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FOR HEALTH TECHNOLOGY

Public and Private Health Insurance Pricing for Innovative and Expensive Drugs in the U.S.

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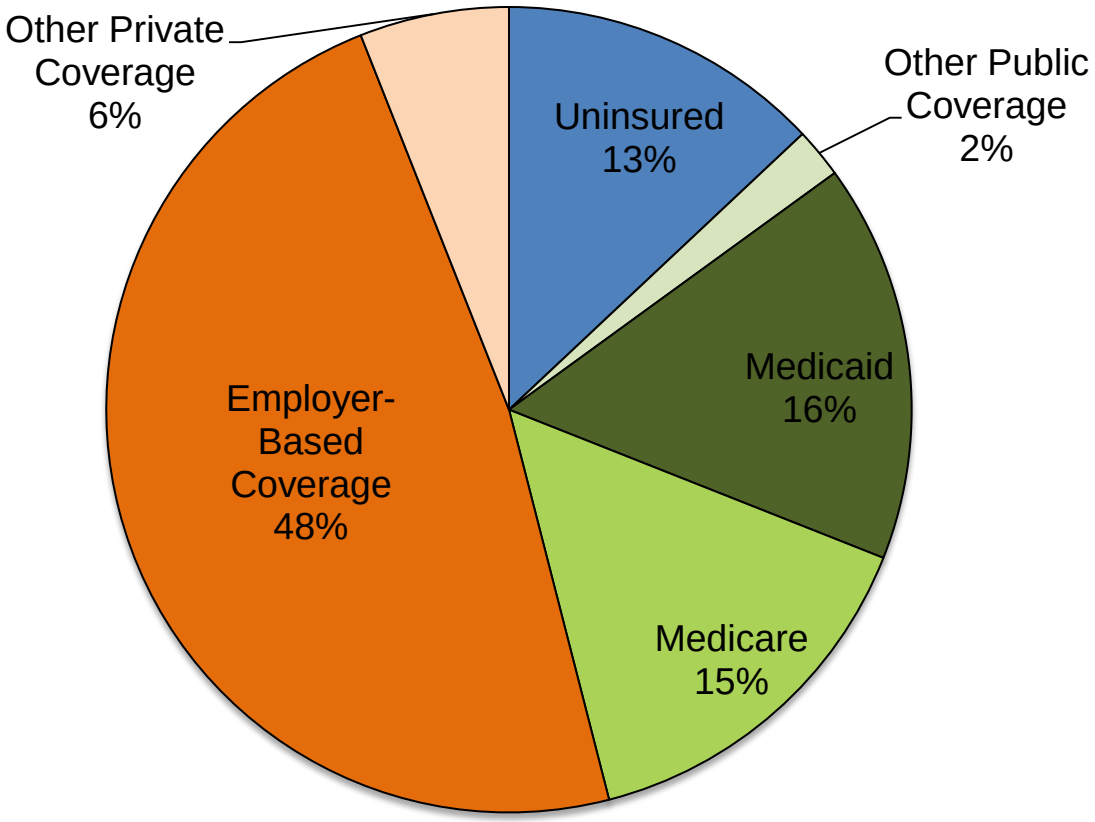
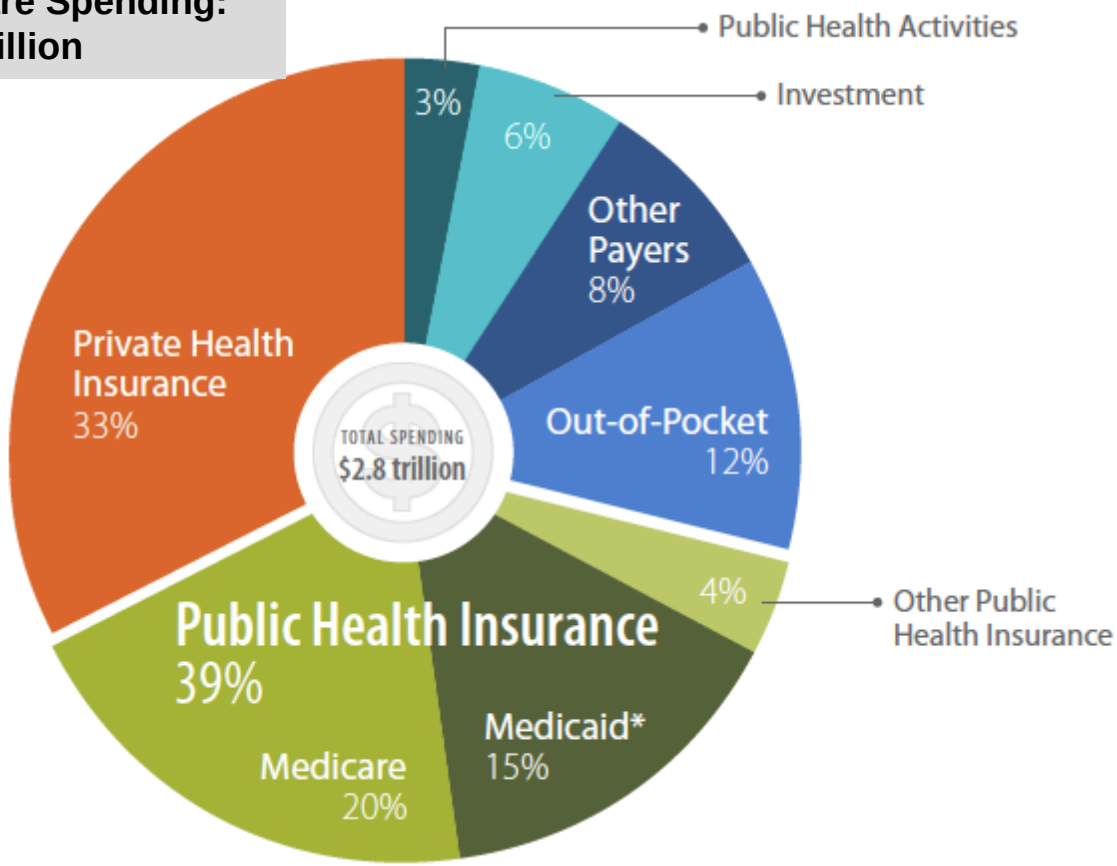
Distribution of Health Insurance in 2013 (Total US Population 315 million)



