Context of Medicare drug spending

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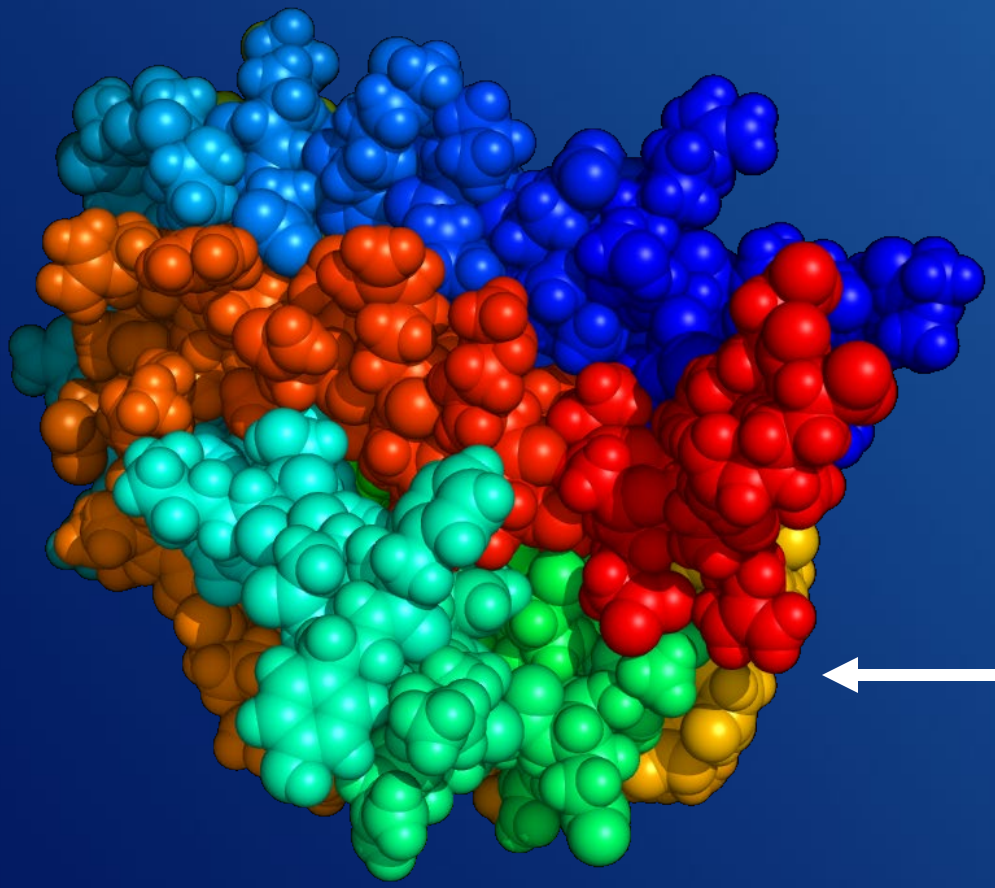
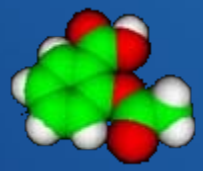
MEDPAC

Roadmap

- Research, development, and regulatory approval of drugs and biologics
- Drug pricing
- Manufacturing and distribution channels

