U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE

June 21, 2020

TO: Members, Committee on Energy and Commerce

FROM: Committee Republican Staff

RE: Hearing entitled, "Oversight of the Trump Administration's Response to the COVID-19 Pandemic"

The Committee on Energy and Commerce will hold a hybrid hearing that includes both in person and remote attendance on Tuesday, June 23, 2020, at 11:00 a.m., entitled "Oversight of the Trump Administration's Response to the COVID-19 Pandemic."

I. WITNESSES

- Anthony S. Fauci, M.D., Director, National Institute for Allergy and Infectious Diseases, National Institutes of Health;
- Admiral 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; and
- Robert R. Redfield, M.D., Director, Centers for Disease Control and Prevention.

II. BACKGROUND

a. History and Spread of COVID-19

Coronaviruses (CoV) are a large family of viruses that causes illness ranging from the common cold to more severe diseases such as Middle East Respiratory (MERS-CoV), which was first identified in Saudi Arabia in 2012, and Severe Acute Respiratory Syndrome (SARS-CoV), which was first identified in the Guangdong province of southern China in 2002.[1] Coronaviruses are zoonotic, meaning they are transmitted between animals and people, and several known coronaviruses are circulating in animals that have not yet infected humans. For example, SARS-CoV was transmitted from civet cats to humans, and MERS-CoV was transmitted from dromedary camels to humans.[2] A novel coronavirus (nCoV), like the one that is currently being

[1] World Health Organization, *Coronavirus* (last visited on Mar. 3, 2020), *available at* https://www.who.int/health-topics/coronavirus; World Health Organization, Middle East respiratory syndrome coronavirus (MERS-CoV) (Dec. 20, 2019), *available at* https://www.who.int/news-room/q-a-detail/middle-east-respiratory-syndrome-coronavirus-(mers-cov); World Health Organization, *International travel and health, SARS* (Severe Acute Respiratory Syndrome) (last visited Mar. 3, 2020), *available at* https://www.who.int/ith/diseases/sars/en/.
[2] World Health Organization, *Coronavirus* (last visited on Mar. 3, 2020), *available at* https://www.who.int/health-topics/coronavirus.

transmitted, is a new strain that has not been previously identified in humans. COVID-19 is the infectious disease caused by the most recently discovered coronavirus, SARS-CoV-2, which was discovered as a result of the outbreak in Wuhan, China in December 2019.[3] Currently, the specific source of the COVID-19 outbreak is unknown.

Common signs of COVID-19 infection include respiratory symptoms, fever or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, and diarrhea.[4] The Center for Disease Control and Prevention's (CDC) website notes that this list does not include all possible symptoms and it will continue to update the list as they learn more about the virus. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure, and even death. Anyone can have mild to severe symptoms, but older adults and people who have underlying medical conditions, such as heart or lung disease or diabetes, seem to be at higher risk for developing more serious complications. According to the CDC, symptoms may appear two to 14 days after exposure.[5]

While initial cases were reported in Wuhan, China and other countries starting in early December 2019, the first reported patient in the U.S. with confirmed COVID-19 was in Washington state on January 22, 2020.[6] On January 31, 2020, the U.S. Department of Health and Human Services (HHS) Secretary, Alex M. Azar II, declared a public health emergency for the U.S. to aid the nation's health care community in responding to COVID-19, and announced travel restrictions and quarantines for individuals traveling from China, beginning on February 2, 2020, via a Presidential Proclamation issued by President Trump.[7] Additional travel restrictions for other countries have been issued since. During the week of February 23, 2020, CDC reported community spread of the virus in California, Oregon, and Washington. On March 11, 2020, the World Health Organization (WHO) announced that COVID-19 can be characterized as a pandemic.[8] According to the WHO, this is the first pandemic caused by a coronavirus.

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[3] World Health Organization, *Q&A on coronavirus* (COVID-19) (Feb. 23, 2020), *available at* https://www.who.int/news-room/q-a-detail/q-a-coronaviruses.
[4] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19), Symptoms* (last reviewed May 13, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.
[5] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19), Symptoms* (last reviewed Feb. 29, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/about/symptoms.html.
[6] Jennifer Harcourt, Azaibi Tamin, et. al., *Centers for Disease Control and Prevention, Emerging Infectious Diseases*, Vol. 26, Num. 6-June 2020, *Severe Acute Respiratory Syndrome Coronavirus 2 from Patient with Coronavirus Disease, United States* (May 18, 2020), *available at* https://wwwnc.cdc.gov/eid/article/26/6/20-0516_article.
[7] Proclamation on Suspension of Entry as Immigrants and Nonimmigrants of Persons who Pose a Risk of Transmitting 2019 Novel Coronavirus (Jan. 31, 2020), *available at* https://www.whitehouse.gov/presidential-actions/proclamation-suspension-entry-immigrants-nonimmigrants-persons-pose-risk-transmitting-2019-novel-coronavirus/.
[8] World Health Organization, *WHO Director-General's opening remarks at the media briefing on COVID-19 – 11 March 2020* (Mar. 11, 2020), *available at* https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020.

As of June 19, 2020, there are 188 countries/regions with a total of 8,514,522 confirmed COVID-19 cases and 454,522 deaths.[9] Within the U.S. there are 55 U.S.-affiliated jurisdictions reporting cases of COVID-19, including all 50 states, the District of Columbia, Guam, the Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands.[10] While there are 55 jurisdictions reporting cases, different parts of the country are seeing different levels of COVID-19 activity. For example, of the U.S. jurisdictions reporting cases, there are 38 states who have reported more than 10,000 cases of COVID-19.[11] As of June 18, 2020, CDC reports that there are 2,155,572 cases and 117,632 deaths from COVID-19 in the U.S.[12] However, CDC does not know the exact number of COVID-19 illnesses, hospitalizations, and deaths because the virus "can cause mild illness, symptoms might not appear immediately, there are delays in reporting and testing, not everyone who is infected gets tested or seeks medical care, and there may be differences in how states and territories confirm numbers in their jurisdictions."[13]

b. Transmission of COVID-19

While we are still learning about how COVID-19 spreads, the virus is thought to spread mainly from person-to-person between people who are in close contact with one another (within six feet), through respiratory droplets produced when an infected person coughs, sneezes, or talks.[14] These droplets can land in the mouths or noses of people who are nearby or possibly be inhaled into the lungs. In addition, COVID-19 may spread by people who are not showing symptoms, also known as someone who is asymptomatic or pre-symptomatic.[15] In addition to person-to-person spread, it may be possible to contract COVID-19 by touching a surface or object that has the virus on it and then touching your mouth, nose, and possibly eyes.[16] Further, while it appears the virus can spread from people to animals, at this time, the CDC believes that the risk of transmission from animals to people is low.[17] According to the CDC, the virus is spreading more efficiently than influenza, but not as efficiently as measles.[18]

There is currently no vaccine to prevent COVID-19, therefore, the best way to prevent illness is to avoid being exposed to the virus. In addition, CDC has issued detailed recommendations on how everyone can help protect themselves from COVID-19 by doing things

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[9] Johns Hopkins University & Medicine, Coronavirus Resource Center, COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (last visited June 19, 2020), *available at* https://coronavirus.jhu.edu/map.html.
[10] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19), Cases in the US* (last updated June 18, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html#accordion-1-collapse-2.
[11] *Id*.
[12] *Id*.
[13] *Id*.
[14] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19), How It Spreads* (last reviewed May 22, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fprepare%2Ftransmission.html.
[15] *Id*.
[16] *Id*.
[17] *Id*.
[18] *Id*.

