GHTC global health technologies coalition

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# FY22 Report Language Outcomes

## R&D-related language included in House FY22 State, Foreign Operations, and Related Programs report

___= *language similar to that submitted by GHTC*

**House**

*Public access plan*.—The Committee urges USAID to continue implementing its Public Access Plan on increasing access to results of federally funded scientific research and directs the USAID Administrator to report to the Committees on Appropriations not later than 60 days after enactment of this Act on progress made towards implementation.

*Global Health Security*.—The Committee encourages the USAID Administrator to integrate global health security programming with other health programming at the country level. Funds available for global health security should also support the strengthening of the primary health care system in partner countries as a foundation for responding to emerging health threats. The Committee includes further language under Reports in this heading.

Funds shall be made available to support continuous and robust global health security surveillance programs, including the collection and analysis of data on unknown viruses and other pathogens and coordination with other partners and countries to share data. Research into zoonotic disease should utilize the unique resources and expertise of natural history museums. Life sciences research, advanced data analytics and scientific innovation should be used to support disease surveillance, detection, reporting and contact tracing, and the delivery of diagnostics and treatments. The Committee encourages the Department of State to work with other countries and international institutions, including the World Health Organization, to better understand the landscape of potential pandemic pathogen research internationally, and to develop international norms, model standards, and model review mechanisms for the oversight of research. The Committee supports United States participation in multilateral vaccine development partnerships to support epidemic preparedness.

*Malaria.*— Within the funds made available for malaria, the Committee encourages USAID's continued support for public-private partnerships; research and development; diagnostics and vector control; and access and delivery of anti-malarial medicine, including effective pediatric formulations and alternatives to counter resistance. The Committee continues to encourage USAID to support the development and introduction of anti-malarial tools targeted to young children and those that interrupt transmission of the disease.

*Research*.—The Committee supports USAID's role in health-related research and supports continued investments in new global health technologies. The Committee encourages USAID to include efforts to find new diagnostic and treatment tools for tuberculosis and effective, affordable contraceptives in their research agenda. The Committee includes further language under Reports in this heading.

*Tuberculosis (TB)*.—The Committee recommendation includes funding to combat drug-susceptible and drug-resistant tuberculosis. The Committee encourages support for new products to prevent and treat tuberculosis and encourages investment in new drugs, vaccines, and diagnostics. The USAID

Administrator is directed to consult with the Committees on Appropriations regarding the use of funds in this Act for such purposes. The Committee includes further language under Reports in this heading.

*Vaccines*.—The Committee notes USAID's investments in malaria and HIV/AIDS vaccine development and supports continued efforts at not less than the prior year level to create effective vaccines for malaria and HIV/AIDS as part of a comprehensive prevention, diagnostic, and treatment strategy. The Committee notes the potential of advances in development of broadly neutralizing antibodies for long-lasting prevention of HIV infection as part of this research.

The Committee directs the USAID Administrator to undertake vaccine development efforts to prevent and respond to outbreaks from deadly viruses from funds provided for global health security. The Committee encourages the USAID Administrator and the Global AIDS Coordinator to consider the procurement of low dead space, retractable syringes to maximize each dose of procured vaccines or administered drug. Additionally, vial-level temperature monitoring should be used on all temperature sensitive vaccines, including for coronavirus, to minimize wastage and maximize supply. The Committee directs the USAID Administrator to consult with the Committees on Appropriations on amounts proposed for vaccine development and administration for fiscal year 2022.

[Under Reports] *Research.*—The Committee directs the USAID Administrator to continue the annual report on health-related research, which is important for transparency and oversight of the agency's work on global health research, to be submitted not later than 45 days after enactment of this Act and posted on a public website.

*Microbicides.*—The Committee recommends continued support for microbicide development and directs OGAC to coordinate with USAID, the National Institutes of Health, other Federal agencies, and donors in order to advance microbicide development and implementation. The Committee directs OGAC to work with USAID on a plan for product rollout and access and update the Committees on Appropriations on a regular basis on the use of funds in fiscal year 2022.

