



COVID-19 Second Wave Preparedness Part 3: Health Care Supply Chain

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Containing a Second COVID-19 Outbreak – Health Care Supply Chain Preparedness

I. The Strategic National Stockpile

A. What is the status of the Strategic National Stockpile (SNS)?

- The U.S. faced widespread shortages of critical medical supplies when Coronavirus Disease 2019 (COVID-19) cases quickly increased from March to April 2020. Countries all over the world competed for the same medical supplies such as personal protective equipment (PPE), ventilators, testing supplies, and medicines, disrupting global supply chains. Production capabilities were significantly slowed in Asia where most global PPE manufacturing occurs.¹ In some cases, health care responders nationwide consumed a year’s worth of medical supplies within weeks.²
- In addition, and further complicating the availability of supplies in the Strategic National Stockpile (SNS), HHS “did not replenish [PPE] to previous levels following the H1N1 pandemic of 2009, because of a lack of funding.”³
- First created in 1998 as the “National Pharmaceutical Stockpile program,” the SNS is a “national repository of antibiotics, chemical antidotes, antitoxins, life-support medications, IV administration, airway maintenance supplies, and medical/surgical items.”⁴ In 2003, the program was renamed as the SNS and became jointly managed by the U.S. Department of Homeland Security (DHS) and the U.S. Department of Health and Human Services (HHS).⁵ The Project BioShield Act of 2004 returned the program to HHS for oversight and guidance, largely by the Centers for Disease Control and Prevention (CDC).⁶ In 2018, oversight of the SNS was administratively transferred to the Office of the Assistant Secretary for Preparedness and Response (ASPR) from CDC.⁷
- The Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 legislatively gave authority for managing SNS assets, in consultation with CDC, to ASPR.⁸ ASPR’s management responsibilities include procurement, storage, deployment, and replenishment of the SNS supplies.

¹ *Federal Government’s Procurement and Distribution Strategies in Response to the Covid-19 Pandemic: Hearing before Sen. Comm. on Homeland Security and Government Affairs*, 116th Cong., Statement of Peter Gaynor, U.S. Federal Emergency Management Agency Administrator, U.S. Department of Homeland Security, and John Polowczyk, Rear Admiral, Supply Chain Stabilization Task Force, Department of Defense (June 9, 2020), available at <https://www.hsgac.senate.gov/imo/media/doc/Testimony-Gaynor%20&%20Polowczyk-2020-06-09.pdf>.

² *Id.*

³ U.S. Government Accountability Office, *COVID-19: Opportunities to Improve Federal Response and Recovery Efforts*, GAO-20-625 (June 25, 2020) available at <https://www.gao.gov/assets/710/707839.pdf>.

⁴ U.S. Department of Health and Human Services, Radiation Emergency Medical Management, *Strategic National Stockpile*, available at <https://www.remm.nlm.gov/sns.htm> (last visited July 29, 2020).

⁵ *Id.*

⁶ *Id.*

⁷ *Id.*

⁸ Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019, (P.L. 116-22), enacted on June 24, 2019.

- Historically, the SNS has largely contained materials relevant to chemical, biological, radiological, and nuclear (CBRN) events and limited quantities of PPE, including N95 respirators, face masks, face shields, gowns, coveralls, and gloves.⁹
- The SNS was not designed to simultaneously supply every state, territory, tribe, and locality in the U.S. as a sole source for preparedness. For example, in 2012, HHS did not forecast the SNS' 2020 needs to include being the sole supplier of states during a global pandemic, as reported by a joint review working group of the Chair of the National Biodefense Science Board and the Chair of the Office of Public Health Preparedness and Response Board of Scientific Counselors.¹⁰
- With respect to what are typically widely-available supplies such as PPE, the SNS is intended to serve as a stop-gap source of medical supplies and medicines for use during domestic public health emergencies in which adequate amounts of state and local supplies may be depleted and not immediately available.¹¹ It also contains specialized assets, such as smallpox vaccines that are unlikely to be stockpiled locally.¹²
 - SNS assets are provided by HHS at no cost to receiving authorities. State and local officials are responsible for unpacking and distributing the assets after delivery by the federal government, commonly referred to as the “last mile.”
- Before the COVID-19 pandemic, the U.S. did not have a coordinated storage system for emergency supplies that listed state or local stockpiles or other supply reserves.¹³ In addition, declines in public health funding at the federal and state levels, the growth of “just in time” inventory models, and a belief that the federal SNS would provide supplies all may have contributed to state shortages of critical supplies.¹⁴
 - In 2009, CDC’s Emerging Infectious Diseases journal published a report that recommended creating stockpile reserves through buying essential items periodically as money became available; however, and for a variety of

⁹ U.S. Department of Health and Human Services, Public Health Emergency, *Inventory Management and Tracking System (IMATS), Sustaining the Stockpile* (Mar. 12, 2020), available at <https://www.phe.gov/about/sns/Pages/imats.aspx>.

¹⁰ U.S. Department of Health and Human Services, Public Health Emergency, *National Biodefense Science Board Recommendations* (Apr. 13, 2013), available at <https://www.phe.gov/Preparedness/legal/boards/nbsb/recommendations/Documents/nbsb-bsc-sns-2020-final.pdf>.

¹¹ U.S. Department of Health and Human Services, Public Health Emergency, *Inventory Management and Tracking System (IMATS), Sustaining the Stockpile* (Mar. 12, 2020), available at <https://www.phe.gov/about/sns/Pages/imats.aspx>.

¹² U.S. Centers for Disease Control and Prevention, *Vaccines* (Dec. 2, 2019), available at <https://www.cdc.gov/smallpox/clinicians/vaccines.html>.

¹³ Dennis Wagner, *Overwhelmed hospitals, equipment shortages: Coronavirus pandemic plays out as state planners expected*, USA TODAY (Apr. 3, 2020), available at <https://www.usatoday.com/story/news/2020/04/13/coronavirus-preparation-states-foresaw-shortages-ppe-equipment-triage-states/2974897001/>.

¹⁴ David Lieb, Cuneyt Dil, *AP Review: State supply stocks sparse and dated before virus*, THE ASSOCIATED PRESS (Apr. 23, 2020), available at <https://apnews.com/1f123d323b4089a6f7b242abcceb6d08>.

reasons, public health offices, hospitals, and medical clinics largely ordered supplies as needed.¹⁵

- Many states had at least a small supply of critical supplies like N95 respirators and other medical equipment before the COVID-19 pandemic. However, many of these supplies were past their expiration dates. For example, Michigan had 53,500 gloves, 5,120 N95 masks, 5,000 surgical masks and 500 face shields before the COVID-19 pandemic.¹⁶ Missouri had a left-over supply of 663,920 N95 respirator masks, 253,800 surgical masks, 154,000 gloves, 17,424 face shields and 14,048 gowns provided by CDC after the H1N1 flu pandemic of 2009-2010.¹⁷ Stockpiles in California, Colorado, Connecticut, Illinois, Michigan, Nevada, New Hampshire, New Mexico, Ohio, Pennsylvania, Virginia, Vermont, Washington, and West Virginia all included at least some leftovers from the H1N1 influenza pandemic.¹⁸
- Many states depended on the federal government to store provisions in case of emergencies. For example, according to Michigan’s Governor, the state relied on the federal government to prepare for a pandemic. New Hampshire maintained a small reserve of supplies, but, according to the state Health and Human Services Commissioner, relied on the national stockpile for anything needed longer than a week. One Virginia official stated that stockpiling supplies was a federal responsibility.¹⁹
 - **States should consider building independent medical supply stockpiles to be better prepared to manage critical shortages of medical resources.**
- At the start of the COVID-19 pandemic, ASPR had the following relevant supplies in the SNS:
 - Antiviral drugs (oseltamivir and zanamivir); PPE (gloves, N95 respirators and surgical masks, and gowns); and limited intravenous (IV) antimicrobials for secondary infections.²⁰
 - The reported number of N95 respirator masks that were stocked in the SNS before the pandemic has varied from 18 million to 30 million.²¹

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ U.S. Centers for Disease Control and Prevention, *Receiving, Distributing, and Dispensing Strategic National Stockpile Assets: A guide to Preparedness, Version 11* (Mar. 28, 2014), available at <https://stacks.cdc.gov/view/cdc/77036>.

²¹ U.S. Government Accountability Office, *COVID-19: Opportunities to Improve Federal Response and Recovery Efforts*, GAO-20-625 (June 25, 2020), available at <https://www.gao.gov/assets/710/707839.pdf>.

- The number of ventilators in the SNS ready for deployment was 16,600.²²
- The COVID-19 pandemic was the first instance in which the SNS was utilized for a nationwide response and, given the more limited purpose of the SNS and relevant supplies in inventory, it was not sufficient to supply the PPE needs of the entire nation.
 - **Congress and the Executive Branch should clarify the role of the SNS during a global pandemic or biological event which affects the whole country, including mechanisms for coordinating health care resources to the states and territories, to provide a shared understanding of the SNS' role in that situation.**
- ASPR began deploying the first half of PPE in SNS inventory in early March 2020, at the request of state governors or their designees, primarily based on a population pro-rata formula using 2010 U.S. Census data. Additional allocations were distributed to areas with high virus transmission by request.²³ All 50 states, plus four large metropolitan areas, received allocations during the first SNS distribution phase.²⁴
- On March 13, 2020, the President simultaneously declared a nationwide emergency pursuant to both the National Emergencies Act (NEA) and the Stafford Act due to COVID-19. Declaring an emergency pursuant to the NEA and the Stafford Act nationally for the same threat or hazard appears to be unprecedented, and each has distinct authorities that do not invoke the authorities of the other.²⁵
 - The President's proclamation under the NEA is generally considered an effort to protect the nation as a whole, and among other things, authorized the Secretary of HHS to "temporarily waive or modify certain requirements of the Medicare, Medicaid, and State Children's Health Insurance Programs and of the Health Insurance Portability and Accountability Act Privacy Rule[.]"²⁶
 - According to CRS, "[t]his [was] the first time the President has unilaterally declared a nationwide Stafford Act emergency; universal presidential

²² D'Angelo Gore, *Trump Inherited More Ventilators Than Have Been Distributed*, FACTCHECK.ORG (June 22, 2020), available at <https://www.factcheck.org/2020/06/trump-inherited-more-ventilators-than-have-been-distributed/>.

²³ U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, *Strategic National Stockpile Response to COVID-10 Frequently Asked Questions*, Public Health Emergency (Apr. 17, 2020), available at <https://www.phe.gov/emergency/events/COVID19/SNS/Pages/FAQ.aspx>.

²⁴ U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, *Strategic National Stockpile Response to COVID-10 Frequently Asked Questions*, Public Health Emergency (Apr. 17, 2020), available at <https://www.phe.gov/emergency/events/COVID19/SNS/Pages/FAQ.aspx>.

²⁵ Congressional Research Service, *Presidential Declarations of Emergency for COVID-19: NEA and Stafford Act*, INSIGHT IN1 1264 (Mar. 19, 2020), available at <https://crsreports.congress.gov/product/pdf/IN/IN11264>.

²⁶ *Id.*

declarations, however, have been made for incidents on a limited scale.”²⁷ Further, “[t]he Stafford Act emergency declaration for COVID-19 authorized one form of Federal Emergency Management Agency (FEMA) assistance: Public Assistance emergency protective measures (authorized under Stafford Act Section 502).”²⁸

- With supplies running low, HHS requested assistance from the U.S. Department of Defense (DoD). On March 16, 2020, DoD agreed to provide five million N95 respirator masks and up to 2,000 deployable ventilators to HHS.²⁹ While not included in the SNS, and in an effort to speed the supply of swabs for COVID-19 testing manufactured internationally to the U.S., DoD operationalized the Air Force to airlift one million COVID-19 test swabs to the U.S. from Italy.³⁰ As of April 3, 2020, the Air Force had made nine flights between the U.S. and Italy to deliver more than four million swabs to the U.S.³¹
- On March 19, 2020, under direction from the White House Coronavirus Task Force, FEMA was repositioned from its supportive role under HHS to become the new lead agency directing the whole-of-government response to the COVID-19 pandemic.³² Specifically, HHS was designated as the lead federal agency for the public health and medical response, and FEMA led the overall federal response coordination.
- Federal interagency coordination efforts were organized under the Unified Coordination Group (UCG), co-chaired by the leaders of FEMA and ASPR.³³ To address top priorities, eight task forces were created which worked in conjunction with FEMA’s National Response Coordination Center (NRCC).³⁴ Pursuant to an agreement between ASPR and FEMA, in early April 2020, FEMA started assisting

²⁷ *Id.*

²⁸ *Id.*

²⁹ Ellen Mitchell, *Pentagon to give 5M respirator masks, 2,000 ventilators to HHS in response to coronavirus outbreak*, THE HILL (Mar. 17, 2020), available at <https://thehill.com/policy/defense/488085-pentagon-to-give-5m-respirator-masks-2000-ventilators-to-hhs>.

³⁰ Ryan Pickrell, *The US Air Force flew 1 million coronavirus test swabs to the US from Italy, and more are likely on the way*, BUSINESS INSIDER (Mar. 20, 2020), available at <https://www.businessinsider.com/air-force-flew-coronavirus-test-swabs-to-us-from-italy-2020-3>.

³¹ U.S. Department of Defense, *Air Force to Make 9th Flight to Deliver Testing Swabs* (Apr. 3, 2020), available at <https://www.defense.gov/Explore/News/Article/Article/2136285/air-forces-to-make-9th-flight-to-deliver-testing-swabs/>.

³² *Federal Government’s Efforts for Procurement and Distribution of Critical Medical Equipment and Supplies in Response to the COVID-19 Pandemic: Hearing before the H. Select Subcomm. on the Coronavirus Crisis*, Statement of Rear Admiral John Polowczyk, Supply Chain Stabilization Task Force, U.S. Department of Defense (July 2, 2020), available at <https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/Rear%20Admiral%20JOHN%20POLOWCZYK%20Testimony.pdf>.

³³ *Id.*

³⁴ U.S. Government Accountability Office, *COVID-19: Opportunities to Improve Federal Response and Recovery Efforts Report to the Congress*, GAO-20-625 (June 25, 2020), available at <https://www.gao.gov/reports/GAO-20-625/>.

ASPR with SNS supply acquisitions.³⁵ The task force efforts are discussed further in Section II B (a).

- The UCG used a data-driven approach to allocate remaining shipments from the SNS and directed them through the NRCC for distribution.³⁶ The NRCC had a broad view into where resources were most urgently needed, based on knowledge from monitoring of disease activity locations nationwide and information about the remaining SNS resources.³⁷ These shipments exhausted much of the remaining relevant supplies in the SNS; ten percent of the remaining PPE supplies in the SNS were reserved to supply frontline responders.³⁸
 - Supply requests were conveyed using emergency supply shortage notifications, which were relayed from local levels to state emergency managers or public health departments, who then relayed the notifications to FEMA’s Regional Response Coordination Centers (RRCC) for vetting by FEMA, HHS, and CDC.³⁹ After the RRCCs prioritized the notifications, they forwarded them to the NRCC for adjudication.⁴⁰
- FEMA started accepting donations of medical supplies and pharmaceuticals on behalf of the SNS because existing law prohibited the SNS from accepting donations of equipment or medical countermeasures (MCMs) without going through a complex transaction with HHS and the General Services Administration.⁴¹
 - As mentioned above, donations to the SNS included five million N95 respirator masks and 2,000 deployable ventilators from DoD.⁴²

³⁵ Memorandum of Understanding Between the Federal Emergency Management Agency and the U.S. Department of Health and Human Services, Office of Assistant Secretary of Preparedness Response (Apr. 5, 2020) (on file with Committee).

³⁶ *Federal Government’s Procurement and Distribution Strategies in Response to the Covid-19 Pandemic: Hearing before Sen. Comm. on Homeland Security and Government Affairs*, 116th Cong., Statement of Peter Gaynor, U.S. Federal Emergency Management Agency Administrator, U.S. Department of Homeland Security, and John Polowczyk, Rear Admiral, Supply Chain Stabilization Task Force, Department of Defense (June 9, 2020), available at <https://www.hsgac.senate.gov/imo/media/doc/Testimony-Gaynor%20&%20Polowczyk-2020-06-09.pdf>.

³⁷ *Id.*

³⁸ U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, *Strategic National Stockpile Response to COVID-10 Frequently Asked Questions*, Public Health Emergency (Apr. 17, 2020), available at <https://www.phe.gov/emergency/events/COVID19/SNS/Pages/FAQ.aspx>.

³⁹ *Federal Government’s Procurement and Distribution Strategies in Response to the Covid-19 Pandemic: Hearing before Sen. Comm. on Homeland Security and Government Affairs*, 116th Cong., Statement of Peter Gaynor, U.S. Federal Emergency Management Agency Administrator, U.S. Department of Homeland Security, and John Polowczyk, Rear Admiral, Supply Chain Stabilization Task Force, Department of Defense (June 9, 2020), available at <https://www.hsgac.senate.gov/imo/media/doc/Testimony-Gaynor%20&%20Polowczyk-2020-06-09.pdf>.

