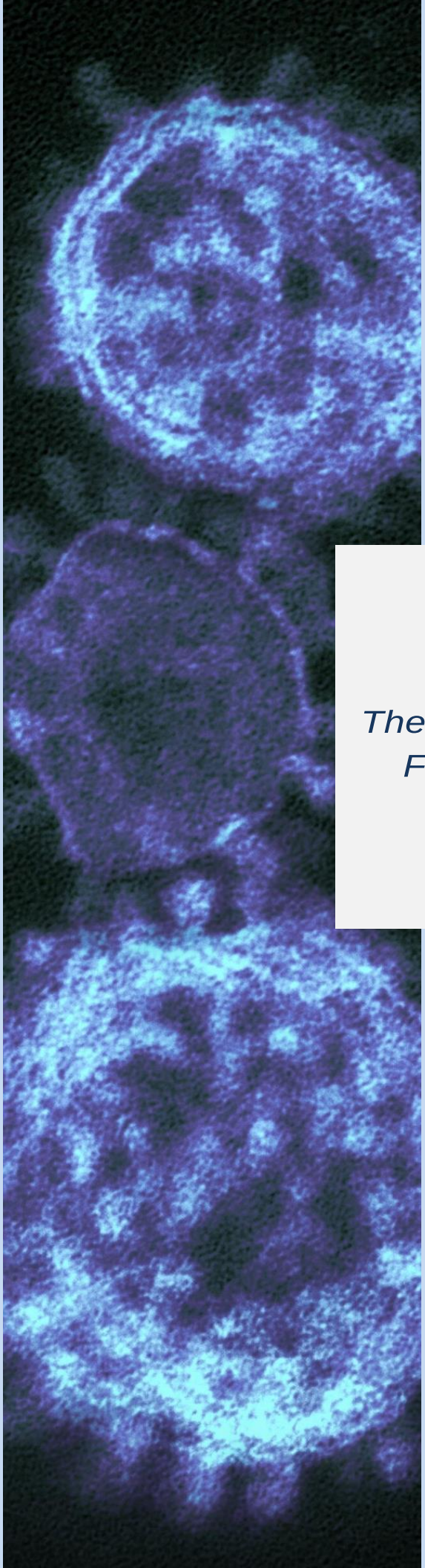

U.S. SENATE COMMITTEE ON HEALTH,
EDUCATION, LABOR, AND PENSIONS
RANKING MEMBER PATTY MURRAY (D-WA)

A Nation in Crisis

The Consequences of Federal Leadership Failures on the COVID-19 Diagnostic Testing System

DEMOCRATIC STAFF REPORT

JULY 2020

Contents

Introduction

"Testing is truly the cornerstone of a response strategy"[1]

Six months into a pandemic that has killed over 120,000 people in the United States, the nation still faces major challenges in diagnosing the 2019 novel coronavirus (COVID-19). From the U.S. Centers for Disease Control and Prevention's (CDC) failure to quickly develop a functional diagnostic test after the disease's first known arrival in the U.S., to President Trump's insistence on an extremely limited federal role in expanding and overseeing testing capacity nationwide, the disastrous federal response has resulted in limited diagnostic testing capacity. It has led to the inability to adequately identify and mitigate the spread of the virus, forcing states to shut down their economies for months. Although there are currently between 500,000 and 600,000 tests being conducted per day, on average, the U.S. is still far from where experts say the nation should be to effectively track and contain the disease and to get the nation back to work and school safely.

As part of the work to oversee the Trump Administration's response to the COVID-19 pandemic and ensure the nation is prepared for future disease outbreaks, Senator Murray directed the Democratic staff of the Health, Education, Labor, and Pensions (HELP) Committee to examine the COVID-19 diagnostic testing landscape from the beginning of the pandemic to present. Democratic staff conducted 24 interviews, including with five manufacturers of COVID-19 diagnostic tests and test equipment, five clinical laboratories, and five industry associations representing manufacturers, laboratories, and public health departments and officials across the country. The staff also interviewed health officials in nine states and cities: California, the District of Columbia, Minnesota, Ohio, Pennsylvania, Rhode Island, Virginia, Washington, and Wisconsin. This report does not make specific attributions to individual entities, but the full list of entities interviewed is available in the appendix.

This report describes the lessons staff learned from those conversations and identifies a clear need for action to continue increasing testing capacity across the country, particularly as states and localities face increasing cases and seek to reopen their economies. The report begins with background on what is involved in COVID-19 diagnostic testing, follows with a discussion of the challenges in standing up a testing system during the first six months of the pandemic, then examines progress and remaining deficiencies in the current testing landscape, and finally identifies recommendations that can be implemented in response to this pandemic, distributing a COVID-19 vaccine, and preparing for future pandemics.

Staff interviewed only a small sample of the entities involved in standing up diagnostic testing in the United States; this report is not a comprehensive assessment of the state of diagnostic testing in this country nor the experience of each state, lab, or company. For example, it does not include an in-depth discussion of the CDC's missteps in developing and distributing a test, which has been widely reported and is under investigation by the Department of Health and Human

[1] Democratic Staff Call, May 29, 2020

Services' Office of Inspector General. Rather, it is intended to provide a sample of experiences and identify common threads to lay out lessons learned and recommend future action.

Background

Types of COVID-19 tests

There are two different types of COVID-19 tests: a viral test and a serology test.[2] A viral test is a diagnostic test that detects the presence of an active infection and is used to determine whether a person is *currently infected* with COVID-19.[3] A viral test is useful for health care providers to provide appropriate medical interventions and enact certain protective protocols and for public health experts to conduct contact tracing to restrict further spread of the virus.[4] A serology test detects the presence of antibodies to the virus and is used to determine whether a patient has developed an immune response to COVID-19, which can occur because the patient was *previously infected*.[5] While serology tests may be useful for public health experts to determine what percent of the population has previously been infected with COVID-19, it is not yet known whether the presence of antibodies, and at what levels, indicate a person has developed protective immunity against reinfection from COVID-19.[6] This report will focus exclusively on viral diagnostic tests for COVID-19.

There are two types of viral tests currently used to diagnose COVID-19 in the United States: molecular tests and antigen tests. **Molecular tests** detect the presence of the virus's genetic material in a sample taken from a patient's nose or throat or a sample of saliva.[7] Virtually all molecular diagnostic testing for COVID-19 in the U.S. uses polymerase chain reaction (PCR), a technique that replicates the virus's genetic material until it becomes detectable.[8] **Antigen tests** detect the presence of viral proteins, rather than genetic material, by binding fragments of a virus, called antigens, to the membrane.[9] Molecular PCR tests have been shown to be more accurate than antigen tests when properly performed; the Food and Drug Administration (FDA) has authorized only two antigen tests for use in diagnosing COVID-19 and has cautioned that

[2] https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/testing.html
[3] https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/testing.html
[4] https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html; https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html; https://www.cdc.gov/coronavirus/2019-ncov/php/principles-contact-tracing.html
[5] https://coronavirus.jhu.edu/testing/testing-faq/facts-viral-and-serology-tests
[6] https://www.cdc.gov/coronavirus/2019-ncov/lab/serology-testing.html; https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html
[7] https://www.mayoclinic.org/diseases-conditions/coronavirus/expert-answers/covid-antibody-tests/faq-20484429
[8] https://www.gao.gov/assets/710/707071.pdf; https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas#individual-molecular
[9] https://www.gao.gov/assets/710/707071.pdf; https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-antigen-test-help-rapid-detection-virus-causes

negative results from an antigen test may need to be verified with a molecular PCR test.[10] As of July 8, the FDA has authorized more than 100 molecular diagnostic tests for COVID-19.[11]

Materials necessary for testing

PCR testing involves collecting a patient's sample, extracting viral genetic material from the sample, and testing the sample to detect the presence of the virus.[12] Each of these steps requires particular equipment, materials, and other supplies.[13]

- Personal Protective Equipment (PPE), such as gowns, masks, and gloves, is used at a testing site, such as a health care provider's office, emergency room, or drive-thru testing site, to protect the individuals who collect and transport a patient's sample from becoming infected or infecting the patient themselves.[14]

- Swabs are inserted into a patient's nose or throat to collect a sample to test for COVID-19.[15] Initially, only nasopharyngeal swabs were authorized for use for COVID-19 diagnostic tests, but FDA now provides information on its website about validated alternative swabs, for use where a nasopharyngeal swab is not available.[16] In addition, FDA has issued emergency use authorizations (EUAs) for tests for use with other types of swabs, such as nasal and throat swabs.[17]

- Viral Transport Medium or Media (VTM) is a specialized solution, typically stored in tubes, in which a specimen is placed for safe transport from a collection site to a laboratory.[18]

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[10] https://www.crs.gov/Reports/IF11516?source=search&guid=05fd4113e23d4ec28a83b17821094b57&index=0; https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-antigen-test-help-rapid-detection-virus-causes; https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas#individual-antigen

[11] https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

[12] https://www.scientificamerican.com/article/heres-how-coronavirus-tests-work-and-who-offers-them/

[13] https://www.businessinsider.com/how-coronavirus-throat-tests-work-rt-pcr-method-explained-2020-4; https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-testing-faqs.html

[14] https://clinlab.ucsf.edu/specimen-transport; https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html; https://www.crs.gov/Reports/IF11488?source=search&guid=9c580db1822442838ef7988dc576a6b2&index=0

[15] https://chicago.suntimes.com/coronavirus/2020/5/4/21247351/coronavirus-covid-19-swabs-things-to-know-illinois-gov-j-b-pritzker

[16] https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2#troubleobtainingviraltransport; https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html

[17] https://www.fda.gov/media/136522/download; https://www.fda.gov/media/139443/download

[18] https://www.umass.edu/ials/covid19/viral-transport-media; https://path.upmc.edu/Virology/G-02.htm

- Extraction kits and reagents are used to extract genetic material from the sample so that it can be tested.[19] Extraction kits and reagents are used to isolate the viral genetic material from the sample prior to testing.[20]

- Test instruments and platforms are the machines used to run patient samples to detect the presence of the virus.[21] There is a range of platforms on the market that run COVID-19 diagnostic tests, from simple, manual, low-throughput machines to large, automated, high-throughput machines.[22] Further, some platforms run "self-contained" test kits with pre-defined components and protocols for a distinct test (such as a point-of-care test), whereas other platforms can perform multiple tests or be combined with other instruments within a specific laboratory.[23] At present, COVID-19 testing platforms are, for the most part, not interoperable – each COVID-19 test can only be run on its manufacturers' machines and components, placing a potential limit on testing capacity if there are any issues (for example, shortages in test components) for a given platform.[24]

