

WORKING DOCUMENT - BARBADOS AND BOLIVIA

PROPOSAL 1

Prize Fund for Development of Low-Cost Rapid Diagnostic Test for Tuberculosis

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The Problem

Tuberculosis is a major health problem, associated with nearly 2 million deaths in 2006.¹ It is particularly deadly for patients who are co-infected with HIV/AIDS, and for patients who are infected with new strains of multi-drug resistant (MDR) TB. The first step in the treatment of tuberculosis is to identify who suffers from the disease. There is a dearth of innovation in this area, with the current basic technology involving the use of trained personnel examining sputum with microscopes over a period of days. The lack of an inexpensive and easy-to-use rapid diagnostic tool is a major gap in the efforts to manage and treat this disease, particularly in developing countries, where the healthcare infrastructure is poor, resources are limited, and the long delays in testing are particularly problematic.

Despite investments in grants through programs like the Foundation for Innovative New Diagnostics (FIND), there is almost no progress on the development of a new test.

Commercial incentives for investing in such a test are quite low. The biggest targets for the test are low-income persons living in developing countries. By definition, an “inexpensive” diagnostic test will not have a high price.

Only a handful of academic researchers have focused on this problem, and many academic and private sector researchers neglect to share information, materials or technology that may be relevant to this neglected but important R&D problem.

1 WHO, 2006 *Tuberculosis Facts*.

Proposal for a TB Diagnostic Prize Fund, featuring three complementary Prize Mechanisms

The WHO should set up a TB Diagnostic Prize Fund that would be initially resourced at \$100 million. The money would be used to resource several initiatives involving prizes.

Grand Prix

The entire \$100 million “Grand Prix” would be awarded once an entrant provided a diagnostic test that satisfied, at least, the following technical criteria:

1. Feasible to manufacture for less than \$1 per unit (or another number).
2. Work with a standard of infrastructure that is relevant to healthcare delivery realities in developing countries.
3. Provides results within three hours.
4. Provides false negatives only __ percent of the time.
5. Provides false positives only __ percent of the time.

The prize would be offered for seven years. After seven years, if there is no winner of the Grand Prix, the reward could be withdrawn, or offered with a different level of funding and/or terms of reference.

Until the Grand Prix is claimed, the \$100 million would be invested and the earnings would be used to resource two other, smaller prize programs that would advance the work on the diagnostic device.

Intellectual Property Rights For Grand Prix

A licensing agency would be created for acquiring needed rights for the relevant patents, data and know-how for the diagnostic test—the TB Licensing Agency (TBLA). In order to claim the Grand Prix, the winner would have to grant licenses to all patents, data and know-how needed for competitive supply of the test, worldwide.

Small Technical Challenge Prizes

Part of the earnings would be invested in innovation inducement prizes that focus on solving small technical challenges, such as the type of prize competitions now being offered by firms like the Lilly-launched start-up company, InnoCentive, or non-profit organizations such as the X-Prize Foundation. These prize competitions could be done in-house, or outsourced to firms or non-profit organizations with expertise in managing such innovation prizes.

Biannual “Best Contributions” Prizes

The other type of prizes would be a biannual prize competition for the “best contributions” to the scientific and engineering know-how needed to develop the test. The “best contribution” prizes, given every two years, would feature up to three prizes, if entrants were considered sufficiently good. No prizes would be given if there were no impressive entrants, and the money would be reinvested and re-allocated to the next round of prizes.

Developing Country Researcher Set-Aside

At least half of the rest of the “best contributions” prize money would be a set-aside for research teams working in developing countries.

Incentives for Collaboration and Access to Knowledge

In order to ensure there are incentives for openness and sharing among researchers, the Grand

Prix 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, on 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, non-remunerated licenses.

The biannual “best contributions” prizes would only be available to technologies that were placed in the public domain, or licensed to the TBLA.

To qualify for the “best contributions” prize, 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.

Administration

The prize would be placed in the WHO, but administered by a committee which included the following representatives:

- One from TDR,
- One from UNITAID,
- One from the Global Fund,
- One from the Global Alliance for TB drug development,
- One representative selected by a representative coalition of leading groups in developing countries that represent the interests of TB patients.

Conflict of interest rules would be put into place. No employees of TDR, UNITAID, the Global Fund or the Global Alliance could win any of the prizes.

Funding

Governments would contribute to the prize.

Option 1

Participating high-income countries would be expected to contribute 90 percent of the funds. Developing countries would be expected to contribute 10 percent. Participating high-income countries would contribute in proportion to GDP

For example, if there was participation by the US, Japan, the richest 15 members of Europe, and 13 other high-income countries, the United States contribution would be \$33 million, the richest 15 members of Europe (by per capita income) would collectively contribute \$34 million, Japan would contribute \$11 million, and a group of 13 high-income countries (Australia, Canada, Hong Kong, Iceland, Israel, Korea, Kuwait, Norway, Qatar, Saudi Arabia, Singapore, Switzerland and the United Arab Emirates) would collectively contribute \$12 million, based upon relevant income shares. Using more recent data, the US contribution would fall somewhat, given the recent decline in the dollar and rise in oil prices, and other country contributions would rise somewhat.

Option 2

Contributions could be based on voluntary commitments, an amount based upon windfall profits from high oil prices, sales of luxury automobiles, airline tickets, or some other method or combination of approaches.

WHO Meeting on this Proposal

The WHO should hold a meeting in February of 2009 to consider a proposal for a Prize Fund for Development of Low-Cost Rapid Diagnostic Test for Tuberculosis. This proposal is responsive to resolution WHA 60.30