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**Homeland Security &
Governmental Affairs**

U.S. Senator Gary Peters | Chairman

Historically Unprepared

*Examination of the Federal
Government's Pandemic
Preparedness and Initial COVID-19
Response*

*A HSGAC Majority Staff Report
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EXECUTIVE SUMMARY

The COVID-19 pandemic has devastated communities in the United States and across the globe. As of November 2022, over six and a half million people worldwide have died directly from COVID-19, with more than one million lives lost in the United States alone. For almost three years, the pandemic has upended both lives and livelihoods, leading to record unemployment levels, lost businesses, and challenges for many seeking to obtain basic necessities like food or shelter. It has disrupted the continuity of society, leaving parents without childcare, students without consistent schooling, and teachers navigating new forms of learning. The pandemic has also exacerbated other preexisting public health crises, including mental health, suicide, and addiction. Vulnerable populations have suffered disproportionate health disparities and economic harm.

Many of these deaths and much of the economic fallout could have been prevented. Although the federal government has prepared for public health threats for decades—creating planning documents, working with states to build response capabilities, and identifying shortfalls based on prior public health emergencies like H1N1 influenza, Ebola, and Zika—these actions proved insufficient for COVID-19. Despite repeated warnings, systemic inadequacies in public health surveillance systems, years of insufficient funding, overdependence on foreign supply chains, and growing medical and public health staffing shortages, all contributed to what has become one of the worst public health responses in U.S. history.

Recommended reforms to address lessons from prior public health crises—including conflicting authorities, overlapping roles and responsibilities, and interagency coordination challenges—have gone unimplemented for years. Prior pandemic planning focused primarily on influenza pandemics and failed to sufficiently account for the emergence of other novel pathogens that might present new challenges. Decades of increasing overreliance on foreign sources, predominately in Asia, for essential drugs and medical supplies—including the materials needed to make these products—left the U.S. with insufficient domestic manufacturing capacity to rapidly produce and distribute critical medical supplies.

The COVID-19 pandemic was not the first extraordinary crisis the federal government has faced in recent years, nor will it be the last. In a wide-ranging 2006 review of the federal response to Hurricane Katrina—one of the worst natural disasters on record in the U.S.—this Committee identified four key factors that contributed to the government’s failed response: “(1) long-term warnings went unheeded and government officials neglected their duties to prepare for a forewarned catastrophe; (2) government officials took insufficient actions or made poor decisions in the days immediately before and after landfall; (3) systems on which officials relied on to support their response efforts failed; and (4) government officials at all levels failed to provide effective leadership.” Fifteen years later, facing a public health crisis with many of the same critical federal preparedness and response priorities that apply in disaster response efforts, the federal government repeated these same failures with respect to its preparation for and initial response to the COVID-19 pandemic.

To better understand the initial federal response to the COVID-19 pandemic and assess reforms needed to address how our nation prepares for and responds to future public health threats, U.S. Senator Gary Peters, Chairman of the Homeland Security and Governmental Affairs Committee, directed Majority Committee staff to investigate the federal government’s initial actions in response to the evolving COVID-19 threat, evaluate the sufficiency of those actions, and propose recommendations to strengthen federal readiness for future public health crises. This report examines the federal government’s initial actions as the novel coronavirus threat emerged in late 2019 and early federal response efforts through March 2020 as the virus quickly spread throughout the U.S. and around the world. The report details the Committee’s findings and recommendations following an almost two year review.

For decades, officials and experts in both the private and public sector warned that planning deficiencies and a failure to adapt prior responses to new public health threats would hamper any future response. As detailed in this report, the initial federal response and actions taken by the Trump Administration at the time did not reflect the severity of the crisis and ultimately failed to effectively mitigate the spread of COVID-19.

Detection and Surveillance. On December 30, 2019, the U.S. Department of Health and Human Services’ (HHS) Centers for Disease Control and Prevention (CDC) learned of an emerging novel pathogen, now known as SARS-CoV-2 (the virus that causes COVID-19), through publicly available information in an open source report. The Department of Defense (DOD) and Department of Homeland Security (DHS) learned of the emerging threat through the same public report. None of the agencies interviewed by this Committee between 2021 and 2022, including DOD, DHS, and HHS, used classified or nonpublic information to identify the existence of the emerging novel coronavirus threat, which had been circulating in China for multiple weeks prior.

While China withheld information that would have helped inform decision-making, the U.S. failed to heed critical public warnings that foreshadowed the severity and transmissibility of the virus. These included public news reports of activity in China throughout January 2020 that identified rapid construction of a new 1,000 bed hospital in Wuhan, where the outbreak in China began, a video of bodies covered in sheets throughout a hospital hallway, and multiple citywide mask mandates and lockdowns. In late January 2020, the Deputy National Security Advisor received firsthand accounts from Chinese scientists, which were immediately reported to former President Trump, indicating there was uncontrolled community spread of the virus in China, asymptomatic spread in roughly half of the cases, and warned, “don’t think 2003, think 1918”—the year of the most severe pandemic in over a century. By the end of January 2020, the virus had spread to 18 countries and multiple governments began initiating export bans on personal protective equipment (PPE). By early February 2020, current and former federal officials—performing analyses using publicly available data—recognized what the Trump Administration did not: that the gravity and extent of the unfolding threat would likely require rapid and widespread interventions beyond containment.

The early months of 2020 were flooded with a series of missteps and missed opportunities. Throughout January and February 2020, CDC’s surveillance missed at least half of the cases that came into the country, resulting in false assurances to the American people that

there was no community spread in the U.S. Blood samples from donors in nine states later revealed the virus was circulating in the U.S. as early as mid-December 2019. The U.S. confirmed its first case of COVID-19 on January 21, 2020. Ten days later, then HHS Secretary Alex Azar declared a public health emergency and the United States implemented travel restrictions from China. Throughout February 2020, the State Department noted a multitude of public actions taken by China in response to growing case numbers, including plans to convert gymnasiums and exhibition centers into hospitals and release over \$28 million for hospitals near Wuhan to purchase medical supplies. Ultimately, the Trump Administration waited until March 16, 2020—fifty-five days from the date of the first confirmed case—to implement its first wide scale attempt at nationwide mitigation of viral spread.

Testing. CDC’s initial efforts to develop and manufacture a test to diagnose patients failed and the agency took weeks to identify the underlying problem. While public reporting suggests a consensus on the cause of CDC’s test kit failure, information obtained by the Committee indicates there were and continue to be conflicting internal accounts of not only what went wrong, but also the reasons for those failures. CDC’s and the Food and Drug Administration’s (FDA) insufficient private sector engagement from the outset, coupled with unaddressed regulatory barriers, left the U.S. without sufficient testing capacity and surveillance needed to effectively assess the virus’s spread. Throughout January and February 2020, CDC’s in-house diagnostic test, which required all samples to be processed in Atlanta and came with a multi-day turnaround, and its flawed COVID-19 test kits, which posed a number of problems, were the only options available to a subset of American people that fit within CDC’s narrow testing guidance. As of February 29, 2020—by which time tens of thousands of Americans had likely been infected—CDC had tested fewer than 1,200 individuals for COVID-19.

Medical Supply Chain. Insufficient domestic manufacturing capacity in the U.S. and a lack of visibility into supply chain dependence further impacted federal response efforts. By early February 2020, China nationalized its medical supply production and several countries had imposed export restrictions on PPE. FDA lacked authority to require suppliers to report critical manufacturing information and agencies relied on inefficient methods, such as phone calls and voluntary surveys, to collect needed supply chain data from manufacturers, some of whom were hesitant to share their supply chain information. Unprecedented demand coupled with limited supply exposed long known supply chain vulnerabilities from U.S. dependence on foreign sources for critical medical products, including surgical masks, gowns, and gloves—all of which relied on foreign sources for at least 80 percent of production.

Although the federal government had known for years—as detailed in prior public reports and interviews with the Committee—that its federal stockpile contained only a small fraction of the PPE needed to protect health care workers, the Trump Administration allowed the State Department to ship 17.8 tons of donated PPE to China using repatriation flights throughout early February 2020. In mid-February 2020, HHS internally assessed that there were “no known immediate problems with medical supply chains,” contrary to multiple contemporaneous reports of PPE supply chain issues. For example, a February 7, 2020 State Department memorandum for the Deputy Secretary of State reported a large PPE manufacturer would only be able to produce “10 percent of its hazmat and surgical gown inventory” due to a lack of fabric needed from its Wuhan-based supplier, and a February 8, 2020 DHS interagency report noted 96 percent

of pharmacy owners and managers reported a shortage of surgical masks. By late March 2020, dire supply shortages of PPE left health care providers having to reuse N95 respirators or wearing garbage bags in some states.

Despite repeated and direct warnings from domestic manufacturers, the federal government failed to enter into any large-scale PPE contracts until March 21, 2020. As a result, PPE product delivery from those contracts did not begin until May 2020 due to logistics and supply shortages. The orders delivered during the month of May comprised less than two percent of the federal government's initial contracts for 598 million N95 respirators from five manufacturers. When one domestic PPE manufacturer sent multiple warnings and requests to ramp up U.S. production throughout the months of January, February, and March 2020, the federal government declined to engage. Months later, in May 2020 when the federal government decided to extend a one-year federal PPE contract to that same PPE manufacturer, the company declined the contract offer as too short, and therefore not sustainable, noting it would use its excess capacity to try and obtain long-term hospital contracts.

By April 2020—within a month and a half of beginning shipments—the federal government distributed the entirety of its PPE supply held for states from the Strategic National Stockpile. In addition, the federal government decided to distribute that PPE proportionally to the states based on population rather than need. According to federal PPE request and distribution records from March 2020, there was at least a week delay between several states requesting supplies and the Strategic National Stockpile distributing those supplies.

Throughout March 2020, the Strategic National Stockpile sent fractions of state requested PPE to hot spots and according to a later report, acknowledged it “lacked the ability” to target PPE distribution and other critical products to hospitals. For example, throughout March 2020 New York received approximately 20 percent of the surgical masks it requested and New Jersey received less than 5 percent of the N95 respirators it requested as both states experienced surges in cases. By contrast, Wyoming received over 1,000 percent more N95 respirators than it requested and North Dakota, which made no PPE requests, received over 73,000 N95 respirators. The Strategic National Stockpile distributed the last of its PPE held for states on April 19, 2020—the same day it made the decision to begin allocating PPE based on need, not population. In the months that followed, however, HHS reported there was “no formula” used to determine allocations of PPE based on need. The Federal Emergency Management Agency (FEMA) reported using a “prioritization process” to make resource allocation recommendations by analyzing broad data sets, such as demographics and COVID-19 case information, but it was unable to provide the Committee with specifics on how it calculated distribution decisions.

Funding. As of January 2020, HHS's two emergency funds were nearly empty and insufficient to address pandemic response needs. One account, the Public Health Emergency Fund, had received no new appropriations since 1999. Then HHS Secretary Azar told the Committee he notified the Office of Management and Budget in early February 2020 that “the government would need a large supplemental appropriation to invest in vaccines, diagnostics, and therapeutics, to contract with PPE manufacturers, and to fund new border control initiatives.” The Administration, however, waited until late February 2020 to request supplemental funding from Congress while federal agencies struggled to purchase supplies and

support states without a sufficient source of emergency funds. In its February 24, 2020 supplemental funding request, the Office of Management and Budget wrote, “[t]o this point, no agency has been inhibited in response efforts due to resources or authorities.” Numerous accounts from federal officials interviewed by the Committee, however, reported that a lack of funding significantly constrained agencies’ response efforts.

Federal Response Strategies. Throughout February 2020, current and former federal officials became increasingly concerned about the spread of the virus and the need to implement community mitigation measures, such as social distancing and limitations on public gatherings, to reduce the spread. Publicly available hospitalization data for the Hubei province analyzed by current and former federal officials and shared with senior federal officials in early February revealed about a ten-fold increase in patients each week since mid-January. On February 9, 2020, using publicly available data, a senior health official from the U.S. Department of Veterans Affairs warned key senior officials that COVID-19 was more transmissible and deadlier than H1N1 and the U.S. was only a “couple of weeks” behind the spread in China. Despite this analysis, which was relayed directly to the Assistant Secretary for Preparedness and Response (ASPR) and DHS Chief Medical Officer, the Trump Administration failed to take decisive action and adequately convey the threat to the American people, including its reasoning behind critical public health guidance decisions. Instead, the Administration remained focused on containing the virus by trying to keep it out of the U.S., rather than implementing needed measures to mitigate its spread within the country.

Communications. Contradictory and inadequate communications left Americans confused and unclear on what to do to minimize their risk and over time, eroded public trust in public health guidance. Throughout February 2020, the Administration repeatedly told the public, “the risk is low.” Dr. Anne Schuchat, who later led CDC’s response, told the Committee there was an “avoid bad news bias” on the part of senior administration officials and a “lack of understanding of optimal risk communications—that sharing even bad news is helpful and reassuring” and “not sharing bad news increases suspicion and distrust.”

After CDC briefed the public on February 25, 2020 and told Americans, “it’s not so much a question of if this will happen anymore but rather more of a question of exactly when this will happen and how many people in this country will have severe illness,” warning there would be a “significant disruption” to everyday life due to the virus, the White House required approval of all telebriefings, media requests, and guidance documents, resulting in lengthy delays of critical health guidance and restricting CDC’s ability to share information directly with the public. Former officials interviewed by this Committee stated that there was nothing CDC relayed in the February 25 telebriefing that was inaccurate. CDC official Dr. Nancy Messonnier, who delivered the message told the Committee “there was consternation about the way in which CDC communicated and consternation about the messages CDC had relayed.” According to Olivia Troye, then senior advisor to Vice President Pence, from that point forward, the White House wanted “to make sure they had full control of the messaging” and the Vice President’s Communications Director “locked down” all communications, requiring White House approval of “any public statements.”

From March through June 2020, CDC was not permitted to conduct public briefings, despite multiple requests by the agency and CDC media requests were “rarely cleared.” HHS stated that by early April 2020, “after several attempts to get approvals,” its Office of Assistant Secretary for Public Affairs “stopped asking” the White House “for a while.” Despite repeated recommendations from experts in and outside government advocating for the use of face masks, federal officials issued conflicting statements regarding the efficacy of face masks in the initial months of the response. It took until April 3, 2020 for the federal government to formally recommend the use of face masks—a policy that President Trump publicly declined to follow at the same press conference announcing the guidance. In the months that followed, President Trump repeatedly told the public that the virus would “disappear,” promoted unproven and dangerous treatments over preventative measures, and undermined public health officials. A 2021 internal State Department review found, “the politicized internal debate on science and mitigation measures undermined international trust in U.S. leadership.”

Leadership. Multiple shifts in federal leadership and organizational structures resulted in misplaced priorities with strategic long-term planning overshadowed by immediate operational concerns, such as repatriation of U.S. citizens and travel concerns. Unclear leadership structures led to confusion, and insufficient planning resulted in some military personnel being displaced from their bases to house repatriated citizens. Experts and officials interviewed by the Committee stated that the execution of leadership changes within the Administration were sudden and poorly planned, noting some senior federal officials learned of the changes through the media. When the White House announced that Vice President Pence would lead the White House Task Force in place of HHS on February 26, 2020, the HHS Secretary, CDC Director, and the ASPR all learned of the decision only shortly before the public announcement. When the HHS Secretary directed the ASPR to lead the department’s pandemic response on March 2, 2020, the ASPR learned of his new role through a news report. Despite leading HHS’s pandemic response efforts, the White House Task Force removed the ASPR from subsequent task force meetings.

President Trump waited until March 13, 2020 to declare a nationwide emergency under the Stafford Act, which triggered the subsequent release of emergency aid from the Disaster Relief Fund. Contrary to federal pandemic planning—including the Administration’s COVID-19 specific response plan issued in mid-March that confirmed HHS as the response lead—on March 18, the President ordered the FEMA Administrator to “take over” and lead the federal response the next day. Then FEMA Chief of the National Response Coordination Center described a “surreal experience reorganizing the government in two hours.” This was the first time FEMA had served as the lead for an infectious disease emergency and prior pandemic planning did not contemplate FEMA leading a federal pandemic response. Although officials involved in the response noted eventual improvements after the change, rapid shifts in leadership during the crisis caused confusion and coordination challenges.

By that time, detected cases were increasing rapidly, escalating week by week to tens of thousands of cases per day and by the end of March, the United States reported over 100,000 confirmed COVID-19 cases, higher than any other country. The consequences were immense. Unemployment claims soared to historic levels, healthcare workers struggled to obtain PPE, and schools abruptly transitioned to remote learning. Ultimately, the federal government’s failure to

promptly recognize the threat, mount a cohesive response, implement timely mitigation measures, and effectively communicate steps the public could take to protect themselves, resulted in the avoidable yet devastating loss of human life.

* * * * *

While the federal government made a series of missteps throughout the initial response, there were also successes that deserve to be acknowledged. The federal government’s rapid mobilization, known as Operation Warp Speed, swiftly and successfully coordinated with the private sector to develop a vaccine for the novel COVID-19 virus in record time, building on years of prior federal investments in scientific research and was widely considered to be a resounding success. In addition, the tireless and ongoing work of frontline health care workers and officials fully engaged in the response saved countless lives.

However, multiple systemic problems unaddressed at the outset of the pandemic remain. These issues include insufficient funding, overlapping roles, supply chain vulnerabilities, inadequate surveillance capabilities, and insufficient testing capacity, among many others. These problems have been flagged by experts and oversight agencies for years, yet have been largely overlooked by all branches of the federal government.

The American people should not have to suffer through a crisis of this magnitude for the federal government to ensure our nation is adequately prepared to address public health threats. To safeguard our country, Congress and the executive branch must learn from the failures of the initial response to this pandemic and make necessary reforms to increase public health emergency funding, clarify the roles of federal agencies, bolster our nation’s supply chain resilience, modernize our public health infrastructure, better engage and communicate with State, Local, Tribal, and Territorial (SLTT) partners and private industry, and ensure a swift, comprehensive, and science-based response to any future emerging health threat.

In preparation for this report, Committee staff conducted over 90 interviews and briefings with experts, including doctors, academics, and public health associations, as well as current and former officials with HHS, including the office of the ASPR, CDC, FDA, DOD, DHS, FEMA, the Department of State, and the White House. Staff also reviewed over 70,000 pages of documents, including statutes, presidential directives, agency guidance, preparedness plans, after-action reports, watchdog reports, congressional testimonies, journal articles, and other documents provided to the Committee to assess the federal government’s initial response to COVID-19 and identify needed reforms.

The Committee will continue to pursue information necessary to conduct additional review of the COVID-19 pandemic response. While this report reviews federal pandemic preparedness and initial federal response efforts, there are other critical issues, including long-recognized racial and economic health inequities and disparities, the development of therapeutics and vaccines, and the role of social media in misinformation and disinformation that this Committee will continue to examine as part of its oversight of the federal pandemic response.

FINDINGS OF FACT AND RECOMMENDATIONS

FINDINGS OF FACT

Pandemic Preparedness

- The U.S. failed to sufficiently invest in public health preparedness across multiple Administrations:** For over two decades, the federal government has failed to provide adequate funding for public health and make sustainable investments to modernize infectious disease surveillance programs, synchronize data systems, and build health care surge capacity, among other critical preparedness measures. The Public Health Emergency Fund, established to support state and local health system capacity during emergencies, received no new appropriations since 1999, leaving the account virtually empty since 2012. CDC's 2019 infectious disease reserve account also had limited funds in January 2020 and annual funding for ASPR's Hospital Preparedness Program, designed to support health care surge capacity during emergencies, has decreased by nearly half since 2003.
- Statutory authorities and policy directives that dictate federal leadership during public health emergencies overlap and lack clarity:** Existing statutes and policy directives delineating federal agency responsibilities during public health emergencies overlap, resulting in a lack of clarity between shared HHS and DHS responsibilities. While the Public Health Service Act identifies HHS as the lead federal agency for a pandemic response, the Stafford Act generally delegates authority to FEMA to lead disaster relief and emergency assistance, and Homeland Security Presidential Directive 5 places DHS in charge of managing domestic incidents. Within HHS, overlapping roles and responsibilities among agencies, specifically CDC and ASPR, cause tension and confusion regarding public health response leadership and activities.
- Federal pandemic preparedness planning is insufficient to address current threats:** Although federal preparedness structures have been in place and revised for decades, pandemic planning from 2005-2019 had been narrowly focused on influenza and failed to adequately incorporate other potential infectious disease threats. Of the influenza-based pandemic plans that have been developed and updated, HHS has failed to sufficiently engage the private sector and address operational shortfalls. While states rated pandemics as one of the top five threats and hazards in 2016, only three percent of FEMA's 2017 national exercises addressed infectious disease and biological incidents. There are also critical gaps between DOD intelligence and medical communities, including insufficient information sharing and a lack of medical intelligence analysts at combatant commands.
- HHS's organizational structure is insufficient to effectively respond to public health emergencies:** As currently structured, HHS is not effectively organized to respond to public health emergencies or coordinate with SLTT partners. While HHS and ASPR maintain separate regional offices, CDC generally does not have a regional presence. Without unified and robust regional offices across agencies and clear lines

of command and communication, HHS and its components lack the ability to effectively assess and implement key decisions related to guidance, staffing, and allocation of resources needed to both work with and provide assistance to SLTT partners during public health crises. After finding “persistent deficiencies” for more than a decade, GAO added HHS’s leadership and coordination of public health emergencies to its “high risk list” in January 2022.

5. **The federal government has known for years that the Strategic National Stockpile would be insufficient to meet pandemic needs:**

In 2007, the federal government found “significant work remain[ed]” to ensure sufficient critical medical countermeasures during pandemics. Nearly a decade later, CDC assessed that the gap between supply and demand of N95 respirators needed for a pandemic would present “a logistic challenge” and require a minimum of 1.7 to 3.5 billion respirators for health care workers. The Strategic National Stockpile never replenished the PPE it deployed as part of the H1N1 pandemic response due to insufficient funding. As of January 2020, the Strategic National Stockpile contained only a fraction of anticipated pandemic needs—12.5 million N95 respirators—on hand, many of which were expired and unusable. In addition, critical information on Strategic National Stockpile data, such as the type and amount of supplies stockpiled is not available to all senior ASPR officials, even if this information is relevant to their work.

6. **The U.S. medical supply chain lacks sufficient domestic manufacturing capacity for critical medical products:**

U.S. overreliance on concentrated foreign sources for critical medical products, such as antibiotics and PPE, has increased over the past two decades, widening vulnerabilities in a medical supply chain that continues to rely on “just-in-time” deliveries. In April 2020, HHS reported that at least 80 percent of production for surgical masks, gowns, and gloves originated from foreign sources. FDA estimates nearly 80 percent of active pharmaceutical ingredient manufacturers are located overseas. A 2017 internal memorandum to the Associate Director of National Security Programs for the White House Office of Management and Budget identified a likely shortage of PPE and “an alarming shortage of vaccines and even syringes” as a significant pandemic response gap. In January 2020, HHS’s after-action report from its 2019 Crimson Contagion interagency exercise found that the U.S. “lacks domestic manufacturing capacity” to produce “sufficient quantities of [PPE], needles, and syringes.”

7. **The federal government does not have sufficient visibility into where and in what quantities critical medical products, and their components, are manufactured:**

The federal government still lacks sufficient visibility into the medical supply chain, posing a significant threat to national security. Prior to the COVID-19 pandemic, medical device manufacturers, like PPE suppliers, were not required to inform FDA of potential supply chain disruptions. ASPR has even less supply chain visibility than FDA. With limited visibility on the location and availability of critical medical products, FDA and ASPR sent surveys and questionnaires to industry contacts to voluntarily provide information on whether their supply chains might be affected by the COVID-19 outbreak. This lack of visibility, which extends to the key inputs used

to make these products, impaired the agencies' ability to comprehensively assess supply chain vulnerabilities and proactively mitigate anticipated shortages.

8. **The federal government has continually failed to implement key lessons from prior public health crises:** Over ten preparedness-specific recommendations from the Government Accountability Office (GAO), HHS Inspector General, and HHS after-actions reports made since 2007 remain unimplemented. These reviews have identified multiple challenges faced by federal agencies in prior public health emergencies, including inadequate surveillance and information sharing systems; delayed guidance and inconsistent communication; insufficient diagnostic testing and private sector engagement; and unclear leadership roles and responsibilities. Three key recommendations from GAO have remained outstanding for over a decade. These include: addressing leadership roles and responsibilities between DHS and HHS; improving coordination with SLTT partners; and developing interoperable information sharing systems. Despite repeated findings and recommendations, federal agencies have failed to adequately address these systemic issues.

Pandemic Response

9. **CDC, DOD, and DHS identified the emerging novel coronavirus threat through open source reporting several weeks after the virus had been circulating in China:** CDC, DOD's Defense Intelligence Agency and Defense Health Agency's Armed Forces Health Surveillance Branch, and DHS's National Biosurveillance Integration Center learned of the emerging infectious disease threat through the same publicly available open source report in late December 2019, at least several weeks after the virus had already been circulating in China. DOD and DHS officials interviewed by the Committee acknowledged that they did not rely on any classified intelligence to identify the emerging novel coronavirus threat. Contrary to public reporting, DOD officials stated that DOD's National Center for Medical Intelligence did not receive warnings in November 2019 about a potential epidemic spreading in China. DHS assessed the "immediate risk" from the novel coronavirus to the United States as "low" until February 28, 2020. DOD's Defense Health Agency's Armed Forces Health Surveillance Branch did not raise the threat level in its COVID-19 surveillance reports until mid-March after the virus already started surging throughout the country. CDC told the public "the risk remained low" throughout January and February 2020.
10. **Public health data collection across the nation is not standardized:** Public health data collection and reporting methods vary across SLTT levels. Outdated systems and delays in response capabilities result in inefficiencies and negatively impact public health response efforts, such as the ability to effectively engage in contact tracing, identify health disparities, and equitably allocate critical drugs and medical supplies. Reporting systems are often siloed and may be linked to only one disease. During the initial pandemic response, several states relied on manual data entry and fax machines to record and submit COVID-19 data, further delaying the reporting of critical data needed to make timely public health decisions. Although CDC began collecting

limited COVID-19 data in January 2020, regulatory barriers hindered CDC's ability to adapt prior data collection systems to include new COVID-19 data, delaying CDC's collection of hospital data by weeks and ultimately resulting in duplicate systems. The federal government did not have centralized systems to collect COVID-19 testing and hospitalization data until it began building these systems in March 2020.

11. **U.S. public health surveillance systems for monitoring and detecting emerging infectious diseases are inadequate, antiquated, and fragmented:** Federal surveillance systems to monitor and detect potential health threats are fragmented. For over a decade HHS has failed to implement a near real-time electronic nationwide public health situational awareness capability through interoperable systems as mandated by the Pandemic and All-Hazards Preparedness Act in 2006 and its subsequent reauthorizations in the 2013 Pandemic and All-Hazards Preparedness Reauthorization Act and the 2019 Pandemic All-Hazards Preparedness and Advancing Innovation Act. With pre-symptomatic and asymptomatic cases contributing to at least 50 percent of COVID-19 transmission, CDC's existing surveillance systems missed at least half of the initial virus spread.
12. **The federal government changed leadership structures multiple times as the pandemic worsened and federal officials at times lacked clarity as to which agency was in charge:** Multiple leadership shifts from January through March 2020 caused confusion among federal officials and the public and delayed coordination and unified response efforts. Within the first three months of the federal response as COVID-19 continued to spread throughout the U.S., HHS, Vice President Pence through the White House Coronavirus Task Force, and FEMA, all held various leadership roles. When HHS served as the lead federal agency, federal officials lacked clarity as to whether ASPR or CDC was in charge. Federal officials also lacked clarity on which agency led repatriation efforts once planes landed in the U.S. Throughout February 2020, FEMA provided HHS with increasing assistance as the pandemic outgrew HHS's operational capacities and required a whole-of-government response. HHS continued to serve as the lead federal agency until March 18, 2020 when the White House ordered the FEMA Administrator to lead the federal pandemic response and announced FEMA's new role the following day. Federal pandemic planning did not account for FEMA leading a pandemic response.
13. **CDC's failed test kit, inadequate laboratory controls, and narrow testing criteria contributed to insufficient testing capacity in the U.S. throughout February 2020:** CDC's test kit failure resulted in at least a three-week delay for diagnostic testing in the U.S. While subsequent HHS and CDC internal reviews identified multiple insufficient laboratory controls and systems, officials within CDC continue to disagree on the cause of the failure. Despite data from early February demonstrating most COVID-19 cases outside of China did not involve travel to mainland China, CDC did not change its testing criteria—generally limited to individuals who had traveled to China or were in contact with a confirmed COVID-19 case—until February 27, 2020, significantly restricting who could be tested in the U.S. By the end of February, CDC had tested fewer than 1,200 individuals for COVID-19.

- 14. Insufficient engagement with the private sector and regulatory barriers delayed efforts to increase testing capacity as COVID-19 spread throughout the country:** The federal government failed to sufficiently engage the private sector and researchers in the development, authorization, manufacture, and distribution of diagnostic tests until late February 2020. As a result, CDC’s in-house test was the only COVID-19 test available in the U.S. throughout February. Instead of entering into contracts to bolster testing capacity, CDC relied on public health laboratories to begin testing even though public health laboratories are not designed to perform high volume testing. Regulatory barriers also delayed additional private sector options, including academic labs, which could have helped rapidly increase needed testing capacity beyond CDC’s failed test kit. In early March 2020, the White House Task Force engaged commercial laboratories to increase testing capacity and by April 2020, commercial laboratories performed over 80 percent of the nation’s COVID-19 testing.
- 15. Communications about COVID-19 were inconsistent and sometimes contradictory and critical federal public health guidance was often delayed:** Throughout February 2020, CDC failed to fully engage the public as the agency assessed community mitigation tactics. CDC also waited too long to implement critical public health guidance, such as the use of cloth face masks and other essential interventions, at times resulting in state and local health officials preemptively writing their own guidance in the absence of federal guidance. After a February 25, 2020 CDC telebriefing warning about the severity of the threat and significant disruption to everyday life, the White House required approval of all subsequent CDC telebriefings, media appearances, and guidance documents. From March 10 – June 11, 2020, CDC was prohibited from conducting briefings. Throughout the response, Americans received information that was often misleading and directly contradictory to public health guidance. For example, in the same press conference on April 3, 2020, the federal government introduced and President Trump declined to follow public health guidance recommending the use of cloth face masks. In addition, limitations on what CDC could and could not publish resulted in critical guidance documents, such as recommendations on how hospitals should wash gowns, being delayed by weeks.
- 16. The Strategic National Stockpile distributed the entirety of its PPE supply held for states based on population, not need:** Despite known gaps in contingency planning, including a 2017 internal memorandum that found there was “no plan to prioritize or adjudicate competing requests for scarce resources” and cautioned against continuing to rely on “reactive strategies” for agencies to assess resource demands, the Strategic National Stockpile distributed critical medical supplies, like PPE, to states based on population throughout March 2020. As a result, hot spots in states with higher cases received fractions of the PPE requested and states with fewer cases received larger amounts of PPE than requested. For example, throughout March 2020, California received only 17.5 percent of the N95 respirators it requested while Wyoming received over 1,000 percent more N95 respirators than it requested. Challenges in supply distributions left many state requests for PPE taking over a week to be delivered and other deliveries sent without notice or identification of the contents

included. On April 19, 2020 the Strategic National Stockpile delivered the last of its PPE held for states. At that time, the federal government began allocating PPE based on need, but it did not rely on any formula or plan to determine allocations. HHS did not memorialize how need-based distribution decisions were made.

17. **The federal government knew there would be a shortage of critical medical products, like PPE, but failed to take needed action:** For over a decade, the federal government has known that the U.S. medical supply chain is largely dependent on foreign sources, predominantly in China and India, for critical medical products, like PPE, which would result in dire shortages in the event of a pandemic. By the end of January 2020, multiple countries issued PPE export bans, China nationalized its PPE supply, and domestic manufacturers warned federal officials of impending supply shortages, as the 2019 federal pandemic exercise, Crimson Contagion, predicted would occur. Despite these warnings, the federal government failed to take timely action to increase supply through emergency contracts, executive authorities, or supplemental funding requests and instead resorted to considering revising CDC guidance to support conservation tactics for existing PPE. The federal government first awarded large-scale contracts for N95 respirators on March 21, 2020 after receiving funding from Congress—two months after the first case of COVID-19 was identified in the U.S. Product deliveries did not begin until May 2020 due to logistic challenges and supply shortages.

RECOMMENDATIONS

Pandemic Preparedness

- 1. Invest in sustainable multi-year funding for public health emergency preparedness and response across all levels of government:** The federal government must increase funding to support and maintain a robust public health infrastructure at both the federal and State, Local, Tribal, and Territorial (SLTT) levels through flexible funding that is available over a multi-year period to allow for sustained and dedicated investments. Efforts should include the use of long-term contracts and long-term private-public partnerships to ensure modernized public health surveillance, integrated data systems, health care surge capacity, domestic manufacturing capabilities for essential medical products, robust workforce and training, and innovative stockpiles of critical medical countermeasures. Congress should also require an integrated cross-agency biodefense budget request to eliminate potential duplication in activities and programs, improve clarity on federal biological threat spending, and strengthen federal coordination to address emerging health threats. Federal agencies must also have access to sufficient and flexible funding streams during public health emergencies, such as the Public Health Emergency Fund.
- 2. Clarify agency roles in pandemic preparedness and response:** Congress and the executive branch should clarify DHS and HHS's roles during public health emergencies requiring a whole-of-government response, such as pandemics. This includes reevaluating relevant statutes, policy directives, and planning documents to ensure an operational and clear understanding of shared roles and responsibilities during public health emergencies and defining organizational structures for crises that may exceed an agency's capacity. Once clarified, Congress and the executive branch should ensure agencies have the appropriate authorities and resources to execute designated roles and responsibilities.
- 3. Ensure federal preparedness planning anticipates future public health threats, involves regular operational exercises, and includes coordination across all levels of government and the private sector:** Future pandemic preparedness planning must be comprehensive, operational, and engage all stakeholders. It should focus beyond influenza and include SLTT partners as well as relevant private sector entities in developing operational preparedness plans that are regularly exercised. Federal pandemic planning should address a whole-of-government response that includes information sharing both within and between federal agencies. Specifically, federal interagency planning should also address repatriation efforts, including the clarification of operational roles among agencies, and ensure an operational unified coordination structure to execute a swift and comprehensive response to emerging public health threats.

4. **Reassess HHS’s organizational structure to improve coordination with SLTT partners:** HHS should reevaluate its organizational structures and better align efforts across its agencies and other federal response departments. Congress should fund HHS to establish strong, all-encompassing regional response offices that allow a singular touchpoint for SLTT partners, similar to FEMA’s regional response offices, to improve coordination and communication, better support state and local entities, and streamline information sharing during public health crises. Federal departments and agencies, including DOD, DHS, and HHS, should identify respective capacities and capabilities for public health responses to ensure partner agencies are aware of that capacity and how it can be operationalized in accordance with federal planning doctrine. Congress should also ensure HHS and its agencies have sufficient authorities and funding to bolster its operational capacity needed to staff, reassign, and deploy personnel to support critical missions during public health emergencies.
5. **Reform the Strategic National Stockpile at both the federal and state levels:** ASPR must request, and Congress must provide, sufficient funding to both resource and maintain federal and state stockpiles. Congress should also clarify the role of the federal Strategic National Stockpile (SNS), align funding accordingly to address how the SNS is expected to support states during public health emergencies, authorize vendor-managed inventory agreements, and require that ASPR regularly assess the usability, quantity, and related supply chain vulnerabilities of all SNS contents. ASPR should also issue clear guidance to states on federal SNS expectations, the role and maintenance of state stockpiles, and access to the federal SNS during emergencies. Furthermore, ASPR must ensure the structure and processes of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) align with statutory requirements.
6. **Invest in sustainable domestic manufacturing capacity for critical medical products:** The federal government must support sustainable domestic manufacturing capacity for critical medical products, such as antibiotics, PPE, and other medical countermeasures, through developments in advanced manufacturing and strategic, long-term public-private partnerships and contracts to increase domestic manufacturing capacity, decrease overreliance on foreign sources for critical supplies, and ensure readiness for emerging health threats.
7. **Require manufacturers to report critical supply chain information, federal agencies to conduct supply chain risk assessments, and FDA to share key manufacturing data with the Strategic National Stockpile:** To increase the federal government’s visibility into the medical supply chain and bolster preparedness for future public health crises, federal agencies, including DOD, DHS, and HHS, should conduct biannual medical supply chain risk assessments to identify vulnerabilities and potential threats. Congress should also require manufacturers to report information on key starting materials, export restrictions, and increased demand for both finished medical products and their critical inputs to FDA that can be shared with other agencies as needed for national security purposes. FDA should enter into a new memorandum of understanding with ASPR to ensure the Strategic National Stockpile

has the data it needs to inform purchases, reduce reliance on foreign sources, and mitigate potential supply chain risks.

8. **Increase accountability for implementing lessons from prior public health emergencies:** Over the past two decades, recommendations from reviews of the federal government’s response to multiple public health emergencies and planning exercises have often gone unimplemented. Congress should require department and agencies to track all outstanding recommendations from exercises and after-action reports related to biological incidents and pandemic preparedness on a publicly accessible website. Recommendations that have remained open for more than two years should be reported to Congress with a corresponding explanation.

Pandemic Response

9. **Strengthen and coordinate federal public health and biodefense capabilities:** Effective public health preparedness and emergency response requires an all-of-government approach with strong, integrated federal surveillance systems to detect and respond to potential health threats. Relevant federal departments should ensure sufficient coordination and information sharing between intelligence and medical communities. The National Security Council should build and maintain sufficient and consistent public health and medical expertise to prepare for and respond to wide-ranging biological threats. Congress should also ensure agencies integrate federal surveillance systems needed to monitor and detect new pathogens and bolster situational awareness, including that sufficient funding and authorities exist for interagency collaboration on biosurveillance efforts and data sharing.
10. **Standardize health data collection to improve future public health responses and minimize burdens on providers:** The federal government should align data collection and reporting both across the nation and at the federal level to improve public health preparedness and response, increase privacy and cybersecurity protections, and minimize burdens on reporting entities. In addition, HHS should identify critical public health data sets and issue relevant data reporting standards. Congress should also reform the Paperwork Reduction Act to streamline and expedite agency information collections, reduce bureaucracy, and increase the quality and effectiveness of data collected to understand and manage complex, multi-agency efforts.
11. **Modernize U.S. public health surveillance systems and information technology infrastructure:** HHS should fully implement a near real-time public health situational awareness capability through interoperable systems as required by the 2006 Pandemic and All-Hazards Preparedness Act and its subsequent reauthorizations in 2013 and 2019. These efforts should also include updating existing systems and integrating systems used at all sectors, including federal, SLTT partners, and relevant private health entities through interoperable data platforms. With multiple data modernization efforts underway, HHS should coordinate federal efforts to ensure there is no

duplication. Congress should also provide flexibility in surveillance funding to encourage interoperable systems capable of information sharing.

12. **Clearly define HHS agency roles during public health emergencies:** HHS should clearly outline each agency's operational roles and responsibilities during public health crises and ensure both ASPR and CDC have the authorities and resources needed to execute their respective responsibilities.
13. **Improve CDC laboratories' information management structure and internal controls:** CDC should continue to implement recommendations from the multiple reviews of its COVID-19 test kit failure through its Laboratory Quality Plan to improve internal quality controls and ensure interoperable laboratory information sharing systems between federal, SLTT, and private health entities. CDC should also establish channels for its personnel to raise concerns outside their chain of command.
14. **Build infrastructure necessary for testing surge capacity and initiate advance contracts that can be rapidly executed during public health crises:** HHS, in partnership with SLTT and private partners should establish policies and protocols to maintain a robust diagnostic testing infrastructure capable of surge capacity during crises. Specifically, HHS should enter into advance contracts with industry to support the swift availability of rapid diagnostic tests, critical testing supplies, and other medical countermeasures during future crises. In addition, CDC, the Centers for Medicare and Medicaid Services (CMS), and FDA should formalize expedited pathways for diagnostic testing during public health emergencies at academic labs. CDC, CMS, and FDA should also build upon their efforts to coordinate the development of diagnostics, address preexisting gaps from prior emergencies, and improve readiness for future public health responses. While CDC has taken steps to enhance surge testing capacity for public health emergencies, it should regularly update and exercise its plans, in coordination with the private sector, to ensure they are operational.
15. **Establish safeguards and processes to ensure timely public health guidance and communications based on reliable scientific analysis and data:** Congress and federal agencies should take steps to ensure public health guidance and communications rely on the best available scientific analysis and data. Congress and the Administration should also consider reforms to protect scientific integrity and provide timely public health guidance, including strengthening whistleblower protections and oversight structures, establishing longer terms for scientific leadership positions, clearly denoting changes in CDC's public health guidance (and the reason for the change), and reassessing CDC's processes for issuing guidance during public health emergencies. In addition, to the extent practicable, CDC should first inform state and local public health departments of new or changing guidance before alerting the public to improve coordination and communication with SLTT partners.

16. **The ASPR should implement a transparent resource allocation plan for public health emergencies when demand exceeds supply:** In coordination with federal, SLTT, and private partners, the ASPR, in coordination with the Strategic National Stockpile and relevant interagency partners, should draft a comprehensive national plan for allocating limited supplies from the Strategic National Stockpile and other federal stockpiles when demand exceeds supply during public health emergencies based on defensible and transparent criteria. The strategy should also account for wide-ranging threats, contingencies, and interagency coordination, and include a plan to quickly and equitably distribute supplies to affected areas across the U.S. The ASPR should also identify gaps in data needed to execute its resource allocation plan. This plan should be updated and exercised regularly.

17. **Provide ASPR with increased authorities and contracting flexibilities to better prepare for and respond to public health emergencies:** In addition to ensuring the Public Health Emergency Fund has adequate funding, Congress should provide ASPR with increased authorities and contracting flexibilities to coordinate and support a rapid response to public health emergencies.

PART 1: PANDEMIC PREPAREDNESS AND RESPONSE STRATEGIES

When planning for and responding to an emergency, the federal government primarily relies on four key resources: the activation of emergency preparedness and response strategies; statutory authorities and policy directives; funding; and planning and guidance documents. These resources must work in tandem to ensure a unified response. An emergency response structure that lacks operational strategies, clearly delineated authorities, sustainable funding, and sufficient planning hampers response efforts.¹ Despite decades of calls to improve readiness and strengthen response structures, the Majority Committee staff found U.S. pandemic preparedness fell short of what was needed during the initial response to the COVID-19 pandemic.

This section assesses key federal preparedness efforts, including the effectiveness of emergency response structures, statutory authorities and policy directives, funding sources, and planning and guidance tools. Many of the issues outlined in this section continue to present challenges to an effective pandemic response.²

I. Response Strategies

U.S. domestic emergency preparedness and response doctrine has long held that effective preparedness planning requires a “whole-of-community” approach, with involvement spanning across federal, state, local, and private sector partners.³ As a result, domestic emergency preparedness and response strategies include often overlapping systems that involve a wide range of participants. In general, U.S. response structures are decentralized and coordinated across federal, State, Local, Tribal, and Territorial (SLTT) government entities.⁴ While U.S. emergency response structures are designed to respond to all hazards—from flooding to biological incidents—these response strategies are generally geared toward more traditional emergencies, such as natural disasters that have geographic and time limitations.⁵ The Department of Homeland Security’s (DHS) National Response Framework notes that “an effective, unified national response requires layered, mutually supporting capabilities. Individuals and communities, the private sector, NGOs, and all levels of government (local, state, tribal,

¹ See Government Accountability Office, *National Preparedness: Additional Actions Needed to Address Gaps in the Nation’s Emergency Management Capabilities* (GAO-20-297) (May 4, 2020); Government Accountability Office, *COVID-19: Federal Efforts Could Be Strengthened by Timely and Concerted Actions* (GAO-2-701) (Sep. 21, 2020); Department of Homeland Security, Federal Emergency Management Agency, *Pandemic Response to Coronavirus Disease 2019 (COVID-19): Initial Assessment Report* (Jan. 2021).

² See Congressional Research Service, *FEMA’s Role in the COVID-19 Federal Pandemic Response* (R47048) (Feb. 20, 2022); Department of Homeland Security, Federal Emergency Management Agency, *Pandemic Response to Coronavirus Disease 2019 (COVID-19): Initial Assessment Report* (Jan. 2021).

³ Government Accountability Office, *Biodefense: After-Action Findings and COVID-19 Response Revealed Opportunities to Strengthen Preparedness*, at 9 (GAO-21-513) (Aug. 2021).

⁴ Congressional Research Service, *Congressional Primer on Responding to and Recovering from Major Disasters and Emergencies*, at 1-2 (R41981) (June 3, 2020).

⁵ See Department of Homeland Security, National Response Framework, Fourth Edition (Oct. 28, 2019); Department of Homeland Security, Federal Emergency Management Agency, National Preparedness System (<https://www.fema.gov/emergency-managers/national-preparedness/system>) (accessed Nov. 28, 2022); Department of Homeland Security, Presidential Policy Directive 8 (Mar. 30, 2011).

territorial, insular area, and federal) should each understand their respective roles and responsibilities and how to complement each other in achieving shared goals.”⁶ The early days of the COVID-19 pandemic revealed a frightening truth about these structures that today many Americans have experienced firsthand—the U.S. was chronically underprepared and, in the words of then CDC Director Dr. Robert Redfield, “the government was not set up for a national response to a respiratory pandemic.”⁷

The National Preparedness System, developed by the Federal Emergency Management Agency (FEMA) within DHS, outlines “an organized process for everyone in the whole community” to prepare for, respond to, and recover from emergencies.⁸ It delegates emergency management responsibilities across SLTT government entities, with varying levels of control between state and local governments.⁹ Under the National Preparedness System, “public health, healthcare, and emergency medical services” is identified as one of 32 core capabilities needed to address “the greatest risks” to the nation.¹⁰ The Public Health System operates predominately at the local level, with the majority of states having locally governed health departments.

⁶ Department of Homeland Security, *National Response Framework, Fourth Edition*, at 25 (Oct. 28, 2019); Department of Homeland Security, Federal Emergency Management Agency, National Preparedness System (<https://www.fema.gov/emergency-managers/national-preparedness/system>) (accessed Nov. 28, 2022).

⁷ Dr. Robert Redfield, Centers for Disease Control and Prevention Director (Mar. 2018 – Jan. 2021), Interview with Senate Committee on Homeland Security and Governmental Affairs (Feb. 7, 2022) (hereinafter “Interview with Dr. Robert Redfield (Feb. 7, 2022)”).

⁸ Department of Homeland Security, Federal Emergency Management Agency, National Preparedness System (last updated July 31, 2020) (<https://www.fema.gov/emergency-managers/national-preparedness/system>). Preparedness is divided into five “mission areas”: prevention, protection, mitigation, response, and recovery. See Department of Homeland Security, Federal Emergency Management Agency, National Preparedness Goal (last updated July 20, 2020) (<https://www.fema.gov/emergency-managers/national-preparedness/goal>). The Post-Katrina Emergency Management Reform Act of 2006 (PKEMRA), Pub. L. No. 109-295, Title VI, 120 Stat. 1394 (2006), mandated the implementation of the National Preparedness System and a National Preparedness Goal, which was executed through Presidential Policy Directive 8 (PPD-8) and is discussed later in this report.

⁹ See Susan Wolf-Fordham, *Integrating Government Silos: Local Emergency Management and Public Health Department Collaboration for Emergency Planning and Response*, The American Review of Public Administration (July 24, 2020). The Committee refers to “states” as defined under the Stafford Act, which includes D.C. and territories. See Robert T. Stafford Disaster Relief and Emergency Assistance Act of 1988, Pub. L. No. 100-707, Sec. 102(4).

¹⁰ Department of Homeland Security, Federal Emergency Management Agency, Mission Areas and Core Capabilities (<https://www.fema.gov/emergency-managers/national-preparedness/mission-core-capabilities>) (accessed Nov. 28, 2022); Department of Homeland Security, Federal Emergency Management Agency, *National Preparedness Goal, Second Edition* (Sept. 2015) (<https://www.fema.gov/emergency-managers/national-preparedness/goal>).

Table 1. Components of the Architecture of the U.S. Public Health System¹¹

Key Components of the Architecture of the U.S. Public Health System.	
Level of Government and Agencies	Examples of Authority
<p>Federal</p> <p>The 21 federal agencies that have major public health authority include the Centers for Disease Control and Prevention, the Food and Drug Administration, the National Institutes of Health, the Environmental Protection Agency, and the Department of Agriculture.</p>	<p>Guidance and oversight for the control of infectious and chronic illness</p> <p>Food-safety standards and inspections of production</p> <p>Regulation of drugs, devices, vaccines, tobacco products, and cosmetics</p> <p>Support for research and development of new public health approaches, therapies, and countermeasures</p> <p>Regulation of toxic pollutants and greenhouse gases</p> <p>Laboratory testing services for rare or novel pathogens not available at local and state labs</p>
<p>State</p> <p>Of 50 state public health agencies, 29 are independent agencies and 21 are a unit of a larger umbrella agency; 27 have a state board of health or similar entity.</p>	<p>Public health emergency response</p> <p>Programs and policies to address maternal–child health, environmental health, chronic illness, tobacco control, and infectious disease</p> <p>Vital statistics</p> <p>Infectious and chronic disease surveillance</p> <p>Maintenance of immunization registries</p> <p>Licensing and regulation of health care service providers</p> <p>Newborn screenings</p> <p>Laboratory testing, including foodborne illness testing and influenza typing</p>
<p>Local</p> <p>Of 2459 local health departments, 1887 are locally governed, 404 are units of the state health department, and 168 have shared governance; 70% have a local board of health.</p>	<p>Response to reports of foodborne illness</p> <p>Regulation, inspection, and licensing of businesses such as restaurants and day care centers</p> <p>Environmental inspections, including checks of septic systems and recreational water</p> <p>Adult and childhood immunization programs</p> <p>Community outreach and education on public health topics such as food safety, physical activity, and health screenings</p> <p>Screening for diseases or conditions such as tuberculosis and sexually transmitted diseases</p>

Below is an overview of the lead federal agencies, SLTT partners, and private entities involved in components of the National Preparedness System and the Public Health System.

FEMA

FEMA coordinates preparedness, response, and recovery support functions in major disasters and emergencies declared under the Stafford Act from flooding and hurricanes, to wildfires and terrorist attacks. In the past decade, this scope has expanded to include certain public health outbreaks.¹² FEMA is organized into ten regions across the U.S. and territories, which coordinate with their respective states to provide support to SLTT efforts when necessary.¹³ David Bibo, former Deputy Associate Administrator for Response and Recovery,

¹¹ From The New England Journal of Medicine, Megan Wallace and Joshua M. Sharfstein, *The Patchwork U.S. Public Health System*, Volume No. 386, 1-4. Copyright © (2022) Massachusetts Medical Society. Reprinted with permission from Massachusetts Medical Society.

¹² Prior to the COVID-19 pandemic, the President issued emergency declarations under the Stafford Act for the West Nile virus in New York and New Jersey; however, CDC served as the lead federal agency for both of these incidents. Congressional Research Service, *FEMA’s Role in the COVID-19 Federal Pandemic Response*, at 4 note 17 (R47048) (Feb. 10, 2022).

¹³ Department of Homeland Security, Federal Emergency Management Agency, Regions (<https://www.fema.gov/about/organization/regions>) (accessed Nov. 14, 2022).

told the Committee, “FEMA’s robust regional structure... is a powerful tool in a nationwide incident.”¹⁴

In the event of a disaster or other incident, FEMA may provide financial support for state and local response and recovery through the Disaster Relief Fund (DRF) if the President declares a major disaster or emergency under the Stafford Act.¹⁵ Existing pandemic planning and guidance documents traditionally place FEMA in a support role to the Department of Health and Human Services (HHS) for critical needs, such as logistics and interagency coordination. As discussed in Sections II and IV, federal planning notes that FEMA can be designated to lead a federal government response or provide supplemental operational coordination support for the primary authority during “complex incidents.”¹⁶

FEMA maintains the National Response Coordination Center (NRCC), a multiagency emergency activation center located within at FEMA’s headquarters in Washington, D.C. By statute and policy, the FEMA Administrator has overall responsibility and authority for operating the NRCC.¹⁷ During emergencies, the NRCC provides situational awareness, planning, and resource support both within the federal government and to SLTT partners.¹⁸ Depending on the threat level, FEMA may activate the NRCC at various levels of involvement from Level III, the lowest level where operations remain largely within FEMA, to Level I, the highest level which entails coordination among all relevant agencies.¹⁹ According to FEMA officials, the NRCC’s activations have increased over time and responsibilities continue to expand to provide for events ranging from natural disasters such as floods and wildfires, to border security and medical support.²⁰

¹⁴ David Bibo, Former Deputy Associate Administrator of the Office of Response and Recovery at Federal Emergency Management Agency (Jan. 2019 – July 2022) (served as Acting Associate Administrator from Jan. 2020 – Dec. 2021), Interview with Senate Committee on Homeland Security and Governmental Affairs (Dec. 21, 2021) (hereinafter “Interview with David Bibo (Dec. 21, 2021)”).

¹⁵ Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. § 5121 *et seq.*

¹⁶ Department of Homeland Security, *Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans*, at 13 (Jan. 2017) (https://www.fema.gov/sites/default/files/2020-07/fema_incident-annex_biological.pdf) (noting “DHS/FEMA may be called upon to lead or provide supplemental operational coordination support for the primary authority during complex incidents”).

¹⁷ See 6 U.S.C. § 314(a) (17); Department of Homeland Security, Federal Emergency Management Agency, *National Incident Management System, Third Edition*, at 47 (Oct. 2017).

¹⁸ Federal Emergency Management Agency, National Response Coordination Center (NRCC) Site Visit and Briefing with Senate Committee on Homeland Security and Governmental Affairs Staff (Oct. 6, 2021) (hereinafter “NRCC Site Visit and Briefing (Oct. 6, 2021)”).

¹⁹ Department of Homeland Security, Federal Emergency Management Agency, Activation Levels (<https://emilms.fema.gov/IS2200/groups/163.html>) (accessed Nov. 15, 2022); *see also* NRCC Site Visit and Briefing (Oct. 6, 2021).

²⁰ NRCC Site Visit and Briefing (Oct. 6, 2021).

HHS

During a public health emergency, existing statutory authority and planning documents place HHS as the lead federal department, a role HHS has traditionally played in prior pandemics.²¹ Given the possible wide-ranging response efforts involved in a public health emergency—from data collection and surveillance to the approval and distribution of medical countermeasures—responsibilities for public health preparedness and response are divided across the federal government, as detailed in Table 1.²² This includes, among other departments and agencies, the Centers for Disease Control and Prevention (CDC), the Office of the Assistant Secretary for Preparedness and Response (ASPR), the Food and Drug Administration (FDA), and the Centers for Medicare and Medicaid Services (CMS).²³

*Assistant Secretary for Preparedness and Response.*²⁴ ASPR houses critical preparedness and response components, including the Strategic National Stockpile (SNS) and the Biomedical Advanced Research and Development Authority (BARDA).²⁵ The SNS contains stockpiles of pharmaceuticals, medical supplies, and other medical countermeasures designed to “provide for and optimize the emergency health security of the United States . . . in the event of a

²¹ See Public Health Service Act, 42 U.S.C. Subchapter XXVI (National All-Hazards Preparedness for Public Health Emergencies); Department of Homeland Security, National Response Framework, Fourth Edition, at 40 (Oct. 28, 2019) (describing Emergency Support Function #8, Public Health and Medical Services); Department of Homeland Security, Federal Emergency Management Agency, *Pandemic Crisis Action Plan, Version 2.0* (Jan. 2018) (on file with Committee).

²² See Megan Wallace and Joshua M. Sharfstein, *The Patchwork U.S. Public Health System*, *The New England Journal of Medicine* (Jan. 6, 2022).

²³ Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Public Health Emergency Declaration (<https://www.phe.gov/Preparedness/legal/Pages/phedeclaration.aspx>) (accessed Nov. 15, 2022); Food and Drug Administration, Emergency Preparedness and Response (<https://www.fda.gov/emergency-preparedness-and-response>) (accessed Nov. 15, 2022); Centers for Disease Control and Prevention and Office of Public Health Preparedness and Response, *An Overview of the Office of Public Health Preparedness and Response* (<https://www.cdc.gov/cpr/documents/phpr-overview-fact-sheet-2016.pdf>) (accessed Nov. 15, 2022).

²⁴ In July 2022, ASPR changed its name to the Administration for Strategic Preparedness and Response. See Department of Health and Human Services, *HHS Strengthens Country’s Preparedness for Health Emergencies, Announces Administration for Strategic Preparedness and Response (ASPR)* (July 22, 2022) (<https://www.hhs.gov/about/news/2022/07/22/hhs-strengthens-countrys-preparedness-health-emergencies-announces-administration-for-strategic-preparedness-response.html>). Because this report focuses on events that occurred before ASPR’s name change, this report will reference ASPR by its former name, the Office of the Assistant Secretary for Preparedness and Response.

²⁵ Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Strategic National Stockpile (accessed Nov. 15, 2022) (<https://www.phe.gov/about/sns/Pages/default.aspx>); Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority (<https://aspr.hhs.gov/AboutASPR/ProgramOffices/BARDA/Pages/default.aspx>). Since 2018, ASPR has managed the SNS. Before that, CDC oversaw and operated the SNS. See Department of Health and Human Services, Radiation Emergency Medical Management, Strategic National Stockpile (<https://remm.hhs.gov/sns.htm#:~:text=In%202018%2C%20oversight%20of%20Strategic,United%20States%20or%20its%20territories>) (accessed Nov. 28, 2022).

bioterrorist attack or other public health emergency.”²⁶ BARDA supports the transition of medical countermeasures such as diagnostics, therapeutics, and vaccines from research through advanced development toward consideration for federal approval and inclusion into the SNS.²⁷

In the event of a public health threat, HHS has the ability to activate its operations centers, including the Secretary Operations Center (under HHS and executed by ASPR) and the Emergency Operations Center (under CDC).²⁸ HHS’s Secretary’s Operations Center (SOC) serves as the “primary emergency operations center for HHS” in response to any crisis.²⁹ The SOC’s level of activation depends on the threat, ranging from a low activation level (IV), which consists of 24-hour situational awareness monitoring and reporting, to higher activation levels (I–III) that can include representatives from all HHS components.³⁰ According to ASPR, “higher levels of activation are implemented based on the Commander’s Information Requirements with level 1 being the highest level for large no notice disasters with national public health consequences.”³¹ Dr. Kevin Yeskey, former Principal Deputy Assistant Secretary for Preparedness and Response, explained to the Committee that the SOC is the “main communications receiver for all information. It’s always staffed, 24/7 and 365 days a year.” He noted that after the federal response to Hurricanes Maria and Irma in 2017, ASPR went through a number of drills to improve the SOC’s responsiveness and effectiveness in handling notifications and requests for assistance from SLTT partners.³²

Centers for Disease Control and Prevention. Established in 1946, CDC began as a malaria response agency.³³ According to multiple public health officials interviewed by this Committee, CDC’s responsibilities have expanded over the years.³⁴ Today, CDC’s mission is

²⁶ 42 U.S.C. § 247d-6b.

²⁷ Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority (<https://www.phe.gov/about/barada/Pages/default.aspx>) (accessed Nov. 16, 2022).

²⁸ The Food and Drug Administration (FDA) also has an Emergency Operations Center, managed by its Office of Crisis Management. *See* Food and Drug Administration, Virtual Tour of the FDA Emergency Operations Center (<https://www.fda.gov/about-fda/office-security-and-emergency-management/virtual-tour-fda-emergency-operations-center>) (accessed Nov. 16, 2022).

²⁹ Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, HHS Secretary’s Operations Center (<https://www.phe.gov/Preparedness/responders/soc/Pages/default.aspx>) (accessed Nov. 16, 2022).

³⁰ *Id.*

³¹ *Id.*

³² Dr. Kevin Yeskey, Former Principal Deputy Assistant Secretary for Preparedness and Response at the Office of Assistant Secretary for Preparedness and Response (Apr. 2018 - May 2020), Interview with Senate Committee on Homeland Security and Governmental Affairs (Nov. 17, 2021 and Dec. 2, 2022) (hereinafter “Interview with Dr. Kevin Yeskey (Nov. 17, 2021 and Dec. 2, 2021)”).

³³ Department of Health and Human Services, Centers for Disease Control and Prevention, History (<https://www.cdc.gov/about/history/index.html>) (accessed Nov. 16, 2022).

³⁴ *See, e.g.* Interview with Dr. Robert Redfield (Feb. 7, 2022); Dr. Robert Kadlec, Former Assistant Secretary for Preparedness and Response (Aug. 2017 – Jan. 2021), Interview with Senate Committee on Homeland Security and Governmental Affairs (Dec. 6, 2021) (hereinafter “Interview with Dr. Robert Kadlec (Dec. 6, 2021)”).

wide-ranging and includes the prevention of diseases, detection and response to emerging public health threats, identification of causes of death, disease, and disability, and the promotion of health and safety within communities, among many other initiatives.³⁵

CDC’s Emergency Operations Center (“EOC”) regularly monitors for a variety of threats from natural disasters to public health emergencies 24/7, 365 days a year.³⁶ The decision whether to activate the Incident Management System (IMS)—a scalable structure used across the federal government to respond to domestic emergencies—within the CDC ultimately rests with the CDC Director.³⁷ Similar to the SOC, the EOC’s level of activation varies based on the scale of the incident, from Level III, the lowest level with a limited number of staff to Level I, the highest level involving agency wide coordination. CDC has activated its EOC to Level 1 four times prior to 2020, including Hurricane Katrina (2005); H1N1 influenza pandemic (2009); Ebola outbreak (2014); and Zika virus response (2016).³⁸

In addition, CDC provides funding, technical expertise, and coordination to support public health emergency responses at the SLTT levels. For example, CDC maintains its Laboratory Response Network, which taps into other networks, such as the Council of State and Territorial Epidemiologists, to bolster public health surveillance and response efforts during public health emergencies. CDC’s Laboratory Response Network, established in 1999, includes “state and local public health, veterinary, military and international labs” and is responsible for maintaining an “integrated network of laboratories” capable of responding to an array of threats, including bioterrorism, chemical terrorism, emerging infectious diseases, and other public health emergencies.³⁹

Dr. Deborah Birx, Former White House Coronavirus Task Force Coordinator (Mar. 2020 – Jan. 2021), Interview with Senate Committee on Homeland Security and Governmental Affairs (Jan. 6, 2022) (hereinafter “Interview with Dr. Deborah Birx (Jan. 6, 2022)”); Joseph Grogan, Former Director of the United States Domestic Policy Council (Jan. 2019 – May 2020), Interview with Senate Committee on Homeland Security and Governmental Affairs (Jan. 25, 2022) (hereinafter “Interview with Joseph Grogan (Jan. 25, 2022)”).

³⁵ Department of Health and Human Services, Centers for Disease Control and Prevention Mission, Role and Pledge (<https://www.cdc.gov/about/organization/mission.htm>) (accessed Nov. 28, 2022).

³⁶ See Department of Health and Human Services, Centers for Disease Control and Prevention, CDC’s EOC (<https://www.cdc.gov/cpr/eoc/eoc.htm>) (accessed Nov. 28, 2022); see also Department of Health and Human Services, Center for Disease Control and Prevention, Center for Preparedness and Response, CDC Emergency Operations Center: How an EOC Works (<https://www.cdc.gov/cpr/eoc/how-eoc-works.htm>) (accessed Feb. 15, 2022).

³⁷ See Department of Health and Human Services, Centers for Disease Control and Prevention, CDC’s EOC (<https://www.cdc.gov/cpr/eoc/eoc.htm>) (accessed Nov. 28, 2022) (noting “a team of subject matter experts within [the Division of Emergency Operations] and across CDC [] decide whether to activate the Incident Management System,” and this assessment is reported to the Director of Center for Preparedness and Response, who then provides a recommendation to the CDC Director).

³⁸ Centers for Disease Control and Prevention, The CDC Field Epidemiology Manual: Emergency Operations Centers and Incident Management Structure (<https://www.cdc.gov/eis/field-epi-manual/chapters/EOC-Incident-Management.html>) (accessed Nov. 17, 2022).

³⁹ Department of Health and Human Services, Centers for Disease Control and Prevention, Emergency Preparedness and Response: Partners in Preparedness (<https://emergency.cdc.gov/lrn/>) (accessed Nov. 28, 2022).

HHS, through ASPR, CDC, and other entities, also has the ability to activate emergency health response capabilities, such as the National Disaster Medical System or the U.S. Public Health Service Commissioned Corps, which can deploy personnel to provide medical support and resources depending on the nature of the threat.⁴⁰

Multiple individuals interviewed by the Committee noted that ASPR's and CDC's organizational structure is compartmentalized and disjointed, making it difficult to establish clear lines of communication and coordinated support to SLTT partners during emergencies.⁴¹ Former White House Coronavirus Response Coordinator, Dr. Deborah Birx told the Committee that HHS's organizational structure—both the physical location of its various offices as well as the allocation of responsibilities within HHS—is a key area of concern with respect to needed reforms to public health preparedness and response in the U.S. Specifically, Dr. Birx explained, there is “duplication and lack of clarity on command and control in a crisis between ASPR and CDC.”⁴²

The lack of uniform regional offices across HHS also present challenges during a crisis. While HHS has regional offices across the United States that are operated by multiple components and programs, there is not a singular pathway for SLTT partners to receive assistance.⁴³ As a result, the Majority Committee staff found that access to resources and support from the federal government can be unclear. Former Principal Deputy Assistant Secretary for Preparedness and Response, Dr. Kevin Yeskey told Committee staff that ASPR has a regional office presence; however, CDC does not, resulting in confusion on who to talk to and where to submit requests.⁴⁴ Dr. Yeskey explained that interacting with states without a designated structure creates overlap and friction between ASPR and CDC. He noted, “sorting out roles is a challenge for people at the state level because they don't want to step on anyone's

⁴⁰ Commissioned Corps of the US Public Health Service, Who We Are (<https://www.usphs.gov/about-us>) (accessed Feb. 15, 2022); Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Disaster Medical Assistance Teams (<https://www.phe.gov/Preparedness/responders/ndms/ndms-teams/Pages/dmat.aspx>) (accessed Feb. 15, 2022).

⁴¹ See Interview with Dr. Deborah Birx (Jan. 6, 2022); Interview with Dr. Robert Kadlec (Dec. 6, 2021); Interview with Dr. Kevin Yeskey (Nov. 17, 2021 and Dec. 2, 2021); Dr. Laura Wolf, Former Director of Critical Infrastructure Protection at the Office of Assistant Secretary for Preparedness and Response (tenure Sept. 2009 – Feb. 2022), Interview with Senate Committee on Homeland Security and Governmental Affairs (Nov. 30 2021) (hereinafter “Interview with Dr. Laura Wolf (Nov. 30, 2021)”); see also Josh Dozor, Former Deputy Assistant Administrator for Response at the Federal Emergency Management Agency (tenure Aug. 2008 – May 2020), Interview with Senate Committee on Homeland Security and Governmental Affairs (June 7, 2021 and July 27, 2021) (hereinafter “Interview with Josh Dozor (June 7, 2021 and July 27, 2021)”) (noting HHS's operational organizational structure at the headquarters and regional levels across ASPR, CDC, and the Office of the Assistant Secretary for Health, and other agencies is compartmentalized and disjointed).

⁴² Interview with Dr. Deborah Birx (Jan. 6, 2022).

⁴³ See Department of Health and Human Services, HHS Regional Offices (<https://www.hhs.gov/about/agencies/iea/regional-offices/index.html>) (accessed Nov. 28, 2022); Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, ASPR Regional Emergency Coordinators (<https://aspr.hhs.gov/REC/Pages/default.aspx>) (accessed Nov. 28, 2022).

⁴⁴ Interview with Dr. Kevin Yeskey (Nov. 17, 2021 and Dec. 2, 2021).

toes, but they want to get what they need.”⁴⁵ Dr. Robert Kadlec, former Assistant Secretary for Preparedness and Response, agreed: “HHS needs ASPR regional offices structured like and integrated with FEMA. FEMA has very functional, very supportive, very interactive regional offices with their state emergency management counterparts—they do a lot to make sure the states know who they are and what they bring to the table.” While HHS has small regional offices with regional emergency coordinators from ASPR located in each office, Dr. Kadlec noted that the offices do not reflect the entire HHS mission, as there are no equivalent CDC or FDA regional offices.⁴⁶ CDC told the Committee that prior to the COVID-19 pandemic, it did not have a regional presence. Throughout the federal COVID-19 response, CDC hired a small number of staff to directly support jurisdictional health departments and coordinate closely with federal partners in the regional offices; however, funding constraints limit permanent regional placements.⁴⁷

Food and Drug Administration. FDA also plays a critical role in public health emergency responses. The agency is responsible for protecting public health by “ensuring the safety, efficacy, and security” of drugs and medical devices, as well as the safety of the nation’s food supply, among other things.⁴⁸ During public health emergencies, FDA has the ability to issue flexible regulatory guidance. In addition, FDA may authorize the emergency use of certain medical countermeasures, such as diagnostics, therapeutics, and vaccines that would otherwise take months, if not years, to go through the formal clearance, approval, and licensure processes.⁴⁹ In order for FDA to issue an Emergency Use Authorization (EUA), the HHS Secretary must declare that circumstances exist to justify an EUA based on one of four threat determinations made by DOD, DHS, or HHS, as detailed in the chart below.⁵⁰

⁴⁵ *Id.*

⁴⁶ Interview with Dr. Robert Kadlec (Dec. 6, 2021).

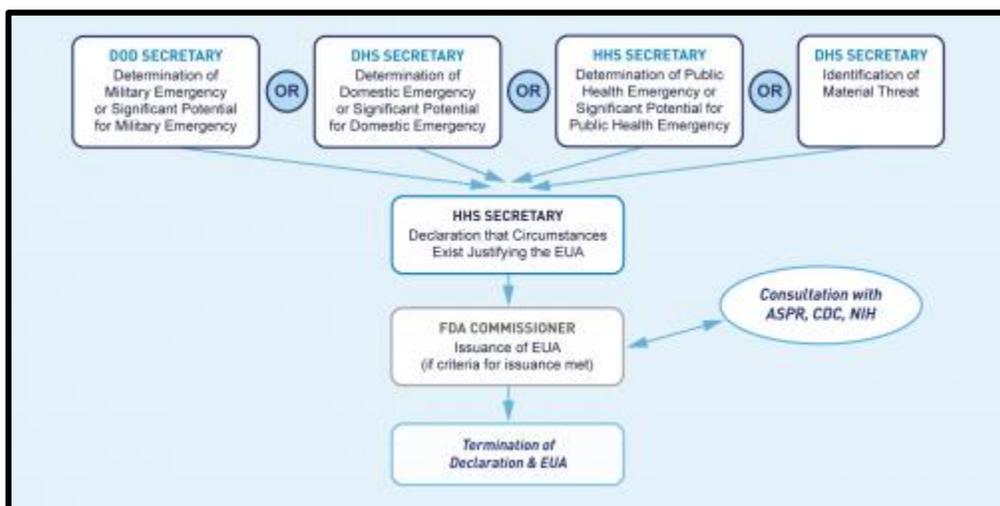
⁴⁷ HHS Communication to Senate Committee on Homeland Security and Governmental Affairs Staff (Oct. 27, 2022).

⁴⁸ Food and Drug Administration, What We Do (<https://www.fda.gov/about-fda/what-we-do>) (accessed Nov. 28, 2022); *see also* Food and Drug Administration, Emergency Preparedness and Response (<https://www.fda.gov/emergency-preparedness-and-response>) (accessed Nov. 28, 2022).

⁴⁹ Federal Food, Drug and Cosmetic Act of 1938, Pub. L. No. 75-717, Sec. 564 (as amended through Pub. L. No. 117-103 (2022)).

⁵⁰ Federal Food, Drug and Cosmetic Act of 1938, Pub. L. No. 75-717, Sec. 564 (as amended through Pub. L. No. 117-103 (2022)); Food and Drug Administration, Summary of Process for EUA Issuance (June 9, 2021) (<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/summary-process-eua-issuance>).

*FDA Summary of the Process for Emergency Use Authorization Issuance*⁵¹



Centers for Medicare and Medicaid Services (CMS). Housed under HHS, CMS serves a critical regulatory and policy-making role through its ability to waive certain requirements and implement regulatory flexibilities during public health emergencies.⁵² Through its implementation and oversight of federal health insurance programs such as Medicare, Medicaid, and the Children’s Health Insurance Program (CHIP), CMS collects a variety of health information, including data from hospitals and nursing homes, among other entities that receive federal funding.⁵³ In addition, through its Clinical Laboratory Improvement Amendments (CLIA) Program, CMS, along with CDC and FDA, regulates all clinical laboratories that perform testing on human specimens (with the exception of research laboratories and other selected facilities) for the purposes of clinical diagnosis, treatment, or prevention.⁵⁴

⁵¹ Food and Drug Administration, Summary of Process for EUA Issuance (June 9, 2021) (<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/summary-process-eua-issuance>).

⁵² 42 U.S.C. § 247d-6b.; Department of Health and Human Services, Centers for Medicare & Medicaid Services, Waivers & flexibilities (<https://www.cms.gov/about-cms/agency-information/emergency/epr/resources/waivers-and-flexibilities>) (accessed Nov. 28, 2022).

⁵³ Department of Health and Human Services, Centers for Medicare & Medicaid Services, *Inventory of Resources for Standardized Demographic and Language Data Collection*, (Mar. 2022) (<https://www.cms.gov/about-cms/agency-information/omh/downloads/data-collection-resources.pdf>).

⁵⁴ See 42 CFR § 493.3 (b); Department of Health and Human Services, Centers for Medicare & Medicaid Services, Clinical Laboratory Improvement Amendments (<https://www.cms.gov/regulations-and-guidance/legislation/clia>) (accessed Nov. 28, 2022).

State, Local, Tribal, and Territorial Public Health Efforts

Public health preparedness structures vary among SLTT government entities. While seven states operate local health departments at the state level, most states have locally governed health departments.⁵⁵ Every state and territory also has a central public health laboratory, as do many localities, to support community testing and surveillance.⁵⁶ SLTT partners generally have preexisting relationships with federal agencies to share information. For example, CDC’s Laboratory Response Network (described above) and CDC’s National Notifiable Diseases Surveillance System are critical programs that facilitate collaboration and information sharing between SLTT partners and the federal government.⁵⁷ Challenges still exist, however, in information technology and data capacity with a significant amount of state and local public health laboratories still using paper-based as opposed to electronic systems.⁵⁸

Private Sector

The private sector plays a critical role in emergency preparedness and response efforts.⁵⁹ Federal agencies, through procurement relationships, memoranda of understandings, and other partnerships, have the ability to develop longstanding relationships with various partners, such as health care providers, commercial laboratories, manufacturers, and distributors, among others. Multiple individuals interviewed by the Committee, however, noted underinvestment and insufficient engagement between the federal government and the private sector.⁶⁰ These shortfalls are discussed in Part II of this report.

⁵⁵ National Association of County & City Health Officials, *2019 National Profile of Local Health Departments*, at 24 (2020) (https://www.naccho.org/uploads/downloadable-resources/Programs/Public-Health-Infrastructure/NACCHO_2019_Profile_final.pdf).

⁵⁶ Association of Public Health Laboratories, *About Public Health Laboratories* (<https://www.aphl.org/aboutAPHL/Pages/aboutphls.aspx>) (accessed Nov. 28, 2022).

⁵⁷ *Id.* See also Department of Health and Human Services, Centers for Disease Control and Prevention, *The Laboratory Response Network Partners in Preparedness* (<https://emergency.cdc.gov/lrn/>) (accessed Nov. 28, 2022); Department of Health and Human Services, Centers for Disease Control and Prevention, *National Notifiable Diseases Surveillance System (NNDSS)* (<https://www.cdc.gov/nndss/index.html>) (accessed Nov. 28, 2022).

⁵⁸ Megan Wallace and Joshua Sharfstein, *The Patchwork U.S. Public Health System*, *New England Journal of Medicine* (Jan. 6, 2022); see also Amy Gleason, Director of Data, Strategy, and Execution (Mar. 2020 – Mar. 2022), *Pandemic Ready Interoperable Modernization Effort (PRIME) Lead* (May 2020 – Oct. 2021), Digital Services Expert, United States Digital Service (Oct. 2018 - present) Interview with the Senate Committee on Homeland Security and Governmental Affairs (Jan. 31, 2022) (hereinafter “Interview with Amy Gleason (Jan. 31, 2022)”).

⁵⁹ Federal Emergency Management Agency, *National Preparedness System* (<https://www.fema.gov/emergency-managers/national-preparedness/system>) (accessed Nov. 28, 2022); Federal Emergency Management Agency, *Whole Community* (<https://www.fema.gov/glossary/whole-community>) (accessed Nov. 28, 2022).

⁶⁰ Dr. Luciana Borio, Former Director for Medical and Biodefense Preparedness at the National Security Council (2017 – 2019), Interview with Senate Committee on Homeland Security and Governmental Affairs (May 4, 2021) (hereinafter “Interview with Dr. Luciana Borio (May 4, 2021)”); National Independent Laboratory Association, Interview with Senate Committee on Homeland Security and Governmental Affairs (May 24, 2021) (hereinafter “Interview with National Independent Laboratory Association (May 24, 2021)”); American Clinical Laboratory Association, Interview with Senate Committee on Homeland and Governmental Affairs (May 27, 2021)

National Security Council

Established in 1947, the NSC is housed within the Executive Office of the President and serves as a coordinator among federal departments and agencies to develop and implement national security policy and long term strategic planning.”⁶¹ With regard to emerging infectious diseases, Mr. Ruggiero explained, “the NSC works closely with senior officials at CDC, HHS, the intelligence community, and [other agencies] to monitor disease outbreaks.”⁶²

While the NSC has coordinated biodefense capabilities across the government for decades, its structure has undergone a number of changes. Since 1998, the Biodefense Directorate within the NSC has restructured at least five times under five different Presidential Administrations, detailed in Figure 1 below.

Figure 1. Evolution of Biodefense Components within the National Security Council⁶³



(hereinafter “Interview with American Clinical Laboratory Association (May 27, 2021)”); Centers for Disease Control and Prevention, Briefing with Senate Committee on Homeland Security and Governmental Affairs Staff (July 12, 2021) (hereinafter “CDC Briefing (July 12, 2021)”); Northwest Washington Healthcare Response Network, Interview with Senate Committee on Homeland Security and Governmental Affairs (May 4, 2021) (hereinafter “Interview with Northwest Washington Healthcare Response Network (May 4, 2021)”); Dr. Richard Besser, Former Acting Director of Centers for Disease Control and Prevention (Jan. 2009 - June 2009), Interview with Senate Committee on Homeland Security and Governmental Affairs (Apr. 7, 2021) (hereinafter “Interview with Dr. Richard Besser (Apr. 7, 2021)”); Dr. Nicolette Louissaint, Former Executive Director of Healthcare Ready (July 2017 – Jan. 2022), Interview with Senate Committee on Homeland Security and Governmental Affairs (Feb. 17, 2021) (hereinafter “Interview with Dr. Nicolette Louissaint (Feb. 17, 2021)”); Dr. Rick Bright, Former Director of the Biomedical Advanced Research and Development Authority (2017 – 2020, tenure at BARDA 2010-2020), Interview with Senate Committee on Homeland Security and Governmental Affairs (Mar. 17, 2021 and Nov. 4, 2021) (hereinafter “Interview with Dr. Rick Bright (Mar. 17, 2021 and Nov. 4, 2021)”); Association of State and Territorial Health Officials, Interview with Senate Committee on Homeland Security and Governmental Affairs (Apr. 27, 2021) (hereinafter “Interview with Association of State and Territorial Health Officials (Apr. 27, 2021)”).

⁶¹ Gail Wilensky, *The Importance of Reestablishing a Pandemic Preparedness Office at the White House*, The JAMA Forum (2020); Columbia Law School and Columbia Climate School, *NSC Directorate for Global Health Security and Biodefense Dissolved* (undated) <https://climate.law.columbia.edu/content/nsc-directorate-global-health-security-and-biodefense-dissolved> (accessed Nov. 28, 2022).

⁶² Anthony Ruggiero, Former Senior Director for Counterproliferation and Biodefense at the National Security Council (July 2019 - Jan. 2021), Interview with Senate Committee on Homeland Security and Governmental Affairs (Jan. 26, 2022) (hereinafter “Interview with Anthony Ruggiero (Jan. 26, 2022)”).

⁶³ Figure prepared by the Majority Committee staff. See Congressional Research Service, *The National Security Council: Background and Issues for Congress* (R44828) (June 3, 2021); Gail Wilensky, *The Importance of Reestablishing a Pandemic Preparedness Office at the White House*, The JAMA Forum (2020); Columbia Law School and Columbia Climate School, *NSC Directorate for Global Health Security and Biodefense Dissolved* (undated) <https://climate.law.columbia.edu/content/nsc-directorate-global-health-security-and-biodefense-dissolved> (accessed Nov. 28, 2022); National Academies of Sciences, Engineering, and Medicine, *A Strategic Vision for Biological Threat Reduction: The U.S. Department of Defense and Beyond*, at 9 (2020); Bipartisan Commission on

In 1998, the Clinton Administration opened the first ever Biodefense and Health Security Office within the NSC.⁶⁴ Following the September 11th terrorist attacks, President George W. Bush stood up the Homeland Security Council (HSC), a parallel unit to the NSC.⁶⁵ In response to the subsequent Anthrax attacks in 2001, President Bush added a specific group dedicated to biodefense within the HSC known as the White House Biodefense Policy Coordinating Committee.⁶⁶ When President Obama took office in 2009, he eliminated the HSC and the biodefense office within it, dispersing these functions to multiple other directorates throughout the NSC.⁶⁷ In response to the 2014 Ebola outbreak, President Obama stood up a Directorate for Global Health Security and Biodefense within the NSC.⁶⁸ The mission of the Directorate was to track emerging global health threats, including infectious diseases, biological agents and toxins, and bioterrorism.⁶⁹ When President Trump took office, the White House reorganized the NSC and consolidated the Directorate for Global Health Security and Biodefense staff within the counterproliferation and biodefense directorate.⁷⁰ In 2021, President Biden reestablished the Directorate for Global Health Security and Biodefense as a part of the Defense Policy, Weapons of Mass Destruction and Arms Control office within the NSC.⁷¹

The Majority Committee staff found differing opinions on the effectiveness of the Trump Administration’s reorganization of the NSC. Some former officials noted that the NSC steadily lost institutional medical and public health expertise while others indicated the level of public health expertise was sufficient. Dr. Luciana Borio, former Director for Medical and Biodefense Preparedness at the NSC, left the office in 2019 and explained how “the vacancy left a vacuum [of public health expertise] because they didn’t fill the position with similar experience.”⁷² Former DHS Chief Medical Officer, Dr. Duane Caneva, previously worked at the NSC between

Biodefense, *A National Blueprint For Biodefense: Leadership And Major Reform Needed To Optimize Efforts*, at 7 (Oct. 2015) (https://biodefensecommission.org/wp-content/uploads/2015/10/National-Blueprint-for-Biodefense-2021_reprint_v4_web-1.pdf) (hereinafter “Report of the Bipartisan Commission on Biodefense (Oct. 2015)”); Exec. Order No. 13987, 86 Fed. Reg. 7019 (Jan. 25, 2021).

⁶⁴ Gail Wilensky, *The Importance of Reestablishing a Pandemic Preparedness Office at the White House*, *The JAMA Forum* (2020); Columbia Law School and Columbia Climate School, *NSC Directorate for Global Health Security and Biodefense Dissolved* (undated) <https://climate.law.columbia.edu/content/nsc-directorate-global-health-security-and-biodefense-dissolved> (accessed Nov. 28, 2022).

⁶⁵ White House, Homeland Security Council (<https://georgewbush-whitehouse.archives.gov/hsc/>) (accessed Nov. 28, 2022).

⁶⁶ National Academies of Sciences, Engineering, and Medicine, *A Strategic Vision for Biological Threat Reduction: The U.S. Department of Defense and Beyond*, at 9 (2020).

⁶⁷ Report of the Bipartisan Commission on Biodefense (Oct. 2015).

⁶⁸ *Id.*

⁶⁹ Columbia Law School and Columbia Climate School, *NSC Directorate for Global Health Security and Biodefense Dissolved* (undated) <https://climate.law.columbia.edu/content/nsc-directorate-global-health-security-and-biodefense-dissolved> (accessed Nov. 28, 2022).

⁷⁰ *Id.*

⁷¹ Exec. Order No. 13987, 86 Fed. Reg. 7019-7021 (Jan. 20, 2021).

⁷² Interview with Dr. Luciana Borio (May 4, 2021).

2007 and 2009 as the Director of Medical Preparedness Policy and told the Committee that there were originally three NSC physician staff members covering biodefense, medical preparedness, or public health policy portfolios and by 2020, there were none.⁷³ Dr. Caneva explained, “the NSC lost the availability of expertise to inform decision makers of public health policy implications. We have smart people there, but they didn’t have public health expertise.”⁷⁴

Other former NSC officials disagreed. Former senior NSC official Anthony Ruggiero told the Committee that as of January 2020, the NSC Biodefense Directorate had “two directors with public health experience”—a virologist and an epidemiologist, with an “additional director who assisted in biodefense.”⁷⁵ Mr. Ruggiero noted that, in comparison, other directorates at the NSC had fewer personnel in their focus area.⁷⁶ Former Deputy National Security Advisor Matthew Pottinger told Committee staff that the NSC Biodefense Directorate worked more efficiently after the reorganization because under the Obama Administration, biodefense and health preparedness directors were spread out across multiple directorates. According to Mr. Pottinger, the 2018 reorganization consolidated directors into a single office with a higher-ranking Senior Director (directorship head) at the commissioned officer level of Deputy Assistant to the President. Nevertheless, Mr. Pottinger stated that both of the structures—in the Obama and Trump Administrations—were “inadequate to respond to a major crisis.”⁷⁷ Dr. Lawler shared similar concerns and stated that in 2020 and 2021, there was not sufficient technical expertise (both public health and medical) within the NSC and the White House.⁷⁸

II. Statutory Authorities and Policy Directives

The federal government has numerous statutory authorities and policy directives that assist in structuring its response to various crises. These provisions aim to provide a systemic and adaptable approach in preparing for and responding to domestic emergencies and emerging threats.⁷⁹ Despite a unified intent, several statutory authorities and policy directives that govern

⁷³ Dr. Duane Caneva, Former Chief Medical Officer for the Department of Homeland Security (Apr. 2018 - Jan. 2021); Former Director of Medical and Public Health Preparedness Policy at the National Security Council (Feb. 2017 - Feb. 2018); Former Director of Medical Preparedness Policy at the Homeland Security Council (Oct. 2007 - June 2009), Interview with Senate Committee on Homeland Security and Governmental Affairs (Nov. 15, 2021) (hereinafter “Interview with Dr. Duane Caneva (Nov. 15, 2021)”).

⁷⁴ *Id.*

⁷⁵ Interview with Anthony Ruggiero (Jan. 26, 2022).

⁷⁶ *Id.*

⁷⁷ Matthew Pottinger, Former Deputy National Security Advisor (Sept. 2019 - Jan. 2021), Interview with Senate Committee on Homeland Security and Governmental Affairs (Jan. 25, 2022) (hereinafter “Interview with Matthew Pottinger (Jan. 25, 2022)”).

⁷⁸ Dr. James Lawler, Former Director for Medical Preparedness and Biodefense Policy at the Homeland Security Council (June 2006 - May 2008) and Director for Medical Preparedness Policy at the National Security Council (Apr. 2009 - Oct. 2010), Interview with Senate Committee on Homeland Security and Governmental Affairs (May 6, 2021) (hereinafter “Interview with Dr. James Lawler (May 6, 2021)”).

⁷⁹ See Department of Homeland Security, *National Response Framework* (Oct. 28, 2019); Government Accountability Office, *Influenza Pandemic: Further Efforts Are Needed to Ensure Clearer Federal Leadership Roles and an Effective National Strategy* (GAO-07-781) (Aug. 2007); Government Accountability Office, *Influenza Pandemic: Gaps in Pandemic Planning and Preparedness Need to be Addressed* (GAO-09-909T) (July 2009);

leadership during health emergencies are in conflict, often resulting in confusion of roles and responsibilities during crises.⁸⁰ Between 2007 and 2011, GAO highlighted in three separate reports the lack of clarity and overlapping roles between the DHS and the HHS during a pandemic response.⁸¹ A decade later, in March 2021, GAO again reiterated this concern and emphasized the “critical importance of clearly defining the roles and responsibilities for the wide range of federal departments and other key players involved when preparing for pandemics and addressing unforeseen emergencies.”⁸²

This section provides an overview of relevant statutes and policy directives that authorize national emergency and public health management response efforts.

Statutory Authorities

- **Public Health Service Act.** The Public Health Service Act (PHSA) directs the HHS Secretary to “lead all federal public health and medical response to public health emergencies and incidents covered by the [National Response Framework].”⁸³ Through the PHSA, the HHS Secretary has the authority to declare a public health emergency under Section 319, authorizing additional HHS activities and forms of assistance, such as accessing emergency funding (if available), waiving grant or administrative requirements to ease the burden on SLTT partners and other partners, and allowing for temporary staff reassignments by grantees in response to the threat.⁸⁴

Government Accountability Office, *Influenza Pandemic: Lessons from the H1N1 Pandemic Should Be Incorporated into Future Planning* (GAO-11-632) (June 2011).

⁸⁰ See Government Accountability Office, *Influenza Pandemic: Further Efforts Are Needed to Ensure Clearer Federal Leadership Roles and an Effective National Strategy* (GAO-07-781) (Aug. 2007); Government Accountability Office, *Influenza Pandemic: Gaps in Pandemic Planning and Preparedness Need to be Addressed* (GAO-09-909T) (July 2009); Government Accountability Office, *Influenza Pandemic: Lessons from the H1N1 Pandemic Should Be Incorporated into Future Planning* (GAO-11-632) (June 2011).

⁸¹ See Government Accountability Office, *Influenza Pandemic: Further Efforts Are Needed to Ensure Clearer Federal Leadership Roles and an Effective National Strategy* (GAO-07-781) (Aug. 2007) (noting that “[a]lthough [the HHS] Secretary is to lead the public health and medical response and [the DHS] Secretary is to lead overall nonmedical support and response actions, the [National Strategy for Pandemic Influenza Implementation Plan] does not clearly address these simultaneous responsibilities or how these roles are to work together”); Government Accountability Office, *Influenza Pandemic: Gaps in Pandemic Planning and Preparedness Need to be Addressed* (GAO-09-909T) (July 2009) (finding “[l]eadership roles and responsibilities for an influenza pandemic need to be clarified, tested, and exercised”); Government Accountability Office, *Influenza Pandemic: Lessons from the H1N1 Pandemic Should Be Incorporated into Future Planning* (GAO-11-632) (June 2011) (noting “[t]he shared leadership roles between HHS and DHS were not fully implemented during [the H1N1] pandemic [and]...some state officials cited concerns about the shared federal leadership roles in the early days of the pandemic response”).