Source: The Henry J. Kaiser Family Foundation, State Health Facts (2013)

U.S. Health Expenditures by Type of Payer (2012)

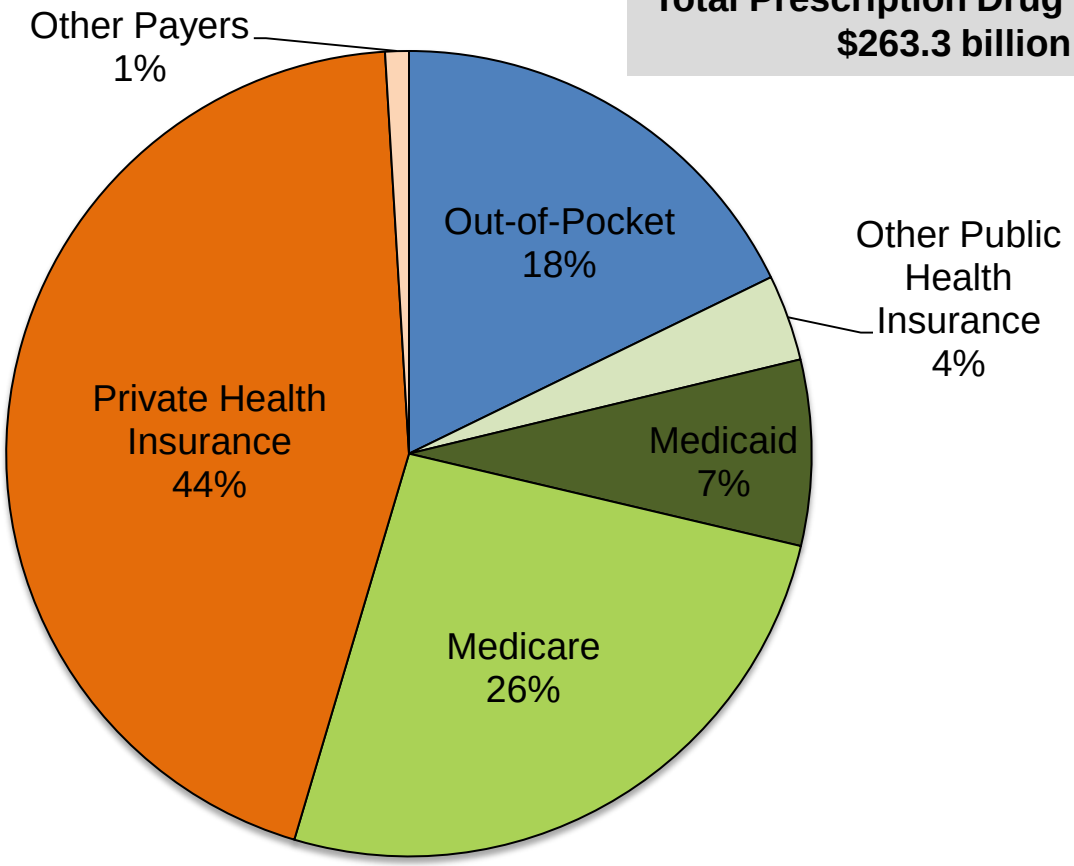
Total Health Care Spending: $2.8 Trillion



