



Achieving a bold vision for global health: Policy solutions to advance global health R&D

2016 Policy Report

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About the Global Health Technologies Coalition

The Global Health Technologies Coalition (GHTC) works to save and improve lives by encouraging the research and development of essential health technologies. We are a coalition of more than 25 nonprofit organizations advancing policies to accelerate the creation of new drugs, vaccines, diagnostics, and other health tools that bring healthy lives within reach for all people. GHTC is housed at PATH and funded by the Bill & Melinda Gates Foundation and our members.

This 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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Introduction

In the past two decades, the world has experienced landmark gains in global health: deaths among children younger than five years have been cut in half, maternal deaths have declined by 45 percent, and for the first time an AIDS-free generation is within reach.¹ Men, women, and children are more likely to enjoy long, healthy lives today than at any other time in human history.

These gains did not occur by happenstance. They were driven by unprecedented global commitment from countries of all economic levels to set and achieve ambitious goals for longstanding global health priorities, including maternal and child health, HIV/AIDS, malaria, tuberculosis (TB), neglected tropical diseases (NTDs), and family planning. The international community pursued these goals through bold national health programs—supported by foreign aid and technical assistance from the United States and other donors—and through multilateral initiatives like the Millennium Development Goals (MDGs), which aligned the global community around a core set of common health objectives.

The dramatic results achieved in global health demonstrate that transformative change is possible when people come together around a common set of goals to mobilize resources and drive collective action. More simply: these achievements prove that goalsetting matters and that goalsetting works.

While remarkable strides have been made toward a world in which every person has the opportunity to lead a healthy life, work toward the MDGs remains unfinished. Endemic infectious diseases and other health challenges continue to claim millions of lives each year, and new and emerging challenges, like the Ebola and Zika viruses and the growth of antimicrobial resistance, threaten to cause devastating health and economic impact, undermine global health security, and undo past progress.

In January, the world embarked on a bold and ambitious new agenda for health and human development that seeks to confront these challenges and finish the job. The global community set collective goals, known as the Sustainable Development Goals (SDGs), to end infectious and neglected disease epidemics, including HIV/AIDS, malaria, TB, and NTDs; sharply reduce maternal and child mortality; ensure universal access to reproductive health services; and improve the health of all people. Endorsed by the US government, these global goals align with the United States' own agenda

for global health and reflect our longstanding commitment to harnessing American ingenuity and leadership to save lives and create a safer world.

Research and development (R&D) for new health technologies is key to achieving these goals. Innovation has always been at the forefront of advancements in global health—from novel vaccines for polio and smallpox that sharply reduced child illness and death, to new packaging and delivery systems that help essential treatments remain effective without refrigeration, to innovative diagnostics that can rapidly detect diseases in low-resource settings and better facilitate treatment.

The world needs new and improved vaccines, drugs, diagnostics, devices, and other health technologies to continue the arc of progress and reach new goals for health. The global community will not curb the spread of TB without a more streamlined treatment regimen and new tools to combat growing drug resistance; it cannot sustainably address maternal and child deaths without new innovations for women's health and family planning that can be used in low-resource settings; and it will not be able to accelerate the end of the HIV/AIDS epidemic without a cure for HIV or new tools to treat and prevent virus transmission, including a vaccine and microbicides.

A bold vision for global health must be matched with a bold vision for global health R&D. Achieving ambitious global health goals will require equally ambitious goals to accelerate R&D for new global health tools. As the United States works to drive dramatic improvements in health over the next 15 years—and beyond—it must lead by example and set bold national goals, develop smart policies, and invest to advance global health R&D.

The United States has a vested interest in the success of a global agenda for health, both to advance our strategic and humanitarian interests abroad and to protect the health of Americans. Now more than ever, it is clear that diseases know no borders. The Ebola outbreak and the recent spread of infectious diseases like Chagas, dengue fever, chikungunya, and Zika virus throughout the Americas remind us that in an interconnected world, Americans are not immune to health crises that have historically impacted only other geographies. R&D for new tools to address global diseases benefits both global health security and the well-being of American citizens living at home and abroad.

This report presents three goals the United States should pursue to advance global health through R&D, including specific policy actions for Congress and the Administration to take to achieve these goals and maintain US leadership in global health innovation.

GOAL 1: Sustain current investments and mobilize new resources to support global health R&D through traditional public financing and innovative approaches.

GOAL 2: Improve coordination, alignment, and transparency of global health R&D efforts across US agencies and with international partners.

GOAL 3: Streamline and strengthen regulatory pathways for global health products.

The United States can play an invaluable leadership role in the global agenda for health. That leadership starts with strong and sustainable policies at home. With the right goals and decisive action, US policymakers can set a global example and accelerate progress toward a world where innovation ensures health and opportunity for all.

HEALTH INNOVATION: THE KEY TO GETTING TO ZERO

	How far we've come	What challenges remain	Getting to zero
Malaria	58% reduction in malaria mortality since 2000, driven in part by the scale-up of bed nets and introduction of new antimalarial therapies. ¹	½ the global population remains at risk for malaria, and drug-resistant strains are growing. ²	To eliminate malaria, it is critical that we continue to invest in promising new innovations, like a malaria vaccine, that go beyond barrier-method protection and target the disease at its source.
TB	45% reduction in TB mortality since 1990, due in part to new treatments for drug-resistant TB and new diagnostic tools that improve detection and treatment. ¹	2-year treatment course for patients with multidrug-resistant TB. ³ In 2014, TB killed 1.5 million people, surpassing deaths from HIV/AIDS. ⁴ TB incidence rates are no longer declining—they have stagnated in recent years at around a 2% decline. ⁵	To end the epidemic of TB and drug-resistant TB, new, shorter treatments are needed, coupled with preventative vaccines and enhanced diagnostics.
Maternal mortality	45% reduction in maternal mortality since 1990, due in part to the introduction and scale-up of new tools to reduce complications from childbirth, like postpartum hemorrhage and pre-eclampsia. ¹	14 times greater risk of maternal mortality in developing regions than in developed regions. ¹	To dramatically reduce maternal deaths, new cost-effective tools are needed to address life-threatening complications from childbirth and women need expanded options to improve healthy spacing and timing of pregnancies.
Child mortality	53% reduction in under-five mortality since 1990, fueled by widespread vaccination and expansion of new treatments for common childhood infections. ¹	1 out of every 12 children in sub-Saharan Africa dies before the age of five. ⁶	To reduce child deaths, basic research is needed to understand the causes of and interventions for preterm birth, and new interventions are required to address other leading childhood killers, like diarrhea and malaria.
HIV/AIDS	7.8 million deaths and at least 9 million new HIV infections cumulatively averted through HIV/AIDS programs since 2000. ⁷ 15.8 million people accessing AIDS treatment in 2015. ⁸	1.4 million new HIV infections in sub-Saharan Africa in 2014. ⁷ HIV prevalence is more than 1-½ times higher among adolescent females than among adolescent males in sub-Saharan Africa. ⁷	To accelerate the end of the HIV/AIDS epidemic, research is needed to develop an HIV cure and advance new tools to expand access and adherence to treatment, and to prevent HIV, including a vaccine, microbicides, and antiretroviral-based prevention.
NTDs	90% reduction in new cases of NTD African trypanosomiasis since 1998. ⁸ Elimination of NTD onchocerciasis (river blindness) from Colombia and Ecuador. ⁸	More than 1 billion people in 149 countries worldwide remain affected by more than 14 NTDs. ⁹	Many NTDs with the highest death rates, including human African trypanosomiasis, visceral leishmaniasis, and Chagas disease, lack effective treatments or cures. To end the epidemic of NTDs, new drugs, diagnostics, and vaccines are needed.



