Recommendations for the Pandemic and All-Hazards Preparedness Act (PAHPA) of 2023

Why PAHPA 2023 matters

PAHPA 2023 is scheduled to reauthorize the Administration for Strategic Preparedness and Response (ASPR) and the Biomedical Advanced Research and Development Authority (BARDA) and will be an opportunity to strengthen research programs for national and global health security.

This memo includes policy recommendations from the Global Health Technologies Coalition (GHTC) to achieve that end.

BARDA and global health security

BARDA uses special contracting mechanisms to sponsor the late-stage development of medical countermeasures (MCMs)—vaccines, drugs, diagnostics, and other medical devices—for naturally occurring biothreats that lack a commercial market—including emerging infectious diseases (EIDs), pandemic influenza, and antimicrobial resistance (AMR).

BARDA focuses on US national health security, but many of the products it supports have global impact. BARDA has advanced at least 82 projects for AMR innovations, 100 products for COVID-19, and 8 FDA-approved products for Ebola and Zika—many of which have been used around the world.

BARDA co-led the US government's COVID-19 product portfolio through Operation Warp Speed with supplemental funding from Congress that was 43 times larger than its 2020 baseline funding. BARDA's success demonstrates how new products can be advanced against global health security threats with sufficient funding and direction.

Recommendations for PAHPA 2023

PAHPA 2023 is an opportunity to strengthen the nation's ability to develop MCMs against EIDs, AMR, and pandemic influenza—and to ensure support for that research is inclusive and the benefits are equitable. GHTC recommends the following policies:

Authorize an EID Division with new funding

BARDA led the development of MCMs for Ebola, Zika, and COVID-19, but surprisingly, this work has primarily been advanced through emergency supplemental funding bills because BARDA does not have a dedicated funding line for EIDs. This lack of consistent and predictable funding has forced BARDA to take a reactive rather than proactive stance on EIDs, putting the agency and the United States on the back foot when faced with novel threats.

Recommendations:

- **Authorize an EID Division.**
- **Authorize US$775 million per year for the division.**

This recommendation aligns with the American Pandemic Preparedness Plan and the *BARDA Stategic Plan 2022-2026*, which includes an explicit objective to establish an EID Division. Funding at $775 million has been validated by both the agency and external partners as the amount needed to launch an EID Division.

Prioritize deliverability in low-resource settings

Deliverability and administration of new MCMs are often blocked by the constraints of low-resource settings in the United States and abroad where there are limited or inconsistent access to refrigeration, sanitation, electricity,

highly trained health care workers, laboratories, or other resources. For example, these constraints impeded global deliverability of first-generation COVID-19 vaccines and therapeutics. Operation Warp Speed was successful at quickly developing safe and effective vaccines, but its leadership told GHTC that deliverability for low-resource settings was not being considered in vaccine portfolio decisions.

These constraints must be considered from the earliest stages of product development. This approach creates products that are more effective everywhere.

Recommendations:

- **Require ASPR to conduct a study on issues that may adversely affect the rapid delivery and administration of MCMs to individuals living in low-resource settings in the United States and globally during public health emergencies.**
- **In the reauthorization of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), include the Administrator for the US Agency for International Development (USAID).**
- **Authorize BARDA to support national and global community engagement activities as part of MCM development including support of clinical trial networks.**

These recommendations and their global orientation are aligned with objectives in the *BARDA Strategic Plan 2022-2026*, the American Pandemic Preparedness Plan, the *US National Action Plan on Combatting Antibiotic-Resistant Bacteria*, and the *National Biodefense Strategy and Implementation Plan*.

USAID—which has led MCM development efforts for Ebola and Zika and has a strong network of global partners—should be included in the PHEMCE.

Strengthen BARDA'S AMR mandate

AMR to drugs targeting bacteria, fungi, viruses, and parasites threatens the public health response to many diseases and the lives of Americans at home and abroad. Antibiotic resistance alone caused an estimated 1.27 million deaths in 2019—yet, as of 2021, the global pipeline of antibiotics was still insufficient. Without a course correction, global mortality is expected to reach 10 million per year by 2050 with significant mortality among children and newborns. AMR will threaten the scientific advancements of the treatments and common medical procedures that depend on antimicrobials that work. Antimicrobials are critical for infections secondary to chemical, biological, radiological, and nuclear (CBRN) events.

Recommendations:

- **Authorize BARDA's AMR portfolio and funding in all accounts at $500 million per year.**
- **Attach the Pioneering Antimicrobial Subscriptions To End Up surging Resistance (PASTEUR) Act.**

BARDA funds the development of AMR products at every stage of clinical development. This includes sponsorship of the Combating Antibiotic Resistance Bacteria Biopharmaceutical Accelerator (CARB-X), the partnership created under the *US National Action Plan for Combating Antibiotic-Resistant Bacteria*. Today, more than half of CARB-X funding is leveraged from other governments and private foundations. This work has operated under the US National Action Plan and an Obama-era executive order and should be reaffirmed and authorized as a stand-alone priority.

The PASTEUR Act would bridge a commercial valley of death by creating a subscription-model payment program to incentivize the development of new AMR drugs.

Continue to prioritize pandemic influenza

A pandemic influenza outbreak remains one of the most prominent threats to national and global public health. BARDA has been a global leader in sponsoring pandemic influenza MCMs.

Recommendation:

- **Reauthorize BARDA to develop a broad range of influenza products, such as treatments, vaccines, non-vaccine prophylactics, and diagnostics.**

Maintain BARDA's authority to develop products for at-risk populations

The Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (P.L. 116-22) and previous reauthorizations enable BARDA to prioritize "children, pregnant women, older adults, and other at-risk individuals" (42 USC § 247d-7e(c)(6)) in the development of MCMs. At minimum, this language should be maintained.

Prioritize transparency

BARDA has responded to requests to publicly report on its investments, providing valuable information to innovators and stakeholders that engage with the agency and invest in MCM development. This reporting should be used for all BARDA investments including CBRN, EID, and AMR countermeasures.

This transparency is important for oversight, reduces duplication, and promotes collaboration and coordination with other federal agencies and external partners engaged in global health security research.

Congress should require transparency through PAHPA reauthorization so that this reporting persists regardless of future changes to BARDA leadership.

Recommendation:

- **Direct BARDA to regularly and publicly report on its product-level investments to the greatest extent possible without compromising national security, and as part of that reporting, to detail the funding amount, threat area, product type, and phase of development for each MCM.**

This policy would be a minimal burden to the agency since it already provides reporting on its website for COVID-19 and CBRN threats.

Eliminate the sunset for the medical countermeasure innovation partnership

The 21st Century Cures Act authorized BARDA to enter a partnership with a nonprofit entity to accelerate MCMs through venture capital practices. BARDA has since entered a successful partnership that has leveraged matched external funding to sponsor at least eight promising innovations. This authority will expire, however, on September 30, 2023 without renewal (42 USC § 247d-7e(c)(4)(E)(ix)).

Recommendation:

- **Eliminate the sunset clause for BARDA's medical countermeasures innovation partnership authority.**

Authorize loan authorities

BARDA needs a mechanism to support the finance of large-scale projects that could better prepare the United States and the world for future biological threats.

Recommendation:

- **Authorize loan authorities for BARDA like the US Department of Energy.**

With loan authorities, BARDA would be capable of supporting projects like innovative biomanufacturing facilities, such as for microneedle patch vaccines.

The Global Health Technologies Coalition urges Congress to integrate these recommendations into the reauthorization of PAHPA to strengthen the health security of our nation and the world.