

**Global Health Technologies Coalition Testimony for the Record
House Foreign Affairs Subcommittee on International Development,
International Organizations and Global Corporate Social Impact
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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—thank you for the opportunity to provide testimony for the record as the House Foreign Affairs Subcommittee on International Development, International Organizations and Global Corporate Social Impact consider the important topic of “Innovation in Development Policy: Maximizing Impact and Results.”

Innovation is the heart of GHTC’s mission: our members, working in nearly one hundred countries worldwide, are committed to advancing innovation to save lives. The impact of COVID-19 over the past year has perhaps made that mission more tangible than ever before, as everyday Americans track news of clinical trial results for COVID-19 vaccine candidates, eagerly await the availability of continuously improving options for diagnostics, and watch scientists and clinicians refine tools and standards of treatment for infected individuals, driving up the survival rate for this devastating disease. Today, Americans appreciate in a very real way that innovation saves lives, that research and development (R&D) must be the tip of the spear of our response to health emergencies, and that infectious diseases that emerge in communities halfway around the world are just as real and pressing hazards to our health, economy, and security as traditional geopolitical threats.

However, COVID-19 is not the first urgent threat to global health, nor will it be the last pandemic. **As we refine our institutions and systems to prevent, contain, and defeat emerging health threats, we must also recommit to innovation to mitigate the impact of enduring threats such as HIV/AIDS, malaria, tuberculosis (TB), neglected tropical diseases (NTDs), antimicrobial resistance (AMR), and the leading causes of preventable deaths of mothers and children—challenges which in many areas of the world have worsened as COVID-19 has overwhelmed health systems.**

While the global community was on a very positive trajectory towards improving global health in the decade leading up to the COVID-19 pandemic, even the statistics collected before the pandemic reveal serious challenges: In 2019, TB killed 1.4 million people, surpassing deaths from HIV/AIDS, and 1.7 million people were newly diagnosed with HIV. Nearly half of the global population remains at risk for malaria and drug-resistant strains are growing. Women and children remain the most vulnerable, with around 68% of all global maternal deaths occurring in sub-Saharan Africa and 1 out of every 13 children in that region dying before the age of 5—often from vaccine-preventable or other communicable diseases. These figures highlight the tremendous global health challenges that were present before COVID-19 and will persist once the pandemic has been contained, which illustrates why sustained investment in global health innovation to deliver new and improved tools is so critical.

The impact of such investment has been on full display over the past year 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. Today, we have a robust set of tools to defeat this threat in high-

income countries, but still lack critical tools designed 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 to securing America from this historic threat by preventing additional strain mutation.

Thankfully, the United States has among its many resources an entity well-suited to tackle this challenge: the US Agency for International Development (USAID). As the only US agency with a mission and vision focused exclusively on global development, USAID 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. USAID is a leader in innovation and has brought business-minded approaches, novel platforms and practices, innovative financing models, and public-private partnerships, such as product development partnerships, to the development and rollout of global health technologies. By investing seed capital in promising ideas, USAID leverages private-sector, nonprofit, and external government funding, partnerships, and expertise.

The agency has made a major impact in global health innovation with modest resources compared to many US R&D agencies under the Department of Health and Human Services. To name just a few examples, USAID has in recent years supported research to develop safe, effective, accessible, and acceptable tools for use in the developing world to prevent HIV, including investigational HIV vaccines; microbicides and a microbicide vaginal ring to prevent HIV infection in women; and a low-cost, rapid, disposable HIV/AIDS diagnostic test for infants. USAID has played 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 tuberculosis, including the world's first child-friendly TB medicines and a new all-oral treatment regimen that reduces the time it takes to treat drug-susceptible tuberculosis from 6 months to 4 months. USAID has supported the development of vaccines, antimalarials, insecticides, and novel vector control tools against malaria, including a promising single-dose cure. Finally—among many other areas of health impact—USAID has developed interventions to help women and children during childbirth in low-resource settings that may not have electricity, refrigeration, or access to trained health workers, including oxygen therapies.

Despite USAID's uniquely positioned capacities and the gaps it fills in the global health R&D ecosystem, there continues to be low recognition of the agency's leadership and success in the R&D space by the public and policymakers. More importantly, R&D is often overlooked as an integral part of USAID's mission and an essential enabler of the progress the agency seeks to enable in global health. This has, regrettably, persisted during the COVID-19 pandemic.