⁴⁰ *Id.*

⁴¹ Global Biodefense, *SAFE Act Introduced to Improve Strategic National Stockpile* (April 17, 2020), available at <https://globalbiodefense.com/2020/04/17/safe-act-introduced-to-improve-strategic-national-stockpile/>.

⁴² C. Todd Lopez, *DOD Poised to Provide Masks, Ventilators, Labs for Coronavirus Fight*, Defense News, U.S. Department of Defense (Mar. 17, 2020), available at <https://www.defense.gov/Explore/News/Article/Article/2115200/dod-poised-to-provide-masks-ventilators-labs-for-coronavirus-fight/>.

- After the U.S. Food and Drug Administration (FDA) issued Emergency Use Authorizations (EUA) for chloroquine phosphate and hydroxychloroquine on March 28, 2020, and remdesivir on May 1, 2020, the U.S. government accepted donations of chloroquine phosphate and hydroxychloroquine sulfate on March 29, 2020, and donations of remdesivir on May 3, 2020, and May 18, 2020.⁴³ In addition, on June 28, 2020, HHS signed a Memorandum of Agreement with Gilead Sciences, Inc. and AmerisourceBergen to secure additional treatment courses of remdesivir for use in American hospitals.⁴⁴ These drugs are not usually stocked in the SNS.⁴⁵
- **Congress should consider whether the SNS should be allowed to accept donations of certain products.**
- Due of the limited number of ventilators remaining in the SNS and the limited private sector supply chain capacity to meet the demand, on March 31, 2020, FEMA designated ventilators in the SNS as strategic national assets to be distributed on a case-by-case basis to states where hospitals could demonstrate an “exigent need” to sustain life within 72 hours.⁴⁶ At that point, NRCC only shipped ventilators to states in the quantities needed to manage the immediate crisis.⁴⁷
- The Coronavirus Aid, Relief, and Economic Security Act” (CARES Act) was enacted on March 27, 2020.⁴⁸ The CARES Act enhanced SNS supplies by including “personal protective equipment, ancillary medical supplies, and other applicable supplies required for the administration of drugs, vaccines, and other biological

⁴³ U.S. Department of Health and Human Services, *HHS accepts donations of medicine to Strategic National Stockpile as possible treatments for COVID-19 patients* (Mar. 29, 2020), available at <https://www.hhs.gov/about/news/2020/03/29/hhs-accepts-donations-of-medicine-to-strategic-national-stockpile-as-possible-treatments-for-covid-19-patients.html>; U.S. Department of Health and Human Services, Public Health Emergency, *Remdesivir, ASPR’s Portfolio of COVID-19 Medical Countermeasures under Investigation*, available at <https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/remdesivir.aspx>. On June 15, 2020, FDA revoked the EUA that allowed chloroquine phosphate and hydroxychloroquine sulfate to be used to treat certain hospitalized patients. U.S. Food and Drug Administration, *FDA Revokes Emergency Use Authorization for Chloroquine and Hydroxychloroquine* (June 15, 2020), available at <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-chloroquine-and>.

⁴⁴ U.S. Department of Health and Human Services, Public Health Emergency, *Remdesivir, ASPR’s Portfolio of COVID-19 Medical Countermeasures under Investigation*, available at <https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/remdesivir.aspx>.

⁴⁵ U.S. Food and Drug Administration, *MCM Emergency Use Authorities* (Sept. 23, 2019), available at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/mcm-emergency-use-authorities>.

⁴⁶ The Council of State Governments, *FEMA Advisory - Coronavirus (COVID-19) Pandemic Ventilator Request, COVID-19 Resources for State Leaders* (Mar. 31, 2020), available at <https://web.csg.org/covid19/2020/04/01/coronavirus-covid-19-pandemic-ventilator-request/>.

⁴⁷ *Federal Government’s Procurement and Distribution Strategies in Response to the Covid-19 Pandemic: Hearing before Sen. Comm. on Homeland Security and Government Affairs*, 116th Cong., Statement of Peter Gaynor, U.S. Federal Emergency Management Agency Administrator, U.S. Department of Homeland Security, and John Polowczyk, Rear Admiral, Supply Chain Stabilization Task Force, Department of Defense (June 9, 2020), available at <https://www.hsgac.senate.gov/imo/media/doc/Testimony-Gaynor%20&%20Polowczyk-2020-06-09.pdf>.

⁴⁸ Coronavirus Aid, Relief, and Economic Security Act (P.L. 116-136), enacted on March 27, 2020.

products, medical devices, and diagnostic tests in the stockpile.”⁴⁹ The additional requirements were designed to ensure that supplies needed for COVID-19 response, such as swabs, diagnostic test kits, ventilators, and PPE, would be stocked in the SNS’ inventory. While some supplies described in the enhancement had already been included in the SNS, diagnostic test kits were included for the first time and the Act made clear which items should be stockpiled for pandemic preparation. The CARES Act provided at least \$16 billion for SNS supplies through Public Health and Social Services Emergency Funds.⁵⁰

- On May 15, 2020, President Trump announced the Strategic National Stockpile 2.0 initiative (SNS 2.0) in which 90 days of supplies would be maintained for use during any COVID-19 flare ups as the American economy reopened.⁵¹ The President’s plan for SNS 2.0 increased supply inventory for items such as ventilators and respirators, improved SNS inventory management and distribution, and acquired medical supply data from hospitals and manufacturers.
- As discussed in more detail in Section I D, on May 15, 2020, ASPR solicited input on the proposed SNS 2.0 strategy, structure, and role of public-private partnerships in ensuring adequate supplies for the SNS 2.0. ASPR also sought information that explained constraints in meeting pandemic supply demands and sought input about how the U.S. government could assist with improving supply availability.⁵² The request for information was targeted towards private sector manufacturers, distributors, trade associations, and other external organizations who might partner with the U.S. government.⁵³
- On May 15, 2020, HHS published a request for information seeking feedback on its proposed development of an IT infrastructure to help manage and analyze supplies in the SNS.⁵⁴ The plans included building an IT control tower for SNS communication and data visibility, allowing public and private sectors to share real-time supply chain information with the government, and ensuring access to predictive analytics to forecast supply requirements.⁵⁵ The purpose is to ensure the SNS has enough reserves of major items needed for pandemic responses and enhance domestic manufacturing capacity to reduce dependence on foreign supply sources.⁵⁶

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ Alex Ruoff, Jeannie Baumann and Brandon Lee, *Health Care Briefing: Trump Touts Stockpile Plan After Shortages*, BLOOMBERG GOVERNMENT (May 15, 2020), available at <https://about.bgov.com/news/health-care-briefing-trump-touts-stockpile-plan-after-shortages/>.

⁵² *NEXTGEN SNS RFI*, BETA.SAM.GOV (May 14, 2020), available at <https://beta.sam.gov/opp/2bcb8d7cba6c475b925f283d3eb67047/view>.

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ *Id.*

- Due to the COVID-19 pandemic, PPE supplies, including N95 respirators, remain in short supply and health care responders are using PPE supplies faster than supplies can be replenished.⁵⁷ The SNS continues to deploy PPE and other supplies and equipment across the country, prioritizing high transmission areas, and basing the quantities supplied on the population of the affected area.⁵⁸ FEMA and HHS are working to purchase PPE from all sources, including international and domestic vendors, and procure donations from the private sector.
- In the course of this work, concerns have been raised not only about the effective delegation of the SNS to the UCG at FEMA, but also that states were not properly allocating supplies within the state. Concerns have also been raised that, due to the limited resources within the SNS, states were having to compete with one another and/or against the federal government to acquire additional supplies.
- **Congress and the Executive Branch should examine the use of the SNS in the first wave of the pandemic, the coordination of the SNS' response activities with FEMA, and potential overlaps in authorities and responsibilities among HHS, FEMA, and DoD, and put in place any needed changes or processes to most effectively replenish and manage the SNS.**
- **Congress should seek information on how DoD, the Veterans Health Administration, and state and local stockpiles are managed, and determine best practices for how the SNS can most efficiently and effectively supplement state supplies.**
- **Congress and the Executive Branch should explore whether any of the HHS plans for enhanced SNS IT communication and supply management can be expedited for implementation before the fall. With the forecasted increased medical supply demand, it will be important for SNS management to be able to detect and respond to any rapidly shifting conditions in the global supply chain through monitoring manufacturing capacity of key suppliers as well as import and export controls.**

B. What materials need to be restocked in advance of a potential fall resurgence?

- The federal government and the states need to continue ensuring that front line medical professionals and others have the supplies needed to combat the first wave of the pandemic, while building up reserves for a likely resurgence in the fall.
 - HHS Assistant Secretary for Public Health, Admiral Brett Giroir testified before the House Committee on Energy and Commerce on June 23, 2020, that

⁵⁷ U.S. Fire Administration, *PPE Supply for Emergency Medical Services*, available at https://www.usfa.fema.gov/coronavirus/infection_control/ppe_supply_for_ems.html (last visited July 28, 2020).

⁵⁸ U.S. Department of Health and Human Services, *Deploying PPE and Other Medical Supplies and Equipment from the Strategic National Stockpile* (July 2, 2020), available at <https://www.phe.gov/emergency/events/COVID19/SNS/Pages/deploy.aspx>.

the UCG is working with SNS 2.0 to have a 60- to 90-day supply of PPE to include gloves, gowns, goggles, respirators, and face shields. He further testified that governors in every state are also preparing supplies for 60 to 90 days.⁵⁹

- On July 2, 2020, Admiral Polowczyk testified that 70 percent of states and territories had up to 90 days of supplies on hand and all others had at least 30 days of supplies.⁶⁰ Some states are working towards 90 to 120 days of supplies. The SNS, with assistance from the Defense Logistics Agency (DLA), is working towards stockpiling 90 days of supplies.⁶¹
- The SNS, through ASPR and the Secretary of HHS, is able to enter into acquisition agreements using the long-standing HHS Defense Production Act (DPA) Title I authorities for health resources, similar to DoD's use of DoD Title I authorities for procurements and acquisitions.
 - **Congress and the Executive Branch should review HHS' procurement and acquisition processes and staffing to assess if barriers prevent the SNS from using HHS DPA authorities, which provide mechanisms for priority rating SNS agreements and orders or allocate distribution of a contractor's stock inventory.**⁶²
- Efforts are underway to restock the SNS. For example:
 - On March 21, 2020, ASPR issued a procurement order for up to 600 million N95 respirators over the next 18 months, to act as a guaranteed order encouraging manufacturers to increase production of N95s for use by health care professionals.⁶³ The guaranteed offer provides assurance to manufacturers that they will not be left with excess supplies if private sector orders are cancelled once the COVID-19 response subsides.
 - On March 27, 2020, President Trump invoked the DPA directing General Motors (GM) to produce ventilators needed for COVID-19 patients with severe illness. On April 2, 2020, President Trump invoked the DPA to compel six additional domestic manufacturers to build ventilators and respirators. Ford Motor Company teamed up with General Electric and 3M to

⁵⁹ *Oversight of the Trump Administration's Response to the COVID-19 Pandemic: Hearing Before the H. Comm. On Energy and Commerce*, 116th Cong. (June 23, 2020), available at <https://energycommerce.house.gov/committee-activity/hearings/full-committee-hearing-on-oversight-of-the-trump-administrations>.

⁶⁰ U.S. Federal Emergency Management Agency, *Coronavirus Pandemic Whole-of-America Response*, By the Numbers (July 22, 2020) (on file with Committee).

⁶¹ *Id.*

⁶² Congressional Research Service, *The Defense Production Act (DPA) and COVID-19: Key Authorities and Policy Considerations*, IN11231 (Mar. 18, 2020), available at <https://fas.org/sgp/crs/natsec/IN11231.pdf>.

⁶³ U.S. Department of Health and Human Services, *HHS to Procure N95 Respirators to Support Healthcare Workers in COVID-19 Outbreaks* (Mar. 4, 2020), available at <https://www.hhs.gov/about/news/2020/03/04/hhs-to-procure-n95-respirators-to-support-healthcare-workers-in-covid-19-outbreaks.html>.

join their forces in ventilators and respirators production; their partnership has been called “Project Apollo.”⁶⁴

- As of August 16, 2020, the federal government has approximately 98,153 total ventilators available in the SNS.⁶⁵ To put into context the volume of available ventilators, on April 6, 2020, near the peak of the early months of the pandemic, a total of 7,920 ventilators were deployed from the SNS, with 4,400 of those sent to New York.⁶⁶ The SNS has contracts to produce more than 180,000 ventilators by the end of the year.⁶⁷
- PPE supplies related to the COVID-19 pandemic that should be stored in the SNS are in flux given that the federal government is simultaneously shipping and acquiring supplies to support the ongoing pandemic outbreak areas.⁶⁸
 - As discussed in Section II B, the federal government has utilized a number of efforts to increase the availability of PPE, including Project Air Bridge and partnerships with wholesale distributors to prioritize limited supplies to hard-hit areas when needed.
- If the nationwide demand for medical supplies continues to exceed supply, then delivery of supplies from the SNS may need to be prioritized, as it was in the immediate response to the pandemic.
 - **Congress and the Executive Branch should clearly identify the criteria by which supplies from the SNS should be prioritized, if necessary, and clearly identify these criteria for the states.**
- Procuring new items to replace SNS stock and maintaining its inventory may require additional congressional funding and oversight.
 - **While Congress has provided additional funds for the SNS, Congress should consider whether additional funds are needed in both the short- and long-term to adequately stock and maintain the SNS.**

⁶⁴ Michael Biesecker and Tom Krisher, *Becoming ‘King of Ventilators’ may result in unexpected glut*, FEDERAL NEWS NETWORK (May 10, 2020), available at <https://federalnewsnetwork.com/government-news/2020/05/becoming-king-of-ventilators-may-result-in-unexpected-glut/>.

⁶⁵ U.S. Federal Emergency Management Agency, *Coronavirus Pandemic Whole-of-America Response, By the Numbers* (Aug. 17, 2020) (on file with Committee).

⁶⁶ Elise Reuter, *Here’s how much equipment states with the most COVID-19 cases received*, MEDCITY NEWS (Apr. 8, 2020), available at <https://medcitynews.com/2020/04/heres-how-much-equipment-states-with-the-most-covid-19-cases-received/>.

⁶⁷ Rebecca Ballhaus, Rachael Levy, *Trump Administration Details Plans to Overhaul Medical Stockpile*, THE WALL STREET JOURNAL (May 14, 2020), available at <https://www.wsj.com/articles/trump-administration-details-plans-to-overhaul-strategic-national-stockpile-11589475628>.

⁶⁸ *NEXTGEN SNS RFI*, BETA.SAM.GOV (May 15, 2020), available at https://beta.sam.gov/opp/d262bb77bb014a2cb422c8dc3ed0e636/view?keywords=75a50120nextgensns&sort=-relevance&index=opp&is_active=true&page=1.

- Biopharmaceutical products currently held in the SNS are primarily for responding to a biodefense emergency, and in many instances are products that do not otherwise have a commercial marketplace. However, the global effects of the COVID-19 pandemic have caused shortages in several key biopharmaceutical products or active pharmaceutical ingredients (APIs). FDA separately maintains a shortage list of critical drugs for saving and preserving life.⁶⁹ Given the reliance on foreign sources for supplies and ingredients for pharmaceutical manufacturing, some have suggested adding additional finished products and APIs to the SNS' inventory.
 - As discussed in more detail in Section II F, and recognizing the importance of increasing domestic manufacturing of key APIs, in May 2020, HHS announced a four-year, \$354 million agreement between the Biomedical Advanced Research and Development Authority (BARDA), part of ASPR, and a Phlow-led team that will manufacture API supplies for medicines for patients hospitalized with COVID-19.⁷⁰
- **Congress and the Executive Branch should consider whether the SNS should maintain a broader array of MCMs and drugs critical to saving and preserving life, in addition to its historical supply of drugs.**
- **Congress and the Executive Branch should study whether APIs can and should be included in the SNS, as there are concerns with the feasibility of such a requirement.**
- **Congress and the Executive Branch should consider whether, and if so, what, potential therapeutics for COVID-19 should be included in the SNS once authorized or approved by FDA.**

C. Where should restocked materials be held?

- Currently, the SNS maintains warehouses across the country. However, there may be other innovative solutions that allow the SNS to maintain materials outside of the traditional warehouse locations, or otherwise increase the availability of these supplies.
 - For example, the SNS could enter into partnerships with manufacturers of critical goods to expand their manufacturing capacity and accordingly receive first priority for a certain set of supplies, such as those being manufactured at a specific plant or assembly line, when an emergency situation exists.

⁶⁹ Recommendations from September 20, 2018 Summit with American Hospital Association, American Society of Anesthesiologists, et. al., *Drug Shortages as a Matter of National Security: Improving the Resilience of the Nation's Healthcare Critical Infrastructure* (Sept. 20, 2018), available at <https://www.ashp.org/~media/assets/advocacy-issues/docs/Recommendations-Drug-Shortages-as-Matter-of-Natl-Security>.