# R&D-related language included in House FY22 Labor, Health and Human Services, Education, and Related Agencies report

___= language similar to that submitted by GHTC

**General Summary of the Bill**

*HIV Initiative*
Advances in medications for the prevention and treatment of HIV, improved diagnostic tests, and new outbreak detection technology provide a unique opportunity to alter the trajectory of HIV infection rates in the U.S. with a goal of eliminating new HIV infections. This bill provides a total of $688,000,000, which is an increase of $245,000,000 for the third year of the Ending the HIV Epidemic Initiative, which began a new era of moving the U.S. from HIV prevention to HIV epidemic control.

**HHS – Office of the Secretary**

Global Health Research.—The Committee requests an update in the fiscal year 2023 Congressional Budget Justification on how CDC, FDA, BARDA, and NIH—including the Fogarty International Center—jointly coordinate global health research activities with specific measurable metrics used to track progress and collaboration toward agreed upon health goals.

**NIH**

*National Institute of Allergy and Infectious Diseases*

*Combating Antibiotic-Resistant Bacteria*.—The Committee supports NIAID's efforts related to combating antibiotic-resistant bacteria. These funds enable NIAID to support research on antimicrobial (drug) resistance, including basic research on how microbes develop resistance, new and faster diagnostics, and clinical trials designed to find new vaccines and treatments effective against drug-resistant microbes.

*Emerging Diseases*.—The Committee supports the work of NIAID in researching emerging coronaviruses, and urges NIAID to fund basic science on a host of deadly viruses, including SARS–CoV–2, Ebola, Marburg, and Nipah viruses. The Committee notes the importance of using high containment BSL–3 and BSL–4 labs in this effort. The Committee is aware of the success of non-animal approaches to identify how viral proteins interact with host proteins and their pathways. The Committee notes the success of these approaches with SARS–CoV–2 to identify new therapeutic approaches. The Committee encourages NIAID to support research into viruses, including Ebola, Marburg, and Nipah viruses, to help identify small molecule drugs to block infection by a host of deadly viruses.

*Microbicides*.—The Committee recognizes that with NIH and USAID leadership, research has shown the potential for antiretroviral (ARV) drugs to prevent HIV infection in women. The Committee encourages NIH to continue coordination with USAID, the State Department, and others to advance ARV-based microbicide development efforts, with the goal of enabling regulatory approvals of the first safe and effective microbicide for women and supporting an active ARV-based microbicide pipeline to produce additional solutions to prevent HIV and to help end the epidemic.

*Rapid Vaccine Development Platforms for Emerging Infectious Disease.*—The Committee recognizes the importance of being able to quickly, efficiently, and safely develop and manufacture vaccines against emerging infectious diseases. Vaccines play a pivotal role in host protection against infectious diseases and have significantly reduced mortality worldwide. Older methods of developing vaccines are no match

for a host of emerging and reemerging pathogens that call for a tailored and speedy response, such as the developing coronavirus variants. Today, innovations in how vaccines are developed enable faster production of platforms capable of making and initially testing a new vaccine in less than 120 days that then are tailored to specific pathogens as manufacturing begins, based on science and data, not speculation. Such rapid vaccine platform technologies can vastly decrease the time it takes to develop, manufacture and distribute vaccines. Therefore, the Committee includes $50,000,000 to support research and development of rapid vaccine platform technologies and requests a briefing on these efforts within 180 days of enactment of this Act.

*Universal Influenza Vaccine*.—The Committee includes no less than $250,000,000, an increase of $30,000,000 over the fiscal year 2021 level and the fiscal year 2022 budget request, to support basic, translational, and clinical research to develop a universal influenza vaccine that provides robust, long-lasting protection against multiple subtypes of flu, rather than a select few. Such a vaccine would eliminate the need to update and administer the seasonal flu vaccine each year and could provide protection against newly emerging flu strains, potentially including those that could cause a flu pandemic. The Committee requests an update on these efforts within 60 days of enactment of this Act.

*Viral Vector Platforms*.—The Committee notes that viral vector platforms have a proven track record for successfully producing vaccines against infectious diseases for many decades and believes well-established viral vectors with a robust safety record for use in children, pregnant women, or other high-risk populations should be continuously developed and adjusted to potential emerging infections in the future. The Committee encourages investments in vaccine centers with long-term experience in the development of viral vectors covering multiple virus-based vaccine platforms, with particular emphasis on entities that have established collaborations with high-security facilities (BSL–4) for preclinical studies.

*Fogarty International Center (FIC)*

Mission.—FIC's mission is to support and facilitate global health research conducted by U.S. and international investigators, building partnerships between health research institutions in the U.S. and abroad, and training the next generation of scientists to address global health needs.

