Global Health Technologies Coalition

2014 Policy Report

Innovation for a changing world:

The role of US leadership in global health R&D

PATH/Evelyn Hockstein

The US government has long supported discoveries that have changed the face of public health around the world.

Photo: PATH/Gabe Bienczycki.

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About the Global Health Technologies Coalition

The Global Health Technologies Coalition (GHTC) is a group of more than 30 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.

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Introduction

For generations, the United States government has invested in the lifesaving potential of research and innovation, supporting discoveries that have changed the face of public health around the world. Investments in research by the US government have led to the creation of breakthrough health tools that eradicated smallpox and substantially reduced polio and measles cases worldwide. Recent scientific innovations have contributed to the development of remarkable vaccines, drugs, diagnostics, devices, insecticides, and other products for HIV/AIDS, tuberculosis, malaria, women's health, neglected tropical diseases, and childhood killers such as diarrhea and pneumonia.

In order to sustain progress in global health and to address emerging needs, continued support from the US government is needed. Safe and effective drugs, vaccines, and diagnostics do not exist for many neglected diseases (see the Policy Cures website for a full definition of diseases included in this term). Millions still die every year from infectious diseases, and emerging issues such as drug resistance pose a threat to health across the globe. A sustained investment in research and development (R&D) is urgently needed to ensure that new global health tools are available to address current and future health challenges.

However, at the same time that unwavering support for global health research is required more than ever before, the political and economic environment in the United States has changed radically. Over the past year, US policymakers allowed political gridlock and stalemates to stand in the way of reaching a timely agreement on the federal budget. This resulted in indiscriminate and widespread cuts to federal government programs through sequestration, as well as a government shutdown that impacted global health research projects. The recent fiscal year 2014 bipartisan budget agreement was a welcome shift away from this trend, and should be applauded as such. However, several programs that fund global health research remain underfunded, and there is still much work to be done. Policymakers must continue to make progress in supporting promising scientific developments leading toward new and improved health tools for neglected diseases.

The life sciences field is responsible for more than seven million US jobs and contributes $69 billion annually to the US gross domestic product. Denying federal agencies, such as the NIH, the funding they need to continue vital health research will result in a host of damaging consequences to global public health, patients' lives, scientific careers, and the domestic economy.

Fortunately, there are several upcoming opportunities for US policymakers to strengthen their leadership in science and innovation, both domestically and on a global scale. This report offers clear recommendations that Congress and the Administration can implement to reverse these worrying budgetary trends, create American jobs while saving lives, and boost domestic scientific expertise, while fortifying the US legacy in global health R&D. Recommendations include:

- Congress should develop a long-term budget solution that protects funding for global health product development. Additionally, policymakers in Congress must ensure that the 2015 federal budget demonstrates a renewed commitment to global health research.
- US agencies engaged in global health product development—including the Centers for Disease Control and Prevention, Department of Defense, Food and Drug Administration (FDA), NIH, and US Agency for International Development—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 levels for global health product development programs at federal agencies.
- 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.
- Congress should pass the 21st Century Global Health Technology Act.
- 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 work with other Member States to ensure that the global health R&D demonstration projects selected at the upcoming World Health Assembly are high impact and that new funding is available to support their implementation.
- US policymakers should ensure that global health research is included as an integral component of the post-2015 international development framework.

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

"There have also been revolutionary breakthroughs in AIDS research. The discoveries of treatments that can reduce new HIV infections by 96 percent have brought a message of energy and hope that is tangible and invigorating as we recommit to ending this epidemic."

Rep. Barbara Lee (D-CA)

Continued and consistent US investment in R&D is needed to see promising new tools through development and delivery.

Photo: PATH/Evelyn Hockstein.

Budget and appropriations

The United States government has long played a leading role in the development of new health technologies for populations globally. In fact, the US government is the largest supporter of global health research and development (R&D) in the world, supporting the development and delivery of breakthrough technologies such as vaccines, drugs, diagnostics, microbicides, and devices. Between 2000 and 2010, the US government was involved in the development of 53 percent—or 24 of the 45—vaccines, drugs, diagnostics, and devices introduced for global health (for more information, see the GHTC publication: Saving lives and creating impact: Why investing in global health research works (PDF).

Continued and consistent US investment in R&D will provide the support needed to see promising new tools through development and delivery. However, at the same time that new health tools hold the promise to make an incredible impact on global public health, the political and economic environment in the United States is shifting dramatically. Budget constraints over the past several years are putting essential and lifesaving programs at risk, including funding for global health product development. These budget constraints are resulting in harmful reductions in US financial support for global health R&D, which, according to a five-year review conducted by Policy Cures, has seen declines since 2009. This ongoing reduction in US support for global health R&D has already jeopardized the future of promising health tools in the research pipeline.

For instance, several US agencies that play a critical role in the development and delivery of new global health tools have experienced concerning budget cuts over the past several years. The Centers for Disease Control and Prevention (CDC), Department of Defense (DoD), Food and Drug Administration (FDA), National Institutes of Health (NIH), and US Agency for International Development (USAID) all work with a range of academic, nonprofit, private-sector, US government, and international partners to advance global health R&D, bringing much-needed skills, resources, and expertise. Unfortunately, the budget environment in the United States has resulted in shrinking and inconsistent funding for these key agencies.

Support for global health R&D in 2012 varied across US federal agencies, according to the annual G-FINDER report on the Policy Cures website. For instance, US public funding for R&D targeting neglected diseases increased for the first time since 2008 (up $86.3 million, or 6.4 percent). This change was entirely due to increased investment by the NIH (up $94.1 million, or 7.9 percent), offset slightly by the CDC, which once again decreased its funding (down $7.9 million, or 62.4 percent). Each agency plays a hard-to-replace role in the global health research spectrum, so robust funding of each is essential. The NIH is the world's largest funder of global health research, and focuses on the earliest stages of global health R&D, while USAID and the CDC build upon basic research to develop products and ensure they reach those who need them. The CDC also contributes valuable surveillance and health

research systems, strengthening programs that ensure the sustainability of global health R&D. The DoD conducts R&D for new global health tools at every stage of research, with a focus on those diseases that impact US troops abroad. The FDA plays an essential role in regulating new products to ensure safety and quality. And finally, the US Department of Health and Human Services, which includes the NIH, CDC, and FDA, has a growing global health mandate, being seen as a "go-to" for other agencies working on global health issues as well as representing the United States in international dialogues.

