GHTC
global health technologies coalition

advancing **innovation** to save lives

March 18, 2020

The Honorable Nita Lowey
Chairwoman
House Appropriations Committee
2365 Rayburn House Office Building
Washington, DC 20510

The Honorable Kay Granger
Ranking Member
House Appropriations Committee
1026 Longworth Office Building
Washington, DC 20510

The Honorable Rosa DeLauro
Chairwoman
House Appropriations Subcommittee on
Labor, Health and Human Services, Education,
and Related Agencies
2413 Rayburn House Office Building
Washington, DC 20510

The Honorable Tom Cole
Ranking Member
House Appropriations Subcommittee on
Labor, Health and Human Services, Education,
and Related Agencies
2207 Rayburn House Office Building
Washington, DC 20510

Dear Members of the Appropriations Committee:

As members of the Global Health Technologies Coalition (GHTC)—a group of 30 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, and neglected tropical diseases (NTDs), and ending preventable child deaths. Strong investment in global health R&D is even more critical at a moment when the world is responding to the threat of the Novel Coronavirus Disease 2019 (COVID-19), a crisis laying bare the fact that we do not have all of the tools we need to protect our health. We recognize that you face many difficult decisions and are grateful for the Committee's ongoing support for global health R&D within the Department of Health and Human Services. 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 Biological Advanced Research and Development Authority (BARDA) in fiscal year (FY) 2021.

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—both rapidly emerging threats like COVID-19 and slow-burning health emergencies like the rise of antimicrobial resistance. This means rejecting cuts to global health, medical research, and global health security programs called for by the Administration in FY18, FY19, FY20, and FY21, and supporting at minimum sustained

funding at FY20 levels for the NIH (including the National Institute of Allergy and Infectious Diseases (NIAID), National Center for Accelerating Translational Science (NCATS), the Office of AIDS Research, and the Fogarty International Center), CDC's Center for Global Health (CGH) and National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), and BARDA.

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 the Department of Health and Human Services (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. Today, HHS is leading a rapid research response to develop desperately needed treatment and prevention tools to respond to the COVID-19 health emergency, demonstrating the power of American research institutions to respond to both long-standing and emerging global health crises. It is critical to sustain and build on this leadership: More than 80 percent of Americans say that it is important for the United States to work to improve health globally through R&D.

As our world becomes more interconnected—a trend made clear by the rapid 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 in recent months by COVID-19 and in the recent past by the 2014 Ebola epidemic in West Africa and the ensuing Zika outbreak, health crises abroad can become health crises at home, and protecting the well-being of Americans requires a globally focused approach. The impact of the rVSV-ZEBOV (ERVEBO) Ebola vaccine candidate currently being deployed in the ongoing epidemic in the Democratic Republic of the Congo (DRC), developed with clinical trial support from NIH, demonstrates the power of having the right tool at the right time to respond to a health emergency. ERVEBO has been used to vaccinate more than 250,000 at-risk individuals to date. With a 97.5% efficacy rate against the Ebola Zaire virus, this vaccine is highly protective and is now a vital tool for this and future Ebola outbreaks. In the first week of March 2020, the last known Ebola patient in DRC was discharged from a treatment facility, and while the country is in a waiting period before the outbreak can be officially declared over, it is clear that the new tools developed with US government support were vital to the containment of this deadly outbreak. Today's investments in global health innovations to prevent and treat diseases in the developing world such as extensively drug-resistant tuberculosis, malaria, and NTDs will save millions of lives in the future from perpetual and emerging health challenges and bolster global health security.

Today, "global health" is taking on new meaning as the COVID-19 emergency is underscoring that many diseases are only a plane ride away from striking American communities. At the same time, changing population and climate dynamics mean that other diseases are reoccurring in the United States; it is therefore critical to our nation's public health that we work to combat these deadly diseases.

National Institutes of Health

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

- 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, and first long-acting product, to demonstrate clinical efficacy in reducing HIV risk.

- Participating in the basic research that led to the development of the first-ever microbicide gel to show proof-of-concept in reducing HIV risk.

- Conducting basic and preclinical research that provides the foundation for new product discovery and development and supporting and conducting early-stage clinical trials of promising products.

- Developing the in-country research capacity of developing world partners. The Fogarty International Center supports global health research at more than 100 US universities and research centers around the world.

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

- 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.

- Supporting product development to address pandemic threats like Ebola and Zika, including support for clinical trials of the rVSV-ZEBOV Ebola vaccine deployed in the most recent epidemic in DRC.

- Leading a rapid research response to the threat of COVID-19, including supporting clinical trials for multiple therapeutic and vaccine candidates, building on their broad research experience with coronaviruses enabled by years of growing funding for NIH—a clear demonstration of how long-term investments can have an immediate impact on an emerging disease threat.

