

March 22, 2023

VIA ELECTRONIC DELIVERY

The Honorable Dawn O'Connell
Assistant Secretary for Preparedness & Response
U.S. Department of Health and Human Services
200 Independence Ave., SW
Washington, D.C. 20201

Dear Assistant Secretary O'Connell:

This year marks the fourth year since the onset of the COVID-19 pandemic. It has taken a toll on our nation and the American people – more than 100 million confirmed cases of COVID-19, more than one million deaths, and millions continuing to suffer the devastating effects of long COVID. With President Biden's announcement that the public health emergency (PHE) would be terminated on May 11, 2023, we must not lose sight of the need to prepare for future COVID-19 variants and future infectious disease outbreaks. Domestic manufacturing of medical supplies and public health screening tools, such as rapid at-home antigen tests, are essential components to our preparedness and response efforts, and I strongly encourage you to work on shoring up domestic capacity to manufacture such supplies for future responses to infectious disease threats.

Domestic manufacturing of COVID tests, personal protective equipment (PPE), and other products used to care for patients and safeguard first responders is critical to national security. As we saw during the early days of the pandemic, supply of critical medical countermeasures was restricted due to a reliance, in part, on supplies from outside the United States. As a result, Congress appropriated billions of dollars throughout the COVID-19 pandemic to bolster domestic manufacturing and infrastructure. This taxpayer investment enhanced our preparedness capabilities with domestically sourced manufacturing, while supporting American businesses and workers. Building domestic manufacturing capabilities and supporting domestic manufacturing are important to preparing America for its next public health crisis.

I commend the Administration on its efforts to ensure that Americans have access to COVID tests, through mail order, pharmacies, nursing homes, community health centers, and elsewhere. Pharmacies have played a particularly important role by enabling access to low-cost testing for Maine people living in rural and underserved communities. With the end of the PHE nearing, access to tests for these most vulnerable populations will diminish further because of the end of Medicare coverage and payment for at-home tests and testing performed in pharmacies.

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Unfortunately, not all efforts included a relentless focus on domestic manufacturing. During the United States Postal Service (USPS) mail order program, the Administration distributed numerous tests manufactured outside the US, including from China. Outsourcing one of our key public health response supplies concerns me from numerous angles – hindering a quick response to an infectious disease crisis, reliance on other nation’s medical supplies, and national security, to name a few.

I appreciate that the administration must balance funding concerns with maximizing response capabilities – but one key lesson we must take away from the past three years is that domestic capacity is a critical piece of public health response efforts, and must be supported and prioritized. Additionally, I encourage the administration to consider positioning our country to purchase more tests domestically for the remainder of the COVID-19 pandemic and in preparation for future pandemics; it takes too long to procure tests from abroad during a public health emergency; and it is vital that our nation, and the Strategic National Stockpile (SNS), remains fully stocked and supplied.

While the Administration’s response did include some domestic manufacturing of tests, PPE, and other critical medical countermeasures, more is needed to bolster domestic manufacturing capacity. The White House is reportedly considering spending remaining COVID funds to purchase tests, vaccines, and treatments for the uninsured.¹ I strongly urge the administration to prioritize domestic manufacturing in the continuing COVID-19 crisis response. As Congress looks to continue preparing our country for future infectious disease outbreaks, I ask that you respond to the following questions by April 15, 2023:

- Can you please share the percentage of tests manufactured outside the US that were purchased by the Administration as part of the USPS mail order test distribution program?
- Last year, I wrote to you about the Request for Information—for Preservation and Expansion of Current Domestic Capacities for Laboratory-Based Testing and Manufacturing of Over-The-Counter (OTC) Rapid Antigen and Point-Of-Care (POC) Nucleic Acid Amplification Tests (NAATs). We encourage ASPR to seriously consider recommendations relating to warm base manufacturing. What action has or will ASPR take in response to the Request for Information?
- As Congress looks to reauthorize the Pandemic and All-Hazards Preparedness Act (PAHPA), are there specific legislative proposals you would recommend we consider towards better preparing our domestic and warm-base manufacturing capacity for future pandemics?
- As test manufacturers start reducing their capacity to make tests after the PHE, what impact do you think this will have on access in rural and underserved communities? Would test manufacturers be more likely to maintain capacity if they had stable reimbursement after the PHE through government programs such as Medicare?

¹ Cancryn, Adam and Lim, David. “White House Mulls Post-COVID Emergency Backstop for Uninsured”, *Politico*, 16 February 2023. <https://www.politico.com/news/2023/02/16/white-house-post-covid-emergency-backstop-uninsured-00083127>.

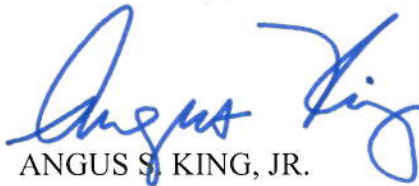
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- Subtitle D of the PREVENT Pandemics Act, included in the Consolidated Appropriations Act of 2023 (P.L. 117-328), includes policies that will enable the modernization and strengthening of our supply chain for vital medical products. How does HHS or ASPR plan to use these authorities to improve domestic manufacturing capacity?
- At-home testing authority was created through a demonstration program that is not tied legislatively to the PHE, and the Administration could continue pharmacy testing per authority under the Public Readiness and Emergency Preparedness (PREP) Act until October 2024.² How will the administration continue to support testing infrastructure and access to at-home tests?
- I applaud the Department's FY2024 budget request, which proposes a \$20 billion mandatory investment across HHS to prepare for pandemics and other biological threats, including \$10.54 billion specifically allocated to ASPR for, among other priorities, R&D for diagnostics for high priority pathogens, scaling up domestic manufacturing capacity, and bolstering supply chains. How does HHS or ASPR plan to use this funding to bolster domestic diagnostic manufacturing towards supporting warm-base manufacturing?

Again, I applaud the Administration's efforts in responding to the COVID-19 pandemic. I appreciate you considering domestic manufacturers as you work to help our nation's most vulnerable populations including nursing home residents and the uninsured. I look forward to your response.

Sincerely,



ANGUS S. KING, JR.
United States Senator

² 42 U.S.C. 247d-6d(b)(2)(B)