US policymakers also have been unable to come to an agreement on the annual federal budget and a long-term fiscal plan in recent years, resulting in a highly unusual and unpredictable process by which policymakers make fiscal decisions. The annual appropriations process has been replaced by a series of continuing resolutions that fund federal programs at flat levels, although Congress reversed this trend by passing an omnibus spending bill for FY2014. When adjusted for inflation, flat funding equates to falling budgets for health research programs—thereby eroding scientific progress and America's longstanding position as the preeminent driver of medical innovation. Additionally, medical breakthroughs do not happen overnight. In almost all instances, game-changing discoveries result from years of incremental research to understand how disease starts and progresses. Therefore, the uncertainty of continuing resolutions and increasingly shrinking budgets makes planning for the future almost impossible.

This uncertain and unpredictable process has led policymakers to make budgetary decisions over the past year that have negatively impacted global health R&D, including allowing sequestration, or widespread and indiscriminate cuts to the federal budget, to take place. Since taking effect in March 2013, it has become clear that sequestration cuts have damaged health research projects across the US government. As just one example of the harmful effects of sequestration on global health R&D, tuberculosis (TB) research at federal agencies such as the NIH, CDC, and USAID has been reduced significantly. The Tuberculosis Trials Consortium, a research nexus based in Atlanta, Georgia that conducts TB clinical trials across nine countries in collaboration with the US government, nonprofits, and drug companies, reported shutting down clinical trial sites in the US and abroad due to sequestration. If US policymakers do nothing to prevent further widespread cuts to the federal budget, such reductions have the potential to push back TB research years, and, in the case of some clinical trials, permanently end research.

Other data highlight how sequestration is impacting lives across the globe. As a result of sequestration cuts to US international aid programs, it is estimated that:

- HIV/AIDS treatment for 165,400 people will not be available, potentially leading to 37,700 more AIDS-related deaths and 74,300 more children becoming orphans.
- An estimated 1.2 million fewer insecticide-treated bednets will be procured, leading to more than 3,100 deaths due to malaria; 2 million fewer people will receive malaria treatment.
- Approximately 36,000 fewer people with TB will receive treatment, leading to 4,300 more deaths from this disease; 200 fewer people with multidrug-resistant TB will receive treatment.

More information is available on the amfAR website.

Sequestration is not only limiting access to currently available treatment and prevention tools, leading to an increase in HIV/AIDS, TB, and malaria deaths—it is also hindering research into new tools that are critically needed to fight these and other diseases. Although policymakers recently agreed upon a budget deal that prevents a second round of sequestration cuts—thereby avoiding repeating these mistakes for the time being—Congress still has not been able to return to a regular and predictable process of determining the annual federal budget.

Not long after the initial round of sequestration cuts hit US federal agencies, policymakers in Congress were again unable to come to a budget agreement, resulting in a federal government shutdown in October 2013. Although the government re-opened after two and a half weeks, the impact of the shutdown on health research efforts was serious. The shutdown had an immediate impact on health and research programs across the US government:

- The **NIH** suspended new clinical trials as soon as the shutdown began. The agency did not process grant applications during the shutdown and ordered 73 percent of its more than 18,600 employees to stay home.
- While many of **USAID's** ongoing programs remained safe during the shutdown by using existing funding, the agency did not invest in any new R&D funding, contracts, or grants during this period.
- The **CDC** continued to operate some activities funded through mandatory spending, but the shutdown impacted the agency's ability to support much of its ongoing R&D and disease surveillance activities. Additionally, two-thirds of the CDC's staff were furloughed.

- The **FDA** continued activities related to critical public health issues but ceased the majority of laboratory research, routine inspections, monitoring, and notification programs. The agency also reported that product approval times may be delayed as a result of understaffing.

For long-term research of global health products, the impact of the shutdown could be severe and lasting. Losing weeks of data collection during a critical research period or two weeks of a key experiment that took months or years to set up will have repercussions for years, slowing or even stopping the development of promising new health tools currently in the research pipeline. With so many new global health products nearing completion, these delays and budget cuts not only harm future research projects, they put years of earlier investments at risk.

Sequestration and the government shutdown have far-reaching effects on health research, thereby delaying or halting the development and delivery of groundbreaking new tools with the potential to save lives and improve public health around the world. Moreover, they damage the United States' reputation as a leader in science, hurt the American economy, and cost domestic jobs. Countless scientists at federal agencies were furloughed during the government shutdown, and cutting millions of dollars to critical health research is chasing away a generation of young American scientists. The economic benefits of the US investment in research are wide reaching, and federal agencies must be assured of the funding they need to continue vital health research in the spirit of protecting global public health, patients' lives, scientific careers, and the domestic economy.

The United States now stands at a critical juncture. US policymakers recently passed into law a budget plan that prevents another government shutdown, eases some of the pain from sequestration cuts, affords a small increase in discretionary spending, and provides some degree of budget stability. Unfortunately, the plan does not provide a long-term, comprehensive fiscal solution. Although the budget compromise continues underfunding of key global health R&D programs like those at the NIH, this budget deal is a good step forward. However, US policymakers still need to develop a long-term and reliable solution to permanently avoid the inconsistent budgeting process they have adopted in recent years.

