Financing Innovation

Gerard Anderson, PhD
Professor and Director of
Johns Hopkins Drug Access and Affordability Initiative
The Politics of R&D

• While we can probably agree that innovation benefits society, a related question is are we financing innovation correctly?

• While economists know that R&D are sunk costs and should not be used to justify the high cost of a drug or a price increase, the pharmaceutical lobby often uses R&D as a justification for its high prices and price increases

• Need to examine the relationship between R&D spending and innovation
What is the Cost of R&D

• Tufts Center for Study of Drug Development quantified the R&D costs over time:
  – $231 million in 1991
  – $802 million in 2003
  – $2580 million in 2014
  – Real cost increases averaged 7.9% per year

• Why is the R&D cost increasing so much faster than inflation?
Cost of Capital

• 40% of the $2.6 billion is the cost of capital according to the Tufts study

• The 2014 Tufts study estimated the cost of capital at 10.5%

• The direct cost of developing a new drug is closer to $1.3-$1.6 billion
  – Cost reflects many failures
How is the $1.3- $1.6 billion spent?

• Ome concern is that some of this money is not actually spent on research

• Is the money being spent on scientists and equipment?

• Unfortunately, how R&D dollars are spent is proprietary information

• Last month in my testimony I requested the House Oversight Committee to review how drug companies are spending research dollars
The Model of How R&D is Financed Is Changing

• No longer is all of the R&D being done within the drug company

• New model
  – Initial research done in academic medical centers using NIH funds
  – some VC money funds phase 1 and 2 clinical trials
  – pharmaceutical company purchases the research during phase 3, completes the phase 3 trials, and markets the drug

• Is this new model more efficient in producing innovation?
Gilead and Solvaldi - An Example

- Emory researchers conducted the basic science and early testing using NIH funds

- Venture capital supported the next round

- NIH and VC each put in approximately $200 million

- Gilead purchased the company (Pharmasset) for $10 billion

- Gilead doubled the price Pharmasset was going to charge to recoup its $10 billion investment
Incentives To Clinical Researchers

- Did the possibility to earn $10 billion influence the type of research the academics chose?

- Have we created a bidding war for promising drugs?

- Is this the most cost effective way to develop new drugs?

- You need to pay a premium for the research that fails – but how much is needed to motivate researchers?
Policy Questions

• How much of the purchase price for the R&D for the drug should be tax deductible?

• Is internal development or external purchasing of R&D more cost effective?

• Should the government get a price reduction when government funds helped develop the drug?
Bayh-Dole

- Bayh-Dole allows the government to lower the price if the government has invested in the drug development

- 5 requests to NIH to use Bayh-Dole; none granted

- What would be the effect on university and industry relationships? Will it affect use of NIH research?

- What is the appropriate return on the NIH investment?
A Case Study In Innovation - Orphan Drugs

• There are 5000 rare diseases but only 5% have drugs to treat the disease

• What is the best way to motivate research in rare diseases?

• Do we need to revise the Hatch Waxman law?

• According to Hatch Waxman, rare diseases have less than 200,000 potential patients

• Current Government Incentives for orphan diseases
  – 25% tax credit (used to be 50%)
  – Additional market exclusivity period
Success – Growing Number of Orphan Drug Approvals 1980-2018
However

- Still have many disease without drugs. Are additional incentives needed?

- At same time, many drugs with orphan approvals also are blockbuster drugs

- 6 out of top 10 best selling drugs in Medicare also have orphan designations
Top Ten Drugs in US by Spending (2016 in $ billions)

- **Humira (B,S,O)**: $13.6
- **Harvoni (S, O)**: $10.0
- **Enbrel (B,S,O)**: $7.4
- **Lantus Solostar (B)**: $5.7
- **Remicade (B,S,O)**: $5.3
- **Januvia**: $4.8
- **Advair Diskus**: $4.7
- **Lyrica**: $4.4
- **Crestor (O)**: $4.2
- **Neulasta (O)**: $4.2
Orphan Drug Approvals for New and Existing Drugs

- New Drug with Orphan Designation - 61.5%
- Existing Drug with Orphan Designation - 38.5%
Cost of Clinical Trial

- Averages $19 million with wide variation (1)

- The more effective the drug the less the cost for the clinical trial
  - Fewer patients and shorter duration needed for approval

Significant Return on Investment

• For a drug that has already been developed
  – Only $19 million spent on clinical trial
  – Potential for $2 billion in additional revenue
    • PBM typically puts only one drug on formulary
    • Concern about malpractice if give the generic version of drug to a patient that has orphan status

• Argument that need to make a significant profit on blockbuster drugs to support innovation

• But is excess profits from orphan designation the best way to encourage innovation?
Thank You