

Global Health Technologies Coalition Outside Witness Testimony
Jamie Bay Nishi, GHTC Director
Subcommittee on State, Foreign Operations, and Related Programs, U.S. Senate
Addressing USAID

On behalf of the Global Health Technologies Coalition (GHTC), a group of 37 nonprofit organizations, academic institutions, and aligned businesses advancing policies to accelerate the creation of new drugs, vaccines, diagnostics, and other tools that bring healthy lives within reach for all people, I am providing testimony on fiscal year (FY) 2022 appropriations for global health programs at the US Agency for International Development (USAID). These recommendations reflect the needs expressed by our members working across the globe to develop new and improved technologies for the world's most pressing health issues. We appreciate the Committee's support for global health, particularly for continued research and development (R&D) to advance new drugs, vaccines, diagnostics, and other tools for longstanding and emerging health challenges, including COVID-19. To this end, we strongly urge the Committee to continue its established support for global health R&D by robustly funding the global health accounts at USAID and the State Department, at or above the levels included in the President's budget request; instructing USAID to prioritize R&D within each of the disease and condition areas under the Global Health Programs account and to consider setting minimum funding targets for innovation activities in each health area from future increases to the account; and instructing USAID to develop and publicly release a new five-year strategy on health-related R&D detailing how USAID will work across programs to implement a holistic global health R&D strategy—developed with input from program leads within the Global Health Bureau, consultations with nonprofit and private-sector partners, and leadership of other relevant federal departments and agencies.

US investment in the development of new vaccines, drugs, devices, diagnostics, and other health technologies is essential to addressing some of the world's most pressing health challenges—achieving an AIDS-free generation; curbing the spread of malaria, tuberculosis (TB), and neglected tropical diseases (NTDs); addressing antimicrobial resistance; and ending preventable child deaths. Over the past year, the importance of strong investment in global health R&D has become clearer than ever before as scientists raced to develop the tools desperately needed to diagnose, treat, and prevent COVID-19. We have watched with awe as scientists have shattered speed records for vaccine development, forged unique collaborations to advance science across borders, and deployed an unprecedented amount of energy and resources from a range of health areas to tackle this global foe—upending assumptions about how science works, and how fast. Now, well over a year into the official declaration of the COVID-19 global pandemic, we have a robust set of tools to defeat this threat in high-income countries but still lack the tools needed to meet the unique needs of patients and health workers in low-resource settings, where basic resources like electricity, laboratory capacity, and reliable cold chain storage cannot be taken for granted. This is the next frontier of R&D for COVID-19: ensuring that we have the right tools to defeat this pandemic in every corner of the globe, which is ultimately essential for securing America against this historic threat.

We are grateful for the Committee's ongoing support for global health R&D and recognize that you face difficult decisions in balancing many priorities for annual appropriations and the allocation and use of emergency appropriations for unprecedented R&D and public health needs over the past year. We welcome the recent allocations of emergency funding for Gavi, the Vaccine Alliance; Global Health Programs at USAID; the President's Emergency Plan for AIDS Relief (PEPFAR); and the Global Fund to Fight AIDS, Tuberculosis and Malaria in the last two COVID-19 relief packages—however, we note that critical needs remain unmet, including funding to support the development and deployment of COVID-19 products designed for use in low-resource settings, and that USAID has yet to allocate the contribution to the Coalition for Epidemic Preparedness Innovations (CEPI) included in the American Rescue Plan Act. New global health tools and technologies hold promise to dramatically improve the lives of those living in the poorest countries around the world both to extinguish the COVID-19 pandemic and tackle long-

standing global health challenges, and even as we work to scale up delivery of existing tools, we ask for your support for continued innovation in FY22.

Critical Need for New Global Health Tools: While we have made tremendous gains in global health over the past fifteen years, millions of people around the world are still threatened by HIV/AIDS, TB, malaria, and other neglected diseases and health conditions. In 2019, TB killed 1.4 million people, more than any other infectious disease at that time, while 1.7 million people were newly diagnosed with HIV. Nearly half of the global population remains at risk for malaria, with drug-resistant strains growing. Women and children remain the most vulnerable. Around 68% of all global maternal and child deaths occurring in sub-Saharan Africa, with 1 out of every 13 children in the region dying before the age of 5—often from vaccine-preventable or other communicable diseases. These figures highlight the tremendous global health challenges that remain and the need for sustained investment in global health research to deliver new tools to combat endemic and emerging threats.

