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The Impact of Pharmaceutical Price Controls on R&D

Presentation to the *Judicial Education Program*
AEI-Brookings Joint Center for Regulatory Studies
May 16, 2005



Robert B. Helms

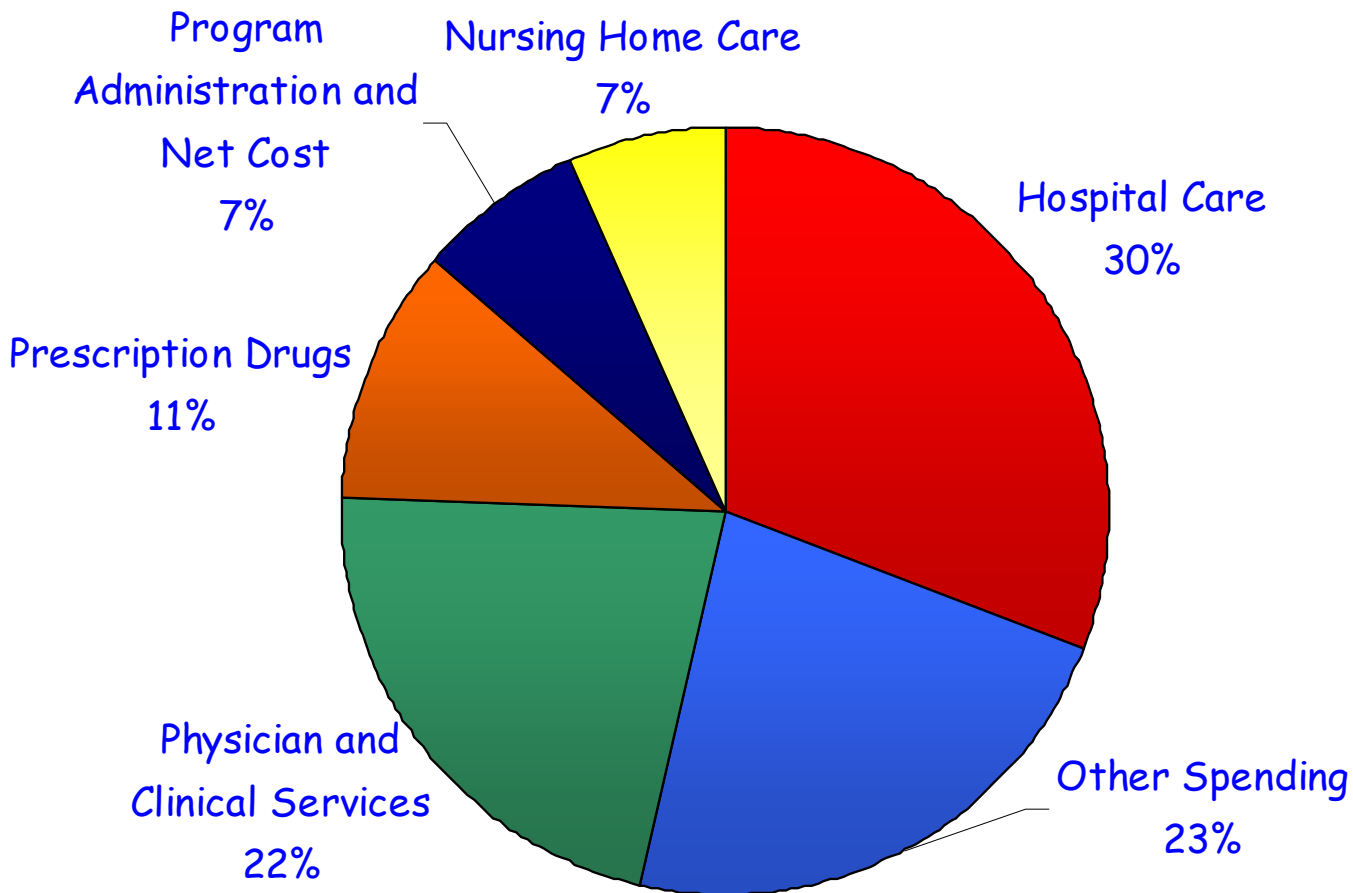
Resident Scholar

American Enterprise Institute

Pharmaceutical Economics

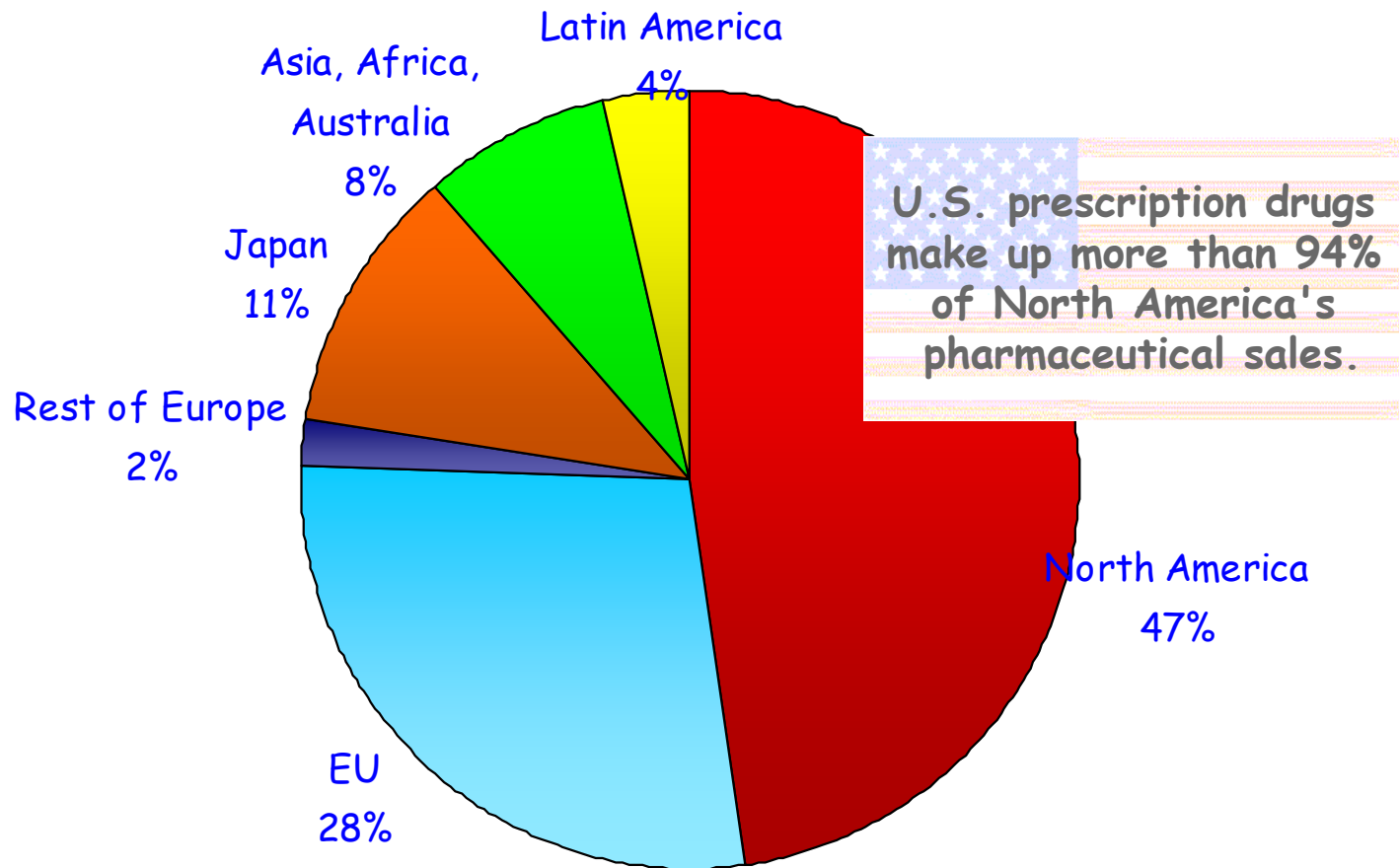
- The pharmaceutical industry today
- Competitive behavior in the high-tech health industry
 - The effects of regulation
 - Pricing in domestic and international markets
 - The effects of price controls
 - The nature of industry competition

