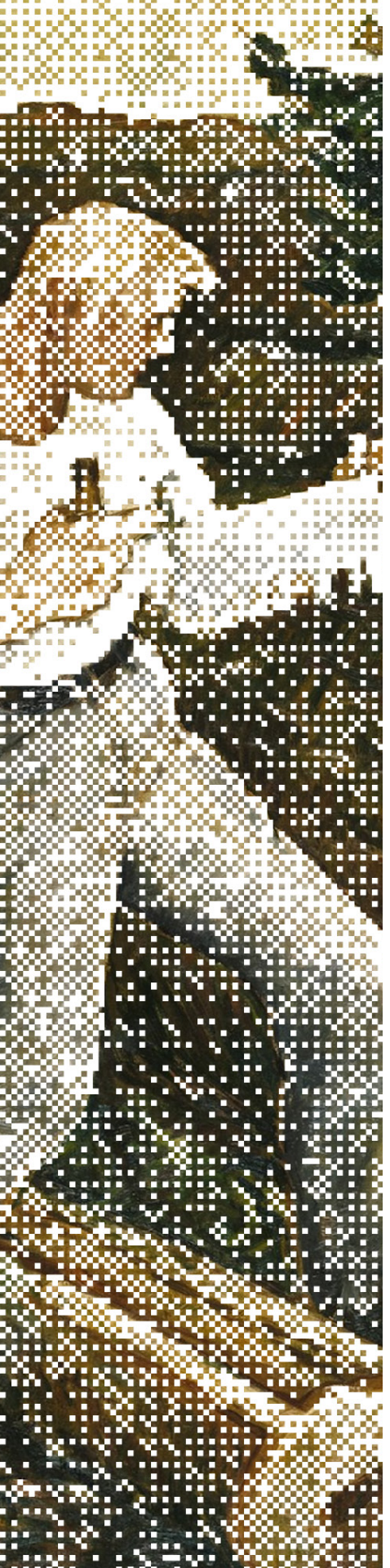

■ Frontier Science & Technology

Modernizing Civilian Defenses Against Biological Threats

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SUMMARY

America faces a growing risk of biological threats. The confluence of emerging biotechnology and unstable geopolitics means that there may soon be more adversaries with the capability and intent to use biology to attack the US.

To protect our population, we need a potent civilian biodefense enterprise that can rapidly develop and deploy countermeasures against changing future threats. America's current version of this enterprise, the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE), is burdened with artificial constraints on some of its resources that tie them to (primarily pharmaceutical) countermeasures against an outdated list of threats.

First, PHEMCE leadership should regularly identify technology areas beyond pharmaceuticals where additional innovation would help the US maintain protection dominance, and second, Congress should remove the requirement that ties Project BioShield funding to a specific list of "material threats." If implemented, these two changes will ensure that the PHEMCE will have the dexterity it needs to address future biological threats.

PROBLEM

Progress in synthetic biology and artificial intelligence has opened a vast new territory of innovations that could transform American health—but it may also provide bad actors with new capabilities to launch biological attacks against the people of the United States. In the current moment of global turbulence, it is more important than ever that we establish and retain security against both state and non-state adversaries.

If they materialize, the biological threats of the next 20 years and beyond could be potent and spread rapidly. To defend against these threats, America will need scientific prowess to engineer detection mechanisms and countermeasures. We will need manufacturing and logistical muscle to produce and deploy these defenses. And we will need a lean, efficient, and speedy government to coordinate this response.

Our current civilian biodefense apparatus, led by an interagency coordinating body called the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE), did its job well for the known threat agents of the 2000s and 2010s. To ensure that it continues to achieve its mission of "enhancing the nation's capabilities to prepare for and respond to national health security threats," the PHEMCE and its components must be unburdened and re-equipped with a modernized arsenal of abilities and tools.

