The Strategic National Stockpile and COVID-19

Rethinking the Stockpile

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CT-A530-1
Testimony presented before the Senate Committee on Homeland Security and Governmental Affairs on June 24, 2020.

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Published by the RAND Corporation, Santa Monica, Calif.

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Before the Committee on Homeland Security and Governmental Affairs
United States Senate

June 24, 2020

Good afternoon, Chairman Johnson, Ranking Member Peters, and distinguished members of the committee. I thank you for the opportunity to testify today regarding the Strategic National Stockpile (SNS). I will focus my remarks on the role of the stockpile during pandemics, concentrating on the parts that the federal government and state, local, tribal, and territorial (SLTT) governments play in responding to pandemics and how the SNS supports their efforts. I will also provide recommendations for rethinking our national stockpiling capabilities for future biological events, including pandemics.

Introduction

COVID-19 has exposed serious weaknesses in our national preparedness for and response to a global pandemic. The global tally of confirmed cases and deaths from the novel coronavirus—the severe acute respiratory syndrome coronavirus 2, or SARS-CoV-2—continues to grow, and the disease continues to spread to previously uninfected parts of the globe. COVID-19 has spread to over 210 countries and territories, causing over eight million confirmed cases and almost a half-million deaths worldwide, yet the progression of the disease shows little sign that the worst is over.

In the United States, we have had over two million confirmed cases and over 120,000 deaths to date,[3] which is considerably less than was projected had nonpharmaceutical interventions (including social distancing; home quarantine; closures of schools, universities, and businesses;

[1] The opinions and conclusions expressed in this testimony are the author's alone and should not be interpreted as representing those of the RAND Corporation or any of the sponsors of its research.

[2] The RAND Corporation is a research organization that develops solutions to public policy challenges to help make communities throughout the world safer and more secure, healthier and more prosperous. RAND is nonprofit, nonpartisan, and committed to the public interest.

[3] Worldometer, "COVID-19 Coronavirus Pandemic," webpage, updated June 18, 2020, https://www.worldometers.info/coronavirus/.

and case isolation) not been put in place. These measures, although slow to be implemented, flattened the curve of viral spread.

Early estimates from studies done by the Imperial College of London estimated the United States could suffer 2.2 million deaths,[4] while the U.S. Centers for Disease Control and Prevention (CDC) estimated 200,000 to 1.7 million deaths, assuming no interventions.[5] Still, the most recent estimates have U.S. coronavirus deaths rising to nearly 150,000 by early August.[6] These totals do not include "excess deaths" during this pandemic that are likely to further increase associated COVID-19 mortality.[7]

Despite these assessments, the federal response has been slow and inconsistent and has deservedly become a target of criticism, especially regarding critical equipment and supplies. One former senior emergency management coordinator for the City of Chicago summed up the federal response, stating, "Let's be clear: The federal government has failed. If we maintain the status quo, the cavalry is not coming. Pandemic prevention efforts were ineffective. Pandemic preparedness efforts were ineffective. Pandemic coordination efforts were ineffective."[8]

Although the old adage claims "all disasters are local," preparedness and response consist of a series of nested systems designed to support local authorities when their capabilities become overwhelmed. The SNS is a critical part of that support. To this end, the Public Health Service Act has authorized the Secretary of Health and Human Services, in coordination with the Secretary of Homeland Security, to maintain a stockpile of drugs, vaccines, and other medical products and supplies (known as the SNS) to provide for the emergency health security of the United States and its territories.[9]

With respect to the COVID-19 response, understanding the SNS's history provides an important point of departure. In addition, SNS support has been negatively affected by several key issues that occurred pre-COVID-19 and during the response. They include unrealistic

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[4] Sabine L. van Elsland and Ryan O'Hare, "COVID-19: Imperial Researchers Model Likely Impact of Public Health Measures," Imperial College London, March 17, 2020, https://www.imperial.ac.uk/news/196234/Covid19-imperial-researchers-model-likely-impact.

[5] Sheri Fink, "Worst-Case Estimates for U.S. Coronavirus Deaths," *New York Times*, March 13, 2020, https://www.nytimes.com/2020/03/13/us/coronavirus-deaths-estimate.html.

Josh Katz, Margot Sanger-Katz, and Kevin Quealy, "Could Coronavirus Cause as Many Deaths as Cancer in the U.S.? Putting Estimates in Context," *New York Times*, March 16, 2020, https://www.nytimes.com/interactive/2020/03/16/upshot/coronavirus-best-worst-death-toll-scenario.html

[6] Joseph Guzman, "US Coronavirus Deaths Could Rise to Nearly 150,000 by Early August, According to Leading Computer Model," *The Hill*, June 9, 2020, https://thehill.com/changing-america/resilience/natural-disasters/501804-us-covid-19-deaths-could-surpass-145000-by.

[7] *Excess deaths* are typically defined as the difference between the observed numbers of deaths during specific periods and expected numbers of deaths during the same periods. From CDC, "Excess Deaths Associated with COVID-19," webpage, updated June 17, 2020, https://www.cdc.gov/nchs/nvss/vsrr/covid19/excess_deaths.htm.

[8] Thomas Henkey, "Perspective: It Is Not Too Late to Get the Coronavirus Response Right," *Homeland Security Today*, April 1, 2020, https://www.hstoday.us/subject-matter-areas/emergency-preparedness/perspective-it-is-not-too-late-to-get-the-coronavirus-response-right/.

