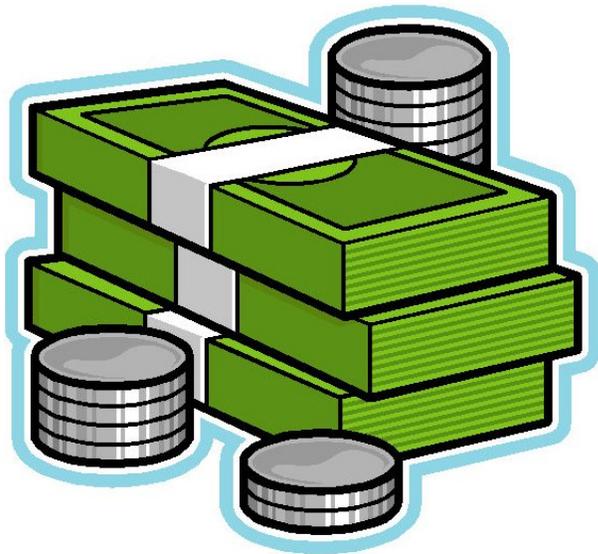
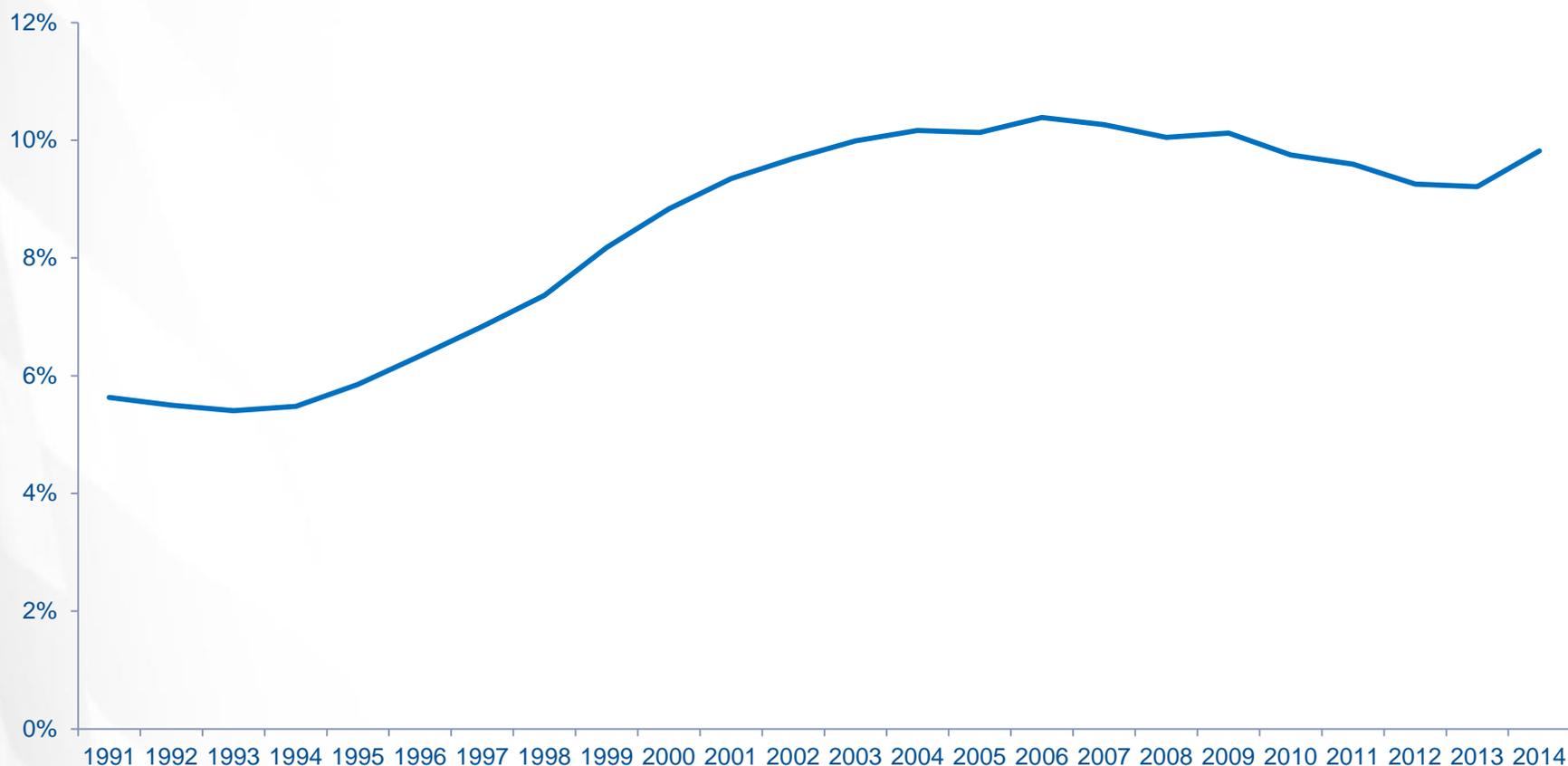