⁸² Government Accountability Office, *High-Risk Series: Dedicated Leadership Needed to Address Limited Progress in Most High-Risk Areas* (GAO-21-119SP) (Mar. 2021).

⁸³ Public Health Services Act of 1944, Pub. L. No. 78-410 (as amended by Pandemic and All-Hazards Preparedness Act of 2006, Pub. L. No. 109-417, Sec. 101).

⁸⁴ Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, A Public Health Emergency Declaration (<https://www.phe.gov/Preparedness/legal/Pages/phedeclaration.aspx>) (accessed Nov. 21, 2022).

- Pandemic and All-Hazards Preparedness Act.** In 2006, the Pandemic and All-Hazards Preparedness Act (PAHPA) amended the PHS Act and established the Office of the Assistant Secretary for Preparedness and Response (ASPR), housed under HHS Secretary. Under PAHPA, the ASPR “serve[s] as the principal advisor to the [HHS] Secretary on all matters related to federal public health and medical preparedness and response for public health emergencies.”⁸⁵ PAHPA also provided new preparedness authorities and programs within ASPR, including a mechanism to invest in the development of medical countermeasures through the creation of the Biomedical Advanced Research Development Authority (BARDA) and the development of a National Health Security Strategy every four years.⁸⁶
- Stafford Act.** The Robert T. Stafford Disaster Relief and Emergency Assistance Act of 1988 (Stafford Act) amended the Disaster Relief Act of 1974 and created many of FEMA’s emergency response authorities.⁸⁷ The Stafford Act delegates authority to the President to direct other federal agencies to exercise response capabilities in the event of an emergency. Since 1979, the President has delegated response authorities to FEMA through Executive Orders 12148 and subsequently 12673.⁸⁸ At the request of a governor or a chief executive of an affected area, the President may declare a major disaster or an emergency if the response capabilities of the SLTT exceed its capacity.⁸⁹ The Stafford Act also permits the President to declare an emergency unilaterally if primary responsibility for the response rests with the federal government. Once the President declares a major disaster or emergency, the Stafford Act authorizes FEMA to provide assistance in the form of financial relief from the Disaster Relief Fund or direct assistance (deploying FEMA personnel to support emergency medical care or structural repairs) to SLTT partners and other eligible entities.⁹⁰ The Stafford Act has rarely been used for responding to infectious disease threats and FEMA has not always served as the lead federal agency during all Stafford Act declarations.⁹¹

⁸⁵ Pandemic and All-Hazards Preparedness Act of 2006, Pub. L. No. 109-417, Sec. 102.

⁸⁶ Pandemic and All-Hazards Preparedness Act of 2006, Pub. L. No. 109-417, Sec. 401.

⁸⁷ Disaster Relief Act of 1974, Pub. L. No. 93-288 (as amended by Robert T. Stafford Disaster Relief and Emergency Assistance Act of 1988, Pub L. No. 100-707).

⁸⁸ Robert T. Stafford Disaster Relief and Emergency Assistance Act of 1988, Pub L. No. 100-707, Sec. 402(1); Exec. Order No. 12148, 44 Fed. Reg. 43239 (July 20, 1979); Exec. Order No. 12673, 54 Fed. Reg. 12571 (Mar. 23, 1989).

⁸⁹ Robert T. Stafford Disaster Relief and Emergency Assistance Act of 1988, Pub L. No. 100-707, Sec. 106 (detailing major disaster programs); Robert T. Stafford Disaster Relief and Emergency Assistance Act of 1988, Pub L. No. 100-707, Sec. 107 (detailing emergency assistance programs).

⁹⁰ *Id.* at Sec. 107 (including coordinating assistance, providing technical assistance, removing debris, and assisting in the distribution of medicine and other supplies).

⁹¹ The Stafford Act has been invoked for the West Nile virus in New York and New Jersey; a chemical spill in West Virginia; water contamination in Flint, Michigan; and the COVID-19 pandemic. *See* Congressional Research Service, *Stafford Act Assistance for Public Health Incidents* (IN11229) (Mar. 22, 2021).

- **Homeland Security Act.** The Homeland Security Act of 2002 created the Department of Homeland Security. The Act also restructured federal response authorities for major disasters, taking responsibility away from FEMA and giving it to the Secretary of Homeland Security, acting through an Under Secretary for Emergency Preparedness and Response.⁹² In 2006, following the aftermath of Hurricane Katrina, the Post-Katrina Emergency Management Reform Act, amended the Homeland Security Act and directed the FEMA Administrator to “lead the Nation’s efforts to prepare for, protect against, respond to, recover from, and mitigate against the risk of natural disasters, acts of terrorism, and other man-made disasters, including catastrophic incidents.”⁹³

Presidential Policy Directives

Presidential directives, such as Presidential Policy Directives and Homeland Security Presidential Directives, direct the actions of the Executive Branch and articulate the policy of the Administration.⁹⁴ They may be based in statutory or constitutional authorities, or a combination thereof.⁹⁵ Several recent directives have followed major domestic crises like the September 11th terrorist attacks and Hurricane Katrina. The following directives aim to improve and define emergency preparedness and incident response. These policy directives, however, often overlap and at times conflict with statutory authority (*see* Table 2).

- **Homeland Security Presidential Directives 5 and 8 (HSPD-5 and HSPD-8).** In 2003, President George W. Bush issued Homeland Security Presidential Directive 5 (HSPD-5), to improve the management of domestic incidents. HSPD-5 directed the United States government to “establish a single, comprehensive approach to domestic incident management.”⁹⁶ One year later, in March 2004, DHS developed the National Incident Management Structure (NIMS), a regularly updated “consistent nationwide” approach to incident management for all levels of government, nongovernmental organizations, and the private sector.⁹⁷ HSPD-5 focused on incident response and identified the DHS Secretary as “the principal federal official for domestic incident management.” Months later, President Bush issued Homeland Security Presidential Directive 8 (HSPD-8) as a companion to HSPD-5, which focused on preparedness and called for the development of a National Preparedness Goal, among other activities.⁹⁸

⁹² Homeland Security Act of 2002, Pub. L. No. 107-296, Sec. 502.

⁹³ Department of Homeland Security Appropriations Act of 2007, Pub. L. No. 109-295, Sec. 611.

⁹⁴ *See, e.g.*, Congressional Research Service, *Presidential Directives: An Introduction* (IF11358) (Nov. 13, 2019)

⁹⁵ *Id.*

⁹⁶ Department of Homeland Security, *Homeland Security Presidential Directive 5* (Feb. 28, 2003).

⁹⁷ Department of Homeland Security, Federal Emergency Management Agency, *National Incident Management System* (Oct. 2017).

⁹⁸ Department of Homeland Security, *Homeland Security Presidential Directive 8* (Dec. 17, 2003).

- **Presidential Policy Directive 8 (PPD-8).** The issuance of Presidential Policy Directive 8 (PPD-8) in 2011 by President Obama superseded HSPD-8. PPD-8 focused on national preparedness and created requirements for national planning frameworks aimed to strengthen U.S. security and resilience against “acts of terrorism, cyberattacks, pandemics, and catastrophic natural disasters” through an “all-of-Nation” approach.⁹⁹ In response to the Post-Katrina Emergency Management Reform Act of 2006 mandate, PPD-8 tasked the DHS Secretary with developing a National Preparedness Goal and a National Preparedness System.¹⁰⁰ The Directive also created the requirement for “the development of national planning frameworks and associated interagency operational plans.” The national Federal Interagency Operational Plans (FIOPs) support the five national planning frameworks: prevention, protection, mitigation, response, and recovery.
- **Presidential Policy Directive 44 (PPD-44).** Five years later, in 2016, President Obama issued PPD-44, a document designed to clarify agency roles when “there is neither Presidential declaration under the Stafford Act nor clear Federal roles and responsibilities pertaining to incident response established in current law or regulation.”¹⁰¹ PPD-44 acknowledges “an agency that is authorized to respond may become overwhelmed by the scale of the incident, even as the situation demands the employment of robust incident management capability because lives, property, or the environment are at stake.”¹⁰² According to PPD-44, during such incidents, the President can designate a lead federal agency and senior response official to lead coordination of the federal government’s incident response.¹⁰³ PPD-44 can improve response time by allowing the President to designate a lead federal agency before issuing a national disaster declaration. In addition, PPD-44 also permits agencies to agree on recognizing a lead federal agency without formal designation by the President.¹⁰⁴

⁹⁹ Department of Homeland Security, *Presidential Policy Directive 8* (Mar. 30, 2011).

¹⁰⁰ Congressional Research Service, *National Preparedness: A Summary and Select Issues* (R46696) (Feb. 26, 2021).

¹⁰¹ Department of Homeland Security, *Presidential Policy Directive 44* (Nov. 7, 2016) (on file with the Committee).

¹⁰² *Id.*

¹⁰³ *Id.*

¹⁰⁴ Department of Homeland Security, *Presidential Policy Directive 44* (Nov. 7, 2016) (on file with the Committee).

Table 2. Overview of Statutory Authorities and Policy Directives¹⁰⁵

Authority	Description	Lead Agency
Public Health Service Act	Title 28 of the PHS Act directs the HHS Secretary to “lead all federal public health and medical response to public health emergencies and incidents covered by the [National Response Framework] developed pursuant to section 314(6) of title 6, or any successor plan.” ¹⁰⁶	HHS
Stafford Act	The Robert T. Stafford Disaster Relief and Emergency Assistance Act of 1988 (Stafford Act), amended the Disaster Relief Act of 1974, and created many of FEMA’s emergency response authorities. The Stafford Act provides authority to the President to direct other federal agencies to exercise response capabilities in the event of an emergency. ¹⁰⁷ Many of these response authorities have since been delegated to FEMA.	FEMA
Homeland Security Act	The Homeland Security Act of 2002 restructured response authorities for major disasters under the DHS Secretary. In 2006, following the aftermath of Hurricane Katrina, the Post-Katrina Emergency Management Reform Act amended the Homeland Security Act and directed that the FEMA Administrator “lead the Nation’s efforts to prepare for, protect against, respond to, recover from, and mitigate against the risk of natural disasters, acts of terrorism, and other man-made disasters, including catastrophic incidents.” ¹⁰⁸	FEMA
Directive	Description	Lead Agency
HSPD-5	HSPD-5 focused on an incident management system for domestic responses and identified the DHS Secretary as “the principal Federal official for domestic incident management.” ¹⁰⁹	DHS
HSPD-8	Homeland Security Presidential Directive 8 (HSPD-8) is a companion to HSPD-5, which focused on all-hazards preparedness and called for the development of a National Preparedness Goal, among other activities. PPD-8 superseded HSPD-8. ¹¹⁰	DHS
PPD-8	PPD-8 focused on national preparedness and created requirements for national planning frameworks aimed to strengthen U.S. security and resilience against “acts of terrorism, cyberattacks, pandemics, and catastrophic natural disasters” through an “all-of-Nation” approach. ¹¹¹ The Directive tasked the DHS Secretary with developing a National Preparedness Goal and a National Preparedness System.	N/A
PPD-44	PPD-44, a nonpublic document that allows the President to designate a lead federal agency when there is neither a presidential major disaster declaration nor an emergency under the Stafford Act. ¹¹²	President’s discretion if certain factors are met

In December 2017, the National Security Council’s Domestic Resilience Group identified a number of gaps in federal preparedness planning. According to the NSC’s Domestic Resilience Group, departments and agencies agreed to review HSPD-5 and PPD-44 to “deconflict the existing guidance, reflect on lessons learned, and clarify roles and responsibilities

¹⁰⁵ Committee analysis of selected statutory authorities and policy directives.

¹⁰⁶ Public Health Services Act of 1944, Pub. L. No. 78-410 (as amended by Pandemic and All-Hazards Preparedness Act of 2006, Pub. L. No. 109-417, Sec. 101).

¹⁰⁷ Disaster Relief Act of 1974, Pub. L. No. 93-288 (as amended by the Robert T. Stafford Disaster Relief and Emergency Assistance Act of 1988, Pub L. No. 100-707, Sec. 106).

¹⁰⁸ Homeland Security Act of 2002, Pub. L. No. 116-2135 (as amended by the Post-Katrina Emergency Management Reform Act of 2006, Pub. L. No. 109-295, Sec. 611).

¹⁰⁹ Department of Homeland Security, *Homeland Security Presidential Directive 5* (Feb. 28, 2003).

¹¹⁰ Department of Homeland Security, *Homeland Security Presidential Directive 8* (Dec. 17, 2003).

¹¹¹ Department of Homeland Security, *Presidential Policy Directive 8: National Preparedness* (Mar. 30, 2011).

¹¹² Department of Homeland Security, *Presidential Policy Directive 44* (Nov. 7, 2016) (on file with the Committee).

through updated domestic incident management policy.”¹¹³ An Informational Memorandum for the Associate Director of National Security Programs from December 2017 also recommended that HSPD-5 and PPD-44 be “updated to streamline policy guidance and reflect lessons learned,” noting “it is imperative that these directives be updated to address areas that are in need for more effective response, leadership, and collaboration.”¹¹⁴

To date, neither HSPD-5 nor PPD-44 has been revised. OMB informed the Committee, however, that NSC has led “a comprehensive interagency effort to review all Domestic Incident Management policies,” including PPD-44 and HSPD-5 “to identify opportunities to streamline and enhance implementation.”¹¹⁵ Currently, NSC is working with interagency partners to “update the tasks under PPD-44 to better reflect lessons learned from recent domestic incident response efforts” and “review department and agency capabilities to serve as lead Federal agency under this policy.” According to OMB, “these updates will inform the effective implementation of PPD-44 for future incidents.”¹¹⁶

Former government officials interviewed by this Committee differed in their positions on which federal agency should serve as the lead during a public health emergency. David Bibo, former Deputy Associate Administrator for Response and Recovery, told Committee staff, “I think a reasonable person can look at each of the legal constructs and say each of the parties, ASPR, HHS, and FEMA, could conceivably be tagged with leadership. The policy question that has been extant for a very long time—longer than the pandemic—is how do those things get operationalized in real life . . . most of the [preparedness plans] developed left open the possibility there could be different approaches.”¹¹⁷

Former FEMA Administrator Craig Fugate told the Committee that FEMA’s traditional role in pandemic preparedness and response is a “support role . . . FEMA is a full-time crisis management agency and its main job is to support federal agencies.”¹¹⁸ Former ASPR Dr. Nicole Lurie told the Committee that leadership in public health emergencies should come from HHS and be a “shared responsibility between CDC and ASPR, with CDC generally serving as the spokesperson and ASPR coordinating the response.”¹¹⁹

¹¹³ Office of Management and Budget, *Summary of Conclusions for Meeting of the Deputies Committee* (Dec. 12, 2017) (on file with Committee, OMB HSGAC 994).

¹¹⁴ Office of Management and Budget, *Memorandum for the Associate Director, National Security Programs: Deputies, Bio-Incident Tabletop, Tuesday, Dec 12, 2017 from 1:30pm-3:00pm in WH SitRm* (Dec. 8, 2017) (on file with Committee, OMB HSGAC 900).

¹¹⁵ OMB Correspondence to Senate Committee on Homeland Security and Governmental Affairs Staff (Nov. 16, 2022).

¹¹⁶ *Id.*

¹¹⁷ Interview with David Bibo (Dec. 21, 2021).

¹¹⁸ Craig Fugate, Former Federal Emergency Management Agency Administrator (May 2009 - Jan. 2017), Interview with Senate Committee on Homeland Security and Governmental Affairs (Apr. 22, 2021) (hereinafter “Interview with Craig Fugate (Apr. 22, 2021)”).

¹¹⁹ Dr. Nicole Lurie, Former Assistant Secretary for Preparedness and Response (2009 - 2016), Interview with Senate Committee on Homeland Security and Governmental Affairs (Feb. 4, 2021) (hereinafter “Interview with Dr. Nicole Lurie (Feb. 4, 2021)”).

Other former officials, however, observed that FEMA’s coordination abilities uniquely position it to lead a pandemic response. Former FEMA Deputy Administrator for Resilience Dr. Daniel Kaniewski noted, “FEMA is unique among federal agencies in being able to provide a government wide pandemic response.” Public health is a part of pandemic response, he continued, “but also logistics, equipment, moving people . . . these are things that emergency managers [at FEMA] deal with regularly.”¹²⁰ Dr. Kevin Yeskey, former Principal Deputy Assistant Secretary for Preparedness and Response, explained that while HHS has insight into its own resources, and some insight into other agencies’ resources, FEMA “knows the resources across the federal government.”¹²¹ Former FEMA Administrator Pete Gaynor told the Committee, HHS was not built to enact whole-of-government emergency response actions and effectively engage at regional levels. With overlapping statutory agency roles and responsibilities, he noted, “the scale and scope of a pandemic should dictate which agency leads response efforts.”¹²²

III. Funding

Congress has established several funds for federal, state, and local resources to prepare for and respond to public health emergencies. For years, however, preparedness funding has been inadequate and inconsistent to meet the needs of pandemic threats. From FY 2010 to FY 2020, the U.S. spent approximately \$3.2 trillion annually on health, but directed only about three percent of that spending toward public health and prevention.¹²³ A 2021 analysis found that state government funding for public health has remained flat between 2008 and 2018, despite increasing national health expenditures.¹²⁴ Many individuals interviewed by the Committee expressed concern regarding the lack of funding for public health preparedness.¹²⁵ Dr. David

¹²⁰ Dr. Daniel Kaniewski, Former Deputy Administrator for Resilience at the Federal Emergency Management Agency (Sept. 2017 - Jan. 2020), Interview with Senate Committee on Homeland Security and Governmental Affairs (May 6, 2021) (hereinafter “Interview with Dr. Daniel Kaniewski (May 6, 2021)”).

¹²¹ Interview with Dr. Kevin Yeskey (Nov. 17, 2021 and Dec. 2, 2021).

¹²² Pete Gaynor, Former Federal Emergency Management Agency (FEMA) Administrator (Jan. 2020 - Jan. 2021), Acting FEMA Administrator (Mar. 2019 - Jan. 2020), Interview with Senate Committee on Homeland Security and Governmental Affairs (June 9, 2021) (hereinafter “Interview with Pete Gaynor (June 9, 2021)”).

¹²³ Department of Health and Human Services, Centers for Medicare and Medicaid Services, *National Health Expenditure Data: National Health Expenditures; Nominal Dollars, Real Dollars, Price Indexes* (2020).

¹²⁴ Y. Natalia Alfonso, et. al., *US Public Health Neglected: Flat Or Declining Spending Left States Ill Equipped to Respond to COVID-19*, Health Affairs (Apr. 2021); see also Peterson Center on Healthcare and Kaiser Family Foundation, *How has U.S. spending on healthcare changed over time?* (Feb. 25, 2022) ([https://www.healthsystemtracker.org/chart-collection/u-s-spending-healthcare-changed-time/#Total%20national%20health%20expenditures,%20US%20\\$%20per%20capita,%201970-2020](https://www.healthsystemtracker.org/chart-collection/u-s-spending-healthcare-changed-time/#Total%20national%20health%20expenditures,%20US%20$%20per%20capita,%201970-2020)).

¹²⁵ Interview with Dr. Richard Besser (Apr. 7, 2021); Interview with David Bibo (Dec. 21, 2021); Interview with Greg Burel (Feb. 26, 2021); Association of Public Health Laboratories, Interview with Senate Committee on Homeland Security and Governmental Affairs (Apr. 19, 2021) (hereinafter “Interview with Association of Public Health Laboratories (Apr. 19, 2021)”); Interview with Association of State and Territorial Health Officials (Apr. 27, 2021); Interview with Dr. Rick Bright (Mar. 17, 2021 and Nov. 4, 2021); Interview with Jonathan Greene (July 8, 2021); Interview with Melissa Harvey (Nov. 3, 2021); Dr. Daniel Jernigan, Deputy Director for Public Health Science and Surveillance at CDC (Aug. 2021 - present), Former Director of Influenza Division (June 2015 - Aug. 2021), Former CDC COVID-19 Response Incident Manager (Jan. 2020 - Mar. 2020), Former CDC Lead at National

Marcozzi, Chief Clinical Officer at the University of Maryland Medical Center, specifically expressed concern regarding “value construct and the science to guide both medical and public health preparedness investments.”¹²⁶

Based on its review, the Majority Committee staff found that while HHS has published annual national health expenditures data by category (e.g., public health) for decades, there is no universal aggregate federal funding data that is publicly available and specifically categorizes emergency and public health preparedness expenditures. Changes in accounting structures, multiple funding sources, and a lack of specificity limit the ability to deduce funding categorizations, such as public health preparedness.¹²⁷

In the event of a public health incident, the HHS Secretary has two funds from which they can draw resources to support response efforts as shown in Table 3 below. The Public Health Emergency Fund (PHEF), created in 1983, allows the HHS Secretary to access “no-year” funding, meaning the funds are carried over from year to year in the event of a public health emergency.¹²⁸ While the PHEF received an initial \$30 million appropriation, the account has received no new appropriations since FY 1999 and has been nearly empty since at least FY

Response Coordination Center for COVID-19 Response (Mar. 2020 - June 2020), Interview with Senate Committee on Homeland Security and Governmental Affairs (Dec. 15, 2021) (hereinafter “Interview with Dr. Daniel Jernigan (Dec. 15, 2021)”); Dr. Robert Johnson, Biomedical Advanced Research and Development Authority (BARDA) Director of Influenza and Emerging Infections Diseases Division (Feb. 2006 – present), Interview with Senate Committee on Homeland Security and Governmental Affairs (July 9, 2021) (hereinafter “Interview with Dr. Robert Johnson (July 9, 2021)”); Interview with Dr. Robert Kadlec (Dec. 6, 2021); Interview with Dr. Daniel Kaniewski (May 6, 2021); Kyle McGowan, Former Chief of Staff at CDC (Apr. 2018 - Aug. 2020), Interview with Senate Committee on Homeland Security and Governmental Affairs (Dec. 2, 2021) (hereinafter “Interview with Kyle McGowan (Dec. 2, 2021)”); Dr. Julie Morita, Executive Vice President of Robert Wood Johnson Foundation (June 2019 - present), Interview with Senate Committee Homeland Security and Governmental Affairs (Apr. 15, 2021) (hereinafter “Interview with Dr. Julie Morita (Apr. 15, 2021)”); National Association of County and City Health Officials (NACCHO), Interview with Senate Committee on Homeland Security Governmental Affairs (Apr. 28, 2021) (hereinafter “Interview with National Association of County and City Health Officials (Apr. 28, 2021)”); Interview with Northwest Washington Healthcare Response Network (May 4, 2021); Dr. Anne Schuchat, Former Principal Deputy Director of CDC (Sept. 2015 – May 2021) and Former CDC COVID-19 Response Incident Manager (Mar. 20, 2020 – May 1, 2020), Interview with Senate Committee on Homeland Security and Governmental Affairs (Dec. 14, 2021) (hereinafter “Interview with Dr. Anne Schuchat (Dec. 14, 2021)”); Steve Solomon, Vice Chairman of LifeScience Logistics, Interview with Senate Committee on Homeland Security and Governmental Affairs (June 10, 2020) (hereinafter “Interview with Steve Solomon (June 10, 2020)”); Interview with Dr. Kevin Yeskey (Nov. 17, 2021 and Dec. 2, 2021); Interview with Dr. Laura Wolf (Nov. 30, 2021).

¹²⁶ Dr. David Marcozzi, Chief Clinical Officer at University of Maryland Medical Center (served as University of Maryland Medical Center COVID-19 Incident Commander), Interview with Senate Committee on Homeland Security and Governmental Affairs (Apr. 7, 2021) (hereinafter “Interview with Dr. David Marcozzi (Apr. 7, 2021)”).

¹²⁷ See Crystal Watson, et al., *Federal Funding for Health Security in FY2019*, National Library of Medicine (Sept. and Oct. 2018); Blue Ribbon Study Panel on Biodefense, *Budget Reform for Biodefense: Integrated Budget Needed to Increase Return on Investment* (Feb. 2018); Congressional Research Service, *FEMA’s Role in the COVID-19 Federal Pandemic Response* (R47048) (Feb. 10, 2022).

¹²⁸ Rebecca Katz, Aurelia Attal-Juncqua, and Julie E. Fischer, *Funding Public Health Emergency Preparedness in the United States*, American Journal of Public Health (Sept. 2017).

2012.¹²⁹ In FY 2019, Congress established an Infectious Diseases Rapid Response Reserve Fund to support CDC in preventing, preparing for, or responding to an infectious disease emergency.¹³⁰ As shown below, these funding sources were either nearly empty or insufficient to address pandemic response needs.¹³¹

Table 3. Public Health Emergency Federal Funding Sources¹³²

Fund Source	Purpose	Status (as of January 1, 2020)
Public Health Emergency Fund (PHEF)	To provide access to special funding during a public health emergency.	\$56,508.00
Infectious Diseases Rapid Response Reserve Fund (IDRRRF)	To support CDC in preventing, preparing, and responding to infectious disease emergencies.	\$105 million

Federal funding for a broad range of incidents and crises is also available under the Disaster Relief Fund (DRF).¹³³ The DRF is an appropriation managed by FEMA and consists of “no-year” funding. The DRF has consistently received both annual and supplemental appropriations to support Stafford Act activities. FEMA however, can only access these funds if the President declares an emergency or major disaster under the Stafford Act.¹³⁴ The Stafford Act requires that state, territorial, or tribal executives request assistance and the President make a declaration before most DRF resources may be accessed. At that time, FEMA can make funds available to other agencies as necessary through mission assignments to address the disaster.¹³⁵ Given this prerequisite, these funds are often not immediately available to HHS during a public

¹²⁹ See *id.*; Jennifer B. Alton and Ellen P. Carlin, *Now is the time to resource the Public Health Emergency Fund*, The Hill (Feb. 28, 2020) (<https://thehill.com/blogs/congress-blog/healthcare/485163-now-is-the-time-to-resource-the-public-health-emergency-fund>).

¹³⁰ Department of Defense and Labor, Health and Human Services, and Education Appropriations Act and Continuing Appropriations Act of 2019, Pub. L. No. 115-245, Sec. 231.

¹³¹ See HHS Correspondence to Senate Committee on Homeland Security and Governmental Affairs Staff (Nov. 16, 2022); Office of Management and Budget, *SF 133: Department of Health and Human Services Infectious Diseases Rapid Response Reserve Fund* (Nov. 9, 2020) (on file with Committee); Office of Management and Budget, *SF 133: Department of Health and Human Services Public Health Emergency Fund* (Nov. 9, 2020) (on file with Committee).

¹³² Office of Management and Budget, *SF 133 Report on Budget Execution and Budgetary Resources, FY 2020* (Jan. 2020) (compiling as quarterly reporting as required by 31 U.S.C. § 1512(d)). HHS Correspondence to Senate Committee on Homeland Security and Governmental Affairs Staff (Nov. 16, 2022); Office of Management and Budget, *SF 133: Department of Health and Human Services Infectious Diseases Rapid Response Reserve Fund* (Nov. 9, 2020) (on file with Committee); Office of Management and Budget, *SF 133: Department of Health and Human Services Public Health Emergency Fund* (Nov. 9, 2020) (on file with Committee).

¹³³ Congressional Research Service, *The Disaster Relief Fund: Overview and Issues* (R45484) (Jan. 20, 2022).

¹³⁴ *Id.*

¹³⁵ Congressional Research Service, *The Disaster Relief Fund: Overview and Issues* (R45484) (Jan. 20, 2022).

health emergency.¹³⁶ Prior to the COVID-19 pandemic, no President had invoked the Stafford Act for a major disaster declaration due to a biological event, and past Presidents rarely employed the Stafford Act for an emergency declaration during an infectious disease threat.¹³⁷

Grants and cooperative agreements are also a tool used by the federal government to support SLTT pandemic preparedness and response efforts.¹³⁸ As detailed in Table 4, SLTT pandemic preparedness is primarily funded through three HHS grant programs; however, funding for these programs remains insufficient.¹³⁹

Table 4. Key HHS Grants to SLTT Partners for Pandemic Preparedness¹⁴⁰

Grants and Cooperative Agreements	Agency	Purpose
Hospital Preparedness Program (HPP) PHSA § 319C-2	HHS/ASPR	Improve the capacity of the health care system to plan for and respond to large-scale emergencies and disasters.
Public Health Emergency Preparedness (PHEP) Cooperative Agreement PHSA § 319C-1	HHS/CDC	Help state, local, and territorial public health departments strengthen their abilities to effectively prepare for and respond to a range of public health threats.
Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases (ELC) Cooperative Agreement PHSA § 2821	HHS/CDC	Provide financial support for public health departments, including laboratories, to detect, respond to, control, and prevent infectious diseases.

¹³⁶ Rebecca Katz, Aurelia Attal-Juncqua, and Julie E. Fischer, *Funding Public Health Emergency Preparedness in the United States*, American Journal of Public Health (Sept. 2017).

¹³⁷ See Rebecca Katz, Aurelia Attal-Juncqua, and Julie E. Fischer, *Funding Public Health Emergency Preparedness in the United States*, American Journal of Public Health (Sept. 2017); see also Congressional Research Service, *FEMA’s Role in the COVID-19 Federal Pandemic Response* (R47048) (Feb. 10, 2022).

¹³⁸ Congressional Research Service, *National Preparedness: A Summary and Select Issues* (R46696) (Feb. 26, 2022). DHS grants include the Emergency Management Performance Grant and Regional Catastrophic Preparedness Grant Program, both of which are aimed at boosting readiness broadly. DHS also provides grants that support preparedness for particular sectors or for particular threats, such as Assistance to Firefighters Grants (primarily focused on enhancing the safety of firefighters in response to fire-related hazards) or the Homeland Security Grant Program (primarily focused on preparing for and responding to acts of terrorism).

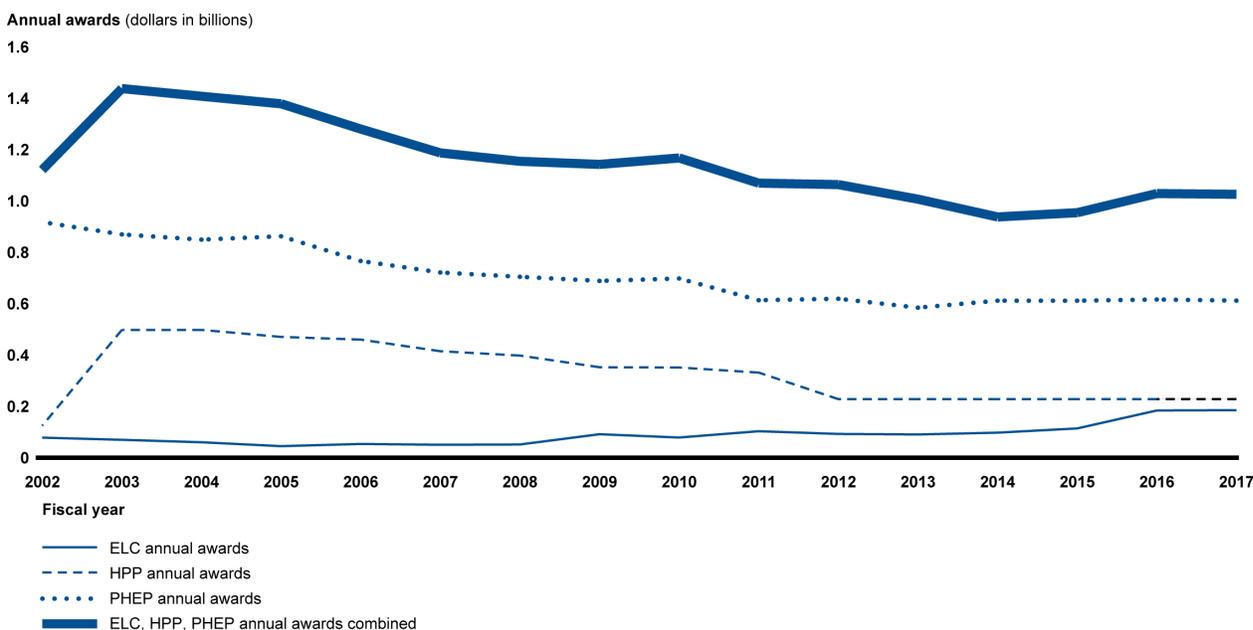
¹³⁹ Trust for America’s Health, *The Impact of Chronic Underfunding on America’s Public Health System: Trends, Risks, and Recommendations, 2020* (Apr. 2020) (<https://www.tfah.org/report-details/publichealthfunding2020/>); Department of Health and Human Services, Centers for Disease Control and Prevention, *Final PHEP Budget Period 3 (Fiscal Year 2021) Funding* (accessed Nov. 21, 2022).

¹⁴⁰ Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, About the Hospital Preparedness Program (<https://www.phe.gov/Preparedness/planning/hpp/Pages/about-hpp.aspx>) (accessed Nov. 21, 2022); Department of Health and Human Services, Centers for Disease Control and Prevention, Public Health Emergency Preparedness Program and Guidance (<https://www.cdc.gov/cpr/readiness/phep.htm>) (accessed Nov. 21, 2022); Department of Health and Human Services, Centers for Disease Control and Prevention, *ELC Base & COVID-19 Funding* (June 2021) (<https://www.cdc.gov/ncezid/dpei/pdf/elc-2021-funding-fact-sheet-H.pdf>).

The combined amount awarded for these key public health preparedness programs decreased from about \$1.4 billion in FY 2003 (at the highest level) to about \$1 billion in FY 2017.¹⁴¹ The graph below, produced by GAO, illustrates the total award amount for the three programs from FY 2002 to FY 2017.¹⁴²

Awards Provided to States and Other Jurisdictions through Three Key HHS Preparedness and Capacity-Building Programs, FYs 2003 – 2017¹⁴³

Figure 1: Awards Provided to States and Other Jurisdictions through Three Key HHS Preparedness and Capacity-Building Programs, Annual Appropriations, Fiscal Years 2002-2017



Source: GAO analysis of Office of the Assistant Secretary for Preparedness and Response and Centers for Disease Control and Prevention awards data. | GAO-18-362

For the Hospital Preparedness Program’s (HPP) and Public Health Emergency Preparedness (PHEP) grants, the authorization and amount appropriated has generally decreased since 2003. From FY 2002 to FY 2020, the HPP’s annual funding peaked at about \$518 million in FY 2003 and FY 2004, but has since decreased by about 50 percent to approximately \$255

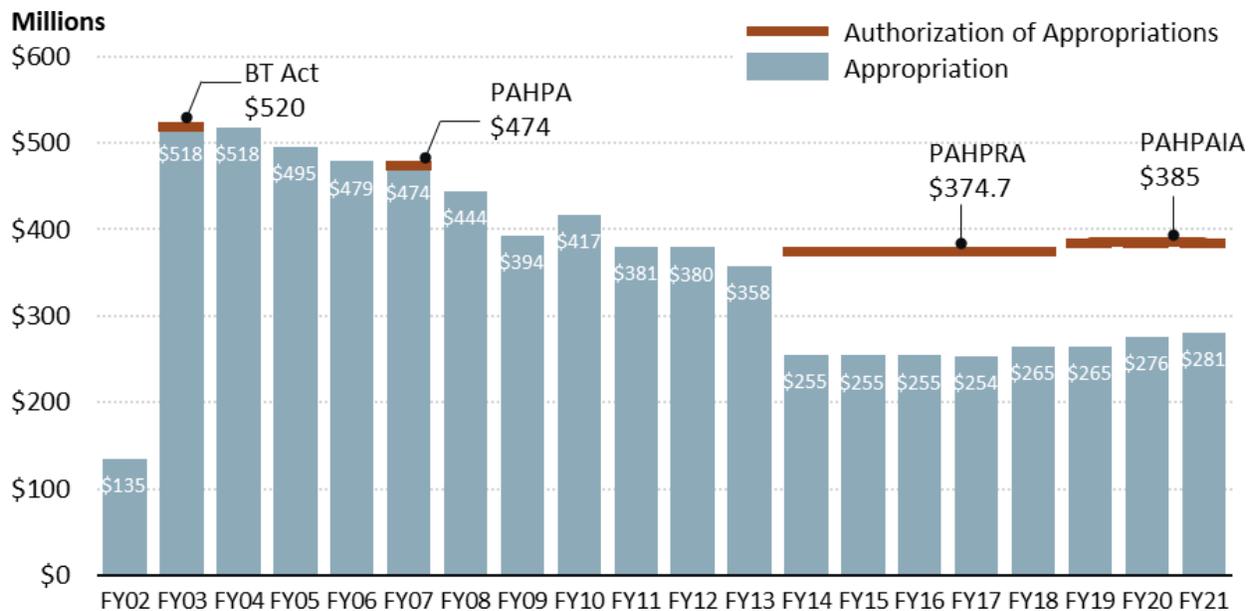
¹⁴¹ Government Accountability Office, *Infectious Disease Threats: Funding and performance of Key Preparedness and Capacity-Building Programs* (GAO-18-362) (May 2018).

¹⁴² *Id.*

¹⁴³ *Id.* GAO notes “[t]he Department of Health and Human Services (HHS) provides funding to states, localities, territories, and freely associated states to aid capacity building and preparedness for public health threats, including infectious disease threats, natural disasters, or terrorist events through three key programs: Epidemiology and Laboratory Capacity for Infectious Diseases (ELC), the Hospital Preparedness Program (HPP), and Public Health Emergency Preparedness (PHEP). This figure includes data on annual awards to states and other jurisdictions provided through these three programs with funding from annual appropriations to address preparedness for public health threats that include, but are not limited to, infectious disease threats.”

million from FY 2014 to FY 2017.¹⁴⁴ According to an analysis conducted by the Congressional Research Service (shown below), although funding increased slightly between FY 2018 and FY 2021 to approximately \$281 million, that amount represents about half of the funding the HPP received in 2003.¹⁴⁵ In addition to HPP program funding, Congressional authorizations also decreased from over \$500 million in FY 2003 to less than \$400 million after FY 2014.

Funding History for the Hospital Preparedness Program (HPP) Cooperative Agreement¹⁴⁶



Sources: Compiled by CRS from reports accompanying annual LHHS appropriations laws for years when program amounts specified, otherwise based on HHS annual “Budget in Brief,” other congressional budget justification documents, and text of public laws presented.

Notes: Amounts mostly reflect appropriations as enacted. Final funding levels may differ from amounts shown due to post-appropriations transfers and other adjustments. Amounts include funds for the Emergency System for Advance Registration of Health Professionals (ESAR-VHP). Aside from initial supplemental appropriations used for the program’s establishment in FY2002 (P.L. 107-117), amounts do not include supplemental appropriations provided for public health emergency response purposes to specific incidents, including funding for pandemic influenza (FY2006 and FY2009), Ebola (FY2015), and the COVID-19 pandemic (FY2020 and FY2021).

Acronyms used: BT Act is the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, P.L. 107-188. PAHPA is the Pandemic and All-Hazards Preparedness Act, P.L. 109-417. PAHPRA is the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, P.L. 113-5. PAHPAIA is the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019, P.L. 116-22.

The amount for FY2013 reflects sequestration as required under the Budget Control Act (BCA, P.L. 112-25).

PAHPAIA authorizes the appropriation of \$385 million for each of FY2019 through FY2023 and PAHPRA authorized the appropriation of about \$374.7 million for the HPP for each of FY2014 through FY2018. The two earlier laws authorized the specified amounts for one fiscal year (FY2003 and FY2007 respectively), as shown, and “such sums as may be necessary” for each of several subsequent fiscal years.

¹⁴⁴ Memorandum from Congressional Research Service, Funding History for Public Health and Hospital Preparedness Cooperative Agreement to States (Mar. 3, 2020).

¹⁴⁵ *Id.*

¹⁴⁶ *Id.* (noting amounts in nominal dollars).

In an interview with the Committee, Dr. Kevin Yeskey said, “when you divide [HPP money] by fifty states, four metro areas and multiple territories, and then divide that by the number of health care coalitions, it’s not enough to allow hospitals to make substantial investments in preparedness.”¹⁴⁷ Melissa Harvey, former Director of National Healthcare Preparedness Programs within ASPR (which oversees HPP), told the Committee that during her tenure, out of a staff of 36, there were only three staff members with civilian [or] private sector clinical healthcare experience.¹⁴⁸ Ms. Harvey also stated that the HPP never received sufficient attention, staffing, or funding. She said, “[the program] was set up to fail with the authorities and funding it was given.” As of July 2022, HPP provides funding through cooperative agreements to public health departments in 62 jurisdictions and 326 health care coalitions.¹⁴⁹

Funding for PHEP also decreased by about 25 percent from its highest level in FY 2005 at \$872 million to \$633–\$660 million between FY 2011 and FY 2017 (the lowest amount in FY 2013 reflects sequestration). The authorization of appropriations for PHEP has also decreased over this period as shown below.¹⁵⁰

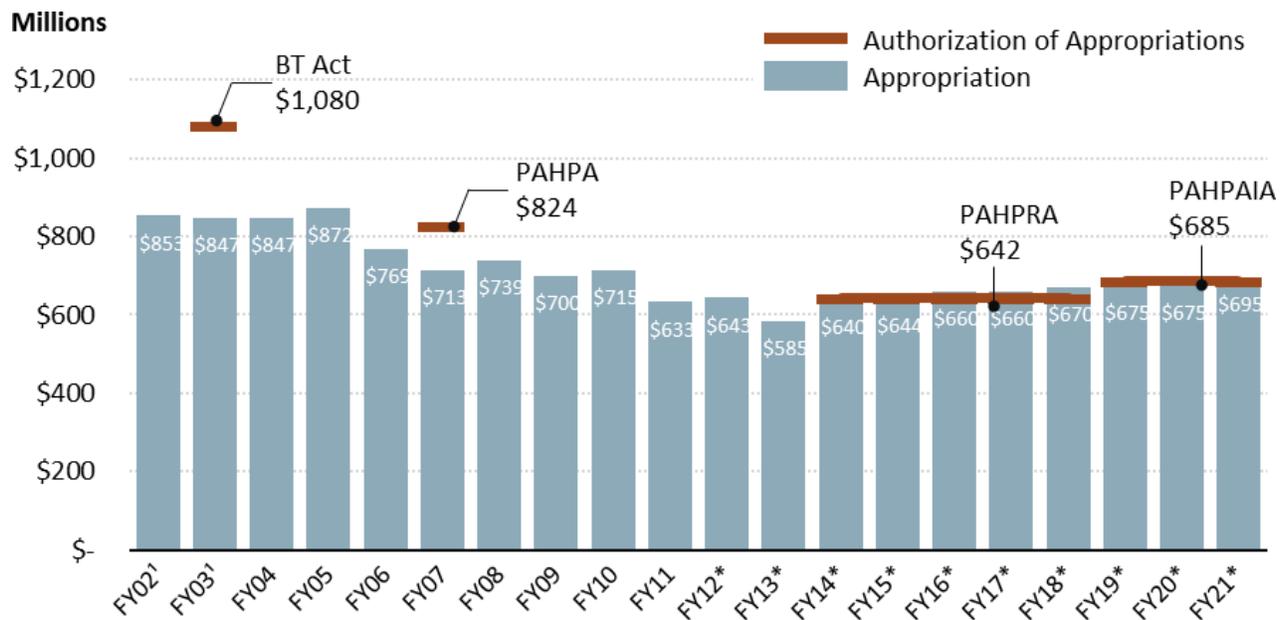
¹⁴⁷ Interview with Dr. Kevin Yeskey (Nov. 17, 2021 and Dec. 2, 2021).

¹⁴⁸ Melissa Harvey, Former Director of Health Systems for Medical Operations at the Department of Homeland Security (Aug. 2019 – Feb. 2021), Director of National Healthcare Preparedness Programs at ASPR (2014 – 2019) (detailed to HHS/FEMA COVID-19 Healthcare Resilience Task Force from Feb. 2020-June 2020), Interview with Senate Committee on Homeland Security and Governmental Affairs (Nov. 3, 2021) (hereinafter “Interview with Melissa Harvey (Nov. 3, 2021)”).

¹⁴⁹ Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Hospital Preparedness Program (HPP) (<https://aspr.hhs.gov/HealthCareReadiness/HPP/Pages/default.aspx>) (accessed Nov. 21, 2022).

¹⁵⁰ Memorandum from Congressional Research Service, Funding History for Public Health and Hospital Preparedness Cooperative Agreement to States (Mar. 3, 2020) (noting amounts are in nominal dollars).

Funding History for Public Health Emergency Preparedness (PHEP) Grants¹⁵¹



Sources: Compiled by CRS from reports accompanying annual Labor, Health and Human Services, Education and Related Agencies (LHHS) appropriations laws, annual CDC congressional budget justifications, HHS annual “Budget in Brief,” CDC operating plans, and text of the public laws presented, except as noted below.

Notes: Amounts mostly reflect appropriations as enacted. Final funding levels may differ from amounts shown due to post-appropriations transfers and other adjustments. Aside from initial supplemental appropriations used for the program’s establishment in FY2002 (P.L. 107-117), amounts do not include supplemental appropriations provided for public health emergency response purposes to specific incidents including funding for smallpox vaccination (FY2003), pandemic influenza (FY2006 and FY2009), Ebola (FY2015), Zika (FY2016), or the COVID-19 pandemic (FY2020-FY2021).

¹PHEP cooperative agreement amounts were not specified in appropriations language in FY2002 and FY2003. Amounts shown based on information provided to CRS by CDC, March 3, 2022.

*Amounts for FY2012 through FY2021 are adjusted to reflect implementation of the CDC Working Capital Fund (WCF), a revolving fund that pays for centralized agency services. During FY2012 and later years, funds formerly provided to CDC’s Cross-cutting Activities account were distributed among program accounts, which then transferred funds to the WCF for services used. As a result, amounts for FY2012 through FY2021 are not comparable to amounts for earlier years. The adjustment has the effect of increasing program account levels (though funds are later transferred to WCF). See the CDC section in CRS Report R43304, *Public Health Service Agencies: Overview and Funding (FY2010-FY2016)* for more information.

The amount for FY2013 reflects sequestration as required under the Budget Control Act (BCA, P.L. 112-25).

Acronyms used: BT Act is the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, P.L. 107-188. PAHPA is the Pandemic and All-Hazards Preparedness Act, P.L. 109-417. PAHPRA is the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, P.L. 113-5. PAHPAIA is the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019, P.L. 116-22.

PAHPAIA authorizes the appropriation of \$685 million for each of FY2019 through FY2023 and PAHPRA authorized the appropriation of \$642 million for each of FY2014 through FY2018. The two earlier laws authorized the specified amounts for one fiscal year (FY2003 and FY2007, respectively), as shown, and “such sums as may be necessary” for each of several subsequent fiscal years.

According to the Association of Public Health Laboratories (APHL), the Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases (ELC) Cooperative Agreement, which supports public health departments, has never been fully funded.¹⁵² Former CDC Director Robert Redfield testified before Congress in March 2020,

¹⁵¹ *Id.*

¹⁵² Interview with Association of Public Health Laboratories (Apr. 19, 2021).

“[w]e’ve under invested in the public health labs” and expressed the need to build “core capabilities” including staff, equipment, and data.¹⁵³

This multi-Administration pattern of underfunding, broken by short bursts of emergency funding in times of crisis, undermines preparedness efforts at the federal, state, and local levels. David Bibo, told the Committee that the U.S. would have been better positioned to respond to the COVID-19 pandemic had there been longstanding public health investment in SLTT partners and federal agencies.¹⁵⁴ He stated, “the level of disinvestment in public health that takes place between incidents is really stark. It’s time for a generational level investment that is dual use” so that funding can be used to combat a variety of threats—not just pandemics.¹⁵⁵ Melissa Harvey explained that when health care systems are designed to be “as lean as possible, [we] shouldn’t be surprised that when there is a disaster, there is no slack in the system.”¹⁵⁶

Impact of Insufficient Federal Funding

The lack of sustained federal investments in public health infrastructure has directly impacted U.S. preparedness and response efforts at multiple levels. Below are some examples.

Strategic National Stockpile (SNS). Since 2018, ASPR has managed the SNS. The SNS is designed to provide support in response to public health emergencies and maintains medical countermeasures like vaccines, pharmaceuticals, and medical supplies that can be deployed during a crisis when resources are strained.¹⁵⁷ The SNS’s mission has expanded over the years, making it a challenge to build sufficient inventory to address a growing number of threats.¹⁵⁸ In a recent report, GAO found that “[i]n most years since fiscal year 2009, appropriations for the SNS were equal to or more than what the administration requested.”¹⁵⁹ According to GAO, ASPR officials explained that their funding requests have not always reflected SNS needs “because there are competing priorities and tradeoffs and the budget process involves aligning SNS budgetary needs with broader HHS needs and the President’s budget priorities.”¹⁶⁰

¹⁵³ House Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies, Testimony During Hearing of Director Robert Redfield, Centers for Disease Control and Prevention, *Hearing On Centers for Disease Control and Prevention Budget Request for FY 2021*, 116th Cong. (Mar. 10, 2020) (H. Hrg. 116-XX).

¹⁵⁴ Interview with David Bibo (Dec. 21, 2021).

¹⁵⁵ *Id.*

¹⁵⁶ Interview with Melissa Harvey (Nov. 3, 2021).

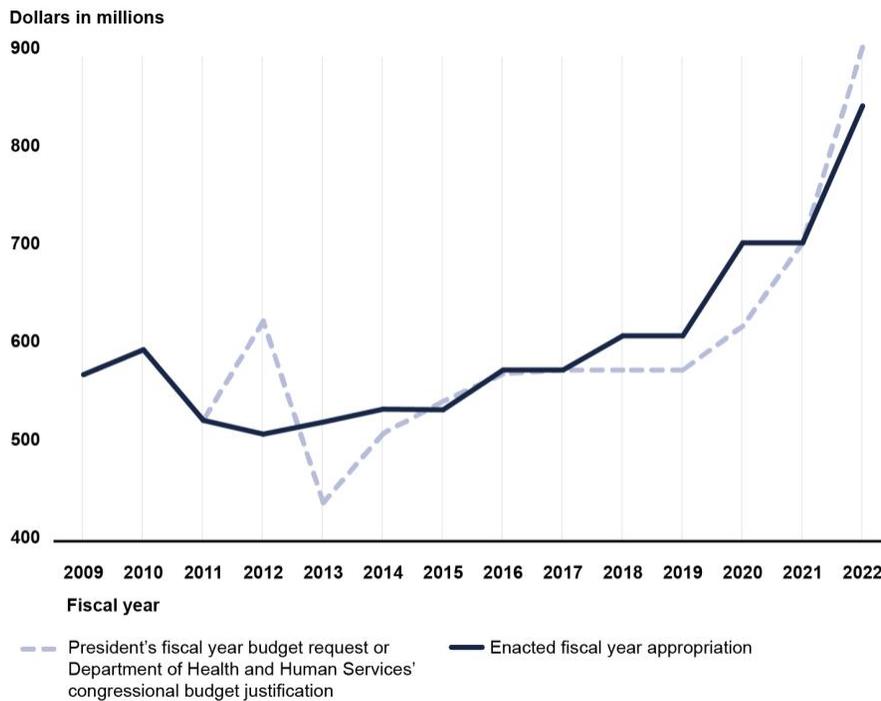
¹⁵⁷ Department of Health and Human Services, Office of the Assistant for Preparedness and Response, Strategic National Stockpile (<https://www.phe.gov/about/sns/Pages/default.aspx>) (accessed Nov. 21, 2022).

¹⁵⁸ Government Accountability Office, *HHS Should Address Strategic National Stockpile Requirements and Inventory Risks*, at 1, 27 (GAO-23-106210) (October 2022); Anna Nicholson et al., *The Nation's Medical Countermeasure Stockpile: Opportunities to Improve the Efficiency, Effectiveness, and Sustainability of the CDC Strategic National Stockpile: Workshop Summary* (2016).

¹⁵⁹ Government Accountability Office, *Public Health Preparedness: HHS Should Address Strategic National Stockpile Requirements and Inventory Risks* (GAO 23-106210) (Oct. 2022).

¹⁶⁰ *Id.*

GAO Analysis of Strategic National Stockpile (SNS) Requested and Regular Appropriations¹⁶¹



Source: GAO analysis of Department of Health and Human Service (HHS) data. | GAO-23-106210

Former SNS Director Greg Burel told the Committee that the SNS never received sufficient funding to carry out its mission.¹⁶² Following the H1N1 pandemic in 2009, the SNS was unable to replenish the PPE needed to protect health care and frontline workers in the event of a national crisis.¹⁶³ As of December 2019, the SNS did not have even half of the 90-day supply target inventory on hand in many categories of critical PPE.¹⁶⁴ In addition, prior to the COVID-19 pandemic, the SNS did not contain testing supplies, such as nasal swabs, transport media, and pipette tips.¹⁶⁵

¹⁶¹ *Id.* GAO notes “[t]he figure only depicts enacted regular appropriations for the SNS. For the requested amounts, we used the Department of Health and Human Services’ congressional budget justification for fiscal years 2019 and 2020 and the President’s budget request for all other fiscal years.”

¹⁶² Greg Burel, Former Director of the Strategic National Stockpile (Mar. 2007 – Jan. 2020), Interview with Senate Committee on Homeland Security and Governmental Affairs (Feb. 26, 2021) (hereinafter “Interview with Greg Burel (Feb. 26, 2021)”).

¹⁶³ *Id.*; Peter Guinto, Former Chief of Contracts, U.S. Air Force (Aug. 2010 – Apr. 2022), Interview with Senate Committee on Homeland Security and Governmental Affairs (Apr. 8, 2021) (hereinafter “Interview with Peter Guinto (Apr. 8, 2021)”).

¹⁶⁴ Government Accountability Office, *COVID-19: Urgent Actions Needed to Better Ensure an Effective Federal Response* (GAO-21-191) (Nov. 2020).

¹⁶⁵ Government Accountability Office, *Public Health Preparedness: HHS Should Address Strategic National Stockpile Requirements and Inventory Risks*, at 38 (GAO 23-106210) (Oct. 2022).

Richard Beeny, CEO of LifeScience Logistics, a third-party logistics manager for the federal SNS, told the Committee, “there was a shift away from stockpiling things that were needed for [a pandemic], like PPE, in favor of more pharmaceutical and biological products, which are high dollar items.”¹⁶⁶ Steve Solomon, Vice Chairman of LifeScience Logistics, noted that while some states maintain their own stockpiles of medical supplies, this number has decreased over time as federal resources have waned due to the short term nature of the funding to support state efforts.¹⁶⁷

In a 2020 GAO survey of eight states, all states reported that the supplies they received from the SNS “were not sufficient to meet their needs.”¹⁶⁸ GAO noted most of the states surveyed recommended that the SNS provide more transparency about the extent of available supplies to set realistic expectations.¹⁶⁹ Mr. Burel told the Committee that, generally, ASPR would work “with states and localities on preparedness so they could sustain themselves for thirty days or so, but state stockpiles have largely been removed over time due to funding issues.”¹⁷⁰ In an interview with Committee staff, Mr. Beeny explained that most states do not have their own stockpiles and lack sufficient resources, including the underlying information technology infrastructure, to readily receive and effectively store medical supplies.¹⁷¹

Data Modernization. According to multiple current and former officials, insufficient funding posed challenges to data modernization efforts. For example, when announcing a data modernization initiative in 2018, former Centers for Medicare and Medicaid Administrator Seema Verma noted the reliance on fax machines at CMS.¹⁷² In 2016, GAO also identified CMS as one of several agencies using common business-oriented language (COBOL), a 50-year-old programming language.¹⁷³ Nicholas Uehlecke, a former senior advisor to the HHS Secretary, told the Committee that during his time with the agency in 2020, HHS still used outdated technology, including fax machines to transmit information.¹⁷⁴

¹⁶⁶ Richard Beeny, Chief Executive Officer of LifeScience Logistics, Interview with Senate Committee on Homeland Security and Governmental Affairs (June 10, 2021) (hereinafter “Interview with Richard Beeny (June 10, 2021)”).

¹⁶⁷ Interview with Steve Solomon (June 10, 2020).

¹⁶⁸ Government Accountability Office, *COVID-19: Sustained Federal Action is Crucial as Pandemic Enters Its Second Year*, at 82 (GAO-21-387) (Mar. 2021).

¹⁶⁹ Government Accountability Office, *COVID-19: Sustained Federal Action is Crucial as Pandemic Enters Its Second Year* (GAO-21-387) (Mar. 2021); *see also* Interview with Peter Guinto (Apr. 8, 2021).

¹⁷⁰ Interview with Greg Burel (Feb. 26, 2021).

¹⁷¹ Interview with Richard Beeny (June 10, 2021).

¹⁷² Former Administrator Seema Verma, Centers for Medicare and Medicaid Services, Remarks as Prepared for Delivery at the ONC Interoperability Forum in Washington, DC (Aug. 6, 2018).

¹⁷³ Government Accountability Office, *Information Technology: Federal Agencies Need to Address Aging Legacy Systems*, at 26 (GAO-16-468) (May 2016).

¹⁷⁴ Nicholas Uehlecke, Former Senior Advisor to HHS Secretary, Interview with Senate Committee on Homeland Security and Governmental Affairs (Nov. 4, 2021) (hereinafter “Interview with Nicholas Uehlecke (Nov. 4, 2021)”).

Individuals interviewed by the Committee stated that CDC’s outdated infrastructure hinders the collection and distribution of critical data.¹⁷⁵ “Prior to COVID, there was already a deficiency in ways to collect, analyze, and communicate data” to CDC, representatives from the National Association of County and City Health Officials (NACCHO) said.¹⁷⁶ NACCHO expressed frustration at the “ailing infrastructure and lack of IT staff and financial support,” noting that CDC still uses fax machines to communicate with local-level public health officials.¹⁷⁷

Despite CDC efforts to improve data systems, CDC’s Deputy Director for Public Health Science and Surveillance, Dr. Daniel Jernigan, explained that the agency receives categorical funding, which leads to individual programs at CDC receiving their own funds at different times used for developing and maintaining siloed systems. This process causes scalability issues and results in systems that lack interoperability.¹⁷⁸ For example, Dr. Jernigan noted, “we have AIDS systems that do not talk to STD systems [and] we have immunization systems that do not align with logistics.” Dr. Jernigan told the Committee that many local jurisdictions do not have easy access to state-level data. He explained that the process of “connecting a case report with a death report is often done manually.”¹⁷⁹ According to a recent analysis in the *New England Journal of Medicine*, “only three percent of local health departments reported that their information systems are all interoperable.”¹⁸⁰

Since 2002, statutory authorities and policy directives have also called for the implementation of integrated public health and biological threat surveillance systems to improve the federal government’s ability to identify and track potential health threats, including infectious diseases. While these statutes have mandated the establishment of “integrated” and “interoperable” surveillance systems—both between federal agencies, state and local public health departments, and relevant private sector entities, significant gaps remain. Currently, U.S. public health surveillance systems are fragmented across federal agencies and state and local public health departments. Table 5 below outlines prior statutory authorities and policy directives that have directed the establishment of integrated public health and biosurveillance capabilities and the corresponding lead federal agency.

¹⁷⁵ Interview with National Association of County and City Health Officials (Apr. 28, 2021); Interview with Amy Gleason (Jan. 31, 2022).

¹⁷⁶ Interview with National Association of County and City Health Officials (Apr. 28, 2021).

¹⁷⁷ *Id.*

¹⁷⁸ Interview with Dr. Daniel Jernigan (Dec. 15, 2021).

¹⁷⁹ *Id.*

¹⁸⁰ Megan Wallace and Joshua Sharfstein, *The Patchwork U.S. Public Health System*, *New England Journal of Medicine* (Jan. 6, 2022).

Table 5. Overview of Statutory Authorities, Policy Directives, and Related National Strategies Requiring the Establishment of Integrated Biosurveillance Systems

Authority	Description	Lead Agency
Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ¹⁸¹	Directed the HHS Secretary to establish an “integrated system or systems of public health alert communications and surveillance networks” between federal and state public health official and public and private health-related facilities, among other relevant entities. This legislation has served as the basis for a number of public health and pandemic preparedness activities, including CDC’s National Syndromic Surveillance Program, through which CDC receives data from multiple sources, including emergency departments, health care facilities, and laboratories. ¹⁸²	HHS
Pandemic and All-Hazards Preparedness Act of 2006 ¹⁸³	Directed the HHS Secretary through collaboration with SLTT partners to establish a “near real-time electronic nationwide public health situational awareness capability through an interoperable network of systems to share data and information to enhance early detection of rapid response to, and management of, potentially catastrophic infectious disease outbreaks and other public health emergencies that originate domestically or abroad.”	HHS
Implementing Recommendations of the 9/11 Commission Act of 2007 ¹⁸⁴	Established the National Biosurveillance Integration Center and tasked the Center with detecting potential biological threats by consolidating surveillance information from “all relevant surveillance systems maintained by [federal] agencies[.]” obtaining information from private sources to enhance critical surveillance gaps, and utilizing information technology systems that allow for data integration among federal agencies and close to “real-time” identification of biological threats.	DHS
Policy Directives and National Strategies	Description	Lead Agency
HSPD-21 ¹⁸⁵ (2007)	Directed the HHS Secretary to establish an operational national surveillance system for human health with information sharing capabilities between federal, state, and local public health authorities and clinical health care providers. The directive also: 1) specified that “to the extent feasible, the system shall be built using electronic health information systems;” 2) required that it “incorporate flexibility and depth of data necessary to respond to previously unknown or emerging threats to public health;” and 3) “integrate its data into the national biosurveillance common operating picture as appropriate.”	HHS
National Biosurveillance Strategy (2012)	Based on the principles set forth in HSPD-21, the 2012 National Biosurveillance Strategy aimed to build upon existing capabilities through information sharing, increased capacity, innovative technology, and improved partnerships.	EOP
NSPM-14 and the 2018 National Biodefense Strategy ¹⁸⁶	NSPM-14 directed the implementation of the 2018 National Biodefense Strategy, as required by the National Defense Authorization Act of 2017, which included interagency coordination on biodefense policies, information sharing, and the	HHS

¹⁸¹ Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, Sec. 103.

¹⁸² Congressional Research Service, *Tracking COVID-19: U.S. Public Health Surveillance and Data* (R46588) (Nov. 2, 2020); Department of Health and Human Services, Centers for Disease Control and Prevention, *What is Syndromic Surveillance?* (<https://www.cdc.gov/nssp/overview.html>) (accessed Nov. 21, 2022).

¹⁸³ Pandemic and All-Hazards Preparedness Act of 2006, Pub. L. No. 109-417. This directive is included in subsequent reauthorizations (2013 and 2019), which required CDC to improve and maintain its biosurveillance networks. Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019, Pub. L. No. 116-22, Sec. 205.

¹⁸⁴ Implementing Recommendations of the 9/11 Commission Act of 2007, Pub. L. No. 110-53, Sec. 1101.

¹⁸⁵ Department of Homeland Security, *Homeland Security Presidential Directive 21* (Oct. 18, 2007).

¹⁸⁶ White House, *Presidential Memorandum on the Support for National Biodefense* (Sep. 18, 2018) (<https://trumpwhitehouse.archives.gov/presidential-actions/presidential-memorandum-support-national-biodefense/>). The National Defense Authorization Act of 2017 directed the DOD, HHS, DHS, and the Department of Agriculture to develop a “national biodefense strategy and associated implementation plan,” which was subsequently released in 2018 and reviewed by GAO in 2020. *See* National Defense Authorization Act of 2017, Pub. L. No. 114-328, Sec.

	establishment of a Biodefense Steering Committee responsible for “monitoring and coordination.”	
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Since 2006, HHS has repeatedly failed to implement a “near real-time nationwide public health situational awareness capability through an interoperable network of systems” as mandated by Congress in 2006, 2013, and 2019.¹⁸⁷ While funding “may be a key limitation,” between 2010 and 2023, HHS has not requested specific funding to carry out the 2006 mandate to create an interoperable situational awareness system.¹⁸⁸ CDC told the Committee that authority for this specific initiative has not been delegated to CDC and that its narrow funding streams and authorities limit data collection efforts.¹⁸⁹ According to CDC, the statutory mandates to develop a situational awareness capability under the 2006 Pandemic and All Hazards Preparedness Act (and its subsequent reauthorizations) are “separate and distinct” from the funding it has received for CDC’s Data Modernization Initiative.¹⁹⁰

Significant gaps also remain in DHS’s National Biosurveillance Integration Center’s (NBIC) mission and initiatives. In 2015, GAO assessed the NBIC’s efforts and noted that challenges, including limited resources and authorities, hamper the Center’s ability to successfully carry out its mission.¹⁹¹ Six years later, GAO found that no significant changes to NBIC’s structure or authorities had occurred and “several long-standing problems—such as data sharing across disparate missions—have combined to inhibit the achievement of [NBIC’s] mission.”¹⁹² While the 2007 Homeland Security Policy Directive (HSPD-21) delegates leadership of biosurveillance for human health to the HHS Secretary, DHS’s National Biosurveillance Integration Center is tasked, by statute with “integrating biosurveillance information” from relevant federal agencies and “maintaining biological situational awareness” to detect and respond to potential threats.¹⁹³

1086; Government Accountability Office, *National Biodefense Strategy: Additional Efforts Would Enhance Likelihood of Effective Implementation* (GAO-20-273) (Feb. 2020).

¹⁸⁷ See Pandemic and All-Hazards Preparedness Act of 2006, Pub. L. No. 109-417, Sec. 202; Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, Pub. L. No. 113-5, Sec. 204; Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019, Pub. L. No. 116-22, Sec. 205; Government Accountability Office, *COVID-19: Pandemic Lessons Highlight Need for Public Health Situational Awareness Network* (GAO-22-104600) (June 2022).

¹⁸⁸ Congressional Research Service, *Tracking COVID-19: U.S. Public Health Surveillance and Data* (R46588) (Nov. 2, 2020); Department of Health and Human Services, Centers for Disease Control and Prevention, *Justification of Estimates for Appropriation Committees: Fiscal Year 2010* (2009); Department of Health and Human Services, Public Health and Social Services Emergency Fund, *Justification of Estimates for Appropriation Committees: Fiscal Year 2023* (2022).

¹⁸⁹ HHS Communication to Senate Committee on Homeland Security and Governmental Affairs (Nov. 30, 2022).

¹⁹⁰ *Id.*

¹⁹¹ Government Accountability Office, *Biosurveillance: Challenges and Options for the National Biosurveillance Integration Center* (GAO-15-793) (Sep. 2015).

¹⁹² *Id.*

¹⁹³ White House, *Homeland Security Presidential Directive 21* (Oct. 18, 2007); Implementing Recommendations of the 9/11 Commission Act of 2007, Pub. L. No. 110-53, Sec. 1101.

Medical Countermeasure Development. Challenges regarding the availability of medical countermeasures are well documented. A 2019 Biodefense Industrial Base Report authored by the MITRE Corporation and prepared for ASPR found that the federal government has failed to provide sufficient “dedicated multi-year or no-year funding for medical countermeasure development,” reducing private sector investments, stalling innovation, and impairing long-term planning.¹⁹⁴ The report noted, “[t]here is a budgetary misalignment with threats when the budget is based on historical levels.” Dr. Robert Johnson, Director of Influenza and Emerging Infectious Diseases Division of ASPR’s BARDA, told the Committee one difficulty in procuring needed medical countermeasure development is that private manufacturers are hesitant to engage without federal public health agencies having a steady funding stream.¹⁹⁵ Dr. Johnson stated, “companies need signals . . . you have to spend significantly to get players engaged.”¹⁹⁶

Staffing. Inconsistent funding has also prevented public health agencies from maintaining a consistent, well-trained workforce at both the federal, state, and local levels. For example, at the federal level, Dr. Rick Bright, former Director of BARDA, described how in 2018 “most of ASPR was restructured [and] there was a hiring freeze that never got lifted so [they] couldn’t fill positions.” When the pandemic hit, ASPR was “completely understaffed,” which “bootstrapped a lot of [ASPR’s] ability to respond.”¹⁹⁷ The Association of Public Health Laboratories (APHL) informed the Committee that although public health departments are able to staff up when there is an infusion of federal supplemental funding, they are forced to lay off staff when the funding stops, only to try and hire back the workforce when new money comes in.¹⁹⁸ The number of staff employed by local public health departments has decreased since 2008—from over 184,000 before the 2008 recession to an estimated 153,000.¹⁹⁹ Staff from NACCHO told the Committee that public health is “a people-based, relationship-based science,” so funding cuts that impact the workforce also undermine readiness. NACCHO explained, “preparedness isn’t putting something in a binder and having it sitting on a shelf, it has to be exercised.”²⁰⁰

¹⁹⁴ MITRE Corporation, *2019 Biodefense Public Report: Implementation of the National Biodefense Strategy* (2019). See also Congressional Research Service, *COVID-19 and Domestic PPE Production and Distribution: Issues and Policy Options* (R46628) (Dec. 7, 2020); Government Accountability Office, *COVID-19: Federal Efforts Could Be Strengthened by Timely and Concerted Actions* (GAO-20-701) (Sept. 2020); Government Accountability Office, *COVID-19: Federal Efforts Could Be Strengthened by Timely and Concerted Actions* (GAO-20-701) (Sept. 2020).

¹⁹⁵ Interview with Dr. Robert Johnson (July 9, 2021).

¹⁹⁶ *Id.*

¹⁹⁷ Interview with Dr. Rick Bright (Mar. 17, 2021 and Nov. 4, 2021).

¹⁹⁸ Interview with Association of Public Health Laboratories (Apr. 19, 2021)

¹⁹⁹ Megan Wallace and Joshua Sharfstein, *The Patchwork U.S. Public Health System*, *New England Journal of Medicine* (Jan. 6, 2022). See also *Hollowed-Out Public Health System Faces More Cuts Amid Virus*, *Kaiser Health News* (July 1, 2020) (<https://khn.org/news/us-public-health-system-underfunded-under-threat-faces-more-cuts-amid-covid-pandemic/>) (finding “at least 38,000 state and local public health jobs have disappeared since the 2008 recession”).

²⁰⁰ Interview with National Association of County and City Health Officials (Apr. 28, 2021).

State and Local Efforts: At the state and local level, insufficient funding levels often place agencies at a disadvantage even before an emergency exists. “At best, public health funding has been held flat, but most has been reduced,” NACCHO told Committee staff, noting local public health agencies often “start a response in a hole because of the years of disinvestment.”²⁰¹ Similarly, APHL noted degraded physical infrastructure at public health labs, resulting in labs not staying up-to-date with the most current equipment and facilities or paying for equipment maintenance.²⁰²

IV. Plans, Guidance, and Exercises

Since 2005, DHS, HHS, and the Executive Office of the President have developed and updated various planning and guidance documents to prepare for and respond to disasters and public health incidents.²⁰³ This section summarizes key federal preparedness plans, guidance, and exercises and identifies shared, conflicting, and often vague roles and responsibilities tasked to agencies.

Planning and Guidance Documents

DHS has issued several emergency management guidance documents over the last two decades, applicable to a broad range of local and national disasters. Underlying these plans is the National Incident Management System (NIMS), which provides a standardized system for managing resources, coordinating activities, and communicating across stakeholders.²⁰⁴ All of the frameworks and guides referenced below are intended to abide by the principles set forth in NIMS.²⁰⁵

²⁰¹ *Id.*

²⁰² Interview with Association of Public Health Laboratories (Apr. 19, 2021).

²⁰³ Department of Health and Human Services, *HHS Pandemic Influenza Plan* (Nov. 2005); Department of Health and Human Services, *Pandemic Planning Update II* (Nov. 13, 2006); Department of Homeland Security, Federal Emergency Management Agency, *Emergency Support Function #8 – Public Health and Medical Services Annex* (Jan. 2008); Department of Health and Human Services, *Pandemic Planning Update VI* (Jan. 8, 2009); National Security Council, *Playbook for Early Response to High-Consequence Emerging Infectious Disease Threats and Biological Incidents* (2016); Department of Homeland Security, *Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans* (Jan. 2017); Department of Health and Human Services, *Pandemic Influenza Plan 2017 Update* (2017); Department of Homeland Security, Federal Emergency Management Agency, *Pandemic Crisis Action Plan, Version 2.0* (Jan. 2018) (on file with Committee, DHS FEMA 308-339); Department of Homeland Security, *National Response Framework, Fourth Edition* (Oct. 28, 2019); Department of Health and Human Services, *PanCAP Adapted, U.S. Government COVID-19 Response Plan* (Mar. 13, 2020) (on file with Committee, DHS FEMA 6-108); Department of Homeland Security, Federal Emergency Management Agency, *Pandemic Response to Coronavirus Disease 2019 (COVID-19): Initial Assessment Report* (Jan. 2021).

²⁰⁴ Department of Homeland Security, Federal Emergency Management Agency, *National Incident Management System, Third Edition* (Oct. 2017) (https://www.fema.gov/sites/default/files/2020-07/fema_nims_doctrine-2017.pdf).

²⁰⁵ *Id.*

- **National Response Framework (NRF).** Developed in response to the Post-Katrina Emergency Management Reform Act of 2005 and updated approximately every three to five years, the NRF serves as a guide for how the nation responds to “all types of incidents.”²⁰⁶ The doctrine builds on the principles set forth in NIMS and is designed to be “scalable, flexible, and adaptable.” It describes federal roles and external stakeholders for ensuring core capabilities in response to wide-ranging threats and hazards from natural disasters to biological incidents.²⁰⁷ The NRF is supplemented by a set of 15 Emergency Support Functions (ESFs), which identify the primary agency responsible for coordinating federal response efforts in specific situations. For example, ESF #1 addresses transportation and the Department of Transportation is designated the “ESF Coordinator” and primary agency for coordinating federal efforts.²⁰⁸ ESF #8 addresses federal coordination for public health and medical services during a crisis and assigns HHS as the primary agency responsible with ASPR carrying the responsibility to coordinate preparedness, response, and recovery efforts.²⁰⁹
- **Federal Interagency Operational Plans: Biological Incident Annex (BIA).** There are five Federal Interagency Operational Plans (FIOPs), one for each emergency management area: prevention, protection, mitigation, response, and recovery. These plans “describe how the federal government aligns resources and delivers core capabilities.”²¹⁰ For “unique” threats or hazards, such as cyber, power outages, terrorism, or biological incidents, among other topics, there are “incident annexes that address specific operational roles and responsibilities.”²¹¹ Implemented in 2008, the Biological Incident Annex (BIA) serves as an incident annex to FIOPs.²¹² The BIA assumes HHS will act as the “lead federal agency” for biological incidents.²¹³ Under the BIA, ASPR leads the coordination of federal preparedness and response efforts for public health

²⁰⁶ Department of Homeland Security, *National Response Framework, Fourth Edition*, at ii (Oct. 28, 2019) (https://www.fema.gov/sites/default/files/2020-04/NRF_FINALApproved_2011028.pdf).

²⁰⁷ *Id.* The first National Response Plan was published in 2004; *id.* at 1.

²⁰⁸ Department of Homeland Security, Federal Emergency Management Agency, *Emergency Support Function #8 – Public Health and Medical Services Annex* (Jan. 2008) (<https://www.fema.gov/pdf/emergency/nrf/nrf-esf-01.pdf>).

²⁰⁹ *Id.*

²¹⁰ Department of Homeland Security Federal Emergency Management Agency, Federal Interagency Operational Plans (<https://www.fema.gov/emergency-managers/national-preparedness/frameworks/federal-interagency-operational-plans>) (accessed Nov. 13, 2022). *See also* Congressional Research Services, *FEMA’s Role in the COVID-19 Federal Pandemic Response* (R47048) (Feb. 10, 2022).

²¹¹ Department of Homeland Security Federal Emergency Management Agency, Federal Interagency Operational Plans (<https://www.fema.gov/emergency-managers/national-preparedness/frameworks/federal-interagency-operational-plans>) (accessed Nov. 13, 2022).

²¹² Department of Homeland Security, *Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans*, at vii (Jan. 2017) (https://www.fema.gov/sites/default/files/2020-07/fema_incident-annex_biological.pdf). The 2008 Biological Incident Annex served as a supplement to the National Response Framework as the FIOPs were not formally implemented until 2011 through PPD-8. *See id.* (noting the 2017 BIA replaces the 2008 BIA to the National Response Framework).

²¹³ *Id.* at 17.

emergencies.²¹⁴ HHS maintains contact among interagency partners and, if needed, may request assistance from DHS/FEMA to coordinate with other agencies across the federal government.²¹⁵

While both the NRF and the BIA provide structural frameworks for federal agencies to follow, the plans described below are intended to serve as operational guides during a potential pandemic.²¹⁶ Although HHS has issued pandemic preparedness plans for over a decade, its focus has been primarily an influenza pandemic threat. HHS officials have acknowledged that preparedness planning often did not reflect operational realities.²¹⁷

- **Pandemic Influenza Plan.** In 2005, HHS published its first Pandemic Influenza Plan, which provides a “blueprint for all HHS pandemic influenza preparedness and response planning.”²¹⁸ HHS has updated the plan four times since 2005 with the most recent update in 2017.²¹⁹ This plan (and the subsequent updates), however, are “generally limited” to HHS’s operational role and “have been viewed to provide little, if any, discussion of the roles of other federal entities.”²²⁰ Notably, HHS’s pandemic influenza plan updates from November 2006, January 2009, and June 2017 “did not contain new information regarding federal department roles and responsibilities for pandemic response.”²²¹
- **Pandemic Crisis Action Plan (PanCAP) and Pandemic Crisis Action Plan-Adapted (PanCAP-A).** Originally developed in 2013 and revised in 2018, the Pandemic Crisis Action Plan describes “the concept of operations and broad organizational construct for

²¹⁴ *Id.*

²¹⁵ *Id.* at 13.

²¹⁶ Department of Homeland Security, Federal Emergency Management Agency, *Pandemic Response to Coronavirus Disease 2019 (COVID-19): Initial Assessment Report*, at 23 (Jan. 2021); Department of Health and Human Services, *PanCAP Adapted, U.S. Government COVID-19 Response Plan* (Mar. 13, 2020) (on file with Committee, DHS FEMA 6-108); Department of Health and Human Services, *HHS Pandemic Influenza Plan* (Nov. 2005) (<https://www.cdc.gov/flu/pdf/professionals/hhspandemicinfluenzaplan.pdf>); National Security Council, *Playbook for Early Response to High-Consequence Emerging Infectious Disease Threats and Biological Incidents* (2016). Although the Pandemic Playbook is not a public document, a draft provided to the media has been published by Politico. See *Trump team failed to follow NSC’s pandemic playbook*, Politico (Mar. 25, 2020) (<https://www.politico.com/news/2020/03/25/trump-coronavirus-national-security-council-149285>). See also *Evidence counters McConnell claim that Obama team left no pandemic ‘game plan’ for Trump*, PolitiFact (May 14, 2020) (<https://www.politifact.com/factchecks/2020/may/14/mitch-mcconnell/evidence-counters-mcconnell-claim-obama-team-left/>).

²¹⁷ Interview with Dr. Richard Besser (Apr. 7, 2021); Interview with Jonathan Greene (July 8, 2021).

²¹⁸ Department of Health and Human Services, *HHS Pandemic Influenza Plan*, at 2 (Nov. 2005).

²¹⁹ Department of Health and Human Services Centers for Disease Control and Prevention, National Pandemic Influenza Plans (<https://www.cdc.gov/flu/pandemic-resources/planning-preparedness/national-strategy-planning.html>).

²²⁰ Memorandum from Congressional Research Service to Senate Committee on Homeland Security and Governmental Affairs (Mar. 27, 2021).

²²¹ *Id.*

pandemic influenza response, triggers, indicators, phased ESF activities, and agency roles and responsibilities.”²²² FEMA developed and updated the plan in partnership with HHS. The 2018 PanCAP states, “HHS is the [lead federal agency] responsible for managing all federal public health and medical response,” which “includes a pandemic. FEMA is [also] responsible for coordinating federal support for consequence management.”²²³ Should the impact of a pandemic “become widespread and require a coordinated federal response” beyond public health and medical assistance, the PanCAP designated FEMA as the “lead coordinator for federal disaster response” with HHS maintaining its role leading the pandemic response.²²⁴ Primarily designed for an influenza pandemic response, FEMA and HHS revised the plan in February 2020 at the direction of the National Security Council as the COVID-19 threat level evolved.²²⁵ On March 13, 2020 FEMA issued a revised draft, referred to as the PanCAP-Adapted or “PanCAP-A,” which operationalized potential scenarios for the federal response in accordance with the NRF, FIOPs, BIA, and other federal authorities.²²⁶ The PanCAP-A places CDC as the HHS lead agency whereas other planning documents (NRF and BIA) designate ASPR as the lead for HHS.²²⁷

²²² Department of Homeland Security, Federal Emergency Management Agency, *Pandemic Response to Coronavirus Disease 2019 (COVID-19): Initial Assessment Report*, at 23 (Jan. 2021). See also Department of Homeland Security, Federal Emergency Management Agency, *Pandemic Crisis Action Plan, Version 2.0* (Jan. 2018) (on file with Committee, DHS FEMA 308-339); Department of Health and Human Services, *PanCAP Adapted, U.S. Government COVID-19 Response Plan* (Mar. 13, 2020) (on file with Committee, DHS FEMA 6-108).

²²³ Department of Homeland Security, Federal Emergency Management Agency, *Pandemic Crisis Action Plan, Version 2.0*, at 9 (Jan. 2018) (on file with Committee, DHS FEMA 308-339) (noting “[t]he federal interagency supports HHS, as requested, to assist SLTT partners with related preparedness and response activities.”).

²²⁴ *Id.* at 7. The PanCAP anticipated that a Stafford Act declaration would result in FEMA coordinating federal support “for consequence management” through the National Response Coordination Center. *Id.* at 10. The PanCAP anticipated that a Stafford Act declaration would result in FEMA coordinating federal support “for consequence management” through the NRCC (on file with Committee, DHS-FEMA 316, 326).

²²⁵ Federal Emergency Management Agency, Briefing with Senate Committee on Homeland Security and Governmental Affairs Staff (Aug. 3, 2021) (hereinafter “FEMA Briefing (Aug. 3, 2021)”). See also Department of Homeland Security, Federal Emergency Management Agency, *Pandemic Response to Coronavirus Disease 2019 (COVID-19): Initial Assessment Report*, at 23 (Jan. 2021).

²²⁶ Department of Health and Human Services, *PanCAP Adapted, U.S. Government COVID-19 Response Plan* (Mar. 13, 2020) (on file with Committee, DHS FEMA 6-108); Interview with Josh Dozor (June 7, 2021 and July 27, 2021).

²²⁷ Department of Health and Human Services, *PanCAP Adapted, U.S. Government COVID-19 Response Plan*, at 67 (Mar. 13, 2020); Department of Homeland Security, *Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans*, at 17 (Jan. 2017); Department of Homeland Security, *National Response Framework, Fourth Edition* (Oct. 28, 2019).

The Executive Office of the President has also developed select pandemic planning documents, noted below.

- **National Strategy for Pandemic Influenza and National Strategy for Pandemic Influenza Implementation Plan.** In November 2005 and May 2006, respectively, the White House Homeland Security Council released its approach to preparing for and responding to an influenza pandemic. The National Strategy listed three key pillars: preparedness and communication, surveillance and detection, and response and containment.²²⁸ Neither the National Strategy nor the Implementation Plan has been revised in over 15 years.²²⁹
- **Playbook for Early Response to High-Consequence Emerging Infectious Disease Threats and Biological Incidents (“Pandemic Playbook”).** In 2016, the National Security Council within the Executive Office of the President (EOP) developed a “Pandemic Playbook” to help consolidate existing authorities, guidance, and plans and incorporate lessons learned from prior infectious disease outbreaks, like H1N1, Zika, and Ebola.²³⁰ The Pandemic Playbook provides decision-making tools and suggested steps to take at each stage of a potential pandemic, including one caused by a novel coronavirus.²³¹ Former NSC Director for Medical and Biodefense Preparedness, Dr. Luciana Borio, opined that the Pandemic Playbook “could not make up for a lack of deep expertise and leadership.”²³² She described the document as a simple roadmap that was not very helpful to public health experts.²³³

Table 6, below, illustrates the overarching components in each planning document, highlighting similarities and differences.

²²⁸ See Homeland Security Council, *National Strategy for Pandemic Influenza* (Nov. 2005) (<https://www.cdc.gov/flu/pandemic-resources/pdf/pandemic-influenza-strategy-2005.pdf>); Homeland Security Council, *National Strategy for Pandemic Influenza Implementation Plan* (May 2006) (<https://www.cdc.gov/flu/pandemic-resources/pdf/pandemic-influenza-implementation.pdf>).

²²⁹ See Memorandum from Congressional Research Service to Senate Committee on Homeland Security and Governmental Affairs (Mar. 27, 2021).

²³⁰ National Security Council, *Playbook for Early Response to High-Consequence Emerging Infectious Disease Threats and Biological Incidents* (2016).

²³¹ *Id.*

²³² Interview with Dr. Luciana Borio (May 4, 2021).

²³³ *Id.*

Table 6. Overview of Key Federal Pandemic Planning and Guidance Documents²³⁴

Agency	Existing Plans	Purpose		Incident Type			Lead Federal Agency
		Management System and Framework	Operational Guidance & Procedures	All Hazard	Biological	Pandemic	
DHS	National Response Framework ²³⁵	×		×			HHS-ASPR
	Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans (BIA) ²³⁶	×			×	×	HHS, option to request FEMA assistance ²³⁷
	Pandemic Crisis Action Plan (PanCAP) ²³⁸		×			×	HHS
HHS	Pandemic Influenza Plan and updates ²³⁹		×			×	HHS
	Pandemic Crisis Action Plan Adapted (PanCAP-A) ²⁴⁰		×			×	HHS-CDC, option to request FEMA assistance
EOP	Playbook for Early Response to High-Consequence Emerging Infectious Disease Threats and Biological Incidents ²⁴¹		×			×	HHS

²³⁴ Committee analysis of federal emergency pandemic planning and guidance documents.

²³⁵ Department of Homeland Security, *National Response Framework, Fourth Edition* (Oct. 28, 2019).

²³⁶ Department of Homeland Security, *Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans* (Jan. 2017). See also Department of Homeland Security, Federal Emergency Management Agency, *Pandemic Response to Coronavirus Disease 2019 (COVID-19): Initial Assessment Report*, at 99 (Jan. 2021) (noting that the BIA and the PanCAP “do not outline the organizational structure of federal government response when HHS is designated as the lead federal agency”).

²³⁷ The BIA states, “[g]iven FEMA’s experience and important role in assisting the American people during crises, the PPD states that FEMA may assist the lead agency in coordinating the Federal incident response.” See Department of Homeland Security, *Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans* (Jan. 2017).

²³⁸ Department of Homeland Security, Federal Emergency Management Agency, *Pandemic Crisis Action Plan, Version 2.0* (Jan. 2018) (on file with Committee, DHS FEMA 308-339).

²³⁹ Department of Health and Human Services, *HHS Pandemic Influenza Plan* (Nov. 2005) (<https://www.cdc.gov/flu/pdf/professionals/hhspandemicinfluenzaplan.pdf>); Department of Health and Human Services, *Pandemic Planning Update II* (Nov. 13, 2006) (<https://www.cdc.gov/flu/pandemic-resources/pdf/panflureport3.pdf>); Department of Health and Human Services, *Pandemic Planning Update VI* (Jan. 8, 2009) (<https://www.cdc.gov/flu/pandemic-resources/pdf/panflureport6.pdf>); Department of Health and Human Services, *Pandemic Influenza Plan 2017 Update* (2017) (<https://www.cdc.gov/flu/pandemic-resources/pdf/pan-flu-report-2017v2.pdf>).

²⁴⁰ Department of Health and Human Services, *PanCAP Adapted, U.S. Government COVID-19 Response Plan* (Mar. 13, 2020) (on file with Committee, DHS FEMA 6-108).

²⁴¹ National Security Council, *Playbook for Early Response to High-Consequence Emerging Infectious Disease Threats and Biological Incidents* (2016).

Exercises

While federal planning documents are designed to be flexible and scalable for any evolving threat, multiple officials emphasized the importance of conducting regular exercises to ensure plans are operational and well executed.²⁴²

From 2010-2019, CDC reported conducting a total of fifteen pandemic exercises (including tabletops and virtual events), holding anywhere from zero to three pandemic exercises each year (nine of which were interagency).²⁴³ Of the exercises CDC performed, 13 centered on pandemic influenza. From 2010-2019, ASPR reported conducting or being a major participant in a total of 83 preparedness exercises, holding anywhere from five to sixteen exercises each year (in total, 76 were interagency).²⁴⁴ ASPR's exercises ranged from natural disasters, bioterrorism, and pandemic influenza, among other emergencies. Of the exercises ASPR performed, 11 exercises involved pandemic influenza.²⁴⁵ FDA indicated that it conducted a total of 26 preparedness exercises (12 of which were interagency) between 2014 and 2019, holding anywhere from 3 to 11 exercises each year.²⁴⁶ As referenced throughout this section, in 2019 HHS conducted its largest influenza pandemic exercise to date known as Crimson Contagion.

DOD also reported conducting pandemic warning exercises hosted by the National Center for Medical Intelligence (NCMI).²⁴⁷ Reports from these exercises in years prior to the COVID-19 pandemic found a lack of institutional knowledge across agencies, a need for clear roles and responsibilities across the government, and a need for seamless access to medical intelligence, for a robust preparation and response. Specifically, the Committee identified critical gaps between DOD intelligence and medical communities, including insufficient information sharing and a lack of medical intelligence analysts at combatant commands. DOD's exercises also found that pandemics would require a whole of government response, and that the broader federal government should plan for how the whole U.S. government would respond during a potential pandemic event.

Every year, FEMA holds a National Level Exercise (NLE) that involves federal interagency partners. In a Committee briefing, FEMA official Erin Hoffman, Director of

²⁴² Interview with Dr. Richard Besser (Apr. 7, 2021); Interview with Melissa Harvey (Nov. 3, 2021); Joe Nimmich, Former Federal Emergency Management Agency Deputy Administrator (Sep. 2014 - Jan. 2017), Interview with Senate Committee on Homeland Security and Governmental Affairs (Mar. 25, 2021); Interview with Dr. Kevin Yeskey (Nov. 17, 2021 and Dec. 2, 2021); Interview with National Association of County and City Health Officials (Apr. 28, 2021).

