Global Health Technologies Coalition

2013 Policy Report

Renewing US leadership:

Policies to advance global health research

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About the Global Health Technologies Coalition

The Global Health Technologies Coalition (GHTC) is a group of more than 25 nonprofit organizations working to increase awareness of the urgent need for tools that save lives in the developing world. These tools include new vaccines, drugs, microbicides, diagnostics, and other devices. The coalition advocates for increased and effective use of public resources, incentives to encourage private investment, and streamlined regulatory systems. The GHTC is housed at PATH.

The Global Health Technologies Coalition's 2013 policy report is available online at **www.ghtcoalition.org.**
More information about these issues can be shared by request from **info@ghtcoalition.org.**

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"Our future depends on reaffirming America's role as the world's engine of scientific discovery and technological innovation. Our policies should be based on the best science available and developed with transparency and public participation."

~ President Barack Obama

Introduction

The fruits of science have saved the lives of millions around the world. Investments in research from a range of global partners has led to the creation of new vaccines, drugs, and other health tools that eliminated smallpox, dramatically reduced measles cases, and contributed to the near-eradication of polio across the globe. More recent scientific breakthroughs contributed to the development of lifesaving vaccines, drugs, diagnostics, devices, insecticides and other products for HIV/AIDS,[1] tuberculosis (TB),[2,3] malaria,[4,5] women's health,[6,7] neglected tropical diseases,[8-10] and childhood killers such as diarrhea and pneumonia.[11]

The United States government and its citizens have long invested in the promise of science and innovation, supporting lifesaving health discoveries like those listed above. In fact, the US government is the largest supporter of global health research and development (R&D) in the world.[12] Health research breakthroughs not only serve a remarkable humanitarian purpose; US investments in global health R&D reap domestic rewards by creating US jobs, spurring business activity, and engaging a range of partners in the US private, nonprofit, public, and academic sectors. R&D also guarantees that new medical products will have a much greater public health impact at a lower cost, thereby reducing expenditures over the long term.

In order to sustain the progress in global health product development and to address emerging and evolving needs, continued support from the US government and its domestic and international partners is needed. For many neglected diseases, adequate drugs, vaccines, and diagnostics simply do not exist. Infectious diseases still claim the lives of millions each year, and emerging challenges such as drug and insecticide resistance pose a threat to health across the globe. New vaccines, drugs, tests, and other health tools are desperately needed, and progress cannot be made without a sustained investment in R&D.

This report offers actionable recommendations that Congress and the administration can implement to strengthen the US legacy in global health R&D and, more importantly, save lives around the world. These recommendations are especially timely, given that the US government is facing contentious budget negotiations that will have critical implications for its wide range of R&D activities that stretch across numerous federal agencies, departments, and branches. Recommendations include:

- Congress and the administration must protect and—where possible—increase funding for global health research and product development. Policymakers must prevent sequestration and ensure that the 2014 federal budget demonstrates a renewed commitment to global health research, with bolstered funding levels across the US government for R&D programs.
- Where they have budget discretion, US agencies engaged in global health research and product development must sustain robust investments in the development and delivery of new tools for public health worldwide.
- The US government should develop a strategy to coordinate its global health research and product development efforts.
- The US Food and Drug Administration (FDA) should continue to elevate global health in its mandate by creating an office of neglected diseases, building stronger partnerships with global regulatory stakeholders, ensuring that it can review health products for all neglected diseases, taking steps to increase transparency by reporting to Congress on its neglected disease activities, and strengthening its internal capacity on global health.
- The US government should collaborate with other governments and donors worldwide on incentives, innovative financing, and R&D funding coordination—particularly at the upcoming World Health Assembly (WHA) negotiations on a proposed global health R&D framework.

There could not be a better time for the United States to renew its global health R&D legacy, as President Obama's administration—now charting a course for its second term—and new and returning lawmakers in Congress are setting the country's fiscal and policy priorities. Global health R&D must be among these priorities. The global magnitude of sickness and death caused by these infectious diseases is enormous, and Americans are increasingly at risk. US leaders must address fiscal challenges and simultaneously strengthen the country's resolve to prevent millions of needless deaths, harnessing American ingenuity and partnerships with the private, philanthropic, and academic sectors to catalyze the development of products needed to disarm major global health threats. Science offers great promise, and there is much to lose by pulling back now.

Advancing global health research in challenging fiscal times and changing leadership

Due in large part to unflagging support for global health R&D from the United States and its partners, there has been a remarkable increase in the number of global health products developed in recent years, with 45 new tools registered between 2000 and 2010. The US government was involved in the development of more than half of these new, lifesaving health tools introduced in the beginning of the 21st century.[12] Additionally, the US government contributes around 45 percent of the total investment in global health R&D each year and 70 percent of all government investment worldwide.[12]

Global public health science is now at a critical juncture, with 365 new global health products in the research pipeline as of April 2012. The US government supports R&D efforts for 200 of these promising new tools.[12] Much of this support from the US government for global health R&D comes from federal agencies such as Centers for Disease Control and Prevention (CDC), the Department of Defense (DoD), the FDA, the National Institutes of Health (NIH), and the US Agency for International Development (USAID). These agencies demonstrate a continued commitment to innovation for global health products, including new medicines, vaccines, diagnostics, microbicides, devices, and insecticides. Each of these US agencies works with a range of academic, nonprofit, private-sector, US government, and international partners to advance global health R&D, bringing much-needed and unique skills, resources, and expertise (see "Critical and unique expertise across the US government").

