

Bolstering BARDA's role in combatting naturally occurring threats and emerging infectious diseases

BARDA founding and public health mission

The Biomedical Advanced Research and Development Authority (BARDA) was founded in 2006 through the *Pandemic and All-Hazards Preparedness Act*, in the wake of the anthrax attacks on the US Capitol, in recognition that the United States needed a nimble platform to support late-stage development of medical countermeasures (MCMs) that have limited or no commercial markets but are urgently needed to protect the American public from man-made and naturally occurring threats.

To fulfill this mission, BARDA partners with industry to bridge the “valley of death” between basic research and advanced-stage product development for MCMs—an area where more traditional US government research enterprises do not operate. It uses unique contracting mechanisms and “Other Transaction Authority” to forge innovative and long-term partnerships with the private sector and leverages diverse incentive mechanisms to engage new and diverse stakeholders in priority public health countermeasure development.

BARDA's historical role in naturally occurring threats and emerging infectious diseases

Since its founding, BARDA has been authorized to engage in the development of MCMs for naturally occurring threats and emerging infectious diseases

(EIDs). However, BARDA does not have a sustainable funding stream for this work, and its EID activities have been piecemeal and primarily limited to public health emergencies linked to supplemental funding.

In 2009, BARDA was called upon to support vaccine development for H1N1—a strain of influenza commonly known as swine flu—following a public health emergency declaration. Due to its unique and unmatched capabilities in the MCM product development, BARDA has been a key player in developing vaccines for pandemic influenza ever since. In 2014, BARDA was again tapped to accelerate the development of countermeasures to address the Ebola outbreak with funding through one-time, emergency appropriations. BARDA also became a critical player in Zika countermeasure development through emergency funding dedicated to the US Zika response. This engagement has generated impressive results: In just one year (2014-2015) BARDA advanced the development of 12 vaccine, antiviral, immunotherapeutic, and diagnostic candidates for Ebola.

BARDA also plays a role in MCMs for naturally occurring threats through work in antimicrobial resistance (AMR). Historically, BARDA's engagement on AMR focused on developing antibiotics that simultaneously addressed biothreat and public health concerns. A 2014 Executive Order—*Combatting Antibiotic-Resistant Bacteria*—broadened BARDA's ability to advance AMR MCMs explicitly for public health needs. This workstream has not been authorized through legislation.

Limitations of current BARDA structure

While BARDA has found some success in working with partners to accelerate critically needed countermeasures for naturally occurring threats and EIDs, the authority faces considerable constraints which limit its ability to sustain and increase these activities.

First, BARDA's EID workstream has primarily been funded through one-time, emergency appropriations—not dedicated or sustained funding. This forces BARDA to engage reactively in EID MCM development instead of proactively managing an EID MCM portfolio. As research and development (R&D) is an inherently long process, this often means that countermeasures are accelerated during a crisis, but are not ready to be deployed and used as part of the response, despite a significant influx of funding. Relying on emergency funding for EID work also limits BARDA's ability to engage in longer-term threat forecasting and invest in countermeasures for the emerging and reemerging infectious diseases that pose the greatest threats to American health. We do not always know today what the next threat will be, so this type of forecasting is essential to public health preparedness.

Unpredictable funding and prioritization for EID countermeasures also hinders BARDA's ability to engage industry partners who are critical to bringing these products across the finish line. One-time funding and emergency declarations incentivize industry to engage in EID MCMs, but often the health crisis, political interest, and funding wanes before a product is completed, removing critical supports that help justify industry decisions to attend to a public health need in lieu of more commercially attractive R&D. During the H1N1, Ebola, and Zika responses, industry mobilized to support MCM development, only for government support to dry up before R&D was completed. There are serious concerns that this legacy and

unsustainable structure will jeopardize future industry engagement in MCM development in future public health crises. (See attached *STAT News* article for more information.)

There are also challenges to BARDA's continued work in AMR for public health pathogens. Because this workstream was initiated through an executive order, it is not a permanent part of BARDA's structure and has only limited funding. As with BARDA's EID work, predictable funding and government engagement are critical to bringing needed industry partners to the table.

The 2018 reauthorization of the *Pandemic and All-Hazards Preparedness Act* offers Congress the opportunity to solidify and bolster BARDA's crucial work in MCMs for naturally occurring threats, EIDs, and AMR. The Global Health Technologies Coalition urges Congress to recognize the unique and unparalleled capabilities of BARDA in the MCM development pipeline and ensure this important work can continue and flourish.