



Advising the Congress on Medicare issues

Context of Medicare drug spending

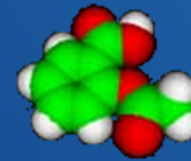
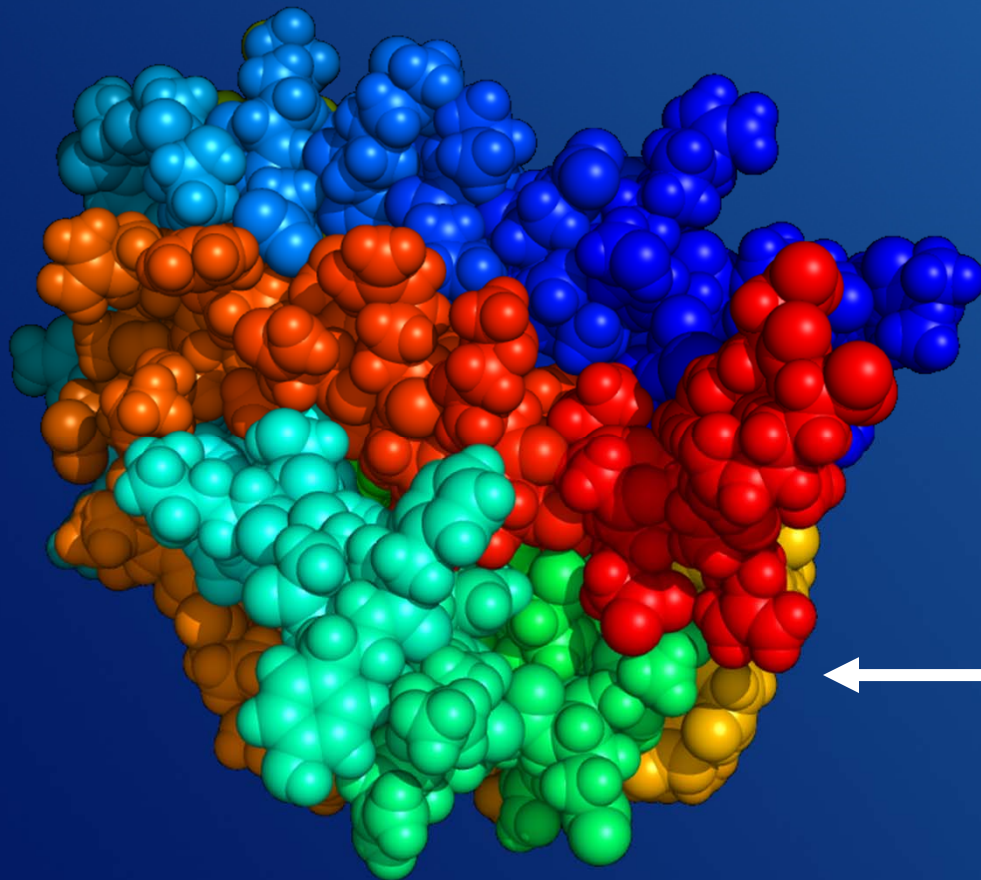
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Roadmap