[9] Association of State and Territorial Health Officials, "Emergency Use Authorization Toolkit: Strategic National Stockpile," webpage, accessed June 11, 2020, https://astho.org/Programs/Preparedness/Public-Health-Emergency-Law/Emergency-Use-Authorization-Toolkit/Strategic-National-Stockpile-Fact-Sheet/.

expectations for the SNS, historical underfunding of the stockpile, lack of timely decisions regarding energizing supply chains, and the federal government's altering of the mission of the SNS during this national emergency.

The History of the Strategic National Stockpile

The history of the SNS dates to 1998, when President William J. Clinton signed into law authorization for a national pharmaceutical stockpile (NPS). The U.S. Congress appropriated $51 million for pharmaceutical and vaccine stockpiles that were to be established under the CDC and within the Department of Health and Human Services (HHS).[10] Understanding the roots of the SNS is very important to understanding the response to the COVID-19 pandemic.

In fact, the rapid establishment of the NPS was in response to President Clinton's growing interest in bioterror preparedness and response. As former HHS Secretary Donna Shalala, now Congresswoman Shalala, said at the first National Symposium on Medical and Public Health Response to Bioterrorism in February 1999, "We are creating, and will be maintaining, an unprecedented national stockpile of drugs and vaccines for civilian use in case of a bioterrorist attack."[11] This early history is critical because it established the mission for the SNS as being related to bioterrorism.

The 2001 anthrax attacks, allegedly perpetrated by a scientist working at an Army disease research lab, reinforced concerns about bioterrorism and resulted in a series of Homeland Security Presidential Directives related to bioterrorism. The so-called Amerithrax attacks sickened 17 and killed five, reinforcing the case that a stockpile to be used in the event of a bioterrorism event was necessary to bolster our national biodefenses. In fact, the NPS was used in response to the Amerithrax attacks.

One of the measures undertaken during the George W. Bush administration in March 2003 was renaming the NPS to the SNS. The SNS is stored in climate-controlled facilities and has been geographically dispersed to allow for rapid deployment in the event of an emergency. Over time, the contents of the SNS have been expanded, as have the stockpile's uses. Specifically, the new SNS was expanded from "drugs and vaccines" to a stockpile of antibiotics, vaccines, antitoxins, chemical antidotes, and other medical supplies.

The original bioterror mission has been expanded and now includes preparedness and response for chemical, biological, radiological, and nuclear (CBRN) threats; pandemic influenza; and natural disasters, such as hurricanes and earthquakes. The SNS has antiflu drugs, generic medical supplies (such as ventilators, personal protective equipment [PPE] and needles), and

[10] Public Law 105–277, Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999, October 21, 1998, https://www.govinfo.gov/content/pkg/PLAW-105publ277/pdf/PLAW-105publ277.pdf.

[11] Olivia B. Waxman, "Coronavirus Is Putting the U.S. Strategic National Stockpile to the Test. Here's the Surprising Story Behind the Stash," *Time*, March 11, 2020, https://time.com/5800393/coronavirus-national-stockpile-history/.

even rapidly deployable medical centers complete with beds.[12] Portions of the SNS deployed to Hurricanes Katrina and Rita in 2005, were used for the 2009 H1N1 influenza outbreak, and were available for use during the 2014 Ebola response in the United States.

Decisions about which medicines and material should be included in the SNS are made by the HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). This governing body coordinates federal efforts to enhance CBRN and emerging infectious diseases preparedness from a medical countermeasure (MCM) perspective.[13]

The PHEMCE is led by the Office of the Assistant Secretary for Preparedness and Response (ASPR) and includes the following HHS internal agency partners: the CDC, the Food and Drug Administration, and the National Institutes of Health (NIH). It also includes several interagency partners: the Department of Defense, the Department of Veterans Affairs, the Department of Homeland Security (DHS), and the Department of Agriculture.[14] DHS uses the integrated CBRN risk assessment models, formerly run by the Science and Technology Directorate and now under the Countering Weapons of Mass Destruction Office, to develop material threat determinations (MTDs) for CBRN-related risks. These determinations signal the need for MCMs for these threats. The DHS Secretary issues the MTD, and the requirement is forwarded to the HHS and PHEMCE for action.

In the case of an emergency, state governors can request deployment of the SNS, but the federal government ultimately makes the determination to release the stockpile. During exercises, scenarios are developed that cause the SLTT capacity to become overwhelmed and therefore lead to a request for SNS support. These exercises train the SLTT participants in the procedures for requesting SNS support and require federal authorities to determine whether and how to support the requested deployments.

This process played out in the initial phases of the COVID-19 response as SLTT health systems became overwhelmed and states began requesting supplies. However, COVID-19 presented an unusual set of circumstances involving nearly simultaneous requests from all 56 SLTT authorities. The quantities of material in the stockpile were not nearly enough to fill all of the requests, resulting in a heated competition. More on this will be discussed later because it is important to considering the future of the SNS.

The overwhelming number of requests highlighted four shortfalls regarding the stockpile: (1) unrealistic expectations for the SNS, (2) the historical underfunding of the stockpile and SLTT public health preparedness, (3) a lack of timely decisions regarding energizing supply chains, and (4) the federal government's altering of the mission of the SNS during the national emergency.

