

The 2Bs Proposal (Barbados & Bolivia)

A Working Document

To be or Not to be!

Background to the Proposals

- WHA60.30 sub-paragraph 4
- Element 7.3 of Global Strategy
- Influential strategic thinking by authors on funding mechanisms
- Supplement other proposals
- Consensus on issues by 2Bs
- Providing templates that can be used for other conditions

WHA60.30

3. REQUESTS the Director-General:

- (4) to encourage the development of proposals for health-needs driven research and development for discussion at the Intergovernmental Working Group that includes a range of incentive mechanisms including also addressing the linkage of the cost of research and development and the price of medicines, vaccines, diagnostic kits and other health-care products and a method for tailoring the optimal mix of incentives to a particular condition or product, with the objective of addressing diseases that disproportionately affect developing countries;

Element 7.3 of Global Strategy

- (7.3) Setting up a global R&D fund to address the identified R&D gaps in Type II and Type III diseases and the needs of developing countries in relation to Type I diseases.
- (a) of this fund, money will be earmarked and provided for research in the form of grants for R&D for these diseases in advance, as well as prize/rewards for path-breaking research after it is accomplished.
 - (b) of this fund, money will be earmarked and provided to buy out patents to ensure that health products are made available at affordable prices in developing countries.
 - (c) financing for this fund will come from contributions by countries, donors, industry and taxing of international financial transactions as agreed to by Member States.
 - (d) an operational mechanism will be set up for this fund as agreed to by Member States

Intention

- The Proposal is a working document that we are asking member states to consider as a response to their request to the WHO Director General to WHA 60.30 sub-paragraph 4. We are concretely asking member states when discussing GS and particularly in the plan of action to endorse our proposals to have expert bodies meet in 2009 to consider some of these proposals or to table their own.

Purpose

- The proposals are not replacing any text in the negotiations to date but instead they are supplements to ideas being thrown out, e.g. the proposal by India to have an R&D Fund and Kenya's addition of Clinical Trials to India's proposal

Purpose

- Another purpose is to stimulate thinking in advance, so that we can have many alternative funding mechanisms and to move the process forward.
- The intention is not so much to go into too much technical details now.
- IGWG will be asked to endorse meetings in March 2009 and beyond to explore the proposals.

The Proposals

- The 2Bs have made 6 proposals.
- Prizes.
 - Five involve prizes, including four prizes to address global health priorities, and one to address cancer treatments in developing countries.
- Public Funding of Clinical Trials as a Public Goods

Proposal 1: Prize Fund for Development of Low-Cost Rapid Diagnostic Test

- This is an example of a prize fund to address a discrete public health need.
 - TB is a public health threat that kills nearly 2 million persons a year, most of whom are poor people living in developing countries.
 - There is a need for a rapid low cost diagnostic test that can be manufactured cheaply.
 - Since by definition high prices are to be avoided, a \$100 million prize is a way to making the development of the test attractive to investors.

Proposal 2: Prize Fund for the Development of New Treatments for Chagas Disease.

- According to the WHO, the annual impact of Chagas disease is estimated at 649,000 DALYS and 13,000 deaths. It is one of the diseases targeted by the WHO TDR program.
- Chagas disease is caused by the parasite *Trypanosoma cruzi*, which is transmitted to animals and people by insect vectors that are found only in the Americas (mainly, in rural areas of Latin America where poverty is widespread).
- In order to stimulate R&D for one or more new treatments, a prize fund of \$250 million.
 - Open source incentives, and interim progress prizes.
 - The prize is tied to open licensing of inventions.

Proposal 3: Priority Medicines and Vaccines Prize Fund (PMV/pf).

- This is a proposal for a sustainable system of prizes to stimulate innovation in four areas of public health need, including R&D for Type III and Type II diseases, new antibiotics, and treatments for emerging public health threats.
- Additional features:
 - Open source incentives
 - Open licensing of inventions

Proposal 4: Prizes as a Reward Mechanism for New Cancer Treatments.

