Submitted electronically

February 4, 2022

The Honorable Patty Murray
Chair
Committee on Health, Education, Labor, and Pensions
United States Senate
Washington, DC 20510

The Honorable Richard Burr
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate
Washington, DC 20510

Re: Discussion Draft of the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (PREVENT Pandemics Act)

Dear Chair Murray and Ranking Member Burr,

Thank you for the opportunity to provide comments on the discussion draft of the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (PREVENT Pandemics Act). We applaud the Health, Education, Labor, and Pensions (HELP) Committee's leadership to address gaps exposed during the COVID-19 pandemic in the nation's public health and medical preparedness and response system. We look forward to collaborating with the Committee on policies that will improve and strengthen our nation's capabilities to prepare for and respond to future public health emergencies.

FasterCures and the Center for Public Health are centers of the Milken Institute, a nonprofit, nonpartisan think tank. As part of the Milken Institute, FasterCures and the Center for Public Health work to catalyze practical, scalable solutions to address the challenges of our biomedical and public health systems, respectively. Guided by a conviction that the best ideas, under-resourced, cannot succeed, we conduct research and analysis and convene top experts, innovators, and influencers from different backgrounds and competing viewpoints. We leverage this expertise and insight to construct programs and policy initiatives.

In this letter, we offer our comments on the discussion draft, which have been informed by our research and input from multi-stakeholder convenings on these topics.

Title II—Improving Public Health Preparedness and Response Capacity

Modernizing our nation's biosurveillance capabilities to enable situational awareness during public health emergencies is vital to our defense against future public health threats. Thus, we fully support the provisions included in Section 211.

We urge the Committee to expand the provisions in this section to explicitly include how our biosurveillance system can be improved to support early warning capabilities (i.e., the ability to detect pathogens that transmit from wildlife and livestock to humans). In the future, many new pathogens are expected to be zoonotic in origin due to land use, food production practices, and population growth—both at home and abroad. As zoonotic outbreaks become more frequent, biosurveillance systems will need to monitor the effects of these changes on animal health and their potential spillover to humans.

A need for stronger early warning capabilities was identified during a series of convenings we held in 2020–2021. We brought together experts from the US and around the world to begin to identify areas in which investment would be most impactful in preventing future pandemics. A key takeaway from this work was the need for a coordinated early warning system that would collect and analyze data and generate insights on the places and animal populations at highest risk of spillover to humans. We describe this vision fully in our June 2021 publication, "A Global Early Warning System for Pandemics: Mobilizing Surveillance for Emerging Pathogens."

Over the past six months, we have continued to convene global and public health experts to outline the vital elements of an early warning system. Such a system would:

- Monitor microbe, animal, and human interfaces;
- Provide strategic information on the geographies and animal populations at highest risk of zoonotic spillover to humans;
- Capture traditional data and nontraditional data sources of outbreak information;
- Characterize pathogens in pre- and early event settings to provide information on their evolution and risk;
- Capture and integrate human behaviors (e.g., population migration, conflict, and climate events) to better identify potential areas of risk;
- Leverage data collected from historical and current events and outbreaks for insights (such as on the behaviors and practices that drive spillover);
- Leverage the newest genomic sequencing technologies and most advanced prediction methods; and
- Ensure all data captured are translated into insights to support outbreak response and decision-making.

As noted in the list of elements above, an effective early warning system must have access to cutting-edge genome sequencing technologies as well as forecasting and analytics tools. Given this, we support the provisions laid out in Sections 212 and 214. In addition, integration of traditional and nontraditional data sources is critical to generating insights that can inform decision-making. Thus, we support the provisions in Section 213 that call for the dissemination of standards and other steps to facilitate data exchange and information sharing across disparate data systems. Although this section already foresees a role for private entities, we would like to reinforce the importance of private datasets to augment and enrich public health data systems.

Robust early warning capabilities can enable us to pre-empt zoonotic disease outbreaks that could become future pandemics. We strongly recommend the Committee expand the provisions in these sections to recognize and promote early warning capabilities as a key component of an effective biosurveillance system.

Title V—Enhancing Development and Combating Shortages of Medical Products

The Milken Institute is committed to ensuring that the positive lessons and developments from our collective experience during the COVID-19 pandemic are not lost. To that end, we are pleased to see the PREVENT Pandemics Act take up issues related to enhancing the development of medical products and are supportive of all the sections under Title V. Sections 502, 503, 505, 506, and 508 are particularly resonant with the recommendations we made in our 2021 report, "Lessons Learned from COVID-19: Are There Silver Linings for Biomedical Innovation?" and the accompanying "Implementation Roadmap". Specifically, we highlight the need for modernizing clinical trials, increasing the collection and use of real-world data and evidence in product development and evaluation, improving the guidance process at FDA, and prioritizing investment in platform technologies that can benefit many researchers and developers. The Roadmap also identifies specific near-term goals and actions that stakeholders can take to start leveraging our collective learnings to prevent future pandemics and improve biomedical innovation across the board.

