



MEMORANDUM

June 19, 2020

To: Committee on Energy and Commerce Members and Staff

Fr: Committee on Energy and Commerce Staff

Re: Hearing on “Oversight of the Trump Administration’s Response to the COVID-19 Pandemic”

On **Tuesday, June 23, 2020, at 11 a.m. (EDT), in the John D. Dingell Room, 2123 of the Rayburn House Office Building and remotely, via Cisco Webex online video conferencing**, the Committee on Energy and Commerce will hold a hearing entitled, “Oversight of the Trump Administration’s Response to the COVID-19 Pandemic.”

I. BACKGROUND

A. Impact

The first case of coronavirus disease of 2019 (COVID-19) in the United States was reported by the Centers for Disease Control and Prevention (CDC) on January 21, 2020.¹ Ten days later on January 31, Secretary Alex Azar of the Department of Health and Human Services (HHS) declared the disease a public health emergency.² The first death in the United States of an individual known to have COVID-19 occurred on February 6.³ The World Health Organization declared the disease a pandemic on March 11, and on March 13, President Trump declared a national emergency.⁴

¹ Centers for Disease Control and Prevention, *First Travel-related Case of 2019 Novel Coronavirus Detected in United States* (Jan. 21, 2020) (press release).

² U.S. Department of Health and Human Services, *Secretary Azar Declares Public Health Emergency for United States for 2019 Novel Coronavirus* (Jan. 31, 2020) (press release).

³ *1st Known U.S. COVID-19 Death Was Weeks Earlier Than Previously Thought*, NPR (Apr. 22, 2020).

⁴ *Coronavirus: COVID-19 is Now Officially a Pandemic, WHO Says*, NPR (Mar. 11, 2020); White House, *Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak* (Mar. 13, 2020).

As of June 18, 2020, as reported by the CDC, there were 2,178,710 reported COVID-19 cases and 118,365 related deaths in the United States.⁵ While a second major increase of COVID-19 cases, or infections could occur in the fall, experts agree that the United States has not yet recovered or emerged from the first wave.⁶ While some of the hardest hit states have recently begun to show a decrease in confirmed cases, other states with relatively lower disease incidence are beginning to see new surges in confirmed cases.⁷ In addition, some states, such as Texas, Florida, and Arizona, have recently seen a surge in cases that some experts believe may be due to easing of social distancing and other mitigation measures.⁸

B. Testing and Contact Tracing

COVID-19 tests fall into two main categories. Viral tests are used to help diagnose active infection, including molecular tests and antigen tests. Serology tests are used to help determine if a person was previously exposed to the virus via detection of antibodies in a blood sample. As of June 18, 2020, a total of 26,500,497 tests (including both viral and serology tests as reported to CDC by most states) in the United States had been reported to the CDC.⁹

On February 4, 2020, the HHS Secretary declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for COVID-19.¹⁰ As of June 18, 2020, 108 in vitro diagnostic products have been granted emergency use authorization (EUA), including several with at-home collection options, by the Food and Drug Administration (FDA).¹¹ Additionally, 37 laboratory-developed tests (LDTs) have received an EUA for use in a

⁵ Centers for Disease Control and Prevention, *Coronavirus Disease 2019 Cases in the U.S.* (www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html) (accessed June 17, 2020).

⁶ *Fauci says "we're still in a first wave" of coronavirus pandemic*, CBS News (June 17, 2020) (www.cbsnews.com/news/coronavirus-first-wave-fauci/).

⁷ *Is This the Second Wave of COVID-19 in the U.S.? Or are We Still in the First?* NBC News (Jun. 16, 2020) (www.nbcnews.com/health/health-news/second-wave-covid-19-u-s-or-are-we-still-n1231087).

⁸ *Florida, Texas and Arizona set records for daily COVID-19 cases*, The Hill (June 17, 2020) (thehill.com/policy/healthcare/503199-florida-texas-and-arizona-set-records-for-daily-covid-19-cases?utm_source=&utm_medium=email&utm_campaign=30784).

⁹ Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19) Cases in the U.S.* (www.cdc.gov/coronavirus/2019-ncov/cases-updates/testing-in-us.html) (accessed June 15, 2020).

¹⁰ U.S. Department of Health and Human Services, *Determination of Public Health Emergency*, 85 Fed. Reg. 7316 (Feb. 7, 2020) (notice).

