GHTC
global health technologies coalition

advancing **innovation** to save lives

January 31, 2021

The Honorable Richard Hudson
Ms. Molly Brimmer
2112 Rayburn House Office Building
Washington, DC 20515

The Honorable Jim Banks
Mr. Andrew Keyes
1713 Longworth House Office Building
Washington, DC 20515

The Honorable Tom Cole
Mr. Shane Hand
2207 Rayburn House Office Building
Washington, DC 20515

Dear members and staff of the Healthy Future Task Force Security Subcommittee:

The Global Health Technologies Coalition (GHTC)—a group of 40 organizations advancing policies to accelerate the creation of new vaccines, drugs, diagnostics, and other health tools for enduring and emerging global health challenges—writes in response to the request for information from the Healthy Future Task Force Security Subcommittee.

US government support for the development of medical countermeasures (MCMs) is essential to preparing for future health security threats. Department of Health and Human Services (HHS) agencies, including the National Institutes of Health (NIH), the Centers for Disease Control and Prevention, the Biomedical Advanced Research and Development Authority (BARDA), as well as the Department of Defense and US Agency for International Development, are key sponsors advancing the development of innovative health products that have helped the country and world prepare for and respond to health security emergencies.

Unfortunately, throughout the COVID-19 pandemic, the biomedical research and development (R&D) ecosystem has continued to prioritize the development of new products designed for use in well-resourced health systems—despite the public health need for products that can be used everywhere, including low-resource settings. Consequently, many first generation COVID-19 health innovations have been difficult or even impossible to implement effectively and expediently in low-resource settings in the United States and around the world—settings with limited access to reliable electricity, sanitation, refrigeration, health worker and laboratory expertise, and strong supply chains. For communities without these resources, many health products, such as multi-dose vaccines requiring ultracold storage or IV therapeutics, are difficult or even impossible to deliver and use effectively at the scale needed.

Strengthened US government policies are essential for better preparing the world for the next pandemic, and here we recommend policies that would equip the US biomedical R&D ecosystem to

effectively develop medical countermeasures in the future which are deployable in all settings. Our input is focused on questions 3(a), 3(b), 4, 7(d), and 8 in the request for information transmitted in December.

3(a). What changes to the vaccine development and approval process proved most beneficial to the timely development of COVID-19 vaccines? What changes might the federal government have made that would prove more beneficial still?

The unprecedented speed at which COVID-19 vaccines were developed was made possible by pre-pandemic federal investments in science and pandemic preparedness coupled with historic levels of investment by the federal government when the pandemic struck to de-risk R&D across multiple stages of clinical development. For instance, the development of nearly all successful COVID-19 vaccine candidates (as well as many therapeutics and diagnostics) was built upon decades of basic research either sponsored or conducted by the NIH National Institute of Allergy and Infectious Disease. The rapid clinical development of mRNA-1273, the NIAID-Moderna vaccine, specifically, was made possible through global clinical trials networks established by NIH and other agencies for HIV/AIDS and other diseases. To prepare for future pandemics, the federal government should continue to invest robustly in NIH and NIAID, emphasizing basic research and development of prototype vaccines against the viral families that pose potential future threats to humans.

Operation Warp Speed (OWS), known today as the Countermeasures Acceleration Group (CAG), was successful in rapidly producing and deploying several effective COVID-19 vaccines in record time, in part thanks to close collaboration with regulators at stages much earlier in the R&D process than is typical to compress the timeline between clinical results, regulatory review, and emergency use authorization. The success of this model must be caveated, however, by the fact that the vaccines produced by OWS (most of which require cold-chain storage, multiple doses, and trained health care workers to deliver) are difficult and costly to distribute and administer in low-resource settings around the world—including rural communities in the United States. Meeting the needs of low-resource settings should be prioritized as part of the goal of developing a safe and effective product as quickly as possible. In 2020, unfortunately, GHTC heard directly from OWS leadership that the needs of low-resource settings were important but not a top priority being considered in vaccine portfolio investment decisions. **In future pandemic preparedness and response efforts, policy should dictate that vaccine portfolio investment decisions incorporate the needs of low-resource settings from the outset, including through specific inclusion in target product profiles guiding R&D strategy and awards.** This is smart policy not only for low-resource settings, but for effective health emergency response everywhere, as products designed for low-resource settings are inherently easier to deploy in any setting. In other fields, this approach is known as *designing to the edges* or designing products that will work for the most extreme cases—which produces better products for everyone.