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Policy recommendations

US leadership in science and innovation has transformed global public health. Many game-changing and lifesaving scientific advances are now within reach, while hundreds of new products are in the research pipeline. Even in these difficult fiscal times, US policymakers must persist in their support of global health research. The Global Health Technologies Coalition (GHTC) recommends the following actions:

- **Congress and the presidential administration must prevent sequestration and develop a long-term budget solution that protects and—where possible—increases funding for global health product development.** Additionally, policymakers in Congress and the administration must ensure that the 2014 federal budget demonstrates a renewed commitment to global health research, with bolstered funding levels across the US government for product development programs.
- **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.

Critical and unique expertise at US agencies

Several federal agencies and branches in the US government play critical and unique roles in global health research and product development, complementing each other in important ways through activities such as data and information sharing. Congress, CDC, DoD, FDA, NIH, and USAID have historically supported efforts to develop lifesaving health tools—examples of scientific and policy advances over the past year are listed below.

PATH/Evelyn Hockstein

The **CDC** developed a new diagnostic test to detect the dengue virus in people with symptoms of dengue fever. The test was also approved by the FDA for use in the United States and can be performed using equipment and supplies that many public health laboratories already use to diagnose the flu.[13]

DoD's Walter Reed Army Institute of Research continued to advance R&D for an HIV/AIDS vaccine, as new research revealed increased efficacy of the RV144 HIV vaccine candidate against certain strains of the virus.[14] Additionally, the **US Military HIV Research Program** has joined partners from the public, private, and philanthropic sectors to create a collaborative effort to carry forward a coordinated, multicountry effort to follow up on promising RV144 trial results.[15]

The **FDA** awarded additional grants to spur the development of new vaccines and drug regimens to combat TB, continuing the agency's support for both a TB vaccine and drug product development partnership over the past two years that includes US academic institutions in Maryland, Missouri, and New York.[16]

The **NIH's National Institute of Allergy and Infectious Diseases** awarded a grant to the biotechnology company Antigen Discovery for its efforts to develop a malaria vaccine, as well as a diagnostic test that can predict vaccine-provided protection against the disease.[17] The **NIH's Fogarty International Center** and other centers also announced that they are awarding $20.3 million over the next five years to build a network of US academic institutions to provide a mentored research experience in developing countries to early-career scientists, physicians, and other health professionals.[18]

USAID administrator Rajiv Shah released his annual letter, outlining major issues and initiatives that have shaped the agency since its inception 50 years ago. Shah charted a course forward for USAID, detailing areas that the agency should focus on in the coming years to make inroads in international development. One major area of focus was global health, and Shah emphasized the role of science, technology, and innovation in meeting USAID's international health goals through R&D for drugs, vaccines, and other tools for issues such as child health and HIV.[19]

Congress has also introduced key pieces of legislation over the past year that can help advance global health research. Rep. Barbara Lee (D-CA) released the *Ending the HIV/AIDS Epidemic Act of 2012*, which outlines a policy and financing framework to achieve an AIDS-free generation in the United States and globally. The bill calls for accelerated research to develop new HIV prevention and treatments tools, a cure, and a vaccine.[20] Congress also recognized the importance of the FDA in domestic and global health issues, passing the *FDA Safety and Innovation Act*.[21] Provisions in the act—which President Obama also signed into law—provided the FDA with much-needed funding to carry out regulatory activities, including those for global health products. Finally, former Rep. Howard Berman (D-CA) introduced the *Global Partnerships Act of 2012*, which would reform US foreign assistance efforts, including those focused on global health. The bill would also promote research and innovation in US foreign assistance efforts.[22]

New products hold the key to health improvement worldwide

Previous US government investments in research to develop new vaccines, drugs, diagnostics, microbicides, devices, insecticides, and other tools have led to some of the greatest advances in global health to date, saving countless lives and resulting in billions of dollars in cost savings.

- An innovative vaccine-development model formed between PATH and the World Health Organization (WHO) brought together partners from four continents and resulted in MenAfriVac™, the first-ever vaccine developed specifically to address an African health issue. The vaccine, which targets meningitis A, has since been delivered to more than 100 million people in Africa's meningitis belt since its launch in 2010. No cases of meningitis A have been reported in those who received the vaccination.[23]
- A new diagnostic test for TB, called GeneXpert, was launched in 2010 by the Foundation for Innovative New Diagnostics and its partners. The test offers the potential to more quickly and easily identify infection and could speed treatment to improve changes of survival for patients and reduce the burden on health workers' time.[12]
- Since 2009, the distribution of more than 150 million courses of child-friendly Coartem® Dispersible (artemether-lumefantrine), co-developed with Novartis and the Medicines for Malaria Venture, is estimated to have saved 340,000 young lives from malaria.[24]

