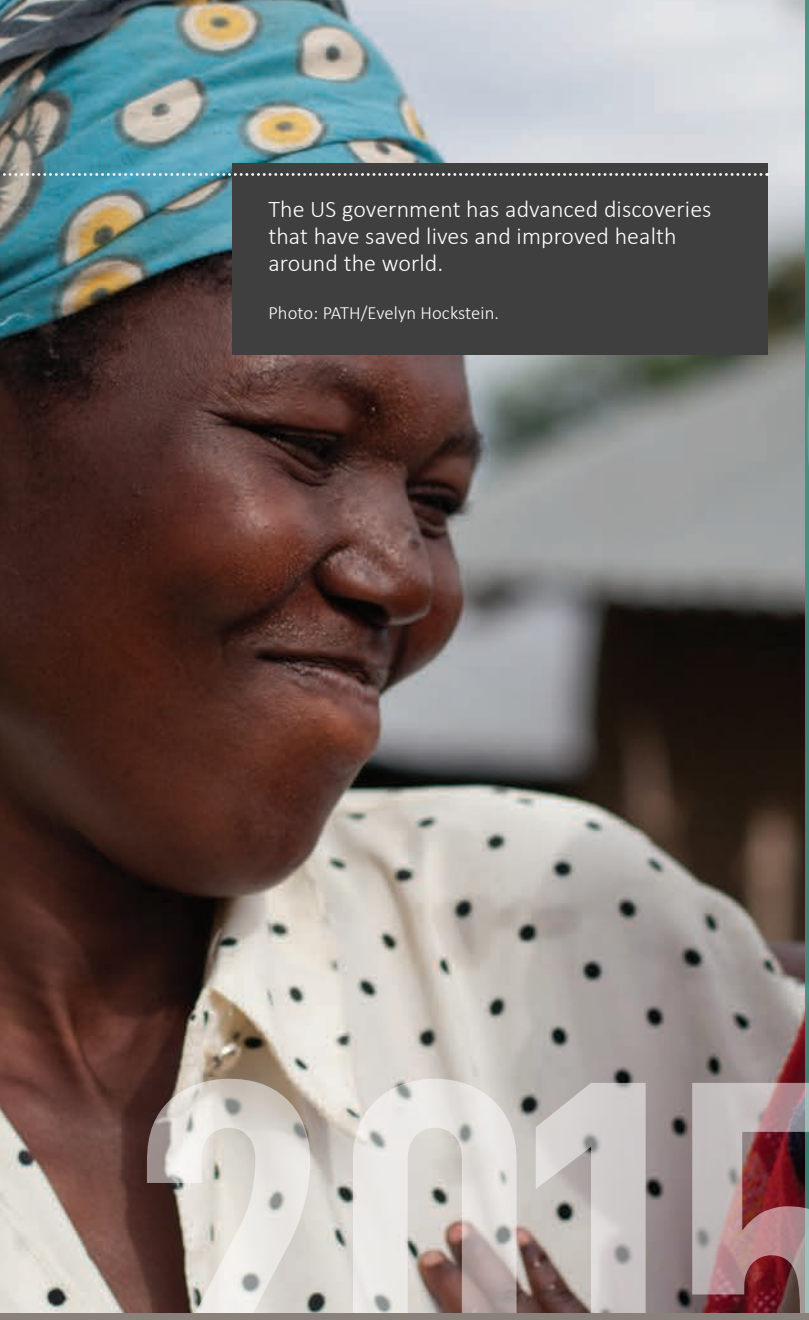
Global Health Technologies Coalition

2015 Policy Report

Meeting the challenge, seizing the opportunity:

US leadership can advance global health R&D

PATH/Aaron Joel Santos



The US government has advanced discoveries that have saved lives and improved health around the world.

Photo: PATH/Evelyn Hockstein.

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About the Global Health Technologies Coalition

The Global Health Technologies Coalition (GHTC) is a group of 25 nonprofit organizations working to increase awareness of the urgent need for technologies that save lives in the developing world. These tools include new vaccines, drugs, microbicides, diagnostics, devices, and other products. The coalition advocates for increased and effective use of public resources, incentives to encourage private sector investment, and streamlined regulatory processes. The GHTC is housed at PATH and funded in part by the Bill & Melinda Gates Foundation.

Acknowledgments

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Overview

US-led investments in medical research and innovation are a powerful engine for advancing discoveries and technologies that save the lives of millions in the United States and around the world. Innovations in health have led to the elimination of smallpox, the near eradication of polio, and dramatically extended the lives of those living with HIV/AIDS. More recent scientific breakthroughs have contributed to the development of new vaccines, drugs, diagnostics, devices, and other health tools that are producing incredible gains in the fight against tuberculosis (TB), malaria, HIV/AIDS, neglected tropical diseases, and maternal and child deaths. The fruits of American taxpayer investment in global health innovation are undeniable: 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.[1],[2]

Despite these remarkable achievements, there is still much work to be done. Infectious diseases and other health challenges continue to claim the lives of millions of people each year, and safe and effective tools are not yet available to prevent, diagnose, or treat many neglected diseases. As the world has achieved hard fought gains against many leading killers, growing problems like antibiotic and antimicrobial drug resistance threaten to undermine this progress. In addition, this past year, the world experienced the worst Ebola outbreak in history—a crisis that claimed thousands of lives, 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 these current and emerging health challenges, and continued progress will not be achieved without robust US investment in research and development (R&D) and a policy environment that fosters innovation.

In a time of great scientific promise and grave global health need, US policymakers have allowed challenging fiscal circumstances and political gridlock to weaken America's leadership in global health research and innovation. The past several years have been marked by reduced or flat-funded budgets for global health research, as well as widespread and damaging cuts produced by sequestration and a government shutdown. Although the fiscal year (FY) 2014 and FY 2015 bipartisan budget agreements were a promising departure from past budgetary stalemates, key global health research programs remained underfunded. Additionally, it is likely that sequestration will further threaten global health budgets in FY 2016, contributing to budget uncertainty and difficulty in long-term planning.

US policymakers must strive to accelerate scientific innovation and facilitate the rapid introduction of new safe, effective, and affordable health technologies through both sustained investment in global health R&D and the advancement of smart policies. US investment in global health innovation not only saves lives, but also produces direct benefits for Americans by creating jobs, spurring economic growth, improving US relations abroad, and enhancing national security.

Over the next year, there will be several opportunities for US policymakers to act decisively at the domestic and global levels to strengthen global health research and product development. This report offers actionable recommendations for the US Congress and Administration to accelerate innovation, confront existing and emerging global health challenges, and reaffirm America's role as the world's engine of scientific discovery and medical innovation. Recommendations include the following.

- The US Congress should provide robust and stable funding in FY 2016 for global health R&D through global health programs at US agencies, as well as allocate additional resources if 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.
  - Improve coordination and alignment across agencies and programs engaged in global health research and product development.
- The US Food and Drug Administration 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 at 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.

Robust, consistent, and flexible funding is essential to advancing promising new tools through development and delivery.

Photo: PATH/Will Boase.