Prescription Drug Pricing



Prescription Drugs As a Percent of Total National Health Expenditures, 1991-2014



Source: GAO analysis of data from the Centers for Medicare and Medicaid Services, National Health Expenditure Accounts

Types of Prescription Drugs

Brand drugs

- marketed under a proprietary, trademark-protected name
- patent protection can last up to 20 years, and other market exclusivity periods may apply

Generic drugs

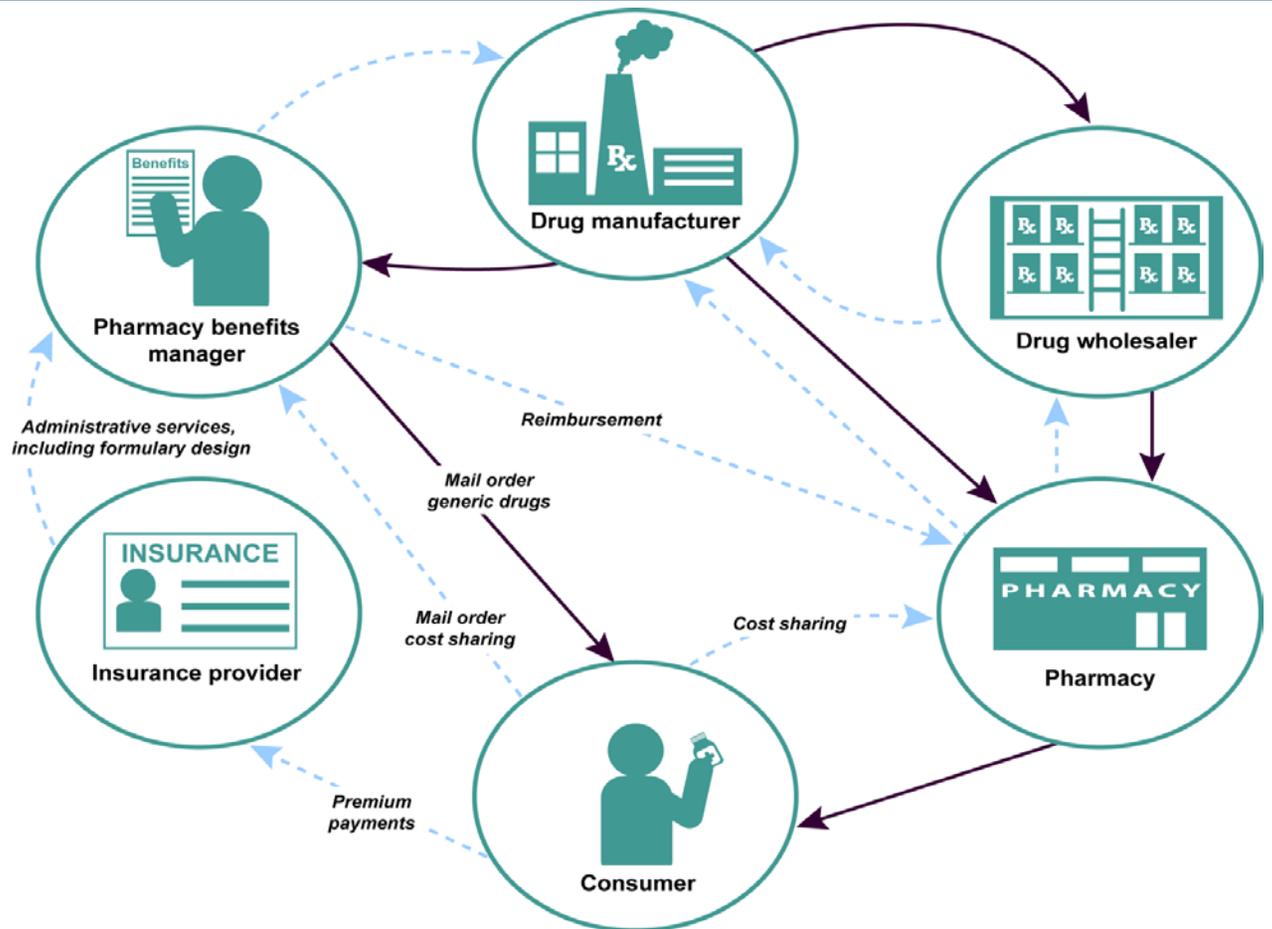
- same active ingredient, strength, dosage form, and route of administration as the brand counterpart
- enter the market with FDA approval after the patent and any applicable market exclusivity for the brand expire