Policymakers in Congress and the Administration are also beginning the process to determine the fiscal year (FY) 2015 appropriations. It is critical that leaders in Congress and the Administration agree upon a federal budget for FY 2015 that protects global health research and other key programs at the CDC, DoD, FDA, NIH, and USAID. The FY 2015 federal budget should fund global health and R&D programs at robust levels, as the cuts to global health and R&D programs seen in recent years are damaging and severely hinder scientific progress. Additionally, federal agencies are responsible for protecting global health R&D funding in their budget plans. Agencies themselves should therefore secure robust funding and support for the global health R&D programs under their purview.

Finally, the current fiscal climate means that traditional public financing is uncertain. Given this reality, US policymakers should also increasingly look to incentives and innovative financing mechanisms to ensure that health R&D progress can continue. These mechanisms leverage shrinking US funding, create efficiencies, and catalyze investments from all sectors needed for successful global health product development.

In 2013, sequestration resulted in damaging cuts to global health R&D programs.

Photo: PATH/Evelyn Hockstein.

THE DEVASTATING IMPACT OF SEQUESTRATION ON US AGENCIES ENGAGING IN GLOBAL HEALTH R&D

After policymakers in Congress and the Administration were unable to reach a long-term plan for the federal budget, sequestration took effect in March 2013. Sequestration resulted in automatic, across-the-board cuts to all federal global health research programs. Since taking effect, it has become clear that sequestration has the potential to halt the most promising developments in global health research and development (R&D) in years. In particular, five federal agencies that make significant contributions to global health R&D will see damaging cuts to their budgets:

- **Centers for Disease Control and Prevention (CDC)**. Sequestration required the CDC to cut 5 percent, or $285 million, of its fiscal year (FY) 2013 budget. These cuts impacted the agency's ability to protect the health of Americans at home—and also hindered its ability to ensure global disease detection. For instance, the CDC's Center for Global Health saw a cut of $18 million due to sequestration, while the National Center for Emerging and Zoonotic Infectious Diseases saw a cut of $13 million. Both of these centers support groundbreaking global health research and product development activities.
- **Department of Defense (DoD)**. Sequestration forced the DoD to implement $37 billion in overall reductions in the space of six months, according to an article on Politico. Research at the Walter Reed Army Institute of Research, the Naval Medical Research Center, and the Military HIV Research Program could be postponed or stopped altogether. These programs support research to develop tools for neglected tropical diseases, malaria, and HIV.
- **Food and Drug Administration (FDA)**. Through the FDA, the United States plays an important role in regulating global health products, which helps ensure that safe and effective health tools reach people in need worldwide. Indiscriminate budget cuts could slow the FDA's ability to review products and delay patients' access to them. For instance, the FDA lost millions of dollars in user fees in the FY 2013 sequester. Although Congress has agreed to a temporary solution to let the FDA keep its user fees in FY 2014 and FY 2015, this remains yet another example of the incredible damage that indiscriminate budget slashing can inflict.
- **National Institutes of Health (NIH)**. Sequestration slashed the agency's overall budget by $1.71 billion compared with FY 2012, to $29.15 billion, a cut of about 5 percent. As a result, the NIH expects to fund 8,283 new and competing research grants this year, a drop of 703 grants. Including ongoing grants that are ending, the total number of research grants will drop by 1,357 awards.
- **US Agency for International Development (USAID)**. Due to sequestration cuts to both USAID and the US Department of State, more than $400 million could be cut from the international aid budget. Cuts of this magnitude will severely hinder USAID's ability to continue as a leading supporter of global health product development, including for microbicide, HIV vaccine, and device research.

NEW PRODUCTS HOLD THE KEY TO BETTER HEALTH WORLDWIDE

A historical commitment to research helped create existing health tools—such as antiretroviral drugs to treat HIV and bednets to prevent malaria—that have contributed to tremendous progress in fighting disease. Unfortunately, recent decisions—or lack thereof—by US policymakers are unraveling the nation's longstanding role as a leader in science and innovation. Sequestration, flat funding levels, and the threat of federal government shutdowns are putting scientific progress at risk by reducing research budgets and creating general uncertainty about the future of US-funded health projects. Ongoing research supported by the US government and currently at risk includes:

- Several **new drugs** in the pipeline to treat tuberculosis (TB) and malaria. For example, US funding supported the development and distribution of more than 200 million courses of child-friendly Coartem® Dispersible (artemether-lumefantrine), co-developed by Medicines for Malaria Venture and Novartis, estimated to have saved 340,000 young lives between 2009 and 2013. These new drugs are an important step toward new treatment regimens for people with drug-resistant strains.
- **Modern reproductive health technologies** vital to lowering maternal mortality by avoiding unplanned pregnancies and improving birth outcomes. An estimated 222 million women in developing countries want to delay the birth of their next child or limit the size of their family but are not using contraception. Many new technologies will become available in the near future, helping to improve reproductive health for women.
- An **antiretroviral-based microbicide** that offers hope for women's HIV prevention. Even using conservative assumptions about microbicide efficacy and coverage, research conducted by the Microbicides Initiative suggests that the three-year cumulative impact of microbicide use could result in 2.5 million HIV infections averted among women, men, and children in lower-income countries. This could lead to a $2.7 billion savings in health system costs and an additional $1 billion in productivity savings gained from preventing absenteeism and retraining and replacing workers.
- **New insecticides** that could help control insects that spread diseases such as dengue fever, Chagas, filariasis, and leishmaniasis. These diseases are among the major causes of death in developing countries.
- **Cost-effective diagnostics** that are under development for malaria, HIV, and TB. These diagnostics could be administered in a variety of health care settings and could rapidly and accurately diagnose disease.
- A **preventive HIV vaccine,** which will be necessary to achieve and sustain an end to the global AIDS pandemic. Models show that adding even a partially effective HIV vaccine to the current range of prevention and treatment options could dramatically lower the rate of HIV infections.

Waning resources for health research and development (R&D) also means that countless projects not currently supported by the US government will never benefit from future US investment. Increased funding for global health R&D across the US government is desperately needed to not only sustain projects that currently receive US support—but also to bolster projects, including the examples below, that do not currently benefit from US funding.

