



Policy recommendations to accelerate development and delivery of global health tools

The United States has long been at the forefront of research and development (R&D) for diseases that affect populations worldwide. Thanks to US investment and innovation, undeniable progress has been made in preventing, diagnosing, and treating conditions such as HIV/AIDS, malaria, tuberculosis, tropical diseases, pneumonia, and diarrheal diseases.

Despite this tremendous progress, existing tools in the arsenal against global health diseases are not sufficient to address drug resistance and new infectious disease threats. In addition, no vaccines exist for some of the most intractable diseases, such as malaria and HIV/AIDS, and no treatments are available for some of the tropical diseases that affect one billion people each year.

To ensure that the United States maximizes its investment in global health and continues its efforts to save lives worldwide, the Global Health Technologies Coalition (GHTC) urges Congress and the Administration to consider the following policy actions.

Public financing

- **Include research and product innovation as a key component of the overall US global health strategy, including in the president's new Global Health Initiative.** A commitment to global health research and product innovation should be included as a priority in all US global health efforts and should be seen as complementary to existing programs.
- **Increase US funding for and coordination of global health research to develop new tools.** Policymakers should ensure that funding for global health R&D meets the needs of US agencies to carry out product development. Sufficient funding is needed for agencies such as the Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Department of Defense (DoD), National Institutes of Health (NIH), and United States Agency for International Development (USAID).
- **Bolster documentation of US investments in global health R&D.** US contributions to global health R&D are significant, but it has historically been challenging to determine the full breadth of this investment. Congress should commission a Congressional Research Service report to examine US Government funding for global health R&D. The Administration should request that USAID develop a six-year strategy for R&D, to begin when the agency's current strategy expires, and that USAID produce annual reports on the progress of this strategy.

Regulatory systems

- **Ensure timely implementation of recommendations from new FDA review groups.** Congress should ensure that new, congressionally authorized groups—mandated to review and make recommendations on review processes for rare and neglected disease products—are convened in a timely manner. In addition, Congress should allocate sufficient resources to the FDA to ensure that recommendations are submitted and implemented in a swift timeframe.
- **Pursue stronger partnerships between the United States and global regulatory stakeholders.** The United States should increasingly collaborate with the World Health Organization (WHO) and national regulatory authorities to accelerate access to global health products. Congress should allocate adequate financial and political support to the FDA and USAID so that they can offer regulatory assistance, where appropriate.
- **Strengthen FDA's engagement with other agencies and product developers.** The FDA should increase its collaboration with other US Government agencies that conduct R&D for global health tools. An initial step in this direction would be to include the FDA in existing and future interagency global health committees.
- **Expand membership in FDA advisory committees to include developing country representatives.** Advisory committees within the FDA provide important expertise and guidance to agency centers on scientific decisions, as well as on safety and efficacy evaluations of new products. These committees could benefit from developing country perspectives when reviewing products intended for the developing world.

Incentives and innovative financing mechanisms

- **Form a cross-agency working group to explore US participation in a portfolio of incentives and innovative financing mechanisms.** This group should consider adopting a set of criteria to use when evaluating the role of the United States in supporting specific mechanisms. These criteria should be applied to the evaluation of multiple mechanisms with the goal of supporting one or two new mechanisms in 2011.
- **Ensure that a vigorous assessment is conducted of each incentive mechanism in which the US invests.** During and following implementation of an incentive mechanism or innovative financing strategy, US policymakers should ensure that a robust assessment takes place to monitor effectiveness and impact of the mechanism.
- **Support US involvement with the Leading Group on Innovative Financing for Development and other international groups working on financing for health.** US involvement should eventually lead to the nation's participation in future innovative financing mechanisms, such as an Advance Market Commitment (AMC). As directed by the Lantos-Hyde Act, the US Government should consider participating in future negotiations for AMCs for new vaccines, as well as other finance mechanisms.

US policymakers should assure that innovation and research are central components of US global health efforts. These policy actions provide Congress and the Administration with a solid foundation to boost the research and innovation needed to address global health diseases and to ensure that the most effective tools are available now and in the future.



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The Global Health Technologies Coalition (GHTC) seeks to engage and inform US decision-makers about policies to accelerate the creation of new tools to address longstanding global health problems in low-resource settings. These tools include new vaccines, drugs, microbicides, diagnostic tests and other products. The coalition advocates for increased and effective use of public resources, incentives to encourage private investment, and improved regulatory systems. The GHTC is housed at PATH and funded by the Bill & Melinda Gates Foundation.