With increased investment and support from the US government, further gains are achievable. Ongoing research that promises new breakthroughs for global health include:

- The 2010 results of an advanced clinical trial of an **ARV-based microbicide** offer hope for women's HIV prevention. Though more testing is needed, a microbicide could give women the power to protect themselves with or without their partners' cooperation. In sub-Saharan Africa, where the epidemic has hit hardest, women 15 to 24 years old are at least twice as likely to be infected with HIV as young men.
- **New insecticides** 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.
- A new drug, bedaquiline, recently became the first **new TB treatment** approved in more than 40 years. Another treatment, delamanid, is on the verge of approval. These new drugs are an important first step toward a new treatment regimen for people with multidrug-resistant TB that will be more effective and better-tolerated. Almost 44 percent of patients with TB in countries like Russia, Peru, and Thailand are resistant to at least one second-line drug.
- **Modern reproductive health technology** holds the key 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, ensuring that reproductive health for all people will improve.
- **New vaccines for neglected tropical diseases** such as leishmaniasis, schistosomiasis, hookworm infection, and Chagas disease are now under product development and in clinical trials. These diseases are the most common infections of the world's poor, while Chagas disease is now endemic in the southern United States, and leishmaniasis is infecting American troops returning from the Middle East.[25]
- **A new oral drug for sleeping sickness**, fexinidazole, recently entered late-stage clinical trials in patients in the Democratic Republic of the 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.[26]
- Investments in discovery science and clinical research have brought researchers closer than ever to a **preventive HIV vaccine**, a tool that will be necessary to achieve and sustain the global AIDS pandemic's end. Modeling projections show that under current trends of HIV incidence, a vaccine of only 50-percent efficacy given to a third of the population in low- and middle-income countries could prevent around one-fifth of new infections.[27]
- The **RTS,S malaria vaccine** candidate is currently being tested and could be available for young children as early as 2015. Such a vaccine would reduce the burden of sickness and death from malaria. Every year, malaria kills hundreds of thousands of people, most of them young African children.

MenAfriVac is a trademark of Serum Institute of India Ltd.
Coartem Dispersible is a registered trademark of Novartis Pharma AG.

Almost 400 new global health products are in the research pipeline, and the US government is supporting more than half of these promising candidates. A consistent US investment in R&D will provide the momentum needed to push promising new tools over the research finish line.

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A continued and consistent US investment in R&D, supporting all stages of the global health research pipeline, will provide the momentum needed to push promising new tools over the research finish line. However, at the same time that research and innovation are offering the possibility of new health tools that can make an impact around the world, the political and economic environment in the United States is changing dramatically. Budget constraints over the past few years—both in the United States and globally—mean that even the most essential programs are at risk, including funding for global health product development. These budget constraints are resulting in harmful reductions in US support for global health R&D, which put the nation's legacy as a scientific and humanitarian leader at risk. In addition, the very nature of the R&D process means that budget cuts will have long-lasting and damaging effects on current and future health tools already in the research pipeline. Once interrupted by funding reductions, many R&D projects halt and cannot be seamlessly picked up again if funding is resumed in the future. Stopping or prolonging the R&D process causes scientific regression, undermining past investments and resulting in increased long-term costs by delaying the introduction of more efficient and effective products.

The nation is operating under uncertain and unorthodox budgetary times, which places enormous constraints on global health R&D. In January 2013, policymakers in Congress and the White House crafted a compromise budget measure that delays the so-called "fiscal cliff" by raising taxes for wealthier Americans but deferring decisions on widespread and indiscriminate federal budget cuts—or sequestration—by two months.[28] The delay means that lawmakers will debate sequestration at the same time as they make decisions on the federal budget for the rest of fiscal year (FY) 2013 and all of FY 2014.

The FY 2013 and 2014 budget plans and sequestration will have widespread effects on funding levels for global health and R&D programs across the US government. It is vital that the final FY 2013 and FY 2014 budgets reverse the trend of decreased global health and R&D funding seen in recent years. The latest Global Funding of Innovation for Neglected Diseases (G-FINDER) survey, for example, detailed a decline in US government investment in global health research and product development that totaled more than $30 million in 2011. This marks the second consecutive year of funding cuts, which means that US funding for global health R&D is now more than $100 million below its 2009 peak.[29]

This downward trend noted by the G-FINDER report was also reflected in the draft versions of FY 2013 appropriations bills, which have threatened some global health and R&D programs at CDC, DoD, FDA, NIH, and USAID with flat funding

levels or severe cuts.[30-32] Even flat funding creates the potential for fewer medical research grants from NIH, diminished support from USAID for clinical trials, and other harmful effects on research activities.

There are hopeful signs that congressional support for global health R&D programs could result in repaired funding levels for 2013. For instance, some Senate committees with oversight of CDC, FDA, NIH, and USAID included increased FY 2013 funding levels for these agencies in draft appropriations bills, compared with House appropriations bills.[33-35] It is unclear whether Congress will ultimately pass these higher numbers in the final budget process, but the attempt to increase global health and R&D budgets is welcome. Additionally, members of Congress have included important language in

> *"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)

At risk: US legacy in global humanitarian and health research efforts

As the global financial crisis and the prospect of a domestic fiscal cliff impacted federal budget negotiations in the United States, new data emerged that revealed the effects of declining US support for global health and R&D programs.

