GHTC
global health technologies coalition

advancing **innovation** to save lives

April 19, 2021

The Honorable Patrick Leahy
Chairman
Senate Appropriations Committee
437 Russell Senate Office Building
Washington, DC 20510

The Honorable Richard Shelby
Vice Chairman
Senate Appropriations Committee
304 Russell Senate Office Building
Washington, DC 20510

The Honorable Christopher Coons
Chairman
Subcommittee on State, Foreign Operations, and Related Programs
218 Russell Senate Office Building
Washington, DC 20510

The Honorable Lindsey Graham
Ranking Member
Subcommittee on State, Foreign Operations, and Related Programs
290 Russell Senate Office Building
Washington, DC 20510

Dear Members of the Appropriations Committee:

As members 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—we write to highlight the critical role of US programs that support global health research and development (R&D) and encourage your continued support for this important work.

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, more than 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 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.

We are grateful for the Committee's ongoing support for global health R&D and recognize that you face many difficult decisions in balancing many important 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 the US Agency for International Development (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, including funding to support the development and deployment of COVID-19 products designed for use in low-resource settings. 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 we ask for your continued support in fiscal year 2022 (FY22).

To this end, for FY22 we strongly urge the Committee to sustain and grow funding for research to develop new global health products and innovations through the Global Health Programs account under the State Department and USAID. This means supporting at minimum sustained funding at FY21 levels for each disease or population-specific program under State and USAID global health accounts, and supporting funding increases where possible, including those outlined in the President's FY22 discretionary budget request. To ensure R&D is appropriately prioritized, we also urge you to instruct USAID to prioritize R&D within each of the disease and condition areas under USAID's Global Health Programs account, and to consider setting minimum funding targets for innovation activities in each health area from future increases to global health accounts. Global health innovation and implementation must not be seen as competing priorities, but rather part and parcel of the US commitment to improving global health.

We also urge you to 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 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—vital to ensuring that innovation fuels USAID's global health mission and R&D is appropriately prioritized—should detail how USAID coordinates with stakeholders in support of 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 toward global health goals. Once developed and released, detailed annual reporting on this strategy—which should be made publicly, and promptly, available on the USAID website, which for several years has been inconsistent—will be vital to enable appropriate congressional oversight and encourage open collaboration between USAID and external innovation partners.

The United States has long played a leading role in research and innovation for new technologies to combat global health challenges. Global health research through USAID and the State Department has supported such breakthroughs as new treatments for malaria, innovative microbicides and long-acting pre-exposure prophylaxis to prevent transmission of HIV in low-resource settings, and interventions to help women and infants in childbirth. Notably, decades of research on global health challenges, including HIV/AIDS, severe acute respiratory syndrome, and other diseases, laid the groundwork for understanding the molecular biology and immunology of COVID-19, and 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 that 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. It is critical to

sustain and build on US leadership in biomedical R&D, on display like never before over the past year. Now is not the time to let up on the gas but rather to accelerate progress toward 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.

In addition, as our world becomes more interconnected, it is clear that global health R&D provides direct benefits to US citizens and that investments in global health R&D are investments in global health security. Evidenced not only by COVID-19 but also recently by the 2014 Ebola epidemic in West Africa and 2016 Zika emergency, health crises abroad can quickly become health crises at home, and protecting the well-being of Americans requires a globally focused approach. The recent impact of the rVSV-ZEBOV (ERVEBO) Ebola vaccine—which was developed with funding in part from the US government—demonstrates the power of having the right tool at the right time to respond to a health emergency. The vaccine helped contain the 2018-2020 Ebola outbreak in the Democratic Republic of the Congo (DRC), the second-deadliest Ebola outbreak in history.

As humans continue to live closer to wildlife, the threat of emerging infectious disease outbreaks will intensify. COVID-19 has demonstrated once again that we do not readily have all the tools needed to prevent, diagnose, and treat many neglected and emerging infectious diseases—a reality that was brought into sharp focus during the Zika epidemic and West African Ebola epidemic just a few years ago. Today's investments in global health innovations to prevent and treat diseases prevalent in low-resource settings—such as extensively drug-resistant TB, malaria, and NTDs—will save millions of lives and prevent unnecessary suffering from enduring and emerging health challenges.

With less than one-half of one percent of the federal budget, USAID works around the world to support US goals in global health and development and strengthen relationships with key US partners. Global health R&D at USAID has supported the development, introduction, and scale-up of affordable health products, as well as policies and practices appropriate for addressing health issues in developing countries. In this work, USAID harnesses its comparative advantage of strong on-the-ground presence in low- and middle-income countries to support end-to-end product development, including through human-centered design, support for clinical trials, and introduction of global health technologies appropriate for the low-resource settings where they will be used. **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 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. In March 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.

