Global Health
Technologies Coalition

2012 Policy Report

Sustaining progress:

Creating US policies to spur global health innovation

Contents

About the Global Health Technologies Coalition

The Global Health Technologies Coalition (GHTC) is a group of 40 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, 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 by the Bill & Melinda Gates Foundation.

The Global Health Technologies Coalition's 2012 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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"Foreign aid must be viewed as an investment, not an expense."

~ Representative Kay Granger (R-TX)

Introduction

In recent years, the global public health landscape has seen incredible progress. Scientific leadership and a commitment to research have led to the development of game-changing innovations—including new vaccines, drugs, and diagnostic products—that are transforming global public health. Other groundbreaking health tools are closer than ever before, like the first-ever malaria vaccine,[1] new HIV prevention options,[2,3] desperately needed tuberculosis (TB) therapies,[4,5] and drugs to treat neglected tropical diseases (NTDs) that affect the poorest of the poor.[6] From the numerous health products already benefiting populations around the world to the next generation of lifesaving innovations under development today, the United States serves as a leader in driving the research that saves lives abroad and right here at home.

The United States has long played a critical role in driving innovation for the world's neglected diseases, including HIV/AIDS, malaria, TB, NTDs, and childhood killers like pneumonia and diarrheal diseases. These diseases disproportionately impact people living in low-income countries, although some also affect populations in the United States and are resurging.[7-9] And while the tools needed to test, treat, and prevent neglected diseases are getting better, in many cases, adequate drugs, vaccines, and diagnostics are simply not available. For instance, the world still does not have a vaccine for HIV, and the vaccine for TB is almost 100 years old and ineffective in preventing the most infectious form of the disease for most populations. Many treatments and diagnostics for NTDs such as visceral leishmaniasis, sleeping sickness, schistosomiasis, and Chagas are painful, expensive, and ineffective. And children in low-income countries still die every day from diarrhea, pneumonia, and other diseases that are preventable and treatable in the United States.

Although new health tools and technologies—including drugs, vaccines, diagnostics, microbicides, devices, and insecticides—are urgently needed, the recipients live in low-income countries and have limited purchasing power, leaving pharmaceutical companies with few financial incentives to invest in the development of such products. Support from the United States and other donors for developing new global health products is critical to minimizing gaps that can result from these market dynamics.

The US Government is not alone in this effort and partners with several stakeholders engaged in research and development (R&D) around neglected diseases, including academic institutions, the private sector, and other donors and governments. One mechanism used by governments and private foundations to pool expertise from different sectors and connect dedicated sources of funding and expertise with leading researchers is product development partnerships (PDPs). PDPs use a business model that focuses exclusively on finding solutions to neglected diseases. They also combine private-sector capacity with public-sector knowledge—an important feature of the PDP model, as these partnerships are one of the key mechanisms to increase industry engagement in global health R&D.[10] And because of investments from donors such as the US Government, PDPs have become central to developing new tools to treat, prevent, and diagnose neglected diseases. Approximately 16 products developed by PDPs have been launched in the last decade, including several major breakthroughs.[11]

By working with all of these stakeholders, the United States can continue its legacy of advancing innovation to save lives around the world. The historic US commitment to global health research has seen dramatic results, from the eradication of smallpox to the development of HIV/AIDS drugs, bed nets to prevent malaria, and a new meningitis vaccine that costs less than 50 cents per dose.[12-20] US investments in global health research can produce real results, and the nation must persist in our efforts to develop the next generation of lifesaving health products. US leaders have the opportunity to seize on this bipartisan legacy and recent scientific advancements and stay focused on the end goal—saving lives around the world. The United States cannot give up now.