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

Background: Drugs versus biologics



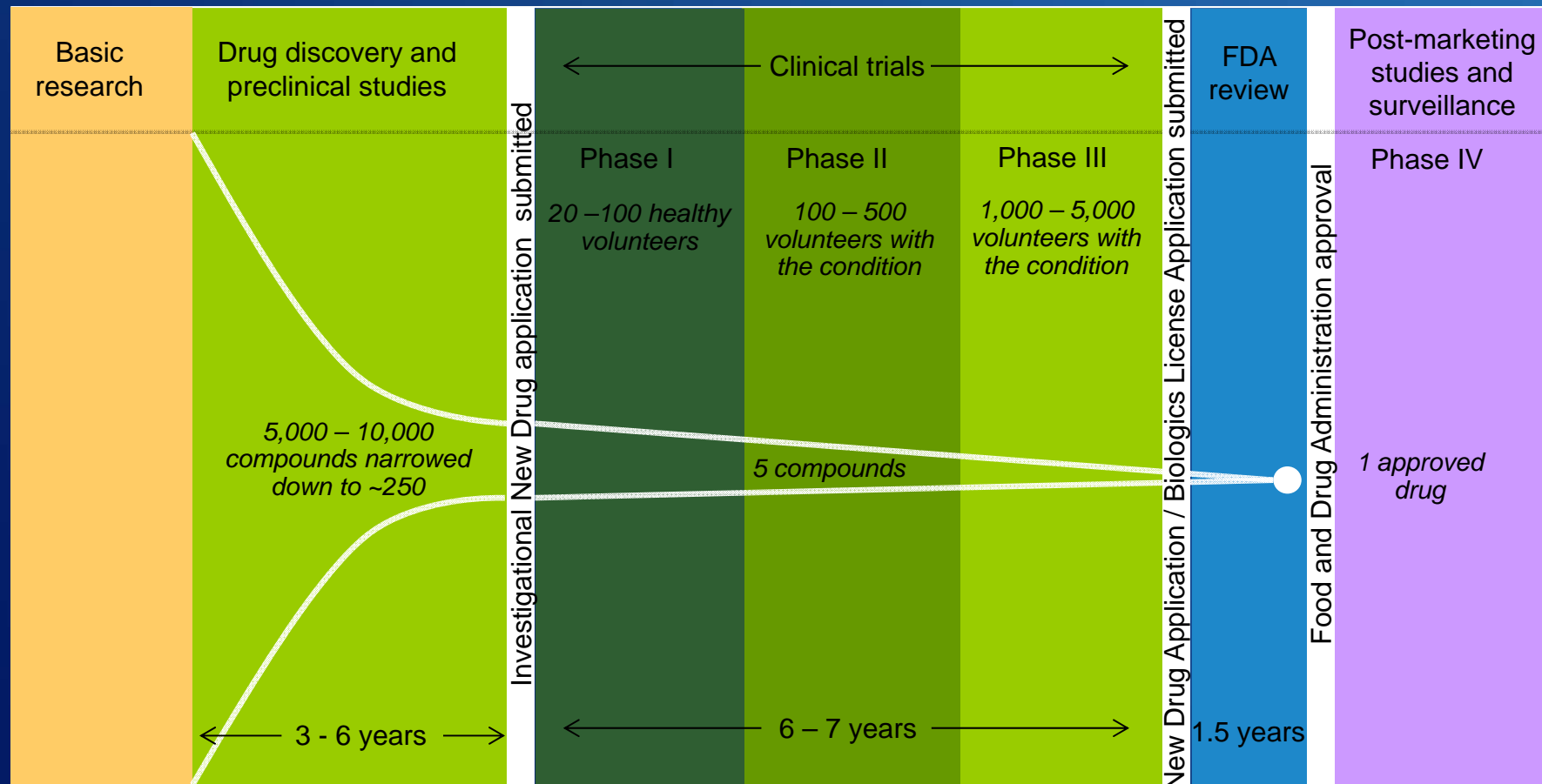
Small molecule drug:
Synthesized via a chemical
process (pictured: aspirin)

