2016 Policy Report Executive Summary

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

Introduction

In the past two decades, the world has achieved 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. People are more likely to enjoy long, healthy lives today than at any other time in history.

These gains were driven by unprecedented commitments to set and achieve ambitious health goals facilitated by bold national health programs, supported through foreign aid and technical assistance from the United States and other donors, and multilateral initiatives, such as the Millennium Development Goals (MDGs). The results demonstrate that transformative change is possible when people come together around common goals to mobilize resources and drive collective action. More simply: goalsetting works.

In January, world leaders launched a bold new agenda for health and development, embodied in the Sustainable Development Goals (SDGs). Endorsed by the US government, the SDGs and related health targets align with the US agenda for global health and reflect our longstanding commitment to harnessing American ingenuity and leadership to save lives and create a safer world.

A bold vision for global health must be matched with a bold vision for global health research and development (R&D). Innovation has always been at the forefront of advancements in global health, and setting ambitious goals to develop new and improved vaccines, drugs, diagnostics, devices, and other health innovations is critical to continue progress.

As the world's leader in global health innovation, the United States has a crucial role to play in accelerating R&D to achieve the next big milestones in global health. We have an opportunity to lead by example, set bold national goals, develop smart polices, and invest to develop new tools and technologies that advance US strategic and humanitarian interests abroad, promote global health security, and protect the health of US citizens. Recent outbreaks of infections from the Ebola and Zika viruses have made it clear that diseases know no borders, and global health is linked to American health.

This executive summary—as well as the longer report on which it is based—presents three goals the United States should pursue to advance global health through R&D. Our recommendations include specific policy actions that Congress and the Administration should 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

Ambitious efforts to reach global health goals will require increased investment in R&D. Filling the gap between current investment and future 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.

Despite leading the world in health innovation, US government investment in neglected disease R&D has been largely stagnant or declining since peaking in 2009. In 2014, with emergency Ebola funding removed, US investment in neglected disease R&D was 13 percent, or $221 million, less than the 2009 peak. 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. To prevent stagnant investment levels from jeopardizing past progress and bridge the gap between R&D resources and need, US policymakers must sustain robust funding for global health R&D, while also pursuing innovative solutions to mobilize new resources from other sectors and nations.

Recommended policy actions

1. *Congress: Sustain robust public financing for US agencies engaged in global health R&D*. In the fiscal year 2017 budget, Congress should appropriate the following amounts for each agency and department:

   - US Agency for International Development (USAID) global health programs: $3.73 billion.
   - Department of State global health programs: $6.2 billion.
   - National Institutes of Health: $34.5 billion.
   - Centers for Disease Control and Prevention, National Center for Emerging and Zoonotic Infectious Diseases and Center for Global Health: $1.09 billion.
   - Food and Drug Administration (FDA): $2.9 billion.
   - Department of Defense (DoD): 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*. One model to explore is an independent, nonprofit, grant-making foundation that would receive pledged public funds upon reaching a threshold level of outside contributions.

3. *Congress: Create new incentive mechanisms or reform existing mechanisms to encourage increased private-sector participation in global health R&D*. Use of incentive mechanisms such as prizes, advance market commitments, and tax credits should be expanded, and the efficacy of these and other incentive tools, including the FDA Priority Review Voucher, should continue to be monitored.

4. *Agencies: Set percentages of disease or global health-related program budgets to be directed to R&D*. Most global health R&D programs are not directly appropriated by Congress. To ensure sufficient investment, agencies should articulate what percentage of overall global health budgets will be directed to R&D and how this allocation will further core program objectives. Percentage targets should be flexible to capitalize on scientific breakthroughs or to address changes and shifts in epidemics.

5. *US Department of Health and Human Services, USAID, and DoD: Prioritize programs that support local R&D capacity-building activities for low- and middle-income countries (LMICs) when making funding allocations*. To lay the groundwork for a more sustainable approach to financing R&D, US agencies should build the capacity of LMIC governments and research institutions.