Source: California Healthcare Foundation, Health Care Costs 101, 2014 Edition

U.S. Prescription Drug Expenditures by Type of Payer (2012)

Total Prescription Drug Spending: $263.3 billion

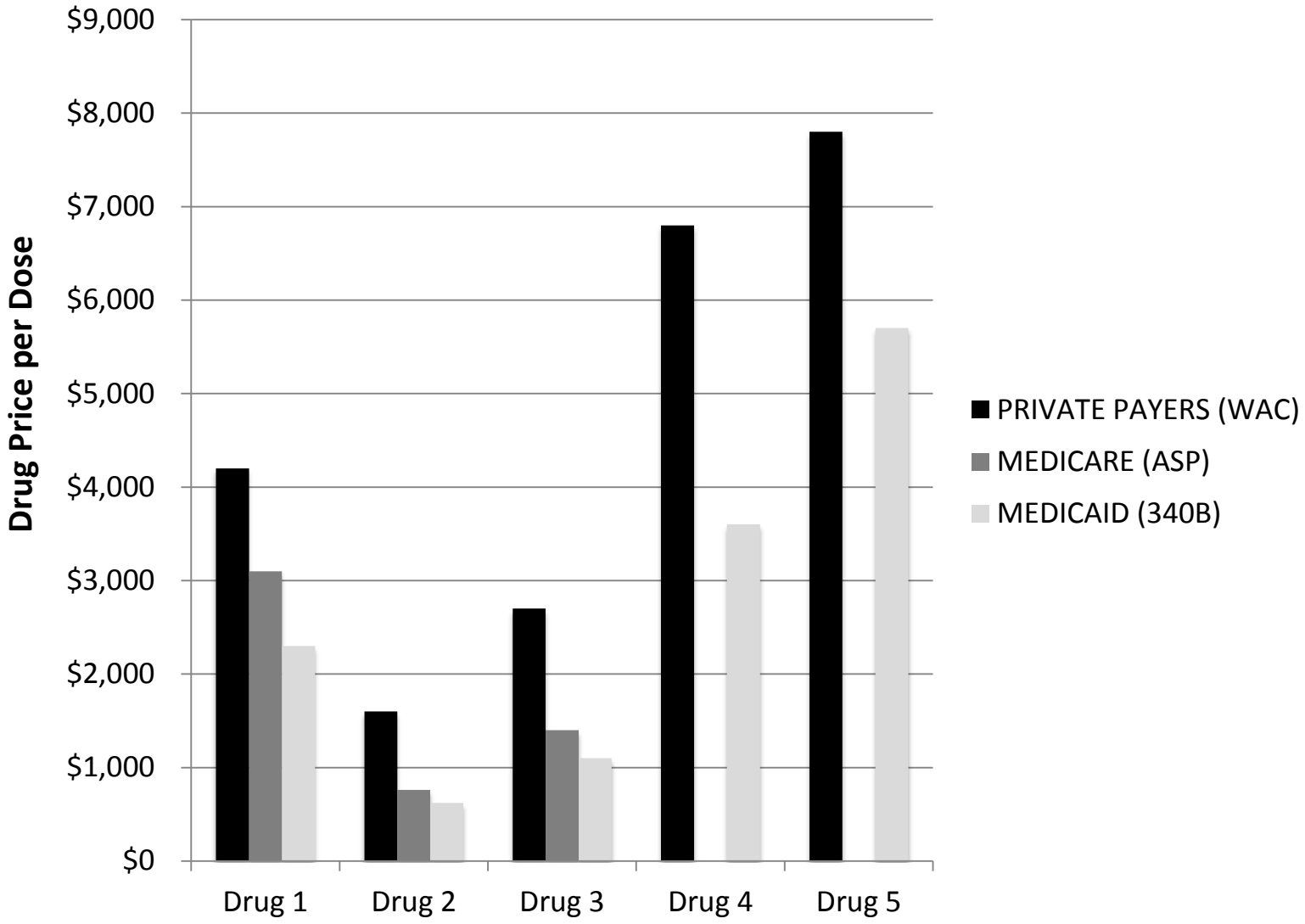


Source: California Healthcare Foundation, Health Care Costs 101, 2014 Edition

Three Drug Pricing Regimes

1. Negotiated prices for private insurers
   - Private insurers (and PBMs) negotiate prices with manufacturers
     - The outcome (price) depends on the characteristics of the drug and of the organizations
2. Mandated prices for public programs
   - Public and quasi-public programs pay discounted prices, with the extent of the discount varying across program
     - The price paid by public programs thus is linked to the prices negotiated by private purchasers, with a discount
3. Pricing debate for Medicare (the largest buyer)
   - Public payer currently bases reimbursement on prices paid by private payers, but in considering shift to reference pricing and/or mandatory discounts