⁷⁰ U.S. Department of Health and Human Services, *HHS, Industry Partners Expand U.S.-Based Pharmaceutical Manufacturing for COVID-19 Response* (May 19, 2020), available at <https://www.hhs.gov/about/news/2020/05/19/hhs-industry-partners-expand-us-based-pharmaceutical-manufacturing-covid-19-response.html>.

- Similarly, wholesale distributors could be incentivized to hold additional inventory of common supplies, like PPE, and cycle product through their distribution systems rather than storing it in warehouses, eliminating possible issues with the expiration of supplies. This could minimize the need for warehousing large amounts of inventory of commonly used critical supplies and increase the amount of such supplies readily available in an emergency.
- The SNS has long included “push packs” – supplies ready for rapid deployment to anywhere in the U.S. or its territories within 12 hours of a federal decision to deploy.⁷¹
 - **The Executive Branch should consider whether similar “push packs” should be created and maintained for pandemic PPE supplies, such as masks and gloves.**
- The SNS does not necessarily have to hold all medical products in SNS-specific warehouses. For example, the SNS could enter into contracts with companies to maintain the availability of certain supplies to the SNS, similar to how DoD manages its supply chains.⁷²
- Options for holding larger amounts of PPE and other products include increasing the supply in the SNS, and improving inventory management or the holding of mini stockpiles of critical supplies by other entities, such as wholesale distributors. For example:
 - In a Just-In-Case (JIC) logistics inventory management for purchasing and storing supply reserves, stock is in direct possession of the SNS and delivery of goods is guaranteed.⁷³ The downside to this strategy is the need for increased personnel and storage space.⁷⁴
 - A Just-in-Time (JIT) logistics inventory management strategy relies on contractors, which offers increased efficiency and reduced costs. However, products may be subject to delayed delivery due to manufacturing disruptions or commercial stock depletion.⁷⁵
 - Expanded use of vendor managed inventories (VMI) could also be considered. VMI allows for a single purchase of a product and rotation of that inventory back into the commercial marketplace. The SNS has used VMIs on a very

⁷¹ U.S. Department of Health and Human Services, Chemical Hazards Emergency Management, *Strategic National Stockpile (SNS)* (Mar. 10, 2020), available at <https://chemm.nlm.nih.gov/sns.htm>.

⁷² Mario Parker, Justin Sink, and Jordan Fabian, *Trump Unveils Medical Supply Plan After Criticism Over Shortages*, BLOOMBERG (May 14, 2020), available at <https://www.bloomberg.com/news/articles/2020-05-14/trump-administration-seeking-a-90-day-viral-supply-stockpile>.

⁷³ Congressional Research Service, *National Stockpiles: Background and Issues for Congress*, IF11574 (June 15, 2020), available at <https://fas.org/sgp/crs/natsec/IF11574.pdf>.

⁷⁴ *Id.*

⁷⁵ *Id.*

limited basis for many years. Increasing the frequency and use of VMIs could increase public-private partnerships, reduce storage space needed for supplies, improve supply data insights, and keep inventory from expiring. VMIs also provide an opportunity for public-private partnerships.

- **Congress and the Executive Branch should evaluate the most efficient and effective management strategies to modernize the SNS, and implement any needed legislative or regulatory changes to effectuate such a modernization.**

D. What additional changes, if any, should be made to the SNS?

- As discussed previously, the CARES Act made enhancements to the SNS that require stocking “personal protective equipment, ancillary medical supplies, and other applicable supplies required for the administration of drugs, vaccines, and other biological products, medical devices, and diagnostic tests.”⁷⁶ The additional SNS requirements were designed to ensure that supplies needed for COVID-19 response would be stocked in SNS inventory.
- HHS is undertaking plans for SNS 2.0 that build on the partnership among ASPR, DoD, and FEMA to support, manage, and oversee SNS procurement and activities.⁷⁷
 - In May 2020, ASPR released a request for information to “solicit input on the proposed strategy and structure of the [SNS] and the role of public-private partnerships in achieving this vision.”⁷⁸ According to the request for information, HHS and ASPR want the SNS to achieve the following:
 - **“More coverage:** Ensure sufficient reserve of 100% of major items associated with COVID-like pandemics;”
 - **“More insights:** Utilize predictive analytics to forecast requirements;”
 - **“More capability:** Utilize various inventory management strategies and improve visibility, providing real-time insights into supply and demand;”
 - **“Less vulnerability:** Enhance domestic manufacturing capacity to reduce dependence on foreign sources of supply.”⁷⁹

⁷⁶ Coronavirus Aid, Relief, and Economic Security Act (P.L. 116-136), enacted on March 27, 2020.

⁷⁷ *NEXTGEN SNS RFI*, BETA.SAM.GOV (May 15, 2020), available at https://beta.sam.gov/opp/d262bb77bb014a2cb422c8dc3ed0e636/view?keywords=75a50120nextgensns&sort=-relevance&index=opp&is_active=true&page=1.

⁷⁸ *Id.*

⁷⁹ *Id.*

- SNS 2.0 is intended to include a "Supply Chain IT Control Tower" to create visibility of supplies across the end-to-end supply chain. Originally created by FEMA during the first wave of the COVID-19 pandemic under the Supply Chain Stabilization Task Force, the control tower will be data-driven using information from distributors, hospitals, and other sources.
 - The Supply Chain Control Tower is intended to (1) create visibility, including end-to-end inventory levels, manufacturer capacity, distribution flows, and point-of-care consumption; (2) provide insights, including demand forecasting, gap prioritization, and scenario modeling; and (3) orchestrate response, including capacity planning and acquisition strategy, targeted distribution, and strategy and policy refinement.⁸⁰
- The original SNS was conceived for storing medical assets that were not commercially available and was not designed to function as a medical supply chain or as a supply chain director.
- **Congress should work with the Executive Branch and stakeholders to consider whether, and if so, how SNS 2.0 can optimize a national health care supply chain central leadership position to improve supply availability and visibility and facilitate the allocation of critical medical supplies for supplies that are stocked in the SNS 2.0 for the COVID-19 response.**⁸¹
- **Congress should conduct oversight of the SNS 2.0 program and, depending on the findings, consider codifying the program if effective.**
- For years, the SNS' inability to use or sell products before their expiration has been noted as a concern. When Committee staff visited an SNS warehouse in the fall of 2019, many pallets appeared to contain expired product. According to media reports, many respirators, disposable gowns, and surgical and face masks in the SNS distributed to health care workers in response to the COVID-19 pandemic were purchased in 2007 with supplemental funds for pandemic influenza preparedness.⁸²
 - The SNS participates in the Federal Shelf Life Extension Program for federal stockpiles, a program administered by DoD and managed by FDA through an Interagency Agreement.⁸³ FDA conducts stability testing and when a product is tested as safe, the program will extend the use-by dates of non-biological

⁸⁰ *Id.*; The Supply Chain Stabilization Task Force is discussed in more detail in Section II B (a).

⁸¹ *Id.*

⁸² Arianna Skibell, *Health care workers using expired gear during pandemic and 'hoping for the best*, NC POLICY WATCH (Mar. 30, 2020), available at <http://www.ncpolicywatch.com/2020/03/30/health-care-workers-using-expired-gear-during-pandemic-and-hoping-for-the-best/>.

⁸³ U.S. Food and Drug Administration, *Expiration Dating Extension*, MCM Legal, Regulatory, and Policy Framework (June 3, 2020), available at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/expiration-dating-extension>.

pharmaceuticals beyond their original use-by dates by 12 to 24 months and sometimes longer, which allows deferment of the drug replacement costs. Delays in testing for this program could limit the SNS' ability to deploy expired but usable product in an emergency.

- **Once the immediate wave of the COVID-19 pandemic has waned, ASPR and FDA should determine the extent to which relevant product in the SNS is expired and awaiting testing, and expedite testing under the Federal Shelf Life Extension Program.**
 - In addition to the Federal Shelf Life Extension Program, FDA has the ability to extend medical products to be used beyond their manufacturer-labeled expiration dates through EUA authorities, when section 564 of the Food, Drug and Cosmetics (FD&C) Act statutory criteria for EUA issuance is met.⁸⁴ FDA also has the authority to extend the expiration date of eligible FDA-approved MCMs stockpiled for use in CBRN emergencies through FDA's expiration dating extension authority under section 564A(b) of the FD&C Act, established by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013.⁸⁵
 - On March 2, 2020, FDA provided an EUA to allow all expired disposable filtering facepiece respirators (FFRs or respirators) held in approved stockpiles approved by the National Institute for Occupational Safety and Health (NIOSH) to be used beyond their manufacturer-labeled expiration dates, provided they are not damaged and have been stored in accordance with manufacturers' storage conditions in strategic stockpiles, including the SNS.⁸⁶
 - **Congress should consider whether additional authorities are needed for the SNS to be able to cycle products through before expiration.**
- E. Bipartisan members of the Committee on Energy and Commerce have recently introduced legislation to address many of the issues identified above and provide greater flexibilities and authorities to the SNS.
- The bipartisan Strengthening America's Strategic National Stockpile Act of 2020, was introduced on July 13, 2020, and was favorably reported by the House Committee on Energy and Commerce on July 15, 2020.⁸⁷ This legislation would amend the Public Health Services Act with the following proposed changes to the SNS:

⁸⁴ *Id.*

⁸⁵ *Id.*

⁸⁶ U.S. Food and Drug Administration, *Emergency Use Authorization, Emergency Use Authorization (EUA) information, and lists of all current EUAs*, available at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covidppe> (last visited July 28, 2020). This EUA was initially posted on March 2, 2020, and was revised on March 27, 2020, and again on March 28, 2020.

⁸⁷ H.R. 7574, *Strengthening America's Strategic National Stockpile Act of 2020* (July 13, 2020), 116th Congress (2019-2020).

- The stockpile may transfer to another federal department or agency, on a reimbursable basis, any product that is less than six months from expiration, on the conditions that the stockpile is able to replenish the supplies and the transfer is in the best interest of the government.⁸⁸
- The SNS may enter into contracts for procurement of equipment maintenance services to keep contents in good working order.⁸⁹
- The SNS may increase emergency stock of critical medical supplies; geographically diversify production of the supplies; purchase, lease or enter into joint ventures to produce medical supplies; and work with medical supply distributors to manage domestic reserves by refreshing and replenishing stock.⁹⁰
- The HHS Secretary may establish a pilot program to award grants to states to expand or maintain their strategic stockpiles of commercially available drugs, medical equipment, and PPE provided the state contributes at least the matching funds.⁹¹
- Not later than January 1, 2021, HHS shall develop and implement improved, transparent processes for SNS supply requests, criteria for prioritization of distribution, and any differences in processes developed when emergencies are geographically related or nationwide.⁹²

II. Additional Supply Chain Issues

A. How was U.S. health care resource supply chain management impacted by COVID-19?

- On January 22, 2020, the first patient in the U.S. was identified with confirmed COVID-19 in Washington State.⁹³ On January 30, 2020, the World Health Organization (WHO) declared the 2019-nCoV outbreak a Public Health Emergency of International Concern.⁹⁴
- China is a global supplier of PPE, medical devices, antibiotics, and active pharmaceutical ingredients. In January 2020, however, to address China's need for medical supplies during the first weeks and months of the COVID-19 pandemic, the Chinese imported needed medical supplies from overseas which decreased medical

⁸⁸ *Id.*

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² *Id.*

⁹³ Centers for Disease Control and Prevention, Emerging Infectious Diseases, Volume 26, Number 6—June 2020, *Severe Acute Respiratory Syndrome Coronavirus 2 from Patient with Coronavirus Disease, United States*, available at https://wwwnc.cdc.gov/eid/article/26/6/20-0516_article.

⁹⁴ World Health Organization, *Rolling updates on coronavirus disease (COVID-19)* (June 29, 2020), available at <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/events-as-they-happen>.

supply stock available in other countries.⁹⁵ When China subsequently closed its economy for virus mitigation, the reduction in export and increased demand led to worldwide shortages of critical medical supplies.⁹⁶ Moreover, when Chinese workers returned to work from quarantine and in-country manufacturing production resumed, the Chinese government initially directed that production of certain critical supplies be retained for domestic use.⁹⁷

- According to media reports, a DHS intelligence report stated that Chinese leaders “intentionally concealed the severity” of the COVID-19 pandemic in early 2020, while at the same time increased imports and decreased exports of medical supplies. According to the same report, China delayed reporting to the WHO that the virus “was a contagion” in order to procure medical supplies from abroad.⁹⁸
- Due to the pandemic, more than 80 countries, including China, India, and countries in the European Union, imposed limits or formal bans on certain exports, including medical ventilators (for which Singapore and China accounted for 35 percent and 17 percent, respectively, of U.S. imports in 2019), breathing and gas masks (France, the United Kingdom, and Italy combined accounted for 47 percent of U.S. imports in 2019), computed tomography (CT) scanners (Germany accounted for 50 percent of U.S. imports in 2019), medical protective equipment of textile materials (China accounted for 72 percent of U.S. imports in 2019), digital and infrared thermometers (China accounted for 36 percent of U.S. imports in 2019), pharmaceuticals (Ireland, Germany, Switzerland, and Italy combined accounted for 53 percent of U.S. imports in 2019), and tetracycline and penicillin (China accounted for 90 percent and 52 percent, respectively, of U.S. imports in 2019).⁹⁹
- In mid-February 2020, the WHO warned that global demand for PPE from medical providers was 100 times higher than normal, prices were 20 times higher, stockpiles were depleted, and there was a four- to six-month backlog on filling supply orders.¹⁰⁰ In March 2020, the WHO estimated that for each month worldwide, 89 million medical masks, 76 million gloves, and 1.6 million medical goggles were needed for the global COVID-19 response and estimated that the health care industry must increase manufacturing by 40 percent.¹⁰¹

⁹⁵ Congressional Research Service, *COVID-19: China Medical Supply Chains and Broader Issues*, R46304 (Apr. 6, 2020), available at <https://www.everycrsreport.com/reports/R46304.html>.

⁹⁶ *Id.*

⁹⁷ *Id.*

⁹⁸ Will Weissert, *DHS report: China his virus’ severity to hoard supplies*, THE ASSOCIATED PRESS (May 4, 2020), available at <https://apnews.com/bf685dcf52125be54e030834ab7062a8>.

⁹⁹ Congressional Research Service, *Export Restrictions in Response to the COVID-19 Pandemic* (May 15, 3030) available at <https://www.crs.gov/reports/pdf/IF11551>; Congressional Research Service, *COVID-19: China Medical Supply Chains and Broader Trade Issues* (Apr. 8, 2020) available at <https://crsreports.congress.gov/product/pdf/R/R46304>.

¹⁰⁰ Martha Mendoza and Juliet Lindeman, *Imports of medical supplies plummet as demand in US soars*, THE ASSOCIATED PRESS (Mar. 20, 2020), available at <https://apnews.com/6d9382c1e8ee36f9ed1a4dfe7815ceb1>.

¹⁰¹ Research and Markets, *Global Personal Protective Equipment Market Study (2020 to 2025) - Growth, Trends and Forecasts (2020 – 2025)*, GLOBE NEWS WIRE (June 8, 2020), available at <https://www.globenewswire.com/news-release/2020/06/08/2044788/0/en/Global-Personal-Protective-Equipment->

- U.S. imports of hand sanitizer and swabs both dropped by 40 percent in March 2020, imports of N95 mask dropped 55 percent and over-the-counter medical shipments decreased.¹⁰² Medical thermometer shipments that arrived in March 2020 were half the amount that arrived during the same period the previous year.¹⁰³
- In early April 2020, an analysis by the Society for Healthcare Organization Procurement Professionals concluded that the cost of an N95 mask had increased 1,513 percent from pre-pandemic prices and the cost of a gown increased by 2,000 percent.¹⁰⁴
- Surging demand, deficient supply sources and, to a lesser extent, panic buying, hoarding, and misuse of PPE, disrupted the global supply chain and risked the health of people all over the world.¹⁰⁵
- Moreover, the air cargo industry has been transformed because of the pandemic. Passenger airline air cargo operation capacity decreased 75 percent and freighter aircraft capacity operations increased 10 percent, resulting in a net global change of 30 percent reduction in overall air cargo capacity. Urgent shipments of PPE and pharmaceutical and medical devices replaced pre-pandemic cargo commodity shares of flowers, electronics, fashion, and food. World air cargo volume was down 23 percent in March 2020.¹⁰⁶
 - **If air cargo capacity remains low, the Executive Branch should consider whether contract arrangements should be made to secure additional space for transportation of medical supplies to the U.S. through use of air cargo services with FedEx, UPS, and DHL which were the least disrupted during the initial outbreak.**¹⁰⁷
- Supply chains that use digital technologies and digital data to maintain workflow and manage logistics were less adversely impacted than those without digital support. Companies that have incorporated technology into their supply chains and workflow

Market-Study-2020-to-2025-Growth-Trends-and-Forecasts.html.

¹⁰² Martha Mendoza and Juliet Lindeman, *Imports of medical supplies plummet as demand in US soars*, THE ASSOCIATED PRESS (Mar. 20, 2020), available at <https://apnews.com/6d9382c1e8ee36f9ed1a4dfe7815ceb1>.