GHTC offers the following recommendations for strengthening USAID's global health innovation mission and impact as the Committee considers the broader role of innovation in development—both in this critical juncture in the global response to the COVID-19 crisis and as the US looks beyond the pandemic to other emerging and enduring threats to global health and prosperity.

First and foremost, USAID's unique health innovation capabilities must be elevated as part of the whole-of-US-government response to COVID-19. In previous global health crises like the West African Ebola epidemic and the Zika epidemic, USAID helped crowdsource and advance to

market innovative tools to fight these threats via its Grand Challenges programs led by the Center for Innovation and Impact (CII). In March of 2020, the agency issued a request for information for proposals for low-cost, scalable innovations that could support the international COVID-19 response and received hundreds of responses from eager innovators, but has not had a source of emergency funding to advance them. **We encourage authorizers and appropriators to urge the Administration to direct some of the funding for global health activities at USAID included in the American Rescue Plan Act towards innovation activities, such as the launch of a Grand Challenge for COVID-19 and Global Health Security.** We believe at \$200 million is needed for the most pressing innovation gaps, particularly in the areas of diagnostic development and scale-up and innovations to advance and adapt oxygen therapies in low-resource settings, among other needs.

USAID has a proven track record of success in advancing innovations during health emergencies. 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 manage the flow rate of IV 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. It would be a serious oversight if the agency were not encouraged and funded to advance a Grand Challenge for COVID-19 given the scale of this threat and the agency's impact during previous global health emergencies.

In complement, from the same tranche of funding included in the American Rescue Plan Act, **the full \$300 million in emergency funding requested by CEPI, the Coalition for Epidemic Preparedness Innovations, should be allocated by USAID for the immediate phase of their COVID-19 response.** CEPI is a global co-funded effort to develop vaccines for emerging infectious diseases now working to advance eight COVID-19 vaccines from early-stage development through manufacturing and approval. By investing in CEPI, the US government can leverage funding from other global funders to support promising vaccine candidates designed with global access in mind while not bearing the full cost of development.

Beyond the acute phase of global response and recovery from the COVID-19 pandemic, longstanding challenges within USAID—in the areas of leadership, coordination, strategy, funding, and reporting—should be addressed to better enable their life-saving global health innovation work. GHTC offers the following recommendations to that end:

USAID should establish a Chief Science and Product Development Officer for global health.

Several different entities and offices at USAID play a role in setting and advancing the agency's global health R&D priorities and activities. The decentralization of R&D decision-making—with global health funding appropriated by discrete disease and health areas by Congress and decisions on where and how much to invest in R&D then made within each of the Global Health Bureau's technical offices—creates a complex labyrinth to navigate for innovators to pursue opportunities for partnership with the agency. To address these longstanding challenges, USAID's Global Health Bureau should establish a Chief Science and Product Development Officer (CSO) role that will function at the level of a Deputy Assistant Administrator. This position should ensure that USAID is delivering on the agency's vision and strategy for R&D, have direct oversight over CII, and serve as a clear focal point for inter- and intra-agency collaboration and external stakeholder and public engagement. The CSO should also chair USAID's Global Health Research Working Group and work in close concert with research leads in technical offices and collaborate on cross-sector initiatives.

In complement, **the mandate of the USAID Center for Innovation and Impact should be strengthened to improve the coordination of global health innovation activities.** USAID established CII, which sits within the Global Health Bureau, to serve as a center for excellence for global health innovation at USAID. CII applies business-minded approaches to the development, introduction, and scale-up of health interventions and can help design innovative programs. Although CII has introduced new approaches to complement efforts already being supported across the Global Health Bureau, its work is significantly demand driven. Outside of overhead funding the program receives, which is taken as a small percentage from all health-area offices, CII receives the remainder of its funding from health area offices that choose to engage the Center's expertise on specific initiatives. Therefore, many approaches or best practices incubated at CII remain at the pilot scale and are not utilized or integrated across health portfolios, and CII's work specifically on product development remains limited. Addressing these gaps would help strengthen and better coordinate USAID's global health innovation portfolio.