New tools and technologies are critical, both to address unmet global health needs and to address challenges of drug resistance, outdated and toxic treatments, and difficulty administering current health technologies in poor, remote, and unstable settings. We must also continue investing in the next generation of tools to prepare for emerging threats. The COVID-19 pandemic has again demonstrated that we do not have all the tools needed to prevent, diagnose, and treat many neglected and emerging infectious diseases—a reality foreshadowed by the recent Zika and Ebola epidemics. The life-saving effects of the COVID-19 vaccines demonstrate the power of having the right tools to respond to a health emergency. These new vaccines, developed with critical funding from the US government, are highly effective and built upon past global health research advances. Notably, the Johnson & Johnson vaccine is based on technology used in its Ebola vaccine and Zika, respiratory syncytial virus, and HIV/AIDS vaccine candidates and the Moderna-National Institute of Allergy and Infectious Diseases (NIAID) vaccine platform was previously being used to develop vaccines against other respiratory viruses and the chikungunya virus. This demonstrates how strong, sustained investment in R&D allows us to tackle today's health threats and prepare for those of the future. It is critical we keep investing in the development of next-generation tools to fight existing and emerging disease threats so that we have tools ready to go when we need them.

USAID Contributions to Global Health R&D: USAID is the only US agency with a mandate to focus on global health and development. For that reason, the agency is uniquely positioned to support the end-to-end development of new global health technologies—from defining a global health challenge, designing a tool to address it, developing that tool through clinical trials, and delivering that tool to communities most in need—in a way that is not replicated elsewhere in the US government, particularly for late-stage research and product development. USAID's global presence and unique understanding of the needs of patients in different settings and contexts is key to developing health innovations that are transformative on the ground. We applaud the efforts that USAID has made in fostering innovation in health technologies, including:

- Partnering across government agencies and among private-sector partners to identify breakthrough innovations to combat infectious disease epidemics in response to recent outbreaks of Ebola and Zika. USAID's Fighting Ebola Grand Challenge identified 1,500 innovative technologies to advance the fight against Ebola and advanced 14, including a low-cost, battery-operated tool used during both the Ebola and COVID-19 responses that manages the flow rate of intravenous treatments with a simple gravity system, replacing the need for expensive, difficult-to-use infusion pumps. The Combating Zika and Future Threats Grand Challenge received over 900 crowdsourced technology proposals and selected 26 projects to fund, which cut across vector control, vector and disease surveillance, diagnostics, and other interventions. In March of 2020, USAID issued a request for information for proposals for low-cost, scalable innovations that could support the international COVID-19 response, including new products and service delivery approaches. It received hundreds of proposals for potentially game-changing innovations, but funding is urgently needed to advance and scale them, potentially through the launch of a Grand Challenge focused on COVID-19 and global health security.

- Establishing a five-year partnership with CEPI to advance the development of vaccines against priority emerging infectious diseases including Lassa fever, Middle East Respiratory Syndrome (MERS), Nipah, Chikungunya, Rift Valley Fever, and Ebola.
- Supporting research to develop safe, effective, and accessible tools to prevent HIV in the developing world—including HIV vaccines and microbicides, which have tremendous potential to prevent HIV infection in women—and a low-cost, rapid, disposable HIV/AIDS diagnostic test designed for infants.
- Supporting the development of vaccines, antimalarials, insecticides, and novel vector control tools against malaria, including a promising single-dose cure.
- Playing a key role in the global effort to fight TB by supporting research to develop innovative, new drug regimens and diagnostics for drug-susceptible and drug-resistant TB, including the world’s first child-friendly TB medicines, developed with critical seed funding from USAID and introduced in 2015, and a new all-oral treatment regimen that reduces the time it takes to treat drug-susceptible TB from six months to four months. USAID expertise on implementation and scale-up of these innovations is a critical piece of the product development cycle and ought to be appropriately prioritized.
- Developing interventions to help women and children during childbirth in low-resource settings where there may not be electricity, refrigeration, or trained health workers.
- Developing new drugs and diagnostics for a select group of neglected tropical diseases (NTDs), including tools to fight dengue and other mosquito-borne diseases that have been deployed from Indonesia to the Florida Keys with promising results.

Global Health R&D Funding at USAID—Addressing Critical Gaps: USAID is an important partner in global health product development, and it is critical for the agency to bolster this function of its global health programming. This means that global health programs within USAID require robust funding to ensure they have appropriate resources, both for ongoing programs and forward-looking R&D efforts.

For the vast majority of USAID’s global health programming, there are no dedicated funding streams or programs expressly supporting global health R&D. This means that decisions on USAID’s investments in developing new global health technologies—the tools needed to make programming more successful and efficient and to further the agency’s global health mission—are made at the program level, based on overall funding allocations for each disease or population-specific health area. To ensure research is appropriately prioritized, global health programs need appropriate resources. GHTC strongly supports increasing funding for USAID Global Health Programs at or above the levels proposed in the President’s FY22 budget request to allow for transformative investments in the new drugs, vaccines, diagnostics, and other tools to accelerate global health gains while sustaining current programming needs.

