

# The Medical Innovation Prize Fund<sup>1)</sup>

- A New paradigm for R&D Incentives

James Love (美 CPTech 소장)

## The Medical Innovation Prize Fund

*A new paradigm for R&D incentives*

James Love

30 April 2005

---

1) 이 문서는 2005년 4월 29일 영상미디어센터에서 열린 정보공유연대 IPLeft 월례포럼에서 미국 CPTech 소장인 James Love가 발표한 것이다.

The development of new drugs is expensive, and requires both investment and efficient management of investments

Pre-clinical

Clinical

- Phase I
- Phase II
- Phase III

Where does the money come from?

- “Push” mechanisms
  - Public funding
  - Tax credits and other subsidies
  - New push mechanisms such as competitive intermediators
- “Pull” mechanisms
  - Potential profits from marketing successful projects
  - New pull mechanisms such as “Prize” funds

## Problems of the current “pull” mechanism

- Exclusive rights lead to pricing abuses and barriers to access
- Low levels of investment in products that provide incremental health care benefits
- Low levels of investment in treatments for the poor (neglected diseases)
- Wasteful marketing outlays

### US FDA Priority and Standard NME Approvals

Calendar Years 1993-2002



Priority and Standard NMEs For Calendar Years 1993-2002



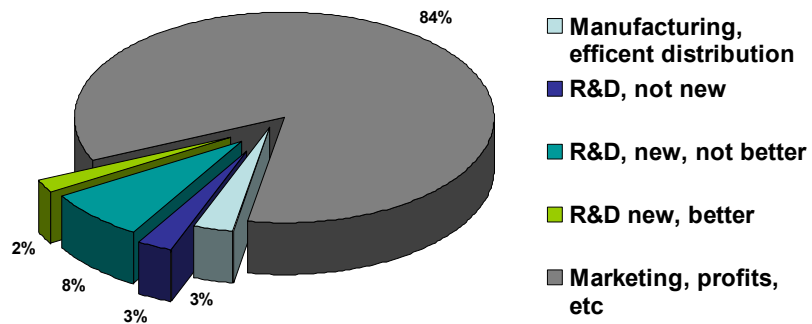
**Number of patients in clinical trials cited in  
US FDA approval letters for NCEs  
2000 - 2002**

---

---

---

- About 13 percent of global pharma sales are reinvested in R&D
- Most R&D (11 of 13 percent) is invested in older products, or “me too” products
- Approximately 2 percent is invested in products the US FDA considers significantly better than existing treatments



## US: Cancer Weapons, Out of Reach

Robert Wittes, June 15, 2004, Washington Post

Since most colorectal-cancer patients for whom these drugs are medically appropriate receive them not singly but in combination with other chemotherapeutics, the monthly AWP is more like \$11,000 for combinations including Avastin and \$16,000 for Erbitux. Providers pass these costs on to patients, along with charges that cover the costs of pharmacy and dispensing. Courses of treatment generally last several months, but they can be much longer for patients who respond favorably. In other words, the cumulative cost of treatment can be astronomical.

## US: Cancer Weapons, Out of Reach

Robert Wittes, June 15, 2004, Washington Post

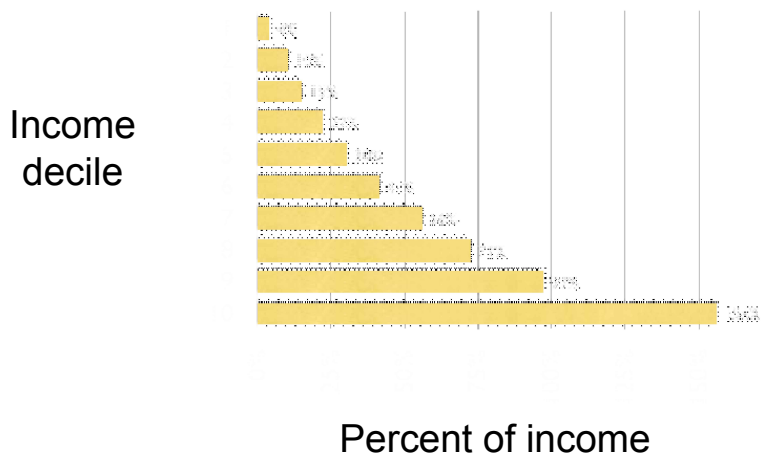
- Although the uninsured and medically indigent may feel the effects of these pricing decisions most keenly, those with insurance will also face a nasty dilemma. The increasing co-pay percentages of most plans and the capping of benefits in others will compel a major financial outlay for those determined to have the treatments. And those who do not want their families to assume the financial burden will be left with bitter resentment.

## US: Cancer Weapons, Out of Reach

Robert Wittes, June 15, 2004, Washington Post

- 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.