such as wearing masks, thoroughly washing their hands, and avoiding close contact with people who are sick, among other things.[19]

c. COVID-19 Racial and Ethnic Disparities

On April 17, 2020, the CDC reported on race and ethnicity data from 580 COVID-19 patients hospitalized from a community with a population comprised of 59 percent white people and 18 percent black people. The study found that 45 percent of the hospitalizations were white, while 33 percent were black, suggesting black people overrepresent hospitalized patients.[20] More recent CDC data tracks with the April 17th report and shows age-adjusted hospitalization rates are highest among American Indian/Alaska Native (AI/AN) and black people, followed by Hispanic or Latino people.[21] AI/AN people have a rate approximately five times that of white people, black people have a rate approximately 4.5 times that of white people, while Hispanics or Latinos have a rate approximately 3.5 times that of white people.[22]

Until recently, efforts to obtain a clear data picture for persons belonging to racial and ethnic minority groups were hampered by an inconsistent patchwork of incomplete reporting at the state level. In the early months of the pandemic, state-collected information on the race and ethnicity of COVID-19 patients were incomplete or withheld from the CDC. Some states were not releasing any demographic information, and other states were missing information because of incomplete reporting from health practitioners.[23] Many states had not been explicitly categorizing AI/AN in their demographic results, instead categorizing them under the label "other."[24] Overall, an April data analysis by CDC found that the agency was missing about 78 percent of the necessary state and local data in communities of color.[25]

There has recently been a significant push at the federal level to improve reporting. On March 27, 2020, Congress passed, and President Trump subsequently signed into law, the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, which required every

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[19] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19), Protect Yourself* (last reviewed on Apr. 24, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html.

[20] Centers for Disease Control and Prevention, *Hospitalization Rates and Characteristics of Patients Hospitalized with Laboratory-Confirmed Coronavirus Disease 2019 — COVID-NET, 14 States, March 1–30, 2020*, Morbidity and Mortality Weekly Report (Apr. 17, 2020), *available at* https://www.cdc.gov/mmwr/volumes/69/wr/mm6915e3.htm?s_cid=mm6915e3_w.

[21] Centers for Disease Control and Prevention, Coronavirus Disease 2019 (COVID-19), Cases, Data & Surveillance (last updated June 5, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html.

[22] *Id*.

[23] Soo Rin Kim and Matthew Vann, *Many States Are Reporting Race Data For Only Some COVID-19 Cases And Deaths*, FIVETHIRTYEIGHT (May 7, 2020), *available at* https://fivethirtyeight.com/features/many-states-are-reporting-race-data-for-only-some-covid-19-cases-and-deaths/.

[24] Rebecca Nagle, *Native Americans being left out of US coronavirus data and labelled as 'other'*, THE GUARDIAN (Apr. 24, 2020), *available at* https://www.theguardian.com/us-news/2020/apr/24/us-native-americans-left-out-coronavirus-data.

[25] Sherita Hill Golden, *Coronavirus in African Americans and Other People of Color*, Johns Hopkins Medicine, *available at* https://www.hopkinsmedicine.org/health/conditions-and-diseases/coronavirus/covid19-racial-disparities (last updated Apr. 20, 2020).

laboratory conducting testing to detect SARS-CoV-2 or to diagnose cases of COVID-19 to report the results from each test to the Secretary of HHS.[26] Following the CARES Act, on April 23, 2020, Congress passed, and President Trump subsequently signed into law, the Paycheck Protection Program and Health Care Enhancement Act, which included several provisions requiring the reporting and analysis of data on COVID-19 cases, hospitalizations, and deaths, including two required COVID-19 reports "disaggregated nationally by race, ethnicity, age, sex, geographic region, and other relevant factors".[27] In accordance with the recently signed legislation, HHS announced new guidance on June 4 specifying that additional data, such as race, ethnicity, age and sex, must be reported to HHS by laboratories along with COVID-19 test results. The guidance also standardized reporting to ensure that public health officials have access to comprehensive and nearly real-time data to inform decision making in their response to COVID-19.[28]

The reasons for the disproportionate burden of COVID-19 illness and death among ethnic and minority communities are not fully understood. There is evidence that older adults and those with underlying medical conditions, such as heart or lung disease or diabetes, are at higher risk for developing more serious complications from COVID-19. The CDC found that about 78 percent of intensive care unit patients and 71 percent of hospitalized COVID-19 patients had one or more reported underlying health condition.[29] While about 1 in 5, or 20 percent, U.S. adults under age 65 are at a higher risk for severe illness from COVID-19 due to an underlying health condition, in minority communities, the numbers are over 1 in 3, or 34 percent.[30]

Racial and ethnic minority populations are at higher risk for COVID-19 complications and death due to a disproportionate burden of underlying comorbidities, such as diabetes, hypertension, obesity, and asthma. Thus far, there is limited evidence as to whether genetics play any role in increased risk for these comorbidities in minority populations. For example, there has been some success in identifying novel genetic variants for Type-2 Diabetes, but there are numerous variants and the predisposition to diabetes is multifactorial, meaning that an individual's risk of developing Type-2 Diabetes is influenced by the combination of genetic variation at multiple sites across the genome, acting in concert with other factors, such as nutrition and the gut microbiome.

During the last decade, large-scale genetic studies have identified over 400 distinct genetic signals influencing Type-2 Diabetes risk, but most of these DNA sequence variants are

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[26] Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Pub. L. 116-136 (2020).
[27] Paycheck Protection Program and Health Care Enhancement Act, Pub. L. 116-139 (2020).
[28] Centers for Disease Control and Prevention, *HHS Announces New Laboratory Data Reporting Guidance for COVID-19 Testing* (June 4, 2020), *available at* https://www.cdc.gov/media/releases/2020/p0604-new-lab-data-reporting.html.
[29] Berkeley Lovelace Jr., *CDC says diabetes, lung disease, heart disease and smoking may increase risk of severe coronavirus illness*, CNBC (Mar. 31, 2020), *available at* https://www.cnbc.com/2020/03/31/cdc-says-diabetes-lung-disease-heart-disease-and-smoking-may-increase-risk-of-severe-coronavirus-illness.html.
[30] Samantha Artiga, et. al., *Growing Data Underscore that Communities of Color are Being Harder Hit by COVID-19*, Kaiser Family Foundation, *available at* https://www.kff.org/coronavirus-policy-watch/growing-data-underscore-communities-color-harder-hit-covid-19/ (last updated Apr. 21, 2020).

widely shared between different racial and ethnic populations.[31,32,33] Genetic variations for cardiovascular disease and obesity are also complex and have generally been found to be consistent across racial/ethnic groups.[34,35,36] There are indeed some medical conditions with higher prevalence in certain groups and there are differences in how some minority groups respond to certain drugs.[37,38] An uncommon form of chronic renal failure is associated with a mutation in a gene related to lipid metabolism (*ApoL1*), and one copy of this version of the gene is found in almost 90 percent of West Africans.[39] However, these are traits linked to single genes, affecting a small subset of many populations, such as some southern Europeans and south Asians who also have a predisposition to sickle cell anemia in addition to the black population.[40]

According to the CDC, the conditions in which people live, learn, work, and play contribute to their health, ultimately leading to different levels of health risks and outcomes among certain racial and ethnic minority groups.[41] These same comorbidities are often experienced by residents of rural areas as well,[42] suggesting that communities with fewer resources and decreased access to quality health services are at higher risk for poor health outcomes.

Increased exposure to infectious individuals is a potential contributing factor to the disproportionate burden of illness in minority communities. The virus is thought to spread mainly from person-to-person between people who are in close contact with one another (within six feet), through respiratory droplets produced when an infected person coughs, sneezes, or

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[31] Anubha Mahajan, et. al. Fine-mapping type 2 diabetes loci to single-variant resolution using high-density imputation and islet-specific epigenome maps. *Nature Genetics*. 2018;50(11):1505-1513. doi:10.1038/s41588-018-0241-6

[32] Miriam S. Udler, et. al. Genetic Risk Scores for Diabetes Diagnosis and Precision Medicine. *Endocrine Reviews*. 2019;40(6): 1500–1520. https://doi.org/10.1210/er.2019-00088.