COVID–19 has shown the importance of FIC's essential role in global infectious disease health research training, pandemic preparedness, and global health security by assisting low- and middleincome countries (LMICs) in advancing their own research and health solutions and tools. The FIC has developed important partnerships in countries to not only fight infectious diseases, but also to build their capabilities to detect and treat infectious diseases. The COVID–19 pandemic illustrates the importance of FIC's efforts to strengthen country capacity to enable cutting edge research at the origin of outbreaks, improving the likelihood that emerging diseases can be addressed at their source—ultimately protecting American health security. The Committee believes these longstanding relationships and unique capabilities position FIC to play an important and expanded role in pandemic preparedness, including developing a network of modeling hubs and joint research programs to engage LMIC investigators to collaboratively train for pandemic preparedness. The Committee requests information from FIC in the fiscal year 2023 Congressional Budget Justification about how FIC training programs and research collaborations have, and with additional resources can, increase efforts to advance global health security and pandemic preparedness. The Committee is particularly interested in understanding FIC's unique capabilities and capacities as well as coordination with other Federal government agencies engaged in these efforts.

*Office of the Director*

*COVID–19 Technology Access Pool*.—The Committee understands that the World Health Organization has developed a COVID–19 Technology Access Pool (C–TAP), which aims to facilitate access to COVID–19 health products by sharing intellectual property through pooling and voluntary agreements. The Committee strongly urges the Secretary, in partnership with NIH, to consider what contributions NIH could make to C–TAP.

*Modeling and Simulation Technology Deployment*.—The Committee encourages NIAID, NIBIB, and other NIH Institutes and Centers as appropriate, to support the development and study of in silico approaches to accelerate vaccines for emerging infectious diseases including, but not limited to, computational simulation, data analytics, and the digital patient model, with the objective of reducing the time to market for virus vaccines.

*Natural History Museums as Critical Contributors to Virus Research*.—The Committee notes that the nation's natural history museums provide an unparalleled resource for studying zoonotic diseases such as COVID–19. These museums hold millions of animal samples collected over decades from across the globe, offer deep and broad scientific expertise, and are uniquely positioned to assist in preparing for and predicting the next pandemic-causing viruses. The Committee encourages increased utilization and support of this largely untapped resource.

**CDC**

*HIV/AIDS, Viral Hepatitis, Sexually Transmitted Diseases, and Tuberculosis Prevention*

Tuberculosis.—The Committee includes an increase of $5,000,000 to enable CDC, along with State and local entities, to provide TB screening, identification, treatment and prevention services, and to restore funding to the TB Trials Consortium. The Committee is concerned that the COVID–19 pandemic caused significant impacts on individuals with TB and on State and local TB programs, including delays in care for people with TB and postponement of identification and treatment of individuals with latent TB infection, stalling efforts to eliminate TB in the U.S.

*Emerging and Zoonotic Infectious Diseases*

*Antibiotic Resistance.*—The Committee includes an increase of $5,000,000. The Committee recognizes the importance of effectively combatting antibiotic resistant bacteria as part of CDC's broader efforts to mitigate the clinical and public health impacts of the COVID–19 outbreak. Furthermore, the Committee recognizes the importance of addressing the problem of antibiotic-resistant bacteria through a ''One Health'' approach and by tracking resistance through local, regional, national, and global surveillance. The Committee encourages CDC to competitively award research activities that address aspects of antibiotic resistance related to ''One Health,'' including global surveillance and research and development for new tools to counter antibiotic resistance among entities, including public academic medical centers, veterinary schools with agriculture extension services, and public health departments whose proposals are in line with CDC's strategy for addressing antibiotic resistant bacteria.

*Natural History Museums*.—The Committee notes that the nation's natural history museums provide an unparalleled resource for studying zoonotic diseases such as COVID–19. These museums hold millions of animal samples collected over decades from across the globe, offer deep and broad scientific expertise, and are uniquely positioned to assist in preparing for and predicting the next pandemic-causing viruses. The Committee encourages increased utilization and support of this largely untapped resource.