### Price of Singulair as a share of per capita income in South Africa



# Novartis at the World Bank in 2004

- We consider India to be a market of 50 million



THE SECRETARY OF COMMERCE  
Washington, D.C. 20230

His Excellency  
Kim Won-Gil  
Minister of Health and Welfare of the Republic of Korea  
Seoul

Dear Mr. Minister:

I would like to express my serious concern regarding Korea's proposed modifications to its pharmaceutical pricing system, part of its recently announced Comprehensive Plan for stabilizing the National Health Insurance Program. . . . If not addressed appropriately, this issue is likely to develop into a serious trade dispute.

Under the reference pricing system proposed in the Plan, patients would incur a co-payment for certain pharmaceutical products within a given therapeutic category based upon the cost of those products. Research-based, innovative pharmaceuticals are often more expensive than generics and other products; therefore, it is mainly these products that would be subject to a co-payment requirement. Requiring patient co-payments for only some products within a therapeutic category would create a distinctive for patients to use these pharmaceuticals, regardless of their effectiveness. . .

In recent years, the U.S. Government and industry have engaged in a productive dialogue with Korean health care policy makers. I hope that the agreements reached through this cooperative process will not be undermined as a result of decisions that have not been fully discussed and mutually agreed upon. The United States has considerable expertise and experience in health care financing matters, and we look forward to the opportunity to work with you to find ways to bring high-quality health care to the Korean people in a fiscally prudent and equitable manner.

Warm regards,  
Donald L. Evans

c.c: Hwang Doo-yun, Minister of Trade

# Paradigm Shift

Change the trade framework from one that focuses solely on the protection of intellectual property rights or drug prices to a new mechanism that addresses directly the need to ensure adequate and sustainable global investment in medical R&D

1. Separate the Market for Products from the Market for Innovation

2. Introduce more innovation and competition in the business methods we use to finance innovation

Medical Innovation Prize Fund  
*(US HR 417)*

- The Medical Innovation Prize Fund is created as an independent entity.
- Trustees include some public officials (heads of NIH, Medicare, etc), and members of the public appointed by the President
- The fund is supported by contributions equal to 50 basis points of US GDP (approximately 60 billion USD per year)

## *How the MIPF works*

- Intellectual property rules, including patents, are left intact through the development of new medicines.
- At point of FDA marketing approval, exclusive rights are eliminated, and generic competition is permitted.
- Firms that register new products receive money from the Medical Innovation Prize Fund Fund

## What are the Prizes?

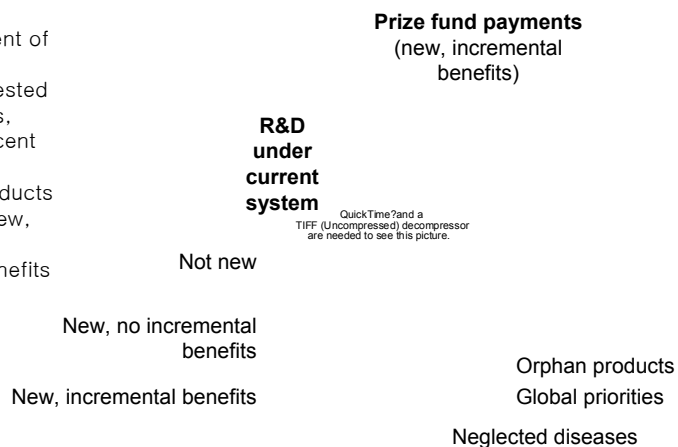
- For a 10 year period, the innovator is eligible for prize payments
- The payments are based upon evidence of incremental benefits to health
- It does not matter who sells the product – only the innovators receives the reward
- Path breaking innovative products can receive payments even when replaced in market share by follow-on products

## Minimum allocations to priority research

- 2 basis points for global neglected diseases (\$2.4 billion)
- 5 basis points for orphan drugs (\$6 billion)
- 2 basis points for research on AIDS, including AIDS vaccines, global infectious diseases, and medicines to treat bio-terrorist (\$2.4 billion)

The MIPF payments exceed outlays on R&D, and are targeted at products providing incremental health care benefits

About 13 percent of current pharma sales are reinvested in R&D. Of this, roughly 15 percent are spent on developing products that are both new, and have incremental benefits over existing medicines.



Marginal Cost Pricing – “push approaches” – *Competitive Intermediators, known as R&D Investment Funds*

Employers are required to contribute to private R&D investment funds (RDIFs).

RDIFs compete against each other.