GOAL 1:

Sustain current investments and mobilize new resources to support global health R&D through traditional public financing and innovative approaches

Goalsetting is effective and powerful, but only when backed with adequate resources. Ambitious goals for health must be matched with ambitious goals for funding.

Achieving the global goals for maternal and child health and infectious diseases is possible, but not at the current level of investment in R&D. The hard truth is that current global investment in R&D is insufficient to realize these gains. A group of renowned economists and health experts laid out a roadmap for achieving the dramatic health gains envisioned in the SDGs within a generation, highlighting investment in health R&D as one of the most effective ways to drive health improvements. To achieve these gains, the group called for a doubling of current global investment in health R&D from \$3 billion to \$6 billion by 2020.¹⁰ Filling this gap between current investment and need will require a full-scale, collective effort that mobilizes investments from nations of all economic levels, as well as the private and philanthropic sectors, to develop and deliver the next generation of health technologies.

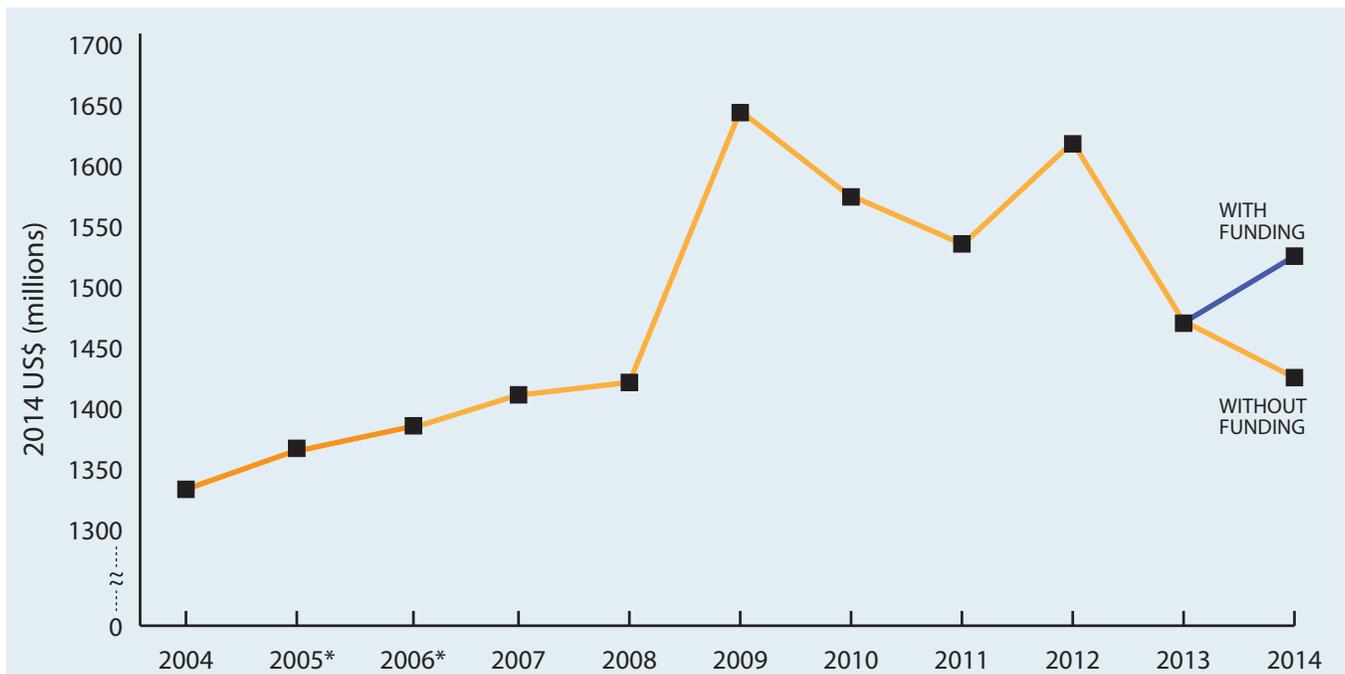
The United States is the world leader in public investment in global health R&D, contributing around 70 percent of public investment and 45 percent of global investment, including private and philanthropic funding. Between 2000 and 2010, the US government nearly doubled its annual financial commitment to global health R&D, helping catalyze the development of breakthrough health solutions like the first blood test for HIV, a new vaccine to prevent meningitis in Africa, and new diagnostic tests to target drug-resistant TB. Today, the United States is the lead funder in R&D for 26 of the 30 most neglected diseases and, as of 2012, supported more than half of the global health products in the development pipeline.¹¹

To achieve the health gains envisioned in the SDGs, a doubling of current investment in health R&D from \$3 billion to \$6 billion is needed by 2020.

- Lancet Commission on Investing in Health

Despite this historical leadership, in recent years, the United States has failed to match our political commitment to advance global health with investments in R&D. Policymakers have allowed challenging fiscal circumstances to weaken the United States' leadership in global health innovation. According to the Global Funding of Innovation for Neglected Diseases (G-FINDER) survey, which tracks annual spending on neglected disease R&D, US government year-over-year spending on neglected disease R&D has been largely stagnant or declining since peaking in 2009.

US INVESTMENT IN NEGLECTED DISEASE R&D WITH AND WITHOUT EBOLA FUNDING INCLUDED



While 2014 saw an uptick in overall US funding for neglected disease R&D, this increase was entirely driven by emergency funding to address the Ebola epidemic in West Africa. With Ebola R&D funding removed, US investments actually fell 2 percent from 2013, a base year which already saw an 11 percent reduction in US health R&D investments from the prior year due to sequester-related cuts. In all, US non-Ebola R&D investment in 2014 was at its lowest level since G-FINDER began tracking in 2007 and nearly 13 percent, or \$221 million, less than the 2009 peak.¹²

Public funding of global health R&D is critical because neglected diseases and other global health conditions offer limited commercial incentives for the private sector. Cuts in US investment can interrupt research programs and delay the

* Estimates. Data sources: (1) Global Health Technologies Coalition, Policy Cures. Saving lives and creating impact: Why investing in global health research works. Sydney: Policy Cures; 2012. (2) Moran M, Chapman N, Abela-Oversteegen L, et al. Neglected Disease Research and Development: The Ebola Effect. G-FINDER | 2015. Sydney: Policy Cures; 2015.

development of urgently needed health technologies, creating a negative ripple effect at a time when we need to mobilize greater multisector and international investment in R&D to advance the next generation of health technologies to reach development objectives.

The recent Ebola and Zika virus outbreaks highlight the critical need for R&D to address a range of neglected and infectious diseases and drive home the repercussions of waiting for an epidemic to trigger investments in global health technologies. In one stark example, cuts to US funding for Ebola R&D in 2012 permanently stalled development of a promising Ebola vaccine. As a result, the global community did not have tools in-hand to respond to the outbreak and required a rapid mobilization of R&D resources. Now that the Ebola crisis has waned, some US policymakers have proposed redirecting emergency Ebola funding to address the next global health

emergency—Zika—while efforts to advance Ebola product development and strengthen the health systems of affected countries to prevent or control a future outbreak still remain unfinished. While an appropriate Zika response requires immediate investment in R&D to fight the virus’s spread, redirecting funding committed to Ebola before we finish the job would be shortsighted and leave the world only marginally better equipped than it was when the epidemic began.