A Lack of Leadership on Testing

The Trump Administration's failures to lead on testing have resulted in chaotic communication, no clear strategy, and avoidable infections

The Trump Administration's failure to stand up an effective and efficient COVID-19 testing system has resulted in irrevocable harm to the nation's health and economy. Had there been competent, consistent leadership from the federal government, the United States could have avoided critical delays and better addressed supply shortages, allowing testing capacity to expand more rapidly.[25] Instead, President Trump and his Administration largely took a hands-off approach. Weeks into the spread of the virus in the United States – when the country had tested 11,000 people total, while South Korea tested that many people each day – President Trump was asked about the country's lagging testing capacity and said, "I don't take responsibility at all."[26] At the same time, Department of Health and Human Services (HHS) Secretary Alex Azar falsely assured the nation that "[t]here has not been an instance where a

[19] https://www.internationalreagentresource.org/QuickLinks/Covid19FAQ.aspx
[20] https://www.internationalreagentresource.org/QuickLinks/Covid19FAQ.aspx; https://www.crs.gov/Reports/IF11516?source=search&guid=05fd4113e23d4ec28a83b17821094b57&index=0
[21] https://www.youtube.com/watch?v=tgyzdgf66eM
[22] http://www.clpmag.com/2017/11/horizons-point-care-testing/; https://www.biocompare.com/Life-Science-News/562900-SARS-CoV-2-COVID-19-Research-News-Latest-Updates/
[23] https://apnews.com/e4f2fc48e6052eaf6f80e9135e00cda0; https://www.npr.org/sections/health-shots/2020/04/17/835958797/crispr-and-spit-might-be-keys-to-faster-cheaper-easier-tests-for-the-coronavirus; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7108255/
[24] https://www.washingtonpost.com/news/powerpost/paloma/the-health-202/2020/04/22/the-health-202-here-s-one-big-reason-u-s-coronavirus-tests-are-lagging-test-kits-made-by-private-companies/5e9f0cba602ff10d49aea8b1/
[25] https://www.nytimes.com/2020/05/25/health/coronavirus-testing-trump.html
[26] https://www.politico.com/news/2020/03/13/trump-coronavirus-testing-128971

public health official needed to test somebody for the novel coronavirus where they couldn't get tested."[27]

Scarce testing impeded the nation's ability to track the spread of the disease, causing irreversible damage

The CDC initially produced flawed COVID-19 diagnostic tests, which limited the entire country's ability to respond to the virus as it spread. After COVID-19 was identified in China in late 2019, the CDC began working to create a COVID-19 diagnostic test to distribute to public health laboratories.[28] The CDC elected to develop a three-component test, although the third component was not necessary to detect COVID-19 and other tests, such as the one developed by the World Health Organization (WHO), functioned with only two components.[29] The CDC diagnostic test design was completed in mid-January, and test kits were manufactured by CDC and shipped to public health labs by early February.[30] But it quickly became clear to the public health labs that received initial distribution of CDC tests that some of the tests were defective: more than 90 percent of the labs that first received test kits found the tests produced false positives or inconclusive results.[31]

Later investigations found that contamination of one of the test components was likely to blame for the faulty tests, but it was not until the end of February that the CDC advised public health labs to exclude the third component and restart testing with the CDC test.[32] In the interim, test manufacturers offered to assist in determining what had gone wrong with CDC's test, but the relationships did not materialize.[33] FDA also advised CDC to stop manufacturing kits, leading CDC to instead work with an outside contractor to manufacture kits to distribute to public health labs.[34]

As the federal public health agencies worked through February to figure out what went wrong and to develop a reliable test, neither the CDC test nor any tests from commercial laboratories

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[27] https://www.cbsnews.com/news/coronavirus-us-response-testing-alex-azar-hhs-secretary/
[28] https://www.washingtonpost.com/context/summary-of-the-findings-of-the-immediate-office-of-the-general-counsel-s-investigation-regarding-cdc-s-production-of-covid-19-test-kits/a750fbf7-9a4f-4062-8fcc-c6cf42600578/?itid=lk_interstitial_manual_8
[29] https://www.washingtonpost.com/investigations/contamination-at-cdc-lab-delayed-rollout-of-coronavirus-tests/2020/04/18/fd7d3824-7139-11ea-aa80-c2470c6b2034_story.html
[30] https://www.washingtonpost.com/context/summary-of-the-findings-of-the-immediate-office-of-the-general-counsel-s-investigation-regarding-cdc-s-production-of-covid-19-test-kits/a750fbf7-9a4f-4062-8fcc-c6cf42600578/?itid=lk_interstitial_manual_8; https://www.washingtonpost.com/investigations/contamination-at-cdc-lab-delayed-rollout-of-coronavirus-tests/2020/04/18/fd7d3824-7139-11ea-aa80-c2470c6b2034_story.html
[31] https://www.cdc.gov/media/releases/2020/t0212-cdc-telebriefing-transcript.html; https://www.washingtonpost.com/investigations/contamination-at-cdc-lab-delayed-rollout-of-coronavirus-tests/2020/04/18/fd7d3824-7139-11ea-aa80-c2470c6b2034_story.html
[32] https://www.washingtonpost.com/investigations/contamination-at-cdc-lab-delayed-rollout-of-coronavirus-tests/2020/04/18/fd7d3824-7139-11ea-aa80-c2470c6b2034_story.html
[33] Democratic Staff Call, May 12, 2020
[34] https://www.washingtonpost.com/investigations/contamination-at-cdc-lab-delayed-rollout-of-coronavirus-tests/2020/04/18/fd7d3824-7139-11ea-aa80-c2470c6b2034_story.html

and diagnostic companies was available nationally, outside of the CDC's internal laboratory.[35] It was not until the end of March that all 50 states, the District of Columbia, Puerto Rico, and Guam were successfully using the CDC diagnostic tests.[36] This meant that, for nearly six weeks after COVID-19 was first diagnosed in the United States – a critical period during which the virus was spreading across the country – the nation was left without a reliable and effective COVID-19 diagnostic testing apparatus.[37]

The lack of testing limited the entire country's ability to respond.[38] As a result of the delay, states were unable to quickly identify cases of COVID-19 in the community and isolate those individuals in order to reduce spread of the disease.[39] Most of the states we interviewed indicated the absence of an accurate diagnostic test delayed their ability to identify and address the spread of COVID-19.[40] States estimated the errors delayed their response by up to six weeks, depending on the state.[41] One public health official explained that, had the nearly 3,000 percent increase in testing capacity they achieved in just six weeks occurred back in January, they could have had adequate testing capacity in their state by the end of February.[42] Another lamented the "colossal mistake" of relying on the ability to execute one test flawlessly.[43]

Once the CDC's new test was distributed and some commercial tests became available, the Trump Administration admitted to other problems within the testing system. On March 10 – when more than 1,000 people were confirmed to be infected across the United States – HHS Secretary Alex Azar said, "we don't know exactly how many" people have been tested for COVID-19.[44] The same day, CDC Director Robert Redfield admitted U.S. labs may not have an adequate stock of the supplies necessary to "operationalize" the test, indicating that the Administration was aware of the potential challenges posed by such shortages early in the response.[45] Dr. Redfield said he did not know how the CDC would handle a scarcity of certain supplies, such as extraction kits and reagents.[46] On March 16, when asked how many Americans

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[35] https://www.washingtonpost.com/context/summary-of-the-findings-of-the-immediate-office-of-the-general-counsel-s-investigation-regarding-cdc-s-production-of-covid-19-test-kits/a750fbf7-9a4f-4062-8fcc-c6cf42600578/?itid=lk_interstitial_manual_8

[36] https://www.washingtonpost.com/investigations/contamination-at-cdc-lab-delayed-rollout-of-coronavirus-tests/2020/04/18/fd7d3824-7139-11ea-aa80-c2470c6b2034_story.html

[37] https://www.washingtonpost.com/investigations/contamination-at-cdc-lab-delayed-rollout-of-coronavirus-tests/2020/04/18/fd7d3824-7139-11ea-aa80-c2470c6b2034_story.html

[38] Democratic Staff Call, May 29, 2020; https://www.nytimes.com/2020/03/28/us/testing-coronavirus-pandemic.html

[39] Democratic Staff Call, June 10, 2020; Democratic Staff Call, June 2, 2020; Democratic Staff Call, June 4, 2020; Democratic Staff Call, May 23, 2020; Democratic Staff Call, May 29, 2020

[40] Democratic Staff Call, June 10, 2020; Democratic Staff Call, June 2, 2020; Democratic Staff Call, June 4, 2020; Democratic Staff Call, May 23, 2020; Democratic Staff Call, May 29, 2020

[41] Democratic Staff Call, June 10, 2020; Democratic Staff Call, May 29, 2020

[42] Democratic Staff Call, May 29, 2020

[43] Democratic Staff Call, May 29, 2020

[44] https://www.cnbc.com/2020/03/11/us-coronavirus-cases-surpass-1000-johns-hopkins-university-data-shows.html; https://www.cnn.com/2020/03/10/politics/alex-azar-americans-tested-for-coronavirus-cnntv/index.html

[45] https://www.politico.com/news/2020/03/10/coronavirus-testing-lab-materials-shortage-125212

[46] https://www.politico.com/news/2020/03/10/coronavirus-testing-lab-materials-shortage-125212

had been tested, Admiral Giroir responded, "There is a number. I don't have that number."[47] Despite recognizing supply challenges and the lack of an accurate picture of testing nationwide, the Trump Administration did not take necessary steps to respond.