Major federal programs would be set back: In 2012, several reports were released that detailed potential negative outcomes for federal research programs and people's lives worldwide. Sequestration would result in automatic and sweeping cuts to all federal programs in order to reduce government spending by $109 billion per year for nine years. The White House's Office of Management and Budget released a report on the potential impact of sequestration on federal agencies, which found that sequestration would result in cuts as high as 9.4 percent and almost $700 million for agencies such as CDC, DoD, FDA, NIH, and USAID.[36-38] Other reports found that cutting funding for global health and R&D programs would barely make a dent in reducing the US federal deficit but would have a crippling impact on people's health and lives around the world.[38]

US investments in global health R&D have already been cut: The December 2012 G-FINDER survey provided a five-year review of global investments in neglected disease R&D. It found that while the United States has maintained its position as the top funder of neglected disease R&D, US funding still decreased in 2011 by $30.6 million. US funding is now more than $100 million below its 2009 peak. The majority of the decrease in US funding came from NIH, which reduced global health R&D funding by $27.6 million—these decreases are likely due to the end of funding from the *American Recovery and Reinvestment Act*.[39] Other decreases were seen from USAID ($4.6 million) and CDC ($3.9 million).[29]

Product development partnerships, essential for progress, are stretched thin with low budgets. The United States and other donors have begun to shift away from product development, instead focusing on early-stage, basic research. This contributed to a drop in funding of more than $128 million since 2008 for product development partnerships (PDPs), which are key drivers of new global health tools.[29] PDPs accounted for an impressive 40 percent of new global health products registered between 2000 and 2010.[12] These changing investment patterns put the development of new products for neglected diseases at risk.

While research and innovation are offering the possibility of new health tools that can make an impact around the world, the political and economic environment in the United States is changing dramatically. US policymakers should ensure that the federal budget protects funding and programs for global health product development.

draft FY 2013 appropriations bills, highlighting the need for research on health technologies appropriate for low-resource settings.[40] Policymakers in Congress and the administration should include these repaired funding levels and supportive language in the finalized federal budget for 2013 and maintain them throughout budget negotiations in the coming months. Congress and the administration should also:

- Prevent the widely acknowledged damaging sequestration from taking place, and pass a long-term fiscal plan that protects funding and programs for product development. If the damaging effects of sequestration do take place, agencies must do their best to protect product development priorities within their budgets.
- In an effort to reverse the recent trend of ever-decreasing funding levels for global health R&D, Congress and the administration should agree on a federal budget for FY 2014 that protects global health research and other key programs at CDC, DoD, FDA, NIH, and USAID. The FY 2014 federal budget should fund global health and R&D programs at robust levels, as the cuts to global health and R&D programs seen since 2009 are damaging and severely hinder scientific progress.
- Federal agencies are also responsible for protecting global health R&D funding in their budget plans. Agencies themselves should therefore secure funding and support for the global health R&D programs under their purview.
- Finally, while it is critical that Congress, the administration, and federal agencies protect funding for global health research, this support must not come at the expense of other international development efforts, which often collaborate with global health programs to address critical development challenges.

As leaders in Congress and the administration make these challenging decisions regarding the federal budget, they should keep in mind that the American public strongly supports US investments in new global health advancements. According to a 2011 Research!America poll, 78 percent of Americans think it is important for the United States to support global health research.[41]

US leadership after the 2012 elections

After the 2012 presidential election, reaction quickly ensued regarding what President Obama's second term could mean for international development efforts.[42,43] President Obama strongly supported science and innovation during his first term, often citing the power of science to solve development challenges, forge diplomatic ties, and transform economies around the world.[44-46] Research and product development were also strong components of international development and global health programs launched during the first term of President Obama's administration.[47] And key administration leaders repeatedly cited the need for research and innovation in the fight against disease and other global challenges.[48-53] Now that the administration has entered its second term, it is crucial that its leaders continue to recognize the importance of science and research in international health and development efforts, particularly as new appointments to leadership positions[54] are made.

The 2012 elections resulted in some critical changes in Congress (See "Changing leadership in the US government").[55,56] As new and returning members and leaders in Congress work with the administration to create a federal budget and develop global health-related legislation, it is vital that they protect funding for global health R&D and the US agencies engaged in this lifesaving work. Specifically, over the next year, policymakers in the US will address:

- Sequestration and a long-term fiscal plan.
- The FY 2013 budget.
- The FY 2014 budget.
- Potential reauthorization of the President's Emergency Plan for AIDS Relief.
- The Ending AIDS Act of 2012 (see "Critical and unique expertise across the US government").
- The Global Partnerships Act of 2012 (see "Critical and unique expertise across the US government").
- The new Office of Global Health Diplomacy (see "Changing leadership in the US government").