Public financing

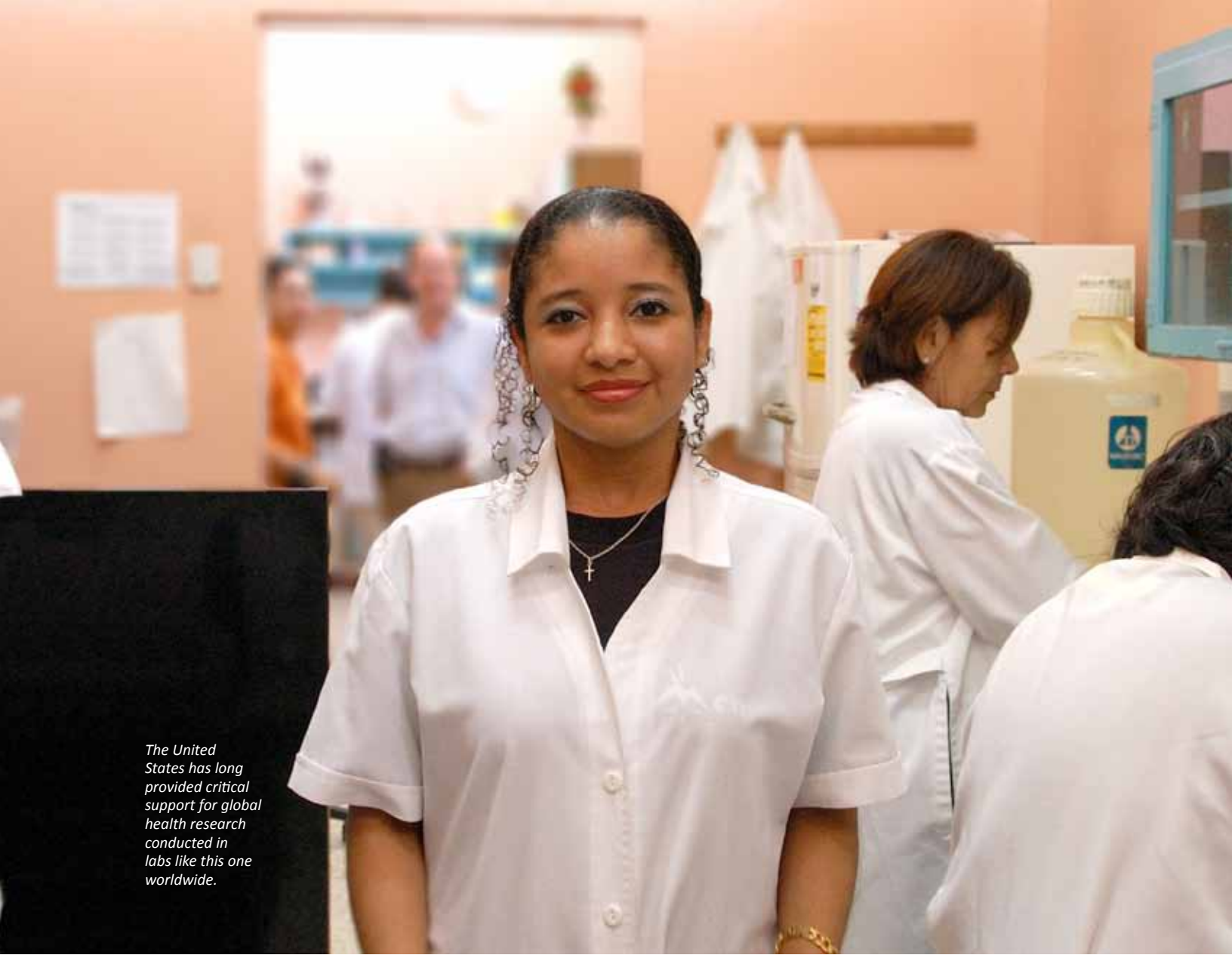
The United States has long demonstrated leadership and dedication to research and science. Indeed, America's ingenuity and innovative entrepreneurial spirit have played a major role in internationally hailed global health successes. Much of this leadership and scientific dedication can be found at US agencies such as the Centers for Disease Control and Prevention (CDC), Department of Defense (DoD), Food and Drug Administration (FDA), National Institutes of Health (NIH), and the US Agency for International Development (USAID). These agencies have demonstrated a continued commitment to innovation for global health products, including new medicines, vaccines, diagnostics, microbicides, devices, and insecticides. Investments in global health research by these US agencies not only contribute to the development and delivery of new global health tools, they also lead to an array of other benefits, such as increased collaboration with international R&D organizations, the facilitation of technology transfer, the sharing of best practices, and capacity-building for countries where global health diseases are endemic. Each of these US agencies plays a unique role in global health research, complementing each other in critical ways (see "A commitment to global health innovation in the US Government").

In just the past two years, there have been extraordinary scientific advances in the prevention and treatment of many of the diseases that afflict low-income countries and limit their potential for development. At the same time that research and innovation are offering new tools and new hope, the political and economic environment in the United States is changing significantly. Today's budget constraints mean that even the most essential programs are at risk, and over the past year, Congress has reduced funding for foreign affairs and international aid programming.[21,22] Amidst these drastic cuts to broader international aid efforts, some global health and R&D programs have seen slight increases or flat funding levels.[23] However, these increases are not enough to make up for the huge disparity in current funding levels for global health R&D and what is actually needed to fully fund these lifesaving efforts. While support for some global health and R&D programs has modestly increased or remained flat-funded, support for other global health R&D programs—including funding for some key PDPs—has been severely cut.

