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ONE HUNDRED SIXTEENTH CONGRESS

Congress of the United States
House of Representatives
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May 13, 2020

The Honorable Anna Eshoo
Chairwoman
Subcommittee on Health
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairwoman Eshoo,

Since the majority is proceeding with a hearing without any input from the minority, I write to offer another opportunity to work together in a bipartisan fashion to address critical issues facing our nation during the ongoing pandemic. I have previously written on three separate occasions to suggest hearings on urgent, bipartisan issues that the Subcommittee should be examining in the wake of the COVID-19 outbreak. I now write to request that the Committee on Energy and Commerce hold a hearing before the Health Subcommittee on testing capacity and the availability of personal protective equipment (PPE) that is critically needed for the ongoing COVID-19 response in the United States. I appreciate the efforts of Chairman Pallone to organize a telebriefing on issues related to testing for Members of the Committee on May 4, 2020, with Admiral Brett Giroir, Assistant Secretary of Health at the U.S. Department of Health and Human Services (HHS). I also found Chairman Pallone's tele-forum for Members of the Committee on testing with outside experts, held May 8, 2020 to be informative. Both telebriefings were organized with the feedback of the minority. Building off the bipartisan work of Chairman Pallone, I believe now is the time to work together to discuss COVID-19 testing in the public forum of the Health Subcommittee, including best practices for implementing comprehensive testing policies, testing capacity, and access to both tests and the supplies needed to administer and run them.

As you know, public health experts across the country agree that expanded testing is needed in order to properly track the spread of the virus and to safely reopen our economy and get Americans back to work. Despite delays in testing development and approval at the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) at the beginning of the response, as of May 12, 2020 more than 9.6 million tests for COVID-19 have

now been performed in the U.S. About 7 weeks ago the U.S. was only conducting about 2,500 tests per day, and now we conduct well over 250,000 tests per day. While more is needed, this is a dramatic improvement, and testing capacity is likely to grow as new and innovative tests continue to be developed. Congress, recognizing the importance of widespread diagnostic testing, took action to encourage the development of localized testing strategies. Between the Coronavirus Preparedness and Response Supplemental Appropriations Act,[1] the Families First Coronavirus Response Act,[2] the Coronavirus Aid, Relief, and Economic Security (CARES) Act,[3] and the Paycheck Protection Program and Health Care Enhancement Act,[4] Congress has directed billions of dollars toward testing. Critically, Title I of the Paycheck Protection Program and Health Care Enhancement Act also requires that:

> …not later than 30 days after the date of enactment of this Act, the Governor or designee of each State, locality, territory, tribe, or tribal organization receiving funds pursuant to this Act shall submit to the Secretary its plan for COVID-19 testing, including goals for the remainder of calendar year 2020, to include: (1) the number of tests needed, month-by-month, to include diagnostic, serological, and other tests, as appropriate; (2) month-by-month estimates of laboratory and testing capacity, including related to workforce, equipment and supplies, and available tests; and (3) a description of how the State, locality, territory, tribe, or tribal organization will use its resources for testing, including as it relates to easing any COVID-19 community mitigation policies…

It is imperative that we review the implementation of Title I of this Act to ensure that these dollars are going where they are needed most to fill in the gaps in testing capacity, and that states and localities are aware of, and utilizing, all testing methods at their disposal.

The Committee should also examine the supply chain for products needed to administer and run COVID-19 tests, a critical component of efforts to effectively increase nationwide testing capacity. For much of the testing being conducted today, providers and laboratories need swabs, transport media, RNA extraction kits, and reagents. The Health Subcommittee should examine the current availability of these products, how we have increased the availability of those products since the pandemic started, and our ability to scale-up manufacturing to increase production in order to provide an adequate supply of these materials across the country.

The Health Subcommittee should have a robust conversation on testing strategies. Experts have different points of view on important components related to successful testing regimens, and we should be actively looking at those questions and helping to promote best practices. For example, who should be tested and how often? Should testing practices differ across communities with varying degrees of infection? Additionally, given that each test being developed and deployed has its own benefits and limitations, the Committee should examine what the appropriate role is for each of these tests. For example, what role should antibody testing play in a comprehensive testing strategy and what is its importance, particularly as we are

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[1] Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, Pub. L. 116-123 (2020).
[2] Families First Coronavirus Response Act, Pub. L. 116-127 (2020).
[3] The Coronavirus Aid, Relief, and Economic Security Act, Pub. L. 116-136 (2020).
[4] Paycheck Protection Program and Health Care Enhancement Act, Pub. L. 116-139 (2020).

in the early stages of determining whether infection confers immunity and how long antibodies may be present? We should also examine the role that new technologies can play, and whether states and localities can or should be able to quickly adjust their own testing plans to accommodate new tests as this is a particularly active area of development. For example, FDA recently issued the first emergency use authorization for an antigen test, a new type of diagnostic, that is highly accurate at identifying positive infections, but has less sensitivity than other tests, and therefore may not detect all active infections.

In addition to the tests, and supplies needed to perform the tests, the Committee should examine what resources are needed to perform an appropriate level of surveillance and contact tracing across the U.S, and how these needs differ in different parts of the country. Some recent estimates of the number of individuals who will need to be hired to achieve an adequate level of contact tracing have ranged from 100,000 to 300,000 individuals. The Committee should be engaged in these issues to help inform what resources are needed to achieve the level of testing, contact tracing, and surveillance needed in our country to successfully track and contain the current outbreak, as well as future outbreaks.

Congress must also continue to oversee federal efforts to procure and distribute sufficient amounts of PPE. This is critical since diagnostic testing capacity is interdependent on the supply of PPE. Severe disruptions to the global supply chain have dangerously reduced the U.S. supply of PPE, ultimately putting health care provider and patient lives at risk. Exploring this issue is relevant not only to testing, where it is necessary for safe sample collection and processing, but it is also a valuable use of the Subcommittee's time given its importance to all frontline health care workers, who rely on PPE to protect themselves, and their patients from contracting the virus and possibly infecting others.

Federal partners such as HHS, the Federal Emergency Management Agency (FEMA), and the private sector have worked together to obtain and distribute testing platforms, test kits, PPE, and testing supplies, such as swabs and reagents. In addition, the International Reagent Resource has played a critical role in supplying COVID-19 diagnostic supplies to registered users, including reagents, swabs, and transport media.[5] However, additional work is needed to ensure a stable supply chain and the continued availability of supplies for COVID-19 testing. As the Committee with jurisdiction over food and drug safety, public health and research, consumer protections, and commerce, now is the time to work together in a bipartisan fashion and consider proposals that will improve the U.S. testing capacity and capabilities, and strengthen our ability to procure diagnostic supplies in order to ensure we are able to quickly identify and contain future viral outbreaks. Thank you for your consideration and I look forward to working with you on these important issues.

[5] International Reagent Resource, *available at* https://www.internationalreagentresource.org/ (last visited May 11, 2020).

Sincerely,

Michael C. Burgess, M.D.
Republican Leader
Subcommittee on Health