

Designing Medical Innovation Prizes



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12 December 2008

Unbranding Medicines: the politics, promise, and challenge of
generic drugs
Harvard Interfaculty Initiative on Medicines and Society

Deficits in the current system of funding R&D

- Efficiency
 - Excess incentives to invest in marketing and medically unimportant products,
 - Insufficient incentives to invest in medically important products.
- Access and Fairness
 - High prices and rationing
- Difficulties of allocating costs of reward system among different users.

2006 FDA NME Approvals

Most NMEs address serious health problems

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

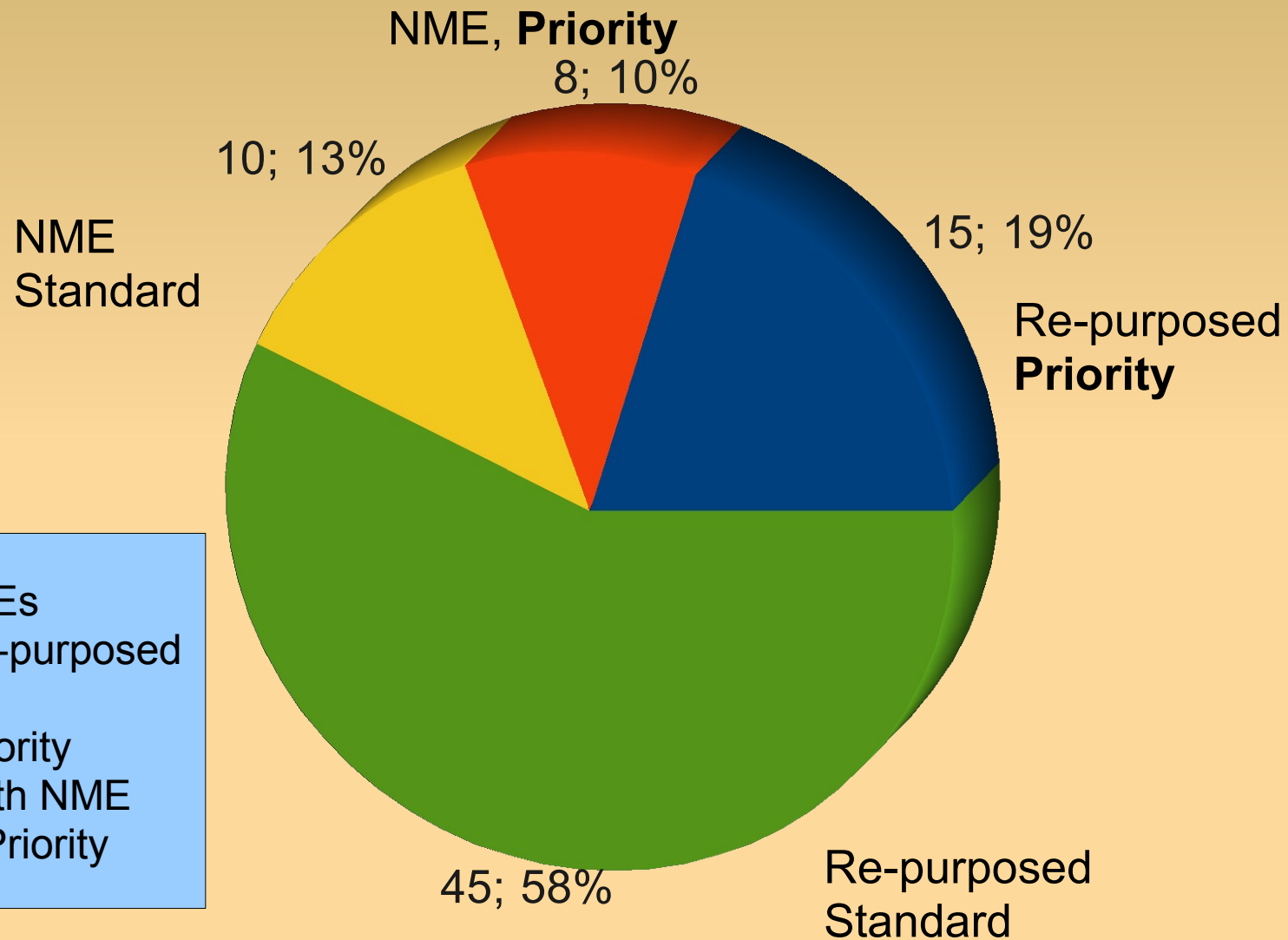
smoking cessation.

Many new drug approvals are medically unimportant

2007 US FDA Approvals of New Drugs

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

2007 US FDA Approvals of New Drugs



- 23% NCEs
- 77 % Re-purposed
- 29 % Priority
- 10 % Both NME and Priority

What is the value of a new drug?

- Stylized example
 - Zocor (simvastatin) is followed by
 - Lipitor (atorvastatin calcium).
- How do you price Lipitor, given the availability of Zocor?
 - If better, should Lipitor be priced about the same or somewhat higher than Zocor?
 - What is the value added of Lipitor, given the availability of Zocor?

