



Global Health  
Technologies Coalition

2015 Policy Report

# Meeting the challenge, seizing the opportunity:

US leadership can advance global  
health R&D

US investments in medical research and innovation lead to discoveries and technologies that save millions of lives and improve health in the United States and around the world. New vaccines, drugs, diagnostics, devices, and other health tools have helped to reduce the toll of HIV/AIDS, tuberculosis, malaria, neglected tropical diseases, and other global health challenges. Since 1990, the mortality rate for children younger than five years has fallen by half, maternal deaths have declined by 45 percent, and deaths from infectious diseases have dropped by about 25 percent around the world.

Despite these remarkable achievements, there is still much work to be done. Infectious diseases and other health challenges kill millions each year, and safe and effective tools are not yet available to prevent, diagnose, or treat many neglected diseases. Problems such as the worst Ebola outbreak in history and growing resistance to antibiotics and antimicrobials have starkly revealed the challenges of drug development for neglected diseases and underscored the threat of infectious diseases and other persistent health challenges in an increasingly interconnected world.

New global health tools are urgently needed to address existing and emerging health challenges. Progress will not be achieved without robust US investment and leadership in research and development (R&D) and a policy environment that fosters innovation.

## The world needs a comprehensive, sustainable approach to financing global health R&D

The US government is the world's largest funder of global health R&D. It provides more than \$1 billion each year for this work, led by five key agencies: the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), US Agency for International Development (USAID), Department of Defense (DoD), and Food and Drug Administration (FDA).

Between 2000 and 2010, the US government nearly doubled its annual financial commitment to global health R&D, and more than half of the 45 global health products registered in this decade were developed with US government support. Since its peak in 2009, however, US funding for global health R&D has generally declined and has suffered damaging cuts related to sequestration and a government shutdown.

Consistent, flexible, and robust funding is needed to advance innovation and product development, which requires many years of continuous effort. Sustained investment in R&D will not only save lives and contribute to economic development in other countries, but will also benefit the United States by driving economic growth, producing long-term savings, improving US relations abroad, and enhancing national security.

## Lessons from Ebola

The worst Ebola outbreak in history has already killed more than 10,000 people. It has also highlighted the lack of investment in new technologies, drugs, and vaccines for diseases primarily affecting low-income populations and underscored the need for forward-thinking investments in research and preparedness, so we have the necessary tools to combat the world's next global health emergency. Although Ebola was first identified more than 40 years ago, when the outbreak occurred, there was still no approved vaccine or treatment. As we have witnessed, in a highly interconnected world, infectious diseases that emerge in one region can threaten all.

As US policymakers determine the fiscal year (FY) 2016 federal budget, it is critical that they recognize the need for and benefits of robust, stable funding for global health R&D. Additional funding may be needed if new health emergencies arise. Avoiding another round of devastating sequestration cuts in 2016 will be essential to making progress against ongoing threats to global health.

The flexibility to shift funding where it can have the greatest impact as research provides new insights is critical to maximize advances in global health. Highly restricted funding hinders the ability of researchers and product developers to pursue promising scientific leads that may fall outside original project scopes. Flexible funding streams allow researchers to meet the goal of discovering new cures, treatments, and other breakthroughs, while successfully managing the varied and constantly changing needs of the R&D process.

The US government will also benefit from a more comprehensive approach to financing that includes incentives and innovative mechanisms, in addition to traditional public financing. Mechanisms such as prizes and small business innovation awards, priority review vouchers, advance market commitments, procurement tools, tax credits, patent pools, and solidarity taxes can help leverage existing funding resources and incentivize innovation from all sectors.

## The goal: A strategic, coordinated approach to US global health R&D

Strategic, coordinated, and forward-looking US policies and programs are as important as robust funding for leveraging existing resources, accelerating product development, and improving health.

Currently there is no overarching strategy aligning the US government's priorities and activities related to global health R&D. Most coordination across agencies occurs in an informal, ad-hoc manner. Improved coordination of R&D can be achieved by incorporating R&D into the Global Health Security Agenda and creating a whole-of-government strategy for global health R&D.

The FDA plays a vital role in global health product regulation. National regulatory authorities in many developing countries lack the expertise and resources to review new health technologies and monitor clinical trials, and the FDA has expanded its global engagement to help meet this need. To accelerate innovation, the FDA should adopt a more strategic and coordinated approach to its engagement in global regulatory issues. This includes building its internal capacity for global health and neglected disease activities and implementing mechanisms to better align the agency's various centers and offices working in these areas. It should also improve its coordination with other US agencies and strengthen its partnerships with global, regional, and national regulatory authorities and initiatives. The US Congress needs to provide the FDA with sufficient funding and authority for these activities.

As efforts to achieve the Millennium Development Goals draw to a close, world leaders are creating a new agenda for global health and development that will establish priorities and galvanize action for the next 15 years. During 2015, US policymakers will help to finalize goals and targets that will be approved at the 70th session of the United Nations General Assembly in September. Policymakers should ensure that these goals reflect the critical role of R&D in improving health outcomes, driving economic progress, and reducing poverty.

## Conclusion and recommendations

US policymakers have an opportunity to act decisively at both the domestic and global levels to accelerate innovation, confront existing and emerging health challenges, and reaffirm America's role as the world's engine of scientific discovery and medical innovation. The Global Health Technologies Coalition offers the following recommendations to Congress and the Administration:

- The US Congress should provide robust and stable funding for global health R&D, as well as allocate additional resources for global health emergencies as needed.
- The Administration should develop a long-term strategy that proposes sufficient, consistent, and flexible funding needed to advance the development of lifesaving health tools.
- The US government should continue its leadership in pioneering and advancing innovative approaches to incentivize and finance global health research and product development at the national and global levels.

- The US government should improve coordination and alignment across agencies and programs engaged in global health research and product development.
- The FDA should adopt a more strategic and coordinated approach to advancing its engagement in global health regulatory issues.
- US policymakers should ensure that global health R&D is included as an integral component of the global post-2015 development agenda being adopted this year by the United Nations.

As the world creates a new agenda for global development and seeks to collectively confront existing and emerging health challenges, the time is right for US policymakers to strengthen the nation's investments in research and product development and reaffirm our resolve to harness American ingenuity to save lives, improve health, and enhance economic prosperity and security around the world.

## FY 2016 budget

In the FY 2016 budget, Congress should appropriate:

- \$469 million for the Center for Global Health and \$699 million for the National Center for Emerging and Zoonotic Infectious Diseases at the CDC.
- \$2.8 billion for the FDA.
- At least \$32 billion for the NIH.
- \$10.078 billion for global health programs at the Department of State and USAID.
- Strong funding levels to support global health R&D at the DoD.

## For more information

For details about these issues, view the Global Health Technologies Coalition's full annual policy report online at [www.ghtcoalition.org](http://www.ghtcoalition.org).

## COALITION MEMBERS

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