How the U.S. Health Dollar is Spent



Source: CMS, 2003 data

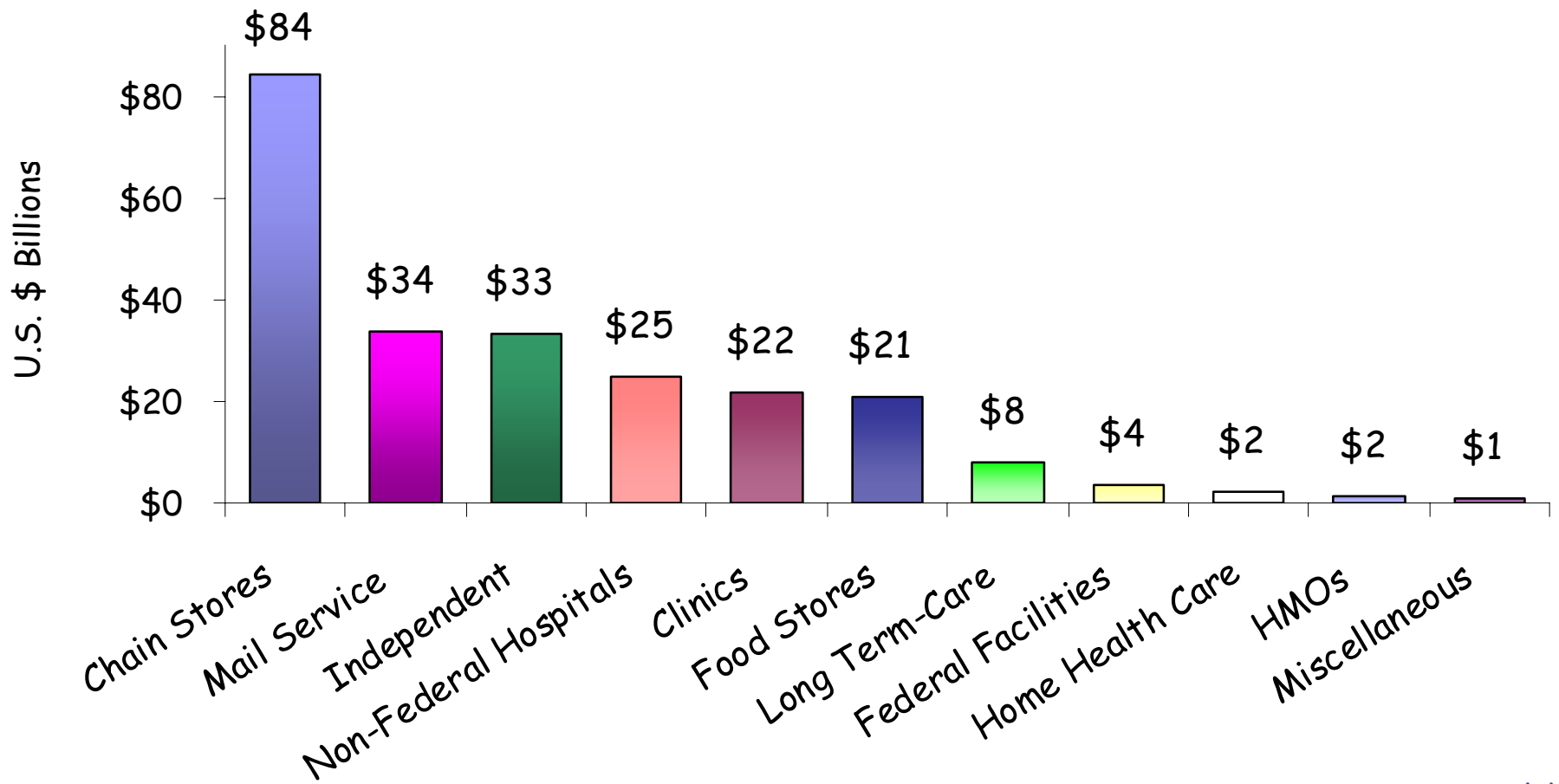
Global Pharmaceutical Sales by Region, 2004



Source: IMS Health

How Are Drugs Sold?

U.S. Purchase Activity by Channel, 2003



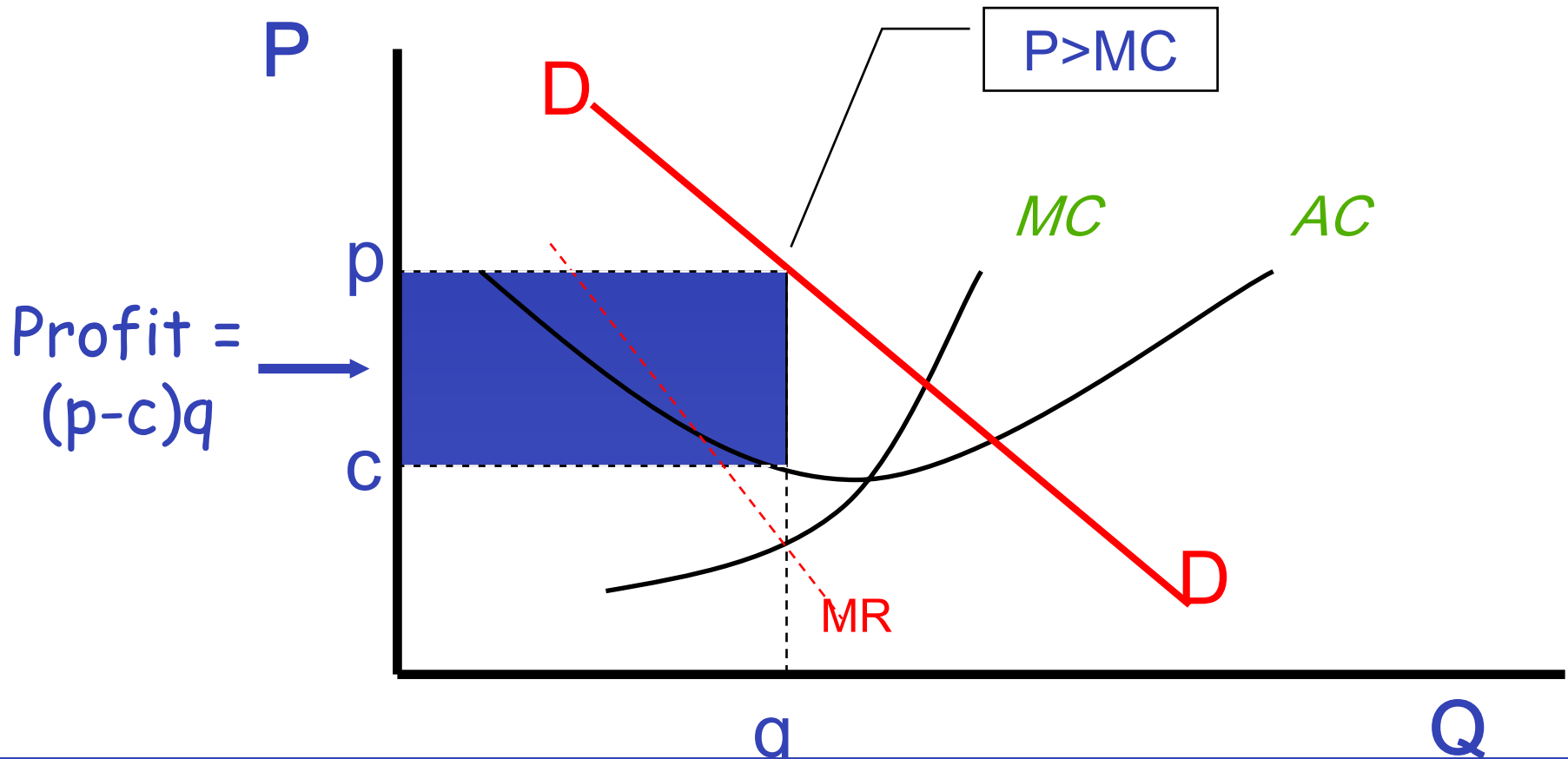
Source: IMS Health

The Pharmaceutical Market

- Joint product—Rx plus information
- Products high in value relative to their bulk
- High sunk costs by time of marketing
- Patent protection for some years
- Government regulation is important
 - New product approvals
 - Manufacturing
 - Promotion, marketing, and distribution
 - Prices in most countries, *but not the US*

