Written Testimony to the House Appropriations Subcommittee on State, Foreign Operations and Related Programs on the FY 2014 Budget Request by Margaret McGlynn, President and CEO of the International AIDS Vaccine Initiative (IAVI)

Chairwoman Granger, Ranking Member Lowey and members of the Committee, thank you for the opportunity to provide testimony on the budget request for Fiscal Year 2014. I respectfully submit this testimony on behalf of the International AIDS Vaccine Initiative (IAVI), a public-private product development partnership whose mission is to ensure the development of safe, effective, accessible, preventive HIV vaccines for use throughout the world. In the President's Fiscal Year 2013 Budget Request, IAVI received $28.7 million through its partnership with the U.S. Agency for International Development (USAID).

Progress against HIV/AIDS and ongoing challenges

Through the generosity of the American people, the President's Emergency Plan for AIDS Relief (PEPFAR) brings lifesaving antiretroviral treatment to over 5 million people in low- and middle-income countries today. And just last year on World AIDS Day, PEPFAR released its blueprint to attain the objective of an AIDS-Free Generation. The blueprint reflects the enormous progress we have made in combatting this disease, the hope and possibility of ending the epidemic, and the serious challenges that stand in our way of achieving this previously elusive goal. As part of its multipronged goal, the PEPFAR Blueprint embraces continued support for the development of new biomedical tools for HIV prevention, specifically mentioning microbicides and vaccines. We have always believed the HIV pandemic requires a response that includes both the expansion of existing treatment and prevention programs *and* the development and swift rollout of new prevention strategies—especially vaccines. A recent report from the bipartisan Center for Strategic and International Studies noted, "**Since the best-known prevention interventions are still only partially protective against HIV infection, research on new and even more-effective prevention technologies, for example HIV vaccines and**

microbicides, and their impact on HIV transmission is needed to stop the virus' spread."[1] And as we've seen in the U.S. with smallpox, polio, measles, and many other diseases that once ravaged American health, no medical technology has the track record to end infectious disease like a vaccine.

The World Needs an AIDS Vaccine

A preventive AIDS vaccine will save lives, result in significant cost savings, reduce the funds needed for future HIV/AIDS treatment, and free up those resources for other critical priorities. The PEPFAR Blueprint places support for innovative research to develop new prevention technologies high among the action steps along the way to an AIDS-Free Generation.[2] Simply put, an AIDS vaccine would have a transformative impact.

Modeling has shown that a vaccine would not need to be 100% effective to have a significant impact on new infections – in fact, a vaccine that was only 70% efficacious distributed to 40% of the population in low-and-middle income countries would avert one-third of new HIV infections over the first decade after introduction, or about 8.9 million new infections under current incidence trends.[3] That translates to 8.9 million individuals who would not need lifelong ARV treatment, and around $70 billion saved in treatment costs[4].

An AIDS vaccine will also be a powerful tool for women around the world. Globally, HIV/AIDS is the leading cause of death in women ages 15-44, when they are most economically productive and most needed by their children and communities. Women desperately need new HIV prevention tools to protect themselves and their children from HIV infection and the devastating human and economic hardship that is the consequence of this disease.

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[1] Global Health Policy in the Second Obama Term http://csis.org/publication/global-health-policy-second-obama-term
[2] PEPFAR Blueprint: Creating an AIDS-Free Generation http://www.pepfar.gov/documents/organization/201386.pdf
[3] The Potential Impact of an AIDS Vaccine in Low- and Middle-Income Countries http://www.iavi.org/Information-Center/Publications/Documents/Global%20Impact%20Brief.pdf
[4] AIDS Vaccines: Exploring the Potential Cost/Benefit http://www.iavi.org/Information-Center/Publications/Documents/Costs%20Impact%20Brief.pdf

Unprecedented Progress

Innovative research and development toward an AIDS vaccine is moving us ever closer to a game-changing health technology that will enable countries to overcome the crippling burden of HIV, fueled by the same U.S. commitment to assist those currently living with HIV/AIDS. The 2009 efficacy trial in Thailand, conducted in cooperation by the U.S. and Thai governments, demonstrated for the first time that a vaccine *can* prevent transmission of HIV.

