

ONE HUNDRED SIXTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**  
COMMITTEE ON ENERGY AND COMMERCE  
2125 RAYBURN HOUSE OFFICE BUILDING  
WASHINGTON, DC 20515-6115

Majority (202) 225-2927  
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April 20, 2020

The Honorable Deborah L. Birx, M.D.  
Coronavirus Task Force Coordinator  
The White House  
1600 Pennsylvania Avenue NW  
Washington, DC 20500

Dear Dr. Birx:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee is examining the Trump Administration's response to the coronavirus disease 2019 (COVID-19).

As President Trump continues to push for relaxing social distancing guidelines and quickly reopening society, I am increasingly concerned about the lack of widespread testing in the United States, and what the ramifications will be if social distancing efforts are prematurely eased without robust testing in place to detect the spread of COVID-19.

On April 16, the White House released a document entitled "Guidelines: Opening Up America Again," but this document articulates no national strategy or plan for how the Administration will expand testing capacity. In fact, the greatest detail this document provides on the subject of testing is three bullets under a section titled "Core State Preparedness Responsibilities." Instead of showing leadership, competence, and vision in a time of crisis, it appears the Trump Administration is abdicating its responsibility and forcing states and communities to fend for themselves and find their own way out of this pandemic.

The Administration must develop and release a comprehensive and strategic testing plan, including the strategy for increasing diagnostic and serological testing capacity, the types and levels of testing necessary, benchmarks with clear timelines, the estimated costs involved in implementing such a plan, and specific guidelines to ensure adequate testing in rural and other underserved areas. It is critical this plan also involve testing capacity in non-health care settings in order to help expand testing availability and make testing more accessible. Without such a plan, our response to COVID-19 will be greatly hindered and may pose severe consequences for communities across the country.

Public health experts agree that a robust, national testing strategy is critical to combating COVID-19. As former Food and Drug Administration (FDA) Commissioner Dr. Scott Gottlieb

and other top public health experts recently wrote in their report *National Coronavirus Response: A Road Map To Reopening*, before states can begin to reopen, we need to “increas[e] testing capacity to accommodate the ability to test everyone with symptoms and their close contacts.”<sup>1</sup> And as a draft “Framework for Reopening America” reportedly written by the Federal Emergency Management Agency (FEMA) and the Centers for Disease Control and Prevention (CDC) delineates, “reopening will entail a significant risk of resurgence of the virus. Reopening is therefore conditioned on: confidence that incidence of infection is genuinely low [and] a surveillance system that is well functioning and capable of promptly detecting any increase in incidence[.]”<sup>2</sup>

Asked recently whether the country was prepared to begin reopening the economy, Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases, said, “We have to have something in place that is efficient and that we can rely on, and we’re not there yet.”<sup>3</sup> The President’s recently-formed “Opening Our Country Council,” comprised of dozens of business and labor leaders, also reportedly “told President Trump that his administration needed to dramatically increase the availability of coronavirus testing before the public would be confident enough to return to work, eat at restaurants or shop in retail establishments[.]”<sup>4</sup>

It is my understanding that a proposed national testing strategy was being developed within the agencies and was recently sent to the White House for review. However, I have seen no such plan, and it now appears the White House either does not have or does not intend to release one.

The Administration’s decision not to release a national testing plan is just the latest in a long line of failures related to COVID-19 testing. I have been alarmed by coronavirus testing efforts in the United States from the beginning of the Administration’s response to COVID-19. Initially, rather than utilizing the test distributed by the World Health Organization (WHO), CDC opted to develop its own test, and then struggled to make it widely available. After a possible contamination in CDC’s test that resulted in inconclusive results, CDC had to revise its test, causing delays of up to three weeks.<sup>5</sup> Shortages in both the test and related testing supplies further undermined the country’s ability to detect the spread of coronavirus, and CDC eventually expanded its testing criteria only after complaints that some high-risk patients were not eligible for tests.

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<sup>1</sup> Dr. Scott Gottlieb *et al.*, *National Coronavirus Response: A Road Map To Reopening*, American Enterprise Institute (Mar. 28, 2020).

<sup>2</sup> *CDC, FEMA have created a plan to reopen America. Here’s what it says*, Washington Post, Apr. 14, 2020.