When compared with funding for broader foreign affairs and international aid efforts, it is noteworthy that global health and R&D programs so far have seen more modest increases or flat funding levels. However, the budget climate in the United States continues to be severe, and US policymakers are beginning to implement austerity measures that could impact funding for global health R&D. Indeed, the continuing fiscal situation undoubtedly puts these programs at risk in the future, when global health R&D programs could see even more severe funding cuts than have already occurred. Moreover, it is important to note that even if Congress prioritizes funding for global health R&D efforts, this does not mean that R&D funding within these programs will automatically increase. Because not all global health R&D programs are congressionally appropriated, there is no guarantee that US agencies themselves will protect R&D funding within their own budgets. Agencies themselves must therefore prioritize increased funding for global health R&D within these critical programs. Finally, while it is critical that Congress and US agencies continue to prioritize funding for global health research, this support must not come at the expense of other international development efforts, which often work in tandem with global health programs to address longstanding development challenges.

The rest of the world is struggling with the same global financial crisis that is challenging the United States. The fourth annual G-FINDER (Global Funding of Innovation for Neglected Diseases) survey report, released in December 2011, mapped the global level of investment in development of new vaccines, drugs, diagnostics, and other tools that address 31 neglected diseases. The report also documented funding levels and trends in 2010, showing that the global financial crisis has had a significant impact on global financing for R&D. Funding dropped 3.5 percent in 2010 among donors surveyed—including public donors, private foundations, and the pharmaceutical industry. In addition, contributions from the public sector, which plays an important role in funding neglected disease R&D, fell by 6 percent in 2010, or $US125 million when adjusted for inflation and reported as 2007 US dollar amounts.[24] And while the United States remained the largest government funder of global health research in absolute terms in 2010, US funding for global health R&D dropped by 5 percent, or $US74.5 million after adjusting for inflation.[24]

US policymakers are responsible for setting priorities which reflect the needs and values of the American public and providing funding for those policies. According to national and state polls conducted by Research!America, Americans believe that funding for global health research, which draws on American innovation to solve international health



The United States has long provided critical support for global health research conducted in labs like this one worldwide.

crises, should be included among these priorities.[25] Setting and funding policy priorities will be particularly relevant in 2012, since it is a presidential election year. It is important that candidates from all parties support the progress made through global health R&D programs and promote a continued emphasis on science, technology, and innovation in US global health and development programming. Indeed, presidential candidates and policymakers can be assured that a commitment to science and research for new global health products will not only improve the lives of people in need worldwide, it also reaps rewards in the United States in terms of job creation and economic growth,[26-31] increases stability, and improves America's image abroad. Investing in global health research also produces cost-savings and efficiencies.[32] Many new global health products in the research pipeline are poised to create even further cost-savings and make huge public health impacts, by reducing the burden of disease and saving lives worldwide. By prioritizing and supporting global health product development, US leaders can help bring forth solutions for treating, preventing, and diagnosing neglected diseases in endemic countries worldwide. Policymakers must protect global health R&D funding in order to help sustain the momentum for new health tools; support them in all stages of research; and deliver them to people in need worldwide. Policymakers in Congress and the Administration have difficult choices ahead of them, but there has never been a more important time to prioritize funding for global health research.

A commitment to global health innovation in the US Government

Congress and the Administration have demonstrated a strong commitment to global health science, research, and product development over the past year. Some examples of recent policy advances are listed below.

In an effort to accelerate product development, the **NIH** has created—and Congress has funded—a new National Center for Advancing Translational Sciences (NCATS) to spur innovation and new technologies, including those for neglected diseases of the developing world.[33] NCATS will help move products further down the research pipeline, making investments more attractive to the private sector. However, concerns have been raised about the formation of NCATS, and the NIH should therefore ensure that the center is properly structured with the mandate to address some of the most pressing problems facing global health product development.[34] Also this past year, the NIH's National Institute of Allergy and Infectious Diseases announced that its six current HIV/AIDS clinical trials networks will begin to include research for major infectious diseases other than HIV/AIDS.[35] This means that future clinical trials can build on the infrastructure and capacity already in place, leading to reduced costs and greater efficiencies for future research.

USAID Administrator Rajiv Shah continues to reinforce the agency's leadership in science and technology to advance international development. In a speech at the NIH in February 2011, Shah charted a course forward for the United States' international development programs. Shah said that under the plan, USAID will fully harness the power of science and technology for global health and development. He also announced a USAID center of excellence to accelerate product development and field introduction. The center will bring together industry experts and academic fellows, and invest seed capital in promising ideas.[36]

The **CDC** is one of the many partners providing support to research conducted on the RTS,S malaria vaccine candidate over the past several years. The first results from a large-scale Phase 3 trial of RTS,S were published in October 2011.[1] The CDC also conducts important global disease mapping and surveillance, including operational research on integrated mapping of NTDs over the past year. These guidelines produce up-to-date maps of the distribution of different NTDs to guide and target resources efficiently. The guidelines also increase the reliability of estimates of disease burden, measure the impact of NTD control efforts, and provide a planning tool for national control programs.

