Key Points

- **Among public health agencies, BARDA is uniquely positioned to defend the country against future pandemics and bioweapons.**
  - BARDA was the key interface between the U.S. government and the biomedical industry in the development of the Moderna mRNA vaccine, the single biggest success against COVID.
- **BARDA is chronically underfunded.**
  - BARDA is the only agency mandated to provide advanced R&D for biomedical countermeasures, but doesn't have enough money to fulfill that mandate.
- **BARDA needs agility and vision.**
  - To leverage the power of the biotech industry, BARDA needs the authority to strike deals more quickly.

Context

1. **BARDA is uniquely mandated to defend the country against future pandemics and bioweapons and bring public health security technologies to market.**

   The Biomedical Advanced Research and Development Agency's (BARDA) is the premier biomedical countermeasure development agency for the U.S. federal government and our frontline layer of defense in responding to future pandemics and bioweapons. BARDA was created in 2006 as part of the Pandemic and All Hazards Preparedness Act. The goal of the agency is straightforward: promote advanced research, innovation, and development of medical countermeasures in a way that the private sector alone cannot. This includes financial investments as well as core support services and subject-matter expertise. The agency has consistently punched above its weight in developing countermeasures against biological, radiological, and nuclear hazards.

   BARDA takes its cues from the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), a coordinating body housed at the Office of the Assistant Secretary for Preparedness and Response in HHS. PHEMCE is responsible for deciding what countermeasures are needed, and then turns to BARDA to perform the advanced research, innovation, and development necessary for actual use.[1] BARDA can take discoveries from the NIH, or projects

1 PHEMCE includes the Director of the CDC, the Director of the NIAID within the NIH, and the Commissioner of the FDA, and partners with senior leadership from the VA, DoD, DHS, and USDA.

that have graduated from ARPA-H, and bring them across the finish line of FDA approval and into the Strategic National Stockpile (SNS).

2. **BARDA fills key gaps in private funding models for biosecurity.**

BARDA is tasked with harnessing the private sector to fund defenses against high risk, low-probability hazards that aren't addressed by commercial markets. The agency's work has led to 62 medical countermeasures that have received a greenlight from the FDA. These successes include the Moderna mRNA vaccine that was developed as part of Operation Warp Speed (OWS). Pound for pound, BARDA has been easily the most effective federal agency in our national COVID response.

BARDA supports advanced development of diagnostics and therapies for chemical, radiological, and biological threats. To respond to chemical and nuclear attacks, BARDA has helped develop four separate burn treatments. BARDA has also developed four treatments to counter the effects of radiation exposure. For biological attacks, BARDA has an FDA-approved diagnostic for bacillus anthracis, the bacteria that causes anthrax, as well as a vaccine for post-exposure prophylaxis, monoclonal antibodies, and two different anthrax antitoxins.

BARDA's biological countermeasures against smallpox offer a clear example of work that otherwise wouldn't be done by commercial markets. Smallpox has been eradicated, but still exists in CDC and Russian freezers, is highly contagious, and kills one third of those infected. To head off risks of a smallpox bioweapon, BARDA has led advanced development of two different smallpox antivirals and one smallpox vaccine through FDA approval, and all three are now part of the SNS.

BARDA is also well-positioned to address new threats. Following the 2013-2016 Ebola outbreak, BARDA developed a rapid antigen test for the Ebolavirus as well as two monoclonal antibody therapies, both of which received FDA approval in 2020, and a vaccine, which was approved in 2019.

One particularly notable advantage of BARDA, relative to other federal biomedical funders, is that it has Congressional authorization to use a broad suite of innovative procurement models such as prizes, milestone-based awards and payments, advanced market commitments, and funding for university-affiliated research centers. However, despite its many successes, BARDA is not always able to work with the best industry partners because the agency's funding is relatively small and often unstable.

