GHTC
global health technologies coalition

advancing **innovation** to save lives

April 19, 2021

The Honorable Rosa DeLauro
Chairwoman
House Appropriations Committee
Chairwoman
Subcommittee on Labor, Health and Human Services, Education, and Related Agencies
2413 Rayburn House Office Building
Washington, DC 20515

The Honorable Kay Granger
Ranking Member
House Appropriations Committee
1026 Longworth House Office Building
Washington, DC 20515

The Honorable Tom Cole
Ranking Member
Subcommittee on Labor, Health and Human Services, Education, and Related Agencies
2207 Rayburn House Office Building
Washington, DC 20515

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 (AMR); 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 safe and effective 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 recognize that you face 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 are grateful for the Committee's long-standing support for global health R&D within the Department of Health and Human Services (HHS). New global health tools and technologies hold promise to dramatically improve the lives of those living in the poorest countries around the world—and protect American health security—and we ask for your continued support for programs that support global health R&D within the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Biomedical Advanced Research and Development Authority (BARDA) in fiscal year 2022 (FY22).

To achieve this goal, we urge you to maintain robust funding for NIH, provide funding to match CDC's ever-increasing responsibilities in global health and global health security, and support funding that allows BARDA to prioritize critical work in emerging infectious diseases and other global health challenges—both emerging threats like COVID-19 and slow-burning health emergencies like the rise of AMR. We support the bold increases proposed in President Biden's FY22 discretionary budget request for critical R&D agencies including NIH (including the Fogarty International Center (FIC), the National Institute of Allergy and Infectious Diseases (NIAID), the National Center for Advancing Translational Sciences (NCATS), and the Office of AIDS Research) and CDC (including the Center for Global Health (CGH) and National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)), and call for increased funding for BARDA to sustain the leading role it has assumed over the past year in product development for naturally occurring threats such as COVID-19.

The United States has long played a leading role in research and innovation for new technologies to combat global health challenges. Global health R&D at HHS has yielded such results as the first blood test for HIV/AIDS, rapid diagnostics for the plague and rabies, and accelerated translation of basic research to product development for diseases of public health importance. Over the last year, HHS has led an unprecedented research response to develop desperately needed treatment and prevention tools to respond to the COVID-19 pandemic, demonstrating the power of American research institutions to respond to both long-standing and emerging global health crises. 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 our global community 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.

As our world becomes more interconnected—a reality underscored by the rapid global spread of COVID-19—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 the 2016 Zika outbreak, health crises abroad can become health crises at home, and protecting the well-being of Americans requires a globally focused approach. With the development of the first vaccines, the end of COVID-19 in the United States is within sight, but without global distribution of prevention and control technologies, the SARS-CoV-2 virus will continue to mutate in communities around the globe, perpetually threatening US progress toward containment of the pandemic.

Beyond the impact we are already seeing from COVID-19 tools, the rVSV-ZEBOV (ERVEBO) Ebola vaccine, developed with clinical trial support from NIH, is another demonstration of the power of having the right tool at the right time to respond to a health emergency. With a 97.5 percent efficacy rate against the Ebola Zaire virus, this vaccine is highly protective and helped contain the 2018-2020 Ebola outbreak in the Democratic Republic of the Congo (DRC), the second-deadliest Ebola outbreak in history. New outbreaks of Ebola in Guinea and DRC in 2021 make clear that tools developed with US government support will continue to be invaluable for the containment of deadly infectious diseases. 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 in the future from enduring and emerging health challenges.

The COVID-19 pandemic underscores that "global health" includes the United States, too, and that some American communities can be especially vulnerable to deadly infectious diseases and face similar resource constraints—such as a lack of deep freezers for vaccine storage—that communities face around the world. Changing population and climate dynamics will likely only accelerate this trend; it is therefore critical to our nation's public health that we work to combat these deadly diseases through continued innovation.

National Institutes of Health

NIH carries out a wide variety of global health research activities—through FIC, NIAID, the Office of AIDS Research, and NCATS—that make the United States a leader in research globally. **Recent NIH global health research activities include:**

- Leading or supporting product development to address pandemic threats like COVID-19, Ebola, and Zika. Most recently, NIH has supported the development of COVID-19 vaccine, therapeutic, and diagnostic candidates and the rVSV-ZEBOV (ERVEBO) investigational Ebola vaccine that was critical to containing the 2018-2020 Ebola epidemic in DRC.

- Developing the research capacity of global partners. FIC supports global health research at more than 100 US universities and research centers around the world, including in low- and middle-income countries. Many FIC-trained scientists now hold high-ranking academic and government positions in their home countries and have made critical contributions to long-standing global public health challenges, such as HIV/AIDS, and emerging threats, like Zika and Ebola.

- Supporting studies in the search for new HIV/AIDS interventions, including research that led to the use of oral pills for pre-exposure prophylaxis, or PrEP, which employs antiretroviral treatments to prevent HIV infection.