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

US global health R&D programming is split across seven US agencies and departments, in numerous centers or programs, and in partnership with multiple bilateral and multilateral initiatives. Although each agency offers unique, complementary expertise, there is little formal coordination or alignment of activities. Congressional oversight of these initiatives is equally fragmented, with eight congressional committees holding authority over global health R&D activities.

Multilateral institutions and the international health R&D community also face coordination and alignment challenges. Effective coordination and information-sharing at the international level will help leverage resources, promote best practices, and encourage collaboration to accelerate development of the full spectrum of health innovations needed to address endemic and emerging health challenges.

Recommended policy 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, set government-wide priorities, and delineate agency roles and responsibilities. It could also include a coordinator to manage implementation.

2. *Congress: Pass and implement the Global Health Innovation Act*. The Global Health Innovation Act is a bipartisan bill passed by the US House of Representatives in December 2015 to improve transparency and coordination of US global health R&D programs. Companion legislation must be introduced and passed through the Senate so the bill can be signed into law.

3. *Agencies: Compile an annual aggregated report of global health R&D activities*. Creating an aggregated report of US agencies' activities in global health R&D would enhance transparency and visibility of those activities, expose gaps in programming, and highlight opportunities for collaboration.

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 (GHSA)*. The GHSA has a mandate to coordinate health security activities across US agencies and to partner with other nations to address disease threats. By adopting health R&D as a core programmatic 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*. By tracking global health R&D financing and activities, the new Global Observatory on Health R&D could serve as a critical tool to promote international coordination and collaboration. To be effective, it requires data, metrics, and other information from key players in global health R&D, including the United States.

Goal 3: Streamline and strengthen regulatory pathways for global health products

Many LMICs lack the technical capacity to effectively regulate health products, and the time needed to register medicines and vaccines typically ranges from four to seven years. Achieving ambitious global health goals will require efficient, predictable, scientifically robust pathways to streamline the regulatory process and promote access to new medicines and health technologies.

The FDA plays an important role in ensuring 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 can facilitate and streamline review by lower-resourced national regulatory authorities. By bolstering the FDA's engagement in global health and deploying its resources to support capacity-building and regulatory harmonization in LMICs, the United States can help streamline and strengthen pathways to support efficient approval and timely introduction of health technologies needed to reach global health goals.

Recommended policy 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 in order to provide regulatory authorities in LMICs the scientific guidance they need.

2. *Congress: Explicitly incorporate neglected tropical diseases (NTDs) into existing FDA pathways and programs for rare and orphan diseases*. While many NTDs meet the definition of a rare or orphan disease under the 1983 Orphan Drug Act, orphan and rare disease programs do not explicitly identify NTDs as within scope. This lack of clarity might discourage use of these programs for NTDs.

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*. Through the Emerging Infectious Disease Task Force, renamed the Ebola Task Force during the 2014-2015 Ebola outbreak in West Africa, the FDA quickly and successfully deployed a range of activities to speed Ebola product development. The FDA should explore ways to use this coordination model to enhance 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 strengthen the capacity of LMICs to review and regulate health products in line with international standards. It should also bolster support for and engagement with bilateral and regional regulatory harmonization initiatives to help safe, effective technologies reach patients faster.

Conclusion

National and international efforts to achieve the MDGs led to enormous gains in global health. Reaching ambitious health targets defined by the United States, and embedded in the new SDGs, will require going beyond current health interventions and developing new vaccines, drugs, diagnostics, and other technologies to continue the arc of progress.

The United States has an opportunity to further expand its leadership in global health innovation by advancing the development and delivery of new technologies to meet global health goals. By embracing the policy goals and recommended actions outlined in this document, US policymakers can accelerate the development of tools urgently needed to combat endemic and emerging health challenges and help to create a world where innovation ensures health and opportunity for all.

For more information

View the Global Health Technologies Coalition's full annual policy report at www.ghtcoalition.org.

COALITION MEMBERS

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

AERAS

ASTMH
American Society of Tropical Medicine & Hygiene
Advancing Global Health Since 1903

AVAC
Global Advocacy for HIV Prevention

DNDi
Drugs for Neglected Diseases *initiative*

Elizabeth Glaser Pediatric AIDS Foundation
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fhi360
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Treatment Action Group

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