

House Energy and Commerce Committee, Health Subcommittee Hearing – “Legislative Solutions to Bolster Preparedness and Response for All Hazards and Public Health Security Threats.”

June 13, 2023

Questions for the Record

Ms. Phyllis Arthur Responses

The Honorable Earl L. “Buddy” Carter

- 1. As Congress further examines future emerging public health threats, it’s important to highlight the threat of antimicrobial resistance (AMR) and consider the importance of antimicrobials to national health security. A recent Advisory Committee report includes the recommendation that “AMR therapeutics... that will be most needed during a public health emergency should be identified, stockpiled, and replenished accordingly in the Strategic National Stockpile and the National Veterinary Stockpile.” One of the established mechanisms by which the U.S. government can develop and procure effective medical countermeasures, like antimicrobials is through Project BioShield. How can Project BioShield serve as an effective strategy to develop and procure antimicrobials, protect national security, and ensure patient access in the event of a future public health emergency, such as a pandemic?**

Project BioShield was created in 2004 to accelerate the availability of medical countermeasures (MCMs) to protect against recognized threat agents. Administered by BARDA, Project BioShield contracts fund both late-stage development activities and procurement for the Strategic National Stockpile (SNS). To date, BARDA has awarded two Project BioShield contracts to develop/procure small molecule antimicrobials to counter bacterial biowarfare agents.¹ These contracts provide a near-term stabilizing effect to the recipient companies through procurement sales and support for mandatory post-approval studies. It is important to maintain and increase funding for Project BioShield to align with current public health needs, specifically for procuring antimicrobials as outlined in BARDA’s current Strategic Plan.

In addition to maintaining – and strengthening – procurement channels for novel antimicrobials through Project BioShield, stakeholders across governments, academia, public health, industry, and patient organizations acknowledge that commercial market reforms are also sorely needed to ensure our nation has the AMR products it needs, and specifically recommends implementing “pull incentives” like novel subscription models. A bipartisan and bicameral policy under consideration in Congress – the PASTEUR Act – is a critical additional step that is needed to pay for antimicrobials in a way that drives innovation and appropriate use.

- 2. A recent Organization for Economic Cooperation and Development (OECD) study found that funding for “pandemic preparedness was generally insufficient, particularly in light of the major human and financial costs associated with global health crises similar to the COVID-19 pandemic.” Overall funding for preparedness and response follows a**

¹ Venatorx Pharmaceuticals Awarded BARDA Project BioShield Contract. 3 October 2022.

cycle of panic and neglect, where funds are appropriated during emergencies, but not continued once the crisis abates. As a result, capabilities gained and lessons learned are often lost, resulting in the need for more emergency spending when the next crisis arises. According to former SNS Director Greg Burel, the SNS has experienced “mission gallop” and was never “envisioned to be the first stop in response to pandemics and emerging infectious disease.” As Burel stated, “We wouldn’t expect the U.S. military to go into battle with half of its firepower.” From your perspective, how can ASPR and the SNS be better prepared for all potential threats – including maintaining domestic manufacturing capabilities, stockpiling new countermeasures, maintaining and replenishing the products already stockpiled?

I agree with the assessment of the OECD and former Director Burel that pandemic preparedness is underfunded, and the SNS is a prime example. Prior to the Covid-19 pandemic, the SNS had experienced a decade of nearly flat funding.² The level at which it was funded was well below professional judgement, and not nearly enough for it to perform its core duties, let alone keep up with a decade of inflationary costs. This led the ASPR and the SNS to make decisions based on severe budgetary constraints that left the nation underprepared, such as neglecting to replenish supplies of expiring smallpox vaccines that, if they had been replenished, could have been used to more rapidly respond to last year’s Mpox outbreak.

As it stands today, the SNS is underfunded almost \$1 billion, with the recent Public Health Emergency Medical Counter Measures Enterprise (PHEMCE) Multi-year Budget recommending that the SNS be funded at \$1.963 billion for FY24, as compared to the \$975 million appropriated in FY23.³ Underfunding not only means that the SNS is unable to maintain and replenish its current stockpile, but it also means that that it is unable to procure new products. This is a serious problem in the medical countermeasure space where, for many countermeasures with limited or no commercial market, the SNS represents the primary market. If the SNS is unable to procure the countermeasures developed by industry in partnership with BARDA and required to be stockpiled based on the material threat assessment made by the Department of Homeland Security and the PHEMCE, then not only are the American people at risk, but the products may no longer be financially sustainable for industry. The success of BARDA (77 FDA approvals through public-private partnerships) should lead to a stronger national health defense, and not represent a cliff for products being approved with no market or SNS and BioShield budget to procure them.

In order to be better prepared, BIO recommends:

1. The SNS must be fully funded to ensure that it can fulfil its core duties of procurement, maintenance, and replenishment, and to never leave the nation unprotected.
2. The requirements set by the PHEMCE and the ASPR must be met.
3. Congress must conduct regular and transparent reviews of requirements and share them with industry.
4. Industry must be consulted as part of the requirements setting process, and contracting plans should be made for the lifecycle of the countermeasure.
5. SNS and Project BioShield funding should be multi-year, as it was when BioShield was established, to ensure that long-term maintenance and contracting are achieved, and to give industry partners the ability to plan for their long-term commitments.

