Biomedical Advanced Research and Development Authority

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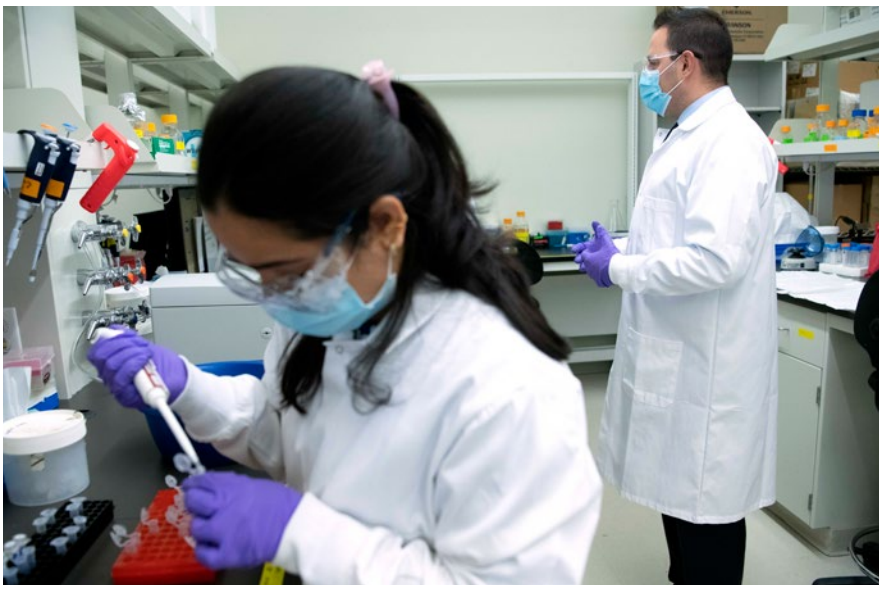
The Biomedical Advanced Research and Development Authority (BARDA), within the Office of the Assistant Secretary for Preparedness and Response (ASPR) in the Department of Health and Human Services, supports the advanced development of vaccines, drugs, and other medical countermeasures to protect Americans against threats to public health, including emerging infectious diseases, antimicrobial resistance (AMR), and pandemic influenza. BARDA is perhaps the world's leading institution for developing medical countermeasures against global health security threats through public-private partnerships. BARDA works with industry to bridge the "valley of death" between basic research and product development, so-called because many potential medical innovations stall after public funding for basic research drops off but before other public, private, or nonprofit research and development (R&D) funders pick up later-stage product development efforts. Through unique contracting and incentive mechanisms, BARDA's partnerships ensure promising research is translated into urgently needed medical products by creating commercial incentives for private-sector partners.

BARDA has been the primary US funder of new medical countermeasures against COVID-19, distributing billions of dollars in supplemental funding from Congress to advance and procure new vaccines, therapeutics, diagnostics, and other technologies for use against the pandemic. In 2020, BARDA received an influx of more than $25 billion in emergency supplemental funding, an amount 43 times the size of its annual appropriations and 16 times the size of its annual budget.



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Policy recommendations

Establish a permanent funding line with an annual appropriation of at least $300 million to enable sustained work on emerging infectious diseases; antimicrobial resistance, including drug-resistant tuberculosis; and pandemic influenza.

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 Act of 2019, which specifically authorized BARDA to implement "strategic initiatives" to develop medical countermeasures against emerging infectious diseases, pandemic influenza, and AMR. BARDA, however, was established in response to the anthrax attacks, and this historical legacy has bent the agency toward developing medical countermeasures against man-made threats over naturally occurring ones.

While BARDA has responded to 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 stalls science as public health emergencies unfold, Congress should establish a permanent funding line with an annual appropriation of $300 million to sustain BARDA's work on emerging infectious diseases, pandemic influenza, and AMR, including drug-resistant tuberculosis (TB).

Such an increase in funding would bolster BARDA's capacity to support 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 and to expand its work on pandemic influenza and AMR. The latter should include support for pediatric indications; multidrug-resistant sexually transmitted infections; the Centers for Disease Control and Prevention's (CDC) 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 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. In particular, BARDA's work on AMR should be expanded to include drug-resistant TB, the leading cause of death globally from AMR. Our progress against TB is at great risk as drug resistance intensifies. 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" to the United States in congressional testimony provided by CDC.

Photo credit: Penn State

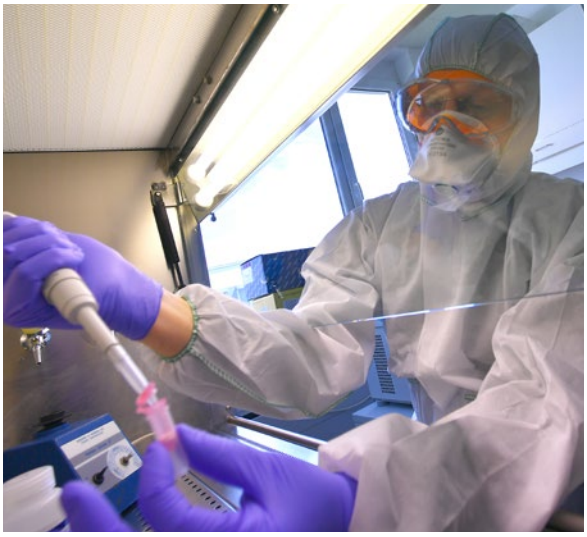
Prioritize development of products that are deployable in low-resource settings in the United States and around the world and require minimal infrastructure and medical expertise.

COVID-19 has cast a harsh light on how first-to-market medical technologies are rarely appropriate for all geographies, and BARDA should explicitly recognize this reality in its grant-making process. Tools developed for well-resourced health care settings often do not meet the needs of low-resource settings, and COVID-19 has reaffirmed that many low-resource settings—including rural communities in the United States—will face challenges implementing technologies that require robust health infrastructure, such as vaccines that require ultra-cold chain storage and multiple doses. Limited health infrastructure creates challenges for implementing treatments that require intravenous delivery, such as monoclonal antibodies, and diagnostics that require expensive laboratory equipment. With focused funding, first-line tools could be designed for implementation in low-resource settings, obviating the challenges commonly faced in those regions. In other fields, this is typically called "designing to the edges," or designing products that will work for the most extreme cases, which leads to better products for everyone.

Continue to report work on emerging infectious diseases, antimicrobial resistance, and pandemic influenza in the five-year budget plan of the Assistant Secretary for Preparedness and Response, and provide regular, publicly available updates on both COVID-19 and non-COVID-19 funding.

BARDA/ASPR is the primary coordinating agency for the Public Health Emergency Countermeasures Enterprise, which coordinates the development of medical countermeasures across many federal agencies, including BARDA, the National Institutes of Health, CDC, the Department of Defense, and others. ASPR is required to annually produce a five-year budget report that includes projected costs for development of medical countermeasures. In the last completed budget (2018 to 2022), this spending was delineated by disease area, which is important for providing insight into how the agency is applying its strategy and contributing to the global health R&D ecosystem.

To allow stakeholders to properly identify BARDA's contributions to public health R&D, including changes to its funding priorities in response to emerging epidemics, forward-looking budgetary information should be supplemented by regularly updating pathogen, product, and project-level data. BARDA has provided this kind of detailed information in relation to its COVID-19 funding via medicalcountermeasures.gov since early 2020. We urge BARDA to broaden the coverage provided by the medical countermeasures portal to include all its funding—not limited to investments funded under the COVID-19 emergency supplements—in a similar format to the existing COVID-19 data, to provide access to the underlying data in tabular form, and to continue to provide regular updates even after the current crisis has passed.



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