Background: Drugs versus biologics





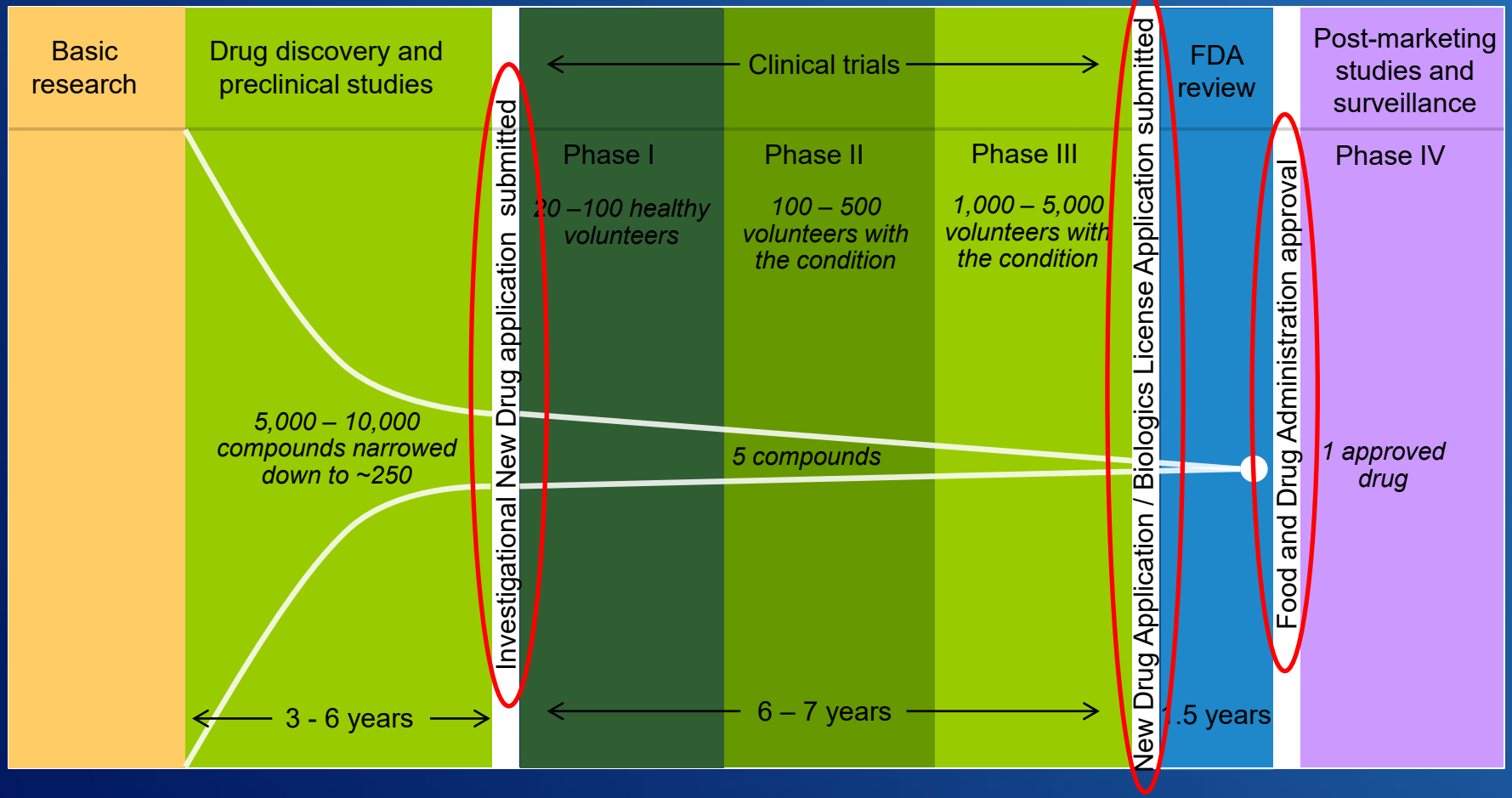
Small molecule drug: Synthesized via a chemical process (pictured: aspirin)

Biologic: Synthesized from a living organism or its products (pictured: EPO)

Federal government's role

- Support biomedical research (e.g., National Institutes of Health)
- Ensure safety and effectiveness of medicines
- Balance incentives for encouraging private innovation with incentives for price competition
  - Financing
    - Basic research
    - Tax credits
    - Major payer for biopharma products
  - Grant temporary monopolies to innovators
    - Patent and Trademark Office awards 20-year patents
    - Food and Drug Administration (FDA) grants marketing approval typically well into patent life
  - Prohibit importation and control resale of drugs among purchasers