"If America is going to remain a world leader in research that does contribute to longer and healthier lives, federal funding for medical research has to be a national priority." [39]

Sen. Richard Durbin (D-IL)

Sustainable financing

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

Longstanding US support for global health research and development (R&D) has led to the creation of breakthrough technologies that have driven significant progress in improving health worldwide. For example, globally, new vaccines, drugs, diagnostics, and other health technologies led to 4.2 million fewer child deaths in 2013 compared to 1990, and access to antiretroviral therapy for HIV-infected individuals has saved 6.6 million lives since 1995.[3],[4]

There has been a remarkable increase in the number of global health products registered in recent years, thanks in large part to US investment. 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 government support.[5] More recently, several promising technologies supported by the US government have advanced through clinical trials, including microbicides to prevent HIV infection, novel regimens to shorten tuberculosis treatment, and new vaccines against neglected tropical diseases.

While we celebrate these real advances, neglected infectious diseases and persistent health challenges continue to have a foothold and needlessly take millions of lives each year. Recent global health crises like the Ebola outbreak and growing threats like antibiotic and antimicrobial drug resistance, make clear that the United States has a stake in ensuring the world has the vaccines, drugs, diagnostics, and other health tools needed to address these challenges.

The Ebola outbreak of 2014, which has claimed the lives of more than 10,000 worldwide and infected several US citizens, has drawn considerable public attention to the critical role the public sector must play in financing and supporting global health R&D, particularly in the case of neglected diseases and unaddressed health challenges, which offer little financial incentive for investment by the private sector.[6] Yet, despite this urgent need, the United States invests less than 0.01 percent of its gross domestic product in global health R&D—far less than is needed to tackle these challenges.[5]

In order to advance the development of critically needed health tools, US policymakers must move the government

toward a more sustainable and comprehensive approach to financing global health research and product development. This includes providing robust and stable funding over an extended period of time, as well as introducing funding streams that are flexible enough to address the varied and changing needs of the research and product development process. This also includes advancing incentives and innovative approaches to engage multiple stakeholders in financing R&D.

Strong and stable funding spurs innovation

Robust and stable US investment in R&D is essential to bringing new global health tools through the discovery, development, and delivery stages. Unfortunately, budget constraints over the past several years have resulted in harmful reductions in US investment in global health R&D, which has been stagnant or in decline since 2009.

According to Policy Cures' most recent Global Funding of Innovation for Neglected Diseases survey, which tracks annual spending on neglected disease R&D, following a peak in 2009, US government year-over-year spending on global health R&D fell each year until 2012, when it saw only a small increase. In 2013, funding fell dramatically—by $184 million, or 11 percent—from the previous year, mostly due to sequestration cuts to the US National Institutes of Health (NIH) and the US Agency for International Development (USAID). As well, overall total global investment in neglected disease R&D fell by 6.2 percent. Although the United States remains the largest funder of global health R&D, as of 2013, total US funding was $185 million less than 2009 levels. (All figures are in 2013 US dollars.)[7]

The challenges faced by US policymakers in negotiating an annual federal budget and planning for long-term fiscal needs have created an uncertain funding environment for global health R&D that undermines America's scientific and humanitarian leadership. Instead of passing forward-looking annual spending packages, the US Congress has either relied on continuing resolutions that provide only flat funding for federal programs—effectively decreasing their funding when adjusted for inflation—or widespread and indiscriminate budget cuts brought about by sequestration.

No endeavor can deliver results without dependable and adequate financing. Global health R&D is no exception. In most cases, medical breakthroughs result from years of research that build incrementally on past discoveries. Funding cuts lead to interruptions or delays in research programs, which in turn causes scientific regression, undoes past investments, and results in increased costs over the long term, as well as delays in the introduction of lifesaving products. Further, budget uncertainty makes smart strategic planning nearly impossible.

The passage of omnibus spending bills for fiscal year (FY) 2014 and FY 2015 represents a promising step forward; the United States avoided another government shutdown, reversed some of the damages of sequestration, and provided some level of budget security. However, outside of the $5.4 billion in emergency funding for Ebola, the FY 2015 omnibus largely provided flat funding for global health programs at US agencies. Total FY 2015 funding for global health programs at the US Department of State and USAID increased by only 0.2 percent. Baseline funding for global health programs at the US Centers for Disease Control and Prevention (CDC) increased by 0.2 percent, while funding for the CDC's National Center for Emerging and Zoonotic Infectious Diseases increased by 3.8 percent. The US Food and Drug Administration (FDA) received a 1.5 percent increase, which does not account for revenue generated from user fees, while the NIH received a 0.5 percent increase. (See chart below for specific numbers).[8]

While the FY 2015 increases are certainly welcome, they only go part of the way toward reversing the significant

	FY 2014 ENACTED (MILLIONS)	FY 2015 OMNIBUS (MILLIONS)	PERCENT CHANGE
State and USAID global health programs	$8,439	$8,454	+ 0.2
CDC global health	$415.7	$416.5	+ 0.2
CDC National Center for Emerging and Zoonotic Infectious Diseases	$390	$405	+ 3.8
FDA (without user fees)	$2,561	$2,599	+ 1.5
NIH	$29,926	$30,084	+ 0.5

losses from previous years, and sequestration is still a troubling threat if US policymakers fail to arrive at a solution to avoid it. Sequestration could usher in another round of damaging cuts to global health programming at US agencies, which would not only delay the development of lifesaving tools, but also damage America's reputation as a leader in science, hurt the US economy, and cost the nation domestic jobs.

The US economy benefits significantly from US investment in global health R&D. In fact, around 64 cents of every dollar spent by the US government on global health R&D goes directly to US-based researchers and product developers, creating jobs, spurring business activity, and strengthening US competitiveness in research and technology.[5] During challenging budgetary times, US policymakers must weigh carefully how they set the nation's priorities and allocate funding. Spending for global health R&D—which creates jobs, drives economic growth, and produces long-term savings, while improving the health of Americans and people worldwide—should remain a top US priority.

As US policymakers determine FY 2016 funding, it is critical that they agree on a budget that avoids indiscriminate cuts, and instead provides robust and stable funding for strategic investments in global health R&D programming taking place at the CDC, FDA, NIH, State (including USAID), and the Department of Defense. Additionally, if future acute global health emergencies arise, it is critical that additional funding be allocated, so agencies and programs can respond adequately to these crises without depleting financial resources intended for other essential activities.

The Administration should aspire to develop forward-looking strategies, backed with funding, that move the United States closer to the fiscal environment best suited to foster the development of technologies to address critical health and development goals. This includes proposing robust funding levels, but also ensuring that funding has the flexibility needed to catalyze innovation and advance new products.