The **DoD**'s US Military HIV Research Program (MHRP) at the Walter Reed Army Institute of Research (WRAIR) led the historic RV144 HIV vaccine trial in Thailand, which showed the first evidence of efficacy in an HIV vaccine candidate. In September 2011, MHRP presented results of extensive laboratory studies that provide new clues about the types of immune responses that may have played a role in the protection seen in the trial. These studies are the result of nearly two years of work by more than 100 researchers at 25 institutions, who collaborated to understand how the RV144 vaccine regimen prevented HIV infection in some vaccine recipients.[37] WRAIR also played a key role in the early development and testing of the RTS,S malaria vaccine,[1] as well as the development of a simplified intravenous artesunate regimen to treat severe malaria.

The **FDA** continued to bolster its support for global health over the past year, including its partnership with the Critical Path to TB Drug Regimens (CPTR). CPTR is working closely with regulatory scientists at the FDA and other regulatory partners to develop the tools that are needed to allow testing of new TB drugs in combination, cutting years off the development timeline.[4] The FDA is also devoting resources and support to its new "Strategic Plan for Regulatory Science," which aims to modernize the science used in developing and evaluating health products. The hope is that improved regulatory science at the FDA will help speed new global health products to patients worldwide.[38]

Over the past year, several members of **Congress** have introduced legislation that prioritizes research and science to advance global health and international development. In September 2011, Rep. Howard Berman (D-CA) released a proposal to reform and modernize US foreign assistance programs. The proposal includes several initiatives that emphasize a need to support global health research and innovation.[39] In June 2011, several Republican and Democratic Members of Congress in the House of Representatives introduced the 21st Century Global Health Technology Act, a bill that would provide USAID with authority to strengthen its support for the development of health technologies.[40] Congress also prioritized funding for the FDA—which is bolstering its role in global health—during this year's appropriations process, providing the agency with an increase of about $US50 million for Fiscal Year 2012, compared with Fiscal Year 2011 levels.[41]

"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. … 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

Policy recommendations

US leadership in science and innovation has advanced the landscape of global public health to the point that many game-changing and lifesaving scientific advances are now within reach. Even in these constrained fiscal times, US policymakers must persist in their support of global health research. They should consider the following actions:

Protect and sustain funding for global health product development. In this tight budget environment, it is critical that US policymakers continue to support and advance the important leadership role that the nation plays in research and science. Indeed, the United States plays a critical leadership role on a global scale in funding global health research, and other major donors could be inclined to maintain their commitments if the United States persists. To do so, the US Government should partner with a diverse set of stakeholders, including non-traditional product developers. Congress should also protect funding for agencies engaged in global health research and product development, including the CDC, DoD, FDA, NIH, and USAID, as well as ensure R&D funding for a wider range of diseases, particularly those with the highest mortality rates and the least adequate tools. Yet this support cannot come at the expense of robust funding for the entire set of poverty-focused humanitarian and development accounts, which complement each other and ultimately serve the common goal of building a healthier and more prosperous world.

Include global health research and product development in key health and development policies. In the coming year, Congress and the Administration have several opportunities to advance global public health through key policies. When major global health policies and guidance documents, such as those informing US President's Emergency Plan for AIDS Relief (PEPFAR), are developed, they should emphasize the need for increased research and product development to prevent infectious diseases in developing countries.

Advance promising initiatives that will spur global health product development. As referenced in Box 1, several initiatives announced over the past year have potential to advance global health research and innovation. These include NIH programs to spur research for neglected diseases, USAID's efforts to accelerate product development and reinforce science and technology, programs at the CDC and DoD to support R&D, and the FDA's growing role in global health. Policymakers at US agencies can demonstrate their commitment by moving forward with those initiatives that will improve global health, support product development, and have the potential to foster cross-agency collaboration and minimize duplicative efforts.

Regulatory pathways

Regulatory processes help ensure that new health products are safe and effective before they reach the populations who need them. In the United States and countries around the world, regulatory agencies—such as the FDA, European Medicines Agency (EMA), and 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 in the product development process, including the review of products and the manufacturing process, approval and monitoring of clinical trials, and licensing of new products—as the FDA does for health products intended for American consumers.