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[12] Nell Greenfieldboyce, "Why Even a Huge Medical Stockpile Will Be of Limited Use Against COVID-19," *National Public Radio*, March 14, 2020, https://www.npr.org/sections/health-shots/2020/03/14/814121891/why-even-a-huge-medical-stockpile-will-be-of-limited-use-against-covid-19.

[13] HHS, ASPR, "Public Health Emergency Medical Countermeasures Enterprise," webpage, accessed June 12, 2020, https://www.phe.gov/Preparedness/mcm/phemce/Pages/default.aspx.

[14] HHS, ASPR, 2020.

Unrealistic Expectations for the Strategic National Stockpile

The original rationale for the SNS stemmed from bioterrorism preparedness and response. Over time, the mission expanded to include CBRN threats, emerging infectious diseases, and natural disasters. As the mission changed, the types of materials the SNS was charged with stockpiling also changed to include a variety of countermeasures against CBRN threats, as well as general MCMs, such as antivirals and antibiotics, that would have use against naturally occurring biological pathogens (such as the COVID-19 virus), nuclear accidents, natural disasters, and CBRN terrorist events.

Stockpiling supplies is only part of the process. Procedures must be developed and exercised for dispensing the material. Distributing portions of the SNS throughout the United States cuts down on transportation times. However, moving the supplies from these regional sites to the "last mile" (i.e., to where they are needed) and then knowing how to employ the materials has been a longstanding challenge. For example, in 2016, some users of the SNS material at the SLTT levels did not have adequate training in the use of the countermeasures and equipment.[15] To address this concern, one assessment offered the following recommendation: "The SNS should not only deliver MCMs to local public health authorities, but also support local-level dispensation efforts, provide clinical guidance about the use of MCMs, and implement the appropriate systems to monitor treatment compliance during adverse events."[16]

Another challenge inherent to the growth in missions has been stockpiling of materials with little thought on the practicalities of how that countermeasure would be used. For example, the SNS had 300 million doses of smallpox vaccines, which would be enough for almost the entire country. However, that is not the likely way that response to a smallpox attack would be handled. The vaccine often causes side effects, is not recommended for either children under two or their parents and cannot be given to immunocompromised individuals. Therefore, it is more likely that a ring vaccination technique that relies on contact tracing and vaccinating only those who have been exposed would be the more likely option for use of the vaccine. In fact, this was how humankind eliminated smallpox as a naturally occurring disease in the late 1970s.[17]

Although large-scale events were often considered in discussions about the SNS, these discussions did not account for the realities of such events. The scenarios were often geographically limited in exercises. For example, in addressing response to an improvised nuclear device, the exercise would look at a single device being exploded in a major city. Exercises that saw all 56 states, territories, and the District of Columbia affected simultaneously (or nearly simultaneously) were not played out to conclusion, meaning that the effects of the rapid depletion of SNS supplies were not fully played out. Most exercises dealing with pandemic influenza were tabletop exercises that did not exercise the last mile.

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[15] National Academies of Sciences, Engineering, and Medicine, *The Nation's Medical Countermeasure Stockpile: Opportunities to Improve the Efficiency, Effectiveness, and Sustainability of the CDC Strategic National Stockpile: Workshop Summary*, Washington, D.C.: National Academies Press, 2016, p. 6.

[16] National Academies of Sciences, Engineering, and Medicine, 2016, p.6.

[17] World Health Organization, "Smallpox," webpage, undated, https://www.who.int/csr/disease/smallpox/en/.

This is not to say that those who developed and maintained the SNS were unaware of the shortcomings, but these same understandings and expectations were not necessarily held by the SLTT governments, which were depending on federal support from the SNS. In reference to the stockpile capacity, the 2016 National Academies of Sciences, Engineering, and Medicine chairperson of a study of the SNS concluded, "It's never going to be as big as you want, because it's just too expensive to do that."[18] In fact, the SNS provides a nearly immediate capacity for rapid response to emergencies but should be considered a bridge that allows private sector manufacturers to ramp up their production.[19] Unfortunately, during the COVID-19 response, this ramping up was slow in coming. Even today, supplies for testing and PPE remain in short supply and certainly constitute less than is required.

Historical Underfunding of the Stockpile and SLTT Public Health Preparedness

The stockpile contains approximately $8 billion worth of supplies and requires rotation of stocks to ensure they remain current. The annual budget is approximately $575 million.[20] However, neither the stockage levels nor funding were ever considered to be adequate for large-scale biological events, certainly not ones that affected all 56 states, territories, and the District of Columbia simultaneously. One former director of the stockpile cited several challenges to maintaining the stockpile, including limited funds, costly treatments that are not mass-manufactured because the afflictions are so rare, and treatments with short shelf lives. The director of the stockpile for more than a decade (before retiring in January 2020) said, "The stockpile was never intended to meet every need.[21] Of note, the 2020 SNS budget has been raised to $705 million.

Congressional underfunding of the SNS has also resulted in shortages in the stockpile. Congressionally ordered budget cuts resulted in some of the stocks that were used during the 2009 H1N1 response not being replenished (most notably, 85 million N-95 masks).[22]

Shortfalls in resources for state and local public health departments have also resulted in underperformance during the COVID-19 response. State and local public health departments have been under-resourced for decades, with one analysis indicating that 52 health agencies (48 states, three territories, and the District of Columbia) had reported budget cuts from 2008 to

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[18] Greenfieldboyce, 2020.

[19] Greenfieldboyce, 2020.