Price Searchers Market

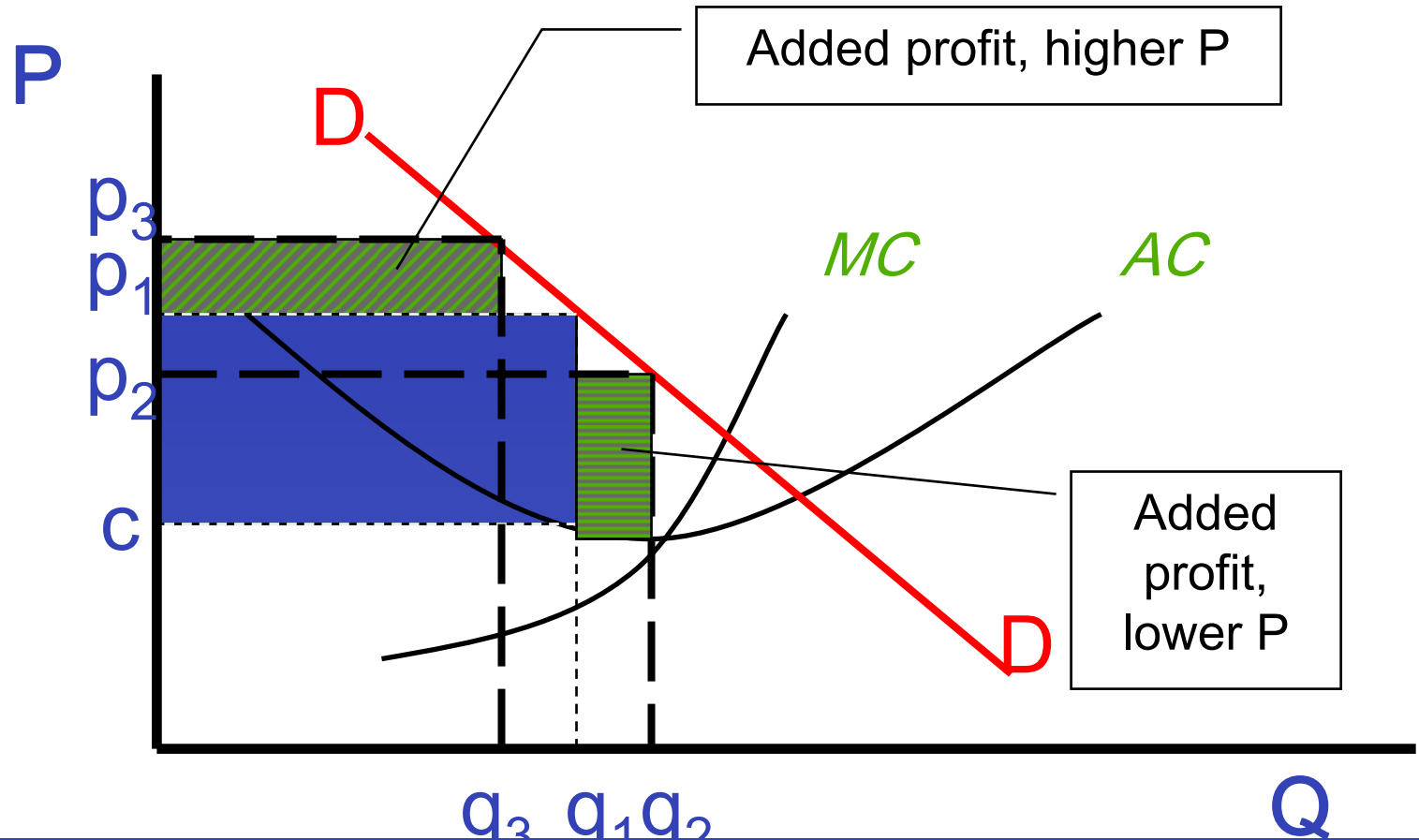
Short run equilibrium



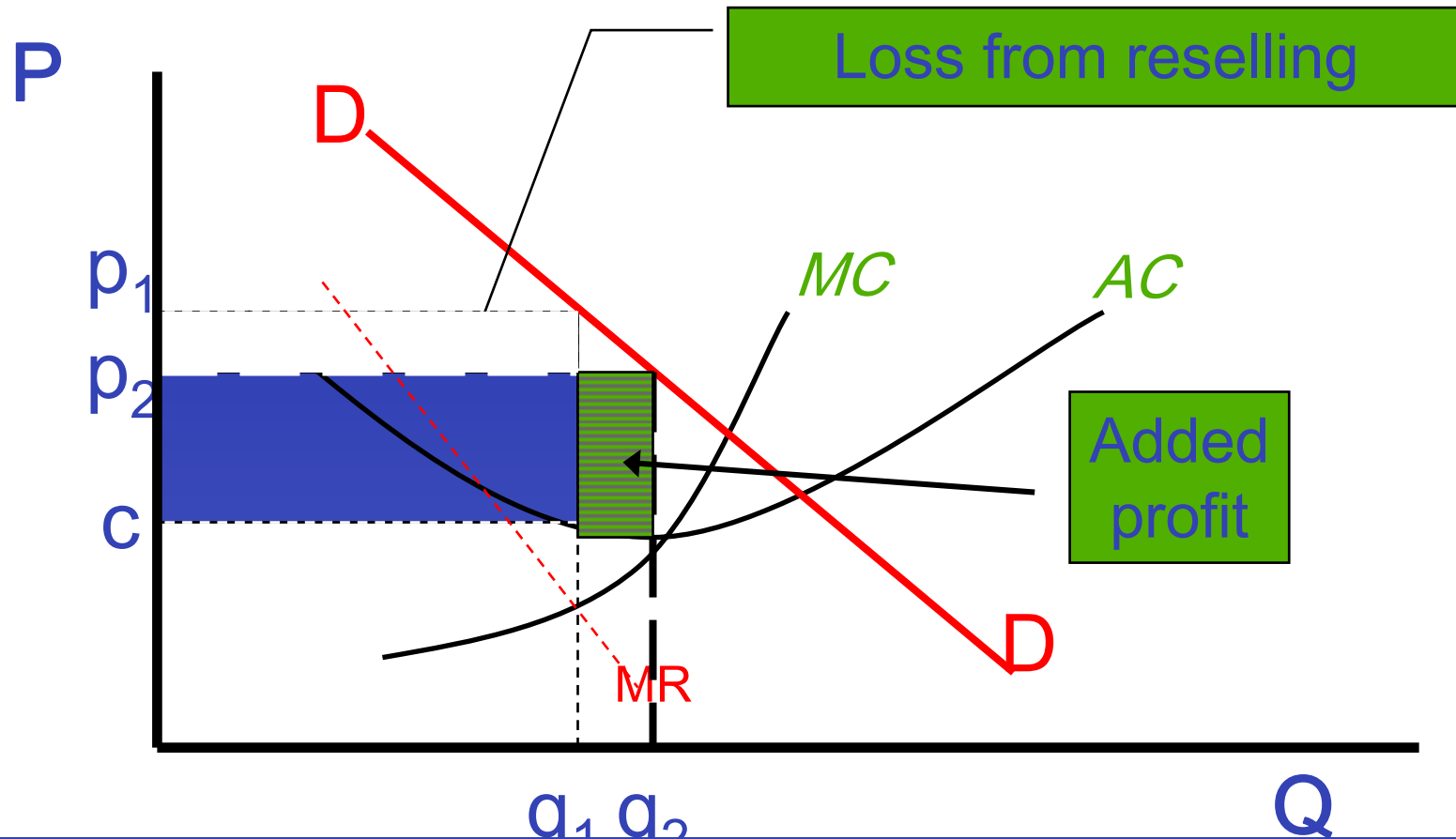
The Incentive to Increase Profits by Separating Markets

- Charging a single price may not maximize profits
- Charging different prices to different customers is common in many markets
- Two conditions to be successful
 - Must be a price searcher
 - Must keep markets separate - prevent reselling
- Old name: price discrimination
- New names:
 - Multi-part pricing
 - Multi-market pricing
 - Ramsey pricing