²⁴³ Department of Health and Human Services, Centers for Disease Control and Prevention, *CDC Pandemic Exercise History FYs 2010-2022* (received Feb. 28, 2022) (on file with Committee).

²⁴⁴ Department of Health and Human Services, Assistant Secretary for Preparedness and Response, *Exercise History Response 2-24-2022* (received Feb. 28, 2022) (on file with Committee).

²⁴⁵ *Id.*

²⁴⁶ Food and Drug Administration, *FDA Office of Emergency Management Exercise Conduct 2014-2021* (received Feb. 28, 2022) (on file with Committee).

²⁴⁷ Department of Defense, Defense Intelligence Agency, *Pandemic Exercise After-Action Reports (2018-2020)* (on file with Committee).

National Exercises and Technological Hazards, told the Committee that in 2017, her division recommended part of the 2018 NLE include a pandemic response: “we encouraged Crimson Contagion because HHS and the interagency determined we weren’t prepared to do a pandemic exercise at the NLE-level.”²⁴⁸ Ultimately, the interagency pandemic exercise (now known as Crimson Contagion) did not occur until 2019 because hurricanes remained FEMA’s biggest threat at the time as shown in the excerpt below.²⁴⁹

Excerpt from FEMA’s 2017 Proposed National Level Exercise Concept for FY 2018²⁵⁰

NLE 2018 Proposed Exercise Design: The proposed exercise design would take place spring/summer 2018:

- Begin with a Category 4 or 5 hurricane affecting the East Coast; causing severe loss of life and damage to residences, businesses, and critical infrastructure (*Ardent Sentry*).
- Include hurricane impact to the Washington, D.C. area, causing the federal government to implement continuity of operations activities (*Eagle Horizon*).
- Conclude with a multi-day examination of long-term recovery efforts (*Silver Phoenix II*).
- Provide a progressive, national-level exercise that will examine our Nation’s greatest challenges in response, recovery, and continuity planning.
- Address multiple Principals’ Objectives, to include: long-term recovery (PO #5) and catastrophic incidents (PO #7); flexibility to include Non-Stafford Act incidents (PO #2), cybersecurity (PO #4), and pandemic response (PO #6).
- Incorporate multiple exercises to reduce costs and increase participation across the homeland security enterprise.

The National Exercise Division would lead the overall planning efforts to ensure NLE 2018 expands upon *Ardent Sentry* and *Eagle Horizon* by examining the whole community’s ability to conduct life-saving and life-sustaining operations during a catastrophic incident, while integrating recovery coordination efforts.

Recommendation: Review and approve this concept. Upon approval, NED will commence coordination activities for NLE 2018.

Approve / date CPW 1/9/17 Disapprove / date _____
 Modify / date _____ Needs discussion / date _____

Although FEMA’s proposed National Level Exercise for 2018 did not ultimately address pandemic response, its National Exercise Program (NEP) addressed biological incidents as a priority within the 2017-2018 Principals Objectives (PO). The Principal Objectives are the National Security Council’s exercise priorities for a two-year cycle. NSC’s Principal Objectives for 2017-2018 (as well as subsequent cycles) listed “Infectious Disease and Biological Incidents”

²⁴⁸ FEMA Briefing (Aug. 3, 2021).

²⁴⁹ FEMA Briefing (Aug. 3, 2021). See also Department of Homeland Security, Federal Emergency Management Agency, *Memorandum on Proposed National Level Exercise (NLE) 2018 Initial Concept* (Jan. 17, 2017) (on file with Committee, DHS-FEMA, 1226-1227).

²⁵⁰ Department of Homeland Security, Federal Emergency Management Agency, *Memorandum on Proposed National Level Exercise (NLE) 2018 Initial Concept* (Jan. 17, 2017) (on file with Committee, DHS-FEMA, 1226-1227). While the proposed exercise design listed pandemic response as a Principals’ Objective to address, it was not included in the 2018 National Level Exercise due to the need to address hurricanes.

as one of the seven objectives.²⁵¹ As detailed below, the proposed National Exercise Program for 2018 highlighted a number of preexisting vulnerabilities in federal preparedness structures, including information sharing, insufficient federal guidance, and pandemic response capabilities.²⁵²

Excerpt from FEMA’s Proposed National Exercise Program for FY 2018²⁵³

National Exercise Program (NEP) Engagement

The 2017-2018 NEP Cycle includes a Principal Objective specifically to examine the ability of all levels of government to address infectious disease pandemics and biological incidents.

- Analysis informing the development of the 2017-2018 NEP Principal Objectives identified specific capability gaps related to biological and emerging infectious diseases. Over half of states and territories highlighted human pandemics as an area of concern in the 2015 Threat and Hazard Identification and Risk Assessments (THIRAs), while State Preparedness Report data showed a significant decline in public health, healthcare, and emergency medical services capability based on self-reporting.
- After-action results from both real-world responses and exercises demonstrated confusion over roles and responsibilities, a lack of access to required resources, and uncoordinated public messaging.
- NEP exercises conducted in 2016 have addressed areas of concern, but were limited in scope and progression from discussion-based events.

As shown below, FEMA’s National Exercise Program (NEP) Mid-Cycle Report for 2017-2018 found that while pandemics were rated as “one of the top five threats and hazards by states in 2016,” only three percent of NEP exercises aligned with NSC Principals’ Objective for

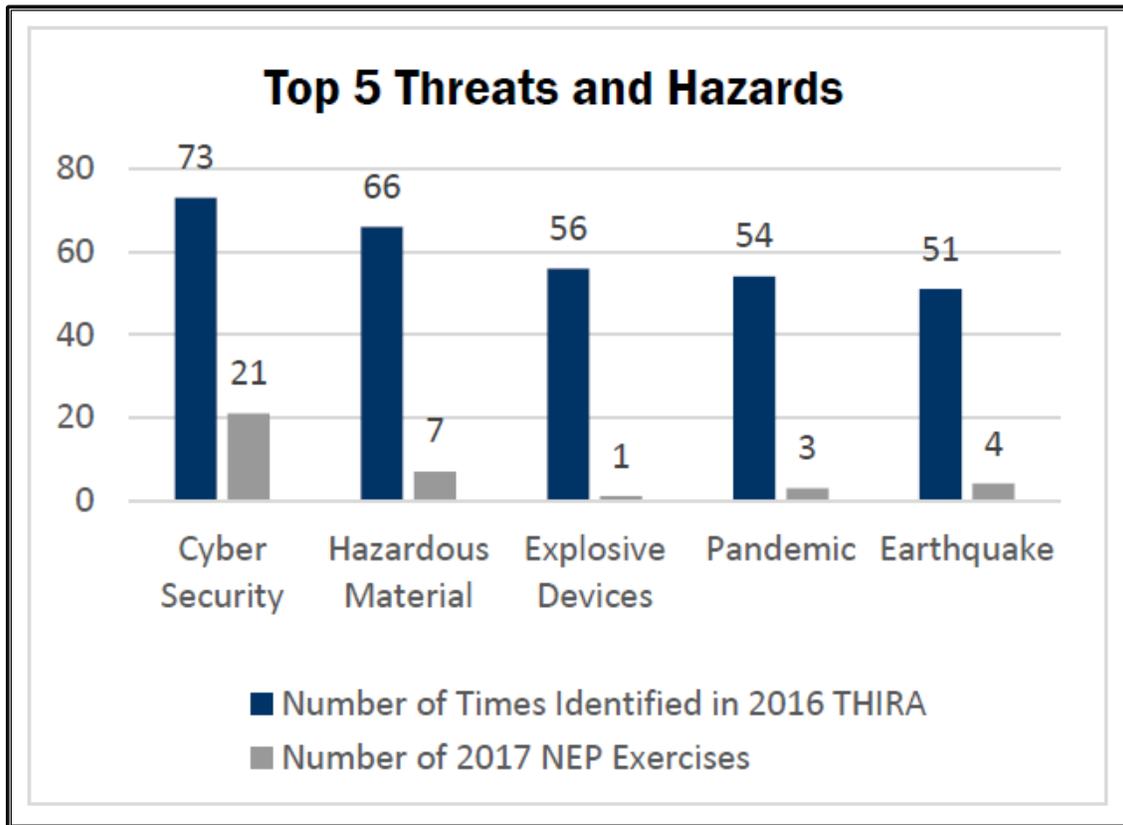
²⁵¹ FEMA Briefing (Aug. 3, 2021). The seven Principals’ Objectives identified in FEMA’s 2017-2018 National Exercise Program Mid-Cycle Report include: intelligence and information sharing; lead federal agency coordination; multidisciplinary response operations; cyber coordination; recovery coordination; infectious disease biological incidents; and catastrophic incidents. See Office of Management and Budget, *National Exercise Program: 2017-2018 Mid-Cycle Report* (Jan. - Dec. 2017) (on file with Committee, OMB HSGAC 977-984).

²⁵² Office of Management and Budget, *Department of Health and Human Services Exercise Resourcing Background as of July 2017* (undated) (on file with Committee, OMB HSGAC 887).

²⁵³ Office of Management and Budget, *Department of Health and Human Services Exercise Resourcing Background as of July 2017* (July 2017) (on file with Committee, OMB HSGAC 820).

Infectious Disease and Biological Incidents.²⁵⁴ The report noted, “the low number of pandemic exercises could indicate a need for additional focus, or a disconnect in reporting collaboration between state departments of public health and offices of emergency management.”²⁵⁵

***FEMA’s National Exercise Program 2017-2018 Mid-Cycle Report:
Top Five Threats & Hazards²⁵⁶***

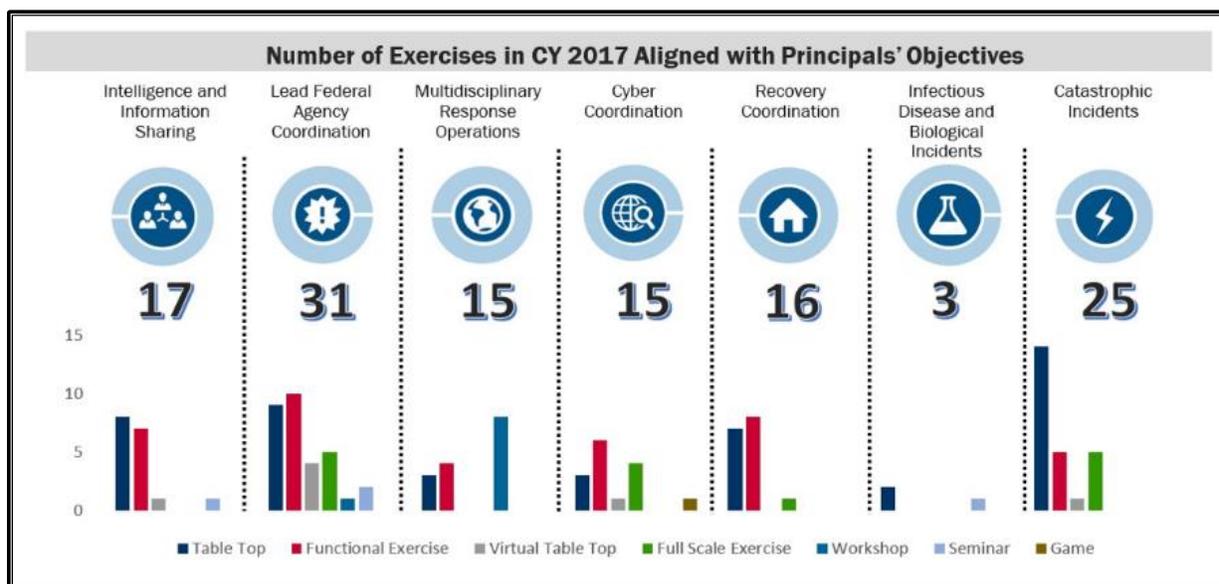


²⁵⁴ Office of Management and Budget, *National Exercise Program: 2017-2018 Mid-Cycle Report*, at 2 (Jan. - Dec. 2017) (on file with Committee, OMB HSGAC 977-984).

²⁵⁵ *Id.*

²⁵⁶ *Id.*

*Number of Exercises in CY 2017 Aligned with Principal's Objectives*²⁵⁷



In 2019, the federal government conducted the largest influenza pandemic exercise to date known as Crimson Contagion. This series of exercises entailed a multi-state whole-of-government simulation led by HHS to test the nation’s response to a novel influenza virus pandemic.²⁵⁸ The Crimson Contagion exercise simulated a fast-spreading airborne influenza virus scenario that originated in China and made its way to the U.S., infecting 110 million people and killing nearly 600,000.²⁵⁹ According to HHS, the repeated federal response failures during the prior outbreaks under HHS’s lead “highlighted the need for the nation to better prepare for incidents in which DHS/FEMA is not the lead federal agency.”²⁶⁰ While the exercise placed HHS in the lead, former FEMA senior official Josh Dozor told the Committee that participants contemplated shifting operational coordination roles from HHS to FEMA under certain circumstances.²⁶¹

Following the exercise series, HHS issued an after-action report in January 2020 that identified a number of shortfalls in the federal government’s capacity to respond to a pandemic, including access to emergency funding; confusion around leadership roles; medical supply chain challenges; and incompatible information management systems.²⁶² These after-action report findings previewed many of the challenges during the initial response to the COVID-19

²⁵⁷ *Id.*

²⁵⁸ Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, *Crimson Contagion 2019 Functional Exercise After-Action Report*, at 5 (Jan. 2020).

²⁵⁹ *Id.* at 9-10.

²⁶⁰ *Id.* at 5.

²⁶¹ Interview with Josh Dozor (June 7, 2021 and July 27, 2021).

²⁶² Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, *Crimson Contagion 2019 Functional Exercise After-Action Report* (Jan. 2020).

pandemic and are detailed in Part II. Multiple officials from different agencies told the Committee that the after-action findings from *Crimson Contagion* came too late to implement in the initial stages of the COVID-19 pandemic.²⁶³

The Executive Office of the President also participates in pandemic preparedness planning exercises. In 2017, the National Preparedness Policy Review Sub-Policy Coordination Committee Charter, housed within NSC, conducted a review of the current state of national preparedness policy.²⁶⁴ The review identified a number of recommendations that have yet to be adequately addressed, including:

- **Clarify** federal interagency roles and responsibilities across the five National Preparedness mission areas.
- **Rescind, revise, or replace** outdated policies.
- **Maximize** alignment and efficiencies across department and agency authorities, resources, and programs.
- **Align** policies incorporating lessons from years of implementation.
- **Identify** a process for establishing targets and measures.

Many of the challenges that occurred as a result of the federal response to the COVID-19 pandemic were previously anticipated in pandemic response assessments conducted by federal agencies and departments. For example, a 2017 internal memorandum from a Defense Health Examiner within DOD to the Associate Director of National Security Programs noted, “HHS/CDC and DHS have significant pandemic response gaps and shortfalls,” including inadequate surge capacity and infrastructure.²⁶⁵ A 2018 Senior Officials Exercise Program on Pandemic Response also identified multiple anticipated challenges in responding to pandemic threats, including:²⁶⁶

- Border screening measures and border closures (noting such actions would have limited effectiveness for an influenza pandemic).
- Implementation of non-pharmaceutical measures during a pandemic.

²⁶³ See, e.g., Interview with Dr. Rick Bright (Mar. 17, 2021 and Nov. 4, 2021). Dr. Bright noted that “much of the information and early draft reports had been shared and circulated for review and comment” and although “[m]uch of the after-action report was available...many still chose to ignore it or failed to implement what was learned.” See Dr. Rick Bright, Written Response to Senate Committee on Homeland Security and Governmental Affairs Staff (received Sept. 1, 2022). See also Interview with Greg Burel (Feb. 26, 2021); Interview with Pete Gaynor (June 9, 2021).

²⁶⁴ Office of Management and Budget, *National Preparedness Policy Review Sub-Policy Coordination Committee Charter* (June 13, 2017) (on file with Committee, OMB HSGAC 827-829); Federal Emergency Management Agency, *Senior Officials Exercise Program: Concept Paper* (Mar. 22, 2017) (on file with Committee, OMB HSGAC - 884-888).

²⁶⁵ Office of Management and Budget, *Memorandum for the Associate Director, National Security Programs: Deputies, Bio-Incident Tabletop, Tuesday, Dec 12, 2017 from 1:30pm-3:00pm in WH SitRm* (Dec. 8, 2017) (on file with Committee, OMB HSGAC – 897-900)

²⁶⁶ Office of Management and Budget, *Senior Officials Exercise Program, SOE 18-5: Pandemic Response, Background Paper* (updated Nov. 2018) (on file with Committee, OMB HSGAC 1169-1174).

- Respiratory protective device shortage, specifically a “significant lack” of respirators and face masks for health care workers during a pandemic influenza and insufficient supplies in stockpiles.
- Limited supply of pandemic vaccine.

Through the National Preparedness Policy Review Sub-Policy Coordination Committee Charter’s review of 36 After Action Reports between 2004-2016, the Committee identified recommendations to address critical and longstanding gaps in pandemic preparedness, including the need to: (1) enhance training and exercises to improve coordination and communication within federal leadership groups; (2) develop policies to address “critical infrastructure and supply chain interdependencies;” and (3) “[e]stablish declaration criteria and subsequent funding sources related to standing up a Federal pandemic influenza response.”²⁶⁷

In January 2021, FEMA released an assessment of their COVID-19 response efforts. In its report, the agency recognized the potential conflict of responsibilities during certain incidents: “[a]lthough FEMA has been delegated the authority to lead the administration of disaster relief and emergency assistance functions under the Stafford Act, the Public Health Service Act also gives HHS authority to lead the federal public health and medical response to public health emergencies.”²⁶⁸ FEMA noted, “[t]hese parallel and overlapping authorities require a shared understanding of how agencies will coordinate with one another in a response.”²⁶⁹ HHS did not provide any documents or information in response to the Committee’s request regarding whether HHS conducted an assessment of its COVID-19 response, stating only that they are “continu[ing] to assess the response to the COVID-19 pandemic” and that after action reports “are always subject to change and capture a point in time.”²⁷⁰

The Majority Committee staff found that numerous assessments prior to COVID-19 identified many of the challenges the federal government ultimately struggled to address during the initial response to the COVID-19 pandemic. These challenges are detailed in Part II.

V. Medical Supply Chain Readiness

Decades of concentrated overreliance on foreign sources for critical medical products and a lack of transparency in where those products are manufactured and sourced has resulted in a hollowed-out U.S medical supply chain that lacks resiliency. In 2019, the U.S-China Economic and Security Review Commission (USCC) reported that the U.S. is so dependent on China for supply, including the key components of generic drugs, and the Chinese market is so lacking in effective health and safety regulations, that “the American public, including its armed forces, are

²⁶⁷ Office of Management and Budget, *Exercise & Evaluation Sub-PCC – National Preparedness Policy Review After Action Review Trend Analysis* (on file with Committee, OMB HSGAC 838-840).

²⁶⁸ Department of Homeland Security, Federal Emergency Management Agency, *Pandemic Response to Coronavirus Disease 2019 (COVID-19): Initial Assessment Report*, at 31 (Jan. 2021).

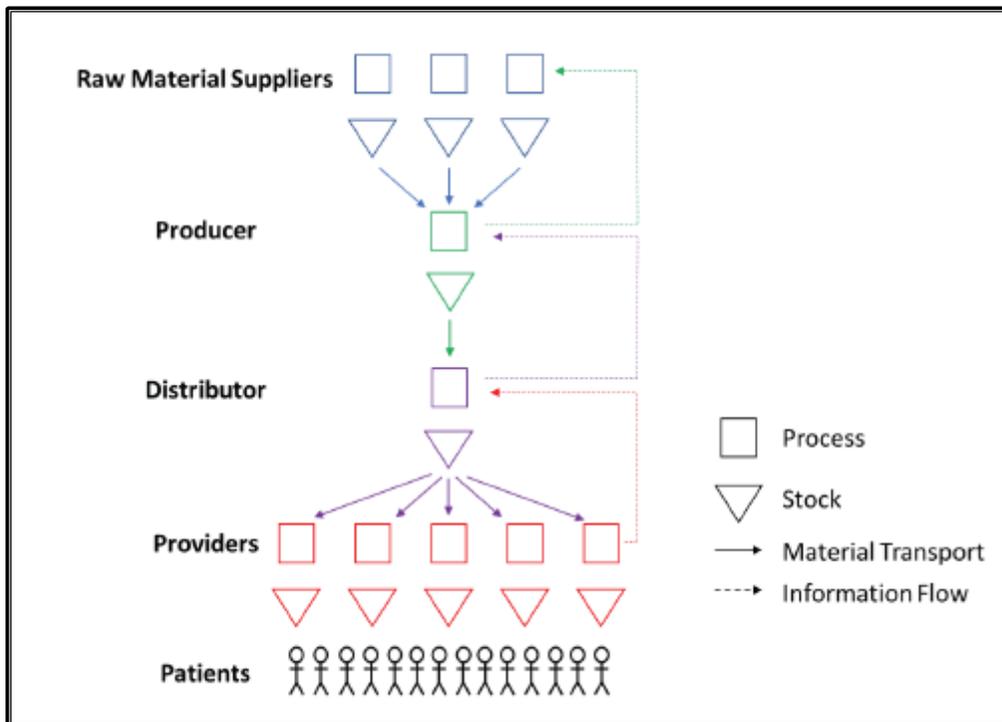
²⁶⁹ *Id.*

²⁷⁰ HHS Correspondence to Senate Committee on Homeland Security and Governmental Affairs Staff (Dec. 1, 2022).

at risk of exposure to contaminated and dangerous medicines . . . Should Beijing opt to use U.S. dependence on China as an economic weapon and cut supplies of critical drugs, it would have a serious effect on the health of U.S. consumers.”²⁷¹

In a March 2022 report, the National Academies of Sciences, Engineering, and Medicine (NASEM) found that “the investment, both financial and human capital, that government and private industry has made in the supply chain reliability of medical product supply chains has not been sufficient to meet public health need.”²⁷² GAO identified a number of factors that led to manufacturers’ shift overseas, “including the preference for large factory sites; lower labor and energy costs; and fewer environmental regulations governing the buying, handling, and disposing of toxic chemicals involved in drug manufacturing.”²⁷³ The diagram below details the general flow of medical products and the multiple entities involved in medical supply chains.

Diagram of Medical Product Supply Chain from NASEM²⁷⁴



²⁷¹ U.S.-China Economic and Security Review Commission, *2019 Report to Congress*, at 10-11 (Nov. 2019).

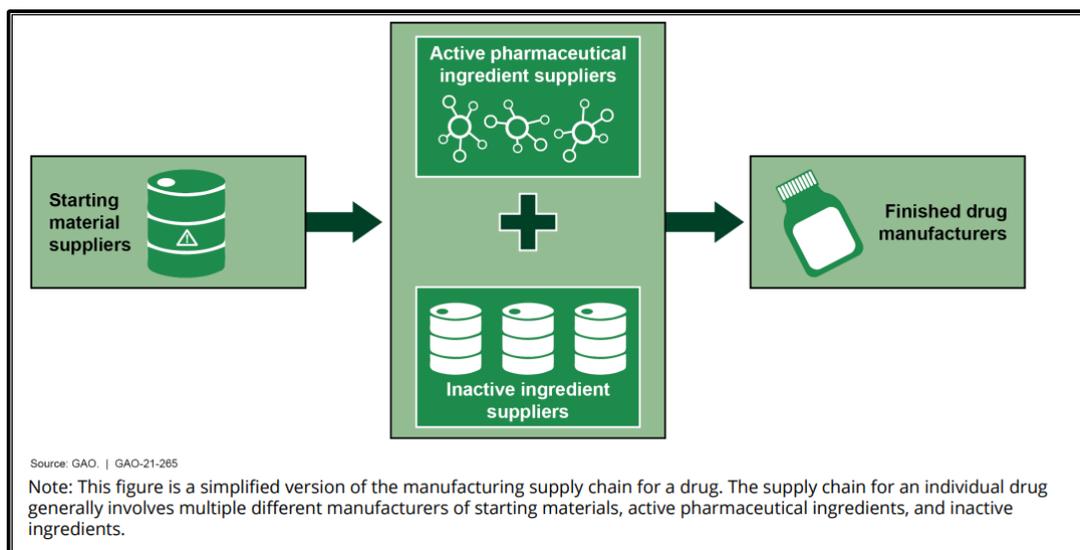
²⁷² National Academies of Sciences, Engineering, and Medicine, *Building Resilience into the Nation’s Medical Product Supply Chains*, at 2, 31 (2022).

²⁷³ Government Accountability Office, *COVID-19: Critical Vaccine Distribution, Supply Chain, Program Integrity, and Other Challenges Require Focused Federal Attention*, at 138 (GAO-21-265) (Jan. 2021).

²⁷⁴ National Academies of Sciences, Engineering, and Medicine, *Building Resilience into the Nation’s Medical Product Supply Chains*, at 3 (2022).

The manufacturing of medical products, much of which relies on foreign sources, includes not only finished products, but also component production, such as key starting materials and active pharmaceutical ingredients (APIs) necessary for pharmaceutical production as shown below, in addition to other raw materials needed to manufacture medical devices.²⁷⁵ FDA estimates nearly 80 percent of active pharmaceutical ingredient manufacturers are located overseas.²⁷⁶

GAO Illustration of Simplified Drug Manufacturing Supply Chain²⁷⁷



Although the United States has outsourced pharmaceutical manufacturing to a number of countries, China and India are the primary destinations of this outsourcing.²⁷⁸ For PPE, the overall loss of textile manufacturing in the United States has undermined the domestic industrial base for both specific PPE products, and the ability to pivot to produce new textile products in an emergency—in 1991, 56.2 percent of all clothes purchased in the United States were made in the United States. By 2012, it was only 2.5 percent.²⁷⁹

Combined, outsourcing and an overreliance on foreign sources for key drugs, PPE, and their respective inputs has placed the United States at increased risk during a public health crisis.²⁸⁰ In 2007, a one-year review of the National Strategy for Pandemic Influenza

²⁷⁵ Government Accountability Office, *COVID-19: Critical Vaccine Distribution, Supply Chain, Program Integrity, and Other Challenges Require Focused Federal Attention* at 138 (GAO-21-265) (Jan. 2021).

²⁷⁶ Food and Drug Administration, *FDA at a Glance: FDA Regulated Products and Facilities* (Nov. 2021) (<https://www.fda.gov/media/154548/download>).

²⁷⁷ *Id.*

²⁷⁸ *Id.*

²⁷⁹ Dana Thomas, *Fashionopolis: Why What We Wear Matters*, at 5 (2020).

²⁸⁰ Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, *Crimson Contagion 2019 Functional Exercise After-Action Report* (Jan. 2020); National Academies of

Implementation Plan found, “significant work remains at the Federal, State, local and healthcare facility level to address the projected demand for antiviral medications, personal protective equipment (including surgical masks and respirators), antibiotics, ventilators, and other medical materiel required during a pandemic.”²⁸¹ Nearly a decade later, in 2015, the problem remained unaddressed: CDC estimated demand for respirators and surgical masks during a hypothetical influenza pandemic and found that regardless of the hypothetical pandemic’s scale, the number of respirators and surgical masks needed would present “a logistic challenge for US public health agencies.”²⁸² Specifically, a “base case scenario” would require between 1.7 and 3.5 billion respirators and a “maximum demand scenario” would require up to 7.3 billion respirators.

A 2017 internal memorandum to the Associate Director of National Security Programs identified a “likely shortage[] of PPE gear” and “an alarming shortage of vaccines and even syringes” as gaps in federal pandemic preparedness.²⁸³ In addition to known supply shortfalls, the memorandum noted the lack of sufficient contingency planning, highlighted in the excerpt below.

Sciences, Engineering, and Medicine, *Building Resilience into the Nation’s Medical Product Supply Chains* (2022); Interview with Peter Guinto (Apr. 8, 2021).

²⁸¹ Homeland Security Council, *National Strategy for Pandemic Influenza: Implementation Plan One Year Summary*, at 29 (July 2007) (https://web.archive.org/web/20071030015258/https://www.whitehouse.gov/homeland/nspi_oneyear.pdf).

²⁸² Cristina Carias et al., *Potential Demand for Respirators and Surgical Masks During a Hypothetical Influenza Pandemic in the United States*, at 1, *Clinical Infectious Diseases* (Apr. 10, 2015).

²⁸³ Office of Management and Budget, *Memorandum for the Associate Director, National Security Programs: Deputies, Bio-Incident Tabletop, Tuesday, Dec 12, 2017 from 1:30pm-3:00pm in WH SitRm* (Dec. 8, 2017) (on file with Committee, OMB HSGAC – 897-900).

*Excerpt: Informational Memorandum from
Defense Health Official dated December 8, 2017²⁸⁴*

Challenges

Unfortunately, HHS/CDC and DHS have significant pandemic response gaps and resource short-falls. In this table-top exercise, the civilian health care system will be overwhelmed. The US healthcare system does not have adequate surge capacity or infrastructure to deal with large-scale outbreaks of infectious diseases. There's likely to be a shortage of PPE gear and an alarming shortage of vaccines and even syringes. For example, in preparedness work for a possible H7N9 Influenza pandemic, HHS Biomedical Advanced Research Authority acknowledged it only has 11 million syringes and related supplies available in the Strategic National Stockpile, yet needs at least 40 million syringes for first responders and healthcare staff. In spite of numerous Homeland Security Directives and policy guides, there is no plan to prioritize or adjudicate competing requests for scarce resources. I believe this table top exercise to underline that we cannot continue to rely on **reactive** strategies for agencies to work out resource/supply demands.

Additionally, a lack of visibility into where critical medical products are manufactured and sourced has also resulted in increased national security risks.²⁸⁵ For pharmaceuticals, FDA estimates that approximately “78 [percent] of active pharmaceutical ingredient manufacturers are located outside of the U.S.,” however, FDA has less visibility into the volume of products and critical inputs produced in each country.²⁸⁶ NASEM found that “purchasers of medical products often do not know where [the products they purchase] are produced and almost never know where the ingredients and components they contain are sourced from.”²⁸⁷

Currently, the U.S. medical supply chain operates on a “just in time” delivery model, meaning that hospitals only purchase supplies on an as needed basis due to a general lack of

²⁸⁴ *Id.*

²⁸⁵ See, e.g., Government Accountability Office, *COVID-19: Critical Vaccine Distribution, Supply Chain, Program Integrity, and Other Challenges Require Focused Federal Attention* (GAO-21-265) (Jan. 2021); U.S.-China Economic and Security Review Commission, *2019 Report to Congress* (Nov. 2019).

²⁸⁶ Department of Health and Human Services, Food and Drug Administration, *FDA at a Glance* (Nov. 2021) (<https://www.fda.gov/media/154548/download>); House Subcommittee on Health, Testimony Submitted for the Record of Director Dr. Janet Woodcock, Center for Drug Evaluation and Research, Food and Drug Administration, *Hearing on Safeguarding Pharmaceutical Supply Chains in a Global Economy*, 116th Cong. (Oct. 30, 2019) (H. Hrg. 116-XX) (“72 percent of the API manufacturers supplying the U.S. market [are] overseas...[as of 2019] data available to FDA do not enable us to calculate the volume of APIs being used for U.S.-marketed drugs from China or India, and what percentage of U.S. drug consumption this represents . . . we do not know whether Chinese facilities are actually producing APIs, how much they are producing, or where the APIs they are producing are being distributed worldwide, including in the United States.”); Coronavirus Aid, Relief, and Economic Security (CARES) Act, Pub. L. No. 116-136 (2020) (while the CARES Act requires annual reporting on volume for certain pharmaceuticals and APIs, significant gaps in supply chain visibility remain).

²⁸⁷ National Academies of Sciences, Engineering, and Medicine, *Building Resilience into the Nation's Medical Product Supply Chains*, at 5 (2022).

storage. This model leaves little or no buffer in the event a critical drug or medical supply manufacturer experiences difficulty obtaining needed APIs or raw materials, discovers product contamination, or experiences another manufacturing difficulty that impacts supply availability.²⁸⁸ Dr. Robert Handfield, Professor of Supply Chain Management at North Carolina State University, testified, “[t]he U.S. healthcare system relies on suppliers that are primarily overseas and leaves us at the mercy of export policies and priorities of other nations[,] which led to shortages.”²⁸⁹ Former Director of the Strategic National Stockpile, Greg Burel, told Committee staff, “industry’s reliance on just in time manufacturing, puts the nation at risk” as he emphasized the importance of requiring a 90-day backstop of critical supplies.²⁹⁰ Several former government officials interviewed by the Committee noted that entities, like hospitals and distributors, did not have their own stockpiles of PPE, further stressing the medical supply chain.²⁹¹

In 2006, HHS established the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), a multiagency group of representatives from federal departments, including DOD and DHS, responsible for coordinating public health emergency medical countermeasure preparedness needs.²⁹² PHEMCE’s Enterprise Senior Council, chaired by the ASPR with members from CDC, FDA, and other components, is designed to play a critical role in determining which medical countermeasures to stock in the SNS.²⁹³ In 2018, ASPR restructured PHEMCE in an attempt to resolve security concerns and accelerate procurement procedures for the SNS.²⁹⁴ In July 2021, GAO reported “interagency partners” had concerns about PHEMCE’s restructuring, including “effectiveness of interagency collaboration and transparency” and ASPR officials “acknowledged the changes ASPR made to the PHEMCE from 2018-2020 did not fully achieve the desired aims and created other challenges.”²⁹⁵

GAO, after assessing PHEMCE, found that ASPR failed to conduct statutorily required annual SNS reviews from 2017 through 2019, which would have informed inventory

²⁸⁸ Government Accountability Office, *Drug Shortages: Certain Factors Are Strongly Associated with This Persistent Public Health Challenge* (GAO-16-595) (July 2016).

²⁸⁹ Senate Committee on Homeland Security and Government Affairs, *COVID-19 Part II: Evaluating the Medical Supply Chain and Pandemic Response Gaps*, 117th Cong. (May 19, 2021) (S. Hrg. 117-XX).

²⁹⁰ Interview with Greg Burel (Feb. 26, 2021).

²⁹¹ See, e.g. See, e.g. *id.*; Interview with Dr. James Lawler (May 6, 2021); Senate Committee on Homeland Security and Governmental Affairs, Testimony Submitted for the Record of Dr. Shereef Elnahal, University Hospital, Newark, New Jersey, *Hearing on COVID-19 Part II: Evaluating the Medical Supply Chain and Pandemic Response Gaps*, 117th Cong. (May 19, 2021) (S. Hrg. 117-XX).

²⁹² Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) (<https://www.phe.gov/Preparedness/mcm/phemce/Pages/default.aspx>) (accessed Nov. 23, 2022).

²⁹³ Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, PHEMCE Partners (<https://medicalcountermeasures.gov/phemce/>) (accessed Nov. 23, 2022).

²⁹⁴ Government Accountability Office, *COVID-19: Continued Attention Needed to Enhance Federal Preparedness, Response, Service Delivery, and Program Integrity* (GAO-21-551) (July 2021).

²⁹⁵ *Id.* at 20.

procurements for 2020-2022.²⁹⁶ These SNS reviews provide recommendations to HHS on SNS medical countermeasure procurements and include an annual report to Congress.²⁹⁷ A GAO analysis of the SNS reviews also found that while the SNS inventory contained the majority of medical countermeasures recommended by PHEMCE, it did not include the quantities recommended.²⁹⁸ According to CDC officials, the changes ASPR made to some recommended quantities of certain medical countermeasures “lacked clear rationale or basis” and occurred when “PHEMCE was not operational.”²⁹⁹

In the year leading up to the COVID-19 pandemic, both DHS and HHS envisioned challenges posed by an influenza pandemic. In July 2019, FEMA’s National Threat and Hazard Identification and Risk Assessment “identif[ied] the Nation’s realistic worst-case scenarios and their impacts.”³⁰⁰ FEMA contemplated a pandemic that would result in a “shortage of medical supplies, equipment, beds, and health care workers as hospitals are quickly overwhelmed, with up to millions of individuals seeking outpatient medical care and millions more requiring hospitalization.”³⁰¹ In January 2020, HHS’s After-Action Report on Crimson Contagion found the United States lacked sufficient domestic manufacturing capacity and raw materials for “almost all pandemic influenza medical countermeasures, including vaccines, therapeutics, PPE, needles and syringes, and N95 masks.”³⁰²

VI. Lessons from Prior Public Health Emergencies

Past pandemics, epidemics, and other public health outbreaks—though unique in scale and scope—offer critical lessons about federal preparedness and response efforts. Increasing in severity and frequency, multiple public health threats, including respiratory illnesses such as severe acute respiratory syndrome (SARS), H5N1 avian influenza, H1N1 swine influenza pandemic, and Middle East respiratory syndrome (MERS), occurred in the U.S. between 2003 and 2012.³⁰³ Non-respiratory diseases, like Ebola and Zika, also influenced public health preparedness and response efforts within the last decade. The Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services (IPBES) has identified urbanization, climate

²⁹⁶ *Id.*

²⁹⁷ *Id.*

²⁹⁸ Government Accountability Office, *Public Health Preparedness: HHS Should Address Strategic National Stockpile Requirements and Inventory Risks*, (GAO-23-106210) (Oct. 2022).

²⁹⁹ *Id.* at 26. According to CDC officials, changes in inventory “were made without the typical subject matter expert input that had been used to inform procurements in earlier years.” *Id.*

³⁰⁰ Department of Homeland Security, Federal Emergency Management Agency, *2019 National Threat and Hazard Identification and Risk Assessment (THIRA)*, at 1 (July 25, 2019).

³⁰¹ *Id.* at 21.

³⁰² Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, *Crimson Contagion 2019 Functional Exercise After-Action Report*, at iv (Jan. 2020).

³⁰³ Olga Jonas, *Global Health Threats of the 21st Century*, Finance and Development (Dec. 2014) (<https://www.imf.org/external/pubs/ft/fandd/2014/12/pdf/jonas.pdf>).

change, and the effects of globalization as causes drastically increasing the risk that disease outbreaks become pandemics.³⁰⁴

An analysis of past public health emergencies demonstrates the federal government’s continued failure to learn from prior crises. Concerns related to surveillance systems, communications and guidance, and diagnostic testing have been raised since the 2009 H1N1 influenza pandemic and even earlier for interagency coordination challenges. As shown below in Table 7, GAO, HHS’s Office of Inspector General, and HHS’s after-action reports from public health emergencies and response exercises repeatedly identified these longstanding issues. For example, there are at least three key recommendations from GAO that have remained outstanding for over a decade, including leadership roles and responsibilities between DHS and HHS, coordination with SLTT partners, and the development of information sharing systems.³⁰⁵ In a January 2022 review, GAO noted that since 2007, HHS has received 115 recommendations (49 made during the current COVID-19 pandemic) related to its leadership and coordination of public health emergencies. While HHS has implemented 33 of the recommendations, 72 remain outstanding.³⁰⁶ GAO, in the same review, added HHS’s “leadership and coordination of a range of public health emergencies” to its “high risk” list, which involves federal programs and operations that either need transformation or are vulnerable to fraud, waste, abuse, and mismanagement.³⁰⁷

Table 7 details unaddressed issues from past reports that have reappeared during subsequent emergencies.

³⁰⁴ Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services, *IPBES Workshop on Biodiversity and Pandemics: Workshop Report, 2-4* (2020). See e.g. International Panel on Climate Change, *Climate Change 2022: Impacts, Adaptation and Vulnerability*, United Nations (Apr. 1, 2022) (explaining that “the assessment of climate change impacts and risks as well as adaptation is set against concurrency unfolding non-climate global trends, e.g. . . . a pandemic”); Andrea Dobson, et. al., *Ecology and economics for pandemic prevention*, Science (July 24, 2020) (explaining that curbing deforestation, wildlife trade, farmed animal spillover would reduce pandemic risk); Kate Jones, et. al., *Global trends in emerging infectious diseases*, Nature (Feb. 21, 2008) (explaining that the rise in EID “corresponds to climate anomalies occurring during the 199002, adding support to hypotheses that climate change may drive the emergence of diseases that have vector sensitive to changes in environmental conditions such as rainfall, temperature and severe weather events”).

³⁰⁵ Government Accountability Office, *Influenza Pandemic: Further Efforts Are Needed to Ensure Clearer Federal Leadership Roles and an Effective National Strategy* (GAO-07-781) (Aug. 2007); Government Accountability Office, *Public Health Information Technology: Additional Strategic Planning Needed to Guide HHS’s Efforts to Establish Electronic Situational Awareness Capabilities* (GAO-11-99) (Dec. 2010); Government Accountability Office, *National Preparedness: Improvements Needed for Acquiring Medical Countermeasures to Threats from Terrorism and Other Sources* (GAO-12-121) (Oct. 2011).

³⁰⁶ Government Accountability Office, *COVID-19: Significant Improvements Are Needed for Overseeing Relief Funds and Leading Responses to Public Health Emergencies* (GAO-22-105291) (Jan. 2022).

³⁰⁷ *Id.*

Table 7. Unaddressed Issues Identified in Past Public Health Incidents

Issue	HHS Reports	HHS OIG Reports	GAO Reports
Surveillance Systems ³⁰⁸	2012, 2016	2019	2010, 2017*
Communication and Guidance ³⁰⁹	2016	2019	2017
Diagnostic Testing ³¹⁰	2012		2017, 2021
Leadership and Coordination ³¹¹	2016	2019	2007, 2009, 2011, 2017, 2021
Medical Supply Chain ³¹²	2012, 2016		2003, 2011, 2016, 2021

*Indicates more than one report was issued on the topic that year.

Surveillance Systems. Surveillance systems are critical to quickly identifying and responding to any public health threat.³¹³ Outdated and incompatible U.S. systems, however, have remained a recurring issue through multiple pandemics over the last decade. In 2009, the U.S. faced a pandemic influenza virus with the H1N1 pandemic strain, which spread quickly across the world.³¹⁴ There was an estimated 60.8 million cases, 274,304 hospitalizations, and

³⁰⁸ HHS Report, *An HHS Retrospective on the 2009 H1N1 influenza Pandemic to Advance All Hazards Preparedness* (June 15, 2012); J. Fielding, et al., *Report of the Independent Panel on the U.S. Department of Health and Human Services (HHS) Ebola Response*, at 3-15 (June 2016); HHS OIG Report (A-04-16-03567), at 18-24 (Aug. 2019); GAO Report (11-99) (Dec. 2010); GAO Report (17-445) (May 2017); GAO Report (GAO-17-377) (Sept. 2017).

³⁰⁹ J. Fielding, et al., *Report of the Independent Panel on the U.S. Department of Health and Human Services (HHS) Ebola Response* (June 2016); DHS OIG Report (A-04-16-03567) (Aug. 2019) GAO Report (17-445) (May 2017); GAO Report (17-377) (Sep. 2017).

³¹⁰ HHS Report, Office of the Assistant Secretary for Preparedness and Response, *An HHS Retrospective on the 2009 H1N1 influenza Pandemic to Advance All Hazards Preparedness* (June 15, 2012); GAO Report (17-445) (May 2017); GAO Report (21-265) (Jan. 2021).

³¹¹ J. Fielding, et al., *Report of the Independent Panel on the U.S. Department of Health and Human Services (HHS) Ebola Response* (June 2016); HHS OIG Report (A-04-16-03567) (Aug. 2019); GAO Report (07-781) (Aug. 2007); GAO Report (09-909T) (July 2009); GAO Report (11-632) (June 2011); GAO Report (GAO-17-187) (Jan. 2017); GAO Report (21-119SP), at 14-18 (Mar. 2021).

³¹² HHS Report, *An HHS Retrospective on the 2009 H1N1 influenza Pandemic to Advance All Hazards Preparedness*, at 39-42 (June 15, 2012); J. Fielding, et al., *Report of the Independent Panel on the U.S. Department of Health and Human Services (HHS) Ebola Response*, at 20 (June 2016); GAO Report (03-924) (Aug. 2003); GAO Report (11-632) (June 2011); GAO Report (16-595) (July 2016); GAO Report (21-265) (Jan. 2021).

³¹³ Congressional Research Service, *Tracking COVID-19: U.S. Public Health Surveillance and Data* (R46588) (Nov. 2, 2020) (<https://sgp.fas.org/crs/misc/R46588.pdf>).

³¹⁴ The most recent pandemic before H1N1 was H3N2 in 1968. Estimated number of deaths caused by H3N2 was 1 million worldwide and about 100,000 in the United States. Most deaths were in people 65 years and older. The H3N2 virus continues to circulate as a seasonal influenza virus. Department of Health and Human Services, Centers for Disease Control and Prevention, *1968 Pandemic (H3N2 virus)* (<https://www.cdc.gov/flu/pandemic-resources/1968-pandemic.html>).

12,469 deaths globally by the time the CDC ended primary response actions.³¹⁵ Although the federal government undertook a number of measures to respond to the pandemic, the lack of real-time and precise surveillance data created challenges.³¹⁶

In 2014, when the World Health Organization reported an Ebola virus disease outbreak in West Africa, the lack of quality surveillance information again impacted HHS's decision-making.³¹⁷ A 2019 HHS Office of Inspector General report on the Ebola response found that HHS did not always have access to sufficient information during the response.³¹⁸ Two years later, when the Zika virus was a major threat to U.S. public health, health care workers reported continued challenges with interoperable surveillance systems.³¹⁹

Communications and Guidance. Accurate, understandable, and timely communication to the public is critical during an evolving public health crisis. During the early part of the Ebola crisis, CDC's public messaging did not portray the likelihood of spread in the U.S. or acknowledge the public's fear.³²⁰ A 2019 HHS-OIG report found, "HHS did not have effective external communication protocols during its Ebola crisis response" noting it "unlike during a domestic response, HHS did not have a designated point of contact for sharing or receiving information with the public and other HHS partners."³²¹ The Zika virus outbreak presented similar communication challenges. Specifically, GAO reported that ineffective communication systems led to inconsistent public health guidance.³²²

Diagnostic Testing. For over a decade, the federal government has been aware of concerns regarding diagnostic testing capacity. During the 2009 H1N1 pandemic, HHS

³¹⁵ Department of Health and Human Services, Centers for Disease Control and Prevention, *2009 H1N1 Pandemic* (<https://www.cdc.gov/flu/pandemic-resources/2009-h1n1-pandemic.html>)

³¹⁶ Department of Health and Human Services, *An HHS Retrospective on the 2009 H1N1 Influenza Pandemic to Advance All Hazards Preparedness*, at Chapter 2 (June 15, 2012).

³¹⁷ World Health Organization, *WHO escalates response to Ebola outbreak* (January 8, 2014) (<https://www.euro.who.int/en/health-topics/health-emergencies/ebola-outbreak-2014/news/news/2014/08/who-escalates-response-to-ebola-outbreak>); Department of Health and Human Services Office of Inspector General, *HHS Did Not Always Efficiently Plan and Coordinate Its International Ebola Response Efforts* (A-04-16-03567) (Aug. 2019).

³¹⁸ Department of Health and Human Services Office of Inspector General, *HHS Did Not Always Efficiently Plan and Coordinate Its International Ebola Response Efforts* (A-04-16-03567) (Aug. 2019).

³¹⁹ Government Accountability Office, *Emerging Infectious Diseases: Actions Needed to Address the Challenges of Responding to Zika Virus Disease Outbreak*, at 33 (GAO-17-445) (May 2017).

³²⁰ J. Fielding, et al., *Report of the Independent Panel on the U.S. Department of Health and Human Services (HHS) Ebola Response*, at 6 (June 2016).

³²¹ Department of Health and Human Services Office of Inspector General, *HHS Did Not Always Efficiently Plan and Coordinate Its International Ebola Response Efforts* (A-04-16-03567) (Aug. 2019) (<https://oig.hhs.gov/oas/reports/region4/41603567.pdf>).

³²² Government Accountability Office, *Emerging Infectious Diseases: Actions Needed to Address the Challenges of Responding to Zika Virus Disease Outbreak*, at 32 (GAO-17-445) (May 2017). For example, communication challenges within CDC resulted in the need to establish specific communication channels within CDC subcomponents that had not existed before the Zika virus outbreak.

identified problems with testing availability and accuracy, which led to frustration within the clinical community and created concerns for using tests as a tool for both diagnostic and surveillance purposes.³²³ Eight years later, a 2017 GAO report on Zika, found that CDC “did not make publicly available data comparing the performance characteristics of different CDC diagnostic tests that it distributed during the outbreak.”³²⁴ While CDC entered into a Memorandum of Understanding (MOU) with the American Clinical Laboratory Association, the Association of Public Health Laboratories, and the Council of State and Territorial Epidemiologists in 2018 to strengthen a common understanding and collaborative effort for future responses to public health emergencies, GAO subsequently found that it did not have any material effects on increasing the testing capacity.³²⁵

Leadership and Interagency Coordination. For more than a decade, GAO has found “persistent deficiencies” in HHS’s leadership of public health emergencies.³²⁶ Since 2007, GAO has raised concerns regarding the overlapping responsibilities between HHS and DHS in response to pandemics, noting “both departments share leadership responsibilities—HHS to manage the federal public health and medical response and DHS to lead domestic incident management and federal coordination.” In its 2007 report, GAO recommended that the agencies work together to “ensure that the federal leadership roles are clearly defined and understood and that leaders are able to effectively execute shared responsibilities.”³²⁷ Two years later, GAO specifically identified confusion regarding agency leadership during a pandemic, finding that leadership roles often involve “shared responsibilities” between DHS and HHS, and “it is not clear how these would work in practice.”³²⁸ The 2009 H1N1 pandemic again highlighted the confusion of shared leadership roles and responsibilities between DHS and HHS and GAO again, in 2011, recommended that the two agencies conduct rigorous testing, training, and exercises to test shared leadership roles and responsibilities between the agencies.³²⁹ Nearly fifteen years since the H1N1 pandemic, the problem remains unaddressed.

³²³ Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, *An HHS Retrospective on the 2009 H1N1 influenza Pandemic to Advance All Hazards Preparedness*, st iv-v (June 15, 2012).

³²⁴ Government Accountability Office, *Emerging Infectious Diseases: Actions Needed to Address the Challenges of Responding to Zika Virus Disease Outbreak*. GAO-17-445 (May 2017).

³²⁵ Centers for Disease Control and Prevention, *Memorandum of Understanding Between American Clinical Laboratory Association, Association of Public Health Laboratories, Council of State and Territorial Epidemiologists and Centers for Disease Control and Prevention/Center for Surveillance, Epidemiology and Laboratory Services/Division of Labor Systems* (Apr. 30, 2018); Government Accountability Office, *COVID-19: Continued Attention Needed to Enhance Federal Preparedness, Response, Service Delivery, and Program Integrity*, at 76 (GAO-21-551) (July 2021).

³²⁶ Government Accountability Office, *COVID-19: Significant Improvements Are Needed for Overseeing Relief Funds and Leading Responses to Public Health Emergencies* (GAO-22-105291) (Jan. 2022).

³²⁷ Government Accountability Office, *Influenza Pandemic: Further Efforts Are Needed to Ensure Clearer Federal Leadership Roles and an Effective National Strategy*, at 8 (GAO-07-781) (Aug. 14, 2007).

³²⁸ Government Accountability Office, *Influenza Pandemic: Gaps in Pandemic Planning and Preparedness Need to be Addressed*, at 6 (GAO-09-909T) (July 2009).

³²⁹ Government Accountability Office, *Influenza Pandemic: Lessons from the H1N1 Pandemic Should Be Incorporated into Future Planning*, at 21 (GAO-11-632) (June 2011).

PART 2: INITIAL FEDERAL RESPONSE TO THE COVID-19 PANDEMIC

The federal government failed in its initial response to the COVID-19 pandemic to take timely and comprehensive actions to protect public health and mount an effective defense against the virus's spread. While China withheld information that would have helped inform decision-making, federal officials failed to recognize and agree on the severity of the threat, despite multiple warning signs, including publicly available information, about the virulence and transmissibility of the evolving threat. As this report finds, the federal government focused far too long on an ineffective containment strategy at the expense of implementing needed community mitigation measures and long-term strategic planning. The federal government's public health surveillance systems and diagnostic testing capabilities also proved insufficient to effectively identify and track the emerging infectious disease threat. These shortcomings delayed meaningful response efforts that hinged on timely execution. This included failures to rapidly develop widespread testing capacity, mitigate anticipated medical supply shortages, and implement needed interventions, such as social distancing, the use of face masks, and limits on mass gatherings.

As detailed throughout this section, in interviews with the Committee, numerous current and former officials acknowledged that the federal government—at great cost to public health—failed to adopt sufficient efforts to address early and public signs of asymptomatic spread. In an interview with Committee staff, Dr. Deborah Birx, who would become the White House Coronavirus Task Force Coordinator in March 2020, stated that in early January 2020, from her State Department post in Africa, she was able to monitor public reports and social media posts that clearly showed the evolving threat. Dr. Birx told the Committee:

[I viewed] a post of a physician in China walking the hallways in a hospital with body bags in the hallway. Hospitals only become overwhelmed like that when there is unrelenting community spread, and the fact that they weren't seeing community spread told me it was asymptomatic. Then, when China started clearing ground and building a 1,000 bed hospital in January, I realized this was catastrophic.³³⁰

The Trump Administration also failed to effectively coordinate interagency efforts and respond as the threat evolved. Shifts in leadership were abrupt and poorly executed, the Administration did not request supplemental funding until late February 2020, and by mid-April 2020, the federal government depleted the entirety of its PPE supply for states, and failed to distribute those supplies based on need.

This section examines the initial federal response to the COVID-19 pandemic beginning with the federal government's identification of the emerging novel coronavirus threat in late December 2019 and its subsequent efforts to contain and mitigate the spread of the virus from January through March 2020. It assesses critical aspects of the federal pandemic response and resulting fallout from actions that either failed, were delayed, or were insufficient to address the

³³⁰ Interview with Dr. Deborah Birx (Jan. 6, 2022).

rapidly evolving infectious disease threat, including with respect to surveillance, diagnostic testing, communications, shifts in leadership structures, repatriation, funding, and medical supply chain challenges.

I. COVID-19 Spread throughout the U.S.

On December 30, 2019 CDC first learned of “undiagnosed pneumonia” cases in Wuhan, China.³³¹ On January 5, the World Health Organization (WHO) publicly reported that on December 31, 2019, “it was informed of cases of pneumonia of unknown cause” in the city of Wuhan.³³² One week later, on January 13, Thailand reported the first case outside of China. Within a week, Japan and South Korea both reported their first cases of COVID-19.³³³

Despite multiple and frequent attempts by CDC officials to communicate with officials in China, the Chinese government withheld critical information from the WHO and other countries, including the U.S. as cases rapidly spread throughout China and the rest of the world.³³⁴ HHS Secretary Azar reported to the Committee that he recalled first speaking with President Trump about the evolving COVID-19 threat on Saturday, January 18, 2020, and “told the President that the virus could potentially be a serious public health threat.”³³⁵

On January 21, 2020, the U.S. identified its first confirmed case of COVID-19.³³⁶ Blood samples from donors in nine states between mid-December and mid-January later revealed the virus was circulating in the U.S. prior to this first recognized case.³³⁷ On January 30, the WHO

³³¹ Program for Monitoring Emerging Diseases (ProMED) International Society for Infectious Diseases, *Pro/AH/EDR> Undiagnosed pneumonia – China (HU): RFI* (Dec. 30, 2019) (www.promedmail.org/promed-post/?id=6864153); *see also* Interview with Dr. Anne Schuchat (Dec. 14, 2021).

³³² World Health Organization, *COVID-19 – China* (Jan. 5, 2020) (www.who.int/emergencies/disease-outbreak-news/item/2020-DON229) (accessed Nov. 13, 2022).

³³³ World Health Organization, *Novel Coronavirus (2019-nCoV) Situation Report – 1*, at 1 (Jan. 21, 2020) (www.who.int/docs/default-source/coronaviruse/situation-reports/20200121-sitrep-1-2019-ncov.pdf).

³³⁴ Alex Azar, Secretary of the Department of Health and Human Services (Jan. 2018 - Jan. 2021), *Written Response to Interrogatories from the Senate Committee on Homeland Security and Governmental Affairs* (Mar. 1, 2022) (hereinafter “Alex Azar Interrogatories (Mar. 1, 2022)”); Interview with Matthew Pottinger (Jan. 25, 2022); Interview with Dr. Robert Redfield (Feb. 7, 2022); Olivia Troye, Former Homeland Security and Counterterrorism Adviser to Vice President Pence (May 2018 - Aug. 2020), Interview with Senate Committee on Homeland Security and Governmental Affairs (Dec. 8, 2021) (hereinafter “Interview with Olivia Troye (Dec. 8, 2021)”).

³³⁵ Alex Azar Interrogatories (Mar. 1, 2022).

³³⁶ Centers for Disease Control and Prevention, *First Travel-related Case of 2019 Novel Coronavirus Detected in United States* (Jan. 21, 2020) (<https://www.cdc.gov/media/releases/2020/p0121-novel-coronavirus-travel-case.html#print>).

³³⁷ Sridhar V Basavaraju, et al., *Serologic Testing of US Blood Donations to Identify Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)–Reactive Antibodies: December 2019–January 2020*, *Clinical Infectious Diseases*, at e1004 (Volume 22, Issue 12) (Nov. 30, 2020).

declared the outbreak a public health emergency of international concern.³³⁸ One day later, HHS Secretary Alex Azar declared the novel coronavirus outbreak a public health emergency in the U.S. under Section 319 of the Public Health Service Act, which was retroactively dated to January 27, 2020.³³⁹ When HHS Secretary Azar declared the COVID-19 outbreak a public health emergency, he also announced travel restrictions from China under Section 212(f) of the Immigration Nationality Act (INA).³⁴⁰

A. Early Indications and Warnings

CDC, the Defense Intelligence Agency's National Center for Medical Intelligence (NCMI), the Defense Health Agency's Armed Forces Health Surveillance Branch, and the Department of Homeland Security's National Biosurveillance Integration Center all learned of the emerging infectious disease threat through the same publicly available open source report, a ProMED post, at least a month after the virus had already been circulating in China.³⁴¹ CDC officials confirmed to the Committee that they first viewed the report on December 30, 2019 and DOD officials first became aware of the report one day later, on December 31, 2019.³⁴² DOD told the Committee an April 2020 news report was incorrect in its claims that the National Center for Medical Intelligence warned as early as November 2019 of a potential epidemic spreading throughout China.³⁴³ DOD officials confirmed for the Committee that DOD did not rely on any classified intelligence to identify the emerging novel coronavirus threat.³⁴⁴ DOD also told the Committee news reports' assertions that such warnings were conveyed through an intelligence report to the Pentagon's Joint Staff, the National Security Council, the White House, and the

³³⁸ World Health Organization, *WHO Director-General's statement on IHR Emergency Committee on Novel Coronavirus (2019-nCoV)* (Jan. 30, 2020) ([www.who.int/director-general/speeches/detail/who-director-general-s-statement-on-ihf-emergency-committee-on-novel-coronavirus-\(2019-ncov\)](http://www.who.int/director-general/speeches/detail/who-director-general-s-statement-on-ihf-emergency-committee-on-novel-coronavirus-(2019-ncov))).

³³⁹ Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, *Determination that a Public Health Emergency Exists* (Jan. 31, 2020) (www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx).

³⁴⁰ White House, Press Briefing by Members of the President's Coronavirus Task Force (Jan. 31, 2020); *see also* Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, *Determination that a Public Health Emergency Exists* (Jan. 31, 2020) (<https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>); White House, *Proclamation on Suspension of Entry as Immigrants and Nonimmigrants of Persons who Pose a Risk of Transmitting 2019 Novel Coronavirus* (Jan. 31, 2020) (<https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-suspension-entry-immigrants-nonimmigrants-persons-pose-risk-transmitting-2019-novel-coronavirus/>).

³⁴¹ Program for Monitoring Emerging Diseases (ProMED), International Society for Infectious Diseases, Pro/AH/EDR> Undiagnosed pneumonia – China (HU): RFI RFI, International Society for Infectious Diseases (Dec. 30, 2019) (www.promedmail.org/promed-post/?id=6864153); Interview with Dr. Anne Schuchat (Dec. 14, 2021); Department of Defense, Defense Intelligence Agency, Briefing with Senate Committee on Homeland Security and Governmental Affairs Staff (Dec. 14, 2021) (hereinafter "DOD-DIA Briefing (Dec. 14, 2021)"); DHS National Biosurveillance Integration Center, Communication to Senate Committee on Homeland Security and Governmental Affairs (Nov. 18, 2022); *see also* Jonathan Pekar et. al., *Timing the SARS-CoV-2 index of cases in Hubei province*, Science Magazine (Mar. 18, 2021).

³⁴² DOD-DIA Briefing (Dec. 14, 2021); *see also* Interview with Dr. Anne Schuchat (Dec. 14, 2021).

³⁴³ DOD-DIA Briefing (Dec. 14, 2021).

³⁴⁴ *Id.*

President's Daily Brief were also incorrect. No such intelligence product or briefing exists according to DOD.³⁴⁵

Instead, DOD, DHS, and CDC generally relied on publicly available information, including public news reports from China, to inform their analysis of the emerging threat.³⁴⁶ The online ProMED report, titled, *Undiagnosed Pneumonia – China (Hubei) Request for Information*, stated “[o]n the evening of [30 Dec 2019], an ‘urgent notice on the treatment of pneumonia of unknown cause’ was issued, which was widely distributed on the Internet by the . . . Medical Administration and the Medical Administration of Wuhan Municipal Health Committee.”³⁴⁷

A Research Director for the Defense Intelligence Agency told the Committee, “the first indication we had altogether came from open source [*i.e.*, public] reporting on the 31st of December.”³⁴⁸ Dr. Schuchat explained, “[t]he detection of the virus in China was a signature event reported through ProMED and acted upon immediately by CDC. We realized it might be like SARS or MERS.”³⁴⁹ Former NSC senior official who served as the Director for Medical Preparedness and Biodefense Policy Dr. Lawler told the Committee, “[i]deally, what should have been happening in November and December is our intelligence communities should have been alerting us that we had an outbreak of unusual disease in Wuhan that was creating large numbers of unusual cases of pneumonia . . . with that intelligence failure, where we have no visibility into that space internationally, we are inevitably going to be caught by surprise, and we will be caught by surprise in the next pandemic as well.”³⁵⁰

³⁴⁵ *Id.* See also *Intelligence report warned of coronavirus crisis as early as November: Sources*, ABC News (Apr. 8, 2020) (<https://abcnews.go.com/Politics/intelligence-report-warned-coronavirus-crisis-early-november-sources/story?id=70031273>).

³⁴⁶ See generally Department of Health and Human Services, Centers for Disease Control and Prevention, *2019 Novel Coronavirus (nCoV) Incident Management Updates* (Jan. 6 – Feb. 28, 2020) (on file with the Committee); Department of Defense, *Armed Forces Health Surveillance Branch Health Surveillance Update: Integrated Biosurveillance Section* (Jan. 22- Feb. 25, 2020) (on file with the Committee); Department of Homeland Security, National Operations Center COVID-19 Placemats (Feb. – Mar. 2020) (on file with Committee); see also DHS National Biosurveillance Integration Center, *Communication to Senate Committee on Homeland Security and Governmental Affairs* (Nov. 18, 2022).

³⁴⁷ Program for Monitoring Emerging Diseases (ProMED), International Society for Infectious Diseases, Pro/AH/EDR> Undiagnosed pneumonia – China (HU): RFI RFI, International Society for Infectious Diseases (Dec. 30, 2019) (www.promedmail.org/promed-post/?id=6864153).

³⁴⁸ Department of Defense, Defense Intelligence Agency, Briefing with Senate Committee on Homeland Security and Governmental Affairs Staff (Dec. 14, 2021); see also *Intelligence report warned of coronavirus crisis as early as November: Sources*, ABC News (Apr. 8, 2020) ([www.abcnews.go.com/Politics/intelligence-report-warned-coronavirus-crisis-early-november-sources/story?id=70031273](https://abcnews.go.com/Politics/intelligence-report-warned-coronavirus-crisis-early-november-sources/story?id=70031273)). According to DOD, the product described in the ABC news article does not exist.

³⁴⁹ Interview with Dr. Anne Schuchat (Dec. 14, 2021).

³⁵⁰ Interview with Dr. James Lawler (May 6, 2021).

Insufficient Information from China

Once it became known that a novel virus was circulating, China’s government failed to be transparent about the extent of the virus spread or provide meaningful on-the-ground access to the American government.³⁵¹ Dr. Nancy Messonnier who served as Director of the National Center for Immunization and Respiratory Diseases at CDC explained, “China’s government did not provide the U.S. government with sufficient data, information, and on-the-ground access to assess the extent of the virus spread.”³⁵² Then Deputy National Security Advisor Mr. Pottinger told the Committee that “it was the lack of new information” that disturbed him and the U.S. was having “zero luck getting access [to information on the virus] through CDC or HHS.”³⁵³

Neither the CDC Director nor the HHS Secretary received sufficient information about the virus from China. In an interview with the Committee, Dr. Robert Redfield, then Director of CDC, stated he immediately engaged with his counterpart, Dr. George Gao, Director of the Chinese CDC, and offered to send a team from the U.S. to assist.³⁵⁴ He noted that what followed, a rejection of his offer, was “highly irregular.” Dr. Redfield said he believed Dr. Gao “was in the dark [and] found out about this pandemic the same time I did.”³⁵⁵ In Dr. Redfield’s opinion, “the Wuhan Health Department and the Wuhan government had probably been working on this back in September [2019].”³⁵⁶

Despite repeated offers of assistance, then HHS Secretary Azar also informed the Committee that China did not “officially acknowledge[]” the U.S. government’s offer of assistance until January 29 and that it was not until mid-February 2020 when an international WHO team, consisting of two American experts from the National Institutes of Health and CDC, arrived in China.³⁵⁷ Secretary Azar explained to the Committee that “the Chinese government was not forthcoming or transparent regarding information related to COVID-19.”³⁵⁸ According to Dr. Larry Kerr, then Director of Pandemics and Emerging Threats at HHS, when Secretary Azar had phone calls with China’s Health Minister Ma Xiaowei (hereinafter “Minister Ma”),

³⁵¹ Dr. Larry Kerr, Former Director of Pandemics and Emerging Threats, Department of Health and Human Services (Dec. 2015 - Feb. 2022), Interview with Senate Committee on Homeland Security and Governmental Affairs (July 28, 2021) (hereinafter “Interview with Dr. Larry Kerr (July 28, 2021)”); Interview with Matthew Pottinger (Jan. 25, 2022); Interview with Dr. Anne Schuchat (Dec. 14, 2021).

³⁵² Dr. Nancy Messonnier, Centers for Disease Control and Prevention Director of the National Center for Immunization and Respiratory Diseases (Apr. 2016 - May 2021) (CDC service 1995 - 2021), Interview with Senate Committee on Homeland Security and Governmental Affairs (Jan. 5, 2022) (hereinafter “Interview with Dr. Nancy Messonnier (Jan. 5, 2022)”) (noting CDC was “not getting as much information” as it wanted from China and China’s lack of sharing impacted the CDC’s ability to understand the virus’ implications for the U.S”).

³⁵³ Interview with Matthew Pottinger (Jan. 25, 2022).

³⁵⁴ Interview with Dr. Robert Redfield (Feb. 7, 2022).

³⁵⁵ *Id.*

³⁵⁶ *Id.*

³⁵⁷ Alex Azar Interrogatories (Mar. 1, 2022).

³⁵⁸ *Id.*

Minister Ma would “listen politely but never respond.”³⁵⁹ Dr. Kerr noted that during one call between Secretary Azar and Minister Ma in late January, Minister Ma spoke uninterrupted for 20 minutes on a 30-minute call. Dr. Kerr stated that the logistics of these calls were frustrating, including the translation, which made it difficult to communicate.³⁶⁰ After a January 27, 2020 call between Secretary Azar and Minister Ma, Minister Ma wrote that he would not be able to speak with Secretary Azar again soon.³⁶¹

Warning Signs of Virus Spread

Although China withheld critical information and denied the U.S. on the ground access, there were multiple publicly available indications from China that provided warnings of the impending worldwide threat. The timeline below (Table 8) details publicly reported events in China that signaled the potential for a public health emergency in other countries.³⁶²

³⁵⁹ Interview with Dr. Larry Kerr (July 28, 2021).

³⁶⁰ *Id.*

³⁶¹ U.S. Department of State, *Novel Coronavirus Task Force Call*, (Feb. 4, 2020) (on file with Committee, STATE-2021-02-0005766)

³⁶² *Hong Kong Steps up Response to Mystery Disease from China*, Voice of America (Jan. 4, 2020) (www.voanews.com/a/east-asia-pacific_hong-kong-steps-response-mystery-disease-china/6182085.html); *China Grapples With Mystery Pneumonia-Like Illness*, New York Times (Jan. 6, 2020) (www.nytimes.com/2020/01/06/world/asia/china-SARS-pneumonialike.html); *A video of medics in hazmat suits scanning plane passengers for China’s mysterious Wuhan coronavirus is stoking fears of a pandemic*, Business Insider (Jan. 21, 2020) (www.businessinsider.com/china-virus-wuhan-outbreak-medics-scan-plane-passengers-2020-1); *see also Hazmat Suits on Planes as Fear of Wuhan China Virus Spreads*, Bloomberg (Jan. 21, 2020) (<https://www.bloomberg.com/news/articles/2020-01-21/hazmat-suits-deployed-on-planes-as-security-tightens-over-virus>); *Chinese cities cancel New Year celebrations, travel ban widens in effort to stop coronavirus outbreak*, Washington Post (Jan. 23, 2020) (www.washingtonpost.com/world/coronavirus-china-wuhan-latest/2020/01/23/2dc947a8-3d45-11ea-afe2-090eb37b60b1_story.html); *China locks down cities with 18 million to contain deadly coronavirus*, Los Angeles Times (Jan. 23, 2020) (www.latimes.com/world-nation/story/2020-01-22/chinese-city-stops-outbound-flights-trains-to-fight-virus); *China building 1,000-bed hospital over the weekend to treat coronavirus*, Reuters (Jan. 23, 2020) (www.reuters.com/article/us-china-health-hospital-idUSKBN1ZN07U); *China’s Wuhan to build second designated hospital to treat coronavirus patients: state media*, Reuters (Jan. 25, 2020); *Watch: China Is Building a Huge Coronavirus Hospital in 6 Days*, New York Magazine, Intelligencer (Jan. 24, 2020); *Coronavirus outbreak: Video shows dead bodies in halls of China hospital*, New York Post (Jan. 24, 2020) (www.nypost.com/2020/01/24/coronavirus-outbreak-video-shows-dead-bodies-in-halls-of-china-hospital/); *China’s Wuhan to build second designated hospital to treat coronavirus patients: state media*, Reuters (Jan. 25, 2020); *‘We’ll admit them if they’re dying: Virus outbreak pushes China’s stretched health care workers to breaking point*, CNN (Jan. 31, 2020).

Table 8. Selected January 2020 Warning Signals from China

Date Reported	Publicly Reported Event	
Jan. 4, 2020	Hong Kong's Health Department implements a "thermal imaging system at Hong Kong's airport to screen for body temperature of arriving passengers.	
Jan. 6, 2020	Reports of workers wearing hazmat suits to disinfect and shut down the Hunan Seafood Market.	
Jan. 21, 2020	Medics wearing PPE on planes to check passengers' temperatures.	
Jan. 23, 2020	Chinese cities cancel Lunar New Year celebrations.	
	China places at least three cities, totaling 18 million people, under a lock down and requires "all residents wear masks in public places."	
	Reports that China is building "a new 1,000-bed hospital" to treat COVID-19 patients.	
Jan. 24, 2020	Video shows dead bodies "piling up" in hallways of a hospital in China.	
Jan. 25, 2020	Reports show Wuhan building a second hospital to treat COVID-19 patients.	
Jan. 31, 2020	Video shows "overcrowded hospitals" and tents set up outside of hospitals.	

Several officials and experts interviewed by this Committee recognized these public warning signs.³⁶³ Melissa Harvey, then Director of Health Systems at DHS, told the Committee, “[w]e realized this was in our country already. We had seen videos of modular hospitals going up in China. You don’t need an intel background to know what that means.”³⁶⁴ Dr. Birx has since written publicly about similar concerns:

The Chinese [government] may not have been giving accurate data about the number of cases and deaths, but the rapid spread of this disease could be counted in other ways, including in how many Chinese workers were being employed to build new facilities to relieve the pressure on the existing and impressive Wuhan Health Service Centers. ***You build a 1,000 bed hospital in 10 days only if you are experiencing unrelenting community spread of a highly contagious virus that has eluded your containment measures and is now causing serious illness on a massive scale. In other words, you build a 1,000 bed hospital in 10 days only if you need a 1,000 bed hospital right now.***³⁶⁵

By the end of January 2020, the virus had spread to 18 countries and governments began initiating export bans on PPE products.³⁶⁶ In addition, China began imposing restrictions on U.S. medical supply companies located in China (also discussed in Section VIII, Medical Supply Chain Challenges). For example, on January 27, 2020, the State Department received information that the Shanghai Economic & Information Technology Commission “was requiring 3M to sell all of their [N95] respirators to Shanghai medical related [state-owned enterprises].”³⁶⁷ This “directive” granted the Chinese government the ability to “requisition the [3M] factory.”³⁶⁸ A January 29, 2020 Task Force Supply Chain report from ASPR noted, “China is expected to

³⁶³ Interview with Dr. Deborah Birx (Jan. 6, 2022); Interview with Melissa Harvey (Nov. 3, 2021); Interview with Dr. James Lawler (May 6, 2021); Interview with Dr. Carter Mecher (July 29, 2022).

³⁶⁴ Interview with Melissa Harvey (Nov. 3, 2021).

³⁶⁵ Dr. Deborah Birx, *Silent Invasion: The Untold Story of the Trump Administration, Covid-19, and Preventing the Next Pandemic Before It's Too Late* (2022) (emphasis added).

³⁶⁶ Department of State, *Export Restrictions Tracker* (Mar. 27, 2020) (on file with Committee, STATE 2021-02-0001340 - 2021-02-0001364) (detailing export bans from several countries, including China’s January 24, 2020 ban on surgical mask and filter material exportation); Department of Health and Human Services, Centers for Disease Control and Prevention, *Novel Coronavirus (nCoV) Response Significant Activities (SIGACTs)* (Jan. 29, 2020) (on file with Committee, HSGAC-0037576); World Health Organization, *Novel Coronavirus (2019-nCoV) Situation Report – 10*, at 1 (Jan.30, 2020) (www.who.int/docs/default-source/coronaviruse/situation-reports/20200130-sitrep-10-ncov.pdf).

³⁶⁷ Department of State, *Email from Embassy Beijing: China Coronavirus: Mission China CG Wuhan Evacuation; PRC Leadership Accelerates Response* (Jan. 27, 2020) (on file with the Committee, STATE-2021-02-0004541). According to a State Department memorandum to the Deputy Secretary, “3M employs a “local-for-local” business model; all U.S. supplies are produced domestically.” See Department of State, *Information Memo for the Deputy Secretary: Personal Protective Equipment – Supply Chains, Risks, and Mitigation* (Feb. 7, 2020).

³⁶⁸ Department of State, *Email From Embassy Beijing: China Coronavirus: Mission China CG Wuhan Evacuation; PRC Leadership Accelerates Response* (Jan. 27, 2020) (on file with the Committee, STATE-2021-02-0004541).

implement a [30 day] ban on PPE (gloves and masks),” and U.S. members of the Health Industry Distributors Association “reported being asked to sell N95s to China.”³⁶⁹ ASPR also identified medical supply chain concerns including, the raw materials needed to make PPE being dominated by China and potential supply disruptions due to “panic and stockpiling and export banning,” among others.³⁷⁰

The State Department also chronicled key actions China took throughout January and early February 2020 to mitigate the spread of COVID-19, detailed below.³⁷¹ On February 5, the State Department noted, “[a]uthorities in Wuhan plan to convert another eight existing venues, including gymnasiums, exhibition centers, and sports centers into hospitals to receive patients.”³⁷²

***February 4, 2020 Internal State Department Coronavirus
Timeline and Map of China’s Actions***³⁷³

<u>Coronavirus Timeline – China</u>	
January 23	Wuhan and Huangguang sealed off.
January 24	Remaining 14 cities in Hubei sealed off.
January 26	Hubei suspended all airport services except at Shennongjia airport in the far west of the province.
January 27	Hubei suspended services for the application of passports and exit permits to HK, Macao, and Taiwan.
January 29	All provinces and autonomous regions had gone to level-one public emergency response by this date.
February 2	Wenzhou, Zhejiang severely restricts public movement, limits entry and exit.
February 3	Hangzhou, Zhejiang and Taizhou, Zhejiang severely restrict public movement, limit entry and exit.
February 3	Three cities in the northeastern province of Heilongjiang restrict public movement and entry of non-residents. Provincial capital Harbin is unaffected.
<p>Further information: Taizhou and provincial capital Hangzhou followed Wenzhou in severely limiting intra-city movement, placing Zhejiang Province second to Hubei in number of citizens on lockdown. One member of household can leave home every two days for supplies. Much but not all highway access to the cities is restricted, with non-residents advised at checkpoints not to enter. Major regional transit hub Hangzhou Airport remains open. Nationwide, many large and medium-sized cities have restricted or ended intra-city bus service.</p>	

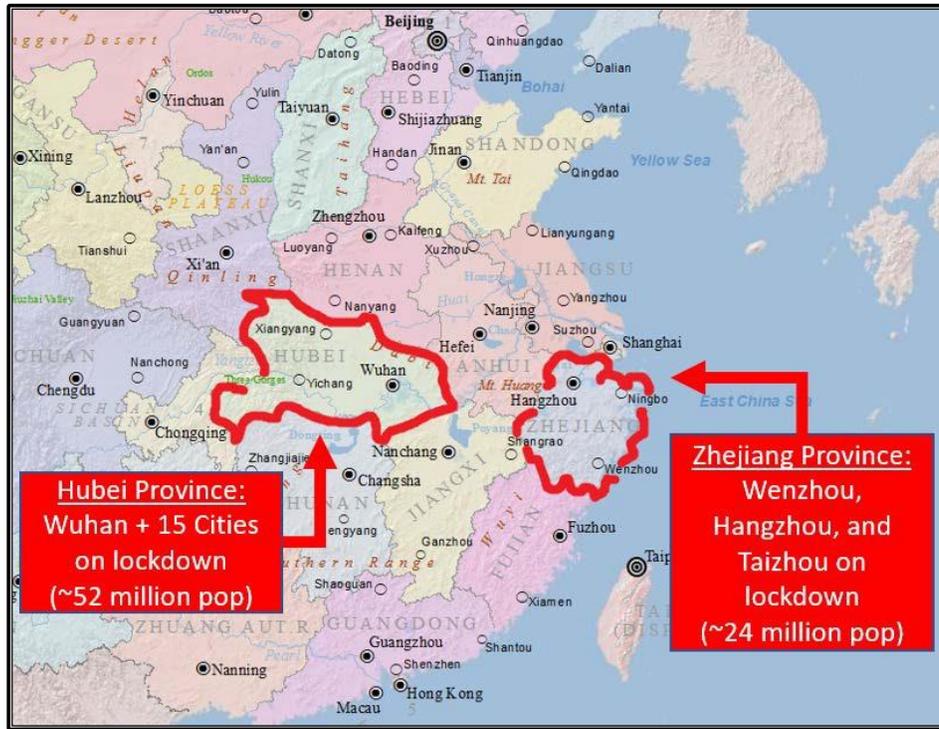
³⁶⁹ Department of Health and Human Services, Assistant Secretary for Preparedness and Response, *Commercial Supply Chain Review (2019 nCov)* (Jan. 29, 2020) (on file with Committee, HSGAC – 0042782).

³⁷⁰ Department of Health and Human Services, Assistant Secretary for Preparedness and Response, *2019 nCoV Supply Chain Task Force- Storyboard* (Jan. 29, 2020) (on file with Committee, HSGAC – 0042781).

³⁷¹ Department of State, *Coronavirus Timeline – China*, (on file with Committee, STATE-2021-02-0005769).

³⁷² Department of State, *Email from Office of International Health and Biodefense to Principal Deputy Assistant Secretary, Bureau of Oceans and International Environmental and Scientific Affairs* (Feb. 5, 2020) (on file with Committee, STATE-2021-02-0005808).

³⁷³ Department of State, *Coronavirus Timeline – China*, (on file with Committee, STATE-2021-02-0005769)



Firsthand Accounts of Virus Spread

Throughout the initial months of the crisis, various Administration and public health officials maintained contact with colleagues in China and received disturbing accounts of the virus’s spread. For example, then Assistant Secretary for Preparedness & Response (ASPR), Dr. Robert Kadlec told the Committee he received information from Chinese health care providers who were on the ground in hospitals that demonstrated “[human to human transmission] occurred earlier than January 20 and maybe as early as late December because healthcare workers were getting infected.”³⁷⁴

Matthew Pottinger, then Deputy National Security Advisor, stated he received firsthand accounts from Chinese scientists in late January that contained two critical pieces of information.³⁷⁵ First, there was “uncontrolled community spread far beyond the city of Wuhan and far beyond Hubei province, all the way to Guangdong province in the south.” This information, according to Mr. Pottinger, was contrary to public information provided by the World Health Organization. Second, “the disease was spreading asymptotically in roughly half the cases,” rendering CDC’s symptomatic screening efforts largely ineffective.³⁷⁶ For

³⁷⁴ Interview with Dr. Robert Kadlec (Dec. 6, 2021).

³⁷⁵ Interview with Matthew Pottinger (Jan. 25, 2022).

³⁷⁶ *Id.*; see also Rahul Subramanian, Qixin He, and Mercedes Pascual, *Quantifying asymptomatic infection and transmission of COVID-19 in New York City using observed cases, serology, and testing capacity*, Proceedings of the National Academy of Sciences, at 1 (Feb. 10, 2021); Mitch Anderson, *Asymptomatic coronavirus infections contribute to over 50% of spread, according to UChicago study*, University of Chicago Medicine (May 11, 2021)

comparison, during the 2003 Severe Acute Respiratory Syndrome (SARS) outbreak, a study that examined health care workers found that asymptomatic spread accounted for approximately 13 percent of cases.³⁷⁷

When Mr. Pottinger asked his source in China whether COVID-19 would be worse than SARS, the source responded, “don’t think 2003, think 1918”—the year of the most severe pandemic in recent history.³⁷⁸ Mr. Pottinger told the Committee he relayed this information to then National Security Advisor Robert O’Brien, who “almost immediately” arranged for Mr. Pottinger to brief the President. After briefing the President, Mr. Pottinger attended a meeting with public health officials, including Dr. Redfield and Dr. Anthony Fauci, at the White House to relay what he learned about asymptomatic spread. According to Mr. Pottinger, these public health officials were “quite skeptical of the idea that 50 percent asymptomatic spread would be a factor in a respiratory disease because it’s unprecedented.”³⁷⁹

That same week, Mr. Pottinger recommended the President restrict travel from China, but told the Committee he faced pushback from an array of officials, including public health, defense, and economic experts.³⁸⁰ Mr. Pottinger explained his rationale: “in a typical month, we have something like 20,000 arrivals a day from China and reducing that number to approximately 1,000 Americans returning home would have been a meaningful kind of factor that would actually slow the process of seeding new outbreaks in the U.S.” According to Mr. Pottinger, public health officials believed travel restrictions would not be effective. However, later analysis subsequently confirmed Mr. Pottinger’s conclusions.³⁸¹ In the weeks that followed the President’s implementation of travel restrictions, “every public health official on the task force agreed we slowed the spread,” Mr. Pottinger told the Committee.³⁸²

Changes to Chinese PPE Imports and Exports in Early 2020

One potential early indicator regarding the severity of the emerging novel coronavirus threat may have been changes in Chinese PPE shipments. When reflecting on the negative impact of trade restrictions, a March 19, 2020 State Department cable to all diplomatic and consular posts noted, “China has restricted the free market flow of N95 respirators globally

(www.uchicagomedicine.org/forefront/coronavirus-disease-covid-19/asymptomatic-coronavirus-infections-contribute-to-over-50-percent-of-spread).

³⁷⁷ Annelies Wilder-Smith, et al., *Asymptomatic SARS Coronavirus Infection among Healthcare Workers, Singapore*, National Library of Medicine National Center for Biotechnology Information (July 2005).

³⁷⁸ Interview with Matthew Pottinger (Jan. 25, 2022); *see also* Department of Health and Human Services, Centers for Disease Control and Prevention, Influenza (Flu): History (<https://www.cdc.gov/flu/pandemic-resources/1918-commemoration/1918-pandemic-history.htm>) (accessed Nov. 30, 2022).

³⁷⁹ Interview with Matthew Pottinger (Jan. 25, 2022).

³⁸⁰ *Id.*

³⁸¹ Matteo Chinazzi, et al., *The effect of travel restrictions on the spread of the 2019 novel coronavirus (COVID-19) outbreak*, National Library of Medicine National Center for Biotechnology Information (Apr. 24, 2020).

³⁸² Interview with Matthew Pottinger (Jan. 25, 2022).

These types of export restrictions undermine the global community’s ability to ensure medical supplies are available to limit the spread of COVID-19 and protect the global population in a time of crisis.”³⁸³ In May 2020, DHS analyzed trade data and found China likely delayed alerting the WHO and other nations about the possible severity of COVID-19 until well after the Chinese government had increased PPE imports and decreased exports in January and February 2020, meaning changes in PPE imports and exports could have provided advanced warning of the threat.³⁸⁴

Specifically, in May 2020, DHS issued two reports on their trade data analyses. One report found with “high confidence” that China likely “increased imports and decreased exports for several key medical supplies in January 2020.”³⁸⁵ The other report concluded that the “Chinese government intentionally concealed the severity of COVID-19 from the international community in early January while it stockpiled medical supplies by both increasing imports and decreasing exports.”³⁸⁶ In an August 2022 response to the Committee, DHS raised concerns regarding the accuracy of its prior findings, explaining that both reports are “under consideration for substantive recall” based on concerns including “data reliability, source corroboration, and reliance on assumptions.”³⁸⁷ This section details the findings in DHS’s May 2020 reports and the concerns DHS has subsequently raised with the Committee. Specifically, DHS told the Committee, “analytic judgments from the May 2020 [Intelligence and Analysis (I&A)] products do not reflect DHS or the Intelligence Community’s current position on China and COVID-19, China’s intent, or their actions taken during the outbreak.”³⁸⁸

Relying on publicly available global trade data, a May 2020 review by DHS’s Economic Security Mission Center analyzed China’s trade data for the period between October 2019 and

³⁸³ Department of State, *Request for Information on Medical-Related Export Restrictions* (Mar. 19, 2020) (on file with Committee, STATE-2021-02-0002209).

³⁸⁴ Department of Homeland Security, *Intelligence Enterprise Reference Aid: Trade Data Provides Indicators that China Stockpiled Medical Supplies in January* (May 1, 2020) (on file with Committee, IA-44129-20); Department of Homeland Security, *Intelligence Enterprise Homeland Intelligence Article: New Analytic Technique Indicates China Likely Hid Severity of COVID-19 from the International Community While it Stockpiled Medical Supplies* (May 1, 2020) (on file with Committee, IA-44130-20). The Committee notes that a redacted version of this report is publicly available on DHS’s website (www.dhs.gov/sites/default/files/publications/china_and_covid-19.pdf) (accessed Nov. 30, 2022).

³⁸⁵ Department of Homeland Security, *Intelligence Enterprise Reference Aid: Trade Data Provides Indicators that China Stockpiled Medical Supplies in January* (May 1, 2020) (on file with Committee, IA-44129-20).

³⁸⁶ Department of Homeland Security, *Intelligence Enterprise Homeland Intelligence Article: New Analytic Technique Indicates China Likely Hid Severity of COVID-19 from the International Community While it Stockpiled Medical Supplies* (May 1, 2020) (on file with Committee, IA-44130-20).

³⁸⁷ DHS Correspondence to Senate Committee on Homeland Security and Governmental Affairs Staff (Aug. 24, 2022).

³⁸⁸ DHS Correspondence to Senate Committee on Homeland Security and Governmental Affairs Staff (Aug. 24, 2022 and Nov. 30, 2022).

February 2020 and compared it to similar data from the previous five years.³⁸⁹ Several medical products, DHS noted, “exhibited at least a two-sigma standard deviation, meaning there is a 95 percent probability that these increased imports and decreased exports of medical supplies were not within a normal range.”³⁹⁰ China released combined data for January and February 2020, breaking with its prior years’ practice of releasing trade data each month.³⁹¹ According to DHS, “the Chinese Government would have started mobilizing its purchasing agents and identifying international suppliers in early January for those purchases to be reflected in worldwide January export statistics.”³⁹²

As shown below, DHS found significant changes in Chinese imports and exports of critical PPE and other medical supplies. For example, in January 2020, China increased imports of medical supplies such as surgical facemasks (278 percent), surgical gowns (72 percent), and surgical gloves (32 percent), while decreasing exports of surgical facemasks (48 percent), surgical gloves (53 percent), and surgical gowns (37 percent), medical ventilators (45 percent), and intubation kits (56 percent), among others.³⁹³

³⁸⁹ Department of Homeland Security, *Intelligence Enterprise Reference Aid: Trade Data Provides Indicators that China Stockpiled Medical Supplies in January*, at 1 (May 1, 2020) (on file with Committee, IA-44129-20).

³⁹⁰ Department of Homeland Security, *Intelligence Enterprise Homeland Intelligence Article: New Analytic Technique Indicates China Likely Hid Severity of COVID-19 from the International Community While it Stockpiled Medical Supplies*, at 1 (May 1, 2020) (on file with Committee, IA-44130-20).

³⁹¹ Department of Homeland Security, *Intelligence Enterprise Reference Aid: Trade Data Provides Indicators that China Stockpiled Medical Supplies in January* (May 1, 2020) (on file with Committee, IA-44129-20).

³⁹² Department of Homeland Security, *Intelligence Enterprise Homeland Intelligence Article: New Analytic Technique Indicates China Likely Hid Severity of COVID-19 from the International Community While it Stockpiled Medical Supplies*, at 1 (May 1, 2020) (on file with Committee, IA-44130-20).

³⁹³ *Id.* at 1-2. DHS notes that they “relied upon worldwide imports of Chinese medical supplies as a proxy for Chinese exports, the February worldwide import data likely reflects a January reduction in exports from China as cargo typically takes over 30 days to ship via ocean freight.”