Each of these federal policy initiatives provides the US government with the chance to fully fund and support global health research and product development.

It is also worth noting that supporting global health research can help bolster bipartisan efforts to improve health worldwide and to boost the US economy. Approximately 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, building US research and technological capacity, and providing an investment in the US economy.[12] Indeed, global health R&D is a smart economic investment for the United States that:

- **Drives job creation**. As just one example of the many states positively impacted by global health R&D, the bioscience and life sciences industries in New York employ 80,000 people in the state. In 2011, New York received more than $2 billion in NIH grants, more than half of which went to universities and nonprofit research centers.[57-59]
- **Spurs business activity**. Biomedical research, including for global health, in the United States is a $100 billion enterprise. Approximately 65 percent of research is supported by private industry; 30 percent by the government; and 5 percent by charities, foundations, or individual donors.[60]
- **Engages academic institutions**. In the last 20 years alone there has been an unprecedented interest in global health among faculty and students in North American universities.[61]

US investments in research to create new childhood vaccines and other lifesaving health tools saves lives around the world, while also reaping countless domestic rewards such as creating jobs, boosting the economy, and spurring business activity.

"We have never witnessed a time of greater promise for advances in medicine than right now."

~ NIH Director Francis Collins

- **Benefits the health of American citizens**. There are an estimated five million impoverished Americans who live with neglected tropical diseases—including a previously hidden burden of neglected diseases among the poor in the southern United States. The major neglected tropical diseases in the United States now include Chagas disease, cysticercosis, dengue, toxocariasis, and others.[62-64]

US contributions to global health R&D are also important instruments of bipartisan efforts to promote effective foreign policy and diplomacy efforts, highlighting the United States at its best—building capacity in developing countries and creating products that are not only needed but also appreciated. Finally, global health research helps to promote domestic and internal security, as addressing global health issues and health inequalities around the world helps to stabilize volatile environments.

"Amid these financial threats and budgetary realities, it is inevitable that some will question the role of the United States in global development. But I would assert this morning that development assistance, when properly administered, remains a bargain for US national security and for our own economic and moral standing in the world."

~ former Sen. Richard Lugar (R-IN)

Changing leadership in the US government

The 2012 elections resulted in critical changes to congressional committees that will have far-reaching effects on US global health R&D policies. Additionally, key agencies and departments in the administration have been affected by recent leadership changes. In such an uncertain fiscal climate, policy and funding decisions can bring a drastic change in the research landscape. These changes in leadership have the potential to herald continued success of global health R&D, but could also have damaging effects through funding cuts and poor policy decisions. Noteworthy appointments that could impact funding and policies for global health R&D are outlined below.

President Obama nominated Sen. John Kerry (D-MA) as the new **secretary of state**. Kerry will become the president's chief foreign affairs adviser, carrying out the president's foreign policies including those that impact global health R&D.[65] President Obama also nominated former Sen. Chuck Hagel (R-NB) as the new **secretary of defense,** overseeing DoD's operations, such as the agency's support for global health product development.

US Global AIDS Coordinator Ambassador Eric Goosby leads a new **Office of Global Health Diplomacy** at the State Department. The Global Health Diplomacy office was announced in July 2012 as the successor to the Global Health Initiative.

Rep. Ed Royce (R-CA) is the new chair of the **House Foreign Affairs Committee**, and Rep. Eliot Engel (D-NY) is the new ranking member. The committee oversees legislation that impacts international development and global health efforts, including bills that affect USAID's funding and policy priorities.

Sen. Barbara Mikulski (D-MD) is the first woman to head the **Senate Appropriations Committee**, while Sen. Richard Shelby (R- AL) is the new lead Republican on the committee. The committee is tasked with overseeing how federal dollars are allocated across the US government, including for global health research activities at key federal agencies.

Rep. Nita Lowey (D-NY) is the new **House Appropriations Committee** ranking member, while Rep. Hal Rogers (R-KY) continues in his role as chair. The committee is in charge of finalizing and approving all appropriations bills from the House of Representatives, including legislation that impacts funding and policies for CDC, DoD, FDA, NIH, and USAID.

Under the House Appropriations Committee, the **Appropriations Subcommittee for Labor, Health and Human Services, Education, and Related Agencies** has a new chair. Rep. Jack Kingston (R-GA) will lead the subcommittee in setting initial funding levels for the CDC and NIH, and Rep. Rosa DeLauro (D-CT) will continue in her role as ranking member.

Sen. Bob Corker (R-TN) is the new ranking member on the **Senate Foreign Relations Committee**, and Sen. Robert Menendez (D-NJ) is likely to be named the new committee chair to fill Sen. Kerry's role as he leaves to become the secretary of state. The committee is instrumental in developing and influencing US foreign policy, including international development and global health policies.

Coordinating US investments and policies in global health R&D

In recent years, there has been increasing interest and activity from a range of US agencies and offices on global health R&D. This support has primarily taken the form of:

- Funding programs and implementing policies for product development, such as global health strategies that include R&D as a focus area.[66]
- Engaging in efforts to improve global regulatory processes to ensure that new health products are safe and effective before they reach the populations who need them.
- Supporting a range of incentives and innovative financing mechanisms to encourage all stakeholders to invest in global health R&D, and to better prioritize and coordinate global health R&D.