Sustainable funding for global health R&D is vital for developing the full range of tools needed to address global health challenges; it is far more cost effective than emergency investments during times of crisis. A recent study that examined the risk of infectious disease outbreaks projected that large-scale global disease pandemics could cost the global economy more than \$60 billion a year, while investing in the interventions needed to protect against these outbreaks, including R&D, would cost only a fraction of that—\$4.5 billion—each year.¹³ We do not know which region or which disease will pose the next global public health emergency, and we still do not have the tools needed to detect, diagnose, treat, and prevent many life-threatening diseases. Public investment in global health R&D today is a down payment on the essential innovations for tomorrow.

In this era of substantial need coupled with tough spending decisions, US policymakers must lay the foundation for future progress by sustaining robust and stable US funding in global health R&D, while also pioneering ways to leverage our investments and maximize our impact. The United States needs smart policies and innovative mechanisms to mobilize new resources from other sectors and nations. For example, incentive mechanisms—like prizes, small business innovation awards, priority review vouchers, advance market commitments, and tax credits—can help incentivize greater private-sector engagement in R&D for neglected diseases and health conditions with little to no viable commercial markets. New financing mechanisms, like foundations that match public funding with privately raised investments, social impact bonds, or pooled funds, can also help leverage funding from diverse and nontraditional partners.

One approach that has been particularly effective in mobilizing resources for global health R&D is public-private partnerships. These partnerships encourage greater private-sector investment in R&D by pooling contributions from public and nonprofit organizations to reduce the risk of investing in product development for neglected diseases.

The US strategy to mobilize new resources for R&D should also reflect shifts in the economic, development, and innovation landscapes in emerging economies. No longer are developed countries the only contributors to health innovation; nations like Brazil, China, India, and South Africa are growing their medical innovation sectors, and the economies of low- and middle-income countries (LMICs) have grown substantially in recent years, enabling them to double domestic health spending.¹⁴ By making investments in R&D capacity-building in LMICs in the short term, US policymakers can foster a more sustainable long-term approach to addressing global health challenges as these nations begin to invest in R&D to address the health needs of their own populations.



PATH/Gabe Blenczycki

While the United States looks to mobilize new resources from other nations and sectors, we must remember, first and foremost, that leadership starts at home. As the largest investor in global health R&D, the United States cannot fall behind on its investments. The nature of the R&D process means that any reductions in US funding could have a long-lasting and devastating impact on the development of current and future health tools already in the research pipeline.

As the international community continues to make progress in developing vaccines to combat HIV/AIDS and malaria or new diagnostics to improve treatment of infectious diseases, the United States must consider how we can intensify efforts to see these products through development and into use. Thanks to US leadership in global health R&D, the global health pipeline has grown from 215 products under development in 2004 to nearly 500 products today, with 22 percent of these innovations supported by the public sector and 58 percent supported through public-private partnerships.¹⁵ Sustained attention and funding from all sectors will be needed to get these promising products over the finish line and into the hands of populations in need.

Recommended policy actions

GOAL: SUSTAIN CURRENT INVESTMENTS AND MOBILIZE NEW RESOURCES TO SUPPORT GLOBAL HEALTH R&D THROUGH TRADITIONAL PUBLIC FINANCING AND INNOVATIVE APPROACHES.

To prevent stagnant investment levels from jeopardizing past progress and bridge the gap between R&D resources and need, Congress and the Administration should pursue the following actions.

1. Congress: Sustain robust public financing for US agencies engaged in global health R&D.

In the fiscal year 2017 budget, Congress should demonstrate strong support for global health programs by appropriating the following amounts for each agency, department, and program working in global health R&D:

(IN US\$ THOUSANDS)	
Global health programs at the US Agency for International Development	\$3,726,000
HIV/AIDS	\$350,000
Malaria	\$874,000
Maternal and Child Health	\$880,000
Neglected Tropical Diseases	\$125,000
Nutrition	\$230,000
Tuberculosis	\$400,000
Family Planning in all accounts	\$1,000,000
Global health programs at the Department of State	\$6,195,000
US President’s Emergency Plan for AIDS Relief	\$4,845,000
National Institutes of Health	\$34,500,000
National Institute of Allergy and Infectious Diseases	\$4,710,000
Office of AIDS Research	\$3,100,000
National Center for Advancing Translational Sciences	\$685,000
Fogarty International Center	\$70,450
National Institute for Child Health and Human Development	\$1,399,000
Centers for Disease Control and Prevention	
Center for Emerging Zoonotic and Infectious Diseases	\$629,485
Center for Global Health	\$457,000
TB program, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention	\$142,256
Food and Drug Administration	\$2,900,000
Department of Defense	Robust agency-wide funding for global health R&D

2. Congress: Investigate the possible benefits, implications, and feasibility of establishing a public-private funding mechanism for global health R&D to leverage new US investments with matching funds from the private and philanthropic sectors.

Research should be conducted to explore a mechanism that uses new government funding for global health R&D as a potential catalyst to mobilize new and matching contributions from the private and philanthropic sectors. One model to consider is establishment of an independent, nonprofit, grant-making foundation, modeled after the National Endowment for Democracy or the US Institute for Peace, that leverages US government investment in the fund by requiring it be matched at least dollar-for-dollar with private and philanthropic funding. In this possible mechanism, pledged public funds would be released only upon reaching a threshold level of matched outside contributions. In order to align with priorities across relevant agencies and sectors, research should outline key perspectives and considerations to ensure that such a mechanism would encourage coordinated cross-sector commitment to global health R&D, mobilize additional resources, and multiply the impact of US investments.

3. Congress: Create new incentive mechanisms or reform existing mechanisms to encourage increased private-sector participation in global health R&D.

New targeted and strategic incentive mechanisms, like prizes, advanced market commitments, and tax credits will help incentivize greater private sector engagement in R&D for neglected global diseases and conditions and bridge the divide between need and availability. In cases where mechanisms already exist, like the FDA Priority Review Voucher—which rewards companies that develop and secure FDA approval for technologies addressing NTDs with a transferrable or sellable voucher for expedited FDA regulatory review of another product—Congress should monitor these mechanisms to ensure they are effectively encouraging new investment in neglected disease R&D and promoting affordability and access to lifesaving technologies. Congress should also ensure that existing and future legislation designed to promote private-sector investment in R&D for neglected diseases upholds developer responsibility to collect data critical to informing safe and effective treatment in vulnerable populations, such as children.¹⁶



PATH/Will Boase

Spotlight: Leveraging investment for greater health impact at USAID

The US Agency for International Development (USAID) has proactively forged partnerships with the public and private sectors and other nations to mobilize new resources to address pressing development challenges, including health. The agency currently has more than 250 active public-private partnerships through which \$1 billion in USAID investment has leveraged an additional \$1.3 billion in private-sector contributions.¹⁷

The agency pioneered the use of innovative financing platforms including a prize competition series called Grand Challenges for Development to identify and finance promising innovations to advance global health and development. Launched in 2011, the Saving Lives at Birth (SLAB) Grand Challenge focuses on identifying and advancing innovations to address maternal and newborn health. In its first four rounds, SLAB provided \$47 million in funding for 81 technologies and interventions which have already reached more than 1.5 million mothers and babies, saving thousands of lives. USAID funding for SLAB is leveraged with contributions from the Bill & Melinda Gates Foundation and the governments of Canada, Norway, the United Kingdom, and Korea—which joined last year, pledging \$5 million.¹⁸