Flexible funding is conducive to progress

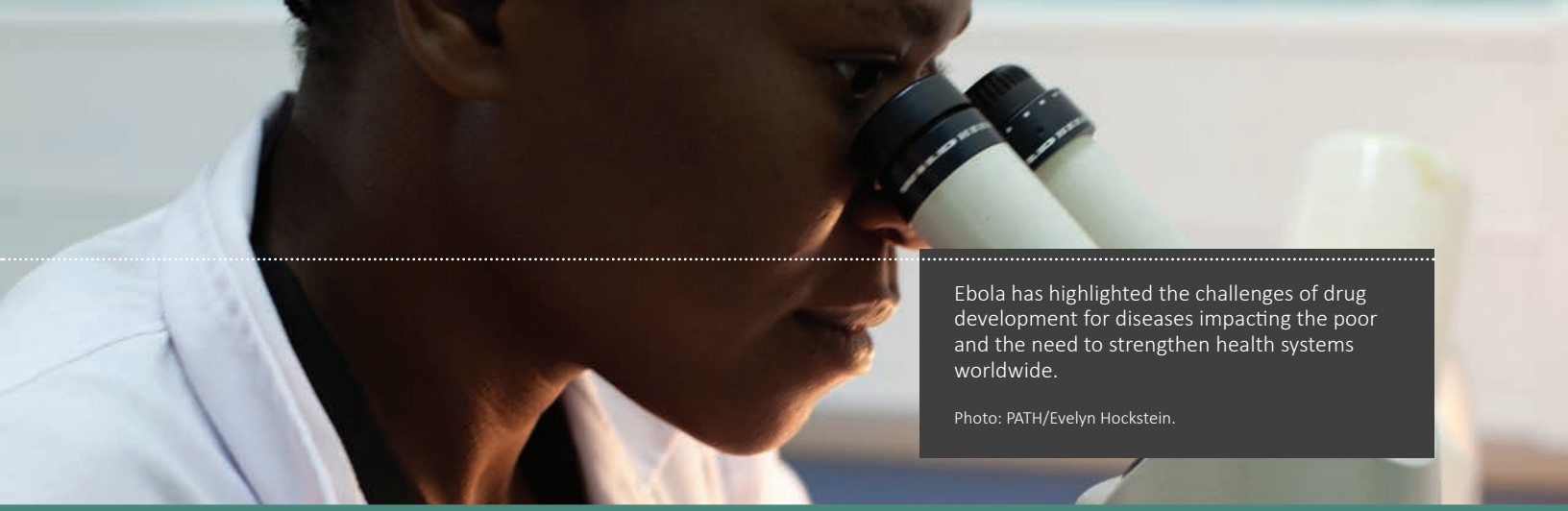
Highly restricted R&D funding streams that define strict parameters for how funding can be spent impede the ability of researchers and product developers to pursue scientific leads that hold great promise for public health but where the science has shifted from researchers' original project scopes. More 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. Agencies should expand the availability of less restricted funding, allowing recipients to build institutional capacity, support the development of a range of products at different stages in the development process, and shift focus as promising scientific opportunities arise. In addition to improving the flexibility of funding, agencies can improve the research ecosystem by structuring grant funding strategically to reduce administrative burdens for recipients as much as possible.

Engaging multiple partners in financing R&D is essential

Given the uncertain fiscal climate, it is also important that the US government take a comprehensive approach to financing global health R&D, one that includes traditional public financing as well as incentives and innovative financing mechanisms. These mechanisms—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 involved in global health product development.

The United States should be applauded for its continued leadership in pioneering and advancing innovative approaches to incentivize and finance global health R&D at both the national and global levels. Over the past few years, the US government has implemented several new programs that have the potential to be transformative in spurring global health innovation. Many of these programs and their impact on global health will be examined later in this report.

While current efforts are commendable, it is critical that the United States continue to engage with other governments, donors, civil society, private industry, and nongovernmental organizations to ensure that these efforts are harmonized with a broader, whole-of-government approach to advancing global health R&D. It is also critical that stakeholders implementing these programs put in place monitoring and evaluation frameworks to measure the efficacy of the programs to guide future policymaking.



Ebola has highlighted the challenges of drug development for diseases impacting the poor and the need to strengthen health systems worldwide.

Photo: PATH/Evelyn Hockstein.

"We need to be far better prepared for protecting American citizens from contagious diseases that can spread like wildfire from a single health care worker or other infected individual who returns from an affected country. Fortunately, only one death from Ebola occurred in the US, but it could have been far worse. Now is the time to reassess how we should respond domestically and internationally to regional epidemics and prepare accordingly. We cannot afford to waste time and resources making the same mistakes and relearning old lessons." [40]

Sen. Patrick Leahy (D-VT)

WILL WE LEARN FROM THE LESSONS OF THE EBOLA OUTBREAK?

The worst Ebola outbreak in history has thus far impacted nine countries, including the United States, infected more than 24,000 people, and claimed the lives of more than 10,000.[6] It has also shed light on the weakness of health systems and the lack of investment in research and development (R&D) for diseases primarily impacting the poor, as well as underscored the need for forward-thinking investments in research and preparedness so that we will have the necessary tools to combat the world's next global health emergency and keep Americans safe.

The Ebola outbreak highlights the critical need to strengthen health systems overall, with a particular focus on low-income countries, where infectious diseases thrive and spread easily. Critical weaknesses in the health systems of those nations first impacted—including health worker shortages, lack of appropriate equipment, limited knowledge and training, and insufficient information-sharing systems—contributed to the spread of the disease. Anecdotal reports suggest that as the epidemic grew, it further overwhelmed already weak systems and undermined progress in treating malaria and improving maternal and child health by both limiting the capacity of health facilities to address patient needs outside of Ebola and frightening individuals away from seeking treatment at hospitals and health centers.[9],[10] Mitigating and containing the risk of health epidemics in the future will require increased investments in health system strengthening today.

The Ebola outbreak also highlights the dangers of an insufficient global health R&D ecosystem that produces few products for diseases impacting the poorest and most marginalized populations. Ebola was identified nearly 40 years ago, but when the most recent outbreak occurred, there was still no approved vaccine or treatment for the virus. Most health R&D is funded by the private sector; however, Ebola—a disease with rare outbreaks largely impacting poor nations—offers little commercial incentive for investment by the private, for-profit sector.[11] This situation is not unique to Ebola, but a pervasive problem in advancing R&D for all poverty-related and neglected diseases and health challenges. In fact, of the 850 health products approved by regulators between 2000 and 2011, only 37 focused on

neglected diseases.[12] In addition, according to the most recent Global Funding of Innovation for Neglected Diseases survey, only 12 percent of investment in neglected disease R&D came from the private sector, while two-thirds of the funding was provided by the public sector.[7]

Much of the progress achieved toward the development of Ebola vaccines and treatments is the result of US government investment over the past two decades, primarily by biodefense programs. However, this investment proved insufficient to advance the tools needed to stem this outbreak. A full toolkit of resources, including rapid diagnostic tests, protective gear, disinfection methods, novel vaccines and treatments, and enhanced surveillance systems, are needed to contain the outbreak and prevent future outbreaks. The US government should continue to support efforts to develop these tools for Ebola and for other potential future new disease outbreaks; however, it is also important that it not do so at the expense of research programs for malaria, HIV/AIDS, tuberculosis, and other neglected diseases and global health challenges that impact many more people annually.

As the Ebola epidemic has demonstrated, in an interconnected world, no matter how geographically distant a threat may seem, a threat to some is a threat to all. Even infectious diseases thought to be readily containable can have devastating regional and international impact if we do not have the necessary tools or systems in place. In order for the United States to be prepared to address emerging disease threats worldwide that could impact Americans, our government must increase long-term investments in health system strengthening and R&D so we have the tools and ability to detect, treat, and prevent future epidemics.