However, some countries with widespread epidemics do not have the expertise or resources to appropriately review new health tools or monitor clinical trials. When countries with neglected disease epidemics do not have sufficient capacity to regulate the safety and efficacy of medical products, citizens' health can suffer severely. For instance, a lack of regulatory capacity can result in long delays in bringing critical drugs, vaccines, and diagnostics to people who need them most. It can also result in unregulated access to unsafe health products, such as diagnostic tests that misdiagnose diseases or drugs that are not safe for use in certain populations. Fortunately, the United States is poised to help address these regulatory issues worldwide. As the agency charged with protecting the health of American consumers, the FDA is uniquely positioned to increase US involvement in global health issues. Indeed, the FDA has a large amount of expertise that it can use to strengthen global regulatory capacity and ensure the safety of new tools, and the agency has a long history of sharing its knowledge to benefit communities around the world (see "A pivotal year for FDA's global health efforts").[42]

FDA expertise can be leveraged to benefit local regulatory authorities in endemic countries, in order to strengthen these countries' capacity to protect the health of their populations. Stronger local capacity to regulate products abroad also translates to better prevention and treatment of diseases here at home. As FDA Commissioner Margaret Hamburg has noted, because of globalization, the agency has a vested interest in improving regulatory capacity around the world in order to ensure that health products reaching the United States from overseas are safe and effective.[43] Finally, improving regulatory capacity in developing countries helps ensure the sustainability of US development efforts. By providing technical assistance and sharing expertise to help improve regulatory knowledge and capacity in endemic countries, the FDA can help ensure that its investments in global health and development are cost-effective over the long term. When authorities in endemic countries are able to bolster their regulatory knowledge and expertise over the long term, the need for US technical and economic assistance eventually will be mitigated.

Fortunately, there are several global bodies with which the FDA has partnered in this effort. Both the World Health Organization (WHO) and the EMA lead programs that aim to improve access to certain global health products that meet specific international standards. Under its Prequalification Programme, WHO provides guidance on the quality, safety, and efficacy of drugs, vaccines, and diagnostics for United Nations procurement agencies.[44,45] Although WHO is not a regulator, other groups, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria, the GAVI Alliance, and UNITAID, also use its Prequalification Programme. In addition, the program is an important assurance of quality and safety to countries without sufficient regulatory capabilities. However, the prequalification process can result in significant costs and delays in bringing new products to endemic countries, sometimes taking 18 to 24 months.

The EMA's Article 58 process provides a scientific opinion on certain vaccines and drugs intended for markets outside of the European Union. The EMA conducts Article 58 evaluations in close cooperation with WHO. The FDA has entered into agreements with WHO and the EMA in an effort to share information and documents with each other about certain investigational health products. Additional mechanisms at the FDA for sharing information with other regulatory agencies—including those from countries with NTDs and WHO—would accelerate the development and introduction of new products for global health.

The FDA can also engage with PDPs and other non-traditional product developers in this effort. These developers often step in to bridge the gap when there is no promise of significant markets to motivate private-sector investment to create global health products. PDPs are important global health partners, and work closely with local regulatory authorities and global regulatory stakeholders to advance new products through the development pipeline toward registration and delivery.

Because of the complicated global processes associated with the regulation of health products for neglected diseases, PDPs and other non-traditional product developers, such as nongovernment organizations and academic groups, could benefit from the FDA's experience and knowledge in this area.

> *"By helping more countries build their regulatory capacity, we build confidence in the safety and quality of the goods they send us. But we're doing much more. We're helping them establish the regulatory powers necessary to support safe products for their own domestic use, and a strong, reliable export market."*
>
> ~ FDA Commissioner Margaret Hamburg

A pivotal year for FDA's global health efforts

The FDA has demonstrated through several actions over the past year that it can play a strengthened role in the introduction of global health tools. These include:

FDA Commissioner Margaret Hamburg announced in August 2011 **structural and personnel changes at the agency** that will have implications for global health. Under the reorganization, the FDA's programs will be divided into directories that better reflect the agency's core functions. One of the directories focuses on global issues, and a new directorate for Global Regulatory Operations and Policy has been established.[46] In July 2011, Hamburg announced a new **"entrepreneur-in-residence" program** to promote medical innovation by finding ways to help the FDA and small businesses work together to introduce new products quickly and safely.

