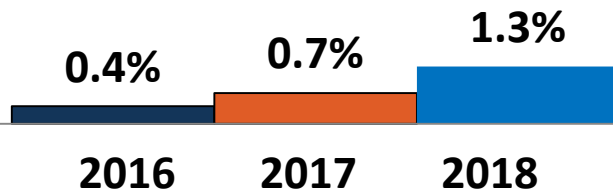
NOTE: Analysis includes 20 national and near-national stand-alone prescription drug plans in Baltimore, MD (zip code 21201) and reflects pricing at a Rite Aid pharmacy in this zip code.

SOURCE: Georgetown/Kaiser Family Foundation analysis of 2016 Medicare Plan Finder data.

46

Future Projected Trend, All Payers, 2016-2018

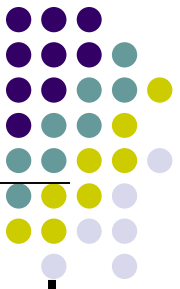
Trend Forecast: Traditional Drugs



Trend Forecast: Specialty Drugs



What Does the Future Hold?



- Factors to watch that will influence trends
 - Approvals of new drugs (brands, generics, biologics, biosimilars)
 - Trends in drug benefit management by public and private payers
 - Price sensitivity by consumers and prescribers
 - Price transparency
 - Evidence on comparative effectiveness
 - Innovations in value-based purchasing