The Ethics of Drug Pricing

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Why is Drug Pricing Important?

I. Worsening crisis unique to the U.S.
II. Vulnerable market for extreme price manipulation (case study)
III. Lack of transparency
IV. Affects most of us

Figure 2. Annual Per-Capita Drug Spending, 2014 (US$ purchasing power parity-adjusted)

U.S. drug spending far exceeds that of other industrialized nations. Data in blue is from the Organisation for Economic Co-Operation and Development, and represents both prescription and over-the-counter drug spending. The U.S. figure, in red, solely includes prescription drug spending, and is based on invoice prices calculated by the QuintilesIMS Institute. (Sources: OECD, QuintilesIMS, FREOPP analysis)
In the News
Agenda:

I. Identify Agents in the Pharmaceutical Industry
II. Breakdown of Pharmaceutical Supply Chain
III. Address 3 Major Issues:
   A. 340B Drug Pricing Program
   B. Pharmacy Benefit Managers
   C. The Monopoly - Orphan Drugs, Patent Protection
IV. Review Ethical Considerations
V. Conclusion
The Agents:

agent: “a being with the capacity to act” (Schlosser).
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The Flow of Drugs
Consumers

Pharmacies

Manufacturer

Copay

Drugs

Payment for Wholesale Drugs

Shipped Drugs
The Flow of Money
Insurance Contract

Insurers ➔ Consumers

Premium

Pharmacies ➔ Payment for Dispensed Drugs
Overview: Pharmaceutical Supply Chain
Issue 1: 340B
Issue 2: PBMs
Issue 3: the Monopoly
What is 340B?

- § 340B “Drug Discount Program” of the Public Health Service Act requires drug companies to sell their medications at a discounted price for vulnerable or uninsured persons (Sec. 340B)
Who is affected by 340B?

- Uninsured folks
- Underinsured folks
- Ryan White clinics
- Hospitals:
  - Children’s hospitals, critical access, disproportionate share, free standing cancer, rural referral centers, sole community
- Specialized Clinics:
  - Black Lung Clinics, Comprehensive Hemophilia Diagnostic Treatment Centers, Title X Family Planning, Sexually Transmitted Disease, Tuberculosis (340B Eligibility)
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How might conscientious objector play a factor in this federal program? Is there potential for bias? If so, what is problematic?
Abuse

- Under 340B, hospitals are selling discounted drugs at full price
- This abuse will become more prevalent as hospitals consolidate (Let340B).
Why not extend it to all people and all types of care?
Issue 1: 340B
Issue 2: PBMs
Issue 3: the Monopoly
Issue #2: PBMs

I. Third-party administrators of prescription programs for commercial health plans, self-insured employer plans, Medicare Part D plans, federal and state employee benefits (referred to as: insurers)

II. Reduce costs of drugs for plan sponsors and improve health

III. 2016: Manage benefits of 266 million Americans, 4 billion prescriptions

IV. Big 3: Express Scripts, CVS Caremark, Optum Rx
   A. CVS Health - Fortune 500 Rank #7 - $184.8 billion in revenue
   B. Express Scripts - Fortune 500 Rank #25 - $100.1 billion in revenue
   C. PBMs are more profitable and have higher profits than other drug channel companies (Drug Channels Institute Analysis of 2018 Fortune 500 list)
Issue #2: PBMs

I. Pharmacies pay network joining fees

II. Spread = The Price PBMs Charge Insurers - Price PBMs Pay Pharmacy

III. MAC Lists and Clawbacks
   A. Maximum Allowable Cost lists = highest amount PBM will pay for a given drug
      1. Pharmacies and insurers are not informed of MAC prices, how they are determined, or how drugs are excluded from the list
   B. Profit from Name Brand Drugs > Profit from Generics

IV. Gag Clauses and Copayments
   A. Gag Clauses prohibit pharmacists from informing patient of how/where to get cheaper medication
   B. Copayments > Actual Drug Costs

V. Question: What is the biggest ethical issue regarding PBMs, in your opinion?
Issue #2: PBMs

I. Solution: Remove Gag Clauses
   A. Indiana has done it

II. Solution: Amazon
   A. Innovation
   B. Haven - partnership with Berkshire Hathaway & JP Morgan Chase
   C. Acquisition of PillPack
   D. Disrupt current supply chain, promote price transparency, eliminate PBMs altogether
Issue 1: 340B
Issue 2: PBMs
Issue 3: the Monopoly — Orphan Drugs
Issue: Monopoly Power - Orphan Drug Rule

I. Passed in 1983 - “Provide financial and regulatory incentives encouraging more pharmaceutical companies to invest in R&D efforts to discover drug regimes to treat rare diseases and conditions, as well as to facilitate the FDA approval of these drug products” (Hemphill)

A. 7 years of market exclusivity following FDA approval
B. 50% tax credit for clinical research
C. Grand funding for clinical testing
D. Waiver of filing fees (+$1 mil in 2008)
E. FDA protocol assistance
I. **Problem:** There is **no limit** for how much drug companies can charge for “orphan drugs”
   A. Extreme price gouging
   B. Example: Imatinib - $30,000 (2001) to $92,000 (2012), est. treatment of 9,000 patients, 6 additional orphan drug classifications

II. **Problem:** Big Pharma is misusing Orphan Drug Rule for its benefits
   A. 7 of top 10 selling drugs in U.S. are classified as orphan drugs (Johns Hopkins Medicine, 2015)
   B. Humira (Abbvie), the top selling drug in the U.S., is classified as an orphan drug
   C. Sales of these orphan drugs are expected to reach **$176 million** by 2020, account for 19% of prescription drug sales (Johns Hopkins Medicine, 2015)

III. **Question:** Would a utilitarian argue for or against price controls on orphan drugs?
Issue 1: 340B
Issue 2: PBMs
Issue 3: the Monopoly — Patent Protection
Brand-Name Drugs

A company holds a patent on a drug for 20 years. However, the patent dates from when the drug is invented. It still may take many years before the drug reaches the marketplace, which can shrink the time frame for the company to make back its investment and any profit. Once the patent expires, and because the formula is already known, other companies can make their own generic versions and charge much less.

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Solution: Advance Generic Entry

- Effective solution
- Bipartisan support
- Competition, faster expiration of patents

Does the benefit of medical accessibility outweigh the financial costs of shorter patent life?

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Ethical Considerations

I. What is the most concerning issue to you? Have you dealt with situations like these in your own life?

II. How might Ross evaluate pharma’s current use of the orphan drug rule?

III. In applying Aquinas’ precepts, how does “preserving human life” differ for consumers of drugs vs. pharmaceutical companies?


