



April 15, 2009

Secretariat for Public Health,
Innovation and Intellectual Property
World Health Organization
20 Avenue Appia
CH-1211 Geneva 27
Switzerland

Re: Intergovernmental Working Group on Public Health, Innovation & Intellectual Property

To the Secretariat:

The AIDS Vaccine Advocacy Coalition (AVAC) welcomes this opportunity to comment on your request for proposals on new and innovative sources of funding to stimulate R&D from the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property responding to Paragraph 4(7) of Resolution WHA61.21. AVAC is an international, nonprofit public interest organization dedicated to accelerating ethical research and eventual global delivery of vaccines and other HIV prevention options to fight the AIDS pandemic.

AVAC applauds WHO's efforts to identify new and innovative sources of funding to stimulate R&D tools and approaches to encourage innovation, research and development to address diseases predominantly affecting underserved populations. The challenge of this inquiry is that the global economic slowdown has tightened budgets leaving fewer traditional avenues to increase funding through governmental programs or through private sector investment. AVAC strongly supports investment in HIV prevention research and development; however, it recognizes that governmental investment in such research may not increase overall in the near future. The new stimulus packages funded by national governments, such as the American Recovery and Reinvestment Act of 2009 do not always support investment in global health initiatives. With those concerns in mind, we submit the following proposals:

- 1. Spur Investment in Improved Diagnostics through Access to Existing Diagnostics in Developed World Health Systems.** Improved diagnostics are needed for HIV, TB and other diseases affecting underserved populations. Early disease diagnosis provides for better treatment options and opportunities for informed prevention options. Investment in new diagnostic systems is vital to ensure that people in rural and underserved areas are able to access treatment and make informed health decisions. Unfortunately, diagnostics and testing are not fully funded by health care systems even in the developed world. In the United States, for example, HIV testing is not provided under a number of health care systems that serve underserved population. Greater update and delivery of diagnostic services globally would have the effect of increasing the market for, and private sector investment in, new diagnostic interventions. National private and public health systems and insurance plans should be strongly encouraged to support and reimburse diagnostic testing for HIV, TB and malaria, as well as other diseases that affect underserved populations. The development of a demand for diagnostic services will fuel investment in new technologies, as well as improving health outcomes for those tested.
- 2. Encourage Efficiencies in Biomedical Research.** Biomedical research and development to address diseases predominantly affecting underserved populations is funded by a range of funders across and within different countries. For example, AIDS vaccine research and development has been funded by 22 different countries, as well as multilateral organizations and sixteen philanthropies. At a time of reduced or flat investment, efficient and synergistic investment in research and development is critical. In the HIV research field there are a number of collaborations (such as the Collaboration for AIDS Vaccine Discovery and the Center for HIV/AIDS Vaccine Immunology) developed to share information across research networks. Although benefits of these collaborations are still being assessed, the need for collaboration remains. These cross-network collaborations can reduce duplication and also strengthen North-South research collaborations. Ultimately they may also result in collaborations to support regulatory capacity in developing countries.

3. **Leveraging Private Sector Investment Through Public R&D Funding.** Vaccine development requires a different approach from drug development. Vaccine research and development has particular intellectual property and development requirements which pose unique challenges. Vaccine development requires greater participation by commercial vaccine developers. Commercial vaccine developers are familiar with the regulatory and logistical challenges posed by testing candidates in healthy populations, and the public health field needs to identify new ways to encourage and harness expanded industrial involvement.

Support for the activities of commercial vaccine developers may be an additional way of leveraging additional funds for research and development. In the US, for example, researchers at commercial vaccine developers have been provided public sector funds for preclinical research or for clinical trial support that have permitted them to advance AIDS vaccine candidates. These public sector investments have also been matched by private sector investment in AIDS vaccines research and development estimated to be \$84 million in 2007.¹ In difficult economic times, public sector investments may maintain a competitive advantage in incentivizing private sector investment. In the United States, for example, public funds are non-dilutive capital, which do not change the ownership structure and are therefore more attractive to firms that may already have trouble raising funds in the marketplace. Looking at new mechanisms to partially support private sector research, with commitments to developing world access, are a model that needs to be more fully developed in these times.

¹ Sustaining the HIV Prevention Research Agenda: Funding for Research and Development of HIV Vaccines, Microbicides and other HIV Prevention Options 2000-2007 (available at www.hivresourcetracking.org)

Thank you for consideration of these comments, and AVAC looks forward to working with you to expand and accelerate innovation, research and development to address diseases predominantly affecting underserved populations.

Yours sincerely,

A handwritten signature in black ink, appearing to read "Mitchell Warren". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

Mitchell Warren
Executive Director