The Trump Administration refused to leverage the power of the federal government to coordinate testing nationwide

As challenges persisted in coordinating and standing up a successful testing system, the Trump Administration refused to develop and implement a national testing plan.[48] Instead, the Administration left states with minimal support to stand up their own testing plans and procure supplies, sometimes bidding up prices against one another or even competing against the federal government.[49] All states interviewed identified the lack of leadership, coordination, guidance, assistance, or planning from the Trump Administration as barriers to standing up a national testing infrastructure and ramping up testing capacity.[50] Wyoming Governor Mark Gordon lamented the lack of federal support to boost testing capacity, noting, "It's a perilous set of circumstances trying to figure out how to make this work, and until we've got the testing up to speed — which has got to be part of the federal government stepping in and helping — we're just not going to be there."[51] One test manufacturer explained that once they recognized the federal government would not be taking the lead on testing, the company began working state-by-state by mid-March to share with governors which machines were in their state and where, and to help shift machines from lower-need to higher-need regions.[52]

After demanding for three months that the Trump Administration address its lack of progress and leadership on testing, on April 21, Congress stepped in to require the Administration to submit a national COVID-19 strategic testing plan.[53] Congress required the plan provide state, local, and Tribal governments with a comprehensive understanding of the COVID–19 testing landscape, disparities in testing across communities, and the federal resources available to support state and local testing plans.[54] On May 24, HHS submitted the required report to Congress.[55] The report

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[47] https://www.whitehouse.gov/briefings-statements/remarks-president-trump-vice-president-pence-members-coronavirus-task-force-press-briefing-3/
[48] https://www.nytimes.com/2020/04/20/us/politics/congress-coronavirus-bill.html
[49] https://www.nytimes.com/2020/03/31/us/governors-trump-coronavirus.html; https://www.bloomberg.com/news/articles/2020-03-19/trump-told-governors-to-buy-own-virus-supplies-then-outbid-them
[50] Democratic Staff Call, May 26, 2020; Democratic Staff Call, June 10, 2020; Democratic Staff Call, June 2, 2020; Democratic Staff Call, June 3, 2020; Democratic Staff Call, May 29, 2020; Democratic Staff Call, May 29, 2020; Democratic Staff Call, June 4, 2020; Democratic Staff Call, May 23, 2020; Democratic Staff Call, May 13, 2020
[51] https://www.startribune.com/ap-fact-check-trump-falsely-blames-governors-for-virus-test/569770822/
[52] Democratic Staff Call, May 12, 2020
[53] https://www.help.senate.gov/ranking/newsroom/press/following-sen-murray-proposal-democrats-secure-testing-expansion-in-latest-covid-19-package
[54] P.L. 116-139.
[55] https://www.democrats.senate.gov/imo/media/doc/COVID%20National%20Diagnostics%20Strategy%2005%2024%202020%20v%20FINAL.pdf

was met with criticism for not providing clear explanations for how national testing targets were set, how they would be met, and what would be done if they were not met.[56]

In addition to refusing to create a national testing strategy, President Trump also resisted calls to ramp up domestic production of critical supplies. State officials, Members of Congress, and experts urged President Trump to use the Defense Production Act (DPA), which gives the President the authority to compel production of critical supplies, require the private sector to prioritize orders from the federal government, and take over allocation of supplies.[57] In conversations with Democratic staff of the Senate Health, Education, Labor, and Pensions Committee, multiple states explained how the invocation of the DPA would have been particularly helpful for swab production and viral transport media, but states struggled to convince the White House to use its authority.[58] President Trump issued an Executive Order on March 18 referencing the DPA, but waited weeks after states and labs raised the alarm about swab shortages to finally announce use of the DPA for swab production.[59]

States demanded clarity from the federal government, but communication was muddled, decentralized, and unreliable

Nearly every entity interviewed struggled to identify which person or entity within the federal government was in charge of different aspects of the testing response. By mid-March, there appeared to be several different federal entities leading on testing and supplies. On March 12, Secretary Azar designated Admiral Brett Giroir, the Assistant Secretary for Health, to lead the Department's testing response and coordinate testing efforts across the CDC, FDA, state and local public health departments, and private and public clinical laboratories.[60] When President Trump declared a national emergency the following day, which activated the Federal Emergency Management Agency's (FEMA) formal involvement in the response, the agency issued a statement clarifying that "HHS remains the lead federal agency directing the federal response to COVID-19."[61] One week later on March 19, Vice President Pence designated FEMA to lead the federal response on behalf of the White House Coronavirus Task Force by "play[ing] the central role in coordinating [] federal support" to states and localities.[62] Shortly thereafter, Rear Admiral John Polowczyk of the Defense Logistics Agency (DLA) was placed at FEMA to lead supply

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[56] https://www.washingtonpost.com/health/trump-administration-vows-in-new-report-to-distribute-100-million-swabs-to-states-by-years-end/2020/05/24/9c02d240-9d06-11ea-ac72-3841fcc9b35f_story.html; https://www.nytimes.com/2020/05/25/health/coronavirus-testing-trump.html

[57] https://www.politico.com/news/2020/03/26/dpa-white-house-coronavirus-medical-supplies-150583; https://www.reed.senate.gov/imo/media/doc/Senate%20Letter%20to%20POTUS%20RE%20DPA%20.17.20%20(1).pdf; https://www.cfr.org/in-brief/what-defense-production-act

[58] Democratic Staff Call, June 10, 2020; Democratic Staff Call, June 4, 2020; Democratic Staff Call, May 29, 2020

[59] https://www.whitehouse.gov/presidential-actions/executive-order-prioritizing-allocating-health-medical-resources-respond-spread-covid-19/; https://www.politico.com/news/2020/04/19/trump-dpa-testing-swabs-reported-shortages-195721

[60] https://www.hhs.gov/about/news/2020/03/13/secretary-azar-designates-admiral-giroir-coordinate-covid-19-diagnostic-testing-efforts.html

[61] https://www.fema.gov/news-release/2020/03/13/president-donald-j-trump-directs-fema-support-under-emergency-declaration

[62] https://www.dhs.gov/coronavirus/federal-response; https://www.whitehouse.gov/wp-content/uploads/2020/03/COVID-Response-and-Recovery-Guidance.pdf

chain efforts, although he admitted on March 29, "Today, I, as leader of FEMA's supply chain task force, am blind to where all the product is."[63] At the same time, President Trump's son-in-law and senior advisor, Jared Kushner, was reportedly leading a separate effort with his own team of government officials and private industry representatives, focused on launching a testing project in cities with large outbreaks, including Seattle and New York City, and on procurement, particularly of swabs needed for diagnostic testing.[64] Rather than lead the nation to a successful testing system, these overlapping and uncoordinated leadership efforts sowed confusion and further added to the Administration's failed response.[65]

It was unclear through much of the spring who within the federal government was in charge of testing and where to direct requests for assistance to ramp up testing capacity. Given the lack of clarity on who was in charge, half of the labs and a third of the states interviewed used the inefficient, but necessary, strategy of requesting the same assistance from various parts of the federal government. Interviewees shared a variety of experiences:

- A lab company reached out to as many as five different federal government entities, as well as multiple Senate offices, in efforts to resolve the same supply issues.[66]
- Almost five months into the pandemic, a clinical lab still did not have clarity about how allocation of reagents and instrument allocation was being coordinated – nor whether there was any coordination at all.[67]
- A public health lab was still in the dark about who was responsible for supplies, where they were being distributed, and whether a single government entity was responsible for distribution.[68]
- A state health department said it was so unclear early on who they should contact, they would contact anyone in the federal government who might be able to help. [69]
- One state's testing officials still have not gotten clear communication on whether to direct requests for supplies to FEMA or HHS, nor on what requests the federal government is able to fulfill.[70]
- Another state's testing officials described the FEMA supply distribution process as "incredibly frustrating," particularly in contrast to FEMA's leadership during natural disaster responses.[71] The state added the process for ordering supplies was unclear, and orders had been canceled without explanation.[72]

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[63] https://www.dhs.gov/coronavirus/federal-response; https://www.whitehouse.gov/wp-content/uploads/2020/03/COVID-Response-and-Recovery-Guidance.pdf; https://www.axios.com/coronavirus-supply-chain-task-force-2b6be629-170c-4874-9991-7f8b3f6c5320.html
[64] https://www.washingtonpost.com/politics/kushner-coronavirus-team-sparks-confusion-plaudits-inside-white-house-response-efforts/2020/03/18/02038a16-6874-11ea-9923-57073adce27c_story.html
[65] https://www.washingtonpost.com/politics/kushner-coronavirus-team-sparks-confusion-plaudits-inside-white-house-response-efforts/2020/03/18/02038a16-6874-11ea-9923-57073adce27c_story.html
[66] Democratic Staff Call, May 19, 2020
[67] Democratic Staff Call, May 19, 2020
[68] Democratic Staff Call, May 13, 2020
[69] Democratic Staff Call, May 23, 2020
[70] Democratic Staff Call, June 3, 2020
[71] Democratic Staff Call, June 4, 2020
[72] Democratic Staff Call, June 4, 2020

Numerous states and labs reported that, even when the federal government shared information about testing, it could be contradictory or unreliable. For example, when the federal government distributed Abbott ID NOW machines to every state, one state raised concerns about the test's accuracy after recent studies revealed the test might yield false negative results.[73] While the state received assurances from Admiral Giroir and Vice President Pence that the test's sensitivity was adequate, FDA was communicating the opposite message, alerting the public of the potential accuracy concerns raised by those studies.[74] The state was left unsure of whether the machines it had received were accurate enough to use.[75]

In mid-April, the federal government sent each state a document purporting to outline COVID-19 diagnostic testing capacity by state, determined according to a list of laboratories in each state with testing capacity.[76] However, the actual capacity of a given platform and laboratory is dependent on numerous additional factors, such as staffing, expertise, logistics, and supply of components.[77] Ultimately, the majority of the states we interviewed found the capacity information to be inaccurate or so delayed it was unhelpful.[78] Several states noted that, by the time the list was distributed, they had already gathered the information for themselves.[79] The Administration-compiled list even identified labs the states could not access or labs that were not receiving supplies to actually run tests.[80] When the White House released reports that purported to forecast lab capacity in each state, one state called the information "laughable" and "just ridiculous," because it overstated the capacity of smaller labs, including hospitals, universities, and state public health labs.[81] The state official expressed it was more harmful for the Trump Administration to present the falsely optimistic picture than to be transparent and honest about where there was insufficient capacity.[82]

The lack of clarity and accuracy has made it nearly impossible for states and labs to rely on the Administration to help them accurately estimate their own capacity and supply needs. Without coordination or direction, it has been difficult for states to make decisions about how to procure supplies consistently and how best to allocate resources – including how to balance between areas with increasing case counts and areas that are working to maintain a flat curve.[83] Consistent, reliable communication about whether allocation is happening at the federal level or