¹¹ U.S. Food and Drug Administration, *In Vitro Diagnostics EUAs* (www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas)

clinical laboratory setting in which each was developed.¹² FDA has also allowed individual states and territories to review and perform diagnostic tests without FDA review.¹³ The agency has recently taken action to address the marketing of adulterated and misbranded antibody tests, as well as to revoke an EUA from antibody test with performance concerns related to accuracy.¹⁴

Testing is critical to directing appropriate treatments to patients as well as to guiding public health decisions, including strategies for reopening communities. However, achieving widespread testing has been hampered by problems of access to testing and shortages of swabs, reagents, and personal protective equipment.¹⁵ According to public health officials, lack of robust COVID-19 testing early in the pandemic contributed and led to a growth in cases. This lack of testing continues to hamper our Nation's ability to control the spread of COVID-19.¹⁶

Contact tracing individuals who may have faced exposure is also critical to control the transmission of COVID-19. Through this containment strategy, individuals previously in contact with an infectious patient are identified and encouraged to take steps to avoid further

¹² U.S. Food and Drug Administration, *Emergency Use Authorization* (www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization) (accessed Jun. 18, 2020).

¹³ U.S. Food and Drug Administration, *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency* (www.fda.gov/media/135659/download) (accessed Jun. 18, 2020).

¹⁴ U.S. Food and Drug Administration, *Coronavirus (COVID-19) Update: FDA Issues Warning Letters to Companies Inappropriately Marketing Antibody Tests, Potentially Placing Public Health at Risk* (June 17, 2020) (www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-warning-letters-companies-inappropriately-marketing-antibody) (press release); U.S. Food and Drug Administration, *Coronavirus (COVID-19) Update: FDA Revokes Emergency Use Authorization for Chembio Antibody Test* (June 16, 2020) (www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-chembio-antibody-test) (press release).

¹⁵ *Testing Remains Scarce as Governors Weigh Reopening States*, New York Times, (Apr. 25, 2020) (www.nytimes.com/2020/04/25/us/politics/virus-testing-shortages-states-trump.html).

¹⁶ *The Lost Month: How a Failure to Test Blinded the U.S. to COVID-19*, New York Times (Mar. 28, 2020) (www.nytimes.com/2020/03/28/us/testing-coronavirus-pandemic.html); *Testing Remains Scarce as Governors Weigh Reopening States*, New York Times, (Apr. 25, 2020) (www.nytimes.com/2020/04/25/us/politics/virus-testing-shortages-states-trump.html); *As coronavirus testing expands, a new problem arises: Not enough people to test*, Washington Post (May 17, 2020) (www.washingtonpost.com/health/as-coronavirus-testing-expands-a-new-problem-arises-not-enough-people-to-test/2020/05/17/3f3297de-8bcd-11ea-8ac1-bfb250876b7a_story.html).

spreading the virus, including self-isolation.¹⁷ This process requires well-trained public health staff with specialized skills.¹⁸ Public health leaders have estimated that this workforce will need to grow by 180,000 workers before an effective vaccine is projected to be available.¹⁹ These leaders recommend funding not only for the contact-tracing workforce but also for support for identified contacts of COVID-19-positive individuals, who may require housing, financial assistance, or other resources during self-isolation.²⁰

C. Treatment

There is currently no FDA-approved drug to treat COVID-19 in the United States. On March 28, 2020, FDA issued an EUA for the antimalarials -- chloroquine and hydroxychloroquine -- to treat COVID-19, only to revoke the EUA on June 15 due to mounting evidence against its effectiveness and citing serious side effects including heart problems.²¹ Clinical trials examining the drug's use in treating COVID-19 are expected to continue, and as hydroxychloroquine is approved for other uses, it may still be used off-label by doctors to treat COVID-19 patients.²² FDA also warned on June 15 that hydroxychloroquine may weaken the effectiveness of remdesivir, which has shown to shorten COVID-19 recovery time in a clinical

¹⁷ Centers for Disease Control and Prevention, *Case Investigation and Contact Tracing: Part of a Multipronged Approach to Fight the COVID-19 Pandemic* (www.cdc.gov/coronavirus/2019-ncov/php/principles-contact-tracing.html) (accessed June 17, 2020).

¹⁸ *Id.*

¹⁹ *Ex-Officials Call for \$46 Billion for Tracing, Isolating in Next Coronavirus Package*, NPR News (Apr. 27, 2020) (www.npr.org/2020/04/27/845165404/ex-officials-call-for-46-billion-for-tracing-isolating-in-next-coronavirus-packa).

²⁰ *Id.*

²¹ *FDA Ends Emergency Use of Hydroxychloroquine for Coronavirus*, Politico (June 15, 2020) (www.politico.com/news/2020/06/15/fda-ends-emergency-use-of-hydroxychloroquine-319872).