We recognize and are grateful for Congress' work to bolster funding for the critical programs supported by NIH. To deliver on the remarkable progress being made across the institutes, it is vital that we renew this commitment to health research. Focusing on the earliest stages of global health R&D, NIH research—across NIAID, the Office of AIDS Research, the Fogarty International Center, NCATS, and other institutes—is imperative for ensuring that lifesaving products progress to later stages of development and ultimately become available to the communities who need them.

Centers for Disease Control and Prevention

CDC also 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, such as the 2014 Ebola outbreak in West Africa and the most recent outbreak in DRC, is essential to protecting citizens both at home and abroad. The work of its 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:**

- Monitoring, tracking, and responding to infectious diseases worldwide.

- Providing critical intelligence needed to effectively implement control and prevention programs for infectious diseases.

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

- Monitoring diseases domestically to make the public aware of the emergence of an infectious disease from abroad.

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

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

Within the CDC, CGH and NCEZID are critical to global health R&D and global health security efforts. Important work at NCEZID includes the development of 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 tuberculosis.

Programs at CGH—including the Divisions of Global HIV and TB, Global Immunization, Parasitic Diseases and Malaria, and Global Health Protection—have also yielded tremendous results in the development and refinement of vaccines, drugs, microbicides, and other tools to combat HIV/AIDS, TB, malaria, and neglected tropical diseases like leishmaniasis and dengue fever. In addition, 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 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 USAID Neglected Tropical Diseases Program, 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 efforts in the Democratic Republic of Congo to quash that country's tenth outbreak of Ebola, the second largest Ebola outbreak in history, as well as CDC's engagement with the international community on a coordinated Global Health Security Agenda (GHSA). In recent years, much of CDC's global health security activities have been supported by emergency supplemental funding for Ebola and Zika, though growing annual appropriations for global health security are helping build stronger and more resilient programs. GHTC urges the Committee to continue to support an increase to annual appropriations for the Division of Global Health Protection (DGHP) within the Center for Global Health to ensure these activities continue. 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

DGHP's efforts globally with domestic preparedness efforts to ensure Americans are protected at home and abroad. For both, we ask for a minimum of no less than FY20 levels. To sustain and accelerate our life-saving work to mitigate the "everyday emergencies" of persistent global health threats like HIV/AIDS, TB, malaria, NTDs, and vaccine-preventable diseases—that cause unnecessary deaths and suffering often absent from the headlines—we also urge sustained investment across all CGH divisions, and where possible, growth to account for their increased workload and vital support functions provided to US and multilateral global health programs.

BARDA

BARDA plays an unmatched role in global health R&D by providing an integrated, systematic approach to the development and purchase of critical vaccines, diagnostics, drugs, and other tools for public health emergencies. By leveraging unique contracting authorities and targeted incentive mechanisms, BARDA partners with diverse stakeholders from industry, academia, and nonprofits to bridge the "valley of death" between basic research and advanced-stage product development for medical countermeasures—an area where more traditional US government research enterprises do not operate.

Since its founding in 2006, BARDA has been authorized to engage in the development of medical countermeasures for naturally occurring threats, including emerging infectious diseases. This work was bolstered in the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019, which specifically authorized BARDA to implement "strategic initiatives" to develop countermeasures against emerging infectious diseases, pandemic influenza, and antimicrobial-resistant pathogens. However, the majority of BARDA's work in this space has been funded through one-time, emergency supplemental appropriations for Ebola and Zika. But new naturally occurring threats continue to emerge and demand resources: today, BARDA is mobilizing to support the development of urgently needed medical countermeasures for COVID-19. For BARDA to continue bridging the "valley of death" for urgently needed medical countermeasures for the full spectrum of naturally occurring threats, including emerging infectious diseases, pandemic influenza, and antimicrobial-resistant pathogens—areas where private-sector investment is scarce—increased funding, along with greater clarity into the use of existing funding streams and prioritization of disease threats, is needed.

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 rejecting cuts to critical research and global health security programs, and at minimum no less than sustained funding at FY20 levels for NIH (including NIAID, NCATS, the Office of AIDS Research, and the Fogarty International Center), CDC's CGH and NCEZID, and BARDA.

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 or (202) 540-4379 if you have questions or need any additional information.

Sincerely,

American Society of Tropical Medicine and Hygiene

AVAC

Drugs for Neglected Diseases *initiative*

Elizabeth Glaser Pediatric AIDS Foundation

FIND

Global Health Council

HarvestPlus

International AIDS Vaccine Initiative

Infectious Diseases Society of America

International Partnership for Microbicides

Innovative Vector Control Consortium

Medicines for Malaria Venture

PATH

RESULTS

Sabin Vaccine Institute

Treatment Action Group

TB Alliance

Washington Global Health Alliance