

Recommendations for the National Strategic Pandemic-Response Stockpile

By an Ad Hoc Pandemic-Response Subgroup of Former Members of
President Obama's Council of Advisors on Science and Technology

May 20, 2020

Background and Rationale

In 2002, the federal government established the Strategic National Stockpile (SNS), a pharmaceutical and vaccine stockpile, jointly managed by the Department of Homeland Security (DHS) and the Department of Health and Human Services (HHS), to provide for public health emergencies. The SNS extended earlier stockpile programs for use in case of chemical, biological, radiological or nuclear attack¹. In 2006, Congress funded the addition of protective equipment to the stockpile, adding 52 million surgical masks and 104 million N95 respirator masks². That legislation assigned to the HHS Assistant Secretary for Preparedness and Response (ASPR), responsibility for coordination of the stockpile for the Secretary of HHS. During the spring 2009 H1N1 pandemic, much of the mask stockpile was depleted³.

In March 2013, Congress enacted the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013⁴. Section 403 of the Act

“Reauthorizes the Strategic National Stockpile for FY2014-FY2018. Requires the Secretary of HHS to: (1) submit to the appropriate congressional committees, to the extent that the disclosure of such information does not compromise national security, the annual review of the contents of the Stockpile; and (2) review and revise the contents of the Stockpile to ensure that the potential depletion of countermeasures currently in the Stockpile is identified and appropriately addressed, including through necessary replenishment.”

On October 1, 2018, the full responsibility for the SNS was transferred from CDC to ASPR⁵. The stockpile was not replenished, however. In March 2020, the Secretary of HHS reported that the stockpile held 30 million surgical masks and 12 million N95 masks⁶.

¹ Public Health Security and Bioterrorism Preparedness and Response Act of 2002, [Pub L 107-188, H. R. 3448](#)

² Pandemic and All-Hazards Preparedness Reauthorization Act of 2006, <https://www.govinfo.gov/content/pkg/PLAW-109publ417/pdf/PLAW-109publ417.pdf>

³ Anita Patel, Maryann D'Alessandro, Karen J. Ireland, W. Greg Burel, Elaine B. Wencil, and Sonja A. Rasmussen, “Personal Protective Equipment Supply Chain: Lessons Learned from Recent Public Health Emergency Responses,” *Health Security* **15**(3), 1 June 2017, <https://doi.org/10.1089/hs.2016.0129>; Manjoo, Farhad (March 25, 2020). "Opinion | How the World's Richest Country Ran Out of a 75-Cent Face Mask". *The New York Times*. ISSN 0362-4331. <https://www.nytimes.com/2020/03/25/opinion/coronavirus-face-mask.html>

⁴ [Pub.L. 113–5, H.R. 307](#)

⁵ HHS FY19 PHSSEF Justification of budget estimates for Appropriations Committee, pg. 3-5, 92, <https://www.hhs.gov/sites/default/files/fy-2019-phssef-cj.pdf>

⁶ Ben Elgin and John Tozzi, “Hospital Workers Make Masks From Office Supplies Amid U.S. Shortage,” Bloomberg News, March 20, 2020. <https://www.bloomberg.com/news/articles/2020-03-18/hospital-makes-face-masks-covid-19-shields-from-office-supplies>

During the period from 2006 until now, many studies have projected the needs, in the event of a pandemic, for surgical and high-intensity respirator masks,⁷ other personal protective equipment (PPE), durable equipment such as ventilators, and supplies used for testing, together with estimated quantities that should be stockpiled to help satisfy that need⁸. In 2016, the National Academies of Science, Engineering, and Medicine (NASEM) held a workshop to study the SNS program and recommend improvements⁹.

The result of the failure to act on the recommendations of these studies and to appropriate and carry out the funding and actions authorized in Public Law 113-5 (as well as the failure to renew the authorization beyond 2018) has been that the United States was unprepared for the supply needs of the Spring 2020 COVID-19 pandemic. The extraordinary shortage of supplies in Spring 2020 has been well-documented in the press and has been exacerbated by supply-chain changes such as just-in-time manufacturing and globalization, and by the lack of a coordinated Federal/State plan to deploy existing supplies rapidly to locations of greatest need. There has been a persistent shortage of ventilators, testing kits, masks and other PPE, mitigated only in part by funding appropriations in late March and in April.