In 2011, the FDA's **Center for Biologics Evaluation and Research (CBER)** released a strategic plan for Fiscal Years 2012—2016, which increasingly addresses the center's role in global public health. Under the strategy, CBER will promote research and collaboration with nonprofit groups, such as PDPs. It will also increase collaboration with international regulatory partners such as WHO and national regulatory authorities.[47]

The FDA's 2011 **"Strategic Plan for Regulatory Science"** calls for a modernization of the science used in developing and evaluating health products. The FDA has recognized that regulatory science needs to become more adaptive as the agency's mandate has become more global. A stronger regulatory science capacity at the FDA could have important implications for domestic and global health, including an improved ability to speed medical products to patients around the world by reducing some uncertainties associated with clinical trials, such as unclear regulatory pathways and the need for harmonization across different bodies. The plan also aims to facilitate the development of health products for special populations, including patients with neglected diseases of the developing world, for which safe and effective therapies are desperately needed.[48]

Finally, the FDA's **Center for Drug Evaluation and Research (CDER)** released draft guidance in 2011 for developing drugs for neglected diseases of the developing world. The new guidance is intended to aid drug sponsors in developing drugs to prevent and treat neglected diseases, including TB, malaria, and several NTDs, which place a great burden on the world's resources.[49] In December 2011, **CBER** also released revised guidance on developing vaccines to protect against global infectious diseases such as HIV, TB, malaria, and NTDs.[50]

With increased support from the FDA, local regulatory authorities in countries with high disease burdens can help ensure that facilities like this one in India produce safe, effective, and appropriate health tools.

Policy recommendations

The FDA has the opportunity to make significant contributions to global regulatory issues, helping to deliver new drugs, vaccines, diagnostics, and other health products to the hands of the people who desperately need them. These efforts will also benefit the United States by ensuring the safety and efficacy of imported health products, as well as by improving the capacity of regulatory authorities in endemic countries, ultimately alleviating the need for US assistance. It is recommended that the FDA and Congress take the following actions:

- **Build stronger partnerships with non-US regulatory stakeholders.** In order to speed the introduction of new global health products, the FDA should consider a formal arrangement with WHO so that the FDA and WHO can conduct simultaneous review of products that intend to seek WHO prequalification. This collaboration can build on arrangements already in place between WHO and the FDA's Center for Biologics Evaluation and Research and Center for Drug Evaluation and Research. Under the formal arrangement, the FDA should work in parallel with WHO's Prequalification Programme, much like what is done under the EMA's Article 58 process.

- **Prioritize the FDA's internal capacity in neglected diseases.** The FDA should provide training opportunities in neglected diseases and hire additional staff with expertise in this area. The agency should also include experts from endemic countries on FDA advisory boards when products for neglected diseases will be reviewed. In addition, the FDA should share its regulatory science expertise with endemic country regulatory authorities in an effort to build capacity and ensure sustainability.

- **Bolster the FDA's engagement with groups developing global health tools.** The FDA should establish new review teams and/or specific points of contact for non-traditional product developers, including PDPs, and establish mechanisms to facilitate informal discussions and increase communications with these sponsors. The FDA can build on the model established by its new "entrepreneur-in-residence" program.

- **Demonstrate robust congressional support for the FDA's role in global health.** Congress should support the FDA's increasing role in global health, including the agency's role in capacity-building and sustainability of regulatory systems in endemic countries. Congress should also support the agency's efforts to bolster its internal capacity in neglected diseases.

Incentives and innovative financing

To create and deliver new global health products, a diverse group of stakeholders needs to engage in the R&D continuum, from the initial spark of 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 and distinct 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 limited ability to pay for these health tools. Commercial incentives—the traditional drivers of health research and product development for the biotechnology and pharmaceutical industry—are therefore 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.[51]

To address this problem, 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. Incentives and innovative financing mechanisms can leverage expertise and resources for multiple sectors and players, particularly when combined with global health research investments from the US Government and other donors. These mechanisms often align with US priorities because in many cases, they provide a potentially cost-effective and entrepreneurial way of spurring innovative thinking to address longstanding health and development problems, while also engaging a wide array of stakeholders.

Incentive mechanisms generally reduce the risk and uncertainty associated with investing in global health R&D by encouraging private industry to invest through measures known as "pull" mechanisms.[52] Innovative financing mechanisms identify new ways of raising and allocating funding to stimulate global health R&D across all sectors, in what are known as "push" mechanisms.[53] It is critical that the US Government consider and invest in both push and pull mechanisms in order to help address gaps in the global health product development process. Indeed, many of these mechanisms have been implemented in the United States and other countries, and include priority review vouchers (PRVs), small business innovation awards, procurement pools, tax credits, and patent pools. In addition, several governments and donors launched a pilot Advance Market Commitment (AMC) to accelerate delivery of pneumococcal vaccines to millions of children worldwide.

