

COVID-19 Rapid Response Impact Initiative | White Paper 23

Policy Lessons from the History of Pandemic Preparedness

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This white paper draws lessons for policy progress from the recent history of pandemic preparedness in the United States, with a focus on the Strategic National Stockpile of medical and protective equipment that forms an essential element of pandemic response efforts. This paper finds that supplies of vital protective equipment in the Strategic National Stockpile were greatly diminished in the years preceding the Coronavirus Disease 2019 (COVID-19) pandemic; this atrophy of pandemic vigilance contributed to prolonged shortages of equipment needed to protect healthcare workers and first responders from infection during the COVID-19 pandemic. This paper proposes a strategy of reform for the Strategic National Stockpile designed to secure a sustained evolution of vigilance for the purpose of defending the United States against future pandemics.

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01 Introduction

The Coronavirus Disease 2019 (COVID-19) pandemic has revealed major gaps in the pandemic preparedness of the United States (Alexander 2020). Pandemics pose a perpetual threat to public health across the world, and it is therefore important to apply the lessons learned from the COVID-19 pandemic to improve preparedness for the likelihood of future pandemics. The purpose of this paper is to draw lessons for progress from the recent history of U.S. pandemic preparedness, with a focus on the national stockpile of medical and protective equipment that forms an essential element of pandemic response efforts. Beginning in 1999 the federal government established a stockpile of medical and protective supplies at secret sites across the country; this network of sites is now known as the Strategic National Stockpile and constitutes the largest emergency medical stockpile in the United States (Burel 2019a, 2019c; Herrera and Gottron 2020; Murray and Glover 2020; Patel et al. 2017). The usefulness of the Strategic National Stockpile for pandemic preparedness became fully evident in 2009, when the stockpile distributed substantial supplies of protective and medical equipment to assist with the response to the 2009 H1N1 influenza pandemic (National Academies of Sciences, Engineering, and Medicine 2016). Yet supplies of protective equipment were not subsequently replenished in the stockpile during the period of 2009 to 2019, and the stockpile was therefore much less prepared for the COVID-19 pandemic than it was for the 2009 H1N1 pandemic (Manjoo 2020; Reinhard and Brown 2020). During the COVID-19 pandemic in the United States, the prior depletion of the national stockpile contributed to widespread and prolonged shortages of equipment needed to protect healthcare workers and first responders from infection by the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) pathogen that caused the pandemic (GAO 2020; Jacobs 2020).

This paper argues that the diminishment of supplies in the Strategic National Stockpile is an important example of the atrophy of vigilance in pandemic preparedness. In this context, the atrophy of vigilance refers to the erosion of safeguards against pandemics over time as public and political attention shifts

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Introduction

away from public health hazards to other policy topics and funding priorities. Research has identified the atrophy of vigilance as a significant problem in the management of hazards that can lead to declining safety over time (Freudenburg 1992). However, research has also demonstrated that the atrophy of vigilance can be counteracted by reforms that allow for the evolution of vigilance—a sustained strengthening of safeguards against a hazard over time (Busenberg 1999). This paper argues that the early years of the Strategic National Stockpile established a trajectory of evolving vigilance for pandemic preparedness that subsequently eroded into the atrophy of vigilance due to diminishing public and political attention to the subject of pandemics. This paper further argues that the management of the stockpile should be reformed to focus on a sustained evolution of vigilance for the purpose of defending the U.S. against future pandemics. The stockpile of critical supplies for pandemic preparedness should be sustained and improved over time through a process of policy learning, defined as the application of new ideas and information to policy decisions (Busenberg 2001). Future investments in the Strategic National Stockpile should focus on securing the evolution of vigilance in pandemic preparedness through a strategy of policy learning designed to adapt dynamically in response to experience, advancing technologies, and the unending hazard of rapidly evolving pathogens. This paper was developed by combining information and insights from the academic literature, government reports, presidential documents, statutes, federal regulations, and media reports. These sources are the basis of the policy history described next.

