

United States Senate
WASHINGTON, DC 20510

March 16, 2020

Vice President Mike Pence
The White House
Office of the Vice President
1600 Pennsylvania Avenue, N.W.
Washington, DC 20500

Admiral Brett Giroir, M.D.
Assistant Secretary for Health
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Vice President Pence and Assistant Secretary Giroir:

We write to Vice President Pence in his capacity as head of the White House Coronavirus Task Force (Task Force) and to Assistant Secretary Giroir in his capacity as coordinator for diagnostic testing efforts¹ to request information on the Trump Administration's failure to ensure that diagnostic tests are available for coronavirus disease 2019 (COVID-19). This failure has resulted in a significant delay in detecting and responding to the first cases of COVID-19 in the United States, dramatically increasing the scope of the epidemic, and placing millions at risk. These problems—caused in part by the Administration's lack of strong support for public health infrastructure prior to the COVID-19 outbreak and its mismanagement of test kit deployment as the crisis emerged—have been exacerbated by the numerous false statements by Vice President Pence, by other members of the Task Force, and by President Trump about the status of testing.²

In early January, Chinese scientists first posted the genome of the novel coronavirus causing COVID-19, and less than one week later, Berlin virologists had developed the first diagnostic test for the disease.³ Shortly thereafter, other countries began producing their own diagnostic tests, and by the end of February, the World Health Organization (WHO) had distributed COVID-19 tests to nearly 60 countries.⁴

¹ U.S. Department of Health and Human Services, "Secretary Azar Designates Admiral Giroir to Coordinate COVID-19 Diagnostic Testing Efforts," March 13, 2020, <https://www.hhs.gov/about/news/2020/03/13/secretary-azar-designates-admiral-giroir-coordinate-covid-19-diagnostic-testing-efforts.html>.

² Washington Post, "Tracking Trump's false or misleading coronavirus claims," March 14, 2020, <https://www.washingtonpost.com/politics/2020/03/14/tracking-trumps-false-or-misleading-coronavirus-claims/>.

³ Politico, "How testing failures allowed coronavirus to sweep the U.S.," Joanne Kenen, March 3, 2020, <https://www.politico.com/news/2020/03/06/coronavirus-testing-failure-123166>.

⁴ *Id.*

On February 5, 2020, the Centers for Disease Control and Prevention (CDC) began shipping hundreds of three-reagent diagnostic tests to state and local labs.⁵ However, by mid-February, states began reporting that the tests distributed by the CDC were delivering inconclusive results.⁶ According to the Association of Public Health Laboratories, only six state public health labs nationwide were able to verify the CDC test for use.⁷ The CDC cited manufacturing issues with one of the reagents, and promised to promptly re-manufacture the tests.⁸

After a multi-week delay, on February 26, 2020, the CDC announced it had fixed the issue with the test kits.⁹ Later, a scientist from the U.S. Food and Drug Administration (FDA) reported potential contamination at the CDC labs where tests were being made.¹⁰ It is not clear whether this contamination caused delays or is related to the manufacturing issues cited by the CDC.¹¹ During this critical period, fewer than 500 patients were tested nationwide.¹²

All the while, state, academic, and commercial labs could not use their own diagnostic tests without first obtaining FDA authorization.¹³ On February 29, 2020, the FDA finally announced an “accelerated policy...to achieve more rapid testing capacity in the United States,” which allowed qualified labs that develop their own validated tests to conduct testing for a period of up to 15 days prior to seeking FDA authorization.¹⁴

Due to this unavailability of tests, the CDC was forced to issue extremely narrow testing criteria. Originally, the CDC only allowed people who had traveled to China or who had been in close contact with someone known to have COVID-19 to receive a test.¹⁵ As a result, at least one

⁵ CDC, “Shipping of CDC 2019 Novel Coronavirus Diagnostic Test Kit Begins,” February 6, 2020, <https://www.cdc.gov/media/releases/2020/p0206-coronavirus-diagnostic-test-kits.html>.

⁶ CNN, “Some coronavirus test kits shipped to states are not working as expected, the CDC says,” Faith Karimi and Jen Christensen, February 13, 2020, <https://www.cnn.com/2020/02/13/health/us-coronavirus-test-kits/index.html>.

⁷ Politico, “U.S. isn’t ready to detect stealth coronavirus spread,” David Lim, February 26, 2020, <https://www.politico.com/news/2020/02/26/coronavirus-cdc-117779>.

⁸ CDC, “Transcript for CDC Telebriefing: CDC Update on Novel Coronaviruses,” Press Briefing Transcript, February 12, 2020, <https://www.cdc.gov/media/releases/2020/t0212-cdc-telebriefing-transcript.html>.

