The Pharmaceutical Industry: What do policy makers need to know about it?

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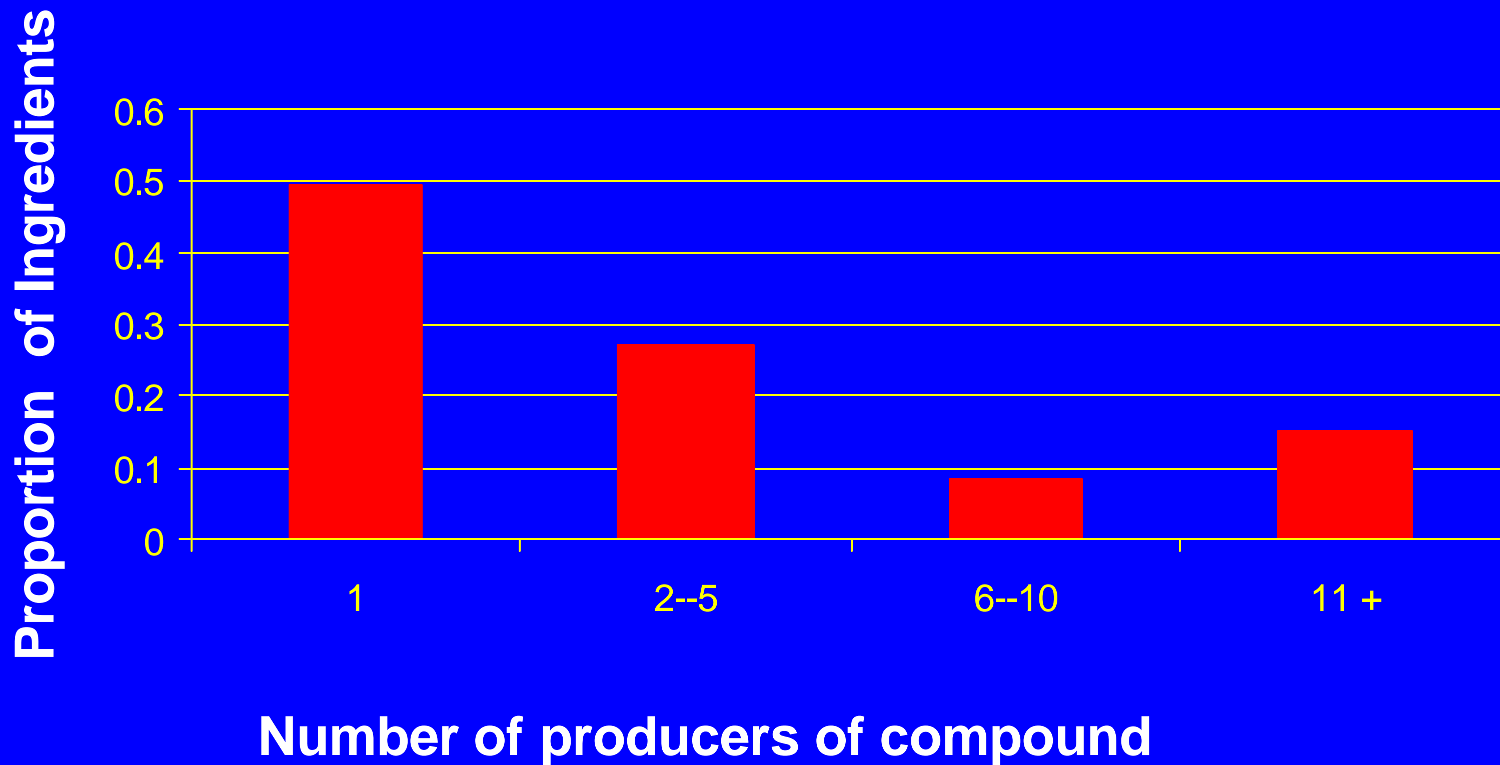
Two pharmaceutical industries

- **An industry of differentiated products**
  - Sometimes known as the “research-intensive” pharmaceutical industry.
  - Products have brand names.
  - Have some degree of monopoly power. (i.e., they are price setters.)
    - Pure monopoly (no close competition for the intended market)
    - Oligopoly (small number of distinct products, not perfect substitutes)
    - Monopolistic competition (large number of distinct products, not perfect substitutes)
- **A commodities industry**
  - Sometimes known as the “generics” industry.
  - Manufacturers are price takers.

