

# Designing Prizes

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First, some data on clinical trials,  
and industry economics

# Who pays for Phase I, II and III Clinical Trials

<b>Disease</b>	<b>No industry</b>	<b>Some industry</b>	<b>Only industry</b>
Restless Leg Syndrome	1%	1%	98%
Influenza	5%	4%	90%
Erectile dysfunction	6%	1%	93%
Hair Loss	7%	1%	92%
Asthma	11%	2%	87%
Obesity	16%	3%	81%
Diabetes	17%	10%	73%
Alzheimer's	22%	3%	75%
Heart Disease	26%	16%	58%
Depression	27%	17%	56%
TB	31%	19%	50%
AIDS	51%	22%	27%
Cancer	51%	8%	40%
Antibiotic	52%	10%	37%
Malaria	74%	4%	22%

*Source: Aisola and Love, Who Pays for Clinical Trials? Forthcoming*

# Industry Economics

- Global revenues more than \$750 billion
- Global private second R&D less than 10% of revenues
- Premium for monopoly is more than \$.5 trillion.
- Few new drugs have significant impact on health outcomes.

# Most NMEs address serious health problems

## 2006 FDA NME Approvals

chronic angina

chronic hepatitis B (CHB)

chronic idiopathic constipation

cutaneous manifestations in patients with cutaneous T-cell lymphoma (CTCL)

EGFR-expressing metastatic colorectal carcinoma

esophageal candidiasis

genital and perianal warts (Condylomata acuminata)

gastrointestinal stromal tumor

glycemic control in patients with type 2 diabetes mellitus

Helicobacter pylori infection and duodenal ulcer disease

human immunodeficiency virus (HIV)

Hunter syndrome (Mucopolysaccharidosis II, MPS II)

idiopathic Parkinson's disease

myelodysplastic syndrome (MDS)

myeloid leukemia

neovascular (wet) age-related macular degeneration.

Pompe disease (GAA deficiency).

prevention of sunburn

prophylaxis of invasive Aspergillus and Candida infections

schizophrenia.

seasonal and allergic rhinitis

smoking cessation.

# Many new drug approvals are medically unimportant

## 2007 US FDA Approvals of New Drugs

	<b>NME</b>	<b>Re-Purposed</b>	<b>All</b>
<b>Priority</b>	8	15	23
<b>Standard</b>	10	45	55
<b>All</b>	18	60	78
<b>Priority</b>	10%	19%	30%
<b>Standard</b>	13%	58%	71%
<b>All</b>	23%	77%	100%

# Why prizes?

## Selected Innovation Prizes and Reward Programs, KEI Research Note 2008:1

Prizes . . . offer certain important advantages over grants or temporary monopolies. When designed well, prizes can reach a wider community of problem solvers than will grants and, like the prospect of a commercial monopoly, bring in new actors following unconventional approaches, and stimulate private decision-making and entrepreneurship. Prizes can be used when the desired output is not patentable, or the use of the patent system is too costly and bureaucratic, or when the private market for the outcome is inadequate or does not exist. If prizes are used as an alternative to a monopoly as the incentive for private investment, it is possible to avoid a wide range of costs associated with monopolies, including not only high prices and barriers for access to the inventions, but also obstacles to follow-on innovation. Prizes can also be tailored as incentives in ways that are simply not possible with rewards that are tied to the monopoly prices of the outputs. Some of the areas where prizes are thought to have important advantages are cases where it socially and economically important to have marginal cost pricing and/or free access to the outputs of the R&D efforts, or where it is important to reward the development of translational and transition technologies and products that will not by themselves be commercially viable, but which serve to advance the state of the useful arts and sciences.

# Prizes, v 1

# Context, the United States:

## The Medical Innovation Prize Fund (S.2210, 110<sup>th</sup> Congress)

- Eliminate product monopolies
- Large cash prizes reward developers of new medicines

# S.2210 proposed levels of funding

- \$80 billion per year at current US GDP
- 18 percent in set-asides for certain priority areas
  - \$8 billion for orphan drugs; and
  - \$3.2 billion for global neglected diseases;
  - \$3.2 billion for global infectious diseases and other global public health priorities, including research on AIDS, AIDS vaccines, and medicines for responding to bioterrorism.