02 The Development of the Strategic National Stockpile

The origins of the Strategic National Stockpile are found in a 1998 public health initiative from the Clinton administration intended to create the first federal stockpile of medical countermeasures as a preparedness measure for biological or chemical attacks on the civilian population of the United States (Burel 2019a, 2019c; Clinton 1998, 1999a). The stockpile was originally named the National Pharmaceutical Stockpile, and was placed under the management of the Centers for Disease Control and Prevention (CDC) within the U.S. Department of Health and Human Services (HHS). The National Pharmaceutical Stockpile began operating in 1999, with a congressional appropriation of \$51 million for fiscal year 1999 (Alexander 2020; Burel 2019a, 2020). Congressional support for the National Pharmaceutical Stockpile soon wavered. The stockpile became the target of budget cuts in an appropriations bill for fiscal year 2000 that provided less than half of the stockpile funds requested by President Clinton; these budget cuts were averted when Clinton vetoed the bill (Clinton 1999b). Congress subsequently enacted appropriations legislation that fully funded the \$52 million requested by Clinton for the stockpile in fiscal year 2001 (Clinton 2000; Herrera and Gottron 2020).

The stockpile budget and supplies were greatly reinforced during the George W. Bush administration due to concerns over bioterrorism and pandemics (Bush 2004a, 2004b, 2005a, 2005b). In 2002 the stockpile was renamed the Strategic National Stockpile, and the stockpile budget was augmented by an order of magnitude (Herrera and Gottron 2020). The period of 2002 through 2008 was characterized by a constructive evolution of vigilance in the Strategic National Stockpile, as increased funding allowed the reinforcement of the stockpile with supplies of protective equipment that would be useful in pandemics (Murray and Glover 2020; Patel et al. 2017). During this period, the stockpile was briefly transferred to the new Department of Homeland Security, then subsequently returned to HHS. The Homeland Security Act of 2002 (Public Law 107-296) transferred the Strategic National Stockpile to the Department of Homeland Security, although the CDC would continue to manage normal stockpile operations. The

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Project BioShield Act of 2004 (Public Law 108-276) transferred the Strategic National Stockpile back to HHS (Alexander 2020). In 2005, the Bush administration announced a national strategy for pandemic influenza that highlighted the importance of the Strategic National Stockpile in pandemic preparedness (Bush 2005a, 2005b). The stockpile distributed substantial supplies in support of the 2005 responses to Hurricanes Katrina and Rita (Alexander 2020; Burel 2019b). The response to Hurricane Katrina revealed major gaps in national disaster management systems, and increased the political impetus for progress in pandemic preparedness (DeLeo 2015). In 2006, the Pandemic and All-Hazards Preparedness Act (Public Law 109-417) placed the Strategic National Stockpile under the authority of the HHS Assistant Secretary for Preparedness and Response (ASPR). The value of the stockpile for pandemic preparedness was demonstrated in 2009 when the federal government distributed huge quantities of protective and medical items to assist in the response to the 2009 H1N1 influenza pandemic (Burel 2019b; National Academies of Sciences, Engineering, and Medicine 2016). The national response to the 2009 H1N1 pandemic was generally effective, but pandemic preparedness subsequently suffered. The atrophy of vigilance quickly set in as congressional and media attention to the subject of pandemic influenza faded in the aftermath of the 2009 H1N1 pandemic (DeLeo 2015). In the years following the 2009 H1N1 pandemic, the stockpile did not replenish supplies of vital respiratory protection equipment in high demand during the pandemic (Reinhard and Brown 2020). The result was a depleted and inadequate supply of protective equipment in the stockpile at the inception of the COVID-19 pandemic. As shown next, the stockpile was subject to the atrophy of vigilance during the period between pandemics.