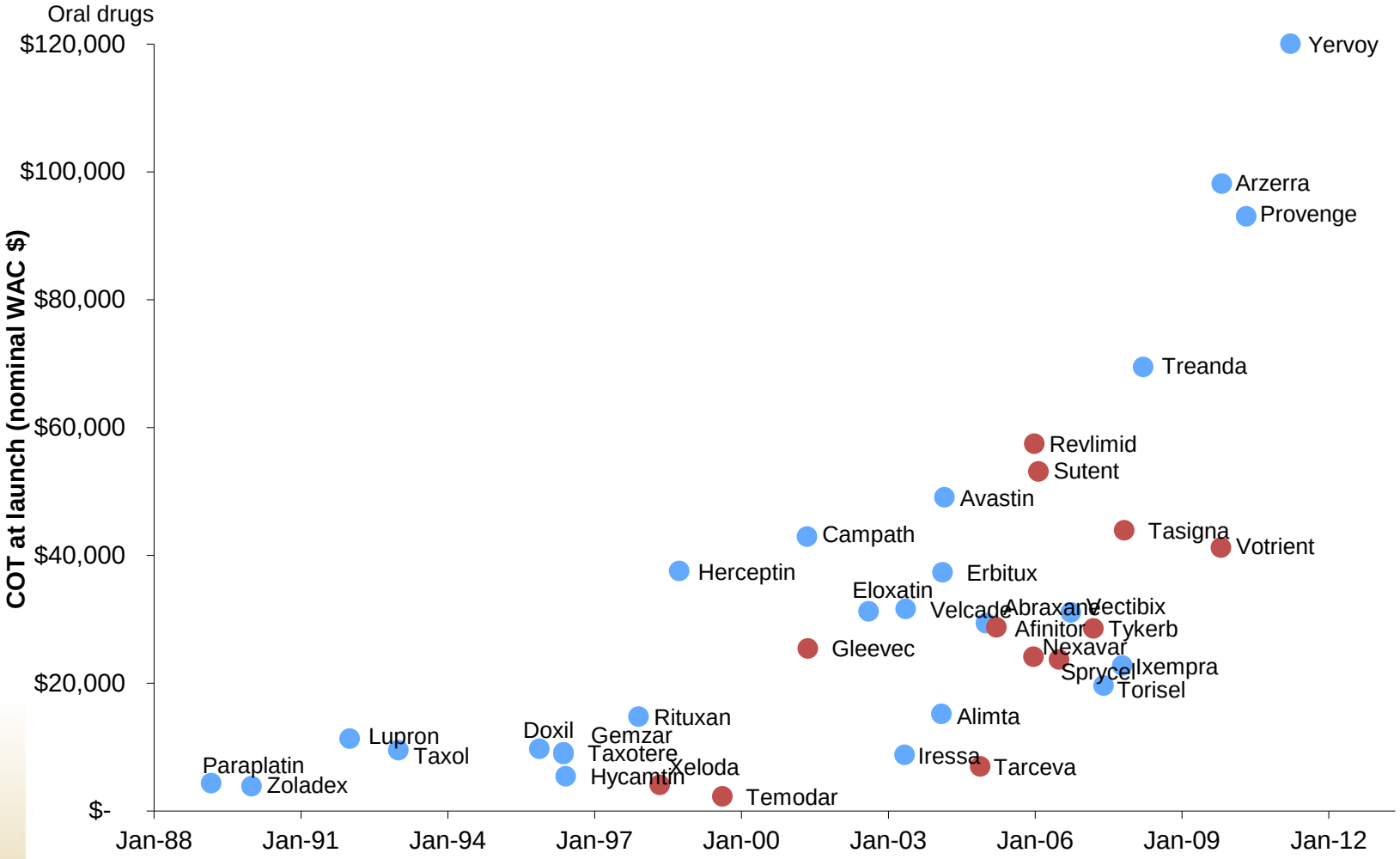
Private Payer, Public Program, and Medicare Prices for Selected Cancer Drugs



1. Negotiated Pricing for Private Insurers

- Private insurers and PBMs negotiate prices with pharmaceutical manufacturers
  - Level of price depends on extent of therapeutic substitution
    - Generics priced at 80% discount from brand
    - Preferred brands priced below list price, with differential depending on extent of competition
  - There is no competition and discounting for therapeutically unique products
    - By state regulation and the ACA, insurers must cover all drugs within 5 protected classes, including oncology
    - This implies they have no leverage to obtain discounts