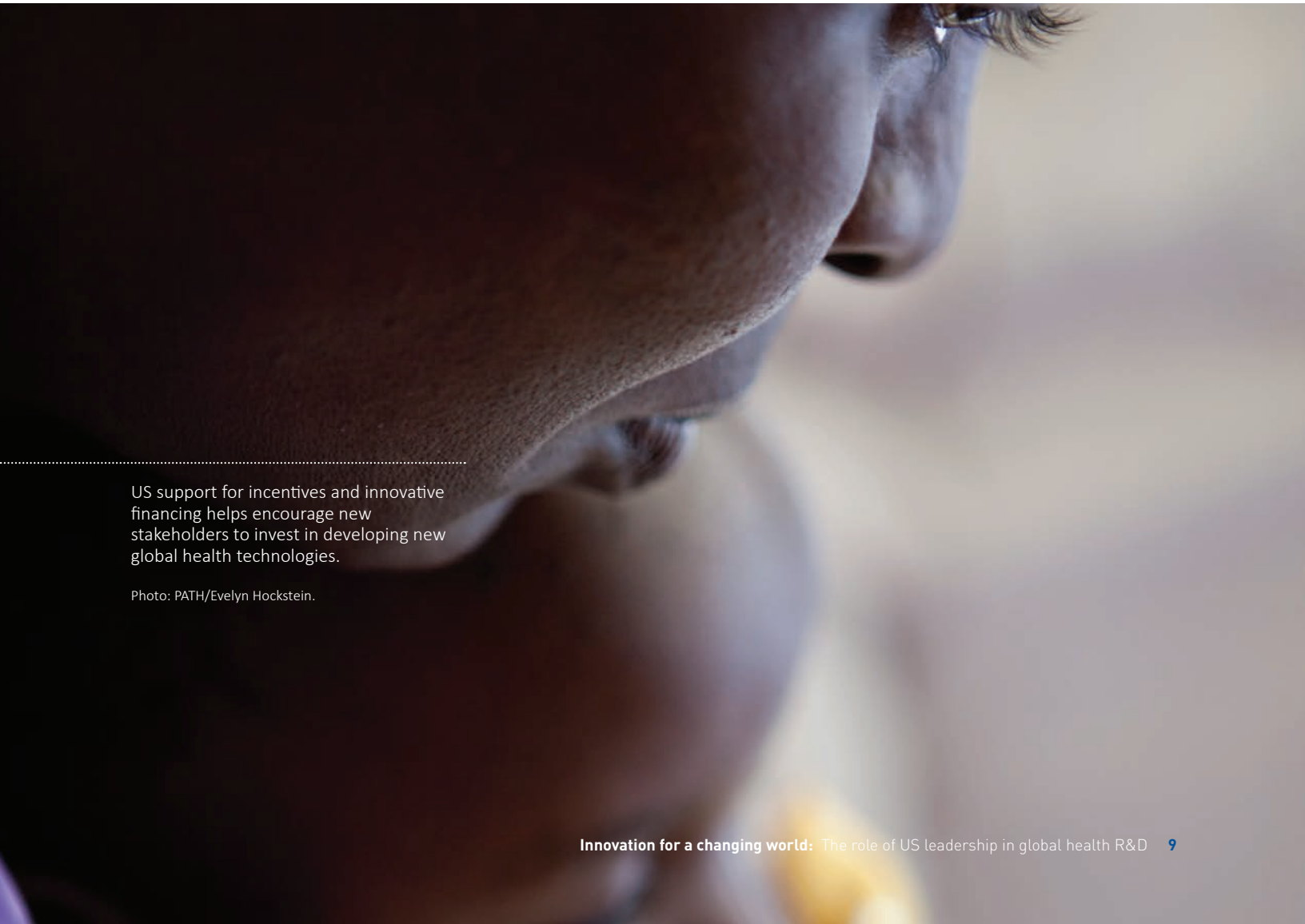
- New **vaccines for neglected tropical diseases**—such as leishmaniasis, schistosomiasis, hookworm infection, and Chagas disease—are now under development and in clinical trials. These diseases are the most common infections of the world's poor, and Chagas is now endemic in the southern United States.
- A new **oral drug for sleeping sickness**, fexinidazole, recently entered late-stage clinical trials in patients in the Democratic Republic of Congo. As a simple, short-course oral pill, fexinidazole could transform care for African sleeping sickness, which is fatal without treatment, and could potentially reduce its incidence among the most afflicted populations and accelerate elimination of the disease.
- Several candidates for a **new vaccine to prevent TB** are in Phase I or Phase II clinical trials. Preventing TB is one of the most cost-effective ways of reducing the disease's burden in endemic countries, especially with the rise of multidrug-resistant and extensively drug-resistant TB. The investment needed to develop a vaccine is a fraction of what it would cost to treat one of the world's deadliest and most expensive infectious diseases, now estimated to cost upward of $8 billion per year to support TB control efforts in low- and middle-income countries.

INCREASED US SUPPORT NEEDED FOR INCENTIVES AND INNOVATIVE FINANCING

The United States has long played a critical role in advancing incentives and innovative financing for global health research. Incentives and innovative financing mechanisms aim to encourage all stakeholders—including private biotechnology and pharmaceutical companies, nonprofit product development organizations and other groups, academic partners, and public research institutes—to invest in global health research and development (R&D). Many of these mechanisms have been implemented in the United States and other countries and include advance market commitments, priority review vouchers, prizes and small business innovation awards, procurement pools, tax credits, patent pools, and solidarity taxes.

