United States Senate Committee on

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

December 2022

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.

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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

1. **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.

2. **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.

3. **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.

4. **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 defendable 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.