Specialty drugs (brand or generic)

- treat chronic, complex, or life-threatening conditions
 - often manufactured through biologic processes
 - typically high cost
-

Which Stakeholders Influence Drug Prices?

- Every stakeholder in the flow of prescription drugs influences the price of the drug.
- Drug prices are fluid and may change frequently, especially for generics.
- Rebates and coupons, common among brand drugs, also impact what is actually paid for a drug.



— Movement of generic drugs
 - - - Payment for services or generic drugs

Source: GAO. | GAO-16-706

What Factors Influence Drug Prices?

Brand drugs

- Drug manufacturers may consider several factors when setting prices for brand drugs, including
 - the drug's patent status and market exclusivity
 - the size and characteristics of the patient market
 - the cost and availability of therapeutically equivalent drugs.

Generic drugs

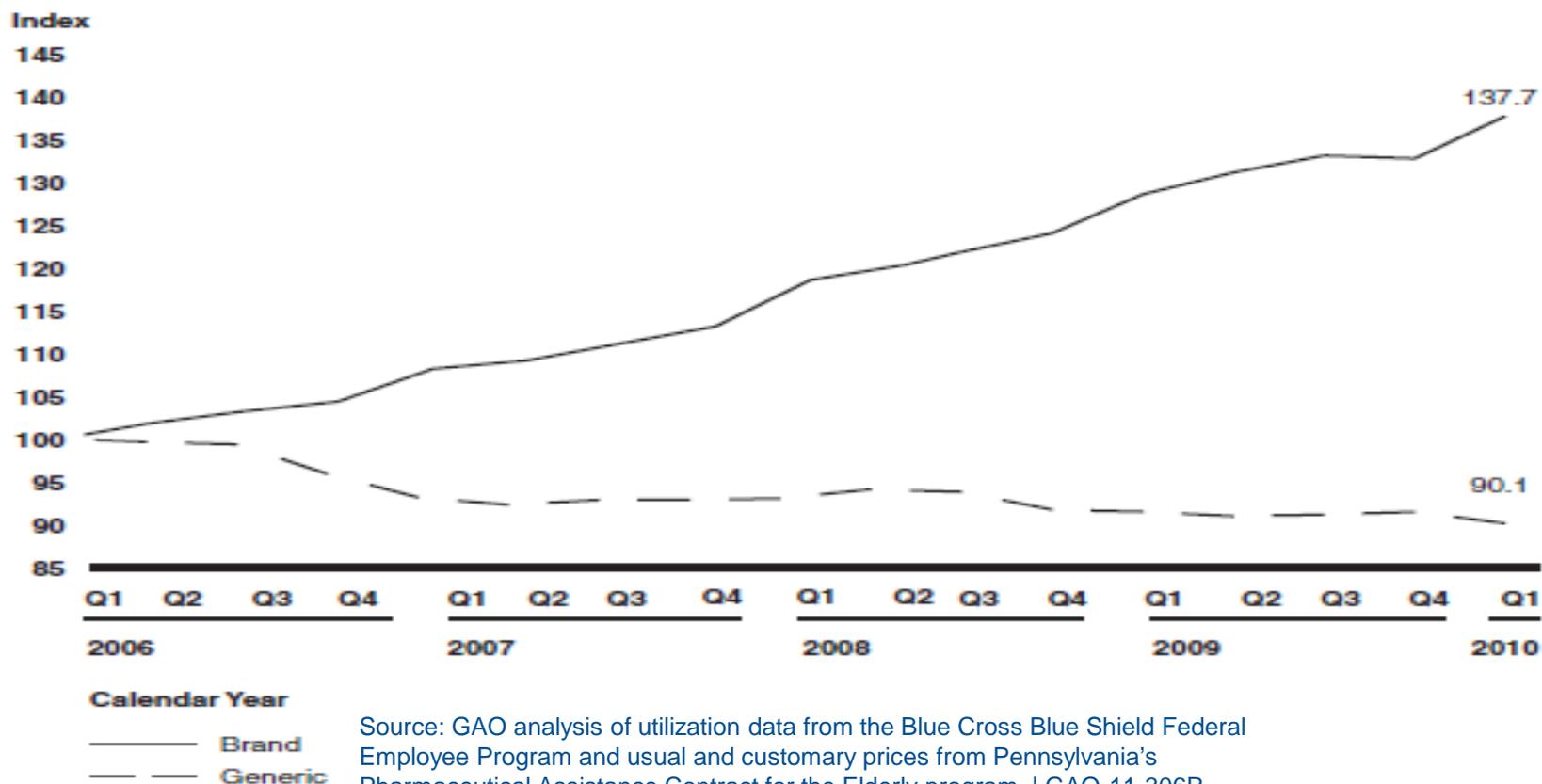
- Generic entry and the introduction of competition into the drug market usually result in a large drop in drug prices.
- Generic prices, according to stakeholders, can be influenced by:
 - access to active pharmaceutical ingredients
 - volume of drug production
 - supplier/buyer consolidation
 - low incentive to enter the market
 - FDA backlog in approving generic drugs.