For example, the US Department of Commerce this past year announced the winners of the US Patent and Trademark Office's (USPTO) Patents for Humanity program. USPTO launched the Patents for Humanity program in February 2012 as part of an Obama Administration initiative to promote innovations to solve longstanding development challenges, including in global health. The program is a competition that recognizes patent owners and licensees that address global challenges in health and standards of living. The winners included:

- Gilead Sciences, for making HIV drugs available to the world's poor using a network of generics manufacturers in Asia and Africa.
- University of California, Berkeley, for developing research and license agreements to provide a lower-cost, more reliable way to produce anti-malarial compounds.
- Becton Dickinson, for creating a fast, accurate tuberculosis diagnosis machine and placing 300 systems in 22 high-burden countries.



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

Photo: PATH/Evelyn Hockstein.

POLICY RECOMMENDATIONS

Congress should develop a long-term budget agreement that protects funding for global health product development. Additionally, policymakers in Congress should ensure that the 2015 federal budget demonstrates a renewed commitment to global health research, with increased funding levels wherever possible across the US government for health product development programs. Specifically, the congressional fiscal year (FY) 2015 appropriations should demonstrate strong support for global health programs at the Centers for Disease Control and Prevention (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 Food and Drug Administration (FDA) at $4.7 billion, the National Institutes of Health (NIH) at least at $32 billion, and global health programs at the US Department of State and US Agency for International Development (USAID) at $10.358 billion. Finally, Congress should include robust funding for global health research and development (R&D) within the Department of Defence (DoD) FY 2015 appropriations legislation.

Where they have budget discretion, US agencies engaged in global health product development—including the CDC, DoD, FDA, NIH, and USAID—must sustain robust investments in the discovery, development, and delivery of new tools for public health worldwide. Specifically, every global health program at these agencies should sustain and—where possible—increase funding and support for global health product development.

The Administration should protect funding levels for global health product development programs at federal agencies. Specifically, as the White House Office of Management and Budget (OMB) begins its upcoming negotiations with US agencies on the FY 2016 federal budget, OMB should ensure that global health R&D programs at the CDC, DoD, FDA, NIH, and USAID are protected from budget cuts.

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. Health technologies for different diseases are at various stages of development, and different technologies face unique scientific obstacles and potential for commercial returns. In addition, many different institutions are engaged in product development. Given this diversity, no single mechanism is capable of filling all the gaps in the product development pipeline while encouraging the full range of R&D activities needed.

"Investing in medical research not only makes certain that patients and health care providers will continue to have access to lifesaving treatments, but also ensures that innovation in the field of biomedical research will help the U.S. remain globally competitive and continue to drive economic growth."

Sen. Richard Burr (R-NC)

"Today, we at FDA recognize that to successfully protect the health of the American people—which is our mandate—we must think, act, and engage globally. Our interests must be broader than simply those within our own borders, and this requires us to be a part of, and act collaboratively with, a wider regulatory enterprise that encompasses medical product regulators worldwide."

FDA Commissioner Margaret Hamburg

Despite a challenging political climate, policymakers have advanced key policies to support global health research over the last year.

Photo: PATH/Gabe Bienczycki.

Policies and programs with groundbreaking potential

In the midst of the challenging and uncertain fiscal climate in the United States, there have been several promising developments in global health research and development (R&D) over the past year. US policymakers have taken steps to improve the global health R&D landscape, in the United States and globally. These actions have primarily focused on:

- Proposing legislation to strengthen US global health R&D programming, improve efficiencies, and enhance the transparency and accountability of US global health and foreign aid initiatives. Policymakers have also increased efforts to better align the work of US federal agencies engaged in global health product development efforts.
- Engaging in efforts to improve and streamline global regulatory processes to ensure that new health products are safe and effective and that they quickly reach the populations who need them.
- Participating in global discussions to improve the coordination and financing of global health research and development (R&D), as well as to ensure that research and innovation are included in global international development frameworks.

Legislation with the promise to advance global health and research

Over the past year, members of Congress introduced several pieces of legislation that have the potential to strengthen the US government's investments in global health and product development.

In April 2013, Reps. Albio Sires (D-NJ) and Mario Diaz-Balart (R-FL) introduced the 21st Century Global Health Technology Act, a bipartisan bill that would make several important and welcome changes to global health R&D programs at the US Agency for International Development (USAID). A companion version of the bill is expected to be introduced in the Senate soon with bipartisan support. The bill would advance US leadership in global health research, development, and introduction by solidifying USAID's product development work, promoting the alignment of global health R&D activities across the US government, and ensuring the transparency and accountability of US global health R&D activities.

US investments in foreign aid received further bipartisan support in Congress when a group of legislators in both the House and Senate introduced the Foreign Aid

Transparency and Accountability Act of 2013. Sens. Marco Rubio (R-FL) and Ben Cardin (D-MD) and Reps. Ted Poe (R-TX) and Gerry Connolly (D-VA) introduced the companion bills. The act would put in place guidelines on foreign aid that would apply to all relevant US federal agencies, along with metrics to measure progress. It would also result in greater transparency and accountability of US government foreign assistance investments.

Finally, Democrats and Republicans came together to demonstrate 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 bipartisan leadership in fighting HIV/AIDS worldwide and addressing global health challenges.

All of these pieces of legislation illustrate what can be achieved when members of Congress come together to support smart, effective, and lifesaving global health and international development programs. Policymakers in Congress should seize the opportunity to support legislation, such as the 21st Century Global Health Technology Act, that has the potential to strengthen US global health and research programs by improving efficiencies, enhancing transparency and accountability, and promoting the alignment of US federal agencies engaged in global health product development efforts.

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

The United States also has a role in regulating global health products, which helps ensure that new tools are safe and effective before they reach people around the world. In the United States and other countries, regulatory agencies—such as the FDA, European Medicines Agency, and national regulatory authorities in countries where diseases of poverty are endemic—play a critical role in this process. However, some countries with widespread epidemics do not have the expertise or resources to appropriately review new health tools or monitor clinical trials. This can result in long delays in bringing critical drugs, vaccines, and diagnostics to people who need them most, or in unregulated access to unsafe health products.