[33] Maggie C. Y. Ng. Genetics of Type 2 Diabetes in African Americans. *Current diabetes reports*. 2015;15(10): 74. doi:10.1007/s11892-015-0651-0

[34] Jay S. Kaufman, et.al. The Contribution of Genomic Research to Explaining Racial Disparities in Cardiovascular Disease: A Systematic Review. *American Journal of Epidemiology*, 2015;181(7): 464–472. https://doi.org/10.1093/aje/kwu319

[35] Mohamed T. Hassanein, et. al. Fine mapping of the association with obesity at the FTO locus in African-derived populations. *Human Molecular Genetics*. 2010;19(14):2907-2916. doi:10.1093/hmg/ddq178

[36] *Behavior, environment, and genetic factors all have a role in causing people to be overweight and obese*, Centers for Disease Control and Prevention, *available at* https://www.cdc.gov/genomics/resources/diseases/obesity/index.htm (last updated January 19, 2018).

[37] Nita A. Limdi, et. al. Warfarin pharmacogenetics: a single VKORC1 polymorphism is predictive of dose across 3 racial groups. *Blood*. 2010;115(18):3827-3834. doi:10.1182/blood-2009-12-255992.

[38] Prithu Sundd, et. al. Pathophysiology of Sickle Cell Disease. *Annual review of pathology*. 2019;14: 263-292. doi:10.1146/annurev-pathmechdis-012418-012838.

[39] Saharon Rosset, et al. The population genetics of chronic kidney disease: insights from the MYH9–APOL1 locus. *Nature Reviews Nephrology*. 2011;7: 313–326. https://doi.org/10.1038/nrneph.2011.52

[40] Gelpi AP and Perrine RP. Sickle Cell Disease and Trait in White Populations. *JAMA*. 1973;224(5):605–608. doi:10.1001/jama.1973.03220180029007.

[41] *The Coronavirus Disease 2019 (COVID-19), Racial & Ethnic Minority Groups*, Centers for Disease Control and Prevention, *available at* https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/racial-ethnic-minorities.html, (last updated June 4, 2020).

[42] *Rural Health Disparities*, Rural Health Information Hub, *available at* https://www.ruralhealthinfo.org/topics/rural-health-disparities#life-expectancy, (last updated Apr. 22, 2019).

talks.[43] In part because of their close proximity to each other, vulnerable seniors residing in nursing homes represent 42 percent of COVID-19 fatalities, even though the residents of such facilities only account for 0.6 percent of the total U.S. population.[44] Due to proximity to others, certain occupations increase the chances of infection, and the types of work where those in some racial and ethnic groups are overrepresented, such as service jobs in congested settings like restaurants, bars, and hotels, can contribute to their risk for getting sick with COVID-19.[45] Multi-generational households, which may be more common among some communities of color, face more challenges in isolating family members who are sick when space is limited. Living in densely populated areas and relying on public transportation, either to get to work or obtain resources make social distancing not feasible, increasing risk of exposure.[46]

In addition to the disease itself, the economic crisis caused by the pandemic has exacerbated existing health disparities. A recent study by the National Bureau of Economic Research found that the number of actively working business owners in the U.S. decreased by 3.3 million (22 percent) between February and April. Open black-owned businesses fell 41 percent, Hispanic-owned businesses 32 percent, and Asian-owned businesses 26 percent. Active immigrant-owned businesses dropped by 36 percent.[47] The paper did not determine whether the shutdowns of these small businesses would be temporary or longer term. Other studies have also found that communities of color are some of the most deeply impacted by the economic damage caused by the pandemic.[48] Many individuals from minority communities were employed in hourly-wage jobs that were cut as a result of the pandemic and subsequent lockdown. School closures have also disproportionately impacted lower-income children, who are more often from racial and ethnic minority families. Overall, these communities already faced economic hardships[49] and the economic slowdown from the pandemic has worsened those effects. Thus, inequalities that persisted before COVID-19 in underserved communities have played a role in contributing to the exacerbated racial disparities that have been brought to light in the pandemic.

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[43] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19), How It Spreads* (last reviewed May 22, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/faq.html#How-COVID-19-Spreads.

[44] Gregg Girvan and Avik Roy, *Nursing Homes & Assisted Living Facilities Account for 42% of COVID-19 Deaths*, The Foundation for Research on Equal Opportunity. (May 7, 2020) *available at* https://freopp.org/the-covid-19-nursing-home-crisisby-the-numbers-3a47433c3f70?source=collection_home---1------0----------.

[45] Emily Woodruff, *3 out of 4 hospitalized coronavirus patients were black, Ochsner study finds. But why?*, THE TIMES-PICAYUNE | THE NEW ORLEANS ADVOCATE (June 1, 2020), *available at* https://www.nola.com/news/coronavirus/article_636523dc-a456-11ea-bdcd-a7ca2b50195e.html.

[46] *The Coronavirus Disease 2019 (COVID-19), Racial & Ethnic Minority Groups*, Centers for Disease Control and Prevention, *available at* https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/racial-ethnic-minorities.html, (last updated June 4, 2020).

[47] Robert W. Fairlie, *The Impact of COVID on Small Business Owners: Evidence of Early-stage Loss from the April 2020 Current Population Survey*, National Bureau of Economic Research (June 2020), *available at* https://www.nber.org/papers/w27309.pdf.

[48] Lauren Aratani and Dominic Rushe, *African Americans bear the brunt of Covid-19's economic impact*, THE GUARDIAN (Apr. 28, 2020), *available at* https://www.theguardian.com/us-news/2020/apr/28/african-americans-unemployment-covid-19-economic-impact.

[49] Diana Farrell, et. al., *Racial Gaps in Financial Outcomes*, Big Data Evidence, J.P. Morgan and Chase Co. Institute, (April 2020), *available at* https://institute.jpmorganchase.com/institute/research/household-income-spending/report-racial-gaps-in-financial-outcomes.

III. CONGRESSIONAL RESPONSE TO COVID-19

Congress has passed legislation in response to the COVID-19 pandemic, including historic levels of funding. Recent actions taken by Congress include the following:

- On March 5, 2020, Congress passed the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, and on March 6, 2020, President Trump signed the bill into law.[50] The Act provided $8.3 billion in emergency funding for domestic and global efforts in responding to the COVID-19 outbreak. Of the $8.3 billion, $6.7 billion was designated for the domestic response and $1.6 billion was designated for the international response.[51] Of the $6.7 billion that was designated for the U.S. response, $6.2 billion was for HHS, including $3.4 billion for the Office of the Secretary – Public Health and Social Services Emergency Fund; $1.9 billion for the CDC; $836 million for the National Institute of Allergy and Infectious Diseases; and $61 million for the FDA.[52]

- On March 18, 2020, Congress passed, and President Trump subsequently signed into law, the Families First Coronavirus Response Act.[53] The Act provided more than $2.5 billion in additional emergency relief for domestic efforts in responding to the COVID-19 outbreak by providing paid sick leave and free coronavirus testing, expanding food assistance and unemployment benefits, and requiring employers to provide additional protections for health care workers.