¹⁰³ *Id.*

¹⁰⁴ James Berklan, *Analysis: PPE costs increase over 1,000% during COVID-19 crisis*, MCKNIGHT'S LONG-TERM CARE NEWS (Apr. 9, 2020), available at <https://www.mcknights.com/news/analysis-ppe-costs-increase-over-1000-during-covid-19-crisis/>.

¹⁰⁵ Research and Markets, *Global Personal Protective Equipment Market Study (2020 to 2025) - Growth, Trends and Forecasts (2020 – 2025)*, GLOBE NEWS WIRE (June 8, 2020), available at <https://www.globenewswire.com/news-release/2020/06/08/2044788/0/en/Global-Personal-Protective-Equipment-Market-Study-2020-to-2025-Growth-Trends-and-Forecasts.html>.

¹⁰⁶ Mike Meyer, Paul Bingham, and Anne Strauss-Wieder, *TRB Webinar: The Supply Chain and COVID-19*, The National Academies of Sciences, Engineering, and Medicine (Apr. 8, 2020), available at <https://www.nationalacademies.org/event/04-08-2020/trb-webinar-the-supply-chain-and-covid-19>.

¹⁰⁷ *Id.*

for a digital workforce were more easily able to improve productivity either through conducting virtual business, relying on artificial intelligence, or tracking inventory.¹⁰⁸

- As discussed in the following sections, the federal government and private sector undertook a number of initiatives to restore supply chains and increase domestic manufacturing of critical products.

B. What efforts were undertaken by the federal government to address the worldwide shortage of PPE and other critical supplies?

- Thousands of employees across the Executive Branch have worked in tandem with the private sector and Congress to address the supply chain ramifications of the COVID-19 pandemic. While this report lays out major initiatives of the Executive Branch, it does not include all of the work done to address the worldwide shortages of critical supplies.
- During the pandemic, and to increase the supply of needed medical supplies, the federal government’s response has involved a number of temporary authorities related to contracting provided under the Stafford Act, the DPA, and emergency acquisitions under the Federal Acquisition Regulation (FAR) Part 18. These emergency authorities give the federal government greater ability to acquire goods in a streamlined and accelerated manner. Many of the typical contracting requirements are temporarily waived. For example, agencies are not required to provide full and open competition for “contracting actions involving urgent requirements.”¹⁰⁹ In addition, for the COVID-19 response, some acquisition threshold limits were increased.
- On March 20, 2020, the Office of Management and Budget (OMB) issued a memorandum to agencies outlining flexibilities authorized in connection with the President’s emergency declaration, including increases to the micro-purchase threshold (MPT), the simplified acquisition threshold (SAT), and the threshold for using simplified procedures for certain commercial items, to enable more rapid response and increased dollar amounts for commercial purchases.¹¹⁰
 - An MPT is a dollar amount below which micro-purchases of supplies or services using simplified acquisition procedures can be made and is usually

¹⁰⁸ Ridhika Batra, *The COVID-19 pandemic will expedite long-standing transformations in supply chains and entertainment digitization*, ATLANTIC COUNCIL (June 15, 2020), available at <https://www.atlanticcouncil.org/blogs/new-atlanticist/the-covid-19-pandemic-will-expedite-long-standing-transformations-in-supply-chains-and-entertainment-digitalization/>.

¹⁰⁹ Federal Acquisition Regulations, Part 6 – Competition Requirements, 6.302-2 - Unusual and compelling urgency, (FAR 6.302-2), available at <https://www.acquisition.gov/content/part-6-competition-requirements>.

¹¹⁰ Executive Office of the President, Office of Management and Budget, Memorandum to the Heads of Executive Departments and Agencies, From: Margaret M. Weichert, Deputy Director for Management, Subject: Managing Federal Contract Performance Issues Associated with the Novel Coronavirus (COVID-19) (Mar. 20, 2020), available at <https://www.whitehouse.gov/wp-content/uploads/2020/03/M-20-18.pdf>.

\$10,000.¹¹¹ OMB raised the MPT to \$20,000 for domestic purchases and to \$30,000 for purchases outside the U.S.¹¹²

- A SAT is the dollar amount below which a non-Federal entity may purchase property or services using small purchase methods and is usually \$250,000.¹¹³ OMB raised the SAT to \$750,000 for domestic purchases and to \$1.5 million for purchases outside the U.S.¹¹⁴
- The threshold for using simplified procedures for certain commercial items is greater than the simplified acquisition threshold dollar amount but does not exceed \$7 million, except for a \$13 million threshold for acquisitions described in FAR 13.500(c).¹¹⁵ OMB authorized use of simplified acquisition procedures up to \$13 million.¹¹⁶
- Executive Orders 13909 and 13911 delegated DPA authorities to the Secretaries of HHS and DHS to ensure that the nation's public health and health care systems were able to surge capacity needed to respond to the spread of COVID-19, through domestic expansion and production of health and medical resources, including PPE and ventilators.¹¹⁷
 - **In order to ensure the stability of supply chains, Congress and the Executive Branch should evaluate how federal agencies coordinate contracting considerations, and ensure that they clearly communicate their actions and plans regarding medical supply chain coordination efforts to ensure process transparency.**
- In March 2020, the Office of the U.S. Trade Representative (USTR) determined to not impose tariffs on certain critical products such as ventilators, oxygen masks, and

¹¹¹ 41 U.S.C. 1902(a).

¹¹² Executive Office of the President, Office of Management and Budget, Memorandum to the Heads of Executive Departments and Agencies, From: Margaret M. Weichert, Deputy Director for Management, Subject: Managing Federal Contract Performance Issues Associated with the Novel Coronavirus (COVID-19) (Mar. 20, 2020), available at <https://www.whitehouse.gov/wp-content/uploads/2020/03/M-20-18.pdf>.

¹¹³ 2 CFR 200.88.

¹¹⁴ Executive Office of the President, Office of Management and Budget, Memorandum to the Heads of Executive Departments and Agencies, From: Margaret M. Weichert, Deputy Director for Management, Subject: Managing Federal Contract Performance Issues Associated with the Novel Coronavirus (COVID-19) (Mar. 20, 2020), available at <https://www.whitehouse.gov/wp-content/uploads/2020/03/M-20-18.pdf>.

¹¹⁵ 48 CFR Subpart 13.5.

¹¹⁶ Executive Office of the President, Office of Management and Budget, Memorandum to the Heads of Executive Departments and Agencies, From: Margaret M. Weichert, Deputy Director for Management, Subject: Managing Federal Contract Performance Issues Associated with the Novel Coronavirus (COVID-19) (Mar. 20, 2020), available at <https://www.whitehouse.gov/wp-content/uploads/2020/03/M-20-18.pdf>.

¹¹⁷ 85 FR 16227, *Prioritizing and Allocating Health and Medical Resources to Respond to the Spread of COVID-19* (Mar. 23, 2020), available at <https://www.federalregister.gov/documents/2020/03/23/2020-06161/prioritizing-and-allocating-health-and-medical-resources-to-respond-to-the-spread-of-covid-19>; 85 FR 18403, *Delegating Additional Authority Under the Defense Production Act With Respect to Health and Medical Resources To Respond to the Spread of COVID-19* (Apr. 1, 2020), available at <https://www.federalregister.gov/documents/2020/04/01/2020-06969/delegating-additional-a-authority-under-the-defense-production-act-with-respect-to-health-and-medical>.

nebulizers in an effort to increase critical supplies while reducing costs for imported critical medical supplies to the U.S. USTR had already issued a large number of tariff exclusions in 2019 for health-related products as a result of working together with HHS to ensure that critical medicines and other essential medical products were not subject to additional tariffs.¹¹⁸

- **Congress and the Executive Branch should review critical medical equipment temporary tariff exclusions to determine if additional exclusions are needed, and if any approved exclusions need to be extended to assist in the response to the pandemic.**
- The temporary procurement flexibilities in place needed for the COVID-19 pandemic response should be used for their intended purpose of acting swiftly, but the Executive Branch should remain diligent in properly vetting potential suppliers. Public funding, and federal funding in particular, is tied to numerous compliance obligations that do not apply in the private sector, and companies that never previously conducted business with the federal government are working as federal government contractors for the first time. Federal contracts are governed by responsibilities in the FAR, such as record-keeping and auditing requirements, and failure to comply could trigger exposure under the federal False Claims Act.
 - **Government contractors and suppliers, particularly those working with the federal government for the first time, should ensure that they are in compliance with all provisions of their agreements.**
 - **Before a resurgence of COVID-19 cases, the Executive Branch should identify and coordinate response distribution roles and responsibilities and ensure agencies, and any other FEMA-facilitated third parties, avoid duplication of effort to ensure efficient operations.**
 - a. Major efforts undertaken by FEMA and ASPR
- As discussed above, in the early weeks of the pandemic, HHS, through ASPR, dispensed much of its relevant supplies in the SNS, which were limited, to the states. It quickly became clear that more supplies, and better coordination of supply and demand, was needed. FEMA and HHS, along with other federal partners, undertook several major initiatives to increase access to critical supplies.
- In addition to procurement efforts to resupply materials traditionally held in the SNS, FEMA, HHS, and other federal entities have worked to procure and distribute health care supplies specific to the COVID-19 response. For example:

¹¹⁸ Office of the U.S. Trade Representative, *USTR: Response to Coronavirus Crisis*, Executive Office of the President USTR (Mar. 20, 2020), available at <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2020/march/ustr-response-coronavirus-crisis>.

- FEMA has been working to source and procure testing materials, including testing swabs and transport media. As of August 5, 2020, FEMA has procured and delivered more than 41.9 million swabs and 32.9 million units of media.¹¹⁹
- As of August 17, 2020, FEMA, HHS, and CISA, along with other federal agencies processed and distributed over 350 million cloth face coverings for critical infrastructure workers.¹²⁰
- To address the imbalance between supply and demand for PPE, ventilators, supplies needed for diagnostic testing, and other medical supplies, the Supply Chain Stabilization Task Force was assembled on March 20, 2020, to address widespread shortfalls amidst the global competition for supplies.¹²¹ The primary mission of the Supply Chain Stabilization Task Force is to source PPE, ventilators, and other critical resources to respond to requests by states, tribes, and territories through the NRCC using a four-prong approach of Preservation, Acceleration, Expansion, and Allocation.¹²²
 - The Supply Chain Stabilization Task Force works in conjunction with FEMA's NRCC and consists of a multi-faceted team across the U.S. government, as well as liaisons from the private sector. In support of this effort, over a dozen agencies and departments, including DoD, DLA, HHS, CDC, DHS, and the U.S. Department of Veterans Affairs (VA), are embedded within the Supply Chain Stabilization Task Force to coordinate response efforts.¹²³
 - The Supply Chain Stabilization Task Force, in conjunction with other agencies and task forces, sourced PPE, swabs, ventilators, and other critical resources for points of care nationwide, with a special consideration given to supporting health care workers on the front line and then other priority groups,

¹¹⁹ U.S. Federal Emergency Management Agency, *Weekly Update: Coronavirus Pandemic Whole-of-America Response* (Aug. 5, 2020) (on file with Committee).

¹²⁰ U.S. Federal Emergency Management Agency, *Weekly Update: Coronavirus Pandemic Whole-of-America Response* (Aug. 17, 2020) (on file with Committee).

¹²¹ *Federal Government's Efforts for Procurement and Distribution of Critical Medical Equipment and Supplies in Response to the COVID-19 Pandemic: Hearing before the H. Select Subcomm. on the Coronavirus Crisis*, Statement of Rear Admiral John Polowczyk, Supply Chain Stabilization Task Force, U.S. Department of Defense (July 2, 2020), available at <https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/Rear%20Admiral%20JOHN%20POLOWCZYK%20Testimony.pdf>.

¹²² U.S. Federal Emergency Management Agency, *Coronavirus (COVID-19) Pandemic: Supply Chain Stabilization Task Force* (Mar. 30, 2020), available at <https://www.fema.gov/fema-supply-chain-stabilization-task-force>.

¹²³ *Federal Government's Efforts for Procurement and Distribution of Critical Medical Equipment and Supplies in Response to the COVID-19 Pandemic: Hearing before the H. Select Subcomm. on the Coronavirus Crisis*, Statement of Rear Admiral John Polowczyk, Supply Chain Stabilization Task Force, U.S. Department of Defense (July 2, 2020), available at <https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/Rear%20Admiral%20JOHN%20POLOWCZYK%20Testimony.pdf>.

including first responders and critical infrastructure workers in lifeline industries who are unable to practice social distancing due to the nature of their work.¹²⁴

- The Supply Chain Stabilization Task Force coordinated and communicated with industry through the National Business Emergency Operations Center (NBEOC), FEMA’s virtual clearinghouse for two-way information sharing between public and private sector stakeholders.¹²⁵ NBEOC enhances communication and collaboration with private industry partners and ensures their integration into disaster operations at strategic and tactical levels. NBEOC members are linked into FEMA’s NRCC, activated RRCCs, and the broader emergency management operations network, which includes state and federal partners.¹²⁶
- FEMA has used various contracting mechanisms to secure health resources during the COVID-19 response, with over three-quarters of their procurements being for medical and surgical equipment, such as reusable surgical gowns and N95 respirators or masks for medical professionals.¹²⁷
 - Some of the Supply Chain Stabilization Task Force procurement responsibilities previously led by FEMA transitioned May 29, 2020 to DoD’s DLA while FEMA focuses resources to prepare for wildfire and hurricane season.¹²⁸
 - **Congress and the Executive Branch should examine whether the procurement and supply distribution responsibilities among agencies should be more clearly delineated before any subsequent waves of the COVID-19 pandemic occur.**
- Project Air Bridge was created to greatly reduce the time it took for U.S. medical supply distributors to receive PPE and other critical medical supplies and get them to their customers.¹²⁹ The length of transit for cargo freight to ship to the U.S. by sea is about four weeks, which was too long to wait for critical supplies. Under Project Air Bridge, the six largest U.S. distributors, which represent more than 90 percent of the medical supply chain, ordered supplies from overseas factories, then FEMA

¹²⁴ *Id.*

¹²⁵ U.S. Federal Emergency Management Agency, *National Business Emergency Operations Center* (May 1, 2020), available at <https://www.fema.gov/nbeoc>.

¹²⁶ *Id.*

¹²⁷ U.S. Government Accountability Office, *COVID-19: Opportunities to Improve Federal Response and Recovery Efforts Report to the Congress*, GAO-20-625 (June 25, 2020), available at <https://www.gao.gov/reports/GAO-20-625/>.

¹²⁸ *Id.*; Memorandum of Understanding Between the Federal Emergency Management Agency and the Department of Health and Human Services, Office of Assistant Secretary of Preparedness Response (Apr. 5, 2020) (on file with Committee).

¹²⁹ U.S. Federal Emergency Management Agency, *FEMA COVID-19 Supply Chain Task Force: Supply Chain Stabilization*, FEMA Advisory (Apr. 8, 2020), available at <https://www.fema.gov/news-release/2020/04/08/fema-covid-19-supply-chain-task-force-supply-chain-stabilization>.

organized and paid for the airlifts that transported supplies in a matter of days as opposed to weeks.¹³⁰

- On average, the cost of each flight was approximately \$750,000 to \$800,000, depending on the carriers and cargo being air lifted.¹³¹
- As part of the agreement with the distributors, when flown in via the air bridge, half of the supplies were directed to areas identified by the National Resource Prioritization Cell to hotspots to alleviate the hardest hit parts of the country.¹³² The remaining 50 percent of supplies entered that distributor's normal supply chain to customers across the U.S.¹³³ Using distributors to deliver supplies leveraged the existing and effective commercial supply chain distribution ecosystem, rather than having states or the federal government create new distribution supply chains.¹³⁴
- Between March 29, 2020 and June 30, 2020, 249 Project Air Bridge flights helped to move supplies up to nine times faster than cargo deliveries by sea.
 - The prioritized distributions included nearly 1.5 million N95 respirators, more than 2.5 million face shields, 937 million gloves, 113.4 million surgical masks, 1.4 million coveralls, 50.9 million gowns, more than 2.4 million thermometers and 109,000 stethoscopes.¹³⁵
 - The UCG approved phasing out Project Air Bridge with the final flight landing in the U.S. around June 30, 2020. If needed, Project Air Bridge could be reinitiated to expedite deliveries of medical items should the U.S. have a future emergent need for critical PPE due to COVID-19.¹³⁶

¹³⁰ Anne Flaherty, Kaitlyn Folmer and Benjamin Siegel, *Kushner-backed program chartering flights to address hospital shortages raises questions in Congress*, ABC NEWS (Apr. 23, 2020), available at <https://abcnews.go.com/Politics/kushner-backed-program-charters-flights-medical-supplies-behalf/story?id=70291872>.

¹³¹ *Id.*

¹³² Hearing before U.S. House of Representatives Select Subcommittee on the Coronavirus Crisis, *Federal Government's Efforts for Procurement and Distribution of Critical Medical Equipment and Supplies in Response to the COVID-19 Pandemic*, Statement of Rear Admiral John Polowczyk, Supply Chain Stabilization Task Force, U.S. Department of Defense (July 2, 2020), available at <https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/Rear%20Admiral%20JOHN%20POLOWCZYK%20Testimony.pdf>.