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

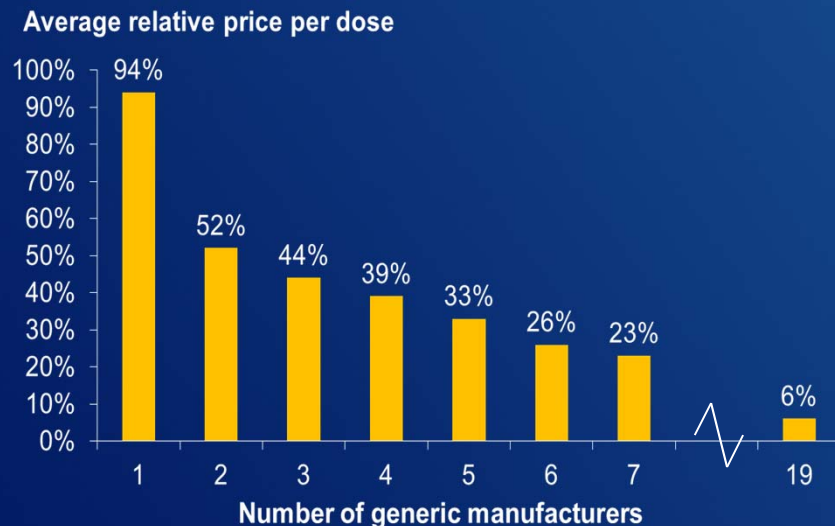


FDA approval triggers data and market exclusivity periods

- 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



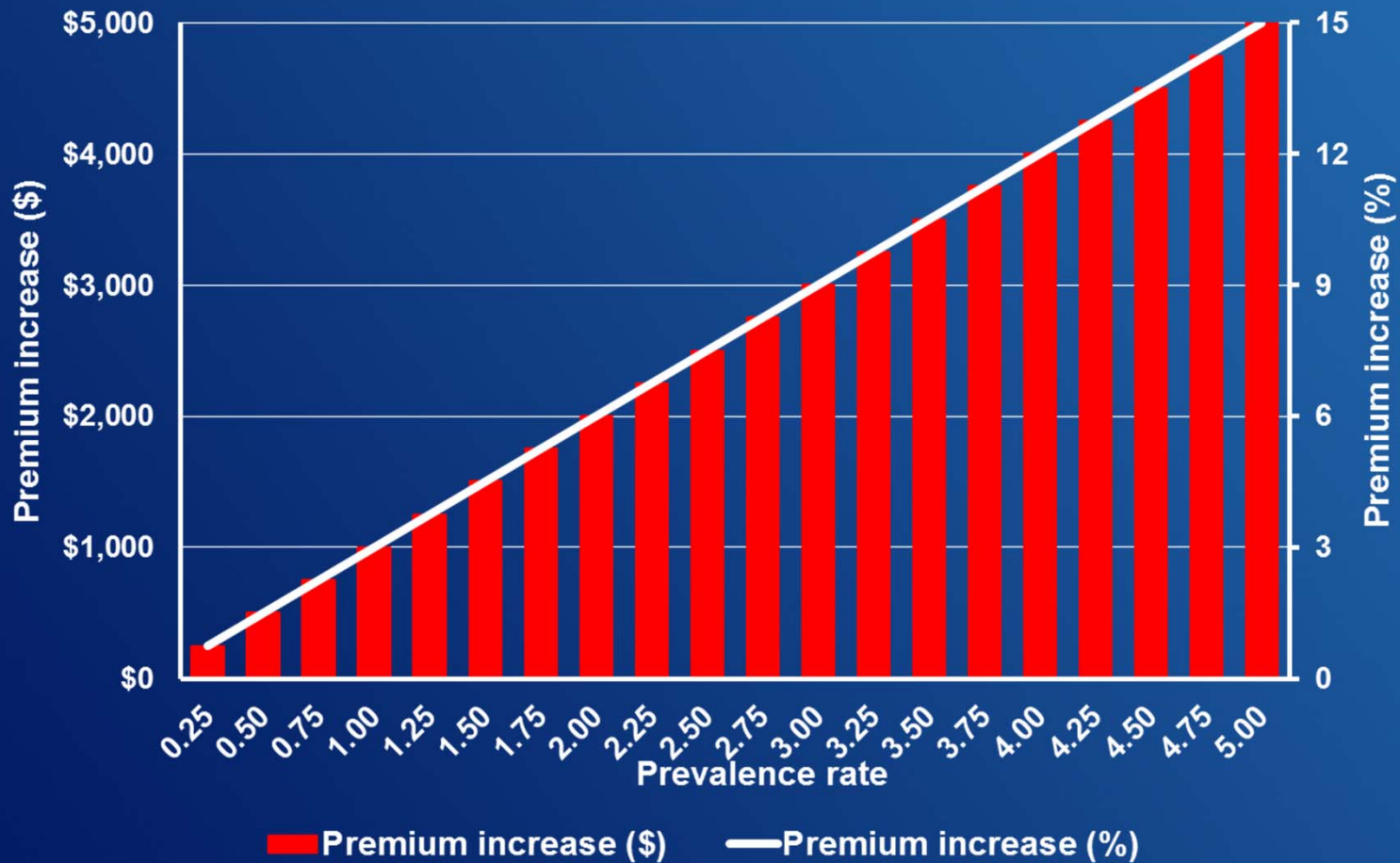
Source: FDA analysis of retail sales data from IMS Health, IMS National Sales Perspective™, 1999-2004, extracted Feb. 2005.