US LEADERSHIP: SPEARHEADING INCENTIVES & INNOVATIVE FINANCING STRATEGIES

The US government has played a critical role in advancing innovative approaches to incentivize and finance global health research and product development at both the domestic and global levels. These approaches complement traditional government investment in research and development (R&D) by creating incentives that encourage a broad range of stakeholders—private biotechnology and pharmaceutical companies, nonprofit product developers, academic partners, and public research institutes—to invest in global health R&D.

In recent years, the United States has pioneered several promising new incentive programs and financing mechanisms, described below.

Grand Challenges for Development

The Grand Challenges initiative is a competition that provides funding to individuals or teams developing promising technologies or innovations to advance global development. For three years, the program has included a Saving Lives at Birth Challenge, financed and operated by the US Agency for International Development (USAID) and other private and public funders, focused on identifying and advancing innovations to improve maternal and newborn health. While still in its nascent stages, the program has already produced one breakthrough innovation, called the Odón Device, which aids in delivery when complications occur during the second stage of labor and which will be further developed and introduced over the next few years.[13] In 2014, the Fighting Ebola Challenge, operated by USAID, the White House Office of Science and Technology Policy, US Centers for Disease Control and Prevention, and US Department of Defense, was introduced to identify novel solutions to help health care workers protect themselves and others from Ebola.

US support for incentives and innovative financing helps encourage a broad range of stakeholders to invest in developing new global health technologies.

Photo: PATH/Aaron Joel Santos.

Pooled fund for R&D at the World Health Organization

At the 69th World Health Assembly in May 2014, World Health Organization Member States passed a resolution calling for the establishment of a pooled fund for global health R&D housed at the World Health Organization. Pooled funding mechanisms can help advance R&D by mobilizing additional resources, dispersing risks, and improving coordination among key players. While this fund is still in the very early stages of development, the United States should be applauded for its efforts to advance this alternative approach to financing R&D for neglected diseases and should encourage other Member States to participate in and contribute to this voluntary fund, while not reducing their current R&D investments.

Global Innovation Fund

At the 69th session of the United Nations General Assembly in September 2014, the US government, in partnership with the governments of the United Kingdom, Sweden, and Australia, and the philanthropic investment firm Omidyar Network, launched this $200 million fund to provide grants, loans, and equity investments to finance piloting, testing, and scaling of innovations to address development challenges, including global health. Given the fund's potential to advance global health innovation, the US government, through USAID, should actively contribute to managing and monitoring the fund to ensure investments are truly groundbreaking.

Global Financing Facility

In September 2014, the US government, in partnership with the World Bank Group and the governments of Canada and Norway, announced the creation of the Global Financing Facility (GFF) to provide financial resources to developing countries to support their efforts to end preventable maternal, newborn, and child deaths. The GFF also aims to catalyze the development of critically needed tools to achieve this aim. The GFF is still in an early stage of development; however, the US government should eventually contribute to the fund and work with other partners to identify the stages of the product development process for which the fund's resources can be most useful.

NEW PRODUCTS WITH THE PROMISE TO IMPROVE GLOBAL HEALTH ARE AT RISK

The United States' historic commitment to global health research and development (R&D) has paid off: the development of vaccines, drugs, diagnostics, and other health tools has saved countless lives and resulted in billions of dollars in cost savings. Unfortunately, years of flat funding and sequestration have led to reduced research budgets and uncertainty about the future of US-funded global health R&D projects. With so many promising global health tools entering later stages of the product development process, where costs escalate, it is more critical than ever that the US government continue to sustain investments.

Ongoing R&D supported by the US government that could be at risk if sequestration is implemented or future cuts occur includes:

- New **drugs and novel drug regimens** under development to treat tuberculosis (TB), including those focused on treating children and patients with drug-sensitive and drug-resistant forms of the disease. New drugs and regimens have real potential to shorten treatment times, significantly reducing the costs of treatment.
- New **tools to prevent and treat malaria**, including new drugs and transmission-blocking vaccines. In 2014, the drug treatment candidate tafenoquine, which was granted the Breakthrough Therapy designation by the US Food and Drug Administration, entered Phase 3 clinical trials. Additionally, US funding has supported the development and dispersal of more than 250 million courses of Coartem® Dispersible, the first pediatric dispersible artemisinin-based combination therapy developed for children, since it was introduced in 2009.[14]
- A **preventive HIV vaccine**. Researchers are currently expanding on results of a 2009 trial that demonstrated for the first time that a vaccine can reduce the risk of HIV infection, as well as pursuing other groundbreaking vaccine research.
- **Cost-effective, easy-to-use diagnostic tools** under development for malaria, HIV, human African trypanosomiasis (sleeping sickness), and TB. These tools are designed for low-resource settings and allow for rapid and accurate diagnosis of disease.
- **Antiretroviral-based microbicides** that would provide women with an important new tool to protect themselves from HIV. There are currently two microbicide products in late-stage clinical trials, and others are in the pipeline.
- New **vaccines and drugs for neglected tropical diseases (NTDs)**, such as leishmaniasis, human African trypanosomiasis, filarial diseases, schistosomiasis, hookworm, dengue, and Chagas disease, currently under development, including several in clinical trials. NTDs affect more than one billion people worldwide.
- New **drugs, vaccines, and diagnostic tools for Ebola** that are under development or in early-stage clinical trials. US government agencies are working with international partners to fast-track the development, testing, and approval of these desperately needed tools.
- **Modern reproductive health technologies** that lower maternal and child mortality by enabling women to practice healthy timing and spacing of their pregnancies. Innovative family planning tools are needed to address the unique needs of women in low-resource settings.

The development of promising technologies could be at risk if sequestration or budget cuts occur.

Photo: PATH/Evelyn Hockstein.

POLICY RECOMMENDATIONS

To strengthen the funding landscape for global health research and development (R&D), the Global Health Technologies Coalition recommends the following actions.

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. In the fiscal year (FY) 2016 federal budget, Congress should demonstrate strong support for global health programs by appropriating:

- $469 million for the Center for Global Health and $699 million for the National Center for Emerging and Zoonotic Infectious Diseases at the Centers for Disease Control and Prevention (CDC).
- $2.8 billion for the Food and Drug Administration (FDA).
- At least $32 billion for the National Institutes of Health (NIH).
- $10.078 billion for global health programs at the Department of State and US Agency for International Development (USAID).
- Strong funding levels to support global health R&D at the Department of Defense (DoD).

Furthermore, it is critical that Congress allocate additional funding so agencies can respond to acute global health emergencies without depleting resources needed for other programs.

The Administration should develop a long-term strategy that proposes sufficient, consistent, and flexible funding needed to advance the development of lifesaving health tools. Unanticipated budget cuts and funding shifts can severely hinder scientific progress and undermine past investment and progress in R&D. As the White House Office of Management and Budget (OMB) begins planning the FY 2017 federal budget, OMB should ensure that budget lines for global health programs at the CDC, the DoD, the FDA, the NIH, and State (including USAID) reflect the unique needs of the R&D process.