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[73] Democratic Staff Call, May 23, 2020
[74] Democratic Staff Call, May 23, 2020; https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-informs-public-about-possible-accuracy-concerns-abbott-id-now-point
[75] Democratic Staff Call, May 23, 2020
[76] https://www.npr.org/sections/health-shots/2020/05/14/855550073/white-house-list-of-testing-labs-wasnt-helpful-states-say
[77] https://www.npr.org/sections/health-shots/2020/05/14/855550073/white-house-list-of-testing-labs-wasnt-helpful-states-say
[78] Democratic Staff Call, May 29, 2020; Democratic Staff Call, June 10, 2020; Democratic Staff Call, May 26, 2020; Democratic Staff Call, June 4, 2020; *but see* Democratic Staff Call, May 29, 2020
[79] Democratic Staff Call, June 4, 2020; Democratic Staff Call, May 29, 2020; Democratic Staff Call, June 10, 2020
[80] https://www.npr.org/sections/health-shots/2020/05/14/855550073/white-house-list-of-testing-labs-wasnt-helpful-states-say
[81] Democratic Staff Call, May 26, 2020
[82] Democratic Staff Call, May 26, 2020
[83] Democratic Staff Call, May 29, 2020; Democratic Staff Call, May 19, 2020

by manufacturers would have assisted in knowing who to contact for assistance in procuring supplies.[84]

The lack of federal leadership left the nation without the supplies to detect and contain COVID-19

Every part of the testing pipeline faced supply shortages

As tests slowly became more available to labs and health care providers, significant challenges remained in procuring the supplies necessary to administer and process them.[85] Nearly every entity interviewed described the lack of supplies for manufacturing, administering, and processing a COVID-19 test as a consistent and serious barrier to developing a functional testing system through the spring.[86] Testing manufacturers, labs, and states each reported serious issues in obtaining the appropriate supplies including swabs, reagents, extraction materials, and PPE.[87]

Companies and states shared they faced significant problems obtaining an adequate supply of nasopharyngeal swabs. According to one test manufacturer, swabs were hard to come by as global suppliers focused first on China, then Europe, then the United States, making nasopharyngeal swabs particularly scarce to come by as their use expanded globally.[88] The shortages pushed some labs to consider alternatives to nasopharyngeal swabs, such as 3-D printed swabs.[89] One lab noted that such uses were unprecedented and described anecdotal reports of 3-D swabs breaking off in patients' noses during testing.[90]

There were also shortages of testing platforms, partly due to challenges in procuring supplies needed to manufacture and operate them. This left labs unable to acquire and run enough machines to meet demand, which, for at least one company, was at times an even greater problem than obtaining test supplies.[91] Even as manufacturers shifted resources away from other products to focus solely on COVID-19, they struggled to build machines quickly enough to meet global demand.[92] They had to undertake significant investments and explore alternate sources of supplies, as they worked to build new platforms or provide replacement parts for existing

[84] Democratic Staff Call, May 19, 2020
[85] Democratic Staff Call, May 29, 2020; Democratic Staff Call, June 10, 2020; Democratic Staff Call, May 23, 2020
[86] Democratic Staff Call, May 23, 2020; Democratic Staff Call, June 10, 2020; Democratic Staff Call, May 29, 2020; Democratic Staff Call, May 29, 2020; Democratic Staff Call, June 2, 2020; Democratic Staff Call, May 26, 2020; Democratic Staff Call, May 8, 2020; Democratic Staff Call, May 14, 2020; Democratic Staff Call, May 12, 2020; Democratic Staff Call, May 19, 2020; Democratic Staff Call, May 28, 2020; Democratic Staff Call, May 21, 2020; Democratic Staff Call, May 19, 2020
[87] *Id.*
[88] Democratic Staff Call, May 8, 2020
[89] Democratic Staff Call, May 21, 2020; Democratic Staff Call, May 19, 2020
[90] Democratic Staff Call, May 13, 2020
[91] Democratic Staff Call, May 19, 2020
[92] Democratic Staff Call, May 14, 2020

platforms.[93] As one manufacturer noted, ending the pandemic simply cannot rely on the ability of manufacturers to produce more testing machines.[94]

Several interviewees described an ongoing wave of supply chain challenges. A shortage at just one point in the testing apparatus can bring the whole testing pipeline to a halt and leave equipment standing idle.[95] States and labs explained that because tests and platforms are generally not interchangeable, the inability to procure just one component could render an entire testing platform unusable.[96]

- One state described supply chain issues as a game of whack-a-mole; as soon as one problem was solved, another problem emerged.[97]
- Another state reported that when it finally began to receive test kits, it was still hampered in its ability to perform tests because it did not have the swabs or viral transport media for those tests.[98]
- A manufacturer shared they could manufacture five million tests, but did not have a matching quantity of components for extraction.[99]
- Two states continued to face challenges in procuring sufficient PPE for testing, with one state noting the lack of PPE remained a barrier to conducting additional testing.[100]

Lack of federal coordination resulted in competition among states, unreliable quality of supplies, and higher prices

Initially, the federal government largely left states on their own to handle the widespread global shortages of the supplies needed to run diagnostic tests. One state estimated supply procurement in it had been roughly 90 percent state-driven.[101] Another state described the situation as "a scramble."[102] All 50 states, in addition to local officials, labs, and health care systems, competed for the same supplies, often simultaneously against the purchasing power of the federal government itself.[103] New York Governor Andrew Cuomo explained, "It's like being on eBay with 50 other states."[104] Virginia Governor Ralph Northam lamented, "We're all out there bidding literally against each other."[105] Maryland Governor Larry Hogan later reflected, "We have 50 states — 55 including all the territories — competing with one another, and with the

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[93] Democratic Staff Call, May 14, 2020; Democratic Staff Call, May 14, 2020
[94] Democratic Staff Call, May 12, 2020
[95] Democratic Staff Call, May 21, 2020; Democratic Staff Call, May 29, 2020
[96] Democratic Staff Call, May 29, 2020; Democratic Staff Call, May 19, 2020; Democratic Staff Call, May 23, 2020; Democratic Staff Call, June 4, 2020; https://www.politico.com/news/2020/04/22/coronavirus-testing-problem-america-201372
[97] Democratic Staff Call, June 4, 2020
[98] Democratic Staff Call, May 29, 2020
[99] Democratic Staff Call, May 12, 2020
[100] Democratic Staff Call, June 2, 2020; Democratic Staff Call, June 3, 2020
[101] Democratic Staff Call, May 29, 2020
[102] Democratic Staff Call, June 10, 2020
[103] Democratic Staff Call, May 19, 2020; Democratic Staff Call, May 21, 2020; https://www.wsj.com/articles/coronavirus-testing-hampered-by-disarray-shortages-backlogs-11587328441
[104] https://www.nytimes.com/2020/03/31/us/governors-trump-coronavirus.html
[105] https://www.nbc12.com/2020/03/27/governor-ralph-northam-is-asking-federalized-testing-during-covid-pandemic/

federal government, and with other states around the world over very limited resources in a crazy market on stuff that we've never had to buy before and that we never should have been buying. But we had to do it because there was no alternative."[106]

After the federal government placed the burden on states, it sometimes compounded problems with the process by outbidding states for supplies or stepping in to claim the supplies for itself.[107] In some cases, states learned their orders had been canceled or requisitioned in order to divert supplies to the federal government, while in other cases, states were given no notice.[108] One state discovered weeks after placing an order that FEMA had taken over ordering through that vendor, so all existing orders were canceled and had to be reordered, though it was several weeks before that was communicated to the state.[109] The situation became so complicated and absurd that states resorted to extraordinary measures, even disguising their orders so as to avoid the federal government detecting and claiming them.[110] Massachusetts Governor Charlie Baker engaged in a reportedly "tense, weeks long saga" to import 1.2 million masks from China on the New England Patriots' team plane, all under the guise of a "private humanitarian mission" to avoid detection by the federal government.[111]

This unfettered and unorganized competition among various entities that could have been working together resulted in a surge in prices.[112] Kansas Governor Laura Kelly warned the bidding war was "driving up the cost of PPE tremendously for every state."[113] A non-profit examining health care procurement found that, by early April, the cost of some masks had jumped around 1,500 percent, isolation gowns 2,000 percent, and reusable face shields 900 percent from pre-COVID-19 levels.[114] The competition also left states vulnerable to scams as they grew desperate for any source of supplies.[115] One state interviewed said it resorted to procuring supplies from less reliable or unverified sources.[116] The officials suspected other states had to do the same and lamented the intense competition and absence of central coordination, which prevented states from sharing such information and experiences.[117]

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[106] https://www.rollingstone.com/politics/politics-features/larry-hogan-maryland-governor-coronavirus-trump-white-house-covid-republican-party-1013038/
[107] https://www.nytimes.com/2020/04/06/us/politics/coronavirus-fema-medical-supplies.html; https://www.bloomberg.com/news/articles/2020-03-19/trump-told-governors-to-buy-own-virus-supplies-then-outbid-them
[108] Democratic Staff Call, June 10, 2020; Democratic Staff Call, May 23, 2020; https://www.bloomberg.com/news/articles/2020-03-19/trump-told-governors-to-buy-own-virus-supplies-then-outbid-them; https://www.latimes.com/politics/story/2020-04-07/hospitals-washington-seize-coronavirus-supplies
[109] Democratic Staff Call, June 4, 2020
[110] https://www.vox.com/2020/4/4/21208122/ppe-distribution-trump-administration-states
[111] https://www.wsj.com/articles/a-million-n95-masks-are-coming-from-chinaon-board-the-new-england-patriots-plane-11585821600; https://www.vox.com/2020/4/4/21208122/ppe-distribution-trump-administration-states
[112] https://abcnews.go.com/US/competition-state-local-governments-creates-bidding-war-medical/story?id=69961539
[113] https://www.cnn.com/2020/04/16/politics/ppe-price-costs-rising-economy-personal-protective-equipment/index.html
[114] http://cdn.cnn.com/cnn/2020/images/04/16/shopp.covid.ppd.costs.analysis_.pdf
[115] https://www.latimes.com/politics/story/2020-06-10/in-the-race-to-buy-face-masks-some-states-got-screwed
[116] Democratic Staff Call, June 10, 2020
[117] Democratic Staff Call, June 10, 2020

While the federal government has expanded its role in distributing testing supplies, it has been an unreliable partner

In recent months, the federal government has stepped in to distribute some supplies to states. However, states reported those efforts as being severely problematic, frustrating, unclear, and inconsistent.[118] States sometimes received a different amount or type of supplies than what was promised or requested.[119] For example, one state was relieved when FEMA pledged to deliver hundreds of thousands of swabs and VTM for each of May and June, but the state never received their full allocation for May.[120] Another state received a shipment of nasal swabs, despite only using nasopharyngeal swabs at this time.[121] At other times, states had no idea what they would be receiving or when it would arrive—making it impossible to rely on federal assistance.[122]