*DHS Analysis of Chinese Imports/Export of PPE and other Medical Supplies*³⁹⁴

Month-over-Month Percentage Change for Products Showing Statistically Significant Deviations			
HTS	Medical Product	Jan/ Feb Import Increase	Feb. Export Decrease
3005.10	Adhesive Tape		(-54%)
3005.90	Wadding and Gauze Bandages		(-62%)
3808.94	Hand Sanitizer (Hydrogen Peroxide)	(+6%/+210%)	
3926.20	Surgical Gloves	(+32%/+331%)	(-53%)
4015.11	Surgical Gloves - Vulcanized Rubber		(-71%)
4015.19	Medical Gloves - Vulcanized Rubber		(-49%)
5601.21	Cotton Balls and Swabs		(-58%)
6116.10	Gloves - Knitted with Plastic or Rubber		(-62%)
6210.10	Surgical Gowns	(+72%/+327%)	(-37%)
6210.40	Protective Garments for Medical Use (Male) - Plastics	(-29%/+20%)	(-62%)
6210.50	Protective Garments for Medical Use (Female) - Plastics		(-71%)
6216.00	Gloves - Textile with Plastic or Rubber		(-52%)
6307.90	Surgical Face Masks	(+278%/+252%)	(-48%)
6505.00	Disposable Hair Nets		(-57%)
9004.90	Protective Spectacles		(-44%)
9018.31	Syringes		(-48%)
9018.32	Tubular Metal Needles		(-61%)
9018.39	Catheters		(-60%)
9018.90	Intubation Kits		(-56%)
9019.20	Medical Ventilators	(+3.1%/+54%)	(-45%)
9022.12	CT Scanners		(-53%)
9025.11	Liquid-filled Thermometers		(-53%)
9025.19	Other Thermometers		(-50%)
9027.80	Instruments for Physical or Chemical Analysis		(-57%)

DHS’s May 2020 reports also found that “the Chinese Government intentionally concealed the severity of COVID-19 from the international community” in early January [2020] while it stockpiled medical supplies by both increasing imports and decreasing exports.³⁹⁵ In that report, DHS noted, “the Chinese Government attempted to hide its actions by denying there were export restrictions and obfuscating and delaying provision of its trade data.”³⁹⁶ DHS’s analysis suggested that China—in anticipation of impending supply shortages—waited to notify the WHO that COVID-19 was contagious until after they had begun to stockpile medical

³⁹⁴ Department of Homeland Security, *Intelligence Enterprise Reference Aid: Trade Data Provides Indicators that China Stockpiled Medical Supplies in January*, at 2-3 (May 1, 2020) (on file with Committee, IA-44129-20). DHS used world imports and exports to China and Hong Kong as a proxy for Chinese imports and exports. Therefore, Chinese export numbers likely lag behind actual Chinese exports by several weeks.

³⁹⁵ Department of Homeland Security, *Intelligence Enterprise Homeland Intelligence Article: New Analytic Technique Indicates China Likely Hid Severity of COVID-19 from the International Community While it Stockpiled Medical Supplies*, at 1 (May 1, 2020) (on file with Committee, IA-44130-20).

³⁹⁶ *Id.*

supplies.³⁹⁷ While DHS evaluated other explanations for the shift in Chinese import and export activities in January 2020, it ultimately determined they were not as compelling as the explanation put forth above.³⁹⁸

DHS’s May 2020 analyses recognized that “persistent analysis of worldwide trade data flows” could provide an early warning in the event of another pandemic or other global threat.³⁹⁹ Specifically, DHS suggested that “[f]or future health crises, trade data from even a single country can be highly diagnostic . . . because China produces about 80 percent of the world’s supply of surgical face masks, its stockpiling of facemasks (sic) indicates a significant health concern.”⁴⁰⁰

In August 2022 in response to questions from the Committee, DHS told the Committee that it had retracted its “high confidence” characterization for the judgment that China likely “increased imports and decreased exports for several key medical supplies in January 2020.” According to DHS, “reliance on proxy trade data and data modeling without other corroborating information sources does not merit a ‘high confidence’ in the judgment as reflected in [the initial May 2020 report].”⁴⁰¹ DHS has also raised concerns regarding its conclusion that the “Chinese government intentionally concealed the severity of COVID-19 from the international community in early January,” noting that “subsequent classified analyses by other Intelligence Community agencies has called the strength of [this conclusion] into question.”⁴⁰²

As support for its decision to change the confidence level in its original judgment, DHS I&A told the Committee that “[f]ollow-on I&A review of the cited products finds that the standard for confidence levels in their analytic judgments is not supported by data reliability, source corroboration, reliance on assumptions, and logical argumentation required under the Intelligence Community’s analytic tradecraft standards” and that “current intelligence-at a higher level of classification-overturms the previous judgments offered in these statements herein.”⁴⁰³

³⁹⁷ *Id.* (noting “trade data shows that China likely stockpiled medical supplies for domestic use before its official notification to the World Health Organization (WHO) that COVID-19 was contagious”).

³⁹⁸ *Id.* at 3.

³⁹⁹ *Id.* at 2.

⁴⁰⁰ *Id.*

⁴⁰¹ DHS Correspondence to Senate Committee on Homeland Security and Governmental Affairs Staff (Aug, 26, 2022). DHS told the Committee the analysis “did not take into consideration public reporting that China was experiencing a heavier than normal outbreak of flu cases during the same timeframe.” *Id.*

⁴⁰² *Id.*

⁴⁰³ DHS Correspondence to Senate Committee on Homeland Security and Governmental Affairs Staff (Aug, 24, 2022).

B. Containment Strategy

Despite an array of early warnings throughout January and February 2020, the Administration remained focused on a containment strategy that included travel restrictions, airport screenings, testing, and contact tracing. While CDC acknowledged in a January 31, 2020 internal document that such measures “may not prevent the eventual establishment of ongoing, widespread transmission of the virus in the U.S.,” it noted “they are being implemented to slow the progression of the virus” and provide time for health care facilities and the public to prepare for potential increased spread.⁴⁰⁴ The underlying problem, however, was that CDC did not have the tools to identify whether those goals were being achieved and during the limited time they had, the federal government failed to sufficiently coordinate and implement needed preparations.

In interviews with the Committee, experts in and outside of government cautioned against continuing a containment strategy. Former NSC Director for Medical Preparedness Policy, Dr. Lawler, stated that “by the middle of January, it was obvious to all of us that this outbreak was much worse than the Chinese government was admitting to, was much more widespread, [and] was clearly spreading from person to person, even though that was not something admitted in official releases from the Chinese government. This conclusion is based on the collective capability and insights of a network [of infectious disease experts], including lots of contacts internationally.”⁴⁰⁵ Despite this assessment, Dr. Lawler told the Committee, “CDC convinced people that we were still in a containment mode—that we could prevent the disease from transiting borders into the U.S. and spreading internationally. That horse was already out of the barn.”⁴⁰⁶ Dr. Birx told the Committee she believed the virus was “seeded everywhere” and in early January 2020, she told then Deputy National Security Advisor Matthew Pottinger that she was concerned with the U.S. continuing to try and contain the virus outside of the country instead of preparing for and mitigating the virus spread within the United States.⁴⁰⁷

Travel screening procedures at airports proved ineffective at preventing transmission of the virus due to pre-symptomatic and asymptomatic spread.⁴⁰⁸ Outdated data systems coupled with incomplete information from airlines delayed effective contact tracing efforts. Insufficient diagnostic testing (discussed in Section VI) left CDC unable to timely and comprehensively

⁴⁰⁴ Department of Health and Human Services, Centers for Disease Control and Prevention, *2019 Novel Coronavirus (nCoV) IM Update: Response Day 25* (Jan. 31, 2020) (on file with Committee, HSGAC-0039197).

⁴⁰⁵ Interview with Dr. James Lawler (May 6, 2021).

⁴⁰⁶ *Id.*

⁴⁰⁷ Interview with Dr. Deborah Birx (Jan. 6, 2022).

⁴⁰⁸ Centers for Disease Control and Prevention, Briefing with Senate Committee on Homeland Security and Governmental Affairs Staff (Dec. 13, 2021) (hereinafter “CDC Briefing (Dec. 13, 2021)”); Centers for Disease Control and Prevention, *Identification and Monitoring of International Travelers During the Initial Phase of an Outbreak of COVID-19—California, February 3 – March 17, 2020*, Morbidity and Mortality Weekly Report (May 15, 2020).

identify and track the spread of the virus throughout February. This section discusses challenges CDC faced in implementing its containment strategy.

Travel Screenings and Restrictions

While complete containment of any airborne virus is unlikely, travel screenings and restrictions can help delay virus introduction and spread, and provide time for implementing domestic mitigation measures.⁴⁰⁹ On January 17, 2020 CDC, in coordination with DHS, began screening passengers returning from Wuhan, China at three U.S. airports: San Francisco (SFO), New York (JFK), and Los Angeles (LAX).⁴¹⁰ Two weeks later, on January 31, 2020 President Trump issued a travel order restricting travelers from China.⁴¹¹ On February 2 and 3, 2020, DHS expanded the number of airports authorized to receive flights from China and conduct enhanced screening procedures to include: Chicago (ORD), Seattle (SEA), Honolulu (HNL), Atlanta (ATL), Washington-Dulles (IAD), Newark (EWR), Dallas/Fort Worth (DFW), and Detroit (DTW).⁴¹² Shortly thereafter, nearly 60 airline companies began suspending or reducing their flights to China and other countries that were impacted by COVID-19, including Russia, Australia, and Italy.⁴¹³ As of February 5, 2020, DHS estimated a 71 percent decrease of inbound air passenger arrivals since January 1, 2020.⁴¹⁴ Despite the decrease in travelers, CDC found that travel screenings, which did not account for potential asymptomatic or pre-symptomatic passengers, “detected few COVID-19 cases and required considerable resources.”⁴¹⁵

Other travel restrictions that also could have been helpful came too late. On March 11, the World Health Organization declared the COVID-19 outbreak a pandemic.⁴¹⁶ That same day, President Trump announced the U.S. would suspend “all travel from Europe to the United States

⁴⁰⁹ Paolo Bajardi, et al., *Human mobility networks, travel restrictions, and the global spread of 2009 H1N1 pandemic*, National Library of Medicine National Center for Biotechnology Information (Jan. 2011).

⁴¹⁰ Centers for Disease Control and Prevention, *Public Health Screening to Begin at 3 U.S. Airports for 2019 Novel Coronavirus (“2019-nCoV”)* (Jan. 17, 2020).

⁴¹¹ President Donald J. Trump, White House, Proclamation on Suspension of Entry as Immigrants and Nonimmigrants of Persons who Pose a Risk of Transmitting 2019 Novel Coronavirus (Jan. 31, 2020).

⁴¹² Department of Homeland Security, *DHS Issues Supplemental Instructions for Inbound Flights with Individuals Who Have Been In China* (Feb. 2, 2020).

⁴¹³ *The Airlines Halting Flights as Virus Outbreak Spreads*, Bloomberg (March. 13, 2020) (www.bloomberg.com/graphics/2020-china-coronavirus-airlines-business-effects/).

⁴¹⁴ Department of Homeland Security, *DHS National Operations Center 2019-nCoV Placemat* (Feb. 8, 2020) (on file with Committee).

⁴¹⁵ Centers for Disease Control and Prevention, *Risk Assessment and Management of COVID-19 Among Travelers Arriving at U.S. Designated Airports, January 17-September 13, 2020*, Morbidity and Mortality Weekly Report (Nov. 13, 2020). Travel screening involved identifying passengers who had visited one of the specified countries in the past 14 days, collecting travelers’ contact information, and screening for signs of illness, including a temperature check, and a questionnaire about a passenger’s “signs and symptoms (fever, cough, and difficulty breathing) in the preceding 24 hours or exposure to a person with COVID-19 in the preceding 14 days”. *Id.*

⁴¹⁶ World Health Organization, WHO Director-General’s opening remarks at the media briefing on COVID-19 (Mar. 11, 2020).

for the next 30 days.”⁴¹⁷ In an interview with the Committee, Mr. Pottinger stated, “it was a battle—I argued strongly in favor of closing the door on European travel for a period of several weeks throughout February.”⁴¹⁸ Mr. Pottinger explained that there were economic concerns and resistance from public health officials regarding the effectiveness of travel restrictions. These measures, however, implemented nearly two months after the first cases in the U.S. were detected, were too late to be of value. Mr. Pottinger told the Committee he learned in March during a Task Force meeting that the “great majority of outbreaks” in the U.S. were seeded by travelers from Europe, not travelers from China.⁴¹⁹

Contact Tracing

While travel restrictions reduced the number of travelers, limiting the potential for virus spread, inadequate data systems and gaps in data collection hindered federal efforts to effectively conduct contact tracing. In July 2022, GAO found that CDC’s “outdated data management system,” developed in the mid-2000s, impaired its ability to conduct contact tracing because the system “was not designed for rapid assessment or aggregation of public health data across individuals’ cases.”⁴²⁰ For example, Michigan Department of Health and Human Services told the Committee that CDC’s communications on “international travelers that were funneled to screening airports resulted in dozens of separate email messages (at least one per flight) daily that became a challenge to negotiate.”⁴²¹

Although CDC has made efforts since 2005 to require that airlines maintain an electronic database with passenger and crew contact information for public health purposes, gaps in information collection and sharing impaired CDC’s and DHS’s ability to effectively track potentially exposed passengers.⁴²² Since 2017, airlines have been required to provide CDC certain passenger information (e.g. traveler name and contact information) for public health purposes upon request from the CDC Director. This rule, however, did not require airlines to collect specific information and instead only required airlines to provide such data that is already

⁴¹⁷ President Donald J. Trump, Presidential Address on the Coronavirus Outbreak, C-Span (Mar. 11, 2020). Europe did not implement travel restrictions until March 17, 2020. At that time, the European Union banned non-essential travel into 26 countries. See Charles Michel, European Commission, Conclusions by the President of the European Council following the video conference with members of the European Council on COVID-19 (March 17, 2020).

⁴¹⁸ Interview with Matthew Pottinger (Jan. 25, 2022).

⁴¹⁹ Matthew Pottinger, Written Response to Senate Committee on Homeland Security and Governmental Affairs Staff (received Mar. 1, 2022).

⁴²⁰ Government Accountability Office, *Contact Tracing for Air Travel: CDC’s Data System Needs Substantial Improvement* (GAO-22-105018) (July 2022).

⁴²¹ Michigan Department of Health and Humans Services, Written Response to Senate Committee on Homeland Security and Governmental Affairs State Public Health Agency Questionnaire (Dec. 2, 2021) (on file with Committee).

⁴²² Centers for Disease Control and Prevention, Briefing with Senate Committee on Homeland Security and Governmental Affairs Staff (Dec. 13, 2021). See also Department of Homeland Security, Federal Emergency Management Agency, *U.S. Government Response to the 2019 Novel Coronavirus (SARS-CoV2)* (Feb. 14, 2020) (on file with Committee, HSGAC-001728) (noting “chokepoints/critical gaps” include “reliable and accessible traveler tracking for contact tracing” and “diagnostics and test kits”).

available and maintained by the airline.⁴²³ As a result, when travel screenings for COVID-19 began in mid-January, some airlines were not in a position to provide basic passenger information to CDC.⁴²⁴

On February 7, 2020, CDC issued an Interim Final Rule that enabled the agency to require airlines to collect, and provide to CDC, certain contact information for a limited subset of travelers, which included passengers and crew arriving from foreign countries who “may be at risk of exposure to a communicable disease.”⁴²⁵ Nearly two weeks later, on February 18, CDC extended the Order under the Interim Final Rule to require that airlines collect and transmit contact information for any passengers travelling from the People’s Republic of China within 14 days of the passenger’s date of entry into the U.S.⁴²⁶

Although CDC and DHS began collecting information directly from passengers on January 17, 2020 at the initial three screening airports (LAX, JFK, and SFO), Clive Brown, Chief of CDC’s Quarantine and Border Health Services Branch, told the Committee that CDC did not officially start collecting information to conduct contact tracing from airlines until March 2, 2020 due to incomplete data from airlines and a lack of interoperable systems.⁴²⁷ By this time, COVID-19 had already been spreading throughout the country for over six weeks—since the first diagnosed case on January 20, 2020.⁴²⁸

⁴²³ Department of Health and Human Services, *Control of Communicable Diseases*, 82 Fed. Reg. 6890 (Jan. 19, 2017) (final rule).

⁴²⁴ CDC Briefing (Dec. 13, 2021).

⁴²⁵ Department of Health and Human Services, *Control of Communicable Diseases; Foreign Quarantine*, 85 Fed. Reg. 7874 (Feb. 7, 2020) (interim final rule) (stating, “[g]iven the limitations associated with the current regulatory requirements, CDC is exercising its statutory authority to require any airline with a flight arriving into the United States, including any intermediate stops between the flight’s origin and final destination, to collect and, within 24 hours of an order by the CDC Director, transmit to CDC the following five data elements with respect to each passenger and crew member who may be at risk of exposure to a communicable disease, to the extent that such information exists for the individual, and in a format acceptable to the Director”).

⁴²⁶ Department of Health and Human Services, *Collection of Certain Data Regarding Passengers and Crew Arriving from Foreign Countries by Airlines*, 85 Fed. Reg. 10439 (Feb. 18, 2020) (interim final rule) (85 FR 10439) (noting “Each airline is hereby ordered to collect and provide information about any passenger (excluding the special administrative regions of Hong Kong and Macau) within 14 days of the date of the passenger’s entry or attempted entry into the United States via that airline’s carriage (“Designated Passengers”)”). CDC rescinded the Order specific to the People’s Republic of China effective September 29, 2020. *See* 85 FR 60998. It was not until October 25, 2021 when CDC issued an order that required airlines to collect passenger information on all foreign flights arriving into the United States. *See* Department of Health and Human Services, *Control of Communicable Diseases*, 86 Fed. Reg. 61246 (Oct. 25, 2021) (interim final rule); Department of Health and Human Services, *Timeline: CDC’s Efforts to Collect Contact Information for Air Passengers Arriving into the United States for Public Health Follow-up* (received on Jan. 1, 2022) (on file with Committee).

⁴²⁷ CDC Briefing (Dec. 13, 2021); *see also* Centers for Disease Control and Prevention, *Risk Assessment and Management of COVID-19 Among Travelers Arriving at Designated U.S. Airports, January 17 – September 13, 2020*, Morbidity and Mortality Weekly Report (MMWR), 69(45):1681-1685 (Nov. 13, 2020); *see also* CDC Briefing (Dec. 13, 2021).

⁴²⁸ CDC Briefing (Dec. 13, 2021).

C. Need for Mitigation Strategy

As evidence of the virus's transmissibility became clearer in late January and throughout February, increasing numbers of experts and officials raised concern about the need to shift from a strategy of containment to a strategy of mitigation. The Administration's focus, however, remained on keeping the virus out of the country. Dr. Daniel Jernigan, CDC's Deputy Director for Public Health Science and Surveillance, who led CDC's response from January through March 2020, told the Committee, "the strategy component of preparedness was not as robust because of the significant focus on the near-term tactical issues [e.g. repatriation and travel concerns]. The near-term needs were a significant part of the discussion and the later implementation needs were less of a focus."⁴²⁹ Dr. Anne Schuchat, then Principal Deputy Director of CDC, explained how the federal government was more focused on the "issue of the moment," rather than planning for anticipated challenges and focusing on a "threat that was very real."⁴³⁰ She noted, "[d]rills and exercises suggested we would need to do mitigation . . . but much of the interagency focus was on cruise ships. So while ships were taking a great deal of tactical time, the issues of PPE production and mitigation were not getting sufficient attention."⁴³¹

In an interview with Committee staff, Melissa Harvey, then Director of Health Systems at DHS, also expressed concern about the lack of mitigation measures in place:

We were all concerned that nothing was happening . . . From a public perception standpoint, we knew we needed to screen at airports. No one was putting up a fight on that. But if that was DHS's only role, we were really missing something. There is a whole lot more you can do to protect the homeland than that."

Ms. Harvey told the Committee that when she and other DHS staff emphasized the need to implement mitigation measures across the country, they were told it wasn't a priority or it wasn't for DHS to do, and DHS would continue airport screenings.⁴³² A January 30, 2020 summary of an internal FEMA call on the COVID-19 response noted that when they asked CDC and ASPR about "where the next operational issues might arise," both agencies were focused on repatriation (e.g. getting Americans home safely) and "it's been difficult to move beyond [that]."⁴³³

Despite the public warning signs from China, it was not until the end of January 2020 when CDC began issuing daily "Situation Reports" and ASPR began issuing daily "Senior

⁴²⁹ Interview with Dr. Daniel Jernigan (Dec. 15, 2021).

⁴³⁰ Interview with Dr. Anne Schuchat (Dec. 14, 2021).

⁴³¹ *Id.*

⁴³² Interview with Melissa Harvey (Nov. 3, 2021).

⁴³³ Federal Emergency Management Agency, *Internal FEMA 2019 Novel Coronavirus Synchronization Call* (Feb. 4, 2020) (on file with Committee, HSGAC-001714).

Leadership Briefs” on the status of the virus and federal response efforts.⁴³⁴ Dr. Duane Caneva, then Chief Medical Officer for DHS, told the Committee, “by the end of January, it was pretty clear that what China was trying to do to contain the virus was unprecedented.”⁴³⁵ Dr. Caneva noted, however, that at the time, they did not know if China’s stringent lockdown mandate was due to China’s knowledge regarding the severity of the virus, China’s ability to exert that level of control on the public, or a combination of both.”⁴³⁶

Initiation of “Red Dawn” Email Correspondence

In mid-January, Dr. Caneva began an email chain dubbed “Red Dawn” with former colleagues and experts in biodefense, public health, coronaviruses, and emergency preparedness.⁴³⁷ The initial group included then ASPR Dr. Robert Kadlec, then VA Senior Medical Advisor Dr. Carter Mecher, and former BARDA Deputy Director Dr. Richard Hatchett, among others, conversing outside of their official capacities. Dr. Caneva told the Committee, “our communication revved up with our concerns . . . it was like economists trying to predict a recession, but with limited information.”⁴³⁸ Dr. Mecher explained to the Committee that the Red Dawn email communications were used as “a sounding board” and forum to generate discussion. He noted that at the time, Dr. Kadlec and Dr. Caneva “were drinking out of a fire hose,” and Dr. Kadlec asked if he could expand their discussion group to include current officials from HHS and ASPR.⁴³⁹ According to Dr. Mecher, “Dr. Kadlec was trying to lean forward and be aggressive . . . [his main concern] was preparing our healthcare systems to respond to the surge.” Melissa Harvey, a participant in the group and then Director of Health Systems at DHS, said the group was “coming up with innovative solutions at the state, local, and private sector levels in the absence of government doing what government should have been doing, which is testing and surveillance, and those things that are inherently core public health department government functions.”⁴⁴⁰

As detailed below, during the first week of February, some experts within the “Red Dawn” email group began advocating for a shift from a containment to mitigation, a strategy involving the implementation of community mitigation measures (also known as non-pharmaceutical interventions), which can range from social distancing, limits on public gatherings, school or business closures, and stay-at-home orders, among other interventions. The federal government, however, took weeks, and in some cases months, to issue broad mitigation

⁴³⁴ See generally Department of Health and Human Services, Centers for Disease Control and Prevention, *CDC 2020 Novel Coronavirus (nCoV) Situation Report #001 – #047* (Jan. 27, 2020 – Mar. 31, 2020) (on file with Committee); Department of Health and Human Services, Assistant Secretary for Preparedness and Response, *2019 Novel Coronavirus (2019-nCoV) – HHS Senior Leadership Briefs* (Jan. 30, 2020 – Mar. 31, 2020) (on file with Committee).

⁴³⁵ Interview with Dr. Duane Caneva (Nov. 15, 2021).

⁴³⁶ *Id.*

⁴³⁷ *Id.*

⁴³⁸ *Id.*

⁴³⁹ Interview with Dr. Carter Mecher (July 29, 2022).

⁴⁴⁰ Interview with Melissa Harvey (Nov. 3, 2021).

guidance—far longer than state authorities took to implement community mitigation measures in response to the 1918 pandemic.⁴⁴¹

With an insufficient amount of national surveillance data on the virus, Dr. Mecher used publicly available data from other countries to quickly assess the severity of the virus. He told the Committee, “all of the information [I used] was from open sources . . . I had no special access.”⁴⁴² In a February 2, 2020 email, which included multiple senior federal officials from ASPR and DHS, Dr. Mecher wrote:

I don’t think most people including emergency managers or hospital leaders understand or appreciate exponential growth and what that means for them. Look at the data from China and look at the velocity in terms of the number of cases and number of deaths—it isn’t linear. Once it hits, it moves and accelerates. Once you are near the breaking point, you can be sure of it that however bad you think it is, it is going to become exponentially worse over time.⁴⁴³

Dr. Mecher emphasized the readily ascertainable magnitude of the threat, despite the known deficiencies in the data from China. He continued in his message that,

We know the data from China is incomplete (in terms of the real disease burden), but just look at the increase in the cumulative number of cases and deaths over the past 2 weeks. 2 weeks ago this wasn’t on most people’s radar. Today it is the cumulative case count increased 2 orders of magnitude in 2 week [*sic*], so did the number of deaths. So if hospital [*sic*] thought things were bad on 1/18, things were 10 times worse a week later, and things were 100 times

⁴⁴¹ See Department of Health and Human Services, Centers for Disease Control and Prevention, *2019 Novel Coronavirus (nCoV) IM Update: Response Day 54* (Feb. 28, 2020) (on file with Committee, HSGAC-0038688-0038690) (discussing mitigation measures such as washing hands and social distancing); White House, *15 Days to Slow the Spread* (Mar. 16, 2020) (<https://trumpwhitehouse.archives.gov/articles/15-days-slow-spread/>); Centers for Disease Control and Prevention, *2019 Novel Coronavirus (nCoV) IM Update: Response Day 89* (Apr. 3, 2020) (on file with Committee, HSGAC-0012581) (discussing masking announcement); White House, Homeland Security Council, *National Strategy for Pandemic Influenza Implementation Plan One Year Summary* (July 17, 2007) (<https://georgewbush-whitehouse.archives.gov/homeland/pandemic-influenza-oneyear.html>) (noting that St. Louis, which implemented mitigation measures only two days after its first reported cases, experienced less than half the rates of pneumonia and influenza deaths than Philadelphia, which implemented nearly identical mitigation measures just roughly 14 days later than St. Louis); Richard J Hatchett, et al., *Public health interventions and epidemic intensity during the 1918 influenza pandemic*, Proceedings of the National Academy of Sciences of the United States of America 104 (18) 7582-7587 (May. 1, 2007); National Institute of Health: *Rapid Response was Crucial to Containing the 1918 Flu Pandemic Historical Analyses Help Plan for Future Pandemics* (April 2, 2007).

⁴⁴² Interview with Dr. Carter Mecher (July 29, 2022).

⁴⁴³ Department of Health and Human Services, *Email from Dr. Carter Mecher to Dr. Duane Caneva (DHS); Dr. Robert Kadlec (ASPR); Dr. Kevin Yeskey (ASPR); Dr. Robert Johnson (BARDA), Dr. Gary Disbrow (BARDA), Dr. John Redd (ASPR), Melissa Harvey (DHS), Dr. David Marcozzi,; Dr. James Lawler, among other recipients* (Feb. 2, 2020) (on file with Committee, HSGAC-42558).

worse two weeks later. These numbers are just the tip of the iceberg in terms of the real numbers of infected in China.⁴⁴⁴

The next day, on February 3, 2020 Dr. Mecher emailed—again to high level senior officials within ASPR and DHS—regarding the severity of the threat and risk of asymptomatic spread:

We are at a very different place than we ever were with H1N1. Isolating those who are suspected/confirmed to have disease (either at home or in a healthcare setting) is ongoing. This NPI [referring to isolation] is just commonsense and has been implemented. Given the evidence of disease transmission by asymptomatic/infected individuals, it is pretty clear that we need more than isolation of the ill to slow disease transmission . . . I would assume we have crossed the severity threshold for full implementation of the NPIs and I would back off if additional information proves that our concerns re severity are unfounded. Taking the opposite approach (remaining agnostic [with regard to] severity and holding back until the severity threshold is proven is too risky, because if we are wrong, we will have lost our only opportunity to influence the dynamics of this pandemic—we don't get a second chance. There is no taking a Mulligan with NPIs.⁴⁴⁵

Using dated but relevant slides developed for pandemic flu, Dr. Mecher continued to push for “**Early, Targeted, [and] Layered**” implementation of NPIs and emphasized the importance of speed. He cautioned:

One could think of the NPIs like a fire extinguisher. It will be effective if the fire is caught earlier (say only a grease fire in a pan on the top of a stove). But once the fire has spread and half the house is ablaze, you can empty the fire extinguisher, but it won't do much (probably as effective as just throwing [it] through a window). The problem with implementing NPIs too late is you get all the downsides and little benefit, so speed is critical. The challenge is that these NPIs need to be implemented before things get bad—when the sun is still shining, the sky is blue[,] and there is only a slight breeze. As you can appreciate, the communication for this will be very challenging.⁴⁴⁶

⁴⁴⁴ *Id.*

⁴⁴⁵ Department of Health and Human Services, *Email from Dr. Carter Mecher to Dr. Duane Caneva (DHS); Dr. Robert Kadlec (ASPR); Dr. Kevin Yeskey (ASPR); Dr. Robert Johnson (BARDA), Dr. Gary Disbrow (BARDA), Dr. John Redd (ASPR), Melissa Harvey (DHS), Dr. David Marcozzi,; Dr. James Lawler, among other recipients* (Feb. 3, 2020) (on file with Committee, HSGAC-0042556-0042557).

⁴⁴⁶ Department of Health and Human Services, *Email from Dr. Carter Mecher to Red Dawn Group* (Feb. 3, 2020) (on file with Committee, HSGAC-0042553).

On February 3, Dr. Mecher also circulated updated hospitalization data from January 14-February 3, 2020 for the Hubei province and noted there was “about a 10 fold increase each week.”⁴⁴⁷ Former NSC senior official Dr. James Lawler responded, “as is consistent with prior SARS experience, also important to follow the recovered #, which I assume is the number discharged. Hubei only lists 300 recovered. That means everybody else is still in the hospital. That’s a long hospital dwell time – much longer than flu on average. That eats up your bed availability in a hurry.”⁴⁴⁸

By February 4, Dr. Mecher estimated that the U.S. was “a couple of weeks behind China and maybe a month or so behind [the city of] Wuhan,” and recommended focusing on “getting ready with NPIs—and getting leadership and the public prepared.”⁴⁴⁹ Days later, China’s National Development and Reform Commission “announced it would release \$28.6 million for three hospitals near Wuhan, earmarked for the purchase of ventilators, electrocardiograph monitors, bedside blood filters, and other medical equipment.”⁴⁵⁰

Without any action on NPIs from the federal government, on February 9, 2020 Dr. Mecher emailed Assistant Secretary for Preparedness and Response, Dr. Kadlec and DHS’s Chief Medical Officer, Dr. Caneva, directly and included a slide deck titled, *Comparison of 2019-nCoV to SARS and H1N1*.⁴⁵¹ Dr. Mecher wrote, “[I]ook at slides #2 #3 that compare SARS with nCoV [novel coronavirus] and H1N1 with nCoV. It looks to be even more transmissible than H1N1 and far more deadly. And it moves much faster than SARS but not as deadly.”⁴⁵²

⁴⁴⁷ Department of Health and Human Services, *Email from Dr. Carter Mecher to Dr. Duane Caneva (DHS); Dr. Robert Kadlec (ASPR); Dr. Kevin Yeskey (ASPR); Dr. Robert Johnson (BARDA), Dr. Gary Disbrow (BARDA), Dr. John Redd (ASPR), Melissa Harvey (DHS), Dr. David Marcozzi,; Dr. James Lawler, among other recipients* (Feb. 3, 2020) (on file with Committee, HSGAC-0042748).

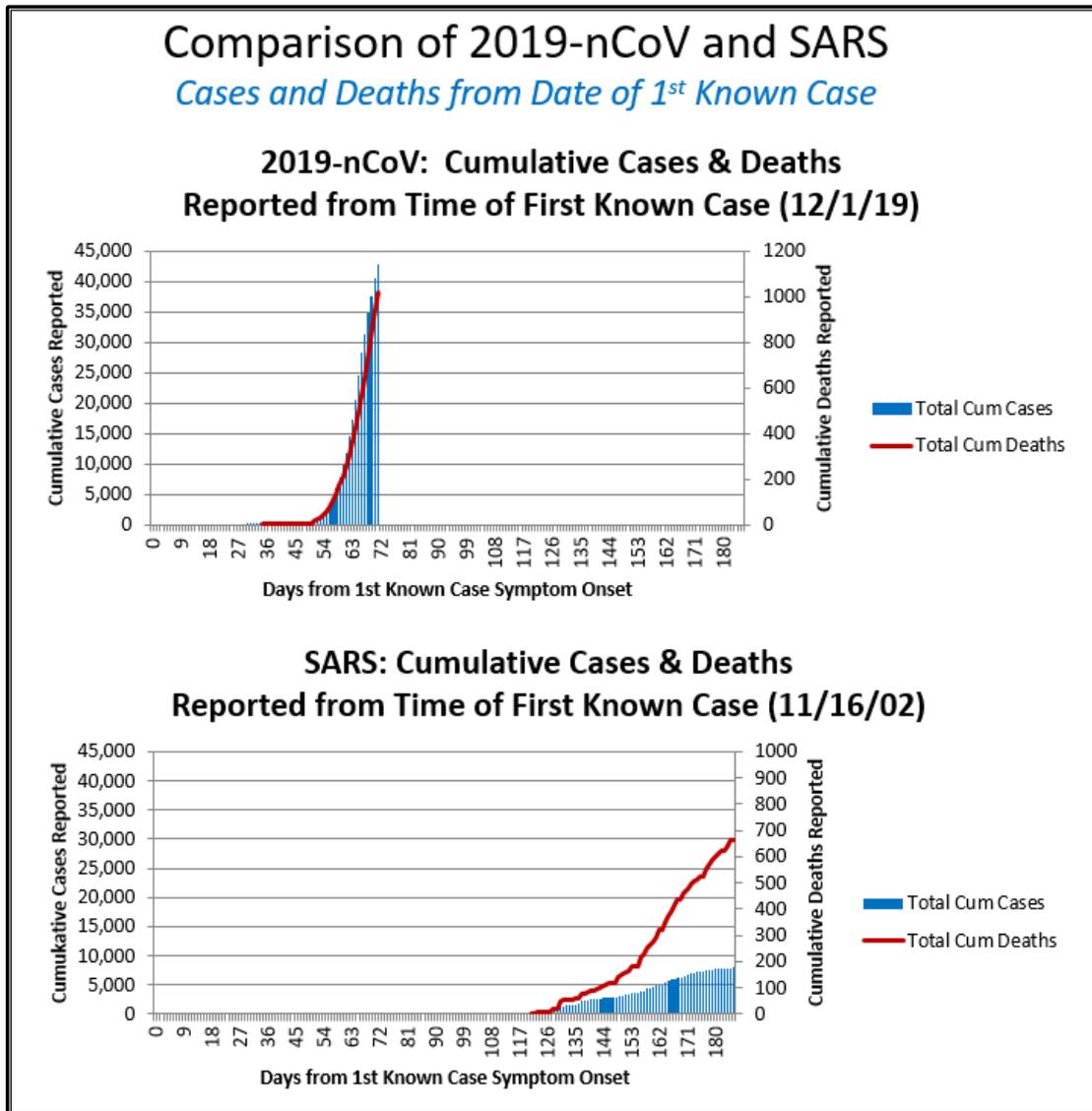
⁴⁴⁸ Department of Health and Human Services, *Email from Dr. James Lawler to Dr. Carter Mecher; Dr. Robert Kadlec; Dr. Duane Caneva (DHS); Dr. Kevin Yeskey (ASPR); Dr. Robert Johnson (BARDA), Dr. Gary Disbrow (BARDA), Dr. John Redd (ASPR), Melissa Harvey (DHS), Dr. David Marcozzi, among other recipients* (on file with Committee, HSGAC-004276).

⁴⁴⁹ Department of Health and Human Services, *Email from Dr. Carter Mecher to Dr. Duane Caneva (DHS); Dr. Robert Kadlec (ASPR); Dr. Kevin Yeskey (ASPR); Dr. Robert Johnson (BARDA), Dr. Gary Disbrow (BARDA), Dr. John Redd (ASPR), Melissa Harvey (DHS), Dr. David Marcozzi; Dr. James Lawler, among other recipients* (Feb. 4, 2020) (on file with Committee, HSGAC-0042543).

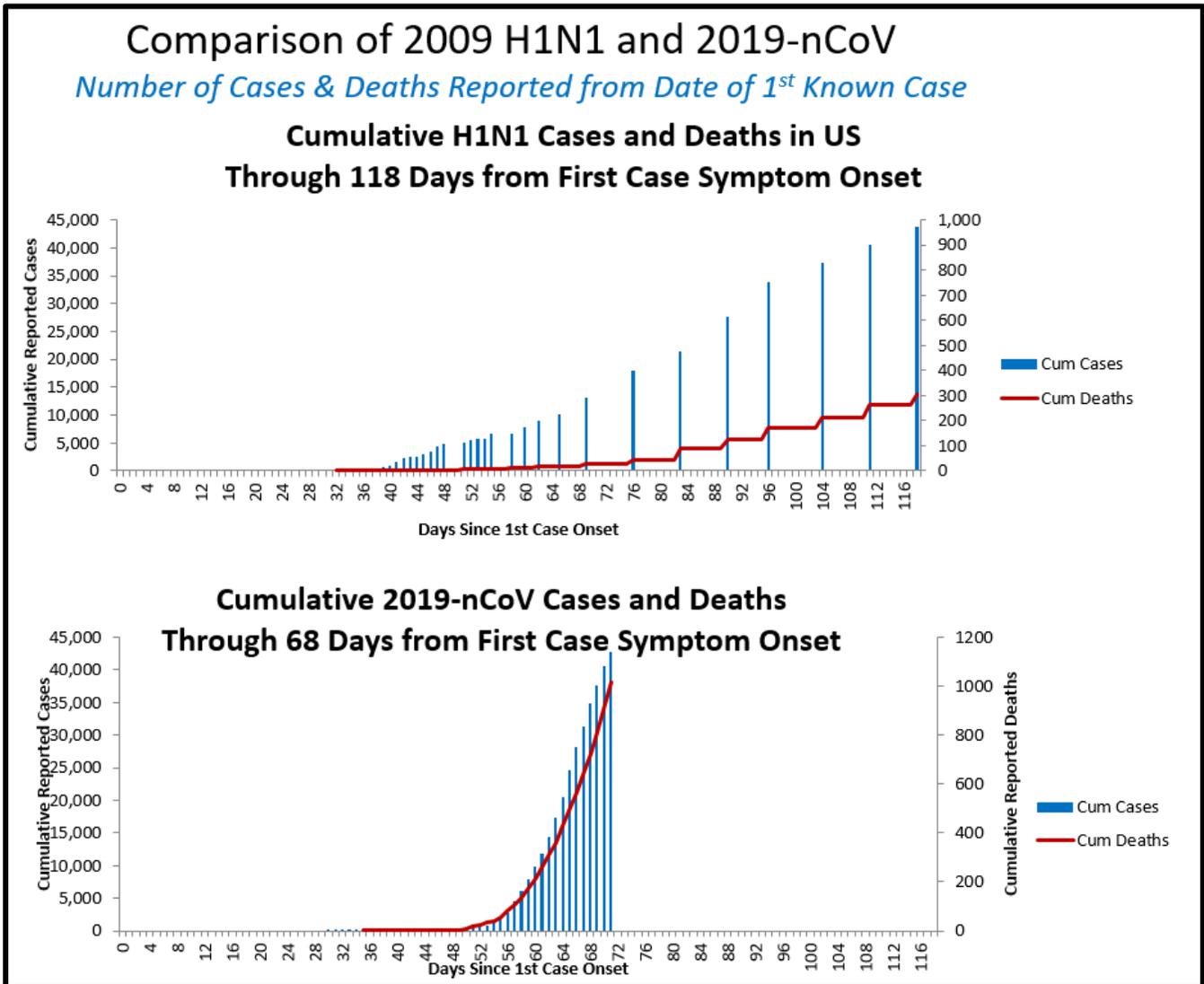
⁴⁵⁰ Department of State, *Coronavirus Global Response Coordination Unit: SITREP No. 1* (Feb. 8, 2020) (on file with Committee).

⁴⁵¹ Department of Health and Human Services, *Email from Dr. Carter Mecher to Dr. Robert Kadlec and Dr. Duane Caneva* (Feb. 9, 2020) (on file with Committee, HSGAC-0042562); *see also* Dr. Carter Mecher, *Comparison of 2019-nCoV to SARS and H1N1 Slides* (Feb. 9, 2020) (on file with Committee).

⁴⁵² Email from Dr. Carter Mecher to Dr. Robert Kadlec and Dr. Duane Caneva (Feb. 10, 2020) (on file with Committee, HSGAC-0042562).



⁴⁵³ Dr. Carter Mecher, *Comparison of 2019-nCoV to SARS and H1N1 Slides* (Feb. 9, 2020) (on file with Committee); *see also* Department of Health and Human Services, *Comparison of 2019-nCoV and SARS* (attached to Feb. 9, 2020 email) (on file with Committee, HSGAC 42562-42579). The Committee notes slight discrepancies in the version produced by HHS and received by Dr. Mecher.



Dr. Kadlec responded, “Carter really helpful and scary too. Where did you get the data? I want to show this to Redfield and Fauci.” Dr. Mecher noted that he received the data from the WHO situation updates and CDC.⁴⁵⁵

⁴⁵⁴ *Id.*

⁴⁵⁵ Department of Health and Human Services, *Email from Dr. Robert Kadlec to Dr. Carter Mecher and Dr. Duane Caneva* (Feb. 10, 2020) (on file with Committee, HSGAC-0042562).

***Emails Correspondence between then-VA Senior Official Dr. Mecher
and then-ASPR Dr. Kadlec⁴⁵⁶***

From: Kadlec, Robert (OS/ASPR/IO) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A182EDA693D040D3832BAE6EFCF7A255-KADLEC, ROB]
Sent: 2/10/2020 11:04:31 AM
To: Redd, John (OS/ASPR/SPPR) [john.redd@hhs.gov]; Shuy, Bryan (OS/ASPR/IO) [bryan.shuy@hhs.gov]; Friedrichs, Paul (MIL) [paul.a.friedrichs.mil@mail.mil]; Yeskey, Kevin (OS/ASPR/IO) [kevin.yeskey@hhs.gov]; Greene, Jonathan (OS/ASPR/EMMO) [jonathan.greene@hhs.gov]; Bright, Rick (OS/ASPR/BARDA) [rick.bright@hhs.gov]; Disbrow, Gary (OS/ASPR/BARDA) [gary.disbrow@hhs.gov]; Johnson, Robert (OS/ASPR/BARDA) [robert.johnson@hhs.gov]; Hassell, David (Chris) (OS/ASPR/IO) [david.hassell@hhs.gov]
Subject: FW:
Attachments: 2019-nCoV Comparison.pptx

Pretty unsettling data.

From: Carter Mecher <cmecher@charter.net>
Sent: Monday, February 10, 2020 5:53 AM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Caneva, Duane (DHS.GOV) <duane.caneva@hq.dhs.gov>
Subject: RE:

The SARS data is all from WHO (from their situation updates). The H1N1 data is from CDC. Let me add a few slides to help clarify. This is all part of the daily update I share with the group. Take a look.

Sent from [Mail](#) for Windows 10

From: Kadlec, Robert (OS/ASPR/IO)
Sent: Monday, February 10, 2020 5:40 AM
To: Carter Mecher; Caneva, Duane (DHS.GOV)
Subject: RE:

Carter really helpful and scary too. Where did you get the data? I want to show this to Redfield and Fauci

From: Carter Mecher <cmecher@charter.net>
Sent: Sunday, February 9, 2020 11:17 PM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Caneva, Duane (DHS.GOV) <duane.caneva@hq.dhs.gov>
Subject:

Look at slides #2 #3 that compare SARS with nCoV and H1N1 with nCoV

It looks to be even more transmissible than H1N1 and far more deadly. And it moves much faster than SARS but not as deadly.

Sent from [Mail](#) for Windows 10

⁴⁵⁶ Department of Health and Human Services, *Email Correspondence between Dr. Robert Kadlec and Dr. Carter Mecher* (Feb. 9-10, 2020) (on file with Committee, HSGAC-0042562).

Federal Actions Failed to Address Evolving Threat

Despite former officials from the Red Dawn email chain sounding the alarm to high-level DHS and ASPR officials, the federal government did not change its course. A February 12, 2020 HHS presentation to the White House titled, “Containment & Mitigation Planning,” contemplated the right amount of data needed to move toward a mitigation phase.⁴⁵⁷ While a February 14 internal FEMA planning document mapped out potential triggers to initiate different response strategies (including community mitigation) and accurately predicted “chokepoints [and] critical gaps” (such as potential critical supply and staffing shortages) the federal government would soon face, the Majority Committee staff found federal preparations were limited and delayed.⁴⁵⁸

When asked whether any concerns were raised that the federal government did not have sufficient data and surveillance to timely identify the criteria that would trigger a mitigation phase, Dr. Redfield told the Committee, “no.”⁴⁵⁹ He noted, however, “[b]y the third week of February, [CDC] saw that asymptomatic transmission was going to have some impact” and there needed to be considerations for moving from a containment to mitigation strategy.

On February 20, 2020, Dr. Kadlec presented a COVID-19 tabletop exercise to the White House Task Force that discussed potential outcome scenarios and proposed discussion topics, such as: available authorities; transition from containment to mitigation strategies; triggers to implement continuity of operations plans; and risks to the medical supply chain and health care system, among other topics.⁴⁶⁰ Dr. Kadlec told the Committee, “[t]his was a difficult meeting, we didn’t have good situational awareness... we didn’t know about the asymptomatic spread.”⁴⁶¹ Mr. Azar noted that as the White House Task Force “analyzed the data and considered various scenarios, we determined that community spread of the disease in more than one community was likely,” and as a result, the Task Force would recommend shifting to implementing mitigation measures.⁴⁶²

Growing Federal Consensus on Threat Level

Many experts and public health officials expressed increasing alarm as they learned more about the disease and the country’s vulnerability became clear. In interviews with the Committee, numerous officials stated that by mid-February 2020, several administration officials

⁴⁵⁷ Department of Health and Human Services, *PCC Brief 2019-nCoV: Containment & Mitigation Planning* (Feb. 12, 2020) (on file with Committee, HSGAC 42624-426251).

⁴⁵⁸ Department of Homeland Security, Federal Emergency Management Agency, *U.S. Government Response to the 2019 Novel Coronavirus (SARS-CoV2)* (Feb. 14, 2020) (on file with Committee, HSGAC-001728-001733).

⁴⁵⁹ Interview with Dr. Robert Redfield (Feb. 7, 2022).

⁴⁶⁰ Department of Health and Human Services, *Coronavirus Disease 2019 Response Tabletop Exercise Situational Manual* (Feb. 20, 2020) (on file with Committee, HSGAC 0042608-0042619).

⁴⁶¹ Interview with Dr. Robert Kadlec (Dec. 6, 2021).

⁴⁶² Alex Azar Interrogatories (Mar. 1, 2022).

began to recognize the increasing threat.⁴⁶³ Olivia Troye, then Special Advisor to Vice President Pence, told the Committee, “[i]n February, you kind of see a shift where we're increasingly concerned, because we are seeing that this virus is really spreading, and we're watching it, we're tracking it. I remember CDC and others they're starting to raise the alarm saying we've really got to start preparing the American public.”⁴⁶⁴ Ms. Troye acknowledged, however, “it was a mixed conversation.” According to Ms. Troye, HHS officials had differing opinions on how to address the virus and what to say to the public. She explained that the White House wanted to avoid panic and focused on “how to relay information without completely alarming people.”⁴⁶⁵

Former ASPR Dr. Kadlec told the Committee, “a blind man could see [the spread].” He stated, “first of all, the Chinese themselves have human-to-human transmission on January 20, it was evident that was occurring well earlier than that, maybe as early as late December. Healthcare workers were getting infected.”⁴⁶⁶ According to Dr. Redfield, it was not until the last week of February when CDC “knew that a containment strategy was not going to contain the virus” and there was a need to move to mitigation tactics.⁴⁶⁷ Dr. Schuchat told the Committee that “internally at CDC, as we saw containment not working, we began to move toward mitigation,” but acknowledged, “it took longer than necessary to have those policies (e.g. social distancing and masking) supported at a national level.”⁴⁶⁸

On February 23, 2020 when the scientific evidence suggested seemingly healthy individuals could spread the virus during its incubation period, Dr. Kadlec replied, “Is this true?! If so we have a huge whole [sic] on our screening and quarantine effort.”⁴⁶⁹ Just a few days earlier Dr. Mecher cautioned, “[w]hat has me worried is what happened on the [Diamond Princess] cruise ship is a preview of what will happen when this virus makes its way to the US healthcare system (not to mention institutionalized high-risk populations in the US, like nursing homes). I’m not sure that folks understand what is just over the horizon.”⁴⁷⁰

⁴⁶³ Interview with Dr. Robert Kadlec (Dec. 6, 2021); Dr. Mark McClellan, Former Centers for Medicare and Medicaid Services Commissioner (2004-2006) and Former FDA Commissioner (2002-2004), Interview with Senate Committee on Homeland Security and Governmental Affairs (Feb. 2, 2021); Interview with Dr. Anne Schuchat (Dec. 14, 2021); Interview with Olivia Troye (Dec. 8, 2021).

⁴⁶⁴ Interview with Olivia Troye (Dec. 8, 2021).

⁴⁶⁵ *Id.*

⁴⁶⁶ Dr. Robert Kadlec, Former Assistant Secretary for Preparedness and Response (Aug. 2017 - Jan. 2021), Interview with Senate Committee on Homeland Security and Governmental Affairs (Dec. 6, 2021).

⁴⁶⁷ Dr. Robert Redfield, Former Director of Centers for Disease Control and Prevention (Mar. 2018 - Jan. 2021), Interview with Senate Committee on Homeland Security and Governmental Affairs (Feb. 7, 2022).

⁴⁶⁸ Dr. Anne Schuchat, Former Deputy Director of Centers for Disease Control and Prevention (Sep. 2015 - May 2021) and Incident Manager of the COVID-19 Response (Mar. 20, 2020 – May 1, 2020), Interview with Senate Committee on Homeland Security and Governmental Affairs (Dec. 14, 2021).

⁴⁶⁹ Department of Health and Human Services, *Email from Dr. Robert Kadlec to Red Dawn Group* (Feb. 23, 2020) (on file with Committee).

⁴⁷⁰ *Id.*

Delayed Implementation of Community Mitigation Measures

The Administration did not begin implementing community mitigation measures until February 27, 2020, waited until March 16, 2020 to implement its first wide-scale attempt at nationwide mitigation, and took weeks after that to recommend the public wear cloth face masks, which did not occur until April 3, 2020.⁴⁷¹ With delayed and limited federal guidance, states began implementing their own community mitigation measures.⁴⁷² On March 16, 2020, President Trump announced “15 Days to Slow the Spread,” guidance intended to help protect Americans during the global Coronavirus outbreak.⁴⁷³

Delayed response efforts in the U.S. proved costly. On February 26, 2020, the CDC confirmed its first case of possible community spread and two days later, on February 28, the U.S. reported its first death from COVID-19.⁴⁷⁴ Dr. Helen Chu, a principal investigator for the laboratory that identified one of the early cases of COVID-19, told the Committee how the genetic sequencing they conducted suggested the virus had already been circulating through the community for five weeks.⁴⁷⁵ Later autopsies would reveal two California residents had died from the disease between one to three weeks earlier.⁴⁷⁶ None of these deceased patients had recently traveled internationally, indicating they had acquired the virus from community

⁴⁷¹ See Centers for Disease Control and Prevention, *Community Mitigation Guidance for COVID-19 Response in the United States: Nonpharmaceutical Interventions for Community Preparedness and Outbreak Response* (Feb. 27, 2020) (<https://web.archive.org/web/20200228190416/https://www.cdc.gov/coronavirus/2019-ncov/preparing-individuals-communities.html>); White House, *15 Days to Slow the Spread* (Mar. 16, 2020) (<https://trumpwhitehouse.archives.gov/articles/15-days-slow-spread/>); Centers for Disease Control and Prevention, *Recommendation Regarding the Use of Cloth Face Coverings, Especially in Areas of Significant Community-Based Transmission* (Apr. 3, 2020) (<https://web.archive.org/web/20200403233258/https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/cloth-face-cover.html>)

⁴⁷² See, e.g., Centers for Disease Control and Prevention, *Morbidity and Mortality Weekly Report: Timing of Community Mitigation and Changes in Reported COVID-19 and Community Mobility — Four U.S. Metropolitan Areas, February 26–April 1, 2020*, at 453 (69(15);451–457) (Apr. 17, 2020) (showing that Louisiana (March 11, 2020), New York (March 7, 2020), California (March 4, 2020), and Washington (February 29, 2020) were among the states that declared emergencies prior to President Trump’s March 20, 2020 announcement. Many of these states also implemented community mitigation measures before March 16, including the following: limits on mass gatherings, limits on senior living facilities, and school closures).

⁴⁷³ White House, *15 Days to Slow the Spread* (Mar. 16, 2020) (<https://trumpwhitehouse.archives.gov/articles/15-days-slow-spread/>).

⁴⁷⁴ Centers for Disease Control and Prevention, *CDC Confirms Possible Instance of Community Spread of COVID-19 in U.S.* (Feb. 26, 2020); Centers for Disease Control and Prevention, Transcript for the CDC Telebriefing Update on COVID-19 (Feb. 29, 2020).

⁴⁷⁵ Dr. Helen Chu, Associate Professor of Internal Medicine and Infectious Disease at the University of Washington, Principal Investigator of the Seattle Flu Study, Interview with Senate Committee on Homeland Security and Governmental Affairs (June 2, 2021) (hereinafter “Interview with Dr. Helen Chu (June 2, 2021)”).

⁴⁷⁶ *Coronavirus Death in California Came Weeks Before First Known U.S. Death*, The New York Times (Apr. 22, 2020) (www.nytimes.com/2020/04/22/us/coronavirus-first-united-states-death.html).

transmission.⁴⁷⁷ Subsequent research suggests that cases in the U.S. were present as early as January 7, 2020 and experts continue to examine whether there is evidence of earlier spread.⁴⁷⁸

As further discussed below, throughout the month of February 2020, operational efforts, such as repatriation, overshadowed strategic and long-term planning, which included the need to build testing capacity and mitigate anticipated PPE shortages. Dr. Mecher told the Committee, “it’s hard to flip the switch . . . there needed to be a ramp-up period” for bolstering testing, surveillance, and PPE in addition to preparing our healthcare systems for expected surges and preparing the public for the non-pharmaceutical interventions.”⁴⁷⁹ The Majority Committee staff found the federal government, however, did not use this critical time effectively.

D. Repatriation

U.S. law requires the Secretary of State to develop and implement policies and programs to provide for the safe and efficient evacuation of U.S. government personnel, their dependents, and private citizens when their lives are endangered.⁴⁸⁰ Between January 17 and June 10, 2020, the United States repatriated approximately 100,000 American citizens and 6,000 State Department employees and family members from more than 160 countries and dozens of cruise ships from around the world.⁴⁸¹ This number represents more than 90 times the number of individuals the State Department repatriated in 2019 and over 15 times the number of repatriated individuals coordinated by the State Department in the five years before the pandemic.⁴⁸² From January 28 to February 17, 2020, the U.S. government repatriated 808 U.S citizens from Hubei Province, China and 329 U.S. citizens from the Diamond Princess cruise ship docked in Yokohama, Japan.⁴⁸³ On March 19, 2020, the State Department established a Repatriation Task Force to assist with efforts to return citizens home to the U.S.⁴⁸⁴

⁴⁷⁷ Department of Health and Human Services, Centers for Disease Control and Prevention, *Washington State Report First COVID-19 Death*, Press Release (Feb. 29, 2020); Centers for Disease Control and Prevention, *Morbidity and Mortality Weekly Report: Evidence for Limited Early Spread of COVID-19 Within the United States, January–February 2020* (69(22);680–684) (June 5, 2020).

⁴⁷⁸ National Institutes of Health, *NIH study offers new evidence of early SARS-CoV-2 infections in U.S.* (June 15, 2021).

⁴⁷⁹ Interview with Dr. Carter Mecher (July 29, 2022).

⁴⁸⁰ 22 U.S.C § 4802(b).

⁴⁸¹ Department of State, *COVID-19 Interim Review: Lessons Learned from the Department of State’s Response to the COVID-19 Pandemic (December 19 - December 2020)*, at 4 (June 2021) (on file with Committee, STATE-2021-02-0000352).

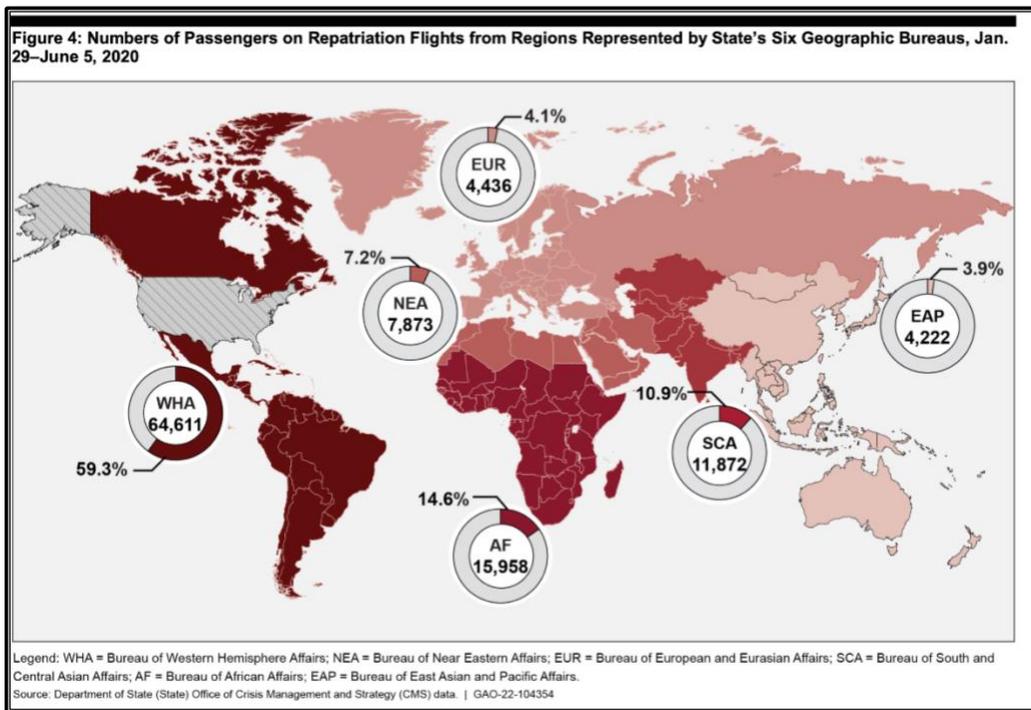
⁴⁸² Government Accountability Office, *COVID-19: State Carried Out Historic Repatriation Effort but Should Strengthen Its Preparedness for Future Crises*, at 9 (GAO-21-104354) (Nov. 2021).

⁴⁸³ Departments of State and Health and Human Services, *Joint Statement by U.S. Department of State and U.S. Department of Health and Human Services on Repatriation of American Passengers From the Diamond Princess Cruise Ship* (Feb. 17, 2020); Government Accountability Office, *COVID-19: HHS Should Clarify Agency Roles for Emergency Return of U.S. Citizens during a Pandemic*, at 2 (GAO-21-334) (Apr. 2021).

⁴⁸⁴ U.S Embassy and Consulates in Italy, Briefing with Senior State Department Official on Updates on State Department’s Response to COVID-19 (Mar. 24, 2020) (senior State Department official explained, “[o]n

ASPR, DOD, FEMA, CDC, HHS’s Administration for Children and Families (ACF), and the State Department all played a role in repatriation during the initial months of the pandemic. While the U.S. was successful in returning individuals home, problems with communication, interagency coordination, and inconsistent health guidance hampered the effectiveness of overall repatriation efforts. In some instances, as detailed below, these problems resulted in possible threats to the health and safety of U.S. citizens.⁴⁸⁵

Numbers of Passengers on Repatriation Flights from Regions Represented by State’s Six Geographic Bureaus, January 29–June 5, 2020⁴⁸⁶



According to an analysis conducted by GAO, there was a lack of clarity surrounding repatriation roles and responsibilities among agencies that created significant confusion during the initial response.⁴⁸⁷ In any repatriation effort, the State Department had the authority until a plane landed in the United States; however, who was responsible for implementing quarantine and other

March 19th, we stood up a 24/7 repatriation task force here in D.C. to coordinate and support those efforts”) (<https://it.usembassy.gov/briefing-with-senior-state-department-officials-on-covid-19-march-24-2020/>).

⁴⁸⁵ Government Accountability Office, *COVID-19: HHS Should Clarify Agency Roles for Emergency Return of U.S. Citizens during a Pandemic* (GAO-21-334) (Apr. 2021).

⁴⁸⁶ Government Accountability Office, *State Carried Out Historic Repatriation Effort but Should Strengthen its Preparedness for Future Crises*, at 12 (GAO-22-104354) (Nov. 2021).

⁴⁸⁷ Government Accountability Office, *COVID-19: HHS Should Clarify Agency Roles for Emergency Return of U.S. Citizens during a Pandemic*, at 15-22 (GAO-21-334) (Apr. 2021).

assistance after that remained unclear.⁴⁸⁸ State, CDC, and ACF officials told GAO that ASPR was in charge of repatriation effort. ASPR officials told GAO they were not the lead but, rather, a support to other HHS agencies.⁴⁸⁹

In an interview with the Committee, Jonathan Greene, Deputy Assistant Secretary and Director of the Office of Operations and Resources within the Assistant Secretary for Preparedness and Response, reiterated that ACF is the lone agency within HHS with a lead role over repatriation and that ASPR served only in a support role to secure and service quarantine locations.⁴⁹⁰ Dr. Kevin Yeskey, former Principal Deputy Assistant Secretary for Preparedness and Response, told the Committee that much of ASPR's responsibilities for COVID-19 repatriation fell outside their mission. He explained, "[w]e had to do meal service, transportation, take baggage off airplanes, take bags to rooms, provide security . . . because ACF said individuals were repatriated only after they go through quarantine."⁴⁹¹ Dr. Schuchat told Committee staff that the CDC's authority was to "oversee the federal quarantine process, but [their] understanding was that ASPR was in charge of repatriation." CDC was not in a position to handle all the contracts necessary to support repatriation efforts, like fencing and food services.⁴⁹²

State Personnel Greeting Passengers and Collecting Information before Repatriation Flights in India⁴⁹³



In addition to unclear leadership structures for repatriation, the Administration also lacked a large-scale and well-integrated plan for the quarantine of repatriated travelers. HHS began requesting assistance from DOD as early as January 29, 2020 to house repatriated

⁴⁸⁸ *See id.*

⁴⁸⁹ *Id.* at 18-19.

⁴⁹⁰ Jonathan Greene, Deputy Assistant Secretary and Director of the Office of Operations and Resources, Office of the Assistant Secretary for Preparedness and Response (July 2020 - current) and Former Director of Emergency Management and Medical Operations at the Office of Assistant Secretary for Preparedness and Response (June 2019 - July 2020), Interview with Senate Committee on Homeland Security and Governmental Affairs (July 8, 2021) (hereinafter "Interview with Jonathan Greene (July 8, 2021)").

⁴⁹¹ Interview with Dr. Kevin Yeskey (Nov. 17, 2021 and Dec. 2, 2021).

⁴⁹² Interview with Dr. Anne Schuchat (Dec. 14, 2021).

⁴⁹³ Government Accountability Office, *State Carried Out Historic Repatriation Effort but Should Strengthen Its Preparedness for Future Crises*, at 30 (Figure 7) (GAO-22-104354) (Nov. 2021).

Americans.⁴⁹⁴ In some instances, housing repatriated citizens at U.S. military installations displaced military families.⁴⁹⁵ In an interview with Committee staff, Dr. Schuchat noted, “we had a patchwork of plans, but no investment or planning to put large numbers of people in temporary housing. A key problem within our control was the inability to have automated sharing of traveler contact information.”⁴⁹⁶ As a result, even when CDC knew certain travelers were in contact with others who were infected, they did not have the ability to share this information quickly with local public health departments who could have alerted travelers that they were exposed and followed-up on their health status.

Confusion also stemmed from HHS Office of General Counsel’s (OGC) determination that flights from Wuhan, China were not “a repatriation” but instead an “evacuation and quarantine,” placing the authority within CDC.⁴⁹⁷ According to GAO, CDC claims this determination, “which would have had significant implications,” was not communicated to them.⁴⁹⁸ By categorizing the flights as “evacuation and quarantine,” funds from the U.S. Repatriation Program were not used for repatriation efforts.⁴⁹⁹ Another issue that caused confusion was the differing systems that the State Department and CDC used to issue travel advisories, a problem that has since been resolved through both agencies “adopt[ing] a common standard warning system, clarifying travelers’ questions while ensuring that the U.S. government can communicate a unified message regarding U.S. citizens’ health and security welfare.”⁵⁰⁰

In addition, conflicting State Department policies and pandemic planning documents provided divergent repatriation guidance and created confusion.⁵⁰¹ Ambassador Jess L. Baily who led the State Department’s internal review of the agency’s COVID-19 interim review told the Committee, “it was a very unusual crisis for the State Department.”⁵⁰² The State Department’s June 2021 internal review found that varying guidance, planning documents, and other shifts led to

⁴⁹⁴ Department of Defense, *Letter from HHS Secretary Alex M. Azar to DOD Secretary Mark T. Esper* (Jan. 29, 2020) (on file with Committee, Production 7, 0002).

⁴⁹⁵ See Federal Emergency Management Agency, *Email from FEMA official to FEMA and DHS officials* (Feb. 1, 2020) (noting “DoD has informed military personnel in current housing at these bases the requirement to move into hotels in town in order to make room for the US evacuees”) (on file with Committee, HSGAC 1686-1687).

⁴⁹⁶ Interview with Dr. Anne Schuchat (Dec. 14, 2021).

⁴⁹⁷ Government Accountability Office, *COVID-19: HHS Should Clarify Agency Roles for Emergency Return of U.S. Citizens during a Pandemic*, at 15 (GAO-21-334) (Apr. 2021).

⁴⁹⁸ Government Accountability Office, *COVID-19: HHS Should Clarify Agency Roles for Emergency Return of U.S. Citizens during a Pandemic*, at 14-15 (GAO-21-334) (Apr. 2021). See also Government Accountability Office, *Biodefence: After-Action Findings and COVID-19 Response Revealed Opportunities to Strengthen Preparedness* (GAO-21-513) (Aug. 2021).

⁴⁹⁹ *Id.*

⁵⁰⁰ Department of State, *COVID-19 Interim Review: Lessons Learned from the Department of State’s Response to the COVID-19 Pandemic* (June 2021) (on file with Committee, STATE-2021-02-0000405).

⁵⁰¹ *Id.* at STATE-2021-02-0000402.

⁵⁰² Department of State, Briefing with Senate Committee on Homeland Security and Governmental Affairs Staff (Sept. 29, 2021) (hereinafter “State Department Briefing (Sept. 29, 2021)”).

“uncertainty over what scenarios warranted a large-scale repatriation operation, as well as the level of ‘immediate danger’ or ‘destitution’ that triggered a Department-facilitated repatriation.”⁵⁰³ The document also raised concerns regarding citizens’ ability to shelter in place while on short-term visits, logistics of return flights, and the financial burden incurred by the Department.⁵⁰⁴ The cost of the COVID-19-related repatriation efforts (\$250 million), according to the State Department, “is financially unsustainable for ... the Department as a whole.”⁵⁰⁵

The lack of clarity as to who was in charge of certain repatriation efforts once planes landed in the United States—ACF, CDC or ASPR—and the absence of clear operational guidance led to several missteps, including significant safety risks. For example, CDC and ASPR disagreed on whether to transport individuals who had not tested positive for COVID-19 with those who had tested positive for the virus. According to then ASPR Dr. Kadlec, he almost “came to blows” with a senior CDC official over roles and responsibilities regarding the Diamond Princess cruise ship repatriation. Dr. Kadlec told the Committee that CDC was attempting to conduct operations ASPR was leading, but “CDC didn’t understand how to and who was making operational decisions.”⁵⁰⁶ State and ASPR leadership ultimately chose to fly all individuals back together.⁵⁰⁷ According to GAO, State Department officials noted that both ASPR and CDC leadership approved flying COVID-19 positive repatriates with those who tested negative; however, reports indicate that CDC expressed significant concerns.⁵⁰⁸ Once the repatriates were back in the U.S. and taken to DOD facilities for quarantine, there was no federal quarantine order in place initially to prevent repatriates from leaving the facilities and potentially spreading COVID-19 to others.⁵⁰⁹

The Committee also learned of concerns regarding the reporting of COVID-19 test results to repatriated individuals in February 2020. According to Dr. Stephen Lindstrom, then Team Lead for the Respiratory Viruses Diagnostic Team within CDC, instead of waiting for the test results to be reported to state public health labs, as required by federal regulations, CDC prematurely released results for certain repatriated Americans, which in one instance resulted in providing inaccurate information.⁵¹⁰ According to CDC, test results for repatriated evacuees “were either communicated verbally or in writing in addition to the standard secure [reporting system] pathways” and when

⁵⁰³ Department of State, *COVID-19 Interim Review: Lessons Learned from the Department of State’s Response to the COVID-19 Pandemic* (June 2021) (on file with Committee, STATE-2021-02-0000402–0000403).

⁵⁰⁴ *Id.*

⁵⁰⁵ *Id.*

⁵⁰⁶ Interview with Dr. Robert Kadlec (Dec. 6, 2021).

⁵⁰⁷ Government Accountability Office, *COVID-19: HHS Should Clarify Agency Roles for Emergency Return of U.S. Citizens during a Pandemic*, at 19 (GAO-21-334) (Apr. 2021).

⁵⁰⁸ *Id.*

⁵⁰⁹ *Id.* at 18.

⁵¹⁰ Dr. Stephen Lindstrom, Research Microbiologist, Office of the Director, Division of Viral Diseases (July 2020 – present) and Former Team Lead, Respiratory Viruses Diagnostic Team, Respiratory Viruses Branch (Aug. 2018 – July 2020), Interview with Senate Committee on Homeland Security and Governmental Affairs (Feb. 15, 2022) (hereinafter “Interview with Dr. Stephen Lindstrom (Feb. 15, 2022)”).

“verbal and email test results were shared . . . these reports were documented and shared with [the Centers for Medicare and Medicaid Services] as non-conforming events.”⁵¹¹

GAO found that “HHS was not prepared for a repatriation event in response to a pandemic, because the department and component agencies had not exercised that scenario.”⁵¹² HHS senior official Jonathan Greene who led ASPR’s repatriation efforts acknowledged challenges with the initial repatriation efforts, and noted that HHS “never expected to repatriate at this scale and scope . . . HHS never trained for it, never thought about it.”⁵¹³ State Department repatriation officials said they were “latched up” with CDC officials and that while there may have been some “initial debates about quarantine, there was never a confusion—it was an honest discussion.”⁵¹⁴ Mr. Greene told the Committee, “[w]e did the best we could to bring people back safely.”⁵¹⁵

II. Changes in Federal Agency Roles and Responsibilities

Throughout the first three months of the federal response starting in January 2020, the Administration shifted overall responsibilities for the federal pandemic response from HHS to the White House and later to FEMA. Former CDC Chief of Staff, Kyle McGowan, told the Committee “one of the biggest failings we had in this response was the constant changing of who is in charge. You would never fight a war that way. Why would you fight a pandemic that way?”⁵¹⁶

In multiple interviews with the Committee, current and former officials acknowledged insufficient coordination and leadership changes resulted in delay, confusion as to who was in charge when, and conflicting priorities and public guidance. Despite a need to change course, many senior officials interviewed by this Committee could not provide explanations for the shifts in leadership and some noted that they learned of the change after it occurred, at times through media reports.⁵¹⁷ Although some former officials described initial confusion resulting from the shifts in leadership, others stressed the growing seriousness and novelty of the pandemic as a reason for the changes.

⁵¹¹ Dr. Wendi Kuhnert, Senior Advisor for Laboratory Science at the Centers for Disease Control and Prevention (2019 – present) (CDC service 2001-present), Written Responses to Homeland Security and Governmental Affairs Staff (received Aug. 5, 2022).

⁵¹² Government Accountability Office, *Biodefence: After-Action Findings and COVID-19 Response Revealed Opportunities to Strengthen Preparedness*, at 42 (GAO-21-513) (Aug. 2021). See also Government Accountability Office, *COVID-19: HHS Should Clarify Agency Roles for Emergency Return of U.S. Citizens during a Pandemic*, at 20 (GAO-21-334) (Apr. 2021).

⁵¹³ Interview with Jonathan Greene (July 8, 2021).

⁵¹⁴ Department of State, Briefing with Senate Committee on Homeland Security and Governmental Affairs Staff (July 26, 2021).

⁵¹⁵ Interview with Jonathan Greene (July 8, 2021).

⁵¹⁶ Interview with Kyle McGowan (Dec. 2, 2021).

⁵¹⁷ Interview with Dr. Daniel Jernigan (Dec. 15, 2021); Interview with Olivia Troye (Dec. 8, 2021); Interview with Nicholas Uehlecke (Nov. 4, 2021).

While the scope and severity of the COVID-19 pandemic brought—and continues to bring—unprecedented challenges to federal response efforts that necessitated changes in planning and strategy, the Majority Committee staff found that continually shifting leadership roles and structures during the initial federal response contributed to coordination problems, avoidable delay, and a lack of accountability. Compounding this confusion is a longstanding lack of clarity in the roles and responsibilities between CDC and ASPR, which resulted in many senior officials being unclear on agency responsibilities.⁵¹⁸ Multiple officials interviewed by the Committee agreed that by February, the pandemic was not just a public health problem: COVID-19 was beginning to affect a wide segment of the country and required a whole of government response.⁵¹⁹

As detailed in Table 9 below and throughout the section, the federal government set up additional emergency response structures as the virus continued to spread.

Table 9. Activation of Federal Emergency Response Structures

Date	Agency	Response Structure
January 6, 2020	HHS-CDC, National Center for Immunization and Respiratory Diseases	Incident Management Structure
January 21, 2020	HHS-CDC	Emergency Operations Center
January 24, 2020	HHS-ASPR	Secretary’s Operations Center
January 31, 2020	Executive Office of the President	White House Coronavirus Task Force
March 5, 2020	DHS-FEMA	National Resource Coordination Center

A. Jan. 2020: Activation of Emergency Operations Centers

On January 3, 2020, former HHS Secretary Azar directed HHS to notify the National Security Council (NSC) of the “emergence of a suspected novel coronavirus.”⁵²⁰ In response to the emerging novel coronavirus threat, CDC stood up an Incident Management Structure (IMS) out of their National Center for Immunization and Respiratory Diseases (NCIRD), led by Dr. Messonnier, then Director of NCIRD, on January 7, 2020.⁵²¹ Dr. Schuchat, who at the time

⁵¹⁸ See e.g., Government Accountability Office, *COVID-19: HHS Should Clarify Agency Roles for Emergency Return of U.S. Citizens during a Pandemic* (GAO-21-334) (Apr. 2021).

⁵¹⁹ See e.g. Interview with David Bibo (Dec. 21, 2021); Interview with Joseph Grogan (Jan. 25, 2022); Interview with Olivia Troye (Dec. 8, 2021); Interview with Dr. Kevin Yeskey (Nov. 17, 2021 and Dec. 2, 2021); Paul Mango, Former Deputy Chief of Staff for Policy at Department of Health and Human Services (July 2019 - Jan. 2021, Interview with Senate Committee on Homeland Security and Governmental Affairs (Nov. 17, 2021) (hereinafter “Interview with Paul Mango (Nov. 17, 2021)”).

⁵²⁰ Alex Azar Interrogatories (Mar. 1, 2022).

⁵²¹ Interview with Dr. Nancy Messonnier (Jan. 5, 2022); Department of Health and human Services, Center for Disease Control and Prevention, *Initial Public Health Response and Interim Clinical Guidance for the 2019 Novel Coronavirus Outbreak — United States, December 31, 2019–February 4, 2020*, at 141 (Vol. 69, Num. 5) (Feb. 7, 2020) (www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6905e1-H.pdf); Department of Health and Human

served as CDC’s Principal Deputy Director, told the Committee that the “IMS is a formal approach to dealing with a complex emergency—it’s flexible and it scales.”⁵²² At that time, CDC’s mission was to “prepare[] domestically for potential novel pneumonia cases in the US and provide[] support in order to understand the current outbreak in Wuhan, China.”⁵²³

After confirming the first U.S. case of COVID-19, CDC activated its Emergency Operations Center (EOC) on January 21, 2020 to set up an agency level response.⁵²⁴ Shortly thereafter, on January 23, CDC changed its mission statement to prevent additional COVID-19 cases in the United States and work with international and domestic partners on virus mitigation measures.⁵²⁵ CDC’s EOC set up task forces, many of which worked with SLTT partners, including state and local health departments.⁵²⁶ Dr. Schuchat explained CDC’s focus at that time was to “support the state and local health departments that have the jurisdictions over their area to detect, respond to, and prevent spread of the virus.”⁵²⁷

On January 24, HHS activated its Secretary’s Operations Center, located at ASPR in response to the evolving threat. HHS also set up six task forces to organize response efforts: medical countermeasures, health care resilience, repatriation, incident management, supply chain, and communications.⁵²⁸ According to Jessica Falcon, who serves as Director of ASPR’s Office of Security, Intelligence, and Information Management, these task forces were “never fully developed” and “there was no permanent structure at ASPR for the COVID-19 response at

Services, Centers for Disease Control and Prevention, *2020 Pneumonia Response Initial IM Update: NCIRD Center Level Response- Day 2* (Jan. 7, 2020) (on file with Committee, HSGAC-0039827-0039841).

⁵²² Interview with Dr. Anne Schuchat (Dec. 14, 2021).

⁵²³ Department of Health and Human Services, Centers for Disease Control and Prevention, *2020 Pneumonia Response Initial Update* (Jan. 6, 2020) (on file with Committee, HSGAC-0039857).

⁵²⁴ Interview with Dr. Daniel Jernigan (Dec. 15, 2021); Department of Health and Human Services, Centers for Disease Control and Prevention, *2019 nCoV Response Incident Manager Meeting* (Jan. 21, 2020) (on file with Committee, HSGAC-0039782).

⁵²⁵ Department of Health and Human Services, Centers for Disease Control and Prevention, *2019 Novel Coronavirus (nCoV) IM Update: Response Day 17* (Jan. 23, 2020) (on file with Committee, HSGAC-0038859) (stating that, “CDC will implement strategies to prevent additional cases of nCoV in the United States. CDC will coordinate with international and domestic partners to provide clinical and infection control guidance and implement other methods to mitigate the impact of this virus”).

⁵²⁶ Department of Health and Human Services, Centers for Disease Control and Prevention, *2019 Novel Coronavirus (nCoV) IM Update: Response Day 17* (Jan. 23, 2020) (on file with Committee, HSGAC-0038860).

⁵²⁷ Interview with Dr. Anne Schuchat (Dec. 14, 2021).

⁵²⁸ Department of Health and Human Services, *PanCAP Adapted, U.S. Government COVID-19 Response Plan*, at 8 (Mar. 13, 2020) (on file with Committee, DHS FEMA 6-108). Department of Health and Human Services, Assistant Secretary for Preparedness and Response, *2019 Novel Coronavirus (2019 nCoV) – ASPR Senior Leadership Brief* (Jan. 31, 2020) (on file with Committee, HSGAC-0037207).

that time.”⁵²⁹ As cases began to rapidly spread across the globe, FEMA activated its National Resource Coordination Center on March 5, 2020 to further support response efforts.⁵³⁰

B. Jan. 14 – 29, 2020: National Security Council Coordination

Beginning on January 14, the NSC coordinated federal response efforts through daily Policy Coordinating Committee (PCC) meetings, which were attended by multiple federal agencies at the assistant secretary level.⁵³¹ Mr. Pottinger, who served as Deputy National Security Advisor, told the Committee, “I authorized [these meetings] to keep trying to pump our intelligence community, CDC, and international partners for information.” The following week, Mr. Pottinger initiated and chaired deputy cabinet level meetings as the threat continued to evolve.⁵³²

Former CDC Chief of Staff Kyle McGowan explained that the NSC “was designed to be a coordinating factor between the White House, DOD, and the State Department for international affairs and complex incidents.” Although there are imperfections, Mr. McGowan stated, “it is a structure that everyone knows, recognizes, and allows for an outlet to move forward.”⁵³³ Mr. McGowan described the structure as one where decisions are made from the bottom up, with career officials problem solving and proposing recommendations that are eventually brought to the principals for a discussion and ultimate decisions.⁵³⁴

Although the NSC provided a structure and forum for debate and decision-making, what remained unclear during this time period was the distribution of roles and responsibilities between ASPR and CDC. Based on Committee interviews with current and former officials from CDC, ASPR, and DHS who were involved in the initial federal response, there was no consensus on which HHS agency was leading certain federal response efforts—a problem that extended far beyond the federal government and trickled down to SLTT partners and the private sector.⁵³⁵

Melissa Harvey, then Director of Health Systems at DHS, told the Committee that “it was unclear from the beginning whether CDC or ASPR was in charge.” She described receiving questions from the private sector, like hospitals, asking who was leading certain efforts, such as

⁵²⁹ Jessica Falcon, Director of Security, Intelligence, and Information Management at Assistant Secretary for Preparedness and Response (Jan. 2019 – Sept. 2022), Interview with Senate Committee on Homeland Security and Governmental Affairs (July 22, 2021) (hereinafter “Interview with Jessica Falcon (July 22, 2021)”).

⁵³⁰ Interview with David Bibo (Dec. 21, 2021).

⁵³¹ Interview with Matthew Pottinger (Jan. 25, 2022).

⁵³² *Id.*

⁵³³ Interview with Kyle McGowan (Dec. 2, 2021).

⁵³⁴ *Id.*

⁵³⁵ Interview with Melissa Harvey (Nov. 3, 2021); Interview with Dr. Robert Kadlec (Dec. 6, 2021); Interview with Dr. Anne Schuchat (Dec. 14, 2021); Interview with Dr. Kevin Yeskey (Nov. 17, 2021 and Dec. 2, 2021); Interview with Dr. Laura Wolf (Nov. 30, 2021).

supply chain issues.⁵³⁶ Dr. Laura Wolf, then Director of ASPR’s Critical Infrastructure Protection Division, told the Committee that “before FEMA took over, there was confusion as to who was leading between ASPR and CDC.” She explained that there was “some structure for certain things” like repatriation, but confusion in other areas.⁵³⁷ Dr. Schuchat, told the Committee that “the Secretary might have said ASPR was in charge, but that wasn’t how the response was operating [and] ASPR was not focused on the broader strategic landscape.”⁵³⁸

When the Committee asked then ASPR, Dr. Robert Kadlec, about the division of roles and responsibilities, he acknowledged, “there was ambiguity [about] who was in charge” and noted, “this deficiency was highlighted prior to the pandemic with the exercise Crimson Contagion conducted in the Fall of 2019.”⁵³⁹ This lack of clarity, combined with longstanding tension between ASPR and CDC, created challenges within the agencies that affected response efforts. Former Principal Deputy Assistant for Preparedness and Response Dr. Kevin Yeskey told the Committee, “when there is infighting within leadership, whether it’s public or not, it affects morale. Those problems require interventions and that wasn’t happening.”⁵⁴⁰

C. Jan. 29 – Feb. 26, 2020: HHS Leads through White House Task Force

On January 29, 2020, the White House announced the President’s Coronavirus Task Force (“White House Task Force”), a multi-agency group, tasked with leading the federal response to the pandemic. Comprised of twelve senior officials from National Security Council, DHS, HHS, Department of State, and Department of Transportation, among other agencies, the Task Force’s objective was to “lead the Administration’s efforts to monitor, contain, and mitigate the spread of the virus.”⁵⁴¹ HHS Secretary Azar chaired the White House Task Force, which was coordinated through the National Security Council.⁵⁴² According to then Deputy National Security Advisor Matthew Pottinger, the leadership structure in place before the establishment of the White House Task Force was inadequate to deal with the growing

⁵³⁶ Interview with Melissa Harvey (Nov. 3, 2021).

⁵³⁷ Interview with Dr. Laura Wolf (Nov. 30, 2021).

⁵³⁸ Interview with Dr. Anne Schuchat (Dec. 14, 2021).

⁵³⁹ Interview with Dr. Robert Kadlec (Dec. 6, 2021).

⁵⁴⁰ Interview with Dr. Kevin Yeskey (Nov. 17, 2021 and Dec. 2, 2021).

⁵⁴¹ Press Secretary, White House, Statement from the Press Secretary Regarding the President’s Coronavirus Task Force (Jan. 29, 2020) (Dr. Hahn (FDA commissioner) and Dr. Kadlec (ASPR) were not in the initial group of representatives on the Task Force); *See also* Alex Azar Interrogatories (Mar. 1, 2022) (noting that, Dr. Kadlec, as the head of ASPR, was “inadvertently excluded from the initial list of participants,” and Dr. Hahn was later added to the task force “on or around March 1, 2020”).

⁵⁴² White House, Statement from the Press Secretary Regarding the President’s Coronavirus Task Force (Jan. 29, 2020) (<https://trumpwhitehouse.archives.gov/briefings-statements/statement-press-secretary-regarding-presidents-coronavirus-task-force/>). Secretary Azar clarified to the Committee that while HHS had a “critical role within the Task Force,” the Task Force “was always run by a White House official, as no Cabinet secretary can command the efforts of peer Cabinet colleagues.” Secretary Azar stated that the Task Force did not create new direct reports for him and he continued to report directly to the President. *See* Alex Azar Interrogatories (Mar. 1, 2022).

pandemic: “[w]e needed to elevate coordination to someone higher than an assistant [secretary] level,” explaining the need for the HHS Secretary to lead the White House Task Force.⁵⁴³

Joe Grogan, then Director of the White House Domestic Policy Council, told the Committee that “it was important to have one person who was focused on [the COVID-19 response], who would be solely responsible for coordinating [the response and] who was experienced in communication, management, and had a political sense.”⁵⁴⁴ While Mr. Grogan initially recommended the White House institute a czar, he told the Committee that a czar and a task force could coexist. Ultimately, he agreed with the decision to form the White House Task Force.⁵⁴⁵

ASPR and FDA were originally not represented on the White House Task Force.⁵⁴⁶ Mr. Azar explained that Dr. Kadlec, as the head of ASPR, was “inadvertently excluded from the initial list of participants” and was later added, given that the ASPR “is the Incident Manager for Emergency Support Function 8.”⁵⁴⁷ Mr. Azar noted that because the FDA Commissioner reports to the HHS Secretary, he was not immediately added to the Task Force.⁵⁴⁸ On March 1, 2020, the White House added the FDA Commissioner to the Task Force.⁵⁴⁹

ASPR and CDC officials told the Committee that the shift to HHS as the lead federal agency in charge resulted in confusion. Then CDC Chief of Staff Kyle McGowan described the transition as a restructuring that eliminated the previous forum to discuss critical policy issues: “with HHS, the meetings were more about these are statements of fact that we will not be debating because we’ve all settled on it.” He explained how the bottom-up decision-making process—with lower level subject matter experts engaged in “healthy discussions” to provide decision makers “better recommendations”—became a top-down structure where disagreement was not permitted. According to Mr. McGowan, although there were daily calls, they were informational in nature.⁵⁵⁰ Dr. Schuchat echoed these concerns. In an interview with the Committee, she said “the period of early February revolved around challenges on repatriation and airports” and noted the difficulty in focusing on critical policy issues like supply chain or

⁵⁴³ Interview with Matthew Pottinger (Jan. 25, 2022).

⁵⁴⁴ Interview with Joseph Grogan (Jan. 25, 2022).

⁵⁴⁵ *Id.*

⁵⁴⁶ White House, Statement from the Press Secretary Regarding the President’s Coronavirus Task Force (Jan. 29, 2020) (<https://trumpwhitehouse.archives.gov/briefings-statements/statement-press-secretary-regarding-presidents-coronavirus-task-force/>).

⁵⁴⁷ Alex Azar Interrogatories (Mar. 1, 2022); *see also* Federal Emergency Management Agency, *Emergency Support Function #8 – Public health and Medical Services Annex* (June 2016) (www.fema.gov/sites/default/files/2020-07/fema_ESF_8_Public-Health-Medical.pdf) (Emergency Support Function 8 “provides planning and coordination of Federal public health, healthcare delivery, and emergency response systems,” among other related tasks).

⁵⁴⁸ Alex Azar Interrogatories (Mar. 1, 2022).

⁵⁴⁹ *Id.*

⁵⁵⁰ Interview with Kyle McGowan (Dec. 2, 2021).

mitigation: “it was more about which Congressman was upset or what was in the news or if we could follow-up on something.”⁵⁵¹

Former officials and experts told the Committee that HHS’s fragmented structure presented difficulties in leading such a complex and multi-faceted response.⁵⁵² HHS requested support from FEMA in early February to assist with response efforts. Dr. Yeskey told the Committee “[ASPR] needed the ability and the expertise to convene the federal interagency in a more meaningful way.”⁵⁵³ He continued, “FEMA is responsible for convening the federal interagency in the case of an emergency [and while] HHS has a lot of experience in management, coordinating federal interagency partners is not something HHS has much experience in, so we invited FEMA to help.”⁵⁵⁴

Former FEMA Administrator Pete Gaynor noted that HHS’s request for FEMA personnel (in February 2020) originated at the “operator level,” which demonstrated the regularity of these operational relationships between HHS and FEMA.⁵⁵⁵ As early as February 7, HHS began planning how it would organize its response as lead federal agency in coordination with FEMA. In an email dated February 7, 2020, an ASPR senior official wrote, “current concept is that we/HHS would lead functional elements but receive augmentation and/or LNOs [liaison officers] from FEMA and ESF’s as required which would likely be scalable to expand and contract as required.”⁵⁵⁶ According to a February 8, 2020 DHS report, the agency determined that in the event of a pandemic, the federal government would use the “DHS/HHS Pandemic Crisis Action Plan (PanCAP 2018)” as the “base document,” which was reviewed by National Security Council, specifically the Weapons of Mass Destruction (WMD) and Resilience Directorates.⁵⁵⁷

On February 7, 2020 FEMA announced it would activate personnel to support HHS as the lead federal agency.⁵⁵⁸ On February 10, FEMA deployed a Crisis Action Planning team, led

⁵⁵¹ Interview with Dr. Anne Schuchat (Dec. 14, 2021).

⁵⁵² Interview with David Bibo (Dec. 21, 2021); Interview with Josh Dozor (June 7, 2021 and July 27, 2021); Interview with Dr. Robert Kadlec (Dec. 6, 2021); Interview with Dr. Kevin Yeskey (Nov. 17, 2021 and Dec. 2, 2021).