The fault is not with the Federal Government alone. According to Greg Burel, Director of SNS from March 2007 to December 2019, SNS planning assumed that state stockpiles would also be in place, as they were in the past. For the most part, however, those stockpiles were not replenished and maintained after the 2008 financial crisis¹⁰.

Sections 3101, 3102, and 3103 of Title III of the recently enacted Coronavirus Aid, Relief, and Economic Security (CARES) Act¹¹ are relevant to the stockpile recommendations. Sec. 3101 provides funding (\$1.5 million) to NASEM for a consensus study of America's stockpile supply chain security. Sec. 3102 adds items to the SNS to be used for a bioterrorist attack or other public health emergency. Sec. 3103 concerns use of respiratory protective devices. Congress has appropriated \$27 billion to the Public Health and Social Services Emergency Fund to remain available until September 30, 2024 to cover the items in the above sections. Of the \$27 billion, not more than \$16 billion is available for the SNS for critical medical supplies, PPE, and life-saving medicine; \$3.5 billion is for the HHS Biomedical Advanced Research and Development Authority (BARDA). Funds, amount not specified, from the \$27 billion may be used to develop

⁷Potential demand for respirators and surgical masks during a hypothetical influenza pandemic in the United States. Carias C, Rainisch G, Shankar M, et al *Clinical Infectious Diseases* 2015; **60** (suppl 1):S42-S51; https://academic.oup.com/cid/article/60/suppl_1/S42/356585 .

⁸ Studies have also analyzed the needs for pharmaceuticals and vaccines, which are not summarized here.

⁹ Hanfling D., Equipment, supplies, and pharmaceuticals: how much might it cost to achieve basic surge capacity? *Acad Emerg Med*. 2006 Nov;13(11):1232-7. Epub 2006 Jun 26. <https://www.ncbi.nlm.nih.gov/pubmed/16801633>; National Academies of Sciences, Engineering, and Medicine. 2016. *The Nation's Medical Countermeasure Stockpile: Opportunities to Improve the Efficiency, Effectiveness, and Sustainability of the CDC Strategic National Stockpile: Workshop Summary*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/23532>

¹⁰ <https://www.cbsnews.com/news/q-a-with-greg-burel-former-director-of-the-strategic-national-stockpile/>

¹¹ [Pub.L. 116-136, H.R. 748](#)

and demonstrate innovations and enhancements to manufacturing platforms to support the SNS.¹²

It is possible that the 2020 phase of the COVID-19 epidemic will decrease during the late spring, but it also may well be that there is a resurgence in the fall. Preparation for such a resurgence needs to be initiated now. It needs to be at a national level, in close collaboration and coordination with state and local officials. Even after this current phase tails off (if in fact it does so), focus on curtailing the disease needs to be maintained as the country pursues its financial recovery. Indeed, the second requires the first.

It is imperative that the SNS be rebuilt by September 1, 2020, and that state and local stockpiles be ramped up as well. As U.S. supply chains for relevant tests, masks, PPE, etc. increase, and begin to provide quantities needed, continued domestic manufacturing should be encouraged for stockpile replenishment. It will likely be necessary to continue to invoke the Defense Production Act¹³. The acquisitions need not be limited to U.S. suppliers.

The SNS and other stockpiles are intended to serve not only pandemic response but the response to other emergencies as well. The hurricane and wildfire seasons are approaching. In addition to funding the stockpile, it may be necessary to replenish the FEMA \$50 billion Emergency Fund. We have not explored that issue.

Even if the stockpile had been maintained at levels projected to be needed, the COVID-19 experience illustrates that the demands of a particular public health emergency (or the occurrence of multiple overlapping emergencies) may exhaust the stockpile before the needs have been satisfied. For robust preparedness, stockpile planning must incorporate “on the fly” provision of additional supplies.