In response to the 2014-2015 Ebola epidemic, USAID, in partnership with the CDC, DoD, and White House Office of Science and Technology Policy, launched the Fighting Ebola Grand Challenge to identify and advance novel solutions to protect health care workers. In just two months, the agency received more than 1,500 applications, and offered 14 grants to further develop and test solutions.¹⁹

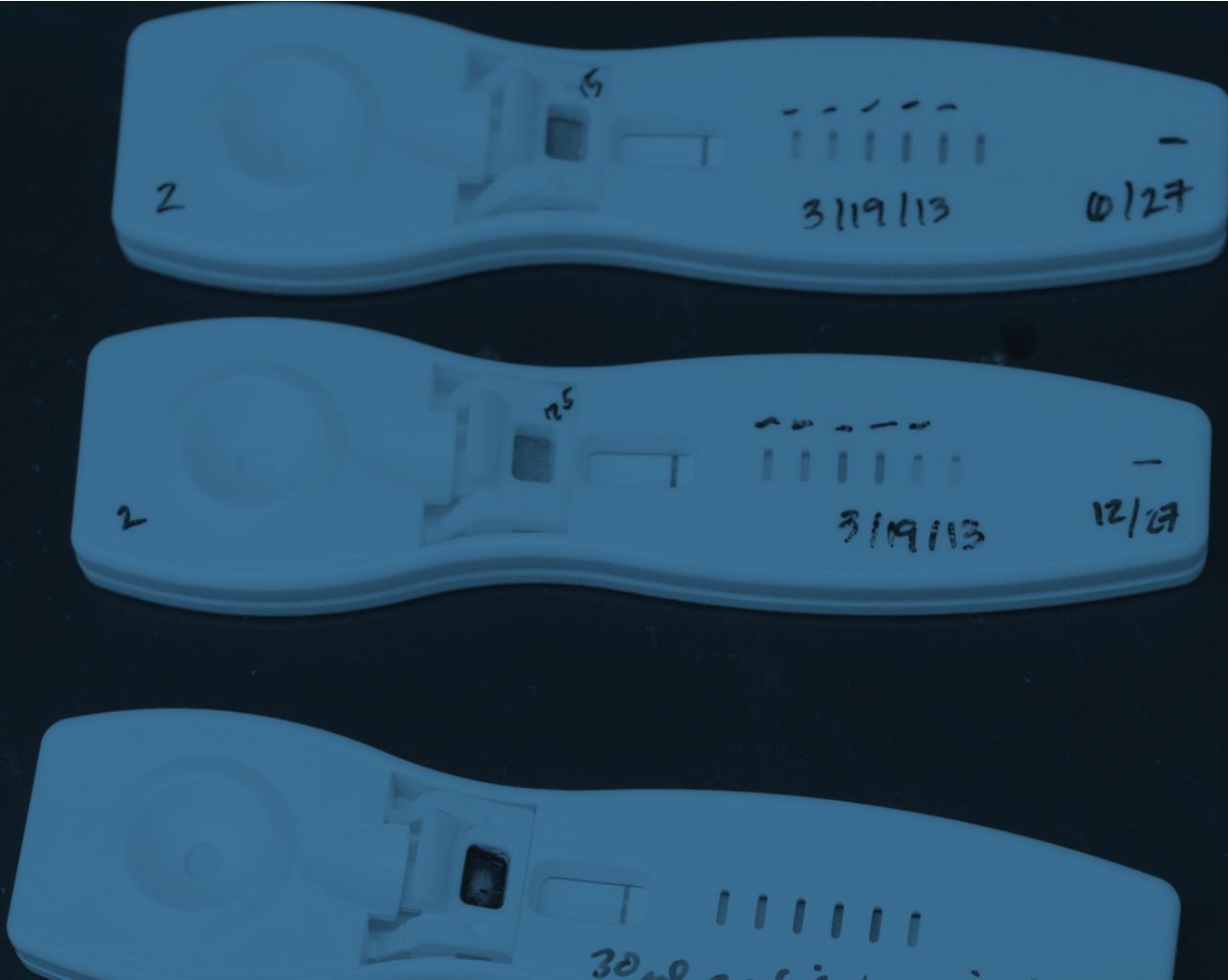
Through the six Grand Challenges held to date, USAID has received more than 7,400 ideas—a third from LMICs—and funded 224 of them, committing \$76 million and leveraging an additional \$125 million.¹⁹

4. Agencies: Set percentages of disease or global health-related program budgets to be directed to R&D.

As most global health R&D programs are not directly appropriated by Congress, agencies must prioritize funding for developing global health technologies within their existing programs. In the long term, investments in R&D can lead to game-changing innovations that save lives and produce cost savings, but in the short term these investments do not always yield immediate returns. In an era of tighter budgets and emphasis on metrics and reporting, agencies may feel pressure to prioritize programming aimed at achieving immediate and demonstrable results over investing in the development of products that will yield significant impact over longer time horizons. To ensure R&D is incorporated in US global health programs and activities and that sufficient investments are made to generate progress, agencies should articulate what percentage of overall disease or global health-related budgets will be directed to R&D and how this allocation will further core program objectives. Targets should be evidence based, grounded in science, and help to inform a minimum threshold—thus avoiding the risk of becoming a funding ceiling. Percentage targets should be flexible to capitalize on scientific breakthroughs or address changes and shifts in epidemics—as we learned from the response to Ebola and the immediate need for R&D to address Zika virus.

5. US Department of Health and Human Services (HHS), USAID, and US Department of Defense (DoD): Prioritize programs that support local R&D capacity-building activities for LMICs when making funding allocations.

To maximize the impact of US investments and lay the groundwork for a more sustainable long-term approach to financing R&D for endemic and emerging health needs, US agencies should prioritize programs that build the capacity of governments and research institutions in LMICs to conduct R&D to improve the health of their own populations. US agencies can pursue this objective through multiple types of programs. The US Centers for Disease Control and Prevention's (CDC) activities with partner nations explicitly target R&D capacity by building high-quality laboratory systems, training the R&D workforce, and helping build knowledge-sharing networks that facilitate the exchange of information, sharing of research tools, and collaboration. Other programs such as the US President's Emergency Plan for AIDS Relief, while primarily targeted at development activities, also have significant influence on R&D capacity through training of medical personnel, collaborating with local principal investigators in operational research projects, and supporting local research through innovation grants and challenges.



GOAL 2:

Improve coordination, alignment, and transparency of global health R&D efforts across US agencies and with international partners

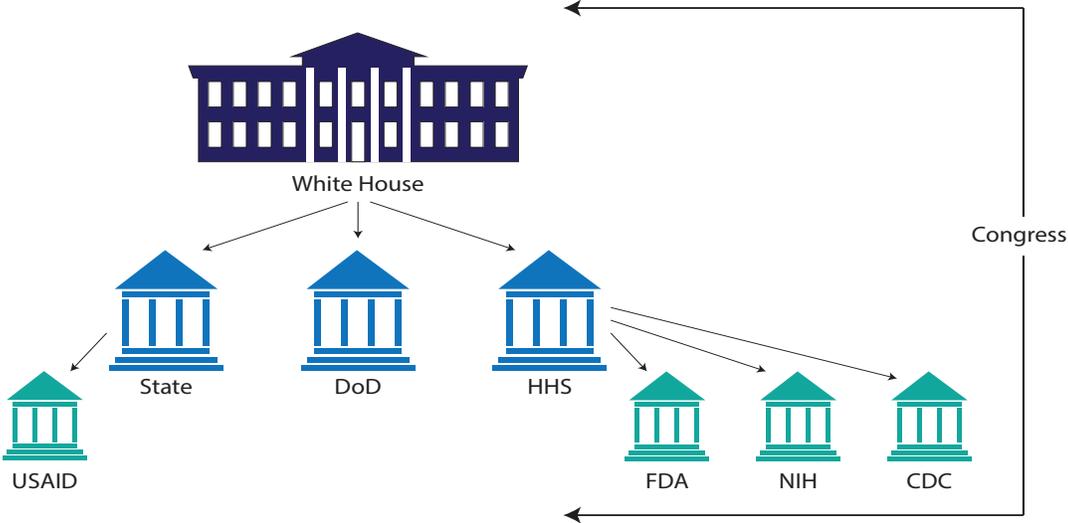
A perennial challenge in global health innovation is aligning the many actors involved in the research, development, and delivery of new global health technologies. The US government plays a pivotal role in global health R&D, and setting goals to enhance coordination, alignment, and transparency—both among agencies and with our international partners—will better leverage resources, expertise, and capacity to advance health innovation to achieve our ambitious global health agenda.



