What Can be Done to Stem the Rising Cost of Pharmaceuticals?

Sean D. Sullivan, PhD

Dean
Professor of Pharmacy, Public Health and Medicine
School of Pharmacy
University of Washington
Your Money or Your Life
Pyrimethamine

- Available since 1953
- Nobel Prize Medicine – Nucleic acid metabolism -> Discovery
- Worldwide distribution
- On the WHO essential medicines list
- Indications:
  - Prevention and treatment of malaria
  - Toxoplasma Gondii infection (HIV+ patients)
- No patent, single supplier in the US.
Pyrimethamine

• Price:
  – 12+ manufacturers in India ($0.04 to $0.10 per tablet)
  – Brazil - $0.02 per tablet
  – GSK provides the medication in the UK for $20 per 30-day supply ($0.66 per tablet)
  – GSK supplied the drug in the US at a price per tablet of $1.00 in 2002.
  – In 2010, GSK sold rights to market the drug in the US to CorePharma.
  – In 2014, CorePharma supplied the drug at $13.00 per tablet and generated ~$10,000,000 in sales.
Martin Shkreli – CEO, Turing
CEO: 5,000-percent drug price hike "not excessive at all"

When Turing Pharmaceuticals bought the 62-year-old drug called Daraprim in August, the company immediately raised the price of one pill from $13.50 to $750.
$660 for epinephrine

Mylan’s EpiPen price increases are Valeant-like in size, Shkreli-like in approach

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*EpiPen price rose more than sixfold in the last several years*
US Rx Market

• $424.8 Billion (2015) – On an invoice (list price) basis – 12.5% above 2014
• The US is 50% of the global market by expenditures.
• 1% of prescriptions account for 25% of total sales.
• 80% of dispensed medications are generic – some no longer multi-source.
• Large, multinational firms.
US Rx Market

• An expensive and extensive development and regulatory approval process.
  – High failure rates, even at late stage of development

• An industrial policy/environment that encourages and rewards innovation.
  – 20 year patent granting an effective monopoly position
  – The last free-pricing environment
  – No federal sector price negotiation
US Rx Spending Growth (2010-2020est)

Chart 30: U.S. Spending Growth 2010-2020 US$Bn

Source: IMS Health, Market Prognosis, National Prescription Audit, IMS Institute for Healthcare Informatics, Jan 2016
Rx Market - Pricing

- **List prices** are set by the manufacturer/marketer/distributor.

- **Net or acquisition prices** are negotiated between the seller and the buyer/payer (hospital, VA, insurer, PBM). In rough terms, rebates are generated as **discounts off of the list price**.

- In markets with no central price negotiation and little competition (labeled indication or therapeutic alternative), manufacturers offer few discounts.
  - In the US, anticipated discounts are baked into the list price.

- Prices do not fall over the life of the patent.
Entry Price

Cancer Drugs Hit Market at Ever-Higher Prices

The median monthly cost for new cancer drugs in the U.S. has soared since the 1970s despite an increasing number of available brands.

Note: Costs are monthly Medicare prices for each drug the year it was introduced, adjusted for inflation; drugs approved through early December 2014 are included.
Source: Peter Bach and Geoffrey Schnorr at Memorial Sloan Kettering Cancer Center
Taking Price Increases

The price of many top-selling prescription medicines has increased steadily over the past seven years.