Adding a Small Market Increases Profits

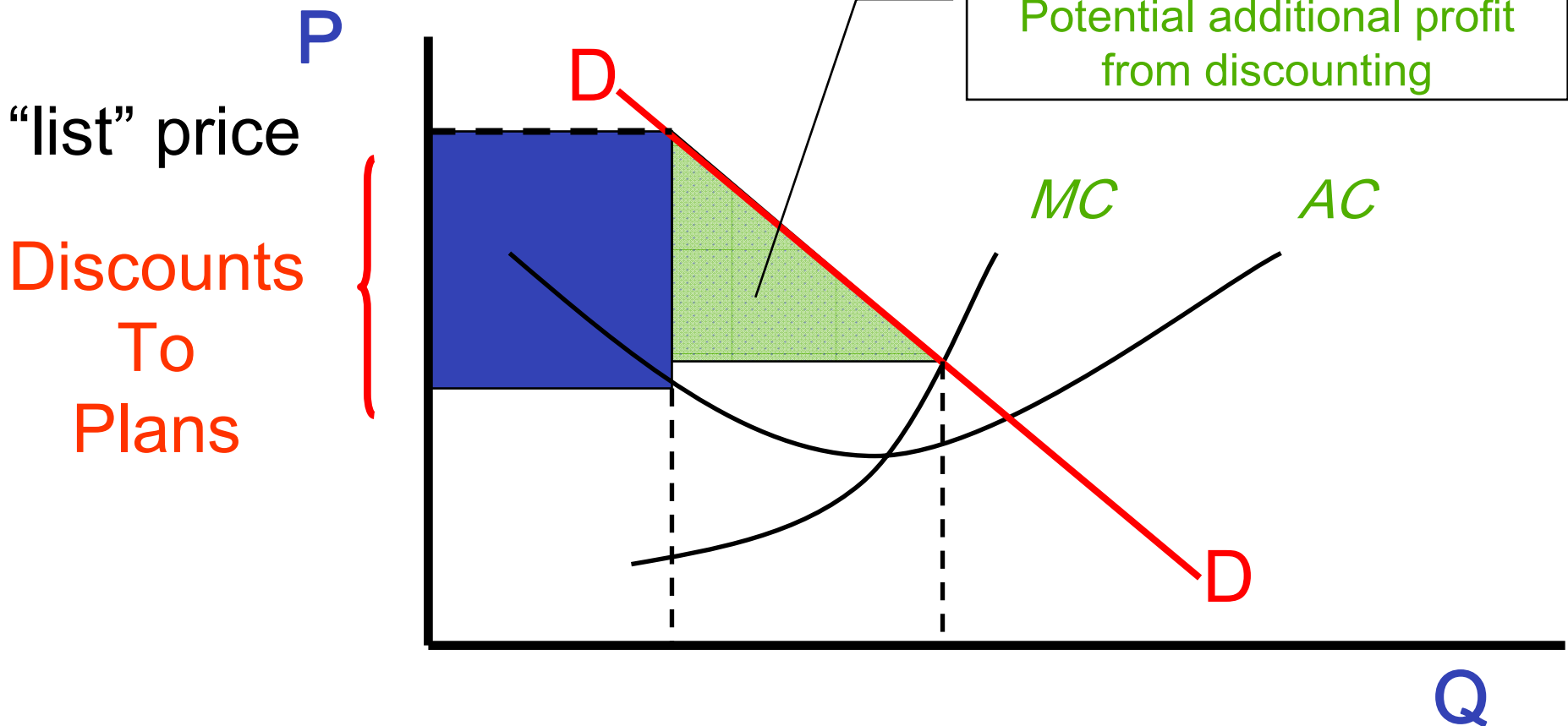


But, you lose if you can't prevent reselling



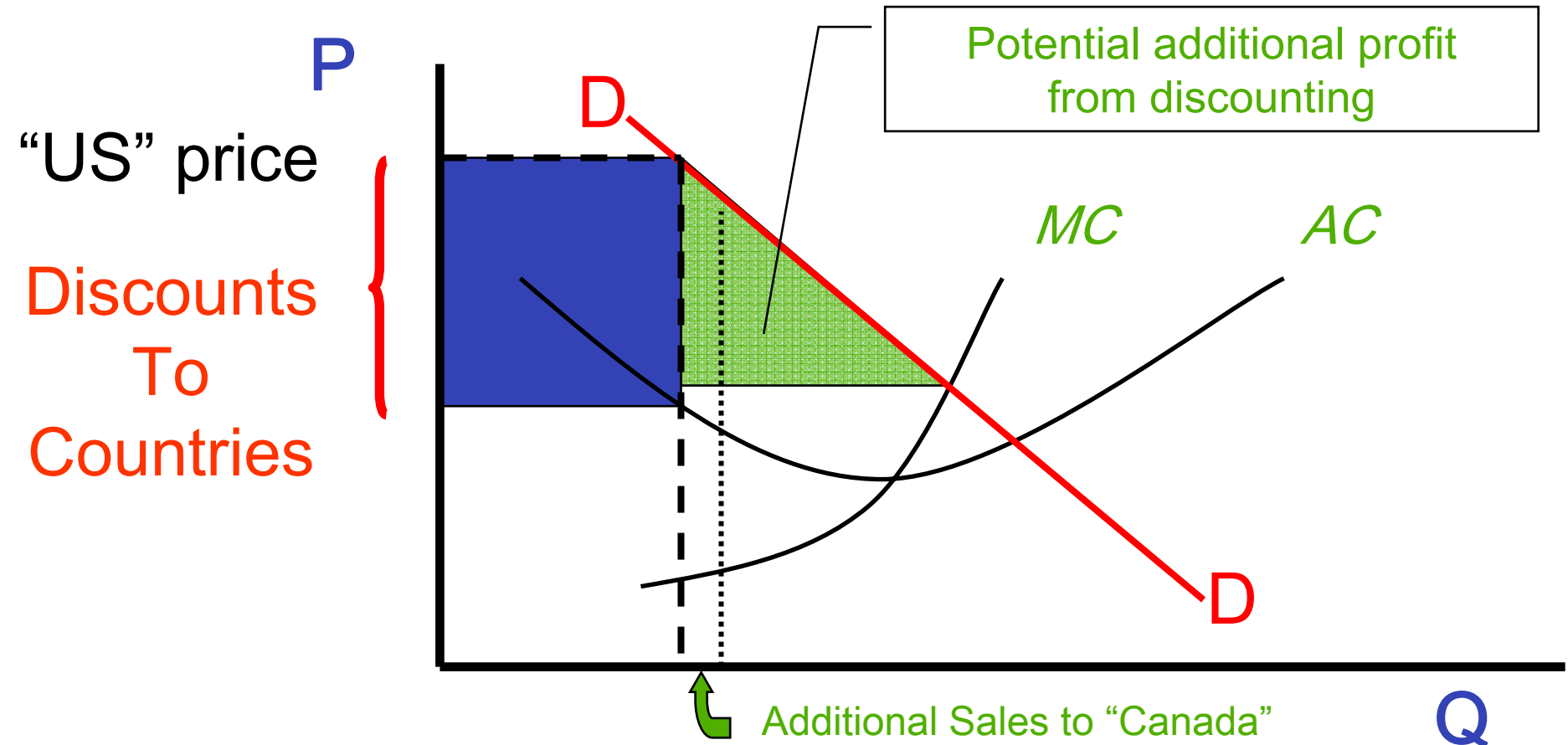
Pricing in Domestic (US) Market

Discounts to VA, PBMs, Health Plans



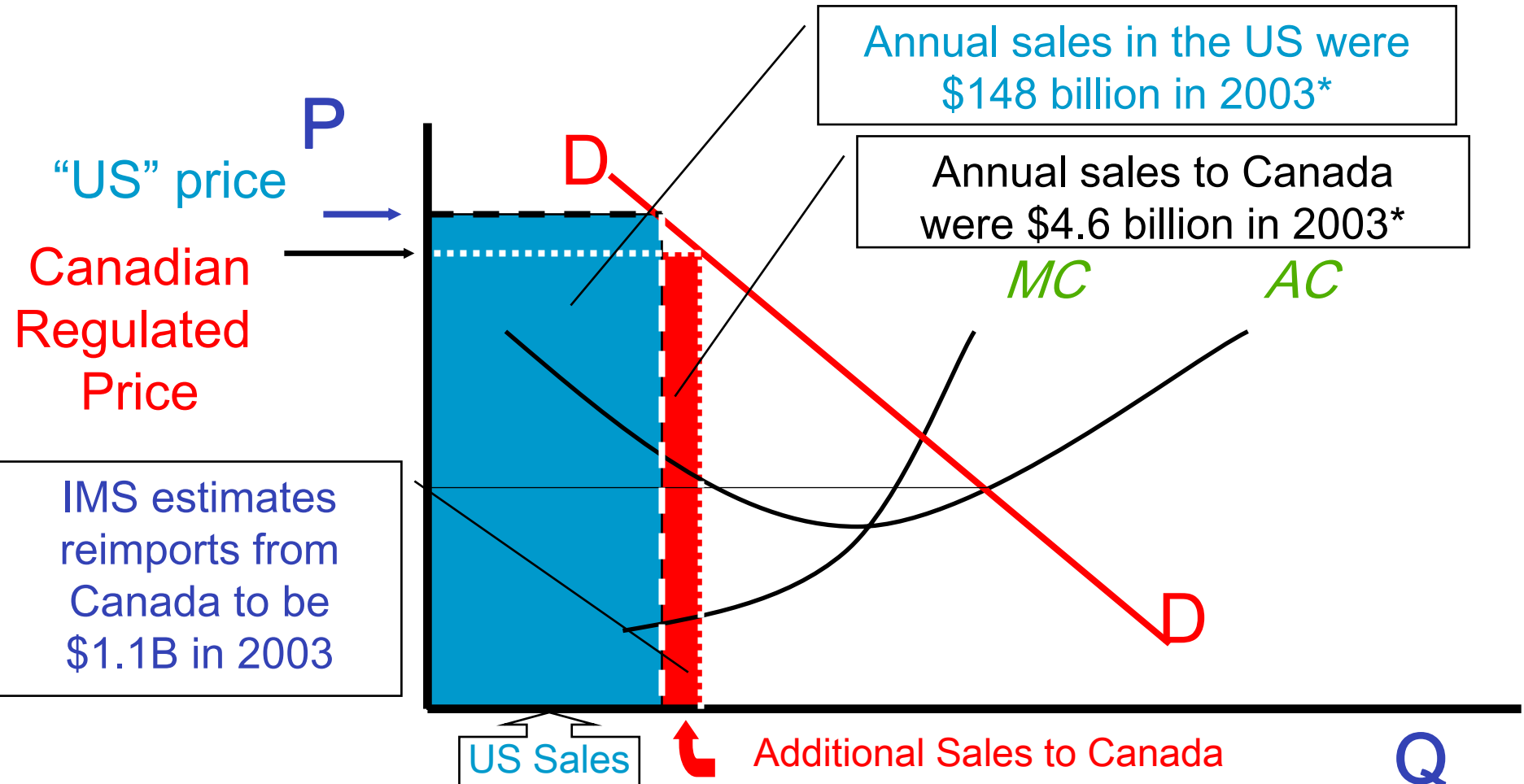
Pricing in International Markets

Discounts to Canada, Spain, France, etc.