- Use different strategies to develop new products (prizes, direct funding, open source projects, etc)

Government regulates RDIFs for transparency, etc

More generally,

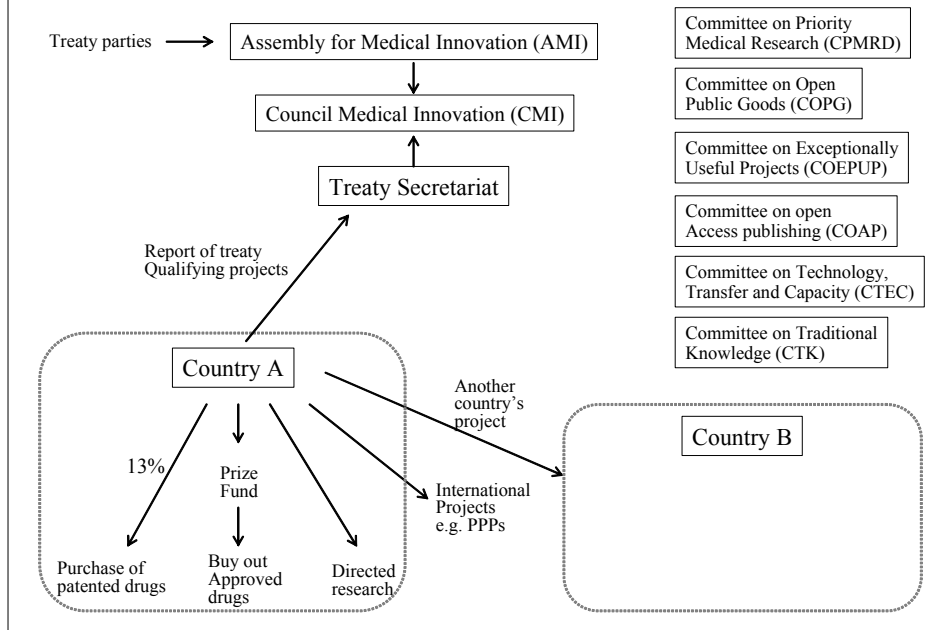
Encourage and facilitate decentralized decision making and a diversity of financing mechanisms

Create obligations and incentives to invest in priority research and public goods

## Priority Setting

- TRIPS/Multilateral/Regional/Bilateral/ Unilateral trade and IPR agreements
  - Obligations to provide incentives to invest to products that fetch high prices
- New Trade Framework
  - Obligations to support costs of R&D, regardless of public or private
  - Minimum quotas for investments in priority research
  - System of credits to provide incentives to invest in
    - Neglected diseases
    - Open public goods
    - Technology transfer and capacity building

## Treaty mechanisms overview



## Basic obligations

- Fraction of GDP finances medical R&D
  - High income
  - Middle
  - Low

## What fraction of GDP for R&D?

- Possible approaches
  - Using World Bank income groups, a graduated rate:
    - High Income, 15 basis points (.0015)
    - High Middle Income, 10 basis points (.001)
    - Lower Middle Income, 5 basis points (.0005)
    - Low Income, 0 basis points of GDP (0)
  - A rate based upon per capita income in USD divided by 10,000,000, with a maximum rate (20 to 30 basis points)
  - A sliding scale using the UNDP Human Development Index

## Methods of finance

Projects that support QMRD (including PMRD) are selected by Member States. Eligible finance mechanisms include:

- Public sector support for QMRD
- Tax expenditures, such as tax credits for QMRD investments
- Philanthropic expenditures on QMRD
- QMRD funded by businesses or non-profit organizations under government mandates,
- National expenditures on relevant medical products, to the degree that such expenditures create incentives for investments in QMRD,
- Innovation prizes or other innovation incentives, to the degree that such expenditures support QMRD.

## Measurement rules

- **No double counting.** The mechanisms to finance QMRD (including PMRD) can be complex, involving mixed sources of finance and transnational flows of products and investments. The regulations shall provide that each investment only be counted once.
- **Source of finance rather than location of investment.** For purposes of measuring support for QMRD and PMRD, measurement will be based upon the source of finance rather than the location of R&D activity.
- **Evidence based estimates.** In cases where measured investments are based upon estimates of the relationship between outlays on products or incentives and actual R&D investments, the estimates shall be based upon the best empirical evidence of such relationships.

What can we learn from  
efforts to curb global  
warming?



## ONE NEWS

### Kyoto gives hope to wind power

Mar 05, 2003

The first significant impact of New Zealand signing the Kyoto protocol is being felt with two new wind farms coming a step closer to producing electricity.

The government has made its first use of the tradeable carbon credits under the Kyoto Protocol, giving them to Meridian Energy and TrustPower in recognition of the benefits of their proposed wind farms.

Carbon trading allows a heavily-polluting country to offset some of its carbon dioxide emissions so it can still meet the obligations it signed up to under the Kyoto Protocol.

The power companies say the projects would not be economically viable if it was not for the credits which will eventually be sold on the international market.



A wind turbine

#### RELATED LINKS

- [Rush for carbon credits](#)
- [Wind turbine violates consent](#)
- [Farmers fight greenhouse tax](#)

## Credits for Certain R&D Projects

- Several types
  - Priority research/neglected diseases
  - Open research
  - Exceptionally useful projects
  - Preservation and dissemination of traditional medical knowledge
  - Technology transfer, capacity building
- Tradable between countries
- Some caps

## For more information

Consumer Project on Technology

<http://www.cptech.org>

<http://www.cptech.org/workingdrafts/rndtreaty.html>

Subscribe to ip-health, or bellagio-rnd