Global social movement

- Major social movement to move toward a new paradigm that does not pit innovation and access against each other.

innovation
+access **ia**

innovation
+access **ia**

innovation
+access **ia**

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.

Innovation Inducement Prizes

Version 1.0

Context, the United States:

The Medical Innovation Prize Fund

(S.2210, 110th 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.

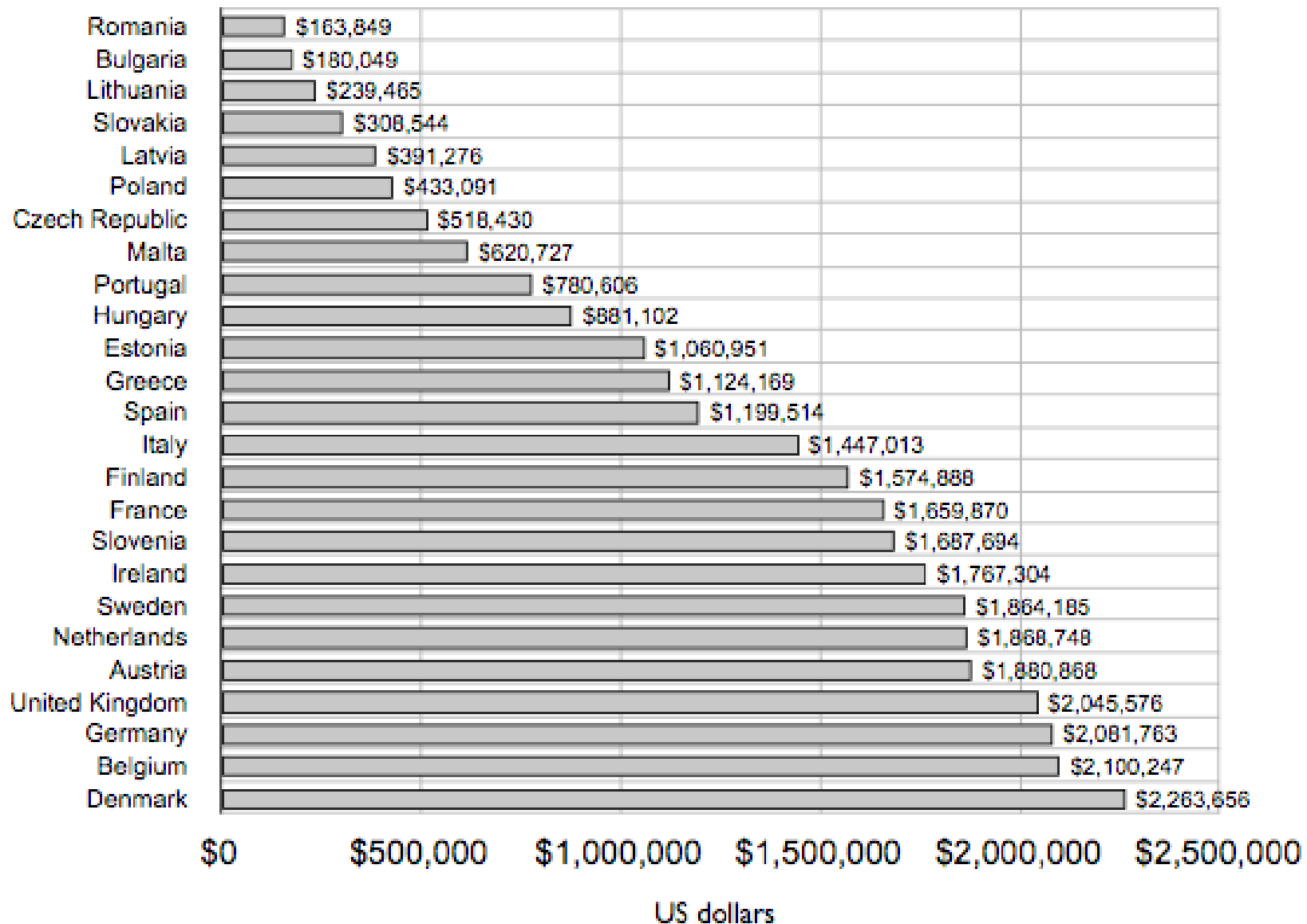
Some important features of the US prize fund design (S.2210, 110th Congress)

