How "Exclusive Use" and Health Insurance Interact

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Clash of Two Great Ideas

- Health Insurance to protect against financial risk
  - Increases demand
  - Reduces sensitivity to price
    - Makes demand curves steeper
    - Increases optimal monopoly price
- Patent protection to create incentives for innovation
  - Grants exclusive rights to the invention
- Each idea alone has great merit
- When combined, they can create a serious problem

"**Clash of the Titans: Patents and Insurance for Prescription Drugs,**"
CE Phelps and G Madhavan, in press, *Science Translational Medicine*

Four key US laws granting exclusive use

- Bayh Dole
  - Gave universities (etc.) first priority for filing patents
    - Tech transfer explosion followed
- Orphan Drug Act of 1983
  - Financial benefits, guaranteed period of exclusivity
  - Over 600 new drugs through the program
- Hatch Waxman 1984
  - Extended exclusivity to 25 years (de facto)
  - Processes to enhance generic entry after exclusivity ends
- 1997 FDA Modernization Act
  - Pediatric formulation adds 6 months to *all* formulations' exclusivity period

Comparable international laws

- Most industrialized countries share common patent law structures
  - Coordinated through World Intellectual Property Organization (WIPO)
  - Typically 20 year market exclusivity from filing date
- Orphan Drug laws
  - US Orphan Drug Act (1983)
    - 200,000 persons (about 6 per 10,000 in 2018)
  - Japan Orphan Drug law ("nanbyou diseases")
    - About 14 per 10,000 persons (large increase in 2017)
  - European Union Orphan Drug law
    - 5 per 10,000 persons, must be life threatening or debilitating

The Essential Conflict

- Consumers have an insurance plan with coinsurance rate C
  - Insurance plan pays (1-C) percent
- Profit-maximizing price for exclusive market seller (monopolist) is inversely related to C. Lower C, higher price.
- Monopoly profits are doubly-related to C
  - Lower coinsurance increases total number of doses sold
  - Lower coinsurance increases optimal price for exclusive-rights sellers.

Garber, Jones and Romer (GJR) analysis

- Analyzed three different structures of demand for prescription drugs.
- Key assumption: Coinsurance rate is set to maximize economic welfare, ignoring dynamic effects on growth of pharmaceuticals
- In this base case, monopoly profits exceed gains in economic well being of consumers.
- When coinsurance rates are set optimally, the incentives for innovation are often excessive.
- The problem gets worse when sellers can engage in price discrimination
  - This is the primary purpose of "copay coupons" and other direct to consumer discounts.

Garber A, Jones C, Romer P, Insurance and Incentives for Medical Innovation, *Forum for Health Economics and Policy* 2006; 9(2):ISSN (Online) 1558-9544,

