Impact of Federal Policy on Innovation, Competition, and Costs

Gerard Anderson, PhD
Professor
5 Important Federal Drug Policy Roles

- Conducts basic biomedical research - NIH
- Determines safety and efficacy – FDA
- Determines market exclusivity period- FDA
- Monitors competitive behavior – FTC/Justice
- Purchases drugs – Many federal programs

Will focus primarily on role of government as purchaser
The US Pays Twice As Much As Other Countries For Most Brand Name Drugs

International Federation of Health Plans
2013 Comparative Prices - DRUGS

<table>
<thead>
<tr>
<th>DRUGS</th>
<th>Swiss</th>
<th>UK</th>
<th>Spain</th>
<th>Netherlands</th>
<th>USA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enbrel</td>
<td>$1,017</td>
<td>$1,117</td>
<td>$1,386</td>
<td>$1,509</td>
<td>$2,225</td>
</tr>
<tr>
<td>Gleevec</td>
<td>$3,633</td>
<td>$2,697</td>
<td>$3,348</td>
<td>$3,321</td>
<td>$6,214</td>
</tr>
<tr>
<td>Humira</td>
<td>$981</td>
<td>$1,102</td>
<td>$1,498</td>
<td>$1,498</td>
<td>$2,246</td>
</tr>
<tr>
<td>Copaxone</td>
<td>$1,357</td>
<td>$862</td>
<td>$1,191</td>
<td>$1,190</td>
<td>$3,903</td>
</tr>
<tr>
<td>Gilenya</td>
<td>$2,499</td>
<td>$2,299</td>
<td>$2,287</td>
<td>$2,428</td>
<td>$5,473</td>
</tr>
<tr>
<td>Celebrex</td>
<td>$138</td>
<td>$112</td>
<td>$164</td>
<td>$112</td>
<td>$225</td>
</tr>
<tr>
<td>Cymbalta</td>
<td>$76</td>
<td>$46</td>
<td>$71</td>
<td>$52</td>
<td>$194</td>
</tr>
<tr>
<td>Nexium</td>
<td>$60</td>
<td>$42</td>
<td>$58</td>
<td>$60</td>
<td>$215</td>
</tr>
<tr>
<td>Totals</td>
<td>$9,761</td>
<td>$8,277</td>
<td>$10,003</td>
<td>$10,170</td>
<td>$20,695</td>
</tr>
</tbody>
</table>

Higher US Branded Drug Prices And Spending Compared To Other Countries May Stem Partly From Quick Uptake Of New Drugs

ABSTRACT: The United States spends considerably more per capita on prescription drugs than other countries in the Organization for Economic Cooperation and Development (OECD). Drawing on the Intercontinental Medical Statistics Midas database, we examined the variation in drug prices among selected OECD countries in 2005, 2007, and 2010 to determine which country paid the highest prices for brand-name drugs, what factors led to variation in per capita drug spending, and what factors contributed to the rate of increase in drug spending. We found that depending on how prices were weighted for volume across the countries, brand-name prescription drug prices were 5-198 percent higher in the United States than in the other countries in all three study years. (A limitation is that many negotiated price discounts obtained in the United States may not be fully reflected in the results of this study.) A contributor to higher US per capita drug spending is faster uptake of new and more expensive prescription drugs in the United States relative to other countries. In contrast, the other OECD countries employed mechanisms such as health technology assessment and restrictions on patients’ eligibility for new prescription drugs, and they required strict evidence of the value of new drugs. Similarly, US health care decision makers could consider requiring pharmaceutical manufacturers to provide more evidence about the value of new drugs in relation to the cost and negotiating prices accordingly.

International comparisons can shed light on health care prices in different countries. It is difficult to compare the costs of a hospital stay or a physician visit among different countries. However, it is somewhat easier to compare the prices and use rates of drugs, given that drug compounds contain the same active ingredient and come in comparable presentations in different countries. In this article, we examine the variations in drug prices among selected Organization for Economic Cooperation and Development (OECD) countries to determine which countries paid the highest prices for brand-name drugs, what factors led to variations in per capita drug spending, and what factors contributed to the rate of increase in drug spending during the period 2005-10.