In an effort to help address regulatory issues worldwide, the FDA has played an increasingly critical role in global health over the past several years. This support has primarily taken the form of leading numerous international programs, as well as building global regulatory partnerships to better coordinate regulatory activities worldwide and equip local regulatory authorities with the skills they need to independently facilitate medical product reviews. And as a stringent regulatory authority, the FDA's review of products can often facilitate subsequent review in the countries where the products ultimately will be used.

Despite these successes, there are still several areas where the FDA can build upon its recent global activities to make the biggest possible impact on the lives of people around the world. For instance, the neglected tropical disease Chagas currently is not on the list of global health conditions for which the FDA is legally allowed to conduct priority review of health products under the Priority Review Voucher program. The agency should therefore ensure its authority to review health products for all neglected diseases. Additionally, where it has budget authority, the FDA should sustain robust investments in its global health work. Because the FDA also needs support from Congress to carry out its global activities, Congress should provide the agency with sufficient funding and authority to do so.

Engaging in global discussions

Over the past year, US policymakers have engaged in ongoing global discussions that will have critical implications for global health research, science, and product development.

The first area focuses on a global effort to improve the financing and coordination of neglected disease R&D. This effort follows the 2013 World Health Assembly (WHA), at which Member States passed a resolution that, among other activities, calls for the implementation of several health R&D demonstration projects to address identified gaps that disproportionately affect low- and middle-income countries.

Recently, the US government—through the Department of Health and Human Services (HHS)—has been involved in discussions with other WHA Member States regarding global health R&D demonstration projects. At the most recent World Health Organization Executive Board meeting in January 2014, representatives from Member States agreed that selected demonstration projects be further evaluated during a series of meetings to be held later this year. Demonstration projects endorsed at the

WHA will then move forward for implementation, if funding is secured. It is critical that the US government use its position as a global leader to ensure that the demonstration projects selected at the WHA are high impact and that new funding is available to support their implementation. Additionally, the US government should ensure that a monitoring and evaluation plan is established to track progress and ensure that the selected demonstration projects are scalable and improve global health R&D coordination and financing.

The second area of focus is ongoing discussions about a new international development framework to replace the current Millennium Development Goals (MDGs), a set of eight global development targets which expire in 2015. The US government—through agencies such as USAID and HHS—has been involved in discussions about priorities and targets that should be included in the post-2015 development agenda. So far, there have been promising signs that research, science, and innovation will be included as components—at least to some degree—in the post-2015 agenda.

Previous investments in research to develop new vaccines, drugs, diagnostics, and other health tools have helped to propel progress toward the MDG targets. Global health research has also led to some of the greatest global health advances to date, saving countless lives and resulting in billions of dollars in cost savings. According to a recently released report from a group of global experts, an estimated 11 percent of economic growth between 2000 and 2011 was attributable to reductions in mortality, much of it driven by the development and delivery of new health tools.

The US government must therefore ensure that a strong and explicit commitment to global health research, science, and innovation is included in dialogues and discussion on the post-2015 agenda published by the UN Foundation, particularly as the Sustainable Development Goals are developed. International commitments to R&D will be critical to realize new development goals while contributing to economic development through improved health and strengthened capacities for science, technology, and innovation.

These discussions present the United States with the opportunity to ensure that a commitment to health R&D and innovation is demonstrated on a global scale, thereby strengthening its role as a leader in science and research for health and development.

21ST CENTURY GLOBAL HEALTH TECHNOLOGY ACT

Reps. Albio Sires (D-NJ) and Mario Diaz-Balart (R-FL) demonstrated bipartisan support for global health research and development (R&D) when they introduced the 21st Century Global Health Technology Act. The bill would help make great inroads in global public health by strengthening global health research throughout the US Agency for International Development's (USAID) health portfolio. The bill would:

- Formalize the current HealthTech program, which, for two decades, has ensured that products and medicines developed for use in low-resource settings reach the people who need them.
- Establish USAID's mandate to conduct R&D within its health programs, and request that research be included as part of each type of global health work it undertakes.
- Request reporting from USAID to Congress on its health-related R&D strategy, including its collaboration and coordination with other federal departments and agencies, to increase transparency.
- Request that USAID work with other agencies to develop a cross-US government strategy for global health research. The United States is currently involved in 200 of the 365 global health products in the R&D pipeline, with work spread among several agencies, including USAID. It is important to coordinate funding, monitoring, and strategy across the entire US government global health R&D environment.
- Support USAID's Center for Accelerating Innovation and Impact, as well as the elevation of the Science and Technology division as a whole.
- Require no new funding. The 21st Century Global Health Technology Act focuses on existing resources and programs and makes them more streamlined to increase efficiency and efficacy.

STRONG SUPPORT FOR GLOBAL HEALTH R&D AT US AGENCIES

In addition to Congress, several federal agencies in the US government play critical and unique roles in global health research and product development. Over the past year, the Department of Defense (DoD), the Centers of Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the US Agency for International Development (USAID) have demonstrated their continued support for global health research, science, and product development. Examples of scientific and policy advances over the past year are listed below.

DoD: The US Military HIV Research Program (MHRP) continued its efforts to develop a safe and effective HIV vaccine. Researchers began screening participants for a new follow-on study, supported by MHRP, to the RV144 HIV vaccine candidate regimen. MHRP also announced that it was selected as a Clinical Trials Unit and will receive funding from the US National Institute of Allergy and Infectious Diseases to continue work on HIV vaccine and therapeutics research.

CDC: The CDC's National Center for Emerging and Zoonotic Infectious Diseases sustained its strong support of global health product development, advancing research and development (R&D) for new tools such as a dengue vaccine, a plague dipstick test, and a low-cost rabies test.

NIH: The agency continued to advance World RePORT, a system developed by the NIH to track biomedical research funded by the agency worldwide. The NIH also announced that it is investing $100 million over the next three years in the search for an HIV/AIDS cure.