[20] Donovan Slack and Dinah Voyles Pulver, "US Never Spent Enough on Emergency Stockpile, Former Managers Say," *USA Today*, March 27, 2020, https://www.usatoday.com/story/news/investigations/2020/03/27/u-s-never-spent-enough-emergency-stockpile-former-managers-say/2915567001/.

[21] Slack and Voyles Pulver, 2020.

[22] Jane C. Timm, "Fact Check: Trump Falsely Claims Obama Left Him 'Nothing' in the National Stockpile," *NBC News*, May 6, 2020, https://www.nbcnews.com/politics/donald-trump/fact-check-trump-falsely-claims-obama-left-him-nothing-national-n1201406.

2014.[23] The Trump administration's fiscal year 2020 budget proposal would have further exacerbated the issue, calling for significant reductions to the CDC and NIH, which would have received 12 percent and 10 percent reductions, respectively.[24] Of note, these same state and local public health professionals are charged with conducting contact tracing, which is vital to biosurveillance and, ultimately, to halting the spread of the disease and getting people back to work and the economy restarted.

Expecting individual SLTT authorities to resource and maintain large stockpiles of specialized CBRN supplies or the quantities of material that would be required for large-scale events (such as the COVID-19 pandemic) would be unrealistic. In many cases, they lack understanding of the threats, and they lack technical capacity and resources to develop and maintain such a stockpile capability. The requirements would be exacerbated, given the large number of scenarios they would need to prepare for.

The response to COVID-19 at the SLTT level—in particular, the competition for supplies—was also affected by decisions made at the federal level. The HHS is designated as the sector-specific lead agency for the health care and public health sector for all emergencies, including a pandemic. Initially, Secretary of Health and Human Services Alex Azar was in charge of the response. However, the president putting Vice President Mike Pence in charge of the response represented a change in doctrine.

In standing up the White House Coronavirus Task Force on January 29, the president essentially disconnected some of the relationships that were needed to handle routine issues associated with disaster response and recovery. Many of these relationships ran down into state public health offices, which were in charge of the COVID-19 response in their respective states. Not relying on doctrine at the federal level has caused confusion at the state and local level as well. The effect was to reduce emergency management professionals' roles in the decisionmaking and to hinder the ability of the normal information and supply chains to function.

As a result, almost 220 years of U.S. emergency management experience going back to 1803 got a makeover during the COVID-19 response.[25] The notion that preparedness and response consist of a series of nested systems designed to support state and local authorities when their capabilities become overwhelmed was no longer the central organizing construct for this response. Furthermore, it was no longer the process that had been planned and exercised for decades: "The locals execute, the states coordinate, and the feds support." The federal government had created a "parallel response apparatus."[26]

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[23] Association of State and Territorial Health Officials, "Budget Cuts Continue to Affect the Health of Americans," September 2014, https://www.astho.org/budget-cuts-Sept-2014.

[24] Kim Krisberg, "President's Budget Would Hinder US Public Health Progress: Huge Cuts Proposed," *The Nation's Health*, Vol. 49, No. 3, May 2019.

[25] FEMA P-592, Stafford Act, as Amended, and Related Authorities, May 2019, https://www.fema.gov/media-library-data/1582133514823-be4368438bd042e3b60f5cec6b377d17/Stafford_June_2019_508.pdf.

[26] Joel Rose, "A 'War' for Medical Supplies: States Say FEMA Wins by Poaching Orders," *National Public Radio*, April 15, 2020, https://www.npr.org/2020/04/15/835308133/governors-say-fema-is-outbidding-redirecting-or-poaching-their-medical-supply-or.

Lack of Timely Decisions Regarding Energizing Supply Chains

Response to a large-scale event requires making timely decisions according to the emerging situation. It implies having situational awareness, effective communications across the federal government and SLTT governments, coordination and partnership with the private sector for providing key supplies and services, and regular, clear, and accurate strategic communications with citizens who must follow the guidance and direction. Shortfalls in these areas created confusion that prevented the timely emerging of critical supply chains.

Despite China's lack of initial transparency, initial reports of the virus were provided to the CDC by Chinese counterparts on January 3, 2020. U.S. intelligence agencies—which had been following events in China since late November—began regularly reporting on the coronavirus spread throughout January and into early February.[27] By 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.

Despite this information, miscues—particularly at the federal level in the early stages—hindered mounting a coherent national response and rapidly energizing the capabilities that would be essential to understanding the progression of COVID-19. These shortfalls undoubtedly resulted in greater mortality and morbidity because they led to decisions that were some two to four weeks later than would have been useful to contain the spread of the disease in the United States in the early stages of the pandemic.[28]

During this early period, a failed CDC test that had to be recalled and mixed messaging contributed to inaction regarding activating our supply chains and manufacturing capacity. Without adequate testing, biosurveillance and contact tracing were not possible, requiring nonpharmaceutical interventions to prevent the further spread of the disease and attempt to flatten the curve. The federal response also failed to learn the lessons of nations such as South Korea that had been successful in containing the disease.[29]

Delays in declaring a national emergency (and waiting for the World Health Organization to declare the coronavirus outbreak a pandemic) meant that the Federal Emergency Management Agency (FEMA) was limited in its ability to begin preparations. FEMA efforts—largely triggered by the emergency declaration under the Stafford Act—began on March 13, 2020. By mid-April, a "war for medical supplies" was being waged, with one account stating that "FEMA wins by poaching orders."[30] In effect, there was a confused national response, and the different

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[27] Shane Harris, Greg Miller, Josh Dawsey, and Ellen Nakashima, "U.S. Intelligence Reports from January and February Warned About a Likely Pandemic," *Washington Post*, March 20, 2020, https://www.washingtonpost.com/national-security/us-intelligence-reports-from-january-and-february-warned-about-a-likely-pandemic/2020/03/20/299d8cda-6ad5-11ea-b5f1-a5a804158597_story.html.