*Global Health*

*Global Health Security*.—The Committee supports CDC's work to protect global health security through programs that detect, prevent, and respond to infectious diseases and other health threats. Emerging infectious diseases such as COVID–19 and Zika and the global threat of spread of known diseases such as Ebola, represent profound challenges to our health system. The Committee supports CDC's continued work on the development of new tools, especially diagnostics, the application of advanced molecular detection for the identification and tracking of diseases and disease variants at home and abroad, and core technical contributions to developing and validating tools for use by U.S. bilateral and multilateral global health programs and 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. The Committee urges CDC to ensure that the importance of research and development to global health security is appropriately reflected in their international engagements. The Committee requests an update in the fiscal year 2023 Congressional Budget Justification on how CDC is working with FDA, BARDA, and NIH to jointly coordinate global health research activities with specific measurable metrics used to track progress and collaboration toward agreed upon health goals.

*Global Public Health Protection.*—The Committee includes an increase of $245,000,000 to support and enhance CDC's mission to protect the health of our nation including by working across the globe. The Committee supports CDC's global efforts to detect epidemic threats earlier, respond more effectively, and prevent avoidable crises, including by providing support of program implementation and scientific and technical experts in Atlanta and in the field with concentrated efforts on countries, populations, and programs where resources will have the greatest public health impact. In addition, the Committee requests an update in the fiscal year 2023 Congressional Budget Justification on wastewater-based epidemiology and surveillance global detection efforts in the global response to COVID–19, including a professional judgement on the necessary budget and infrastructure requirements to fully operationalize these programs.

*Parasitic Disease and Malaria.*—The Committee provides an increase of $5,000,000 recognizing the important role CDC plays in the fight against malaria and parasitic disease. CDC provides crucial monitoring and surveillance of transmission, evaluation of interventions for effectiveness and impact, development of key diagnostics, and testing of tools in a real world setting that are critical to ensuring that our global health investments are smarter, better, and not wasteful. Therefore, the Committee encourages CDC to continue to research, monitor, and evaluate efforts for malaria and parasitic disease in collaboration across the agency and with other agencies.

**Public Health and Social Services Emergency Fund**

*Office of the Assistant Secretary for Preparedness and Response*

*Cold Chain Technologies.*—The Committee recognizes the limitations that are presented by cold chain requirements for vaccine distribution and storage. The Committee directs the Secretary to explore opportunities for new technologies such as dry power approaches or thin-film freeze drying that allow for vaccines to be physiochemically stable for an extended period without causing degradation or reduction in immunogenicity. The Committee requests an update on such efforts in the fiscal year 2023 Congressional Budget Justification.

*Modeling and Simulation*.—The Committee encourages ASPR to support the development and study of in silico approaches to accelerate vaccines for emerging infectious diseases including, but not limited to, computational simulation, data analytics, and the digital patient model, with the objective of reducing the time to market for virus vaccines.

*Biomedical Advanced Research and Development Authority*

The Committee includes $823,380,000, an increase of $226,680,000, for the Biomedical Advanced Research and Development Authority (BARDA). BARDA, through the Strategic Investor Program and other efforts, supports the advanced development of vaccines, drugs, and therapeutics for potential serious public health threats, including chemical, biological, radiological, and nuclear threats, pandemic influenza, and emerging and re-emerging infectious diseases. BARDA has played an essential role in the response to COVID–19. The Committee encourages BARDA to expand its portfolio of partnerships for broader success

*Broad Spectrum Antimicrobials and CARB–X*.—The Committee urges the Secretary to update the scope of support for the CARB– X program to include pathogens listed in the 2019 CDC Antibiotic Resistant Threats report, which includes products that target fungal pathogens. BARDA's Broad Spectrum Antimicrobials program is developing medical countermeasures that counter identified biothreats and address healthcare and community-acquired multi-drug resistant pathogens.These programs leverage public/private partnerships to develop products that directly support the government wide National Action Plan for Combating Antibiotic Resistant Bacteria and have a proven track record in developing new FDA approved antibiotics.

*Ebola*.—The Committee recognizes BARDA's efforts to address the threat of Ebola with an active portfolio of therapeutics, diagnostics, and vaccines.

*Pandemic Influenza Preparedness*

The Committee includes $335,000,000, an increase of $48,000,000, for the pandemic influenza preparedness program. This funding supports efforts to modernize influenza research and development of vaccines and the next-generation influenza medical countermeasures, preparedness testing and evaluation, and stockpiling, as well as critical domestic vaccine manufacturing infrastructure.