Reimportation from Canada

The effects in the US will be small



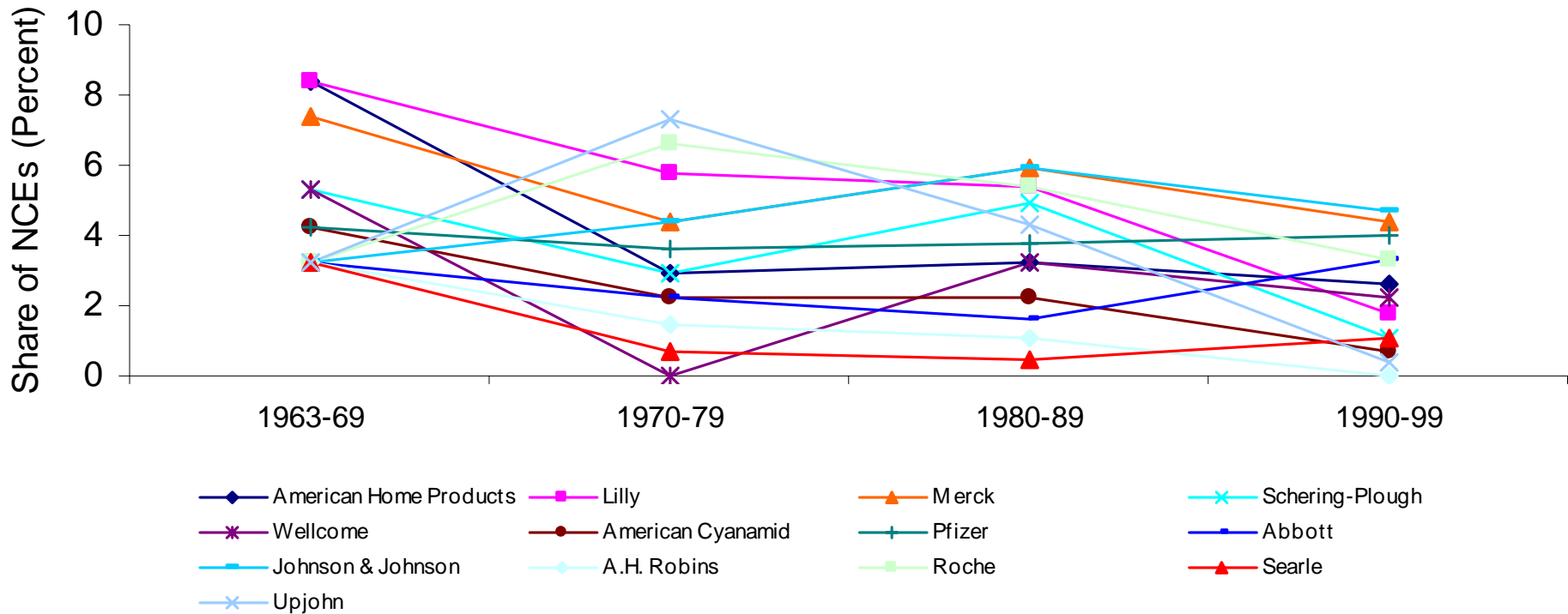
CBO Analysis of Reimportation

- H.R. 2427 passed the House in July 2003
- Would have permitted importation from 25 countries
- Estimated to reduce total US drug spending by about 1 percent (\$40 billion over 10 years)
- Reimportation from Canada would only “produce a negligible reduction in drug spending”

How Do Pharmaceutical Firms Compete?

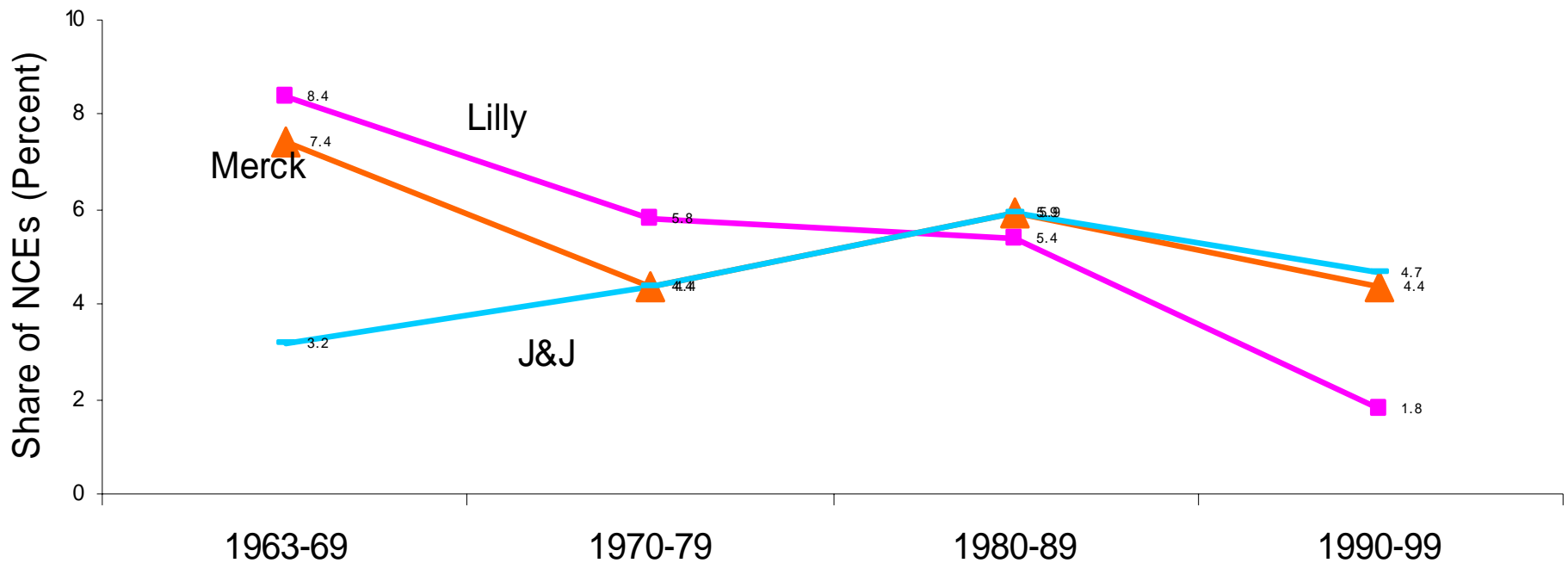
- Development of new drugs
- Marketing of new products purchased or leased from smaller firms
- Managing the FDA approval process
- Promotion to providers and consumers
- Direct price competition typically comes later

Share of NCEs by Leading Companies, 1963-1999



Source: Joseph A. DiMasi, "New Drug Innovation and Pharmaceutical Industry Structure," Drug Information Journal, Table 10.