⁵⁵³ Interview with Dr. Kevin Yeskey (Nov. 17, 2021 and Dec. 2, 2021).

⁵⁵⁴ *Id.*

⁵⁵⁵ Interview with Pete Gaynor (June 9, 2021).

⁵⁵⁶ Federal Emergency Management Agency, *Email from Planning Division Director, Office of Strategy, Policy, Planning and Requirements (ASPR) to ASPR and CDC officials* (Feb. 7, 2020) (on file with Committee, HSGAC-001698).

⁵⁵⁷ Department of Homeland Security, *DHS National Operations Center 2019-nCoV Placemat* (Feb. 8, 2020) (on file with Committee). The 2018 PanCAP designated HHS as the lead federal agency for “federal public health and medical response, which includes pandemic. The federal interagency supports HHS, as requested, to assist [SLTT] partners with related preparedness and response activities.” Federal Emergency Management Agency, *Pandemic Crisis Action Plan, Version 2.0* (Jan. 2018).

⁵⁵⁸ Department of Homeland Security, Federal Emergency Management Agency, *Operations Order #03-2020: Novel Coronavirus – FEMA Support to HHS* (Feb. 7, 2020) (on file with Committee, HSGAC-001703).

by Josh Dozor, then Deputy Assistant Administrator for Response and NRCC Chief, to HHS.⁵⁵⁹ According to David Bibo, then Deputy Associate Administrator for Response and Recovery, Mr. Dozor was one of FEMA’s “most capable interagency operators” who could “bridge the divide between policy and operations.”⁵⁶⁰ The goal of FEMA’s Crisis Action Planning team was to establish and reinforce interagency coordination, assist with public affairs, and build situational awareness across the federal government.⁵⁶¹ Mr. Dozor noted that although HHS is large, “few personnel are able to be deployed by ASPR,” leaving HHS to “depend on FEMA’s staff.”⁵⁶²

Also on February 10, HHS requested the activation of liaisons from Customs and Border Protection (CBP), Transportation Security Administration (TSA), and the United States Coast Guard (USCG) to support its response efforts out of the Secretary Operations Center.⁵⁶³ During this time, an internal planning document dated February 12, 2020 noted that HHS had yet to: (1) “anticipate Strategic National Stockpile (SNS) efficacy and possible deployments to support Federal Points of Distribution/ Dispensing,” (2) “acquire funding to meet objective mission requirements,” and (3) “Utilize Inter Agency Agreements (IAAs) with other Federal Departments/Agencies to execute requires for Federal-to-Federal Support.”⁵⁶⁴ The document also noted CDC had not yet “identif[ied] a source of financial support for States and localities to carry out response [efforts]” among other tasks.⁵⁶⁵

On February 14, FEMA rostered 56 four-person Incident Management Assistance Teams (IMATs) in the event of needed support.⁵⁶⁶ On February 24, FEMA issued Operations Order 05-2020, which deployed additional personnel in support of FEMA’s Crisis Action Planning Team.⁵⁶⁷ The Order noted, “COVID-19 presents immediate operational consideration for how the Agency will execute Stafford Act operations in a pandemic environment.”⁵⁶⁸ Former

⁵⁵⁹ *Id.*; Interview with David Bibo (Dec. 21, 2021).

⁵⁶⁰ Interview with David Bibo (Dec. 21, 2021).

⁵⁶¹ Interview with Josh Dozor (June 7, 2021 and July 27, 2021).

⁵⁶² *Id.*

⁵⁶³ Department of Homeland Security, *DHS National Operations Center Coronavirus Placemat* (Feb. 12, 2020) (on file with Committee).

⁵⁶⁴ Department of Homeland Security, *Appendix A to FACT SHEET on Status of Federal Response Actions to 2019-nCoV IAW Pandemic Crisis Action Plan (PANCAP)* (Feb. 12, 2020) (on file with Committee, HSGAC-001704).

⁵⁶⁵ Department of Homeland Security, *Appendix A to FACT SHEET on Status of Federal Response Actions to 2019-nCoV IAW Pandemic Crisis Action Plan (PANCAP)* (Feb. 12, 2020) (on file with Committee, HSGAC-001704).

⁵⁶⁶ Department of Homeland Security, *DHS National Operations Center COVID-19 Placemat* (Feb. 14, 2020) (on file with Committee).

⁵⁶⁷ Department of Homeland Security, *Operations Order #05-2020: FEMA Pandemic Readiness Planning Support* (Feb. 24, 2020) (on with Committee, HSGAC-001715).

⁵⁶⁸ Department of Homeland Security, *Operations Order #05-2020: FEMA Pandemic Readiness Planning Support* (Feb. 24, 2020) (on with Committee, HSGAC-001715).

Administrator Gaynor told the Committee that FEMA’s regional preparedness response structure allowed the agency to act quickly through its regional offices.⁵⁶⁹

During this time, HHS and FEMA—at the NSC’s request—revised the 2018 version of the Pandemic Crisis Action Plan (PanCAP), which provided an operational guide for federal interagency response efforts, and created a new COVID-19 specific plan in early March 2020, known as the Pandemic Crisis Action Plan Adapted, or PanCAP-A.⁵⁷⁰ According to Mr. Bibo, “all the options in the PanCAP anticipated FEMA playing some sort of role and we assumed that role would get more substantial as things progressed.”⁵⁷¹

D. Feb. 26 – Mar. 17, 2020: Vice President Leads through White House Task Force

On February 26, 2020, President Trump shifted leadership of the federal response from HHS Secretary Azar to Vice President Pence. Mr. Grogan told the Committee that the decision was made because “we recognized this was not just going to be a public health problem . . . it was going to affect all of American life.” In Mr. Grogan’s view, “Vice President Pence understood those points of view and the needs of what a governor would want. He had impact and impeccable integrity. He also had bandwidth.”⁵⁷² According to Mr. Grogan, this shift in leadership “reflected the gravity of the situation.” Olivia Troye, then Special Advisor to Vice President Pence, told the Committee the White House was “concerned about mixed messages” and made the shift in leadership to the Vice President “to make sure they had full control of the messaging in terms of the response.”⁵⁷³

Transition from HHS to Vice President Pence

Officials interviewed by the Committee stated that the execution of leadership changes were sudden and poorly planned, noting some government officials learned of the changes through the media.⁵⁷⁴ Former HHS Secretary Azar told the Committee that he learned of Vice President Pence’s appointment “on the evening of February 26 from the Chief of Staff during a conversation at the White House.”⁵⁷⁵ Then CDC Director Dr. Redfield told the Committee that he learned of the shift “just prior to the public announcement” and “has no personal knowledge

⁵⁶⁹ Interview with Pete Gaynor (June 9, 2021).

⁵⁷⁰ Department of Health and Human Services, *PanCAP Adapted, U.S. Government COVID-19 Response Plan* (Mar. 13, 2020) (on file with Committee, DHS FEMA 6-108). The PanCAP-A also designated HHS to serve as the lead federal agency, “consistent with the Pandemic and All Hazards Preparedness Act (PAHPA) and Presidential Policy Directive (PPD) 44.” *Id.*

⁵⁷¹ Interview with David Bibo (Dec. 21, 2021).

⁵⁷² Interview with Joseph Grogan (Jan. 25, 2022).

⁵⁷³ Interview with Olivia Troye (Dec. 8, 2021). *See also* Section VII (Communications).

⁵⁷⁴ Interview with Dr. Daniel Jernigan (Dec. 15, 2021); Interview with Nicholas Uehlecke (Nov. 4, 2021).

⁵⁷⁵ Alex Azar Interrogatories (Mar. 1, 2022).

of the reason for the change in leadership.”⁵⁷⁶ Dr. Kadlec, then ASPR, told the Committee he found out shortly before the press conference announcing the shift in leadership.⁵⁷⁷ Dr. Jernigan, CDC’s number two lead at the time, told Committee staff that he “learned of the arrangement through a media report.”⁵⁷⁸ A former senior advisor to HHS Secretary Azar, Nicholas Uehlecke, told the Committee the shift “seemed sudden” and that he and some other HHS officials involved in the response learned of it through the White House press conference.⁵⁷⁹ Dr. Kadlec told the Committee that former HHS Secretary Azar was “tapped out” by President Trump due to a lack of confidence.⁵⁸⁰ According to Dr. Kadlec, President Trump lost confidence in Secretary Azar about CDC failures to test for and contain the virus.⁵⁸¹ Mr. Azar stated, he “supported the idea that the White House needed a coronavirus coordinator who could pull together a whole of government approach as a full-time job.”⁵⁸²

In an interview with the Committee, Ms. Troye said she was “given about a three-hour period of a heads up” before the President publicly announced Vice President Pence would lead the response.”⁵⁸³ Ms. Troye recalled, “I was told to prepare remarks should he be tapped for it and to be on standby. I was the only person on his staff who had been tracking [the Coronavirus response] on a daily basis so I wrote the remarks that he was going to deliver just in case the President turned to him and said, we’re going to need you to do this.”⁵⁸⁴

According to the newly drafted PanCAP-A, the Vice President’s office was now responsible for leading all federal communication and messaging both domestically and internationally.⁵⁸⁵ If federal officials had followed the original plan with HHS-led leadership structure, “the response would have failed,” then FEMA Administrator Pete Gaynor told the Committee.⁵⁸⁶ Administrator Gaynor noted that a benefit of having Vice President Pence in charge and accessible was that “primary action people,” like himself, had direct access to the decision maker. According to Administrator Gaynor, “we knew [Vice President Pence’s] intent... there was no filter, no interpretation by intermediaries, making directions and priorities very clear.”⁵⁸⁷

⁵⁷⁶ Dr. Robert Redfield, Written Responses to Senate Committee on Homeland Security and Governmental Affairs Staff (received Mar. 7, 2022).

⁵⁷⁷ Interview with Dr. Robert Kadlec (Dec. 6, 2021).

⁵⁷⁸ Interview with Dr. Daniel Jernigan (Dec. 15, 2021).

⁵⁷⁹ Interview with Nicholas Uehlecke (Nov. 4, 2021).

⁵⁸⁰ Interview with Dr. Robert Kadlec (Dec. 6, 2021).

⁵⁸¹ *Id.*

⁵⁸² Alex Azar Interrogatories (Mar. 1, 2022).

⁵⁸³ Interview with Olivia Troye (Dec. 8, 2021).

⁵⁸⁴ *Id.*

⁵⁸⁵ Department of Health and Human Services, PanCAP Adapted: U.S. Government COVID-19 Response Plan, at 6 (March 13, 2020).

⁵⁸⁶ Interview with Pete Gaynor (June 9, 2021).

⁵⁸⁷ *Id.*

Coordination of federal COVID-19 response activities also moved from the NSC to the Vice President’s office.⁵⁸⁸ Former HHS Deputy Chief of Staff Paul Mango told the Committee that following the move, there were positive changes, including that “Vice President Pence would often ask for more data before a decision . . . [leading a] deliberative group committed to policy and communications.”⁵⁸⁹ According to Dr. Larry Kerr, the federal government’s relationship with states improved somewhat following Vice President Pence taking the lead.⁵⁹⁰ In his view, federal repatriation efforts had frayed relationships between states and federal response efforts. Dr. Kerr told the Committee that the Administration aimed to leverage the Vice President’s former experience as a governor to improve relations with states.⁵⁹¹

Other officials disagreed with the change. Mr. McGowan told the Committee that when the Vice President’s office took over, “every single day, we would come to work, not necessarily knowing who was in charge of reporting up that day because it was constantly changing, which made things difficult.” He noted that the daily HHS phone calls were eliminated and instead everyone would receive an email with specific directives.⁵⁹² The attendance at the White House Task Force meetings also shifted. Mr. McGowan explained how his boss, CDC Director Dr. Redfield, had to be at the White House daily for an in-person task force meeting with only principals where other senior support staff were not permitted to call or listen in.

Communication and coordination with and within HHS also changed. Mr. Azar noted that his “level of involvement in the federal government’s coordination of the pandemic response efforts decreased following the Vice President’s appointment as leader of the Task Force.”⁵⁹³ This hierarchical structure also impacted how agency employees received directives. Dr. Larry Kerr explained that “when everything was housed at HHS . . . I understood very clearly who was providing . . . information . . . we lost enormous visibility when [the lead] shifted to Vice President Pence and the White House Task Force.”⁵⁹⁴ For example, Dr. Kerr noted that he and his colleagues would receive directives, but not have the appropriate context to understand what needed to be done to follow through on the action items. Despite these challenges, Dr. Kerr told Committee staff the pandemic had outgrown the sole capabilities of HHS and complex public health crises required a whole of government response.⁵⁹⁵

⁵⁸⁸ Department of Health and Human Services, PanCAP Adapted: U.S. Government COVID-19 Response Plan, at 16 (March 13, 2020) (noting, “on January 27, the President’s Coronavirus Task Force was formed and charged with leading the USG response. The Task Force was initially led by the Secretary of Health and Human Services and coordinated through the NSC. On February 28, the Task Force transitioned to the Office of the Vice President (OVP”).

⁵⁸⁹ Interview with Paul Mango (Nov. 17, 2021).

⁵⁹⁰ Interview with Dr. Larry Kerr (July 28, 2021).

⁵⁹¹ *Id.*

⁵⁹² Interview with Kyle McGowan (Dec. 2, 2021).

⁵⁹³ Alex Azar Interrogatories (Mar. 1, 2022).

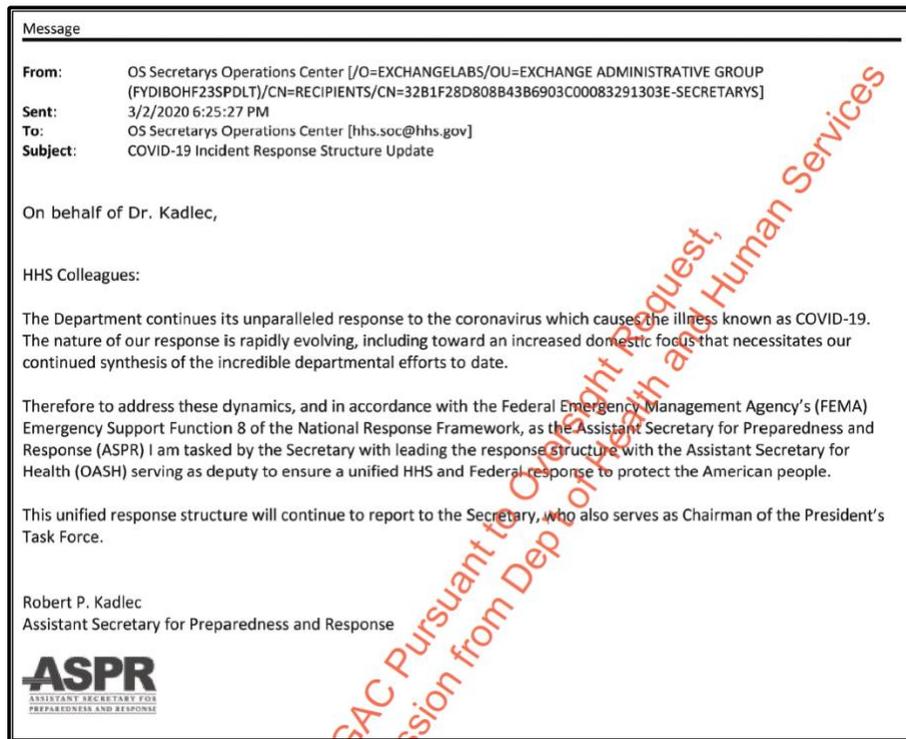
⁵⁹⁴ Interview with Dr. Larry Kerr (July 28, 2021).

⁵⁹⁵ *Id.*

ASPR Designated Lead of HHS Pandemic Response

On March 2, 2020, HHS announced that Dr. Kadlec would lead a unified response within HHS.⁵⁹⁶ Dr. Kadlec told the Committee he learned through a Politico news article titled, “HHS taps Kadlec to run department’s coronavirus response,” that he was tasked to lead HHS’s pandemic response.⁵⁹⁷ Approximately two hours later, HHS circulated an internal email announcement, shown below, on behalf of Dr. Kadlec, noting that he would be “leading the [HHS] response structure . . . to ensure a unified HHS and federal response to protect the American people.”⁵⁹⁸

*March 2, 2020 Email Announcing ASPR would Lead HHS Response*⁵⁹⁹



While the HHS Secretary charged Dr. Kadlec with leading HHS’s response efforts, the White House Task Force removed Dr. Kadlec from meetings after the Vice President began

⁵⁹⁶ Department of Health and Human Services, *Email from OS Secretary’s Operations Center* (Mar. 2, 2020) (on file with Committee, 0042536).

⁵⁹⁷ Interview with Dr. Robert Kadlec (Dec. 6, 2021); *HHS taps Kadlec to run department’s coronavirus response*, Politico (Mar. 3, 2020) (www.politico.com/news/2020/03/02/robert-kadlec-hhs-coronavirus-response-118934).

⁵⁹⁸ Interview with Dr. Robert Kadlec (Dec. 6, 2021).

⁵⁹⁹ Department of Health and Human Services, *Email from OS Secretary’s Operations Center* (Mar. 2, 2020) (on file with Committee, HSGAC 42536).

leading the nation’s response.⁶⁰⁰ Ms. Troye told Committee staff that Vice President Pence’s Chief of Staff asked her to “block him [Kadlec]” from the Task Force meetings.⁶⁰¹ Although Ms. Troye did not provide a particular reason as to why, she explained that Dr. Kadlec was “very vocal” and raised “serious concerns” that the Strategic National Stockpile (SNS) would be depleted.⁶⁰² According to Ms. Troye, Dr. Kadlec also raised concerns about how to equitably distribute supplies and ensure there was a system to distribute based on need, given the limited resources.⁶⁰³ Dr. Kadlec told the Committee, “I got kind of voted off the island of the White House Task Force sometime in March. But Dr. Redfield was there as a figure and had a speaking role. So, I mean, he was there representing CDC equities.”⁶⁰⁴

Increased Emergency Support Activations

By the end of February, HHS fully activated FEMA’s Emergency Support Functions (ESFs) and provided 24/7 support to its Secretary Operations Center. This included ESFs 1 (transportation), 6 (mass care, emergency assistance, temporary housing, and human services), 13 (public safety and security), 14 (cross-sector business and infrastructure), and 15 (public affairs).⁶⁰⁵ On March 5, FEMA stood up its Response Operations Cell, which is the first “NRCC component activation.”⁶⁰⁶ Administrator Gaynor explained that the Response Operations Cell (ROC) activation was an attempt to offer greater support to HHS. The initial NRCC activation at Level 3 was a “smaller footprint” than the full Level 1 activation that would later occur on March 18, 2020.⁶⁰⁷ At the time of the activation on March 5, the NRCC was already an “interagency team,” according to Mr. Dozor.⁶⁰⁸ He told the Committee, “every seat was filled, then we took over space on the floors above us—we had everyone we needed.”⁶⁰⁹ According to FEMA’s Initial Assessment Report, “upon activation of the NRCC, not all response members understood who led the resource allocation mission and how it fit into the overall response,” resulting in the need to “deconflict roles and responsibilities.”⁶¹⁰

⁶⁰⁰ Interview with Dr. Robert Kadlec (Dec. 6, 2021); Interview with Olivia Troye (Dec. 8, 2021).

⁶⁰¹ Interview with Olivia Troye (Dec. 8, 2021).

⁶⁰² *Id.*

⁶⁰³ *Id.*

⁶⁰⁴ Interview with Dr. Robert Kadlec (Dec. 6, 2021).

⁶⁰⁵ Department of Homeland Security, *DHS National Operations Center COVID-19 Placemat* (Feb. 28, 2020) (on file with Committee); Department of Homeland Security, Federal Emergency Management Agency, National Response Framework (accessed July 14, 2022) (www.fema.gov/emergency-managers/national-preparedness/frameworks/response); Federal Emergency Management Agency, *Operations Order 05-2020 (Amendment #01): FEMA Pandemic Readiness Planning Support* (Mar. 4, 2020) (on file with Committee).

⁶⁰⁶ Interview with Pete Gaynor (June 9, 2021).

⁶⁰⁷ *Id.*

⁶⁰⁸ Interview with Josh Dozor (June 7, 2021 and July 27, 2021).

⁶⁰⁹ *Id.*

⁶¹⁰ Federal Emergency Management Agency, *Pandemic Response to Coronavirus Disease 2019 (COVID-19): Initial Assessment Report*, at 51 (Jan. 2021) (noting “to facilitate integration and establish unity of effort,

The following week, agency response efforts continued to progress. On March 14, 2020 FEMA raised the NRCC activation to Level II operations.⁶¹¹ Mr. Bibo told the Committee that FEMA was “engaged in a number of discussions with White House counsel, Staff Secretary, NSC staff, Office of Management and Budget, and others about potential approaches to issuing a Stafford Act declaration.”⁶¹² He recalled, “that week [referring to March 9 – 13, 2020], we went to a meeting at the White House to discuss a range of issues, including the potential use of the Stafford Act.”

The expanding scope of the pandemic continued to stress HHS’s capabilities. While ASPR had regional offices, they had few staff in comparison to FEMA, and CDC had no regional offices.⁶¹³ Dr. Kadlec told the Committee, “ASPR’s footprint was fairly small—about 800 people—FEMA’s was around 20,000. ASPR regional offices are 4-6 people and FEMA regional offices are 150-200 people, depending on the region.”⁶¹⁴ To leverage the small regional ASPR staff, they co-located with the regional FEMA offices and served as advisors to the FEMA Regional Administrators.”⁶¹⁵ Mr. Bibo explained how FEMA’s large regional offices allow for “a deep bench in a way that could be reoriented to go run a vaccination center, for example.”⁶¹⁶ Furthermore, ASPR, unlike FEMA, did not have the ability to detail other employees within HHS, hindering their ability to increase logistics, administrative, or other support personnel roles as the pandemic expanded.⁶¹⁷ According to Mr. Bibo, these disparities led FEMA to recognize that they would need to “provide increasing support as the pandemic progressed.”⁶¹⁸

FEMA embedded experienced logistics personnel at the HHS Secretary’s Operations Center prior to FEMA taking the lead role, and in the [Supply Chain Task Force]”).

⁶¹¹ Department of Homeland Security, *DHS National Operations Center COVID-19 Placemat* (Mar. 14, 2020) (on file with Committee); Department of Homeland Security, Federal Emergency Management Agency, *Operations Order 05-2020 (Amendment #02): COVID-19* (Mar. 4, 2020) (on file with Committee, HSGAC-001718).

⁶¹² Interview with David Bibo (Dec. 21, 2021).

⁶¹³ *Id.*; Interview with Dr. Robert Kadlec (Dec. 6, 2021); Interview with Dr. Kevin Yeskey (Nov. 17, 2021 and Dec. 2, 2021).

⁶¹⁴ Interview with Dr. Robert Kadlec (Dec. 6, 2021).

⁶¹⁵ *Id.*

⁶¹⁶ Interview with David Bibo (Dec. 21, 2021).

⁶¹⁷ Interview with Josh Dozor (June 7, 2021 and July 27, 2021).

⁶¹⁸ Interview with David Bibo (Dec. 21, 2021).

Presidential Emergency Declarations

On March 13, 2020, President Trump issued two emergency declarations. Through Proclamation 9994, the President declared a national emergency under the National Emergencies Act.⁶¹⁹ That same day, he also issued a nationwide emergency declaration under the Stafford Act, stating,

[o]nly the Federal Government can provide the necessary coordination to address a pandemic of this national size and scope caused by a pathogen introduced into our country. It is the preeminent responsibility of the Federal Government to take action to stem a nationwide pandemic that has its origins abroad, which implicates its authority to regulate matters related to interstate matters and foreign commerce and to conduct the foreign relations of the United States.⁶²⁰

Without an emergency Stafford declaration, FEMA is limited in the type of federal assistance it can provide to SLTT partners, nonprofits, and individuals. The President's announcement also invited governors to submit major disaster declaration requests, which allowed FEMA to be responsive to requests for aid from eligible entities. By March 20, President Trump began granting requests for major disaster declarations under the Stafford Act from governors and chief executives of states, tribes, and territories.⁶²¹

Mr. Bibo explained that the President's Stafford Act declaration "opened another door for SLTT partners to come and ask for help."⁶²² Then Administrator Gaynor told the Committee, "I made a conscious choice with FEMA early on that we would push the authority to the regional administrators because there was no way headquarters could operationally control everything after the emergency declaration was announced . . . it's never happened that every region has entered a disaster at once . . . this was the biggest thing FEMA has seen."⁶²³ Mr. Bibo told the Committee that "FEMA suddenly had more awareness about requests because states would tell

⁶¹⁹ 50 U.S.C. §§ 1601 et seq.; White House, *Proclamation 9994: Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak* (Mar. 13, 2020).

⁶²⁰ Stafford Disaster Relief and Emergency Assistance Act, Pub. L. No. 100-707, Sec. 501(b) (1988); White House, Letter from President Donald J. Trump on Emergency Determination Under the Stafford Act (Mar. 13, 2020) (www.trumpwhitehouse.archives.gov/briefings-statements/letter-president-donald-j-trump-emergency-determination-stafford-act/).

⁶²¹ Congressional Research Service, *Congressional Primer on Responding to and Recovering from Major Disasters and Emergencies* (R41981) (June 3, 2020). See, e.g., Donald J. Trump: *President Donald J. Trump Approves Major Disaster Declaration for New York* (March 20, 2020); Donald J. Trump: *President Donald J. Trump Approves Major Disaster Declaration for Washington* (March 22, 2020); Office of Governor Gavin Newsom, *California Secures Presidential Major Disaster Declaration to Support State's COVID-19 Emergency Response* (March 22, 2020).

⁶²² Interview with David Bibo (Dec. 21, 2021).

⁶²³ Interview with Pete Gaynor (June 9, 2021).

[FEMA] that they had already asked HHS or ASPR [for assistance]. It became clear that we would need to find a way to reconcile all those requests and bring order.”⁶²⁴

The COVID-19 Stafford Act emergency declaration was an unprecedented nationwide action for a public health response.⁶²⁵ The declaration authorized emergency funding for assistance, which included alternate care facilities, tribal medical centers, non-congregate sheltering, diagnostic testing and community-based testing sites, disaster medical assistant teams, mobile hospitals, emergency medical care, mobilization of the National Guard, and the transportation and distribution of necessary supplies such as food, medicine, and personal protective equipment.⁶²⁶

Unclear Agency Roles Between HHS and FEMA

Although the President’s emergency disaster declarations offered needed support to SLTT partners, it was unclear within the federal government which agency—HHS or FEMA—would be tasked with leading federal response efforts. Mr. Bibo described March 13 through 18 as “a stormy period where we needed clarity quickly.”⁶²⁷ Throughout the week, Mr. Bibo recalled having a number of discussions about the implications of the President’s Stafford Act declaration: “Beyond delivering aid, what does this mean for the architecture of how [FEMA] was managing and supporting the response? Because now you have [the Pandemics and All Hazards Preparedness Act] and the Stafford Act employed and you have the question of who is going to be first among equals.”⁶²⁸

In an interview with the Committee, then Administrator Gaynor described the week of March 16 as the week “when it all changed because HHS was treading water.”⁶²⁹ Administrator Gaynor noted, even with the FEMA personnel detailed to HHS since February 10, the pandemic was outpacing HHS’s and ASPR’s capabilities. He stated, “I realized that what was coming was much bigger than the capacity HHS/ASPR had at the moment even with the [FEMA officials] I provided.” According to Administrator Gaynor, Josh Dozor—FEMA’s lead at HHS—sent reports to FEMA asking for additional personnel. By mid-March, FEMA had over 50 personnel at HHS: “every day they needed some new capability,” Administrator Gaynor said.⁶³⁰

On March 18, Administrator Gaynor led a briefing in the White House situation room to provide an update on the capacity of FEMA and the NRCC. According to Administrator

⁶²⁴ Interview with David Bibo (Dec. 21, 2021).

⁶²⁵ Congressional Research Service, *FEMA’s Role in the COVID-19 Federal Pandemic Response*, at 1, 11, 23 (R47048) (Feb. 10, 2022).

⁶²⁶ House Committee on Homeland Security and Governmental Affairs, Testimony Submitted for the Record of Administrator Peter Gaynor, Federal Emergency Management Agency, *Hearing on Examining the National Response to the Worsening Coronavirus Pandemic*, 116th Cong., at 8-9 (July 22, 2020) (S. Hrg. 116-80).

⁶²⁷ Interview with David Bibo (Dec. 21, 2021).

⁶²⁸ *Id.*

⁶²⁹ Interview with Pete Gaynor (June 9, 2021).

⁶³⁰ *Id.*

Gaynor, multiple White House and senior public health officials, including Vice President Pence, Jared Kushner, Dr. Fauci, Dr. Birx, HHS Secretary Azar, and Admiral Brett Giroir, attended. While multiple officials were present at the briefing, Administrator Gaynor said, “it was clear [he] was there to brief Vice President Pence.”⁶³¹ Shortly after the briefing, the White House asked him to return again for a discussion about FEMA’s role in the response. During this meeting, President Trump directed Administrator Gaynor to “take over” and lead the operational coordination of the federal response.⁶³²

When Administrator Gaynor returned to FEMA, he received yet another request to go back to the White House to discuss logistics.⁶³³ In this third meeting of the day, with the Vice President, DHS Secretary, HHS Secretary, and other senior officials, Vice President Pence directed Administrator Gaynor to lead the response. When Administrator Gaynor asked whether FEMA’s efforts would be “in support of HHS,” he was told, no—FEMA was now in the lead.⁶³⁴

After returning to FEMA, Administrator Gaynor informed his staff that FEMA would become the lead federal agency in charge of the federal pandemic response.⁶³⁵ According to Administrator Gaynor, his staff held mixed opinions on new FEMA’s role. Some believed that FEMA should remain in a support role, not a lead agency. Others, however, recognizing the President had ordered FEMA to take the lead, thought the new role was appropriate and necessary.⁶³⁶ Mr. Gaynor told Committee staff that he had expected FEMA to play a supporting role to HHS and considered it a “unique” and “historic” situation for FEMA to be placed in the lead for this pandemic response.

Once learning this information, FEMA leadership quickly convened a team with representatives from HHS and ASPR to “chart out how to fold operations together and integrate completely so there wouldn’t be any confusion.”⁶³⁷ Mr. Dozor told the Committee, “we got on a white board [shown below] with HHS and FEMA leadership” and “one by one moved organizations based on what was most important from a process standpoint.” Mr. Dozor described these efforts as “a surreal experience reorganizing the government in two hours.”⁶³⁸

⁶³¹ *Id.*

⁶³² *Id.*

⁶³³ *Id.*

⁶³⁴ *Id.*

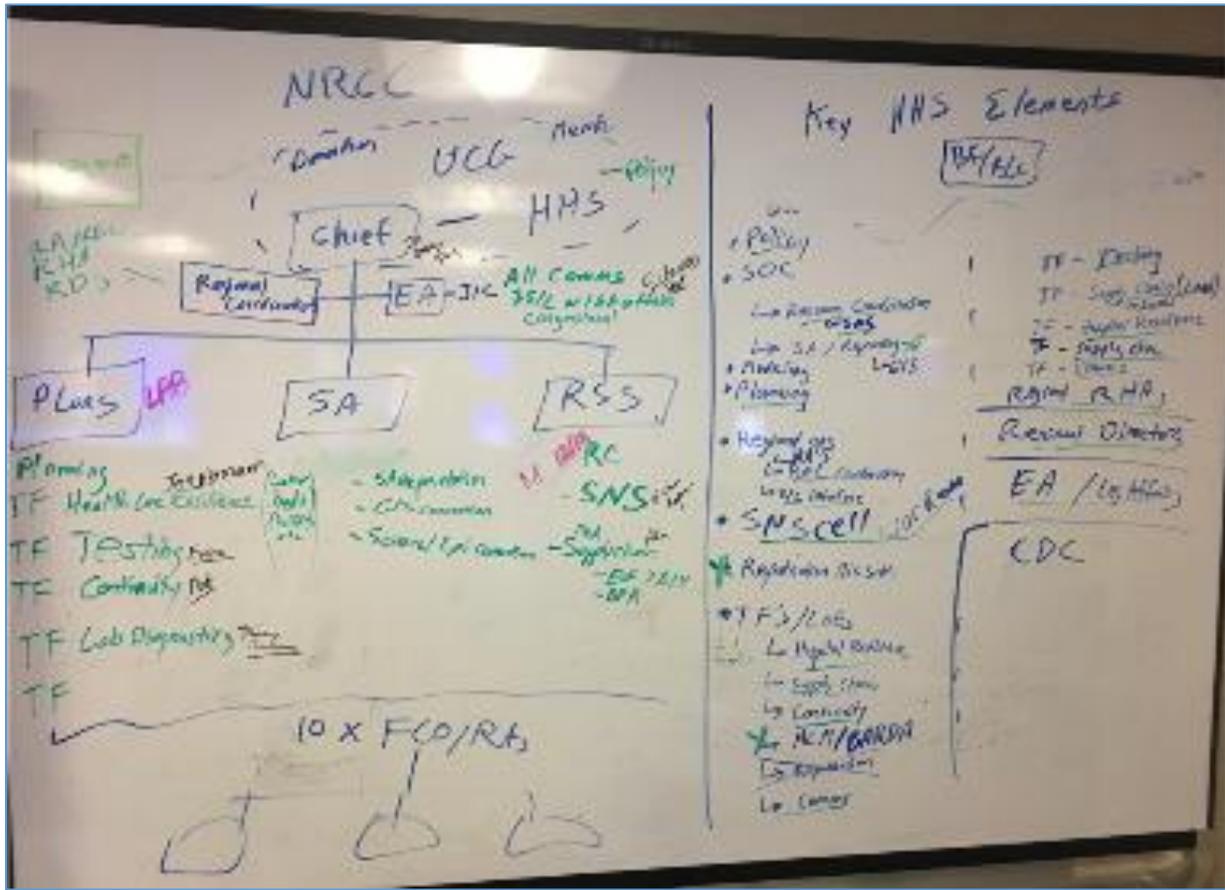
⁶³⁵ *Id.*

⁶³⁶ *Id.*

⁶³⁷ Interview with David Bibo (Dec. 21, 2021).

⁶³⁸ Interview with Josh Dozor (June 7, 2021 and July 27, 2021).

**Photograph of Planning Efforts to Transition
Lead Federal Agency Responsibilities from HHS to FEMA⁶³⁹**



Between March 17-18, HHS and FEMA physically relocated necessary components.⁶⁴⁰ On March 18, FEMA activated the NRCC to Level I operations.⁶⁴¹ By the evening of March 18, HHS personnel had integrated with FEMA and other agencies' personnel at the NRCC.⁶⁴² Mr. Bibo told the Committee that it was a rapid transition to FEMA as the lead, but "it needed to happen quickly."⁶⁴³ Prior pandemic planning did not account for FEMA leading a pandemic response.⁶⁴⁴ In a subsequent report assessing the agency's response to the COVID-19 pandemic,

⁶³⁹ Photograph provided by Josh Dozor, Former FEMA Deputy Assistant Administrator for Response.

⁶⁴⁰ From March 14 – 17, 2020 the NRCC was at Level II operations.

⁶⁴¹ Department of Homeland Security, Federal Emergency Management Agency, *Operations Order 05-2020 (Amendment #04): COVID-19* (Mar. 18, 2020) (on file with Committee, HSGAC-001722).

⁶⁴² Interview with Pete Gaynor (June 9, 2021).

⁶⁴³ Interview with David Bibo (Dec. 21, 2021).

⁶⁴⁴ Department of Homeland Security, Federal Emergency Management Agency, *Pandemic Crisis Action Plan, Version 2.0* (Jan. 2018) (on file with Committee, DHS FEMA 308-339); Department of Health and Human Services, *PanCAP Adapted, U.S. Government COVID-19 Response Plan* (Mar. 13, 2020) (on file with Committee, DHS FEMA 6-108); see also Federal Emergency Management Agency, *Pandemic Response to Coronavirus*

FEMA indicated that while some officials reported clear lines of authority, others—specifically NRCC management staff, task force members, and support staff—reported a “lack of communication” regarding the shift “created a general misunderstanding of roles and responsibilities.”⁶⁴⁵

E. Mar. 19, 2020 – June 2020: FEMA Becomes the Lead Federal Agency

On March 19, 2020 President Trump announced in a video teleconference to state governors that FEMA would serve as the lead federal agency for the pandemic response.⁶⁴⁶ FEMA’s appointment to lead the federal COVID-19 response was historic on many accounts. The Stafford Act has never before been invoked for a pandemic.⁶⁴⁷ Reflecting the novel nature of the virus and associated challenges with the response, the COVID-19 pandemic is the first time the President directed FEMA—as opposed to HHS—to serve as the lead federal agency for an infectious disease emergency. It is also the first time a President granted major disaster declarations for any public health event under current law.⁶⁴⁸ And it is the first time a President declared an emergency for the same incident for all 50 states, the District of Columbia, and territories, as well as tribes that sought an independent declaration.⁶⁴⁹

While this leadership move is unprecedented for a public health emergency, multiple officials interviewed by the Committee noted the unprecedented nature of the pandemic. Dr. Kevin Yeskey explained, “COVID became a continuity of society event. It wasn’t just a health event. It wasn’t just a medical event. This was more than just hospitals and public health. This was a societal changing event. HHS cannot coordinate the Department of Education. FEMA has experience coordinating those kinds of events and they have the tools to do it. HHS does not.”⁶⁵⁰ According to Jessica Falcon, Director of Security, Intelligence, and Information Management at ASPR, the “severity of this pandemic crossing the U.S. is not something we experienced before.”⁶⁵¹ Administrator Gaynor was not previously a part of the White House Task Force and

Disease 2019 (COVID-19): Initial Assessment Report, at 99 (Jan. 2021) (noting “the designation of FEMA as the agency leading [the] federal response on March 18, 2020, and the delegation of resource and supply management responsibilities to FEMA were not adequately addressed in the 2018 PanCAP or any preceding document). FEMA also reported that “FEMA regional pandemic plans either did not exist or do not account for FEMA assuming the role of the agency leading federal response in a pandemic.” *Id.*

⁶⁴⁵ Federal Emergency Management Agency, *Pandemic Response to Coronavirus Disease 2019 (COVID-19): Initial Assessment Report*, at 33 (Jan. 2021).

⁶⁴⁶ President Trump and Vice President Pence, White House, Remarks as Prepared for Delivery at FEMA Headquarters (via video conference with governors on COVID-19) (Mar. 19, 2020).

⁶⁴⁷ Congressional Research Service, *FEMA’s Role in the COVID-19 Federal Pandemic Response*, at 1, 11, 23 (R47048) (Feb. 10, 2022).

⁶⁴⁸ Federal Emergency Management Agency, *Pandemic Response to Coronavirus Disease 2019 (COVID-19): Initial Assessment Report*, at 5 (Jan. 2021).

⁶⁴⁹ Congressional Research Service, *Stafford Act Assistance for Public Health Incidents* (IN11229) (Mar. 22, 2021).

⁶⁵⁰ Interview with Dr. Kevin Yeskey (Nov. 17, 2021 and Dec. 2, 2021).

⁶⁵¹ Interview with Jessica Falcon (July 22, 2021).

described the evolving situation as “a slow boil until all of the sudden, you’re on fire . . . March to June were 20-hour days, 7 days a week.”

Prior to FEMA serving as the lead federal agency, Mr. Bibo told the Committee there was no streamlined approach to request federal assistance or supplies. In an interview with Committee staff, Mr. Bibo stated,

“FEMA made sense of a very chaotic environment. We brought order to the response, which was the most critical part of the early days. I think we had an intuition about what was needed, but we did not have an understanding of the scale and scope. The battlefield was opaque until we got our arms around what SLTT partners needed . . . FEMA had systems that allowed us to scale—including people, process, and technology—better than any other agency.”⁶⁵²

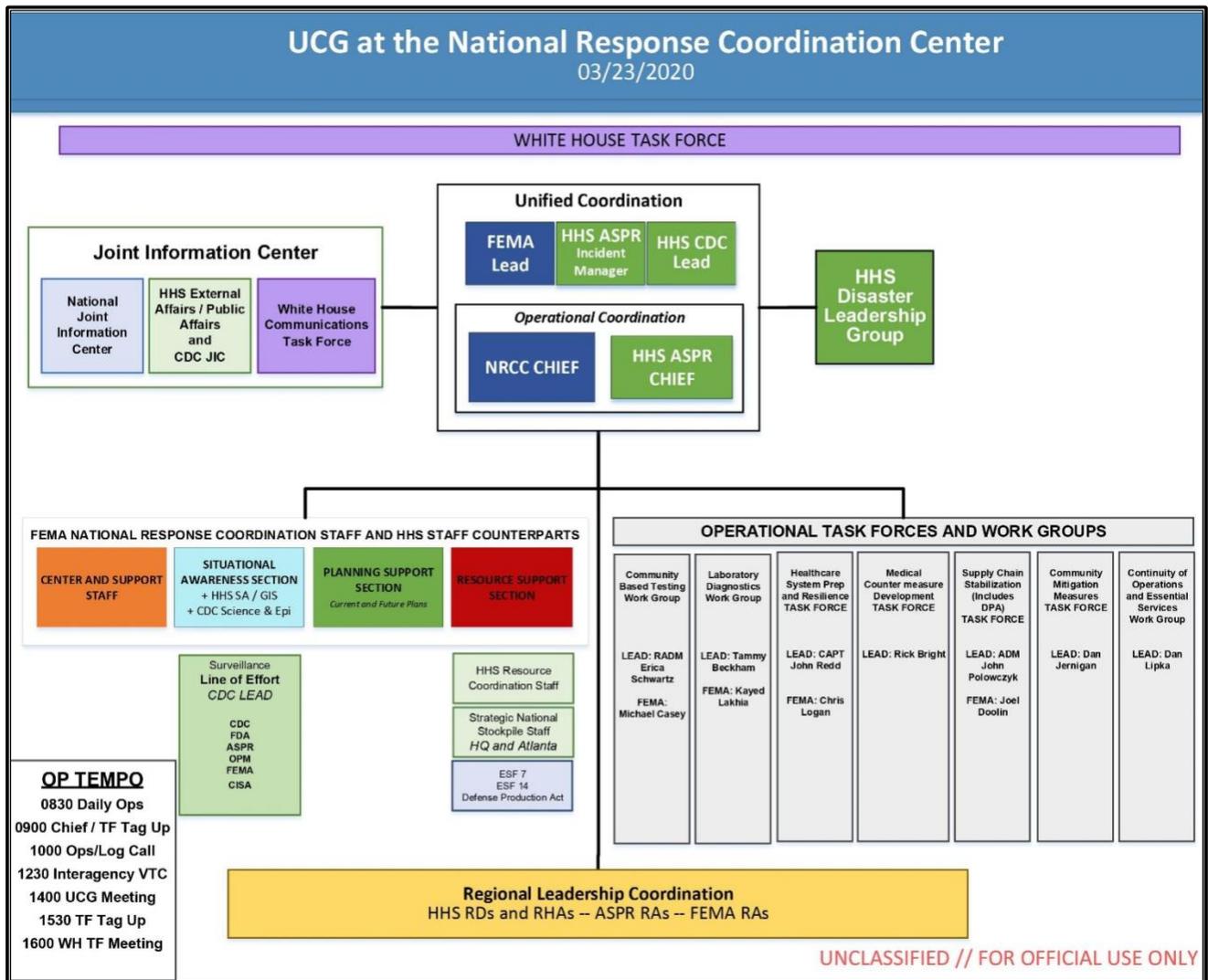
The following day, on March 18, FEMA activated the NRCC to Level 1—the highest level of readiness. As part of the activation, operational task forces, detailed below, transferred from HHS to FEMA.⁶⁵³ The elevation to Level 1, according to then NRCC chief Josh Dozor, represented “a major ramp up” in operations, did not cause any “lag time” in the overall response, and allowed the previously integrated HHS personnel to operate at full capacity.⁶⁵⁴

⁶⁵² Interview with David Bibo (Dec. 21, 2021).

⁶⁵³ Office of Management and Budget, *UCG at the National Response Coordination Center* (Mar. 23, 2020) (on file with Committee, OMB-HSGAC-000001); Department of Homeland Security, Federal Emergency Management Agency, *Operations Order 05-2020 (Amendment #04): COVID-19* (Mar. 18, 2020) (on file with Committee, HSGAC-001722).

⁶⁵⁴ Interview with David Bibo (Dec. 21, 2021).

Federal Response Organizational Chart as of March 23, 2020⁶⁵⁵



FDA officials, however, told the Committee there was a lack of clarity with various groups being stood up and an inadequate understanding of the overall leadership structure, as well as where FDA needed to assist.⁶⁵⁶ Although FDA officials provided ongoing and invaluable support to interagency partners on regulatory issues, such as interpreting emergency use authorizations and requirements for importing medical supplies, one official explained to the

⁶⁵⁵ Office of Management and Budget, *UCG at the National Response Coordination Center* (Mar. 23, 2020) (on file with Committee, OMB-HSGAC-000001).

⁶⁵⁶ Food and Drug Administration, Briefing with Senate Committee on Homeland Security and Governmental Affairs Staff (June 23, 2021) (hereinafter “FDA Briefing (June 23, 2021)”).

Committee how “once we understood the structure and who was doing what, there would be a shift after that—it was the evolving nature of a complex response.”⁶⁵⁷

Despite FEMA’s new role as the lead federal agency for the pandemic response, FEMA officials told the Committee that HHS retained the lead on all public health matters.⁶⁵⁸ According to Mr. Dozor, HHS always had the lead, “both in spirit and in operations . . . HHS always sat at head of table.”⁶⁵⁹ In the beginning of the transition, however, decision making over health issues created confusion. Dr. Yeskey told Committee staff that early on, FEMA unilaterally decided where to send medical resources.⁶⁶⁰ He explained, “we found out FEMA was making decisions on where [medical] resources should be going and we didn’t think they had the skillset to do that, so we instituted a panel, which included FEMA, DOD, and ASPR.”⁶⁶¹ According to Dr. Yeskey, “[t]hings moved quickly after this happened.”⁶⁶²

Despite this initial confusion and as discussed in Section VIII (Medical Supply Chain), the SNS continued to distribute PPE based on population, not need. On March 20, 2020 then HHS Secretary Azar texted Dr. Kadlec, then ASPR: “I’m out of this but might I suggest to you all and the FEMA leadership that we might want to surge PPE into NYC. 90% of new cases are from NY and mostly NYC. We need to relieve the pressure there. But not my call.”⁶⁶³ Secretary Azar sent a follow-up message to Dr. Kadlec: “Again, just to be clear from now on, I will give you suggestions or ideas and clear barriers here but anything I say is not an order. All subject to FEMA processes.”⁶⁶⁴ Mr. Azar explained to the Committee that he understood New York needed PPE due to surging case counts and at the time, but SNS PPE allocations were per capita as opposed to need-based.⁶⁶⁵ Mr. Azar noted, “[a]t that time, FEMA was in charge of the [NRCC], which Dr. Kadlec, as the head of ASPR participated in,” and it was FEMA’s responsibility to make decisions surrounding the allocation and distribution of medical supplies.⁶⁶⁶

⁶⁵⁷ *Id.* On June 15, 2020 the task forces returned to HHS leadership. See Department of Homeland Security, Federal Emergency Management Agency, *Pandemic Response to Coronavirus Disease 2019 (COVID-19): Initial Assessment Report*, at 40 (Jan. 2021).

⁶⁵⁸ Interview with Josh Dozor (June 7, 2021 and July 27, 2021); Interview with Dr. Daniel Kaniewski (May 6, 2021); Carla Gammon, Acting Federal Emergency Management Agency Assistant Administrator for Office of Response and Recovery Logistics Management Directorate (Mar. 2020 - present), Former Federal Emergency Management Agency Deputy Assistant Administrator for Logistics Management Directorate (2013 - 2020), Interview with Senate Committee on Homeland Security and Governmental Affairs (Apr. 27, 2021) (hereinafter “Interview with Carla Gammon (Apr. 27, 2021)”).

⁶⁵⁹ Interview with Josh Dozor (June 7, 2021 and July 27, 2021).

⁶⁶⁰ Interview with Dr. Kevin Yeskey (Nov. 17, 2021 and Dec. 2, 2021).

⁶⁶¹ *Id.*

⁶⁶² *Id.*

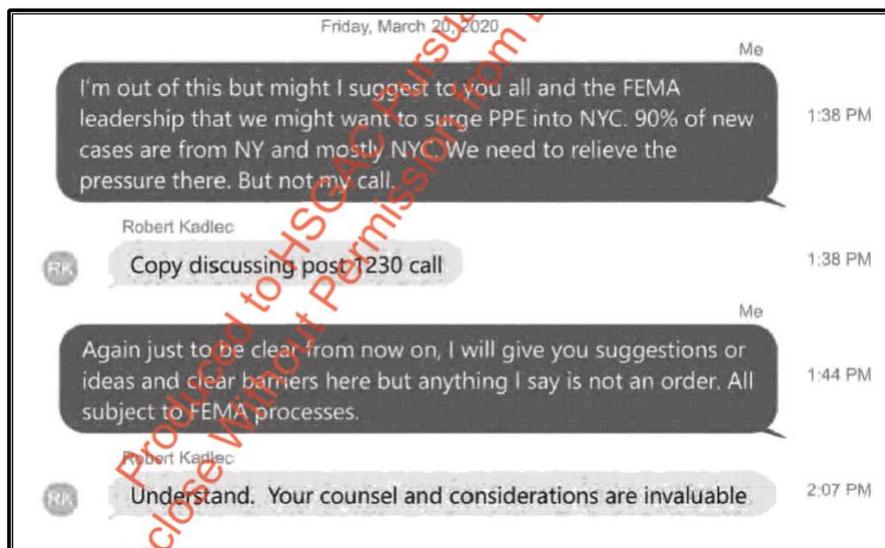
⁶⁶³ Department of Health and Human Services, *Text Messages between Secretary Azar and ASPR Kadlec* (Mar. 20, 2020) (on file with Committee, HSGAC-0036904).

⁶⁶⁴ *Id.*

⁶⁶⁵ Alex Azar Interrogatories (Mar. 1, 2022).

⁶⁶⁶ *Id.*

March 20, 2020 Text Message: HHS Secretary Azar & ASPR Kadlec⁶⁶⁷



As the lead federal agency, FEMA established a Unified Coordination Group (UCG) on March 20, 2020, led by the FEMA Administrator, the ASPR, and a CDC representative.⁶⁶⁸ The UCG served as the decision-making body for the federal pandemic response. GAO subsequently reviewed FEMA’s role and found that FEMA and HHS held complementary roles, corresponding “to their missions and expertise.” For example, GAO noted FEMA “focused on directing nationwide operational needs—such as the logistics of moving material, supplies, and personnel to meet emergent needs and tracking the delivery of these supplies.”⁶⁶⁹

Current and former officials involved in the pandemic response recognized improvements after the lead federal agency transitioned to FEMA. Urgent requests for PPE, according to SNS Director Steve Adams, all funneled through a FEMA coordination center, as opposed to going through multiple layers of HHS, SLTT, or FEMA approval. “We knew the right people were looking at the [PPE] requests,” Mr. Adams told the Committee, explaining that FEMA’s

⁶⁶⁷ Department of Health and Human Services, *Text Messages between Secretary Azar and ASPR Kadlec* (Mar. 20, 2020) (on file with Committee, HSGAC-0036804).

⁶⁶⁸ See Government Accountability Office, *COVID 19: FEMA’s Role in the Response and Related Challenges*, at 5 (GAO-20-685T) (July 14, 2020) (noting the UCG “made up of the FEMA Administrator, HHS Assistant Secretary for Preparedness and Response, and a CDC representative [had the] responsibility for operational command, leadership, and decision-making for the COVID-19 pandemic response”). FEMA’s Initial Assessment Report, however, reports that the UCG had four principals: the FEMA Administrator, the ASPR, the Assistant Secretary for Health Admiral Brett Giroir, and CDC’s Dr. Daniel Jernigan. See Federal Emergency Management Agency, *Pandemic Response to Coronavirus Disease 2019 (COVID-19): Initial Assessment Report*, at 25 (Jan. 2021) (noting “the COVID-9 response was the first time FEMA had implemented a federal interagency UCG”).

⁶⁶⁹ Government Accountability Office, *COVID 19: FEMA’s Role in the Response and Related Challenges*, at 5 (GAO-20-685T) (July 14, 2020).

coordination allowed for a streamlined logistics process.⁶⁷⁰ Similarly, FEMA senior official Carla Gammon told the Committee that operations at HHS were not coordinated prior to the transition, and that FEMA allowed for integration across government and private industry. Ms. Gammon stated, “HHS did a good job [before FEMA took over], but everything was segmented.”⁶⁷¹ A former HHS Senior Advisor to the HHS Secretary agreed: “the move to FEMA had to happen and procurement was name of the game—FEMA had the resources.”⁶⁷²

IV. Funding

Years of underinvestment in public health preparedness and response significantly constrained pandemic preparedness and response efforts and it took until late February 2020 for the Administration to request supplemental funding from Congress. As COVID-19 spread throughout the country in January and February 2020, HHS’s two public health emergency funds were either empty or had minimal funding available.⁶⁷³ HHS’s Public Health Emergency Fund, created in 1983, received no new appropriations since FY 1999 and had a balance of a little over \$50,000. CDC’s Infectious Disease Rapid Response Reserve Fund, established in 2019 for the specific purposes of preparing for and responding to emergency infectious diseases had approximately \$105 million remaining. When the Committee asked HHS to provide clarification on how it spent these funds during the months of January and February 2020, they stated, “[w]e do not have additional information to share.”⁶⁷⁴

Absent a Presidential major disaster or emergency declaration under the Stafford Act—which did not occur until March 13, 2020—FEMA was unable to use funds from the Disaster Relief Fund, a critical source of funding for agencies, states, and localities during emergencies.⁶⁷⁵ The Majority Committee staff found that a lack of consistent and sufficient funding for public health infrastructure and preparedness—a problem that spans multiple Administrations and Congresses—hampered response efforts at both the state and federal levels. As detailed throughout this section, numerous current and former state, local, and federal officials interviewed by the Committee cited a lack of funding as a key reason for delays in the pandemic response efforts.

⁶⁷⁰ Assistant Secretary for Preparedness and Response, Briefing with Senate Committee on Homeland Security and Governmental Affairs Staff (May 6, 2021) (hereinafter “ASPR Briefing (May 6, 2021)”).

⁶⁷¹ Interview with Carla Gammon (Apr. 27, 2021).

⁶⁷² Interview with Nicholas Uehlecke (Nov. 4, 2021).

⁶⁷³ See HHS Correspondence to Senate Committee on Homeland Security and Governmental Affairs Staff (Nov. 16, 2022); Office of Management and Budget, *SF 133: Department of Health and Human Services Infectious Diseases Rapid Response Reserve Fund* (Nov. 9, 2020) (on file with Committee); Office of Management and Budget, *SF 133: Department of Health and Human Services Public Health Emergency Fund* (Nov. 9, 2020) (on file with Committee).

⁶⁷⁴ HHS Correspondence to Senate Committee on Homeland Security and Governmental Affairs (Dec. 1, 2022).

⁶⁷⁵ Stafford Disaster Relief and Emergency Assistance Act, Pub. L. No. 100-707 (Disaster Relief Act of 1974, Pub. L. No. 93-288, as amended).

Approximately eight weeks after the Administration first learned of the evolving COVID-19 threat, on February 24, 2020, the Office of Management and Budget (OMB) initiated a supplemental funding request for federal pandemic response efforts, which amounted to approximately \$1.25 billion in requests for new funds.⁶⁷⁶ While OMB's letter requesting supplemental funding stated, "[t]o this point, no agency has been inhibited in response efforts due to resources or authorities," multiple public health officials interviewed by the Committee said a lack of available funding early on, constrained agencies' response efforts.⁶⁷⁷ In an interview with the Committee, Dr. Kadlec said his office did not enter into any PPE contracts in January and February 2020 because they simply did not have the funding, noting [entering into PPE contracts] "could only begin in early March after Congress passed the CARES Act."⁶⁷⁸ Mr. Azar told the Committee that in early February he "notified OMB that the government would need a large supplemental appropriation to invest in vaccines, diagnostics, and therapeutics, to contract with PPE manufacturers, and to fund new border control initiatives."⁶⁷⁹ The Committee requested from OMB information related to agency funding requests from January and February 2020, but only received publicly available information.

Former SNS Director Greg Burel told the Committee, "I think the SNS had a reasonable level of preparedness for pandemic influenza to deploy antivirals but it was not prepared to supply PPE. It was wholly a matter of inadequate funding for us to be able to do that and there was a rather nebulous expectation that we would do that."⁶⁸⁰ Dr. Rick Bright, former Director of BARDA, told the Committee having a preexisting fund that does not require pre-approval is necessary for an effective response and would help avoid delays in future federal response actions. Dr. Bright specified,

We need a reserve emergency fund for MCMs [Medical Countermeasures] dedicated to BARDA, not the Under Secretary or ASPR, to reduce political influence. You can put any accountability you want on that Director—have [it] approved by special committee—but as long as the money is sitting there and can be accessed without interagency bickering, you can get months ahead in response. OMB played with us for weeks, [indicating, for example, you are] only going to get 8% of your budget. Maybe 30 days later you'll get more. You cannot plan a big response by nickel and diming.⁶⁸¹

⁶⁷⁶ Letter from Acting Director Russell T. Vought, Office of Management and Budget, to Vice President Michael R. Pence, President of the Senate (Feb. 24, 2020) (<https://www.whitehouse.gov/wp-content/uploads/2020/02/Coronavirus-Supplemental-Request-Letter-Final.pdf>).

⁶⁷⁷ Interview with Melissa Harvey (Nov. 3, 2021); Interview with Dr. Robert Kadlec (Dec. 6, 2021); Interview with Dr. Anne Schuchat (Dec. 14, 2021).

⁶⁷⁸ Interview with Dr. Robert Kadlec (Dec. 6, 2021).

⁶⁷⁹ Alex Azar Interrogatories (Mar. 1, 2022).

⁶⁸⁰ Interview with Greg Burel (Feb. 26, 2021).

⁶⁸¹ Interview with Dr. Rick Bright (Mar. 17, 2021 and Nov. 4, 2021).

While acknowledging that HHS needed supplemental funding, then Deputy National Security Advisor Matthew Pottinger told the Committee he did not recall any public health agencies saying they did not have enough money: “when the OMB letter went up on February 24, everyone was on the same page.” Mr. Pottinger recalled, “no one said they wanted to elevate” funding complaints to senior White House officials. According to former White House official Joe Grogan, all operational public health agencies regularly said they needed more funding, but he did not recall meetings in January or February 2020 where OMB denied funding to public health agencies.⁶⁸² Mr. Grogan stated, “the job of OMB is to say, ‘hold on a second, you have resources already, we can reallocate currently existing resources, you have transfer authority, etc.’” He explained, “there is a healthy tension between OMB and any agency. . . that is normal.”⁶⁸³ When asked by the Committee if an earlier or larger supplemental funding would have made a substantial impact in the federal COVID response, BARDA Director of Influenza and Emerging Infections Diseases Division Dr. Robert Johnson said it was difficult to tell as the unknown nature of the virus made it difficult to predict funding needs. Dr. Johnson noted, however, that there were without question competing demands and not enough funding.⁶⁸⁴

On March 5, 2020, Congress passed the *Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020*, an \$8.3 billion funding package of new spending—more than six times the Administration’s initial request.⁶⁸⁵ Of the amount allocated to ASPR, then SNS Director Steve Adams noted it was insufficient to cover high priority critical medical supplies, like PPE and test kits.⁶⁸⁶ On March 12, 2020, Mr. Adams wrote to Dr. Rick Bright via email,

we’ve been asked to acquire critical PPE (500M n-95s, 1B surgical masks, gowns, gloves, etc...) that will likely exceed the supplemental. It has already been suggested we acquire additional high priority items like test kits. To be clear, I’m agnostic about which priorities we’re addressing but we won’t be able to cover everything already identified as a critical priority.⁶⁸⁷

At the end of March 2020, in response to the Trump Administration’s February 24, 2020 \$2.5 billion request for supplemental funding to address the pandemic—only \$1.25 billion of which was for new funding—Congress provided an additional \$2.9 trillion through the *Families*

⁶⁸² Interview with Joseph Grogan (Jan. 25, 2022).

⁶⁸³ *Id.*

⁶⁸⁴ Interview with Dr. Robert Johnson (July 9, 2021).

⁶⁸⁵ Coronavirus Preparedness and Response Supplemental Appropriations Act, Pub. L. 116-123 (2020).

⁶⁸⁶ Dr. Rick Bright, *Office of Special Counsel Complaint, Exhibit 30, Email from Steve Adams to Dr. Rick Bright on Needles/Syringes for COVID-19 response* (Mar. 12, 2020) (on file with Committee).

⁶⁸⁷ *Id.*

V. U.S. Public Health Surveillance

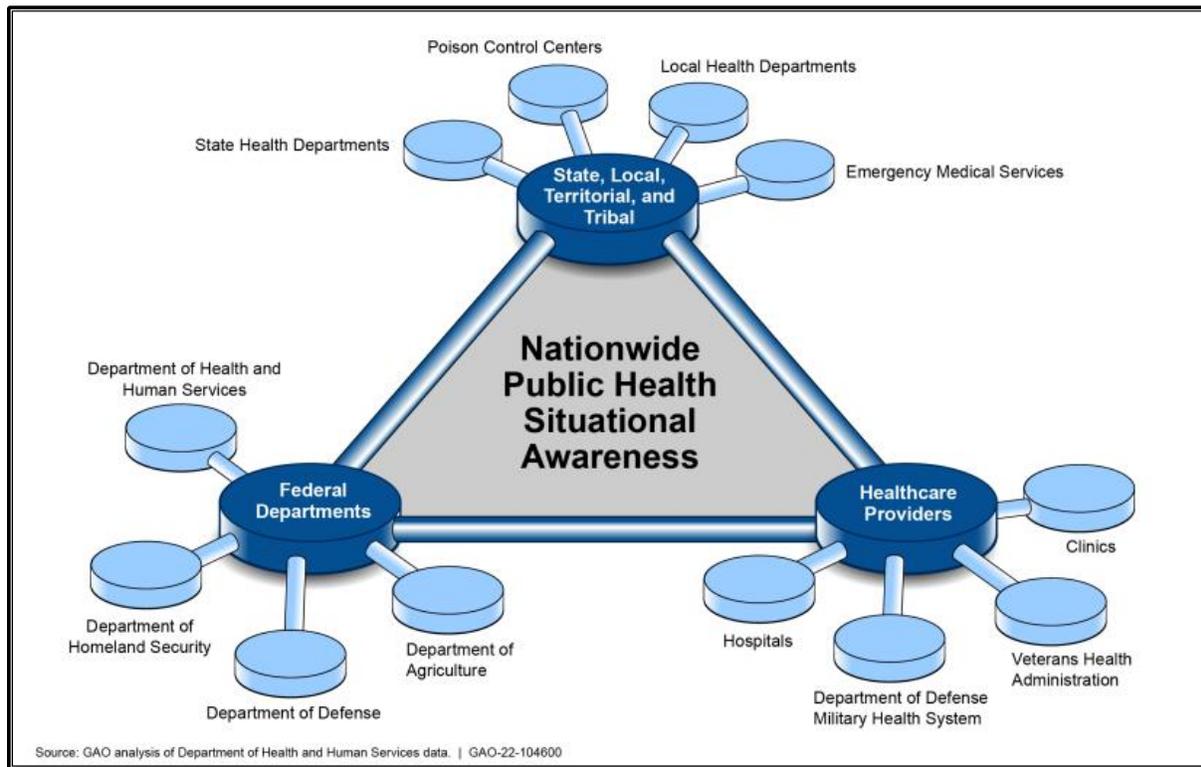
U.S. public health surveillance systems for monitoring and tracking emerging infectious diseases were inadequate to address the unfolding threat from the spread of COVID-19 throughout the U.S. As discussed below, the Committee determined based on its review of interviews and documents that these systems remain inadequate to monitor and track emerging infectious diseases. Public health data systems vary across State, Local, Tribal, and Territorial (SLTT) levels and data reporting standards are not coordinated, which often result in inefficiencies, outdated systems, and delays in emergency response capabilities.⁶⁸⁹ While the federal government receives information from multiple reporting entities to inform its public health situational awareness, as shown below, the Majority Committee staff found that a lack of interoperable and robust systems impaired the federal government’s ability to comprehensively surveil the emerging coronavirus threat. Several former government officials interviewed by the Committee cited poor data and surveillance systems as a primary obstacle to a successful pandemic response.⁶⁹⁰

⁶⁸⁸ Families First Coronavirus Response Act, Pub. L. No. 116-127 (2020); Coronavirus Aid, Relief, and Economic Security (CARES) Act, Pub. L. No. 116-136 (2020); Letter from Acting Director Russell T. Vought, Office of Management and Budget, to Vice President Michael R. Pence, President of the Senate (Feb. 24, 2020) (<https://www.whitehouse.gov/wp-content/uploads/2020/02/Coronavirus-Supplemental-Request-Letter-Final.pdf>).

⁶⁸⁹ Duke University, Margolis Center for Health Policy, *Health Care Data Reporting Beyond the Public Health Emergency: Payment Policies to Support Public Health Surveillance and Population Health* (June 17, 2022) (<https://healthpolicy.duke.edu/sites/default/files/2022-06/Duke-Margolis%20Data%20Reporting%20Issue%20Brief.pdf>).

⁶⁹⁰ Interview with Dr. Deborah Birx (Jan. 6, 2022); Interview with Joseph Grogan (Jan. 25, 2022); Interview with Matthew Pottinger (Jan. 25, 2022); Interview with Dr. Anne Schuchat (Dec. 14, 2021); Former Deputy Chief of the Armed Forces Health Surveillance Division, Interview with Senate Committee on Homeland Security and Governmental Affairs (Nov. 30, 2021) (hereinafter “Interview with Former Deputy Chief of the Armed Forces Health Surveillance Division (Nov. 30, 2021)”).

Illustration of the Types of Entities That Are to Share Information to Support Nationwide Public Health Situational Awareness⁶⁹¹



Federal COVID-19 Specific Reports

Throughout the initial response, federal agencies issued regular internal updates and reports independently detailing each agency’s surveillance of the evolving threat. ASPR issued Senior Leadership Briefs and CDC issued ongoing Incident Management Updates and Situation Reports to share updates on the evolving threat and corresponding federal response efforts.⁶⁹² In an interview with the Committee, Dr. Messonnier stated that “a lack of access to data from China and not having robust surveillance systems immediately in place” served as primary obstacles to detecting the pathogen and the initial pandemic response.⁶⁹³ Dr. Schuchat told the Committee that CDC monitored the threat through their national syndromic surveillance system, sixty

⁶⁹¹ Government Accountability Office, *COVID-19: Pandemic Lessons Highlight Need for Public Health Situational Awareness Network* (GAO-22-104600) (June 23, 2022).

⁶⁹² Department of Health and Human Services, *Incident Management Updates, Situation Reports, and Senior Leadership Briefs* (Jan. – Feb. 2020) (on file with Committee). According to HHS, ASPR’s Senior Leadership Briefs were distributed to multiple federal departments and agencies as well as the American Red Cross, DC Government, Johns Hopkins University’s Applied Physics Lab, and North Carolina state government. See HHS Correspondence to Senate Committee on Homeland Security and Governmental Affairs Staff (Oct. 12, 2022).

⁶⁹³ Interview with Dr. Nancy Messonnier (Jan. 5, 2022). Dr. Messonnier told the Committee that in January 2020, CDC “did not have the raw data from China from which to draw conclusions about the earliest cases” and there was “mixed information coming out of China” about the extent of the spread and source, which impacted CDC’s understanding of the pathogen and therefore, CDC’s ability to “understand [the] implications for the U.S.”

offices in different countries, information from the World Health Organization and other international working groups, communications with state and local health departments, and social media.⁶⁹⁴ CDC did not see a large increase in syndromic surveillance monitoring because the U.S. was also at the height of influenza season and the virus was spreading asymptotically.⁶⁹⁵

Based on CDC’s Situation Reports and Incident Management Updates, CDC’s efforts to use modeling as a predictive tool to inform transmission and the impact of different interventions was limited during the initial months. For example, throughout February 2020, CDC’s modeling team focused on estimating the case fatality rate, the reproduction number, and the number of imported cases.⁶⁹⁶ According to former senior advisor to the HHS Secretary, Jim Parker, modeling requests took “a week to ten days” to complete.⁶⁹⁷ Paul Mango, former HHS Deputy Chief of Staff, told the Committee, “we had a lot of confidence in the CDC when the outbreak started, because of the Ebola performance and we didn’t know what we didn’t know, but several weeks into the response, their data was not current nor was it comprehensive.”⁶⁹⁸

DOD also issued regular surveillance reports on the COVID-19 threat. The former Deputy Chief of the Armed Forces Health Surveillance Branch within the Department of Defense’s Defense Health Agency (DHA), told Committee staff that COVID-specific reports prepared by his office relied primarily on external sources: “we didn’t have any capabilities at the time to do diagnosis and reporting directly so during the first couple months of the pandemic, we relied almost exclusively on what was being reported in the open media.”⁶⁹⁹ He recalled reports of cases doubling from 27 viral pneumonia cases on December 31, 2019 to 59 cases of an “unexplained diagnosis of viral pneumonia” on January 5, 2020, which led his Division to note the threat in their health surveillance update, a document distributed to the Military Health System.⁷⁰⁰ After the World Health Organization confirmed human-to-human transmission on January 22, 2020, DOD’s Armed Forces Health Surveillance Branch began circulating novel coronavirus-specific weekly reports on January 24, 2020.⁷⁰¹

DOD Armed Forces Health Surveillance Branch Integrated Biosurveillance Section (AFHSB/IB) used a scale of low, moderate, and high to categorize the threat level, detailed in

⁶⁹⁴ Interview with Dr. Anne Schuchat (Dec. 14, 2021).

⁶⁹⁵ *Id.*

⁶⁹⁶ Department of Health and Human Services, *CDC Incident Management Updates* (Feb. 2020) (on file with Committee).

⁶⁹⁷ Jim Parker, Senior Advisor to HHS Secretary (May 2018 – Jan. 2021), Interview with Senate Committee on Homeland Security and Governmental Affairs (Dec. 8, 2021) (hereinafter “Interview with Jim Parker (Dec. 8, 2021)”).

⁶⁹⁸ Interview with Paul Mango (Nov. 17, 2021).

⁶⁹⁹ Interview with Former Deputy Chief of the Armed Forces Health Surveillance Division (Nov. 30, 2021).

⁷⁰⁰ *Id.*

⁷⁰¹ Department of Defense, *AFHSB Health Surveillance Update: Integrated Biosurveillance Section* (Jan. 22-28, 2020) (on file with the Committee). The reports were distributed both within DOD and across other federal agencies and departments, including HHS, CDC, DHS, and FEMA.

Table 10 below.⁷⁰² With insufficient surveillance capabilities, DOD’s AFHSB/IB 2019-nCoV Surveillance Summaries categorized the emerging coronavirus threat as “moderate” from January 24 until March 19, 2020, despite rising global case counts.

Table 10. DOD’s ASHSB/IB’s Public Health Threat Classification⁷⁰³

Threat Level	Definition
Low	Health events above endemic levels, but consistent with expected findings, and therefore, no change is currently required to the Force Health Protection (FHP) posture in a country or region.
Moderate	Health events of elevated concern or potential impact to the FHP posture in a country or region.
High	Health events that are serious or immediate threats requiring a change to the FHP posture in a country or region, or indicate that a unit is non-mission capable due to health issues.

DHS also distributed interagency reports from its National Operations Center known as “COVID-19 Placemats.” In these reports, DHS assessed the “immediate risk” to the United States as “low” until February 28, 2020.⁷⁰⁴

Challenges in CDC’s Surveillance Capabilities

Challenges in CDC’s surveillance capabilities are not new. Dr. Carter Mecher, a former VA senior official, told Committee staff he analyzed CDC’s case ascertainment rate from the 2009 H1N1 pandemic and found that the U.S. only identified approximately 2.5 to 4 percent of cases, missing over 95 percent of actual cases.⁷⁰⁵ He cautioned that during January and February, the active and ongoing flu season made it difficult to identify COVID-19 cases because “buried in influenza-like illnesses could be COVID-19 cases,” left undiscovered without testing, noting, “that confusion and context is important for why we were slow out of the gates.” According to then CDC Director Dr. Redfield, CDC’s surveillance capabilities were “deficient” at the start of the pandemic and lacked any global capacity.⁷⁰⁶ Kyle McGowan, then CDC Chief of Staff, also expressed concern. He told the Committee, “CDC failed at surveillance because it was not properly funded to build the surveillance systems needed to better coordinate with the states. Consequently, CDC had to rely on imperfect systems like the influenza-like illness surveillance network.”⁷⁰⁷ Dr. Birx argued that the entire structure of U.S. public health surveillance was inadequate to address this pandemic.⁷⁰⁸ In recent Congressional testimony, Dr.

⁷⁰² *Id.*

⁷⁰³ Department of Defense, *AFHSB Health Surveillance Update: Integrated Biosurveillance Section* (Feb. 19-25, 2020) (on file with the Committee, DOD HSGAC 0142).

⁷⁰⁴ Department of Homeland Security, *DHS National Operations Center 2019-nCoV Placemats* (Feb. 3 – 28, 2020) (on file with Committee).

⁷⁰⁵ Interview with Dr. Carter Mecher (July 29, 2022).

⁷⁰⁶ Interview with Dr. Robert Redfield (Feb. 7, 2022).

⁷⁰⁷ Interview with Kyle McGowan (Dec. 2, 2021).

⁷⁰⁸ Interview with Dr. Deborah Birx (Jan. 6, 2022).

Birx noted, “[d]ata are in siloed systems across the CDC without a single common data collection system, resulting in vast inefficiencies and significant duplication across diseases.”⁷⁰⁹

The Majority Committee staff found that due to CDC’s limited data, the federal government was not able to track the spread of COVID-19 in real time. This shortfall further contributed to decisions that miscalculated the risk to the American people in January and February 2020. Dr. Redfield told the Committee he was concerned that the role of CDC Director had become “a medical historian not a response director.”⁷¹⁰ According to Dr. Redfield, CDC continues to be slow to collect and distribute public health data. He recalled an example of an opioid epidemic briefing he received early on as CDC Director in which the most recent data available was three years old. Dr. Deborah Birx told the Committee that by focusing solely on influenza and respiratory disease syndromic (symptoms) planning and syndromic surveillance, U.S. public health planning and response efforts, “made a choice for decades not to definitely diagnose all viral respiratory diseases by laboratory tests and that was a mistake.”⁷¹¹ She noted, “public health institutions in Africa, provided through U.S. funding and training, are better than U.S. institutions and that is damning.”

Establishment of Data and Analytics Task Force

On March 2, 2020, Dr. Birx became the White House Coronavirus Task Force Coordinator.⁷¹² One of her initial tasks was to increase data on COVID-19 so the federal government could make informed response decisions. According to Dr. Birx, CDC’s data failed to provide a comprehensive assessment of COVID-19’s spread throughout the U.S.⁷¹³ Research from the University of Notre Dame in August 2020 found that as many as 100,000 people in the United States were already infected with COVID-19 in early March 2020, but U.S. public health officials were only reporting 1,514 cases and 39 deaths.⁷¹⁴ Dr. Birx told the Committee, “[CDC] had case reports coming from the states, some by fax, but there was no real time data coming in on test positivity, new hospitalization admissions by age, sex, race, and ethnicity, or fatalities in real time on a regular basis.” Dr. Birx relied on colleagues in Europe in early March to provide updated data on cases, hospitalizations, and deaths that were supplied in real time with age and sex disaggregation to estimate spread in the U.S.⁷¹⁵

Throughout the week of March 9, Dr. Birx established a Data and Analytics Task Force (hereinafter “Data Task Force”), comprised of her colleagues from the State Department and data

⁷⁰⁹ House Select Subcommittee on the Coronavirus Crisis, Testimony Submitted for the Record of Dr. Deborah Birx, Former White House Coronavirus Response Coordinator, *A Hearing with Trump White House Coronavirus Coordinator Dr. Deborah Birx*, 117th Cong. (June 23, 2022) (H. Hrg. 117-89).

⁷¹⁰ Interview with Dr. Robert Redfield (Feb. 7, 2022).

⁷¹¹ Interview with Dr. Deborah Birx (Jan. 6, 2022).

⁷¹² *Id.*

⁷¹³ *Id.*

⁷¹⁴ T. Alex Perkins, et al., *Estimating unobserved SARS-CoV-2 infections in the United States*, Proceedings of the National Academy of Sciences (Aug. 21, 2020).

⁷¹⁵ Interview with Dr. Deborah Birx (Jan. 6, 2022).

systems experts from other federal agencies. Dr. Birx told the Committee, “every day the Vice President said to me, ‘make sure the states have what they need, make sure they have supplies’, but the only way you can guarantee that is to have data for decision making.”⁷¹⁶ The Data Task Force worked out of the NRCC at FEMA and had three initial objectives: (1) create a federal database of case and death count data at the county level; (2) build a centralized system to collect testing data; and (3) develop a centralized reporting system for hospital data.⁷¹⁷ These objectives are discussed below.

COVID-19 Specific Data Systems

Case and Death Count Data: In early March 2020, COVID-19 case and death count data was limited and the federal government, including CDC and the White House Task Force, relied primarily on public data systems, such as Johns Hopkins University’s dashboard, that had more timely data than CDC.⁷¹⁸ While the limited data was partly attributable to the lack of widespread testing, the available CDC data lacked needed granularity.⁷¹⁹

Amy Gleason, a U.S. Digital Service official detailed by the White House to help Dr. Birx establish critical data capabilities, told the Committee that CDC’s case and death count data did not provide information by county.⁷²⁰ Of the approximately 2,000 positive U.S. COVID-19 cases in early March 2020, Ms. Gleason told the Committee CDC’s system only captured about 600 cases. Ms. Gleason also explained that the reporting process at the time was slow as “labs, doctors, and hospitals report to local entities, who report to a state, who then report to the federal government.”⁷²¹

According to Ms. Gleason, early in the pandemic response (e.g. March and April 2020), approximately half of the states submitted data by fax to the federal government, “in significant part because faxing is pervasive throughout public health reporting (not just to the federal government, but also in states).”⁷²² As part of her work, Ms. Gleason traveled to local and state public health departments to assist with implementing reporting systems. She observed that a significant number of states relied on “rudimentary tools” and “manual efforts,” like faxing handwritten data to the state government, which “had to be transcribed” and then sent to the federal government.⁷²³ Many states relied on outdated data systems due to a lack of consistent funding. Ms. Gleason detailed her observations to the Committee:

In one state, the county consistently lost access to cases in their reporting tool, so as a back-up, they had nursing students hand enter

⁷¹⁶ *Id.*

⁷¹⁷ Interview with Amy Gleason (Jan. 31, 2022).

⁷¹⁸ *Id.*

⁷¹⁹ Interview with Dr. Deborah Birx (Jan. 6, 2022).

⁷²⁰ Interview with Amy Gleason (Jan. 31, 2022).

⁷²¹ *Id.*

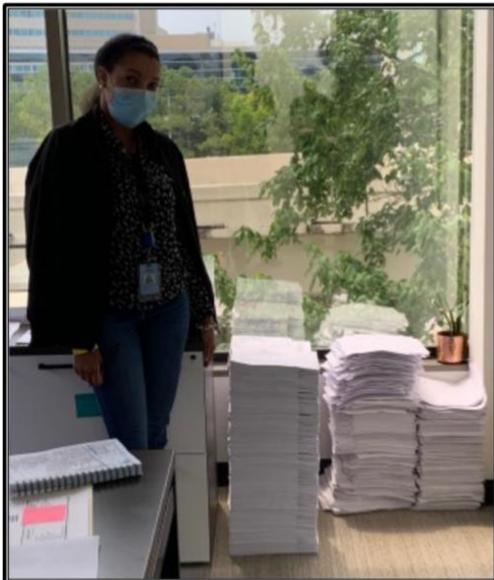
⁷²² *Id.*

⁷²³ *Id.*

cases and information every day to track in an excel sheet . . . In another state, the public health lab had a leak in the ceiling for years, and put plastic garbage bags over their machines to protect them. In another state public health lab, they had a wall falling over. Every advancement our team saw in their tools had come after there was some crisis, like Ebola or Zika, when they got a lump sum of money, then nothing happened, [and] then there was a crisis and they got some more money.⁷²⁴

The photos below, taken during Ms. Gleason’s visits to local public health departments, demonstrate their limited resources and outdated technology.⁷²⁵

Photos of Local Public Health Laboratories⁷²⁶



Local Public Health Department:
A photo of a local health department employee tasked with faxing cases to other jurisdictions.

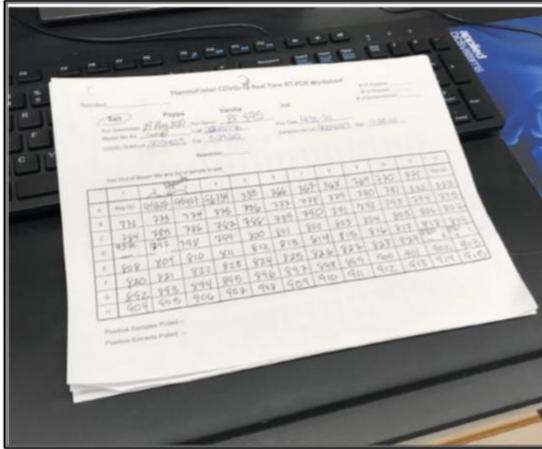


National Guard Member:
A photo of a National Guard member copying order information onto multiple forms.

⁷²⁴ *Id.*

⁷²⁵ Interview with Amy Gleason (Jan. 31, 2022); see also Office of Management and Budget, *Email from Benjamin A. Ward to Senate Committee on Homeland Security and Governmental Affairs* (Feb. 22, 2022).

⁷²⁶ Photographs provided by Amy Gleason, Director of Data, Strategy, and Execution (Mar. 2020 – Mar. 2022), Pandemic Ready Interoperable Modernization Effort (PRIME) Lead (May 2020 – Oct. 2021).



State Public Health Laboratory:
A photo of a state public health laboratory doing manual data entry into a laboratory information management system.



State Public Health Laboratory:
A photo of a state public health laboratory with tarp covering a leak.

According to Ms. Gleason, until the Data Task Force partially stood up a centralized system on March 18, which was finalized by late March, she and her colleagues worked to validate publicly available data they found from the Conference of State Bank Supervisors (CSBS) to obtain data that was updated daily and at the county level to inform the federal government’s situational awareness of the virus’s spread.⁷²⁷

Testing Data: In the beginning of March 2020, the federal government did not have a standardized system to collect testing data.⁷²⁸ Initially, the Data Task Force created a form for hospitals to report their own test results on a daily basis; however, it was not until June 2020 when the federal government was able to collect more comprehensive testing data from public health, commercial, and private labs.⁷²⁹ Ms. Gleason told the Committee that part of the reason for delay was that states had not previously done this level of reporting, “especially reporting both positive and negative results at such a high volume.” As a result, states struggled to obtain the data and report it at the federal level.⁷³⁰ In addition, there were also delays as labs awaited the results. According to Dr. Birx, with a lack of authority—both by CDC and the White House—to require commercial labs and other testing facilities report test results to the federal government, the White House was left with incomplete testing data.⁷³¹

⁷²⁷ Interview with Amy Gleason (Jan. 31, 2022).

⁷²⁸ Interview with Dr. Deborah Birx (Jan. 6, 2022); *see also* Interview with Amy Gleason (Jan. 31, 2022). Ms. Gleason noted that the CDC created a new process to start collecting lab data from commercial labs, public health labs, and individual laboratories.

⁷²⁹ Interview with Amy Gleason (Jan. 31, 2022).

⁷³⁰ *Id.*

⁷³¹ Interview with Dr. Deborah Birx (Jan. 6, 2022).

The implementation of mandatory reporting for COVID-19 lab results to inform virus spread presented several challenges. Shannon West, the first Chief Technology Officer for the Innovation Center at CMS, assisted the White House with COVID-19 data reporting systems.⁷³² According to Ms. West, the federal government never had federal standards on reporting lab data. When she began to draft standards specific for reporting COVID-19 test results, she told the Committee, “people were sending me memos from as early as 2003 that they had written about lab data standardization that had never gotten done.” When asked how she would grade the federal government’s ability to share health care information, she stated, “a D . . . we are bad at building software and we are bad at buying software—those things will continue to perpetuate until we’ve increased the level of talent at federal, state, and local levels.”⁷³³

As part of the supplemental emergency funding provided by Congress in March and April 2020, Congress required public health laboratories to report testing data and subsequently expanded reporting requirements to commercial laboratories.⁷³⁴ Dr. Birx told the Committee, “for the first time in this country, we were able to see what was going on [with COVID-19 testing], when [other countries around] the world already had that data.”⁷³⁵

Hospital Data: In March 2020, CDC tried to leverage its National Healthcare Safety Network (NHSN), a system that hospitals are required to use to report data to the federal government, to include new COVID-19 data.⁷³⁶ Dr. Schuchat, CDC’s then Principal Deputy Director, explained how regulatory barriers, like the Paperwork Reduction Act, presented challenges for CDC to modify mandatory data collection needed for the pandemic response. While provisions in Paperwork Reduction Act can be waived for voluntary data collection during public health emergencies, Dr. Schuchat explained that “in the early period [of the COVID-19 response], there were challenges in the speed with which CDC could adapt its data collection.”⁷³⁷ CDC told the Committee that OMB took the position that the voluntary waiver authority under the 21st Century Cures Act did not apply to CDC’s emergency COVID-19 data collection efforts because the agency was “modifying an existing mandatory collection system,” which required additional approvals under the Paperwork Reduction Act, despite the growing public health

⁷³² Shannon West, Former Chief Technology Officer, Innovation Center, Centers for Medicare and Medicaid Services (Jan. 2020 – Apr. 2021) (CMS tenure Sept. 2017 – Apr. 2021), Detailed to White House for COVID-19 Testing Infrastructure and Data Reporting (Mar. 2020 – July 2020), Interview with Senate Committee on Homeland Security and Governmental Affairs (Jan. 6, 2022) (hereinafter “Interview with Shannon West (Jan. 6, 2022)”).

⁷³³ *Id.*

⁷³⁴ Coronavirus Aid, Relief, and Economic Security (CARES) Act, Pub. L. No. 116-136, Sec. 3718 (2020).

⁷³⁵ Interview with Dr. Deborah Birx (Jan. 6, 2022).

⁷³⁶ Centers for Disease Control and Prevention, Briefing with Senate Committee on Homeland Security and Governmental Affairs Staff (Nov. 8, 2022) (hereinafter “CDC Briefing (Nov. 8, 2022)”).

⁷³⁷ See Interview with Dr. Anne Schuchat (Dec. 14, 2021); see also 21st Century Cures Act, Pub. L. No. 114-255, Sec. 3087 (2016). Section 3087 of the 21st Century Cures Act permits the HHS Secretary to waive requirements for the “voluntary collection of information” under the Paperwork Reduction Act during public health emergencies.

emergency.⁷³⁸ As a result, it took CDC weeks to receive the requisite approval from OMB to modify its National Healthcare Safety Network system to include voluntary COVID-19 reporting. CDC told the Committee these delays led to “duplicate systems” as the leadership stood up additional reporting systems to collect new data elements for COVID-19.

According to Dr. Birx, during the initial months of the pandemic, CDC remained focused on gathering symptomatic data from a subset of hospitals.⁷³⁹ After arriving at the White House, Dr. Birx proposed a new approach: the federal government would collect “current hospitalizations, new admissions, Intensive Care Unit (ICU) capacity, fatalities” and related demographics, including “age, sex, race, and ethnicity from all 6,000 hospitals.”⁷⁴⁰ Dr. Birx told the Committee CDC was not receptive and “explained that they wanted to stay with the hospital surveillance system that they had previously developed.” Dr. Birx noted that she personally traveled to CDC in Atlanta in July 2020 to “beg them” to take on full hospital reporting and provide funding. She estimated that in March, hospital surveillance system data was only available for about “40 percent of the country’s hospitals [and] was particularly underrepresented in rural areas, [such as] Northern California, most of the Central Valley, and much of the middle of the country.” According to Dr. Birx, this meant the federal government could not accurately model patient locations or assess the extent of therapeutics and other assistance needs.⁷⁴¹

Dr. Birx told the Committee that she utilized the comprehensive data reporting model she relied upon in Sub Saharan Africa to collect epidemiological data for COVID-19 in the U.S.⁷⁴² According to Dr. Birx, there are over 50,000 health care sites in Africa—in large part funded by the U.S. government—that report quarterly on critical data compared to approximately 6,000 hospitals and 15,000 nursing homes in the U.S. She told the Committee, “it still stuns me that I could see every client in Africa and know whether they’re virally suppressed [for HIV] or not and how they’re doing in real time and I couldn’t do that in the U.S.”⁷⁴³

Ms. Gleason told the Committee that when she started on the Data Task Force in early March 2020, the only hospital data she received was from FEMA who worked with their regional offices to try and obtain bed numbers and ventilator data.⁷⁴⁴ This data, however, was not comprehensive or representative. Ms. Gleason explained, “FEMA would get five or six total numbers for the entire state and no hospital-level details at all until hospitals started reporting individually in early April 2020.” She said, “CDC looked to hospital data for disease education,” but did not see it as an “operational tool” and “did not gather complete data reporting from hospitals that was required for response operations, such as delivering treatments, supplies, or

⁷³⁸ CDC Briefing (Nov. 8, 2022).

⁷³⁹ Interview with Dr. Deborah Birx (Jan. 6, 2022).