Additional Considerations

Role of Public-Private Partnerships in Public Health Preparedness and Response

The Milken Institute has long supported the role of cross-sector partnerships to achieve systems-level impact, so we are gratified to see this concept reflected in key provisions of the PREVENT Pandemics Act. We are especially supportive of:

- Sections 103 and 104 to call for strong leadership, responsibility coordination, and clear communication;
- Section 201 to ensure equity is a key tenet of response with a focus on social determinants;
- Section 221 to improve recruitment and retention of the frontline public health workforce;
- Section 231 to leverage strategic partnerships to expand a reauthorized Centers for Public Health Preparedness; and
- Sections 401 and 402 to strengthen supply chain coordination with a warm base manufacturing capacity for medical countermeasures and supply chain considerations for the Strategic National Stockpile.

Addressing each of these issues will require all sectors coming together as collaborative partners to promote policies, systems, and environments that protect and improve the health of all people in all communities. In a report released on February 3, "Learning from COVID-19: Reimagining Public-Private Partnerships in Public Health," we call for an evolution from traditional public-private partnerships toward those that emphasize a shared responsibility of all sectors, industries, and communities as agents of public health and accountability for the public good. The report highlights partnerships and case studies that emerged in response to the COVID-19 crisis and offers lessons to

promote and protect public health so that they can be leveraged for the future, both in times of crisis and non-emergencies. The report offers 10 recommendations for how public-private partnerships can be strengthened to maximize their impact on public health preparedness and response.

Antimicrobial Resistance

Antimicrobial resistance (AMR)—which occurs when bacteria, viruses, and other microorganisms adapt over time and no longer respond to the medicines designed to treat infections—is a growing threat in the US and globally. It is frequently referred to as the silent or overlooked pandemic.[1,2] According to the US Centers for Disease Control and Prevention (CDC), antibiotic-resistant diseases afflict more than 2.8 million Americans and claim more 35,000 American lives every year.[3] The CDC estimates first-line antibiotic treatment failures cost the US health-care system $20 billion each year in direct costs and $35 billion in lost productivity.[4]

We believe a comprehensive public health preparedness and response system must integrate planning for all pandemic sources, including AMR. Notably, AMR is absent from many pandemic preparedness discussions, even though access to effective antibiotics is crucial not only to curbing resistance but also to responding to future pandemics, which, like COVID-19, may carry significant risk of hospitalization and secondary bacterial infections.

Despite the need for new antibiotics, development of these medicines has slowed to a standstill due to significant disincentives to investment. To that end, we appreciate the Committee's inclusion of Section 501 in the bill to expand eligibility for the Qualified Infectious Disease Product (QIDP) designation, which plays an important role in encouraging the development of new antibiotics. However, more steps must be taken to spur innovation in antibiotics. The Milken Institute has been working with stakeholders across the ecosystem to examine new incentives that can revitalize the antibiotic pipeline. Through our work, we have found that policies that address payment for antibiotics such as those described in The Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act (S. 2076) and the Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms (DISARM) Act (H.R. 4127) will be critical to stimulating new antibiotic development. Both of these bills seek to change current payment models for antibiotics so that payments are more appropriately tied to their value to public health. We strongly urge the Committee to include AMR in planning for a public health preparedness and response system, as well as to include the PASTEUR and DISARM Acts in the PREVENT Pandemics Act.

Conclusion

Thank you for the opportunity to provide comments on the discussion draft for the PREVENT Pandemics Act. We welcome the opportunity to provide additional detail on the information above and to serve as a resource as you continue to refine the bill.

Sincerely,

Esther Krofah
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FasterCures and Center for Public Health
Milken Institute

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[1] Dodson, Kate. "Antimicrobial Resistance Is the Silent Pandemic We Can No Longer Neglect." United Nations Foundation. November 22, 2021. https://unfoundation.org/blog/post/antimicrobial-resistance-is-the-silent-pandemic-we-can-no-longer-neglect/
[2] Laxminarayan, Ramanan. "The Overlooked Pandemic of Antimicrobial Resistance." The Lancet. January 21, 2022. https://doi.org/10.1016/S0140-6736(22)00087-3
[3] "Antibiotic Resistance Threats in the United States 2019." U.S. Centers for Disease Control and Prevention. December 2019. https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf
[4] "Antibiotic Resistance Threats in the United States, 2013." U.S. Centers for Disease Control and Prevention. April 2013. https://www.cdc.gov/drugresistance/pdf/ar-threats-2013-508.pdf