¹³³ Anne Flaherty, Kaitlyn Folmer and Benjamin Siegel, *Kushner-backed program chartering flights to address hospital shortages raises questions in Congress*, ABC NEWS (Apr. 23, 2020), available at <https://abcnews.go.com/Politics/kushner-backed-program-charters-flights-medical-supplies-behalf/story?id=70291872>.

¹³⁴ *Id.*

¹³⁵ U.S. Federal Emergency Management Agency, *FEMA Phasing Out Project Airbridge*, Release Number HQ-20-161 (June 18, 2020), available at <https://www.fema.gov/news-release/2020/06/18/fema-phasing-out-project-airbridge>.

¹³⁶ *Id.*

- Project Air Bridge was not the only means by which critical supplies entered the U.S. FEMA and HHS procured and obtained large numbers of supplies, and distributors utilized their own networks to expedite supplies to the U.S. For example:
 - As of August 7, 2020, FEMA, HHS, and the private sector coordinated delivery of, or are currently shipping: 208.8 million N95 respirators, 889.5 million surgical masks, 38.1 million face shields, 374.8 million surgical gowns/coveralls, and over 22.5 billion gloves.¹³⁷
 - Since May 20, 2020, 99 non-Air Bridge flights carried over 16.8 million Hanes gowns to the U.S.¹³⁸
 - Since April 12, 2020, 55 non-Air Bridge flights carried over 72.3 million FEMA-procured masks and respirators from 3M to the U.S.¹³⁹
 - On April 8, 2020, ASPR announced that DuPont would expedite the delivery of critical PPE, TYVEK suits, needed for U.S. health care workers responding to the COVID-19 pandemic, up to a possible total of 4.5 million.¹⁴⁰
- **The Executive Branch should consider what metrics will be used to determine if Project Air Bridge will be relaunched and how that coordination will occur if the Supply Chain Stabilization Task Force is no longer operational.**
- **Congress and the Executive Branch should consider whether procedures to replace any of the temporary and stopgap transport and delivery systems being used for the current outbreak should be established before a potential resurgence of cases in the fall, or in the event of future pandemics.**
- **Congress and the Executive Branch should consider how to leverage data and other information gathered by the Supply Chain Stabilization Task Force to best prepare for future demand surges.**
- On April 10, 2020, FEMA published a temporary rule, the Prioritization and Allocation of Certain Scarce or Threatened Health and Medical Resources for Domestic Use, effective through August 10, 2020, that allocates certain scarce or

¹³⁷ U.S. Federal Emergency Management Agency, *Coronavirus Pandemic Whole-of-America Response, By the Numbers* (Aug. 17, 2020) (on file with Committee).

¹³⁸ U.S. Federal Emergency Management Agency, *Weekly Update: Coronavirus Pandemic Whole-of-America Response* (July 7, 2020) (on file with Committee).

¹³⁹ *Id.*

¹⁴⁰ U.S. Department of Health and Human Services, *HHS to Provide Millions of TYVEK Protective Suits for U.S. Healthcare Workers* (Apr. 8, 2020), available at <https://www.hhs.gov/about/news/2020/04/08/hhs-provide-millions-tyvek-protective-suits-us-healthcare-workers.html>.

threatened materials for domestic use, so that they may not be exported from the U.S. without FEMA approval.¹⁴¹ The rule covers five types of PPE: (1) N95 FFRs; (2) other FFRs; (3) Elastomeric, air purifying respirators and particulate filters/cartridges; (4) PPE surgical masks; and (5) PPE gloves or surgical gloves.¹⁴² The intent of the rule is to preserve scarce PPE for domestic use in the response to the COVID-19 emergency.¹⁴³

- In May 2020, FEMA announced their standards and procedures to use the DPA during the pandemic response. The President delegated the DPA authority with respect to health and medical resources to respond to the spread of COVID-19 in Executive Order 13911.¹⁴⁴
 - On May 13, 2020, FEMA published the Emergency Management Priorities and Allocations System regulations governing FEMA’s use of DPA Title I priorities and allocations authority. FEMA included a concept of “rated orders placed by FEMA or a third-party Delegate Agency,” which could allow FEMA to facilitate third-party transactions, similar to the role of a distributor, in contracts that could include support of hospitals or other health entities for ordering PPE, ventilators, and potential treatments.¹⁴⁵ This use of DPA authorities potentially allows FEMA to relieve certain restrictions such as equitable distribution and rationing restrictions that generally apply to allocation actions.¹⁴⁶
 - On August 17, 2020, FEMA announced the formation of a five-year voluntary agreement under Section 708 of the DPA for the manufacture and distribution of critical healthcare resources for the response to COVID-19 and future pandemics.¹⁴⁷ The voluntary agreement formalizes the collaboration between the private sector and federal government for integrated coordination, planning, and information sharing for the manufacturing and distribution of

¹⁴¹ 85 FR 20195, *Prioritization and Allocation of Certain Scarce or Threatened Health and Medical Resources for Domestic Use* (Apr. 10, 2020), available at <https://www.federalregister.gov/documents/2020/04/10/2020-07659/prioritization-and-allocation-of-certain-scarce-or-threatened-health-and-medical-resources-for>.

¹⁴² *Id.*

¹⁴³ *Id.*

¹⁴⁴ 85 FR 18403, *Delegating Additional Authority Under the Defense Production Act With Respect to Health and Medical Resources to Respond to the Spread of COVID-19* (Apr. 1, 2020), available at <https://www.federalregister.gov/documents/2020/04/01/2020-06969/delegating-additional-authority-under-the-defense-production-act-with-respect-to-health-and-medical>.

¹⁴⁵ 85 FR 28500, *Emergency Management Priorities and Allocations Systems (EMPAS)* (May 13, 2020), available at <https://www.federalregister.gov/documents/2020/05/13/2020-10294/emergency-management-priorities-and-allocations-system-empas>.

¹⁴⁶ Jennifer Plitsch, Tyler Evans, and Carl Wiersum, *FEMA Continues to Push Defense Production Act Authority on Several Fronts*, COVINGTON (May 18, 2020), available at <https://www.insidegovernmentcontracts.com/2020/05/fema-continues-to-push-defense-production-act-authority-on-several-fronts/>.

¹⁴⁷ 85 FR 50035, *Voluntary Agreement Under Section 708 of the Defense Production Act; Manufacture and Distribution of Critical healthcare Resources Necessary to Respond to a Pandemic* (Aug. 17, 2020), available at <https://www.federalregister.gov/documents/2020/08/17/2020-18005/voluntary-agreement-under-section-708-of-the-defense-production-act-manufacture-and-distribution-of>.

PPE, pharmaceuticals, and critical health care resources during pandemics and COVID-19, specifically.¹⁴⁸ The voluntary agreement grants special legal relief from antitrust laws to participants for their actions that are within the scope of the agreement and at the direction of the federal government which would otherwise violate antitrust or contract laws.¹⁴⁹ FEMA sought and received approval from the Attorney General and the Federal Trade Commission that the agreement was necessary and appropriately limited in its anti-competitive impact.¹⁵⁰

- In April 2020, the U.S. Department of Justice (DOJ) cleared antitrust concerns of major medical suppliers Cardinal Health, Henry Schein, McKesson, Medline Industries, and Owens & Minor in response to a request from the companies that their activities to prevent and eliminate supply chain bottlenecks, find and create new PPE supply sources, negotiate pricing, distribute supplies to FEMA-designated hotspots, and share data to coordinate those activities would not be seen by DOJ to transgress antitrust laws, effective for one year.¹⁵¹ A company entering into the Coronavirus Voluntary Agreement would not need to seek additional clearances from DOJ and would immediately be able to engage in operations with FEMA without any delay while waiting for DOJ's opinion.
- Numerous DPA-related production actions had been taken by the Administration:
 - On April 8, 2020, HHS announced a \$489.4 million contract with GM for 6,132 ventilators to be delivered to the SNS by June 1, 2020, and 30,000 ventilators by August 2020.¹⁵² This “was the first DPA-rated contract issued in response to the COVID-19 emergency (i.e. using Title I priority-rated orders through the Health Priorities and Allocations System).”¹⁵³

¹⁴⁸ *Id.*

¹⁴⁹ Jennifer Plitsch, Tyler Evans, and Carl Wiersum, *FEMA Continues to Push Defense Production Act Authority on Several Fronts*, COVINGTON (May 18, 2020), available at <https://www.insidegovernmentcontracts.com/2020/05/fema-continues-to-push-defense-production-act-authority-on-several-fronts/>.

¹⁵⁰ Federal Emergency Management Agency, *FEMA Establishes a Voluntary Agreement with Industry to Assist in Pandemic Response* (Aug. 17, 2020) (on file with Committee).

¹⁵¹ U.S. Department of Justice, Assistant Attorney General Makan Delrahim, *Response to McKesson Corporation, Owens & Minor, Inc., Cardinal Health, Inc., Medline Industries, Inc., and Henry Schein, Inc.'s Request for a Business Review Letter* (Apr. 4, 2020), available at <https://www.justice.gov/atr/page/file/1266511/download>.

¹⁵² Congressional Research Service, *Defense Production Act (DPA) and the COVID-19 Pandemic: Recent Developments and Policy Considerations* (Apr. 15, 2020), available at <https://crsreports.congress.gov/product/pdf/IN/IN11337>; U.S. Department of Health and Human Services, *HHS Announces Ventilator Contract with GM under Defense Production Act* (Apr. 8, 2020), available at <https://www.hhs.gov/about/news/2020/04/08/hhs-announces-ventilator-contract-with-gm-under-defense-production-act.html>.

¹⁵³ Congressional Research Service, *Defense Production Act (DPA) and the COVID-19 Pandemic: Recent*

- On April 8, 2020, HHS also announced a \$646.7 million contract with Philips for 2,500 ventilators to be delivered to the SNS by the end of May 2020, and 43,000 ventilators by December 2020.¹⁵⁴ This was the second Title I prioritization action.¹⁵⁵
- On April 11, 2020, DoD announced plans to use Title III authorities through a \$133 million investment dedicated to increasing domestic production capacity of N95 masks.¹⁵⁶
- On April 13, 2020, HHS announced contracts totaling \$533.2 million with General Electric, Hill-Rom, Medtronic, ResMed, and Vyaire for 31,416 ventilators using Title I DPA authorities.¹⁵⁷
- On April 29, 2020, DoD announced an investment of \$75.5 million in DPA Title III funding to increase swab production through a contract with Puritan Medical Products, to establish a new manufacturing facility capable of doubling its monthly output from 20 million to 40 million swabs.¹⁵⁸
- On May 28, 2020, DoD Announced a Defense Production Act Title III COVID-19 PPE Project to increase U.S. production of N95 respirators and mask ventilator filters by over 30 million combined in the subsequent 120 days. DoD, in support of HHS, signed a \$2.2 million contract with Hollingsworth & Vose to increase U.S. domestic

Developments and Policy Considerations (Apr. 15, 2020), available at <https://crsreports.congress.gov/product/pdf/IN/IN11337>.

¹⁵⁴ *Id.*; U.S. Department of Health and Human Services, *HHS Announces Ventilator Contract with Philips under Defense Production Act* (Apr. 8, 2020), available at <https://www.hhs.gov/about/news/2020/04/08/hhs-announces-ventilator-contract-with-philips-under-defense-production-act.html>.

¹⁵⁵ Congressional Research Service, *Defense Production Act (DPA) and the COVID-19 Pandemic: Recent Developments and Policy Considerations* (Apr. 15, 2020), available at <https://crsreports.congress.gov/product/pdf/IN/IN11337>.

¹⁵⁶ *Id.*; U.S. Department of Defense, *First DOD Defense Production Act Title 3 COVID-19 Project* (Apr. 11, 2020), available at <https://www.defense.gov/Newsroom/Releases/Release/Article/2146692/first-dod-defense-production-act-title-3-covid-19-project/>.

¹⁵⁷ Congressional Research Service, *Defense Production Act (DPA) and the COVID-19 Pandemic: Recent Developments and Policy Considerations* (Apr. 15, 2020), available at <https://crsreports.congress.gov/product/pdf/IN/IN11337>; U.S. Department of Health and Human Services, *HHS Announces New Ventilator Contracts, Orders Now Totaling Over 130,000 Ventilators* (Apr. 13, 2020), available at <https://www.hhs.gov/about/news/2020/04/13/hhs-announces-new-ventilator-contracts-orders-now-totaling-over-130000-ventilators.html>.

¹⁵⁸ U.S. Department of Defense, *DOD Details \$75 Million Defense Production Act Title 3 Puritan Contract* (Apr. 29, 2020), available at <https://www.defense.gov/Newsroom/Releases/Release/Article/2170355/dod-details-75-million-defense-production-act-title-3-puritan-contract/>.

production of 27.5 million N95 ventilator filters, and 3.1 million N95 respirators per month, starting in August 2020.¹⁵⁹

- In addition, there were non-production related DPA actions, including:
 - DOJ announced an arrest on March 30, 2020, and the seizure and redistribution of hoarded medical supplies on April 2, 2020, pursuant to the HHS *Notice of Designation of Scarce Materials or Threatened Materials Subject to COVID-19 Hoarding Prevention Measures*, which was issued per Executive Order 13910.¹⁶⁰
 - On April 10, 2020, FEMA, in coordination with Customs and Border Protection, released guidance on the use of the DPA to allocate specified scarce medical supplies exclusively for domestic use and “may not be exported” without FEMA’s authorization.¹⁶¹
- FEMA also assisted in the construction of Alternate Care Sites (ACS), along with the U.S. Army Corps of Engineers (Army Corps), that were requested by several states. FEMA and the Army Corps worked with states to identify potential sites, conduct site assessments, secure funding, secure the property, and then convert the sites for health care use.¹⁶² HHS created an ACS Toolkit as medical operations guidance and technical assistance to help state, local, tribal, and territorial entities in establishing and operationalizing an ACS for COVID-19 related patient care.¹⁶³ The Army Corps’ COVID-19 response efforts resulted in assessments of 1,155 sites, and conversion of arenas, hotels, and convention centers to a total ACS bed count of 15,074 as of May 29, 2020.¹⁶⁴
 - On May 12, 2020, FEMA released a fact sheet which stated that under certain conditions, state, local, tribal, and territorial governments may be reimbursed through FEMA’s Public Assistance Program for costs associated with keeping ACS locations minimally operational and ready for surge capacity use, for no

¹⁵⁹ U.S. Department of Defense, *DOD Announces Defense Production Act Title 3 COVID-19 PPE Project: \$2.2 Billion Investment Will Increase U.S. Domestic Production of N95 Mask Respirator and Mask Ventilator Filter Production by Over 30 Million Combined Over the Next 120 Days* (May 28, 2020), available at <https://www.defense.gov/Newsroom/Releases/Release/Article/2200654/dod-announces-defense-production-act-title-3-covid-19-ppe-project-22-million-in/>.

¹⁶⁰ Congressional Research Service, *Defense Production Act (DPA) and the COVID-19 Pandemic: Recent Developments and Policy Considerations* (Apr. 15, 2020), available at <https://crsreports.congress.gov/product/pdf/IN/IN11337>.

¹⁶¹ *Id.*

¹⁶² U.S. Army Corps of Engineers, *Alternate Care Sites*, available at <https://www.usace.army.mil/Coronavirus/Alternate-Care-Sites/> (last visited July 29, 2020).

¹⁶³ U.S. Department of Health and Human Services, *Federal ACS Toolkit Third Edition* (June 30, 2020), available at <https://files.asprtracie.hhs.gov/documents/acs-toolkit-ed1-20200330-1022.pdf>.

¹⁶⁴ U.S. Army Corps of Engineers, *USACE COVID-19 Response Efforts* (May 29, 2020), available at <https://www.usace.army.mil/Coronavirus/> (last visited Aug. 17, 2020)

more than 30 days after the end of the COVID-19 Public Health Emergency.¹⁶⁵

- **Congress and the Executive Branch should evaluate if additional authorities may be needed to support keeping ACS sites in a “warm” status so that they can be activated, if needed, during a resurgence of COVID-19 cases.**

b. Major efforts undertaken by FDA, CDC, and CMS

- Numerous efforts have been undertaken by FDA to increase the availability of medical supplies and medicines, and to authorize safe alternatives when supplies are in shortage or not available.
- To help increase the availability of ventilators and their accessories, as well as other respiratory devices during the COVID-19 pandemic, FDA issued an umbrella EUA for ventilators and ventilator accessories on March 24, 2020, in response to concerns about the insufficient supply of FDA-cleared ventilators for use in health care settings to treat COVID-19 patients.
 - This EUA provides authorization of certain ventilators, anesthesia gas machines modified for use as ventilators, positive pressure breathing devices modified for use as ventilators, ventilator tubing connectors, and ventilator accessories that FDA determines meet specified criteria for safety, performance, and labeling.¹⁶⁶
 - As of July 1, 2020, FDA had added more than 85 ventilators and accessories for emergency use to the ventilator EUA.¹⁶⁷
- FDA issued EUAs and policies to help increase the availability of PPE, such as respirators, gowns, and surgical masks.¹⁶⁸
 - On April 3, 2020, FDA issued an umbrella EUA for certain FFRs that are not approved by NIOSH and are manufactured in China.¹⁶⁹

¹⁶⁵ U.S. Federal Emergency Management Agency, *Coronavirus (COVID-19) Pandemic: Alternate Care Site (ACS) “Warm Sites”* (May 12, 2020), available at https://www.fema.gov/media-library-data/1589388702153-9c17f0b4bd1dd22531960c39f96a4701/FEMA_Fact_Sheet_ACS_Warm_Sites_5-12-2020_508.pdf.

