PRICING AND REIMBURSEMENT OF PHARMACEUTICALS IN THE US

Patricia Danzon, PhD
Professor Emeritus
The Wharton School
University of Pennsylvania

July 2019
In any industry, including pharmaceuticals, pricing to capture customers’ Willingness-to-Pay (WTP) maximizes profit.

Pricing based on Cost does not assure breakeven or maximize profit.

Ex ante -- at any go/no go decision -- expected revenue must cover expected incremental cost.

At launch, R&D cost is sunk, irrelevant to pricing.
R&D Intensity => Patents => Monopoly Pricing: Health Insurance Exacerbates Monopoly Effect

- WTO requires 20 yr. patents for all novel products, including drugs
- Patents intentionally give innovator firms monopoly power
  - To enable them to recoup sunk R&D costs
- Health insurance reinforces effect of patents for pharmaceuticals and can enable excessive prices (Garber, Jones, Romer, 2006.)
- Insurance provides financial protection but makes patients price-insensitive => firms can raise prices, unless payers constrain
  - Out-of-pocket ~ 14% of total pharmacy spending in 2017 (KFF.Org)
Insurance Protects Patients but Can Exacerbate Monopoly Pricing: Patients are Price-insensitive
Insurance should, in theory, optimally balance financial protection/access/cost control

**Theory**: Some cost-sharing is useful to deter overuse, but with catastrophic protection (stoploss limit)

- Payer reimbursement rules (prices paid + coverage criteria) should balance access/R&D incentives vs. prices/cost
  - Garber, Jones, Romer (2006); Danzon, Towse, Ferrandiz (2013)

**US Pharmaceutical Reimbursement in Practice**: Differs by payer + drug type/location (pharmacy/physician office/in-patient)

- Medicare is barred from negotiating prices
- Pharma firms set prices freely, subject to
  - negotiated voluntary rebates (private plans, Medicare D)
  - mandatory discounts (Medicaid, VA etc.)
1. Pharmacy (a) Traditional Drugs: Pharmacy Benefit Managers (PBMs) Use Tiered Formularies

- Tiered copays e.g. $10/40/85 for generic/preferred/non-preferred brand
- PBMs negotiate rebates off list price in return for preferred status, which moves market share
- In theory, PBMs pass rebates through to Health Plans => Consumers pay lower premiums
- PBMs can stimulate competitive rebating in large classes with several close therapeutic substitutes, where patients are sensitive to co-pay differentials
  - e.g. statins, antidepressants, some insulins
1(b) Specialty drugs (> $670 per month): Less Substitutable, Less Price-sensitivity

- Most specialty drugs are differentiated: patients/physicians have therapeutic preferences; PBMs cannot move share via co-pays

=> PBMs use 4th tier with 25-30% co-insurance + prior authorization

- In practice, high patient co-insurance is usually covered:
  - Medicaid + Medicare low income subsidies; private Medigap
  - Most patients have annual stoploss limit on their cost-sharing
  - Pharma cos. offer coupons, PAPs to cover remaining co-pays

- Medicare pays 80% of cost > $8,140 p.a., Part D plan pays < 15%

- Medicare Part D plans must cover all drugs in 6 protected classes

=> Demand is price-insensitive: Raising price increases firm’s revenue
2. Physician-Office: Infused Biologics + Vaccines

- Covered by Medicare Part B (or private patient’s medical benefit)
- Physicians “buy and bill”, and are reimbursed by Medicare at Manufacturer’s Average Sales Price (ASP)\(_{(T-2)}\) + 6%
- Manufacturers set ASP: Volume-weighted average net sales price
- High ASP => larger absolute margin for providers
- => ASP + 6% rule creates incentives for firms to set *high* list price and avoid discounting
  - Discount in Q T => reduces ASP reimbursement for all customers in T+2
Ex-US: Payers Use Two Reimbursement Prototypes:
1. Comparative/Cost-effectiveness

Comparative Effectiveness
- Payer compares incremental health gain + other savings for new drug vs. comparator => negotiated price premium based on increased benefit
  - France, Japan, Germany etc.