03 The Atrophy of Vigilance in the Strategic National Stockpile

A pronounced atrophy of pandemic vigilance became evident in the Strategic National Stockpile in the wake of the 2009 H1N1 pandemic, reflecting diminished political attention to the subject of pandemic influenza and consequent underfunding of the stockpile (Burel 2020; DeLeo 2015; GAO 2020; Murray and Glover 2020; Reinhard and Brown 2020). This atrophy was most evident in the depleted numbers of N95 filtering facepiece respirators in the national stockpile. N95 respirators are a vital element of pandemic preparedness because they provide a high level of protection against the transmission of respiratory diseases, and these respirators are therefore in great demand by healthcare professionals and first responders during pandemics. The N95 respirator is designed to filter out at least 95 percent of airborne particles, including a wide range of pathogens. To fully achieve this level of protection, the respirator needs to be tested annually on the individual user to ensure a correct fit (and the user also needs to check the seal on the respirator before each use). The tight-fitting N95 respirators differ from surgical masks; loose-fitting surgical masks do not need to be fitted or seal-checked, but provide more limited protection against the transmission of respiratory disease when compared to N95 respirators. Various models of N95 respirators are laboratory-tested for effectiveness by the National Personal Protective Technology Laboratory (NPPTL). Established in 2001, the NPPTL is a division of the National Institute for Occupational Safety and Health (NIOSH) within the CDC (NIOSH 2018). Respiratory protection is a central element of the work of the NPPTL. Laboratory testing and approval of respirators is conducted by the NPPTL according to detailed requirements contained in Title 42, Part 84 of the Code of Federal Regulations (NIOSH 2018). In 2006 the federal government purchased 104 million N95 respirators for the Strategic National Stockpile (Patel et al. 2017). In 2009 the federal government distributed more than 85 million N95 respirators from the Strategic National Stockpile to assist with the 2009 H1N1 influenza pandemic (Alexander 2020; Burel 2019b; National Academies of Sciences, Engineering, and Medicine 2016). However, the supply of N95 respirators in the national stockpile was not substantially replenished in the years between the 2009 H1N1 and COVID-19 pandemics. The majority

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of the N95 respirators purchased for the Strategic National Stockpile in 2006 were gone by 2020, and many of the N95 respirators remaining in the stockpile had expired by 2020 (Alexander 2020; GAO 2020; Khazan 2020; Levey, Christensen, and Phillips 2020; Manjoo 2020; Murray and Glover 2020; Reinhard and Brown 2020). The heavily depleted N95 respirator supply in the Strategic National Stockpile proved gravely inadequate for the demands of the COVID-19 pandemic (GAO 2020). As the COVID-19 pandemic unfolded, additional supplies of N95 respirators were distributed from the Department of Defense and state stockpiles, and the federal government placed large orders for new N95 supplies (GAO 2020; Reinhard and Brown 2020). Nevertheless, N95 respirators remained in short supply for months after the COVID-19 pandemic struck the United States (Jacobs 2020). The respirator shortage led to extraordinary measures in the course of the COVID-19 pandemic. N95 respirators were used for extended periods despite their single-use design, and some N95 respirators were decontaminated and reused (Jacobs 2020). Expired N95 respirators were also distributed for use (Reinhard and Brown 2020). In sum, the COVID-19 pandemic demonstrated the danger posed by the atrophy of vigilance in the Strategic National Stockpile. Figure 1 provides a timeline of the evolution and atrophy of pandemic vigilance in the Strategic National Stockpile.

Year(s)	Event(s)
1998	National medical stockpile proposed by President Clinton.
1999	National Pharmaceutical Stockpile established, veto by President Clinton helps to avert proposed congressional budget cuts to stockpile.
2002	National Pharmaceutical Stockpile renamed Strategic National Stockpile, stockpile budget increased by an order of magnitude, stockpile enters a period of evolving vigilance (2002–2008).
2005	Strategic National Stockpile distributes supplies to assist in the responses to Hurricanes Katrina and Rita.
2006	104 million N95 respirators purchased to reinforce the Strategic National Stockpile.
2009	Strategic National Stockpile distributes more than 85 million N95 respirators to assist in the response to the 2009 H1N1 influenza pandemic.
2009-2019	Atrophy of vigilance in the Strategic National Stockpile; N95 respirator supply is not substantially replenished in the stockpile.
2020	The majority of the N95 respirators purchased for the Strategic National Stockpile in 2006 are gone by the inception of the COVID-19 pandemic. Combined U.S. supply of N95 respirators (from the Strategic National Stockpile, Department of Defense, and state stockpiles) proves inadequate for the demands of the COVID-19 pandemic.