While the United States has technical expertise and financial and operational resources—and bipartisan political support—to drive global health innovation, US efforts can be hampered by the fractured nature of the US health R&D infrastructure. US global health R&D programming is conducted across seven major US agencies and departments—including the National Institutes of Health (NIH), USAID, Department of State, CDC, FDA, HHS, and DoD—in numerous centers or programs and in partnership with multiple bilateral and multilateral initiatives. Congressional oversight of these initiatives is equally fragmented, with eight congressional committees holding authority over global health R&D activities.*

Each agency and department offers unique and complementary expertise in health innovation and sets its own programming and R&D priorities based on its mission, expertise, budget, and congressional guidance. While programs and scientists often collaborate in an informal, ad-hoc capacity, no formal leadership or interagency strategy exists to articulate US global health R&D priorities, delineate divisions of labor, and coordinate activities across agencies and programs. Information-sharing is also uncoordinated: some agencies are transparent in how they set priorities for global health R&D and regularly report on investments and activities; others engage in only piecemeal or anecdotal reporting.

US GOVERNMENT GLOBAL HEALTH R&D ARCHITECTURE



More formal policies and mechanisms to promote interagency coordination and alignment can help leverage resources, close critical programmatic gaps, expose promising opportunities for interagency cooperation on projects, and improve accountability in US global health R&D efforts. These will also promote the sharing of critical learning between agencies and ensure that promising, early-stage research conducted by one agency is picked up and carried through to later-stage product development or introduction by another. Coordination can also help policymakers balance how resources are allocated for a host of R&D projects to better target a range of neglected diseases and conditions or align US investments with areas of greatest need and scientific opportunity.

Multilateral institutions and the international global health R&D community face the same coordination and alignment challenges as the United States. Effective coordination and information-sharing at the international level will help leverage resources, promote best practices, and encourage collaboration to hasten development of the full spectrum of health innovations needed to address endemic and emerging health threats. As in the United States, information-sharing, partnerships, and strategic dialogue can both expedite product development and help address critical gaps in the global health pipeline by exposing that certain neglected diseases, conditions, and technologies remain unaddressed. Greater coordination, transparency, and alignment are needed to foster innovation and speed the development and deployment of technologies needed to reach global health objectives.

* This includes the Senate Committee on Foreign Relations; Senate Committee on Appropriations; Senate Committee on Health, Education, Labor, and Pensions; Senate Armed Services Committee; House Committee on Foreign Affairs; House Committee on Appropriations; House Committee on Energy and Commerce; and the House Armed Services Committee.

Recommended policy actions

GOAL: IMPROVE COORDINATION, ALIGNMENT, AND TRANSPARENCY OF GLOBAL HEALTH R&D EFFORTS ACROSS US AGENCIES AND WITH INTERNATIONAL PARTNERS.

To maximize efficiency of US global health R&D investments and fill gaps in the product development pipeline, Congress and the Administration should pursue the following actions.

1. Congress: Establish a whole-of-government, coordinated global health R&D strategy.

This strategy would define how US agencies work together to advance global health R&D and set government-wide priorities, delineate roles and responsibilities, fill gaps in the product development pipeline, and facilitate effective partnerships and transfers of research within government. As part of this strategy, Congress should also consider establishing a focal point, or coordinator, for implementation, with the ability to oversee alignment and coordination of US global health R&D activities and actively support interagency collaboration. To be most effective, the strategy would need strong bipartisan political support and funding outside of existing global health R&D financing streams.

2. Congress: Pass and implement the Global Health Innovation Act.

The Global Health Innovation Act, a bipartisan bill that passed in the US House of Representatives in December 2015, would improve transparency and coordination of US global health R&D programs.²⁰ The bill formalizes USAID's annual report on health-related R&D and directs the agency to describe how it sets priorities for global health R&D, catalogue its R&D activities and investments, and measure how progress in health innovation advances the agency's global health goals.



PATH/Francesca Holme



PATRI/Matthew Dakin

The bill also encourages the agency to improve coordination and collaboration with other US agencies and partners to ensure critical gaps in product development are filled. Companion legislation must be introduced and passed through the Senate so the bill can be signed into law and implemented.

3. Agencies: Compile an annual aggregated report of global health R&D activities.

By creating an aggregated report of each US agency's activities in global health R&D, the Administration would enhance transparency and visibility of US activities in global health R&D, exposing gaps in programming and highlighting opportunities for interagency collaboration. Reporting mechanisms already exist in some agencies, like the NIH RePORTER system, which tracks all NIH-funded research, and USAID's annual health-related R&D report, which reports on USAID's investments and activities in global health R&D.²¹ These existing mechanisms could form the basis of a cross-government report.

4. Administration and agencies: Incorporate R&D as a prominent component of existing cross-government global health initiatives, such as the Global Health Security Agenda.

The US government can leverage existing cross-government global health initiatives like the Global Health Security Agenda (GHSa) to improve coordination and alignment of US global health R&D activities. The GHSa has a mandate to coordinate global health security activities across US agencies, including HHS, the Department of Agriculture, the Department of State, DoD, and USAID, and to partner with more than 50 nations to enhance the ability to prevent, mitigate, and respond to infectious disease threats.²² The GHSa was used as a convening and coordination platform for US agencies and

international partners during the 2014-2015 Ebola response. By adopting health innovation through R&D as a core goal, the GHSa can help position the global community to respond more quickly and cohesively to future health crises.

5. Agencies: Support the World Health Organization (WHO) Global Observatory on Health R&D by providing data on each agency's R&D portfolios and encouraging similar data contributions from all global R&D actors.