3(b). As Congress looks toward the reauthorization of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act, how might Congress codify what worked during the COVID-19 pandemic for future pandemics?

Since its founding in 2006, BARDA has been authorized to engage in the development of medical countermeasures for naturally occurring health threats. This work was bolstered by the Pandemic and All-Hazards Preparedness and Advancing Innovation (PAHPAI) Act of 2019, which specifically authorized BARDA to implement "strategic initiatives" to develop medical countermeasures against emerging infectious diseases, pandemic influenza, and antimicrobial resistance (AMR). BARDA, however, was established in response to the anthrax attacks, and prior to COVID-19, this legacy had bent the agency toward prioritizing the development of medical countermeasures for man-made threats more than those for naturally occurring ones.

While BARDA has effectively responded to several emerging infectious diseases, including Ebola, Zika, and 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 hamstrings science as public health emergencies unfold, Congress should establish a permanent funding line with an annual appropriation of no less than $300 million to sustain BARDA's work on emerging infectious diseases.** Such an increase in funding would bolster BARDA's capacity to support the development of medical countermeasures for the full range of priority infectious disease threats identified by health experts as most likely to cause the next pandemic.

The agency should also be supported to expand its work on AMR, including work on pediatric indications; multidrug-resistant sexually transmitted infections; CDC's full list of antimicrobial-resistant threats, as detailed in its Antibiotic Resistance Threats in the United States, 2019 report; and continued support for the CARB-X (Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator) program, a major public-private partnership launched in 2016 to develop new products that support the government-wide National Action Plan for Combating Antibiotic-Resistant Bacteria. This work is critical to preventing a post-antibiotic era that would threaten global health security and reverse antibiotic-dependent medical advances. A recent study conducted by the Institute for Health Metrics and Evaluation estimates that in 2019, AMR directly caused 1.3 million deaths globally, and was linked with 5 million deaths overall—making AMR a leading cause of death around the world, with the highest burdens in low-resource settings. To account for this growing global burden, BARDA's work on AMR should be expanded to include drug-resistant TB, a leading cause of death globally from AMR, and antifungals. Our progress against TB is at great risk as drug resistance intensifies, and BARDA currently conducts no research on drug-resistant TB despite its repeated identification as a global health security threat by experts and as a "leading health security threat" by CDC. Procurement for these new antibiotics could be pursued through a subscription model as outlined in the proposed PASTEUR Act and recently highlighted by the G7.

Finally, as referenced above, the next iteration of PAHPAI should authorize BARDA to explicitly prioritize the development of products that are deployable in low-resource settings in the United States and around the world and require minimal infrastructure and specialized health workforce support. COVID-19 has cast a harsh light on how first-to-market medical technologies are rarely appropriate for all settings, and BARDA should explicitly recognize this reality in its award-making process. With focused funding, first-line tools could be designed for implementation in low-resource settings, obviating many challenges commonly faced in the wide-scale global roll-out of new tools.

4. Supplemental appropriations for the United States' early pandemic response and proposed transfers of funds illustrated the need for the Department of Health and Human Services (HHS) to act quickly and draw upon all available funding, despite the existence of the Infectious Disease Rapid Response Reserve Fund and the Public Health Emergency Fund. How can Congress better equip these funds, and other resources, to provide HHS with the support it needs to act nimbly with dedicated funding and without waiting for Congressional action?

As reference in answer to question 3(b), GHTC recommends Congress create a separate $300 million appropriations line for emerging infectious diseases at BARDA, which would enable the agency to respond more quickly to future naturally occurring pandemic threats, in addition to a sustainable appropriation line for AMR product development at BARDA (see below).