The drug discovery, development, and review process



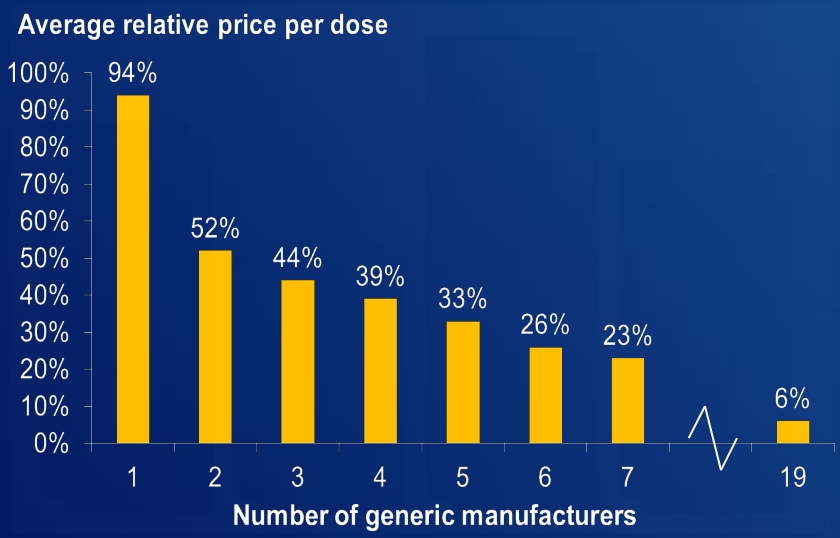
MEDPAC Source: Adapted from Pharmaceutical Research and Manufacturers of America.

FDA approval triggers data and market exclusivity periods

- Data exclusivity
  - Innovator gets period of protection from competition
  - Generic/follow-on manufacturer may not apply to FDA using innovator's clinical test data for
    - 5 years for new chemical entities
    - 3 years for new indications of an existing drug
    - 12 years for biologics
- Market exclusivity—period of protection before FDA may approve a similar product
    - 180 days for first generic entrant
    - 7 years for orphan drugs
    - Pediatric drugs may get 6 months added to exclusivity

Today, generic entry lowers prices more than biosimilars

Dramatic drop in prices as generic entry increases



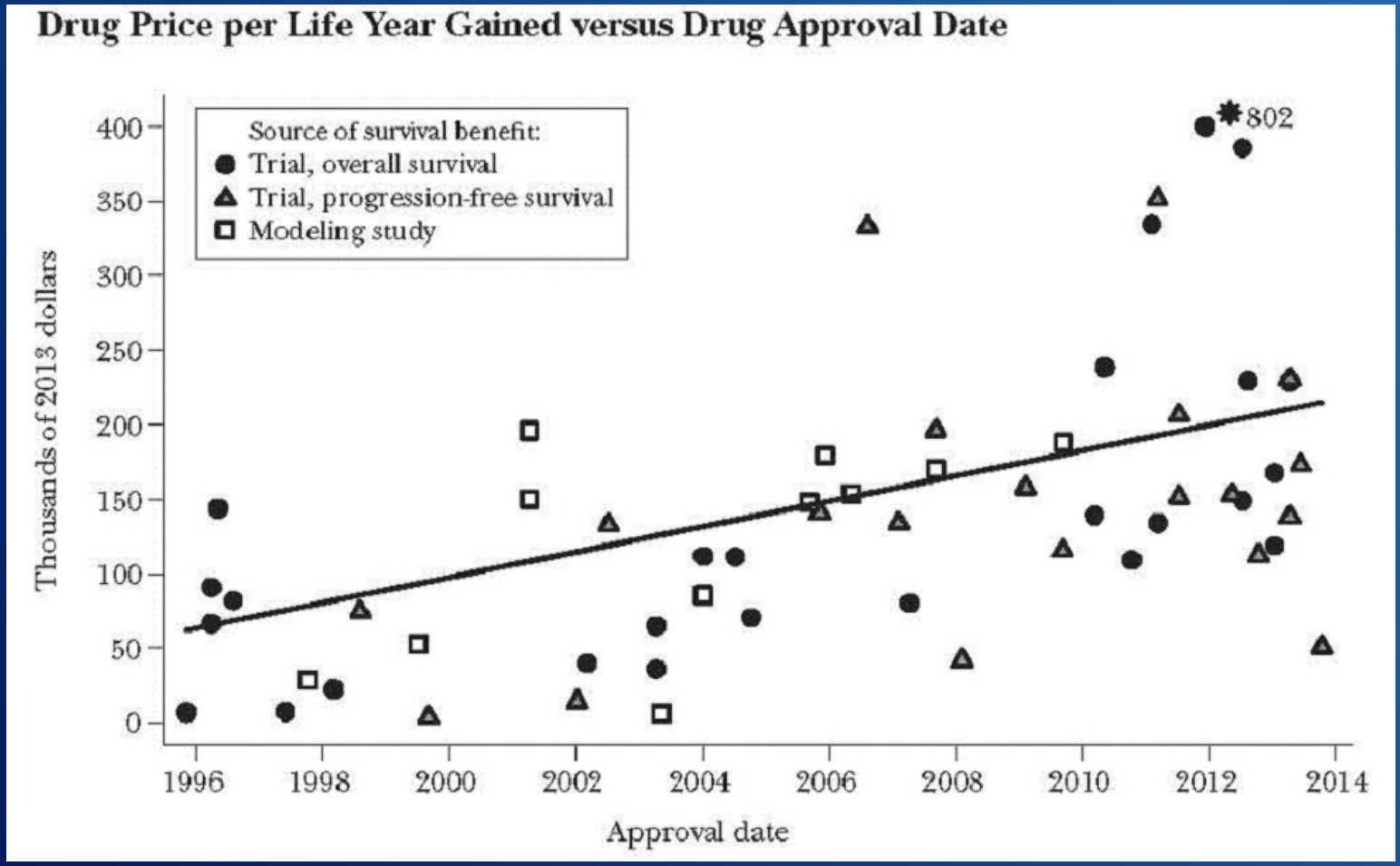
Source: FDA analysis of retail sales data from IMS Health, IMS National Sales Perspective™, 1999-2004, extracted Feb. 2005.