²² *Id.*

trial and received an EUA from FDA to treat severe COVID-19 cases.²³ Deaths were also shown to be lower in remdesivir-treated patients, though the effect was not statistically significant.²⁴

Convalescent plasma has also been investigated and is being studied as a potential means of COVID-19 treatment, and individuals who have recovered from COVID-19 for at least two weeks have been encouraged to donate plasma.²⁵ Over 20,000 patients have been treated with convalescent plasma in the United States, though to date there is no evidence of a therapeutic benefit.²⁶

On April 17, 2020, the National Institutes of Health (NIH) announced a public-private partnership with the Foundation for the NIH aimed at coordinating the various stages of research on treatments and vaccines for COVID-19. The public-private partnership, called the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership includes government agencies, private biopharmaceutical companies, and non-profit organization²⁷ This group, co-chaired by NIH Director Dr. Francis Collins and Dr. Paul Stoffels from Johnson and Johnson, is currently working to prioritize the most promising candidates into and through the clinical trial process.²⁸ One ACTIV partner kicked off the first clinical trial of a COVID-19

²³ U.S. Food and Drug Administration, *Coronavirus (COVID-19) Update: FDA Warns of Newly Discovered Potential Drug Interaction That May Reduce Effectiveness of a COVID-19 Treatment Authorized for Emergency Use* (June 15, 2020) (www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-warns-newly-discovered-potential-drug-interaction-may-reduce) (press release); U.S. Food and Drug Administration, *Coronavirus (COVID-19) Update: FDA Issues Emergency Use Authorization for Potential COVID-19 Treatment* (May 1, 2020) (www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-emergency-use-authorization-potential-covid-19-treatment) (press release).

²⁴ *Coronavirus Drug Remdesivir Shortens Recovery, but is not a Magic Bullet* Scientific American (Apr. 30, 2020) (www.scientificamerican.com/article/coronavirus-drug-remdesivir-shortens-recovery-but-is-not-a-magic-bullet/).

²⁵ U.S. Food and Drug Administration, *Donate COVID-19 Plasma* (www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/donate-covid-19-plasma) (accessed Jun. 17, 2020).

²⁶ *Can Blood Plasma of Recovered COVID-19 Patients Help Prevent Infection in Others?*, NBC News (June 12, 2020) (www.nbcnews.com/health/health-news/can-blood-plasma-recovered-covid-19-patients-help-prevent-infection-n1230846).

²⁷ National Institutes of Health, *Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)* (www.nih.gov/research-training/medical-research-initiatives/activ) (accessed June 17, 2020).

²⁸ *Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV): An Unprecedented Partnership for Unprecedented Times*, JAMA (May 18, 2020) (jamanetwork.com/journals/jama/fullarticle/2766371).

antibody therapy in the United States on June 10, 2020, and if found effective, may be available by the fall.²⁹

D. Vaccine Development

Given the urgency of the COVID-19 pandemic, manufacturers of vaccine candidates have accelerated the development timeline, conducting animal studies concurrently with early human studies and also merging clinical trial phases.³⁰ Several leading vaccine candidates are expected to begin final phases of clinical trials this summer or by early fall, with one candidate expected to enter final human trials as early as next month.³¹ Experts have estimated that a COVID-19 vaccine could be available by the end of 2020 or early 2021, though also warn it is not inevitable that these early candidates will prove effective.³²

Operation Warp Speed, a partnership among HHS entities, including CDC, FDA, NIH, and the Biomedical Advanced Research and Development Authority (BARDA), and the Department of Defense (DoD)³³, aims to deliver 300 million doses of a safe and effective vaccine by January 2021.³⁴ Given the accelerated timeframe for vaccine development, some experts fear FDA will grant one or more vaccines an EUA before clinical trials are completed or conducted on a large enough scale or duration to adequately assess its safety and efficacy.³⁵

²⁹ *US Human Trials Begin for First Antibody Cocktail that Might Treat and Prevent COVID-19*, CNN (Jun. 11, 2020) (<https://www.cnn.com/2020/06/11/health/regeneron-covid-19-antibody-trial-starts/index.html>).

³⁰ *The Health 202: The Hopeful News About Moderna's Coronavirus Vaccine is Extremely Preliminary*, The Washington Post (May 19, 2020) (www.washingtonpost.com/news/powerpost/paloma/the-health-202/2020/05/19/the-health-202-the-hopeful-news-about-moderna-s-coronavirus-vaccine-is-extremely-preliminary/5ec2e480602ff11bb118504f/).

³¹ *Johnson & Johnson to Begin Human Trials for Coronavirus Vaccine in Late July, Earlier than Expected*, CNBC (June 10, 2020) (www.cnbc.com/2020/06/10/johnson-johnson-to-begin-human-trials-for-coronavirus-vaccine-in-late-july-earlier-than-expected.html).