- On March 27, 2020, Congress passed, and President Trump subsequently signed into law, the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act.[54] The CARES Act provided an additional $2.3 trillion in emergency funding relief for domestic and global efforts to address the COVID-19 pandemic, and contains a number of health-related provisions, including insurance coverage of COVID-19 testing. In addition, of the $2.3 trillion, the Act provided for $4.3 billion to CDC, including $300 million to be transferred to the Infectious Diseases Rapid Response Reserve Fund; not less than $500 million for global disease detection and emergency response; and not less than $1.5 billion for grants to or cooperative agreements with states, localities, territories, tribes, tribal organizations, urban Indian health organizations, or health service providers to tribes to carry out surveillance, epidemiology, laboratory capacity, infection control, mitigation, communications, and other preparedness and response activities. CARES also included $11 billion in funding for the Public Health and Social Services Emergency Fund to support the manufacturing, production, and purchase of vaccines, therapeutics, diagnostics, and other medical or preparedness needs. Coverage is provided for any future vaccine under Medicare Part B exempt from the deductible and at no cost in the

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[50] Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, Pub. L. 116-123 (2020).
[51] Stephanie Oum, Adam Wexler, and Jennifer Kates, *The U.S. Response to Coronavirus: Summary of the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020*, KAISER FAMILY FOUNDATION (Mar. 11, 2020), *available at* https://www.kff.org/global-health-policy/issue-brief/the-u-s-response-to-coronavirus-summary-of-the-coronavirus-preparedness-and-response-supplemental-appropriations-act-2020/.
[52] *Id*.
[53] Families First Coronavirus Response Act, Pub. L. 116-127 (2020).
[54] Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Pub. L. 116-136 (2020).

Medicaid program. The law also provides a state option to provide vaccine coverage for the uninsured through the Medicaid program.[55]

- On April 23, 2020, Congress passed, and President Trump subsequently signed into law, the Paycheck Protection Program and Health Care Enhancement Act.[56] The Act provided an additional $484 billion in funding relief to address the COVID-19 pandemic, including health related provisions and additional funding for the Paycheck Protection Program.[57] Among other things, the Act provided an additional $25 billion to the Public Health and Social Services Emergency Fund for necessary expenses to research, develop, validate, manufacture, purchase, administer, and expand capacity for COVID-19 tests to effectively monitor and suppress COVID-19, including, among other things, to conduct surveillance and contact tracing.[58] Of the $25 billion, the Act provided not less than $11 billion to states, localities, territories, and tribes to develop, purchase, administer, process, and analyze COVID-19 tests, scale-up laboratory capacity, trace contacts, and support employer testing, and required states and territories receiving funding to submit to the Secretary of HHS, its plan for COVID-19 testing, including goals for the remainder of calendar year 2020.[59] The state testing plans are required to be submitted no later than 30 days after April 24, 2020, when the Act became law.[60] In addition, the Act provided no less than $1 billion to CDC, and up to $1 billion to cover the cost of testing for the uninsured, among other provisions.[61]

In addition to these major pieces of legislation, Congress continues to monitor the nation's response to the COVID-19 pandemic to evaluate whether additional legislation is needed. In addition to monitoring whether additional resources are needed, Congress will continue to conduct oversight over the COVID-19 response, including new authorities provided and funding appropriated to address COVID-19 within the U.S.

IV. TESTING AND SURVEILLANCE FOR COVID-19

a. Types of Tests for COVID-19

There are currently two types of COVID-19 tests available—diagnostic tests, (viral detection tests) and antibody tests. Results from a diagnostic test indicate whether an individual has a current infection while results from an antibody test indicate whether an individual had a

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[55] *Id*.
[56] Paycheck Protection Program and Health Care Enhancement Act, Pub. L. 116-139 (2020).
[57] Kellie Moss, *The Paycheck Protection Program and Health Care Enhancement Act: Summary of Key Health Provisions*, KAISER FAMILY FOUNDATION (May 1, 2020), *available at* https://www.kff.org/coronavirus-covid-19/issue-brief/the-paycheck-protection-program-and-health-care-enhancement-act-summary-of-key-health-provisions/.
[58] Paycheck Protection Program and Health Care Enhancement Act, Pub. L. 116-139 (2020).
[59] *Id*.
[60] *Id*.
[61] Kellie Moss, *The Paycheck Protection Program and Health Care Enhancement Act: Summary of Key Health Provisions*, KAISER FAMILY FOUNDATION (May 1, 2020), *available at* https://www.kff.org/coronavirus-covid-19/issue-brief/the-paycheck-protection-program-and-health-care-enhancement-act-summary-of-key-health-provisions/.

previous infection. As of June 18, 2020, the U.S. Food and Drug Administration (FDA) had worked with more than 400 tests developers and has authorized 141 tests under Emergency Use Authorizations (EUAs), which include 120 molecular tests, 20 antibody tests, and 1 antigen test.[62] Both molecular tests and antigen tests are diagnostic tests.[63]

As of June 18, 2020, 26,500,497 COVID-19 test results had been reported, and 2,691,985 of those were positive test results.[64] Some states have included both antibody tests and viral tests in their submissions to CDC on total test counts; CDC and states are rapidly moving to a new, more detailed, file format that will differentiate the tests in reporting so that CDC can display the viral test data and serologic test data separately on the CDC COVID Data Tracker.[65]

i. Testing for an Active COVID-19 Infection

Widespread viral detection testing for COVID-19 allows for rapid detection of COVID-19 cases in the U.S. The FDA has therefore issued, and revised, guidance for laboratories and commercial manufacturers to help accelerate the use of tests that are developed.[66]

The FDA has defined COVID-19 molecular tests as tests that detect COVID-19 nucleic acids from human specimens.[67] Molecular tests, also referred to as nucleic acid amplification tests or PCR tests, indicate if a patient is actively infected with COVID-19.[68] The tests detect the presence of characteristic sequences of COVID-19 genetic material (RNA) in respiratory samples of patients. If the viral RNA is detected, it suggests COVID-19 is likely present.[69] Nucleic acid amplification testing requires respiratory samples from the patient since COVID-19 is a respiratory virus.[70] Nasopharyngeal swabs are commonly used to collect the sample for this type of testing, but the FDA has expanded the types of swabs that can be used to collect a sample

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[62] U.S. Food and Drug Administration, *Coronavirus (COVID-19) Update: Daily Roundup June 18, 2020* (June 19, 2020), *available at* https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-daily-roundup-june-18-2020.
[63] U.S. Food and Drug Administration, *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)* (May 2020), *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised.
[64] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19), Testing Data in the US* (last visited June 18, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/testing-in-us.html.
[65] *Id*.
[66] *See* U.S. Food and Drug Administration, *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)* (May 2020), *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised.
[67] U.S. Food and Drug Administration, *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)* (May 2020), *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised.
[68] American Society for Microbiology, *COVID-19 Testing FAQs* (Apr. 29, 2020), *available at* https://www.asm.org/Articles/2020/April/COVID-19-Testing-FAQs.
[69] Amy Maxmen, *Thousands of coronavirus tests are going unused in US labs*, NATURE (Apr. 9, 2020), *available at* https://www.nature.com/articles/d41586-020-01068-3.
[70] American Society for Microbiology, *COVID-19 Testing FAQs* (Apr. 29, 2020), *available at* https://asm.org/Articles/2020/April/COVID-19-Testing-FAQs.

and also approved a test that utilizes a saliva sample, which does not require a swab.[71] There are two types of these diagnostic tests: laboratory-based and rapid point-of-care tests.