Three Examples: Lilly, Merck, and J&J



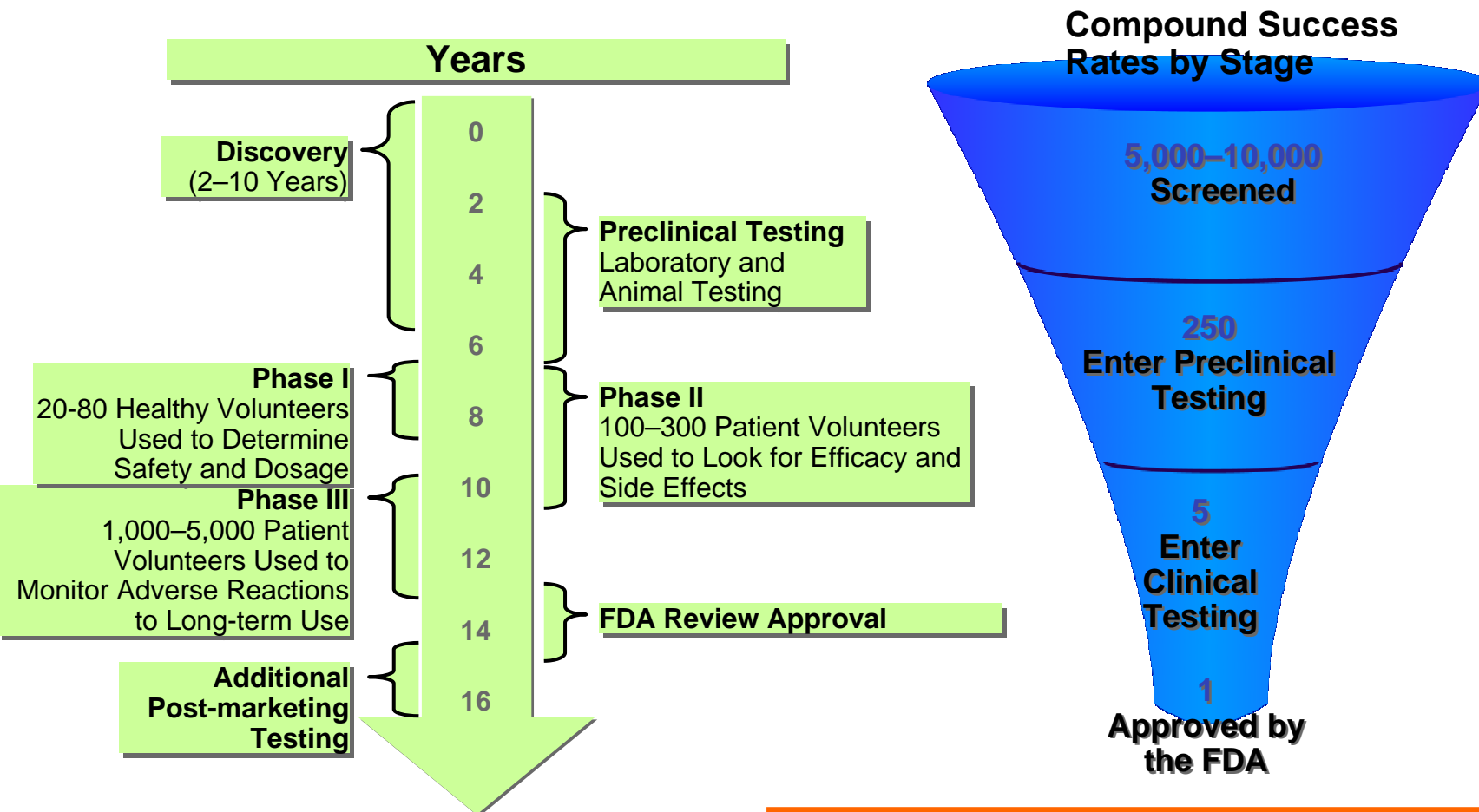
Source: DiMasi

Will Price Controls Affect R&D Investment?

- Life cycle for each product is typically 20 to 25 years
- FDA market approval may take from 13 to 15 years
- Potential revenue is delayed
- Market leadership may be limited
 - New branded products
 - Generics

New Product Development

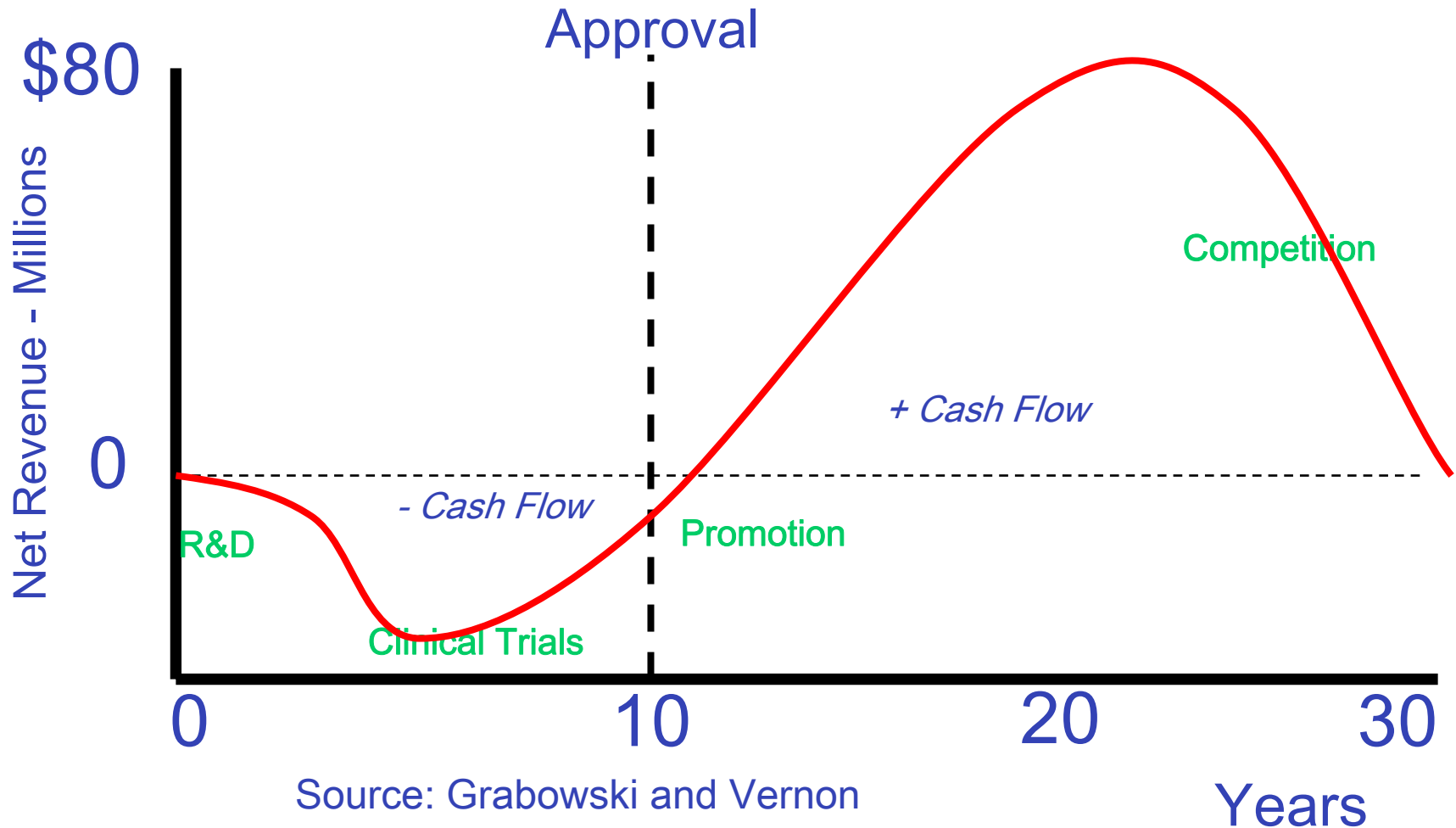
A Risky and Expensive Proposition



Source: Tufts Center for the Study of Drug Development

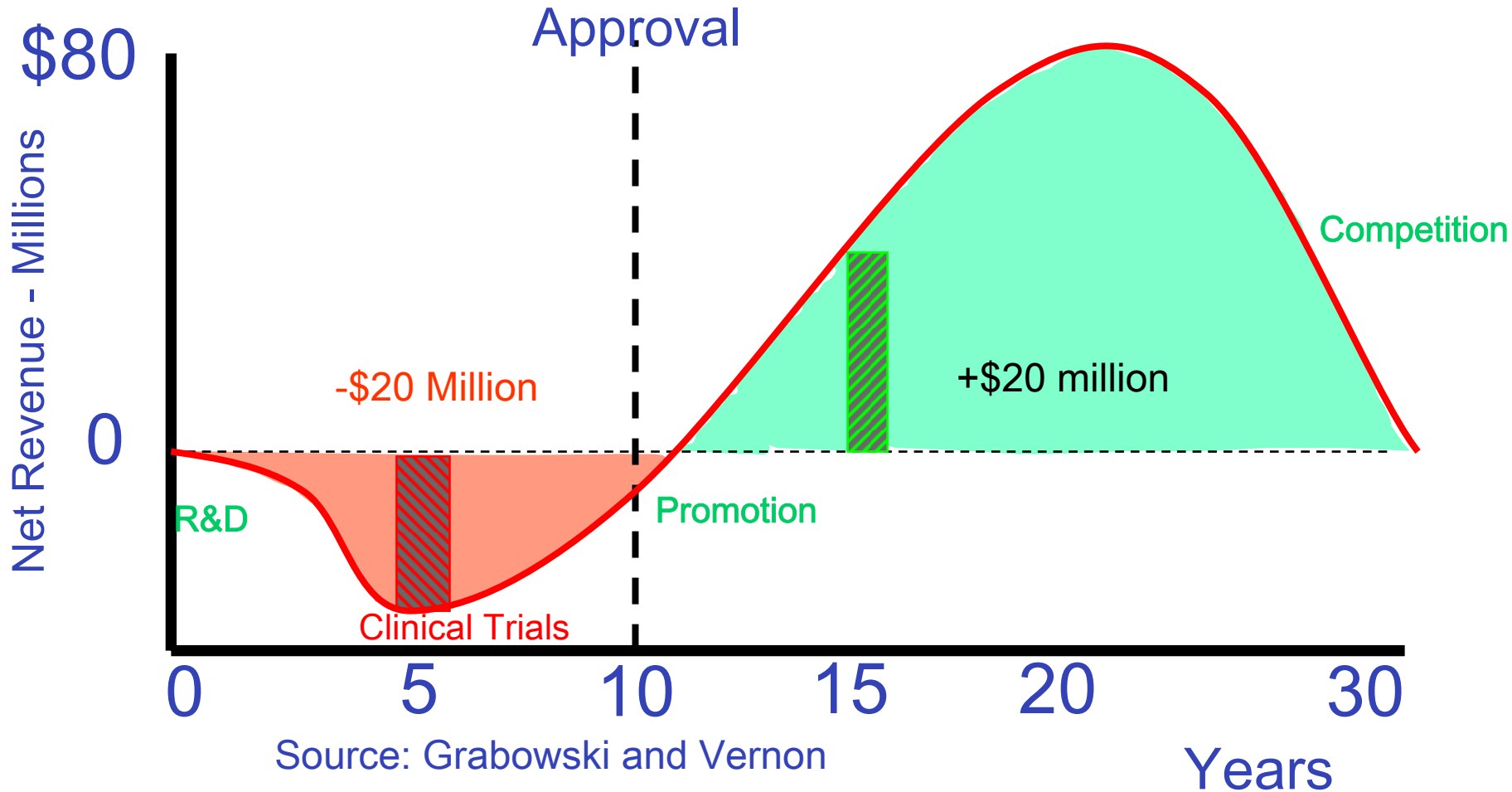
Net Cost: \$802 M invested over 15 years