The AIDS vaccine field has been further buoyed by exciting discoveries by researchers at and affiliated with IAVI and the Vaccine Research Center of the NIH of more than 30 potent new antibodies that neutralize a broad swath of HIV variants. These recent discoveries have revealed HIV's hidden vulnerabilities to scientists and provided valuable targets for designing a potentially highly effective vaccine. This is – by any measure – the most exciting and promising time in the history of our field, with each discovery bringing us one step closer to a transformative tool for global health. Thus, it is no longer a question of **if** we will have an AIDS vaccine, but rather **when**. But that promise cannot be realized without sustained political commitment and continued and predictable research funding – both of which are crucial if we are to realize the returns on this significant investment.

The IAVI Model and Partnership with USAID

IAVI, as a product development partnership, brings together academic, industry and government institutional leaders from both the developed and developing world in the search for an AIDS vaccine. IAVI focuses on improving the design of new AIDS vaccine candidates, accelerating their evaluation in human trials, and ensuring that an eventual vaccine is appropriate for the developing world. IAVI collaborates with over 50 scientific partners across the globe,

many based in the U.S., including small- and medium-sized biotechnology companies, to fill gaps in the AIDS vaccine field, pursuing concepts that hold the promise of high returns but have been neglected because they carry a high risk of failure. These partnerships have contributed to critical scientific breakthroughs in the quest to develop an AIDS vaccine and developed profitable new medical technologies with broader applications, generating profits and creating jobs.

The discovery and characterization of broadly neutralizing antibodies exemplifies IAVI's partnership approach, connecting IAVI's USAID-supported clinical research centers in the developing world, and IAVI's laboratories in London, New York City and La Jolla, with our industry, biotechnology and academic partners around the world. And our close collaborations with institutions in sub-Saharan Africa to conduct world-class epidemiological and clinical research have proven vital to AIDS vaccine development. Further, IAVI is proud to be co-sponsoring a new HIV vaccine design program with the Government of India to leverage India's burgeoning life sciences capacity to accelerate the translation of recent antibody discoveries into potent new vaccine candidates. Together, IAVI and our global network of partners have translated innovative technologies into 22 vaccine candidates, 13 of which have entered human trials in 11 countries. Indeed, IAVI just launched a Phase I study of an innovative new vaccine approach in January 2013 that holds the promise for extended immune responses.

While an effective vaccine is our focus, this research does not take place in a vacuum. Working in close partnership with highly impacted communities both accelerates research and ensures that a vaccine will be acceptable to those communities. IAVI works with our partners in the regions hardest hit by HIV/AIDS to strengthen local health services, promote understanding of AIDS vaccine research, and ensure that clinical trials are conducted efficiently and at the

highest ethical standards. These partnerships help build capacity for science, technology and innovation in developing countries, contributing to economic growth and stability.

IAVI operates with broad support, leveraging funds from several governments as well as numerous foundations, individuals and private sector enterprises. USAID has been a vital partner since 2001 and this partnership has led to critical breakthroughs in AIDS vaccine science, including the aforementioned recent discoveries of broadly neutralizing antibodies. It has also contributed to economic growth, via smart investments in research, both domestically and in the regions hardest hit by AIDS.

Recommendation

A continuation of the $28.7 million included in the President's FY 2013 Budget Request for the USAID-IAVI partnership will capitalize on recent discoveries and speed the development of a vaccine, ultimately saving untold billions of dollars on HIV treatment and care. Our efforts also promote America's foreign policy objectives, including building stronger economies, strengthening our global partnerships and mitigating threats to our national security.

Smart investments in American biotechnological leadership are accelerating the development of game-changing technologies--first among them an AIDS vaccine--and leading to more durable and sustainable responses to the most significant global health and development challenges of our time. Congress in general and the Committee in particular have steadfastly funded HIV vaccine research, a decision which has been critical to the unprecedented progress we are now witnessing. By continuing USAID support for the development of an AIDS vaccine at current funding levels, the Committee will help ensure the discovery of the transformative tool for global health so desperately needed - a vaccine capable of preventing the transmission of HIV.