Two ideas regarding Innovation and Access

James Love, CPTech
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1. Separate market for innovation from market for product
Consequences of exclusive marketing rights to finance R&D on Access
Price of Singulair as a share of per capita income in South Africa

Income decile

Percent of income
Novartis at the World Bank in 2004

• We consider India to be a market of 50 million
US: Cancer Weapons, Out of Reach

- Third-party payers will not react passively to pricing that increasingly threatens their balance sheets, especially as more drugs like these are commercialized over the next few years. They will carefully scrutinize all proposed uses of expensive new drugs. Historically, an FDA judgment of "safe and effective" -- the statutory criterion for drug approval -- has almost automatically triggered an agreement by payers to reimburse, which is the real gateway to widespread use and market success. We may now see payers deciding, for the first time, that certain novel "safe and effective" medicines are simply not worth paying for. In addition, payers will surely try to limit "off-label" uses of these drugs -- that is, uses other than the FDA-approved ones. Unlike other areas of medicine, physicians have commonly prescribed cancer drugs for a broader array of indications than specifically approved by the FDA, as clinical research routinely reveals additional uses after market introduction. A very high bar to new uses by payers is a virtual certainty.
# US FDA Priority and Standard NME Approvals

## Calendar Years 1993-2002

<table>
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<th>Year</th>
<th>Priority</th>
<th>Standard</th>
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<tr>
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<td>12</td>
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<td>2002</td>
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<td>Total</td>
<td>79</td>
<td>180</td>
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<tr>
<td>Percent</td>
<td>31%</td>
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Number of patients in clinical trials cited in US FDA approval letters for NCEs 2000 - 2002

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<th>Priority</th>
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<tr>
<td>Average</td>
<td>1,461</td>
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<td>Median</td>
<td>905</td>
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<td>1,826</td>
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<td>Coefficient of Variation</td>
<td>1.25</td>
<td>.79</td>
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Economics of current pull system
The patent system raises prices and investments in R&D, but it is a costly way to finance R&D, particularly for products that are new and better than existing products.
HR 417, the Medical Innovation Prize Fund Approach
1. Patent system intact through product development and market approval

2. No market exclusivity, generic companies can freely compete

3. Medical Innovation Prize Fund provides financial rewards to developers of new products
The Prizes

1. The US MIPF proposes a fund of .5 percent (50 basis points) of US GDP.
   - $60 billion
   - About 5 times the current royalties on patents
   - The sponsors of the legislation are open to consideration of a higher contribution rate.

2. Payments to innovators over 10 year period are based upon incremental health care benefits

3. Organizations that develop new drugs compete against each other, on the basis of the incremental health care benefits their products deliver
Some of the fund is allocated to priority projects

- Global neglected diseases
  - 2 basis points - $2.4 billion

- Orphan drugs
  - 5 basis points - $6 billion

- Research on AIDS, including AIDS vaccines, global infectious diseases, and medicines to treat bio-terrorism
  - 2 basis points - $2.4 billion
MIPF/HR 417 vs. APC

• The MIPF/HR 417 and APC are different versions of a prize fund approach
  – MIPF/HR 417 is compulsory, APC is voluntary,
  – MIPF/HR 417 provides rewards for any new medicine that provides benefits, with set asides for certain broad groups of priority projects
  – The APC proposals are more narrowly focused in particular treatments (i.e. vaccine for malaria, etc)
  – Both approaches reward successful projects that people use
    • The MIPF/HR 417 only rewards products that actually provide benefits
    • The APC only rewards products that are purchased
2. R&D Treaty
Basic obligations

1. Every country is required to support medical R&D

2. The obligation would be a fraction of GDP

3. The fraction would depend upon the level of development

4. Countries would have flexibility in terms of how the R&D was financed and managed

5. Purchases of patented medicines, public sector research, prize funds, etc., would be allowed, to the degree that they stimulate R&D
Investments in some certain projects that are important earn credits. These credits are tradable between countries.

- Priority research/neglected diseases
- Open research
- Exceptionally useful projects
- Preservation and dissemination of traditional medical knowledge
- Technology transfer, capacity building

(Subject to some caps)
For more information

CPTech
http://www.cptech.org

james.love@cptech.org