² <https://crsreports.congress.gov/product/pdf/R/R47400>

³ <https://aspr.hhs.gov/PHEMCE/Documents/2022-2026-PHEMCE-Budget.pdf>

6. There must be a health defense operations budget design for the PHEMCE that would exclude its funding from the HHS budget caps, such as the funding for the national defense program, and remove it from the budget constraints of the annual appropriations for HHS.
7. Congress should implement the recommendations of the October 2022 GAO report⁴ that recommended a strategy for improving SNS transparency and accountability.

The Honorable Michael Burgess

1. What actions can be taken to address fungal diseases and mitigate their increasing resistance to currently available treatments?

Fungi and bacteria are living organisms that adapt and evolve over time and become resistant to antimicrobials -- a phenomenon known as "antimicrobial resistance," or AMR. AMR is one of the leading public health threats of the 21st century, and a chief concern for our nation's preparedness. In the United States, AMR was associated with over 173,000 deaths in 2019 – the third leading cause of death, behind only heart disease and cancer.^{5,6} Drug-resistant fungus and bacteria can also derail the safe and effective delivery of medical care more broadly for patients receiving chemotherapy, organ transplants, and even those undergoing routine surgical procedures. The rise of antifungal and antibacterial resistance is rapidly rendering our antimicrobial arsenal ineffective, also impeding our ability to respond to any public health emergency.

Public health experts are concerned about recent increases "at alarming rates" in serious and life-threatening fungal infections. For example, *Candida auris* is a fungus that can cause serious bloodstream, skin, and other infections and is often multi-drug resistant – and has caused recent outbreaks in healthcare settings. In 2021, there were nearly 1,500 clinical cases of *Candida auris* in the United States – more than a 300% increase since 2019. Furthermore, *Candida auris* cases resistant to echinocandins – the most commonly prescribed antifungal for such infections – tripled in 2021.⁷

The only way to combat these life-threatening infections is to continually innovate newer, safer antifungals and to ensure their access and appropriate use. However, despite increasing rates of resistance and growing patient need, research and development is dwindling in this critical sector due to unique market challenges faced by antimicrobials. These products tend to be undervalued relative to their societal benefit, are short duration therapies, and experience slow uptake as they tend to be used sparingly to preserve their effectiveness. The existing antifungal and antibacterial product pipelines are inadequate to meet current AMR threats and the antimicrobial ecosystem is in grave danger of collapse.

A robust pipeline of antifungal medicines is necessary to ensure that we have the products we need to address current – and future – fungal threats. Urgent action is needed on reforms to help drive and sustain investment into remedies that address the direct public health threat of resistant fungal infections, but also provide the foundation to support our pandemic and biosecurity preparedness.

⁴ <https://www.gao.gov/products/gao-23-106210>

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<https://vizhub.healthdata.org/microbe/?settings=eyJxIjoia2V5X2ZpbmRpbmdzIiwiaWl6IjoiJmJhcilsljiMiOiJzZXBzaXMiLCI0IjoyMiwiNSI6MSwiNiI6MywiNyI6MywiOCI6MTAyLCI5IjozLCIxMii6MywiMTMiOiEsljiE0IjozLCIxNSI6MSwiMTYiOiEsljiE3IjozLCIxOCI6MjAxOSwiMTkiOmZhbHNiLCIyMCI6dHJ1ZSwiMjIiOiJF9>

⁶ <https://www.cdc.gov/nchs/data/nvsr/nvsr70/nvsr70-09-508.pdf>

⁷ <https://www.acpjournals.org/doi/10.7326/M22-3469>

2. Are those actions included in any of the currently proposed legislation including the PASTEUR Act?

Yes – the PASTEUR Act would create an alternative payment model for novel antimicrobials, including antifungal medicines, that would directly address the unique marketplace for antimicrobials, spurring much needed innovation in this area of medicine. PASTEUR is endorsed by over 230 organizations representing health care providers, public health professionals, patient groups and the pharmaceutical and diagnostics industries, and regarded as a critical piece of the solution to address the unique challenges of the antimicrobial ecosystem.

PASTEUR's subscription model is an innovative way to pay for novel antimicrobials while supporting the pillars of appropriate use. Under PASTEUR, the federal government can enter into contracts with innovators to pay for a reliable supply of novel antimicrobials with payments that are decoupled from the volume of antimicrobials used. This novel model would incentivize the development of novel antimicrobials based upon the value they provide for public health, rather than the volume used.

Through its decoupled subscription contract mechanism, PASTEUR will directly support the appropriate use of antimicrobials. As well, it would strengthen the appropriate use and improve the quality of health care by providing support for antimicrobial stewardship programs (which improve patient outcomes, reduce AMR, and saves money) in rural, safety net and critical access hospitals.⁸ Every year we wait to address the crisis in the antimicrobial ecosystem is another year patients and providers must wait to have access to life saving antifungal and antibacterial medicines.