We compare the prices for a sample of brand-name prescription drugs in Australia, Canada, France, Germany, Switzerland, the United Kingdom, and the United States. We then compare use rates for the same drugs between the United States and the other countries. Last, we discuss possible policy and regulatory factors that may contribute to differences in prices and use rates across these countries.

Historically, a number of methodological...
### Overarching Policy Question – What Is A Fair Price To Pay For Drugs?

#### Innovation
- Drug companies need to earn profits on existing drugs to fund R&D
- Few drugs actually make it to market
- Drugs are very expensive to develop
- Innovation is critical for improved health in future

#### Access and Affordability
- High prices for specialty drugs are restricting access
- High prices for specialty drugs are making it difficult for public programs to balance their budgets
- Drugs not effective if people do not have access to them
**Policy and Empirical Question – Can The Market Determine A Fair Price?**

**YES**
- Drugs are a commodity
- Competitive environment for most generic drugs
- Often there are substitutes for brand name drugs that keep prices reasonable

**NO**
- Few competitors for increasing numbers of generic drugs
- Market exclusivity periods (patents) give brand and specialty drugs monopolies
- Most people have insurance which makes them less price sensitive
- MDs, not patients, choose the drugs
Federal Approaches To Determining Drug Prices- All different!

- **Medicare**
  - Private sector negotiates prices

- **Medicaid**
  - States determine rates and federal government approves the method

- **VA/DoD**
  - Uses formulary and negotiates prices

- **PHS/340B program**
  - Formula based on average manufacturers cost and unit rebate amount
Is There a Rationale For Each Federal Department Having Its Own Mechanism For Purchasing Drugs?

Economics and Ethical Concerns

• Volume purchasing
  - Prices would be lower if government paid one price

• Some departments pay twice as much as other departments for same drug

• No ethical reason why some departments should get better prices

Eliminating drug price differentials across government programmes in the USA

KALIPSO CHALKIDOU*
Director, NICE International, National Institute for Health and Clinical Excellence, London, UK and Visiting Faculty, Johns Hopkins Bloomberg School of Public Health, USA
GERARD F ANDERSON
Professor of Health Policy, and Director, Center for Hospital Finance and Management, Johns Hopkins Bloomberg School of Public Health, USA

RUTH FADEN
Waggener Professor of Bioethics and Director, Johns Hopkins Bloomberg Institute of Bioethics, USA

ABSTRACT: Federal agencies in the USA pay significantly different prices for the same prescription drugs because each agency uses a different approach to derive the payment rate. Because we do not identify any economic rationale or socially accepted moral reasoning that would justify the current level of price variation, we suggest that the federal government should pay a uniform price for each drug. Laws and regulations that give certain federal agencies the ability to earn rebates, use formularies, or permit other special arrangements would need to be eliminated in order to have a single payment rate. This could make some government agencies worse off than others; however, a uniform payment rate would not need to affect beneficiaries’ current financial contributions, access to drugs, benefits or overall public expenditures. At the same time, a single rate would permit the government to adopt a more effective approach to purchasing drugs and send a consistent message to pharmaceutical companies concerning which types of drugs the government wants them to develop for government beneficiaries. How this single price would be derived and how it would compare with the lowest or highest prices currently achieved by government agencies would depend on a variety of policy issues including the government’s desire to encourage pharmaceutical research and development and the need to control health care spending.

Price differentials across government programmes

In 2005, the Congressional Budget Office (CBO) compared the average prices paid by different government programmes relative to the average wholesale

*Correspondence to: Dr Kalipso Chalkidou, Director, NICE International, National Institute for Health and Clinical Excellence, 74 High Holborn, London WC1 V. 6NA, UK. Email: kalipso.chalkidou@nics.org.uk
Why So Many Prices And Mechanisms?