- Supporting 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 supported through a Saving Lives at Birth award.

- 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.

- Supporting the development of vaccines, antimalarials, insecticides, and novel vector control tools against malaria, including a promising single-dose cure.

- Developing 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.

- Supporting development of drugs and diagnostics for a select group of NTDs, including tools to fight dengue and other mosquito-borne diseases that have been deployed from Indonesia to the Florida Keys with promising results.

- Supporting the development and distribution of the child-friendly malaria drug Coartem® Dispersible, which has been distributed in over 50 countries and has saved an estimated 980,000 child lives since its introduction in 2009.

Ongoing investments in the development of new vaccines, drugs, microbicides, and other tools have the potential to greatly accelerate efforts to address HIV/AIDS, TB, malaria, diarrheal disease, and pneumonia, as well as improve maternal and reproductive health. We must ensure that COVID-19 does not unnecessarily derail or even permanently scuttle vital R&D activities around the world, as other enduring health challenges continue to threaten low-resource communities.

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 in order 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. Accordingly, decisions on USAID's investments in new global health technologies 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 sufficient resources. As the Committee weighs long-needed robust increases to global health and development funding, USAID should be encouraged **to set minimum funding targets for innovation activities in each health area from any future increases to global health accounts.** The agency should not be forced to decide between maintaining essential health care delivery programs and making long-term investments in potentially game-changing R&D: robust funding increases will help alleviate the burden on programs already stretched thin by growing requirements and the devastating impact of COVID-19 and allow for forward-thinking investments in R&D that yields tools that are more effective, better suited to the needs of unique populations, and essential to achieving our long-term disease elimination and mitigation goals.

USAID recognizes the value of global health R&D, and how new global health tools can help finally curb infectious disease outbreaks, end preventable maternal and child deaths, and achieve an AIDS-free generation. This reality should be better reflected and articulated in the next five-year strategy on health-related R&D, which we urge the committee to request in the FY22 State, Foreign Operations, and Related Programs bill. Once developed and released, annual reports on the strategy should include specific funding amounts dedicated to research and product development by each program; specific information about health product development goals and timelines; details about USAID investments in drugs, vaccines, diagnostics, and devices; details about collaborations with other federal agencies and private-sector partners; and an assessment of any critical gaps in product development for global health and recommendations for filling such gaps. This report is critical to provide insight and transparency into how USAID thinks strategically about R&D investments, but in recent years has not been made public, a trend that should be reversed to enable transparency and foster open collaborations among innovators.

We urge the Committee to maintain strong support for the Global Health Programs account under the State Department and USAID and urge the agency to invest in R&D for new global health innovations in each of the disease and condition areas within the account. This means supporting <u>at minimum</u> sustained funding at FY21 levels for each disease or population-specific program, and supporting increases where possible, including those outlined in the President's FY22 discretionary budget request.

Continued investment to support research throughout each of USAID's global health accounts is critical to progress in global health. Such investments can ensure that the progress made in global health over the past decade, thanks to increased support from the United States, is not reversed despite the impact of COVID-19.

In addition to bringing lifesaving tools to those who need them most, global health R&D is a smart economic investment for the United States. Investment in global health R&D drives job creation, spurs business activity, and benefits academic institutions: **89 cents of every US dollar spent on global health R&D goes directly to US-based researchers.**

We stand ready to work with you to advance US leadership in global health and global health innovation and ask that support for global health R&D not come at the expense of other humanitarian assistance and development accounts. Now more than ever, Congress must make smart budget decisions. Global health research that improves the lives of people around the world—while at the same time supporting US interests, creating jobs, and spurring economic growth at home—is a win-win investment.

Please do not hesitate to contact GHTC Director Jamie Bay Nishi at jnishi@ghtcoalition.org if you have questions or need any additional information.

Sincerely,

American Society of Tropical Medicine and Hygiene

AVAC

Boston University Social Innovation on Drug Resistance Program

Coalition for Epidemic Preparedness Innovations

Drugs for Neglected Diseases *initiative*

Elizabeth Glaser Pediatric AIDS Foundation

Equalize Health

FIND

Global Antibiotic Research and Development Partnership

Global Health Council

HarvestPlus

IAVI

Infectious Diseases Society of America

International Partnership for Microbicides

Innovative Vector Control Consortium

Medicines for Malaria Venture

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Washington Global Health Alliance