Defining Pharmaceutical Value Across Stakeholders

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Project Aims:

- To understand the historical landscape of the actual and perceived value of pharmaceuticals.

- To analyze key topics in the discussion regarding domestic and global drug pricing.

- To gain an understanding of how to assess the value of drugs to society as a whole.
My role:

- Surveying information and opinions from:
  - Popular press (20+ sources)
  - Pharmaceutical Companies
  - Academic (economic) Literature
  - Think Tanks
  - Government Sources
  - Intergovernmental Organizations

- Contrasting corporate and popular views

- Help to contextualize and define the discussion
Research Topics in the Pharmaceutical Field

- How will changes in global patent law affect the industry?
- How has the generic market impacted the field?
- Are drug prices priced fairly?
- What does the future of pharmaceutical innovation look like?
- How does drug pricing differ from country-to-country?
- What is the future of personalized medicine?
- How has the evolution of drugs paralleled that of drug pricing?
- Can society continue to afford the cost of pharmaceuticals?
The pharmaceutical discussion can be distilled to two key components.

- Can society bear the rising cost of drugs?
  - Sustainability
  - Economic discussion

- And if it can, should it have to?
  - Excessiveness
  - Moral discussion
There is a widespread belief that pharmaceutical prices are **unsustainable** and **excessive**.
Many stakeholders in discussion of sustainability

- Not simple issues of supply and demand
  - Many Intermediaries between producer and consumer
  - Insurers
    - Mix of private and public differs based on country
  - Patients are involved to the extent that they pay OOP
  - Uninsured population – 13% in United States
- Pharmacy benefit managers (PBMs)
- Gaining negotiating power
  - Sovaldi: average discount of 46% after Express Scripts forgoes drug in favor of Viekira Pak

Gallup, “In US, Uninsured Rate Sinks to 12.9%”, 2015.
Herman, B., “Insurers, PBMs, continue to fight for bigger, better, drug price discounts”, Business Insurance, 2015.
Can the system sustainably absorb the cost of drugs?
The issue of **excessiveness** relates to whether drug prices are fair.

- Do rising prices fairly capture added value of drugs?
- Global question – are drug prices too high internationally?
  - Historical context – AIDS in the late 20th Century
- Domestic question – are drug prices too high in the USA?
  - Are US drug prices really higher? To what extent?
- To what extent is tiered pricing justifiable?
  - Policy determines flexibility in pharmaceutical pricing
The Corporate Perspective

- Profit is one of many factors in pricing decisions
- The nature of drugs themselves are changing
  - From acute diseases to chronic illnesses
  - Rational drug design
  - Treating rarer diseases & subsets of diseases
  - Some are vastly more effective
- Domestic and international trends must be considered when assessing appropriate value and price
  - Drug market is increasingly global
Value includes investment in pharmaceutical R&D

R&D productivity is on the decline

Note: R&D costs are estimated from PhRMA annual survey 2009; NMEs are the total number of small molecule and biologic approvals by the FDA.
Source: Bernstein Research “The Long View – R&D Productivity” (September 30, 2010)
Life sciences R&D: Changing the innovation equation in India
Patent policies and generics create insecurity.

- Generic growth leaves shorter time span to recoup R&D costs
- Uncertainty caused by global and domestic patent changes makes drugs more valuable to companies
- PATENT and Innovation acts could hinder industry
- Inconsistent international patent enforcement
Many stakeholders in discussion of excessiveness

- **Patients**
  - OOP and co-payment costs are growing
  - Decrease in choices due to restricted formularies

- **Physicians and Providers**
  - Argue high prices for cystic fibrosis, diabetes, and cancer drugs
  - Do not see rising prices as reflected in patient outcomes
  - Outpatients are largely not covered by Medicare
  - Reduced adherence to medication because of prices

- **Insurers**
  - Difficulty financing the rising costs of drugs

- **Policy-makers & government**
  - Bearing higher costs of drugs as part of fed. budget with ACA
  - Desire and responsibility to provide best care for overall population
There are concerns to be had about sustainability and excessiveness:
- Higher prices already strain healthcare system
  - Strain on patients and payers will grow more significant as drug prices increase
  - Higher prices are not definitively tied to innovation
- Higher drug prices are sometimes justified, but to the extent that...
  - They reflect outcomes – not always case with drugs with marginal benefit
    - Immediacy of benefits must be considered as well (Sovaldi)
    - Budget-Impact and Cost-Effectiveness are both important issues
  - They do not restrict access
    - Reduced patient adherence because of costs is an issue
    - Patients may not even be seeking the treatments they need because of costs
My perspective

Future of pharmaceutical value: hopeful despite recent innovation trends
- Advances in science and medical technology
- Genomics and personalized medicine can help treat diseases previously out of reach
- New technology and metrics can help quantify pharmaceutical value

Policy-makers and pharma can collaborate to:
- Incentivize R&D and create revenue security in areas of public concern
- Create a more transparent, systematic method for pricing based on value
  - Transparency can benefit both consumers and corporations
  - Reduce existing physician uncertainty regarding the value of drugs
- Expand existing treatments to new populations or diseases
- Develop & distribute highly effective and groundbreaking treatments
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