• Currently Medicare pays the highest prices and VA/DOD pay the lowest prices
• Policy Question – What keeps the federal government from paying one price for drugs?
Government (and private industry) Purchases 5 Categories of Drugs

Each category offers unique challenges for purchasers such as the government

- Generics without competition
- Generics with competition
- Brand name drugs
- Specialty drugs
- Biosimilars
Generics Without Competition

- Martin Shkreli took a drug that had been on the market for 60 years and he increased the price by 5000%

- Only one company sold Daraprim

- Price increase caused huge access problems for patients and hospitals

- There are an unknown number of other drugs with only one supplier

- Perfectly legal to increase the price
Generic Drugs Without Competition
One Possible Solution - Deterrence

Congressional Testimony Senate Aging

- Expedited review when no competitors (with or without priority vouchers)
- Allow compounding under certain circumstances
- Importation from company that originally had patent Daraprim originally patented to GSK and it is still manufactured and sold in UK by GSK

In recent years, the increasing prices of off-patent pharmaceuticals have been the subject of intense legislative and media scrutiny. For example, a public meeting held by the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) in 2018 highlighted the issue of price increases and the lack of competition in the market for certain drugs. The panelists discussed the potential for increased scrutiny of drug prices and the role of the FDA in ensuring affordability of off-patent pharmaceuticals.

The FDA has acknowledged the importance of ensuring affordability and access to essential drugs. The agency has taken steps to expedite the review of drugs without competition and to consider alternative sources of supply, such as importation from the country where the patent was originally held. For example, Daraprim, a drug originally patented by GSK, is still manufactured and sold in the UK by GSK.

Congress should continue its investigation to illuminate the business strategies that are distorting the market for generic drugs.
Generics With Competition

• Hatch Waxman
  – Expanded generic industry
  – Percent generic sales increased from 10-88%
  – Low prices for generics with many competitors

• Recent Consolidation
  – Fewer generic competitors
  – Shortages in certain drugs
  – Price hikes where only a few competitors
Challenge – Maintaining Robust Competition in Generic Industry

Top 5 generic companies

1. Teva
2. Novartis- Sandoz
3. Allergan
4. Mylan
5. Sun Pharmaceuticals

Their growing market share

• In 2014, these 5 companies had 47.4% of world wide sales of generic drugs

• Since 2014, there have been numerous mergers including a possible Teva acquisition of Allergan in June 2016
Generics With Competition

• Generic companies sell identical products

• Competition is over price

• The more competition the lower the price
  – On average, prices decline by 20% with each additional entrant in generic market
Brand Price Increases And Prices of New Brands, Not Quantity, Are Responsible For Most Of The Recent Increase In Drug Spending

Source: IMS Health, National Sales Perspectives, Dec 2014
OncoLogic Drugs- Prices Keep Increasing

Monthly and Median Costs of Cancer Drugs at the Time of FDA Approval
1965-2015

Source: Peter B. Bach, MD, Memorial Sloan-Kettering Cancer Center

<table>
<thead>
<tr>
<th>Year of FDA Approval</th>
<th>Median Monthly Price (per 5 year period)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1970</td>
<td></td>
</tr>
<tr>
<td>1980</td>
<td></td>
</tr>
<tr>
<td>1990</td>
<td></td>
</tr>
<tr>
<td>2000</td>
<td></td>
</tr>
<tr>
<td>2010</td>
<td></td>
</tr>
</tbody>
</table>

Monthly Cost of Treatment (2014 Dollars, log scale)

- Individual Drugs
- Median Monthly Price (per 5 year period)
Oncology Drugs—Prices Sometimes Increase When Competitors Enter Market

Price of Gleevec

Year
Price per 100mg pill ($2014)
0
50
100
150
200
250
Nilotinib approved
Dasatinib approved
India patent case decided
Pediatric Ph+ CML indication
5 additional indications, including Ph+ ALL
Specialty Drugs