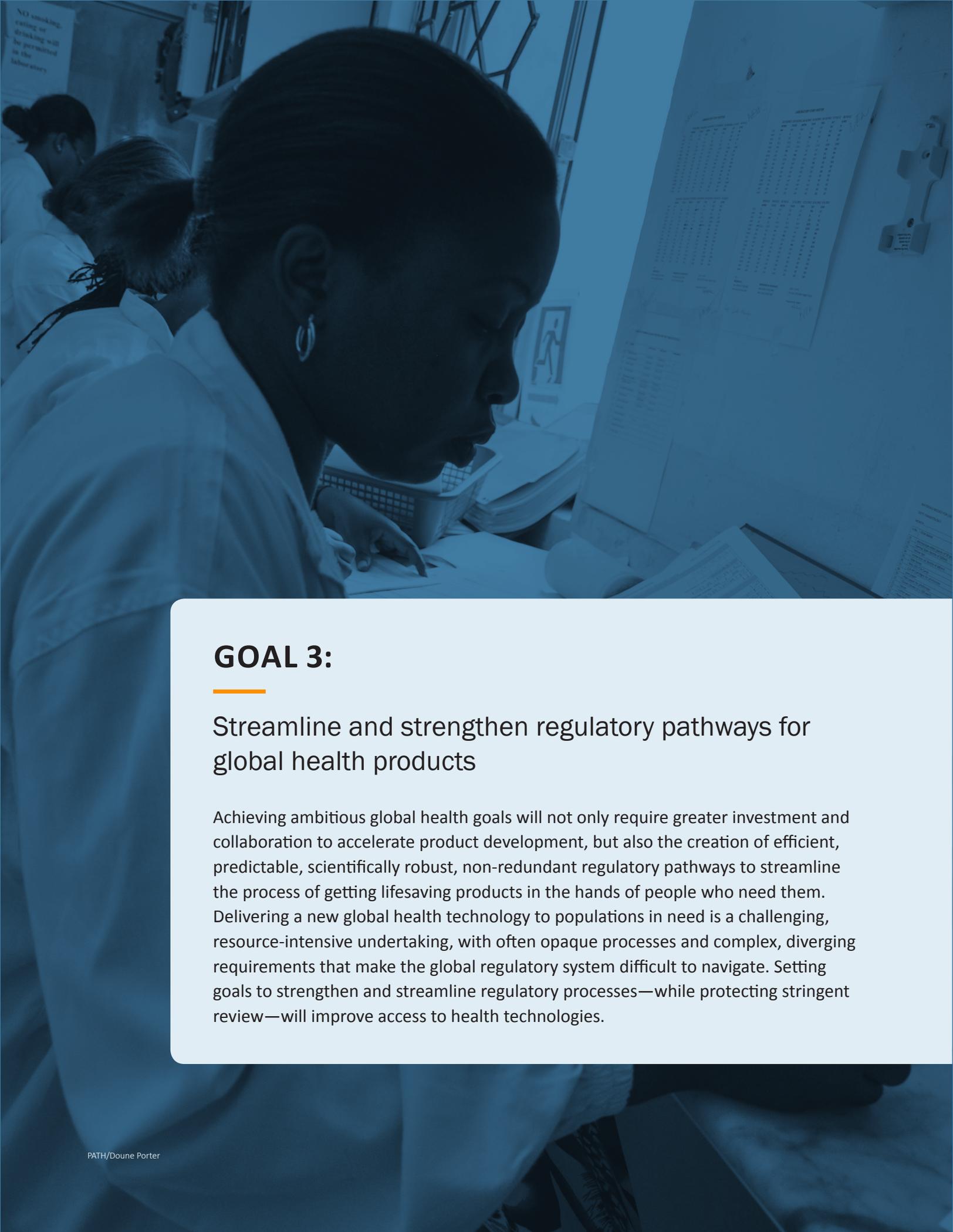
In January, WHO established the Global Observatory on Health R&D, responsible for tracking global health R&D financing and activities. By providing a comprehensive picture of R&D investments, activities, and the current state of the global health product pipeline, this observatory could serve as a critical tool to promote international coordination on global health R&D. It could also help key R&D actors identify gaps and opportunities for collaboration and provide critical information to help donor nations like the United States more effectively allocate resources to match need and scientific opportunity. The ability of this mechanism to work effectively depends on the contributions of data, metrics, and other information from key players in global health R&D, including the United States.

Spotlight: Coordinating across agencies to accelerate Ebola product development

During the 2014-2015 Ebola outbreak, the US government moved with impressive speed to accelerate development of urgently needed treatments, vaccines, and diagnostics to curb the epidemic. Along with White House-level attention and prioritization, several interagency coordination mechanisms were key to accelerating product development and review:

- The **Disaster Leadership Group**, a mechanism headed by the HHS Assistant Secretary for Preparedness and Response (ASPR) to coordinate decision-making during public health emergencies, mobilized leadership from ASPR, the Biomedical Advanced Research and Development Agency (BARDA), CDC, NIH, and FDA to accelerate development of potential treatments and tools for Ebola.²³
- The **Public Health Emergency Medical Countermeasure Enterprise (PHEMCE)**, an interagency coordinating framework to develop and deploy medical countermeasures for chemical, biological, nuclear, and emerging infectious disease threats, discussed and supported research to accelerate the development of Ebola countermeasures. The group, which includes officials from HHS/BARDA, HHS/ASPR, CDC, NIH, FDA, and non-HHS agencies, meets regularly to coordinate US government preparedness efforts for countermeasures for material threats. During an emergency—like Ebola—the enterprise shifts from preparedness coordination to managing a whole-of-government response. PHEMCE also used the Ebola crisis to develop a targeted study plan to help move products through regulatory scientific review to clinical trials.
- The FDA mobilized its existing emerging infectious disease task force into the **Ebola Task Force**, linking subject matter experts from across the agency to coordinate activities to expedite development and deployment of new Ebola interventions. Using existing and well-established intra-agency relationships, the panel provided scientific and regulatory guidance to commercial and US government product developers and facilitated the use of existing prioritization mechanisms to streamline clinical testing and review of Ebola products. Specific programs mobilized for Ebola include the Emergency Use Authorization, which allows for the use of an unapproved medical product during emergencies when there is no adequate, approved, and available alternative, and the Fast Track designation, which facilitates dialogue between product developers and the FDA to expedite the review of drugs that show promise over currently available therapies to treat serious conditions and fill an unmet medical need.²⁴

By deploying resources across agencies and programs and raising Ebola to material threat status, the US government was able to rapidly advance 11 new Ebola diagnostics, several antiviral therapeutics, clinical trials of a promising Ebola vaccine, and other novel treatments, like ZMapp™. These efforts demonstrate the remarkable progress we can make when an emerging infectious disease becomes a security and health threat to the United States.²⁵

A woman in a white lab coat is looking at a computer monitor in a laboratory setting. The image is overlaid with a blue tint. In the background, other people in lab coats are visible, and there are various pieces of equipment and papers on the wall. A sign on the wall reads "NO smoking, eating or drinking will be permitted in the laboratory".

GOAL 3:

Streamline and strengthen regulatory pathways for global health products

Achieving ambitious global health goals will not only require greater investment and collaboration to accelerate product development, but also the creation of efficient, predictable, scientifically robust, non-redundant regulatory pathways to streamline the process of getting lifesaving products in the hands of people who need them. Delivering a new global health technology to populations in need is a challenging, resource-intensive undertaking, with often opaque processes and complex, diverging requirements that make the global regulatory system difficult to navigate. Setting goals to strengthen and streamline regulatory processes—while protecting stringent review—will improve access to health technologies.

Before a new health technology can be marketed or made available in any given country, it must be assessed and approved by that country’s national or regional regulatory authority. Regulatory processes—which include approving and monitoring clinical trials, reviewing marketing application dossiers for products, assuring manufacturing processes, and licensing new products—help to ensure that products are safe, effective, and manufactured in a high-quality manner. While the oversight provided by regulatory agencies is critically important, securing regulatory approval for products intended for LMICs is often a challenging and complex process for product developers.