[28] Daniel M. Gerstein, "The Federal Research Enterprise and COVID-19: A Lesson in Unpreparedness," testimony presented to the House Science, Space, and Technology Committee on May 5, 2020, Homeland Security Operational Analysis Center operated by the RAND Corporation, CT-A360-1, 2020, https://www.rand.org/pubs/testimonies/CTA360-1.html.

[29] Gerstein, 2020.

[30] Rose, 2020.

levels of the government (federal and SLTT) were competing against each other rather than collaborating.

The delay in understanding the urgency of the situation resulted in early failures to take advantage of opportunities to acquire critical supplies. Reports have surfaced that some manufacturers of PPE offered the federal government opportunities to ramp up production of key equipment but their overtures were rebuffed—with one vendor indicating that a senior member of the administration expressed "little immediate interest in the offer."[31]

Debates played out publicly about whether to invoke the Defense Production Act (DPA), which also delayed the decisionmaking at the federal level and resulted in lost time. One account summarizes the president's decision regarding the DPA as "Mr. Trump has elected to rely on the volunteerism of the private sector to obtain additional personal protective equipment, virus test kits and hospital equipment." This is curious because the DPA has been used hundreds of thousands of times by the Department of Defense and over a thousand times by DHS in 2018.[32]

The result of the supply chain mismanagement was critical shortages. One survey taken in April 2020 of 978 institutions, from 47 states and Washington, D.C., found that there were growing shortages of N-95 masks, surgical masks, face shields, booties, gloves, gowns, hand sanitizer, disinfecting wipes ,and thermometers. More than one-third of the institutions responded that they had no face shields, booties, or thermometers. Twenty percent had no N-95 masks or gowns remaining. Nearly all had no supplies remaining of at least one form of PPE.[33] Interestingly, a shipment was made to China in early February of 17 tons of donated U.S. masks and medical supplies that, only a few weeks later, would be in short supply for mounting the U.S. initial response.[34]

Federal Government's Altering of the Mission of the Strategic National Stockpile During the National Emergency

Emergency management in the United States is based on the understanding that all initial response is local. When local authorities no longer have the capacity to mount an effective response, states provide necessary support. When the state capacity is exhausted, federal support is requested by the states and invoked by the president through a Stafford Act declaration. The

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[31] Aaron C. Davis, "In the Early Days of the Pandemic, the U.S. Government Turned Down an Offer to Manufacture Millions of N95 Masks in America," *Washington Post*, May 9, 2020, https://www.washingtonpost.com/investigations/in-the-early-days-of-the-pandemic-the-us-government-turned-down-an-offer-to-manufacture-millions-of-n95-masks-in-america/2020/05/09/f76a821e-908a-11ea-a9c0-73b93422d691_story.html.

[32] Zolan Kanno-Youngs and Ana Swanson, "Wartime Production Law Has Been Used Routinely, but Not with Coronavirus," *New York Times*, March 31, 2020, https://www.nytimes.com/2020/03/31/us/politics/coronavirus-defense-production-act.html.

[33] Zoë Schlanger "Begging for Thermometers, Body Bags, and Gowns: U.S. Health Care Workers Are Dangerously Ill-Equipped to Fight COVID-19," *Time*, April 20, 2020, https://time.com/5823983/coronavirus-ppe-shortage/.

[34] Glenn Kessler, "Did Trump Ship 17 Tons of 'American' Masks and Medical Supplies to China?" *Washington Post*, April 22, 2020, https://www.washingtonpost.com/politics/2020/04/22/did-trump-ship-17-tons-american-masks-china/.

Stafford Act allows the president to declare a major disaster or emergency and provides access to the Disaster Relief Fund. The national emergency management system also has established doctrine for reporting information and making requests for support. The structure includes frameworks, critical functions, and training and exercises designed to test systems and ensure proficiency. An important part of the emergency management doctrine involves managing the logistics and supply chains that support the response. COVID-19 has exposed both the interconnectedness and the shortfalls of these global supply chains.

The state requests for access to the SNS proved to be overwhelming and resulted in a change to the mission statement of the SNS. This change created tensions regarding the 1988 Stafford Act, which describes the process for federal natural disaster assistance for state and local governments. Equally important is that this change upended established national emergency management doctrine that has been repeatedly exercised. This doctrine is embedded in the expectations for and management of the SNS.[35]

Since December 2018, the SNS mission on the HHS website was for the SNS to be available "when state, local, tribal, and territorial responders request federal assistance to support their response efforts" and to ensure the "right medicines and supplies get to those who need them most during an emergency."

