iavi Insights

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Accelerating the development of an AIDS vaccine: A U.S. policy agenda

Exciting scientific achievements are creating a new momentum in the field of AIDS vaccines, spurring even greater urgency for the U.S. government to boost and intensify its leadership role in vaccine research and development. Since 2001, the U.S. government has enjoyed a successful partnership with the International AIDS Vaccine Initiative (IAVI), a public-private product development partnership that researches and develops AIDS vaccine candidates, conducts policy analyses and serves as an advocate for the AIDS vaccine field.

With financial support from the U.S. Agency for International Development (USAID), IAVI is currently working in 26 countries to ensure the development of safe, effective and accessible preventive HIV vaccines for use throughout the world. Maintaining progress toward an AIDS vaccine to eventually end the AIDS pandemic requires sufficient sustained financing and investment from the public and private sectors and innovative U.S. government policies to accelerate progress and encourage private investment in new health technologies.

Key policy priorities for AIDS vaccine development

1 SECURE SUSTAINED FUNDING FOR AIDS VACCINE R&D EFFORTS

- Build on the momentum of recent scientific achievements in the AIDS vaccine field by maintaining critical USAID investment in research and development.

2 ELEVATE GLOBAL HEALTH RESEARCH IN U.S. DEVELOPMENT POLICY AND FOREIGN AID REFORM

- Ensure that science, technology, research and innovation for global health tools are included as key principles in U.S. government policies.
- Increase collaboration across the U.S. agencies that are engaged in research and innovation efforts.
- Support USAID's new Bureau of Policy Planning and Learning, ensure that the agency has a central role in international development policy and bolster documentation of U.S. investments in research.

3 LEAD THE EFFORT TO CREATE INNOVATIVE FINANCING MECHANISMS TO SUPPORT GLOBAL HEALTH R&D

- Coordinate with other donors to support a portfolio of innovative financing and incentive mechanisms and ensure U.S. participation in international discussions on innovative financing.
- Convene a cross-government working group to examine the range of financing gaps, identify a suite of financing and incentive mechanisms and explore which federal agencies can support innovative financing mechanisms.
- Identify strategies to overcome budgetary obstacles to participating in innovative financing mechanisms.

4 PROMOTE STRONG, COORDINATED REGULATORY SYSTEMS

- Support timely implementation of recommendations from new Food and Drug Administration (FDA) review groups.
- Pursue stronger partnerships between the United States and global regulatory stakeholders.
- Expand membership in FDA advisory committees to include developing country representatives.

1 SECURE SUSTAINED FUNDING FOR AIDS VACCINE R&D EFFORTS

IAVI's highest policy priority is to ensure that the scientific effort to discover and develop a safe and effective AIDS vaccine is adequately funded. This requires resources that are not only sufficient in volume but also sustained, given the long-term nature of research endeavors. Since 2001, IAVI and USAID have had a productive partnership, including the current five-year Cooperative Agreement that ends in 2011.

The agency's investments have enabled important discoveries in the AIDS vaccine field, built capacity for clinical research in the regions hit hardest by the pandemic and paved the way for scientific innovation. In the past 10 years, and with USAID's support, IAVI and its network of partners have translated innovative technologies into 15 vaccine candidates, seven of which have entered human trials in 11 countries in Africa, Asia, Europe and North America. IAVI also works with national and global partners to create a supportive policy environment for the development, testing, financing and eventual delivery of an AIDS vaccine in countries where the need is greatest.

USAID's support for IAVI's global network of clinical centers and accredited laboratories has resulted in well-prepared clinical research centers, informed volunteers and mobilized communities. This global network was critical to last year's scientific advance in which researchers identified a pair of novel broadly neutralizing antibodies capable of targeting a wide spectrum of HIV variants. The global collaboration that led to this discovery is finding more such antibodies, which are revealing additional potential vulnerabilities of HIV that may ultimately change the paradigm of AIDS vaccine development.

Also last year, data from the RV144 Phase III HIV vaccine trial in Thailand showed for the first time that an AIDS vaccine could protect humans from HIV infection. Researchers are now analyzing the data to better understand how an effective AIDS vaccine must work, and will use that knowledge to improve current candidates and identify those that warrant further testing. IAVI researchers, although not involved in the trial itself, are working with the various scientific committees to help determine next steps.

USAID's support of IAVI has been invaluable to our successes to date, and has enabled IAVI to leverage additional support from 14 countries. Continued support from USAID will help build on the momentum of recent scientific achievements in the development of an AIDS vaccine, the best hope for ending the AIDS pandemic.

U.S. policy should:

- Maintain critical USAID investment in research and development to continue the momentum of recent scientific achievements in the AIDS vaccine field.

- Encourage U.S. government partners to invest in AIDS vaccine development, including overseas development aid agencies and multilateral agencies such as the World Bank.