# S.2210: language on set-asides for priority research

- (b) Initial Minimum Levels- Of the amount appropriated to the Fund for a fiscal year, the Board shall use (subject to the establishment or modification of an applicable minimum level of funding under subsection (a)) not less than--
- (1) 4 percent of such amount for global neglected diseases;
  - (2) 10 percent of such amount for orphan drugs; and
  - (3) 4 percent of such amount for global infectious diseases and other global public health priorities, including research on AIDS, AIDS vaccines, and medicines for responding to bioterrorism.
- (c) Public Input; Recommendations- The advisory committee on research and development priorities (established pursuant to section 8(b)(3)) shall--
- (1) solicit public input on research and development priorities; and
  - (2) periodically recommend to the Board modifications in the minimum levels of funding for prizes for priority research and development under this section.
- (d) Procedures- The Board shall adopt procedures to establish and periodically modify minimum levels of funding under section 9 for priority research and development.

# Valuation of prizes

- Qualifying products participate in the fund for 10 years
  - A longer qualifying period is possible, and would improve information about the value of the invention, but shift more risk to the drug developer
- Products compete for shares of a prize fund that is fixed in size

# Zero sum competition for shares of fixed size prize fund

- Every drug developer wins something
  - But some win more than others.
- Prizes are based upon a variety of factors
  - The most important of which is the impact of the invention on health care outcomes
  - Impacts are measured against therapeutic alternatives not recently developed.

# Some important features of the US prize fund design (S.2210, 110<sup>th</sup> Congress)

- Increases in utilization do not lead to increased liability by consumers or third party payers
  - No economic incentive to ration access to new medicines
- Would lead to dramatic changes in trade policy
  - U.S. Would not longer export high prices to developing (and developed) countries

# Sequential/Follow-on Innovation

# Product development races

- As science evolves and confidence grows regarding possible solutions, firms may begin development of similar products.
  - To the extent that sooner is better than later, simultaneous development has benefits.
    - Some projects may fail
    - Uncertainty regarding best approach

# S.2210 approach does not discourage races

The benchmark is to products “not recently developed:”

SEC. 9. PRIZE PAYMENTS FOR MEDICAL INNOVATION. (c)(2)

The incremental therapeutic benefit of the drug, biological product, or manufacturing process involved as compared to existing drugs, biological products, and manufacturing processes available to treat the same disease or condition, **except** that the Board shall provide **for cases where drugs, biological products, or manufacturing processes are developed at roughly the same time, so that the comparison is to products that were not recently developed.**

- When products are introduced at roughly the same time, benchmarks are to older product, not to each other.
- However, since rewards are related to utilization, the new products, developed at roughly the same time, will compete against each other for prize money.
  - Each of the new products will be benchmarked against the older standard, and rewarded for the impact on health outcomes (*a function of utilization*).
    - If one drug is used rarely and the other product used more frequently, rewards will be skewed to the one used more frequently

# Valuing first and second movers

# Stylized Example

- Product 1 opens a new field with an efficacy of  $Z$ , and generates  $1,000 * Z$  QALYs
- Product 2 is a small modification of Product 1, and, with an efficacy of  $1.05 * Z$ 
  - Product 2 is better, and completely replaces Product 1 in the market, and generates  $1,050 * Z$  QALYs
  - What should be the relative rewards for Products 1 and 2?

# Under current system

- With patent enforced monopolies, the two innovations compete.
  - With only competition based upon quality, returns to Product 1 fall to zero, and returns to Product 2 are higher than the returns to Product 1.
    - Incentives are large for so called “me too” products.
  - If differences in quality of products is perceived to be unimportant, and competition focusing on price only, returns to Product 1 falls.
  - If marketing drives utilization, costly marketing wars dissipate returns to both companies.