- 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

Context, Europe

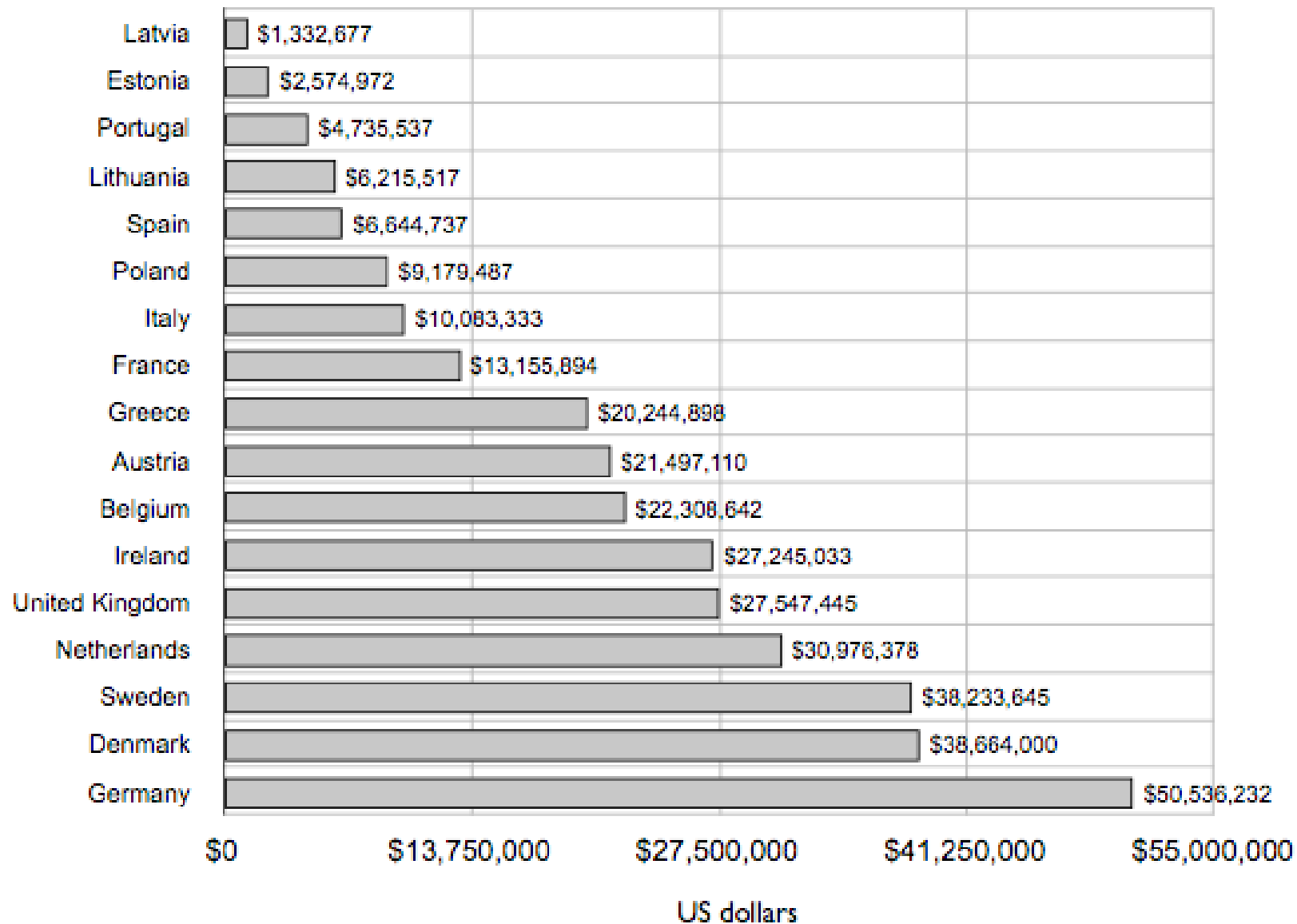
Capacity to pay for cancer treatment in EU Member States

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



Capacity to pay for AIDS treatment in EU Member States

National income divided by number of HIV+ persons



Prizes - version 2

Significant changes

1. Introduce new incentives for sharing access to knowledge and technology
2. Introduce competitive intermediaries to reward interim results
3. Incorporate set-asides to encourage greater collaborations or contributions from southern R&D institutions

Developing Country Context

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.

The Barbados/Bolivia Prize Proposals

April 2008 proposals to the WHO/IGWG

1. Prize Fund for Development of Low-Cost Rapid Diagnostic Test
2. Prize Fund for the Development of New Treatments for Chagas Disease.
3. Priority Medicines and Vaccines Prize Fund (PMV/pf).
4. Prizes as a Reward Mechanism for New Cancer Treatments.
5. Licensed Products Prize Fund (LP/pf) for Donors
6. Global agreement on the funding of clinical trials as public goods

Open Source Dividend

- Problem
 - Excessive secrecy, too little sharing of knowledge, data and technology
 - Low innovation productivity
- Open Source Dividend
 - Allocate a fixed amount of the reward to persons or organizations that provided non-remunerated and non-discriminatory access to knowledge, data, know-how, and technology.
 - Awards would be decided by a time limited jury, evaluating competing claims.

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 Prize

US FDA Priority Review Voucher

- To qualify, register a useful product for a neglected disease
- Reward is a faster approval time for an unimportant drug
- Novartis obtains windfall with Coartem registration

TB Diagnostics Prizes

- Barbados/Bolivia proposal
 - Open Source dividend, interim prizes, open licensing
- X-Prize Foundation discussions
 - No open source dividend. No open licensing.

New initiatives

- WHO biomedical R&D treaty
- WTO agreement on global public goods

For more information

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