⁷⁴⁰ *Id.*

⁷⁴¹ *Id.*

⁷⁴² *Id.*

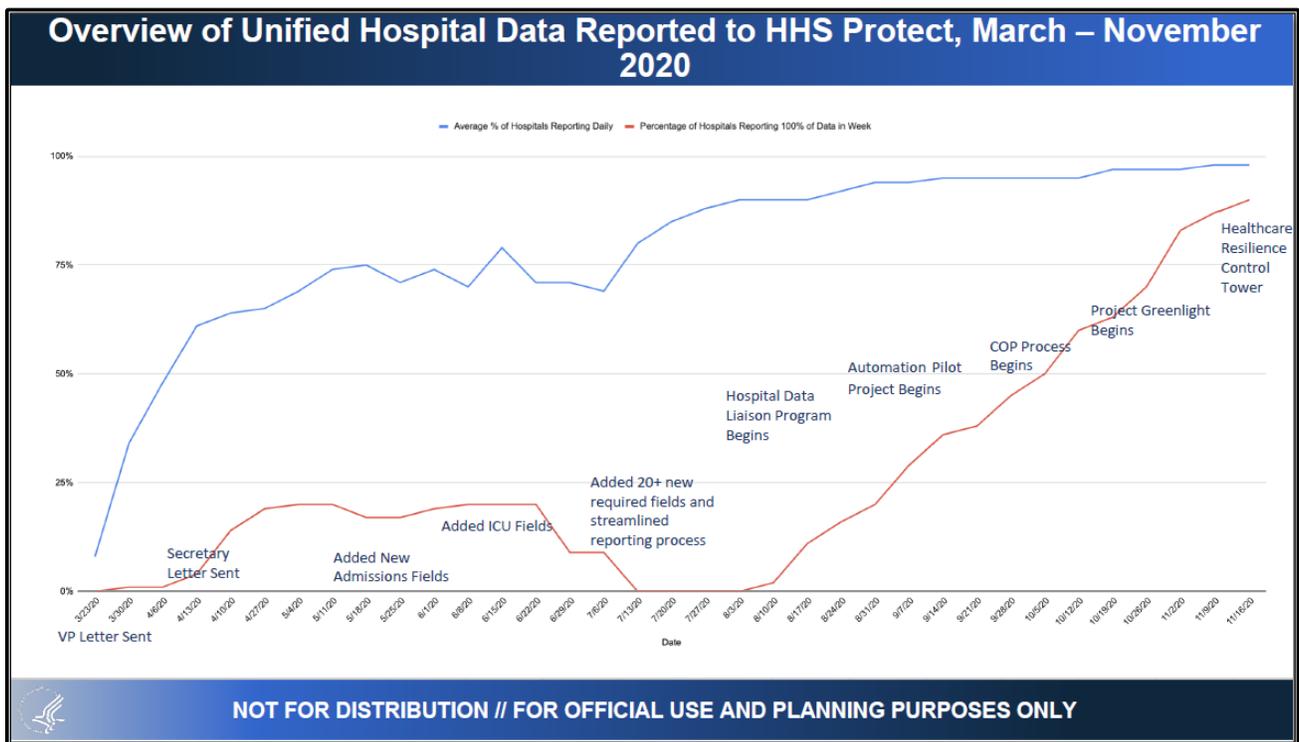
⁷⁴³ *Id.*

⁷⁴⁴ Interview with Amy Gleason (Jan. 31, 2022).

extra bed capacity.”⁷⁴⁵ Former HHS senior advisor Jim Parker told the Committee that the lack of uniform definitions, such as how “hospital bed capacity” is defined, made it difficult to accurately survey health care capacity around the U.S.

Ultimately, the Data Task Force decided to partner with a preexisting contractor, Palantir, to build a centralized reporting system known as “HHS Protect” to collect critical operational hospital data and other COVID-19 data.⁷⁴⁶ The below graph illustrates the dearth of hospital reporting data beginning in March 2020 and the increase in hospital reporting data throughout the year.

Hospital Data Reported to HHS Protect from March – November 2020⁷⁴⁷



⁷⁴⁵ *Id.*

⁷⁴⁶ *Id.*; see Department of Health and Human Services, *Contract to Palantir Technologies Inc.* (Apr. 22, 2020); Department of Health and Human Services, *HHS Protect Public Data Hub* (<https://public-data-hub-dhhs.hub.arcgis.com/>) (accessed Dec. 4, 2022).

⁷⁴⁷ Office of Management and Budget, *Data Strategy & Execution Workgroup: Hospital Liaison Program & Project Greenlight Presentation* (Nov. 30, 2020) (on file with Committee, OMB HSGAC 1878).

While the reporting of hospital data was essential to tracking the spread of the virus, the Committee received concerns regarding the implementation of the mandatory hospital data reporting systems.⁷⁴⁸ For example, Michigan Department of Health and Human Services noted,

Federal mandates of hospital data reporting (and skilled nursing) were rolled out with little warning and very little coordination. As the program continued, changes were often made to data, datasets, and reporting with zero notice, changes during the weekend, and without time for changes to corresponding state systems and time to educate the individuals reporting up to the states.⁷⁴⁹

Overall, the Majority Committee staff found that U.S. public health data collection and surveillance systems—at both the state and federal levels—lack sufficient coordination, integration, and modernization. Dr. Schuchat acknowledged, “the fragmented nature of the data systems for different needs was a problem during the initial COVID-19 response.”⁷⁵⁰ In February 2022, Chris Currie, the Director of GAO’s Homeland Security and Justice Team testified before the Committee that while federal surveillance systems—specifically for biological threats—are fragmented across multiple federal agencies, the “new, innovative surveillance systems [created] to monitor COVID” at the state, local, private sector, and health care system levels during the COVID-19 response, should not be disregarded after the pandemic.⁷⁵¹

VI. Testing Development, Distribution, and Capacity

Robust diagnostic testing is foundational to an effective response during an infectious disease outbreak.⁷⁵² When there are asymptomatic or pre-symptomatic infections, like with COVID-19, diagnostic testing is the only way to effectively determine the extent of infections in a given population. As discussed throughout in this section, the U.S. failed to quickly develop and scale reliable nationwide testing capacity, losing critical time to contain and mitigate the spread of the virus by failing to quickly develop and scale reliable nationwide testing capacity.⁷⁵³

⁷⁴⁸ Michigan Department of Health and Humans Services, Written Response to Senate Committee on Homeland Security and Governmental Affairs State Public Health Agency Questionnaire (Dec. 2, 2021) (on file with Committee).

⁷⁴⁹ *Id.*

⁷⁵⁰ Interview with Dr. Anne Schuchat (Dec. 14, 2021).

⁷⁵¹ Senate Committee on Homeland Security and Governmental Affairs, *Addressing the Gaps in America’s Biosecurity Preparedness*, 117th Cong. (Feb. 17, 2022) (S. Hrg. 117-XX).

⁷⁵² Cassandra D Kelly-Cirino, et al., *Importance of diagnostics in epidemic and pandemic preparedness*, *BMJ Global Health* (Jan. 29, 2019).

⁷⁵³ Dr. Timothy Stenzel, Director of the Office of Health Technology 7 (In Vitro Diagnostics), Center for Devices and Radiological Health, Food and Drug Administration (July 2018 – present), Interview with Senate Committee on Homeland Security and Governmental Affairs (Sep. 21, 2021) (hereinafter “Interview with Dr. Timothy Stenzel (Sept. 21, 2021)”); Interview with Dr. Duane Caneva (Nov. 15, 2021).

The Majority Committee staff found that problems with CDC’s initial COVID-19 test kits, combined with supply shortfalls, limited laboratory infrastructure, narrow testing guidance, and insufficient communication with private industry, left the U.S. without widespread testing capabilities and contributed to at least a three-week delay in distributing effective COVID-19 diagnostic test kits.⁷⁵⁴ With limited testing capacity throughout the initial response, federal officials were unable to form an accurate understanding early in the pandemic of where and how widely COVID-19 had already spread throughout the country. Ultimately, these missteps had far-reaching consequences and left Americans with the false impression that the virus was sufficiently contained.

This section discusses the development and manufacturing of CDC’s COVID-19 test kit, subsequent investigations into CDC’s test kit failure, CDC’s narrow testing guidance, insufficient engagement with the private sector, regulatory barriers, and the impact these challenges had on the initial federal response.⁷⁵⁵

A. Development and Manufacturing

CDC initially developed two types of diagnostic tests: one where public health labs could submit samples to CDC’s headquarters for testing and the other, a test kit that could be sent to public health labs to conduct tests on their own without sending samples to the CDC. CDC developed its in-house diagnostic test quickly and without incident; CDC’s initial diagnostic test kit, however, unexpectedly encountered a number of problems. While public reporting suggests a consensus on the root cause of CDC’s testing failures—that the test kits were contaminated and poorly designed—the Majority Committee staff’s review found that there were and continue to be conflicting assessments of not only what went wrong, but also the reasons for those failures.⁷⁵⁶ The Committee interviewed current and former public health officials, received briefings from FDA and CDC officials, and reviewed relevant documents from HHS and CDC to better understand the cause of CDC’s test kit failures.

At the time of this report, Dr. Stephen Lindstrom, who was initially tasked with developing CDC’s diagnostic test, had submitted complaints to both the Office of Special Counsel (OSC) and the HHS OIG alleging, among other claims, scientific fraud and

⁷⁵⁴ See Department of Health and Human Services, Office of Laboratory Science and Safety, *Root Cause Analysis: Unanticipated Failure of the ‘CDC 2019 – Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel’* (Mar. 24, 2020) (on file with Committee, HHS HSGAC 22290 - 22311) (hereinafter “Root Cause Analysis (Mar. 24, 2020)”); Department of Health and Human Services, Office of the General Counsel, *Summary of the Findings of the Immediate Office of the General Counsel’s Investigation Regarding CDC’s Production of COVID-19 Test Kits* (June 19, 2020) (on file with Committee, HHS HSGAC 32006 - 32008) (hereinafter “HHS OGC Summary of Findings (June 19, 2020)”); Department of Health and Human Services, Office of General Counsel, *Findings of the Office of the General Counsel’s Supplementary Investigation Regarding the CDC’s Production of the Initial COVID-19 Test Kits* (Jan. 14, 2021) (on file with Committee, HHS HSGAC 42769 - 42780) (hereinafter “HHS OGC Supplementary Investigation (Jan. 14, 2021)”).

⁷⁵⁵ Shortages of testing supplies is addressed in Part II, Section VIII (Medical Supply Chain Challenges).

⁷⁵⁶ *C.D.C. Virus Tests Were Contaminated and Poorly Designed, Agency Says*, New York Times (Dec. 15, 2021); *The CDC’s failed race against covid-19: A threat underestimated and a test overcomplicated*, Washington Post (Dec. 26, 2020).

whistleblower retaliation. In December 2020 and June 2021, Dr. Lindstrom filed complaints against HHS and CDC alleging that the agency made knowingly false statements in a scientific publication and took retaliatory actions against him subsequent to the test kit failures and a protected disclosure alleging a supervisor improperly reported COVID test results in violation of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and the Health Insurance Portability and Accountability Act (HIPAA).⁷⁵⁷ OSC has since ruled on Dr. Lindstrom’s complaint, finding CDC could support its decision to reassign Dr. Lindstrom and that Dr. Lindstrom’s other complaints did not rise to the level of prohibited actions.⁷⁵⁸ In OSC’s final decision on Dr. Lindstrom’s complaint, it noted, “[t]he evidence seems to indicate the researchers drew a different conclusion about the likelihood of the core lab causing the contamination than [Dr. Lindstrom].”⁷⁵⁹ The HHS Office of Inspector General is in the process of conducting an audit of HHS’s Production and Distribution of COVID-19 Lab Test Kits, which is expected to be released next year.⁷⁶⁰

Development of CDC’s In-House COVID-19 Test

On January 10, 2020, CDC began developing a diagnostic test for COVID-19 after China publicly posted the genetic sequence for SARS-CoV-2 online.⁷⁶¹ Public health officials told the Committee that it is not uncommon for CDC to develop an initial test for new pathogens.⁷⁶² Dr. Lindstrom, then Team Lead of the Respiratory Viruses Diagnostic (RVD) team told the Committee in an interview that CDC instructed him to develop a test for COVID-19. According

⁷⁵⁷ *Dr. Stephen Lindstrom v. CDC*, Office of Special Counsel (filed Dec. 2020) (on file with Committee) (complaint) (hereinafter “Lindstrom OSC Complaint (Dec. 2020)”); *Dr. Stephen Lindstrom v. CDC*, Office of Special Counsel Complaint No. MA-21-0403 (Apr. 7, 2022) (response to preliminary decision) (on file with Committee) (hereinafter “Lindstrom Response to Preliminary OSC Decision (Apr. 7, 2022)”); *Dr. Stephen Lindstrom*, Department of Health and Human Services, Office of Inspector General (June 11, 2021) (complaint) (hereinafter “Lindstrom HHS OIG Complaint (June 11, 2021)”).

⁷⁵⁸ *See Dr. Stephen Lindstrom v. CDC*, Office of Special Counsel Complaint No. MA-21-0403 (May 24, 2022) (final decision) (on file with Committee).

⁷⁵⁹ *Id.*, at 3.

⁷⁶⁰ Department of Health and Human Services Office of Inspector General, Audit of HHS’s Production and Distribution of COVID-19 Lab Test Kits (<https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000462.asp>) (accessed Nov. 16, 2022).

⁷⁶¹ CDC Briefing (Dec. 1, 2021); Interview with Dr. Stephen Lindstrom (Feb. 15, 2022); *see also Severe acute respiratory syndrome coronavirus 2 isolate Wuhan-Hu-1, complete genome*, National Institute of Health National Library of Medicine (Jan. 17, 2020) (<https://www.ncbi.nlm.nih.gov/nucleotide/MN908947>).

⁷⁶² *See* Interview with Dr. Julie Gerberding (Feb. 8, 2021); Interview with Association of Public Health Laboratories (Apr. 19, 2021); Interview with American Clinical Laboratory Association (May 27, 2021); CDC and FDA Briefing (July 12, 2021); Interview with Dr. Stephen Lindstrom (Feb. 15, 2022). CDC has developed diagnostic tests during prior public health emergencies, including H1N1 and Zika. *See* Department of Health and Human Services, Centers for Disease Control and Prevention, Influenza Diagnostic Testing During the 2009-2010 Flu Season (Sep. 29, 2009) (https://www.cdc.gov/h1n1flu/diagnostic_testing_public_qa.htm); Department of Health and Human Services, Centers for Disease Control and Prevention, Zika Virus: Diagnostic Tests (June 13, 2019) (<https://www.cdc.gov/zika/laboratories/types-of-tests.html>).

to Dr. Lindstrom, his instructions were: “make a test, make it now, qualify it as soon as possible, and do it as fast as you can.”⁷⁶³

Dr. Lindstrom told Committee staff that he presented a plan to CDC officials on January 15, 2020 for developing both the in-house CDC test and a test to send state public health labs.⁷⁶⁴ According to Dr. Lindstrom, the purpose of the January 15 meeting was to inform CDC officials, and obtain their approval, of the RVD lab’s intended process for manufacturing the first test kits. The RVD lab’s plan contained the scope of work, cost, and anticipated timing, including EUA qualification, and the manufacturing and distribution to states. Dr. Lindstrom told the Committee that he recalled being asked how he could shorten the timeline. He noted that it generally takes three to four months to develop a diagnostic test. In this situation, Dr. Lindstrom said he was able to compress the test development timeline by working in parallel instead of sequentially. Dr. Lindstrom told the Committee that his superiors within CDC approved his plan.⁷⁶⁵

On January 16, CDC completed development for an in-house diagnostic test.⁷⁶⁶ Two days later, the test received approval under Clinical Laboratory Improvement Amendments (CLIA) regulations, the established quality standards for laboratory testing on human specimens.⁷⁶⁷ On January 19, public health labs across the country began submitting specimens to CDC for testing and the agency turned its focus to developing a deployable test kit that could be independently processed at public health labs.⁷⁶⁸ On January 21, CDC utilized its in-house test to confirm the first case of COVID-19 in the U.S. Shortly thereafter, on January 24, CDC posted the protocol for its test, the Real-Time RT-PCR Panel for Detection of 2019-Novel Coronavirus, on its website, CDC.gov.⁷⁶⁹

Development of CDC’s COVID-19 Test Kits

The development of diagnostic test kits, which were intended to be sent both nationally and internationally to increase testing capacity, directly involved three components at CDC’s Headquarters in Atlanta, Georgia. Within the Respiratory Viruses Branch, the RVD laboratory, under Dr. Lindstrom, initiated test development and design of the diagnostic test kit, which became known as the “CDC 2019-Novel Coronavirus (2019-nCoV) Real Time RT-PCR Diagnostic Panel.”⁷⁷⁰ In the Division of Scientific Resources (DSR), the Biotechnology Core

⁷⁶³ Interview with Dr. Stephen Lindstrom (Feb. 15, 2022).

⁷⁶⁴ *Id.*

⁷⁶⁵ *Id.*

⁷⁶⁶ HHS OIG Supplementary Investigation (Jan. 14, 2021).

⁷⁶⁷ 42 U.S.C. § 263a; Dr. Stephen Lindstrom, *Email from CDC Laboratory Director, Office of Infectious Diseases, CLIA Compliance Program to Dr. Stephen Lindstrom* (Jan. 18, 2020) (on file with Committee).

⁷⁶⁸ Department of Health and Human Services, *CDC Early COVID-19 Testing Timeline* (July 12, 2021) (on file with Committee).

⁷⁶⁹ *Id.*

⁷⁷⁰ Food and Drug Administration, *Emergency Use Authorization for CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel* (Dec. 1, 2020)

Facility Branch (“Core lab”) created the reagents, or chemical solutions, needed for the test, and the Reagent Diagnostic Services Branch (RDSB) prepared, assembled, and sent the final test kits to the International Reagent Resource (IRR) for distribution to state public health labs.⁷⁷¹

CDC’s diagnostic test kit contained four components: three primer and probe sets which are “short fragments of genetic code used to detect a virus’s genetic code,” called, N1, N2, and N3, and a control component (RP).⁷⁷² The N1 and N2 components were designed to detect SARS-CoV-2, the virus that causes COVID-19. The N3 component was designed to detect both the SARS-CoV-2 virus and other SARS-like viruses.⁷⁷³ Some CDC officials believed that the initial test was “more sensitive than necessary to detect COVID-19.” Others, however, noted that “at the time, sensitivity of the COVID-19 pathogen was unknown” and therefore, appropriate to design such a sensitive test, despite it being more difficult to scale.⁷⁷⁴ Dr. Lindstrom told Committee staff he informed senior CDC officials at the January 15 meeting about his plan to use the three primer and probe sets, which he modeled after a previous Middle East Respiratory Syndrome (MERS) test, a disease caused by a related virus.⁷⁷⁵

CDC’s diagnostic test generally entailed a multi-step process, the majority of which occurs in a laboratory setting.⁷⁷⁶ To ensure the tests are working as designed, scientists use positive and negative control material. For example, positive control material (e.g. virus sample) should yield a positive result and negative control material should yield a negative result. Positive control material validates the effectiveness of a test in identifying a virus (avoiding false negatives) while negative control material ensures the test does not produce false positives.⁷⁷⁷

(<https://www.fda.gov/media/134919/download>). On July 21, 2021 CDC announced its intent to retire the test it developed. See Department of Health and Human Services, Centers for Disease Control and Prevention, 08/02/2021: Lab Alert: Clarifications about the Retirement of the CDC 2019 Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel (Aug. 2, 2021) (https://www.cdc.gov/locs/2021/08-02-2021-lab-alert-Clarifications_about_Retirement_CDC_2019_Novel_Coronavirus_1.html).

⁷⁷¹ See Root Cause Analysis, at 4-5 (Mar. 24, 2020); HHS OGC Supplementary Investigation, at 2 (Jan. 14, 2021).

⁷⁷² Government Accountability Office, *COVID-19: Continued Attention Needed to Enhance Federal Preparedness, Response, Service Delivery, and Program Integrity*, at 69 (GAO 21-551) (July 2021).

⁷⁷³ HHS OGC Supplementary Investigation (Jan. 14, 2021). Justin S. Lee, Jason M. Goldstein, Jonathan L. Moon, et al., *Analysis of the initial lot of the CDC 2019-Novel Coronavirus (2019-nCoV) real-time RT-PCR diagnostic panel*, PLOS One (Dec. 15, 2021).

⁷⁷⁴ *Id.* at 8.

⁷⁷⁵ Interview with Dr. Stephen Lindstrom (Feb. 15, 2022).

⁷⁷⁶ CDC’s Diagnostic test is formally called, “CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel.” See HHS OGC Supplementary Investigation (Jan. 14, 2021).

⁷⁷⁷ Interview with Dr. Stephen Lindstrom (Feb. 15, 2022).

On January 16, the WHO also announced a deployable diagnostic test kit for COVID-19.⁷⁷⁸ CDC declined to use the WHO test in the U.S.⁷⁷⁹ An internal HHS Office of General Counsel report from January 2021, which investigated CDC’s test kit failures, explained the rationale for this decision.⁷⁸⁰ First, the report noted, “the RVD Lab had demonstrated subject matter expertise on coronaviruses and had successfully developed past tests for SARS and MERS.”⁷⁸¹ Further, according to CDC, it had already been working with FDA to validate its test and obtain an EUA, while the WHO test had yet to begin the EUA process. CDC officials interviewed by the Committee indicated that, as a result, using the WHO test in place of CDC’s developed test would not have saved much, if any, time.⁷⁸² Dr. Lindstrom told the Committee that CDC did not “reject the adoption of [another test] without consideration . . . we needed to meet the manufacturing demand in the U.S. and wanted multiple options.”⁷⁸³

Because CDC did not have a live virus sample at the time of test development, the RVD lab needed an alternate source of positive control material to verify its test functioned properly. Dr. Lindstrom told the Committee he had two options: one, obtain synthetic positive control material (i.e. full gene constructs) from outside manufacturers, or two, manufacture the positive control material within CDC.⁷⁸⁴ When Dr. Lindstrom’s staff contacted manufacturers, they learned the turnaround time to process positive control material would be one to two weeks.⁷⁸⁵ Dr. Lindstrom told the Committee that CDC ordered positive control material from two manufacturers. In the interim, Dr. Lindstrom’s lab asked the Core lab if they could create the positive control material. He told the Committee, “they didn’t work for me so I could not make them do it,” but Dr. Lindstrom told the Core lab that if they felt comfortable and understood the risks involved, he would not object. The Core lab agreed to manufacture the positive control material needed.⁷⁸⁶

Multiple CDC officials also told Committee staff that obtaining virus samples from China likely would not have expedited the development process.⁷⁸⁷ Dr. Schuchat explained that while “[a virus sample] would have been helpful, there wasn’t much of a lag since the genetic sequence

⁷⁷⁸ World Health Organization, *Epidemiological Alert Novel coronavirus (nCoV)*, at 4-5 (Jan. 16, 2020) (<https://www.paho.org/en/documents/epidemiological-alert-novel-coronavirus-ncov-16-january-2020>).

⁷⁷⁹ HHS OGC Supplementary Investigation, at 10 (Jan. 14, 2021).

⁷⁸⁰ *Id.*

⁷⁸¹ *Id.* According to FDA, the World Health Organization did not develop the test, review data for the test, or grant emergency use listing for the test. Instead, the World Health Organization “simply bought the test and distributed it mostly to developing countries without evaluating the test.” *See* HHS Correspondence to Senate Committee on Homeland Security and Governmental Affairs Staff (Aug. 12, 2022).

⁷⁸² Interview with Dr. Daniel Jernigan (Dec. 15, 2021); Interview with Dr. Stephen Lindstrom (Feb. 15, 2022); Interview with Dr. Anne Schuchat (Dec. 14, 2021).

⁷⁸³ Interview with Dr. Stephen Lindstrom (Feb. 15, 2022).

⁷⁸⁴ *Id.*

⁷⁸⁵ *Id.*

⁷⁸⁶ *Id.*

⁷⁸⁷ Interview with Dr. Larry Kerr (July 28, 2021); Interview with Dr. Anne Schuchat (Dec. 14, 2021).

provides a tremendous amount of information.”⁷⁸⁸ She noted one downside, however, is that “you do not have clinical specimens to check your tests against.” Dr. Schuchat stated that CDC obtained the genetic sequence from Thailand by January 23, 2020. FDA noted that while the absence of viral material may not pose an issue for diagnostic test development, it can present challenges when assessing whether a test works properly and performs well.⁷⁸⁹ Dr. Lindstrom told the Committee about the risks related to manufacturing positive control material and noted that many labs refuse to manufacture positive control material and other test kit material in the same lab due to contamination concerns. For example, if positive control material inadvertently contaminates the tests kits, there would be false positives.⁷⁹⁰

On January 14, the Core lab started manufacturing the positive control material.⁷⁹¹ According to Dr. Wendi Kuhnert, then Laboratory and Testing Task Force Lead for the COVID-19 response, the Core lab manufactured the positive control material “in a protected way” to reduce any risk of contamination in the facility.⁷⁹² Dr. Kuhnert stated that the positive control material was “deprotected,” meaning that it was then able to be a potential source of contamination, after being delivered to the RVD lab.⁷⁹³ On January 27, the Core lab delivered the positive control material to Dr. Lindstrom’s lab for quality control testing.⁷⁹⁴ Dr. Lindstrom told the Committee he was not aware of the mitigation steps the Core lab took to minimize contamination risk.⁷⁹⁵

CDC’s Application for an Emergency Use Authorization

HHS’s public health emergency declaration on January 31, 2020 opened the door for CDC to seek an EUA from FDA for its diagnostic test.⁷⁹⁶ In a Committee briefing, Dr. Kuhnert, told the Committee, “CDC had been working with FDA and discussing their test design as well as sharing some preliminary data back and forth during the entire development and review

⁷⁸⁸ Interview with Dr. Anne Schuchat (Dec. 14, 2021).

⁷⁸⁹ HHS Correspondence to Senate Committee on Homeland Security and Governmental Affairs Staff (Aug. 12, 2022).

⁷⁹⁰ Interview with Dr. Stephen Lindstrom (Feb. 15, 2022).

⁷⁹¹ Dr. Stephen Lindstrom, *Email from DVD CDC official to DSR CDC official and Dr. Lindstrom* (Jan. 14, 2020) (on file with Committee).

⁷⁹² Dr. Wendi Kuhnert, Senior Advisor for Laboratory Science at the Centers for Disease Control and Prevention (2019 – present) (CDC service 2001-present), Laboratory and Testing Task Force Lead for COVID-19 Response (Jan. 27, 2020 - July 18, 2020), Interview with Senate Committee on Homeland Security and Governmental Affairs (July 14, 2022). (hereinafter “Interview with Dr. Wendi Kuhnert (July 14, 2022)”).

⁷⁹³ *Id.*

⁷⁹⁴ Dr. Stephen Lindstrom, Timeline (received Feb. 15, 2022) (on file with Committee).

⁷⁹⁵ Interview with Dr. Stephen Lindstrom (Feb. 15, 2022).

⁷⁹⁶ Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Public Health Emergency Declaration (<https://www.phe.gov/Preparedness/legal/Pages/phedeclaration.aspx>) (accessed Nov. 16, 2022); *see also* Federal Food, Drug and Cosmetic Act of 1938, Pub. L. No. 75-717, Sec. 564 (as amended through Pub. L. No. 117-103 (2022)).

process, which allowed for a very fast review and approval.”⁷⁹⁷ The RVD lab, as discussed in more detail below, conducted quality control testing on the test kits.⁷⁹⁸ CDC applied for an EUA on February 3, 2020 and received approval from FDA the following day.⁷⁹⁹ State and local public health laboratories started submitting requests for CDC’s test kits on February 5.⁸⁰⁰ The following day, on February 6, Dr. Lindstrom’s lab performed a final quality control test and found one false positive reaction in N3.⁸⁰¹ After retesting the reagent five times, Dr. Lindstrom could not replicate the error and concluded that “all acceptance criteria were met.”⁸⁰²

After Dr. Lindstrom’s lab approved the test kits for distribution, CDC began shipping its manufactured test kits to state public health laboratories later that day, with kits scheduled to arrive the next day.⁸⁰³ According to documents HHS produced for the Committee, CDC’s manufactured test kits were intended to assist the first wave of testing until commercial laboratories and diagnostic companies were able to come online with mass produced test kits.⁸⁰⁴

⁷⁹⁷ CDC Briefing (Dec. 1, 2021)

⁷⁹⁸ Dr. Stephen Lindstrom, *Timeline of COVID-19 Test Kit Development and Manufacturing* (received Feb. 15, 2022) (on file with Committee) (hereinafter “Dr. Lindstrom Timeline of Events (received Feb. 15, 2022)”).

⁷⁹⁹ Food and Drug Administration, *Emergency Use Authorization for CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel* (Feb. 4, 2020) (<https://web.archive.org/web/20200205171538/https://www.fda.gov/media/134919/download>).

⁸⁰⁰ HHS Correspondence to Senate Committee on Homeland Security and Governmental Affairs Staff (May 25, 2022).

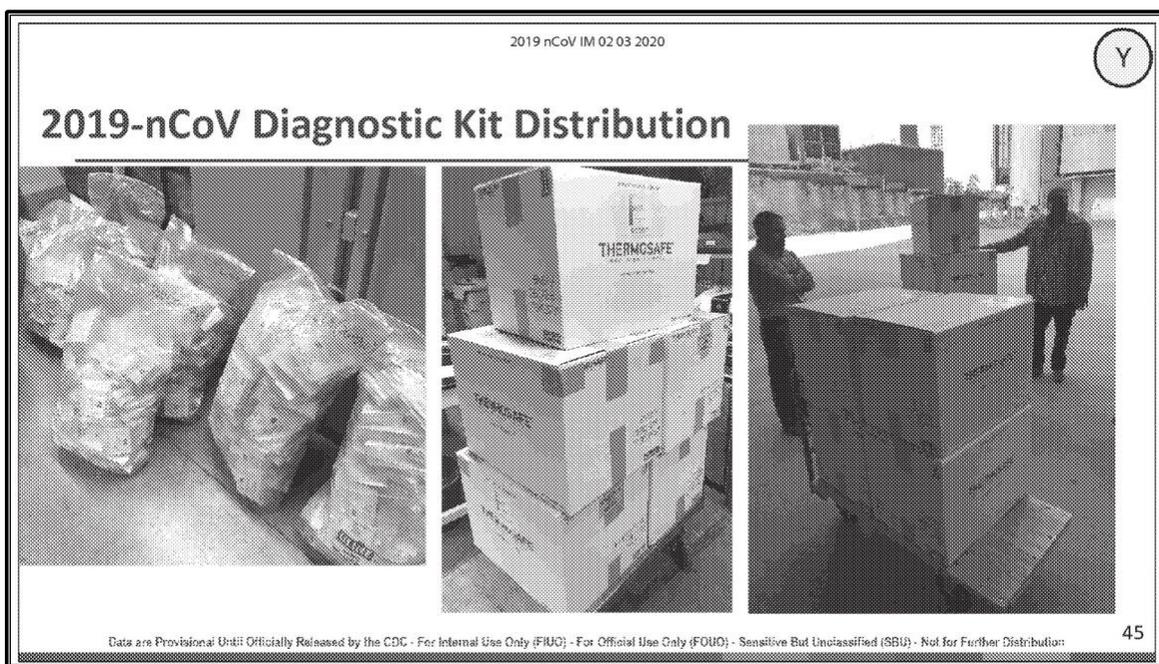
⁸⁰¹ Dr. Lindstrom Timeline of Events (received Feb. 15, 2022).

⁸⁰² *Id.*; Dr. Stephen Lindstrom, *Dr. Lindstrom Comments on Summary of the Findings of the Immediate Office of the General Counsel’s Investigation Regarding CDC’s Production of COVID-19 Test Kits* (received Mar. 8, 2022) (on file with Committee); Lindstrom Response to Preliminary OSC Decision, at 6 (Apr. 7, 2022).

⁸⁰³ Root Cause Analysis, at 6 (Mar. 24, 2020).

⁸⁰⁴ HHS OGC Summary of Findings, at 1 (June 19, 2020). For purposes of this report, the Committee’s reference to “commercial labs” includes all independent labs as defined by CLIA. 42 U.S.C § 263a(a).

CDC Test Kits Prepared for Distribution⁸⁰⁵



By February 6, CDC had shipped the initial test kits to 39 states.⁸⁰⁶ Between February 6 and 10, CDC shipped test kits to 93 “qualified laboratories,” which included all state laboratories, DC, and several DOD laboratories.⁸⁰⁷

B. CDC Diagnostic Test Kit Errors

Some public health laboratories that received CDC test kits in early February, however, were unable to verify performance of the test kits.⁸⁰⁸ CDC first learned about an issue with the test kit from the Nebraska Public Health Laboratory on February 8, 2020. Subsequently, additional public health laboratories alerted CDC and APHL that many of the test kits yielded false positives to control substances that did not contain SARS-CoV-2, specifically in the N3

⁸⁰⁵ Department of Health and Human Services, Centers for Disease Control and Prevention, *2019 Novel Coronavirus (nCoV) Response: IM Update: NCIRD Center Level Response- Day 28* (Feb. 3, 2020) (on file with the Committee, HHS HSGAC 38946).

⁸⁰⁶ See HHS Correspondence to Senate Committee on Homeland Security and Governmental Affairs (May 25, 2022). The Committee notes the discrepancy in the Department of Health and Human Service’s Office of General Counsel Summary report, which stated CDC distributed the test kits to 33 states. On May 25, 2022, CDC told the Committee the correct number of distributed test kits is 39 and provided a list of states that received the test kits. *Id.*

⁸⁰⁷ HHS Correspondence to Senate Committee on Homeland Security and Governmental Affairs Staff (May 25, 2022).

⁸⁰⁸ Root Cause Analysis (Mar. 24, 2020); *Dr. Stephen Lindstrom*, Email from CDC Official to Dr. Stephen Lindstrom (Feb. 9, 2020) (on file with Committee) (noting that the “issue appears to be sporadic as some laboratories are up and running”).

component.⁸⁰⁹ CDC told the Committee that because reporting verification findings was voluntary, CDC only received information from half of the labs that received test kits.⁸¹⁰ According to CDC, some labs never had a problem with the N3 component.⁸¹¹ CDC originally told states that if they were able to validate the tests, they could perform testing and ultimately encouraged labs that did not have an issue to continue to perform testing.⁸¹² Throughout the next week, the number of state labs that were unable to verify the kits grew.⁸¹³ After CDC received these reports, they performed “heightened, quality control testing” and “detected positive reactions in negative control material.”⁸¹⁴

Less than a week later, on February 12, CDC received its first complaint via email of a problem with the N1 component from a public health lab.⁸¹⁵ Dr. Lindstrom told the Committee, “we had not seen issues with N1 before and nor did FDA.”⁸¹⁶ While many public health labs experienced problems and were unable to verify the test kits, other public health labs successfully verified the test kits. By February 21, 2020 out of the 93 labs that received test kits, 36 labs reported problems with N3, 6 labs reported problems with N1, and 7 labs reported being able to successfully verify the test.⁸¹⁷

Throughout February, CDC worked to identify the source of the false reactivity seen with both N1 and N3.⁸¹⁸ CDC initially thought there was a manufacturing issue and proposed to manufacture replacement kits. FDA agreed with their plan. However, this did not solve the issue.⁸¹⁹ According to Dr. Lindstrom, throughout this process CDC continued to experience contamination problems with the test kit material.⁸²⁰ On February 10 and 14, the RVD lab requested that Biosearch and IDT, two commercial manufacturers, manufacture the test kit reagents.⁸²¹ Dr. Lindstrom told the Committee that after submitting purchase orders on February

⁸⁰⁹ Root Cause Analysis (Mar. 24, 2020); HHS OGC Supplementary Investigation (Jan. 14, 2021); Interview with Association of Public Health Laboratories (Apr. 19, 2021)

⁸¹⁰ HHS Correspondence to Senate Committee on Homeland Security and Governmental Affairs Staff (May 25, 2022).

⁸¹¹ Interview with Dr. Wendi Kuhnert (July 14, 2022).

⁸¹² *Id.*

⁸¹³ Interview with Dr. Timothy Stenzel (Sept. 21, 2021).

⁸¹⁴ HHS OGC Supplementary Investigation (Jan. 14, 2021).

⁸¹⁵ Dr. Lindstrom Timeline of Events (received Feb. 15, 2022).

⁸¹⁶ Interview with Dr. Stephen Lindstrom (Feb. 15, 2022).

⁸¹⁷ HHS Correspondence to Senate Committee on Homeland Security and Governmental Affairs Staff (May 25, 2022). Internal CDC email correspondence from February 22, 2020 suggests that 12 labs successfully verified the test kits. *See* Dr. Stephen Lindstrom, *Email from Dr. Stephen Lindstrom to CDC official* (Feb. 22, 2020) (on file with Committee).

⁸¹⁸ CDC Briefing (Dec. 1, 2021).

⁸¹⁹ Interview with Dr. Stephen Lindstrom (Feb. 15, 2022); Interview with Dr. Timothy Stenzel (Sept. 21, 2021).

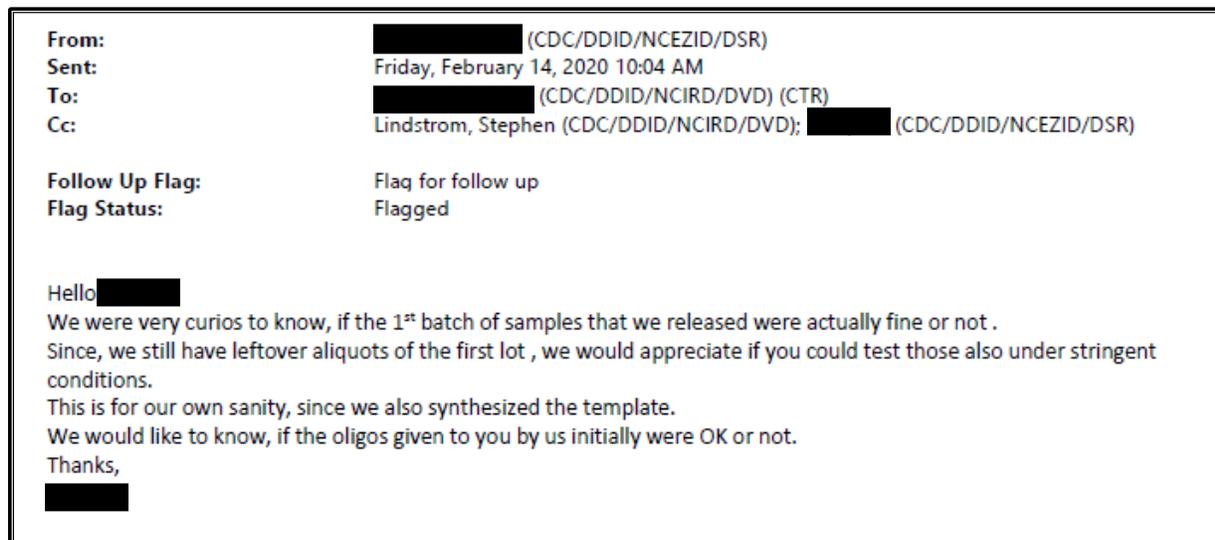
⁸²⁰ Interview with Dr. Stephen Lindstrom (Feb. 15, 2022).

⁸²¹ *Id.*

15, CDC failed to prioritize the order, and therefore it was not processed and placed until February 20 and 21.⁸²²

On February 14, a Core lab employee emailed Dr. Lindstrom and his staff in the RVD lab to request that they test the Core lab’s “leftover aliquots,” (e.g. the N1 component reserve materials) that had never left the Core lab “under stringent conditions.”⁸²³ The Core lab employee wrote, “[t]his is for our own sanity, since we also synthesized the template. We would like to know, if the oligos [reserve material] given to you by us initially were OK or not.”

February 14, 2020 Email from DSR Core Lab Employee to RVD Lab



Dr. Lindstrom told the Committee that the RVD lab’s test results “showed trace amounts of contamination” in the Core lab’s reserve materials for the N1 component.⁸²⁴ He stated that he also provided the post testing material (e.g. material generated from the false positive tests) to CDC’s Polio virus laboratory lab on February 25 for an independent analysis and told Committee staff the results indicated the “genetic sequence matched the original positive control material developed by the Core lab.”⁸²⁵ According to Dr. Lindstrom, the Polio virus laboratory’s review indicated that the false positives with N1 were “due to contamination with material from [the]

⁸²² See Dr. Stephen Lindstrom Communication to Senate Committee on Homeland Security and Governmental Affairs (Nov. 18, 2022); Dr. Stephen Lindstrom, *Centers for Disease Control and Prevention, Order for Supplies or Services: Biosearch Technologies* (Feb. 21, 2020) (on file with Committee); Dr. Stephen Lindstrom, *Centers for Disease Control and Prevention, Order for Supplies or Services: Integrated DNA Technologies* (Feb. 20, 2020) (on file with Committee).

⁸²³ Dr. Stephen Lindstrom, *Email from CDC DSR Core Lab Official to Dr. Stephen Lindstrom* (Feb. 14, 2020) (on file with Committee).

⁸²⁴ Dr. Stephen Lindstrom Communication to Homeland Security and Governmental Affairs Staff (June 10, 2022); Lindstrom Response to Preliminary OSC Decision, at 6 (Apr. 7, 2022).

⁸²⁵ Interview with Dr. Stephen Lindstrom (Feb. 15, 2022) (referring to a February 28, 2020 email reporting “preliminary results” for N1 plate analysis) (on file with Committee).

Core lab,” and based on this finding, he assumed the false positives with N3 were also due to contamination; however, Dr. Lindstrom told the Committee, the N3 false positives were “never confirmed by sequence analysis to be contamination or another manufacturing issue.”⁸²⁶ Dr. Kuhnert, however, told the Committee that the sequencing analysis conducted by the Polio virus lab “did not find the wild type virus [referring to the positive control material],” and therefore, excluded the Core lab as a potential source of contamination.⁸²⁷

On February 17, 2020, a CDC official emailed an action plan noting [the Core lab] would “clean their production equipment” to make sure no contamination is present.⁸²⁸

⁸²⁶ Dr. Stephen Lindstrom, Written Response to Senate Committee on Homeland Security and Governmental Affairs Staff (Aug. 8, 2022).

⁸²⁷ Interview with Dr. Wendi Kuhnert (July 14, 2022).

⁸²⁸ Dr. Stephen Lindstrom, *Email from CDC Official to Dr. Stephen Lindstrom* (Feb. 17, 2020) (on file with Committee).

*February 17, 2020 Email from CDC Official Regarding Contamination*⁸²⁹

From: ██████████ (CDC/DDID/NCEZID/OD)
Sent: Monday, February 17, 2020 12:44 PM
To: ██████████ (CDC/DDID/OD); ██████████ (CDC/DDPHSIS/CGH/OD); ██████████ (CDC/DDPHSIS/CPR/OD); ██████████ (CDC/DDID/NCEZID/DSR); ██████████ (CDC/DDID/NCEZID/DHQP); Lindstrom, Stephen (CDC/DDID/NCIRD/DVD)
Subject: Diagnostic panel updates

Based on conversations yesterday and today with ██████████ and ██████████. I think this is the current lay of the land for the CDC test.

The overall plan is to roll out a series of smaller production runs (approx. 150kits) of the CDC diagnostic panel. This will allow for more efficient (rapid) release of diagnostics to State PHLs. However in parallel we are investigating options for changing the cut-off values for the current test which would widen the CT range for indeterminant results. This later option may not be needed if a small production run could equip SPHL's with the test within the next 1.5 weeks. DSR Has N1 & N3 that can be dried down, but these are from an earlier production run. I think we would be less inclined to want to use these? ██████████ thoughts are that if the production facility is found to be free from contamination today, it may be possible to have a small production run ready for drying/assembly by late this week.

Below are the current events and timelines:

Today

DSR (██████████ facility) will clean their production equipment and run PBS (or other "blank" samples through their production equipment to make sure that no contaminants are present after the cleaning efforts. ██████████ will coordinate with steve to test production blanks (today?) to make sure no contamination is present.

DSR ██████████ will clean and test blanks in the speedvacs

Steve: Do we need new positive control, if so DSR can begin to process that now?
██████████ will provide 12 vials of (dried down PBS) for testing, to make sure the speedvacs do not have contamination.
Steve, can your lab run the blanks from ██████████ and ██████████ (likely less than 20 samples) today?

Tomorrow

Once everything is clean new production will start tomorrow. The question came up as to whether the N 1-3 will come off one at a time or all together as one lot. If the former is true then DSR can begin to work towards getting those materials into vials.

Thanks All!
██████████

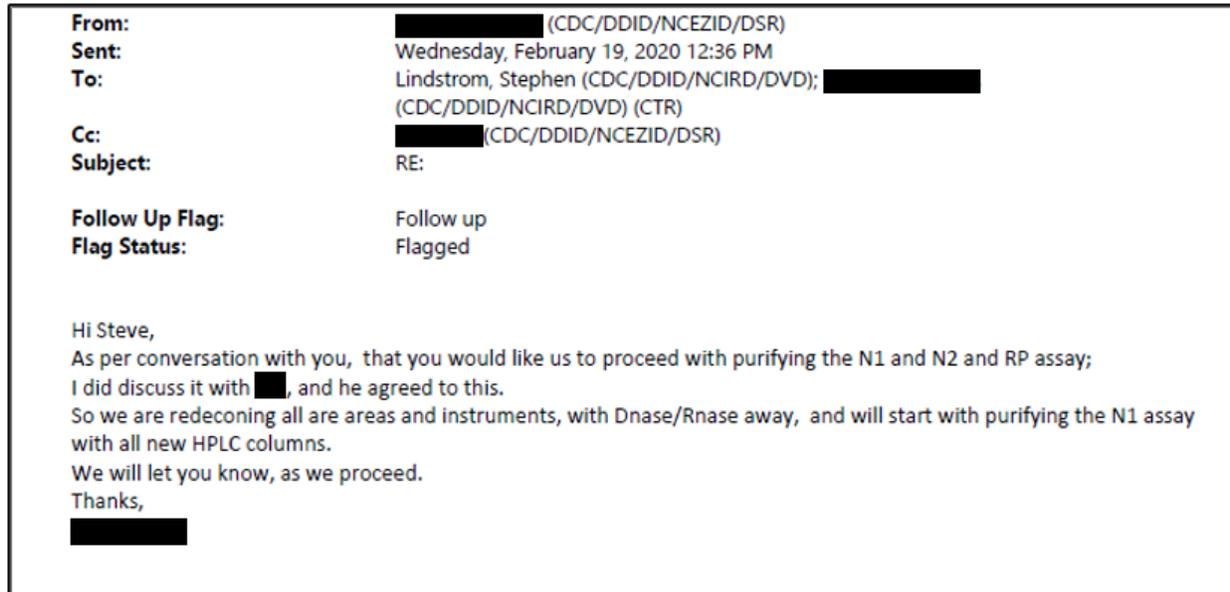
Two days later, on February 19, the RVD lab ran quality control testing and found “N1, N2 and RP were all negative, N3 had two pop-ups,” meaning negative control material still yielded a positive result.⁸³⁰ As a result, the Core lab continued with additional decontamination efforts, detailed in the email below.⁸³¹

⁸²⁹ *Id.*

⁸³⁰ Dr. Stephen Lindstrom, *Email from CDC official to Dr. Lindstrom* (Feb. 19, 2020) (on file with Committee).

⁸³¹ Dr. Stephen Lindstrom, *Email from CD DSR Core Lab Official to Dr. Lindstrom* (Feb. 19, 2020) (on file with Committee).

February 19, 2020 Email from DSR Core Lab Employee to RVD Staff



On February 21, 2020 CDC sent a “high level delegation” to FDA, which had been preplanned to discuss topics outside the pandemic. At the time, however, CDC was still without a functional test kit and FDA was told CDC still had not determined whether the root cause of the test kit failure was either a manufacturing issue or a design flaw.⁸³² In an interview with Committee staff, Dr. Timothy Stenzel, Director of the Office of In Vitro Diagnostics within FDA’s Center for Devices and Radiological Health, which oversees diagnostics, said, “that’s a big difference. If it’s a manufacturing issue, it can be fixed quickly. If it’s a design issue, it would take longer to fix.”⁸³³ Dr. Kuhnert told the Committee, while CDC worked to remanufacture the test kits, they were unaware of the source of the false positive reactivity in both N1 and N3.⁸³⁴ She explained, “our focus at the time during those three weeks was to get a kit out the door to support the public health labs.”⁸³⁵

According to Dr. Kuhnert, she was “not aware that [CDC officials] actually identified specific contamination in the Core lab.”⁸³⁶ Dr. Kuhnert told the Committee, “[t]here was a mistake in the handling of the [manufactured bulk reagents (referring to the other test kit components, such as the primers and probes) and] it should have never left the Core lab,” which

⁸³² Interview with Dr. Timothy Stenzel (Sept. 21, 2021).

⁸³³ *Id.*

⁸³⁴ CDC Briefing (Dec. 1, 2022).

⁸³⁵ *Id.*

⁸³⁶ Interview with Dr. Wendi Kuhnert (July 14, 2022).

created the potential for contamination.⁸³⁷ Dr. Lindstrom, however, told the Committee it was clear the contamination came from the Core lab.⁸³⁸

On February 22, Dr. Stenzel of FDA flew to CDC's headquarters in Atlanta at the request of CDC Director Redfield to investigate the cause of the problem with CDC's test kits.⁸³⁹ Upon arrival, Dr. Stenzel told the Committee he found problems with Dr. Lindstrom's lab. Dr. Stenzel explained the RVD lab (led by Dr. Lindstrom) also received clinical specimens from patients nationwide, some of which were positive for COVID-19. He cautioned, "from a manufacturing perspective, this is a big no." According to Dr. Stenzel, "the RVD lab was a molecularly dirty room and manufacturing should be done in a clean room where there are no molecular specimen present." Manufacturing of reagents for diagnostic tests should be performed in a clean room, a facility that maintains an environment free from airborne contaminants such as dust, viruses, and small particles to ensure that there is no contamination.⁸⁴⁰

As a result, Dr. Stenzel concluded that the "RVD lab at CDC was the likeliest point at which contamination may have occurred" and relayed his findings to CDC.⁸⁴¹ Dr. Stenzel noted, "it only takes a single molecule [virus particle or genome]" to affect the test, which is why manufacturing facilities have unique designs, including separate heating and cooling systems, filtration, and special pressurized rooms.⁸⁴² Dr. Lindstrom told the Committee, however, that Dr. Stenzel "acknowledged [quality control and assurance] standards established by [Dr. Lindstrom's] team were adequate for managing and performing [quality control] testing of commercial products."⁸⁴³

On February 27, IDT, a commercial manufacturer, sent CDC a new lot of test kits and the RVD lab subsequently conducted quality control testing.⁸⁴⁴ Later that evening, CDC sent the new test kits to seven public health laboratories for verification.⁸⁴⁵ CDC agreed to perform quality control testing for IDT and Biosearch test kits, which were based on CDC's test kit design, until other quality control testing capabilities were established."⁸⁴⁶ Dr. Lindstrom told Committee staff that his lab continued to perform quality control testing for the outsourced

⁸³⁷ *Id.*

⁸³⁸ Interview with Dr. Stephen Lindstrom (Feb. 15, 2022).

⁸³⁹ Interview with Dr. Timothy Stenzel (Sept. 21, 2021).

⁸⁴⁰ HHS OGC Supplementary Investigation (Jan. 14, 2021).

⁸⁴¹ Dr. Interview with Dr. Timothy Stenzel (Sept. 21, 2021).

⁸⁴² *Id.*

⁸⁴³ Dr. Stephen Lindstrom, *Dr. Lindstrom Comments on Root Cause Analysis: Unanticipated Failure of the 'CDC 2019 – Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel'* (received Mar. 7, 2020) (on file with Committee).

⁸⁴⁴ Dr. Stephen Lindstrom, *Emails between Dr. Stephen Lindstrom, Dr. Timothy Stenzel, and other CDC officials* (Feb. 27, 2020) (on file with Committee).

⁸⁴⁵ CDC Briefing (Dec. 1, 2021).

⁸⁴⁶ Dr. Stephen Lindstrom, *Email from Dr. Daniel Jernigan to FDA Commissioner Stephen Hahn* (Feb. 29, 2020) (on file with Committee).

manufacturing until March 27, 2020.⁸⁴⁷ By March 5, after verifying the successful performance of the test, CDC reported 62 public health labs used the new CDC test kits without incident.⁸⁴⁸

Ultimately, after assessing the risks and benefits of the N3 assay, Dr. Lindstrom told the Committee CDC determined that the benefits of removing N3 outweighed the risks and submitted an EUA amendment requesting removal of the N3 assay on March 4, 2020.⁸⁴⁹ Ten days later, on March 15, FDA reissued an EUA to CDC for its diagnostic test kit without the N3 assay.⁸⁵⁰

C. Investigations into the Cause of the Test Kit Failures

HHS and CDC conducted internal reviews to determine the cause of the test kit failure. On March 24, 2020, CDC's Office of Laboratory Science and Safety issued an internal assessment called a "Root Cause Analysis."⁸⁵¹ On June 19, 2020 HHS's Office of General Counsel (OGC) issued a summary report of its initial findings.⁸⁵² On January 14, 2021, HHS OGC issued a report detailing its findings after a "supplementary investigation."⁸⁵³ All of these reports, described below, conflict with Dr. Stephen Lindstrom's assessment of the test kit failure.⁸⁵⁴ As described above, based on interviews with this Committee, there are differing opinions within CDC that contradict the agency's public stance on the cause of the failed test kit.

1. Root Cause Analysis

Following the initial test kit failure, on February 13, 2020 CDC initiated an internal review to understand the reasons behind the failed test kit.⁸⁵⁵ Dr. Lindstrom told the Committee he was interviewed as part of the review on February 18, 2020 and offered documents and records.⁸⁵⁶ CDC issued its Root-Cause Analysis Report on March 24, 2020 and subsequently updated the document on October 5, 2020.⁸⁵⁷

⁸⁴⁷ Interview with Dr. Stephen Lindstrom (Feb. 15, 2022).

⁸⁴⁸ CDC Briefing (Dec. 1, 2021).

⁸⁴⁹ Interview with Dr. Stephen Lindstrom (Feb. 15, 2022); Dr. Stephen Lindstrom, *Assessment of Benefits and Risks* (undated) (on file with Committee).

⁸⁵⁰ Food and Drug Administration, *Emergency Use Authorization of the CDC 219-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel* (Mar. 15, 2020) (<https://web.archive.org/web/20200316175900/https://www.fda.gov/media/134919/download>).

⁸⁵¹ Root Cause Analysis (Mar. 24, 2020).

⁸⁵² HHS OGC Summary of Findings (June 19, 2020).

⁸⁵³ HHS OGC Supplementary Investigation (Jan. 14, 2021).

⁸⁵⁴ Interview with Dr. Stephen Lindstrom (Feb. 15, 2022).

⁸⁵⁵ Root Cause Analysis, at 6 (Mar. 24, 2020).

⁸⁵⁶ Interview with Dr. Stephen Lindstrom (Feb. 15, 2022).

⁸⁵⁷ According to Dr. Lindstrom, he did not see the Root Cause Analysis report until February 2021. See Interview with Dr. Stephen Lindstrom (Feb. 15, 2022).

CDC’s investigation “focused on CDC’s failure to detect the problems with the EUA test kit prior to test kit distribution.”⁸⁵⁸ The report found that “multiple compounding factors” contributed to the test kit failure, including inadequate document control procedures and insufficient quality control processes. CDC found that the final quality control testing that approved a lot for distribution was “performed incorrectly” and by the time the error was discovered, “the test kits had already been released for shipment.”⁸⁵⁹ Specifically, the Root Cause Analysis found the “detection of a 33% kit failure” did not result in CDC recalling the test or issuing a performance alert to state public health labs that received the faulty test kit. At the time, CDC did not have clearly defined test approval criteria because “there was no independent quality unit in place to oversee the laboratory’s manufacturing process.”⁸⁶⁰

Dr. Lindstrom told Committee staff that in his view, CDC’s Root Cause Analysis contained multiple inaccuracies.⁸⁶¹ According to Dr. Lindstrom, the test kit failed because of contamination within the Core lab.⁸⁶² He noted that fixing an error within the document control system would not have solved the problem and maintained that his lab used one document control system: Smart Solve, which relies on manual insertions that are prone to error.⁸⁶³ With regard to CDC’s finding of insufficient quality control systems, Dr. Lindstrom told Committee staff that the standards and procedures his lab used to perform quality control testing on CDC’s failed test kit were the same standards and procedures his lab used to perform quality control testing on the commercial test kits.⁸⁶⁴ Dr. Lindstrom disagreed with CDC’s finding of a 33 percent false positive rate in the test kits and stated that the false positive rate was approximately 2.78 percent for N1 and 5.56 percent for N3.⁸⁶⁵

2. HHS Office of General Counsel’s June 19, 2020 Summary Report

In June 2020, HHS’s Office of General Counsel (OGC) issued a “Summary of Findings” examining CDC’s failed test kit. Then HHS Secretary Azar instructed OGC to conduct this review, which began on March 1, 2020.⁸⁶⁶ HHS OGC found that while the Core lab may have been a possible source of contamination, the RVD lab was “the likely source of contamination.” Further, the summary noted that RVD “lab practices may have been insufficient to prevent the risk of contamination, though it is likely that time pressure also contributed.” HHS OGC’s summary report explained that the test kits “are so sensitive that this contamination could have

⁸⁵⁸ Root Cause Analysis (Mar. 24, 2020).

⁸⁵⁹ *Id.*

⁸⁶⁰ Government Accountability Office, *Continued Attention Needed to Enhance Federal Preparedness, Response, Service Delivery, and Program Integrity*, at 72 (GAO-21-551) (July 2021).

⁸⁶¹ Interview with Dr. Stephen Lindstrom (Feb. 15, 2022).

⁸⁶² Lindstrom Response to Preliminary OSC Decision (Apr. 7, 2022).

⁸⁶³ *Id.*

⁸⁶⁴ *Id.*

⁸⁶⁵ *Id.*

⁸⁶⁶ HHS OGC Summary of Findings (June 19, 2020).

been caused by a single person walking through an area with positive control material and then later entering an area where test reagents were being manipulated.”⁸⁶⁷

On June 22, 2020, Dr. Lindstrom wrote to CDC colleagues and expressed concern with a number of the summary’s findings, noting that the document “contains a number of untrue statements that wrongfully implicates RVD as the probable source of reagent contamination in the original EUA kits.”⁸⁶⁸

*June 22, 2020 Email Correspondence between Dr. Lindstrom and CDC Officials*⁸⁶⁹

From: Lindstrom, Stephen (CDC/DDID/NCIRD/DVD)
Sent: Friday, July 10, 2020 11:34 AM
To: [REDACTED] (CDC/DDID/NCIRD/OD)
Subject: FW: HHS Summary of COVID-19 Test kit production
Attachments: HHS review summary_19June2020.pdf

Hi [REDACTED]
This is the message I sent to other leadership regarding the HHS review summary. I have several email communications etc. I can share as evidence to refute these conclusions that show the contamination originated in the core facility. But the original files are quite large. I can place them in a folder if you would prefer. Just let me know.
Thanks!
Steve

From: Lindstrom, Stephen (CDC/DDID/NCIRD/DVD)
Sent: Monday, June 22, 2020 3:17 PM
To: [REDACTED] (CDC/DDID/NCIRD/DVD); [REDACTED] (CDC/DDID/NCIRD/DVD); [REDACTED] (CDC/DDID/NCIRD/OD)
Cc: [REDACTED] (CDC/DDID/NCIRD/DVD) (CTR); [REDACTED] (CDC/DDID/NCIRD/DVD); [REDACTED] (CDC/DDID/NCIRD/DVD)
Subject: HHS Summary of COVID-19 Test kit production

Please see attached HHS investigation summary of the COVID-19 test kit production. This summary is getting a lot of press coverage. It contains a number of untrue statements that wrongfully implicates RVD as the probable source of reagent contamination in the original EUA kits. The contamination of the N1 and N3 oligo sets was unequivocally and repeatedly demonstrated/documentated to have originated in the DSR core facility and that the contamination continued to cause problems and delays with subsequent lots of reagents as we struggled to replace the faulty kits. This information was shared with the HHS investigators so it is not clear why they would conclude that RVD was the source of contamination, unless they received conflicting, incorrect information from others interviewed.

I am happy to discuss further and provide any evidence necessary.
Thank you.
Steve

⁸⁶⁷ *Id.*

⁸⁶⁸ Dr. Stephen Lindstrom, *Email from Dr. Stephen Lindstrom to CDC Officials* (June 22, 2020) (on file with Committee).

⁸⁶⁹ *Id.*

3. HHS Office of General Counsel’s January 14, 2021 Report

HHS’s OGC continued its review of the test kit failure and issued a separate supplemental report on January 14, 2021 that addressed “unresolved questions regarding the test kits.”⁸⁷⁰ The OGC report found that while the RVD lab may have been the source of contamination, the other two components (Core and RDSB) could not be eliminated: “the Core Lab handled positive control materials early on in the process” and the RDSB processes for drying and vialing bulk materials “continued to show false positives even *after* heightened QC [quality control] was performed on the initial lot that was shipped to public health labs.”⁸⁷¹ The report noted Dr. Lindstrom, “acknowledged that given the layout and lack of established QC protocols [in his lab], it is possible his lab could have been the source of contamination.”⁸⁷² In a subsequent interview with Committee staff, however, Dr. Lindstrom clarified that he made this statement “prior to having conclusive proof that the contamination originated with the Core lab.”⁸⁷³ Ultimately, HHS OGC found that the RVD lab “did not possess the funding or personnel to take on a crisis of this proportion” and CDC personnel were under “immense pressure” to produce and distribute a final test kit.⁸⁷⁴

OGC also concluded that “in addition to the probable contamination of a reagent, other factors likely contributed to the test kit’s failure, including inadequate quality control protocols.”⁸⁷⁵ Despite this finding, OGC stated that its investigation “did not reveal any non-compliance with the applicable quality control regulatory requirements.”⁸⁷⁶ Dr. Stenzel, however, told the Committee that “as a manufacturing facility, [FDA] would not allow manufacturing to be done in that type of lab [referring to the RVD lab].”⁸⁷⁷ While HHS OGC’s report found that “it may not have been possible for the CDC to prevent mistakes that occurred in the test kit development process,” it noted that some problems, “with the benefit of hindsight, could possibly have been prevented.”⁸⁷⁸

Although the OGC report did not identify any regulatory violations, it found that CDC’s quality assurance and quality control procedures “lack[ed] uniformity and consistent application across the agency.”⁸⁷⁹ In addition, “some members of the quality assurance team informed OGC that they had concerns about the irregularities,” but reported that after raising these concerns, the

⁸⁷⁰ HHS OGC Supplementary Investigation (Jan. 14, 2021).

⁸⁷¹ *Id.*

⁸⁷² *Id.*

⁸⁷³ Interview with Dr. Stephen Lindstrom (Feb. 15, 2022).

⁸⁷⁴ HHS OGC Supplementary Investigation (Jan. 14, 2021).

⁸⁷⁵ *Id.*

⁸⁷⁶ *Id.*

⁸⁷⁷ Interview with Dr. Timothy Stenzel (Sept. 21, 2021).

⁸⁷⁸ HHS OGC Supplementary Investigation (Jan. 14, 2021).

⁸⁷⁹ *Id.* For example, CDC labs used different document management software, like the “SmartSolve” system and Enterprise Laboratory Information Management System (ELIMS), whereas other labs relied on email or hard copy documents for quality procedures.

RVD Lab “viewed the irregularities as aberrant ‘anomalies’ and moved forward with approval of the test kits.” The report also noted that some CDC personnel stated, “the issue likely would have been detected earlier if heightened quality control testing had been implemented during the test kit development and manufacturing process.” Furthermore, there was no separate “clean” space for handling positive control material or conducting quality control testing in the RVD Lab, which made it “vulnerable to contamination.”⁸⁸⁰

Dr. Lindstrom told the Committee he disagreed with many of the report’s findings. He maintained that the cause of the test kit failure was due to contamination in the N1 and N3 components or other manufacturing issues, which originated in the Core lab.⁸⁸¹ With regard to the report’s finding that a flaw in the test design “could also have contributed to the test kit failure,” Dr. Lindstrom told Committee staff, the N1 design “was never challenged or in dispute” and the data does not support a design flaw with N3.⁸⁸² Dr. Lindstrom provided the Committee with an October 2020 email from a senior employee at a commercial testing company, who “ran a high throughput version of Dr. Lindstrom’s original assay for a month.”⁸⁸³ As shown in the email below, the senior employee found the “N3 assay was not designed incorrectly” and “saw zero inconsistencies in the data relating to N3.”⁸⁸⁴ According to Dr. Lindstrom, major commercial manufacturers continued to manufacture and sell the N3 reagent for COVID-19 testing, suggesting the N3 reagent was not defective.⁸⁸⁵

⁸⁸⁰ *Id.*

⁸⁸¹ Interview with Dr. Stephen Lindstrom (Feb. 15, 2022).

⁸⁸² *See id.*; HHS OGC Supplementary Investigation (Jan. 14, 2021).

⁸⁸³ Dr. Stephen Lindstrom, *Email from Senior Commercial Lab Employee to CDC Official* (Oct. 16, 2020) (on file with Committee).

⁸⁸⁴ *Id.*

⁸⁸⁵ Lindstrom Response to Preliminary OSC Decision (Apr. 7, 2022).

October 16, 2020 Email Correspondence from Senior Commercial Lab Employee⁸⁸⁶

From: [REDACTED]
Sent: Friday, October 16, 2020 7:07 AM
To: [REDACTED] (CDC/DDID/NCEZID/OD) [REDACTED]
Subject: Lindstrom

Hey [REDACTED]

I read the Propublica expose today about issues at the CDC and the Lindstrom section made me kind of angry. I obviously can't post publicly about our experience but it has been very similar to what went on at the CDC. We have gotten contaminated reagents no less than 3 times from both Eurofins and IDT. The Eurofins contamination delayed launch of our multiplex assay by a week and a half and we didn't realize the reagents were contaminated until we started validating instruments on launch day. So I really feel the pain there, and I could very easily see myself in his shoes. Not many people understand the EXTREME pressure we're under to develop these assays and get them launched. We're not cutting corners, and I don't believe Lindstrom was

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either, but sometimes these things happen and it really sucks when they do. If there's any solace I can provide, we ran a high throughput version of Lindstrom's original assay for a month. The results are below. His N3 assay was not designed incorrectly and we saw 0 inconsistencies in the data relating to N3.

RESULT_ALPHA	SPECIMEN_NUMBER
LDTDET	5,445
LDTIND	18
LDTNOT	54,856
PCRINH	5

LDTDET - Detected, LDTIND - Indeterminate, only 1/3 COVID targets positive, LDTNOT - Negative for all 3 targets, positive for RnaseP, PCRINH - Negative for all targets (failed)

It would be awesome if you could share with him if you find that appropriate.

Thanks,

[REDACTED]

HHS's OGC report outlined five key recommendations: 1) implement standard quality control, quality assurance, and document management protocols for all CDC labs; 2) establish guidelines for the use of heightened quality control testing, such as when previous quality control testing reveals abnormalities; 3) create "contingency" contracts with commercial laboratories to immediately assist with manufacturing test kits in future emergencies; 4) develop "additional avenues" for officials to raise complaints outside their chain of command; and 5) consider reallocating funding labs that deal with coronaviruses, which is "likely to be an ongoing global health issue."⁸⁸⁷

⁸⁸⁶ Dr. Stephen Lindstrom, *Email from Senior Commercial Lab Employee to CDC Official* (Oct. 16, 2020) (on file with Committee).

⁸⁸⁷ HHS OGC Supplementary Investigation (Jan. 14, 2021).

D. CDC’s Public Library of Science (PLOS) One Article

In December 2021, twenty-five CDC officials predominately from the Division of Scientific Resources (DSR) published an article titled, *Analysis of the initial lot of the CDC 2019-Novel Coronavirus (2019-nCoV) real-time RT-PCR diagnostic panel*, which contained a summary of their findings from “an internal investigation conducted by CDC” on the causes of the test kit failures.⁸⁸⁸ The article, published by the Public Library of Science (PLOS) One peer-reviewed journal, concluded that “flaws in both assay design and handling of the ‘bulk’ material [referring to the other test kit components, such as the primers and probes], caused the problems with the first lot of the 2019-nCoV Real-Time-PCR Diagnostic Panel.” Specifically, the authors found “contamination with a synthetic template[] that occurred while the ‘bulk’ manufactured materials were located in a research lab for quality assessment” caused false positives with the N1 assay. The authors also concluded that a design flaw contributed to the false positives with the N3 assay. Dr. Lindstrom told the Committee he disagreed with the article’s findings.⁸⁸⁹ According to Dr. Lindstrom, none of the authors “have any experience in real-time PCR assay design or qualification for diagnostic use under CLIA or FDA” and the authors “fraudulently claim[ed] the N1 contamination did not occur in the Core Lab without any supporting evidence or information.”⁸⁹⁰

E. CDC’s Limited Testing Guidance

CDC’s narrow testing criteria significantly limited who could receive a test and as a result, also impaired CDC’s ability to accurately assess the virus spread. Throughout January and February, CDC generally limited testing to symptomatic individuals with a history of travel from China, contact with a symptomatic individual that had traveled to China, or close contact with someone who tested positive for COVID-19.⁸⁹¹ These testing requirements were in place, despite CDC’s analysis in a February 7, 2020 Incident Management Update, shown below, that revealed most confirmed COVID-19 cases outside of mainland China had either “no travel to

⁸⁸⁸ Justin S. Lee, et al., *Analysis of the initial lot of the CDC 2019-Novel Coronavirus (2019-nCoV) real-time RT-PCR diagnostic panel*, PLOS One (Dec. 15, 2021).

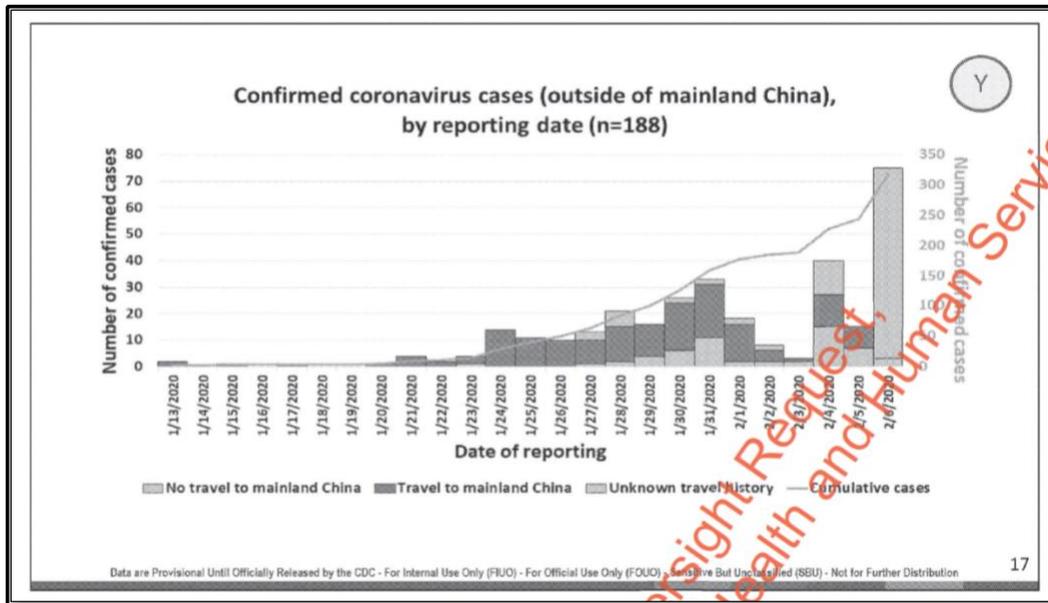
⁸⁸⁹ Dr. Stephen Lindstrom, *Dr. Lindstrom’s Comments on PLOS One Article* (received Mar. 8, 2022) (on file with Committee).

⁸⁹⁰ *Id.*

⁸⁹¹ Department of Health and Human Services, *Timeline from CDC and FDA Briefing for Senate Committee on Homeland Security and Governmental Affairs* (July 12, 2021) (on file with Committee). See, e.g., Centers for Disease Control and Prevention, *Update and Interim Guidance on Outbreak of 2019 Novel Coronavirus (2019-nCoV) in Wuhan, China* (CDCHAN-00426) (Jan. 17, 2020); Centers for Disease Control and Prevention, *Update and Interim Guidance on Outbreak of 2019 Novel Coronavirus (2019-nCoV)* (CDCHAN-00427) (Feb. 1, 2020) (<https://emergency.cdc.gov/han/HAN00427.asp>); Centers for Disease Control and Prevention, *Update and Interim Guidance on Outbreak of 2019 Novel Coronavirus (2019-nCoV)* (CDCHAN-00428) (Feb. 28, 2020) (<https://emergency.cdc.gov/han/2020/HAN00428.asp>).

mainland China” or “unknown travel history.”⁸⁹² According to Dr. Jernigan, Deputy Director for Public Health Science and Surveillance, the narrow testing guidance was in line with CDC practices: “narrow requirements assist clinicians and the capabilities were not there to test for everyone. Focus on severity is a common approach to try and narrow testing requirements.”⁸⁹³ Dr. Schuchat noted that based on pandemic planning, “one thing that wasn’t in the plan was the idea of testing everyone who has symptoms, let alone those who do not have symptoms.”⁸⁹⁴ Dr. Kuhnert told the Committee that during February 2020, “CDC did not have a backlog in testing.”⁸⁹⁵

*Graph from CDC’s February 7, 2020 Incident Management Update*⁸⁹⁶



The Majority Committee staff found that CDC’s narrow testing guidance limited states’ ability to effectively diagnose cases. Michigan Department of Health and Human Services stated CDC’s “specific requirement for direct Wuhan exposure left many symptomatic folks on the sideline for testing and, we believe, that a lot of cases were not identified because of it.”⁸⁹⁷

⁸⁹² Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases, *2019 Novel Coronavirus (nCoV) Response: IM Update: NCIRD Center Level Response- Day 32* (Feb. 7, 2020) (on file with the Committee, HHS HSGAC 39260 - 39344).

⁸⁹³ Interview with Dr. Daniel Jernigan (Dec. 15, 2021).

⁸⁹⁴ Interview with Dr. Anne Schuchat (Dec. 14, 2021).

⁸⁹⁵ CDC Briefing (Dec. 1, 2021).

⁸⁹⁶ Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases, *2019 Novel Coronavirus (nCoV) Response: IM Update: NCIRD Center Level Response- Day 32* (Feb. 7, 2020) (on file with the Committee, HHS HSGAC 39260 - 39344).

⁸⁹⁷ Michigan State Public Health Agency, Written Response to Senate Committee on Homeland Security and Governmental Affairs State Public Health Agency Questionnaire (Dec. 2, 2021). Michigan Department of Health and Human Services also noted, “the requirement that [COVID-19] tests be directed toward the most

Virginia Department of Health also had “significant concerns” regarding the access to testing, which “led to missing cases.”⁸⁹⁸ According to the Virginia Department of Health, “access to testing was severely limited and affected [their] ability to diagnose cases early and contain the virus.” They explained how CDC required approval for each specimen the public health lab wanted to test through consultation with a CDC subject matter expert to “discuss the case and receive approval.”⁸⁹⁹ According to senior official Dr. Mecher, CDC refused a university’s request to test asymptomatic repatriation evacuees from China.⁹⁰⁰

F. Impact of CDC’s Test Kit Failures and Narrow Testing Guidance

CDC’s failed test kit failure delayed the U.S.’s ability to increase testing capacity and resulted in a number of state public health labs not being able to perform tests for at least four to six weeks.⁹⁰¹ Dr. Duane Caneva, former DHS Chief Medical Officer, estimated the impact of this delay: “there was a six-week period where we fumbled the ball . . . we were flying blind.”⁹⁰² He explained that, in accordance with the National Pandemic Plan followed by the federal government, moving from a containment strategy to implementation of mitigation measures ultimately depended on seeing sustained community transmission and “the only way you could ascertain that was by testing.”⁹⁰³ Dr. Mecher described CDC’s testing efforts as “a cascading failure” noting, “not having enough testing gave us a false sense that there wasn’t a fire going on. The virus was spreading, but it was all invisible because we didn’t have testing. Just because you’re not measuring something doesn’t mean it’s not there.” Instead, Dr. Mecher continued, “we didn’t see a lot of positive tests so we took that as evidence that nothing was happening.”⁹⁰⁴

As of February 29, 2020 CDC had tested specimens from 1,195 individuals and its multi-day in-house diagnostic test and flawed test kit were the only COVID-19 tests available in the U.S.⁹⁰⁵ Despite this and CDC’s strict testing criteria, internal documents from late February

severely ill, while understandable, also artificially inflated the case mortality rates in the early days because [health departments] were simply not confirming cases that were not very sick.”

⁸⁹⁸ Virginia Department of Health, Written Response to Senate Committee on Homeland Security and Governmental Affairs State Public Health Agency Questionnaire (Dec. 1, 2021).

⁸⁹⁹ *Id.*

⁹⁰⁰ Interview with Dr. Carter Mecher (July 29, 2022).

⁹⁰¹ See e.g., Governor Mike DeWine, *Governor, Health Director Announce COVID-19 Testing Protocol* (Mar. 7, 2020) (<https://governor.ohio.gov/media/news-and-media/covid-19-testing-protocol>) (noting that Ohio started in-state COVID testing on March 7, 2020). See also APHL Interview (Apr. 19, 2021) (noting, “the initial bad test from CDC caused a delay”).

⁹⁰² Interview with Dr. Duane Caneva (Nov. 15, 2021).

⁹⁰³ *Id.*

⁹⁰⁴ Interview with Dr. Carter Mecher (July 29, 2022).

⁹⁰⁵ Government Accountability Office, *Continued Attention Needed to Enhance Federal Preparedness, Response, Service Delivery, and Program Integrity*, at 69 (GAO-21-551) (July 2021) (noting “CDC’s laboratory tested 3,291 total specimens, representing approximately 1,195 individuals, on behalf of public health laboratories in January and February, 2020. In contrast, other countries around the world quickly scaled up testing in late January

2020 suggested CDC did not have concerns regarding testing capacity. For example, an HHS senior leadership briefing slide from February 26, 2020 stated there were two CDC laboratories conducting diagnostic testing with a total throughput of 400 specimens per day, noting, “testing capacity is more than adequate to meet current demands.”⁹⁰⁶

State public health labs, however, expressed concerns about capacity and delays.⁹⁰⁷ For example, Virginia Department of Health reported, “CDC was not able to keep up with the volume of testing needed.” California Department of Health noted that “airborne isolation rooms for COVID positive patients became scarce while waiting for negative testing results,” explaining that at the time, CDC was the only source of testing and “there could be a delay waiting for results.” In July 2021, GAO also reported that issues with CDC’s communication of test results to public health labs resulted was “inefficient and slow.”⁹⁰⁸

G. Insufficient Private Sector Engagement and Regulatory Flexibility

While multiple individuals interviewed by the Committee acknowledged CDC’s test kit failures, several emphasized that the underlying cause of widespread testing delays was the failure to quickly engage private laboratories. Matthew Pottinger, then Deputy National Security Advisor, told the Committee, “even if [CDC] had gotten the test right out of the starting gate, we would still have had a big problem on our hands because CDC does not make tests to scale.”⁹⁰⁹ Paul Mango, then HHS Deputy Chief of Staff for Policy, told the Committee that the lack of “deep scientific relationships” with the diagnostics industry contributed to limited collaboration and delayed the rapid development of testing capacity.⁹¹⁰ Virginia Department of Health noted

and early February. For example, the South Korean government reported that South Korea was conducting about 20,000 tests each day by the middle of February 2020”).

⁹⁰⁶ Department of Health and Human Services, *Senior Leadership Brief: COVID-19* (Feb. 26, 2020) (on file with Committee, HHS HSGAC 0037511). Potential symptoms for COVID-19 were fewer in February 2020 than at present. In February 2020, CDC listed potential COVID-19 symptoms as fever and/or signs/symptoms of lower respiratory illness (e.g. cough or shortness of breath). See Centers for Disease Control and Prevention, *Update and Interim Guidance on Outbreak of 2019 Novel Coronavirus (2019-nCoV)* (CDCHAN-00427) (Feb. 1, 2020) (<https://emergency.cdc.gov/han/HAN00427.asp>). As of October 2022, CDC lists potential COVID-19 symptoms as “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, diarrhea.” Centers for Disease Control and Prevention, *Symptoms of COVID-19* (October 26, 2022) (<https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html>).

⁹⁰⁷ Virginia Department of Health, Written Response to Senate Committee on Homeland Security and Governmental Affairs State Public Health Agency Questionnaire (Dec. 1, 2021); California Department of Public Health, Written Response to Senate Committee on Homeland Security and Governmental Affairs State Public Health Agency Questionnaire (Dec. 10, 2021).

⁹⁰⁸ Government Accountability Office, *Continued Attention Needed to Enhance Federal Preparedness, Response, Service Delivery, and Program Integrity*, at 73 (GAO-21-551) (July 2021). According to GAO, “APHL and CDC attributed the slowness to the CDC laboratory’s lack of a laboratory information management system that could communicate test results back to the public health laboratories electronically and its reliance instead on telephone calls for positive results and emails for negative results.”

⁹⁰⁹ Interview with Matthew Pottinger (Jan. 25, 2022).

⁹¹⁰ Interview with Paul Mango (Nov. 17, 2021).

that in February 2020, “[w]e did not have a clear understanding about the ability and capacity of testing by national private labs and CDC was not able to provide us with that information when we raised the question on [phone calls].”⁹¹¹ Ultimately, the Majority Committee staff found that the lack of coordination and outreach during January and February, detailed throughout this section, severely limited testing capacity and delayed needed widespread testing capabilities.

HHS’s OGC report found that although CDC “did not err” in developing the initial COVID-19 test kits, it noted that “utilizing commercial labs to streamline the manufacturing of test kits has allowed CDC to better respond to the scale of the COVID-19 pandemic.”⁹¹² Based on interviews with officials from FDA, CDC, and the American Clinical Laboratory Association (ACLA), which represents commercial testing labs throughout the U.S., the Majority Committee staff found a disconnect in communication between commercial labs and the federal government. ACLA told the Committee commercial labs were willing to assist with test development and performance, but through late February 2020, only state and local public health laboratories were permitted to use CDC’s COVID-19 test kits in laboratory testing. According to ACLA, once commercial labs received regulatory clarity, “ACLA member laboratories swiftly developed tests, made available nationwide.”⁹¹³

Dr. Schuchat noted that “the appetite [for diagnostic testing] in the private sector wasn’t robust.”⁹¹⁴ Dr. Lindstrom told the Committee that he contacted companies the second week of January to get quotes on generic manufacturing, but it took “a few weeks” to get usable quotes.⁹¹⁵ He stated, “there was a lack of urgency and a lack of understanding on the commercial manufacturing side.”⁹¹⁶ FDA told the Committee that “any lab can, and always could, submit an EUA request at any time, including a single EUA request from a group of labs working together.”⁹¹⁷ According to FDA, “based on how few notifications FDA received once it issued its guidance on February 29, 2020, it was clear that very few labs had finished developing their tests.”⁹¹⁸

HHS’s OGC report noted, “generally, commercial labs have no interest in developing a test unless there is a sizable market.”⁹¹⁹ According to Dr. Schuchat, there was a structural disincentive for industry to engage in the development and manufacture of tests from January 10 to February 29, 2020.⁹²⁰ FDA told the Committee a “key issue is that commercial manufacturers

⁹¹¹ Virginia Department of Health, Written Response to Senate Committee on Homeland Security and Governmental Affairs State Public Health Agency Questionnaire (Dec. 1, 2021).

⁹¹² HHS OGC Supplementary Investigation (Jan. 14, 2021).

⁹¹³ Interview with Association of Public Health Laboratories (Apr. 19, 2021).

⁹¹⁴ Interview with Dr. Anne Schuchat (Dec. 14, 2021).

⁹¹⁵ Interview with Dr. Stephen Lindstrom (Feb. 15, 2022).

⁹¹⁶ *Id.*

⁹¹⁷ CDC and FDA Briefing (July 12, 2021).

⁹¹⁸ *Id.*

⁹¹⁹ HHS OGC Supplementary Investigation (Jan. 14, 2021).

⁹²⁰ Interview with Dr. Anne Schuchat (Dec. 14, 2021).

had concerns about the lack on return of investment,” stating that “unlike for vaccines, the government didn’t de-risk test development through minimum purchasing agreements and guaranteed reimbursement.”⁹²¹

ACLA began conversations with CDC in January 2020 under an existing Memorandum of Understanding (MOU) between CDC, ACLA, the Association for Public Health Laboratories (APHL), and the Council of State and Territorial Epidemiologists. They told the Committee, “[t]he private sector should have been brought in sooner,” and noted “there was a lack of clarity on whether the private sector could provide tests.”⁹²² The National Independent Laboratory Association (NILA) told the Committee that they contacted CDC in mid-February to request access to CDC’s assay for COVID-19; however, their request was denied.⁹²³ According to NILA, CDC also did not provide sufficient context about the scope of the virus and likely demand for testing, which failed to give independent labs the information they needed to prepare.⁹²⁴ Similarly, NILA and ACLA noted the need for more consistent communication with FDA, which was not a party included in the MOU.⁹²⁵ Dr. Birx told the Committee that after she left the White House, she asked commercial test developers if they were in conversations with CDC [during the initial response] and the commercial labs told her “we were calling them, telling them that we could be of help, and CDC told us that they were fine and didn’t need help.”⁹²⁶

CDC officials acknowledged challenges in sharing their diagnostic test with commercial labs. According to Dr. Kuhnert, there were “intellectual property issues and regulatory constraints” restricting CDC from sharing their test with commercial developers.⁹²⁷ She stated, “we posted the entire recipe for the test very early on, in fact, before we applied for the EUA, so that people could use the information to start on the development of their own test.”⁹²⁸ Dr. Kuhnert noted that another challenge was biosafety requirements for the SARS-CoV-2 virus. She explained that manipulation of the live virus required a biosafety level three laboratory, and “a lot of commercial laboratories, test developers, and commercial development companies did not have access to biosafety level three facilities so there had to be extra time for the virus to be inactivated.”⁹²⁹ Biosafety level three laboratories require facilities to be easily decontaminated

⁹²¹ HHS Correspondence to Senate Committee on Homeland Security and Governmental Affairs Staff (Aug. 11, 2022).

⁹²² Interview with American Clinical Laboratory Association (May 27, 2021).

⁹²³ National Independent Laboratory Association, Correspondence to Senate Committee on Homeland Security and Governmental Affairs Staff (Aug. 1, 2022).

⁹²⁴ National Independent Laboratory Association, Interview with Senate Committee on Homeland Security and Governmental Affairs (May 24, 2021). The term “independent labs” denotes laboratories located outside a hospital setting. *See* Centers for Medicare & Medicaid Services, *Medicare Claims Processing Manual Chapter 16 - Laboratory Services*, at 4 (10.1 – Definitions) (June 2022).

⁹²⁵ Interview with National Independent Laboratory Association (May 24, 2021).

⁹²⁶ Interview with Dr. Deborah Birx (Jan. 6, 2022).

⁹²⁷ CDC Briefing (Dec. 1, 2021).

⁹²⁸ *Id.*

⁹²⁹ *Id.*

and use “controlled” or “directional” airflow to ensure that air flows from non-laboratory areas (such as the hallway) into laboratory areas.”⁹³⁰

According to the Virginia Department of Health, “[t]here was significant delay in allowing state [public health] labs to begin testing their own specimens.”⁹³¹ As a result, “states worked with the Association of Public Health Laboratories (APHL) to bring this issue to CDC’s attention.”⁹³² On February 24, 2020, the APHL sent a letter to FDA urging the agency to allow public health labs to develop and implement their own tests. The letter continued, “[w]e are now many weeks into the response with still no diagnostic or surveillance test available outside of CDC for the vast majority of our member laboratories.”⁹³³ “We believe a more expeditious route is needed at this time.”⁹³⁴

On February 27, 2020 FDA and CDC jointly drafted, *A Plan to Increase Coronavirus-Disease-2019 (COVID-19) Testing in the U.S. – Accelerated EUA Authorization Pathway for High-Complexity Molecular Diagnostics CLIA-Certified Laboratories* (“The Plan”).⁹³⁵ The document outlined steps, which included targeting CLIA high complexity laboratories that could perform “high-volume” testing and a proposed a “pathway for implementing testing.”⁹³⁶ The pathway identified specific steps (e.g. order test materials, validate test, notify FDA, begin testing, etc.) that laboratories needed to take to begin testing and ultimately receive an EUA.⁹³⁷

On February 29, 2020, FDA issued an EUA to New York State’s public health lab (for its own lab as well as on behalf of NYC’s public health lab) and, on the same day, issued guidance allowing Clinical Laboratory Improvement Amendments (CLIA) high complexity laboratories to begin utilizing lab-developed tests prior to applying for an EUA after notifying the FDA.⁹³⁸

⁹³⁰ Department of Health and Human Service, Public Health Emergency, Science Safety Security: Biosafety Level Requirements (<https://www.phe.gov/s3/BioriskManagement/biocontainment/Pages/BSL-Requirements.aspx>) (accessed Dec. 1, 2022).

⁹³¹ Virginia Department of Health, Written Response to Senate Committee on Homeland Security and Governmental Affairs State Public Health Agency Questionnaire (Dec. 1, 2021).

⁹³² *Id.*

⁹³³ Association of Public Health Laboratories (APHL), *Letter from APHL to FDA Commissioner Dr. Stephen M. Hahn* (Feb. 24, 2020) (on file with Committee).

⁹³⁴ *Id.*

⁹³⁵ Department of Health and Human Services, *A Plan to Increase Coronavirus Disease-2019 (COVID-19) Testing in the U.S. – Accelerated EUA Authorization Pathway for High-Complexity Molecular Diagnostics CLIA-Certified Laboratories* (Feb. 27, 2020) (on file with Committee, HHS HSGAC 0042767–68).

⁹³⁶ *Id.*

⁹³⁷ *Id.*

⁹³⁸ Food and Drug Administration, *Coronavirus (COVID-19) Update: FDA Issues New Policy to Help Expedite Availability of Diagnostics* (Feb. 29, 2020) (<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-new-policy-help-expedite-availability-diagnostics>). FDA told the Committee that one of the trade-offs of its policy, which allowed CLIA high-complexity labs to use lab-developed tests before submitting a request for an EUA, meant some labs had not appropriately validated their tests. *See* CDC and FDA Briefing (July 12, 2021).

ACLA called FDA’s February 29 guidance a “call to action.”⁹³⁹ LabCorp began testing using their own assay on March 6, 2020, followed by Quest on March 9, 2020.⁹⁴⁰ On March 16, 2020, FDA granted additional EUA flexibility, which included expanding the applicability of the February 29, 2020 guidance to additional commercial labs.⁹⁴¹

FDA officials disagreed with reports that narrow regulatory guidance delayed commercial diagnostic test development. In a briefing with the Committee, FDA officials stated, “only six labs notified us the first week of February [that they had developed their own test]. Of those six, there were problems with two of them. By end of February, very few labs had finished developing their tests.”⁹⁴² ACLA told the Committee, “any delay of commercial labs offering tests was because of a lack of regulatory clarity as to whether commercial labs were allowed to validate laboratory tests and offer them to the public, including how to obtain positive control materials to validate such tests.”⁹⁴³ ACLA also noted, “there was no upfront dedicated federal fund to support the development and provision of lab testing to respond to a new pathogen, nor a clear reimbursement pathway until later actions by Congress and the Administration.”

