



Global Health
Technologies Coalition

2014 Policy Report

Innovation for a changing world:

The role of US leadership
in global health R&D

For generations, the US government has invested in the lifesaving potential of research and innovation, supporting discoveries that have improved public health around the world. These investments have led to breakthrough tools that eradicated smallpox and drastically reduced the number of polio and measles cases worldwide.

In recent decades, US government funding for research and development (R&D) has supported the creation and introduction of a host of novel technologies and other products to address HIV/AIDS, tuberculosis (TB), malaria, women's health concerns, neglected tropical diseases, and the leading causes of childhood deaths. Between 2000 and 2010, federal support played a crucial role in the development of 53 percent of the 45 vaccines, drugs, diagnostics, and devices introduced for global health.

But changes in the national political and economic environment have eroded the US government's longstanding commitment to health R&D, resulting in an urgent need to restore and stabilize US government investment in R&D to sustain progress in global health and address emerging health threats. This investment is also critical for maintaining US leadership in the field of life sciences, which creates more than seven million jobs in the United States and adds \$69 billion annually to our gross domestic product.

Protecting the longstanding US investment in global health R&D

The US government is the world's leading funder of health R&D. Federal agencies that play a crucial role in the development and delivery of global health technologies include the Centers for Disease Control and Prevention (CDC), the Department of Defense (DoD), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the US Agency for International Development (USAID). Unfortunately, global health R&D budgets at these agencies have dwindled or stagnated since 2009.

The annual appropriations process in Congress has been replaced in recent years with a series of continuing resolutions that have funded federal programs at flat levels, and sequestration and the US government shutdown had additional, immediate impacts on health R&D programs. For example, the NIH suspended new clinical trials and did not process new grant applications; USAID did not initiate new contracts or grants; the CDC was unable to support ongoing R&D and disease surveillance activities; and the FDA ceased most of its laboratory research, routine inspections, monitoring, and notification programs. Long-term adverse effects will undoubtedly slow the development of some promising technologies and may have put earlier investments at risk.

As policymakers determine fiscal year (FY) 2015 appropriations, it is critical that they preserve funding for global health R&D and other key programs at the CDC, DoD, FDA, NIH, and USAID. In addition, each agency needs to protect global health R&D funding within its own budget plan.

US policymakers should also look to incentives and innovative financing mechanisms to ensure sustained progress in global health. These mechanisms—including advance market commitments, priority review vouchers, prizes and small business innovation awards, procurement pools, tax credits, and patent pools—leverage US funding, create efficiencies, and catalyze investments from all sectors.

Policies and programs with groundbreaking potential

Despite the challenging and uncertain fiscal climate in the United States, policymakers have recently taken several important steps to improve the global health R&D landscape.

Legislation with the promise to advance global health and research

Over the past year, members of Congress introduced several pieces of legislation with the potential to strengthen the US government's investments in global health and product development. In April 2013, for example, Reps. Albio Sires (D-NJ) and Mario Diaz-Balart (R-FL) introduced the 21st Century Global Health Technology Act, a bipartisan bill that requires no new funding and which would bolster USAID's product development work, promote the alignment of global health R&D activities across the US government, and ensure the transparency and accountability of R&D activities.

Democrats and Republicans also demonstrated strong bipartisan support for US global health programs when both the House and Senate passed the US President's Emergency Plan for AIDS Relief (PEPFAR) Stewardship and Oversight Act of 2013. This overwhelming congressional support for PEPFAR reaffirmed US leadership in the fight against HIV/AIDS worldwide.

Growing role of the US Food and Drug Administration in regulating global health products

Many low-income countries do not have the expertise or resources to appropriately evaluate new health tools or monitor clinical trials. The FDA has played a critical role in improving and streamlining global regulatory processes to ensure that new tools are safe and effective before they reach people around the world.

The FDA has led numerous international programs and built partnerships to coordinate global regulatory activities and equip local authorities with the skills to conduct independent product reviews. The FDA's stringent review of products often facilitates subsequent reviews in the countries where the products will ultimately be used.

There are areas in which the FDA can build upon its successes to achieve greater impact. For example, it can extend its policies to accommodate priority review of health products for all neglected diseases under the Priority Review Voucher program, including Chagas disease. The agency should also sustain robust investments

in its global health work, and Congress should provide the agency with sufficient funding and authority to do so.

Engaging in global discussions

US policymakers have recently engaged in critical international discussions concerning health research, science, and product development. One area of focus has been the financing and coordination of R&D for neglected diseases. In 2013, the World Health Assembly (WHA) passed a resolution calling for health R&D demonstration projects to address health challenges such as neglected diseases that disproportionately affect low- and middle-income countries. At its most recent meeting in January 2014, the World Health Organization Executive Board selected demonstration projects to be considered for endorsement by the WHA in May 2014. It is critical that the US government ensure that the endorsed demonstration projects are high impact and scalable, and that new funding is available to support their implementation.