Figure 1. Timeline of the Strategic National Stockpile

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04 Recommendations for the Strategic National Stockpile

The fundamental policy lesson of the atrophy of vigilance in the Strategic National Stockpile is the danger of complacency and the need to maintain vigilance so that the stockpile serves as a reliable source of vital protective and medical supplies in future pandemics. The stockpile strategy should be focused on achieving the evolution of vigilance by which vital supplies are maintained and improved over time through a process of policy learning. This paper recommends the following steps meant to achieve policy learning and the continuing evolution of vigilance in the management of the Strategic National Stockpile.

Recommendation 1: Maintain Adequate Supplies for Pandemic Preparedness in the Strategic National Stockpile

The atrophy of vigilance in the Strategic National Stockpile prior to the COVID-19 pandemic provides a critical lesson in the danger of dwindling safety supplies. In the future, the Strategic National Stockpile should be continually funded and managed to maintain a consistent inventory of supplies for pandemic preparedness. The COVID-19 pandemic can serve to indicate what types and quantities of supplies are most needed for pandemic preparedness in the future. A key lesson of the COVID-19 pandemic is that existing stockpiles and supply chains proved unable to fully meet the pandemic-induced demand for vital Personal Protective Equipment (PPE) such as N95 respirators, causing a respirator shortage that persisted for months (Jacobs 2020). PPE supplies are essential for protecting healthcare workers and first responders against a wide range of pathogens, and PPE supplies are therefore likely to be in high demand in future pandemics. PPE supplies designed for medical use (including N95 respirators, surgical masks, face shields, gowns, coveralls, gloves, and other key protective items) should be stocked in the Strategic National Stockpile in sufficient quantities to avert a future occurrence of the kind of widespread and dangerous PPE shortages that occurred during the COVID-19 pandemic in the

Recommendations for the Strategic National Stockpile

Maintain Adequate Supplies

United States (Jacobs 2020). In a sustained pandemic, a well-stocked Strategic National Stockpile can distribute vital items to healthcare and first responder personnel in the short term while also giving industry the time needed to expand production of those items over the longer term. When supplies are distributed from the Strategic National Stockpile in response to emergencies, those supplies should be replaced in the stockpile as soon as possible to avoid a repeat of the longstanding stockpile depletion that occurred following the 2009 H1N1 pandemic.

The stocking and restocking of vital supplies for pandemic preparedness in the Strategic National Stockpile will require an increase in annual federal appropriations for the stockpile. The Strategic National Stockpile has received annual funding in the hundreds of millions of dollars for most of its existence, but the supply problems of the COVID-19 pandemic clearly indicate that this level of funding is inadequate for pandemic preparedness (Herrera and Gottron 2020). In the future, sustained annual appropriations in the billions of dollars will likely be needed to maintain adequate pandemic preparedness supplies in the Strategic National Stockpile, a substantial national investment that pales in comparison to the trillions of dollars spent in the response to the COVID-19 pandemic in the United States (Burel 2020; Murray and Glover 2020). Adequate pandemic preparedness stockpiling is a cost-effective policy strategy that holds the potential to reduce the suffering, loss of life, extraordinary costs, and large-scale social disruptions that could result from future pandemics. Important short-term progress in stockpile funding is found in the Coronavirus Aid, Relief, and Economic Security Act of 2020 (Public Law 116-136) authorizing up to \$16 billion in emergency funding for the Strategic National Stockpile. This emergency funding is important in the short term, but in the long term the national stockpile will likely need sustained annual appropriations in the billions of dollars to prevent a recurrence of the atrophy of vigilance in pandemic preparedness.