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. While current efforts are commendable, it is critical that they be harmonized with a broader, whole-of-government approach to global health R&D and that efforts are undertaken to monitor and evaluate their impact in order to guide future policymaking and secure positive health impact.

"In West Africa, our troops, our scientists, our doctors, our nurses and healthcare workers are rolling back Ebola—saving countless lives and stopping the spread of disease…But the job is not yet done—and the world needs to use this lesson to build a more effective global effort to prevent the spread of future pandemics, invest in smart development, and eradicate extreme poverty." [41]

President Barack Obama

Strategic, coordinated, and forward-looking US policies will help leverage existing resources and accelerate product development.

Photo: PATH/Gabe Bienczycki.

Improving US global health policies

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

While robust, long-term US investment in global health research and development (R&D) is essential for the development of much needed new global health tools, strategic, coordinated, and forward-looking policies and programs are equally important to enable the United States to leverage existing resources, accelerate product development, and improve health.

As of 2012, the US government was contributing to more than 200 of the 365 global health products in the pipeline and serving as a lead funder of R&D for 26 of the 30 most neglected global diseases.[5] US global health R&D also spans five major government agencies, roughly 30 centers or programs, and many initiatives.

Five US agencies play an essential role in the global health R&D ecosystem: the National Institutes of Health (NIH) primarily focuses on the earliest stages of global health R&D, and the US Agency for International Development (USAID) and the Centers for Disease Control and Prevention (CDC) complement that work by building on the basic research to develop products and ensure they reach those who need them. The Department of Defense (DoD) conducts R&D for new global health tools at every stage of research, with a focus on the diseases that impact US military personnel abroad, and the Food and Drug Administration (FDA) plays an essential role in regulating new products to ensure safety and quality. In addition to these five agencies, the Department of Health and Human Services (HHS) has a growing global health mandate and represents the United States in international dialogues, and the National Security Council and White House Office of Science and Technology Policy have become increasingly engaged in conversations about global health R&D needs, particularly pertaining to global health security.

Given the number of US actors involved in global health R&D, the current era of budget austerity and emerging health crises, and from a business efficiency standpoint, it is critical to examine how the US government can improve and better organize its activities.

Coordination is key to efficiency and effectiveness

Improving coordination and alignment of programming across agencies is essential to ensuring US investment in global health R&D achieves the greatest possible impact. 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. It is important to note that US federal researchers often seek out collaborations because they are valuable. The US government should work to strengthen and grow inter- and intra-agency collaborations by advancing more formal policies, mechanisms, and programs that improve coordination and alignment of US agency global health R&D activities.

Implement coordination directives in the fiscal year 2015 budget

The US Congress should ensure that agencies take appropriate steps to implement directives contained in the fiscal year 2015 appropriations bill that call for improved

interagency coordination and reporting on progress achieved. Both the Labor, Health and Human Services, and Education section and the Department of State and Foreign Operations and Related Programs section of the final budget contain language calling for agencies under their jurisdiction to improve coordination and planning with other US agencies to accelerate health research and product development, while the Department of Defense (DoD) section encourages the DoD to continue research partnerships with other agencies.[8]

Incorporate R&D into the Global Health Security Agenda

The Administration should ensure research and innovation are an integral component of the newly created Global Health Security Agenda (GHSA). The GHSA is a five-year initiative, launched in February 2014, to bring together countries across the world to implement activities to enhance their individual and collective ability to prevent, detect, and respond to infectious disease threats. It also has a directive to coordinate global health activities across US agencies, including HHS, the Department of Agriculture, State, the DoD, and USAID. The GHSA faced an early first test during the Ebola outbreak, when it was used as a convening platform for US agencies and international partners involved in the response. In the same way, it could be used as a framework to improve interagency coordination on the development of new tools to combat infectious disease threats.

Establish a whole-of-government strategy for global health R&D

The US government should develop a whole-of-government strategy for global health R&D. Such a strategy would ensure that research gaps are bridged and existing funds are leveraged. However, to be effective, it must navigate divisions of labor across agencies and be organized by a lead entity with the mandate and ability to bring other agencies together to align priorities. Additionally, the strategy should harness the diversity of research models that key agencies use, such as the investigator-driven model at the NIH and the portfolio approach at USAID, to ultimately strengthen the US global health R&D ecosystem.

Promote coordination through transparency and information-sharing

As the US government works toward the development of a whole-of-government strategy to guide global health R&D, it should take other, smaller steps to improve alignment and coordination. Two significant barriers to coordination are the lack of visibility and transparency of R&D activities taking place at different agencies and the dearth of cross-agency information-sharing. To break down these barriers, the US government should develop a map of US agencies' activities in global health R&D and establish mechanisms for open data-sharing across agencies. Organic, informal collaboration between government agencies and programs should be buttressed by more formal mechanisms for research prioritization and planning, eliminating gaps in global health research and product development. Conferences and meetings can also serve as hubs for information-sharing and promoting coordination. Thus, the US government should consider establishing an annual meeting of leaders from agencies conducting global health R&D, and should restore funding for agency representatives to participate in external scientific meetings and conferences.

A more strategic, coordinated FDA will strengthen global health product regulation

While the FDA is best known for protecting the health of American consumers, it has a lesser known history of leveraging its expertise to benefit people worldwide. The agency is playing an increasingly necessary and vital role in global health. In most countries, national regulatory authorities, like the FDA, undertake a range of activities to ensure that products are safe and effective, including reviewing products and manufacturing processes, approving and monitoring clinical trials, and licensing new products. However, in the developing world, where infectious diseases such as HIV/AIDS, tuberculosis (TB), and malaria are endemic, many countries lack both the expertise and resources to review new health tools and monitor clinical trials, resulting in lengthy delays in bringing crucial health tools to market and unregulated access to unsafe health products.

Over the past few years, the FDA has expanded its global engagement to help address these challenges. It has partnered with the World Health Organization (WHO) and national regulatory authorities to assist countries in bolstering their regulatory capacity and has entered into partnerships to better coordinate regulatory activities worldwide. In addition, it has released guidance documents to help guide product developers producing global health products, including novel TB drug regimens and microbicides, and reinforced its willingness to review health tools for diseases not endemic to the United States. The latter is critical since the FDA is a stringent regulatory

authority, so its review of a product can often facilitate and expedite subsequent review in the countries where the product is intended for use.

While the FDA's current engagement in global health is commendable, it 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. This also includes improving its coordination with other US agencies and strengthening its partnerships with global, regional, and national regulatory authorities and initiatives to ultimately accelerate the development and introduction of urgently needed health technologies.

During the Ebola epidemic, the FDA demonstrated that it can effectively coordinate internal and external agency stakeholders to respond proactively during a critical global health emergency. The FDA created an Ebola Task Force with representatives from across the agency to coordinate its activities. The agency also worked closely with representatives from other US agencies and from the scientific community, industry, nongovernmental organizations, and regulators to help expedite the development and availability of technologies with the potential to help bring the epidemic under control. For example, the agency granted emergency authorization for the use of diagnostic tests developed by the CDC and DoD and has been working closely with WHO and national regulatory authorities to evaluate information on potential new medicines.[15] The FDA should apply lessons learned during the Ebola crisis to strengthen its ongoing global health and neglected disease activities.