Shortly after a statement made by Jared Kushner on April 2, 2020, the mission on the website was changed to indicate the SNS was intended to "supplement state and local supplies during public health emergencies" and noted that "many states have products stockpiled as well." The revised mission also stated that the SNS is intended to be "a short-term stopgap buffer when the immediate supply of adequate amounts of these materials may not be immediately available."[36]

The changes to the SNS mission had important implications for states that were depending on the SNS. The reformulation of the purpose of the SNS was not in keeping with the national emergency management doctrine—which focuses on the federal government supporting the states when their capacity is overrun—nor with the planning exercises that were conducted prior to the pandemic. Nor is such an approach practicable given the specialized countermeasures that are stocked in the SNS and the cost of maintaining the stockpile. Furthermore, given the significant underfunding of SLTT public health programs, building and maintaining their own stockpiles would also likely not be a high priority in competition with other public health priorities.

Rethinking the Strategic National Stockpile

The COVID-19 pandemic is highlighting the need to rethink the SNS. The combination of unrealistic expectations for the SNS, historical underfunding of the stockpile, lack of timely decisions regarding energizing supply chains, and the federal government's altering of the mission of the SNS during this national emergency signal that such an examination is in order. It

[35] FEMA P-592, 2019.

[36] Andrew Feinberg, "Strategic National Stockpile Website Changes After Jared Kushner's Controversial Claim It Was Not for States' Use," *Newsweek*, April 3, 2020, https://www.newsweek.com/strategic-national-stockpile-website-changes-after-jared-kushners-controversial-claim-it-was-not-1496051.

should include a consideration of how the stockpile is managed, provisioned, resourced, and accessed to ensure expectations are understood and realistic.

With the COVID-19 response, we are witnessing an inability to scale at the national level to meet the demands of a public health emergency. The United States relies on a "just in time" medical delivery system, which cannot provide the necessary PPE and specialized equipment (such as ventilators) required for a widespread naturally occurring pandemic such as COVID-19. The pandemic is also demonstrating the interconnectedness of the global supply chains, which source PPE and supplies, such as reagents for testing. In previous exercises dealing with public health emergencies, the answer has consistently been to request support from the SNS; yet, as COVID-19 demonstrates, this strategy might not be prudent. In 2018, the stockpile was transferred from the CDC to the ASPR within the HHS. Although the stockpile has a stated purpose that includes providing support during a pandemic response, the stockage levels and types of vaccines and therapeutics indicate a predisposition toward response to a bioterrorism event or a much smaller outbreak event, such as the 2014 Ebola response. Furthermore, some have expressed concern that this transfer from the CDC to ASPR could have played a role in the SNS issues experienced during COVID-19, as ASPR's Assistant Secretary Robert Kadlec shifted focus to "biologic attacks, intentional attacks, terrorist attacks, and definitely away from natural disease outbreaks."[37]

General equipment in the stockpile, such as PPE and ventilators, would be useful regardless of whether the incident is a pandemic or bioterrorism event, but the stockpile was not intended to have enough for supplying a national crisis of this magnitude.[38] The failure to replenish the SNS after previous biological incidents exacerbated the situation and left the stockpile with less than authorized stocks at the beginning of this pandemic.[39] The result of these shortages is that governors have to search on the open market to find needed supplies and the federal government has changed its definition of the stockpile's purpose midway through this pandemic.[40]

The National Security Council under President Obama, in coordination with other government organizations involved with pandemic response, developed a playbook in 2016 that provided a set of priorities and insights for managing a pandemic of this magnitude. It was developed because of the Obama administration's concerns about response to the 2014–2015 Ebola outbreak. Although the Trump administration was briefed about the playbook, it was not used for the COVID-19 response. The playbook covered many of the issues encountered during

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[37] Peter Weber, "Trump Official in Charge of National Stockpile Bet Big on Smallpox and Anthrax, Cut Infectious Disease Funds," *The Week*, May 5, 2020, https://theweek.com/speedreads/912735/trump-official-charge-national-stockpile-bet-big-smallpox-anthrax-cut-infectious-disease-funds.

[38] Lev Facher, "The Coronavirus Outbreak Has Left Medical Supplies in Short Supply. Is the Nation's Emergency Stockpile Ready to Help?" *STAT,* March 10, 2020, https://www.statnews.com/2020/03/10/coronavirus-strategic-national-stockpile.

[39] Doug Palmer, "U.S. Medical Stockpile Wasn't Built to Handle Current Crisis, Former Director Says," *Politico*, April 8, 2020, https://www.politico.com/news/2020/04/08/national-stockpile-coronavirus-crisis-175619.

[40] Nathaniel Weixel, "Trump Administration Changes Definition of National Stockpile After Kushner Remarks," *The Hill*, April 3, 2020.

the COVID-19 response, such as early actions in response to credible threats, use of emergency funds and the SNS, and the DPA.[41]

The complexity regarding developing, maintaining, and employing a stockpile means that SLTT governments will continue to depend on the federal government for much of their stockpiling. In addition, many of the MCMs and supplies cannot necessarily be developed in advance. Each biological pathogen is different, and specific diagnostics, therapeutics, and vaccines must be developed for each. For example, point-of-care diagnostics for use in a clinical setting to identify who is infected and serological tests to determine who has antibodies to COVID-19 must be developed using the genomic sequence of the pathogen to ensure specificity and sensitivity. We also need to be able to mass produce these diagnostics, therapeutics and vaccines at the speed of the disease.