- This is a proposal for a sustainable system of rewards for an important Type I disease, as it relates to the use of these products in developing countries.
- The basic approach
 - De-monopolize all cancer drugs (legalize generics)
 - Reward drug developers from a prize fund.
 - Size of prize fund depends upon budget for cancer treatments.
 - The amounts of prizes are linked to the impact of the drugs on health outcomes (in the developing country).

Proposal 5: Licensed Products Prize Fund (LP/pf) for Donors

- This proposal presents a possible solution for donor-supported markets.
- Links an R&D reward system to voluntary agreements to license the competitive supply of products for AIDS, TB and malaria and for other humanitarian uses.
- Addresses the need for donors that support humanitarian programs to have access to medicines at competitive generic prices, while providing sustainable rewards to innovators.

Proposal 6: for a global agreement on the funding of clinical trials as public goods

- WHO Member States have tentatively reached consensus on a text that agrees that there will be discussions about a possible biomedical R&D treaty.
- One element of such a treaty may be an agreement on public funding of clinical trials.
 - For the development of new drugs and vaccines, and
 - the funding of independent trials for the evaluation of safety and cost-effectiveness of existing products.

Ref: Marcia Angell, Dean Baker, Tom Faunce, Jerome Reichman, Anthony So, etc.

Related Proposals

- India's R&D proposal
- Kenya's addition on Clinical Trials

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Prizes, drawing up:

- Ron Marchant, "Managing Prize Systems: Some Thoughts on the Options," *Knowledge Ecology Studies*, Vol. 2 2008; James Love, "Prizes, not prices, to stimulate antibiotic R&D," *SciDev.Net*, March 26, 2008; Board on Science, Technology and Economic Policy (STEP), *Innovation Inducement Prizes at the National Science Foundation*, National Academies Press, 2007; Thomas C. Erren, "Prizes to solve problems in and beyond medicine, big and small: It can work," *Medical Hypotheses*, 68, 2007, 732–734; Bruce G. Charlton. "Mega-Prizes in Medicine: Big Cash Awards May Stimulate Useful and Rapid Therapeutic Innovation," *Medical Hypotheses*, 68, 2007, 1-3; James Love and Tim Hubbard, "The Big Idea: Prizes to Stimulate R&D for New Medicines," *Chicago-Kent Law Review*, Vol. 82 No. 3, November 2007; Carl Nathan, "Aligning Pharmaceutical Innovation with Medical Need," *Nature Medicine*, March 2007, 13(3):304-8; Joseph Stiglitz, "Scrooge and Intellectual Property Rights: A medical prize fund could improve the financing of drug innovations," *British Medical Journal*, 333, December 23, 2006:1279-80; Gerard Llobet, Hugo Hopenhayn, and Matthew Mitchell, "Rewarding Sequential Innovators: Prizes, Patents and Buyouts," *Journal of Political Economy*, vol. 114(6), December 2006, pages 1041-1068; Juri Saar, "Prizes: The Neglected Innovation Incentive," ESST: The European Inter-University Association on Society, Science and Technology, 2006; Kevin Outterson, "Patent Buy-Outs for Global Disease Innovations for Low and Middle-Income Countries," *American Journal of Law and Medicine*, Vol. 32, 2006; Richard Newell and Nathan Wilson, "Technology Prizes for Climate Change Mitigation," Resources for the Future Discussion Paper, 05-33, 2005; John F. Duffy, "The Marginal Cost Controversy in Intellectual Property," *University of Chicago Law Review*, Vol. 71, No. 1, 2004; Nancy Gallini and Suzanne Scotchmer, "Intellectual Property: When is it the Best Incentive System?," University of California, Berkeley Working Paper E01-303, 2001; Steven Shavell and Tanguy van Ypersele, "Rewards versus Rights," *Journal of Law and Economics*, 44: 525-547, 2001; Michael Kremer, "Patent Buyouts: A Mechanism for Encouraging Innovation," *Quarterly Journal of Economics*, 113: 1137-67, 1998; DF Horrobin, "Glittering Prizes for Research Support," *Nature* 1986; 324:221; Aidan Hollis, An Efficient Reward System for Pharmaceutical innovation, January 2005;

Merci!

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