Additionally, the FDA must continue to revisit and monitor its priority review voucher (PRV) program, which is intended to incentivize R&D for neglected diseases. This program has received increased attention over the past year. In May 2014, a neglected disease voucher was sold for the first time for $125 million.[16] In November, Congress passed legislation that added Ebola to the list of eligible diseases, altered the statute so PRVs can be sold multiple times, and made it easier for the FDA to amend the list of eligible diseases in the future so it can respond more quickly to emerging crises.[17] As the FDA continues to implement and adapt its PRV program, it is critical that the agency ensure PRVs granted for neglected diseases meet public health needs and are granted only in return for new investments in neglected disease R&D; that the mechanism encourages patient access and affordability; and eligibility is expanded to all WHO-recognized neglected tropical diseases and other neglected conditions.

Because the FDA requires support from Congress to carry out its global activities, Congress should provide the agency with sufficient funding and authority to carry out current and new activities in global health.

A successful global development agenda must prioritize R&D

Over the next year, US policymakers will be engaged in global discussions that could have critical implications for global health research and product development. With the deadline for reaching the 2015 Millennium Development Goals quickly approaching, the world is engaging in ongoing debates to set a new agenda for global development that will establish priorities and galvanize action for reducing poverty and achieving sustainable development by 2030.

The US government, through State (including USAID), the Department of the Treasury, and HHS, is engaged in discussions with other nations to finalize a list of new goals and targets to be negotiated and approved at the 70th United Nations General Assembly session in September 2015. These new goals and targets will serve as the basis for the following 15 years of global development efforts.

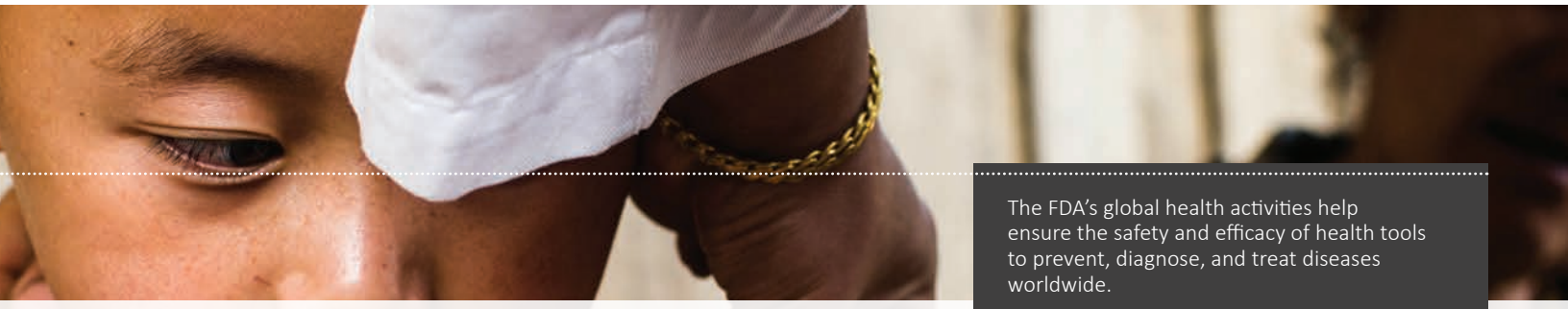
These global discussions present the United States with an opportunity to ensure that its commitment to global health R&D is demonstrated on a global scale, reinforcing its position as the preeminent driver of science and medical innovation.

It is important that US policymakers advocate for these goals and targets to reflect the critical role research and innovation plays not only in improving health outcomes, but also in driving economic progress and reducing poverty. Investment in global health R&D can strengthen scientific infrastructure and human capital, helping to build more vibrant economies in developing nations. In addition, by making people healthier, global health R&D can make economies stronger. The Lancet Commission on Investing in Health found that in low- and middle-income countries (LMICs), the returns on past investment in health care and innovation are enormous. Between 2000 and 2011, health improvements accounted for about 11 percent of economic growth in LMICs. These returns were even larger when full income measurements were used to capture not only growth in national income, but also the value people placed on increased life expectancy—known as the value of their additional life years. In this case, 24 percent of the

growth in full income in LMICs in the same period resulted from health improvements.[18]

Given the wide spectrum of health needs that remain to be fulfilled in LMICs, it is also important that US policymakers advocate for goals and targets that reflect not just the need for new drugs and vaccines, but also new, affordable diagnostics, devices, and other health technologies.

Ultimately, the success or failure of the global post-2015 development agenda will depend not just on the goals and targets included, but also on whether there are adequate financial resources to support their implementation and strong frameworks to measure progress toward them. Thus, as the means of implementing and measuring progress toward this agenda continue to be defined, it is critical that US policymakers support comprehensive indicators that not only measure investment input and R&D output, but also the enabling environment for innovation, which includes infrastructure and human resources, policies, partnerships, capacity strengthening, and access.



The FDA's global health activities help ensure the safety and efficacy of health tools to prevent, diagnose, and treat diseases worldwide.

Photo: PATH/Aaron Joel Santos.

FDA'S NOTEWORTHY LEADERSHIP IN GLOBAL HEALTH

The US Food and Drug Administration (FDA) has continued to build on its leadership in global health by undertaking several actions over the past year to expedite the development and introduction of new tools to prevent, treat, and diagnose global diseases. These include:

- The creation of an Ebola Task Force to coordinate agency activities aimed at accelerating the development and introduction of new health products to diagnose, treat, and prevent Ebola. Over the past year, the FDA worked closely with developers to clarify regulatory requirements, advise on manufacturing and clinical trial design, and expedite the review of data. In an effort to expand the availability of diagnostic tests for Ebola, the FDA also reached out to appropriate commercial product developers to encourage them to engage with the agency in developing tests. In addition, the agency granted access to potential products through its Compassionate Use mechanisms, which permit use of unapproved medical products during emergencies. [19]
- The release of final guidance documents on developing drugs for the treatment and prevention of neglected tropical diseases and developing vaginal microbicides to prevent HIV. [20],[21] This guidance provides recommendations on nonclinical studies and clinical trials that will aid product developers.
- The announcement of a formal collaboration between the FDA Office of International Programs and the Pan American Health Organization to foster regulatory collaboration and strengthen regulatory capacity throughout the Americas. [22]
- Ongoing activities through the Critical Path Initiative to close the gap between early-stage biomedical research and product development to deliver health solutions faster.

HEALTH RESEARCH AND INNOVATION IN THE POST-2015 AGENDA

The global post-2015 development agenda refers to the United Nations (UN)-led process that is defining the global development framework to succeed the Millennium Development Goals (MDGs), set to expire in 2015. Since 2012, there has been an open and consultative process with multiple stakeholders to shape the content of this framework and attempt to reach a consensus on which goals and targets should drive development between 2015 and 2030.