USAID: USAID announced several promising developments in global health innovation over the past year. First, the agency released a report to Congress on its activities in and strategy for global health R&D. In the report, USAID outlined its strategy for global health R&D from 2011 to 2015, which includes continued support for the critical work of the agency's Center for Accelerating Innovation and Impact. The agency's Saving Lives at Birth: A Grand Challenge for Development program also announced new award nominees for innovative solutions to prevent infant and maternal deaths globally.

Finally, a new paper authored by an interagency team from USAID, the CDC, and the NIH outlined the US government's position on promoting research and innovation in global health. It also provides guidance to US missions overseas on how to successfully support research and innovation in the field and tap into technical support in US agency headquarters.

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

Photo: PATH/Evelyn Hockstein.

The FDA plays an important role in ensuring that new global health tools reach those who need them most.

Photo: PATH/Gabe Bienczycki.

Member States have called upon the WHO to improve financing and coordination of global health research.

Photo: PATH/Evelyn Hockstein.

A HISTORY OF GLOBAL ENGAGEMENT

The Food and Drug Administration (FDA) has demonstrated through several recent actions that it can expedite the introduction of global health tools. These include:

- The launch of numerous international programs from its headquarters in the United States and operation of offices and posts in ten countries across the globe, which opened within the last decade. A few years ago, the agency established the Office of International Programs to coordinate and oversee the many global efforts that were initiated over time.
- The FDA's program to review HIV/AIDS drugs delivered in the developing world through the President's Emergency Plan for AIDS Relief.
- The coordination of research and product development to deliver health solutions faster. For instance, the FDA established the Critical Path Initiative to close the gap between early-stage biomedical research and product development.
- The agency's partnership with global bodies, such as the World Health Organization (WHO), to enhance access to medicines for neglected diseases and assist other countries in bolstering their regulatory capacity. Just this past year, the FDA announced a five-year, $7.5 million contract with WHO to support regulatory science and enhance global regulatory capacity. The funding will support WHO's efforts to provide substantial regulatory support to many of its 193 Member States.
- The FDA's contribution to advancing regulatory science by issuing guidance on the co-development of two or more investigational new drugs, which is meant to accelerate the development of novel tuberculosis (TB) drug regimens that can treat both drug-susceptible and drug-resistant TB.

THE WORLD HEALTH ASSEMBLY AND GLOBAL HEALTH R&D

At the World Health Assembly in May 2013, Member States passed a resolution on global health research and product development that, among several priority activities, called on the World Health Organization (WHO) director-general to:

- Establish a global health research and development (R&D) observatory within WHO's Secretariat to monitor and analyze relevant information on health R&D, building on national and regional observatories and existing data collection mechanisms. The observatory would ultimately help identify gaps and opportunities for health R&D and define priorities in consultation with Member States and other stakeholders.
- Facilitate the implementation of a few health R&D demonstration projects to address gaps that disproportionately affect developing countries.
- Review existing mechanisms in order to assess their suitability in coordinating health R&D.
- Explore and evaluate existing mechanisms for contributions to health R&D, and, if there is no suitable mechanism, develop a proposal for effective mechanisms, including pooling resources and voluntary contributions, as well as a plan to monitor their effectiveness independently.

RESEARCH IN THE POST-2015 DEVELOPMENT AGENDA

The post-2015 development agenda refers to a process led by the United Nations (UN) to define the future global development framework. It will succeed the MDGs, which come to an end in 2015.

Preliminary work on the successors to the millennium development goals (MDGs) began in 2011, when UN Secretary-General Ban Ki-moon mandated both an internal UN working group and a high-level panel on the post-2015 development agenda. Since 2012, there have been worldwide official consultations about future development priorities.

In July 2012, the UN Secretary-General appointed an advisory group comprising civil society, private-sector, and government leaders to a High-Level Panel of Eminent Persons on the Post-2015 Development Agenda. In May 2013, the High-Level Panel submitted a report to the Secretary-General on its recommendations on how to arrive at an agreement on the post-2015 agenda. The report's 12 goal areas include a focus on science and innovation, which is a promising start.

However, there is a strong need for greater recognition about the role of new medical innovations in the post-2015 development agenda. US policymakers and world leaders must ensure that an explicit commitment to global health science, research, and product development is a key component of the final post-2015 development framework.

US policymakers can help ensure this goal is realized in several upcoming discussions. For instance, the United States and other UN Member States will debate the post-2015 agenda at the UN General Assembly in September 2014. US leaders will also have the opportunity to continually advocate for the inclusion of global health research and science as Member State negotiations continue into 2015.

World leaders must ensure that innovation is a component of the post-2015 development agenda.

Photo: PATH/Evelyn Hockstein.

POLICY RECOMMENDATIONS

Congress should pass the 21st Century Global Health Technology Act. The bill includes key provisions that would strengthen US global health research and development (R&D) programming, improve efficiencies, and enhance the transparency and accountability of US global health and foreign aid initiatives. It would also help to align the work of US federal agencies engaged in global health product development efforts.

The Food and Drug Administration (FDA) should leverage its expertise to address regulatory issues worldwide. In recent years, the agency has demonstrated noteworthy leadership and interest in global health. To maximize its impact on global public health, the agency's leadership should continue to elevate global issues in its mandate by allocating funding to match the FDA's global health commitments and for all internal activities related to neglected diseases and reinforcing its authority and willingness to review health products for all neglected diseases. The Administration, through the Department of Health and Human Services (HHS), should also support the FDA's increasing engagement in global health.

The US government should increasingly collaborate with other governments and donors worldwide on discussions around global health R&D coordination and financing. At the upcoming WHA in May 2014, Member States will endorse global health R&D demonstration projects for implementation, in an effort to better coordinate and fund global health product development activities worldwide. The US government should work with other Member States to ensure that the selected demonstration projects are high impact and that new funding is available to support their implementation. Additionally, the US government should work with other Member States to ensure that a monitoring and evaluation plan is established. This will help to track progress and ensure that the selected demonstration projects improve global health R&D coordination and financing, and operationalize key principles of the Consultative Expert Working Group on Research and Development: Financing and Coordination report, for example, ensuring affordability and access.