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Manufacturer</th>
<th>Disease</th>
<th>Initial Price</th>
<th>Increase</th>
<th>Final Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xyrem</td>
<td>Jazz Pharmaceuticals</td>
<td>Narcolepsy</td>
<td>$20</td>
<td>+841%</td>
<td>$180</td>
</tr>
<tr>
<td>Humulin R U-500</td>
<td>Eli Lilly</td>
<td>Diabetes</td>
<td>$60</td>
<td>+354%</td>
<td>$252</td>
</tr>
<tr>
<td>EpiPen</td>
<td>Mylan</td>
<td>Allergic reactions</td>
<td>$200</td>
<td>+222%</td>
<td>$600</td>
</tr>
<tr>
<td>Viagra</td>
<td>Pfizer</td>
<td>Impotence</td>
<td>$35</td>
<td>+159%</td>
<td>$91</td>
</tr>
<tr>
<td>Gleevec</td>
<td>Novartis</td>
<td>Leukemia</td>
<td>$350</td>
<td>+158%</td>
<td>$915</td>
</tr>
<tr>
<td>Avonex</td>
<td>Biogen Idec</td>
<td>Multiple sclerosis</td>
<td>$1,400</td>
<td>+147%</td>
<td>$3,476</td>
</tr>
</tbody>
</table>

Q4 '07 | Q1 '14 | '07 | '07 | '07 | '07 | '07 | '14 | '14

GRAPhIC BY BLOOMBERG BUSINESSWEEK. SOURCE: DRX, DATA COMPiled BY BLOOMBERG.
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Traditional Options to Manage Rx Costs

- Limit available options for preferred reimbursement/coverage – drug formularies.
- Add co-payments and co-insurance – incr. patient out-of-pocket costs.
- A third party negotiator (PBM industry) to aggregate lives and bargain for better prices.
- Special categories of purchasing (340B or Medicaid best pricing) – only available to the government sector.
- Limit Patient Population - Prior Authorization, Stepped-Therapy, Medical Policy
Emerging Options to Manage Rx Costs

- Limit prescriber access to sales representatives and samples.
- Adding clinical decision support algorithms to e-prescribing tools.
- Restricting ‘buy and bill’ practices of providers who administer expensive, biologic treatments.
Other Policy Considerations

• Value Frameworks –
  – The role of professional societies
  – Large institutions

• Reduce patent exclusivity period to negate monopoly position of the producer

• When there is a public health imperative, buy the patent and distribute at marginal cost (e.g., Sovaldi).

• Dramatically reform the FDA process – reducing time to market.

• Consider international policies in the US.
International Policies

• Price referencing (Multiple Countries)
• Price-volume agreements (France)
• Explicit use of cost-effectiveness information (UK, Canada, Aus, Taiwan, Korea)
• Mandatory price reductions (Japan, France)
• Innovative contracting agreements (Italy, UK, Aus, US)
Innovative Contracting Models

Financial Utilization Models

- Price volume agreement: e.g. if agreed for 10% patient sub population: full reimbursement for first 10% of patients, reduced reimbursement for next 20% of patients, no reimbursement for all others

Outcomes Based Pricing Models

- Money back guarantee, e.g. full reimbursement for responders, reduced reimbursement for partial responders, no reimbursement for non-responders

Risk Type Based Pricing Models

- Reimbursement linked to value and level of risk factors (e.g. based on diagnostic test)
Questions For Panel

• What types of pharmaceutical innovative contracting models (e.g. performance, outcomes or risk-based agreements) could play a role in an ACO arrangement in which an ACO enters into a shared savings or full risk agreement with the state Medicaid program linked to total cost of care, including pharmacy spending?

• Are there examples of successful innovative pharmaceutical contracting models either in the private or government health care sector that you might suggest Washington HCA consider?

• What types of pharmaceutical innovative contracting models could support improved performance on any of the HB 2572 quality measures that are being adopted in Washington state?

• What barriers and challenges (logistic, financial, legal) exist from your perspective that would limit the ability to implement innovative contracting models? How can these barriers be overcome?
Questions For Panel

- Risk-based agreements often assume that upfront use of a drug results in down-stream savings. How does your health plan currently view/calculate (or take account of...) “ROI” on pharmaceuticals? (intent of this question is to understand payer perspective on ROI, and delve into the notion of “cost saving” vs. “cost-effective”)

- How does a plan’s time horizon affect thinking about/understanding of ROI? (e.g. – if there is an ROI on treating a young patient with hepatitis C who is Metavir 0?)

- What role for PBMs in risk based contracting?