GHTC
global health technologies coalition

advancing **innovation** to save lives

February 4, 2022

The Honorable Patty Murray
The Honorable Richard Burr
Senate Committee on Health, Education, Labor and Pensions
428 Dirksen Office Building
Washington, DC 20510

Dear Senators Murray and Burr:

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 feedback on the discussion draft of the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (PREVENT Pandemics Act).

Continued US government commitment to research and development (R&D) of medical countermeasures (MCMs) and other biomedical products is essential to preparing for future health security threats and reducing health disparities. Department of Health and Human Services (HHS) agencies, including the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Biomedical Advanced Research and Development Authority (BARDA)—as well as the Department of Defense (DoD) and US Agency for International Development (USAID)—are key entities advancing the development of innovative health products that have helped the US and world prepare for and respond to health security emergencies and improve health outcomes for a wide range of enduring health threats.

Unfortunately, throughout the COVID-19 pandemic, the biomedical 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, and are adequately designed for the unique needs of disadvantaged communities. 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 some areas of consideration for the final bill that would better equip the US biomedical R&D ecosystem to effectively develop MCMs in the future which are deployable in all settings and orient the ecosystem towards more equity and impact outside of health emergencies.

GHTC believes the following recommendations would all strengthen the PREVENT Pandemics Act but particularly wishes to emphasize the importance of our recommendations on sections 302 and 303 and our proposed addition of a section 305 on propelling innovations for effective use in all settings.

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**Section 202. National Academies of Sciences Report:**

To ensure that the requested study from the National Academies of Sciences, Engineering, and Medicine also captures the impact of biomedical product design, research, and development on health disparities and their effect on health outcomes, GHTC recommends the following language be inserted between (b) (3) and (4): *"strategies to improve health outcomes and reduce health disparities by incorporating the needs of low-resource, rural, or otherwise disadvantaged communities in the design, research, and development of biomedical products and medical countermeasures by Federal research agencies; and how such strategies can enable the most effective use of such biomedical products and medical countermeasures everywhere they are needed to adequately respond to and mitigate health threats; and…"*

*Context:* 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—most of which require ultra-cold-chain storage, multiple doses, and trained health care workers to deliver—are difficult and costly to distribute and administer in low-resource settings, from rural communities in the United States to low-income countries. Moving forward, federal research agencies' portfolio investment decisions must better incorporate the needs of low-resource settings in product design, research, and development from the outset, including through specific inclusion in target product profiles guiding R&D strategy and awards. This is smart policy not only to reduce health disparities but also to improve health outcomes and mount effective responses everywhere during future health emergencies—since products designed for effective use in low-resource settings and disadvantaged communities are inherently easier to deploy in any setting. In other fields, this approach is known as "designing to the edges," the process of designing products that will work for the most extreme cases—which produces better products for everyone.

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**Section 302. Research centers for pathogens of pandemic concern:**

To facilitate effective collaboration between the research centers described in this section and other multilateral, global, and regional entities advancing clinical development of medical products for priority virus families and other viral pathogens with a significant potential to cause a pandemic—entities including, but not limited to, BARDA and the Coalition for Epidemic Preparedness Innovations (CEPI)—GHTC recommends the following language be added after (e) (2): *"Collaborate with new and existing multilateral, global, regional and domestic R&D entities to understand shared research priorities, leverage resources and scientific expertise, avoid duplication of effort and harmonize priorities, and*

*ensure effective handoff of high-potential preclinical research to domestic and global partners positioned to support clinical research and development of medical countermeasures."*

*Context:* This is one area of the bill which must be strengthened to emphasize the areas in which US engagement on pandemic preparedness research should be conducted with an eye towards end-to-end development of MCMs: connecting the findings of discovery and pre-clinical research to the clinical development work of domestic agencies like BARDA and global partners like CEPI leading in this space. Pushing for synergies and collaborative approaches with multilateral, global, regional, and domestic organizations will ensure the world can most effectively build the needed MCMs in health emergencies while also promoting and enabling equitable access to those MCMs.

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**Section 303. Improving medical countermeasure research coordination.**

To ensure all US agencies in the biomedical R&D ecosystem are adequately consulted on research related to public health and infectious disease threats, GHTC recommends adding USAID and DoD to the list of agencies in (3), in the bolded language which follows: ''by inserting after paragraph (25) the following: (26) shall consult with the Assistant Secretary for Preparedness and Response, the Director of the Biomedical Advanced Research and Development Authority, the Director of the Centers for Disease Control and Prevention**, the Secretary of the Department of Defense, the Administrator of the US Agency for International Development,** and the heads of other Federal agencies and offices, as appropriate, regarding research needs to advance medical countermeasures to diagnose, mitigate, prevent, or treat harm from any biological agent or toxin, including emerging infectious diseases, chemical, radiological, or nuclear agent that may cause a public health emergency or other research needs related to emerging public health threats.''