In LMICs—where infectious diseases like HIV/AIDS, malaria, TB, and NTDs are endemic—regulatory authorities often lack both the expertise and resources to effectively review new health tools. A recent report found that 80 percent of WHO Member States lack the necessary capacity to regulate health products domestically, including the ability to maintain a secure supply chain against substandard and falsified products.²⁶ This can create delays in bringing crucial health tools to market or promote unregulated access to unsafe health products. The overall registration timeline for medicines and vaccines in LMICs (including country of manufacture approval, WHO Prequalification, and local approval from the national regulatory authority) is typically four to seven years (after completion of phase 3 trials and assembly of a marketing application dossier), representing a significant delay compared to higher-income countries, where the average time for product approval is less than two years.²⁷

Different or incompatible regulatory requirements from country to country also make it more challenging for product developers to secure regulatory approval for products across markets. This can be particularly challenging for nonprofit product developers, small or mid-size companies, and research institutions—which often lead development of new products for global health diseases and conditions—as they have fewer resources to support regulatory activities across multiple geographies and less experience navigating the process. This can delay timing of sequential submissions by a manufacturer to various regulatory authorities and delay review and approval of new global health technologies, as developers must resubmit materials or supply new and different information to each regulatory body.²⁸

While the FDA is first and foremost mandated to promote and protect the health of Americans, it can, nonetheless, play an important role in helping to ensure that products to address health needs in LMICs are safe, effective, and manufactured in a high-quality manner. Because the FDA is classified as a stringent regulatory authority, the agency’s review of a product

REGULATORY PROCESS FOR GLOBAL HEALTH PRODUCTS

There is a multi-stage regulatory approval process for many global health products sometimes taking several years before products achieve widespread availability.

SECURE INITIAL APPROVAL FROM A REGULATORY AUTHORITY

Approval from a stringent regulatory authority (SRA) can facilitate WHO prequalification and approval in countries with limited regulatory capacity.

WHO PREQUALIFICATION*

WHO reviews a product for safety, efficacy, and manufacturing quality to determine whether to “prequalify” it, permitting its purchase by global procurers (e.g., United Nations; Gavi, the Vaccine Alliance). When a product has gone through a SRA, the process is abbreviated by relying on the work products of the SRA.

REGULATORY REVIEW & PRODUCT REGISTRATION**

Regulatory approval must be secured in each country where a product is intended for use. Each national regulatory authority (NRA) may have different requirements and many NRAs in LMICs have limited staff and capacity.

COUNTRY A

COUNTRY B

COUNTRY C

* Not all products are within scope of the WHO Prequalification Programme. Additionally, not all products are required to go through prequalification to be eligible for procurement. In some instances, approval by an SRA is sufficient.

** Depending on the product type, the process can be referred to as “approval,” “registration,” “clearance,” or “licensure.” In all of these cases, the word describes the legal authorization for the product to be marketed in a particular country



can facilitate and streamline review by both WHO's Prequalification Programme and lower-resourced national regulatory authorities in other nations. Additionally, because of the United States' longstanding leadership in medical innovation, the FDA is one of the world's leaders in regulatory expertise and infrastructure. This means it has the capacity and experience to review a wide range of novel products. Additionally, it is well positioned to provide technical guidance to organizations developing health products for LMICs, support regulators in LMICs, and engage in regulatory harmonization initiatives.

In recent years, the FDA has expanded its global engagement to help diminish some of the challenges impeding regulatory review and access to health technologies in LMICs. The agency has advanced partnerships with WHO and national regulatory authorities to promote regulatory capacity-building and regulatory harmonization in both LMICs and regional economic communities, which help to build regulatory systems that are able to provide appropriate local oversight for novel global health technologies with more efficient, predictable timelines and less redundancy. In addition, the agency has released new guidance documents to help product developers working on novel TB drug regimens and microbicides navigate the FDA regulatory process, providing transparency into review procedures and requirements to help eliminate delays caused by miscommunication or misinformation. Congress and the Administration should continue to support the FDA's increasing engagement in global health by providing the agency with sufficient resources to fulfill its domestic mandate and carry out existing and new activities in the global health arena.

By bolstering the FDA's engagement in global health and deploying its resources and expertise to support regulatory capacity-building in LMICs and improve harmonization, the United States can help streamline and strengthen regulatory pathways to support efficient approval and timely introduction of health technologies needed to reach US and the international community's global health goals.

Recommended policy actions

GOAL: STREAMLINE AND STRENGTHEN REGULATORY PATHWAYS FOR GLOBAL HEALTH PRODUCTS

To promote access to essential global health products, Congress and the Administration should pursue the following actions:

1. Congress: Direct the FDA to establish a specific mechanism to offer a formal scientific opinion on medical products for their use outside the United States.

This mechanism would permit the FDA to offer a formal scientific opinion on the safety, efficacy, and manufacturing quality of drugs, vaccines, and other health technologies for their use outside the United States. This would help promote

expanded access to health innovations by providing under-resourced regulatory authorities in LMICs with the scientific guidance they need to enable better informed national-level regulatory review. The European Medicines Agency (EMA) has a similar mechanism, known as Article 58, which allows the EMA to offer a scientific opinion on products that will be used exclusively outside the European Community. This program, which is intended to help facilitate regulatory review in LMICs and is operated in close coordination with WHO, could serve as a model for a US mechanism.

2. Congress: Explicitly incorporate NTDs into existing FDA pathways and programs for rare and orphan diseases.

To facilitate regulatory review of treatments for rare and orphan diseases, Congress established specific FDA programs to support product developers working on these diseases. These programs help shepherd qualifying products through regulatory review, provide guidance to product developers, and, in some cases, qualify products for priority review. NTD product developers face similar challenges to developers for rare and orphan diseases, including limited commercial market potential and limited resources or expertise to navigate regulatory review. While many NTDs meet the definition of a rare or orphan disease, as codified in the Orphan Drug Act of 1983, orphan and rare disease programs do not explicitly identify NTDs as within their scope. This lack of clarity might discourage NTD product developers from pursuing use of these programs, and may discourage the FDA from supporting NTD products through these programs due to jurisdictional concerns.

Spotlight: Pioneering a new regulatory pathway to improve access to HIV/AIDS treatments

The US President's Emergency Plan for AIDS Relief (PEPFAR) was launched in 2003 with a focus on delivering lifesaving antiretroviral medications (ARVs) to those most in need. It is the largest program dedicated to fighting a single disease in the history of US government foreign assistance, with a fiscal year 2016 budget of roughly \$5.2 billion.²⁹ Despite the unprecedented resources allocated to PEPFAR, the early phase of the program was plagued by high HIV/AIDS treatment costs because there were no FDA-approved, generic ARVs on the world market due to US patent and market exclusivity.

To address this problem, PEPFAR and the FDA partnered to develop a regulatory approval process to allow both generic ARV formulations as well as new fixed-dose combination ARVs to be eligible for purchase by PEPFAR. Under the program, the FDA reviews generic ARVs to ensure they meet US-approved safety, efficacy, and manufacturing quality standards and then grants "tentative approval," which allows the products to be procured by PEPFAR for use only in programs outside the United States, thus not violating the market protections that exist for products in the United States. Due to the public health imperative of the program, applications under the program are also prioritized for review by the FDA Office of Generic Drugs.