¹⁶⁶ U.S. Food and Drug Administration, *Ventilators and Ventilator Accessories EUAs*, FDA Coronavirus Disease (COVID-19) Emergency Use Authorizations for Medical Devices (July 10, 2020), available at <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/ventilators-and-ventilator-accessories-euas>.

¹⁶⁷ Food and Drug Administration, *FDA COVID-19 Response At-A-Glance Summary* (July 23, 2020), available at <https://www.fda.gov/media/137005/download>.

¹⁶⁸ U.S. Food and Drug Administration, *Personal Protective Equipment EUAs* (July 17, 2020), available at <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas>.

¹⁶⁹ *Id.*

- On April 13, 2020, DoD announced a \$415 million contract awarded to Battelle by DLA for 60 FDA-authorized critical care decontamination system units for the sanitation and reuse of N95 respirators.¹⁷⁰ Each system can decontaminate up to 80,000 N95 used respirators per day, enabling mask reuse up to 20 times.¹⁷¹
- FDA entered into an Memorandum of Understanding with the NIH and the VA in a collaboration with America Makes, a public-private partnership organization that accelerates additive manufacturing and 3D printing technology manufacturing, to address the PPE and medical device shortages in the U.S.¹⁷² An important objective of the initiative is to test and validate designs for clinical setting devices so that manufacturers with 3D printing/additive manufacturing capabilities can fill in supply chain gaps at a large scale.¹⁷³ The adaptability of the advanced manufacturing 3D printing/additive manufacturing technology can make it easier to rapidly switch production lines because the materials are versatile, and products are easily customizable using additive layer-by-layer manufacturing.¹⁷⁴
 - Since March 27, 2020, the effort has matched more than 500,000 3D-printed face shields and more than 348,000 3D-printed face masks with health care providers and others in need, and has published 685 digital models of medical devices, with 33 reviewed for clinical use and 28 for community use.¹⁷⁵ This systemic review process encourages innovation while filtering designs, enabling rapid response, and informing testing criteria with medical device development experience, best practices for 3D printing and FDA, CDC, and NIOSH standards.¹⁷⁶
- FDA has also worked to increase the supply of hand sanitizer in the U.S., which was in extremely short supply in the early months of the pandemic. FDA has published and updated guidance for the production of alcohol-based hand sanitizer in non-

¹⁷⁰ U.S. Department of Defense, *DOD Contract for 60 N95 Critical Care Decontamination Units* (Apr. 13, 2020), available at <https://www.defense.gov/Newsroom/Releases/Release/Article/2148352/dod-contract-for-60-n95-critical-care-decontamination-units-415m-contract-each/>.

¹⁷¹ *Id.*

¹⁷² U.S. Food and Drug Administration, *FDA Efforts to Connect Manufacturers and Health Care Entities: The FDA, Department of Veterans Affairs, National Institutes of Health, and America Makes Form a COVID-19 response Public Private Partnership* (June 19, 2020), available at <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/fda-efforts-connect-manufacturers-and-health-care-entities-fda-department-veterans-affairs-national>.

¹⁷³ National Institutes of Health, *NIH 3D Print Exchange*, available at <https://3dprint.nih.gov/> (last visited June 29, 2020).

¹⁷⁴ *Id.*; GE Additive, *What is Additive Manufacturing*, available at <https://www.ge.com/additive/additive-manufacturing> (last visited July 30, 2020).

¹⁷⁵ U.S. Food and Drug Administration, *3D Printing in FDA's Rapid Response to COVID-19*, available at <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/3d-printing-fdas-rapid-response-covid-19> (last visited June 19, 2020).

¹⁷⁶ National Institutes of Health, *NIH 3D Print Exchange*, available at <https://3dprint.nih.gov/> (last visited Aug. 17, 2020).

traditional settings, such as pharmacies or distilleries, to help create additional supply to meet demand.

- Distilleries have been able to convert their production to medical-grade sanitizer in about two weeks because the companies had many of the necessary ingredients and liquor licenses already in place, and could follow FDA directives.¹⁷⁷
- Many companies plan to continue production while the need exists and believe the major impact of the virus will fundamentally change people's handwashing and sanitizing habits.¹⁷⁸
- FDA has also warned the public against the use of certain hand sanitizers during the COVID-19 pandemic. For example, in June 2020, without having received adverse event reports related to the hand sanitizers, FDA warned consumers against using certain hand sanitizers from a Mexican-based company that were found to contain methanol and have a toxic effect.¹⁷⁹ FDA publicly lists hand sanitizers that have been tested by FDA and are found to contain methanol, recalled by the manufacturer or distributor, or purportedly made at the same facility as products found to contain methanol.¹⁸⁰
- Several provisions in the CARES Act impact FDA's medical supply chain responsibilities related to drug and device shortages, as well as FDA's authority to prioritize applications and inspections to mitigate or prevent shortages. Many of the provisions do not take effect until late September 2020.¹⁸¹ For example:
 - The CARES Act added a new section to the FD&C Act that requires notification of supply disruption to the Secretary of HHS by manufacturers of critical medical devices or devices for which the Secretary determines that information on meaningful supply disruptions is needed during, or in advance of, a public health emergency.¹⁸² Critical medical devices are those that are life-supporting, life-sustaining, or for use in emergency medical care or surgery.¹⁸³ The notification of a permanent manufacture discontinuation of the device that is likely to lead to a meaningful disruption in the supply of the

¹⁷⁷ Micki Wagner, *New Habits, New Products: The Story Behind Liquor Companies Making Hand Sanitizer*, WORTH (May 12, 2020), available at <https://www.worth.com/new-habits-new-products-the-story-behind-liquor-companies-making-hand-sanitizer/>.

¹⁷⁸ *Id.*

¹⁷⁹ U.S. Food and Drug Administration, *FDA advises consumers not to use hand sanitizer products manufactured by Eskbiochem* (June 29, 2020), available at <https://www.fda.gov/drugs/drug-safety-and-availability/fda-advises-consumers-not-use-hand-sanitizer-products-manufactured-eskbiochem>.

¹⁸⁰ U.S. Food and Drug Administration, *FDA's testing and manufacturer/distributor recalls*, available at <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-hand-sanitizers-methanol#products> (last visited July 27, 2020).

¹⁸¹ Coronavirus Aid, Relief, and Economic Security Act (P.L. 116-136), enacted on March 27, 2020.

¹⁸² Coronavirus Aid, Relief, and Economic Security Act (P.L. 116-136, Sec. 3121), enacted on March 27, 2020.

¹⁸³ *Id.*

device and the reasons for such discontinuation or interruption should occur during, or in advance of, a public health emergency.¹⁸⁴

- The CARES Act expands drug manufacturer reporting requirements to include notifications to the Secretary of HHS of a discontinuation or interruption in the manufacture of a drug critical to public health during a public health emergency. It also requires notification of the permanent discontinuance or interruption in the manufacture of the API of those drugs subject to notification requirements that is likely to lead to a meaningful disruption in the supply of the API. The manufacturer must also provide the reason for and expected duration of the drug discontinuation or disruption, the API source, and any known alternative sources.¹⁸⁵
- The Act provides that the review of applications and establishment inspections that could help mitigate or prevent a device shortage shall be prioritized and expedited.¹⁸⁶
- CDC has promulgated over 2,699 documents providing information and guidance for government agencies, corporations, and the public as of August 14, 2020.¹⁸⁷ In addition, CDC published more than 100 guidance documents to advise health care providers on subjects including supply chain-related issues, such as PPE supply planning, strategies for optimizing PPE supplies of disposable medical gloves, eye protection products, gowns, face masks, and N95 respirators, and strategies for respirator conservation.¹⁸⁸ In addition to creating supply conservation guidance to optimize the use of limited supplies, CDC is working with supply chain partners to ensure that health care workers at highest risk have access to PPE, and understanding supply usage, product availability, and when more aggressive measures may need to be taken.¹⁸⁹
- NIOSH has created a PPE Burn Rate Calculator and a PPE Tracker mobile application, both of which facilities can use to track PPE inventory, calculate PPE consumption or “burn rate,” then use both data points to estimate the number of days their PPE supply will last.¹⁹⁰ Inventory totals adjust when restock data is added. The application can track inventory of gowns, gloves, surgical masks, face shields, respirators, and more by the number of boxes or number of individual units. The PPE

¹⁸⁴ *Id.*

¹⁸⁵ *Id.*

¹⁸⁶ *Id.*

¹⁸⁷ U.S. Centers for Disease Control and Prevention, *COVID-19 By the Numbers* (Aug. 17, 2020), available at <https://www.cdc.gov/coronavirus/2019-ncov/cdcreponse/by-the-numbers.html> (last visited Aug. 17, 2020).

¹⁸⁸ U.S. Centers for Disease Control and Prevention, *Strategies to Optimize the Supply of PPE and Equipment* (May 19, 2020), available at <https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html>.

¹⁸⁹ U.S. Centers for Disease Control and Prevention, *CDC’s Response* (July 22, 2020), available at <https://www.cdc.gov/coronavirus/2019-ncov/cdcreponse/index.html>.

¹⁹⁰ U.S. Centers for Disease Control and Prevention, *Personal Protective Equipment (PPE) Burn Rate Calculator* (Apr. 7, 2020), available at <https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/burn-calculator.html>.

burn rate can be calculated by the number of patients being treated and will track changes in PPE usage as patient numbers fluctuate.¹⁹¹

- In May 2020, CDC launched a nationwide initiative to address the staffing needs of state, local, and territorial health departments by providing access to a variety of innovative hiring mechanisms. The initiative complements local efforts to increase staffing capacity by giving flexibility for temporary reassignment of personnel to those applicants and recipients of federal financial assistance affected by COVID-19, realignment and deployment of CDC personnel, and partnering with AmeriCorps and the CDC Foundation to place surge staffing.¹⁹²
- To help hospitals prepare for potential increases or decreases of COVID-19 cases, CDC created a spreadsheet-based tool, COVID-19 Surge, which helps hospital administrators and public health officials estimate the demand for hospital-based services, such as the number of patients that may need ICU care or ventilator support.¹⁹³
- The Centers for Medicare and Medicaid Services (CMS) made sweeping regulatory changes to help the health care system address the COVID-19 patient surge, expand hospital capacity, increase the health care workforce, promote telehealth, and preserve supplies.
 - CMS modified requirements specific to providers and settings including: Hospice Care; End-Stage Renal Dialysis; Home Health Agencies; Physician Services; Long-Term Care Facilities; Skilled Nursing Facilities and/or Nursing Facilities; Rural Health Clinics; Federally Qualified Health Centers; Ground Ambulance; EMTALA; and Hospitals, Psychiatric Hospitals, and Critical Access Hospitals, including Cancer Centers and Long-Term Care Hospitals to allow for maximum mobility of providers to render treatment and extend medical resource supplies.¹⁹⁴
 - To decrease COVID-19 transmission exposure among health care workers and patients. and to minimize the use of PPE and other critical supplies, the U.S. transitioned to unprecedented access to telehealth and connected care.¹⁹⁵

¹⁹¹ *Id.*

¹⁹² U.S. Centers for Disease Control and Prevention, *CDC's Response to Support State, Tribal, Local, and Territorial Health Departments* (May 15, 2020), available at <https://www.cdc.gov/coronavirus/2019-ncov/php/open-america/response-corps.html>.

¹⁹³ U.S. Centers for Disease Control and Prevention, *COVID-19 Surge* (May 25, 2020), available at <https://www.cdc.gov/coronavirus/2019-ncov/hcp/COVIDSurge.html>.

¹⁹⁴ Centers for Medicare and Medicaid Services, *COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers* (July 28, 2020), available at <https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf>.

¹⁹⁵ *Telehealth: Lessons from the COVID-19 Pandemic: Hearing before Sen. Comm. on Health, Education, Labor and Pensions*, 116th Cong., Joint Statement for the Record, Healthcare Information and Management Systems Society (HIMSS) and Personal Connected Health Alliance (PCHAlliance) (June 17, 2020), available at <https://www.himss.org/sites/hde/files/media/file/2020/06/18/himsshhelp-committee-hearing-statement.pdf>.

Telehealth ensures timely access to care, and safe and effective treatment for infected and non-infected patients. Temporary regulatory changes enacted by Congress and CMS provided statutory authority for 1834(m) waivers to remove telehealth restrictions and recognize the patient's home as a reimbursable telehealth originating site.¹⁹⁶ These changes resulted in widespread telehealth access, notably for those in underserved and at-risk communities, and helped prevent exposure for health care workers and patients as well as mitigate PPE supply shortages.¹⁹⁷ Flexibilities for Medicare telehealth services included waiving the specific types of providers eligible to bill Medicare for their professional services via telehealth, and audio-only services became allowable for certain services.¹⁹⁸

- **Congress and the Executive Branch should consider whether the temporary telehealth flexibilities should be extended or made permanent to encourage a stable health care delivery platform on which innovative approaches to health care delivery can be built.**
- c. Major efforts undertaken by other federal agencies
 - DoD has also worked with FEMA and HHS to expand access to supplies and mitigate other supply chain issues.
 - In April 2020, DoD's DLA entered into interagency agreements with HHS and FEMA, in accordance with the Stafford and Economy Acts, to deliver services, personnel, and materials to support COVID-19 response efforts by enabling HHS and FEMA to order supplies directly from DLA.¹⁹⁹
 - The Stafford Act authorizes FEMA to assist in the distribution of medicine, food, and other consumable supplies. Under the Economy Act, agencies may enter into interagency agreements where federal agencies can order goods and services from other federal agencies.²⁰⁰
 - DLA increased production and acquisition of critical supplies through existing large-scale contracts across multiple supply chains to increase product supply

¹⁹⁶ *Id.*

¹⁹⁷ *Id.*

¹⁹⁸ U.S. Centers for Medicare and Medicaid Services, *COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers* (June 25, 2020), available at <https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf>.

¹⁹⁹ Diane Ryder, *DLA leverages partnerships with FEMA, HHS to support pandemic*, DEFENSE LOGISTICS AGENCY (Apr. 22, 2020), available at <https://www.dla.mil/AboutDLA/News/NewsArticleView/Article/2159785/dla-leverages-partnerships-with-fema-hhs-to-support-pandemic/>.

²⁰⁰ Hearing before U.S. House Committee on Armed Services, *Department of Defense COVID-19 Response to Industrial Base Challenges*, Statement of Ellen Lord, Under Secretary of Defense for Acquisition and Sustainment, (June 10, 2020) available at <https://www.congress.gov/116/meeting/house/110794/witnesses/HHRG-116-AS00-Wstate-LordE-20200610.pdf>.

availability.²⁰¹ DLA stocked the USNS Comfort and Mercy with over \$14 million in supplies including PPE, pharmaceuticals, and medical supplies.²⁰²

- As of July 21, 2020, DLA has supported 15,000 nursing homes with 1.2 million eye protection products, 643.5 million face shields, 12.8 million gowns, 64.4 million gloves, and 13.8 million masks.²⁰³
- In addition, DLA operates FedMall—DoD’s e-commerce platform—and created a COVID-19 Contingency Corridor to allow small business contractors to buy non-medical PPE items to help ensure the safety of their non-medical workforce that have had difficulties purchasing supplies.²⁰⁴
- In mid-July 2020, FedMall opened the COVID-19 Contingency Store to eligible state and local governments to shop for non-medical PPE and similar material at, or below, the MPT of \$10,000, without a contract, offered by commercial suppliers that support federal COVID-19 relief efforts.²⁰⁵ Federal law allows state and local governments to buy DLA-managed supplies for first responders including firefighters, law enforcement officers, paramedics, emergency medical technicians, emergency management, public health, clinical care, public works, and other skilled support personnel that provide immediate support services during prevention, response, and recovery operations.²⁰⁶ DLA created a vetting group that determines whether products meet FDA and CDC standards.²⁰⁷
 - FedMall has been a key part of DLA’s COVID-19 response, and customers have ordered over \$14 million in pandemic-related supplies

²⁰¹ Chris Erbe, *Pentagon’s logistics agency pivots to support national COVID-19 response*, DEFENSE LOGISTICS AGENCY (Apr. 30, 2020), available at <https://www.dla.mil/AboutDLA/News/NewsArticleView/Article/2170223/pentagons-logistics-agency-pivots-to-support-national-covid-19-response/>.