³² *White House Pressure for a Vaccine Raises Risk the U.S. will Approve One that Doesn't Work*, Politico (June 15, 2020) (www.politico.com/news/2020/06/15/pressure-coronavirus-vaccine-risk-approval-316094).

³³ U.S. Department of Health and Human Services, *Fact Sheet: Explaining Operation Warp Speed* (Jun. 16, 2020) (www.hhs.gov/about/news/2020/06/16/fact-sheet-explaining-operation-warp-speed.html) (press release).

³⁴ *Id.*

³⁵ *Could Trump Turn a Vaccine into a Campaign Stunt?*, New York Times (June 8, 2020) (www.nytimes.com/2020/06/08/opinion/trump-coronavirus-vaccine.html).

Accelerated vaccine development also raises concerns surrounding vaccine uptake by individuals. According to a poll conducted in May, approximately one quarter of Americans say they have little to no interest in receiving a COVID-19 vaccine, with concern being the speed of vaccine development could compromise its safety.³⁶ Experts estimate that at least 70 percent of Americans would need to be immune to the virus to achieve herd immunity, at which point a sufficient number of people are resistant to prevent spread.³⁷ However, it is estimated that 200 million Americans would need to be infected before reaching this level of immunity without an effective vaccine, which would take more than a year of continued rates of high infection, morbidity, and mortality.³⁸ Even in New York City, which has experienced a far higher death toll than any other metropolitan area, only an estimated 15-21 percent residents are believed to have been exposed to the virus, demonstrating that we are far below herd immunity levels.³⁹

E. Congressional Action

On March 4, 2020, the House passed the Coronavirus Preparedness and Response Supplemental Appropriations Act, which subsequently passed the Senate and was signed into law by President Trump on March 6, 2020.⁴⁰ This legislation provided \$8.3 billion in emergency funding for federal agencies, including the FDA, Centers for Disease Control and Prevention (CDC), and the NIH, to respond to the COVID-19 outbreak.⁴¹

On March 14, 2020, the House passed the Families First Coronavirus Response Act, which subsequently passed the Senate and was signed into law by President Trump on March 18, 2020.⁴² The legislation included supplemental appropriations for federal agencies to respond to the COVID-19 pandemic, including funds for diagnostic testing and services, including \$1 billion in funding for reimbursing providers for testing for the uninsured.⁴³ The legislation also required private health plans, Medicaid, and Medicare to provide coverage of COVID-19 tests

³⁶ *Exclusive: A Quarter of Americans are Hesitant about a Coronavirus Vaccine – Reuters/Ipsos Poll*, Reuters (May 21, 2020) (www.reuters.com/article/us-health-coronavirus-vaccine-poll-exclu/exclusive-a-quarter-of-americans-are-hesitant-about-a-coronavirus-vaccine-reuters-ipsos-poll-idUSKBN22X19G).

³⁷ *Id.*

³⁸ David Dowdy and Gypsyamber D’Souza, *Early Herd Immunity Against COVID-19: A Dangerous Misconception* (<https://coronavirus.jhu.edu/from-our-experts/early-herd-immunity-against-covid-19-a-dangerous-misconception>).

³⁹ *Id.*

⁴⁰ Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, Pub. L. No. 116-123.

⁴¹ *Id.*

⁴² Families First Coronavirus Response Act, Pub. L. No. 116-127.

⁴³ *Id.*

and related items and services without any cost-sharing, prior authorization or other medical management requirements.

On March 27, 2020, Congress passed, and President Trump signed into law, the Coronavirus Aid, Relief, and Economic Security (CARES) Act.⁴⁴ The legislation includes appropriations of \$4.3 million to the CDC for preparedness and response activities, including surveillance and epidemiology laboratory capacity, \$80 million to FDA for efforts including countermeasure development and advanced manufacturing, and \$945 million to the NIH, including \$706 million to the National Institute for Allergy and Infectious Diseases (NIAID) to support vaccine and infectious disease research.⁴⁵ The CARES Act also requires private health plans to cover a broad range of items and services to detect COVID-19 without any cost-sharing.