Several states also reported receiving materials that were unusable:

- One state received swabs that were labeled cotton, but was told by the manufacturer they were polyester.[123] The swabs were also shipped in bulk, meaning the state had to dedicate staff to repackage swabs into individual bags.[124]
- Another state planned and expected to receive thousands of swabs, only to receive synthetic baby swabs that were not sterile unless they were used immediately after opening.[125]
- Yet another state described having to spend an "extraordinary" amount of time to render the supplies they received usable.[126] This included labeling individual vials that arrived with no indication of what kind of fluid they contained, separating into lots vials that arrived leaking and with swabs already in them, and paying to ship swabs that arrived in bulk to another state to be sterilized.[127]
- A fourth state reported not receiving its first shipment of usable swabs until late May, with earlier shipments described as "not much better than Q-tips."[128]

[118] Democratic Staff Call, June 3, 2020; Democratic Staff Call, June 10, 2020; Democratic Staff Call, May 29, 2020; Democratic Staff Call, June 4, 2020; Democratic Staff Call, May 26, 2020; Democratic Staff Call, May 23, 2020; Democratic Staff Call, May 13, 2020

[119] Democratic Staff Call, June 10, 2020; Democratic Staff Call, May 13, 2020; Democratic Staff Call, May 26, 2020

[120] Democratic Staff Call, June 10, 2020

[121] Democratic Staff Call, May 26, 2020

[122] Democratic Staff Call, May 29, 2020; Democratic Staff Call, May 23, 2020; Democratic Staff Call, June 10, 2020; Democratic Staff Call, June 3, 2020

[123] Democratic Staff Call, May 23, 2020

[124] Democratic Staff Call, May 23, 2020

[125] Democratic Staff Call, June 4, 2020

[126] Democratic Staff Call, June 10, 2020

[127] Democratic Staff Call, June 10, 2020

[128] Democratic Staff Call, May 26, 2020

Many Challenges Remain

More than six months into the pandemic, as state officials plead for increased support amidst surging infections and still scant testing in some areas, the Trump Administration continues to defer to states to manage testing on their own.[129] The Trump Administration has continued to muddle the messages about federal leadership and testing support to states. In mid-June, Admiral Giroir announced he would be "demobilized" from his testing lead role and return to his position as Assistant Secretary for Health.[130] HHS confirmed at the time there were no plans to designate a new testing lead.[131] At a HELP Committee hearing several weeks later, Admiral Giroir clarified he was assuming some of his duties as the Assistant Secretary for Health, but also maintaining his role coordinating testing.[132] It remains unclear how this shift will impact federal leadership on testing. Also in mid-June, the Administration announced plans to close some of the 13 remaining federally operated testing sites across five states, including several in Texas, which is experiencing record cases and hospitalizations.[133] The Administration has since walked back some announced closures, but cities and states experiencing high levels of infection are requesting more support.[134] In New Orleans, state and local officials are asking for increased federal support as test sites run out of tests within minutes of opening, and in Phoenix, local officials are begging for federally-supported testing sites as cases surge.[135]

States, manufacturers, and labs have expanded test capacity – largely without federal support – but there are still supply challenges

Supplies are and will continue to be a problem to even maintain current testing levels

After the United States' slow start, substantial progress has been made in expanding testing over the last several months. As of July 7, the United States is conducting around 600,000 tests per day, testing approximately 109 out of 1,000 residents.[136] Nevertheless, there remain significant barriers to continuing to increase the amount of testing. Through late June and early July, as new infections are surging in many states, health officials at all levels are warning of renewed supply

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[129] https://www.politico.com/states/new-york/city-hall/story/2020/06/25/states-plead-for-help-while-white-house-touts-success-in-curbing-virus-1294880
[130] https://www.npr.org/sections/coronavirus-live-updates/2020/06/01/867431135/white-house-coronavirus-testing-czar-to-stand-down
[131] https://www.npr.org/sections/coronavirus-live-updates/2020/06/01/867431135/white-house-coronavirus-testing-czar-to-stand-down
[132] Senate Health, Education, Labor, and Pensions Committee Hearing, "Update on Progress Toward Safely Getting Back to Work and Back to School," June 30, 2020.
[133] https://www.npr.org/sections/coronavirus-live-updates/2020/06/24/883154244/trump-administration-moving-to-close-federally-funded-covid-testing-sites
[134] https://thehill.com/policy/healthcare/504270-trump-admin-ending-support-for-7-texas-testing-sites-as-cases-spike-in
[135] https://www.nola.com/news/coronavirus/article_ba59be0e-bfa0-11ea-af21-db3e7ca7be47.html; https://www.azcentral.com/story/news/local/phoenix/2020/07/06/phoenix-mayor-gallego-fema-denied-coronavirus-testing/3286326001/
[136] https://covidtracking.com/data/us-daily; https://ourworldindata.org/grapher/full-list-cumulative-total-tests-per-thousand-bar-chart

shortages and backlogs at labs.[137] On July 1, Admiral Giroir warned that testing capacity is at risk of being overwhelmed as labs in some states are reaching or near capacity.[138] State and local officials across hard hit states – Arizona, Texas, Louisiana, and others – are having to turn patients away from testing sites or re-impose restrictions on who is eligible for testing.[139]

Most states are still recommending testing primarily for symptomatic individuals and those at high-risk of infection, while they continue to navigate uncertainty around demand for testing now and in the coming months.[140] At the time they were interviewed by Committee staff, some states were still working to get tests to priority populations or to settings where rates of infection were either high or particularly difficult to contain an outbreak – such as congregate care facilities – but most had not reached those goals.[141] A couple of states were able to provide testing in most parts of their states, and were contemplating how to continue to ramp up testing to the levels recommended by public health experts as necessary for population-wide testing and tracing.[142]

National testing capacity remains lower than experts recommend as part of a comprehensive plan to ensure people across the country can safely return to work and school. In late April and early May, several public health experts offered testing goals for the country, based on the reach of the pandemic at the time. For instance, the Edmond J. Safra Center for Ethics at Harvard University called for at least five million tests per day by early June and 20 million tests per day ideally by late July to safely reopen and fully remobilize the economy.[143] The Rockefeller Foundation calculated that, while some epidemiologists estimate a near complete return to work would require testing 20 to 30 million people per day, it would take at least a year for the U.S. to reach that capacity, and a more achievable goal would have been to test three million people per week by mid-June, with potential increases to 30 million people per week by December.[144] The Harvard Global Health Institute estimated the United States needed to conduct over 900,000 tests a day by May 15 in order to safely reopen.[145]

The Trump Administration has been dismissive of goals set by public health experts as unreasonable and unnecessary, while simultaneously claiming to be close to meeting those goals. At an April 23 briefing, when asked if he agreed with Dr. Anthony Fauci's assessment that the country did not have enough testing capacity to begin a phased reopening of the economy,

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[137] https://www.nytimes.com/2020/07/06/us/coronavirus-test-shortage.html
[138] https://www.politico.com/news/2020/07/01/giroir-coronavirus-surge-straining-testing-capacity-347109
[139] https://www.nytimes.com/2020/07/06/us/coronavirus-test-shortage.html
[140] Democratic Staff Call, June 3, 2020; Democratic Staff Call, May 29, 2020; Democratic Staff Call, June 10, 2020; Democratic Staff Call, May 26, 2020; Democratic Staff Call, May 23, 2020; Democratic Staff Call, June 2, 2020; Democratic Staff Call, May 29, 2020; Democratic Staff Call, June 4, 2020
[141] Democratic Staff Call, June 10, 2020; Democratic Staff Call, May 29, 2020; Democratic Staff Call, June 3, 2020
[142] Democratic Staff Call, May 26, 2020; Democratic Staff Call, May 29, 2020
[143] https://ethics.harvard.edu/files/center-for-ethics/files/roadmaptopandemicresilience_updated_4.20.20_1.pdf
[144] https://www.rockefellerfoundation.org/wp-content/uploads/2020/04/TheRockefellerFoundation_WhitePaper_Covid19_4_22_2020.pdf
[145] https://globalepidemics.org/2020/05/07/hghi-projected-tests-needed-may15/

President Trump said, "No, I think we're doing a great job in testing."[146] On April 29, Admiral Giroir said, "there is absolutely no way on Earth, on this planet or any other planet, that we can do 20 million tests a day, or even five million tests a day," calling those numbers "an unreasonable benchmark."[147] Five hours later, when asked if the country would surpass five million tests per day, President Trump said, "We're going to be there very soon."[148] Two weeks later, in a Senate HELP Committee Hearing, Admiral Giroir forecasted that by September, the United States would be able to conduct "at least 40 to 50 million tests per month if needed."[149]

The U.S. is nowhere near close to reaching those numbers, and it is increasingly unlikely the nation will be prepared with sufficient testing capacity to meet the health and economic needs of the country by late summer or even into the fall. Disturbingly, several interviewees, including large clinical labs, reported that despite the Administration's assurances, they did not see how the United States would reach even a million tests per day by the fall, based on their own capacity and their understanding of how much they and their competitors would be able to scale up.[150] One clinical lab company explained that, while they were capable of scaling up to meet their current demand, they were skeptical they and other companies could scale up sufficiently across the country.[151] One of the largest lab companies in the U.S. said the country could reach a million tests per day only if there was a real, clear, and concise plan for how to achieve that.[152]

Unreliable supply chains and uncertainty about demand remain barriers to ensuring sufficient testing in the future

Supplies remain one of the greatest barriers to expanding testing capacity. Nearly every entity interviewed expressed that new supply issues continuously arise, and ensuring they have enough materials remains a day-by-day challenge.[153] When asked whether supply chain issues had stabilized several months into the response, one large lab company responded "no," explaining that while some things have improved, and they feel more prepared to manage problems that do arise, it is still like "a giant jenga running in front of a freight train."[154]

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[146] https://www.statnews.com/2020/04/27/coronavirus-many-states-short-of-testing-levels-needed-for-safe-reopening/
[147] https://time.com/5828843/trump-coronavirus-testing-giroir/
[148] https://time.com/5828843/trump-coronavirus-testing-giroir/
[149] https://www.politico.com/news/2020/05/12/coronavirus-testing-health-251339
[150] Democratic Staff Call, May 19, 2020, Democratic Staff Call, May 19, 2020; Democratic Staff Call, May 28, 2020
[151] Democratic Staff Call, May 19, 2020
[152] Democratic Staff Call, May 28, 2020
[153] Democratic Staff Call, May 28, 2020; Democratic Staff Call, May 12, 2020; Democratic Staff Call, May 8, 2020; Democratic Staff Call, May 29, 2020; Democratic Staff Call, May 18, 2020; Democratic Staff Call, June 2, 2020; Democratic Staff Call, June 4, 2020, Democratic Staff Call, June 10, 2020; Democratic Staff Call, May 29, 2020; Democratic Staff Call, June 3, 2020; Democratic Staff Call, May 19, 2020; Democratic Staff Call, May 21, 2020; Democratic Staff Call, May 19, 2020
[154] Democratic Staff Call, May 28, 2020