Antigen tests look for antigens that the virus produces, which show its presence in blood and saliva. Antigen tests are less precise than PCR tests, but they enable fast and widespread testing. Moreover, the advantage of antigen testing over PCR tests is that it can show whether the virus is intact and still viable, and thus whether the patient is infectious. Dr. Deborah Birx, the White House Task Force Coordinator, has described antigen testing as a significant testing "breakthrough."[72] FDA recently granted an EUA to the first antigen test for COVID-19.[73]

ii. Testing for a Previous COVID-19 Infection

Antibody tests, also commonly referred to as serology tests, are simple blood tests that can detect whether a person has developed antibodies to the COVID-19 virus.[74] A person develops antibodies to a virus when a person is exposed to the virus and their immune system launches an antibody-forming immune response.[75]

Antibody tests must be differentiated from diagnostic tests that identify active infections and should not be used as the sole basis to diagnose an active infection for COVID-19.[76] Rather than detecting the virus itself, antibody tests detect the body's immune response to the infection caused by COVID-19.[77] According to the CDC, it may take an individual one to three weeks after infection to develop antibodies.[78] Currently, a positive antibody test only confirms that a person has or has had a COVID-19 infection.[79] We do not yet know whether a positive COVID-

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[71] On April 10, 2020, the FDA issued an EUA to Rutgers Clinical Genomics Laboratory -Rutgers University for a COVID-19 high complexity molecular-based laboratory developed test that uses saliva as the primary test biomaterial, or sample, for the COVID-19 virus. Rutgers, *New Rutgers Saliva Test for Coronavirus Gets FDA Approval* (Apr. 13, 2020), *available at* https://www.rutgers.edu/news/new-rutgers-saliva-test-coronavirus-gets-fda-approval; U.S. Food and Drug Administration, *Emergency Use Authorizations* (May 6, 2020), *available at* https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd.

[72] NBC News, *Birx: U.S. needs "breakthrough" on antigen testing to aid in reopening* (Apr. 27, 2020), *available at* https://www.nbcnews.com/politics/meet-the-press/birx-u-s-needs-breakthrough-antigen-testing-aid-re-opening-n1192901.

[73] On May 8, 2020, Quidel announced that the company had received an EUA from the FDA to market a rapid antigen COVID-19 diagnostic assay. Thomas M. Burton, *FDA Grants Emergency-Use Status for First Coronavirus Antigen Test*, THE WALL STREET JOURNAL (May 9, 2020), *available at* https://www.wsj.com/articles/fda-to-grant-emergency-use-status-for-first-coronavirus-antigen-test-by-quidel-corp-11589031815.

[74] Cynthia Demarco, *7 things to know about COVID-19*, MD Anderson Cancer Center (Apr. 22, 2020), *available at* https://www.mdanderson.org/publications/cancerwise/7-things-to-know-about-coronavirus-COVID19-antibody-testing.h00-159381156.html.

[75] *Id*.

[76] U.S. Food and Drug Administration, *EUA Authorized Serology Test Performance* (May 6, 2020), *available at* https://www.fda.gov/medical-devices/emergency-situations-medical-devices/eua-authorized-serology-test-performance.

[77] *Id*.

[78] Centers for Disease Control and Prevention, *Testing for COVID-19* (May 1, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/testing.html.

[79] National Cancer Institute, *NCI Part of Federal Effort to Evaluate Antibody Tests for Novel Coronavirus* (May 5, 2020), *available at* https://www.cancer.gov/news-events/cancer-currents-blog/2020/covid-19-nci-antibody-testing-review.

19 antibody test result also means that a person has full or partial immunity to COVID-19.[80] Researchers are currently trying to determine the appropriate use of antibody tests, whether someone who is antibody positive is resistant to reinfection, and if so, how long that person is resistant to reinfection.[81]

b. Testing Capacity

There have been significant obstacles to date in creating a unified and robust testing capacity in the U.S., including limited access to necessary supplies and not fully utilizing all available testing capacity. It has been reported that incomplete utilization has been in part caused by shortages of testing component supplies, staffing shortages, enough tests are not being ordered to fully utilize the capacity, and/or because people who are mildly symptomatic are instructed to stay home and not seek testing or health care, among other factors. In addition, before the passage of the Paycheck Protection Program and Health Care Enhancement Act, many states did not have plans to identify all testing capacity currently available to them.[82] States now must submit plans that consider which populations should be prioritized for testing, where those testing locations should be, which labs should process which tasks. Given these challenges, the U.S. has focused a significant amount of effort on increasing testing capacity, including working with the states to identify the testing capacity available to them and to secure the necessary supplies to meet their goals.[83]

In a recent report to Congress, titled the "COVID-19 Strategic Testing Plan," the Trump Administration highlighted the enhanced testing capacity over the last few months. For example, in early March, only a few thousand COVID-19 tests were performed each day.[84] By mid-May, about 300,000 COVID-19 tests were performed each day, with the number of tests performed increasing by 25 to 30 percent per week.[85] On average, a little over 460,000 tests have been conducted each day in the month of June.[86] According to the plan, the U.S. will be able to perform at least 40 to 50 million tests per month by September.[87]

It has been reported that available capacity at commercial and academic laboratories in the U.S. is not being fully utilized due to a shortage of testing component supplies and low order

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[80] Cynthia Demarco, *7 things to know about COVID-19*, MD Anderson Cancer Center (Apr. 22, 2020), *available at* https://www.mdanderson.org/publications/cancerwise/7-things-to-know-about-coronavirus-COVID19-antibody-testing.h00-159381156.html.
[81] U.S. Food and Drug Administration, *EUA Authorized Serology Test Performance* (May 6, 2020), *available at* https://www.fda.gov/medical-devices/emergency-situations-medical-devices/eua-authorized-serology-test-performance; Centers for Disease Control and Prevention, *Serology Testing* (May 5, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/lab/serology-testing.html.
[82] Rich Lowry, *The Media Said Trump Didn't Have a COVID Testing Strategy. The Media Was Wrong.* THE NATIONAL REVIEW (June 14, 2020), *available at* https://www.nationalreview.com/2020/06/coronavirus-media-wrong-about-trump-testing-strategy/.
[83] *Id*.
[84] U.S. Dep't of Health and Human Services, *Report to Congress, COVID-19 Strategic Testing Plan*, at 10 (May 24, 2020).
[85] *Id*.
[86] The COVID Tracking Project, *US Daily Cumulative Totals*, (last visited June 19, 2020), *available at* https://covidtracking.com/data/us-daily.
[87] *Id*. at 19.

volumes because people who are mildly symptomatic are instructed to stay home and not seek testing, among other factors.[88] The federal government has taken a number of actions to address supply chain issues. For example, through the Laboratory Diagnostic Testing Task Force, the federal government has closely coordinated with commercial manufacturers and laboratories to develop a better understanding of challenges in the supply chain and expected inventory.[89] Moreover, HHS and the Federal Emergency Management Agency (FEMA) have procured swabs and viral transport media that they have provided to states in support of state testing plans.[90] As of June 17, 2020, FEMA has procured and distributed to the states 25.9 million swabs and 16.4 million units of viral transport media.[91]

The Trump Administration has entered into public-private partnerships with stakeholders to increase testing capacity. For example, the Administration worked with private industry to establish a drive-through testing program that continues to expand with the use of provider-administered swab tests at various retail locations. As of June 16, 2020, there were over 3,163 drive-through testing sites nationwide.[92] Similarly, the White House Task Force established the Community-Based Testing Sites (CBTS) program to expand critical testing capacity for symptomatic and asymptomatic individuals, while sharing best practices for testing sample collection and preserving personal protective equipment (PPE).[93]

Additional examples of the steps the federal government has taken to increase testing capacity and testing supplies in the U.S. are discussed in Section V of this memorandum.

c. COVID-19 Surveillance

i. U.S. Surveillance Systems for COVID-19

According to the CDC, "[p]ublic health surveillance is the ongoing, systematic collection, analysis, and interpretation of health related data essential to planning, implementation, and evaluation of public health practice."[94] The U.S.' COVID-19 surveillance goals are to: (1) monitor the spread and intensity of COVID-19 disease in the U.S.; (2) understand disease severity and the spectrum of illness; (3) understand risk factors for severe disease and