Public and private groups in the United States, in concert with the international community, are devising a variety of creative solutions to the COVID-19 supply shortage. Among them are fast manufacturing techniques for ventilators and other equipment¹⁴, reuse of supplies such as masks that are normally used once and discarded¹⁵, rapid conversion of public and private spaces to emergency care facilities¹⁶, methods for rapid test development, deployment, and analysis, etc. In

¹² On May 14, as this memorandum was being completed, the White House issued a fact sheet announcing and describing the Trump Administration’s “plan to restructure the Strategic National Stockpile” to “address the challenges and stockpile deficiencies uncovered during the initial coronavirus response.” White House Fact Sheet, May 14, 2020, <https://www.whitehouse.gov/briefings-statements/president-donald-j-trump-ensuring-strong-national-stockpile-industrial-base-needed-meet-challenge/>

¹³ The Defense Production Act of 1950 was enacted in response to the Korean War. It has been reauthorized over 50 times and remains in force. It has been invoked multiple times to help with emergencies such as war, hurricanes, and terrorism prevention.

¹⁴ Amy Feldman and Alan Ohnsman, How Old-School Manufacturers Learned to Make Ventilators – Virtually Overnight, Forbes online, April 8, 2020. <https://www.forbes.com/sites/amyfeldman/2020/04/08/how-old-school-manufacturers-learned-to-make-ventilators---virtually-overnight/#59e00b5a5063>

¹⁵ Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), April 17, 2020. <https://www.sages.org/n-95-re-use-instructions/>

¹⁶ Matt Hickman, New York’s Javits Center completes transformation into 1,200 bed emergency hospital, *The Architect’s Newspaper*, March 30, 2020. <https://archpaper.com/2020/03/new-york-javits-center-coronavirus-emergency-hospital/>

addition, some industries are re-purposing their manufacturing capabilities to make needed supplies. The successful innovations and manufacturing capabilities should be embedded in the stockpile mission – repositories should be supplemented by just-in-time augmentation and replenishment plans.

Recommendations

Until April 2, 2020,¹⁷ the ASPR described the mission of SNS as follows:

“Strategic National Stockpile is the nation’s largest supply of life-saving pharmaceuticals and medical supplies for use in a public health emergency severe enough to cause local supplies to run out. When state, local, tribal, and territorial responders request federal assistance to support their response efforts, the stockpile ensures that the right medicines and supplies get to those who need them most during an emergency. Organized for scalable response to a variety of public health threats, the repository contains enough supplies to respond to multiple large-scale emergencies simultaneously.”

We believe that version of the mission statement is the appropriate one. We offer the following recommendations to facilitate its being carried out.

Recommendation 1. To quick-start the building of the stockpile and, at the same time, launch a high-level process to structure it for the longer term:

- a. In the next stimulus or supplemental appropriation legislation, Congress should appropriate \$30 billion for COVID-19 stockpile replenishment and preparedness¹⁸. At a minimum, these funds will provide for a major initial boost in the following critical supplies: testing kits, including reagents and swabs; surgical and N95 masks; personal protective equipment for health workers, service personnel, and the population at large; ventilators and other assistive breathing devices; and hospital beds.
- b. Within 30 days of enactment, HHS (drawing on ASPR, the National Institutes of Health, the Centers for Disease Control and Prevention, and the Food and Drug Administration), in consultation with DHS (utilizing FEMA), the Department of Defense, the Veterans Administration, governors, and mayors, and with the assistance of an independent and scientifically and technically knowledgeable, bipartisan advisory group, should submit a detailed plan to Congress as to what tests and equipment and quantities are to be stockpiled, a schedule for acquisition, criteria for allocation and distribution of items, and an allocation of the appropriated funds between the Federal stockpile sites and the state stockpiles.

¹⁷ The administration changed the wording of the ASPR’s description of the SNS on this date. The current wording may be found at <https://www.phe.gov/about/sns/Pages/default.aspx>

¹⁸ This back-of-the-envelope number derives from assuming 10% of 300 million people in the population affected, at \$1000 per person. The CARES appropriation of \$16 billion for SNS would cover funding only for the replenishment of the stockpile for the current phase of COVID-19. The \$30 billion would provide funds for critical supplies for the Federal government and states for the next waves of COVID-19 and future health emergencies.

- c. In that same period, Commerce and DOD shall submit a plan to Congress identifying sources of repurposed rapid manufacturing to supply the necessary acquisitions.
- d. Every month after the 30-day plan is submitted, the Secretary of HHS and the Secretary of DHS should provide to Congress, Agencies within the Administration, Governors, Mayors, County executives, the advisory board and the public, the status of the national emergency stockpile readiness. Those reports should continue until the annual reporting of Recommendation 3 has begun.

