

United States Senate

March 2, 2020

VIA ELECTRONIC DELIVERY

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Secretary Azar:

The community spread of the highly contagious severe acute respiratory syndrome coronavirus 2 (COVID-19) is a significant and growing public health threat. As our Nation transitions in responding to this disease pandemic from the containment phase to mitigating the impact of COVID-19 infections in the United States, it is critical that the U.S. Department of Health and Human Services (HHS) dramatically increase its efforts to improve COVID-19 diagnostic testing procedures, capabilities and capacity.

The announcement of two confirmed American deaths resulting from COVID-19 appears to be the initial tragic sign of the validity of the Centers for Disease Control and Prevention's (CDC) previous warning on February 26, 2020 in regard to COVID-19 infections spreading on U.S. soil, "Ultimately, we expect we will see community spread in this country. It's not so much a question of if this will happen anymore, but rather more a question of exactly when this will happen and how many people in this country will have severe illness."

I am deeply troubled COVID-19 appears to be spreading faster than our knowledge of this virus and outstripping our Nation's pandemic preparedness infrastructure. HHS must prioritize initiatives that can serve as force multipliers to rapidly expand the distribution of COVID-19 testing kits, and expand the number of laboratories with testing capacity, with the goal of being prepared to respond to COVID-19 outbreaks in any State or territory.

Americans are rightfully confused and frustrated over the Federal Government's inability to effectively and efficiently test a mere 450 people, with confirmation taking days, when other countries are now testing tens of thousands of people by the day. The Journal Science reported on Friday, February 28, 2020, "China had five commercial tests on the market 1 month ago and can now do up to 1.6 million tests a week." The World Health Organization (WHO) developed testing capabilities for COVID-19 and issued guidance on how to manufacture and properly use the COVID-19 tests in January 2020. As of last week, the WHO had shipped testing kits to 57 counties around the world.

The Trump administration, for reasons still unknown, declined to follow WHO guidance and delayed providing emergency authority to authorize State and local laboratories to develop "laboratory-developed tests" based on existing CDC and WHO primers and protocols. Instead,

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CDC expended significant resources, the most valuable of which was time, apparently seeking to reinvent the wheel by developing its own unique test that appeared to be more complicated than the WHO test, and worse, proved faulty and ineffective following initial distribution in early February 2020. After confirming COVID-19 community spread on American soil, CDC provided assurance its tests have been adjusted and are now effective. However, the certainty of CDC's assurance is still unknown, and the Trump administration has yet to solve the problem of scaling up testing capacity and efficiency.

Far too many laboratories and all healthcare facilities currently lack access to CDC COVID-19 test kits. A public health emergency is no time to prioritize pride of ownership over pragmatic actions that recognize the grave reality of responding to a potential disease pandemic. The reality is that America was not first when it came to developing guidance on how to manufacture and properly use COVID-19 tests. Our only focus now should be making sure that America is not last when it comes to the effectiveness of our public health emergency response. Accordingly, I call on HHS to act swiftly in implementing the following policies:

1. Expeditiously establish an independent work group of public health experts to continuously monitor, analyze and make any necessary recommendations on the efficiency of the CDC testing kit for COVID-19 and other tests authorized by the U.S. Food and Drug Administration;
2. Partner with manufacturing and distribution entities to enhance production capacity of COVID-19 testing kits;
3. Authorize outside manufacturing and distribution entities to concurrently produce COVID-19 tests following the WHO guidance;
4. Establish performance metrics to measure progress in rapidly expanding manufacturing and distribution capacity for COVID-19 testing kits; and
5. Transparently report progress toward achieving performance goals.

In closing, I want to express my appreciation to the dedicated CDC civil servants who are working tirelessly to respond to the outbreak of COVID-19. The policies I am requesting HHS implement are intended to bolster ongoing efforts and bring additional support to the Federal employees who deserve not only a whole-of-government approach, but full access to the capabilities of State and local authorities, public health experts and relevant industry resources. Thank you in advance for considering my request and I look forward to your prompt response.

Sincerely,



Tammy Duckworth
United States Senator