In July 2014, following more than a year of consultations, the UN Open Working Group on Sustainable Development Goals released its proposal for a new set of goals to succeed the MDGs, which includes 17 aspirational goals with 169 associated targets.[23] In December 2014, Secretary General Ban Ki-Moon, in his synthesis report on the post-2015 agenda, reaffirmed that this Open Working Group proposal will serve as the basis for continued UN Member State negotiations.[24]

In the Open Working Group draft document, the importance of research and innovation for health was acknowledged in targets under three separate goals:

- Goal 3. Ensure healthy lives and promote well-being for all at all ages. A target calls for support for the development of vaccines and medicines for diseases affecting developing countries.
- Goal 9. Build resilient infrastructure, promote inclusive and sustainable industrialization, and foster innovation. Targets call for enhanced international support for research and manufacturing capacity strengthening in developing countries.
- Goal 17. Strengthen the means of implementation and revitalize the global partnership for sustainable development. Targets call for improving partnership between nations and investment in technology transfer.[23]

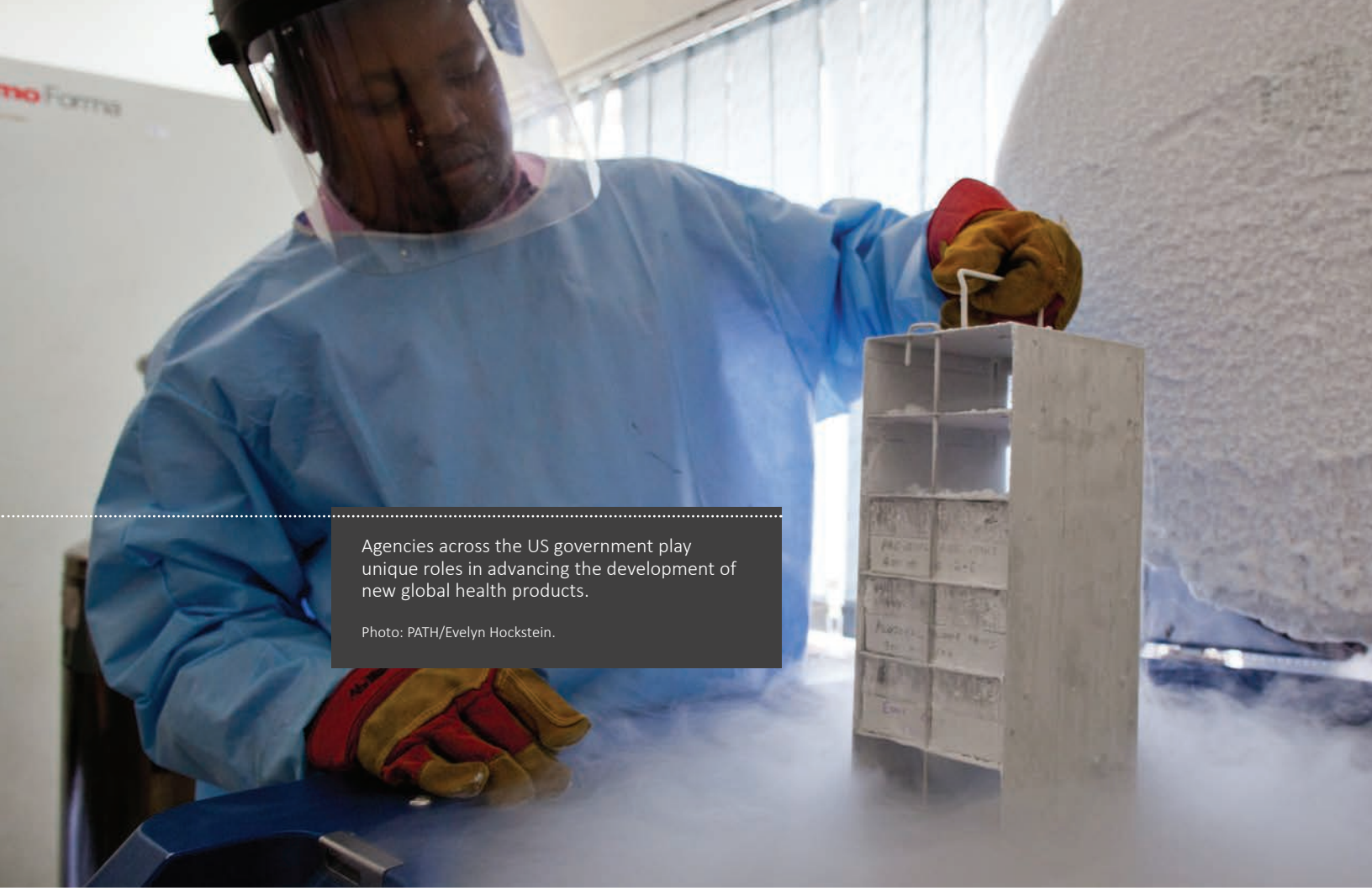
At the 70th session of the UN General Assembly in September 2015, Member States will approve the final list of goals and targets. As negotiations continue, US policymakers, including those at the Department of State and US Agency for International Development, Department of the Treasury, and Department of Health and Human Services, should push for the inclusion of targets that call for support for development of the full spectrum of health technologies, including drugs, vaccines, diagnostics, devices, and other technologies.

In July 2015, representatives from Member States, including the United States, will participate in the Third International Conference on Financing for Development in Addis Ababa, Ethiopia, to discuss how development goals will be financed. At this conference, the US delegation should reinforce the need for strong investments in research and innovation and encourage low- and middle-income countries to embrace the importance of health research and development (R&D) to their long-term growth strategies.

Over the next year, UN Member States will also begin defining indicators to measure progress toward these goals and targets, which likely will be voted on and approved in March 2016. Defining indicators for health research and innovation can be a challenge given the long and complex nature of the R&D process. However, the United States should push for indicators that measure not only financial investments and R&D output, but also the enabling ecosystem for innovation, which includes infrastructure and human resources, policies, partnerships, capacity, and access requirements.

US policymakers must ensure that health research and innovation are a central component of the post-2015 development agenda.

Photo: PATH/Gabe Bienczycki.



Agencies across the US government play unique roles in advancing the development of new global health products.

Photo: PATH/Evelyn Hockstein.

CRITICAL SUPPORT FOR GLOBAL HEALTH R&D AT US AGENCIES

Several US federal agencies play critical and unique roles in advancing global health research and product development, including the Centers for Disease Control and Prevention (CDC), Department of Defense (DoD), Food and Drug Administration (FDA), National Institutes of Health (NIH), Department of Health and Human Services (HHS), US Agency for International Development (USAID), and White House Office of Science and Technology Policy (OSTP). Examples of scientific and policy advances championed by these agencies over the past year are listed below.