²⁰² *Id.*

²⁰³ U.S. Department of Defense, *Defense Logistics Agency COVID-19 Support* (July 21, 2020), available at <https://media.defense.gov/2020/Jul/21/2002460502/-1/-1/0/200721-D-YE683-1001.JPG>.

²⁰⁴ Beth Reece, *FedMall offers COVID-19 protective equipment to small businesses, states and local agencies to follow mid-July*, DEFENSE LOGISTICS AGENCY (June 30, 2020), available at <https://www.dla.mil/AboutDLA/News/NewsArticleView/Article/2242354/fedmall-offers-covid-19-protective-equipment-to-small-businesses-state-and-loc/>.

²⁰⁵ U.S. Department of Defense, *State and Local Government FedMall Purchasing Program*, DEFENSE LOGISTICS AGENCY (July 8, 2020), available at <https://www.dla.mil/Portals/104/Documents/InformationOperations/FedMall/COVID-19%20FedMall%20State%20and%20Local%20Gov%20Contingency%20Corridor%20Flyer%20FINAL.pdf?ver=2020-07-08-111142-283>.

²⁰⁶ Beth Reece, *FedMall offers COVID-19 protective equipment to small businesses, states and local agencies to follow mid-July*, DEFENSE LOGISTICS AGENCY (June 30, 2020), available at <https://www.dla.mil/AboutDLA/News/NewsArticleView/Article/2242354/fedmall-offers-covid-19-protective-equipment-to-small-businesses-state-and-loc/>.

²⁰⁷ Beth Reece, *Defense Logistics Agency Helps Small Businesses During COVID-19 Response*, DEFENSE LOGISTICS AGENCY (July 22, 2020), available at <https://www.defense.gov/Explore/Features/Story/Article/2282514/defense-logistics-agency-helps-small-businesses-during-covid-19-response/>.

since mid-March, with face masks accounting for over one-third of all COVID-19 purchases.²⁰⁸

- **Congress and the Executive branch should consider what, if any, continued streamlined contracting, production, other new emergency authorities, or funding should continue given the global need and increased customer base for critical supplies, such as PPE. For example, HHS could consider creating an entity similar to FedMall where vendors are pre-vetted, or join with DLA, to further expand the vendor and buyer capacity in FedMall.**
- **Congress and the Executive Branch should examine whether the collaboration efforts between HHS, FEMA, DoD, and other agencies were hampered by existing regulations or laws, and if so, consider whether the federal government would benefit from legislative or regulatory changes.**
- To prevent hoarding and price gouging of critical medical supplies, on March 25, 2020, HHS designated 15 categories of PPE health and medical resources as scarce or threatened materials subject to the DPA anti-hoarding provisions.²⁰⁹ As a result, accumulation of these materials for the purpose of resale at prices in excess of prevailing market prices, or in excess of reasonable demands of business, personal, or home consumption, is prohibited with a potential penalty of a fine up to \$10,000, or up to one year imprisonment.²¹⁰
 - On March 24, 2020, the U.S. Attorney General announced a “Department of Justice COVID-19 Hoarding and Price Gouging Task Force” to address COVID-19-related hoarding and price gouging involving sales of critical and scarce medical supplies, equipment, and materials, including respirator masks, medical gloves and coveralls, ventilators, and certain pharmaceuticals.²¹¹ This Task Force intends to investigate and bring charges when necessary against any person or company that accumulates an unreasonably amount of any of those materials for their personal use, or for purposes of selling them far above prevailing market prices.²¹² The DOJ works closely with HHS, FEMA,

²⁰⁸ Beth Reece, *FedMall offers COVID-19 protective equipment to small businesses, states and local agencies to follow-mid-July*, DEFENSE LOGISTICS AGENCY (June 30, 2020), available at <https://www.dla.mil/AboutDLA/News/NewsArticleView/Article/2242354/fedmall-offers-covid-19-protective-equipment-to-small-businesses-state-and-loca/>.

²⁰⁹ 85 F.R. 17592, *Notice of Designation of Scarce Materials or Threatened Materials Subject to COVID-19 Hoarding Prevention Measures* (Mar. 30, 2020), available at <https://www.federalregister.gov/documents/2020/03/30/2020-06641/notice-of-designation-of-scarce-materials-or-threatened-materials-subject-to-covid-19-hoarding>.

²¹⁰ 50 U.S.C. § 4513.

²¹¹ Attorney General William Barr, *Memorandum For All Heads Of Department Components And Law Enforcement Agencies All United States Attorney*, U.S. Department of Justice (Mar. 24, 2020), available at <https://www.justice.gov/file/1262776/download>.

²¹² *Id.*

and state and local law enforcement to investigate and prosecute illegal hoarding and price gouging.²¹³

- In an April 2, 2020 press release, DOJ announced that the Hoarding and Price Gouging Task Force confiscated half-a-million dollars in medical supplies from price gougers.²¹⁴ HHS distributed the items in New York and New Jersey, and would pay the owner of the hoarded items pre-COVID-19 fair market value for the supplies.²¹⁵

C. What efforts have been made to procure supplies for COVID-19 testing and vaccine and therapeutic development?

- Federal agencies have also been involved in procuring supplies for COVID-19 testing and vaccine and therapeutic development. These efforts are extensively discussed in other reports issued by the House Committee on Energy and Commerce, Republican Staff, since June.
 - CDC quickly created a diagnostic test for COVID-19 and initially led testing in the U.S. through the public health infrastructure, which includes CDC and state and local laboratories.²¹⁶
 - On February 29, 2020, FDA issued a new policy to expedite the availability of diagnostic testing and facilitate the expansion from the public health system into commercial settings and leverage significant existing resources throughout the country.²¹⁷
 - As of August 17, 2020, FDA has authorized 214 tests for SARS-CoV-2, the virus that causes COVID-19, under EUAs; which include 175 molecular tests, 37 antibody tests, and 2 antigen tests.²¹⁸
 - To maximize testing capacity that is dependent on supplies, including swabs, transport media, and RNA extraction kits, FDA created testing substitution strategies, which includes validated supply alternatives, that laboratories can use to continue performing tests if they are experiencing a supply issue with a

²¹³ *Id.*

²¹⁴ U.S. Department of Justice, *Department of Justice and Department of Health and Human Services Partner to Distribute More Than Half a Million Medical Supplies Confiscated from Price Gougers* (Apr. 2, 2020), available at <https://www.justice.gov/opa/pr/department-justice-and-department-health-and-human-services-partner-distribute-more-half>.

²¹⁵ *Id.*

²¹⁶ U.S. Centers for Disease Control and Prevention, *CDC Diagnostic Tests for COVID-19*, available at <https://www.cdc.gov/coronavirus/2019-ncov/lab/testing.html> (last updated July 3, 2020).

²¹⁷ U.S. Food and Drug Administration, *Coronavirus (COVID-19) Update: FDA Issues New Policy to Help Expedite Availability of Diagnostics* (Feb. 29, 2020), available at <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-new-policy-help-expedite-availability-diagnostics>.

²¹⁸ U.S. Food and Drug Administration, *Coronavirus (COVID-19) Update: Daily Roundup* (Aug. 17, 2020), available at <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-daily-roundup-july-16-2020>.

test components.²¹⁹ FDA has also provided guidance for 3D printing medical devices and products, to increase testing supplies and PPE used during testing.²²⁰

- Five polymerase chain reaction (PCR) tests that have been granted an EUA by FDA use saliva specimens, thus negating the use of swabs and transport media and avoiding the demand of scarce testing resources.²²¹ As alternatives to lab-based, swab-specimen PCR testing continue to emerge, pressure on the supply chain for testing can be reduced.
- As of early August, the U.S. is averaging 750,000 tests per day with the highest daily total reported as 926,876 tests in one day.²²² Over 67.6 million tests have been conducted by private and public laboratories.²²³
- In April 2020, FDA announced an expansion of COVID-19 testing supply options when U.S. Cotton changed production of its existing Q-tip swabs at an Ohio factory to a swab that could be used for specialized COVID-19 testing; the company can manufacture three million swabs per week and expects to scale up to manufacture 150 million swabs by the end of the year.²²⁴
- On April 29, 2020, DoD invested \$75.5 million in DPA Title 3 funding to help domestic swab supplier, Puritan, produce an additional 20 million to 40 million swabs per month.²²⁵

²¹⁹ U.S. Food and Drug Administration, *Coronavirus (COVID-19) Update: Daily Roundup FDA Press Announcements* (June 3, 2020), available at <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-daily-roundup-june-3-2020>.

²²⁰ U.S. Food and Drug Administration, *Coronavirus Disease 2019 (COVID-19) Emergency Use Authorization for Medical Devices, FDA Coronavirus Disease 2019* (July 10, 2020), available at <https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices>.

²²¹ U.S. Food and Drug Administration, *Coronavirus (COVID-19) Update: FDA Issues Emergency Use Authorization to Yale School of Public Health for SalivaDirect, Which Uses a New Method of Saliva Sample Processing* (Aug. 15, 2020), available at <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-emergency-use-authorization-yale-school-public-health>.

²²² The COVID Tracking Project, *U.S. Historical Data*, available at <https://covidtracking.com/data/us-daily> (last visited Aug. 17, 2020).

²²³ *Id.*

²²⁴ Dan Diamond, *How a 96-hour project helped Trump's team reverse its testing debacle*, POLITICO (May 5, 2020), available at <https://www.politico.com/news/2020/05/05/coronavirus-trump-testing-partnership-236313>; Lynna Lai, *Cleveland-based U.S. Cotton tackles swab shortage for COVID-19 tests*, WKYC (Apr. 23, 2020), available at <https://www.wkyc.com/article/news/health/coronavirus/cleveland-based-us-cotton-tackles-swab-shortage-for-covid-19-tests/95-be469714-dcb0-499a-8c07-445e3460d1a4>.

²²⁵ U.S. Department of Defense, *DOD Details \$75 Million Defense Production Act Title 3 Puritan Contract* (Apr. 29, 2020), available at <https://www.defense.gov/Newsroom/Releases/Release/Article/2170355/dod-details-75-million-defense-production-act-title-3-puritan-contract/>; Puritan, *Puritan Medical Products to Double COVID-19 Swab Production with New Factory* (May 4, 2020), available at <https://www.puritanmedproducts.com/news-and-events/news/post/Press-Release-Puritan-COVID-Swab-New-Factory>.

- On June 3, 2020, FDA released the Testing Supply Substitution Strategies web-based resource to help support labs performing authorized COVID-19 tests when they have supply issues with components of a test.²²⁶ The information does not alter any already issued EUA for a COVID-19 diagnostic test or serve as comment on any FDA regulatory requirement, but it does help address availability concerns regarding certain critical components of COVID-19 diagnostic tests during the COVID-19 pandemic.²²⁷
- FDA recently issued guidance on pooled testing, which could further conserve limited testing supplies and PPE. On June 16, 2020, FDA published a testing template to assist test developers to better understand the validation requirements for getting their tests approved for pool sample testing.²²⁸
 - To preserve testing resources, test developers and labs are interested in using a technique of “pooling” samples which allows a lab to combine several samples together into one batch, or a pooled sample, and then test that pooled sample with a diagnostic test.²²⁹ When the pooled sample results are negative, then all patients are presumed negative.²³⁰ However, if the pooled sample returns as positive, then each individual must be tested to determine who is positive.²³¹ In settings with low prevalence of cases, this method works well.²³²
 - On July 18, 2020, FDA authorized the first diagnostic test for use with pooled samples through issuance of an EUA to Quest Diagnostics.²³³ On July 24, 2020, FDA authorized the second diagnostic test for use with pooled samples through issuance of an EUA to LabCorp.²³⁴
 - **The Executive Branch should continue to examine additional methods to extend testing supplies to meet the high demand.**

²²⁶ U.S. Food and Drug Administration, *COVID-19 Resources for Laboratories and Manufacturers* (June 3, 2020), available at <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2>.

²²⁷ *Id.*

²²⁸ U.S. Food and Drug Administration, *Coronavirus (COVID-19) Update Facilitating Diagnostic Test Availability Asymptomatic Testing and Sample Pooling* (June 16, 2020), available at <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-facilitating-diagnostic-test-availability-asymptomatic-testing-and>.

²²⁹ *Id.*

²³⁰ *Id.*

²³¹ *Id.*

²³² *Id.*

²³³ U.S. Food and Drug Administration, *Coronavirus (COVID-19) Update: FDA Issues First Emergency Authorization for Sample Pooling in Diagnostic Testing* (July 18, 2020), available at <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-first-emergency-authorization-sample-pooling-dia gnostic#:~:text=Today%2C%20the%20U.S.%20Food%20and,swab%20specimens%20collected%20under%20o bservation>.

²³⁴ U.S. Food and Drug Administration, *Coronavirus (COVID-19) Update: FDA Authorizes First Diagnostic Test for Screening of People Without Known or Suspected COVID-19 Infection* (July 24, 2020), available at <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-dia gnostic-test-screening-people-without-known-or>.

- **The Executive Branch should monitor testing supplies for diagnostic and surveillance testing needs. In considering allocation and distribution, the Executive Branch should examine whether use of its DPA allocations authority or other mechanisms, such as voluntary agreements, are available and appropriate to allocate supplies based on outbreak areas and fluctuating testing needs.**
- **The Executive Branch should consider methods to systemically increase real-time communication and improve transparency of information regarding available testing supplies.**
- Beyond the federal procurement of supplies for testing, laboratory workforce capacity and the availability of testing machines and materials specific to processing tests have also been limitations on the overall supply chain for the availability of testing.
 - The surge of laboratory testing for COVID-19 brought swift changes to laboratory processes, equipment, and staffing needs. The federal government has taken action to address laboratory processes and supply needs for testing. The clinical laboratory workforce is a vital component of the healthcare supply chain during the COVID-19 pandemic, and has been responsible for managing new diagnostic tests, providing essential analysis, training new staff, and reporting accurate data, among other responsibilities, all while facing unprecedented demand for testing.
 - An inadequately staffed or trained diagnostic testing laboratory workforce may impact patient wait times, availability of lab services, and pose potential threats to health care safety and quality.²³⁵ Before the pandemic, the laboratory workforce faced an annual shortfall of 4,200 to 5,100 professionals per year.²³⁶ The impact of COVID-19 has substantially increased demands on this workforce in many areas.
 - **Congress and the Executive Branch should consider how to best mobilize and increase this specialized laboratory workforce to improve the U.S.’ laboratory test processing.**
 - Manufacturing of high-throughput laboratory testing machines and materials specific to processing tests has not been able to keep up with demand.²³⁷

²³⁵ American Society for Clinical Laboratory Science, *Addressing the Clinical Laboratory Workforce Shortage* (Aug. 2, 2018), available at <https://www.ascls.org/position-papers/321-laboratory-workforce>.

²³⁶ U.S. Centers for Disease Control and Prevention, *Clinical Laboratory COVID-19 Response Calls-June 2020*, (June 22, 2020), available at <https://www.cdc.gov/safelabs/resources-tools/covid-19-clinical-calls/2020-june.html>.

²³⁷ Allison Martell, Ned Parker, *The U.S. has more COVID-19 testing than most. So why is it falling so short?* REUTERS (July 27, 2020), available at <https://www.reuters.com/article/us-health-coronavirus-usa-testing-insigh/the-us-has-more-covid-19-testing-than-most-so-why-is-it-falling-so-short-idUSKCN24S19H>; Lisa M. Krieger, *Coronavirus: Why your COVID-19 test results are so delayed*, THE MERCURY NEWS (July 29, 2020), available at <https://www.mercurynews.com/2020/07/29/coronavirus-why-your-covid-19-test-results-are-so-delayed/>.

- HHS and DoD recently awarded a contract to Hologic, Inc. to expand production of custom sample collection and processing consumables for COVID-19 testing. The contract, worth up to \$7.6 million, will increase Hologic's production from 4.8 million COVID-19 tests per month to 6.8 tests per month by January 2021.²³⁸
- With respect to supplies for vaccine and therapeutic development and administration, and under the umbrella of Operation Warp Speed, the Administration is procuring supplies such as glass vials and syringes. This is in addition to the extensive efforts to support development of vaccines and therapeutics themselves. For example:
 - On June 19, 2020, BARDA and DoD announced a joint investment in Corning Glass Valor for the purpose of expanding its domestic manufacturing capacity to produce enough Valor glass vials to supply billions of doses of drugs or vaccines over the next three years if needed for the COVID-19 pandemic response, as well as future public health emergencies.²³⁹
 - On July 9, 2020, BARDA and DoD announced technology transfer agreements with two companies, Retractable Technologies, Inc. and Becton Dickinson and Co., to expand their domestic manufacturing capacity for needle and syringe production.²⁴⁰ These agreements are intended to increase the ability in the U.S. to ensure the availability of needles and syringes in support of Operation Warp Speed vaccine administration.

D. How has the federal workforce been engaged to respond to COVID-19?

- Thousands of federal employees across numerous agencies and divisions have been deployed to assist in the COVID-19 response, often assisting with testing, procuring PPE, and more. For example:
 - HHS has deployed more than 4,500 U.S. Public Health Service (USPHS) Commissioned Corps officers during the COVID-19 pandemic response. As one of America's eight uniformed services, the USPHS Commissioned Corps fills essential public health leadership, clinical, and service roles within federal agencies and programs.