- Leading research on the first-ever microbicide vaginal ring, a much-needed women-centered HIV prevention tool and the first long-acting product to demonstrate clinical efficacy in reducing HIV risk.

- Developing tools to combat neglected diseases, including vaccine candidates for dengue fever, schistosomiasis, and trachoma; rapid tests for river blindness and lymphatic filariasis; and new drugs to treat malaria and TB.

We recognize and are grateful for Congress's work to bolster funding for NIH in recent years. Excelling in advancing the earliest stages of global health R&D, NIH research—across FIC, NIAID, the Office of AIDS Research, NCATS, and other institutes and centers—is imperative for ensuring that lifesaving products progress to later stages of development and ultimately become available to the communities who need them.

FIC in particular is a critical conduit between researchers in the United States and their colleagues around the world. The center strengthens international research and laboratory capacity, facilitates global research partnerships, improves surveillance of emerging infectious diseases, and trains the scientists who make critical contributions to long-standing global public health challenges such as HIV/AIDS and emerging threats like AMR, Zika, Ebola, and COVID-19. FIC accomplishes this work with less than one-quarter of one percent of the NIH budget. While funding for NIH increased by 38 percent between fiscal years 2015 and 2020, funding for FIC increased by only 19 percent. In FY21, FIC was appropriated $84 million. **We urge the Committee to consider appropriating FIC an additional $10 million in each of the next five fiscal years to support sustainable growth and long-term planning in pursuit of its mission to build research capacity in partner countries, particularly in light of the growing requirement to bolster local research capacity to detect and address future infectious disease and global health security threats.**

Centers for Disease Control and Prevention

CDC makes significant contributions to global health, leading global disease surveillance, capacity-building, and research in the development of new tools and technologies. CDC's ability to investigate and respond to disease outbreaks—from novel diseases like COVID-19 to recurring threats like Ebola—is essential to saving lives in the United States and abroad. The work of CDC scientists has led to major advances against devastating diseases, including the eradication of smallpox and early identification of HIV/AIDS. **CDC continues to make an impact on global health through critical research activities, including:**

- Developing diagnostic tools to accurately identify global diseases, including the bubonic plague, rabies, Ebola, and emerging threats like COVID-19.

- Monitoring, tracking, and responding to infectious diseases domestically and abroad.

- Contributing to the clinical evaluation of new treatment and prevention strategies for neglected diseases, including coordinating the Tuberculosis Trials Consortium—a global collaboration of researchers from CDC, domestic and international public health departments, academic medical centers, and Veterans Administration medical centers.

- Providing critical scientific and technical support to other agencies and interagency global health

initiatives such as the President's Emergency Plan for AIDS Relief (PEPFAR), the President's Malaria Initiative, and the US Agency for International Development's Neglected Tropical Diseases Program.

- Alerting researchers when new trends or disease strains emerge so that R&D efforts can intensify.

- Training epidemiologists in low- and middle-income countries on how to detect and rapidly respond to infectious disease outbreaks.

Within CDC, CGH and NCEZID are critical to global health R&D and global health security efforts. Important work at NCEZID includes the development of the first COVID-19 diagnostic to receive emergency use authorization from the US Food and Drug Administration, innovative technologies to provide a rapid diagnostic test for the Ebola virus, a new vaccine to improve rabies control, and a new and more accurate diagnostic test for dengue virus. NCEZID leads critical advanced laboratory services, including biosafety labs, which enable CDC to study hazardous pathogens, and advanced molecular detection techniques that allow CDC to identify infectious diseases of unknown origin. The center also plays a leading role coordinating the National Strategy for Combating Antibiotic-Resistant Bacteria, focused on preventing, detecting, and controlling outbreaks of antibiotic-resistant pathogens, such as drug-resistant TB.

Programs at CGH—including the Divisions of Global HIV and TB, Global Immunization, Parasitic Diseases and Malaria, and Global Health Protection—have yielded tremendous results in the development and refinement of vaccines, drugs, microbicides, and other tools to combat HIV/AIDS, TB, malaria, and NTDs like leishmaniasis and dengue fever. CGH plays a critical role in disease detection and response, working to monitor and respond to outbreaks, develop new tools to help detection efforts, train epidemiologists in high-burden regions, and build the capacity of health systems. CGH also provides critical scientific and technical support in developing and validating innovative tools for use by US bilateral and multilateral global health programs and leading laboratory efforts to monitor and combat drug and insecticide resistance—functions essential to ensuring that global health programs are responsive, efficient, and tailored for maximum impact.