How do Public and Private Payers Negotiate or Set Drug Prices?

- **Medicare Part D and Federal Employee Health Benefits Program** rely on competing private plans to negotiate with manufacturers and pharmacies.
- **Medicare Part B** pays based on average sales price.
- **Medicaid** receives statutory rebates based on lowest prices paid by other purchasers.
- **VA and DOD** purchase drugs for distribution at their medical facilities and pharmacies and negotiate prices based on statutory ceilings. Both reimburse retail pharmacies for beneficiary prescriptions.
- **Private health insurance plans** typically contract with pharmacy benefit managers to negotiate rebates or payments with drug manufacturers and discounted prices with networks of retail and mail-order pharmacies.

Rising Brand and Declining Generic Drug Prices Are Not New

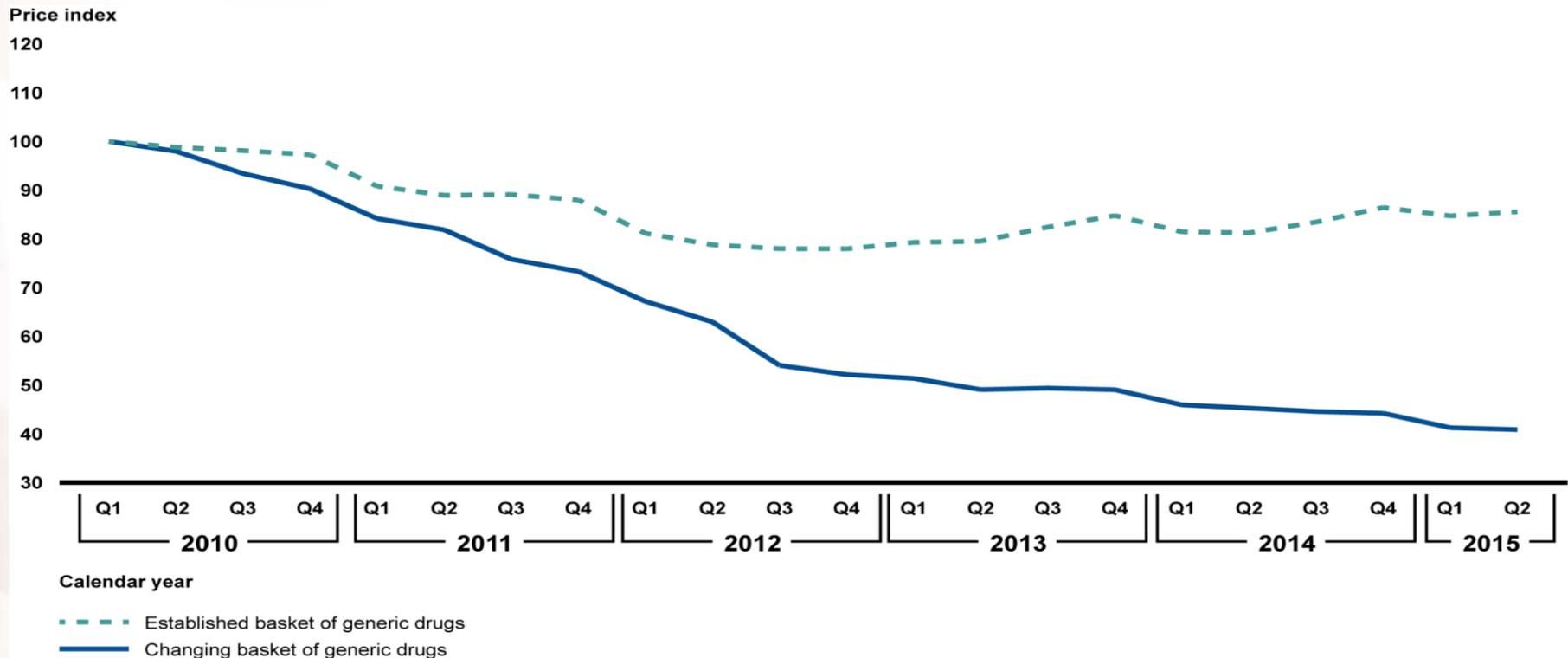
Usual and Customary Price Indexes for a Basket of Commonly Used Brand Drugs and Generic Drugs



Source: GAO analysis of utilization data from the Blue Cross Blue Shield Federal Employee Program and usual and customary prices from Pennsylvania's Pharmaceutical Assistance Contract for the Elderly program. | GAO-11-306R

Generic Drug Prices Have Generally Continued to Decline

Price Trends under Medicare Part D for a Changing Basket and Established Basket



Source: GAO analysis of Medicare Part D prescription drug event data. | GAO-16-706

Some Drugs Have Experienced Extraordinary Price Increases

Brand drugs

- From 2000 to 2008, 416 brand drugs—different drug strengths and dosage forms of the same drug brands—had extraordinary price increases.