*Context*: USAID and DoD play essential roles in the biomedical research ecosystem, excelling, respectively, in the development of new health products that are appropriate, affordable, and accessible for widespread uptake in low-resource settings and the development of health products and MCMs for infectious diseases that threaten troop health and readiness. In concert with stakeholders from NIH, CDC and FDA, DoD played a critical role advancing R&D for COVID-19 vaccines through Operation Warp Speed, now known as the Countermeasures Acceleration Group. While this coordination mechanism proved highly successful in developing COVID-19 vaccines for high-resource settings, moving forward, the mechanism should also coordinate on the development of countermeasures for use in low-resource settings to support rural US communities, warfighters serving abroad and global populations, and include USAID in consultations as it considers target product profiles for future medical countermeasures.

See GHTC's factsheets on USAID and DoD for more background.

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***Proposed new section:*** **Section 305. Propelling innovations for effective use in all settings.**

To prioritize innovations with product profiles that are acceptable and appropriate for rural and low-resource settings (such as rural America, tribal settings, and low-resource settings globally), GHTC suggestions the addition of a new section to Title III to propel BARDA and other research organizations, grant recipients, partners, etc., to reflect earlier language on social determinants of health: *"Section 305. Propelling innovations for effective use in all settings. In awarding funding through grants, contracts, or cooperative agreements under a multidisciplinary research program to advance the discovery and preclinical development of medical products for priority virus families or other emerging infectious disease-related research at US Government Agencies, such as BARDA, priority shall be given to applicants advancing innovations acceptable and appropriate for use in low-resource, remote, and rural settings to mitigate health disparities driven by social determinants of health in those communities and exacerbated in health emergencies."*

*Context*: See section 202 feedback.

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**Title IV - Modernizing and strengthening the supply chain for vital medical products.**

To ensure that Federal efforts to strengthen the supply chain for vital medical products are holistic, maximally effective, and helps address global supply chain challenges, GHTC suggests the addition of language to Title IV calling for the development of a strategy outlining the role of the different divisions, agencies, and institutes within HHS to support global manufacturing capabilities and calling for coordination with other Federal agencies involved in supporting global manufacturing capacity, as well as an annual report on interagency efforts in support of global manufacturing to strengthen pandemic preparedness.

*Context*: Ensuring rapid global access to MCMs and other vital medical products is a critical component of enhancing American health and economic security. COVID-19 has shown repeatedly what happens when populations around the world don't have timely access to vaccines, drugs, or diagnostics: new variants emerge that impact everyone. Strengthening manufacturing capacity, with a focus on lower-middle and upper-middle income countries, is an important step in increasing global access to tools for pandemic prevention. Different parts of the US government, including BARDA and the US Development Finance Corporation, are already making important investments to bolster global manufacturing capacity, but stronger USG coordination is needed to ensure a whole-of-government sustainable approach to investment and technical assistance.

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**Section 502. Modernizing clinical trials.**

The text in (d) International Harmonization reads that the US "may" work with foreign regulators. We agree with the view of several R&D partners that this ought to be reworded as a "should" or "shall" requirement to streamline MCM development effectively at a global level.

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Finally, GHTC notes that the legislation does not include authorization of dedicated funding for BARDA's work on emerging infectious diseases. Adding this authorization is critical to supporting the proactive R&D that is needed to stay ahead of pandemic threats domestically and globally. Over the past decade—and to an unprecedented extent since the emergence of COVID-19—BARDA has played a critical role in advancing the development of MCMs for a range of health threats, including naturally occurring threats, but funding for the agency through base appropriations has not reflected this growing mandate. The Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 specifically authorized BARDA to implement "strategic initiatives" to develop MCMs against emerging infectious diseases, pandemic influenza, and AMR.

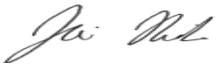
Through emergency supplemental appropriations, BARDA has made a significant impact in R&D for emerging infectious diseases during global health emergencies. Between 2015 and 2017, BARDA helped advance at least three vaccine candidates for Ebola and at least six diagnostics and five vaccine candidates for Zika. BARDA has also worked on galidesivir, a broad-spectrum antiviral with the potential to treat a variety of pathogens, including Ebola, Marburg, yellow fever, and Zika, and was tested in clinical trials against COVID-19. In response to COVID-19, BARDA has supported the development of at least 91 products, including vaccines, diagnostics, therapeutics, and devices through $25 billion in emergency supplemental funding appropriated through COVID-19 relief bills—more than 43 times its base FY20 appropriation.

As COVID-19 continues to wreak havoc on health systems and the global economy, we are at the peak of a now predictable boom-and-bust cycle of reactive global health security spending that ramps up only after the emergence of new infectious disease threats, leading to unnecessary delays in the development of MCMs. As we have all now witnessed, the delay between the emergence of a health threat and the development of appropriate tools to combat it costs lives and disrupts the functioning of our global society. We cannot let this cycle repeat itself once we have conquered the immediate threat of COVID-19. To fully engage BARDA's capacity to develop tools for naturally occurring threats, Congress should establish a permanent funding line with an annual appropriation of $500 million to sustain BARDA's work on emerging infectious diseases. Creating a robust, protected funding line for this work would bolster BARDA's capacity to support development of MCMs for the full range of priority infectious disease threats identified by health experts as most likely to cause the next pandemic.

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 strengthen the PREVENT Pandemics Act.

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
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