The United States has long played a critical role in advancing incentives and innovative financing for global health research. Indeed, a range of stakeholders within the US Government has been involved in the discussion and/or implementation of these mechanisms, including USAID, the Department of the Treasury, White House Office of Science and Technology Policy, Patent and Trademark Office (USPTO), NIH, FDA, and Congress. Because of the diversity of stakeholders, the US Government should ensure that its activities are coordinated. For example, the Department of State's successful efforts to engage other agencies within the US Government around maternal health through programs such as the Mobile Alliance for Maternal Action could serve as a model for inter-agency collaboration on incentives and innovative financing activities.[54] In addition, because many of these mechanisms are new, it is important that the United States continue to assess its investments in order to ensure they are effective and cost-efficient. For instance, there have been several recent indications that incentive mechanisms such as the FDA's PRV program (see "Spurring global health product development"), the pilot AMC, and prize mechanisms can work to develop and deliver critical global health tools—information that can guide US policymakers on the best investments for global health R&D.[55,56,57]

Fortunately, the US Government is not alone in its support for global health incentives and innovative financing mechanisms. In fact, there has been significant traction and interest at the global level in spurring global health product development from a range of partners, including other world governments, multilateral organizations, and donors. The United States plays a strong leadership role in international development, and would be well served by engaging in global discussions on incentives and innovative financing. By participating in these efforts, the US could help ensure progress in developing lifesaving global health products, and advance US interests in the design and implementation of these strategies. US policymakers have the opportunity to build on the achievements of the last year (see "Spurring global health product development") and ramp up its presence in stimulating global health R&D.

Spurring global health product development

Over the past year, a range of stakeholders in the United States has moved on key global health incentives and innovative financing measures. These include:

In September 2011, a **bipartisan group of representatives** introduced the Creating Hope Act of 2011 in the House of Representatives. Reps. Michael McCaul (R-TX), G. K. Butterfield (D-NC), Sue Myrick (R-NC), and Chris Van Hollen (D-MD) introduced the bill, which would make key changes to the FDA's PRV program. The PRV program aims to spur R&D for neglected diseases. The bill quickly gained support in the House, and had 90 co-sponsors as of December 2011.[58] A companion bill in the Senate was introduced in March 2011 by Sen. Robert Casey (D-PA).

In August 2011, **USAID** and its partners awarded $US14 million in prizes to health innovations aimed at saving the lives of mothers and children around the world. The awards were part of Saving Lives at Birth: A Grand Challenge for Development, an incentive program launched in March 2011 and led by USAID in partnership with the Government of Norway, the Bill & Melinda Gates Foundation, Grand Challenges Canada, and the World Bank. The program provides prize grants to spur innovative prevention and treatment approaches for pregnant women and newborns in rural, low-resource settings.[59,60] In early January 2012, USAID released for comment a draft for the second round of the Saving Lives at Birth challenge, with the goal of releasing the final document in early February. In this round, USAID anticipates awarding up to 25 seed grants and 5 transition-to-scale grants, with a maximum of $US13 million.[61,62]

Also in August 2011, the **Office of Management and Budget (OMB)** issued guidance for US agencies on the America COMPETES Act. The act gives all federal agencies the broad authority to use prizes and challenges to foster innovation, and the OMB guidance is a key tool to encourage US agencies to use prizes and challenges for issues like global health research and innovation.[63]

The **World Intellectual Property Organization (WIPO)**, **WHO**, eight of the world's leading pharmaceutical companies, and BIO Ventures for Global Health announced in October 2011 a partnership to launch WIPO Re:Search, a new R&D database to share intellectual property for neglected disease licenses. Partners involved in the database include the NIH and USPTO; private-sector groups; foundations; and nonprofit groups such as the Drugs for Neglected Diseases *initiative*, Medicines for Malaria Venture, PATH, and the Sabin Vaccine Institute. The database was launched to spur R&D for developing countries by finding common ground between the mission of the global health community and the needs of private companies.[64] This database is just one example of several efforts to facilitate increased sharing of intellectual property for global health diseases, and the US Government should encourage and engage in this broader effort.

At the same time that US stakeholders have made progress on incentives and innovative financing mechanisms at a national level, there has been significant activity at the global level on a number of measures, including WHO's Consultative Expert Working Group on Research and Development: Financing and Coordination,[65] as well as global efforts to implement a financial transaction tax for global health and development.[66,67] It is critical that the United States engage in the global discussion around these incentives and innovative financing mechanisms.

"I strongly support investments in global health research. Breakthrough treatments have the potential to save millions of lives while playing a critical role in strengthening health and security at home."

~ Senator Dick Durbin (D-IL)

By increasingly engaging in efforts to spur and incentivize global health research, the United States can help ensure that critical research for vaccines and other health tools continues.