Recommendation 2. In order to strengthen the supply chain as the stockpile is being depleted, Congress should appropriate, in the next stimulus or supplemental appropriation legislation, \$100 million dollars to HHS to fund CDC and FEMA to memorialize and evaluate the supply chain innovations and enhancements used in the COVID-19 pandemic; to update regulations and introduce approvals to facilitate their use; and to inform Congress and the public of changes that have been made.

Recommendation 3. In the next 6 months, as part of a National Strategy for Preparedness, Congress should authorize the replenishment and maintenance of the SNS for a period of 5 years. Congress should appropriate an additional \$12.5 billion, to remain available until September 30, 2025, directing some of that funding for replenishment and maintenance of state stockpiles. In addition to funding for equipment and supplies, that legislation should include funding for

- a. Stockpile maintenance to replace expired supplies and equipment (as in the 2013 Authorization)
- b. Annual reporting (including a publicly releasable version) to the President, Congress, Governors, Mayors, and County executives on:
 - i. the state of the stockpile (including quantities of key components, the distribution of expiration dates for those components, and numerical targets for each component and anticipated timescales to reach those targets);
 - ii. the sustainable use of equipment and supplies, e.g. reuse of PPE such as masks; and
 - iii. the capability to ramp up the supply chain quickly when needed.
- c. An in-depth study by NASEM every 3 years to assess changes in the needs addressed by the stockpile and the means to address them, taking into account particularly advances in biomedicine, technology, and supply chain management.

Recommendation 4. Congress should direct the Federal Trade Commission (FTC) to provide special scrutiny for transactions that affect the provision of health and emergency care, including changes to healthcare providers, equipment providers, pharmaceuticals, and first responders¹⁹.

¹⁹ For example, the Newport Medical Instruments/Covidien merger inhibited the availability of portable ventilators. <https://www.nytimes.com/2020/04/12/opinion/ventilators-coronavirus.html>

Conclusion

The Strategic National Stockpile has been a key component of U. S. preparedness since 2002. In recent years the Nation has let down its guard. It is imperative that the SNS, and in particular, the U.S. pandemic preparedness stockpile be rebuilt by September 2020, and then sustained into the future.

The Ad Hoc Group

The authors are a subset of the members of President Obama's Council of Advisors on Science and Technology (OPCAST) who were involved in producing the six reports dealing with issues related to viral pandemics that his PCAST delivered between 2009 and 2016. In alphabetical order, they are:

Christine Cassel, University of California, San Francisco
Christopher Chyba, Princeton University
Susan L. Graham, University of California, Berkeley
John P. Holdren, Harvard University (OPCAST Co-Chair)
Eric S. Lander, Broad Institute of MIT and Harvard (OPCAST Co-Chair)
Ed Penhoet, University of California, Berkeley
William Press, University of Texas, Austin (OPCAST Vice Chair)
Maxine Savitz, National Academy of Engineering (OPCAST Vice Chair)
Harold Varmus, Weill Cornell Medicine (OPCAST Co-Chair)

The six indicated reports by the Obama PCAST are:

U.S. Preparations for 2009-H1N1 Influenza, 88 pp, August 2009

<https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/pcast-h1n1-report-final2.pdf>

Reengineering the Influenza Vaccine Production Enterprise to Meet the Challenges of Pandemic Influenza, 87 pp, August 2010

<https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/PCAST-Influenza-Vaccinology-Report.pdf>

Realizing the Full Potential of Health Information Technology to Improve Healthcare for Americans: The Path Forward, 108 pp, December 2010

<https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/pcast-health-it-report.pdf>

Propelling Innovation in Drug Discovery, Development, and Evaluation, 110 pp, September 2012

<https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/pcast-fda-final.pdf>

Better Health Care and Lower Costs: Accelerating Improvement through Systems Engineering, 66 pp, May 2014

https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/PCAST/pcast_biodefense_letter_report_final.pdf

Preparing for Biological Threats, 18 pp, November 2016

https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/PCAST/pcast_biodense_letter_report_final.pdf

In the coming weeks and months, the Ad Hoc Group will be issuing additional reports on other aspects of responding to COVID19 and future pandemics, drawing on these earlier studies and subsequent research and experience.

Note: On May 25 edits were made to the wording of Footnote 18 and Recommendations 1.a and 2 in the interest of clarity.