Many lessons have been learned about the shortages in supplies, equipment, and services, including regarding the SNS. On June 9, 2020, this committee heard from a government panel in a hearing titled "Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic." Witnesses included Admiral Brett Giroir, Assistant Secretary for Health at HHS; Peter Gaynor, the FEMA Administrator; and Rear Admiral John Polowczyk, Vice Director for Logistics for the Joint Chiefs of Staff. The testimony included discussions of the challenges presented by this pandemic, with particular focus on obtaining supplies such as PPE and material for testing kits. The witnesses highlighted the global competition for these supplies and the inadequacy of the SNS for meeting these challenges.[42]

Concerning the supply chain challenges, Administrator Gaynor said, "FEMA typically manages abundant resources for disasters that are limited in geographic scope and impact. In responding to COVID-19, FEMA has had a much different and difficult task of managing the lack of critical medical supplies and equipment. Rather than managing resources, we are managing shortages."

The testimony also highlighted the innovations developed for responding to the pandemic. FEMA created a Supply Chain Stabilization Task Force and established an airbridge to "expedite critical supplies already purchased and owned by some of the nation's largest medical distributors with the goal of providing temporary relief through stabilizing supply chains."[43] FEMA also developed a data lake of information and used a health care supply chain tool from the Department of Defense to manage distribution of critical supplies. This was done in real time during the crisis. However, the amount of equipment obtained represented only a fraction of the critical needs. In addition, mixed messaging at the federal level regarding responsibility for

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[41] Dan Diamond and Nahal Toosi, "Trump Team Failed to Follow NSC's Pandemic Playbook," *Politico*, March 25, 2020, https://www.politico.com/news/2020/03/25/trump-coronavirus-national-security-council-149285.

[42] Senate Homeland Security and Governmental Affairs Committee, "Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic," June 9, 2020, https://www.hsgac.senate.gov/evaluating-the-federal-governments-procurement-and-distribution-strategies-in-response-to-the-covid-19-pandemic.

[43] On March 20, 2020, the Supply Chain Stabilization Task Force was established to address the widespread shortfalls amid the global competition for life-saving equipment. The task force consisted of over a dozen departments and agencies across the U.S. government and liaisons from the private sector.

acquiring test kits and conducting testing, the SNS purpose, and obtaining critical equipment shortages created unnecessary confusion, leaving SLTT authorities to fend for themselves. The new system, particularly the airbridge, has received considerable criticism: Although timelines for delivery appear to have been positively affected, it added to the supply chain confusion and has triggered allegations about FEMA poaching state procured supplies, a lack of oversight, and using taxpayer dollars while allowing private companies to benefit financially.

The global competition turned into a national competition among federal, state, local, tribal, and territorial authorities. As the inadequacy of the SNS became clearer, lower levels were left to fend for themselves, as in the case of Maryland's governor procuring a half-million test kits from South Korea.[44] This affected the Emergency Management Assistance Compact, which is the mutual aid agreement among states and territories of the United States.[45] Given the supply shortages, what should have been collaboration between states turned into a fierce competition for resources.

COVID-19 has also proved illuminating regarding global supply chains for essential pandemic supplies. Much of the material for the medical community comes from overseas markets. In early March, one account highlighted that the United States required 300 million respirators and face masks to protect health workers but that the SNS had less than 15 percent of this requirement. Additionally, the United States is the world's largest importer of pharmaceuticals and medical supplies from China, which manufactures some 50 percent of global totals.[46] Notably, Rear Admiral Polowczyk in his testimony spoke of needing to change this dynamic and said, "Using the Defense Production Act, we are creating investment across manufacturers in the U.S. to make domestic production equal to the surging COVID demand."

In short, the national supply system had failed, including the SNS, which failed to deliver as expected, even if those expectations were overhyped and perhaps even unrealistic. Even months into the response, shortages in PPE continue to be an issue.

Recommendations

The response to COVID-19 has exposed key shortfalls in our nation's preparedness and response capabilities. Going forward, the United States should undertake a comprehensive accounting of the COVID-19 pandemic by a bipartisan commission. Basic assumptions—including regarding the role of government at all levels in emergency management and disaster preparedness and response—should be on the table. Several DHS organizations, in addition to departments and agencies that have responsibilities as part of the PHEMCE, should be part of this discussion. The SNS should also feature prominently in these discussions.

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[44] Brakkton Booker, "Maryland Buys 500,000 Test Kits from South Korea, Drawing Criticism From Trump," *National Public Radio*, April 21, 2020, https://www.npr.org/sections/coronavirus-live-updates/2020/04/21/839919655/maryland-gets-500-000-test-kits-from-south-korea-drawing-criticism-from-trump.

[45] Emergency Management Assistance Compact, homepage, undated, https://emacweb.org/.

[46] Nsikan Akpan, "U.S. Has Only a Fraction of the Medical Supplies It Needs to Combat Coronavirus," *National Geographic*, March 3, 2020, https://www.nationalgeographic.com/science/2020/03/us-america-has-fraction-medical-supplies-it-needs-to-combat-coronavirus/.

To this end, I offer five recommendations that focus on the stockpiling, the supply chains, and the decisionmaking process and that should be considered for improving our nation's preparedness and response capabilities.