In early March 2020, Dr. Birx pushed to increase the U.S. testing capacity to two million tests a day by engaging with commercial laboratories.⁹⁴⁴ At Dr. Birx’s request, the Vice President Pence called in commercial lab CEOs to the White House to form a plan to increase testing capacity.⁹⁴⁵ Dr. Birx told the Committee, “if you can’t make the invisible virus visible through seeing the cases before you get to hospitalizations and death, then you’re always just ‘flattening the curve.’ No one wants to be flattening the curve over and over again.” According to CDC testing reports, by early April commercial laboratories performed over 80 percent of the nation’s testing.⁹⁴⁶

⁹³⁹ *Id.*; Interview with American Clinical Laboratory Association (May 27, 2021).

⁹⁴⁰ Department of Health and Human Services, Centers for Disease Control and Prevention, *CDC Early COVID-19 Testing Timeline* (July 12, 2021) (on file with Committee).

⁹⁴¹ *Id.*; 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) (https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-more-regulatory-relief-during-outbreak-continues-help?utm_campaign=20200318%20MCMi&utm_medium=email&utm_source=Eloqua).

⁹⁴² CDC and FDA Briefing (July 12, 2021).

⁹⁴³ Interview with American Clinical Laboratory Association (May 27, 2021).

⁹⁴⁴ Interview with Dr. Deborah Birx (Jan. 6, 2022).

⁹⁴⁵ *Id.*

⁹⁴⁶ Interview with American Clinical Laboratory Association (May 27, 2021); Centers for Disease Control and Prevention, *COVIDView, Key Updates for Week 15, ending April 11, 2020* (Apr. 17, 2020) (<https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/past-reports/04172020.html>).

Academic Laboratories

Academic laboratories had capacity to conduct diagnostic testing, but faced regulatory barriers and unclear guidance from federal officials. Virginia Department of Health told the Committee, “we reached out to our academic health systems to assist with testing and they were reluctant to develop the capability to utilize CDC tests[s] because the assay was technically extremely difficult and the FDA requirements to gaining approval [presented] significant barriers.”⁹⁴⁷ According to then CDC Director Redfield, academic labs were underutilized in the initial response.⁹⁴⁸ The Majority Committee staff found that during the early months of the pandemic, the federal government took too long to engage academic labs and determine how to best use their testing capacity.⁹⁴⁹

As one example, the University of Washington School of Medicine’s Seattle Flu Study (SFS), a “multi-institutional, community-wide pandemic surveillance platform” navigated multiple regulatory challenges and unclear federal guidance as they sought to conduct COVID-19 diagnostic testing to identify potential spread.⁹⁵⁰ On February 7, the SFS lab completed and internally verified its COVID-19 test; however, it did not receive authorization to test samples until February 24, 2020 and it was not until March 23, 2020 when SFS received authorization to report results.⁹⁵¹

After the SFS identified its first case of COVID-19 on February 27, which represented the first evidence of community transmission, CDC guidance barred SFS from informing the patient, and it was unclear if they could alert local, state, and federal public health officials.⁹⁵² Dr. Helen Chu, one of the principal investigators for the SFS, told Committee staff that she and her fellow researchers felt an “ethical obligation,” and after consulting with the Institutional Review Board at their University, they informed both the caregiving hospital and local public health officials, who then informed the family, potentially preventing further spread of the virus.⁹⁵³

⁹⁴⁷ Virginia Department of Health, Written Response to Senate Committee on Homeland Security and Governmental Affairs State Public Health Agency Questionnaire (Dec. 1, 2021).

⁹⁴⁸ Interview with Dr. Robert Redfield (Feb. 7, 2022).

⁹⁴⁹ Brotman Baty Institute, *Summary of Timeline of Early SARS-CoV-2 Testing* (June 25, 2021) (on file with Committee). See also Interview with Dr. Helen Chu (June 2, 2021).

⁹⁵⁰ Chu Lab, Division of Allergy and Infectious Disease, University of Washington, *Community-Based Surveillance for Respiratory Viruses* (<https://www.chulab.org/community-based-surveillance>) (accessed Dec. 1, 2022); see also Brotman Baty Institute, *Summary of Timeline of Early SARS-CoV-2 Testing* (June 25, 2021) (on file with Committee).

⁹⁵¹ Brotman Baty Institute, *Summary of Timeline of Early SARS-CoV-2 Testing* (June 25, 2021) (on file with Committee).

⁹⁵² Interview with Dr. Helen Chu (June 2, 2021); see also University of Washington, *Racing Against a Pandemic* (undated) (<https://www.washington.edu/boundless/racing-against-a-pandemic/>) (accessed Dec. 1, 2022).

⁹⁵³ Interview with Dr. Helen Chu (June 2, 2021).

SFS leadership did not have clarity on whether they should pursue an EUA from FDA or regulatory clearance from the State of Washington.⁹⁵⁴ On March 9, SFS learned that it could no longer conduct testing because they were not a CLIA-certified lab and therefore could not return results to patients, but still had to report positive cases to public health officials. Ten days later, on March 19, SFS’s lab received a CLIA licensure.⁹⁵⁵ Ultimately, on March 23, 2020, the State of Washington certified the lab, allowing SFS to conduct tests and return results. By that time, however, as many as 100,000 people were already infected with COVID-19, but U.S. public health officials were only reporting 1,514 cases and 39 deaths due to limited testing capacity.⁹⁵⁶

VII. Communications

Throughout the initial pandemic response, the Administration failed to follow basic crisis communication principles. While there are varying models of risk and crisis communication for emergencies, CDC’s Crisis and Emergency Risk Communication manual identifies six key principles to communication during a crisis: “be first;” “be right;” “be credible;” “express empathy;” “promote action;” and “show respect.” According to CDC, “good communication [during a crisis] enables organizations to fulfill their mission, maintain public trust, manage limited resources, and most of all, prevent and reduce illnesses.”⁹⁵⁷ The Majority Committee staff found that throughout the initial pandemic response, federal communications failed to follow these basic principles, resulting in widespread confusion and a deep-seeded division on how Americans could best protect themselves and their families.

Dr. Richard Besser, President of the Robert Wood Johnson Foundation and former Acting CDC Director during the H1N1 pandemic, noted the importance of humility and sharing both what is known, not known, and what has changed: “with an emerging pathogen, what you don’t know surpasses what you do know so you need to be transparent as you learn more.”⁹⁵⁸ Dr. Anne Schuchat, then Principal Deputy Director of CDC, told the Committee, “part of pandemic preparedness is risk communication—letting the public know what might happen and engaging the public in the response.”⁹⁵⁹ Dr. Carter Mecher, former senior medical advisor for the Department of Veterans Affairs, pointed out that a complicating factor not previously contemplated in HHS’s 2006 Pandemic Influenza Plan is the presence of widespread social

⁹⁵⁴ *Id.*

⁹⁵⁵ *Id.*

⁹⁵⁶ T. Alex Perkins, et al., *Estimating unobserved SARS-CoV-2 infections in the United States*, Proceedings of the National Academy of Sciences (Aug. 21, 2020).

⁹⁵⁷ See Department of Health and Human Services, Centers for Disease Control and Prevention, *Crisis and Emergency Risk Communication (CERC) Introduction – 2018 Update* (2018). The Biological Incident Annex (BIA) to the Federal Interagency Operational Plans for Response and Recovery also highlights communication as one of the most important aspects in responding to a biological incident: “immediate action should be taken to identify communication systems for public messaging to provide clear, factual, and timely guidance to the public.” Department of Homeland Security, Federal Emergency Management Agency, *Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans* (Jan. 2017).

⁹⁵⁸ Interview with Dr. Richard Besser (Apr. 7, 2021).

⁹⁵⁹ Interview with Dr. Anne Schuchat (Dec. 14, 2021).

media. He told the Committee, “what made this pandemic even more difficult is social media ... Here, social media has played both a good and bad role.”⁹⁶⁰

This section addresses CDC’s communications throughout the initial response, including its adherence to crisis communication principles, its role communicating with the public, and the impact of inconsistent public health communications.

A. Adherence to Crisis Communication Principles

From January 2020 through February 25, 2020, HHS led and coordinated federal communication and messaging related to the COVID-19 pandemic response.⁹⁶¹ During its first press conference on January 28, 2020, Secretary Azar provided an overview of what HHS knew about the emerging virus.⁹⁶² At the same press conference, the Directors of CDC, the CDC’s National Center for Immunization and Respiratory Diseases (NCIRD), and the National Institute of Allergy and Infectious Diseases (NIAID) expanded on actions being taken to prepare for and respond to the threat.⁹⁶³ In subsequent press conferences throughout January and February, Secretary Azar remained the primary spokesperson for the public health and medical response while being supported by subject matter experts within HHS.⁹⁶⁴

CDC provided regular communications on the emerging public health threat through numerous media telebriefings led by subject matter expert Dr. Nancy Messonnier, the Director of CDC’s NCIRD. Between January 17, 2020 and February 29, 2020, CDC held 16 of these briefings on the COVID-19 response.⁹⁶⁵ These briefings informed and updated the public on what the federal government knew about the emerging public health threat and what the federal government was doing in response. They also employed risk communication principles, acknowledging that CDC was still learning about the virus.⁹⁶⁶

⁹⁶⁰ Interview with Dr. Carter Mecher (July 29, 2022).

⁹⁶¹ C-SPAN, *Coronavirus News Conference* (Jan. 28, 2020) (<https://www.c-span.org/video/?468647-1/hhs-secretary-azar-update-us-response-coronavirus>); C-SPAN, *White House Briefing on Coronavirus Response* (Jan. 31, 2020) (<https://www.c-span.org/video/?468862-1/white-house-declares-coronavirus-presents-public-health-emergency-us>); C-SPAN, *Health and Human Services Briefing on the Coronavirus Outbreak* (Feb. 25, 2020) (<https://www.c-span.org/video/?469708-1/hhs-officials-hold-news-conference-coronavirus>).

⁹⁶² C-SPAN, *Coronavirus News Conference* (Jan. 28, 2020) (<https://www.c-span.org/video/?468647-1/hhs-secretary-azar-update-us-response-coronavirus>).

⁹⁶³ *Id.*

⁹⁶⁴ C-SPAN, *Coronavirus News Conference* (Jan. 28, 2020) (<https://www.c-span.org/video/?468647-1/hhs-secretary-azar-update-us-response-coronavirus>); CNBC Television, *White House’s coronavirus task force holds a new conference* (Feb. 7, 2020) (<https://www.youtube.com/watch?v=pdt2krYW4Fk>); C-SPAN, *White House Briefing on Coronavirus Response* (Jan. 31, 2020) (<https://www.c-span.org/video/?468862-1/white-house-declares-coronavirus-presents-public-health-emergency-us>).

⁹⁶⁵ Department of Health and Human Services, Centers for Disease Control and Prevention, 2020 New Releases: Transcripts (<https://www.cdc.gov/media/releases/2020/archives.html>) (accessed July 19, 2022).

⁹⁶⁶ Department of Health and Human Services, Centers for Disease Control and Prevention, Transcript of 2019 Novel Coronavirus Response Telebriefing (Jan. 17, 2020) (<https://www.cdc.gov/media/releases/2020/t0117-coronavirus-screening.html>). This communication structure aligned with previously published pandemic guidance. See Department of Homeland Security, Federal Emergency Management Agency, *Pandemic Crisis Action Plan*

The Committee also found that throughout the initial response communications from administration officials were often incorrect and failed to adhere to core crisis communication principles. Furthermore, policy decision-making at times overrode public health science recommendations. Below are several examples.

Initial Guidance to States

As discussed in Section V, CDC did not have adequate surveillance systems to inform decision-making, which often resulted in unclear and delayed guidance. The Committee requested information from several state public health departments across the country regarding their communications with CDC.⁹⁶⁷ The Committee selected these states based on several factors including the location of airports first selected to receive enhanced screening or other instructions, as well as states that had confirmed cases in January 2020. Ten state public health departments ultimately provided information to the Committee. All of these states reported that CDC’s travel alerts and advisories were helpful in understanding the emerging virus.⁹⁶⁸ Officials

Version 2.0, at 10 (Jan. 2018) (on file with Committee, DHS-FEMA HSGAC – 308-339) (noting “HHS leads and coordinates all federal communication, messaging, and release of public health and medical information both across the USG and internationally with the World Health Organization and affected countries”); Executive Office of the President of the United States, *Playbook for Early Response to High-Consequence Emerging Infectious Disease Threats and Biological Incidents*, at 67 (2016) (noting “HHS leads and coordinates all federal communication, messaging, and release of public health and medical information both across the USG and internationally with the World Health Organization and affected countries”); Department of Homeland Security, Federal Emergency Management Agency, *Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans*, at 44 (Jan. 2017) (noting the HHS Secretary or designee serves as the primary spokesperson for the public health and medical response, supported by subject matter experts within the department”); Department of Health and Human Services, Centers for Disease Control and Prevention, *Pandemic Influenza Plan*, at 31 (2017) (noting “[HHS] staff with subject matter knowledge and long-term experience with influenza and influenza-related topic areas provided the greatest efficiency and effectiveness in pandemic influenza communication”).

⁹⁶⁷ The following state public health departments received questionnaires: Arizona, California, Georgia, Hawaii, Illinois, Michigan, Ohio, New Jersey, New York, Texas, Virginia, and Washington. All states except Ohio and New York submitted responses.

⁹⁶⁸ Arizona Department of Health, Written Response to Senate Committee on Homeland Security and Governmental Affairs State Public Health Agency Questionnaire (Jan. 5, 2021); California Department of Public Health, Written Response to Senate Committee on Homeland Security and Governmental Affairs State Public Health Agency Questionnaire (Dec. 10, 2021); Georgia Department of Health, Written Response to Senate Committee on Homeland Security and Governmental Affairs State Public Health Agency Questionnaire (Dec. 6, 2021); Hawaii Department of Health, Written Response to Senate Committee on Homeland Security and Governmental Affairs State Public Health Agency Questionnaire (Dec. 10, 2021); Illinois Department of Health, Written Response to Senate Committee on Homeland Security and Governmental Affairs State Public Health Agency Questionnaire (Jan. 27, 2021); Michigan Department of Health and Human Services, Written Response to Senate Committee on Homeland Security and Governmental Affairs State Public Health Agency Questionnaire (Dec. 2, 2021); New Jersey Department of Health, Written Response to Senate Committee on Homeland Security and Governmental Affairs State Public Health Agency Questionnaire (Dec. 10, 2021); Texas Department of Health, Written Response to Senate Committee on Homeland Security and Governmental Affairs State Public Health Agency Questionnaire (Dec. 3, 2021); Virginia Department of Health, Written Response to Senate Committee on Homeland Security and Governmental Affairs State Public Health Agency Questionnaire (Dec. 1, 2021); Washington State Department of Health, Written Response to Senate Committee on Homeland Security and Governmental Affairs State Public Health Agency Questionnaire (Dec. 3, 2021).

from Hawaii, Michigan, and New Jersey reported receiving frequent communications with information they could share with local stakeholders.⁹⁶⁹ Officials from the State of Washington said they received direct support from CDC staff on the ground to help investigate one of the first confirmed cases of COVID-19.⁹⁷⁰ Officials from California reported that “guidance was issued more quickly for this response compared to prior infectious disease emergency responses,” but noted that unlike prior responses CDC did not share approved talking points that in the past had been “useful for consistent public messaging.”⁹⁷¹ California officials told the Committee the state had “at least daily communication [with CDC] beginning January 13, 2020.”⁹⁷²

While states reported receiving frequent communications from CDC, federal guidance was at times unclear. For example, the Michigan Department of Health and Human Services (DHHS) reported that CDC’s testing guidance “was not clear, [and] did not indicate what was wrong with the assay and what was failing.”⁹⁷³ Specifically, Michigan DHHS stated that CDC’s guidance on how to conduct and prioritize COVID-19 testing was not helpful.⁹⁷⁴ Officials from the Virginia Department of Health expressed similar concerns noting, “urgent care facilities refused to test because of [a] lack of guidance around open/closed isolation rooms, which resulted in many individuals unnecessarily being transported to the hospital.”⁹⁷⁵ According to an April 2020 report issued by HHS’s Office of Inspector General, “hospitals reported that the multiple changes in [CDC] guidance contributed to a greater sense of confusion, fear, and distrust among staff that they could rely on hospital procedures to protect them.”⁹⁷⁶ Dr. Birx told the Committee that CDC’s confusing guidance stemmed from their lack of data and their analysis of “small convenience data sets,” which at times led to incorrect assumptions.⁹⁷⁷

⁹⁶⁹ Hawaii Department of Health, Written Response to Senate Committee on Homeland Security and Governmental Affairs State Public Health Agency Questionnaire (Dec. 10, 2021); Michigan Department of Health and Human Services, Written Response to Senate Committee on Homeland Security and Governmental Affairs State Public Health Agency Questionnaire (Dec. 2, 2021); New Jersey Department of Health, Written Response to Senate Committee on Homeland Security and Governmental Affairs State Public Health Agency Questionnaire (Dec. 10, 2021).

⁹⁷⁰ Washington State Department of Health, Written Response to Senate Committee on Homeland Security and Governmental Affairs State Public Health Agency Questionnaire (Dec. 3, 2021).

⁹⁷¹ California Department of Public Health, Written Response to Senate Committee on Homeland Security and Governmental Affairs State Public Health Agency Questionnaire (Dec. 10, 2021).

⁹⁷² *Id.*

⁹⁷³ Michigan Department of Health and Human Services, Written Response to Senate Committee on Homeland Security and Governmental Affairs State Public Health Agency Questionnaire (Dec. 2, 2021).

⁹⁷⁴ *Id.*

⁹⁷⁵ Virginia Department of Health, Written Response to Senate Committee on Homeland Security and Governmental Affairs State Public Health Agency Questionnaire (Dec. 1, 2021).

⁹⁷⁶ Department of Health and Human Services, Office of Inspector General, *Hospital Experiences Responding to the COVID-19 Pandemic: Results of a National Pulse Survey March 23-27, 2020* (OEI-20-00300) (Apr. 2020).

⁹⁷⁷ Interview with Dr. Deborah Birx (Jan. 6, 2022).

In interviews with the Committee, public health officials and experts also expressed concern with CDC’s delayed guidance. Dr. David Marcozzi, Chief Clinical Officer at University of Maryland Medical Center, told the Committee that due to the delay in guidance, he directed his health system to “stay ahead” of CDC based on “current information, which allowed optimal response strategies in real-time.”⁹⁷⁸ Officials from the Virginia Department of Health told the Committee that they had to write their own guidance for healthcare workers and nursing homes because CDC’s guidance was delayed.⁹⁷⁹ Officials from both Michigan and Virginia reported that policy changes were generally made via press releases without advanced notice to states. Virginia officials explained how this lack of advanced notice “made it difficult [for state health departments] to prepare for and respond to questions from the media and key constituents in a timely manner.”⁹⁸⁰

Conflicting and Delayed Mask Guidance

During the initial months of the pandemic, federal public health officials did not recommend general use of masks or that the public use cloth face masks. At the time, there was little consensus on the efficacy of cloth masks and other considerations, like supply availability for medical grade masks. Dr. John Brooks, Chief Medical Officer for CDC’s COVID-19 Emergency Response (Jan. 2020 – May 2022), told the Committee that in January 2020, CDC did not know if masking was necessary.⁹⁸¹ Dr. Brooks explained, “we knew mask supply was limited and we wanted to reserve [medical masks] for health care providers. We did not know in January [2020] that using masking for source control would work at a community level.”⁹⁸² He noted, “the only instructions we could find on how to make [cloth] masks [designed to protect against a viral respiratory pathogen like SARS-CoV-2] were from 1918.” According to Dr. Messonnier, CDC did not “have clear evidence of the value of masks,” noting “the science about the effectiveness of masks was not settled” and “there were concerns about whether there was a sufficient supply of PPE for health care workers.”⁹⁸³

Despite the lack of data, however, public health agencies declined to undertake new studies on the subject. Dr. Birx told the Committee, “I asked CDC to study other types of masks [but] CDC would not do the study. ASPR would not do the study. NIH would not do the study.”⁹⁸⁴ Scientists from the University of Tokyo in Japan—not CDC—first released a study on the effectiveness of wearing face masks to prevent the transmission of COVID-19 in October

⁹⁷⁸ Interview with Dr. David Marcozzi (Apr. 7, 2021).

⁹⁷⁹ Virginia Department of Health, Written Response to Senate Committee on Homeland Security and Governmental Affairs State Public Health Agency Questionnaire (Dec. 1, 2021).

⁹⁸⁰ *Id.*

⁹⁸¹ Centers for Disease Control and Prevention, Briefing with Senate Committee on Homeland Security and Governmental Affairs Staff (Aug. 31, 2021) (hereinafter “CDC Briefing (Aug. 31, 2021)”).

⁹⁸² *Id.*

⁹⁸³ Interview with Dr. Nancy Messonnier (Jan. 5, 2022).

⁹⁸⁴ Interview with Dr. Deborah Birx (Jan. 6, 2022).

2020.⁹⁸⁵ When the Committee asked Dr. Schuchat why it took months for CDC to issue mask guidance, she said incomplete information on issues like accessibility, effectiveness, and supply impacted the policy development process.⁹⁸⁶ Dr. Jernigan, Deputy Director for Public Health Science and Surveillance, told the Committee that a reliance by public health officials on a symptomatic flu-based response was the initial reason for a delay in mask guidance.⁹⁸⁷

Instead of relaying to the public what it did not know (e.g. whether masks were an effective tool to reduce virus transmission), public health officials provided conflicting and unclear statements on the use of face masks without sufficient justification. For example, throughout February, CDC first told the public it did not need to wear face masks, then recommended that only people who were sick or caring for someone who is sick wear face masks.⁹⁸⁸ On February 29, 2020 then U.S. Surgeon General Jerome Adams discouraged the use of face masks and told the public, “they are NOT effective” in preventing the spread of COVID-19 through a Twitter post, shown below.

February 29, 2020 Tweet from Former Surgeon General Jerome Adams⁹⁸⁹



⁹⁸⁵ Hiroshi Ueki, et al., *Effectiveness of Face Masks in Preventing Airborne Transmission of SARS-CoV-2*, American Society for Microbiology (Oct. 21, 2020); see also Dr. Deborah Birx, *Silent Invasion*, Chapter 2 (2022).

⁹⁸⁶ Interview with Dr. Anne Schuchat (Dec. 14, 2021).

⁹⁸⁷ Interview with Dr. Daniel Jernigan (Dec. 15, 2021).

⁹⁸⁸ House Committee on Foreign Affairs Subcommittee on Asia, the Pacific, and Nonproliferation, Testimony Submitted for the Record of Dr. Robert Redfield, Centers for Disease Control and Prevention, *Hearing on Coronavirus Disease 2019: The U.S. and International Response*, 116th Cong. (Feb. 27, 2020) (H. Hrg. 116-XX); *A face mask isn't sure protection from coronavirus, but it may be worthwhile – along with these self-defense measures*, Inquirer (Apr. 3, 2020) (<https://www.inquirer.com/health/coronavirus/face-masks-hand-washing-coronavirus-protection-20200304.html>).

⁹⁸⁹ U.S. Surgeon General Jerome Adams, Twitter post (Feb. 29, 2020, 4:08am) (https://web.archive.org/web/20200410210753/https://twitter.com/Surgeon_General/status/1233725785283932160?ref_src=twsrc%5Etfw%7Ctwcamp%5Etweetembed%7Ctwterm%5E1233725785283932160&ref_url=https%3A%2F

A March 4, 2020 White House COVID-19 “Subtask Force Call Read Out” noted a lesson learned from infection control in Hong Kong and South Korea included information that the “universal usage of masks,” specifically paper or cotton masks (not N95s) coupled with “social distancing and “alcohol rub” prevented the spread of COVID-19.⁹⁹⁰

Dr. Brooks told the Committee that CDC began drafting instructions on how to make masks and corresponding guidance toward the end of March.⁹⁹¹ After reviewing multiple studies on asymptomatic transmission throughout March, CDC submitted a memorandum to the White House on March 31 that “summarized the studies” and recommended the use of cloth face masks. When the Committee asked whether Dr. Brooks was aware of any political pressure to change or alter CDC’s guidance on cloth face masks, he responded, “I have never felt under any political pressure to say or not say something,” noting “we didn’t have the evidence” that face masks worked, but released guidance later after the data were “iron clad.”⁹⁹²

CDC, however, failed to clearly explain to the public that it did not know at that time whether cloth masks were an effective tool.⁹⁹³ Dr. Mecher told the Committee, “people don’t care what you’re telling them until they know you care about them,” noting, “if the problem is we don’t think we have enough [face masks], that should be conveyed by saying, ‘ideally, we would want everyone to be wearing masks, but we don’t have enough—we don’t even have enough for our healthcare workers.’” Dr. Mecher cautioned, “you lose trust as soon as the public feels that you are not being truthful to them.”⁹⁹⁴ Dr. Besser told the Committee, “as [CDC] gained more information, their recommendation changed, but the public was not brought along for the journey. We saw very quickly a political schism and the masks became a sign of political affiliation.”⁹⁹⁵

When CDC released guidance in early April recommending that all Americans wear cloth masks, the change added to confusion among the public about how best to protect against the virus.⁹⁹⁶ Dr. Jernigan acknowledged that the change caught states off guard. “This was a

www.inquirer.com/health/coronavirus/face-masks-hand-washing-coronavirus-protection-20200304.html).

⁹⁹⁰ Department of Defense, *Email from DOD official to OSD Pentagon OUSD Policy List OSD POLICY WUCOV Team* (Mar. 4, 2020) (on file with Committee, Production 7A at 11)

⁹⁹¹ CDC Briefing (Aug. 31, 2021).

⁹⁹² *Id.*

⁹⁹³ House Committee on Foreign Affairs Subcommittee on Asia, the Pacific, and Nonproliferation, Testimony Submitted for the Record of Dr. Robert Redfield, Centers for Disease Control and Prevention, *Hearing on Coronavirus Disease 2019: The U.S. and International Response*, 116th Cong. (Feb. 27, 2020) (H. Hrg. 116-105).

⁹⁹⁴ Interview with Dr. Carter Mecher (July 29, 2022).

⁹⁹⁵ Interview with Dr. Richard Besser (Apr. 7, 2021).

⁹⁹⁶ Department of Health and Human Services, Centers for Disease Control and Prevention, Coronavirus Disease 2019 (COVID-19) (Apr. 3, 2020) (<https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/cloth-face-cover.html>); *How Mask Guidelines Have Evolved*, New York Times (July 9, 2021) (<https://www.nytimes.com/2021/04/27/science/face-mask-guidelines-timeline.html>); *Mixed messages on masks from*

significant change in guidance,” Dr. Jernigan said, “[states’] concerns about shifting views were valid.”⁹⁹⁷

Travel Restrictions from Europe and No Sail Orders for Cruise Ships

The Administration did not implement travel restrictions from Europe and no-sail orders for cruise ships until the second week of March 2020, which went against recommendations to do so earlier. Dr. Schuchat told the Committee that the delay in implementing travel alerts for Europe “was a policy barrier, not a recognition of the problems,” and “despite recognition of a terrible outbreak on cruise ships, the U.S. was delayed in executing no-sail orders.” Dr. Schuchat explained how “the give and take with industry slowed things down . . . we recognized asymptomatic spread was happening, but there was sort of a denial at a higher level, or perhaps psychological denial that this was going to be as bad as it is.”⁹⁹⁸

Mr. Pottinger told the Committee that the individuals who were vocal against implementing travel restrictions from Europe “represented U.S. economic interests.” According to Mr. Pottinger, “a combination of fear about economic consequences and reversion to the idea that it may not work anyway,” were the primary causes for the delay.⁹⁹⁹ Mr. Pottinger told the Committee, “in my view, if we had done it six weeks earlier . . . we would have mitigated the spread.”¹⁰⁰⁰

An internal 2021 State Department review that identified lessons learned from the federal response concluded:

“[m]any of the Department’s actions and messaging, or lack thereof, reflected policy emanating from the White House and other agencies at the time, as well as the general complacency within American society. For example, as the President and other officials expressed confidence that the United States would be able to contain the virus, they balked at issuing a broad warning to U.S. citizens about the risks of their overseas travel until March 11, as this not-well-understood virus spread from Asia to Europe, Africa, and the Western Hemisphere. This delay likely increased the number of outbound U.S. travelers who required assistance in returning to the United States in the following months.”¹⁰⁰¹

leaders during pandemic has caused confusion for many, ABC News (May 6, 2020) (<https://abcnews.go.com/US/mixed-messages-masks-critical-tool-slow-pandemic-slowed/story?id=70526293>).

⁹⁹⁷ Interview with Dr. Daniel Jernigan (Dec. 15, 2021).

⁹⁹⁸ Interview with Dr. Anne Schuchat (Dec. 14, 2021).

⁹⁹⁹ Interview with Matthew Pottinger (Jan. 25, 2022).

¹⁰⁰⁰ *Id.*

¹⁰⁰¹ Department of State, *COVID-19 Interim Review: Lessons Learned from the Department of State’s Response to the COVID-19 Pandemic* (June 2021) (on file with Committee, STATE-2021-02-0000402).

Ambassador Jess L. Baily, who led the State Department’s COVID-19 interim review, told the Committee, “concern for the economy, travel, and the cruise industry delayed messaging that would otherwise have helped contain the virus.” He explained, “there was a desire to reassure on the economy, which is important, but there was a certain level of complacency coupled with lack of knowledge.”¹⁰⁰²

Some former officials, however, acknowledged that economic considerations were a necessary aspect of the initial response. “There were going to be economic consequences [from the response],” Ms. Troye told the Committee, adding that policymakers should “bring all the tools to the table that you can use to solve a problem.”¹⁰⁰³ Without considering economic consequences, there “will not be a cohesive view on how to have an all of government response,” she said.¹⁰⁰⁴ Then NSC senior official Anthony Ruggiero expressed that the economic consequences of public health decisions was “one factor—and not inappropriate” to consider in the context of a broad and robust policy debate, noting, “it is an appropriate question for senior leaders to ask, and be prepared to discuss with the President, what the economic impacts of [various policy options] will be if implemented.”¹⁰⁰⁵ Former Deputy National Security Director Matthew Pottinger explained that those pushing economic concerns did so legitimately, stating, “societal and economic health arguments were made good faith.”¹⁰⁰⁶

Mischaracterizing the Threat Level

The Majority Committee staff found that throughout January and February, CDC’s reliance on incomplete data (Section V), coupled with the lack of testing (Section VI), resulted in public statements that understated the severity of the virus. For example, in a February 14 telebriefing CDC officials stated, “there have been a few reports of [pre-symptomatic spread] with the new coronavirus and it is compatible with what we know about other respiratory viruses including seasonal flu . . . the idea is that this virus is behaving in many ways like we’d expect influenza in terms of its spread.”¹⁰⁰⁷

In interviews with the Committee, senior federal officials from the White House and ASPR stated they had serious concerns about the spread of the virus in February 2020, which were regularly discussed in internal meetings.¹⁰⁰⁸ On February 24, President Trump tweeted,

¹⁰⁰² State Department Briefing (Sept. 29, 2021).

¹⁰⁰³ Interview with Olivia Troye (Dec. 8, 2021).

¹⁰⁰⁴ *Id.*

¹⁰⁰⁵ Anthony Ruggiero, Correspondence to Senate Committee on Homeland Security and Governmental Affairs (Aug. 1, 2022).

¹⁰⁰⁶ Interview with Matthew Pottinger (Jan. 25, 2022).

¹⁰⁰⁷ Department of Health and Human Services, Centers for Disease Control and Prevention, Transcript for CDC Media Telebriefing: Update on COVID-19 (Feb. 14, 2020) (<https://www.cdc.gov/media/releases/2020/t0214-covid-19-update.html.html>).

¹⁰⁰⁸ Interview with Dr. Robert Kadlec (Dec. 6, 2021); Interview with Matthew Pottinger (Jan. 25, 2022); Interview with Olivia Troye (Dec. 8, 2021).

“The Coronavirus is very much under control in the USA. We are in contact with everyone and all relevant countries. CDC & World Health have been working hard and very smart. Stock Market starting to look very good to me!”¹⁰⁰⁹

However, former President Trump acknowledged the severity of the virus in a private conversation with journalist Bob Woodward on February 7, 2020, two weeks prior to his public statement through Twitter. According to Mr. Woodward’s interview, President Trump said “you just breathe the air and that’s how it’s passed . . . and so that’s a very tricky one. That’s a very delicate one. It’s also more deadly than even your strenuous flus.”¹⁰¹⁰ Despite this, President Trump subsequently stated in public remarks—that COVID-19 was “like, if you had the flu” and that “it’s going to disappear.”¹⁰¹¹

Throughout the month of February, federal officials continued to inform the American public of their low risk to the COVID-19 virus. According to Ms. Troye, there was a lot of discussion among public health officials about how to keep Americans calm and not cause panic, including what to tell the public about the threat. Ultimately, Ms. Troye said, the Administration coordinated the tagline, “the risk is low.”¹⁰¹²

On February 25, former HHS Secretary Azar stated in a White House press briefing, “the immediate risk to the general American public remains low. But as we have warned, that has the potential to change quickly.”¹⁰¹³ On February 27, Dr. Redfield testified before Congress, “the potential global public health threat posed by this virus is high, but right now, the immediate risk to most Americans is low.”¹⁰¹⁴ Also on February 27 at a White House briefing, HHS Secretary Azar said, “the immediate risk to the American public [from COVID-19] has been and continues to be low. Our containment strategy has been working.”¹⁰¹⁵

¹⁰⁰⁹ President Donald Trump, Twitter post (Feb. 24, 2020, 1:42pm) (<https://web.archive.org/web/20200225153215/https://twitter.com/realDonaldTrump/status/1232058127740174339>).

¹⁰¹⁰ *Woodward book: Trump says he knew coronavirus was ‘deadly’ and worse than the flu while intentionally misleading Americans*, Washington Post (Sep. 9, 2020) (https://www.washingtonpost.com/politics/bob-woodward-rage-book-trump/2020/09/09/0368fe3c-efd2-11ea-b4bc-3a2098fc73d4_story.html).

¹⁰¹¹ White House, Remarks by President Trump in Meeting with African American Leaders (Feb. 28, 2020) (<https://web.archive.org/web/20200228221517/https://www.whitehouse.gov/briefings-statements/remarks-president-trump-meeting-african-american-leaders/>).

¹⁰¹² Interview with Olivia Troye (Dec. 8, 2021).

¹⁰¹³ C-SPAN, *Health and Human Services Briefing on the Coronavirus Outbreak* (Feb. 25, 2020) (<https://www.c-span.org/video/?469708-1/hhs-officials-hold-news-conference-coronavirus>).

¹⁰¹⁴ House Committee on Foreign Affairs Subcommittee on Asia, the Pacific, and Nonproliferation, Testimony Submitted for the Record of Dr. Robert Redfield, Centers for Disease Control and Prevention, *Hearing on Coronavirus Disease 2019: The U.S. and International Response*, 116th Cong. (Feb. 27, 2020) (H. Hrg. 116-105).

¹⁰¹⁵ White House, Remarks by President Trump, Vice President Pence, and Members of the Coronavirus Task Force in Press Conference (Feb. 26, 2020) (<https://trumpwhitehouse.archives.gov/briefings-statements/remarks-president-trump-vice-president-pence-members-coronavirus-task-force-press-conference/>).

Ms. Troye, however, told the Committee that the White House Task Force was at least aware of the threat,

Unfortunately, what was being conveyed publicly, was not what was really happening behind the scenes. . . The people sitting at the table on the Task Force [were] worried. It's not like you had a bunch of people sitting around being like, this is no big deal . . . there is a level of seriousness taking place in these discussions about what this is. This is very real.¹⁰¹⁶

The Administration, however, continued to categorize the risk as “low” throughout early March 2020. On March 6, 2020, then Surgeon General Jerome Adams stated, “the risk to the average American of coronavirus at this time remains low. However, we are seeing pockets in this country of increased cases of coronavirus.”¹⁰¹⁷ On March 11, 2020 President Trump stated in a public briefing, “[t]he vast majority of Americans: The risk is very, very low. Young and healthy people can expect to recover fully and quickly if they should get the virus. The highest risk is for elderly population with underlying health conditions. The elderly population must be very, very careful.”¹⁰¹⁸ In the State Department’s 2021 internal review, the agency concluded “the decision to reassure Americans of their safety to try to avoid damaging the economy delayed warnings to U.S. citizens about travel during a pandemic until well after airlines were cutting flights and borders were closing around the world.”¹⁰¹⁹

B. CDC’s Role

CDC’s public role changed as the pandemic spread and by March 2020, the White House significantly limited CDC’s ability to communicate through public briefings. In mid-February, federal officials became increasingly concerned as the virus continued to spread rapidly across other countries and raised the need to prepare the American people.¹⁰²⁰ Dr. Messonnier told the Committee, “we had been talking to the public for several weeks before that about needing to get prepared, but it felt like the public wasn’t really embracing the sentiment or understanding what we were trying to convey.”¹⁰²¹ Dr. Mecher explained the challenge of risk communication in a

¹⁰¹⁶ Interview with Olivia Troye (Dec. 8, 2021).

¹⁰¹⁷ *Surgeon general says risk of coronavirus remains low, most people will not need hospitalization*, Fox News (Mar. 6, 2020) (<https://www.foxnews.com/media/risk-of-coronavirus-remains-low-most-people-will-not-need-hospitalization>)

¹⁰¹⁸ President Donald Trump, White House, Remarks by President Trump in Address to the Nation (Mar. 11, 2020).

¹⁰¹⁹ Department of State, *COVID-19 Interim Review: Lessons Learned from the Department of State’s Response to the COVID-19 Pandemic* (June 2021) (on file with Committee, STATE-2021-02-0000402).

¹⁰²⁰ Interview with Joseph Grogan (Jan. 25, 2022); Interview with Dr. Nancy Messonnier (Jan. 5, 2022); Interview with Dr. Anne Schuchat (Dec. 14, 2021); Interview with Olivia Troye (Dec. 8, 2021).

¹⁰²¹ Interview with Dr. Nancy Messonnier (Jan. 5, 2022).

political environment is that “it is not an environment where people are going to stick their necks out and potentially be wrong, but you have to take action early in order for it to be effective.”¹⁰²²

According to Dr. Schuchat, there was an “avoid bad news bias” on the part of senior Administration officials and a “lack of understanding of optimal risk communications—that sharing even bad news is helpful and reassuring.”¹⁰²³ Dr. Schuchat expressed the view that “not sharing bad news increases suspicion and distrust and reduces credibility. Principle one in risk communication is to be open and honest, but I don’t believe there was a bias of such communication in the Administration. I think the Administration lost control of messaging when they stopped being open.” Mr. Pottinger told the Committee, “I think the people who didn’t want to panic people legitimately did not think the virus was a threat. Those who wanted to downplay it—they believed that this would just be a bad flu season. It took a lot of time—weeks—for it to sink in that this would be bad and would not be just another flu season.”¹⁰²⁴ According to Dr. Birx, “there was a fundamental difference in how the White House Task Force viewed the pandemic early on and how CDC viewed the pandemic.”¹⁰²⁵ She explained, “CDC was not talking about masking or asymptomatic spread—they were still in containment and still in syndromic mode.”

According to Dr. Messonnier, throughout February, CDC tried to “communicate to the public that . . . [people should] start getting ready.” On February 25, 2020, after seeing more rapid spread in Europe, CDC decided to “escalate” the message to prompt Americans to “take action to get prepared,” without ratchet[ing] up alarm.”¹⁰²⁶

In a February 25 CDC briefing, Dr. Messonnier said, “the global novel coronavirus situation is rapidly evolving and expanding . . . This means that cases of COVID-19 are appearing without a known source of exposure . . . To date, our containment strategies have been largely successful. As a result, we have very few cases in the United States and no spread in the community.”¹⁰²⁷ Dr. Messonnier continued, “[u]ltimately, we expect we will see community spread in this country. It’s not so much a question of if this will happen anymore but rather more of a question of exactly when this will happen and how many people in this country will have severe illness . . . I understand this whole situation may seem overwhelming and that disruption to everyday life may be severe. But these are things that people need to start thinking about now.”¹⁰²⁸ However, in this same briefing, Dr. Messonnier again stated that containment

¹⁰²² Interview with Dr. Carter Mecher (July 29, 2022).

¹⁰²³ Interview with Dr. Anne Schuchat (Dec. 14, 2021).

¹⁰²⁴ Interview with Matthew Pottinger (Jan. 25, 2022).

¹⁰²⁵ Interview with Dr. Deborah Birx (Jan. 6, 2022).

¹⁰²⁶ Interview with Dr. Nancy Messonnier (Jan. 5, 2022).

¹⁰²⁷ Department of Health and Human Services, Centers for Disease Control and Prevention, Transcript for the CDC Telebriefing Update on COVID-19 (Feb. 26, 2020) (<https://www.cdc.gov/media/releases/2020/t0225-cdc-telebriefing-covid-19.html>).

¹⁰²⁸ *Id.*

measures to that point had been effective.¹⁰²⁹ Dr. Messonnier also recognized uncertainty with the novel virus. “I also want to acknowledge the importance of uncertainty. During an outbreak with a new virus, there is a lot of uncertainty,” she said, adding, “[o]ur guidance and advice are likely to be fluid subject to change as we learn more.”¹⁰³⁰

Hours later, the stock market dropped.¹⁰³¹ In an interview with Committee staff, Dr. Messonnier explained that the purpose of her briefing was to “escalate the public’s preparation for the likelihood that this was going to come . . . we wanted people to take action to get prepared. We were not trying to ratchet up alarm, but [wanted people to] take action to get prepared for what we thought was inevitable.”¹⁰³² Mr. Azar explained that Dr. Messonnier’s remarks “were generally consistent with the conclusions reached during the February 21 [COVID-19] tabletop exercise.”¹⁰³³ Other public health officials interviewed by the Committee, including Dr. Schuchat, Dr. Jernigan, and then CDC Chief of Staff Kyle McGowan agreed that Dr. Messonnier’s characterization of the threat was accurate.¹⁰³⁴

Despite the accuracy of her remarks, Dr. Messonnier told the Committee that she later learned that “there was consternation about the way in which CDC communicated and consternation about the messages CDC had relayed.”¹⁰³⁵ While Dr. Jernigan acknowledged that Dr. Messonnier’s remarks were accurate, he noted that her remarks were more forward leaning than previous occasions. “The White House was not aware it was going to be said,” Dr. Jernigan told the Committee, “that briefing was more than what had previously been communicated.”¹⁰³⁶ Ms. Troye told the Committee “the White House was really upset about the stock market timing and was concerned about mixed messages.”¹⁰³⁷ Ms. Troye explained that after Dr. Messonnier’s briefing, the Vice President’s Communications Director “lock[ed] down all communications” requiring “any public statements” to first go to the White House for approval and “any briefing to take place at the White House by either a White House aide or in the presence of the White House.” As a result of this new process, Ms. Troye told the Committee,

¹⁰²⁹ *Id.*

¹⁰³⁰ Department of Health and Human Services, Centers for Disease Control and Prevention, Transcript for the CDC Telebriefing Update on COVID-19 (Feb. 26, 2020) (<https://www.cdc.gov/media/releases/2020/t0225-cdc-telebriefing-covid-19.html>). In the February 25, 2020 briefing, Dr. Messonnier also noted that a “proactive approach of containment and mitigation will delay the emergence of community spread in the United States while simultaneously reducing its ultimate impact,” and told the public that “a team of mathematical modelers [are trying] to predict the trajectory [of the virus]” and “one hypothesis” is that COVID-19 “could potentially be seasonal” as other viral respiratory disease are, like influenza.

¹⁰³¹ *Stocks Slide for 2nd Day as U.S. Sounds Alarm on Coronavirus*, New York Times (Feb. 25, 2020) (<https://www.nytimes.com/2020/02/25/business/stock-markets-covid-19.html>).

¹⁰³² Interview with Dr. Nancy Messonnier (Jan. 5, 2022).

¹⁰³³ Alex Azar Interrogatories (Mar. 1, 2022).

¹⁰³⁴ Interview with Dr. Daniel Jernigan (Dec. 15, 2021); Interview with Kyle McGowan (Dec. 2, 2021); Interview with Dr. Anne Schuchat (Dec. 14, 2021).

¹⁰³⁵ Interview with Dr. Nancy Messonnier (Jan. 5, 2022).

¹⁰³⁶ Interview with Dr. Daniel Jernigan (Dec. 15, 2021).

¹⁰³⁷ Interview with Olivia Troye (Dec. 8, 2021).

“there was mass confusion of how to get things cleared [for public release]. I noticed because I was set in the middle of it, because I was trying to figure out how to get some of this stuff cleared. Every press interview had to be cleared by [the Vice President’s Communications Director and] any media had to be cleared by her. Anything that was going to touch on [COVID-19] had to be clarified.”¹⁰³⁸

The following day, on February 26, President Trump announced that Vice President Pence would replace HHS Secretary Azar as the lead for the federal pandemic response.¹⁰³⁹ After Vice President Pence took over response efforts, CDC’s ability to communicate with the public was significantly curtailed. According to Dr. Messonnier, HHS stopped approving CDC requests for additional telebriefings in March 2020.¹⁰⁴⁰ CDC’s briefings were phased out and from March 10 – June 11, 2020, the agency was prohibited from conducting briefings.¹⁰⁴¹ HHS told the Committee it found four instances “where CDC telebriefings were planned and then cancelled, or denied when proposed” between February 25 and June 9, 2020.¹⁰⁴² According to HHS, “by early April, after several attempts to get approvals, [the Office of Assistant Secretary for Public Affairs] stopped asking [the White House] for a while.”¹⁰⁴³

Dr. Redfield told the Committee that his requests to conduct briefings were almost “universally denied.”¹⁰⁴⁴ He explained, “I did continue to request the ability to do briefings. I thought it was important to the American public, but subject matter experts like [Dr. Messonnier] were not cleared for those briefings.”¹⁰⁴⁵ Dr. Redfield told the Committee that the “lack of clearance was at the HHS level,” but he did not know if HHS received instructions from elsewhere.¹⁰⁴⁶ Dr. Schuchat also received multiple media requests, but rarely was cleared to participate.¹⁰⁴⁷

¹⁰³⁸ *Id.*

¹⁰³⁹ See C-SPAN, President Trump with Coronavirus Task Force Briefing (Feb. 26, 2020) (<https://www.c-span.org/video/?469747-1/president-trump-announces-vice-president-pence-charge-coronavirus-response>).

¹⁰⁴⁰ Interview with Dr. Nancy Messonnier (Jan. 5, 2022). Dr. Messonnier explained that her team “requested approval from HHS and heard back from HHS,” but she did not have visibility into what approval HHS got from the White House.

¹⁰⁴¹ Department of Health and Human Services, Centers for Disease Control and Prevention, 2020 News Releases: Transcripts (<https://www.cdc.gov/media/releases/2020/archives.html>) (accessed July 19, 2022).

¹⁰⁴² HHS Correspondence to Senate Committee on Homeland Security and Governmental Affairs Staff (Feb. 10, 2022).

¹⁰⁴³ *Id.*

¹⁰⁴⁴ Interview with Dr. Robert Redfield (Feb. 7, 2022).

¹⁰⁴⁵ *Id.*

¹⁰⁴⁶ Dr. Robert Redfield, Written Response to Senate Committee on Homeland Security and Governmental Affairs Staff (received Aug. 5, 2022).

¹⁰⁴⁷ Interview with Dr. Anne Schuchat (Dec. 14, 2021).

After February 26, all public statements, including guidance documents, required approval from the White House.¹⁰⁴⁸ President Trump appeared with Vice President Pence at the next Coronavirus Task Force press briefing on February 29, 2020, while Secretary Azar played a supporting role.¹⁰⁴⁹ In the following weeks, President Trump led 18 of the 22 White House Task Force Press briefings in March 2020.¹⁰⁵⁰

When asked by Committee staff if it would have made sense for CDC to conduct separate briefings while the White House was leading the response, Dr. Messonnier told the Committee, “I hesitate to say that. I do not think it would have made sense to have simultaneous messaging” and “a unified message is important.”¹⁰⁵¹ Following the February 25 briefing, Dr. Messonnier said she was not asked by anyone to retract her previous statements about the virus’ potential and noted that CDC still provided public updates via its website, and provided “information to the White House and HHS at all times.”¹⁰⁵² Reflecting back on the events two years later, Dr. Messonnier said, “it is not surprising to me . . . that, as events unfolded and things became more complicated, the American public expects more of the messaging to come from more of a political level. So...the White House and folks in DC took on a stronger role of being the lead in public-facing communication.”¹⁰⁵³

C. Contradiction in Public Messaging

Contradictory statements from the Administration and public health officials degraded public trust in the federal government’s response actions. Several former public health officials interviewed by the Committee had concerns regarding some of the prior Administration’s public statements.¹⁰⁵⁴

Dr. Besser told Committee staff “one of the things we never exercised is what if you are in a situation where the Administration decides not to follow the public health science. Plans can

¹⁰⁴⁸ Interview with Olivia Troye (Dec. 8, 2021).

¹⁰⁴⁹ C-SPAN, President Trump with Coronavirus Task Force Briefing (Feb. 29, 2020) (<https://www.c-span.org/video/?469892-1/president-trump-holds-news-conference-amid-us-death-coronavirus>).

¹⁰⁵⁰ Committee analysis of President Trump’s archive of briefings and statements in March 2020. White House, Briefings and Statements (<https://trumpwhitehouse.archives.gov/briefings-statements/>) (accessed July 19, 2022).

¹⁰⁵¹ Interview with Dr. Nancy Messonnier (Jan. 5, 2022).

¹⁰⁵² *Id.*

¹⁰⁵³ *Id.*

¹⁰⁵⁴ Interview with Dr. Richard Besser (Apr. 7, 2021); Dr. Julie Gerberding, Former Director of Centers for Disease Control and Prevention (July 2002 – Jan. 2009), Interview with Senate Committee on Homeland Security and Governmental Affairs (Feb. 8, 2021) (hereinafter “Interview with Dr. Julie Gerberding (Feb. 8, 2021)”); Dr. Nicole Lurie, Former Assistant Secretary for Preparedness and Response (2009 – 2016), Interview with Senate Committee on Homeland Security and Governmental Affairs (Feb. 4, 2021) (hereinafter “Interview with Dr. Nicole Lurie (Feb. 4, 2021)”); Interview with Dr. Anne Schuchat (Dec. 14, 2021); Interview with Olivia Troye (Dec. 8, 2021).

be clear on paper, but that’s not what went wrong with the COVID-19 response.”¹⁰⁵⁵ In an interview with Committee staff, former CDC Director Dr. Julie Gerberding stated she had spoken in confidence with Trump Administration CDC staff that considered leaving the agency out of concerns that they were contributing to misinformation.¹⁰⁵⁶ Similarly, former ASPR Dr. Nicole Lurie told the Committee, “there was a culture of fear [at ASPR] that if you spoke up, you were going to lose your job.”¹⁰⁵⁷ The State Department’s COVID-19 Interim Review found that “the politicized internal debate on science and mitigation measures undermined international trust in U.S. leadership.”¹⁰⁵⁸

In a recent report by GAO, certain federal officials at CDC, FDA, and NIH told GAO they “observed incidents that they perceived to be potential political interference;” however, officials did not report these incidents for a variety of reasons, including fear of retaliation, lack of clarity on how to report issues, and belief that agency leaders had awareness of the concerns.¹⁰⁵⁹ GAO’s review also found that CDC, FDA, NIH, and ASPR did not have procedures in place that define political interference in scientific decision making or how to report potential political interference.

On March 8, 2020, Chris Christie, former Governor of New Jersey, texted then HHS Secretary Alex Azar, “Alex—Getting increasingly concerned about the messaging/handling of this out of DC. Starting to say so on TV. How can I be helpful to you since I presume you and I are on the same page?”¹⁰⁶⁰ Former FDA Commissioner Scott Gottlieb wrote that, “[h]onest debate is one thing, but our response was demoralized by a sizable enterprise devoted to manufacturing skepticism about any steps that could potentially reduce the scope of the spread, even obviously effective measures like masks or vaccines.”¹⁰⁶¹ Dr. Schuchat shared similar sentiments in her interview with the Committee. She said, “until vaccines became available, individual behavior required trust to wear a mask or social distance. The toll of the pandemic was worse than it needed to be.”¹⁰⁶²

Some former officials involved in the response, however, noted that shifting views from public health officials caused public confusion. Then CDC Director Dr. Redfield told the Committee “certain spokespeople [at federal public health agencies] kept changing their position . . . that loses credibility,” Dr. Redfield observed, adding, “sometimes [public health officials] try

¹⁰⁵⁵ Interview with Dr. Richard Besser (Apr. 7, 2021).

¹⁰⁵⁶ Interview with Dr. Julie Gerberding (Feb. 8, 2021).

¹⁰⁵⁷ Interview with Dr. Nicole Lurie (Feb. 4, 2021).

¹⁰⁵⁸ Department of State, *COVID-19 Interim Review: Lessons Learned from the Department of State’s Response to the COVID-19 Pandemic* (June 2021) (on file with Committee, STATE-2021-02-0000349-456).

¹⁰⁵⁹ Government Accountability Office, *Scientific Integrity: HHS Agencies Need to Develop Procedures and Train Staff on Reporting and Addressing Political Interference* (GAO-22-104613) (Apr. 20, 2022).

¹⁰⁶⁰ Department of Health and Human Services, *Text Message from Former Governor of New Jersey Chris Christie (2014-2018) to HHS Secretary Alex Azar* (Mar. 8, 2020) (on file with Committee, HHS HSGAC 37045).

¹⁰⁶¹ Dr. Scott Gottlieb, *Uncontrolled Spread: Why COVID-19 Crushed Us and How We Can Defeat the Next Pandemic* (2021).

¹⁰⁶² Interview with Dr. Anne Schuchat (Dec. 14, 2021).

and be too digestible and just say what they think people want to hear.”¹⁰⁶³ Nicholas Uehlecke, a former senior advisor to HHS Secretary Azar told the Committee, “[public health officials] responsible for formulating guidance could not get out of their own way.”¹⁰⁶⁴ According to Mr. Uehlecke, “A thought would happen and then it would be said... it didn’t matter if it contradicted what [Dr. Fauci] said yesterday.”

Contradictory messaging also imparted confusion among the public. CDC and the White House published conflicting guidance on social gatherings within one day of each other. On March 15, CDC released guidance advising the public to “cancel or postpone in-person events that consist of 50 people or more throughout the United States.”¹⁰⁶⁵ The following day, on March 16, the White House announced its “15 Days to Slow the Spread” initiative to help protect Americans during the global Coronavirus outbreak, which included mitigation measures such as advising the public to “avoid social gatherings in groups of more than 10 people.”¹⁰⁶⁶

The Majority Committee staff found that the Administration’s contradictory communications undermining the public health science resulted in multiple problems that negatively impacted federal response efforts. Below are some examples.

Loss of Public Trust

From March 9 through April 17, 2020, the White House held daily briefings, typically led by the President.¹⁰⁶⁷ Throughout these briefings, the American people frequently received contradictory messages from political and public health officials. Dr. Schuchat explained that the “principle issue was introducing a partisan angle...It was an all-of-government response that needed an all-of-government communication plan, ideally one that is nonpartisan. It was hard to keep the partisan out of the press conference once the White House became involved.”¹⁰⁶⁸ Dr. Besser cautioned, “[i]n public health emergency response, what is a truism is once things become partisan, you’ve lost.”¹⁰⁶⁹

For example, following Dr. Messonnier’s February 25, 2020 remarks that COVID-19 would impact the U.S. and “disruption to everyday life may be severe,” President Trump countered this public health warning the next day noting, “[w]hen you have 15 people and the 15

¹⁰⁶³ Interview with Dr. Robert Redfield (Feb. 7, 2022).

¹⁰⁶⁴ Interview with Nicholas Uehlecke (Nov. 4, 2021).

¹⁰⁶⁵ Department of Health and Human Services, Centers for Disease Control and Prevention, *Interim Guidance for Coronavirus Disease 2019 (COVID-19)* (Mar. 15, 2020) (<https://web.archive.org/web/20200316043005/https://www.cdc.gov/coronavirus/2019-ncov/community/large-events/mass-gatherings-ready-for-covid-19.html>).

¹⁰⁶⁶ White House, *15 Days to Slow the Spread* (<https://www.justice.gov/doj/page/file/1258511/download>) (accessed Nov. 30, 2022).

¹⁰⁶⁷ See White House, Briefings and Statements (Mar. 2020 – Apr. 17, 2020) (<https://trumpwhitehouse.archives.gov/briefings-statements/>) (accessed Nov. 30, 2022).

¹⁰⁶⁸ Interview with Dr. Anne Schuchat (Dec. 14, 2021).

¹⁰⁶⁹ Interview with Dr. Richard Besser (Apr. 7, 2021).

within a couple of days is going to be down to close to zero, that's a pretty good job we've done... Because of all we've done, the risk to the American people remains very low."¹⁰⁷⁰ In the months that followed, the President repeatedly urged the use of unproven treatments like hydroxychloroquine and, at one briefing, suggested ultraviolet light or disinfectant could somehow be used inside the body.¹⁰⁷¹ This prompted a flood of concerns and warnings by CDC, other public health officials, and even disinfectant manufacturers of the threat posed from introducing disinfectant into the body.¹⁰⁷² After President Trump's statement, data from the American Association of Poison Control Centers showed a 121 percent increase in accidental disinfectant poisonings from the same time period in 2020.¹⁰⁷³

Undermining Guidance

After CDC issued guidance recommending face masks on April 3, 2020, at the same briefing, the President stated, "so it's voluntary. You don't have to do it...I don't think I'm going to be doing it."¹⁰⁷⁴ When asked why President Trump was opposed to masks, he said, "I just don't want to wear one myself."¹⁰⁷⁵ Dr. Redfield told the Committee it was a great disappointment when "the President did not embrace the mitigation step we asked him to [referring to the President's comments on masks]."¹⁰⁷⁶ According to Dr. Schuchat, CDC's inability to communicate with the public in order to provide context behind their public health guidance deteriorated public trust. Dr. Schuchat told the Committee, "The inability for us to communicate directly about the mask guidance left many thinking we had contradicted ourselves. Open communication would have allowed us to say, 'this is what we know now that we didn't know then.' This is why we have updated guidance. The public often saw a whipsaw without a framing that led to reduced credibility in what anyone was saying."¹⁰⁷⁷

¹⁰⁷⁰ White House, Remarks by President Trump, Vice President Pence, and Members of the Coronavirus Task Force in Press Conference (Feb. 26, 2020) (<https://trumpwhitehouse.archives.gov/briefings-statements/remarks-president-trump-vice-president-pence-members-coronavirus-task-force-press-conference/>).

¹⁰⁷¹ *President Trump Suggests 'Injecting' Disinfectant as Coronavirus Cure*, NBC New York (Apr. 23, 2020) (<https://www.youtube.com/watch?v=zicGxU5MfwE>).

¹⁰⁷² Food and Drug Administration, *Coronavirus (COVID-19) Update: FDA Continues to Ensure Availability of Alcohol-Based Hand Sanitizer During the COVID-19 Pandemic, Addresses Safety Concerns* (Apr. 27, 2020) (<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-continues-ensure-availability-alcohol-based-hand-sanitizer-during>); Environmental Protection Agency, *EPA provides critical information to the American public about safe disinfectant use* (Apr. 23, 2020) (<https://www.epa.gov/newsreleases/epa-provides-critical-information-american-public-about-safe-disinfectant-use>); *Improper Use of Disinfectants*, Reckitt Benckiser (Apr. 24, 2020) (<https://www.reckitt.com/newsroom/latest-news/news/2020/april/improper-use-of-disinfectants/>).

¹⁰⁷³ *Accidental Poisonings Increased After President Trump's Disinfectant Comments*, Time (May 12, 2020) (<https://time.com/5835244/accidental-poisonings-trump/>).

¹⁰⁷⁴ White House, Remarks by President Trump, Vice President Pence, and Members of the Coronavirus Task Force in Press Briefing (Apr. 3, 2020) (<https://trumpwhitehouse.archives.gov/briefings-statements/remarks-president-trump-vice-president-pence-members-coronavirus-task-force-press-briefing-18/>).

¹⁰⁷⁵ *Id.*

¹⁰⁷⁶ Interview with Dr. Robert Redfield (Feb. 7, 2022).

¹⁰⁷⁷ Interview with Dr. Anne Schuchat (Dec. 14, 2021).

The Brookings Institute examined Gallup survey data from March through August 2020 that showed political affiliation drove beliefs and behaviors regarding COVID-19 more than any other factor, like local case counts or age. These beliefs also influenced the adoption of state policies on masks and social distancing.¹⁰⁷⁸ Another Brookings study conducted between June 2 and July 1, 2020, found that 20 percent of Americans were not using masks in public to mitigate the spread of COVID-19, despite more states either requiring or strongly suggesting that all residents wear masks when in public.¹⁰⁷⁹ The Majority Committee staff found this lack of cohesion around the science resulted in a disjointed response with inconsistent policies and mandates varying state to state and even by municipality.

Delayed Public Health Guidance

The requirement that the White House approve all CDC-issued public health guidance resulted in significant delays in issuing guidance according to Olivia Troye, then Senior Advisor to Vice President Pence and a lead on the White House Task Force.¹⁰⁸⁰ Ms. Troye told the Committee that the new approval process resulted in “coordination issues” and a confusion with regard to what type of guidance CDC was allowed to post and what type of guidance they were not allowed to post.¹⁰⁸¹ Ms. Troye explained, “sometimes [the White House] sat on [guidance] for weeks. The reason I found out about it was because people started to reach out to me to see if I could help clear things because we were the Task Force.” As one example, Ms. Troye recalled a time where the CDC Chief of Staff phoned her and said, “hospitals are waiting for guidance on how to wash their gowns. Can you please release that so we can get it posted? We post this all the time, but it is for some reason held up in OMB and we can’t get it out.” In response, Ms. Troye had to call OMB and request that the guidance be cleared.¹⁰⁸²

As the response progressed, the Trump Administration’s influence in CDC’s guidance expanded to the point where political officials within HHS altered public health guidance and reports.¹⁰⁸³ For example, in August 2020, the Trump Administration—without scientific justification—changed testing guidance to indicate asymptomatic individuals exposed to

¹⁰⁷⁸ Christos Makridis and Jonathan T. Rothwell, *Politics is wrecking America’s pandemic response* (Sept. 17, 2020) (<https://web.archive.org/web/20201101193457/https://www.brookings.edu/blog/up-front/2020/09/17/politics-is-wrecking-americas-pandemic-response/>); Christos Makridis and Jonathan T. Rothwell, *The Real Cost of Political Polarization: Evidence from the COVID-19 Pandemic* (June 29, 2020) (https://web.archive.org/web/20201103190939/https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3638373).

¹⁰⁷⁹ Brookings Institution, *American individualism is an obstacle to wider mask wearing in the US* (Aug. 31, 2020) (<https://www.brookings.edu/blog/up-front/2020/08/31/american-individualism-is-an-obstacle-to-wider-mask-wearing-in-the-us/>).

¹⁰⁸⁰ Interview with Olivia Troye (Dec. 8, 2021).

¹⁰⁸¹ *Id.*

¹⁰⁸² *Id.*

¹⁰⁸³ Interview with Dr. Deborah Birx (Jan. 6, 2022); *see also* House Select Subcommittee on the Coronavirus, *It was Compromised: The Trump Administration’s Unprecedented Campaign to Control CDC and Politicize Public Health During the Coronavirus Crisis Staff Report* (Oct. 2022).

COVID-19 did not need a test.¹⁰⁸⁴ Officials have since reported various occasions of political appointees having interfered with CDC’s Morbidity and Mortality Weekly Reports (MMWRs) and guidance documents.¹⁰⁸⁵ According to former CDC Chief of Staff, Kyle McGowan “[e]very time that the science clashed with the messaging, messaging won.”¹⁰⁸⁶

Threats Against Public Health Officials

Public health and other federal officials often received threats because of their public statements. Dr. Birx told the Committee she received death threats from both the “right and the left” political perspectives.¹⁰⁸⁷ Her colleagues also received ongoing death threats and, in some cases, received security protection from the federal government.¹⁰⁸⁸ Based on Dr. Birx’s regular interactions with state and local governments, she stated, “it was worse for the public health officials on the ground who were out on TV carrying the message—their homes would be identified and picketed.” Then CDC Director Dr. Redfield also received threats following his public statements.¹⁰⁸⁹ In August 2022, an individual was sentenced to 37 months in federal prison after pleading guilty to making threats against public health officials. In one instance, the individual sent an email to Dr. Fauci threatening to “harm and/or kill Dr. Fauci and members of his family.”¹⁰⁹⁰

Throughout the initial response, the Majority Committee staff found federal communications failed to adhere to the principle tenets of crisis communication. CDC failed to act swiftly throughout January and February to issue clear guidance and the White House’s requirement to clear all guidance resulted in delays. Communication from the White House at times contradicted statements from public health officials and statements from public health officials at times contradicted prior statements from other public health officials, without

¹⁰⁸⁴ *Top U.S. Officials Told C.D.C. to Soften Coronavirus Testing Guidelines*, New York Times (Aug. 26, 2020) (<https://www.nytimes.com/2020/08/26/us/politics/coronavirus-testing-trump-cdc.html>); Centers for Disease Control and Prevention, *Overview of Testing for SARS-CoV-2 (COVID-19)* (Aug. 24, 2020) (<https://web.archive.org/web/20200827033855/https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html>) (stating “[i]f you do have been in close contact (within 6 feet) of a person with a COVID-19 infection for at least 15 minutes but do not have symptoms: [y]ou do not necessarily need a test unless you are a vulnerable individual or your health care provider or State or local public health officials recommend you take one.”)

¹⁰⁸⁵ *Like a Hand Grasping: Trump Appointees Describe the Crushing of the C.D.C.*, New York Times (Dec. 16, 2020) (<https://www.nytimes.com/2020/12/16/us/politics/cdc-trump.html>); House Select Subcommittee on the Coronavirus, *It was Compromised: The Trump Administration’s Unprecedented Campaign to Control CDC and Politicize Public Health During the Coronavirus Crisis Staff Report* (Oct. 2022).

¹⁰⁸⁶ *Like a Hand Grasping: Trump Appointees Describe the Crushing of the C.D.C.*, New York Times (Dec. 16, 2020) (<https://www.nytimes.com/2020/12/16/us/politics/cdc-trump.html>).

¹⁰⁸⁷ Interview with Dr. Deborah Birx (Jan. 6, 2022).

¹⁰⁸⁸ *Id.*

¹⁰⁸⁹ Interview with Dr. Robert Redfield (Feb. 7, 2022).

¹⁰⁹⁰ Department of Justice, U.S. Attorney’s Office, District of Maryland, *Man Who Made Threats Against Dr. Anthony Fauci and Other Federal Officials Sentenced to Over Three Years in Federal Prison* (Aug. 4, 2022) (<https://www.justice.gov/usao-md/pr/man-who-made-threats-against-dr-anthony-fauci-and-other-federal-officials-sentenced-over>).

sufficient explanation. As a result, the public too often received inaccurate and contradictory communication from the federal government. This ultimately contributed to confusion and a loss of public trust. Dr. Birx told the Committee, “there was daylight between science and what [President] Trump was saying, but we were allowed to take actions that were opposite from what the President was saying.”¹⁰⁹¹ However, Dr. Birx cautioned, “once you lose public trust, people don’t know what to do...the public does not understand when experts can’t come to a consensus and give one clear message.”¹⁰⁹² Dr. Mecher told the Committee, “going forward, risk communication should be treated differently than political communication.”¹⁰⁹³

VIII. Medical Supply Chain Challenges

Throughout the initial pandemic response, longstanding vulnerabilities exacerbated the U.S. medical supply chain and resulted in multiple, ongoing shortages of critical medical products, including PPE and essential drugs. In January 2020—as COVID-19 spread around the world—the federal government issued its *Crimson Contagion After-Action Report*, detailing findings from the 2019 government-wide exercise that simulated a highly contagious influenza pandemic. Finding 6.1, titled *Scarcity*, stated:

The U.S. lacks the ability to produce or source some of the raw materials necessary to produce vaccine in sufficient quantities to respond to the domestic requirements of a severe influenza pandemic ... The U.S. also lacks domestic manufacturing capacity for the production of sufficient quantities of personal protective equipment, needles, and syringes. Domestic supplies of on-hand stock of antiviral medications, needles, syringes, N95 respirators, ventilators, and other ancillary medical supplies are limited and difficult to restock, because they are often manufactured overseas.¹⁰⁹⁴

This finding was not new information. In an interview with the Committee, Melissa Harvey, then Director of Health Systems at DHS, said, “I think supply chain shortages—masks in particular—was one of the first things that ran through my mind when we got the email [regarding an emerging infectious disease] on December 31—the reason is that in every exercise or crisis, such as *Crimson Contagion* . . . it was one of the biggest highlights.”¹⁰⁹⁵

As discussed in Part I, for the past two decades, increased offshoring and a concentrated overreliance on foreign sources for critical medical products has resulted in diminished domestic manufacturing capacity for critical drugs, medical supplies, and the key materials needed to

¹⁰⁹¹ Interview with Dr. Deborah Birx (Jan. 6, 2022).

¹⁰⁹² *Id.*

¹⁰⁹³ Interview with Dr. Carter Mecher (July 29, 2022).

¹⁰⁹⁴ Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, *Crimson Contagion 2019 Functional Exercise After-Action Report*, at 39 (Jan. 2020).

¹⁰⁹⁵ Interview with Melissa Harvey (Nov. 3, 2021).

make those products. The federal government also lacked—and continues to lack—sufficient visibility into in where critical medical products are manufactured and in what quantities.¹⁰⁹⁶

Federal officials interviewed by the Committee were well aware of these supply chain challenges. In an interview with the Committee, Dr. Laura Wolf, then Director of Critical Infrastructure Protection at ASPR, stated that since 2009, ASPR knew the U.S. relied predominately on overseas manufacturers for PPE and “there has been very little motivation [from the private sector] to change that dependence because of cost savings.”¹⁰⁹⁷ She explained, ASPR realized the importance of PPE, but “people treat[ed] PPE as a commodity . . . like they could always get more of it.”¹⁰⁹⁸ Dr. Rick Bright, then Director of BARDA, told the Committee, “we’ve known for many, many years that we would need 3.5 billion masks for an outbreak such as [COVID-19]” and that number just covers healthcare workers . . . [ASPR] should have known in early January that we only had a tiny fraction of [the masks needed] in the SNS.”¹⁰⁹⁹ According to Dr. Anne Schuchat, then Principal Deputy Director of CDC, “there was a recognition the [supply of PPE] was all overseas, mostly in China and the SNS did not have much. Assuring we had supply for healthcare workers and then the broader public was a problem.”¹¹⁰⁰

States also recognized PPE supply constraints. For example, the Illinois Department of Health told the Committee, “we had always been advised by ASPR and CDC to hold on to the expired medical material to be used in the case of a public health emergency in which FDA would have the authority to extend the expiry [date] on the material.”¹¹⁰¹

Despite longstanding supply chain vulnerabilities and numerous warnings about limited supply, the Administration failed to take timely and sufficient action to mitigate known PPE supply shortages either through entering into contracts for supplies, increasing domestic production, or utilizing executive authorities. Based on interviews conducted by the Committee, federal officials stated that a lack of funding was the central impediment to addressing PPE supply concerns.¹¹⁰² The Committee, however, received no documentation that ASPR made any official requests for additional funding prior to OMB’s supplemental request on February 24, 2020. As a result, hundreds of thousands of health care workers were unable to obtain needed

¹⁰⁹⁶ See Government Accountability Office, *COVID-19: Critical Vaccine Distribution, Supply Chain, Program Integrity, and Other Challenges Require Focused Federal Attention* (GAO-21-265) (Jan. 2021); U.S.-China Economic and Security Review Commission, 2019 Annual Report to Congress (Nov. 2019).

¹⁰⁹⁷ Interview with Dr. Laura Wolf (Nov. 30, 2021).

¹⁰⁹⁸ *Id.*

¹⁰⁹⁹ Interview with Dr. Rick Bright (Mar. 17, 2021 and Nov. 4, 2021).

¹¹⁰⁰ Interview with Dr. Anne Schuchat (Dec. 14, 2021).

¹¹⁰¹ Illinois Department of Health, Written Response to Senate Committee on Homeland Security and Governmental Affairs State Public Health Agency Questionnaire (Jan. 27, 2021).

¹¹⁰² See Steve Adams, Director of the Strategic National Stockpile (Jan. 2020 – present), Interview with Senate Committee on Homeland Security and Governmental Affairs (Feb. 2, 2022) (hereinafter “Interview with Steve Adams (Feb. 2, 2022)”); Interview with Greg Burel (Feb. 26, 2021); Interview with Dr. Robert Johnson (July 9, 2021); Interview with Dr. Robert Kadlec (Dec. 6, 2021).

protective gear, including respirators and masks, throughout the spring of 2020 as they risked their lives to care for a surge of COVID-19 patients. Similarly, frontline workers also failed to receive needed protective gear as they risked their own health to perform essential tasks.

A. January PPE Supply Warnings

Throughout January 2020, the federal government, including HHS, DHS, and the State Department, received multiple warnings of impending PPE shortages from a variety of sources, including media reports, domestic manufacturers, and other countries that began implementing export bans. Despite these warnings, as detailed below, the federal government did not execute any large-scale PPE contracts until March 21, 2020 with initial delivery dates starting in May 2020 and remaining deliveries stretching into 2022 due to supply shortages and logistics.¹¹⁰³

CDC began identifying reports of PPE shortages in China as early as January 8, 2020.¹¹⁰⁴ A January 9, 2020 CDC internal document highlighted media reports of anticipated N95 shortages: “Hong Kong Hospital Authority reiterated that there is a 3 month supply of PPE, such as surgical masks and N95 respirators.”¹¹⁰⁵ According to a January 14 CDC Incident Management Update, CDC contacted “supply chain partners” to “increase awareness” but noted, “limited reports from industry state[d] no concerns with availability of N95s.”¹¹⁰⁶ Public media reports, however, indicated otherwise and detailed PPE shortages in China increased throughout the month.¹¹⁰⁷

On January 20, 2020 Dr. Robert Johnson, Director of Influenza and Emerging Infectious Diseases at BARDA, wrote to his colleagues, “Is the ASPR (and hopefully through him) the S1 [HHS Secretary], aware of just how **BARDA’s hands are tied due to lack of [Emerging Infectious Disease] funding, and the precious time being lost?** Hopefully this issue is being

¹¹⁰³ HHS Correspondence to Senate Committee on Homeland Security and Governmental Affairs Staff (Mar. 9, 2022).

¹¹⁰⁴ Department of Health and Human Services, Center for Disease Control and Prevention, *2020 Pneumonia of Unknown Etiology Situational Report* (Jan. 8, 2020) (on file with Committee, HHS HSGAC – 42834-42836).

¹¹⁰⁵ Department of Health and Human Services, Center for Disease Control and Prevention, *2020 Pneumonia of Unknown Etiology Response Incident Management Update: NCIRD Center Level Response- Day 4* (Jan. 9, 2020) (on file with Committee, HHS HSGAC 39810).

¹¹⁰⁶ Department of Health and Human Services, Center for Disease Control and Prevention, *Novel Coronavirus (nCoV) 2019 Response IM Update: NCIRD Center Level Response- Day 8* (Jan. 14, 2020) (on file with Committee, HHS HSGAC – 39739-39763).

¹¹⁰⁷ *China’s mask makers cancel holidays, jack up wages as new virus spurs frenzied demand*, Reuters (Jan. 23, 2020) (www.reuters.com/article/us-china-health-masks/chinas-mask-makers-cancel-holidays-jack-up-wages-as-new-virus-spurs-frenzied-demand-idUSKBN1ZM18E); *A Chinese official warned of a shortage of protective masks and suits amid the Wuhan coronavirus outbreak*, Business Insider (Jan. 26, 2020) (www.businessinsider.com/chinese-official-protective-mask-and-suit-shortage-wuhan-coronavirus-2020-1); *China goes global in search for protective suits, masks and goggles as coronavirus infections begin to take off*, South China Morning Post (Jan. 31, 2020) (www.scmp.com/news/china/society/article/3048379/china-goes-global-search-protective-suits-masks-and-goggles).

worked on?”¹¹⁰⁸ In an interview with the Committee, Dr. Johnson explained that BARDA does not receive annual funding to support a pandemic response, but relies on supplemental funding, and as such did not have the funding to issue awards because no funding was available. As a result, “we were not able to do what needed to be done.”¹¹⁰⁹

In the U.S., domestic manufacturers contacted federal government officials directly to warn of PPE supply concerns.¹¹¹⁰ Dr. Bright told the Committee, “it was a lot of the smaller companies that were sounding the alarm.”¹¹¹¹ For example, from January 21-31, 2020, Mike Bowen, CEO of Prestige Ameritech, a domestic PPE manufacturer, repeatedly warned ASPR officials of anticipated PPE shortages. On January 21, Mr. Bowen emailed Dr. Bright, “Homeland Security just called me looking for masks for their airport screeners.”¹¹¹² Two days later, Mr. Bowen specifically offered to help the U.S. government in a “dire pandemic emergency” and noted that “[f]or the past 14 years, [he’d] been warning hospitals that their imported masks are subject to foreign confiscation during a severe pandemic.”¹¹¹³ Mr. Bowen, in the same email, also made clear that he was looking for other potential buyers: “as you can imagine, my phones are ringing now, so I don’t ‘need’ government business.”¹¹¹⁴ As discussed below, the SNS offered Mr. Bowen a PPE contract four months later, which he declined in favor of longer-term contracts.¹¹¹⁵

By the end of January, multiple countries began placing export bans on PPE. Table 11, below, lists some of the export restrictions imposed by other countries throughout January 2020.

¹¹⁰⁸ Dr. Rick Bright, *OSC Complaint Exhibit 4: Email from Dr. Robert Johnson to Dr. Rick Bright* (Jan. 20, 2020) (on file with Committee) (emphasis in original).

¹¹⁰⁹ Interview with Dr. Robert Johnson (July 9, 2021).

¹¹¹⁰ Interview with Dr. Rick Bright (Mar. 17, 2021 and Nov. 4, 2021); Dr. Rick Bright, *OSC Complaint Exhibit 7: Emails between Dr. Rick Bright, ASPR officials, and Mike Bowen*, (Jan. 21-23, 2020) (on file with Committee).

¹¹¹¹ Interview with Dr. Rick Bright (Mar. 17, 2021 and Nov. 4, 2021).

¹¹¹² Dr. Rick Bright, *OSC Complaint Exhibit 6: Email from Mike Bowen to Dr. Rick Bright* (Jan. 21, 2020) (on file with Committee).

¹¹¹³ Dr. Rick Bright, *OSC Complaint Exhibit 7: Email from Mike Bowen to Dr. Rick Bright* (Jan. 23, 2020) (on file with Committee).

¹¹¹⁴ *Id.*

¹¹¹⁵ Department of Health and Human Services, *Email from Mike Bowen to CDC official* (May 7, 2020) (on file with Committee, HHS HSGAC 42896-42897).

Table 11. Selected Export Restrictions Imposed in January 2020¹¹¹⁶

Country	Implementation Date	Reporting Date	Product ¹¹¹⁷
Taiwan ¹¹¹⁸	Jan. 24, 2020	Jan. 23, 2020	“surgical face mask and the filter material required for their manufacture”
China ¹¹¹⁹	on or before January 31, 2020	Not known	medical masks
Russia ¹¹²⁰	on or before January 31, 2020	Mar. 7, 2020	medical masks
Kazakhstan ¹¹²¹	on or before January 31, 2020	Not known	medical masks
Pakistan ¹¹²²	January 30, 2020	March 23, 2020	“articles for Corona virus [<i>sic</i>] prevention” including, N95s, masks, and hand sanitizer
Kyrgyz Republic ¹¹²³	January 31, 2020	March 25, 2020	medical masks
India ¹¹²⁴	January 31, 2020	February 14, 2020	“ban on the export” of PPE “including clothing and masks with immediate effect”

¹¹¹⁶ Committee Analysis of export bans based on information obtained from the State Department and publicly available resources. See Department of State, *Export Restrictions Tracker Mar 27 PM* (Mar. 2020) (on file with Committee, STATE – PPE export data at STATE-2021-02-1340).

¹¹¹⁷ Unless otherwise noted, product names and descriptions are listed as they initially appeared in the State Department’s March 2020 chart detailing PPE export bans. Department of State, *Export Restrictions Tracker Mar 27 PM* (Mar. 27, 2020) (on file with Committee, STATE – PPE export data at STATE-2021-02-0001340).

¹¹¹⁸ *Taiwan bans export of surgical, N95 masks amid China coronavirus outbreak* (Jan. 24, 2020) (www.taiwannews.com.tw/en/news/3863692); *Chinese Taipei: Export ban on surgical face masks and filter material* (Jan 24, 2020) (www.globaltradealert.org/intervention/78866/export-ban/chinese-taipei-export-ban-on-surgical-face-masks-and-filter-material).

¹¹¹⁹ Department of State, *Export Restrictions Tracker Mar 27 PM* (Mar. 2020) (on file with Committee, STATE – PPE export data at STATE-2021-02-0001352) (noting China imposed an export restriction on “medical masks” prior to January 31, 2020). See also Department of Health and Human Services, *2019 nCoV Supply Chain Task Force – Storyboard*, (Jan. 29, 2020) (on file with Committee, HHS HSGAC – 42781) (noting on January 29, 2020 HHS-ASPR reported “China is expected to implement a [] ban on PPE (gloves and masks).”

¹¹²⁰ Department of State, *Export Restrictions Tracker Mar 27 PM* (Mar. 2020) (on file with Committee, STATE – PPE export data at STATE-2021-02-0001352) (noting Russia imposed an export restriction on “medical masks” prior to January 31, 2020).

¹¹²¹ Department of State, *Export Restrictions Tracker Mar 27 PM* (Mar. 2020) (on file with Committee, STATE – PPE export data at STATE-2021-02-0001352) (noting Kazakhstan imposed an export restriction on “medical masks” prior to January 31, 2020).

¹¹²² Department of State, *Mission China Coronavirus Update* (Feb. 12, 2020) (on file with Committee, STATE-2021-02-0001347-48) (reporting “[t]his ban is being broadly interpreted according to contacts but has thus far blocked shipment of chloroquine and “masks” that Post is aware of”).

¹¹²³ Department of State, *Export Restrictions Tracker Mar 27 PM* (Mar. 2020) (on file with Committee, STATE – PPE export data at STATE-2021-02-0001351; see also STATE-2021-02-0001352) (“On January 31, in response to export restrictions on medical masks imposed in Russia, China, and Kazakhstan, the GOKR instituted a ban on export of all types of medical masks . . . On March 23, the government placed a temporary export ban on all disinfectants and antibacterials.”)

On January 31, 2020—the same day HHS Secretary Azar declared COVID-19 a public health emergency—Mr. Bowen told multiple senior ASPR officials that his company “sent 1,000,000 masks to China and Hong Kong.”¹¹²⁵ Mr. Bowen predicted, “China will cut off masks to the USA [and if] so, US hospitals are going to have a very rough time, as up to half of the supply is made in China. A horrible situation will become unbearable.”¹¹²⁶ By the end of January, mask shortages had already spread throughout China and expanded to Europe.¹¹²⁷ Subsequent reports (detailed below) indicated that by early February, China nationalized control of the manufacture and distribution of critical medical supplies.¹¹²⁸

B. Failure to Mitigate Known Supply Chain Concerns

As detailed throughout this section, the Majority Committee staff found that insufficient funding, limited supply chain visibility, and lacking engagement with industry, among other challenges, all contributed to the federal government’s failure to effectively mitigate supply chain concerns.

Insufficient Funding

In interviews with the Committee, ASPR officials said that a longstanding lack of funding hampered procurement options during this time period.¹¹²⁹ Dr. Kadlec, then ASPR told the Committee, “we didn’t have the money” to enter into any PPE contracts prior to March 5, 2020.¹¹³⁰ SNS Director Steve Adams also told the Committee, “the issue in January was that there was no money to make purchases. We didn’t have the funding to go out and buy a bazillion N95s.”¹¹³¹ Jason Stear, Lead Public Health Analyst for Policy and Issues Management at ASPR, explained that the SNS was “in constant contact with commercial partners, signaling their intent [to purchase supplies]—to the extent we could—without having any cash.”¹¹³² Mr. Stear stated, “SNS does not have any contracting officers or authorities” so they have to defer to

¹¹²⁴ On February 8, 2020 India partially lifted the ban to allow the export of surgical masks and certain gloves (excluding nitrile rubber). Department of State, *Export Restrictions Tracker Mar 27 PM* (Mar. 27, 2020) (on file with Committee, STATE – 1343-1344).

¹¹²⁵ Dr. Rick Bright, *OSC Complaint Exhibit 17: Email from Dr. Laura Wolf to Dr. Rick Bright* (Jan. 31, 2020) (on file with Committee).

¹¹²⁶ *Id.*

¹¹²⁷ *Face mask shortage hits Europe and US as coronavirus spreads*, Financial Times (Jan. 30, 2020) (www.ft.com/content/ea0b15e2-436f-11ea-a43a-c4b328d9061c).

¹¹²⁸ Congressional Research Service, *COVID-19: China Medical Supply Chains and Broader Trade Issues* (R46304) (Dec. 23, 2020).

¹¹²⁹ Interview with Steve Adams (Feb. 2, 2022); Interview with Dr. Robert Johnson (July 9, 2021); Interview with Dr. Robert Kadlec (Dec. 6, 2021). In 2018, authority over the SNS moved from CDC to ASPR. See Department of Health and Human Services REMM, *Strategic National Stockpile* (<https://remm.hhs.gov/sns.htm>) (accessed Dec. 1, 2022).

¹¹³⁰ Interview with Dr. Robert Kadlec (Dec. 6, 2021).

¹¹³¹ Interview with Steve Adams (Feb. 2, 2022).

¹¹³² ASPR Briefing (May 6, 2021).

ASPR's contracting staff on questions for emergency acquisition authorities.¹¹³³ Furthermore, SNS Director Adams noted that ASPR also does not have transfer authority to request that another agency enter into a procurement contract.¹¹³⁴ He explained that while ASPR can enter into an interagency agreement for another agency to purchase supplies, ASPR would first need to provide funding in advance, which they did not have.¹¹³⁵

Limited Supply Chain Visibility

The Majority Committee staff found a lack of visibility into where critical medical products are manufactured and in what quantities also created challenges. At the time, federal law did not require medical device manufacturers (e.g. suppliers of N95 respirators, masks, gowns, and gloves) to report potential supply chain interruptions to FDA. As a result, FDA's Center for Devices and Radiological Health (CDRH), which oversees medical supplies distributed throughout the U.S., relied on manufacturers to voluntarily report critical supply chain information.¹¹³⁶ FDA's CDRH told the Committee that prior to January 2020, there was a shortage of gowns, noting, "shortages for gowns earlier in the pandemic were worse than they otherwise needed to be . . . put[ting] health care providers and patients at unnecessary risk."¹¹³⁷ Throughout January 2020, CDRH "reached out to over 1,000 manufacturers to prepare for potential supply chain interruptions and shortages," and in late January, CDRH sent extensive questionnaires to PPE manufacturers to prepare for potential supply shortages related to COVID-19.¹¹³⁸

FDA's Center for Drug Evaluation and Research (CDER), which oversees pharmaceuticals distributed throughout the U.S., first reached out to its pharmaceutical industry contacts by email on January 24, 2020.¹¹³⁹ FDA's CDER recorded responses through an Excel spreadsheet, which later shifted to an emergency portal to better track responses. Captain Valerie Jensen, Associate Director of FDA's Drug Shortage Staff, told the Committee, "we reached out to finished dosage [pharmaceutical] producers and asked them to look at their supply

¹¹³³ *Id.*

¹¹³⁴ Interview with Steve Adams (Feb. 2, 2022).

¹¹³⁵ *Id.*

¹¹³⁶ See Department of Health and Human Services, Food and Drug Administration, *CDRH's outreach email to companies and summary of responses* (received Mar. 8, 2022) (on file with Committee). The passage of the CARES Act on March 27, 2020, required medical device manufacturers to report potential supply chain disruptions to the FDA during public health emergencies. See Coronavirus Aid, Relief, and Economic Security Act of 2020, Pub. L. No. 116-136, Sec. 506J(a); U.S. Food and Drug Administration, *Medical Device Supply Chain Notifications During the COVID-10 Pandemic* (www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/medical-device-supply-chain-notifications-during-covid-19-pandemic) (accessed December 2, 2022).

¹¹³⁷ Food and Drug Administration, Correspondence to Senate Committee on Homeland Security and Governmental Affairs Staff (Aug. 12, 2022).

¹¹³⁸ *Id.*; see also Food and Drug Administration, Center for Devices and Radiological Health, *Information about Personal Protective Equipment* (March 8, 2022) (on file with Committee).

¹¹³⁹ Food and Drug Administration, Briefing with Senate Committee on Homeland Security and Governmental Affairs Staff (Nov. 22, 2021) (hereinafter "FDA Briefing (Nov. 22, 2021)").

chain and whether they were able to obtain APIs [Active Pharmaceutical Ingredients].”¹¹⁴⁰ Because FDA also lacks sufficient visibility into where critical inputs, such as key starting materials and APIs, which give a drug its intended effect, are manufactured, the agency had to rely on manufacturers to provide this information voluntarily.¹¹⁴¹ According to FDA, officials worked with manufacturers who expressed supply chain concerns and remained in contact throughout the pandemic.

ASPR, which houses the SNS, also lacked (and continues to lack) sufficient visibility into critical medical supply chain information. For example, Jessica Falcon, Director of Security, Intelligence, and Information Management at ASPR, told the Committee that her team did not have insight into the availability of medical supplies “unless we called and asked the manufacturer and they were willing to share [that information].”¹¹⁴² Dr. Wolf explained that private sector companies contacted by ASPR were hesitant to share manufacturing and distribution information.¹¹⁴³ SNS officials also had a limited view into the medical supply chain—from raw material sources and manufacturers to distributors and providers—making it difficult to understand the true supply needs of the medical industry.¹¹⁴⁴ According to ASPR, hospitals were often only able get their regular amounts of supplies from distributors, so they went to other suppliers to place larger orders, which caused inflated order numbers and complicated SNS’s ability to gauge industry supply and demand.¹¹⁴⁵

In April 2020, HHS reported, “[o]ur COVID response also revealed a vulnerable dependence on foreign sources of supply,” with surgical masks, gowns, and gloves all relying on foreign sources for at least 80 percent of production. The source for this information cited Global Healthcare Exchange, LLC information and “interviews provided by several PPE distributors and manufacturers.”¹¹⁴⁶

¹¹⁴⁰ *Id.*

¹¹⁴¹ Food and Drug Administration, *Report to Congress: Drug Shortages for Calendar Year 2020* (2020); National Academies of Sciences, Engineering, and Medicine, *Building Resilience into the Nation’s Medical Product Supply Chains*, National Academies Press (2022).