In mid-May, multiple entities identified plastics shortages as the next major supply challenge.[155] One test manufacturer described plastics as the "tightest product right now," and a state recounted hearing from a second manufacturer that plastics shortages could become a limiting factor to conducting more tests.[156] One state reported they have addressed shortages by turning to alternative types of plastics, but noted they would prefer to have visibility into supply so labs could adjust accordingly.[157]

While every entity interviewed continued to face supply chain issues, some states and companies have had more success than others in increasing capacity:

- One test manufacturer reported they were producing more tests than they were selling, while another test manufacturer remained on allocations because demand for their product was still significantly higher than supply.[158]
- One state shared continued PPE shortages were a barrier for health care providers to administer COVID-19 tests in their offices.[159] Without this critical health care setting, state and local health departments were continuing to operate drive thru and community-based clinics for testing, which diverted resources from the health departments' other COVID-19 response activities.[160] At the same time, another state reported it had purchased an "incredible" amount of PPE and was giving it out for free.[161]
- While some states were still unable to provide tests to all symptomatic or high-risk populations, several states were testing asymptomatic individuals, including those in high-risk populations.[162] One state had recently begun testing asymptomatic patients if they requested a test,[163] and another state was proactively encouraging test providers to test asymptomatic individuals.[164]

In the coming months, there may be significant fluctuation in the use of testing capacity at any given time, which creates corresponding challenges in anticipating supply needs. One state warned about continuing to encounter lab capacity issues in the future, particularly without longer-term federal commitments guaranteeing specified shipments of supplies.[165] While the state wants to be able to fully use its lab capacity, it is difficult to make those investments without assurances it will receive all of the requisite supplies.[166]

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[155] Democratic Staff Call, May 12, 2020; Democratic Staff Call, May 8, 2020; Democratic Staff Call, May 29, 2020
[156] Democratic Staff Call, May 12, 2020; Democratic Staff Call, May 29, 2020
[157] Democratic Staff Call, May 29, 2020
[158] Democratic Staff Call, May 12, 2020; Democratic Staff Call, May 18, 2020
[159] Democratic Staff Call, June 2, 2020
[160] Democratic Staff Call, June 2, 2020
[161] Democratic Staff Call, June 4, 2020
[162] Democratic Staff Call, May 29, 2020; Democratic Staff Call, June 10, 2020; Democratic Staff Call, May 29, 2020
[163] Democratic Staff Call, June 3, 2020
[164] Democratic Staff Call, June 10, 2020
[165] Democratic Staff Call, June 10, 2020
[166] Democratic Staff Call, June 10, 2020

The uncertainty about the supply chain goes hand in hand with uncertainty about the course of the pandemic, making it difficult to predict both future supply and demand. Lab companies shared deep uncertainty about the coming months. One lab said unknowns about the stability of the supply chain are the greatest barrier to continuing to ramp up capacity.[167] Another lab echoed that if any component of the pipeline breaks down, they would be unable to continue to perform tests, underscoring the need for comprehensive testing infrastructure to be in place.[168] One lab company raised concerns about pockets of outbreaks as states reopen, noting they did not know how supply could meet that level of demand.[169] Similarly, one state that was on track to continue meeting its testing goals was still concerned about whether its projections would remain accurate, given competition for supplies as other states also ramp up or other countries manage new outbreaks.[170]

Supply issues may get worse through flu season and subsequent waves of COVID-19

Though test capacity is slowly but steadily increasing, states and companies raised concerns about demand for COVID-19 testing through subsequent waves of the virus that intersect with the resurgence of influenza and other respiratory viruses through the fall and winter. As one lab company explained, COVID-19 did not have widespread effects – or at least was not recognized as doing so – until the tail end of this past flu season, so the nation has not yet grappled with concurrent widespread cases of the two diseases.[171] The intersection of these viruses will inevitably exacerbate the challenges already faced in responding to the COVID-19 pandemic and a bad flu season independently, they warned, and it is essential to prepare our diagnostic testing capacity to respond on both fronts.[172] The country has previously faced supply shortages during particularly severe flu seasons, for example, and the two diseases circulating simultaneously will likely aggravate existing COVID-19 supply chain issues.[173] Another lab company admitted it would be challenging to figure out how to respond, unsure of whether they would use the same instruments or could procure enough reagents to test for both diseases.[174]

Multiple states also raised concerns with having sufficient capacity to test for both diseases and warned that preparations must start now to guarantee equipment and reagents:

- One state predicted flu season will bring another spike in infection, which could lead to severe outbreaks unless every symptomatic person is tested for both diseases in an effort to identify and contain infections.[175]
- A second state noted it is contemplating widespread, population testing in preparation for a fall COVID-19 resurgence when flu is also spreading, while a third state said it is "light

[167] Democratic Staff Call, May 19, 2020
[168] Democratic Staff Call, May 21, 2020
[169] Democratic Staff Call, May 19, 2020
[170] Democratic Staff Call, May 29, 2020
[171] Democratic Staff Call, May 21, 2020
[172] Democratic Staff Call, May 21, 2020
[173] Democratic Staff Call, May 21, 2020
[174] Democratic Staff Call, May 19, 2020
[175] Democratic Staff Call, May 26, 2020

years" from being able to test every person with any kind of respiratory or influenza symptoms.[176]

- Another state warned the nation needs to be sure the supply chain for testing supplies remains stable.[177]
- A fifth state shifted testing platforms away from testing for the flu and other viruses to test for COVID-19, so it may not have the capacity to test for both COVID-19 and other viruses for the fall.[178]

There are still not enough tests.

There are not enough tests for widespread testing for school and workplace reopenings

States, labs, and others are working to determine how to incorporate testing into reopening plans and to expand capacity for those situations, but there are many unanswered questions about the quantity of testing needed for safely reopening.[179] One main challenge in planning for how many tests will be needed is the lack of a model or guidance for how to contemplate reopening schools and workplaces safely.[180] One state expressed frustration that CDC had not generated these models, leaving each state on its own to research how to assess rates of infection, contacts, and sample sizes to be able to offer informed guidance for schools.[181]

Demand for testing to reopen workplaces and schools still exceeds supply. Although labs are increasing capacity and working to bring additional machines online to be able to reach demand, it is unclear if they can meet demand from employers nationwide to repeatedly test their workers.[182] Even a fraction of workplaces seeking to regularly test their employees would place demands on the testing system that could far exceed current capacity.[183] Current estimates for testing expansion will not approach what would be needed to test all students and school staff in a given week.[184] One state estimated that planning for Labor Day will require five to six times the amount of testing it is currently conducting, and that amount would still leave it far short of being able to test each student and staff member.[185] Another state said it did not have the testing capacity for students to return to school buildings.[186]

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[176] Democratic Staff Call, May 23, 2020; Democratic Staff Call, June 3, 2020
[177] Democratic Staff Call, June 10, 2020
[178] Democratic Staff Call, June 4, 2020
[179] Democratic Staff Call, May 19, 2020; Democratic Staff Call, June 4, 2020; Democratic Staff Call, May 26, 2020
[180] Democratic Staff Call, May 26, 2020; Democratic Staff Call, June 3, 2020
[181] Democratic Staff Call, May 26, 2020
[182] Democratic Staff Call, May 19, 2020; https://www.nytimes.com/2020/05/22/business/employers-coronavirus-testing.html
[183] https://www.usatoday.com/story/opinion/2020/05/18/coronavirus-testing-not-enough-to-reopen-economy-safely-column/5209647002/
[184] Democratic Staff Call, May 26, 2020
[185] Democratic Staff Call, May 26, 2020
[186] Democratic Staff Call, June 3, 2020

There is not sufficient testing to meet recommended testing frequency in congregate settings

The COVID-19 pandemic has had an outsized impact on residents in congregate care facilities – including nursing homes and long-term care facilities – with data suggesting more than 40 percent of all deaths in this country have been linked to nursing homes and other long-term care facilities for older adults.[187] In addition, some state data suggest people with intellectual disabilities and autism are 2.5 times more likely to die from COVID-19 compared to other state residents, and approximately 15 percent of people with intellectual disabilities and autism who tested positive for COVID-19 died from the disease.[188] Given the high risks posed to older Americans, people with disabilities, and others who may require care in a group setting, states have prioritized testing for congregate care facility residents and staff, although they raised concerns about not having enough tests for regular testing of all residents and staff.[189]

On May 18, the Trump Administration issued recommendations for testing to mitigate spread of COVID-19 in nursing homes.[190] The recommendations suggest a testing plan that maintains capacity to both test all residents if a single resident has symptoms consistent with COVID-19, with continued testing on a weekly basis until all residents test negative, and all staff every week.[191] Some states also are setting their own additional requirements for universal testing among nursing home residents and staff, with some requiring testing of all nursing home staff twice a week.[192] Across states and labs, there is concern about how to reach and sustain this level of testing, given limitations on the number of tests available at present. Lab companies raised concerns about the ability to reach the level of nursing home testing required by some states, particularly for weekly or bi-weekly testing.[193] Many states are not able to meet the recommended testing levels in congregate care settings and are working to detect outbreaks with less frequent testing.[194] Only one state reported being in a "pretty good" place with testing all staff and residents at congregate settings, although some other states were hopeful about the monitoring systems they have in place.[195]

Testing is still not reaching many communities of color and low-wage workers

COVID-19 is revealing long-standing racial and ethnic health disparities; Black, Latinx, and Tribal populations are dying at higher rates than white people.[196] In addition to the stark disparities in health outcomes, Black and Latinx populations also face barriers to testing. Black