- Biosimilars not identical to reference products
- More expensive than generics to develop and produce
- Estimates of price effect
  - CBO (2008) estimated 20%-40% price reduction, varying by product and over time
  - European experience: prices of some biosimilars 20% to 30% lower than innovators
  - Initially, Medicare pays for first biosimilar at a price 3% lower than what it pays for the innovator, but biosimilar's payment rate likely to go down

Emerging new medicines

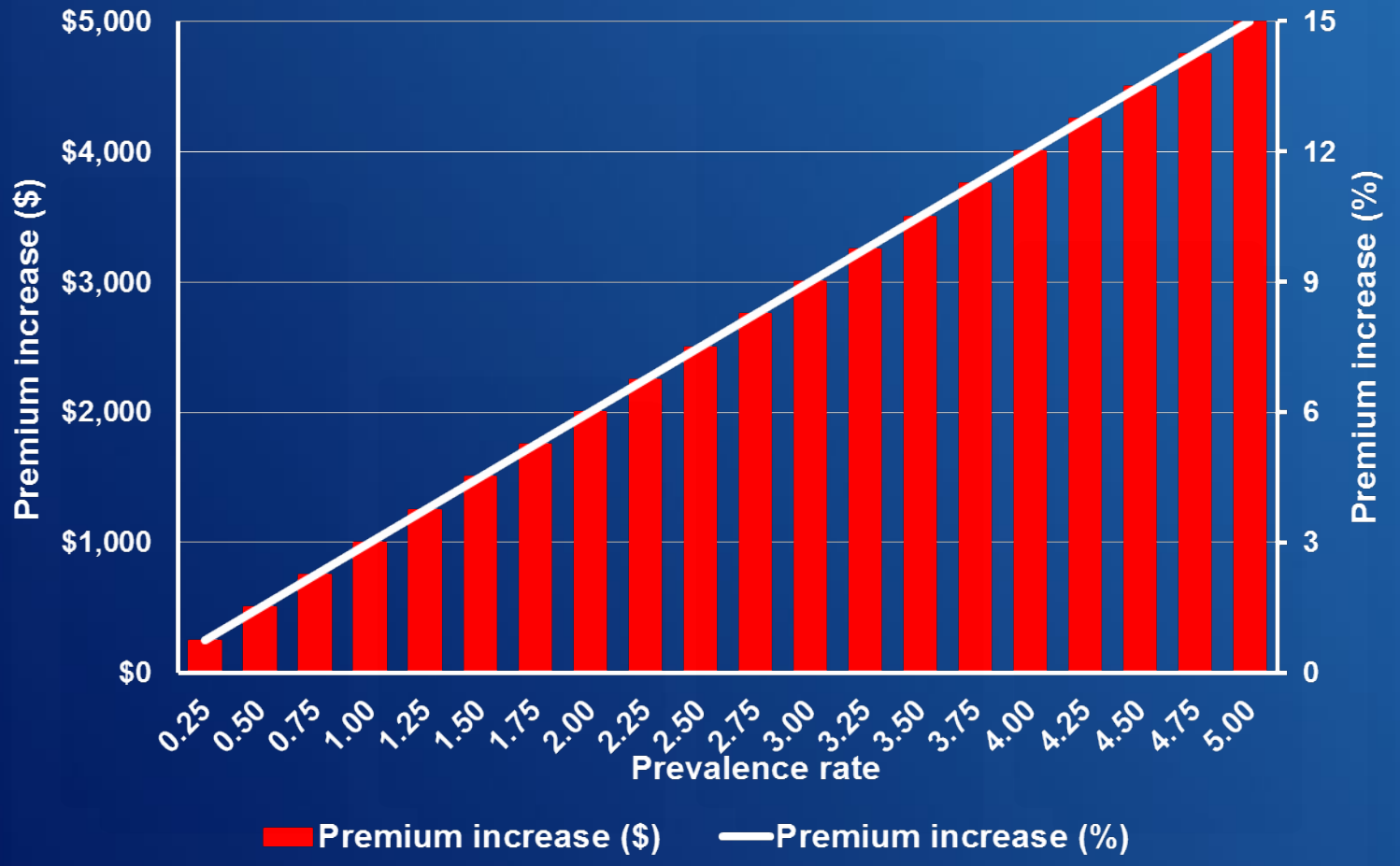
- Numbers of new launches
  - Varies from year to year, but generally growing
  - Number of orphan drugs has increased
  - Debate about numbers of first-in-class v. “me-too” products, speed of regulatory process, evidentiary standards
- Recent approvals affecting Medicare
  - Hepatitis C therapies
  - PCSK9 inhibitors for familial high cholesterol
  - Heart failure therapy
  - Long-acting insulin
- Others in the pipeline