¹¹⁴² Interview with Jessica Falcon (July 22, 2021).

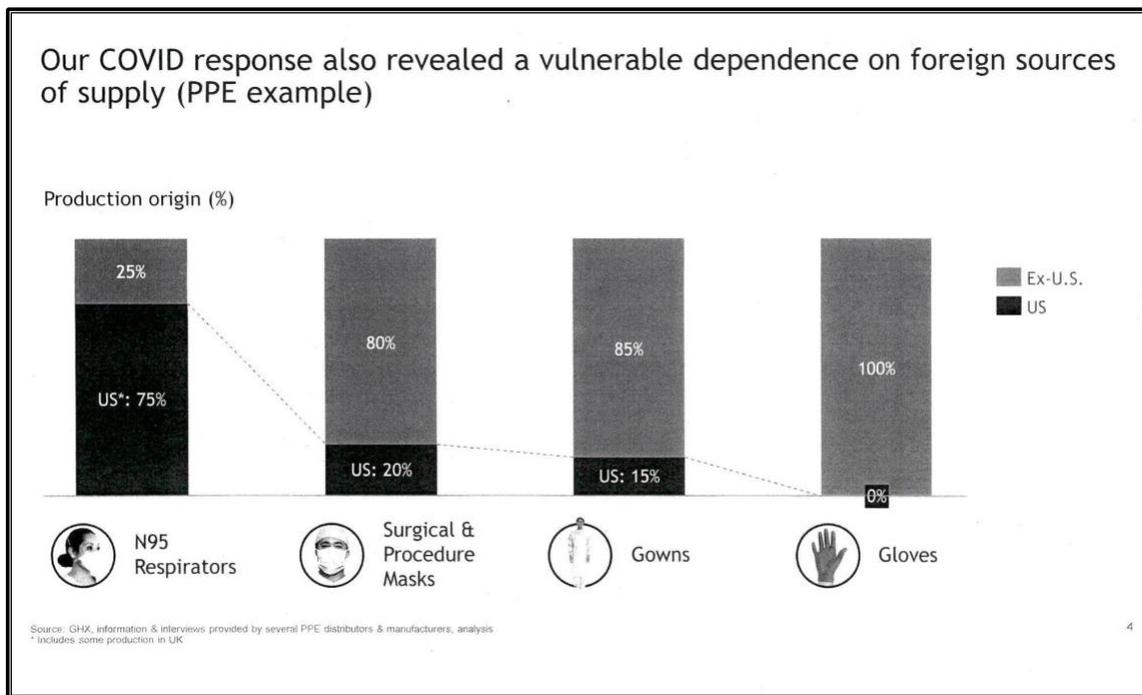
¹¹⁴³ Interview with Dr. Laura Wolf (Nov. 30, 2021)

¹¹⁴⁴ ASPR Briefing (May 6, 2020).

¹¹⁴⁵ *Id.*

¹¹⁴⁶ National Archives and Records Administration, *Department of Health and Human Services, Assistant Secretary for Preparedness and Response, HHS SNS Distribution to States and Helpful Guidance Update* (Mar. 11, 2020) (on file with Committee, NARA P011373).

*Excerpt from April 29, 2020 HHS-SNS Presentation:
PPE Reliance on Foreign Sources¹¹⁴⁷*



Insufficient Engagement with Industry

Based on the Majority Committee staff’s review of relevant documents and interviews, the federal government failed to sufficiently engage and coordinate with private industry. The Committee also found differing views on the early supply situation. As discussed throughout this section, HHS’s efforts to mitigate supply chain challenges, which largely consisted of surveying companies instead of increasing domestic manufacturing capacity, fell far short from what was needed.

There appeared to be a disconnect between the federal government and industry regarding the initial assessment of medical supply needs. According to ASPR’s January 29, 2020 internal supply chain assessment, “major companies such as Honeywell and 3M [reported] increased global face mask demand,” but “based on industry feedback, current domestic inventories [were] sufficient” and the “concern for potential disruption over the next few weeks [was] based on panic and stockpiling and export banning.”¹¹⁴⁸ However, in a July 2021 interview with Committee staff, Jeffrey Jochims, Chief Operating Officer for Owens & Minor, a

¹¹⁴⁷ *Id.*

¹¹⁴⁸ Department of Health and Human Services, Assistant Secretary for Preparedness and Response, *2019 nCoV Supply Chain Task Force- Storyboard* (Jan. 29, 2020) (on file with Committee, HHS HSGAC 42781). The assessment also identified raw materials, such as plastics and polymers, needed to make masks, as a concern due to China dominance on the production for these products. See *id.*

major health care supply distributor, stated that he “saw the beginning stages of a problem in the U.S. in mid-January 2020.”¹¹⁴⁹ He explained, “for many of us this is our fourth pandemic situation . . . [and] by mid-January [Owens & Minor] had shutdown visitation to its distribution centers. We began trying to bring product in extra inventory in advance of the COVID response.” It took until mid-March 2020 before the company had their first contact with the federal government and was invited to join the Administration’s COVID-19 Task Force.¹¹⁵⁰

On January 23, 2020, ASPR convened its first Disaster Leadership Group meeting.¹¹⁵¹ The Disaster Leadership Group is a “HHS senior leader policy committee” run by the ASPR to discuss “policy issues of national significance that impact health security.”¹¹⁵² The purpose of the meeting was to discuss the evolving coronavirus threat and “align USG preparedness and response activities.”¹¹⁵³ As shown below, while the Disaster Leadership Group’s agenda referenced lessons learned from the Crimson Contagion After-Action report, none of the action items from the January 23 meeting identified the need to address impending shortages of critical medical supplies, including PPE.¹¹⁵⁴

¹¹⁴⁹ Jeffrey Jochims, Chief Operating Officer, Owens and Minor (Nov. 2019 – present), Interview with Senate Committee on Homeland Security and Governmental Affairs (July 12, 2021) (hereinafter “Interview with Jeffrey Jochims (July 12, 2021)”).

¹¹⁵⁰ *Id.* Press Conference with President Trump, Vice President Pence, and Members of the Coronavirus Task Force, at 4 (Mar. 30, 2020) (<https://trumpwhitehouse.archives.gov/briefings-statements/remarks-president-trump-vice-president-pence-members-coronavirus-task-force-press-briefing-14/>).

¹¹⁵¹ Department of Health and Human Services, *2020 Novel Coronavirus Disaster Leadership Group Meeting Summary of Issues and Recommendations* (Jan. 23, 2020) (on file with Committee, HHS HSGAC 37510).

¹¹⁵² Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Policy Division: HHS/ASPR/ICC Office of Strategy, Policy, Planning, and Requirements (<https://www.phe.gov/about/offices/program/icc/sppr/Pages/division-of-policy.aspx>) (accessed Nov. 15, 2022).

¹¹⁵³ Department of Health and Human Services, *2020 Novel Coronavirus Disaster Leadership Group Meeting Summary of Issues and Recommendations* (Jan. 23, 2020) (on file with Committee, HSGAC 37510).

¹¹⁵⁴ *Id.*

*Excerpt from January 23, 2020 DLG Meeting Agenda*¹¹⁵⁵

Next Steps:

- CDC to provide clinically relevant information to the appropriate agencies, including HRSA and IHS.
- ASPR and OGA are coordinating to gain access to key viral samples.
- The ASPR will convene ESF-8 colleagues to review the current pandemic influenza plan for potential applicability to the current situation. Additionally, all OPDIVS/STAFFDIVS were requested to similarly review their pandemic influenza plans.
- ASPR and FEMA are evaluating their incident management structures/plans as they are related to the national incident management structure/plan. From lessons learned during Crimson Contagion, the traditional incident command structure may need to be adapted to deal with an emerging infectious disease outbreak, epidemic, or pandemic.
- A follow-up DLG will be scheduled as appropriate, likely either at the beginning or middle of next week.

On January 26, 2020, Dr. Bright again alerted his ASPR colleagues, including then ASPR Dr. Kadlec, Principal Deputy ASPR Dr. Kevin Yeskey, SNS Director Steve Adams, and Critical Infrastructure Protection (CIP) Division Director Dr. Laura Wolf, among others, and wrote, “we have been watching and receiving warnings on this [referring to PPE shortages] for over a week. Something [Critical Infrastructure Protection] and SNS May [sic] want to consider an action plan.”¹¹⁵⁶

On January 29, 2020, SNS sent out a survey it had developed in 2019 to five distributors titled, Analysis of Incident and Logistics Summary (AILS).¹¹⁵⁷ The survey asked seven questions, as shown below. SNS did not send the survey to any manufacturers.¹¹⁵⁸ Nor did SNS ask whether any distributors received product that originated from Asia or which industries (e.g.

¹¹⁵⁵ *Id.*

¹¹⁵⁶ Dr. Rick Bright, *OSC Complaint, Exhibit 12: Email from Dr. Rick Bright, to Dr. Laura Wolf, Jessica Falcon, Dr. Kevin Yeskey, Dr. Robert Kadlec, Dr. Robert Johnson, Steven Adams, et al* (Jan. 26, 2020).

¹¹⁵⁷ Strategic National Stockpile, *SNS CSCAT: Analysis of Incident and Logistics Summary (AILS)* (Jan. 29, 2020) (on file with Committee, HHS HSGAC 36183–36186). Assistant Secretary for Preparedness and Response, Briefing with Senate Committee on Homeland Security and Governmental Affairs Staff (Dec. 9, 2020) (hereinafter “ASPR Briefing (Dec. 9, 2021)”). In the briefing, SNS officials said that the Healthcare Industry Distributors Association selected the distributors who received the questionnaire.

¹¹⁵⁸ *Id.*

nursing homes, hospitals, etc.) and geographic locations were purchasing the most product.¹¹⁵⁹ Four out of the five distributors reported N95 respirators and medical grade masks were among their top ten in demand items.¹¹⁶⁰

*SNS’s Analysis of Incident and Logistics Summary Survey Questions to Distributors*¹¹⁶¹

10. Describe your capacity and or availability for the high demand medical items listed in the AILs. If possible, provide any information about the high demand products you may have. Do you have inventory that could be shifted to the affected area? Have you observed any demands on these items in your operations? What steps might you taking to mitigate a disruption for these items?
11. Have you experienced an increased demand for items not the AILs list? Provide a brief overview of identified item(s).
12. Please identify your top 10 requested items from your customers. Please identify your current top 10 highest ordered items from your supply chain.
13. Have you increased production as a result of the incident? Summarize Item(s) timelines and volumes.
14. Do you conduct operations to or inside the effected area in Asia? Provide details of manufacturing, and or distribution facilities inside effected area
15. Are there any current or projected barriers for your operations that may be impacting your supply chain? Examples may include; manpower (employee absences), transportation, shipping, port congestion, regulatory.
16. Additional comments or questions that you feel would be beneficial to the SNS or that may require our assistance. Please include any additional information that you feel would benefit responses operations.

Days later, another task force embedded within CDC conducted another survey asking Public Health Emergency Preparedness (PHEP) directors “for estimates of PPE stockpiled by local health departments.”¹¹⁶² Dr. Bright told the Committee that the private sector expressed much frustration by the federal government’s repeated “surveys rather than a contract.”¹¹⁶³ According to then ASPR Dr. Kadlec, he directed his staff in January to “build a budget they would need to buy the stuff that we would anticipate [would be in shortage].”¹¹⁶⁴ However, as discussed in Section IV (Funding), it took weeks for the Administration to request supplemental funding.

C. Strategic National Stockpile Supply Shortages

The SNS contained only a small portion of the PPE needed for the initial pandemic response. As shown below, as of January 1, 2020, the SNS contained approximately 12.5 million N95 respirators, many of which turned out to be expired and unusable, in comparison to

¹¹⁵⁹ Strategic National Stockpile, *SNS CSCAT: Analysis of Incident and Logistics Summary (AILs)* (Jan. 29, 2020) (on file with Committee, HHS HSGAC 36183–36186).

¹¹⁶⁰ *Id.*

¹¹⁶¹ *Id.*

¹¹⁶² Department of Health and Human Services, Centers for Disease Control and Prevention, *2019 Novel Coronavirus (nCoV) IM Update: Response Day 28*, State Coordination Task Force at 61 (Feb. 3, 2020) (on file with Committee, HHS HSGAC 38902-38982).

¹¹⁶³ Interview with Dr. Rick Bright (Mar. 17, 2021 and Nov. 4, 2021).

¹¹⁶⁴ Interview with Dr. Robert Kadlec (Dec. 6, 2021).

an estimated 350 million needed respirators per month.¹¹⁶⁵ The SNS also did not contain testing supplies, such as nasal swabs, transport media, and pipette tips.¹¹⁶⁶

The Majority Committee staff found that critical information on SNS stockpiling numbers, such as the type and amount of supplies stockpiled in the SNS, was not available to all senior ASPR officials, even if this information was relevant to their official work.¹¹⁶⁷ For example, Dr. Laura Wolf, ASPR’s Director of Critical Infrastructure Protection, told the Committee, while she did not have access to the SNS stockpile numbers or supplies, she “made the assumption that the stockpile did not have the needed 350 million N95s per month.”¹¹⁶⁸ As discussed in Part I, SNS funding and stockpiling has long failed to meet public health needs.

Strategic National Stockpile PPE Inventory from January 1, 2020 – May 1, 2020¹¹⁶⁹

	SNS Inventory*				
	Total Deployable Inventory				
Item Description	1/1/2020	2/1/2020	3/1/2020	4/1/2020	5/1/2020
N95 Respirators	12,596,480	12,596,480	12,596,480	737,185	78,315
Facemasks/Surgical Masks	30,790,850	30,790,850	30,790,850	1,498,800	1,053,450
Face Shields	5,830,136	5,830,136	5,830,136	259,292	90,220
Surgical Gowns/Coveralls	4,773,438	4,773,438	4,773,438	195,546	37,896
Gloves all types	30,161,495	30,161,495	30,161,495	1,994,520	997,825
Ventilators	16,660	16,660	16,660	9,374	10,932

*All data is in eases. Adjustments were made to inventory reporting starting in 1/1/2020 to better reflect SNS response capacity. As a result, 2020 inventory data only lists deployable product. Ventilators in maintenance and PPE unavailable for deployment are not included in 2020 data. Additionally data discrepancies that led to incorrect reporting early in the COVID-19 response have been corrected for 2020 - 2022 reporting.

On January 30, 2020, ASPR began deploying available items known as National Disaster Medical System caches from the SNS to support repatriation efforts.¹¹⁷⁰ At the start of the COVID-19 pandemic, the SNS had less than one-month’s reserve of key items, including N95

¹¹⁶⁵ HHS Correspondence to Senate Committee on Homeland Security and Governmental Affairs Staff (Feb. 10, 2022); Cristina Carias, et al., *Potential Demand for Respirators and Surgical Masks during a Hypothetical Influenza Pandemic in the United States*, Clinical Infectious Diseases (Apr. 10, 2015).

¹¹⁶⁶ Government Accountability Office, *Public Health Preparedness: HHS Should Address Strategic National Stockpile Requirements and Inventory Risks*, at 38 (GAO 23-106210) (Oct. 2022).

¹¹⁶⁷ Interview with Dr. Laura Wolf (Nov. 30, 2021).

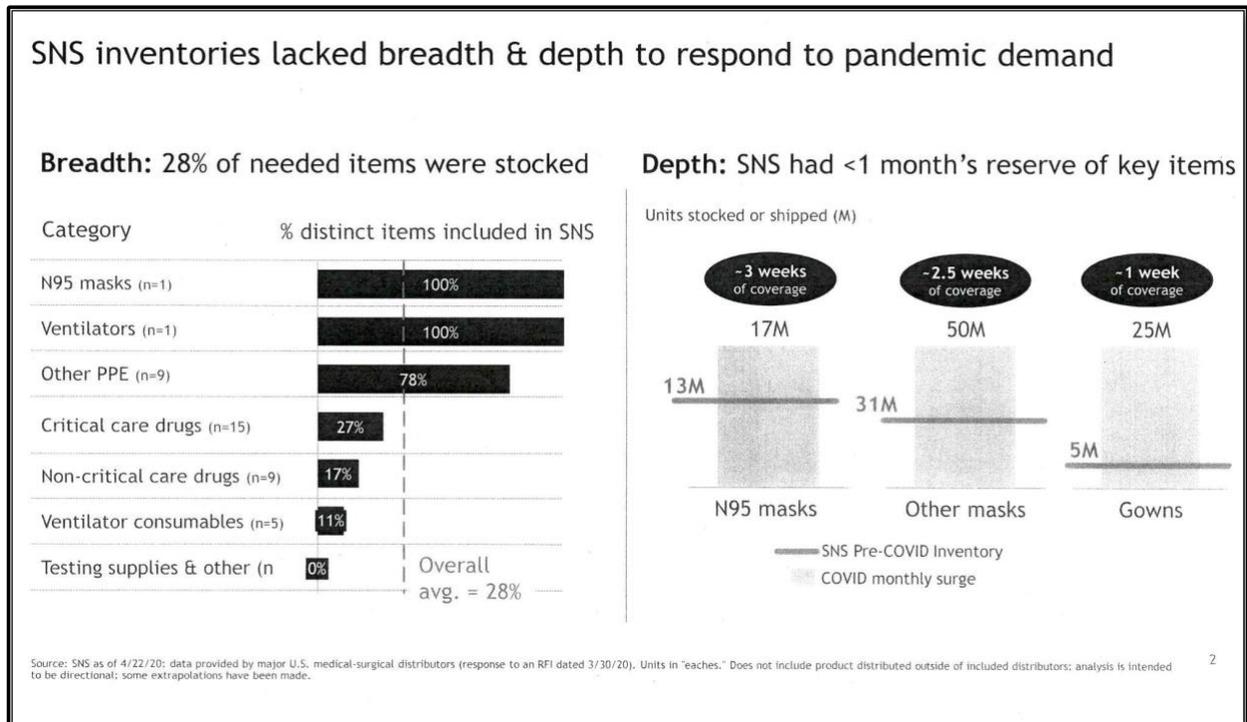
¹¹⁶⁸ *Id.*

¹¹⁶⁹ HHS Correspondence to Senate Committee on Homeland Security and Governmental Affairs Staff (Feb. 10, 2022).

¹¹⁷⁰ HHS Correspondence to Senate Committee on Homeland Security and Governmental Affairs Staff (Dec. 11, 2021). NDMS caches deployed from January 30 to March 15, 2020 included 15 DMATs, 19 Basic Load Resupply Kits, 146 Mobile Life Savings Kits and (MLK), among other items. See *id.*

respirators and gowns.¹¹⁷¹ An HHS report assessed only 28 percent of “needed items” for “an effective COVID-19 medical response” were stocked in the SNS.¹¹⁷²

Excerpt from April 29, 2020 HHS-SNS Presentation: SNS Supplies¹¹⁷³



A February 5, 2020 internal CDC update acknowledged the large gap between PPE market supply and pandemic response needs.¹¹⁷⁴ As shown below, CDC also found—something that was known to most senior ASPR officials before the onset of the pandemic—that the SNS did not have a sufficient amount of N95s and a portion of SNS’s N95 respirators had “exceeded their manufacturer-designated shelf life.”¹¹⁷⁵ ASPR officials told the Committee that many of

¹¹⁷¹ National Archives and Records Administration, *Department of Health and Human Services, Restructuring our Strategic National Stockpile: A Strategy to Enhance Preparedness and Response (SNS), SNS inventories lacked breadth & depth to respond to pandemic demand*, at 61 (Apr. 29, 2020) (on file with Committee, NARA P011311-11379).

¹¹⁷² *Id.* at P011371.

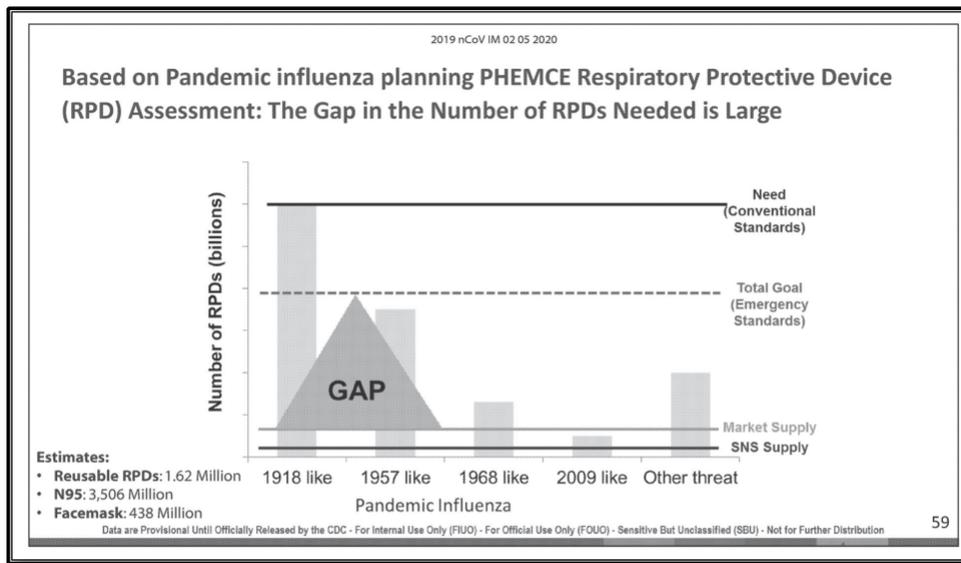
¹¹⁷³ *Id.*

¹¹⁷⁴ Department of Health and Human Services, Centers for Disease Control and Prevention, *2019 Novel Coronavirus (nCoV) IM Update: Response Day 28*, at 59-61 (Feb. 5, 2020) (on file with Committee, HHS HSGAC 38986-39073).

¹¹⁷⁵ *Id.* at 60. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, *Crimson Contagion 2019 Functional Exercise After-Action Report* (Jan. 2020).

the masks in the SNS were more than ten years old.¹¹⁷⁶ According to then BARDA Director, Dr. Bright, “masks in the SNS were purchased during the 2009 H1N1 influenza pandemic and were not replenished. When evaluated [in 2020], some were in smashed boxes, some found in abandoned corners of supply rooms, and many with rotted elastic bands . . . long past their shelf life.”¹¹⁷⁷

Excerpts from CDC’s February 5 Incident Management Update¹¹⁷⁸



¹¹⁷⁶ Interview with Steve Adams (Feb. 2, 2022); Interview with Dr. Rick Bright (Mar. 17, 2021 and Nov. 4, 2021).

¹¹⁷⁷ Dr. Rick Bright, Correspondence to Senate Committee on Homeland Security and Governmental Affairs Staff (Sept. 1, 2022) (noting “some of these compromised products were still shipped out to the field for healthcare workers”).

¹¹⁷⁸ Department of Health and Human Services, Centers for Disease Control and Prevention, *2019 Novel Coronavirus (nCoV) IM Update: Response Day 28*, at 59 (Feb. 5, 2020) (on file with Committee, HHS HSGAC 39045-39046).

Not Enough in Stockpiles

Strategic National Stockpile RPD holdings

Product	Total	Deployable, (incl expired)	Non-expired	Comments
N95s	~18M	~13M	~81K	<ul style="list-style-type: none"> Mix of FDA cleared and/or NIOSH approved models Usable product (in-date or passed NIOSH testing (not appropriate for healthcare deliver or high exposure settings))
Facemask/ Surgical Mask	~31M	~31M		<ul style="list-style-type: none"> Includes aging product from 2009 response
PAPRS	~7k	~7k		

State and local stockpiles (n=76)

- ~5 M > 5 years
- ~0.7 M < 5 years

Data are Provisional Until Officially Released by the CDC - For Internal Use Only (FIUO) - For Official Use Only (FOUO) - Sensitive But Unclassified (SBU) - Not for Further Distribution

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D. February PPE Supply Warnings

Throughout early February 2020, the federal government continued to receive documented reports of PPE shortages and supply chain concerns, but failed to take need action. SNS Director Steve Adams told the Committee that by February 2020, the capability of the commercial medical supply system to produce additional PPE was “not looking good.”¹¹⁷⁹ By early February 2020, China nationalized control of the manufacture and distribution of medical supplies and moved aggressively to secure supplies from foreign markets.¹¹⁸⁰ On February 3, 2020, China’s Ministry of Commerce mandated local governments and industry to secure medical supplies, including PPE and critical drugs, from the global market.¹¹⁸¹

A February 5, 2020 internal State Department email from the Office of International Health and Biodefense reported the following from Embassy Beijing:¹¹⁸²

- Dupont’s manufacturing facilities in Hefei and Shenzhen were “commandeered” by Chinese government officials in an effort to direct production and distribution of Dupont’s Tyvek-brand protective coveralls, according to Dupont contacts. Chinese government authorities required Dupont to ramp up production – by 20 percent within the next 30 days and another 15 percent in the next 4-6 months.

¹¹⁷⁹ ASPR Briefing (May 6, 2020).

¹¹⁸⁰ Congressional Research Service, *COVID-19: China Medical Supply Chains and Broader Trade Issues*, at 1 (R46304) (Dec. 23, 2020).

¹¹⁸¹ *Id.*

¹¹⁸² Department of States, *Email from Office of International Health and Biodefense* (Feb. 5, 2020) (on file with Committee, STATE HSGAC 5808-5809).

- Honeywell reported that the Shanghai Municipal Government had directed it to operate facilities that manufacture PPE for industrial use 24/7 with 3 shifts, and had not permitted one of its facilities to close over the CNY [Chinese New Year] holidays. Honeywell said that the authorities are “guiding” distribution of product – working with vendors to prevent price gouging and to ensure that genuine products are entering the distribution channels.
- [The] Ministry of Industry and Information Technology (which oversees national reserves of resources and goods) has inquired about Honeywell’s manufacturing facilities outside of China and has asked about procuring additional inventory from those facilities. Honeywell has made it clear that they do not have additional capacity at this time due to orders from other regions. Honeywell said that it believes the government has been very “fair and reasonable in the actions taken in light of the national emergency” and made clear that it has not been “taken over” by the government or “lost control” of its operations.

ASPR’s February 7 Senior Leadership Brief (SLB) reported, “CDC anticipates shortages in PPE to occur over the course of the response whether or not the number of US cases rises significantly” and raised additional concerns, including:¹¹⁸³

- FDA CDER and CDRH are carrying out efforts to reach to regulated entities to understand challenges in manufacturing, including logistical concerns of moving product out of China – those efforts are ongoing and focus on PPE, essential medical devices, and drugs.
- Taiwan, India, and China are limiting exports of products, prompting concerns.
- Distributors continue with allocation to help ensure supply is available when needed. There are reports of healthcare private sector being unable to get desired products.
- We continue to receive indicators of PPE supply challenges, including China directly purchasing PPE from manufacturing facilities.¹¹⁸⁴

¹¹⁸³ Department of Health and Human Services, Assistant Secretary for Preparedness and Response, *2019 Novel Coronavirus (2019-nCoV) – ASPR Senior Leadership Brief (Tier 2/3)* (Feb. 7, 2020) (on file with Committee, HSGAC-0037444).

¹¹⁸⁴ *Id.* See also Department of Health and Human Services, *2019 Novel Coronavirus (2019-nCoV) – ASPR SLB*, at 7 (Feb. 7, 2020) (on file with Committee, HHS HSGAC 37438-37446).

On February 7, 2020, a State Department Information Memo for the Deputy Secretary reported, “[g]lobal supply chains of personal protective equipment (PPE) are constricted, and domestic supplies of N95 masks are at nine weeks. The interagency will have a clearer picture the week of February 10.” The memo also noted, “3M will only be able to produce 10 percent of its hazmat and surgical gown inventory in February due to a lack of fabric inputs from its Wuhan-based supplier” and “ASPR reports that U.S. shortages are due to healthcare facilities stockpiling PPE.”¹¹⁸⁵

¹¹⁸⁵ Department of State, *Memorandum from Senior Bureau Official re: Personal Protective Equipment – Supply Chains, Risks, and Mitigation* (Feb. 7, 2020) (on file with Committee, STATE 5428-5430) (noting “ASPR is also working with the interagency to assess supply chain risks for diagnostic kit components and pharmaceutical precursors but has focused on PPE and N95 masks as a top priority. For now, ASPR estimates the U.S. supply of N95 masks is at nine weeks. (Note: The group is not assessing the USAID-WHO stockpile of supplies in Dubai, which is governed by an unrelated mechanism).”

	202001657 United States Department of State Washington, D. C. 20520 February 7, 2020
<u>SENSITIVE BUT UNCLASSIFIED</u>	
<input type="checkbox"/> Read by _____	
INFORMATION MEMO FOR THE DEPUTY SECRETARY	
FROM:	OES – Marcia S. Bernicat, Senior Bureau Official
SUBJECT:	(SBU) Personal Protective Equipment – Supply Chains, Risks, and Mitigation
BLUF:	(SBU) Global supply chains of personal protective equipment (PPE) are constricted, and domestic supplies of N95 masks are at nine weeks. The interagency will have a clearer picture the week of February 10.
<p>(SBU) Global situation to date: Dupont, 3M, and Honeywell reported Chinese officials have commandeered domestic distribution of PPE inventory and banned PPE exports to Taiwan and Hong Kong. Taiwan, India, and Thailand have blocked export of surgical masks, raising fears of global supply chain shortages. HHS's Office of the Assistant Secretary for Preparedness and Response (ASPR) is surveying the interagency, as well as more than 250 U.S. firms, to assess domestic supply and will collate results the week of February 10. ASPR is also working with the interagency to assess supply chain risks for diagnostic kit components and pharmaceutical precursors but has focused on PPE and N95 masks as a top priority. For now, ASPR estimates the U.S. supply of N95 masks is at nine weeks. (Note: The group is not assessing the USAID-WHO stockpile of supplies in Dubai, which is governed by an unrelated mechanism.)</p>	
<p>(SBU) Domestic PPE Production: In the United States, 3M, Kimberley Clark, MSA, and Honeywell are the largest PPE producers. 3M employs a "local-for-local" business model; all U.S. supplies are produced domestically. 3M claims they are the sole domestic supplier for surgical respirators and reports that domestic N95 production remains at full capacity. 3M also maintains a 4-million-mask domestic stockpile for DoD. However, 3M will only be able to produce 10 percent of its hazmat and surgical gown inventory in February due to a lack of fabric inputs from its Wuhan-based supplier. ASPR is assessing the logistics of domestic end-to-end production for all PPE.</p>	
<p>(SBU) Fear-Induced Demand: ASPR reports that U.S. shortages are due to healthcare facilities stockpiling PPE. 3M reports that current "fear-induced" demand exceeds supply 10-fold. 3M has received large orders for N95 surgical respirators from U.S. hospitals (10 million), the European Commission Presidency (2 million), and several other international organizations and foreign governments. Globally, 3M produces 50 million N95 masks per month, with only a percentage of those specifically designated as surgical N95 masks. To meet demand, 3M is scaling up production but fear they will exhaust their stockpiles.</p>	

DHS's February 8 Coronavirus Action Report, which was distributed to the White House, DOD, HHS, CDC, Department of Transportation (DOT), State Department, and Department of Agriculture (USDA), referenced a survey from the National Community Pharmacists Association (NCPA) that noted, "pharmacy owners and managers are experiencing a shortage of personal protective gear, with 96% of respondents reporting a shortage of surgical masks and 38% reporting a shortage of respirator masks."¹¹⁸⁷

¹¹⁸⁶ *Id.* at STATE 5428.

¹¹⁸⁷ Department of Homeland Security, *DHS Coronavirus Action Report: Novel Coronavirus 2019-nCoV* (Feb. 8, 2020) (on file with Committee).

E. Policy Decisions on Mask Guidance

Instead of entering into contracts to increase PPE supply or exploring the use of executive authorities and other emergency contracting mechanisms, CDC and ASPR began “considering revising guidance to support conservation of existing PPE.”¹¹⁸⁸ On February 7, 2020 ASPR’s Disaster Leadership Group convened to “establish a common understanding of the current situation with respect to respiratory protection.”¹¹⁸⁹ Dr. Bright told the Committee:

“I was in that meeting. I said there's a shortage. I'm hearing from manufacturers. I'm hearing from companies saying they're getting calls from China to buy every mask. And we're going to have this crisis on our hands. We don't have enough masks to start with and we're losing the ones we have.”¹¹⁹⁰

However, a summary of the February 7 Disaster Leadership Group agenda provided to the Committee by HHS did not reflect Dr. Bright’s concerns. The summary stated, “all agencies reported that they have enough supply to fulfill current need,” and, “[as of February 7], no frontline teams have placed additional orders for respiratory protection equipment.”¹¹⁹¹

Dr. Bright told the Committee that during the February 7 Disaster Leadership Group meeting, officials from ASPR and CDC discussed whether CDC should change guidance to recommend that health care workers wear surgical masks instead of N95 respirators.¹¹⁹² Dr. Bright also noted the discussion involved “altering CDC guidance to tell regular citizens to not wear N95 masks to reduce any surge on the supply . . . there was this mindset that it would all work itself out and that we could change the demand by changing the CDC guidelines.”¹¹⁹³ However, Dr. Kadlec told the Committee, he was in the February 7 meeting and said “the question was whether another mask could be used rather than a N95 [respirator], like a surgical mask, or whether we could preserve the N95 respirators for healthcare workers and make other masks available to non-medical people.”¹¹⁹⁴ Dr. Wolf also attended the meeting, and told the Committee she was concerned that public health “policy decisions would be made because of supply chain issues.” Dr. Wolf recalled receiving a CDC briefing on potentially changing

¹¹⁸⁸ Department of Health and Human Services, Assistant Secretary for Preparedness and Response, *2019 Novel Coronavirus (2019-nCoV) – ASPR Senior Leadership Brief* (Feb. 6, 2020) (on file with Committee, HHS HSGAC 36275-36282).

¹¹⁸⁹ Department of Health and Human Services, *2020 Novel Coronavirus Supply Chain Disaster Leadership Group Meeting Summary of Issues* (Jan. 23, 2020) (on file with Committee, HHS HSGAC 37558).

¹¹⁹⁰ Interview with Dr. Rick Bright (Mar. 17, 2021 and Nov. 4, 2021).

¹¹⁹¹ Department of Health and Human Services, *2020 Novel Coronavirus Supply Chain Disaster Leadership Group Meeting Summary of Issues* (Jan. 23, 2020) (on file with Committee, HHS HSGAC 37558).

¹¹⁹² Interview with Dr. Rick Bright (Mar. 17, 2021 and Nov. 4, 2021).

¹¹⁹³ *Id.*; Dr. Rick Bright, Correspondence to Senate Committee on Homeland Security and Governmental Affairs Staff (Sept. 1, 2022).

¹¹⁹⁴ Interview with Dr. Robert Kadlec (Dec. 6, 2021).

recommendations to use surgical masks and told the Committee this was not a viable solution because there would be a shortage on surgical masks.

Although the Committee did not identify any CDC guidance in February 2020 that recommended the use of surgical masks as an alternative to N95 respirators, CDC gave presentations to health care systems on strategies for “optimizing N95 supplies.”¹¹⁹⁵ According to an August 2022 GAO report, one hospital official expressed concern regarding changing PPE guidance for “the use of N95 respirators and alternatives, such as surgical masks, given supply challenges.” According to CDC, “its guidance for the care of patients with COVID-19 infection always included an N95 respirator and, early in the pandemic, included the use of masks and other alternatives only when supplies of N95 respirators were insufficient.”¹¹⁹⁶

F. Export of Needed PPE Supplies to China

By February 6, 2020 CDC and ASPR understood the U.S. had insufficient PPE for a pandemic response; however, on that same day, the Administration, through the State Department, sent 17.8 tons of PPE donated by U.S. companies to China.¹¹⁹⁷

Images of PPE Shipments from U.S. Private Donors Sent to China on February 6, 2020¹¹⁹⁸



¹¹⁹⁵ Department of Health and Human Services, Centers for Disease Control and Prevention, *CDC 2019 Novel Coronavirus Response* (Feb. 11, 2020); Department of Health and Human Services, Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19): Webinar for Healthcare Professionals* (last reviewed Feb. 18, 2020) (<https://web.archive.org/web/20200229135504/https://www.cdc.gov/coronavirus/2019-ncov/hcp/healthcare-supply-ppe.html>).

¹¹⁹⁶ Government Accountability Office, *Public Health Preparedness: COVID-19 Medical Surge Experiences and Related HHS Efforts* (GAO-22-105461) (Aug. 17, 2022).

¹¹⁹⁷ Department of State, *Wuhan Evacuation Task Force: SITREP No. 25* (Feb. 6, 2020) (on file with Committee, STATE HSGAC 1509-1510).

¹¹⁹⁸ Department of State, *Email from Task Force with Supplies Photos* (Feb. 3, 2020) (on file with Committee, STATE HSGAC 1101-1102; 1109-1112).

Additional internal reports from the State Department and DHS indicated that HHS donated additional PPE after February 12, 2020.¹¹⁹⁹ Specifically, a State Department Coronavirus Update, reported “HHS confirmed to the National Health Commission (NHC) on February 11 that it will donate PPE supplies to China, including 500,000 N95 medical respirators, 50,000 goggles, 100,000 protective suits, and 10,000 non-contact thermometers.”¹²⁰⁰ According to a February 13, 2020 internal State Department document, HHS’s offer of PPE to China “generated substantial discussion among senior leadership at HHS and at State. HHS indicate[d] that HHS/ASPR made the offer from the U.S. domestic stockpile – without enough coordination.”¹²⁰¹

When the Committee asked HHS for information on any coordinated shipments to China, HHS told the Committee that the U.S. was prepared to donate PPE from the SNS to China in exchange for receiving the COVID-19 viral strain, but China refused.¹²⁰² Between February 7 and at least February 25, HHS was in active discussions with China regarding the donation of PPE supplies. A February 10 letter from Dr. Kadlec to Minister Li Bin of China’s National Health Commission outlined the terms of the donation.¹²⁰³ However, HHS told the Committee they could not confirm the letter was ever sent.¹²⁰⁴ While HHS’s Office of Global Affairs (“OGA”) is responsible for overseeing international correspondence, OGA was “unable to confirm” whether Dr. Kadlec’s letter was sent to China and could not provide the Committee with any information about whether a tracking system exists for correspondence.¹²⁰⁵

¹¹⁹⁹ Department of State, *TFCNOI – Wuhan Evacuation Task Force: SITREP No. 25* (Feb. 6, 2020) (on file with Committee) (noting that “HHS confirmed it will donate PPE supplies to China”); Department of Homeland Security, *DHS COVID-19 Action Report* (Feb. 12, 2020) (on file with Committee).

¹²⁰⁰ Department of State, *Wuhan Evacuation Task Force* (Feb. 6, 2020) (on file with Committee, STATE HSGAC 5264); *See also* Department of Homeland Security, *DHS COVID-19 Action Report* (Feb. 12, 2020) (on file with Committee).

¹²⁰¹ Department of State, *Email to Jonathan Margolis, Acting Deputy Assistant Secretary for Science, Space, and Health, Welcome Home for DAS Margolis* (Feb. 13, 2020) (on file with Committee, STATE 5663).

¹²⁰² HHS Communication to Senate Committee on Homeland Security and Governmental Affairs Staff (June 1, 2021).

¹²⁰³ Department of Health and Human Services, *Letter from Dr. Robert Kadlec to Minister Li Bin* (Feb. 10, 2020) (on file with Committee, HHS HSGAC 0043754-43755).

¹²⁰⁴ HHS Communication to Senate Committee on Homeland Security and Governmental Affairs Staff (June 1, 2022).

¹²⁰⁵ HHS Communication to Senate Committee on Homeland Security and Governmental Affairs Staff (Sept. 9, 2022).

February 10, 2020 Letter from Dr. Kadlec to Minister Li



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Assistant Secretary for
Preparedness & Response
Washington, D.C. 20201

February 10, 2020

Li Bin
Vice Minister, National Health Commission
People's Republic of China
1 Xizhimenwai South Road
Xi Cheng District
Beijing, 100044 China
FAX: 861068792285
desadic@nhc.gov.cn

Dear Minister Li,

I understand that President Trump and Chairman Xi had a productive call covering several topics, including the coronavirus situation in China and globally. During their discussion, President Trump stated to Chairman Xi that the United States was thankful for and impressed with China's strong efforts to deal with the virus and protect both its citizens and people around the world. We echo his view as well.

President Trump indicated that he is willing to support the Government of China's efforts in any way that might be helpful. Accordingly, the US Department of Health and Human Services has decided to donate personal protection equipment for use by medical providers and certain screening equipment towards that goal. We have staged the supplies listed below for immediate transfer to support China's efforts and understand that Guangdong Jiaying Pharmaceutical Co. stands ready to pick them up and deliver them to their intended destinations.

- 500,000 N-95 Medical Respirators for Intensive Care Unit and Clinical settings
- 50,000 Medical grade safety (splash) goggles
- 100,000 Tyvek protective suits
- 10,000 Non-contact Infrared Thermometers

We are also looking forward to sending two of our experts to join with the World Health Organization expert team that China has invited to support these efforts.

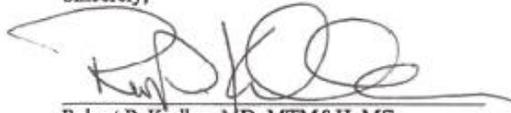
Finally, we are proposing that a currently established joint research collaboration between China and the United States form the nidus of the joint research task force between our two countries, and effective immediately, work together, exchanging researchers, data, and samples towards our common purpose of finding effective medical countermeasures to end this epidemic. I ask that China and the US quickly charge this joint research task force to work with the virus strains to identify diagnosis, treatment and vaccine strategies to mitigate and end the spread of the coronavirus.

We share your view that the situation is not just China's problem, but rather it is everyone's problem, and we stand ready to do our part to help you end the spread of this disease and suffering of

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people around the world. Please indicate that this overall plan is acceptable and provide me with a point of contact so that we can get the needed supplies to you as quickly as possible and arrange for the other items. We stand ready.

Sincerely,



Robert P. Kadlec, MD, MTM&H, MS
Assistant Secretary for Preparedness and Response

Oversight Request,
of Health and Human Services

On February 25, 2020 SNS Director Steve Adams wrote to his contact in China: “we have the critical medical supplies assembled at one of our facilities in the US and ready for immediate shipment after approval from leadership.”¹²⁰⁶ The Committee did not receive any additional documentation related to the planned HHS PPE shipment after February 25, 2020.

When the Committee asked HHS for information documenting why China refused to cooperate, HHS told the Committee the reason was classified. However, following a search, HHS did not identify any classified information about the proposed exchange with China.¹²⁰⁷ HHS ultimately told the Committee it does not know when or why the scheduled PPE shipment was cancelled.¹²⁰⁸ The State Department was also unable to provide any additional information on whether a subsequent PPE donation occurred. Dr. Bright told the Committee that during this time, the U.S. was exporting high quality masks and importing low quality masks.¹²⁰⁹

G. Delayed Federal PPE Procurement and Distribution

Despite multiple, repeated, and well-documented reports of PPE shortages, a February 14 HHS presentation titled, *COVID-19 (2019-nCoV): Medical Supply Chain*, failed to recognize the imminent supply chain concerns.¹²¹⁰ In the presentation’s overview, the first bullet, “Bottom

¹²⁰⁶ Department of Health and Human Services, *Email from Steve Adams to Song Zhiniu* (Feb. 25, 2020) (on file with Committee, HHS HSGAC 43734-43734).

¹²⁰⁷ HHS Communication to Senate Committee on Homeland Security and Governmental Affairs Staff (June 1, 2022).

¹²⁰⁸ *Id.* (July 13, 2021).

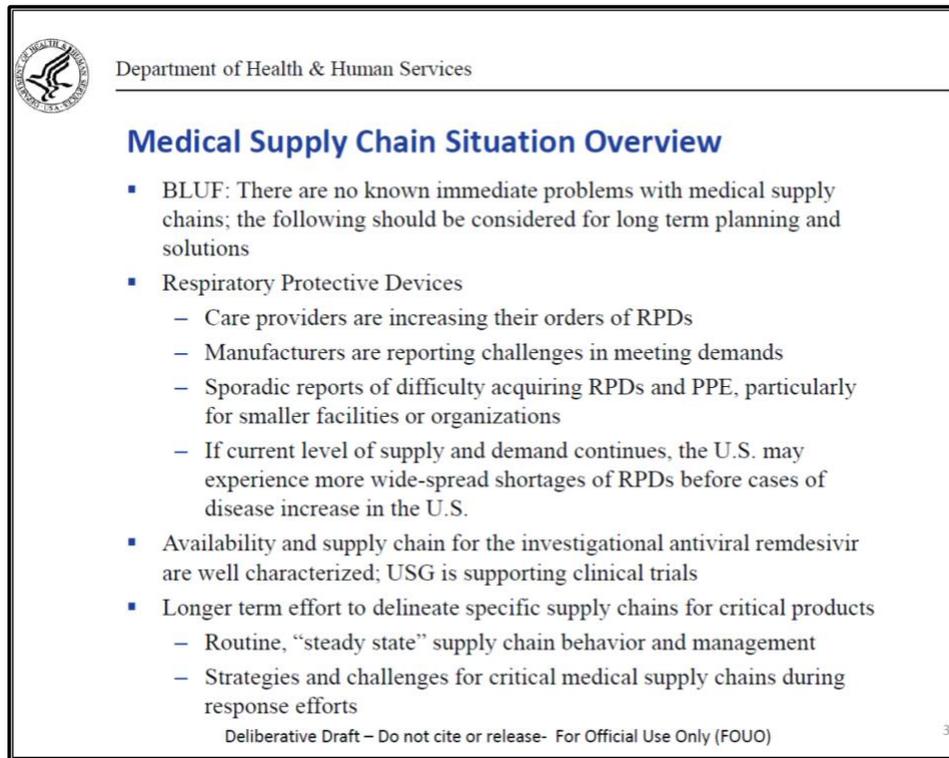
¹²⁰⁹ Interview with Dr. Rick Bright (Mar. 17, 2021 and Nov. 4, 2021).

¹²¹⁰ *Id.*

Line Up Front (BLUF)” read, “[t]here are no known immediate problems with medical supply chains.”¹²¹¹ Despite HHS’s conclusion, the agency acknowledged on that it was “unlikely the US will have enough disposable N95 respirators to meet response needs under current infection control recommendations [and] strategies to address supply and demand are underway.”¹²¹² Throughout the presentation, HHS cited:

- reports from manufacturers whose orders of PPE had increased four to ten-fold;
- reports from distributors whose orders of PPE increased anywhere from two to eight-fold; and
- reports from healthcare systems that were “[o]rdering 2X-8X mores,” (*sic*) “[n]ot receiving full orders, Stockpiling” and reporting that they were “[a]ble to maintain operations, [but] supply is tight.”¹²¹³

*Excerpts from February 14, 2020 HHS COVID-19: Medical Supply Chain Presentation*¹²¹⁴



The screenshot shows a slide from the Department of Health & Human Services. The slide title is "Medical Supply Chain Situation Overview". The content is as follows:

Department of Health & Human Services

Medical Supply Chain Situation Overview

- BLUF: There are no known immediate problems with medical supply chains; the following should be considered for long term planning and solutions
- Respiratory Protective Devices
 - Care providers are increasing their orders of RPDs
 - Manufacturers are reporting challenges in meeting demands
 - Sporadic reports of difficulty acquiring RPDs and PPE, particularly for smaller facilities or organizations
 - If current level of supply and demand continues, the U.S. may experience more wide-spread shortages of RPDs before cases of disease increase in the U.S.
- Availability and supply chain for the investigational antiviral remdesivir are well characterized; USG is supporting clinical trials
- Longer term effort to delineate specific supply chains for critical products
 - Routine, “steady state” supply chain behavior and management
 - Strategies and challenges for critical medical supply chains during response efforts

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¹²¹¹ Dr. Rick Bright, *OSC Complaint, Exhibit 25: COVID-19 (2019-n-CoV):Medical Supply Chain Slides* (Feb. 14, 2020) (on file with Committee); *see also* Interview with Dr. Rick Bright (Mar. 17, 2021 and Nov. 4, 2021).

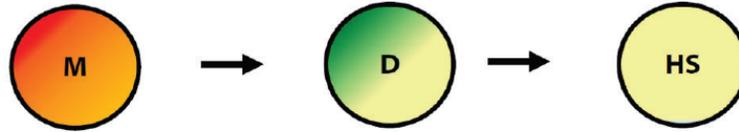
¹²¹² Dr. Rick Bright, *OSC Complaint, Exhibit 25: COVID-19 (2019-n-CoV):Medical Supply Chain Slides* (Feb. 14, 2020) (on file with Committee).

¹²¹³ *Id.*

¹²¹⁴ *Id.*



Current N95 Supply Status: as of 02/12/2020



Reports from Manufacturers (+60%)	Reports from Distributors (+70%)	Healthcare Systems
<ul style="list-style-type: none"> 4X-10X normal orders All are surging (lines, staffing); ramp up time needed, surge planning underway Allocation strategies to fill global orders Global market: <ul style="list-style-type: none"> Raw materials Manufacturing in countries with limited/restricted exports Dedicated lines for global orders 24 locations in the US that make products 	<ul style="list-style-type: none"> 2X-8X normal orders Allocation strategies to fill orders <ul style="list-style-type: none"> % of customer orders (70%-120%) Not serving atypical buyers, limiting PPE sales to non healthcare customers Concerns that orders placed will not be met due to China export restrictions; and Ocean freight/transportation has been down 	<p>Major hospital systems reporting:</p> <ul style="list-style-type: none"> Accelerated burn due to fit testing Ordering 2X-8X mores Not receiving full orders, Stockpiling Able to maintain operations, supply is tight Estimated 2-16 week stockpiles <p>Urgent Care (non-system)</p> <ul style="list-style-type: none"> Increase in orders 2X-5X <p>Pharmacies</p> <ul style="list-style-type: none"> 60% of large chains unable to meet demands Stockouts, delays in resupply



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6

After attending this presentation, Dr. Bright became increasingly concerned that HHS was not taking sufficient actions to procure needed medical supplies. He told the Committee that he subsequently accepted a meeting with Dr. Peter Navarro, former Director of the Office of Trade and Manufacturing Policy within the Executive Office of the President, “when it became clear [HHS] wasn’t going to do anything.”¹²¹⁵ Dr. Bright told the Committee that at the request of Dr. Navarro, during a meeting at the White House, he wrote three memos on why the U.S. needed to act to procure N95 respirators, potential therapeutics (Remdesivir), and vaccine supplies (e.g. needles and syringes).¹²¹⁶ Dr. Navarro “revised [the memos] to put it in his voice and sent to the [White House] Task Force.”¹²¹⁷ Examples of these memos are below.

¹²¹⁵ Interview with Dr. Rick Bright (Mar. 17, 2021 and Nov. 4, 2021).

¹²¹⁶ *Id.*

¹²¹⁷ Dr. Rick Bright, *OSC Complaint, Exhibits 26-28: Memoranda from Dr. Peter Navarro to COVID-19 Task Force* (Feb. 14, 2020) (on file with Committee).

*Examples of Feb. 14, 2020 Memos from Dr. Peter Navarro to White House Task Force*¹²¹⁸

2.14.20

MEMO TO COVID-19 TASK FORCE
THROUGH COS, NSA
FROM PETER NAVARRO
RE: STATUS OF N-95 FACE MASK SUPPLY

This memo follows up a request to immediately secure the N-95 face mask supply. Key questions that need to be answered:

- What is the US inventory and production capacity? We need to designate an agency to assess this and report an answer within 7 days. Not rocket science.
- Has the export of N-95 been halted? If not, why not? We are facing shortages of raw materials that suggest a constrained supply. We should not be exporting any more masks.
- Have orders been placed with US producers to ramp up to full capacity? This is absolutely critical to maintaining the viability of US manufacturing in this space. If these orders are not placed, we will continue to see masks go offshore.

Let's move this in Trump time. These masks are the frontline defense for our health care professionals and we can't waste time.

2.14.20

MEMO TO COVID-19 TASK FORCE
THROUGH COS, NSA
FROM PETER NAVARRO
RE: RAMP UP PRODUCTION OF ANCILLARY SUPPLIES

We face an urgent need to administer large quantities of vaccine once produced. An estimated 850M needles and syringes are required to deliver vaccine.

Our current inventory of these supplies is limited and, under current capabilities, it would take up to two years to produce this amount of specialized safety needles. We may find ourselves in a situation where we have enough vaccine but no way to deliver all of it.

Recommendations

- Direct OSHA and CDC to take steps to liberalize the current policies to allow for the use of non-specialized needles to administer vaccines. Current delivery is with specialized needles with safety caps that have limited production capacity. This one change would significantly increase available inventory.
- Provide HHS Strategic National Stockpile with immediate funding to place orders to ramp up US production to full capacity for needles and syringes needed to deliver a vaccine. We need to immediately determine budget needs and allocate accordingly.
- Direct HHS BARDA to initiate a program to identify all alternate vaccine delivery methods and ramp up production. Other delivery possibilities include jet injectors and similar devices, some of which are already approved to deliver influenza vaccines.

¹²¹⁸ *Id.*

Then DHS senior official, Melissa Harvey told the Committee, the interagency coordination was “not good” and there was a lack of understanding regarding what other agencies were doing. She explained, task forces were siloed and until mid-March 2020, they met very sporadically.¹²¹⁹

Based on interviews with ASPR officials, the Majority Committee staff found a lack of clarity as to which divisions were in charge of procuring needed medical supplies. For example, then BARDA Director, Dr. Bright, told the Committee that the SNS Division along with the Security Intelligence and Information Management (SIIM) Division (including the Critical Infrastructure Protection Branch (CIP)), were responsible for identifying potential suppliers and drafting requests for proposals.¹²²⁰ The Director of SIIM told the Committee, “we do not have the ability to purchase or procure supplies,” and the Director of Critical Infrastructure Protection told the Committee that CIP is not responsible for procuring PPE and procurement lies with the SNS or BARDA.¹²²¹ Former ASPR, Dr. Kadlec told the Committee, that ASPR’s Head of Logistics and the SNS were responsible for procurement.¹²²²

According to Dr. Schuchat, “the interagency discussion was focused more on getting Remdesivir even before it was found to be effective versus focusing on PPE when China was using what it was producing for itself.” She stated, “we didn’t have a turnkey way to start making the volumes that we were going to need.”¹²²³ On February 21, HHS’s requests for assistance from DOD expanded to include personal protective equipment.¹²²⁴

It was not until February 26, 2020 when HHS published its first pre-solicitation for N95 respirators—nearly one month after it declared a public health emergency.¹²²⁵ Weeks later, Mr. Bowen, CEO of domestic PPE manufacturer Prestige Ameritech, contacted CDC to ask for their help in reactivating idle N95 manufacturing lines in Vermont. He cautioned, “what will NOT help is for the government to give me orders that need to be made immediately. That will make my current hospital customers suffer. They will leave me and when the government orders are finished, I’ll go out of business.”¹²²⁶ The federal government never engaged Mr. Bowen on his proposal.

¹²¹⁹ Interview with Melissa Harvey (Nov. 3, 2021).

¹²²⁰ Interview with Dr. Rick Bright (Mar. 17, 2021 and Nov. 4, 2021).

¹²²¹ Interview with Jessica Falcon (July 22, 2021); Interview with Dr. Laura Wolf (Nov. 30, 2021).

¹²²² Interview with Dr. Robert Kadlec (Dec. 6, 2021).

¹²²³ Interview with Dr. Anne Schuchat (Dec. 14, 2021).

¹²²⁴ Department of Defense, *Letter from DOD to HHS* (Feb. 24, 2020) (stating DOD has approved HHS’s request for DOD’s assistance with providing PPE to support the repatriation of U.S. citizens from Japan, among other requests).

¹²²⁵ HHS Correspondence to Senate Committee on Homeland Security and Governmental Affairs Staff (Mar. 9, 2022).

¹²²⁶ Department of Health and Human Services, *Email from Mike Bowen to Centers for Disease Control and Prevention* (Mar. 11, 2020) (on file with Committee, HHS HSGAC – 42898-42899).

**March 11, 2020 Email from Mike Bowen to CDC Official
on Bolstering Domestic PPE Supply¹²²⁷**



On March 21, 2020, ASPR entered into five separate contracts for varying amounts of N95 respirators, totaling 598,028,080; however, the Majority Committee staff found that product deliveries did not begin until at least May 2020. The orders delivered during the month of May comprised less than two percent of ASPR's initial N95 contracts.¹²²⁸ Between March and April 2020, the SNS deployed 90 percent of their PPE supplies, withholding 10 percent to support deployed federal medical personnel.¹²²⁹ From March 12, 2020 to April 19, 2020, SNS distributed the entirety of its PPE supply (with the exception of the 10 percent withheld to support federal medical personnel) to states pro rata based on population.¹²³⁰ A HHS-ASPR slide deck dated March 11, 2020 initially reported that the PPE allocation and distribution policy

¹²²⁷ Department of Health and Human Services, *Email from Mike Bowen to Centers for Disease Control and Prevention* (Mar. 11, 2020) (on file with Committee, HHS HSGAC 42898).

¹²²⁸ HHS Correspondence to Senate Committee on Homeland Security and Governmental Affairs Staff (Mar. 9, 2022).

¹²²⁹ ASPR Briefing (May 6, 2021).

¹²³⁰ HHS Correspondence to Senate Committee on Homeland Security and Governmental Affairs Staff (Aug. 15, 2022). HHS indicated "the pro-rata allocation for each public health authority was determined by 2010 Census data that is proportionate to the population size of each jurisdiction. *See* HHS Correspondence to Senate Committee on Homeland Security and Governmental Affairs Staff (Nov. 16, 2022).

would entail: 25 percent pro rata, 25 percent for areas of “intense transmission,” and 50 percent held in strategic reserve.”¹²³¹ On April 29, 2020, HHS reported, “we lacked the ability to target the distribution of PPE and other critical products to hospitals.”¹²³² When the Committee asked HHS why its March 11, 2020 proposed policy was not utilized to distribute PPE from the SNS, HHS could not provide an answer.¹²³³

According to SNS PPE requests and distribution records in March 2020, there was at least a week delay between some states’ requesting supplies and the SNS distributing those supplies. For example, New York placed its first request on March 6, 2020, but did not receive its first shipment until March 19, 2020; South Dakota placed its first request on March 13, 2020 and received its first shipment on March 22, 2020; and California placed its first request on March 13, 2020 and received its first shipment on March 21, 2020.¹²³⁴

The SNS sent fractions of state requested PPE to hot spots, which needed the most supplies due to rising cases and deaths. For example, throughout March 2020, California received only 17.5 percent of the N95 respirators it requested and New York received approximately 20 percent of the surgical masks it requested and New Jersey received less than 5 percent of the N95 respirators it requested as both states experienced surges in cases.¹²³⁵ By contrast, Wyoming received over 1,000 percent more N95 respirators than it requested and North Dakota, which made no PPE requests, received over 73,000 N95 respirators.¹²³⁶ South Dakota, which, on March 29, 2020 recorded 0 deaths and 90 cases, received over 75,000 N95 respirators.¹²³⁷ By contrast, New Jersey, which recorded over 200 deaths and almost 150 times the number of cases that same day, received less than four times the amount of N95 respirators than South Dakota from the SNS.¹²³⁸

Even among hot spot states, the supplies could have been distributed better to fulfill more requests. Consider the requests for surgical masks in New Jersey and Louisiana. New Jersey received roughly 375,000 fewer surgical masks than requested while Louisiana received roughly

¹²³¹ National Archives and Records Administration, *Department of Health and Human Services, Restructuring our Strategic National Stockpile: A Strategy to Enhance Preparedness and Response* (Apr. 2020) (on file with Committee, NARA P011369).

¹²³² *Id.*

¹²³³ HHS Correspondence to Senate Committee on Homeland Security and Governmental Affairs Staff (Dec. 1, 2022).

¹²³⁴ Department of Health and Human Services, *SNS PPE Distribution through March 29, 2020* (on file with Committee, HHS HSGAC 0043760-0043772).

¹²³⁵ Johns Hopkins University and Medicine, COVID-19 Dashboard by the Center for System and Science Engineering (<https://coronavirus.jhu.edu/map.html>) (accessed August 16, 2022); Department of Health and Human Services, *SNS PPE Distribution through March 29, 2020* (on file with Committee, HHS HSGAC 43760-0043772); Department of Health and Human Services, *March Requests for PPE* (on file with Committee, HHS HSGAC 37689).

¹²³⁶ *Id.*

¹²³⁷ *Id.*

¹²³⁸ *Id.*

382,000 more masks that requested; these excess masks could have been used to fulfill New Jersey’s request in full.¹²³⁹

The SNS distributed the last of its PPE held for states on April 19 2020—the same day it made the decision to begin allocating PPE based on need, not population.¹²⁴⁰ ASPR told the Committee, however, that in the months the followed, there was “no formula” used to determine PPE allocations for distribution based on need.¹²⁴¹ According to HHS, HHS leadership, who no longer work at HHS, made the decisions on how to distribute PPE and did not memorialize the reasoning behind the allocation and distribution of supplies based on need.¹²⁴² While FEMA reported using a “prioritization process” to make resource allocation recommendations by analyzing broad data sets, such as demographics and COVID-19 case information, it was unable to provide the Committee with specifics on how it calculated distribution decisions.¹²⁴³

In May 2020, when the federal government reached back out to Mr. Bowen and offered him a contract, Mr. Bowen declined, noting that “too much of [his] business will go away in the next 12 months. We need to build more long-term businesses.”¹²⁴⁴

May 6, 2020 Email from Mike Bowen Declining Federal PPE Contract¹²⁴⁵



¹²³⁹ *Id.*

¹²⁴⁰ HHS Correspondence to Senate Committee on Homeland Security and Governmental Affairs Staff (Aug. 15, 2022).

¹²⁴¹ HHS Communication to Senate Committee on Homeland Security and Governmental Affairs Staff (Sept. 9, 2022).

¹²⁴² *Id.*

¹²⁴³ Federal Emergency Management Agency, *Coronavirus (COVID-19) Pandemic: National Resource Prioritization Cell, Prioritization Process* (Apr. 18, 2020) (<https://www.fema.gov/fact-sheet/coronavirus-covid-19-pandemic-national-resource-prioritization-cell>).

¹²⁴⁴ Department of Health and Human Services, *Email from Mike Bowen to Adam Lorimer (CDC)* (May 7, 2020) (on file with Committee, HHS HSGAC 42896-42897).

¹²⁴⁵ *Id.*

Dr. Kadlec told the Committee that by March 2020, “we realized that even with the appropriation of new money we could never make enough N95 masks for every American” and he began to strategize on how to create enough masks for all Americans.¹²⁴⁶ Using historical DOD documents from the 1960s that examined how mask materials held up against bio-aerosols, Dr. Kadlec proposed asking manufacturers if they would develop cloth face masks. He explained, “they would be three-ply with the middle one treated with an antiviral substance that would protect against respiratory droplets.”¹²⁴⁷ ASPR worked with Hanes and the U.S. Postal Service to create a plan that would deliver four masks—the average number of people in a household—to every residential address in the U.S.¹²⁴⁸ Dr. Kadlec told the Committee that he was supposed to brief the White House in April, but was not permitted to do so.¹²⁴⁹ According to Dr. Yeskey, Principal Deputy ASPR, “there was resistance . . . my understanding is that the White House said no because [the masks] were white, they looked foolish, and [they] didn’t want people saying they were wearing underwear.”¹²⁵⁰

Although the White House declined Dr. Kadlec’s proposal, Hanes ultimately manufactured 650 billion masks, which were distributed to “faith-based organizations, requesting states, federal departments and agencies, and others.”¹²⁵¹ State governors and local officials, according to Dr. Birx, distributed the masks to high-risk vulnerable individuals. Dr. Birx noted “it was the right thing to get masks to those who couldn’t afford to buy them.”¹²⁵²

On March 29, 2020 as an emergency measure, the Trump Administration instituted Project Airbridge, a private-public partnership designed to airlift PPE to “healthcare users with increased efficiency to meet peak demand.”¹²⁵³ An internal March 23 email from White House Supply Chain Task Force Lead Admiral John Polowczyk noted, “without air shipping, it would take approximately 25 to 40 days for [PPE] to arrive. With air shipping, it will take 2-3

¹²⁴⁶ Interview with Dr. Robert Kadlec (Dec. 6, 2021).

¹²⁴⁷ *Id.*

¹²⁴⁸ Interview with Dr. Kevin Yeskey (Nov. 17, 2021 and Dec. 2, 2021).

¹²⁴⁹ Interview with Dr. Robert Kadlec (Dec. 6, 2021).

¹²⁵⁰ Interview with Dr. Kevin Yeskey (Nov. 17, 2021 and Dec. 2, 2021).

¹²⁵¹ Interview with Dr. Robert Kadlec (Dec. 6, 2021).

¹²⁵² Interview with Dr. Deborah Birx (Jan. 6, 2022),

¹²⁵³ Federal Emergency Management Agency, *Project Air Bridge Distributor Compliance Report* (Apr. 2021) (on file with Committee, HSGAC 967). According to FEMA, “Project Airbridge flights were conducted between March 29, 2020 and June 30, 2020.” Private distributors agreed that 50 percent of all PPE shipped via Project Airbridge would be delivered to counties that “were in the most need for the items” as directed by FEMA (some distributors delivered more than 50 percent. *Id.* at 967-968; *see also* White House, Remarks by President Trump, Vice President Pence, and Members of the Coronavirus Task Force in Press Briefing (Mar. 30, 2020) (<https://trumpwhitehouse.archives.gov/briefings-statements/remarks-president-trump-vice-president-pence-members-coronavirus-task-force-press-briefing-14/>).

days.”¹²⁵⁴ Despite delivering over 1.7 billion pieces of PPE to prioritized areas through Project Airbridge through June 30, 2020, PPE shortages remained.¹²⁵⁵

Shortages of Testing Supplies

In addition to PPE shortages, the U.S. experienced widespread shortages of critical supplies needed to perform diagnostic tests. Diagnostic testing is a resource intensive process, requiring a range of supplies, from high-tech testing platforms to PPE and other basic supplies for test kit materials, including specimen collection swabs and reagents.¹²⁵⁶ Swab shortages began early in the response, with manufacturers initially unable to meet demand.¹²⁵⁷ Reagents, testing platforms, and other supplies were all in shortage at various points of the response.¹²⁵⁸

In an interview with Committee staff, the National Independent Laboratory Association (NILA) described the period between December 2019 and February 2020 as “prep time” for their labs to get ready for COVID-19 testing—time that, due to federal inaction, was lost. “Calls with CDC were informative,” NILA said, but did not help labs prepare for the scale of COVID testing that would be required.¹²⁵⁹ In addition, NILA told the Committee that manufacturers were not able to provide the necessary testing materials in bulk as needed by the labs. “We didn’t know how many people we’d be testing,” NILA noted, “there was no way to prepare for that.”¹²⁶⁰

At a March 4, 2020 meeting with Vice President Pence and other members of the White House Task Force, representatives from the American Clinical Laboratory Association (ACLA) told officials that labs would need sufficient supplies to scale up testing capacity, including swabs, transport media, reagents, pipette tips, and testing platforms.¹²⁶¹ Federal government officials, however, gave competing assessments of whether there were testing supply shortages. CDC told the Committee that they did not become aware of the “emerging issue of extraction reagent shortages” until approximately March 5, 2020.¹²⁶² At that time, CDC “connected with

¹²⁵⁴ Federal Emergency Management Agency, *Email from Admiral John Polowczyk to FEMA and ASPR officials* (Mar. 23, 2020) (on file with Committee, HSGAC 1523).

¹²⁵⁵ Federal Emergency Management Agency, *Project Air Bridge Distributor Compliance Report* (Apr. 2021) (on file with Committee, HSGAC 969).

¹²⁵⁶ Department of Health and Human Services, *Report to Congress: COVID-19 Strategic Testing Plan* (May 24, 2020); Congressional Research Service, *In Focus: COVID-19 Testing Supply Chain* (IF11774) (Feb. 25, 2021).

¹²⁵⁷ *Testing Swabs Run in Short Supply as Makers Try to Speed Up Production*, NPR (Mar. 18, 2020) (<https://www.npr.org/sections/health-shots/2020/03/18/817801222/testing-swabs-run-in-short-supply-as-makers-try-to-speed-up-production>)

¹²⁵⁸ Interview with American Clinical Laboratory Association (May 27, 2021); Interview with National Independent Laboratory Association (May 24, 2021).

¹²⁵⁹ Interview with National Independent Laboratory Association (May 24, 2021).

¹²⁶⁰ *Id.*

¹²⁶¹ Interview with American Clinical Laboratory Association (May 27, 2021).

¹²⁶² HHS Correspondence to Senate Committee on Homeland Security and Governmental Affairs Staff (Jan. 7, 2022).

reagent manufacturers to understand the issues and to develop plans for optimum purchasing and distribution of reagents to Public Health Labs.”¹²⁶³

In a March 12, 2020 email, the Director of Diagnostics and Medical Devices at BARDA wrote to Dr. Bright and other BARDA officials, “CDC confirmed some sites are reporting that supplies are getting low [while FDA] indicated that the swab manufacturers (Puritan and Copan) have huge manufacturing capacity, so the shortage is not likely to be swabs.”¹²⁶⁴ When Dr. Bright contacted FDA, however, he learned there was a “severe shortage of swabs for all diagnostic tests” and the major swab producer, Copan, based in Lombardy, Italy “had just went into total lockdown with a no-fly zone.”¹²⁶⁵ After learning this, Dr. Bright told the Committee he raised the issue with ASPR leadership but “received pushback on taking any action.”¹²⁶⁶ On March 14, Dr. Bright raised concerns to the White House to raise concerns about swab shortages and provided “high level bullets about the [swab] shortage issue and path to resolution.”¹²⁶⁷ Four days later, on March 18, COVID-19 testing czar Admiral Brett Giroir texted then HHS Secretary Alex Azar, “[o]n swabs . . . There is no shortage. We just need to channel states to the commercial market.”¹²⁶⁸

Dr. Bright told the Committee that BARDA received reports from manufacturers and developers that they were running out of reagents and other testing supplies.¹²⁶⁹ Due to insufficient visibility into the diagnostic testing supply chain, Dr. Bright explained that he worked with his team “to figure out where swabs were made and how.”¹²⁷⁰ Ultimately, through working with Dr. Navarro at the White House, Drs. Bright and Disbrow located a swab manufacturer in Italy that supplied approximately 75 percent of the U.S. market and engaged DOD to provide military air support to transport swabs to the U.S.¹²⁷¹ Dr. Bright noted, “military intervention was necessary because of the closed air space [] preventing any export of critical supplies from Italy.”¹²⁷²

¹²⁶³ *Id.*

¹²⁶⁴ Dr. Rick Bright, *OSC Complaint, Exhibit 35: Email from Rosemary Humes to Dr. Rick Bright* (Mar. 12, 2020) (on file with Committee).

¹²⁶⁵ Dr. Rick Bright, *Correspondence to Senate Committee on Homeland Security and Governmental Affairs* (Sept. 1, 2022).

¹²⁶⁶ *Id.*

¹²⁶⁷ Dr. Rick Bright, *OSC Complaint, Exhibit 41: Email from Dr. Rick Bright to Peter Navarro* (Mar. 14, 2020) (on file with Committee).

¹²⁶⁸ Department of Health and Human Services, *Text Message from Admiral Brett Giroir to HHS Secretary Alex Azar* (Mar. 18, 2020) (on file with Committee, HHS HSGAC 42329).

¹²⁶⁹ Interview with Dr. Rick Bright (Mar. 17, 2021 and Nov. 4, 2021).

¹²⁷⁰ *Id.*

¹²⁷¹ Dr. Rick Bright, *OSC Complaint, Exhibit 37-39: Emails between Dr. Rick Bright, Dr. Gary Disbrow, and Peter Navarro* (Mar. 12-13, 2020) (on file with Committee).

¹²⁷² Interview with Dr. Rick Bright (Mar. 17, 2021 and Nov. 4, 2021); Dr. Rick Bright, *Correspondence to Senate Committee on Homeland Security and Governmental Affairs* (Sept. 1, 2022).

The Washington State Department of Health stated that as testing capacity expanded, they requested “considerable testing supplies” from the federal government; however, many of the supplies they received “were not in a mission ready capability” and “there were several instances where un-usable testing supplies were delivered.”¹²⁷³ As a result, Washington state public health officials had to create a structure to “receive inventory, prepare, re-package, and distribute testing supplies.”

H. Impact of Supply Shortages

According to Dr. Daniel Gerstein, a former DHS official who testified before the Committee in June 2020, “[b]y mid-February, global examples of the virus transmissibility and virulence were evident, and a global competition was underway for masks, gowns, ventilators, and reagents and nasal swabs for test kits.”¹²⁷⁴ Dr. Nicolette Louissaint, then Executive Director of Health Care Ready (a non-federal organization involved in coordinating COVID response efforts), explained to the Committee how the U.S. could have offset a lot of challenges it ultimately experienced with critical shortages of drugs and medical supplies including masks and other PPE. According to Dr. Louissaint, though ultimately squandered, “[w]e [the U.S.] had an opportunity to accelerate production and institute controls and conservation tactics.”¹²⁷⁵

Despite the President’s March 13 emergency declarations, which affirmed “federal assistance is needed to supplement State and local efforts and capabilities to “save lives” and protect “public health and safety,” the Trump Administration urged states to procure supplies directly from manufacturers as a lack of domestic manufacturing capacity and high demand led to supply shortages.¹²⁷⁶ At a March 16, 2020 press conference, President Trump stated, “[i]f they’re able to get ventilators, respirators, if they’re able to get certain things without having to go through the longer process of federal government... it’s always going to be faster if they can get them directly.”¹²⁷⁷ Days later he made clear the onus was on the governors, not the federal government:

First of all, governors are supposed to be doing a lot of this work, and they are doing a lot of this work. The federal government is not supposed to be out there buying vast amounts of items and then shipping. You know, we’re not a shipping clerk. The governors are

¹²⁷³ Washington State Department of Health, Written Response to Senate Committee on Homeland Security and Governmental Affairs State Public Health Agency Questionnaire (Dec. 3, 2021).

¹²⁷⁴ Senate Committee on Homeland Security and Governmental Affairs, *Hearing on The Role of the Strategic National Stockpile in Pandemic Response* 116th Cong. (June 24, 2020) (S. Hrg. 116-XX).

¹²⁷⁵ Interview with Dr. Nicolette Louissaint (Feb. 17, 2021).

¹²⁷⁶ See 42 U.S.C. §5122(1); White House, Remarks by President Trump, Vice President Pence, and Members of the Coronavirus Task Force in Press Briefing (Mar. 16, 2020) (<https://trumpwhitehouse.archives.gov/briefings-statements/remarks-president-trump-vice-president-pence-members-coronavirus-task-force-press-briefing-3/>).

¹²⁷⁷ *Id.*

supposed to be—as with testing, the governors are supposed—are supposed to be doing it.¹²⁷⁸

Former Centers for Disease Control (CDC) Director Dr. Julie Gerberding testified before this Committee in June 2020 that “when states and local governments are left to fend for themselves when supplies are scarce, in an uncoordinated way, it can lead to a chaotic free-for-all in the marketplace that is not efficient when time is of the essence.”¹²⁷⁹ The Michigan Department of Health and Human Services told the Committee, “[s]hortages in PPE and testing supplies were difficult challenges early in the response. The federal government, states, and the private sector were all competing for the same resources [and] additional communication and coordination from the federal level could have facilitated many of these processes.”¹²⁸⁰ In January and February, the Illinois Department of Health reported that they “requested assistance for helping [long term care facilities] and medical groups find [PPE] as they were already experiencing supply chain issues.”¹²⁸¹ When the Virginia Department of Health requested PPE and testing swabs from the SNS in late February and early March, the federal “response was timely but supplies were severely limited and issued on a pro-rata basis.”¹²⁸² As a result, the Virginia Department of Health in conjunction with the Virginia Department of Emergency Management “led a ‘Whole of Government’ response and made efforts to “reach[] out to private sector vendors and FEMA.”¹²⁸³

On March 30, 2020, the Republican Governor of Maryland and Democratic Governor of Michigan published an op-ed requesting additional support from the federal government:

There simply aren’t enough test kits, medical supplies and other lifesaving equipment to meet the scope of this pandemic. While states are doing all we can to secure access to these items, the federal

¹²⁷⁸ White House, Remarks by President Trump, Vice President Pence, and Members of the Coronavirus Task Force in Press Briefing (Mar. 19, 2020) (<https://trumpwhitehouse.archives.gov/briefings-statements/remarks-president-trump-vice-president-pence-members-coronavirus-task-force-press-briefing-6/>).

¹²⁷⁹ Senate Committee on Homeland Security and Governmental Affairs, Testimony Submitted for the Record of Julie Gerberding, Co-Chair, Center for Strategic and International Studies Commission on Strengthening America’s Health Security, *Hearing on The Role of the Strategic National Stockpile in Pandemic Response*, 116th Cong. (June 24, 2020) (S. Hrg. 116-XX).

¹²⁸⁰ Michigan Department of Health and Humans Services, Written Response to Senate Committee on Homeland Security and Governmental Affairs State Public Health Agency Questionnaire (Dec. 2, 2021).

¹²⁸¹ Illinois Department of Health, Written Response to Senate Committee on Homeland Security and Governmental Affairs State Public Health Agency Questionnaire (Jan. 27, 2022).

¹²⁸² Virginia Department of Health, Written Response to Senate Committee on Homeland Security and Governmental Affairs State Public Health Agency Questionnaire (Dec. 1, 2021).

¹²⁸³ Virginia Department of Health, Written Response to Senate Committee on Homeland Security and Governmental Affairs State Public Health Agency Questionnaire (Dec. 1, 2021).

government must take extraordinary steps to deliver what we need.¹²⁸⁴

Colorado’s Democratic Governor, Jared Polis, later echoed these concerns: “[t]he federal government left states to fend for themselves . . . this put states in a bidding war against each other within an already distorted market.”¹²⁸⁵

States also reported challenges in working with the federal SNS.¹²⁸⁶ The Washington State Department of Health stated, “[w]orking with the SNS was initially challenging in the early phase of the pandemic as relationships were not well formed and there were distinct differences in the planning assumptions for the response to a pandemic at the federal level versus the [SLTT] levels.”¹²⁸⁷ The Michigan Department of Health and Human Services described difficulties with initial shipments from the SNS:

Initial PPE shipments from the SNS were sent with little notice and without pre-identifying what material was contained in the shipment. Staff received calls from drivers between the hours of 1:00AM and 3:00AM notifying them of morning arrival times at the warehouse. Materials from multiple semi trailers were unloaded and inventoried before resources could be matched to the needs of healthcare facilities and divided between regions of the state for further distribution. This did not allow time for thoughtful and adequate planning and delayed distribution to end users.¹²⁸⁸

As a result of the federal government’s failure to execute a comprehensive national strategy to procure needed supplies and a lack of readily available U.S. domestic manufacturing capacity, hospitals, health care facilities, and frontline workers throughout the U.S. experienced dire shortages of PPE, testing supplies, and critical drugs.¹²⁸⁹ The Michigan Hospital

¹²⁸⁴ *What governors need from Washington during this health emergency*, Washington Post (March 30, 2020) (<https://www.washingtonpost.com/opinions/2020/03/30/larry-hogan-gretchen-whitmer-what-governors-need-washington-during-this-health-emergency/>).

¹²⁸⁵ Senate Committee on Homeland Security and Governmental Affairs, Testimony Submitted for the Record of Governor Jerod Polis, Colorado, *Hearing on COVID-19 Part II: Evaluating the Medical Supply Chain and Pandemic Response Gaps*, 117th Cong. (May 19, 2021) (S. Hrg. 117-XX)

¹²⁸⁶ Michigan Department of Health and Humans Services, Written Response to Senate Committee on Homeland Security and Governmental Affairs State Public Health Agency Questionnaire (Dec. 2, 2021); Washington State Department of Health, Written Response to Senate Committee on Homeland Security and Governmental Affairs State Public Health Agency Questionnaire (Dec. 3, 2021).

¹²⁸⁷ Washington State Department of Health, Written Response to Senate Committee on Homeland Security and Governmental Affairs State Public Health Agency Questionnaire (Dec. 3, 2021) (noting “[o]ver time our working relationship became more effective as we worked together and learned how best to support each other’s mission areas”).

¹²⁸⁸ Michigan Department of Health and Humans Services, Written Response to Senate Committee on Homeland Security and Governmental Affairs State Public Health Agency Questionnaire (Dec. 2, 2021).

¹²⁸⁹ Government Accountability Office, *COVID-19: FEMA’s Role in the Response and Related Challenges* (GAO-20-685T) (July 2020) (“The National Governors Association further noted that a more coordinated federal

Association (MHA) wrote to the Committee, “[w]hen the COVID-19 pandemic hit Michigan in late March 2020, hospitals in Southeast Michigan immediately began experiencing shortages of supplies and equipment that were critical to the ability to provide patient care,” including N95 respirators, gloves, and gowns.¹²⁹⁰ MHA noted, “[w]ithout proper equipment, healthcare workers, patients, and visitors were put at risk of virus exposure, and without proper medical supplies, it was impossible to treat patients effectively and safely.” According to the British Medical Journal, by March 27, 2020 “nearly a third of [medical] facilities were almost out of face masks, 13 [percent] had no more plastic face shields, and about 25 [percent] were completely or nearly out of gowns.”¹²⁹¹

Shortages of PPE forced health care workers to balance patient care with personal risk.¹²⁹² In April 2020, the American Nurses Association reported concerns of employers retaliating against health care workers—from intimidation to firing—“for raising legitimate concerns about their personal safety while caring for patients with COVID-19.”¹²⁹³ In a survey conducted by the National Nurses United in February and March 2020, 87 percent of respondents reported having to reuse a face masks.¹²⁹⁴ Reports cited accounts from health care workers who had to reuse equipment, such as N95 respirators, or use ponchos or trash bags in lieu of proper PPE.¹²⁹⁵

role would help states to obtain personal protective equipment, ventilators, and other critical supplies to protect responders and save lives without competition between states and with the federal government.”).

¹²⁹⁰ Senate Committee on Homeland Security and Governmental Affairs, Statement for the Record of Brian Peters, Chief Executive Officer, Michigan Health and Hospital Association, *Hearing on COVID-19 Part II: Evaluating the Medical Supply Chain and Pandemic Response Gaps*, 117th Cong. (May 19, 2021) (S. Hrg. 117-XX).

¹²⁹¹ Douglas Kamerow, *Covid-19: the crisis of personal protective equipment in the U.S.*, British Medical Journal (Apr. 3, 2020).

¹²⁹² *A pandemic ethical conundrum: Must health care workers risk their lives to treat Covid-19 patients?*, STAT News (July 24, 2020) (<https://www.statnews.com/2020/07/24/a-pandemic-ethical-conundrum-must-health-care-workers-risk-their-lives-to-treat-covid-19-patients/>); *see also* Long H. Nguyen, et al., *Risk of COVID-19 among frontline healthcare workers and the general community: a prospective cohort study*, Lancet Public Health (July 31, 2020).

¹²⁹³ American Nurses Association, *ANA Disturbed by Reports of Retaliation Against Nurses for Raising Concerns About COVID-19 Safety* (Apr. 9, 2020) (<https://www.nursingworld.org/news/news-releases/2020/ana-disturbed-by-reports-of-retaliation-against-nurses-for-raising-concerns-about-covid-19-safety/>).

¹²⁹⁴ House Committee on Oversight and Reform, Testimony Submitted for the Record of Bonnie Castillo, RN, National Nurses United, *Hearing on No Worker Left Behind: Supporting Essential Workers*, 116th Cong. (June 10, 2020) (H. Hrg. 116-97).

¹²⁹⁵ *One Hospital’s Last Resort to Protect Doctors: Yankee Rain Ponchos*. New York Times (Apr. 2, 2020) (www.nytimes.com/2020/04/02/nyregion/coronavirus-yankees-ponchos.html) (reporting “[o]n March 25, the system started ordering doctors and nurses to wear the same N95 masks for up to three days at a time”); *Expired Respirators. Reused Masks. Nurses in the Nation’s Original Covid-19 Epicenter Offer Sobering Accounts of What Could Come*, ProPublica (Mar. 28, 2020) (reporting nurses having to reuse masks and other PPE).

*Nurses at Mount Sinai West*¹²⁹⁶



*Nurses at St. Catherine of Siena Medical Center in Ponchos*¹²⁹⁷



A March 2020 survey by the HHS Office of Inspector General (HHS OIG) found that some hospitals with limited PPE supplies improvised PPE and sought non-traditional supply sources.¹²⁹⁸ Certain hospitals, according to HHS OIG, considered “other materials to substitute for needed supplies (e.g., sandwich bags as thermometer covers, blending ultrasound gel and alcohol from a local distillery to make hand sanitizer).”¹²⁹⁹ The survey also found that delays in test results and heavier than normal use of PPE contributed to supply shortages.¹³⁰⁰

Concerns about supply shortages caused hospitals to prioritize COVID testing “for their employees and for patients with more severe symptoms,” the survey found, hampering hospitals’ ability “to conduct widespread testing of patients and community members to help contain the spread of COVID-19.”¹³⁰¹ The Virginia Department of Health told the Committee that a “lack of SNS material caused a months-long effort to fulfill material requirements both in [health care] and other private/public settings,” noting “CDC and ASPR were supposedly the ‘GO-TO’ fed agencies for material aid [but] neither were able to support requirements. FEMA eventually provided support to our state response.”¹³⁰²

¹²⁹⁶ *As basic supplies run perilously short, hospitals need everyone’s help now*, New York Post (Mar. 25, 2020) (<https://nypost.com/2020/03/25/as-basic-supplies-run-perilously-short-hospitals-need-everyones-help-now/>); *Nurses at NYC hospital receive gowns after Post trash bag exposé*. New York Post (Apr. 2, 2020) (<https://nypost.com/2020/04/02/nurses-at-nyc-hospital-receive-gowns-after-post-trash-bag-expose/>).

¹²⁹⁷ New York State Nurses Association, Twitter Post (Apr. 17, 2020, 2:00 p.m.) (<https://twitter.com/nynurses/status/1251209037179428864>).

¹²⁹⁸ Department of Health and Human Services, Office of Inspector General, *Hospital Experiences Responding to the COVID-19 Pandemic: Results of a National Pulse Survey March 23–27, 2020*, at 21 (Mar. 2020).

¹²⁹⁹ *Id.*

¹³⁰⁰ *Id.* at 8 (noting, “hospitals reported that the multiple changes in [CDC] guidance contributed to a greater sense of confusion, fear, and distrust among staff that they could rely on hospital procedures to protect them,” and, “Delays in test results led to heavier use of PPE until a patient’s status was confirmed”).

¹³⁰¹ *Id.* at 2-3.

¹³⁰² Virginia Department of Health, Written Response to Senate Committee on Homeland Security and Governmental Affairs State Public Health Agency Questionnaire (Dec. 1, 2021).

CONCLUSION

The human and societal cost of the COVID-19 pandemic has been devastating and continues today. Many of the problems identified as part of the initial federal response are longstanding and remain unaddressed. For decades, insufficient funding across multiple administrations has impaired federal agencies' readiness and response capabilities, reducing sustainable investments in public health preparedness. Public health agencies, and the federal government as a whole, lack sufficient global biodefense surveillance capabilities to identify and track emerging infectious disease threats. Conflicting authorities and overlapping roles between federal agencies create confusion during public health emergency responses and unless clarified, will continue to present challenges. HHS's organizational structure hinders its ability to effectively coordinate and communicate with federal agencies, SLTT partners, and the public. Moreover, even with repeated warnings, U.S. medical supply chains lack transparency and continue to rely on just-in-time delivery and concentrated foreign sources for critical medical products. Without sufficient diversification and domestic manufacturing capacity, dire shortages of lifesaving medical products during global crises are inevitable.

Despite several key systemic emergency response shortcomings that have remained unaddressed for decades, early action and a recognition of the threat during the initial months could have mitigated the devastation throughout the spring of 2020.¹³⁰³ Instead, the federal government failed to heed critical warnings signs and relied on a flawed influenza-based approach to a virus that spreads pre-symptomatically and asymptotically in over half the cases. Former CDC Chief of Staff, Kyle McGowan, told the Committee, "public health is a series of nets. The first net may not catch [the threat], so you need to depend on the second and third net. There were big holes in this net of using the influenza-like illness network."¹³⁰⁴ However, the federal government failed to sufficiently prepare for other infectious disease threats. Melissa Harvey, former Director of Health Systems at DHS, told the Committee, "when we used to think about our worst day, it was a major influenza pandemic...but I will say shame on us for not even being ready for what would have been a bad influenza pandemic."¹³⁰⁵ Former CDC Director Redfield told the Committee, CDC "did the best they could with what they had," but added, "CDC has to get back to being a response agency... the nation needs that."¹³⁰⁶

Fifteen years after this Committee issued its report, *A Nation Still Unprepared*, criticizing the federal government's response to Hurricane Katrina, an atypically powerful hurricane, many of the same findings after assessing the initial federal response to an "atypically powerful" pandemic apply: the government failed to heed critical warnings; took insufficient action; lacked sufficient systems to execute response efforts; and failed to provide effective leadership. While the pandemic has resulted in societal changes, Dr. Birx cautioned, "people talk about returning to normal, but I don't ever want to return to normal with our public health

¹³⁰³ Birx says all Covid-19 deaths after the first surge "could have been mitigated or decreased, CNN (Mar. 28, 2021).

¹³⁰⁴ Interview with Kyle McGowan (Dec. 2, 2021).

¹³⁰⁵ Interview with Melissa Harvey (Nov. 3, 2021).

¹³⁰⁶ Interview with Dr. Robert Redfield (Feb. 7, 2022).

infrastructure. We need to fix it—we have the tools today—we need to move infectious disease diagnoses, tracking, and treatment into the 21st century.”¹³⁰⁷ Congress, the federal government, SLTT partners, and the private sector, must work together to provide sustainable funding, build robust testing capacity, modernize surveillance capabilities, and onshore the manufacturing of critical medical products, among many other institutional challenges. If we fail to address these issues, our nation will remain unprepared for the next public health crisis.

¹³⁰⁷ Interview with Dr. Deborah Birx (Jan. 6, 2022).