FIRST, THE PHEMCE MUST BE ABLE TO ADAPT ITS RESOURCE TARGETING TO A RAPIDLY-MOVING THREAT LANDSCAPE. As it stands, there are hundreds of millions of dollars spent every year under PHEMCE's direction—Project BioShield —that are statutorily limited to address a narrow, outdated list of threats that the Department of Homeland Security has issued "material threat determinations" for. This bureaucratic process has historically been sluggish at issuing new threat determinations, so a large chunk of the nation's biodefense funding has been locked up on programs that may not address the threats of the future. We need to clear this unwieldy procedure and enable the PHEMCE to target taxpayer dollars more efficiently.

AND SECOND, THE PHEMCE MUST BE ABLE TO PURSUE INVESTMENTS IN WHATEVER TECHNOLOGICAL COUNTERMEASURES ARE NEEDED TO DEFEND AGAINST FUTURE THREATS, WHETHER PHARMACEUTICAL IN NATURE OR NOT. In the past, the PHEMCE has focused most of its budget on pharmaceutical countermeasures under the "one bug, one drug" paradigm, requiring an entirely new product development cycle for each countermeasure. These product development cycles often take years and cost billions of dollars over their lifetime.

One example of a class of innovations that the current PHEMCE process is largely unequipped to capitalize on: physical transmission-suppression interventions, like air filtration, far-UVC, glycol vapors, and next-generation respirators. These interventions could be much more cost-effective to deploy than pharmaceuticals and prevent pathogen exposure in the first place, obviating the need for treatment. However, they don't currently have a home in the federal advanced research and development (R&D) portfolio. If we let these potential innovations flounder in the Valley of Death, our adversaries may capitalize on them before we do —which would make us differentially more vulnerable to a biological attack. To avoid this outcome, we should remove

burdensome and unnecessary limitations on the solution space that PHEMCE's R&D components are allowed to deploy their resources to tackle.

SOLUTION

Executive

- The Administration for Strategic Preparedness and Response (ASPR), acting as the chair of the PHEMCE, should regularly survey innovative non-pharmaceutical, pathogen-agnostic technologies that could enhance US biological threat preparedness and identify R&D, procurement, advanced manufacturing, or industrial warm-basing investments that PHEMCE components could make to accelerate their readiness for civilian biodefense.

Congressional

- The Senate Health, Education, Labor, and Pensions (HELP) Committee and House Energy and Commerce (E&C) Committee should remove the limitation that Project BioShield Special Reserve Fund appropriations are to be used only for countermeasures against agents that have received material threat determinations. A reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA) would be an appropriate vehicle to make these changes, but given the increasing importance and necessity of biological defense, these changes may warrant their own legislative vehicle.

JUSTIFICATION

The Defense Advanced Research Projects Agency's (DARPA) evolution is a case study of the benefits of removing straightjackets on an R&D agency's programs. In the early days of ARPA, after its establishment in response to Sputnik, it focused nearly exclusively on space technologies. Over time, as strategic competition moved beyond the domain of space, DARPA's core mission of "preventing technological surprise" required it to undertake projects in a wider range of fields, from computing to biology. Had DARPA been statutorily limited to space-based threats, the US may not have been the first to invent and deploy stealth aircraft, mRNA technology, or many other innovations that proved critical to our national security and strategic dominance.

DARPA's history also shows the potential downsides of a stiflingly narrow institutional focus. The Mansfield Amendment of 1973 strictly constrained ARPA's focus to defense-related research. This restriction generated additional paperwork for the agency and hindered its ability to invest in basic R&D with long-term payoffs—including computing projects like ARPANET. Had the 1973 Mansfield Amendment been in place just a few years earlier, the development of the internet would likely have been slowed or crippled entirely.

Like DARPA's liberation beyond a single technology domain—and unlike the Mansfield Amendment's limiting effect on ARPA—we should aim to remove the constraints that impede the PHEMCE as it strives to achieve its mission. ■

FURTHER RESOURCES

- "Public Health Emergency Medical Countermeasures Enterprise (Multiyear Budget: Fiscal Years 2023-2027)," Office of the Assistant Secretary for Preparedness & Response, US Department of Health & Human Services, 2024
- BARDA Broad Agency Announcement Active Areas of Interest
- Willy Chertman, "Creating Advanced Market Commitments and Prizes for Pandemic Preparedness," Institute for Progress, 2022

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