Recommendations for the Strategic National Stockpile

Donate and Replace Near-Expiration Items

Recommendation 2: Donate and Replace Near-Expiration Items in the Strategic National Stockpile

Some of the PPE supplies in the Strategic National Stockpile were found to have expired at the time of the COVID-19 pandemic (Reinhard and Brown 2020). The distribution of expired PPE supplies is not ideal for the protection or morale of the healthcare workers and first responders who form the front line of pandemic response. Supplies nearing expiration in the Strategic National Stockpile should therefore be donated and replaced. Near-expiration supplies in the national stockpile should be offered at no charge to hospitals, healthcare workers, and first responders to provide periodic exercises in the distribution of supplies, to allow the use of the donated items in everyday medical care before they expire, and to allow hospitals to maintain expanded on-site stockpiles that will be ready for immediate use in the event of future pandemics. In the event that the supply of near-expiration items from the Strategic National Stockpile offered for donation by the federal government exceeds the needs for everyday medical care and hospital stockpiling, such items should be offered to state and local governments for emergency management and stockpiling purposes. This strategy follows the examples set by the donation of federal excess medical supplies to the states during the COVID-19 pandemic (Joy 2020). The periodic replacement of supplies in the Strategic National Stockpile will allow the federal government to support the production of protective and medical items by industry, thereby also helping to maintain the industrial capacity to scale up production of these critical items in the event of future pandemics.

Recommendation 3: Expand State, Regional, Local, and Hospital Pandemic Preparedness Stockpiles through Federal Grants and Co-operative Agreements

The storage and distribution capacity of the Strategic National Stockpile may be challenged by the

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Recommendations for the Strategic National Stockpile

Expand State, Regional, Local, and Hospital Pandemic Preparedness Stockpiles

demands of future pandemics. State, regional, local, and hospital pandemic preparedness stockpiles are important because they augment nationwide capacity for the storage and distribution of protective and medical items; these subnational stockpiles should be reinforced through federal grants under the cooperative agreement programs for public health emergency preparedness and hospital preparedness. State, regional, and local pandemic preparedness stockpiles should be augmented under the Public Health Emergency Preparedness (PHEP) Cooperative Agreement that encompasses all fifty states. Increased federal grants under the PHEP agreement should be designed to ensure that current and adequate supplies of protective and medical items are maintained in state, regional, and local pandemic preparedness stockpiles. Hospital stockpiles of protective and medical items should be augmented under the Hospital Preparedness Cooperative Agreement Program (Hospital Preparedness Program) that is the sole source of federal preparedness funding for the hospitals at the forefront of pandemic response (Alexander 2020). National funding for the Hospital Preparedness Program should be increased with the goal of ensuring that pandemic preparedness supplies are stockpiled to the extent possible at hospital sites, and to support regular pandemic-response training for healthcare workers and first responders. In all subnational pandemic preparedness stockpiles, supplies should be promptly replaced when depleted by emergencies or when expired.

The Public Health Emergency Preparedness and Hospital Preparedness cooperative agreement programs have each typically received annual federal appropriations in the hundreds of millions of dollars (Alexander 2020). In the long term, it is likely that billions of dollars of annual federal appropriations for the Public Health Emergency Preparedness and Hospital Preparedness cooperative agreement programs will be needed to adequately reinforce subnational pandemic preparedness stockpiles. These sustained funding increases would constitute national investments for the prevention of the atrophy of vigilance in subnational stockpiles, and would provide further support for the production of protective and medical items by industry.

