How to Realize “Affordable” Drugs—Panel Discussion

Feb. 3, 2017

"The whole business case from the patient’s view”

The Inspire2Live 2017 Annual Congress
Panel:

Lou Garrison (Chair, University of Washington, USA)
Marcel van Raaij, Ministry of Health
Ad Antonisse, AstraZeneca
Huig Schipper (Inspire2Live)
Susan Noyon (Zilveren Kruis)
Casper van Eijck (Erasmus Univ.)
The Price of Medicines: Conventional Economics of Innovative Medicines

February 3, 2017

Lou Garrison, PhD
Professor Pharmaceutical Outcomes Research & Policy Program
Department of Pharmacy
Adjunct Professor, Departments of Global Health and Health Services
University of Washington
Seattle, Washington, USA
22 novel drug approvals in CY 2016 is less than the average number approved annually during the past decade.

From 2007 through 2015 CDER averaged about 30 novel drug approvals per year.

CDER New Molecular Entity (NME) and New Biologic License Application (BLA) Filings and Approvals

<table>
<thead>
<tr>
<th>Year</th>
<th>NME / BLA Approvals</th>
<th>NME / BLA Filings</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>18</td>
<td>35</td>
</tr>
<tr>
<td>2008</td>
<td>24</td>
<td>34</td>
</tr>
<tr>
<td>2009</td>
<td>26</td>
<td>36</td>
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<tr>
<td>2010</td>
<td>21</td>
<td>23</td>
</tr>
<tr>
<td>2011</td>
<td>30</td>
<td>41</td>
</tr>
<tr>
<td>2012</td>
<td>39</td>
<td>41</td>
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<tr>
<td>2013</td>
<td>36</td>
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<td>2014</td>
<td>41</td>
<td>35</td>
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<tr>
<td>2015</td>
<td>45</td>
<td></td>
</tr>
<tr>
<td>2016*</td>
<td>41</td>
<td>22</td>
</tr>
</tbody>
</table>

FDA, 2017
## Key Facts 2016—From PhRMA

### R&D SPENDING

<table>
<thead>
<tr>
<th>Year</th>
<th>PhRMA members³</th>
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<tbody>
<tr>
<td>2015</td>
<td>$58.8 billion (est.)</td>
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<tr>
<td>2014</td>
<td>$53.3 billion</td>
</tr>
<tr>
<td>2013</td>
<td>$51.6 billion</td>
</tr>
<tr>
<td>2012</td>
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<tr>
<td>2011</td>
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<td>2009</td>
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<td>2008</td>
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<td>2007</td>
<td>$47.9 billion</td>
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<tr>
<td>2006</td>
<td>$43.0 billion</td>
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<tr>
<td>2005</td>
<td>$39.9 billion</td>
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<tr>
<td>2000</td>
<td>$26.0 billion</td>
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<tr>
<td>1990</td>
<td>$8.4 billion</td>
</tr>
<tr>
<td>1980</td>
<td>$2.0 billion</td>
</tr>
</tbody>
</table>

### SALES

- Generic share of prescriptions filled:
  - 2000 = 49%
  - 2015 = 91%
Drug Development: Complex, Risky, and Costly

Only about 20-25 percent of drugs tested in humans make it to the market.

New Tufts Estimate--$2.6 Billion Per New Medicine

"... the cost to develop and win marketing approval for a new drug has increased by 145% between the two study periods, or at a compound annual growth rate of 8.5."
What is a “medicine” from an economic perspective?

- One input in a “health production function”:
  - \( H = H(\text{physician visits, hospital care, medicines, own time, OTHER}) \)
  - “OTHER”—the social determinants of population health

- What about an “innovative” drug?
  - Represents new information or knowledge.

- What is unique about new information or knowledge from an economic perspective?
  - It’s a NOT a private good: it’s a “public good.”
  - It’s NOT ONLY a public good, it’s a \text{GLOBAL public good}.