Another area of focus has been a new international development framework to replace the current Millennium Development Goals, eight global development targets which expire in 2015. The US government—through agencies such as USAID and the US Department of Health and Human Services—has participated in discussions about priorities and targets that should be included in the post-2015 agenda. The US government should ensure that the post-2015 agenda includes a strong, explicit commitment to global health research, science, and innovation.

Conclusions and recommendations

Thanks largely to longstanding US government support for health R&D, Americans and billions of people around the world no longer live in fear of diseases such as polio and measles, and most are living longer, healthier, and more productive lives. US policymakers should seize upon recent successes and ensure that the nation continues its legacy of support for global health R&D.

- Congress should develop a long-term budget solution that protects funding for global health product development. Additionally, US policymakers should ensure that the 2015 federal budget demonstrates a renewed commitment to global health research. Specifically, the congressional FY 2015 appropriations should demonstrate strong support for global health programs at the CDC, including \$464 million for the Center for Global Health and \$445 million for the National Center for Emerging and Zoonotic Infectious Diseases. The FY 2015 congressional budget should also fund the FDA at \$4.7 billion, the NIH at least at \$32 billion, and global health programs at the US Department of State and USAID at \$10.358 billion. Finally, Congress should include robust funding for global health R&D within the DoD's FY 2015 appropriations legislation.
- Congress should pass the 21st Century Global Health Technology Act, a bill that would codify USAID's role in R&D without requiring new funding.

New products hold the key to better health worldwide

Reduced US government funding threatens ongoing research and development to advance the following products:

- New drugs to treat TB and malaria, including drug-resistant forms.
- Reproductive health technologies that will reduce maternal deaths and improve birth outcomes by avoiding unplanned pregnancies.
- An antiretroviral-based microbicide to help prevent HIV infection.
- New insecticides to help control insects that spread diseases such as dengue fever, Chagas, filariasis, and leishmaniasis.
- New cost-effective diagnostics for malaria, HIV, and TB.
- A vaccine to prevent HIV infection.

Other promising products that may fail to advance without government funding include new vaccines for neglected tropical diseases and TB and a new oral drug for sleeping sickness.

- US agencies engaged in global health product development—including the CDC, DoD, FDA, NIH, and USAID—should sustain robust investments in the discovery, development, and delivery of new tools for public health worldwide.
- The Administration should do more in the next round of budget negotiations to protect funding for global health product development programs at federal agencies.
- The FDA's leadership should allocate funding to match the agency's global health commitments and reinforce its authority and willingness to review health products for all neglected diseases.
- The US government should support a portfolio of incentives and financing mechanisms to stimulate needed R&D at all stages of the product development process.
- The US government should work with other United Nations Member States to ensure that the health R&D demonstration projects selected at the upcoming WHA are high impact and that new funding is available to support their implementation.
- US policymakers should ensure that global health research is an integral component of the post-2015 international development framework.

By following these recommendations, US leaders can strengthen the nation's investments in research and innovation while bolstering our resolve to save millions of lives around the world.

For more information

For more details about these issues, view the Global Health Technologies Coalition's full annual policy report online at www.ghtcoalition.org.

COALITION MEMBERS

This report was written in consultation with the following members of the Global Health Technologies Coalition.

AERAS | Advancing Tuberculosis
Vaccines for the World



Advancing global health since 1903



DNDi
NORTH AMERICA
Drugs for Neglected Diseases initiative

fhi360
THE SCIENCE OF IMPROVING LIVES

find
foundation
for innovative new diagnostics

 **gappps**
GLOBAL ALLIANCE TO PREVENT
PREMATURITY AND STILLBIRTH
an initiative of Seattle Children's

 **avi** International AIDS
Vaccine Initiative

 INTERNATIONAL
PARTNERSHIP FOR
MICROBICIDES

 INTERNATIONAL
VACCINE INSTITUTE

 **Jhpiego**
an affiliate of Johns Hopkins University

MMV 
Medicines for Malaria Venture

 **PATH**

 *Population Council*

 **PUBLIC
HEALTH
INSTITUTE**

**RESEARCH
AMERICA**
AN ALLIANCE FOR DISCOVERIES IN HEALTH

**Seattle
BioMed** 

 **TB ALLIANCE**
GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT

Washington
**Global Health
ALLIANCE** 



**Global Health
Technologies Coalition**

455 Massachusetts Ave. NW, Suite 1000, Washington, DC 20001

www.ghtcoalition.org