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[88] Brianna Abbott and Sarah Krouse, *Coronavirus Testing Capacity is Going Unused*, THE WALL STREET JOURNAL (Apr. 29, 2020), *available at* https://www.wsj.com/articles/coronavirus-testing-capacity-is-going-unused-11588152602.
[89] U.S. Dep't of Health and Human Services, Report to Congress, COVID-19 Strategic Testing Plan, at 28 (May 24, 2020).
[90] *Id*. at 28.
[91] FEMA Weekly Update: Coronavirus Pandemic Whole-of-America Response (June 18, 2020) (on file with Committee).
[92] Mui, Katie, *Where Can I Get a Drive-Thru Coronavirus (COVID-19) Test Near Me?*, GOODRX (June 19, 2020), *available at* https://www.goodrx.com/blog/drive-thru-coronavirus-testing-near-me/.
[93] Claire Duffy, *Bill Gates explains how the United States can safely ease coronavirus restrictions*, CNN BUSINESS (Apr. 26, 2020), *available at* https://www.stltoday.com/business/bill-gates-explains-how-the-united-states-can-safely-ease-coronavirus-restrictions/article_ed0e7d45-e049-597c-a4eb-ca8687a674ff.html.
[94] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19), FAQ Data & Surveillance* (last updated Apr. 17, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/covid-data/faq-surveillance.html.

transmission; (4) monitor for changes in the virus that causes COVID-19; (5) estimate disease burden; and (6) produce data for forecasting COVID-19 spread and impact.[95]

, CDC is using multiple surveillance systems to monitor COVID-19 in the U.S., but the U.S. does not currently have a unified, comprehensive, and designated national surveillance system specific to COVID-19 and existing efforts leverage coordination with a wide variety of partners.[96] CDC's surveillance program for COVID-19 "is built on a combination of existing influenza and viral respiratory diseases surveillance systems, syndromic surveillance systems, case reporting systems, proactive monitoring for asymptomatic cases in areas of demonstrated vulnerabilities, commercial laboratory reporting, ongoing research platforms employed for the COVID-19 response, and new systems."[97] The CDC uses multiple systems and epidemiology networks that "use laboratory submitted specimens, electronically transmitted data, and other sources to generate an ongoing picture of disease spread, intensity, and severity, and produce data to address the key questions for directing and refining the US response."[98]

On April 3, 2020, the CDC launched a website—COVIDView—which "provides a weekly surveillance summary and interpretation of a variety of surveillance systems that will be used to track the progression and severity of COVID-19 disease throughout the course of the pandemic" in the U.S.[99] The data summarized in COVIDView comes "from a combination of existing influenza and viral respiratory disease surveillance systems, syndromic surveillance systems, and reporting laboratory results," which together "create an ongoing picture of the spread of SARS-CoV-2 and its effects in the United States and provides data to inform the U.S. national public health response to COVID-19."[100] In addition, CDC's COVID Data Tracker contains the total number of COVID-19 cases and deaths in the U.S., as well as breakdowns by state, reported to CDC by state and territorial jurisdictions since January 21 2020, with the exception of those who were repatriated to the U.S. from Wuhan, China, and Japan.[101] In addition to tracking the number of cases, the CDC COVID Data Tracker has a page specifically devoted to U.S. testing figures, including national and state data, which is reported by U.S. laboratories, including commercial and reference labs, public health laboratories (PHLs), and hospital laboratories.[102]

ii. Enhancing the U.S. Surveillance System for COVID-19

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[95] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19), COVIDView, Purpose and Method* (last updated Apr. 17, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/purpose-methods.html.
[96] *Id*.
[97] Centers for Disease Control and Prevention, *CDC Activities and Initiatives Supporting the COVID-19 Response and the President's Plan for Opening America Up Again* (May 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/downloads/php/CDC-Activities-Initiatives-for-COVID-19-Response.pdf.
[98] *Id*.
[99] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19), Purpose & Methods, COVIDView* (last updated Apr. 17, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/purpose-methods.html.
[100] *Id*.
[101] Centers for Disease Control and Prevention, *CDC COVID Data Tracker* (last visited May 28, 2020), *available at* https://www.cdc.gov/covid-data-tracker/.
[102] *Id*.

Congress has previously provided funding to improve public health surveillance, including for a multi-year effort to support modernization of public health data surveillance and analytics. In addition, Congress has taken recent action to enhance surveillance systems.

For example, the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, which was signed into law on March 6, 2020, provided not less than $950 million for grants to or cooperative agreements with states, localities, territories, tribes, tribal organizations, urban Indian health organizations, and health service providers to tribes to carry out surveillance, epidemiology, laboratory capacity, infection control, mitigation, communications, and other preparedness and response activities.[103]

In addition, the Coronavirus, Aid, Relief, and Economic Security Act (CARES Act), which was signed into law on March 27, 2020, provided not less than $500 million for public health data surveillance and analytics infrastructure modernization and not less than $1.5 billion for grants to or cooperative agreements with states, localities, territories, tribes, tribal organizations, urban Indian health organizations, and health service providers to tribes to carry out surveillance, epidemiology, laboratory capacity, infection control, mitigation, communications, and other preparedness and response activities.[104] Further, the Act requires any laboratory that performs tests to detect COVID-19 to report the results, both positive and negative, to the Secretary of HHS during the period of the public health emergency.[105]

In addition, the Paycheck Protection Program and Health Care Enhancement Act, which was signed into law on April 24, 2020, provided an additional $25 billion to the Public Health and Social Services Emergency Fund for necessary expenses to research, develop, validate, manufacture, purchase, administer, and expand capacity for COVID-19 tests to monitor and suppress COVID-19, including, among other things, to conduct surveillance and contact tracing.[106]

d. Executive Branch Actions on Testing

Since early January, the Executive Branch has taken action to prepare for, and respond to, the COVID-19 pandemic, even before the first patient with confirmed COVID-19 was identified in the U.S. For example, on January 7, 2020, CDC established a COVID-19 Incident Management System, and on January 21, 2020, CDC activated its Emergency Operations Center to improve the provision of ongoing support to the COVID-19 response. On January 31, 2020, HHS Secretary Azar declared a public health emergency for the U.S. In addition, on February 25, 2020, President Trump announced that Vice President Pence would lead the Administration's response to COVID-19. On March 13, 2020, President Trump declared a national emergency as a result of the COVID-19 pandemic.

i. Efforts to Increase Testing Capacity in the U.S.

[103] Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, Pub. L. 116-123 (2020).
[104] Coronavirus Aid, Relief, and Economic Security (CARES) Act, Pub. L. 116-136 (2020).
[105] *Id*.
[106] Paycheck Protection Program and Health Care Enhancement Act, Pub. L. 116-139 (2020).

On January 10, 2020, China researchers posted the sequencing of COVID-19 and two weeks later, on January 24, 2020, CDC publicly posted the assay protocol for the reverse transcription polymerase chain reaction (RT-PCR) test. On February 3, 2020, CDC submitted an EUA package to the FDA to expedite FDA's permitted use of the CDC diagnostic panel in the U.S. On February 4, 2020, FDA issued the EUA for the CDC diagnostic panel and distribution of the test kits began the following day. CDC began shipping the sharable viral stocks to the BEI biorepository on February 4, 2020, to enable broad sharing with appropriate entities. On February 8, 2020, CDC was made aware of performance issues with respect to one of the three reagents, which led to some laboratories not being able to verify the test performance. CDC and FDA investigated the problem, and the agencies determined a solution to remanufacture the reagents and distribute new test kits. On February 27, 2020, CDC began distributing new tests kits and the next day approximately 40 PHLs in the U.S. were able to perform the diagnostic test.

On February 29, 2020, FDA issued guidance to provide a policy for certain laboratories—laboratories certified to perform high-complexity testing under the Clinical Laboratory Improvement Amendments (CLIA)—seeking to develop diagnostic tests for COVID-19 in order to achieve more rapid testing capacity.[107] On March 16, 2020, FDA announced updated guidance allowing states to take responsibility for tests developed and used by laboratories in their states.[108] According to this policy, states can set up a system in which they take responsibility for authorizing such tests, and the laboratories will not engage directly with the FDA.[109] In addition, the March 16 guidance expanded the February 29 guidance to include commercial manufacturers distributing and labs using new commercially developed tests in addition to CLIA laboratories.

ii. Efforts to Increase Testing Supplies in the U.S.