# S.2210 approach

- SEC. 9. PRIZE PAYMENTS FOR MEDICAL INNOVATION.(d) (1)
  - In cases where a new drug, biological product, or manufacturing process offers an improvement over an existing drug, biological product, or manufacturing process and the new drug, biological product, or manufacturing process competes with or replaces the existing drug, biological product, or manufacturing process, the Board shall continue to **make prize payments for the existing drug, biological product, or manufacturing process to the degree that the new drug, biological product, or manufacturing process was based on or benefitted from the development of the existing drug, biological product, or manufacturing process.**

# 1<sup>st</sup> and 2<sup>nd</sup>

- Even with zero market share
  - Rewards to Product 1 based upon 1,000\* Z QALY
- Even with 100 percent market share
  - Rewards to Product 2 based upon 50 \* Z QALY

# A strictly proportional (to QALYs) reward structure may not be optimal

Stylized example with fixed development cost of 200

	(000x) QALY	<i>Proportional</i>	feasible <i>only</i>	half <i>fixed</i>
<i>Projects</i>	1	53		226
	2	105		253
	3	158		279
	7	368	438	384
	25	1316	1563	858
Totals	38	2000	2000	2000

# Other valuation issues

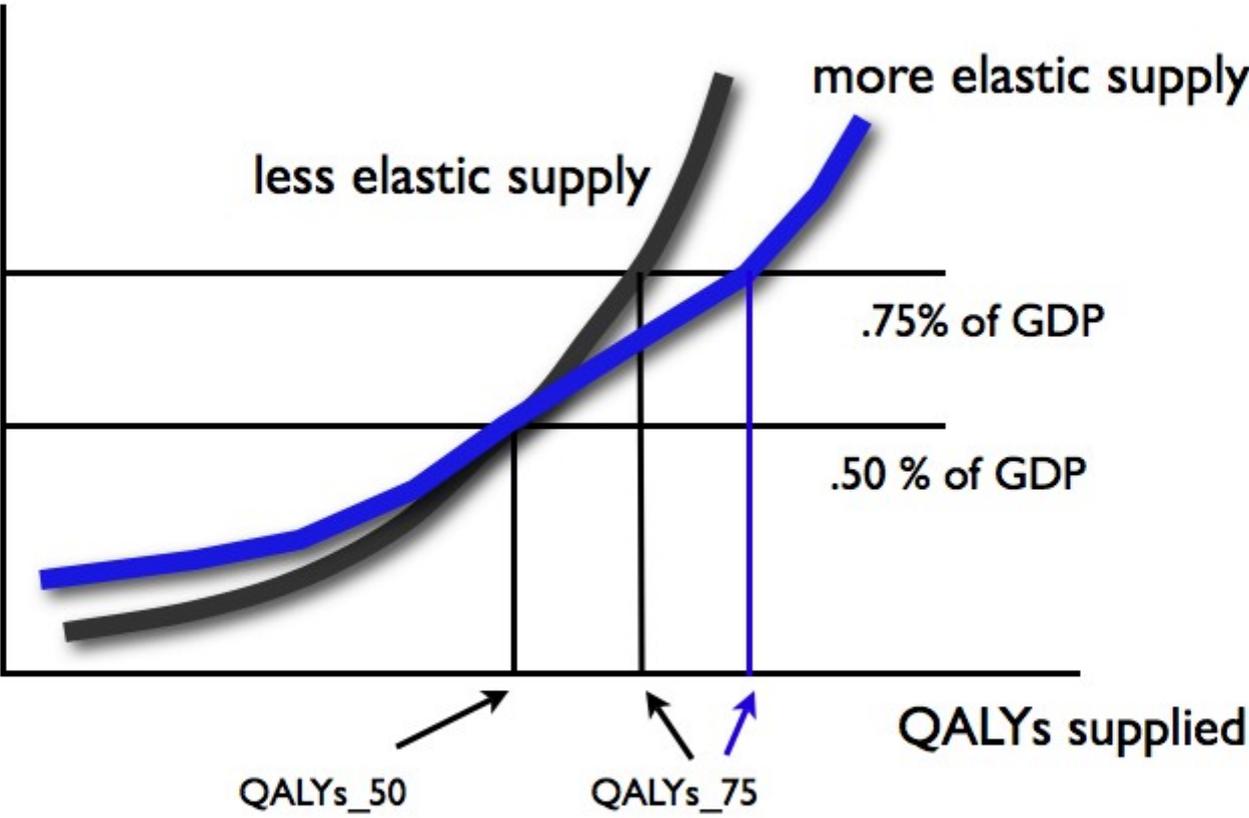
- Society values for treatments for a variety of reasons, including contingencies
  - Bio-terrorism
  - Treatments for SARS or Influenza
  - Antibiotics
- Techniques such as option pricing models can be used to value the availability of products for possible health needs.
- The value of Antibiotics can be better evaluated with a prize than a price, and without creating incentives for inappropriate use.