Romer won Nobel Prize in Economics in 2018

US insurance coverage--retail prescription meds

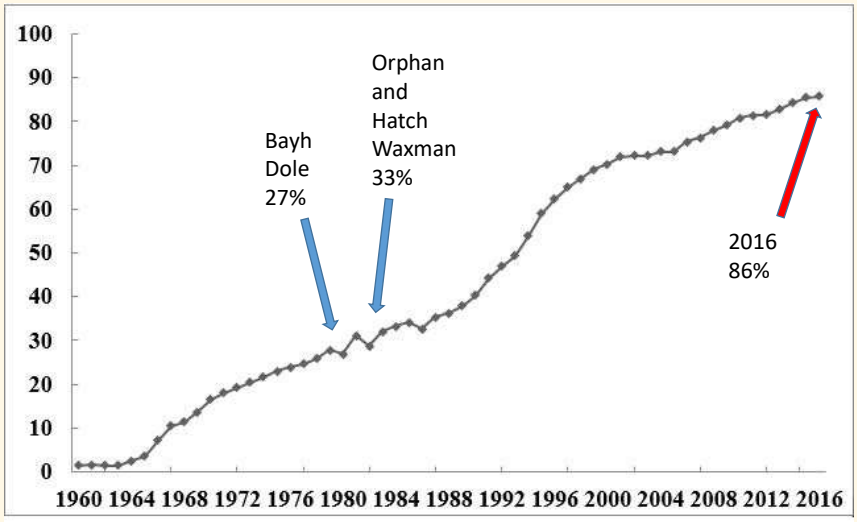


Figure 1: Percent of Retail Drug Spending Paid by Insurance

Source: 2016 CMS National Medical Expenditure Accounts

Conclusions from GJR

- "Because of the large subsidies to demand from health insurance, limits on the lifetime of patents and possibly limits on monopoly pricing may be necessary to ensure that pharmaceutical companies do not possess excess incentives for innovation."
- The complexity: dynamic efficiency depends on the shape of the demand curve, something about which we know very little.
- In all cases analyzed by GJR, monopoly profits either exceeded or totally consumed the net gains in consumer well being.

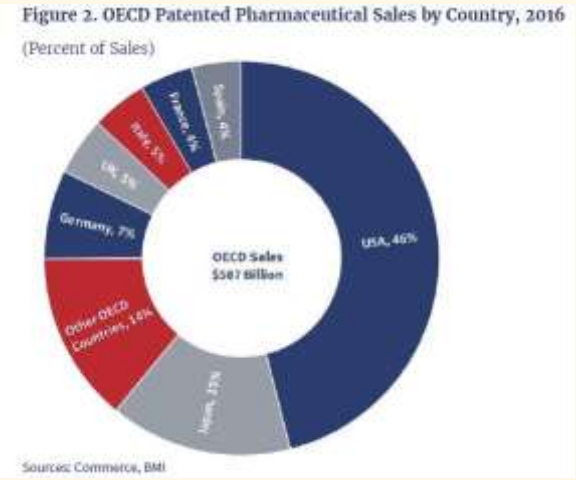
International mechanisms (NASEM Report)

TABLE 3-1
Approaches to Drug Pricing in Other Countries

	Australia	Canada		Germany	India	United Kingdom
National Organization	Pharmaceutical Benefits Advisory Committee	Patented Medicine Prices Review Board	Canadian Agency for Drugs and Technologies in Health	Federal Joint Committee or the Institute for Quality and Efficiency in Health Care	National Pharmaceutical Pricing Authority	National Institute for Health and Clinical Excellence
Applicability	Public payers	All payers	Public payers except in Quebec (non-cancer drugs)	All insurers	All payers	National Health Service
Review Criteria	Comparative effectiveness, safety, and cost-effectiveness; projected usage and overall costs to the health care system	Therapeutic innovation; comparative pricing with respect to France, Germany, Italy, Sweden, the United Kingdom, and the United States	Comparative effectiveness, safety, and cost-effectiveness; patient experiences	Comparative benefit	National List of Essential Medicines prepared on the basis of efficacy, safety, cost-effectiveness, and common diseases	Clinical effectiveness and cost-effectiveness
Decision	Coverage (yes, no, limited)	Price reductions or rebates	Coverage	Price setting after first year on the market	Formulary inclusion or exclusion	Coverage
Binding	Yes	Yes	No	Yes	Yes	Yes

Consequences for Innovation

- US accounts for about half of OECD revenue
- US accounts for 77% of profits in OECD
- US accounts for 71% of profits world wide
- Unilateral price controls would likely reduce innovation
- If so, consumers' total economic well being could rise (Garber, Jones and Romer result)



Conclusions

- That the US pays highest prices is wholly predictable
  - High income
  - Very high coverage for prescription drugs
  - **But very dispersed buying power compared with most other nations**
    - No use of restrictive formularies, no consideration of cost in federal programs
- The increases in the US since 1980s are wholly predictable
  - Insurance coverage for retail drugs increased from 33% to 88%
- Pharmaceutical manufacturers are doing precisely what economists predict when faced with increasingly inelastic demand curves.
- Meaningful price restraints from market forces have mostly evaporated.
- Only the US Congress can alter this situation.
- Getting “other countries” to pay more will have no effect on US prices

Thank you for your attention