<sup>3</sup> *Fauci: ‘We’re not there yet’ on key steps to reopen economy*, Associated Press (Apr. 14, 2020).

<sup>4</sup> *Business Leaders Urge Trump to Dramatically Increase Coronavirus Testing*, Wall Street Journal (Apr. 15, 2020).

<sup>5</sup> *Amid testing concerns, US officials unveil new coronavirus test kits and streamline commercial development*, CNBC (Feb. 28, 2020).

State and commercial laboratories are still struggling with shortages of diagnostic tests, testing supplies, and reagents.<sup>6</sup> Further, questions have been raised about whether CDC's testing criteria guidelines are still too restrictive, preventing more people from receiving necessary tests.<sup>7</sup>

Right now, the Administration's top priority should be forming specific plans to reopen the country in a way that will not jeopardize public health and result in sharp increases in new infections and deaths. Critically, that will rely on greatly expanding testing from its current state.

On average, between 110,000–130,000 tests are now conducted each day. President Trump repeatedly claims the United States is doing more testing than anyone in the world, but the United States still conducts fewer tests per capita than other countries, including Germany, Italy, Canada, and South Korea.<sup>8</sup> Only about one percent of the country's population has been tested—and CDC continues to recommend that tests be reserved for health care workers and high-risk patients with severe symptoms.

It is clear that testing capacity in this country, both for diagnostic COVID-19 tests and serological tests for the presence of COVID-19 antibodies, must be significantly increased before we can safely ease social distancing guidelines. However, I am concerned that expanding testing is not a priority for the Administration given its inability to release a plan. The absence of a coordinated national testing strategy will hamper efforts to ease social distancing guidelines in the coming weeks and months.

As the Energy and Commerce Committee continues its oversight and considers further legislation, it is critical to understand what actions the Administration is taking to expand testing and prepare for eventually easing its guidelines on social distancing. Therefore, by April 24, 2020, please provide the following information:

1. The Administration's plans for expanding testing and revising guidance on social distancing and reopening the economy.
2. What diagnostic testing capacity do you believe will be sufficient to reopen the economy and provide assurance that CDC and its state partners will be able to detect any resurgence in COVID-19 outbreaks?
  - a. Please provide the number of tests you believe will need to be conducted per day, and the criteria you plan to recommend regarding who receives tests (e.g.,

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<sup>6</sup> *Private labs do 85 percent of U.S. COVID-19 tests but still struggle with backlogs, shortages*, NBC News (Apr. 8, 2020).

<sup>7</sup> *Coronavirus testing hits dramatic slowdown in U.S. despite efforts to expand*, Politico (Apr. 14, 2020).

<sup>8</sup> *How the US stacks up to other countries in confirmed coronavirus cases*, Vox (Apr. 16, 2020).

asymptomatic people).

- b. Given the current testing capacity of approximately 110,000 to 130,000 tests per day, when do you plan to reach that capacity?
  - c. What are the Administration's current estimates for the daily amount of tests it will have the capacity to administer by May 1 and then monthly thereafter through December 2020?
3. To date, there has been no agreement among the scientific, medical, and public health communities regarding what clinical protection the presence of COVID-19 related antibodies confer. What is the Administration's plan to ensure the validity of, and expand access to, serological tests to determine whether someone has developed antibodies to COVID-19 and what level of antibodies are needed to provide protection to individuals?
- a. How will those tests factor into the Administration's plans for easing guidelines on social distancing and reopening the economy?
  - b. Please provide the number of serological tests that will need to be conducted per day and the criteria you plan to recommend regarding who receives these tests.
  - c. Given there are currently no available reports on the number of serological tests being conducted per day, when do you plan to reach this capacity goal?
  - d. What are the Administration's current estimates for the daily amount of serological tests it will have the capacity to administer by May 1 and then monthly thereafter through December 2020?
  - e. What studies, if any, is the Administration conducting on COVID-19 and antibody levels to determine whether any protection from reinfection is conferred from antibodies?
  - f. What data and information will the Administration require from developers to verify the validity of serological tests?

Thank you for your assistance. If you have any questions about these requests, please contact Kevin Barstow and Kimberlee Trzeciak of the Committee staff at (202) 225-2927.

Sincerely,



Frank Pallone, Jr.  
Chairman