As so many actors in the US government are involved in global health R&D, it is critical to improve coordination of US research and product development efforts. Smart coordination of varying issues, policies, and programs across the US government will ensure that global health R&D activities have the greatest impact possible.

Despite the complexity and breadth of the US government's activities, there is no overarching strategy that defines the country's goals and priorities for global health research. Such a strategy would ensure that research gaps are bridged, the US government's goals and priorities are clear, and agencies coordinate their activities.

Creating successful policies and programs for global health R&D

Over the past year, several US agencies have launched programs with important implications for global health R&D. In some instances, these programs and policies are part of a broader effort, with individual agencies working in conjunction toward a common goal. For example, the White House Office of Science and Technology Policy brought together a large number of US agencies and other partners in early 2012 to launch a series of initiatives that harness science, technology, and innovation for global development. As part of this broader effort:

- USAID launched its Center for Accelerating Innovation and Impact, which, among other goals, aims to catalyze innovation and partnerships for global health technologies.[67]
- NIH launched a new program to accelerate licenses for nonprofit organizations that are engaged in neglected tropical disease product development, allowing them to use certain inventions and compounds from NIH and FDA laboratories.[68]
- The US Patent and Trademark Office unveiled its Patents for Humanity pilot prize competition, which allows patent applicants whose products benefit "humanitarian needs"—including medical technologies—to win a certificate for expedited patent review.[69]

Policy recommendations

The United States supports global health product development across a range of agencies, bodies, and departments and across a range of issues—from public financing to implementing relevant policies and programs, supporting efforts to improve global regulatory processes, and engaging in incentive financing mechanisms. The Global Health Technologies Coalition (GHTC) recommends the following actions for US policymakers to advance product development and delivery, and to maximize efforts across the US government:

- **The US government should develop a five-year strategy to coordinate its global health research and product development efforts.** The strategy should include provisions that provide greater detail and clarity on the US government's activities and priorities in global health R&D. It should also improve coordination among US agencies to fill gaps and achieve the greatest impact possible, as well as provide metrics to measure success. The US government should begin developing the strategy this calendar year, with the goal of completing it by December 2014. The US government should also release publicly available annual reports on its progress to Congress.
- **The FDA has demonstrated noteworthy leadership and interest in global health regulatory issues over the past four years.** In order to capitalize on this progress, the agency should 1) continue to elevate global health in its mandate by creating an office of neglected diseases, 2) build stronger partnerships with global regulatory stakeholders, 3) add Chagas to the list of diseases for which it can regulate health products, 4) take steps to increase transparency by reporting to Congress on its neglected disease activities, and 5) strengthen its internal capacity on global health.
- **To maximize the impact of its engagement in incentives, innovative financing, and R&D funding coordination, the US government should increasingly collaborate with other governments and donors worldwide.** The upcoming WHA negotiations on a proposed global health R&D framework and observatory are currently the best mechanisms for the United States to exercise leadership for the advancement of global financing, improved priority-setting, and better coordination and collaboration for product development. In the WHA negotiations, the US government should support proposals for a global health R&D observatory, as long as it is advised by an independent group of experts, sufficiently funded, and staffed with an interdisciplinary team.

Agencies also work independently on policies and programs that have the potential to benefit global health product development. For instance:

National Institutes of Health

The National Center for Advancing Translational Science (NCATS) at NIH unveiled a pilot program in May 2012 that aims to speed the creation of new drugs, under which pharmaceutical companies make dozens of their compounds available to researchers. Researchers will then investigate whether the compounds can be repurposed into successful treatments for other diseases.[70,71] Although neglected diseases of the developing world were named as a focus area for NCATS, the program has not yet taken up initiatives targeting global health diseases, nor included global health experts on its advisory council.[72,73] As the largest single funder of global health research and development in the world,[12] NIH must ensure that its initiatives and programs, such as NCATS, continue to support the creation of much-needed new tools for global health.

US Agency for International Development

Over the past year, USAID has not only created new global health centers—such as the Center for Accelerating Innovation and Impact, and the Office of Health Systems—it also has released several independent policies that have important implications for global health research and innovation. In April 2012, the agency released its global health strategic framework for fiscal years 2012 to 2016, which defines USAID's core health priorities. The framework also outlines

"We have to recognize that our responsibilities extend far beyond our shores. … We no longer view ourselves or describe ourselves as a domestic agency. We believe that we have to be a global agency with a global mission and with partnerships … that are global as well."

~ FDA Commissioner Margaret Hamburg

USAID's approaches that guide its global health efforts, including science, technology, and innovation.[74] Concurrent with the release of the framework, USAID launched a new policy to ensure the quality and integrity of the agency's scientific activities.[75] As USAID carries out the goals and priorities of its global health framework, scientific integrity policy, and other relevant strategies, the agency should continue to prioritize science and innovation, particularly for the development of new global health products. Indeed, USAID is often the federal agency best suited to support clinical trials and other efforts needed to ensure that basic research breakthroughs are translated into appropriate health products.