- More than half of these 416 brand drugs were in just three therapeutic classes—central nervous system, anti-infective, and cardiovascular.
- The majority of the price increases were sustained in subsequent years.

Generic drugs

- From the first quarter 2010 to the first quarter 2015, 315 generic drugs billed under Medicare Part D had extraordinary price increases. These drugs were
 - disproportionately topical and ophthalmic drugs
 - often not among the drugs with the highest utilization
- The price increases generally persisted in subsequent years.

Price Increases May Affect Access

- Prices may affect formulary design.
 - New drugs may not be covered if other existing drugs within the same therapeutic class offer clinical or financial advantages.
 - Greater use of formulary tiers can increase consumer cost sharing for more expensive drugs.
 - For example, many Medicare Part D plan sponsors have adopted a five-tier formulary structure: preferred generic and other generic tiers, preferred and nonpreferred brand-name drug tiers, and a specialty tier.
 - Generally, nonpreferred tiers have higher copayments and/or cost sharing than the preferred tiers.
 - High prices, particularly for brand and specialty drugs, may impact health insurance premiums.
-

Policy Discussions in Drug Pricing

- Negotiating drug prices
- Payment incentives
- Benefit design and cost sharing
- Transparency
- Value-based purchasing

For More Information

- Rashmi Agarwal, Assistant Director, agarwalr@gao.gov
- James Cosgrove, Director, cosgrovej@gao.gov
- John Dicken, Director, dickenj@gao.gov
- Oliver Richard, Director, Center for Economics, richardo@gao.gov