- 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

Wider use of specialty drugs could lead to higher premiums



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)

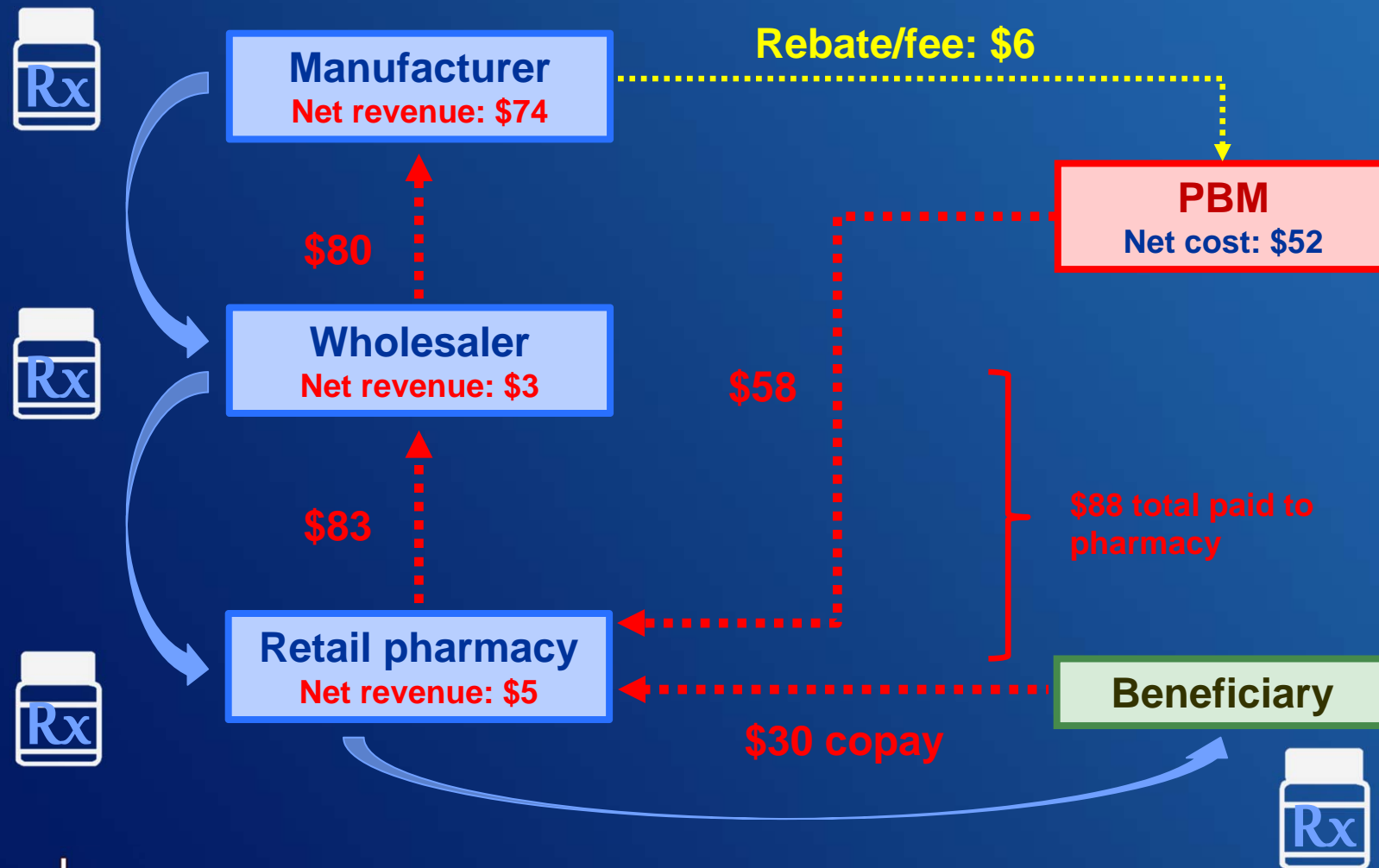
Supply chain: Pharmacies

- Include chain and independent pharmacies, food stores with pharmacies, and mail-order pharmacies
- Account for about $\frac{3}{4}$ 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 $\frac{3}{4}$ 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



For your discussion

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