Price of oncology drugs per life-year gained has increased over time



Source: David Howard, Peter Bach, Ernst Berndt, and Rena Conti, "Pricing in the Market for Anticancer Drugs," *Journal of Economic Perspectives*, vol. 29, no. 1 (Winter 2015): 139-162.

Wider use of specialty drugs could lead to higher premiums



Source: Bradford R. Hirsch et al. "The impact of specialty pharmaceuticals as drivers of health care costs," *Health Affairs* 2014;33:1714-1720.

Factors affecting drug prices

- Demand side
  - Shift from OOP to 3rd-party payment system
  - Shift from private to public insurance
  - Consolidation in the insurance industry
  - Discounts and rebates mandated by law
  - Increase in demand as a result of population aging
- Supply side
  - Increasing complexity of biopharmaceutical products
  - Emphasis on treatments for smaller disease populations (e.g., orphan drugs), often with few competing therapies
  - Cost of borrowing money
  - Patent and temporary monopoly granted by the government
  - Consolidation and/or specialization within the biopharmaceutical industry
  - Changes in the drug supply chain

Drug supply chain

- Manufacturers
- Wholesalers
- Pharmacies
- Pharmacy benefit managers (PBMs)

Supply chain: Manufacturers

- Include manufacturers of brand-name drugs, generic drugs, and biologics
- Develop and/or produce and market drug products
- Set list prices which are typically used as a reference point during price negotiations by supply chain actors
- Negotiate rebates and discounts with PBMs
- Pay a service fee to PBMs – e.g., for administering formularies

Supply chain: Wholesalers

- Provide transactional and logistical efficiencies by linking a manufacturer with >60K outlets that administer or dispense drugs
- Help smaller pharmacies negotiate with generic manufacturers by creating formularies
- In 2013, about 85-90% of all revenues from drug distribution generated by 3 companies (AmerisourceBergen, Cardinal Health, McKesson)