As the number of COVID-19 tests and testing capacity ramped up across the nation, the U.S. began to see supply shortages for various components needed to collect samples and perform the tests, including swabs, transport media, reagents, and PPE for individuals collecting and testing samples. Due to a shortage of supplies needed to administer COVID-19 diagnostic tests, on March 19, 2020, HHS and the U.S. Department of Defense (DOD) coordinated an emergency international airlift of 500,000 swabs and sample kits used in the COVID-19 testing process in an effort to increase diagnostic testing in the U.S. In addition, on March 23, 2020, FDA approved self-collected samples for testing, which was done to reduce the strain on medical supplies and professionals. This approval allowed for foam swabs swabbed shallowly in the nose to be used in lieu of nasopharyngeal swabs. Further, FDA provided updated guidance on

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[107] U.S. Food and Drug Administration, *Coronavirus (COVID-19) Update: FDA Issues New Policy to Help Expedite Availability of Diagnostics* (Feb. 29, 2020), *available at* https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-new-policy-help-expedite-availability-diagnostics.

[108] U.S. Food and Drug Administration, *Coronavirus (COVID-19) Update: FDA Provides More Regulatory Relief During Outbreak, Continues to Help Expedite Availability of Diagnostics* (Mar. 16, 2020), *available at* https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-more-regulatory-relief-during-outbreak-continues-help.

[109] *Id.*

March 24, 2020, regarding the use of swabs, including the types of swabs that providers can use for COVID-19 tests.[110]

On March 29, 2020, President Trump announced that FEMA is working with the private sector to launch Project Airbridge to expedite the movement of critical supplies from other countries to the U.S., including respirators, gloves, surgical masks, surgical gowns, thermometers, face shields, coveralls, stethoscopes, oxygen masks, and cannulas. While these supplies are largely used by health care workers caring for and treating patients, some of these supplies, particularly the PPE, are also used by those administering and performing COVID-19 tests. As of June 17, 2020, Project Airbridge has completed 227 flights with an additional 22 scheduled, or in transit, for a total of approximately 249 flights.[111] Project Airbridge is one example of efforts by the federal government's Supply Chain Stabilization Task Force, which was created "to address limited supply of critical protective and life-saving equipment."[112]

To support the Administration's Testing Blueprint and state goals for testing, FEMA is also working to source and procure testing materials, specifically testing swabs and transport media. As of June 17, FEMA has procured and delivered 25.9 million swabs and 16.4 million units of media.[113]

V. VACCINE AND THERAPEUTIC DEVELOPMENT

In partnership with extensive efforts from the private sector, the federal government is supporting several additional initiatives to help accelerate the development of vaccines and therapeutics for COVID-19. Some of these initiatives include, but are not limited to Operation Warp Speed and the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership.

The Trump Administration established Operation Warp Speed to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics.[114] Operation Warp Speed is a partnership among components of HHS, including the CDC, FDA, NIH, BARDA (Biomedical Advanced Research and Development Authority), and the DOD.[115] The partnership will also engage with private entities and other federal agencies such as the Department of Agriculture, the Department of Energy, and the Department of

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[110] U.S. Food and Drug Administration, *FAQs on Testing for SARS-CoV-2* (last visited May 28, 2020), *available at* https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2#troubleobtainingviraltransport.
[111] Weekly Update: Coronavirus Pandemic Whole-of-America Response (June 18, 2020) (on file with the Committee).
[112] FEMA, *Coronavirus (COVID-19) Pandemic: Supply Chain Stabilization Task Force* (Mar. 30, 2020), *available at* https://www.fema.gov/fema-supply-chain-stabilization-task-force.
[113] FEMA Weekly Update: Coronavirus Pandemic Whole-of-America Response (June 18, 2020) (on file with Committee).
[114] U.S. Dep't of Health and Human Services, *Trump Administration Announces Framework and Leadership for 'Operation Warp Speed'* (May 15, 2020), *available at* https://www.hhs.gov/about/news/2020/05/15/trump-administration-announces-framework-and-leadership-for-operation-warp-speed.html.
[115] U.S. Dep't of Health and Human Services, *Fact Sheet: Explaining Operation Warp Speed* (Jun. 16, 2020), *available at* https://www.hhs.gov/about/news/2020/06/16/fact-sheet-explaining-operation-warp-speed.html.

Veterans Affairs (VA).[116] Among other things, the goal of Operation Warp Speed is to have a significant amount—300 million doses—of safe and effective vaccine for COVID-19 available to Americans by January 2021.[117] Operation Warp Speed is assisting with the development, manufacture, and distribution of medical countermeasures for COVID-19, including vaccines.

The three main areas where Operation Warp Speed will accelerate the timeframe for countermeasures to reach the American public include development, manufacturing, and distribution.[118]

- *Development*: Operation Warp Speed will select the most promising countermeasure candidates and provide coordinated government support to support their development; align protocols for the demonstration of safety and efficacy, which will allow the trials to proceed more quickly; and protocols for the trials will be overseen and set by the federal government.[119]

- *Manufacturing*: The federal government is making investments in manufacturing and distribution at its own risk earlier than usual, giving companies confidence that they can invest in development; manufacturing capacity for selected candidates will be advanced while they are still in development; and manufacturing capacity developed will be used, to the extent practicable, for whatever vaccine is successful, regardless of which companies have developed the capacity.[120]

- *Distribution*: Before the countermeasures are approved or authorized, the program will build the necessary plans and infrastructure for distributing them; Operation Warp Speed will focus on expanding supplies of specialized materials and resources, such as cold-chain supply, glass vials, and other materials, that can be necessary for distribution of countermeasures; and once a product is ready, the Department of Defense's involvement will enable faster distribution and administration.[121]

For the development of vaccines, Operation Warp Speed will select the most promising candidates and provide coordinated government support to assist with their development. As of May 15, Operation Warp Speed had chosen 14 promising vaccine candidates from the list of over 100 vaccine candidates currently in development. From there, 8 vaccine candidates would be selected from the list of 14 to go through additional testing in early stage small clinical trials. Then, large-scale randomized trials for the demonstration of safety and efficacy will proceed for 3 to 5 of the candidates. Finally, additional non-clinical testing will be performed at the same time when possible.[122]

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[116] *Id*.
[117] U.S. Dep't of Health and Human Services, *Trump Administration Announces Framework and Leadership for 'Operation Warp Speed'* (May 15, 2020), *available at* https://www.hhs.gov/about/news/2020/05/15/trump-administration-announces-framework-and-leadership-for-operation-warp-speed.html.
[118] *Id*.
[119] *Id*.
[120] *Id*.
[121] *Id*.
[122] *Id*.

Operation Warp Speed is working to align protocols for the demonstration of safety and efficacy to help clinical trials proceed more quickly. Clinical trial protocols will be overseen by the federal government rather than the more traditional model where pharmaceutical companies design their own protocols.[123]

While some have raised concerns that the federal government is sacrificing safety to quickly advance a vaccine candidate to market, administration officials have stated that while the timelines are being modified, the scientific standards that must be met are not.[124] In order to shorten the development timeline, many of the necessary steps are being conducted concurrently as opposed to completing one step in the process at a time, as is typically done.[125]

For manufacturing, the federal government will make investments in manufacturing and distribution of top vaccine candidates at its own risk—the manufacturing and distribution capacity of the top 3 to 5 leading vaccine candidates will be enhanced while the vaccine candidates are still in development.[126] HHS' agreements with vaccine candidate manufacturers such as AstraZeneca, Moderna, and Johnson & Johnson include investments in manufacturing capabilities.

