

Pandemic and All-Hazards Preparedness Reauthorization Act priorities

The Global Health Technologies Coalition (GHTC) is a group of more than 25 nonprofit organizations working together to advance the creation of new drugs, vaccines, diagnostics, and other urgently needed health tools for neglected diseases and health conditions. We strongly support a robust role for the Biomedical Advanced Research and Development Authority (BARDA) in the advanced development of medical countermeasures (MCMs) to address naturally occurring threats with pandemic and epidemic potential, including emerging infectious diseases (EIDs), pandemic influenza, and drug-resistant infectious diseases through a robust antimicrobial resistance (AMR) portfolio.

To advance these goals through 2018 reauthorization of the Pandemic and All-Hazards Preparedness Act, GHTC recommends the following actions:

Create a separate line item for emerging infectious diseases within BARDA, with authorization at a minimum of \$300 million.

EIDs are emerging at a rapid rate and continue to pose significant risks to American health and public health preparedness. While BARDA is authorized to advance MCMs for EIDs, robust work in the area has only come through emergency funding—notably in the emergency responses to Ebola in 2014 and Zika in 2016. BARDA was awarded this funding in recognition of its unique and unmatched ability to mobilize diverse stakeholders and industry to advance the late-stage development of critical MCMs. Dedicated and sustained funding for EID MCM development will provide certainty and allow BARDA to pursue forward-looking investments in EIDs that help ensure we have countermeasures for naturally occurring threats when we need them. Because we do not always know today what the next threat will be, flexible and certain funding is essential to ensure our preparedness. Reliable annual funding will also reduce reliance on emergency appropriations, which are often greater in scale than annual funding and come too late to provide MCMs needed during an active emergency.

Strengthen antimicrobial resistance work at BARDA by formalizing this work stream and providing opportunities to engage in drug-resistant infectious diseases with pandemic and epidemic potential.

New countermeasures are urgently needed to address the growing threat of AMR, including for drug-resistant infectious diseases with pandemic and epidemic potential. BARDA's current work in AMR is not formalized and does not include multi-drug resistant tuberculosis (TB) or extensively drug-resistant TB, despite projections that drug-resistant forms of TB are the biggest drivers of AMR deaths. Approximately one third of the 700,000 annual deaths from AMR are from drug-resistant TB. AMR is a clear health security interest for the United States, and BARDA is uniquely suited to advance drugs, vaccines, and diagnostics for AMR. Formalizing an AMR workstream, with an inclusive scope, will help advance new urgently needed antibiotics and other health technologies to reinvigorate the antimicrobial pipeline. We also support novel incentive mechanisms to strengthen the AMR MCM pipeline.

Require reporting on BARDA's work in the areas of emerging infectious diseases, pandemic influenza, and antimicrobial resistance in BARDA's five-year budget plan.

The *Pandemic and All-Hazards Preparedness Reauthorization Act* of 2013 (P.L. 113-5) requires the Office of the Assistant Secretary for Preparedness and Response (ASPR) to annually report a five-year budget plan for MCM priorities, to include information about threats, a description of how ASPR allocates resources and measures outcomes to advance priorities, and an assessment of near-, mid-, and long-term needs. Adding EIDs, pandemic influenza, and AMR as reporting requirements will provide insight into BARDA decision-making and ensure that the authority is appropriately considering work in EIDs, pandemic influenza, and AMR in relation to other priority areas of MCM development.