- Free markets will tend to \text{undersupply public goods} (below what is socially optimal).
  - Therefore, intervene, but how?
  - Patents (intellectual property) and subsidies.
Patents (Intellectual Property) for Medicines

• Statutory patent life is 20 years.

• For medicines:
  – Takes 8-12 years to launch product.
  – Implies 8-12 years remaining after approval for marketing

• Provides strong (but limited) protection against competition
  – Generic copies are blocked during patent life
  – But follow-on competition is common
Source: Berndt et al., 2015
Generic Competition and Drug Prices

Average Relative Price per Dose

Number of Generic Manufacturers

Source: FDA analysis of retail sales data from IMS Health, IMS National Sales Perspective (TM), 1999-2004, extracted February 2005
### Table 12.6 Comparison of Pharmaceutical Prices Across Selected Countries

**EXHIBIT 6**

#### Pharmaceutical Price Indexes, Relative to US Prices (US = 100), 2005

<table>
<thead>
<tr>
<th>Country</th>
<th>Comprehensive Indexes&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Originator versus Generic&lt;sup&gt;b,c,d&lt;/sup&gt;</th>
<th>Rx versus OTC&lt;sup&gt;b,c,d&lt;/sup&gt;</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Manuf.&lt;sup&gt;d&lt;/sup&gt; at Exch. Rates&lt;sup&gt;c&lt;/sup&gt;</td>
<td>Public&lt;sup&gt;e&lt;/sup&gt; at Exch. Rates&lt;sup&gt;c&lt;/sup&gt;</td>
<td>Public&lt;sup&gt;e&lt;/sup&gt; at GDP PPPs&lt;sup&gt;f&lt;/sup&gt;</td>
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<tr>
<td>US</td>
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<td>Brazil</td>
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<tr>
<td>Mexico</td>
<td>102</td>
<td>107</td>
<td>157</td>
</tr>
</tbody>
</table>

Note: ATC3 is Anatomical Therapeutic Classification.

<sup>a</sup>Bilateral matching with US by molecule-atc3.
<sup>b</sup>Bilateral matching with US by molecule-atc3-form-strength.
<sup>c</sup>Price converted to US dollars at exchange rates.
<sup>d</sup>Manufacturer prices.
<sup>e</sup>Public prices.
<sup>f</sup>Prices converted to US dollars at gross domestic product (GDP) purchasing power parities (PPPs).
<sup>g</sup>Price index normalized by GDP per capita.

Figure 2
Drug Price per Life Year Gained versus Drug Approval Date

Source of survival benefit:
- Trial, overall survival
- Trial, progression-free survival
- Modeling study

 Thousands of 2013 dollars

Approval date


Journal of Economic Perspectives—Volume 29, Number 1—Winter 2015—Pages 139-162

Pricing in the Market for Anticancer Drugs

David H. Howard, Peter B. Bach, Ernst R. Berndt, and Rena M. Conti
Conclusion: Final Comments

1. Long-term sustainability of the current industry “blockbuster” business model is questionable.

2. Access to innovative medicines remains a significant problem in this system.

3. This is a global problem: global differential pricing is needed—likely to be helpful, but not a “solution.”

Thanks—lgarrisn@uw.edu
Speaker:

Marcel van Raaij, Ministry of Health
Speaker:

Ad Antonisse
**Speaker:** Ad Antonisse (AstraZeneca)

**Key Points/Issues:**

1. Basic science and pharmaceutical science get closer and closer
2. Personalised medicine = Drug + Diagnostics + Funding + Process
3. We do not sell the product. We sell the knowledge.
Speaker:

Huig Schipper
Speaker: Huig Schipper (Inspire2Live)

Key Points/Issues:

1. Pay for Value, cap prices to €100k per QALY
2. Restore power balance by sharing IP with trial patient (organizations), Patients demand their 33% share of IP when signing there informed consent
3. Increase tax by 10% on tobacco, alcohol and sugar. Use the revenue for better accessability for medicines
Speaker:

Susan Noyon (Zilveren Kruis)
Speaker:

Casper van Eijck (Erasmus Univ.).
Thanks for your attention.

Discussion: Q&A