



March 1, 2022

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:

The COVID-19 pandemic has taken a heavy toll on our nation and the American people, and while we continue to learn about the SARS-CoV-2 virus and the disease it causes, we are certain of one thing—we must be prepared for unpredictability of the virus and be able to mobilize into action quickly to save lives. Policymakers can work with American-based manufacturers to ensure medical supplies, such as rapid at-home antigen testing, personal protective equipment (PPE) and transport materials, are readily available within a short timeframe. The administration has recently taken steps to investigate ways to structure potential partnerships, like warm-base manufacturing or indefinite-delivery contracts. We strongly encourage you to continue this work by shoring up domestic supply so that we can respond quickly to new developments regarding COVID-19.

In the spring of 2021, COVID-19 cases were relatively low, and demand for testing decreased dramatically. During this period of low transmission, COVID-19 test manufacturers reduced their production capacity, which later made it difficult to scale up quickly to meet the unprecedented levels of demand during the Delta and Omicron waves. Since the rise in cases began last year, we have also seen a significant increase in demand for viral transport media and glass tubes for transporting samples for laboratory analysis, resulting in medical device shortages at a time when we can least afford it.

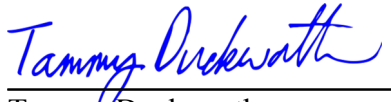
The rapid rise and fall in demand are not isolated to testing. Manufacturers of PPE experienced similar challenges at the beginning of the pandemic, leaving many of our first responders and frontline healthcare workers with limited protection. With each new wave and the continued mutability of the virus, it has become increasingly clear that the Federal government and manufacturers should work together to be prepared for the next public health crisis. We should be thinking now about how we can support our domestic manufacture and supply of all these critical medical countermeasures.

We are pleased that the Biden administration is continuing to exercise its authorities provided by the Defense Production Act (DPA) to respond to the COVID-19 pandemic, and are encouraged

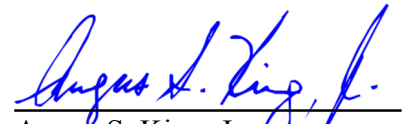
that you are contemplating using DPA authorities to keep manufacturing lines running in times of low demand, stockpile tests and enable vendor-managed inventory of at-home and point-of-care molecular tests. And while testing is an essential part of our nation's response to the pandemic, we urge you to do the same for PPE, glass tubes, viral media and other materials and supplies necessary to ensure the public health and safety of the American people. These types of flexible contracting terms will help prepare for future public health crises.

We applaud the administration for its efforts in responding to the ongoing COVID-19 pandemic, but many individuals, families, communities, hospitals and health systems, schools and essential personnel know all too well that we are not out of the woods yet. We must therefore be ready to respond through testing, vaccination and providing PPE to essential workers at a moment's notice. The recent ASPR 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)—to ensure the nation's testing capacity is an important step in the right direction, but subsequent action is needed to support American workers and the nation's economy. We will continue to work with you to protect the health and well-being of the American people during this period of uncertainty.


Sincerely,



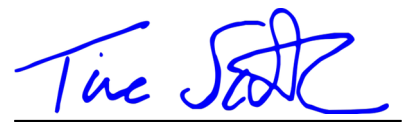
Tammy Duckworth
United States Senator



Angus S. King, Jr.
United States Senator



Robert P. Casey, Jr.
United States Senator



Tina Smith
United States Senator

Cc: Jeffrey Zients