- **CDC:** The CDC joined with other agencies to launch the Global Health Security Agenda, which includes 11 action packages aimed at improving global capacity to prevent, detect, and respond to infectious disease threats.[25] As part of this, the CDC is building on pilot programs completed last year to improve diagnostic testing for infectious diseases, such as the pneumonic and bubonic plagues.[26] In addition to its widespread global efforts to track and stem the spread of Ebola, the CDC supported efforts to develop improved protective gear, monitored the virus for mutation patterns, and supported other agencies conducting vaccine trials.
- **DoD:** The US Military HIV Research Program continued its efforts to advance R&D for an HIV vaccine, conducting follow-up studies on new regimens of the RV144 HIV vaccine candidate.[27] Additionally, the DoD has been actively involved in advancing efforts to develop Ebola vaccines and treatments. The US Army Medical Research Institute of Infectious Diseases funded and supported the development of the experimental ZMapp treatment, while the US Defense Threat Reduction Agency supported development of the VSV-EBOV vaccine candidate, which underwent early-stage clinical testing at the Walter Reed Army Institute of Research.[28]

- **FDA:** The FDA issued new guidance documents for neglected tropical diseases (NTDs) and microbicide product development, expanded collaborations with other regulatory entities, supported developers of Ebola products, and increased access to unapproved Ebola treatments through its Compassionate Use mechanisms. Along with the NIH, the agency received an award for 2014's most outstanding intellectual property deal for its involvement in the development and transfer of technology needed to develop the MenAfriVac® meningitis vaccine.[29]
- **NIH:** The National Center for Advancing Translational Sciences announced new research projects through its Center for Therapeutics for Rare and Neglected Diseases program to develop treatments for neglected diseases, including malaria and Lassa fever.[30] The agency's National Institute of Allergy and Infectious Diseases (NIAID) continued its longstanding support of HIV/AIDS research, funding research to advance development of an HIV vaccine and clinical trials of microbicides to reduce sexual transmission of HIV. NIAID also supported a number of projects to develop diagnostics, vaccines, and treatments for Ebola, including the development of ZMapp and the development and testing of Ebola vaccine candidates.[31]
- **HHS:** As part of the US National Strategy for Combatting Antibiotic-Resistant Bacteria, HHS is establishing a presidential advisory council that will provide recommendations to advance research on new treatments for bacterial infections and support the development of rapid, point-of-care diagnostics.[32] The HHS undertook several actions to accelerate Ebola vaccine and product development. It granted drug makers developing Ebola vaccines legal and financial immunity, and through its Biomedical Advanced Research Authority is funding research, testing, and manufacture of experimental Ebola drugs and vaccines.[33],[34]
- **USAID:** USAID announced several promising new developments in global health innovation over the past year. The agency launched the Global Development Lab, which includes a focus on innovations to advance maternal and child health, as well as a new Grand Challenges competition for Ebola. The agency continued its longstanding support for HIV vaccine research, and issued its first ever grant to fund research and development (R&D) for NTDs.[35] In addition, USAID issued its annual report to the US Congress on its activities and strategy for global health R&D,[36] and in conjunction with HHS, the CDC, and the Department of State, issued a new five-year strategy for the US President's Malaria Initiative, which includes agency support for research to develop and test malaria control interventions.[37]
- **OSTP:** In December 2014, OSTP announced a $2 million US government contribution to help eliminate regulatory bottlenecks that impede access to drugs and diagnostic tools in Africa through the World Bank Global Medicines Regulatory Harmonization Trust Fund, the African Medicines Regulatory Harmonization program, and the East African Community Medicines Regulatory Harmonization programs.[38] OSTP also partnered with the CDC, DoD, and USAID in launching the Grand Challenges competition for Ebola.

POLICY RECOMMENDATIONS

To leverage existing investments and strengthen efforts across the US government to foster innovation and accelerate global health product development, the Global Health Technologies Coalition recommends the following actions.

The US government should improve coordination and alignment across agencies and programs engaged in global health research and product development, including the Centers for Disease Control and Prevention, Department of Defense, Food and Drug Administration (FDA), US Agency for International Development (USAID), National Institutes of Health, Department of Health and Human Services (HHS) Office of Global Affairs, White House Office of Science and Technology Policy, and National Security Council. To achieve this aim, the US government should develop a whole-of-government approach for global health research and development (R&D), incorporate R&D into the Global Health Security Agenda, and increase transparency and information-sharing across agencies and programs conducting global health R&D activities.

The FDA should adopt a more strategic and coordinated approach to advancing its engagement in global health regulatory issues. To capitalize on past progress, the FDA should enhance its internal capacity for global health and neglected disease activities, implement mechanisms to better align the agency's centers and offices conducting this work, and improve its coordination with other US agencies and global, national, and regional regulatory authorities and initiatives. The Administration and Congress should support the FDA's increasing engagement in global health by providing the agency with sufficient authority and funding to conduct current and new activities in this area.

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 at the United Nations (UN). As they engage with global decision-makers and other UN Member States, US policymakers, including those at HHS, the Department of the Treasury, and the Department of State (including USAID), should ensure that outcome documents include explicit support for R&D for a full spectrum of health technologies and acknowledge the critical role health innovation plays in both improving health outcomes and driving economic progress. As the means of implementing and measuring progress toward this agenda continues to be defined, it is critical that US policymakers work to strengthen financing mechanisms and ensure that indicators measure not only R&D outputs, but also the enabling environment for innovation.

"Our mission to contain and eliminate infectious diseases needs a 'one-health' and a 'whole-of-government commitment.' We understand that we may not be able to eliminate them all. We can, however, do much more with prevention, early detection, and effective response. Our vision is possible. We have successfully eradicated both Smallpox and Rinderpest, so we know that when we work together, we can do big things." [42]

HHS Secretary Sylvia M. Burwell

Conclusion

Ensuring the US retains its leadership in science and innovation

Thanks to America's longstanding support for global health research and development (R&D), there have been remarkable improvements in health worldwide. American taxpayer investment has led to the creation of successful vaccines, drugs, and other health technologies that have nearly eliminated polio, dramatically extended the lives of those living with HIV/AIDS, and severely reduced deaths from leading childhood killers such as diarrhea, pneumonia, and malaria. These investments have also helped to create the largest research pipeline for new global health products in history, full of promising innovations with enormous potential to save lives and drive economic progress both at home and abroad.

Unfortunately, challenging fiscal realities have led to reduced US support for global health R&D, which has interrupted scientific progress and put the nation's leadership in science and innovation at risk. Yet there are encouraging signs that the global health challenges of this past year have led to an enhanced understanding of the need for and value of US-supported global health R&D, as well as a renewed commitment among US policymakers to come together to advance policies and initiatives to catalyze the next generation of lifesaving products.

With so many new tools on the cusp of development and in light of recent global health emergencies, policymakers cannot lose ground by scaling back investment in global health innovation. We cannot afford to play catch-up. Through these recommended policy actions, the US Congress and Administration and other global policymakers can meet the challenge and seize the opportunity to save lives, improve health, and enhance economic prosperity and security around the world.

"21st century businesses will rely on American science, technology, research and development. I want the country that eliminated polio and mapped the human genome to lead a new era of medicine—one that delivers the right treatment at the right time." [41]

President Barack Obama

US policymakers must meet the challenge and seize the opportunity to save lives, improve health, and enhance prosperity and security worldwide.

Photo: PATH/Gabe Bienczycki.

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COALITION MEMBERS

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

AERAS

ASTMH
American Society of Tropical Medicine & Hygiene

AVAC
Global Advocacy for HIV Prevention

DNDi
Drugs for Neglected Diseases *initiative*

Elizabeth Glaser Pediatric AIDS Foundation
Until no child has AIDS.

FIND
Because diagnosis matters

gapps
Global Alliance to Prevent Prematurity and Stillbirth
an initiative of Seattle Children's

iavi
International AIDS Vaccine Initiative

IDSA
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