Competition in sale of prescription drugs, 1999
(Ingredient Level Analysis)



Source: Drug Redbook, 1999

- The firms in these two industries partially overlap.
- Some research-based companies own generic subsidiaries.
- Some generic companies produce brand name products.

Stop thinking about the industry
as a collection of companies.

Start thinking about the industry
as a collection of assets.

- The assets of the pharmaceutical industry are marketable brand-name products and commodities.
- Those assets are created through R&D and other kinds of investment in capacity and know-how.
- Ownership of assets is bought, sold, exchanged and shared by investors and the companies they work through.

- Mergers, acquisitions, marketing agreements, strategic alliances, etc. are all transactions aimed at reallocating assets among owners.

- May increase owners' value by:
  - Reducing costs
  - Increasing monopoly power

Sources & limits of monopoly power for brand-name drugs

- **Sources:**
  - Patent protection (20 yrs from application).
  - FDA-administered exclusive marketing rights
    - Orphan drug exclusivity (7 yrs)
    - New dosage forms or combinations (3 yrs on the new form)
    - Pediatric studies (6 mo.'s)
    - De-facto protection of biotechnology drugs
    - First generic entry (6 mo)
  - Technology transfer policies (Gov't supported research)
- **Limits**
  - Limits on patentability
  - The design-around phenomenon: entry of close substitutes
  - Antitrust laws and regulation
  - Ultimate entry of generic competitors (product ♎ commodity)

The FDA plays a unique role in overseeing the creation of new assets, protecting the legal monopoly status of some assets, requiring the destruction of some assets, and managing the transition of monopolies into commodities.

Why give monopoly rights?

- Because discovery and development of new drugs is costly & risky.
- Because investors would not put up the money for discovery & development if they could not hope to be repaid for that investment through prices that are higher than the day-to-day costs of production & distribution.