# Period of evaluation

- On the one hand, you want enough to gather adequate information about the value of the products
- On the other hand, you don't want to force investors to wait too long.
- S.2210 uses a 10 year period, of annual assessments, which is similar to the expected period of monopoly under current system. A somewhat longer period, such as 15 years, would be reasonable.

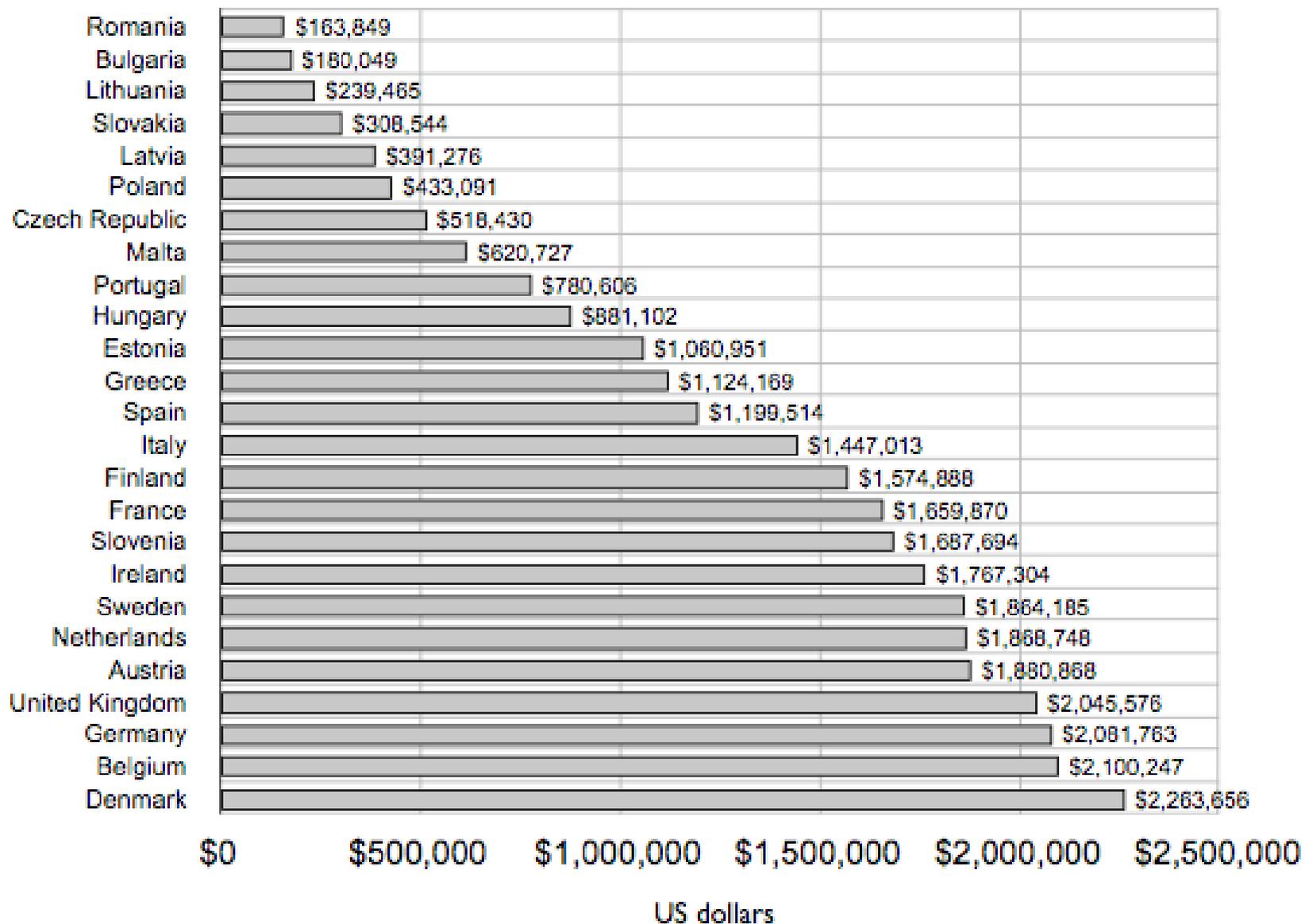
# Supply of QALYs

Size of prize fund



# Capacity to pay for cancer treatment in EU Member States

National income divided by loss of year of life from cancer, measured in DALYs



# What about Development and Technology?

# Prizes, Version 2

# Main additions

- Openness incentives
  - Open Source Dividend juries
- Interim results rewards
  - Best results prizes (TB diagnostic or Chagas prize)
  - Competitive Intermediaries
- Developing country set-asides

# WHO Global strategy and plan of action on public health, innovation and intellectual property

2008: Sixty First World Health Assembly **WHA61.21**

4. Proposals should be developed for health-needs driven research and development that include exploring a range of incentive mechanisms, including where appropriate, **addressing the de-linkage of the costs of research and development and the price of health products** and methods for tailoring the optimal mix of incentives to a particular condition or product with the objective of addressing diseases that disproportionately affect developing countries.

# Bangladesh, Barbados, Bolivia and Suriname proposals to World Health Organization

- Donor Prize
- Cancer Prize
- Chagas Prize
- TB diagnostics prize
- Priority medicines and vaccines