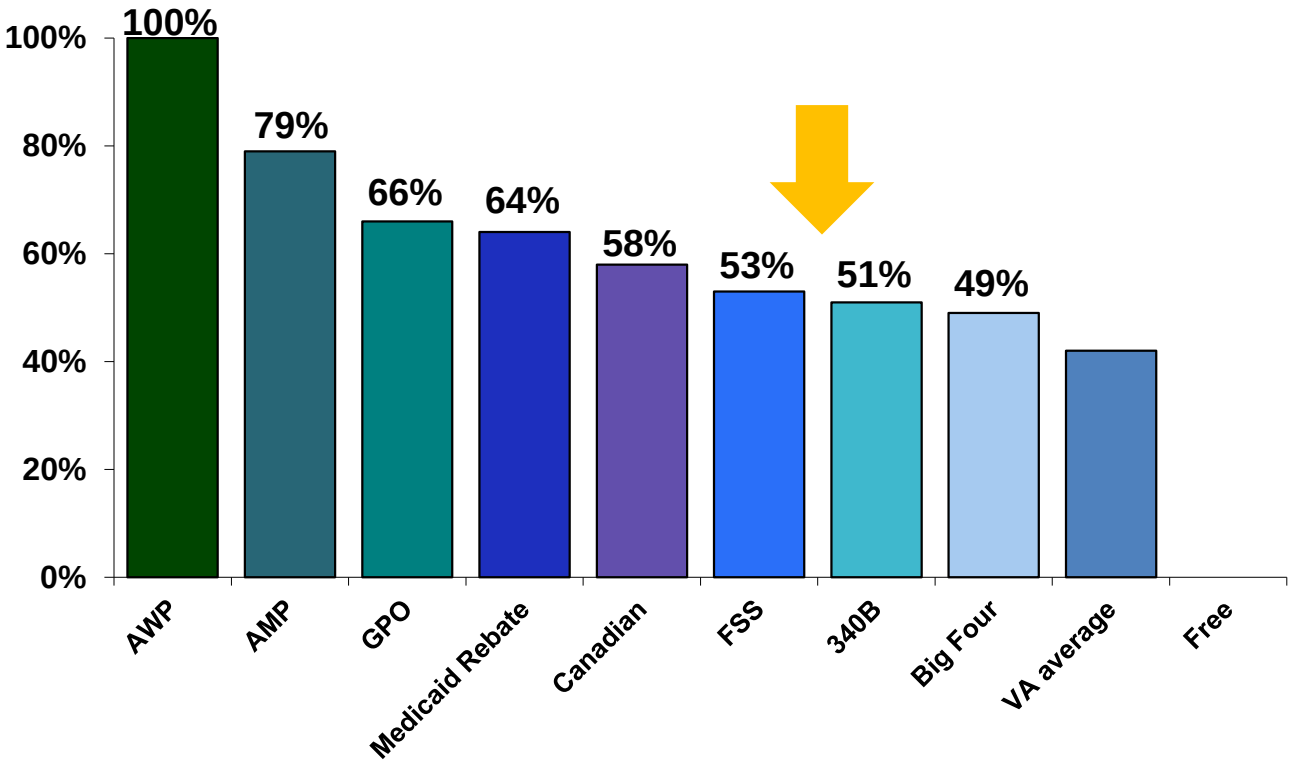
Private Insurer Prices for Cancer Drugs



2. Mandatory Discounts for Public Programs

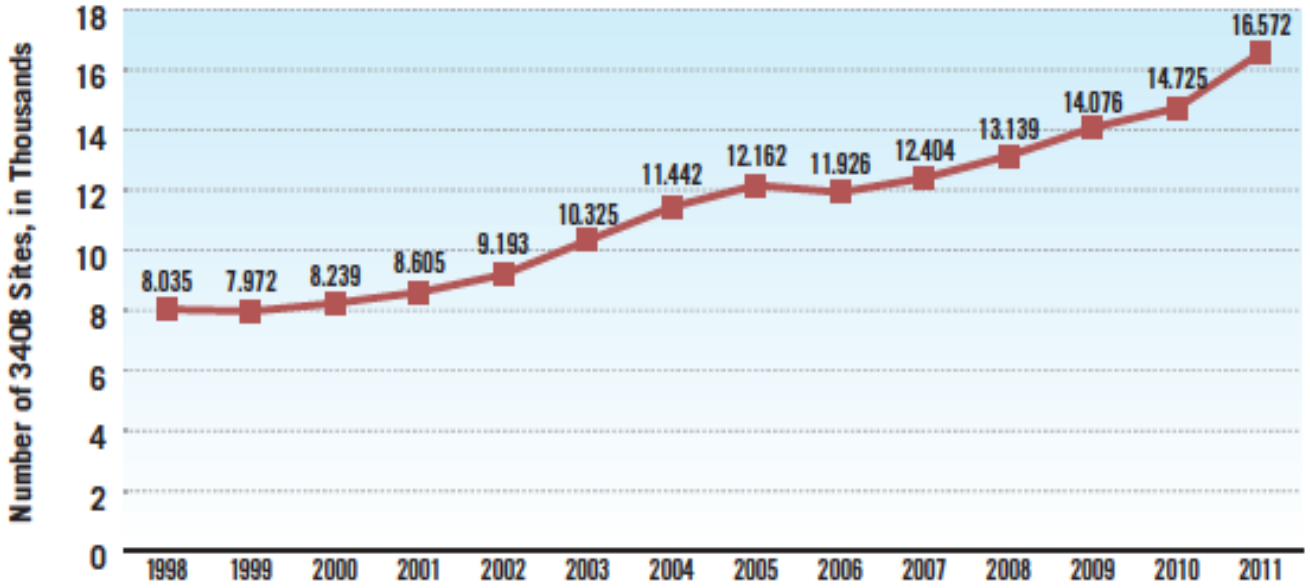
- Medicaid (66 million members)
  - 23% rebate, plus negotiated discounts
- Safety net, cancer hospitals (340B)
  - 23-75% discount on infused drugs, expanding to ambulatory drugs obtained in retail settings
- Federal programs (Veterans, DoD, etc.)
  - Federal supply schedule: minimum 26% discount