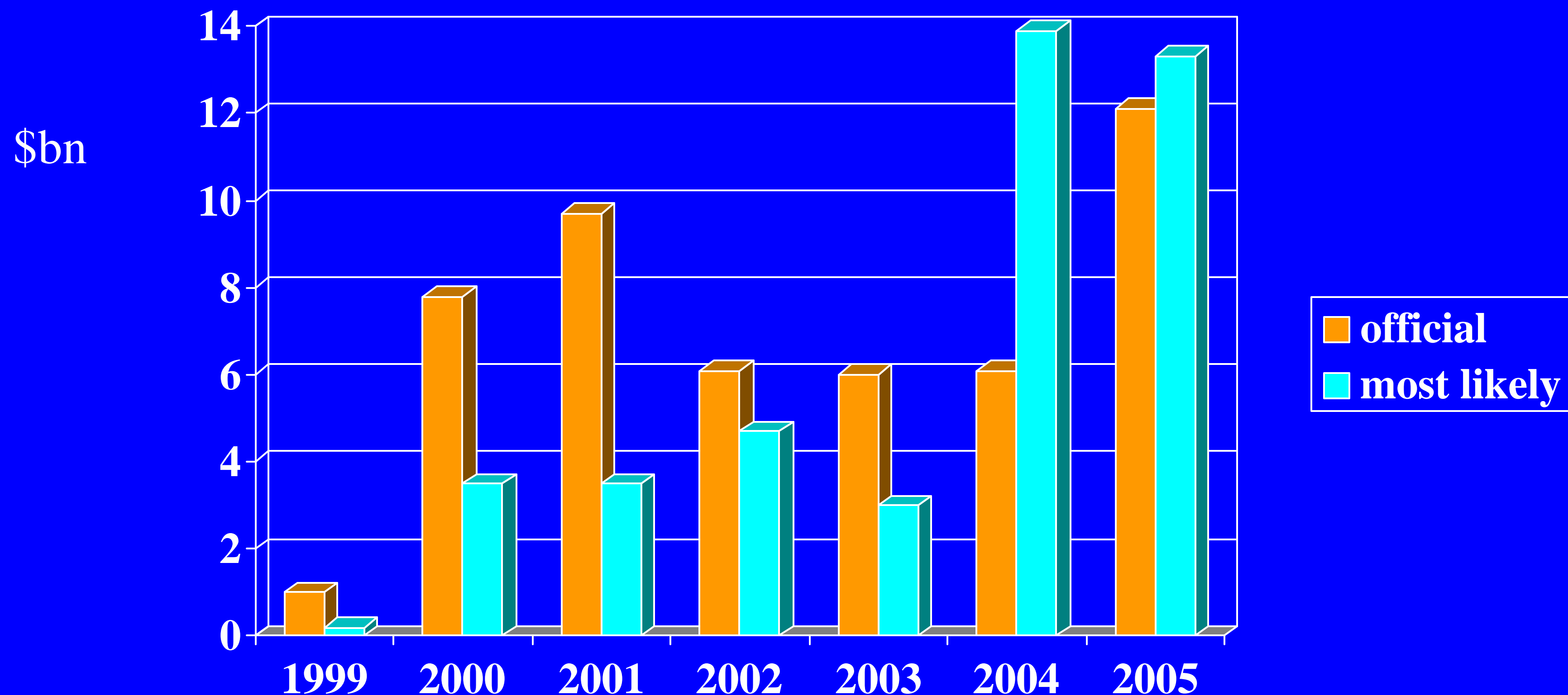
Medical monopolies create special problems not shared by other sectors of the economy.

- **Insurance & third party payment.**
- **Complexity/ignorance/agency.**
- **Ability to price discriminate.**

Policies to limit monopoly power of patent-protected drugs.

- Limit the prices of patent-protected drugs.
- Limit the patent-protection period.
- Encourage more price competition among close competitors (i.e.,create more price sensitivity among consumers or their agents.)

Dollar Value of Significant* Drugs Going off Patent: Official Patent Expiration Dates vs. Estimated Generic Entry Dates



Source: Lehman Brothers Specialty Pharmaceutical Research, Jan. 2000

*Significant drug = revenues of $200 million or more at patent expiry.

Patent Defense Strategies

- **Pediatric exclusivity studies**
- **Alternative delivery systems**
- **Active metabolites, isomers**
- **Drug combinations**
- **Submarine patents**
- **Within-class substitution tactics**
- **Legislation**

Source: Lehman Brothers, Specialty Pharmaceutical Research, Jan. 2000

Average Price of Drugs Used by Medicare Beneficiaries, 1995

(oral solid dosage forms; per-tablet price)

	Single-source drugs	Multi-source drugs
Brand Name AWP	$1.29	$0.60
Brand Name AMP	1.00	0.41
Generic AWP		0.36
Generic AWP or MAC		0.19
Generic AMP		0.08

Preliminary data.

Source: Medicare Current Beneficiary Survey, 1995; AWP from Redbook; AMP from Medicaid Rebate files. MAC prices based on Medicaid FULS.

Conclusions

- **Monopoly power is given by the government for (good) reasons.**
- **Owners of assets (both brand names and commodities) try to increase or extend their monopoly power thru a variety of strategies.**
- **Policy actions to reduce monopoly power will inevitably lead to lower levels of R&D than would occur otherwise.**
- **BUT: the specific policy actions selected will determine which kinds of R&D decline. Some types of R&D may not be worth the lost savings. (e.g., the R&D on an active metabolite.)**