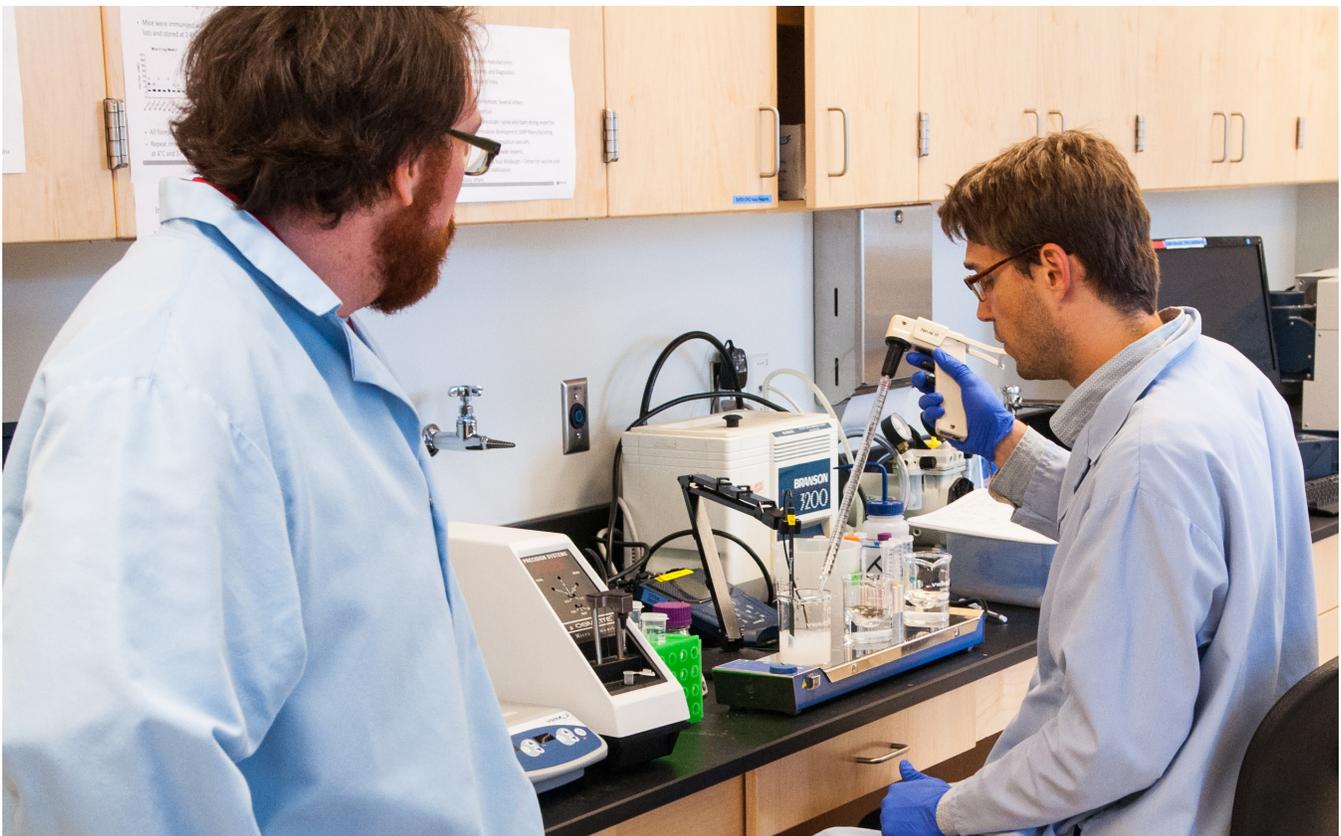
The program has been an unprecedented success; more than 160 generic or novel ARVs have received "tentative approval," allowing their purchase by PEPFAR. This has enabled the program to provide direct treatment to 5.7 million individuals. The approval process for ARVs has dropped from a matter of years to less than six months in almost all cases eligible to be considered through this program because of prioritization by the FDA and because the products did not have to wait for patent or market exclusivity to expire to be assessed.^{30, 31} Such an approach has reduced costs for developers of new ARV formulations, creating a thriving market and stimulating additional investment in ARV research, which is leading to more effective treatments that cause fewer side effects. In addition, the FDA has partnered with WHO to ensure that ARVs given a "tentative approval" under this program are subsequently included on the WHO prequalification list, which enables them to be procured by global humanitarian organizations (e.g., Gavi, the Vaccine Alliance; Global Fund to Fight AIDS, Tuberculosis and Malaria; United Nations Children's Fund) without any additional approvals. This one program has reduced PEPFAR's unit costs for ARVs by an average of 41.8 percent since 2005, increased access to novel medications, stimulated new development, and saved lives.³²

3. FDA: Explore a model similar to the Emerging Infectious Disease Task Force and Ebola Task Force to facilitate a coordinated and streamlined approval process for health technologies needed to address endemic and longstanding infectious disease threats.

The FDA should explore ways to adopt the model of the successful Emerging Infectious Disease Task Force to facilitate a similarly coordinated and streamlined approach to approving health technologies for endemic and longstanding infectious diseases. During the Ebola outbreak, this task force was named the Ebola Task Force, and worked with subject matter experts from across the agency to quickly and successfully deploy a range of coordinated activities to speed Ebola product development. This included working with other US agencies and product developers to clarify regulatory and data requirements, providing input on preclinical and clinical trial design, expediting regulatory review of data as received, and exchanging critical information with counterparts at WHO and other regulatory authorities.²⁴ While emerging infectious diseases often represent a material threat to the United States, other longstanding infectious diseases like TB and malaria have annual death rates that surpass those from Ebola, are similarly—if not more—contagious, and have tremendous R&D needs. The FDA should explore ways in which it can use the successful coordination model for emerging infectious diseases and material threats to enhance US preparedness to respond to longstanding infectious disease threats.

4. Administration: Support programs that strengthen regulatory capacity in LMICs and improve regulatory harmonization.

The US government should continue to expand its support to WHO and to national regulatory authorities in LMICs with the aim of strengthening their capacity to appropriately and non-redundantly review and regulate health products in line with internationally accepted WHO standards. It should also bolster current support for and engagement with bilateral and regional economic community regulatory harmonization initiatives (across both national and stringent regulatory authorities) to help lifesaving technologies reach patients faster, while ensuring these initiatives reflect international high standards of safety, efficacy, and manufacturing quality.



PAT/Patrick McKern

Conclusion

The unparalleled focus of the global community on setting and achieving ambitious goals to improve health worldwide has delivered enormous gains in global health over the last several decades. This deep commitment has galvanized political will, global cooperation, new resources, and innovative partnerships—demonstrating the power of goalsetting to mobilize change.

Yet for all the remarkable progress achieved, infectious diseases and other health challenges continue to claim the lives of millions of people each year, and safe, effective health tools are still not available to prevent, diagnose, or treat many neglected diseases and emerging health threats.

This past year, the United States and the global community signed up to finish the job, embracing a bold new agenda to realize a world free of HIV/AIDS, malaria, and other infectious disease epidemics, where maternal and child deaths are rare, and every person can survive and thrive. But getting there means the international community must go beyond current health interventions and commit to scientific discovery to fuel the development of new vaccines, drugs, diagnostics, and other technologies that will continue the arc of progress.

To achieve a truly transformative future, the global community must now back its global health agenda with a global health R&D agenda. The United States can play an invaluable role in making this possible by embracing a set of national goals to advance the development and delivery of lifesaving new health technologies. First, we must sustain current investments and mobilize new resources to support global health R&D through traditional public financing and innovative approaches. Second, we must improve coordination, alignment, and transparency of global health R&D activities across agencies and with international partners. Finally, we must streamline and strengthen regulatory pathways for global health products.

By embracing these goals and enacting the recommended policy actions in this report, US policymakers can strengthen US leadership in global health R&D and deliver a world where innovation ensures health and opportunity for all

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COALITION MEMBERS

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