As global disease outbreaks have grown in frequency and intensity, CDC's work in novel technology development and global health security has only become more important. This includes the agency's work on COVID-19 globally; efforts to end the 2018-2020 Ebola epidemic in DRC and the most recent outbreaks in Guinea and DRC in 2021; and engagement with the international community on a coordinated Global Health Security Agenda. In recent years, much of CDC's global health security activities have been supported by emergency supplemental funding for COVID-19, Ebola, and Zika, though growing annual appropriations for global health security are helping build stronger and more resilient programs. In addition, costs to sustain CDC's lifesaving work to mitigate persistent global health threats—like HIV/AIDS, TB, malaria, NTDs, and vaccine-preventable diseases often absent from the headlines—continue to rise. **GHTC urges the Committee to support an increase in annual appropriations across all CGH divisions to ensure these activities are sustained or strengthened. As we increase our focus and investment in health security threats, we also urge increased funding for NCEZID, which provides deep technical, scientific, and laboratory expertise to complement CGH's work with domestic preparedness efforts to ensure Americans are protected at home and abroad.**

It is important to note that some of the leading health security threats are not new: prior to the spread of COVID-19 in 2020, TB was the world's leading infectious disease killer, impacting individuals and families around the world—including in all 50 states of the United States. The Tuberculosis Trials

Consortium (TBTC) is a collaboration of researchers from CDC and other domestic and international partners that conduct research on the diagnosis, clinical management, and prevention of TB infection and disease relevant to improving TB programming. TBTC is operated by the Division of Tuberculosis Elimination (DTBE) within the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. Current funding levels for DTBE are the same as in 1994, and with squeezed budgets, DTBE reduced its share of spending on TB research from 20 percent to 10 percent between fiscal years 2005 and 2016. **We urge the Committee to sustainably increase funding to DTBE to continue and build on its progress in TB research.** This is especially critical now because COVID-19 research, which has benefited from past investments in TB R&D, has redirected respiratory disease control resources and expertise from DTBE and its ongoing TB research.

BARDA

BARDA, within the Office of the Assistant Secretary for Preparedness and Response in HHS, supports the advanced development of vaccines, drugs, and other medical countermeasures to protect Americans against threats to public health, including emerging infectious diseases, AMR, and pandemic influenza. BARDA is perhaps the world's leading institution for developing medical countermeasures against global health security threats through public-private partnerships. BARDA works with industry to bridge the "valley of death" between basic research and product development, so-called because many potential medical innovations stall after public funding for basic research drops off but before other public, private, or nonprofit R&D funders pick up later-stage product development efforts. Through unique contracting and incentive mechanisms, BARDA's partnerships ensure promising research is translated into urgently needed medical products by creating commercial incentives for private-sector partners.

BARDA is a leader in the development of new tools to combat the growing threat of AMR. Strong, sustained funding is needed in FY22 to support BARDA's Broad Spectrum Antimicrobials program and CARB-X, which leverage public-private partnerships to develop products in line with the National Action Plan for Combating Antibiotic-Resistant Bacteria. To achieve the goals outlined in the Plan to accelerate basic and applied research for developing new antibiotics and other products, additional funding is urgently needed. We must act now to prevent a "post-antibiotic era" which would render many modern medical advances that depend upon the availability of antibiotics unusable—including treatment for TB globally, which has been hampered in recent years by the rise of multidrug-resistant TB (MDR-TB).

AMR is just one area where BARDA's leadership against naturally occurring health threats has been growing. Over the past year, BARDA has been the primary US funder of new medical countermeasures against COVID-19, distributing billions of dollars in supplemental funding from Congress to advance and procure new vaccines, therapeutics, diagnostics, and other technologies for use against the pandemic. In 2020, BARDA received an influx of more than $25 billion in emergency supplemental funding, an amount 43 times the size of its annual appropriations and 16 times the size of its annual budget.

While BARDA has excelled in responding to emerging infectious diseases, including Ebola, Zika, and now COVID-19, this work has been advanced largely through one-off emergency supplemental appropriations—a trend accelerated in the COVID-19 emergency supplemental bills. Instead of relying on reactive funding that cannot keep pace with emerging threats and stalls science as public health emergencies unfold, **we urge the Committee to consider establishing a permanent funding line with an annual appropriation of $300 million to sustain BARDA's work on emerging infectious diseases, and support increased funding to enable BARDA's leadership in the areas of pandemic influenza and AMR, including MDR-TB.**

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 strongly recommend that you fund NIH, CDC, and BARDA as robustly as possible to uphold vital work in global health R&D and global health security. At a time of constrained budgets but growing health threats, this means sustainably growing funding for NIH (including FIC, NIAID, NCATS, and the Office of AIDS Research), CDC's CGH and NCEZID, and BARDA—and, to properly tackle the leading health challenges facing our world, matching the bold investments in these vital agencies called for in the President's FY22 discretionary budget request.

We stand ready to work with you to advance US leadership in 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

PATH

RESULTS

Sabin Vaccine Institute

TB Alliance

Treatment Action Group

Washington Global Health Alliance