• Responsible for 30% of drug spending but only 1% of all drugs

• Much of the increase in drug spending in 2014/5 was attributable to specialty drugs
Specialty Drugs

Attributes
- Very expensive
- Many are quite effective
- Problems
  - Ability to pay
  - Access

Hepatitis C
- $40,000 - $100,000
- Eliminates hepatitis C
- Problems
  - High cost sharing - Can be 40% of social security income for year
  - Less than 4% of people with hepatitis C are getting drug
  - Hepatitis C is infectious so becomes a public health issue
  - Hepatitis C responsible for highest mortality rate for infectious diseases in US in 2014
Senate Finance Committee Report

- Wyden-Grassley Sovaldi Investigation Finds Revenue-Driven Pricing Strategy Behind $84,000 Hepatitis Drug

- 18-Month Investigation Reveals a Pricing and Marketing Strategy Designed to Maximize Revenue with Little Concern for Access or Affordability
Specialty Drugs Causing Fiscal Problems

• Medicare spending for Hepatitis C increased from $300 million in 2013 to 4.5 billion in 2014

• VA, DOD, PHS all requested additional appropriations

• Medicaid programs have used existing rules (e.g. preauthorization) to limit access but CMS recently told states they cannot reasonably restrict access for people with hepatitis C
Pricing for Specialty Drugs

- Drug companies can set the price
- FDA gives them a time limited monopoly
- Prices may go down when there are effective substitutes
- The drugs are often so effective that they are cost effective even with the high price tags
  - Sovaldi can be cost effective because some people do not need liver transplants that cost $500,000
Two Topical Concerns

Recent Part B Changes in Drug Payment

Bundled payments do not include drugs
Paying for Drugs in Part B - Background ($19 billion dollar issue)

**Before MMA of 2003**

- Drug companies announced a high list price for drugs
- Medicare paid list price (sometimes with small discounts)
- MDs purchased drugs at considerable discount from list price and pocketed the difference
- Most common in oncology

**After MMA of 2003**

- CMS pays average sales price (ASP) + 6% for Part B drugs
- ASP approximates actual acquisition cost
- Physician has economic incentive to choose the more expensive drug since they get 6% administrative fee for administering the drug
- We do not know how often the MD chooses the more expensive drug because of the economic incentive
- More expensive drugs are not harder to administer (although storage fee may be higher)
Current CMS Proposal

• Reduce the payment from ASP + 6% to ASP + 2.5% with additional fixed payment that does not vary by price of drug

• Reduces (but does not eliminate) the incentive for physician to choose the more expensive drug

• Would lower payments to MDs that prescribe expensive drugs (oncologists, ophthalmologists and rheumatologists) and increase payments to most other MDs (largest increases to primary care MDs) that prescribe less expensive drugs
Bundling

- Bundling gives providers the choice of how to most effectively provide medical care by combining many medical services into a single payment and letting the provider choose the best treatment plan.

- In fee-for-service, the first bundled payment was Medicare prospective payment for hospitals.

- In managed care, it is capitation.

- Medicare and private insurers are already combining hospital, physician and post acute care services into a single bundled payment.

- In most cases, drugs remain outside the bundle and yet drugs are an important part of care.

- Policy Question: Should drugs be inside the bundle, and if so, how?
Part D Bundles

• Medicare started with knee and hip replacement bundled payments but over time there will be more bundles

• These bundles include hospital, physician and post acute care services but exclude drugs

• Congress has already mandated ESRD bundle payments should include drugs

• There are many technical challenges to overcome, but including drugs in the bundled payment may increase efficiency since drugs can offset hospital and post acute care services
Prescription Drug Spending Growth By Program

Annual Percent Growth from Previous Year

Historical 2009-2013, Projected 2013-2024

Source: National Health Expenditure Data