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[187] https://www.nytimes.com/interactive/2020/us/coronavirus-nursing-homes.html
[188] https://www.npr.org/2020/06/09/872401607/covid-19-infections-and-deaths-are-higher-among-those-with-intellectual-disabili?utm_campaign=storyshare&utm_source=twitter.com&utm_medium=social
[189] Democratic Staff Call, June 10, 2020; Democratic Staff Call, May 29, 2020; Democratic Staff Call, June 3, 2020
[190] https://www.cms.gov/files/document/qso-20-30-nh.pdf
[191] https://www.cms.gov/files/document/qso-20-30-nh.pdf
[192] https://www.npr.org/sections/coronavirus-live-updates/2020/05/15/857279265/as-nursing-homes-report-more-covid-19-deaths-more-governors-order-universal-test
[193] Democratic Staff Call, May 19, 2020; Democratic Staff Call, May 20, 2020
[194] Democratic Staff Call, May 29, 2020; Democratic Staff Call, June 10, 2020; Democratic Staff Call, May 29, 2020; Democratic Staff Call, June 4, 2020; Democratic Staff Call, May 26, 2020
[195] Democratic Staff Call, May 26, 2020; Democratic Staff Call, June 2, 2020; Democratic Staff Call, June 4, 2020
[196] https://www.brookings.edu/blog/up-front/2020/06/16/race-gaps-in-covid-19-deaths-are-even-bigger-than-they-appear/; https://www.pbs.org/newshour/nation/how-covid-19-is-impacting-indigenous-peoples-in-the-u-s

and Latinx people are more likely to be uninsured and to face barriers accessing health care than white people, which likely contribute both to a lack of clarity on how to get tested in the first place and a reluctance to get the testing or care for fear of cost.[197] Anecdotal data also suggest Black and Latinx people may not be referred for testing as often as white people.[198] Testing sites may also be less accessible to Black and Latinx communities. A recent analysis of Texas testing sites found sites were concentrated in white neighborhoods in four of Texas' largest cities, and an analysis of testing sites in Indianapolis found just three of 30 testing sites were located in neighborhoods with the highest percentage of Black residents.[199] Similarly, Tribal communities experience significant challenges with access to COVID-19 testing. While Indian Health Service facilities offer COVID-19 testing, years of underinvestment and staffing shortages have complicated the response and resulted in a dearth in access to testing.[200] Reports highlight that Tribes are still not receiving enough tests based on their population size, or in some cases, are receiving the wrong supplies.[201]

Workers of color are also more likely to work in low-wage jobs without essential benefits, such as paid sick days; this lack of benefits can create disincentives to getting tested for COVID-19.[202] One state lamented that too many workers fear losing their jobs or necessary income if they or their family members become sick.[203] Data show these realities are most prevalent in Black and Latinx communities. Over 35 percent of essential workers identify as Black or Hispanic, and the numbers are even higher for certain industries.[204] Many essential workers have to sacrifice a paycheck if they take time off when they are sick or are caring for a sick family member, with one survey of retail, grocery, and food-service workers finding more than half reported lacking access to paid sick days.[205] Undocumented workers face even graver threats in trying to access testing and care, as getting tested could mean losing not only their jobs but also their families and homes.[206]

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[197] https://www.kff.org/coronavirus-covid-19/issue-brief/communities-of-color-at-higher-risk-for-health-and-economic-challenges-due-to-covid-19/
[198] https://www.hopkinsmedicine.org/health/conditions-and-diseases/coronavirus/covid19-racial-disparities
[199] https://www.npr.org/sections/health-shots/2020/05/27/862215848/across-texas-black-and-hispanic-neighborhoods-have-fewer-coronavirus-testing-sit; https://www.wfyi.org/news/articles/covid-19-testing-scarce-in-indianapolis-black-neighborhoods
[200] https://www.ihs.gov/sites/newsroom/themes/responsive2017/display_objects/documents/IHS_COVID-19_FAQs_03162020.pdf; https://www.americanprogress.org/issues/green/reports/2020/06/18/486480/covid-19-response-indian-country/
[201] https://www.nbcnews.com/news/us-news/native-american-health-center-asked-covid-19-supplies-they-got-n1200246
[202] https://abcnews.go.com/Business/heroes-hostages-communities-color-bear-burden-essential-work/story?id=70662472
[203] Democratic Staff Call, May 26, 2020
[204] https://www.epi.org/blog/who-are-essential-workers-a-comprehensive-look-at-their-wages-demographics-and-unionization-rates/
[205] https://shift.berkeley.edu/newsroom/essential-but-unprotected-most-service-sector-workers-lack-paid-sick-leave-amid-covid-19-pandemic/
[206] Democratic Staff Call, May 26, 2020; https://www.washingtonpost.com/outlook/2020/05/22/immigrant-workers-have-born-brunt-covid-19-outbreaks-meatpacking-plants/

According to experts, in an effort to reduce disease spread, essential workers who are keeping the country running by caring for patients both in health care facilities and in homes, keeping grocery stores operating, doing deliveries, and working in warehouses or meat-packing plants are among those for whom testing should be the highest priority.[207] But testing has been scarce in most of these settings, despite ample evidence of outbreaks in densely-packed and highly trafficked workplaces.[208] Although some employers may be able to test their workers on a regular basis, without cost being a barrier, many employers who employ workers in low-wage jobs may be unable – or unwilling – to invest in testing their workers with any regularity.[209] These inequities will build on the disparities seen so far in health outcomes.

Recommendations

Although the United States is still in the first wave of the COVID-19 pandemic, there are lessons to be learned, and quickly applied, from states, labs, and manufacturers' challenges in implementing an effective diagnostic testing system from January through June of 2020. It is clear there is urgent and significant work to be done to adequately increase diagnostic testing capacity in the months ahead. Below, the Democratic staff of the Senate Health, Education, Labor, and Pensions Committee provide recommendations about how to improve diagnostic testing in the current pandemic, apply lessons learned and avoid making the same mistakes in distributing a COVID-19 vaccine, and better prepare for future infectious disease outbreaks.

Recommendations to Improve Testing Capacity for the COVID-19 Pandemic

1. **Reestablish a public health official whose sole job is to lead diagnostic testing efforts for the federal government.** The Trump Administration should reestablish and maintain a consistent point person to lead testing efforts, with the goal of creating and implementing a coordinated testing system at the federal level. This person should establish clear communication channels, so states, manufacturers, labs, and others know whom to contact for help with their own testing needs. The Trump Administration should select someone who has substantial expertise in diagnostic testing and overcoming coordination and supply chain issues, and the role must be free from political influence and conflicts of interest and focused on testing as a means to ensure the nation's health and economic security. This person should coordinate the efforts by individual departments and agencies, to facilitate cooperation and communication across the federal government and with states, health systems, and others.

[207] Democratic Staff Call, May 26, 2020; https://www.healthaffairs.org/do/10.1377/hblog20200611.868893/full/
[208] https://www.vox.com/2020/5/19/21259000/meat-shortage-meatpacking-plants-coronavirus; https://www.brookings.edu/research/reopening-america-low-wage-workers-have-suffered-badly-from-covid-19-so-policymakers-should-focus-on-equity/
[209] Democratic Staff Call, May 26, 2020; https://www.nytimes.com/2020/05/22/business/employers-coronavirus-testing.html; https://www.healthaffairs.org/do/10.1377/hblog20200522.280105/full/

2. **Designate funding for diagnostic testing and subsequent public health interventions.** Congress should appropriate additional funding for diagnostic testing capacity and supplies, with a particular focus on state, local, territorial, and Tribal health departments' needs in continuing to implement diagnostic testing systems. Congress should also designate funding for public health measures that follow a positive COVID-19 test, including contact tracing, isolation, and quarantine. The Trump Administration should immediately release the $14 billion in funding it has yet to spend from the CARES Act to state, local, territorial, and Tribal health departments for diagnostic testing efforts, as well as for contact tracing, isolation and quarantine.

3. **Identify the bottlenecks in the testing supply chain.** HHS and FEMA should conduct a review of U.S. testing supplies to this point and for future use to assess the rate-limiting factors and bottlenecks in the supply chain. HHS and FEMA should identify current barriers that create inefficiencies in the testing system, including mismatches between states' testing platforms and available supplies. The federal government should communicate any limitations to state, local, Tribal, and territorial leaders, academic and industry stakeholders, and health care providers, to inform their own planning for future testing capacity. HHS and FEMA should also use this review to identify opportunities to designate supplies to areas of highest need.

4. **Assess and publish inventory of testing supplies.** HHS and FEMA should compile and share information with Congress and states about testing supply inventory and shortages on a weekly basis. This should include: (1) supply of diagnostic tests available for distribution to states; (2) supply of materials required to process and analyze tests available for distribution to states; (3) a clear identification of any potential shortages in critical materials; and (4) a detailed explanation of exactly how the federal government is allocating any supplies in shortage. In order to produce this information on inventory, the federal government should ensure it is receiving routine, reliable information from states, test manufacturers, lab companies, distributors, health care providers, and others in the testing system.

5. **Address shortages and optimize the supply chain.** Congress should consider legislation that incents domestic manufacturing of testing supplies and compels manufacturing of testing supplies that are in critical shortage. This may include invocation of the Defense Production Act to compel and purchase certain supplies. Legislation could also guarantee purchases of products or materials commissioned under any of these mechanisms or contracts, using excess supply to seed the restock of the Strategic National Stockpile (SNS).

6. **Guarantee the federal supply process is responsive to state needs.** FEMA and HHS should establish and maintain a system to provide states with advance notice of when to expect supply shipments, what the shipments will contain, and what preparations may be necessary by the state (i.e. sufficient refrigeration). This will allow states to indicate if they are not in need of certain supplies, and the federal government can reallocate those supplies to other states.

7. **Establish a quality control mechanism for all supplies being distributed by the federal government to states.** Congress should require HHS and FEMA to institute a process to confirm the quality and quantity of all materials being shipped to states for diagnostic testing. The agencies should ensure supplies have been tested for quality, contain accurate labels, and are packaged in such a way that allows them to be useful upon arrival (i.e. not packaged in bulk). The federal government should also certify that all supplies are shipped in a manner that ensures the quality of materials is not degraded in transit. With supply chains already in a precarious position and state public health workforces stretched thin, states should be able to rely on federal government support and not have to dedicate additional resources to assessing quality or correcting mistakes.

8. **Provide detailed guidance for various settings on how to incorporate testing into reopening decisions.** The CDC should issue clear, detailed guidance about testing for workplaces, schools, child care settings, and other locations to incorporate into their reopening plans. While CDC has released some guidance on reopening for critical infrastructure workplaces, schools, and institutions of higher education, it has released few specifics about how different types of workplaces, child care settings, and other entities should administer testing. Instead of each state having to develop its own guidance, clear, widely disseminated CDC guidance would allow workplaces, schools, and others to make informed decisions about testing strategies.