Product Net Cash Flows



Source: Grabowski and Vernon

Up-front Costs vs. Delayed Revenue



Present Value

Time makes a big difference

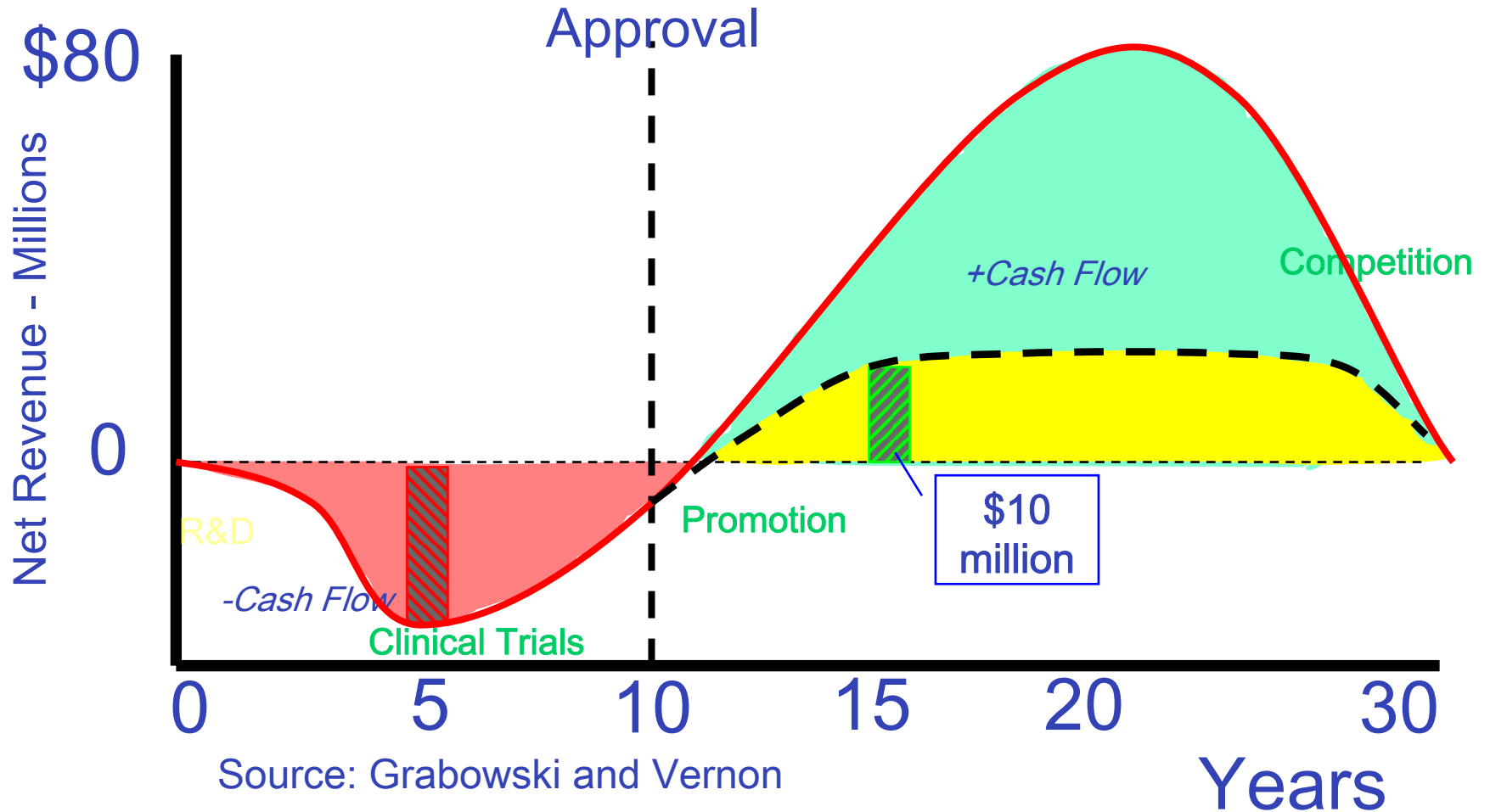
- PV of **\$20 million** in year 15

- $PV_{15} = \frac{20}{(1+.06)^{15}} = \frac{20}{2.40} = \$8.35m$

- PV of **-\$20 million** in year 5

- $PV_5 = \frac{-20}{(1+.06)^5} = \frac{-20}{1.34} = -14.95m$

The Effect of Price Controls



Source: Grabowski and Vernon

Effects of Price Controls

Present Value of \$10m in year 15

- PV of **\$10 million** in year 15

$$\blacksquare PV_{15} = \frac{10}{(1+.06)^{15}} = \frac{10}{2.40} = \mathbf{\$4.17m}$$

- PV of **-\$20 million** in year 5

$$\blacksquare PV_5 = \frac{-20}{(1+.06)^5} = \frac{-20}{1.34} = \mathbf{-14.95m}$$

Effects of Price Controls on Pharmaceutical Industry R&D

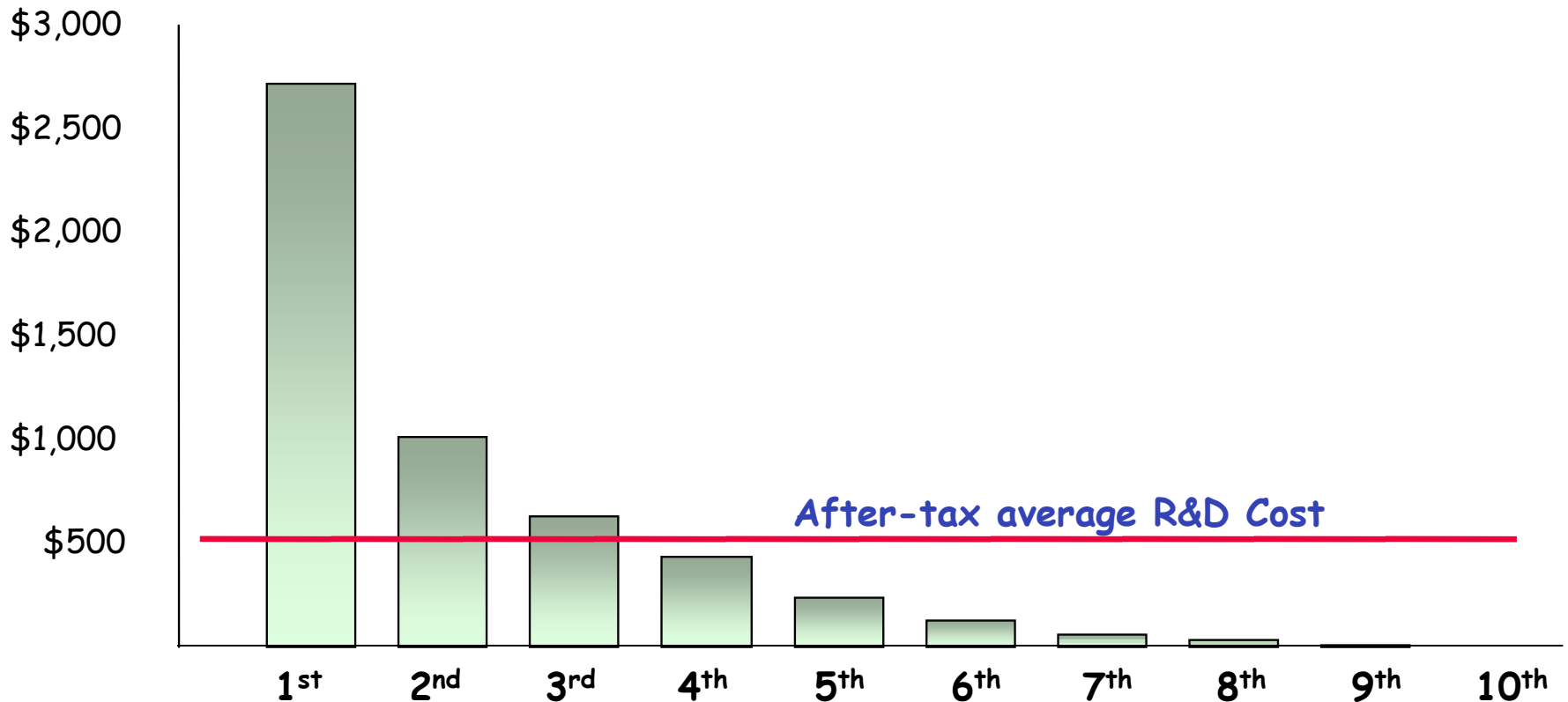
- Investment today is strongly affected by expectations of future costs and revenues
 - The longer the development time, the lower the present value
 - The smaller the expected market (sales), the lower the present value
 - The greater the risk, the lower the expected revenue
 - The higher are interest rates, the lower is the present value (better returns in alternative investments)