Policy recommendations

The United States has historically played a key role in supporting incentives and innovative financing for global health products, and can contribute to global efforts by maintaining its leadership and involvement. US policymakers can build on the momentum from the past year and further accelerate global health R&D with the following actions:

- **Formally establish a cross-agency working group to explore US investment in incentives and innovative financing mechanisms for global health.** Because of the diverse interests and perspectives across the US departments and agencies involved, the government will be more effective if it coordinates around a shared agenda. This working group's role would be to develop recommendations for US leadership in incentives and innovative financing for global health R&D.

- **Engage with civil society, nongovernmental organizations, and private industry when exploring US investments in incentives and innovative financing.** US agencies involved in incentives and innovative financing can benefit from the expertise and experience of civil society groups, nongovernmental organizations, and the biopharmaceutical industry. Consultations with key stakeholders can inform priorities and decisions at each stage of the process, from initial discussions, to developing recommendations for US support, to program evaluation. For instance, USPTO sought public comment on its pilot patent review program,[68,69] and these stakeholders helped inform revisions to the original proposal. Other US agencies would be well served to embrace opportunities for public comment.

- **Engage with other governments and donors to explore and support incentives and innovative financing.** By partnering and coordinating with other governments and donors, US leaders and policymakers can maximize the impact of US engagement, and leverage additional resources to complement and extend US taxpayer investments. By engaging with partners worldwide, the US can help harness the considerable momentum and interest around global health incentives and innovative financing.

- **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. The most effective approach is for the United States to support a portfolio of mechanisms that can address these gaps.

- **Conduct continuous rigorous assessment of each incentive and financing mechanism supported by the United States.** Although a track record exists for some mechanisms, many are new and therefore untested. Assessing the design and implementation of these mechanisms will ensure that US Government funds are used effectively and efficiently.

Conclusion

There has been remarkable progress in the scientific landscape for global health over the past several years, in large part because the US Government has continued to prioritize and support global health R&D through important funding and regulatory policies. Because of this incredible scientific progress toward development of new drugs, vaccines, diagnostics, and other tools, the world stands at a turning point in global health. Indeed, we now have the largest research pipeline for new global health products in history. Many of these health tools are already in advanced clinical trials, including vaccines for malaria, TB, and rotavirus, as well as several new drug candidates for malaria and NTDs, including hookworm.[70,71]

US policymakers are now faced with a critical choice: in today's dire budget climate, the United States can waver in its support for global health innovation, or see the next generation of lifesaving health tools and products over the finish line. There are several strong reasons why the United States should persist in its commitment to developing new tools for global health, including their potential to save lives worldwide, reduce disease disability and burden, and create cost-efficiencies. US efforts to build scientific and regulatory capacity abroad can also help ensure that US investments in global health are sustainable. In many cases, new global health products will be significant improvements that can replace older existing technologies. In others, these new products will become powerful weapons to be used alongside existing tools to fight neglected diseases. Not only will lives be saved with the deployment of more effective health tools, but significant improvements will be made in people's lives as populations grow healthier and more productive.

The United States is not alone in this effort and can partner with a range of committed stakeholders, from PDPs and other non-traditional product developers to academic institutions, global bodies, other donor governments, and the private sector. The recommendations offered in this report provide US policymakers with a platform to elevate the country's involvement in developing and delivering the next generation of lifesaving health products in the research pipeline.

Public financing

- Protect and sustain funding for global health product development.
- Include global health research and product development in key health and development policies.
- Advance promising initiatives that will spur global health product development.

Regulatory pathways

- Build stronger partnerships with non-US regulatory stakeholders.
- Prioritize the FDA's internal capacity in neglected diseases.
- Bolster the FDA's engagement with groups developing global health tools.
- Demonstrate robust congressional support for the FDA's role in global health.

Incentives and innovative financing

- Formally establish a cross-agency working group to explore US investment in incentives and innovative financing mechanisms for global health.
- Engage with civil society, nongovernmental organizations, and private industry when exploring US investments in incentives and innovative financing.
- Engage with other governments and donors to explore and support incentives and innovative financing.
- Support a portfolio of incentives and financing mechanisms to stimulate needed R&D at all stages of the product development process.
- Conduct continuous rigorous assessment of each incentive and financing mechanism supported by the United States.

The United States has historically been a critical driver of innovation for new global health products. By following these recommendations to amplify this role even further, US policymakers can ensure that the nation continues its longstanding commitment to global health R&D and pushes the next generation of lifesaving health products over the research finish line. Even in these constrained budgetary times, US policymakers cannot lose sight of the ultimate goal—saving lives with new drugs, vaccines, diagnostics, and other health products.

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