1. **Reexamine the SNS concept.** The COVID-19 response has exposed critical weaknesses in the SNS; has represented a significant departure from planning, doctrine, and exercises; has left the states, in particular, to fend for themselves; and has caused a loss of confidence in the federal government. The root causes of this underperformance should be evaluated, and actions should be taken to ensure such a deficit does not occur during future events. Specific actions should frame this reexamination. First, Congress could ask for a report evaluating the SNS's performance during COVID-19. Second, the mission of the SNS must be reconsidered. A new mission statement, codified in law and not subject to the whims of any administration, should be developed to signal the capacities and limits of the SNS. Third, the new stockpile concept must be stress-tested and optimized through training and exercises to ensure it meets the preparedness and response goals that have been set.
2. **Develop a strategic national supply chain approach.** Many have called for the United States to decouple manufacturing and supply chains and to develop an indigenous capacity for production of critical supplies and equipment, with some even calling for complete independence from the global market for such items. Although this might not be economically prudent, developing an approach for all critical items that combines stockpiling, direct contracting with manufacturers, warm production lines for some key commodities, procuring large quantities at the national level to take advantage of economies of scale, and shortening supply chains should be looked at to determine the most effective and most efficient methods for ensuring 100 percent of critical needs will be met for envisioned scenarios.[47] Using such an approach would require all critical equipment and supplies to be independently mapped out to allow for a determination of their anticipated availability over time. This approach would require inputs from key stakeholders, including government (federal and SLTT), industry, and the Emergency Support Function (ESF) #8 – Public Health and Medical Services sector.
3. **Increase public health funding.** Years of underfunding of SLTT public health programs should be reversed. Public health should be considered a national security issue and should receive similar priority in funding as the Department of Defense and Intelligence Community. These public health shortages affect preparedness and response for a wide variety of naturally occurring public health events, accidents and natural disasters, and deliberate attacks. For COVID-19, inadequate public health funding affected staff support to government leaders at all levels, biosurveillance activities (including contact tracing), stockpile shortages at the beginning of the pandemic, and broader supply chain issues. Public health shortages have also adversely affected the CDC and NIH. The lack of an operational capability that supports public health emergencies directly relates to shortfalls in public health funding as well. FEMA provides the management structure for all hazard response. ESF #8 represents a loose collection of public and private departments, agencies, and organizations for coordination but does not create a unity of effort in addressing public health emergencies. When considering the lessons learned, perhaps an

[47] Smartsheet, "Supply Chain Management 101: Principles, Examples, and Templates," webpage, undated, https://www.smartsheet.com/supply-chain-management.

important issue to be addressed is the utility of having the national capacity for a more operationally focused national public health enterprise.

4. **Develop the vaccine distribution system now.** An important part of the supply chain for this current pandemic will entail the distribution of a vaccine when it becomes available. Just as with the SNS, the last mile should be considered for vaccine distribution. Some have public health officials have claimed that a vaccine will be available by early 2021, but much remains to be done before a safe and effective vaccine is ready for widespread use: getting the science right, vaccine trials, production and distribution of the vaccines, and administering the vaccine at scale to populations. Given the time, expense, and regulatory requirements of vaccine development, global collaboration would speed up vaccine development, lead to more-rapid approvals, and help determine priorities for vaccine administration.[48] The U.S. government has committed to spending $1.2 billion to obtain 300 million doses of the Oxford vaccine that is in development.[49] This is encouraging, but planning should be ongoing now for administering a COVID-19 vaccine here in the United States and globally. Only after a large portion of the world is immunized will COVID-19 be controlled. Key questions remain: What will be the priority for vaccination? Who will pay for vaccination of the population in the United States (e.g., the government or individual) and globally (e.g., funded by individual nations or similar to PEPFAR[50])? Can a policy that requires individuals to pay the costs be successful? What happens to people who refuse vaccination?
5. **Reestablish U.S. leadership in global public health.** U.S. global leadership is needed now more than ever. International collaboration will continue to be important to understanding the spread of COVID-19 and developing key MCMs. This collaboration will also be important to preventing and managing new instances of the virus in developing countries and for vaccine trials. We should also seek to repair our relationship with the World Health Organization while working to make the organization more accountable. We need the World Health Organization to serve as a conduit for information and to coordinate with other nations as the COVID-19 disease spreads to other parts of the world and for future international health crises.

Conclusion

We should expect to see more pandemic events like COVID-19, given human activities that disrupt environmental habitats, promote the mixing of species, and allow humans and pathogens to crisscross the world along global supply chains. Efforts should be made now to address these events more effectively in the future.

Some have called the novel coronavirus a *black swan event*: an event that is unforeseen. I reject that characterization: We have had ample evidence of the potential for a global pandemic

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[48] Kari Oakes, "COVID-19 Vaccine Race a Balance of Safety and Speed," *Medscape*, April 20, 2020, https://www.medscape.com/viewarticle/929072#vp_2.

[49] Julie Steenhuysen, "Exclusive: U.S. Plans Massive Coronavirus Vaccine Testing Effort to Meet Year-End Deadline," Reuters, May 22, 2020, https://www.reuters.com/article/us-health-coronavirus-usa-vaccine-exclus/exclusive-us-plans-massive-coronavirus-vaccine-testing-effort-to-meet-year-end-deadline-idUSKBN22Y2L3.

[50] The U.S. President's Emergency Plan for AIDS Relief.

and, indeed, more than one national commission to advise on how to plan for one. However, competing priorities, inadequate funding, and a lack of national focus led us to ignore this potentially existential threat until it was too late. Underperformance has contributed to a lackluster national response, including failures in supply chains (and the SNS) that could not respond to the growing demands for critical equipment, supplies, and services.

Thank you again for the opportunity to appear today, and I look forward to your questions.