WORKING DOCUMENT - BARBADOS AND BOLIVIA

PROPOSAL 2

Prize for the Development of New Treatments for Chagas Disease

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The Problem

The United States Center for Diseases Control and Prevention (CDC) describes Chagas disease as follows:

> Chagas (pronounced SHA-gus) disease is named after the Brazilian physician Carlos Chagas, who discovered it in 1909. It 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). Chagas disease (*T. cruzi* infection) is also referred to as American trypanosomiasis. It is estimated that as many as 8 to 11 million people in Mexico, Central America, and South America have Chagas disease, most of whom do not know they are infected. If untreated, infection is lifelong and can be life threatening. The impact of Chagas disease is not limited to the rural areas in Latin America in which vectorborne transmission occurs. Large-scale population movements from rural to urban areas of Latin America and to other regions of the world have increased the geographic distribution and changed the epidemiology of Chagas disease.

Chagas disease is a very painful, debilitating 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.

Nearly all of the victims of Chagas disease are poor people living in developing countries. There is almost no private sector research for Chagas disease.

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.

As the 2006 CIPIH offered the following comment:

> "most recently the genomes of the trypanosomes which cause Chagas disease have been published, the result of a cross-national collaboration including researchers in Africa and South America. While these advances are critical, the Science editorial accompanying publication captured the dilemma well: The Tritryp genomes are thus intrinsically interesting – but what will they contribute to the amelioration of disease? Because of their distinct evolution, trypanosomes present a plethora of potential drug targets, and potential drugs are almost certainly languishing in the chemical libraries of pharmaceutical companies…But we need resources and commitment on a far larger scale to transform drug targets into clinical successes. It is clear that the traditional pharmaceutical industry will not become effectively involved in this area, and the current promotion-and-reward system in academia does not attract or sustain the necessary human and financial resources. Consortia move slowly and are frequently restrained by similar problems, compounded by the egos of scientists and sponsors".

The Basic Proposal – a Prize Fund for Research on Chagas Disease

The WHO should set up a prize fund for Chagas disease. The prize fund should be resourced at $250 million. The money would be used to resource several initiatives involving prizes.

The Chagas Impact Prize Fund

The $250 million principal of the prize should be given to new treatments that improve health outcomes for the populations at risk for Chagas disease. No money should be disbursed from the fund until at least one new medicine, vaccine, medical diagnostic device or other technology is introduced that actually improved health outcomes for persons at risk for Chagas disease.

Once the Chagas Impact Prize Fund begins to make disbursements, it should award prizes equal to no less than $10 million (for a single product in the market) and no more than $25 million (for multiple products in the market), per year. If there are multiple qualifying products, the prizes will be divided among the developers of the technologies on the basis of the relative positive impacts on healthcare outcomes.

The money that is not awarded as prizes will be invested in income-generating securities. The income will be used to fund the following prize programs to advance science on Chagas:

Small Technical Challenge Prizes

Part of the money from investment earnings will be spent on 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 prize would be a biannual prize competition for the "best contributions" to the scientific and engineering know-how needed for new treatments for Chagas. 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.

Intellectual Property Rights for Chagas Impact Prizes

A licensing pool would be created under the name the Chagas Disease Licensing Agency (CDLA) in order to acquire and manage the needed rights for the relevant patents and know-how for the new medicines, vaccines or medical diagnostic tests. In order to make claims on the prize, the winner must grant reasonable and non-discriminatory licenses to all patents and know-how needed for competitive supply of the technologies.

Incentives for Collaboration and Access to Knowledge

In order to ensure there are incentives for openness and sharing among researchers, the Chagas Impact Prize Fund 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 CDLA.

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 the TDR,

- One from the US CDC,
- One from the World Bank,
- One representing GRULAC, the Group of Latin American and Caribbean Countries,
- One from the Public Health Community.

Conflict of interest rules would be put into place. No employees of TDR, CDC, the World Bank or any employee of an organization represented on the committee could win the prizes.

Funding

Governments would contribute to the prize.

WHO Meeting on this Proposal

The WHO should hold a meeting in March of 2009 to consider a proposal for a prize for the development of treatments for Chagas Disease. This proposal is responsive to WHA 60.30