To expand domestic manufacturing capabilities, on June 1, 2020, Emergent BioSolutions announced that they had expanded their 2012 Center for Innovation in Advanced Development and Manufacturing (CIADM) contract with BARDA "to deploy its contract development and manufacturing (CDMO) capacities, capabilities, and expertise to support the U.S. government's efforts to accelerate delivery of COVID-19 vaccines."[127] Under the $628 million task order, Emergent will use $85.5 million to expand Emergent's viral and non-viral CDMO drug product fill/finish capabilities in Camden and Rockville, and Emergent will use $542.7 million to offer molecule-to-market CDMO services and provide manufacturing capacity.[128] The task order creates a U.S.-based manufacturing supply chain for COVID-19 vaccine developers by expanding the original contract with BARDA establishing Emergent's Baltimore Bayview facility as a CIADM to include investments in Emergent's Rockville and Baltimore Camden facilities.[129]

The National Institutes of Health (NIH) is engaged in several efforts to respond to the COVID-19 pandemic, including, but not limited to, accelerating the development and manufacturing of COVID-19 vaccine and treatment options.

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[123] *Id.*
[124] USA Today, *Operation Warp Speed officials deflect criticism: 'We are taking every possible step' for safe COVID-19 vaccine* (June 16, 2020), *available at* https://www.usatoday.com/story/news/health/2020/06/16/administration-promises-safe-effective-covid-19-vaccine-january-operation-warp-speed/3198519001/.
[125] *Id.*
[126] *Id.*
[127] Emergent BioSolutions, *Emergent BioSolutions Joins U.S. Government's Warp Speed Program in Landmark Public-Private CDMO Partnership for COVID-19 Vaccine Development and Manufacturing* (June 1, 2020), available at https://investors.emergentbiosolutions.com/node/19601/pdf.
[128] *Id.*
[129] *Id.*

On April 17, 2020, the NIH announced the ACTIV public-private partnership to speed vaccine and treatment options. The ACTIV partnership is coordinated by the Foundation for the National Institutes of Health (FNIH) and brings together: (1) other divisions of HHS, including BARDA, CDC, and the FDA; (2) other government agencies, including the DOD and the VA; (3) the European Medicines Agency (EMA); and (4) representatives from academia, philanthropic organizations, and several biopharmaceutical companies.[130] The ACTIV partnership will develop a collaborative framework for prioritizing vaccine and drug candidates, streamlining clinical trials, coordinating regulatory processes, and/or leveraging assets among all partners to rapidly respond to the COVID-19 pandemic.[131]

ACTIV has four working groups, each with one cochair from NIH and one from industry: (1) The Preclinical Working Group; (2) The Therapeutics Clinical Working Group; (3) The Clinical Trial Capacity Working Group; and (4) The Vaccines Working Group.[132]

- *The Preclinical Working Group* is "charged to standardize and share preclinical evaluation resources and methods and accelerate testing of candidate therapies and vaccines to support entry into clinical trials."[133] The goals of this working group are to increase access to animal models and identify informative assays.[134]

- *The Therapeutics Clinical Working Group* is "charged to prioritize and accelerate clinical evaluation of a long list of therapeutic candidates for COVID-19 with near-term potential."[135] The goals of this working group are to prioritize and test potential therapeutic agents and develop master protocol for clinical trials.[136]

- *The Clinical Trial Capacity Working Group* is "charged with assembling and coordinating existing networks of clinical trials to increase efficiency and build capacity."[137] The goals of this working group are to develop survey instruments, develop inventory of clinical trial networks, and guide deployment of innovative solutions.[138]

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[130] National Institutes of Health, *Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)* (last visited Jun. 14, 2020), *available at* https://www.nih.gov/research-training/medical-research-initiatives/activ.
[131] National Institutes of Health, *NIH to launch public-private partnership to speed COVID-19 vaccine and treatment options* (Apr. 17, 2020), *available at* https://www.nih.gov/news-events/news-releases/nih-launch-public-private-partnership-speed-covid-19-vaccine-treatment-options.
[132] Francis S. Collins, MD, PhD, Paul Stoffels, MD, *Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV), An Unprecedented Partnership for Unprecedented Times*, JAMA NETWORK (May 18, 2020), *available at* https://jamanetwork.com/journals/jama/fullarticle/2766371?guestAccessKey=5defc755-e585-47e5-b79a-fee2ec2dd42b&utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_content=tfl&utm_term=051820.
[133] *Id.*
[134] *Id.*
[135] *Id.*
[136] *Id.*
[137] *Id.*
[138] *Id.*

- *The Vaccines Working Group* is "charged to accelerate evaluation of vaccine candidates to enable rapid authorization or approval."[139] The goals of this working group are to accelerate evaluation of vaccine candidates, identify biomarkers to speed approval, and provide evidence to address safety concerns.[140]

In April, FDA launched the Coronavirus Treatment Acceleration Program (CTAP), an emergency program for possible therapies, to use every available method to move new treatments to patients as soon as possible, while at the same time finding out whether they are helpful or harmful.[141] FDA received 950 inquiries and proposals for COVID-19 related drug development.[142] As of May 11, 2020, there are 144 active trials of therapeutic agents and another 457 development programs for therapeutic agents in the planning stages.[143]

The National Institute of Allergy and Infectious Diseases (NIAID) is engaged in numerous efforts to respond to the COVID-19 pandemic, including supporting clinical research to prevent, treat, and better understand COVID-19.[144] For example, NIAID is working with Moderna to conduct clinical studies of the vaccine candidate that they developed, mRNA-1273.[145]

BARDA, which is part of the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR), was established to help protect the country from chemical, biological, radiological, and nuclear threats, and also from pandemic influenza and emerging infectious diseases.[146] To respond to the COVID-19 pandemic, BARDA is rapidly developing new partnerships and building a robust COVID-19 Medical Countermeasure Portfolio, among other things.[147] These partnerships include partnerships focused on vaccines, diagnostics, therapeutics, rapidly deployable capabilities, and other items.[148] BARDA has provided more than $2.2 billion in funding to select vaccine candidates, including providing funding for vaccines to ModernaTX,

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[139] *Id*.
[140] *Id*.
[141] Stephen M. Hahn, M.D., Commissioner of Food and Drugs, Peter Marks, M.D., Ph.D., Director, Center for Biologics Evaluation and Research and Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, FDA, *The Path Forward: Coronavirus Treatment Acceleration Program* (Apr. 20, 2020), *available at* https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/path-forward-coronavirus-treatment-acceleration-program.
[142] U.S. Food and Drug Administration, *Coronavirus Treatment Acceleration Program (CTAP), available at* https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap#:~:text=FDA%20has%20created%20a%20special,they%20are%20helpful%20or%20harmful (last accessed on June 19, 2020).
[143] *Id*.
[144] National Institute of Allergy and Infectious Diseases (NIAID), *NIAID COVID-19 Clinical Research* (last visited Jun. 14, 2020), *available at* https://www.niaid.nih.gov/diseases-conditions/covid-19-clinical-research.
[145] *Id*.
[146] U.S. Dep't of Health and Human Services, *Biomedical Advanced Research and Development Authority* (last visited Jun. 13, 2020), *available at* https://www.phe.gov/about/barda/Pages/default.aspx.
[147] U.S. Dep't of Health and Human Services, *BARDA's Rapidly Expanding COVID-19 Medical Countermeasure Portfolio* (last visited June. 13, 2020), *available at* https://www.medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx.
[148] *Id*.

Inc., AstraZeneca and the University of Oxford, Johnson & Johnson, Merck, and Protein Sciences, a Sanofi company.[149]

VI. STAFF CONTACTS

If you have any questions regarding this hearing, please contact J.P. Paluskiewicz and Jen Barblan of the Republican Committee staff.

[149] *Id*.