2 ELEVATE GLOBAL HEALTH RESEARCH IN U.S. DEVELOPMENT POLICY AND FOREIGN AID REFORM

Given the significant contributions to advancing domestic and international health and economic development, investments in health and development research should be enshrined as a central component of U.S. foreign policy. It is crucial that investments in innovation include a focus on global health research and product development, and that these components be elevated in U.S. development policy.

The United States has a long legacy as a leader in global health research, and American innovation has contributed to remarkable advances in preventing, diagnosing and treating conditions such

as HIV/AIDS, malaria, tuberculosis and neglected tropical diseases.

Unfortunately, current policies inadequately recognize the importance and role of product research and development and innovation for global development. In addition, there is a need for improved collaboration across U.S. government agencies that are engaged in research and innovation efforts—including the Centers for Disease Control, the Department of Defense, the Food and Drug Administration, the National Institutes of Health (NIH) and USAID.

U.S. policy should:

- Ensure that science, technology, research and innovation for global health tools are included and implemented as key principles in U.S. government policies such as the Presidential Policy Directive on Global Development, Global Health Initiative, Quadrennial Diplomacy & Development Review and the Congressional rewrite of the Foreign Assistance Act.

- Ensure that there is a mechanism to foster collaboration across the U.S. agencies that are engaged in research and innovation efforts.

- Maintain a balance between making investments now to accelerate the development of technologies needed to solve long-term development challenges and scaling up existing technologies to solve near-term challenges.

- Support USAID's new Bureau of Policy Planning and Learning, ensure that the agency has a central role in international development policy, and bolster documentation of U.S. investments in research.

- Use U.S. diplomatic influence to elevate science, technology and innovation on the agenda of other overseas development aid agencies and other influential multilateral agencies such as the World Health Organization (WHO) and the World Bank.

3 LEAD THE EFFORT TO CREATE INNOVATIVE FINANCING MECHANISMS TO SUPPORT GLOBAL HEALTH R&D

To accelerate the R&D process, new mechanisms for financing global health R&D are needed to supplement investments by traditional donors. Traditional funding—often given in short-term increments—is generally restricted to a specific purpose and is highly susceptible to fluctuations in the political and economic environment. These factors slow R&D by inhibiting

researchers from developing long-term programs, easily switching between lines of research or product candidates and rapidly securing funding to pursue emerging promising science. The U.S. has been engaged in supporting incentive and innovative financing mechanisms, particularly in creating priority review vouchers, offering R&D tax credits and encouraging small businesses to conduct innovative R&D through direct grants.

U.S. policy should:

- Coordinate with other donors to support a portfolio of innovative financing and incentive mechanisms and ensure U.S. participation in international discussions on innovative financing (e.g., the Leading Group on Innovative Financing for Development or the World Health Organization's Consultative Expert Working Group on R&D Financing).

- Convene a cross-government working group on innovative financing—including representatives from the U.S. Treasury, USAID, the Office of Science and Technology Policy and the NIH—to examine the range of financing gaps, identify a suite of financing and incentive mechanisms that could be used and explore which federal agencies may be best positioned to participate in supporting innovative financing mechanisms.

- Identify strategies that the U.S. can use to overcome budgetary obstacles to participating in innovative financing mechanisms. This can include identifying precedents from the Defense Department, USAID and others in making multi-year funding commitments, using loan guarantee instruments and establishing external trusts.

4 PROMOTE STRONG, COORDINATED REGULATORY SYSTEMS

Regulatory processes enable the development and uptake of safe and effective global health technologies. However, they can also impede the research and development of new products. Strong, well-coordinated regulatory systems are critical to ensuring that new global health technologies quickly reach people in need. Many of the regulatory challenges to AIDS vaccine R&D stem from limited regulatory capacity in developing countries where clinical trials are conducted and where critical decisions on risk/benefit need to be weighed.

In developing countries where national regulatory systems are in place, divergent procedures and guidelines for approving clinical trials, assessing new products for licensure and reviewing post-licensure performance and quality make applications for trials more complex, costly and time-consuming. In conjunction with other global and regional institutional partners, the United States should play a stronger role in coordinating with such agencies as the World Health Organization, and working with global and national regulatory authorities to ensure that new products for global diseases are safe, effective, manufactured to acceptable standards and rapidly available to those in need. Existing FDA advisory committees, which provide important expertise and guidance on scientific decisions, as well as safety and efficacy evaluations of new products, could benefit from developing-country perspectives when reviewing products intended for the developing world.

U.S. policy should:

- Pursue stronger partnerships between the United States and global regulatory stakeholders and increase collaboration with the WHO and national regulatory authorities to accelerate access to global health products.

- Assure that WHO's regulatory strengthening efforts at the WHO, FDA and USAID are supported and adequately financed.

- Expand membership in FDA advisory committees to include developing country representatives.