Recommendations for the Strategic National Stockpile

Establish a Sentinel Organization for Pandemic Preparedness Stockpiles

Recommendation 4: Establish a Sentinel Organization for Pandemic Preparedness Stockpiles

The 2006 Pandemic and All-Hazards Preparedness Act (Public Law 109-417) required an annual review of the contents of the Strategic National Stockpile, but this review requirement did not suffice to prevent the subsequent atrophy of vigilance in the stockpile. The oversight of U.S. pandemic preparedness stockpiles should therefore be strengthened by adding a new sentinel organization dedicated to ensuring that both national and subnational stockpiles maintain current and adequate supplies as a defense against future pandemics (Busenberg 1999). The sentinel organization should be a permanent and independent body meant both to prevent the atrophy of vigilance in pandemic preparedness stockpiles, and to provide for a process of continual learning by which these stockpiles and associated programs can be improved over time (Busenberg 2001). Sentinel organizations with missions focused on safety have proven useful in the management of hazardous systems; for example, federally mandated advisory councils have contributed substantially to the safety of oil tanker shipping in Alaska (Busenberg 2013). The sentinel organization for pandemic preparedness should (1) continually assess the state of supplies in national and subnational stockpiles, (2) gather feedback from the healthcare workers and first responders making use of supplies distributed from those stockpiles, and (3) gather information from ongoing PPE tests conducted by the National Personal Protective Technology Laboratory. Feedback from the personnel using supplies distributed from the stockpiles (and the results of PPE tests conducted by the National Personal Protective Technology Laboratory) should be applied to achieve a continual process of policy learning for the purposes of improving stockpile supplies and management over time. In addition, experience with public health emergencies should inform recommendations by the sentinel organization concerning future improvements to stockpile management and supplies. In this way, public health crises can serve as opportunities for policy learning to enhance the future capabilities of the stockpiles. The sentinel organization should provide an annual report to

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Recommendations for the Strategic National Stockpile

Establish a Sentinel Organization for Pandemic Preparedness Stockpiles

the Assistant Secretary for Preparedness and Response, Congress, and the President of the United States to give national leaders an independent assessment of pandemic preparedness stockpiles in the United States, with the purpose of clearly indicating levels of stockpile readiness and needed stockpile improvements. The Public Health Emergency Preparedness and Hospital Preparedness cooperative agreement programs should incorporate provisions for the sentinel organization to provide its assessment and reporting function for state, regional, local, and hospital pandemic preparedness stockpiles. In essence, the sentinel organization would constitute an independent institution designed to draw attention to gaps in pandemic preparedness stockpiles and needs for improvements in those stockpiles.

05 Conclusions

The rapid evolution of pathogens creates an ever-shifting set of health hazards that together constitute a perpetual threat to public health across the world (Fong 2017). Therefore, the COVID-19 pandemic will likely be followed by future pandemics that could pose similar or greater risks to humanity. The atrophy of vigilance in the Strategic National Stockpile in the years preceding the COVID-19 pandemic serves as a warning that pandemic preparedness stockpiles can erode in between pandemics. The extraordinary (and in some cases unmet) demands for protective equipment in the COVID-19 pandemic supports the view that pandemic preparedness stockpiles should be reinforced and maintained with care as critical safeguards against future public health emergencies (Manjoo 2020).

Given the global threat posed by pandemics, there is a need for well-stocked and carefully maintained pandemic preparedness stockpiles worldwide. Such stockpiles will be most useful when combined with additional investments in other key public health strategies designed to (1) improve disease surveillance and reporting worldwide, (2) expand research and development activities to continually investigate medications, vaccines, and other medical countermeasures for pandemic management, (3) increase medical surge capabilities, and (4) improve procedures for the rapid imposition of travel restrictions combined with testing, tracing, supported isolation, and supported quarantine in the event of disease outbreaks with pandemic potential. The overarching purpose of these strategies is to slow or halt disease outbreaks, thereby improving the odds that pandemic preparedness stockpiles will be able to provide adequate supplies in response to disease outbreaks (Allen et al. 2020; Dietz and Black 2012).

In sum, the COVID-19 pandemic should serve as the impetus to improve our preparations for future pandemics. The severe global impact of the COVID-19 pandemic demonstrates that public health policy should be given greater prominence in both national and international affairs. Concerted and well-funded policy efforts are needed to maintain and improve public health systems through a strategy

Conclusions

of policy learning for the purpose of securing the evolution of vigilance against the perpetual threat of evolving pathogens that could cause future pandemics. Those efforts should include an emphasis on the management and improvement of pandemic preparedness stockpiles.

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