Centers for Disease Control and Prevention

This past year, the CDC released its own global health strategy for 2012 to 2015. The strategy includes four broad goals the agency would like to achieve in that timeframe, as well as a focus on global health research and science. The CDC "aspires to create a world where people live healthier, safer, and longer lives," the strategy states, adding that "the agency will draw upon innovation and research to meet these combined challenges and assure even greater health impact in the future."[76] The CDC strategy followed closely on the heels of the first-ever global health strategy from the US Department for Health and Human Services (HHS), which also includes a focus on global health research and serves as a framework for all the agencies and programs within HHS.[77]

Department of Defense

DoD is an essential partner in R&D for new tools and technologies for global health. Researchers at DoD play a critical role in tackling malaria, HIV/AIDS, and neglected tropical diseases. DoD is the only US agency that develops new products from early-stage basic science research all the way through late-stage product development. The agency's infectious disease research and development is conducted mainly through the Walter Reed Army Institute of Research and the Navy Medical Research Center, as well as several overseas research laboratories that partner with local populations. While DoD's mission is protecting US troops, their work ultimately goes beyond this and benefits the people living in the countries where these diseases cause the most harm.[78]

FDA's growing role 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, South Africa's Medicines Control Council, and other national regulatory authorities in countries where diseases of poverty are endemic—play a critical role in this process. Regulating health products can include a range of activities focused on the product development process, including the review of products

FDA's unwavering leadership in global health

The FDA recently approved three critically important health tools for HIV and TB. In July 2012 the agency approved the first over-the-counter, self-administered HIV test that people can use at home.[79] The test has the potential to identify large numbers of previously undiagnosed HIV infections, especially when used by people who are unlikely to use standard screening methods that require a visit to a health care provider.

This was closely followed by an FDA approval for the use of the antiretroviral drug Truvada for HIV prevention in a method called pre-exposure prophylaxis (PrEP).[80] With FDA approval, PrEP has become an additional prevention option for people at risk of HIV worldwide.

The FDA also approved a new treatment for multidrug-resistant TB that can be used as an alternative when other drugs fail. For the first time in 40 years, the FDA approved a drug that attacks TB in a different way from currently available treatments.[81]

PATH/Lesley Reed

and the manufacturing process, approval and monitoring of clinical trials, and licensing of new products—as the FDA does for health products intended for US consumers. 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. The agency has demonstrated a strong commitment to international efforts to ensure the safety of health tools to prevent, diagnose, and treat infectious diseases that affect millions of people worldwide every year.[82] This commitment has been illustrated in several programs, strategies, and guidelines released by the agency and its centers, as well as statements by FDA leaders on the importance of engaging in global issues.[83-86]

The FDA's growing involvement in global health can help improve access to much-needed health tools, as the agency's approval is an important signal of safety and efficacy to countries without sufficient regulatory capabilities. Although the FDA's primary mandate is to regulate health products for the United States, it can leverage its expertise to strengthen local regulatory capacity in countries where neglected diseases are endemic to help ensure the safety of new tools. The FDA's efforts to build local regulatory capacity are imperative, as local regulatory authorities are in the best position to weigh the needs of their citizens against health product characteristics. Additionally, the FDA has a long and growing history of sharing its knowledge to benefit communities around the world and working with global regulatory agencies, such as the European Medicines Agency, and other global partners, such as WHO.[87]

The FDA's global health activities helps ensure the safety and efficacy of health tools to prevent, diagnose, and treat diseases. The agency also helps build local capacity in developing countries to conduct regulatory activities such as monitoring clinical trials and reviewing new health products.

As the FDA sets its priorities for the coming year and beyond, it is critical that global health remains a focus area for the agency. In addition to continuing its support for regulatory science research, the FDA should:

- Build its internal capacity on global health and neglected disease issues by hiring additional staff with such expertise and providing training for existing staff.
- Continue to build stronger partnerships with non-US regulatory stakeholders, such as WHO. For instance, the FDA should consider a formal arrangement with WHO so they can conduct simultaneous reviews of global health products, thereby speeding access to much-needed new health tools worldwide.[88,89]
- Create an office of neglected diseases in the Office of the Commissioner to ensure that neglected diseases and global health issues are consistently elevated at the leadership level.
- Include the neglected tropical disease Chagas on the list of global health conditions for which the FDA is legally allowed to review health products.[90]
- Report on its global health and neglected disease activities in its next report to Congress, scheduled for early 2013, to improve transparency and clarity.[90]

Because the FDA needs support from Congress to carry out its global health work, Congress should provide the agency with sufficient funding and authority to do so.[91]

Engaging needed players for successful global health R&D

To create and deliver new global health products, a diverse group of stakeholders needs to engage in the R&D process, from basic scientific research to final distribution of products to populations most in need. Private biotechnology and pharmaceutical companies, nonprofit groups such as PDPs, academic partners, and public research institutes all play important roles in advancing global health product development. However, new global health products are primarily needed in low-resource countries, where many patients and providers have a limited ability to pay for these health tools. Commercial incentives are often insufficient to spur medical innovation for global health from these private-sector partners. This ultimately leaves a major gap in the financing, expertise, and capacity to conduct R&D for new global health tools.