Challenges

1. **BARDA's support system for promising private sector research is chronically underfunded.**

   The Office of the Assistant Secretary for Preparedness and Response (ASPR), which houses BARDA, only received $2.6 billion in FY22 appropriations, with 71% of the budget dedicated to procuring vaccines against bioterrorist attacks and other medical countermeasures for the SNS. This level of funding pales in comparison to U.S. expenditures on other issues of national defense. For example, the Virginia-class nuclear-powered submarines cost $2.8 billion each. Since 2000, the U.S. has built 22 Virginia-class subs and plans to build 44 more.

   Despite its unique mandate to provide advanced research and development for biomedical countermeasures, less than a third of ASPR's budget ($745M) is available for such endeavors. And only $76 million of that goes to BARDA's Division of Research, Innovation and Ventures (DRIVe). DRIVe, which was established as part of the 21st Century Cures Act as an analogue to biotech venture capital, identifies, derisks, and invests in the most promising transformative technologies for addressing health security challenges.

   But DRIVe's limited funding makes it difficult to deploy enough capital to get the attention of the most promising companies. As a point of comparison, last year the private asset manager Fidelity invested $5.8 billion across 31 funding rounds for biotech companies. In other words, one private fund invested, on average, more than twice BARDA DRIVe's total budget **per biotech company** in 2021. BARDA does not need to compete with biotechnology venture firms at large, but it does need enough funding to be worth a company's time.

2. **BARDA needs stable preparedness funding, not boom and bust cycles.**

   To its credit, Congress does send influxes of money when it wants specific outputs: Congress sent $7.65 billion to combat the 2009 swine flu pandemic caused by the H1N1 influenza virus and has sent $32 billion in additional funds for COVID. However, injections of emergency funds do not provide cost effective outcomes. Medical countermeasure development and procurement require years of sustained funding and private sector relationship development. There is not a mature biosecurity industry ready to supply the government's immediate needs, partly because funding goes through boom and bust cycles as pandemics surge and then fade from memory over time.

   BARDA's advanced research and development needs more funding, especially for flexible medical countermeasures and platforms that can be used against previously unknown disease threats. Existing programs are primarily directed

at specific, known, high-priority threats. As the COVID-19 pandemic has shown, broad research and the flexibility of pan-pathogen platform technologies have incredible life-saving potential. The only reason OWS could produce a vaccine in one year was the program's 15 years of prior coronavirus vaccine research.

Opportunity

1. **BARDA needs flexibility to develop vaccines before the next pandemic hits.**

   BARDA initially focused on developing and stockpiling promising medical countermeasures that were already in development for known, specific national security threats. Although stockpiles are important given the threat landscape, pan-pathogen platforms and broad class countermeasures are cost-effective response mechanisms.

   OWS was a resounding success, achieving its ambitious goal of delivering a safe and effective COVID vaccine in less than a year. The total price tag for the program has reached $18 billion, a bargain compared to the trillions of dollars in social costs from the pandemic. But the federal government could get even more value for its money by developing vaccines **before** the next pandemic hits. The White House Office of Science and Technology Policy estimates it would cost just over $24 billion to have prototype vaccines ready for each of the 26 known viral families that cause human disease. Showing that these vaccines are safe and promote an immune response before we need them will allow for vaccines to be ready for deployment within 100 days after virus identification.

   Given the speed at which biotech moves, BARDA would also benefit from more flexible contracting authorities (e.g., Other Transaction Authority) to make it easier and faster for companies to work with the agency. Carving out DRIVe as an HHS equivalent of In-Q-Tel would give it the further flexibility and autonomy to invest in the biotech industry at the same pace as venture capital firms. While venture capitalists want to steer the market for profit, BARDA can steer the market to save lives.

2. **BARDA is the agency best positioned to stop the next pandemic.**

   More than lockdowns, mask campaigns, or social distancing, new technology in the form of mRNA vaccines and rapid diagnostics was the saving grace of the COVID-19 pandemic. BARDA was critical in enabling these advances, and will be an essential driver in developing countermeasures to address the next pandemic.

   BARDA can create better genomic early warning systems, next-generation personal protective equipment, treatments, and vaccines that can be almost instantly ready to deploy. BARDA is the agency best equipped to use its funding to bring technological discoveries from private research labs into the federal arsenal.