US policymakers should ensure that global health research is included as an integral component of the Sustainable Development Goals being established through dialogue and debate on the post-2015 development agenda. As they engage with global decision-makers—including through Member State negotiations beginning in 2014—US policymakers, particularly those at HHS and the US Agency for International Development (USAID), should work to include an explicit and strong commitment to science and innovation in the post-2015 development framework in order to acknowledge the critical role of research and product development in accelerating and sustaining progress in global health and economic development.

"Today, we at FDA recognize that to successfully protect the health of the American people—which is our mandate—we must think, act, and engage globally. Our interests must be broader than simply those within our own borders, and this requires us to be a part of, and act collaboratively with, a wider regulatory enterprise that encompasses medical product regulators worldwide."

FDA Commissioner Margaret Hamburg

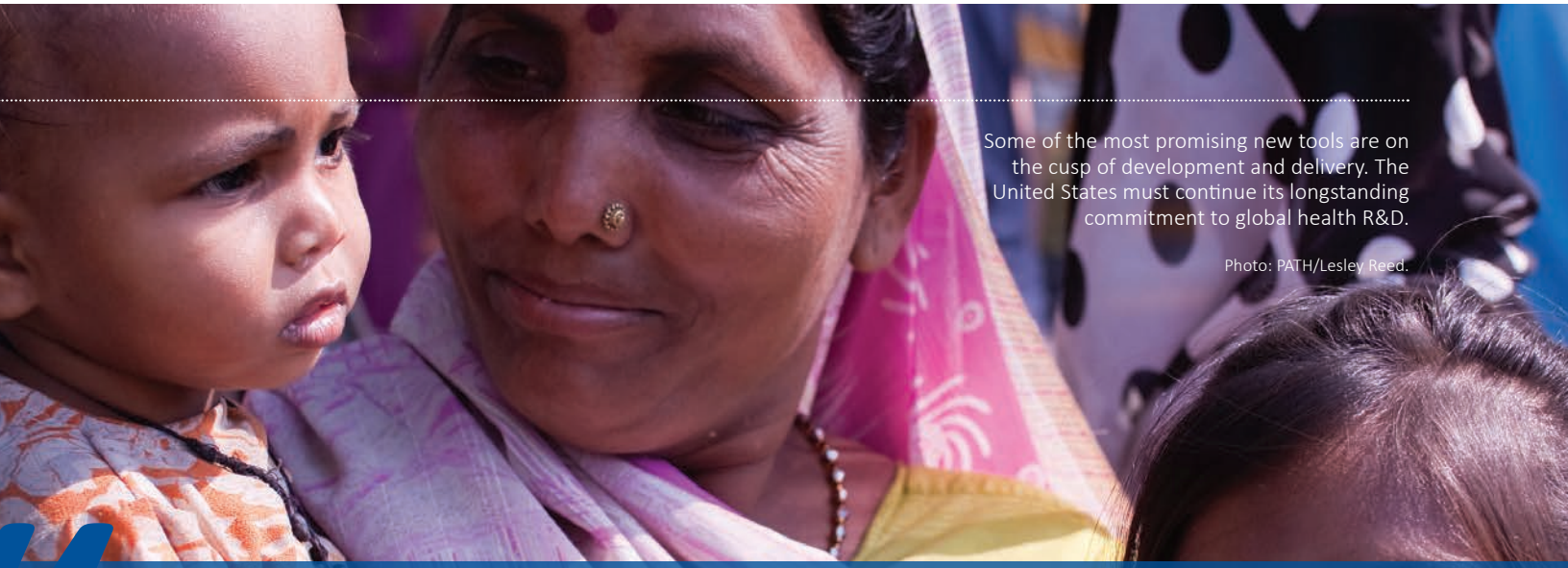
Conclusion

Some of the most promising new tools are on the cusp of development and delivery. The United States must continue its longstanding commitment to global health R&D. Photo: PATH/Lesley Reed.

Thanks to US support for global health research, Americans and millions of people around the world no longer live in fear of diseases such as polio and measles, and many living with infectious and neglected diseases are living longer, healthier lives. The world is now at an important turning point: there are more global health products in the research pipeline than ever before—365 as of April 2012. Astoundingly effective tools, which have resulted in incredible gains for health around the world, are available now because of the historical commitment to research and development (R&D). With so many of tomorrow's new tools on the cusp of development and delivery, we cannot lose ground by pulling back from the United States' legacy in health research.

Reducing US support for health R&D will interrupt scientific progress and leave us without the tools we urgently need to address health needs worldwide. Many biomedical studies cannot survive cuts in funding in the middle of their work. Halting funding would also mean that the world may never benefit from these tools that are so close to development and delivery. Within the next five years, researchers expect new groundbreaking technologies to be developed, and the potential impact of this research is enormous.

US investments have helped create the largest global health product development pipeline in history, which has the potential to deliver some of the most promising solutions to fight infectious diseases at home and abroad. US leaders should seize upon these recent successes and use the recommendations in this report to ensure that the nation continues its longstanding commitment to global health R&D.



Some of the most promising new tools are on the cusp of development and delivery. The United States must continue its longstanding commitment to global health R&D.

Photo: PATH/Lesley Reed.

"We know that the nation that goes all-in on innovation today will own the global economy tomorrow... That's why Congress should undo the damage done by last year's cuts to basic research so we can unleash the next great American discovery – whether it's vaccines that stay ahead of drug-resistant bacteria, or paper-thin material that's stronger than steel"

President Barack Obama

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

AVAC AIDS Vaccine Advocacy Coalition

DNDi North America Drugs for Neglected Diseases *initiative*

fhi360 THE SCIENCE OF IMPROVING LIVES

FIND foundation for innovative new diagnostics

gapps 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

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Research America An Alliance for Discoveries in Health

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