Additionally, **a detailed, comprehensive, and ambitious five-year health research and development strategy should be developed to guide the next phase of USAID's global health innovation work.** The most recent USAID five-year health research and development strategy was released in October 2017, outlining for the years 2017-2022 USAID's commitment to addressing some of the world's most challenging health and development issues through technology development, research and evaluation, and introduction and scale-up of real-world, evidence-based solutions. This strategy is an important articulation of USAID's health innovation mission and, together with the annual reports produced on the strategy, is an essential accountability tool to ensure the agency is on track to meet its goals in health R&D. However, stakeholders note that the strategy as most recently formulated lacks some specificity, missing critical details on how USAID sets goals and targets for innovations by disease area and product type and how this influences investment decisions; how the agency identifies gaps in the global health innovation ecosystem it is best positioned to fill vis a vis where other partners are investing; how different disease and population-specific programs within the Global Health Bureau collaborate on health innovation and make investment decisions jointly and independently; and how the agency considers the input of communities where research will be conducted and where products in development will be used in decision-making—among other issues.

As the agency begins the process of developing its next five-year strategy, global health innovation stakeholders stand ready to share detailed input and feedback. It is important that the agency develop the strategy through in-depth consultations with stakeholders from non-profit/non-governmental organizations, private sector partners, and leaders of other Federal research agencies.

Just as the development of the next five-year health R&D strategy should be a public, participatory process to ensure transparency and foster collaboration, **the public release of the annual report on the strategy is important for oversight of the agency's work on global health R&D and efforts to ensure that investments match identified needs.** Detailed reporting—on the specific funding amounts dedicated to research and product development by each program within the USAID Bureau for Global Health; the agency's specific health product development goals, including timelines for product development; details about ongoing and planned investments in drugs, vaccines, diagnostics, and devices, including collaboration with other agencies and partners; a description of the mechanisms for interagency collaboration and coordination in support of global health product development; and an assessment of any critical gaps in product development for global health and recommendations for filling such gaps—is critical to ensuring that US investments in global health research are efficient, coordinated, and maximally effective.

One final recommendation shapes all of the other challenges and proposals described above. **Increasing funding for R&D within the USAID Global Health Bureau—and pursuing innovative approaches to grow resources for this work while tackling the misperception that funding for innovation comes at the “cost” of global health program delivery—is essential to support and nurture global health innovation at USAID.** A persistent challenge for health innovation activities at USAID is the plain fact that no centralized, protected line of funding exists for this work. This means that decisions to invest 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 funding allocations for each disease or population-specific health area. This creates real challenges given the reality that innovation investments take time to pay off in the form of new and improved health tools, while investments in delivering existing health tools and interventions show immediate impact. Yet, a year into an unprecedented pandemic, it is clear that “making do with the tools we have” is not a sufficient approach to global health. Sustainable investments in innovation have a multiplier effect, making our global health programs more efficient and impactful, ultimately saving taxpayer dollars—and lives.

Congress should explore possibilities for mitigating these challenges by creating new sources of funding for innovation work within the Global Health Bureau, which should not supplant investments by programs in specific R&D priorities, but rather create additional opportunities to make transformative investments in innovation as scientific advances open up new pathways for progress. Appropriators might consider designating some multi-year funding for global health innovation that could be tapped by different programs and replenished by Congress as necessary, enabled by rapid, transparent reporting by the agency.

It is worth noting that decades of investment in global health R&D—in areas including HIV/AIDS, severe acute respiratory syndrome, and other diseases—laid the groundwork for understanding the molecular biology and immunology of COVID-19, and that many of the leading COVID-19 vaccine candidates were built using platforms originally developed for other global health challenges. This demonstrates why sustained and consistent funding for a wide range of current and future global health threats is so critical: science is an iterative process and the R&D ecosystem is composed of inseparable elements which build on and strengthen each other in service of broad progress in biomedical innovation. **Our investments in global health R&D made a decade ago laid the foundation on which COVID-19 tools were rapidly developed and deployed; our investments in R&D today will directly influence the extent of our preparedness for health threats facing us a decade from now.** Now is not the time to let up on the gas but rather to accelerate progress towards applying the best of American innovation to the most pressing global health challenges. We are at a crossroads: **COVID-19 could either derail global health R&D for years to come, by diverting expertise, resources, and research capacity away from enduring threats like HIV/AIDS, malaria, and TB, or unlock a new era in which the advancements made against this one threat are replicated across biomedical R&D.** The mind-blowing speed of scientific progress over the past year need not end when this immediate threat is extinguished: after COVID-19 is defeated, we can launch a new era of commensurate gains across other health areas and disease challenges with sustained investments in R&D and political will to support continued innovation.