How a Firm Would Respond to Price Controls

- Reduce the total R&D investment
- Concentrate on drugs for larger markets
 - Drop small market projects (vaccines)
- Increase short run projects relative to longer term projects
- Reduce the risk profile of projects
 - Drop riskier projects

Most Products that Get to Market Never Make Enough to Recoup R&D Investment

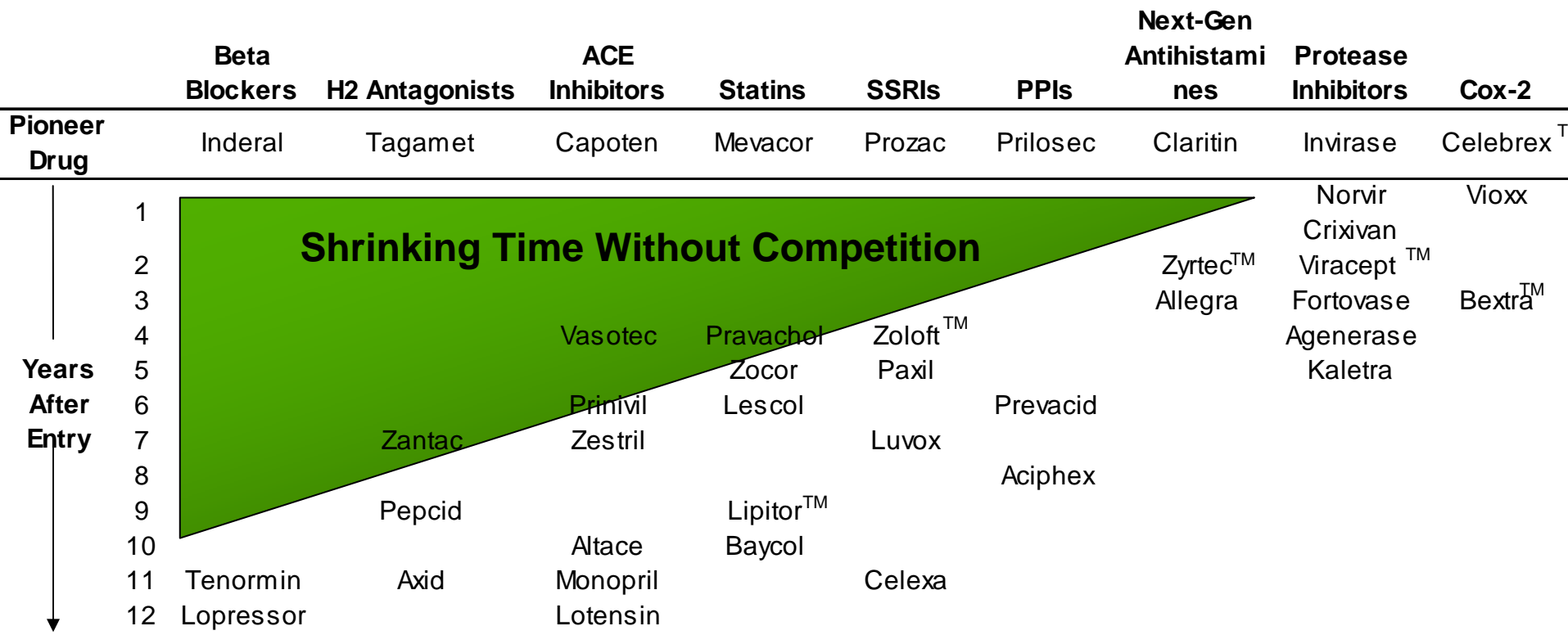
Value of After-Tax Net Lifetime Sales of New Drugs (\$millions)



New Products Grouped in Tenths According to Financial Success

So-Called "Me-Too" Drugs Create a Highly Competitive Marketplace

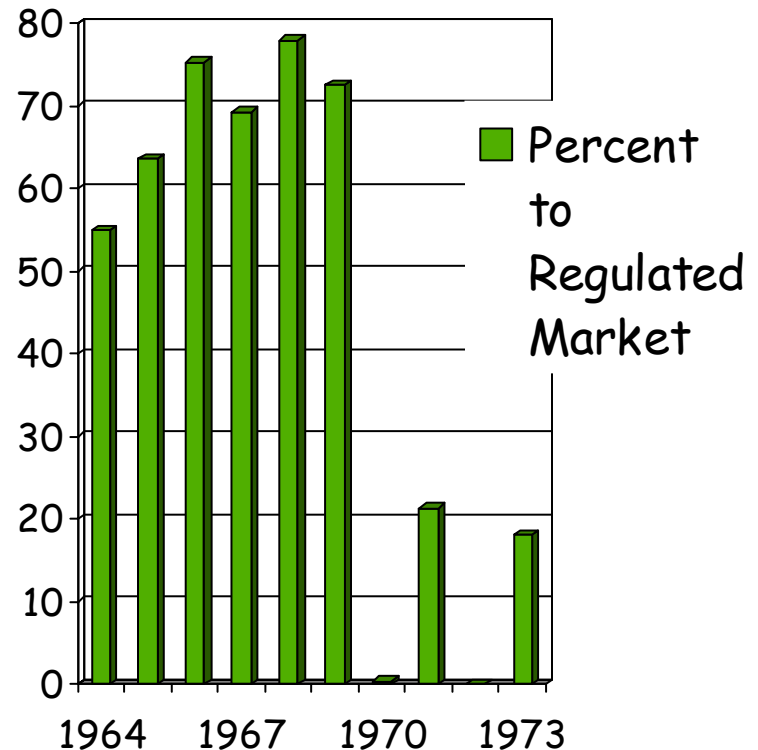
Year of Therapeutic Class Launch



Source: FDA Orange Book

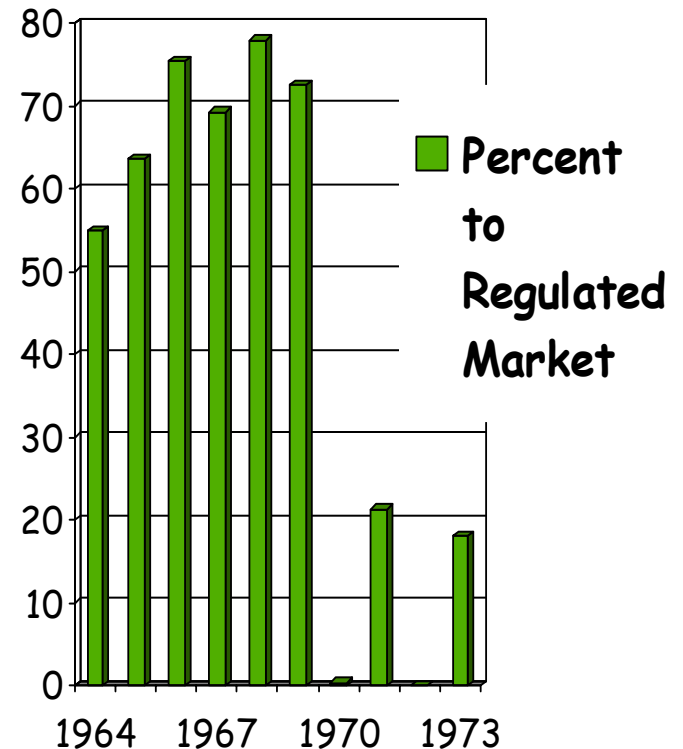
Price Controls in Another Market 1960 - 1973

- Product involved large upfront investment and delayed revenue
- Price Controls imposed in 1965
- Large diversion of product out of regulated market



Field Market for Natural Gas 1960 - 1973

- Supreme Court gave FPC authority to regulate field market prices in 1960
- FPC then took 5 years to establish permanent controls
- Chart shows percent of new gas discoveries going to regulated interstate market
- Large diversion of natural gas to the unregulated intrastate market



Source: Robert B. Helms, *Natural Gas Regulation*, AEI, 1974.

Future Issues

- A change in the Medicare law?
 - The effects of the discount cards?
 - Medicare purchasing or private plans?
 - Reimportation from Canada?
 - The imposition of price controls?
- The role of private sector purchasing?
- Will the blockbuster model survive?
- The effects of cross-border trading?