Cost-effectiveness Analysis (CEA)
- Payer compares incremental cost-effectiveness ratio (ICER) of new drug vs. comparator to a threshold e.g. $50k per QALY
- Threshold differs across countries, reflects WTP/budget/opportunity cost
  - UK (NICE), Australia, Sweden etc.
- This approach => consistent relation between price and value created:
  - \( P_{n}^{\text{max}} = P_{0} + \Delta c + K \Delta E = \text{Value-Based Price (VBP)} \)
  - \( \Delta c = \text{non-drug cost savings}; \Delta E = E_{n} - E_{0} = \text{health gain}; K = \text{WTP ($ per QALY)} \)
Ex-US Reimbursement Prototypes:
2. External Referencing to Other Countries

- Price for drug X in country Y is set at the average/median/minimum of prices for drug X in a basket of foreign countries
  - Many EU countries reference all/some other EU countries
  - International Price Index is proposed for Medicare Part B

Effects of External Referencing (ERP)
- ERP is unrelated to Value or WTP
- Firms raise price or delay/non-launch new drugs in smaller, lower-price referenced countries, rather than lower price in large, high-price countries (Danzon and Wang, 2005; Danzon and Epstein, 2012)
- ERP undermines appropriate price differentials between countries
- In practice, payers/firms negotiate confidential discounts to avoid ERP

Source: Kaiser Family Foundation analysis of data from Express Scripts 2015 Prescription Price Index.
Orphan, Oncology and other Specialty Prices Outpace Traditional Medicines; 2017 Annual Cost, by Launch Year

2016 Ave. Foreign-to-Canadian Price Ratios for On-Patent Drugs and GDP per Capita: OECD Countries

Linking NIH-funding to Affordability/Value-for-Money

- Even if NIH funding share of R&D cost could be measured, this cannot readily be translated to a share of price
  - Prices are based on customers’ willingness to pay, not cost
- NIH funding could be tied to a value-for-money limit on price
  - E.g. Incremental Cost-Effectiveness Ratio $\leq 150k \text{ per QALY}$
- This value-based, CEA with thresholds approach, could be applied to constrain all on-patent prices $\rightarrow$ assure value-for-money of all drugs
- Assures an appropriate return on all public subsidies to medicines, including NIH-funding, R&D tax credits, subsidies via public + private insurance, etc.
- Value-based pricing also leads to efficient resource allocation and creates appropriate incentives for private R&D
Conclusions

- On-patent prices are based on customers’ willingness to pay, not costs.
- Insurance (public + private) pays for 86% of total drug spend (KFF.Org) =>
- On-patent drug pricing reflects reimbursement rules of insurance plans, which currently are not designed to constrain pricing.
- Reflecting NIH funding in prices cannot be based on NIH share of costs.
- NIH funding could be tied to pricing at a specific value-for-money threshold.
  - E.g $150k per QALY
- Such a value-based pricing framework is the most efficient approach to constraining prices on all medicines, and would assure value-for-money of all public subsidies, not just those from NIH.
- Value-based thresholds also reward value-creating private R&D.


Figure 1
Total U.S. Retail Prescription Drug Spending, 2017

Total U.S. Retail Prescription Drug Spending in 2017: $333 billion

NOTE: Total prescription drug spending accounts for rebates.
SOURCE: KFF analysis of 2017 data from the National Health Expenditure Accounts.
Pharmaceuticals are R&D-intensive: R&D Cost Varies by Firm Type and Drug

- R&D is ~17% of sales for innovative pharma firms
- Average cost per approved NME: Estimates vary widely
  - $2.7b. DiMasi et al. (2017): proprietary data, 10 large firms
    - Present value, including cost of capital and failures
  - $757m. Prasad et al. (2017): public data, 10 very small firms
    - Range: $204m. - $2,602m. (at 7% cost of capital)
- These estimates include only private spend on R&D
- Small firms account for > 70% of New Active Substances (NAS)
Late-Stage Pipeline (Phase III+):
Large Firms’ Share ~20%, Smallest Firms Share ~70%