Mandated Discounts



Spread of Mandated 340B Discounts

Figure 2: Historical Growth in 340B Enrollment, 1998–2011 (as of July of Each Year)



Source: Avalere Health analysis of HRSA 340B enrollment files.

- Number of hospitals participating has tripled from 591 to 1,673 since 2005. The number of sites has grown 4x to 4,426
- 340B drug purchases totaled $6B in 2010 and are expected to grow to $12B by 2016 (Berkeley Research Group)

Medicare: The Largest Payer

- Medicare covers 54 million citizens aged 65+ and is responsible for most drug expenditures in oncology
- It has two separate programs for drugs
- Part B covers office-administered (infused) drugs, mostly biologics but also infused chemotherapy
  - This program is administered directly by the government
- Part D covers oral and self-injected drugs obtained from pharmacies, including oral oncology drugs
  - This program is administered by private insurance firms

Pricing for Office-Infused Drugs (Part B)

- Medicare Part B reimburses physicians and hospitals for drugs that are administered directly to patients
  - Physicians and hospitals purchase from manufacturers. They earn a profit margin between the price they pay for the drug and the reimbursement they receive.
- Medicare reimbursement formula: average selling price (ASP) plus 4% administrative fee
- ASP is the average of prices paid by private insurers, net of discounts and rebates

Pricing for Oral Drugs (Part D)

- Medicare Part D covers oral and subcutaneous (SQ) drugs obtained in retail pharmacies (not administered in a physician's clinic or a hospital)
- Patients select a private insurer for drug coverage; this insurer negotiates prices with drug firms
- The purchasing of oral and SQ drugs is fragmented among many private insurers
- Private Part D insurers are mandated to cover all oncology drugs and have no power to reduce prices