⁹ NPR, “CDC Has Fixed Issue Delaying Coronavirus Testing in U.S., Health Officials Say,” Rob Stein, February 27, 2020, <https://www.npr.org/sections/health-shots/2020/02/27/809936132/cdc-fixes-issue-delaying-coronavirus-testing-in-u-s>.

¹⁰ Axios, “Scoop: Lab for coronavirus test kits may have been contaminated,” Jonathan Swan and Caitlin Owens, March 1, 2020, <https://www.axios.com/cdc-lab-coronavirus-contaminated-6dc9726d-dea3-423f-b5ad-eb7b1e44c2e2.html>.

¹¹ *Id.*

¹² Politico, “Azar in the crosshairs for delays in virus tests,” Dan Diamond and Adam Cancryn, March 2, 2020, <https://www.politico.com/news/2020/03/02/azar-crosshairs-delays-coronavirus-tests-118796>.

¹³ ProPublica, “Key Missteps at the CDC Have Set Back Its Ability to Detect the Potential Spread of Coronavirus,” Caroline Chen, Marshall Allen, Lexi Churchill, and Isaac Arnsdorf, February 28, 2020, <https://www.propublica.org/article/cdc-coronavirus-covid-19-test>.

¹⁴ FDA, “Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing under CLIA prior to Emergency Use Authorization for Coronavirus Disease-2019 during the Public Health Emergency,” February 29, 2020, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-diagnostics-testing-laboratories-certified-perform-high-complexity-testing-under-clia-prior>.

¹⁵ Vox, “The coronavirus diagnostic testing snafu, explained,” Julia Belluz and Brian Resnick, February 29, 2020, <https://www.vox.com/science-and-health/2020/2/28/21155917/preparing-for-coronavirus-in-the-us-cdc-diagnostic-testing>.

patient who later tested positive for COVID-19 was initially denied a diagnostic test.¹⁶ On March 3, 2020, the federal government broadened patient testing criteria that had limited early testing; Vice President Pence announced, “subject to doctors’ orders, any American can be tested.”¹⁷ This announcement, however, did not acknowledge the nation’s significant lack of testing capacity, leaving “many with questions about what had happened with testing and what should happen next.”¹⁸

Since then, the Trump Administration has made a series of false promises about the country’s diagnostic capacities, spreading confusing and untrue information about the availability of tests for the general public. On March 6, 2020, President Trump falsely claimed, “[a]nybody right now and yesterday, anybody that needs a test gets a test,” and “[t]hey’re there. They have the tests and the tests are beautiful”—despite the fact that widespread tests were not available.¹⁹ Vice President Pence made similar promises about the availability of tests,²⁰ and earlier this month U.S. Health and Human Services (HHS) Secretary Azar promised the availability of “as many as 4 million tests” by the middle of March.²¹ Though the CDC expanded testing criteria, states and local health authorities are still “clamoring” and “pleading” for additional tests.²²

And just as commercial and academic labs may be able to ramp up testing, they have run into even more barriers: a purported shortage in materials has threatened to hamstring testing capacity. According to CDC Director Robert Redfield, U.S. labs may not have an adequate supply of RNA extraction kits, a critical component that allows the tests to be performed.²³ There have also been reports of potential shortages of cotton swabs, gloves, and other protective gear that is needed to perform test.²⁴

¹⁶ ProPublica, “Key Missteps at the CDC Have Set Back Its Ability to Detect the Potential Spread of Coronavirus,” Caroline Chen, Marshall Allen, Lexi Churchill, and Isaac Arnsdorf, February 28, 2020, <https://www.propublica.org/article/cdc-coronavirus-covid-19-test>.

¹⁷ Journal of American Medicine, “Diagnostic Testing for the Novel Coronavirus,” Joshua M. Sharfstein, MD; Scott J. Becker, MS; Michelle M. Mello, JD, PhD, March 9, 2020, <https://jamanetwork.com/journals/jama/fullarticle/2762951>.

¹⁸ *Id.*

¹⁹ New York Times, “With Test Kits in Short Supply, Health Officials Sound Alarms,” Katie Thomas, Sarah Kliff and Nicholas Bogel-Burroughs, March 6, 2020, <https://www.nytimes.com/2020/03/06/health/testing-coronavirus.html>; Washington Post, “Squandered time: How the Trump administration lost control of the coronavirus crisis,” Ashley Parker, Yasmeeen Abutaleb, and Lena H. Sun, March 7, 2020, https://www.washingtonpost.com/politics/trump-coronavirus-response-squandered-time/2020/03/07/5c47d3d0-5fcb-11ea-9055-5fa12981bbbf_story.html.

²⁰ CBS News, “Government promises 4 million coronavirus tests by next week. What comes next?” Audrey McNamara, March 6, 2020, <https://www.cbsnews.com/news/government-promises-4-million-coronavirus-tests-by-next-week-what-comes-next/>.