While some areas of USAID’s global health portfolio are leading the way in R&D, there are other areas where a lack of resources and prioritization are acute. For example, USAID does not currently incorporate research for new vaccines for TB into its programming, and has made limited investments in new preventative technologies, despite TB being the world’s greatest infectious disease killer prior to COVID-19. USAID could also advance its role in R&D for NTDs. While the agency does important work to provide treatments for five of the most prevalent NTDs, new tools are needed to reach the end game for these diseases, including more sensitive diagnostics to ensure that elimination goals have been met—which, in addition to meeting clear epidemiological needs, would improve resource allocation and ensure that US investments have the desired results. Relatively small investments in R&D for new NTD tools could have an incredible return for both public health and our historic investment in the effort to end NTDs.

USAID recognizes the value of global health R&D, but this recognition is not always clearly articulated in the many strategic documents and frameworks that guide the agency’s work. Congress has an important opportunity to correct this by requesting a new five-year strategy on health-related R&D from USAID detailing how the agency will work across programs to achieve global health R&D goals.

The strategy—vital to ensuring that innovation fuels USAID’s global health mission and R&D is appropriately prioritized—should be developed with input from program leads within the Global Health Bureau, consultations with external nonprofit and private-sector partners, and leadership of other relevant federal departments and agencies. The strategy should detail how USAID coordinates with stakeholders to support innovative global health product development to address critical gaps, particularly for late-stage research and product introduction; include specific investment and target outcomes for research and product development across disease areas and crosscutting challenges like global health security and antimicrobial resistance; and detail where additional USAID investment in innovation could accelerate progress towards global health goals. Once developed and released, detailed annual reporting on this strategy—which should be made promptly available on the USAID website—would be vital for appropriate congressional oversight.

GHTC stresses the need for USAID to continue to prioritize science, technology, and innovation to advance its global health and development mission. GHTC urges the Committee to continue to direct USAID Global Health Programs to include and expand R&D for new tools, allocate sufficient resources to support this work, and encourage detailed, public annual R&D reporting by USAID, which provides the only insight policymakers and advocates have into the agency’s R&D decision-making processes.

Collaboration Across the US Government: In addition to USAID, support for global health R&D in the US government comes from the Department of Defense (DoD), the Department of Health and Human Services (HHS), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Biological Advanced Research and Development Authority (BARDA), and the National Institutes of Health (NIH). Each of these agencies play a unique and essential role in moving new global health technologies from concept to reality, and strong interagency collaboration is essential to leverage limited US government resources and ensure taxpayer dollars are used most effectively. To this end, we urge the Committee to encourage USAID to work with CDC, DoD, FDA, NIH, HHS, and BARDA to develop a whole-of-government strategy for global health R&D to coordinate priorities and resources and streamline operations.

Investing in Global Health R&D as a Strategic National Security and Economic Decision: Global health R&D is important for delivering lifesaving tools to those who need them most. However, US government investments in R&D—through USAID and other agencies—yield benefits in addition to humanitarian and development goals. As COVID-19 has dramatically demonstrated, health crises abroad can become health crises at home, and it is imperative that we sustainably invest in R&D for a broad range of neglected infectious diseases so that we understand emerging disease threats and have tools ready for them. Additionally, global health R&D is a smart economic investment in the United States, where it drives job creation, spurs business activity, and engages academic institutions. **In fact, 89 cents of every US dollar invested in global health R&D benefits US-based researchers**, many of whom conduct their research at US universities. **US government investment in global health R&D between 2007 and 2015 generated an estimated 200,000 new jobs and \$33 billion in economic growth.**

Global health research that improves the lives of people around the world—while also promoting global health security, creating jobs, and spurring economic growth at home—is a win-win investment. Recognizing this, GHTC respectfully requests that the Committee sustain and increase US investment in global health research and product development by robustly funding the global health accounts at USAID and the State Department, at or above the levels included in the President’s budget request; instruct USAID—in collaboration with other agencies involved in global health—to prioritize R&D within each of the disease and condition areas under USAID’s Global Health Programs account; and direct USAID to develop and publicly release a new five-year strategy on health-related R&D detailing how USAID will work across programs to implement a holistic global health R&D strategy. These steps are vital to sustaining the life-saving global health innovation work led by USAID which is fundamental to the achievement of the United States’ broader global health goals—which we all understand more clearly than ever are inseparable from our health and prosperity here at home.