To fill this gap, experts in global health and economics have designed strategies to stimulate and fund innovation for global health products. These strategies—incentives and innovative financing mechanisms—aim to encourage all stakeholders to invest in global health 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.

Many in the global health and development community, including the Global Health Technologies Coalition, have called on the US government to take specific steps regarding incentives and innovative financing. These recommendations include:

- Coordinating the diverse interests and activities of all US agencies and departments involved in incentives and innovative financing.

Positive movement in incentives and innovative financing

The United States has long played a critical role in advancing incentives and innovative financing for global health research. A range of stakeholders within the US government has been involved in the discussion and implementation of these mechanisms,[92] ranging from the FDA's priority review voucher program[93] to the America COMPETES Act, which gives all federal agencies the authority to use prizes and challenges to foster innovation.[94]

Just in the past year, NIH and USAID launched a joint grant program to promote research for improved child survival in developing countries. The incentive program will provide winners with three-year grants worth up to $450,000 to conduct research on diseases and conditions that affect children in developing countries.[95] USAID also launched an innovative partnership with universities to develop solutions to pressing development challenges, including global health.[96] And members of Congress introduced legislation to provide tax credits and other mechanisms for health innovation.[97,98]

PATH/Gabe Bienczycki

The United States can maximize its investments in global health R&D by supporting a range of incentive and innovative financing mechanisms—as well as collaborating with other governments, donors, civil society, private industry, and nongovernmental organizations.

- Monitoring and evaluating each mechanism supported by the United States to demonstrate impact.
- Supporting a portfolio of mechanisms to stimulate R&D at all stages of the product development process.

When exploring investments in innovative financing mechanisms, the United States should also engage with other governments and donors, civil society, nongovernmental organizations, and private industry at each stage of the process—from initial discussions, to developing recommendations for US support, to program evaluation.[99] Implementation of these recommendations will be an effective US government tool for making measurable progress in stimulating global health R&D. Recently, policymakers have taken encouraging steps that can help meet these goals. For instance, Congress passed legislation that establishes an agreement between HHS and the National Academies to conduct a study that evaluates the US government's use of prizes to stimulate medical innovation.[100]

At the same time, there has been significant traction and interest at the global level in incentive mechanisms and financing for global health product development. The US government, through HHS, has been involved in global discussions focused on a set of recommendations offered in early 2012 by the WHO Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG). At the WHO Executive Board meeting in January 2013, after months of sometimes contentious discussions, the United States and other WHO member states recommended moving forward with some specific proposals. These include establishing a global health R&D observatory at WHO to monitor, analyze, and coordinate existing global health R&D pipelines and financing, and to identify R&D gaps and opportunities.[101] This was seen by many in the global health community as an initial step toward improving global health R&D financing and coordination, with more work needed. WHO member states will deliberate on the observatory and other activities at the WHA in May 2012.

Countless new tools are on the cusp of development and delivery. The United States cannot lose ground by pulling back from the nation's legacy in global health research.

Through discussions at the upcoming WHA on the proposed observatory, the US government has a concrete opportunity to achieve a recommendation offered by the global health community—engaging with other global governments, donors, and stakeholders around incentives and innovative financing for global health R&D. While the US government and other governments still need to ensure that specific conditions are met when establishing and implementing the observatory, the WHA discussions are the best mechanism for the United States to work with global partners on incentives and innovative financing. These global discussions present the United States with the opportunity to establish the most effective global health R&D framework and observatory possible, as well as to ensure that critical aspects of global health financing—such as regulatory systems, and developing-country capacity building, and technology transfer—are addressed at the WHA.

"Health is an issue which aligns the interests of the countries around the world. If we can limit the spread of pandemics, all people benefit. A new drug developed on one continent can just as easily cure sick people on another. A safe global food and drug supply chain will mean better health for every country. And a healthier world is one in which every nation will have more productive workers, longer lives, and larger markets for its goods and services."

~ HHS Secretary Kathleen Sebelius

Conclusion

Thanks to longstanding support for research from the United States, the world is now at a promising turning point in global public health, with almost 400 health products in the research pipeline. The US commitment to science and innovation has created effective tools, which have resulted in significant gains for health around the world. With so much accomplished and so many new tools on the cusp of development and delivery, US policymakers cannot lose ground by pulling back from the nation's legacy in health research. The reasons are clear—research has created lifesaving health tools that have contributed to astounding public health successes, but there is no guarantee that today's health tools will meet tomorrow's needs.

While challenging financial realities have put the US legacy in global health R&D at risk, there is hope that the nation's leadership in science, innovation, and global humanitarian efforts can be maintained. The US government has achieved notable successes in global health R&D in recent years, thanks in large part to strong support from policymakers in Congress and the administration. 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. There is too much to lose if the United States pulls back from this legacy now, as US investment has driven the creation of the largest global health product development pipeline in history that is poised to become the next generation of lifesaving products. The US commitment must be renewed.

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