²¹ *Id.*

²² New York Times, “With Test Kits in Short Supply, Health Officials Sound Alarms,” Katie Thomas, Sarah Kliff and Nicholas Bogel-Burroughs, March 6, 2020, <https://www.nytimes.com/2020/03/06/health/testing-coronavirus.html>.

²³ Politico, “Exclusive: U.S. coronavirus testing threatened by shortage of critical lab materials,” David Lim and Brianna Ehley, March 10, 2020, <https://www.politico.com/news/2020/03/10/coronavirus-testing-lab-materials-shortage-125212>.

²⁴ Politico, “Congress livid over lags in coronavirus testing,” Andrew Desiderio and Marianne Levine, March 12, 2020, <https://www.politico.com/news/2020/03/12/coronavirus-testing-127016>.

Now—almost two months since the United States announced its first confirmed coronavirus case²⁵—the United States has over 4,000 confirmed cases and at least 70 deaths, with thousands more under quarantine and surveillance.²⁶ As demand for COVID-19 diagnostic tests overwhelms the limited supply, it is clear that COVID-19 has been spreading undetected and our understanding of the incidences of COVID-19 in the country is marred by a vast undercount.²⁷

The ability to accurately and swiftly test for COVID-19 is critical to informing public health decisions—like social distancing, quarantining, and contact tracing—which can slow the exponential growth of the virus. In the words of one virologist, “I think that we could have probably controlled this, if we had effective testing.”²⁸ The Administration’s continued failure to ensure a sufficient number of diagnostic testing kits for COVID-19 are available, and its inability to provide clear and honest answers about this problem in the midst of this public health emergency, is unacceptable. The American public deserves answers. Please respond to the following questions by no later than March 30, 2020:

1. When did key Task Force officials – including Vice President Pence, Secretary Azar, and Director Redfield – become aware of delays in developing the CDC-approved tests? What actions did these officials take to address these delays?
2. What is the current COVID-19 testing capacity of the CDC and all (a) federal public health laboratories (b) state and local public health laboratories and (c) commercial and academic laboratories?
 - a. What is the limiting factor on the number of tests, and what actions are being taken by the FDA, the CDC, and the Task Force to address this limit?
 - b. Which laboratories or companies, if any, is the Administration prioritizing in its effort to expand both public and private capacity to manufacture and deliver tests? Why is the Administration prioritizing these laboratories or companies?
3. What is the explanation for the misinformation provided to the public about the availability of COVID-19 tests by (1) President Trump (2) Secretary Azar, and (3) Vice President Pence?
4. What guidance is the Task Force, the CDC, and the FDA currently providing to states that do not have enough testing capacity to meet the demand?
5. Is the Task Force aware of any limitations on testing that could be caused by shortages in RNA test kits?
 - a. Is there a shortage or anticipated shortage of any test components?
 - b. What are these limits, and what is the cause of any shortage?
 - c. What plans does the Task Force have to address any current or future shortage?

²⁵ New York Times, “A Timeline of the Coronavirus,” Derrick Bryson Taylor, March 14, 2020, <https://www.nytimes.com/article/coronavirus-timeline.html>.

²⁶ Johns Hopkins University & Medicine, “Coronavirus COVID-19 Global Cases,” Accessed March 16, 2020, <https://coronavirus.jhu.edu/map.html>.

²⁷ Politico, “Trump’s mismanagement helped fuel coronavirus crisis,” Dan Diamond, March 7, 2020, <https://www.politico.com/news/2020/03/07/trump-coronavirus-management-style-123465>.

²⁸ Vox, “The CDC’s rocky effort to get Americans tested for coronavirus, explained,” Brian Resnick and Dylan Scott, March 6, 2020, <https://www.vox.com/science-and-health/2020/3/6/21168087/cdc-coronavirus-test-kits-covid-19>.

6. Is the Task Force aware of any limitations on testing that could be caused by other supply shortages or for any other reasons?
 - a. What are these limits, and what is the cause of the shortages?
 - b. What plans does the Task Force have to address these shortages?
7. What other actions are the Task Force, the CDC, and the FDA considering undertaking to help states and labs who are facing testing supply shortages?

Sincerely,

Elizabeth Warren
United States Senator

Tammy Baldwin
United States Senator

Richard Blumenthal
United States Senator

Cory A. Booker
United States Senator

Sherrod Brown
United States Senator

Robert P. Casey, Jr.
United States Senator

Martin Heinrich
United States Senator

Mazie Hirono
United States Senator

Tim Kaine
United States Senator

Amy Klobuchar
United States Senator

Edward J. Markey
United States Senator

Patty Murray
United States Senator

Bernard Sanders
United States Senator

Tina Smith
United States Senator

Debbie Stabenow
United States Senator

Chris Van Hollen
United States Senator

Ron Wyden
United States Senator