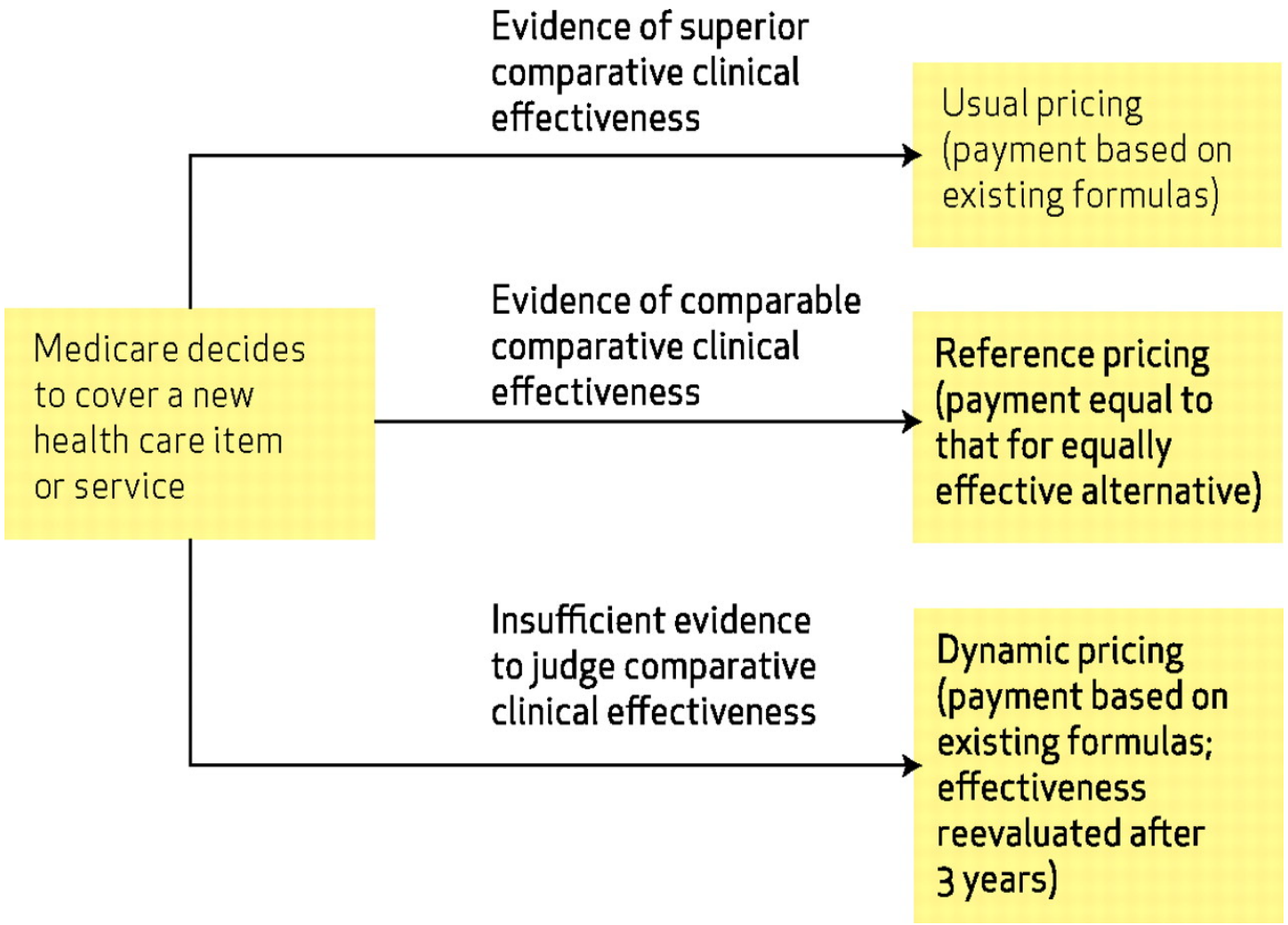
Mandated Price Discounts for Medicare?

- Medicare has linked its prices to those paid by the private insurers, implying high expenditures
- Some budget analysts propose Medicare prices be linked, instead, to the discounted prices paid by Medicaid
- This could happen in stages:
  - Extend Medicaid discount to prices paid by Medicare for beneficiaries who are low income
  - Extend Medicaid discount to private Medicare (Part D) plans for oral and injected drugs

Value-based Pricing for Medicare?

- Other analysts propose that the prices paid by Medicare be based on the incremental clinical value offered by new drugs
- If a new drug cannot prove superiority to existing drugs, it is priced at the lowest level paid by Medicare for an equivalent drug
  - It would no longer be linked to private insurer prices through the ASP mechanism
- This would require enhanced use of comparative effectiveness data

Proposed Medicare Price based on Comparative Effectiveness Research (Pearson and Bach 2010)



Pearson S D , and Bach P B Health Aff 2010;29:1796-1804

Conclusion

- US pays the highest drug prices in the world, but changes are coming
  - Expansion of Medicaid discounts to more providers, patients
  - Debate over mandated discounts for Medicare
  - Increased price pressures from private insurers in the face of therapeutically equivalent drugs
- Firms with breakthrough innovations will receive premium prices, but will need to better document comparative clinical and cost performance
- The bar is rising

Purchasing Medical Innovation analyzes the market and policy dynamics of health care technology, with a focus on the Food and Drug Administration (FDA), insurers, physicians, hospitals, and consumers themselves. The goal is to help the buyers, sellers, and users improve the value of medical technology: better performance at lower cost.