7(d). Please identify any specific gaps in issue areas or programs that would benefit from additional support and promotion of public-private partnerships.

Three specific gaps deserve special mention. First, the US Agency for International Development is the only US agency with both a primary mandate to improve global health and development and a focus on late-stage development of health products specifically designed for populations living in low-resource settings—a focus that distinguishes it from other US R&D agencies. USAID has for decades applied its unique strengths in global health innovation to sponsor the development of dozens of lifesaving technologies, including better treatments for TB and malaria, rapid diagnostics for HIV, insecticide-treated bed nets to prevent mosquito-borne illness, devices that save the lives of newborns and their mothers, and a meningitis A vaccine that has virtually eliminated this disease wherever used. Despite this rich history of impact, USAID's global health innovation mandate has been increasingly constrained by three interrelated challenges: first, that funding for health-related R&D has been declining as a proportion of overall USAID global health spending since 2006; second, that innovation funding at USAID is siloed by health area, limiting opportunities for multipurpose products and responsive research that can be pivoted and deployed in emergencies like the COVID-19 pandemic; and third, that constrained budgets force leaders in the USAID Global Health Bureau to prioritize immediate impact over innovation and long-term progress. To address these interrelated challenges, GHTC has proposed the creation of a **Supporting Innovative Global Health Technologies (SIGHT) Fund, a new and additive source of flexible, catalytic funding at USAID to conduct research, development, and deployment of new global health products, created through a new appropriation to the USAID Global Health Bureau of $750 million in multi-year funding** available over the next three years. This funding, an average of $250 million per year over three years, would raise total USAID investments in global health innovation to a healthy target of approximately 10 percent of overall Global Health Bureau funding, and greatly help the agency expand its research partnerships with private and nonprofit partners. See GHTC's policy brief on the SIGHT Fund proposal for more detail.

Second, the US should establish an annual contribution to the Coalition for Epidemic Preparedness Innovations (CEPI) of $200 million each year over the next five years to support its critical work to advance the development of new vaccines for emerging infectious diseases with pandemic potential, which will complement and reinforce US pandemic preparedness and response efforts by ensuring equitable global access for underserved communities in low- and middle-income countries. While the US

has provided some limited support for CEPI's work on COVID-19 through the allocation of emergency supplemental funding from the American Rescue Plan Act, and USAID has a very limited partnership with CEPI established in 2020, sustained US support is also needed for CEPI's enduring mission to ensure the world is prepared for the next pandemic threat by advancing efforts to compress the vaccine development timeline for emerging infectious diseases to 100 days, including through the development of prototype pathogen research targeting high-risk virus families and beginning early-stage development of vaccines for future viral threats.

Third, CARB-X—which has since its launch in 2016 matured into a robust global AMR R&D partnership and supported 92 preclinical and Phase 1 products—should be allocated stable annual funded at no less than $50 million per year for the next decade within BARDA's AMR budget.

Funding for all three of these priorities is an important step towards strengthening US support for public-private research partnerships addressing some of the most pressing health challenges worldwide.

8. What other policy considerations should Congress examine concerning reauthorization of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act?

Several agencies and programs at HHS, the Department of State, and the Department of Defense contribute to global health R&D, yet there is not a formal mechanism to coordinate and share information about their work—a reality that necessitated the real-time development and implementation of sometimes imperfect coordination mechanisms to keep R&D agencies in sync during COVID-19. Reauthorization of PAHPAI should encourage enhanced dialogue and coordination to advance global health research activities to both ensure greater transparency in the work of the department and accelerate progress towards agreed upon health goals. Improving coordination and prioritization throughout HHS should improve efficiencies, leverage limited resources, and ensure critical gaps are realized and filled. Such coordination would also keep these connections warm and the US R&D ecosystem prepared for future global health security threats.

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R&D for emerging infectious diseases is essential to maintain global health security, but new policies are needed to ensure these initiatives are strengthened and that they prioritize the needs of low-resource settings. We thank you for considering our recommendations to the Healthy Future Task Force Security Subcommittee.

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

Sincerely,

Jamie Bay Nishi
Executive Director, Global Health Technologies Coalition