9. **Use testing to prevent and identify COVID-19 outbreaks in congregate settings.** CMS and CDC should establish testing guidance for congregate settings that accurately reflects continued testing shortages and devises strategies to use current testing capacity to prevent disease outbreaks. Such strategies should incorporate recommendations for testing frequency for both residents and staff. While the supply of tests remains limited, state and federal entities should prioritize tests for facilities that are experiencing active outbreaks.

10. **Ensure testing is reaching communities of color and low-wage workers.** As the United States continues to face testing shortages, public health departments at all levels should prioritize ensuring testing sites are accessible to people who are most impacted by the pandemic, including Black, Latinx, and Tribal communities. Public health departments should assess the current distribution of testing sites to ensure there are ample sites available at flexible hours in communities of color and communities with high numbers of workers at increased risk of exposure. CDC should provide resources for state, local, territorial, and Tribal health departments to engage in culturally and linguistically competent public education efforts to raise awareness of testing sites and how people can get tested.

11. **Prepare testing capacity for the confluence of COVID-19 and seasonal flu infections.** CDC should work with state health departments to ensure there is sufficient testing capacity to detect and respond to subsequent waves of COVID-19 in the United States that overlap with flu season. HHS and FEMA should also examine supply shortages that have emerged through recent months of COVID-19 testing and through past severe flu seasons, to ensure there will be sufficient capacity to test and treat patients diagnosed

with each disease to prevent our health care system from being overwhelmed in the fall and winter of 2020.

Recommendations to Apply Lessons Learned to Vaccine Development and Delivery

1. **Maintain clear leadership by a public health official or entity throughout the entire process of developing, distributing, and administering COVID-19 vaccines.** The Trump Administration should ensure there is clear leadership by an individual or entity within the federal government through all parts of the vaccine process. Operation Warp Speed (OWS) currently serves in this role; public health leaders within OWS should be communicating regularly and openly with the public and with Congress about the status of vaccination development, distribution, and administration efforts. While each agency should maintain key responsibilities – including, for example, CDC's role of supporting and overseeing immunization infrastructure, distribution, and vaccination administration and FDA's role of ensuring a vaccine is safe and effective before use – it is clear that long-term, central, transparent leadership within HHS is needed to avoid repeating the failures exposed through the diagnostic testing system. The individual or entity leading these efforts must be focused on public health and science and be free from political influence or conflicts of interest.

2. **Establish open pathways of communication between the federal government and states.** The federal government should begin working now to create clear communication channels and ensure central coordination to address any vaccine supply, distribution, or administration issues. States, manufacturers, and health care providers should clearly understand which federal public health entity or person is responsible for each aspect of the vaccine enterprise, as well as how to place requests or voice concerns with the appropriate entity.

3. **Establish a consistent and reliable stock of supplies necessary to manufacture, distribute, and administer a vaccine.** In order to reduce the barriers and strained supply lines seen through efforts to build and expand testing capacity, the Trump Administration should start now to identify critical vaccine materials and ensure a consistent, reliable, high quality supply of those materials. HHS should work with FEMA and other federal entities to determine pipelines to develop, procure, and stockpile, as appropriate, critical supplies to manufacture and administer vaccines. Based on these supply assessments, the Trump Administration should consider whether the DPA or other compulsory measures are necessary to increase domestic manufacturing or take other steps to ensure sufficient vaccine supply.

4. **Assess and resolve barriers to vaccine distribution and administration.** The CDC should begin working with states now to assess their capacity to distribute and administer vaccines, as well as any barriers to increasing that capacity. Such assessments should examine opportunities to leverage areas of strength – including use of existing immunization infrastructure and public-private partnerships – and prepare for potential challenges in vaccine distribution.

5. **Develop clear guidance to ensure the vaccine is prioritized for those who need it most.** The CDC should work with federal public health agencies to develop guidance on vaccine prioritization, in coordination with FDA approval or authorization. The guidance should contemplate populations at highest risk of infection based on health factors, employment conditions, and other relevant factors, such as age or relative location to ongoing COVID-19 outbreaks. The guidance should also take into account existing health disparities and ensure vaccines are available in Black, Latinx, and Tribal communities, among others that have historically faced barriers to health care access. The federal and state governments should each work now to assess how to prioritize distribution to those communities identified as highest need by CDC guidance.

Recommendations to Ensure a Stronger Response to Future Infectious Disease Outbreaks

1. **Reestablish public health leadership within the White House.** The federal government should reestablish the global health security staff within the National Security Council, to ensure global health security interests are represented among White House leadership. The federal government should also consider mechanisms to elevate and coordinate public health issues within the White House, to quickly leverage the federal government's ability to marshal resources, funding, and personnel in the event of a public health emergency.

2. **Guarantee long-term investments in public health infrastructure.** Congress should establish permanent, mandatory investments in public health infrastructure for federal, state, local, territorial, and Tribal health departments. Congress should also designate funding to strengthen and modernize public health data systems, with a focus on strengthening electronic results reporting, expanding disease surveillance systems and ensuring they are interoperable, and ensuring sufficient resources for contact tracing, quarantine, and isolation. Such annual investments are necessary to strengthen foundational public health capabilities, bolster the current COVID-19 response, and prepare for future public health emergencies.

3. **Incorporate diagnostic testing into preparedness exercises.** HHS should ensure preparedness efforts for future infectious disease outbreaks, including training exercises, incorporate various diagnostic testing scenarios, including opportunities to address any potential supply chain failures. These efforts should also incorporate strategies that ensure diagnostic testing will be accessible to people who are most likely to be impacted by infectious disease outbreaks, including essential workers.

4. **Diversify test development strategies and provide transparency.** The United States should have an accurate and widely available test to combat the next infectious disease outbreak. The CDC should explore pathways to diversify its work by using various strategies or developing multiple diagnostic tests for future infectious disease outbreaks. This may include leveraging the expertise of other federal agencies, the private sector, and international partners, including the WHO, where needed. CDC should also increase transparency by publicly sharing information on CDC-developed tests that are in development, as well as those that have received FDA clearance or authorization, so

other diagnostic test manufacturers and laboratories can make informed decisions for their own test development.

5. **Increase CDC lab transparency and accountability.** There should be an external accountability mechanism to ensure quality measures are in place at CDC laboratories, with regular inspections of labs engaged in the development and manufacture of diagnostic tests. CDC should periodically, publicly report on any identified deficiencies. These measures are critical to preventing and more quickly responding to any identified contamination or other lab safety issues.

6. **Assess domestic and global supply chains.** HHS should work with FEMA, the Department of Defense, and other relevant federal entities to conduct routine examinations of domestic and global supply chains critical to pandemic response to determine whether the United States should expand domestic production capacity for certain critical supplies in advance of future infectious disease outbreaks. This should include an examination of manufacturing capabilities, as well as distribution mechanisms, for a variety of supplies used for diagnostic testing, vaccination, and other aspects of pandemic response.

7. **Rebuild the national stockpile to be better prepared for diagnostic testing needs.** HHS should add and maintain diagnostic test supplies in the Strategic National Stockpile. This could include stockpiling some supplies, such as swabs, that are easier to store, while stockpiling the necessary equipment to produce other supplies, such as reagents, that cannot be stored for extended periods of time. HHS should also periodically review stockpiled supplies to perform necessary maintenance and replace expired products. Adding testing supplies to the SNS should not, however, be relied upon as the only fallback for diagnostic testing in future infectious disease outbreaks.

8. **Maintain a nationwide assessment of current and projected testing capacity.** HHS should conduct a nationwide assessment of current and anticipated lab capacity for diagnostic testing. This should include working with states, labs, health care systems, and others to understand current and projected lab capacity, recognizing that testing equipment may not be interoperable and is not useable if there are insufficient numbers of tests and testing supplies. This would also allow the federal government to identify gaps in testing capacity, so it can more quickly build public-private partnerships or tap into international partnerships to expand testing capacity.

9. **Fully implement recommendations by independent investigative entities on diagnostic testing.** There are currently several reviews being undertaken by the HHS Office of Inspector General and the Government Accountability Office to examine U.S. development of a diagnostic testing system in response to COVID-19, with a specific focus on CDC processes to produce and distribute diagnostic tests. HHS and its sub-agencies should fully implement all recommendations from these reviews, so they can avoid repeating mistakes on diagnostic testing in future infectious disease outbreaks.

10. **Incorporate an analysis of diagnostic testing development into a comprehensive review following the COVID-19 pandemic.** Congress should establish an independent entity to conduct a thorough review following the COVID-19 pandemic to examine the response and opportunities to improve the nation's health and economic systems in advance of future infectious disease outbreaks. The review should include a detailed analysis of the full spectrum of COVID-19 diagnostic testing challenges, including CDC development and manufacturing of initial diagnostic tests, FDA authorization of diagnostic testing, and HHS standing up testing sites and addressing the supply chain for, and distribution of, testing supplies. While the review should examine opportunities to improve diagnostic testing within current structures, it should also provide recommendations on larger structural changes that will improve diagnostic testing capabilities for future infectious disease outbreaks.

Conclusion

There is still a long path ahead as COVID-19 continues to spread throughout the United States, and testing must remain a central piece of the response. The past six months can be a learning experience for testing for the remainder of this pandemic, as well as for COVID-19 vaccines and for future pandemics.

Widespread testing is an essential part of the response to an infectious disease outbreak. Yet testing alone is not a sufficient response. The United States needs to take this opportunity to strengthen its public health system – at all levels.

Appendix

Associations:

1. Advanced Medical Technology Association (AdvaMed)
2. American Clinical Laboratory Association (ACLA)
3. American Society for Clinical Laboratory Science (ASCLS)
4. Association of Public Health Laboratories (APHL)
5. National Association of County and City Health Officials (NACCHO)

Manufacturers:

1. Abbott
2. Becton Dickinson
3. Cepheid
4. Roche
5. Thermo Fisher

Despite repeated attempts, Hologic was unresponsive to staff requests for information about their role in COVID-19 testing.

Lab Companies:

1. ARUP
2. BioReference Laboratories
3. LabCorp
4. Mayo Clinic Laboratories
5. Quest

Despite repeated attempts, Sonic Healthcare USA was unresponsive to staff requests for information about their role in COVID-19 testing.

State Health Officials:

1. California
2. District of Columbia
3. Minnesota
4. Ohio
5. Pennsylvania
6. Rhode Island
7. Virginia
8. Washington
9. Wisconsin