On April 23, 2020, Congress passed the Paycheck Protection Program and Health Care Enhancement Act, which the President signed the following day.⁴⁶ In addition to supplemental appropriations of \$25 billion to research, develop, validate, manufacture, purchase, administer, and expand capacity for COVID-19 tests, allocated among various entities including the CDC, NIH, BARDA, and FDA, this legislation required HHS to report to Congress regarding COVID-19 cases as well as develop a strategic testing plan.⁴⁷

On May 15, 2020, the House passed the Health and Economic Recovery Omnibus Emergency Solutions (Heroes) Act, which provides an additional \$75 billion for the establishment of a national testing and contact-tracing plan, as well as additional provisions to improve the medical supply chain, enhance the Strategic National Stockpile (SNS) capabilities, and strengthen data collection and reporting related to COVID-19, including data reporting on racial and ethnic health inequities.⁴⁸

F. Administration Actions

On May 24, 2020, pursuant to the Paycheck Protection Program and Health Care Enhancement Act, the Trump administration released its COVID-19 Strategic Testing Plan (Plan) to Congress.⁴⁹ The Plan asserted that the nation would have the capacity to perform 40 million to 50 million tests per month by the end of summer, and recommended that each state test at least two percent of its population through June 2020. Public health experts did warn,

⁴⁴ Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No. 116-136.

⁴⁵ *Id.*

⁴⁶ Paycheck Protection Program and Health Care Enhancement Act, Pub. L. No. 116-139, Title I.

⁴⁷ *Id.*

⁴⁸ H.R. 6800, the Heroes Act.

⁴⁹ *This Is Not the Hunger Games': National Testing Strategy Draws Concerns*, The New York Times (May 25, 2020) (www.nytimes.com/2020/05/25/health/coronavirus-testing-trump.html).

however, that this testing performance goal would be insufficient to bring the outbreak under control.⁵⁰ The Administration states in the Plan that the federal government will purchase 100 million swabs by the end of the year for distribution to states, and notes that collaborations are underway with industry stakeholders to facilitate drive-through testing sites. However, the Plan relies on state efforts to facilitate their own testing capabilities and notes that “The Federal government is supporting and encouraging States, territories, and tribes to build a multi-layered approach that incorporates and fully leverages all components of the testing ecosystem.”⁵¹

In addition to the requirement that HHS submit a testing report to Congress, the Paycheck Protection Program and Health Care Enhancement Act required that no later than 21 days after the bill’s enactment and every 30 days thereafter for the duration of the public health emergency, the Secretary of HHS report to Congress on the number and rates of cases, hospitalizations, and deaths as a result of COVID-19 broken down by race, ethnicity, age, sex, geographic region, and other relevant factors. On May 15, 2020, HHS and CDC submitted a four-page document pursuant to this mandate, which was compiled of webpages from already existing sources and databases.⁵² This document stated that “current data suggest a disproportionate burden of illness and death among racial and ethnic minority groups.”⁵³

In the first initial 30-day report to Congress pursuant to this mandate, released on June 14, 2020, HHS noted the pandemic had “shone a spotlight on the persistent health disparities in this nation,” and specifically stated that “racial and ethnic minority groups are at higher risk of severe complications from COVID-19 due to co-morbidities such as diabetes, hypertension, cancer and other chronic conditions” as well as that “social determinants of health are factors contributing to the disproportionate impact of this virus on racial and ethnic minority groups.”⁵⁴

⁵⁰ *Administration Leaves Testing Responsibility to States in Report to Congress*, Washington Post (May 24, 2020) (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); *‘This Is Not the Hunger Games’: National Testing Strategy Draws Concerns*, New York Times (May 25, 2020) (www.nytimes.com/2020/05/25/health/coronavirus-testing-trump.html).

⁵¹ U.S. Department of Health and Human Services, *Report to Congress: COVID-19 Strategic Testing Plan* (May 24, 2020) (www.democrats.senate.gov/imo/media/doc/COVID%20National%20Diagnostics%20Strategy%2005%2024%202020%20v%20FINAL.pdf).

⁵² Department of Health and Human Services, Centers for Disease Control and Prevention, *Report to Congress, Paycheck Protection Program and Health Care Enhancement Act, Disaggregated Data on U.S. Coronavirus Disease (COVID-19) Testing* (Apr. 2020) (www.help.senate.gov/imo/media/doc/FY%202020%20CDC%20RTC%20on%20COVID-19%20Testing%20Data%20-%20CDCfinalclean.pdf).

⁵³ *Id.*

⁵⁴ *Id.*

II. WITNESSES

The following witnesses have been invited to testify:

Anthony S. Fauci, M.D.

Director

National Institute for Allergy and Infectious Diseases

National Institutes of Health

ADM Brett P. Giroir, M.D.

Assistant Secretary for Health

U.S. Department of Health and Human Services

Stephen M. Hahn, M.D.

Commissioner

U.S. Food and Drug Administration

Robert R. Redfield, M.D.

Director

Centers for Disease Control and Prevention