# Proposal in WHO for “Priority Medicines and Vaccines Prize Fund (PMV/pf)”

## **Incentives for Collaboration and Access to Knowledge**

In order to ensure there are incentives for openness and sharing among researchers, the Final Product Prize money would be divided as follows. The winning entrant would get 90 percent of the prize money. The remaining 10 percent of the prize money would be given to unaffiliated and uncompensated (by the winning entrant) scientists and engineers that openly published and shared research, data materials and technology, in the basis of who provided the most useful external contributions to achieving the end result. This would include research, data, materials and technology that were either placed in the public domain, or subject to open, nonremunerated licenses.

To qualify, published research findings would have to be freely available on the Internet in full text. As an incentive to journals to make articles available to the public for free, 10 percent of the “best contributions” prize given for a published article would be available to a peer-reviewed journal that published the article, on the condition that the journal made the article available for free immediately upon publication.

# Related negotiations on prizes

- FDA Priority Review Voucher
- HIF
- TB Diagnostic Prize

# New initiatives

- WHO Expert Working Group on R&D financing
- WHO biomedical R&D treaty
- WTO agreement on global public goods
- UNITAID Patent Pool
  - (Licensing linked to prize fund?)

# Prizes and the Management of IPR

- Ad hoc approach to management of IPR
  - Nanotechnology
  - Energy and Climate Change Prizes
  - Prizes for health related projects
  - Etc
- Issues similar to those of the Bayh-Dole Act
  - Public Interest in pricing and access to products
  - Public Interest is access to knowledge
  - Public Interest is follow-on innovation

# For more information

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