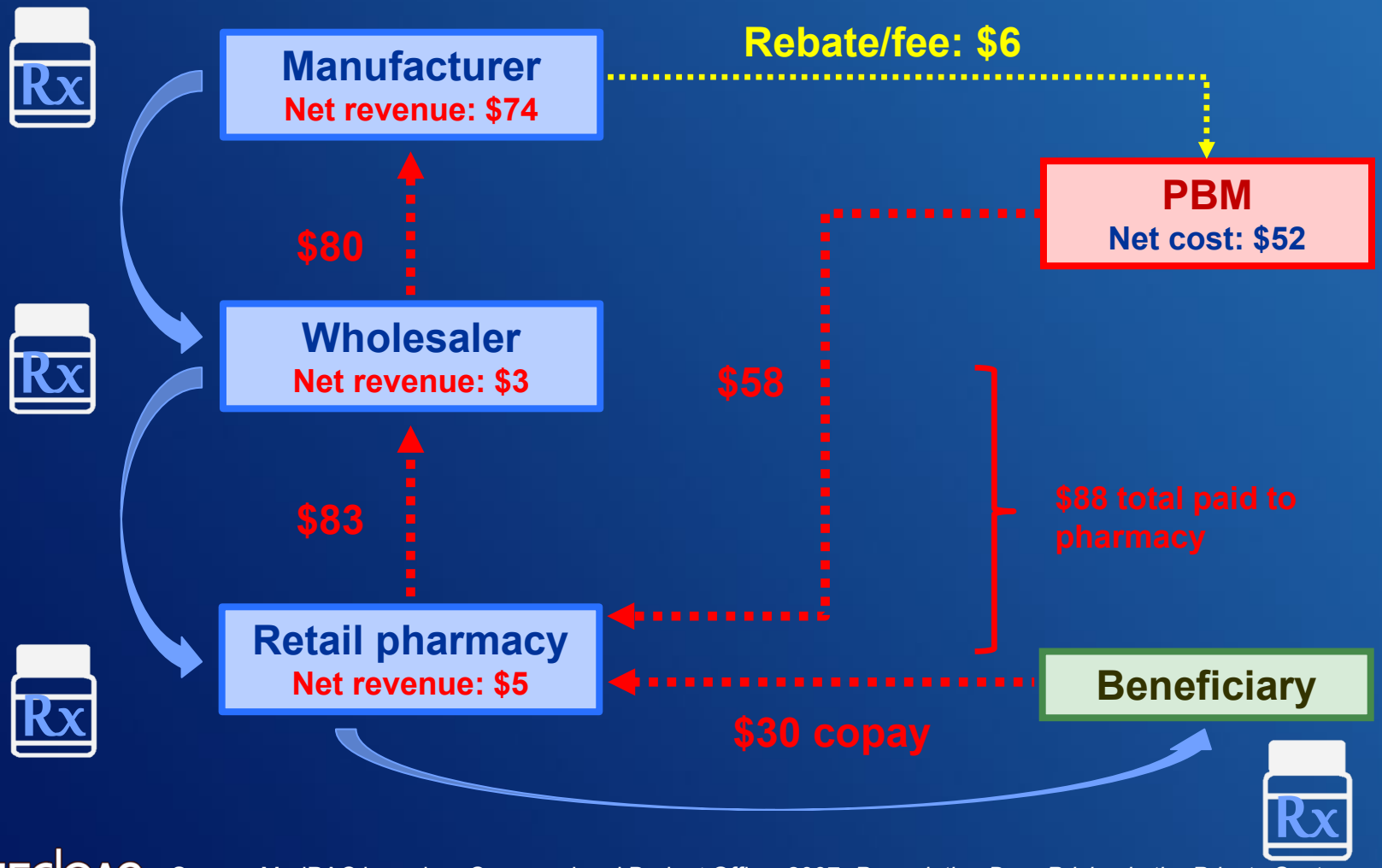
Supply chain: Pharmacies

- Include chain and independent pharmacies, food stores with pharmacies, and mail-order pharmacies
- Account for about ¾ of prescription drug market (remainder via nonretail providers such as hospitals)
- Stock a wide range of drugs and fill prescriptions on demand
- Negotiate rebates with manufacturers of multiple-source drugs (competition among manufacturers provides them with leverage)
- In 2013, about 65% of the prescription dispensing revenues accounted for by 5 pharmacy chains (CVS Health, Walgreens, Express Scripts, Rite Aid, and Walmart)

Supply chain: Pharmacy benefit managers

- Administer a drug benefit on behalf of a health plan or an employer
  - Build pharmacy networks
  - Negotiate payment rates with pharmacies
  - Obtain rebates from manufacturers
  - Manage drug use and spending (e.g., tiered copay, prior authorization)
- Use formularies (list of covered drugs) as leverage in rebate negotiation
- About ¾ of the prescription dispensing revenues accounted for by 4 PBMs (Express Scripts, CVS Health, Prime Therapeutics, Optum Rx)

Hypothetical example of payments for a brand-name drug



Source: MedPAC based on Congressional Budget Office. 2007. *Prescription Drug Pricing in the Private Sector*. Washington, DC: CBO.

For your discussion

- Questions or comments on the material?
- Comments on implications for Medicare?