²³⁸ U.S. Department of Health and Human Services, *HHS and DOD Invest \$7.6M in Hologic to Expand Production of Custom Sample Collection and Processing Consumables for COVID-19 Tests* (July 26, 2020), available at <https://www.hhs.gov/about/news/2020/07/26/hhs-dod-invest-7-6m-hologic-expand-production-custom-sample-collection-processing-consumables-covid-19-tests.html>.

²³⁹ U.S. Department of Health and Human Services, Public Health Emergency, *BARDA Teams Up with DoD's JPEO-CBRND and Corning Incorporated to Expand Production of Corning's Valor Glass Vials* (June 19, 2020), available at <https://www.medicalcountermeasures.gov/newsroom/2020/corning/>.

²⁴⁰ U.S. Department of Health and Human Services, *BARDA and JPEO-CBRND establish partnership with Retractable Technologies, Inc. to expand the capacity to manufacture needles and syringes in the US* (July 9, 2020), available at <https://www.medicalcountermeasures.gov/newsroom/2020/rti/>; U.S. Department of Health and Human Services, *BARDA and JPEO-CBRND establish partnership with Becton Dickinson to expand the capacity to manufacture needles and syringes in the US* (July 9, 2020), available at <https://www.medicalcountermeasures.gov/newsroom/2020/rti/>.

- The USPHS Commissioned Corps is a team of more than 6,100 full-time health professional officers from 11 professional categories dedicated to promoting and advancing public health and disease prevention programs.²⁴¹ Examples of their COVID-19 response missions include officers that repatriated U.S. citizens to our military bases, assisted Community Based Testing Sites with testing, and provided infection control and clinical care in nursing homes, fields hospitals, and other hard hit areas.²⁴²
- The CARES Act gave HHS statutory authority to re-establish a reserve component to the USPHS Commissioned Corps with compensation and benefits.²⁴³ On June 30, 2020, HHS announced the re-establishment of a trained and deployable Ready Reserve Corps to provide surge capacity to deploy clinical care and health professionals for both domestic and global response efforts. The USPHS Commissioned Corps will commission its first officers into the Ready Reserve Corps beginning in Spring 2021, to improve access to care through public health emergency response and maintain a surge capacity of health professionals available for deployment.²⁴⁴
- Approximately 19,015 National Guard professionals continue COVID-19 response efforts in 49 states as of August 14, 2020; earlier this year, more than 31,000 National Guard professionals were deployed across the country.²⁴⁵ As of July 15, 2020, National Guard members have conducted over 7,000 missions in support of COVID-19 response and have administered more than 2.4 million COVID-19 tests or screenings, driven more than 1.6 million miles to deliver more than 190 million PPE items and essential supplies, made more than 18 million masks, increased bed capacity at alternate care facilities by more than 18,000 beds and have disinfected more than 9,840 long-term care, nursing home, and VA facilities.²⁴⁶
 - The President had approved 50 National Guard requests for federal support for the use of National Guard personnel in a Title 32 duty status through August 21, 2020.²⁴⁷ On August 3, 2020, the President

²⁴¹ U.S. Department of Health and Human Services, *Trump Administration Re-Establishes Ready Reserve Corps as Part of the United States Public Health Service* (June 30, 2020), available at <https://www.hhs.gov/about/news/2020/06/30/trump-administration-re-establishes-ready-reserve-corps-as-part-of-the-us-phs.html>.

²⁴² *Id.*

²⁴³ *Id.*

²⁴⁴ *Id.*

²⁴⁵ U.S. Federal Emergency Management Agency, *Coronavirus Pandemic Whole-of-America Response, By the Numbers* (Aug. 17, 2020) (on file with Committee).

²⁴⁶ National Guard, *National Guard continues to protect, support communities* (July 15, 2020), available at <https://www.nationalguard.mil/Resources/Press-Releases/Article/2274930/national-guard-continues-to-protect-support-communities/> (last visited Aug. 17, 2020).

²⁴⁷ U.S. Federal Emergency Management Agency, *Weekly Update: Coronavirus Pandemic Whole-of-America Response* (July 14, 2020) (on file with Committee).

extended 46 authorizations through December 31, 2020 for use of the National Guard, with 44 states and territories receiving 75 percent federal cost share, while Florida and Texas will retain 100 percent federal share.²⁴⁸ On August 7, 2020, the President directed FEMA to fund the 25 percent cost share through September 30 for Arizona, California, and Connecticut.²⁴⁹

- As of August 17, 2020, FEMA has 1,986 employees supporting COVID-19 pandemic response, CDC has 6,511 personnel, and HHS has 349 personnel supporting the outbreak response.²⁵⁰
- The Homeland Security and Justice Team Director for the U.S. Government Accountability Office (GAO), Chris Currie, testified on July 14, 2020, that, “[t]his pandemic and the scale of the federal response is not even closely comparable to any disaster or public health emergency the country has faced.” Director Currie said, “[w]e have seen a marshalling of resources and distribution of supplies that eight months ago we would have thought was impossible.”²⁵¹

E. What efforts have been made by the private sector to address the worldwide shortage of ventilators, PPE, and other critical supplies?

- Similar to the wide array of efforts by the federal government, the private sector has mobilized in an unprecedented response to address numerous worldwide shortages of PPE and other supplies. A sample of efforts to obtain already-existing goods are

²⁴⁸ The White House, *Memorandum on the Extension of the Use of the National Guard to Respond to COVID-19 and to Facilitate Economic Recovery* (Aug. 3, 2020), available at <https://www.whitehouse.gov/presidential-actions/memorandum-extension-use-national-guard-respond-covid-19-facilitate-economic-recovery/>; The White House, *Memorandum on the Extension of the Use of the National Guard to Respond to COVID-19 and to Facilitate Economic Recovery (Florida)* (Aug. 3, 2020), available at <https://www.whitehouse.gov/presidential-actions/memorandum-extension-use-national-guard-respond-covid-19-facilitate-economic-recovery-florida/>; The White House, *Memorandum on the Extension of the Use of the National Guard to Respond to COVID-19 and to Facilitate Economic Recovery (Texas)* (Aug. 3, 2020), available at <https://www.whitehouse.gov/presidential-actions/memorandum-extension-use-national-guard-respond-covid-19-facilitate-economic-recovery-texas/>.

²⁴⁹ The White House, *Memorandum on the Extension of the use of the National Guard to Respond to COVID-19 and to Facilitate Economic Recovery (Arizona)* (Aug. 7, 2020), available at <https://www.whitehouse.gov/presidential-actions/memorandum-extension-use-national-guard-respond-covid-19-facilitate-economic-recovery-arizona/>; The White House, *Memorandum on the Extension of the use of the National Guard to Respond to COVID-19 and to Facilitate Economic Recovery (California)* (Aug. 7, 2020), available at <https://www.whitehouse.gov/presidential-actions/memorandum-extension-use-national-guard-respond-covid-19-facilitate-economic-recovery-california/>; The White House, *Memorandum on the Extension of the use of the National Guard to Respond to COVID-19 and to Facilitate Economic Recovery (Connecticut)* (Aug. 7, 2020), available at <https://www.whitehouse.gov/presidential-actions/memorandum-extension-use-national-guard-respond-covid-19-facilitate-economic-recovery-connecticut/>.

²⁵⁰ U.S. Federal Emergency Management Agency, *Weekly Update: Coronavirus Pandemic Whole-of-America Response* (Aug. 17, 2020) (on file with Committee).

²⁵¹ *Reviewing Federal and State Pandemic Supply Preparedness and Response: Hearing Before H. Comm. On Homeland Security, Sub. Comm. on Emergency Preparedness, Response & Recovery*, 116th Cong. (July 14, 2020), available at <https://homeland.house.gov/activities/hearings/reviewing-federal-and-state-pandemic-supply-preparedness-and-response>.

discussed in this section. Efforts to expand domestic production are discussed in the following section.

- Ventilators were in short supply at the start of the COVID-19 outbreak. As discussed in Section II B (a), the Trump Administration used the DPA to increase the supply of ventilators. Additional private sector initiatives supplemented these actions. For example:
 - The Ford Motor Company announced that it would collaborate with GE Healthcare to produce 50,000 Airon-licensed ventilators by July 2020, with the ability to subsequently produce 30,000 per month as needed.²⁵² The ventilator design is one typically used in transport situations, has FDA-clearance, and has been granted an EUA for use on COVID-19 patients. FDA clearance is when FDA agrees that a registered manufactured medical device is substantially equivalent to a similar legally marketed device.²⁵³ Ford planned to initially produce the ventilators in Airon's Florida plant, and then transition production to a Ford plant in Michigan.²⁵⁴
 - Vyair Medical was awarded a \$407.9 million contract by HHS to produce 22,000 ventilators for the SNS by the end of June.²⁵⁵ Vyair Medical's lightweight, portable LTV2 2200 ventilators received an EUA from FDA to enable rapid deployment.²⁵⁶ Beginning in February, Vyair Medical hired additional workers to add manufacturing shifts, and focused engineering resources on high-priority, high-demand equipment to begin deploying ventilators to areas in need as quickly as they were made.²⁵⁷
 - GE Healthcare announced that the company has doubled its capacity of ventilator production since the COVID-19 outbreak began, and planned to double production again by mid-year to address unprecedented demand.²⁵⁸ This production was independent of its collaboration with Ford to scale up ventilator supplies, in which Ford was providing technical and production

²⁵² Ford, *Ford to produce 50,000 ventilators in Michigan in next 100 days; partnering with GE Healthcare will help coronavirus patients* (Mar. 30, 2020), available at <https://media.ford.com/content/fordmedia/fna/us/en/news/2020/03/30/ford-to-produce-50-000-ventilators-in-michigan-in-next-100-days.html>.

²⁵³ U.S. Food and Drug Administration, *Premarket Notification 510(k)* (Mar. 13, 2020), available at <https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k>.

²⁵⁴ Ford, *Ford to produce 50,000 ventilators in Michigan in next 100 days; partnering with GE Healthcare will help coronavirus patients* (Mar. 30, 2020), available at <https://media.ford.com/content/fordmedia/fna/us/en/news/2020/03/30/ford-to-produce-50-000-ventilators-in-michigan-in-next-100-days.html>.

²⁵⁵ Vyair, *Vyair Medical Begins Fulfilling HHS Contract* (May 5, 2020), available at <https://www.vyair.com/covid-19-news/vyair-medical-begins-fulfilling-hhs-contract>.

²⁵⁶ *Id.*

²⁵⁷ *Id.*

²⁵⁸ GE Healthcare, *GE Healthcare Takes Additional Actions to Help Clinicians Combat Coronavirus* (Mar. 24, 2020), available at <https://www.ge.com/news/press-releases/ge-healthcare-takes-additional-actions-help-clinicians-combat-coronavirus>.

expertise to manufacture a simplified design of GE Healthcare's existing ventilator.²⁵⁹

- Medtronic increased production by more than 40 percent in March 2020 and planned to more than double its manufacturing capacity to supply ventilators for COVID-19 response.²⁶⁰ The company implemented additional manufacturing shifts and new manufacturing shift patterns to bring the plant to 24/7 operation. In April 2020, Medtronic received an EUA from FDA for the Puritan Bennet 560 (PB560) ventilator, a compact, lightweight, and portable ventilator that can be used in clinical settings and at home.²⁶¹ In June 2020, Medtronic announced a partnership with Foxconn Technology Group to immediately increase production of PB560 ventilators for domestic manufacturing of 10,000 ventilators over the next year.²⁶²
- ResMed worked to maximize production to double or triple ventilator output, and scale up ventilation mask production by tenfold.²⁶³
- In addition, in April 2020, the American Hospital Association (AHA) and U.S. hospitals and health systems created the Dynamic Ventilator Reserve, a voluntary exchange program to aid in distributing ventilators to critical areas.²⁶⁴ The Dynamic Ventilator Reserve is an online inventory of ventilators and associated supplies, such as tubing and filters. U.S. hospitals and health systems input available inventory into a database managed by the AHA and can access the inventory as their need for ventilators changes. AHA works with FEMA if the inventory is needed to supplement the SNS.²⁶⁵
- Efforts were also undertaken to identify sources of PPE, particularly for health care workers and other front-line workers. In addition, individuals and businesses donated their own personal supplies to their communities, and large corporations worked to identify sources of PPE within their supply chains.

²⁵⁹ General Electronic, *Teaming Up: GE Healthcare And Ford Partner To Quickly Manufacture Ventilators For COVID-19 Patients* (Mar. 24, 2020), available at <https://www.ge.com/news/reports/teaming-up-ge-healthcare-and-ford-partner-to-quickly-manufacture-ventilators-for-covid-19-patients>.

²⁶⁰ Medtronic, *Correction: Medtronic Continuing to Increase Ventilator Production to Address COVID-19 Pandemic* (Mar. 18, 2020), available at <http://newsroom.medtronic.com/news-releases/news-release-details/correction-medtronic-continuing-increase-ventilator-production>.

²⁶¹ Medtronic, *Medtronic Provides Ventilator Progress Update* (Apr. 8, 2020), available at <http://newsroom.medtronic.com/news-releases/news-release-details/medtronic-provides-ventilator-progress-update>.

²⁶² Medtronic, *Medtronic and Foxconn Partner to Increase Ventilator Production* (June 18, 2020), available at <http://newsroom.medtronic.com/news-releases/news-release-details/medtronic-and-foxconn-partner-increase-ventilator-production>.

²⁶³ ResMed, *ResMed Statement on COVID-19* (Mar. 23, 2020), available at <https://www.businesswire.com/news/home/20200323005663/en/ResMed-Statement-COVID-19>.

²⁶⁴ American Hospital Association, *Public-private Effort Launched to Help Distribute Existing Ventilators to High-need Areas of the U.S.* (Apr. 14, 2020), available at https://www.aha.org/system/files/media/file/2020/04/public-private-effort-launched-distribute-ventilators-high-need-areas-us-3-14-2020-2_1.pdf.

²⁶⁵ *Id.*

- For example, Apple’s Chief Executive Officer Tim Cook reported that the company sourced more than 20 million masks through its global supply chain, and that the company was designing, producing, and shipping face shields for medical workers.²⁶⁶
- #GetUsPPE was founded April 19, 2020, by a team of Emergency Department physicians from across the nation who each personally witnessed the need for PPE as they worked with patients affected by COVID-19.²⁶⁷ The physicians partnered with grassroots organizations across the U.S. that had similar goals and, with a volunteer team, worked to unify the efforts, datasets, and volunteers into one comprehensive resource.²⁶⁸ Visitors on the website GetUsPPE.org can view PPE request and fulfillment data, COVID-19 case data, and more.²⁶⁹ The founders are working to build a national, centralized platform to enable communities access to PPE for healthcare providers.²⁷⁰ As of August 17, 2020, GetUsPPE.org had filled over 13,000 requests with delivery of 2.18 million units of PPE.²⁷¹
- Retailers that do not typically make products such as face masks created programs and released templates so that individuals could make face masks for themselves or others.
 - For example, on March 20, 2020, JOANN Fabric & Co. announced a “Make to Give” mask program, which provides free kits to shoppers with the fabric, elastic, and other materials needed to make masks for health care workers.²⁷² In areas with open stores, customers could either make masks to drop off at the stores or use the classroom sewing machines, complete with instructions and following socially-distanced guidelines.²⁷³ JOANN Fabric provides and donates 100 percent of the supplies needed for the projects for customers who want to help make the essential items.²⁷⁴ JOANN Fabric is also working with larger hospitals and medical facilities to provide fabric, elastic, and clear vinyl, and the chain also partnered with the Neiman Marcus Group for their alterations facilities to receive products and create PPE, such as masks,

²⁶⁶ Sam Byford, *Apple is designing and shipping face shields for medical workers*, THE VERGE (Apr. 5, 2020), available at <https://www.theverge.com/2020/4/5/21209270/apple-face-shields-masks-covid-19-coronavirus>.

²⁶⁷ GetUsPPE.org, *Frequently Asked Questions*, available at <https://getusppe.org/faq/#general> (last visited July 17, 2020).

²⁶⁸ *Id.*

²⁶⁹ *Id.*

²⁷⁰ *Id.*

²⁷¹ GetUsPPE.org, *Getting PPE (Personal Protective Equipment) to Healthcare Workers* (Aug. 17, 2020), available at <https://getusppe.org/>.

²⁷² JOANN, *Make To Give Response*, JOANN & Co, available at <https://www.joann.com/make-to-give-response/> (last visited Aug.17, 2020).

²⁷³ Ella Chochrek, *Jo-Ann Fabrics Customers Have Made Over 25 Million Masks for Health-Care Workers*, Footwear News (Apr. 6, 2020), available at <https://footwearnews.com/2020/business/retail/joann-fabrics-customers-make-masks-health-care-workers-1202961584/>.

²⁷⁴ *Id.*

gowns, and scrubs for health care providers.²⁷⁵ As of August 17, 2020, their efforts have yielded over 230.7 million masks for health care workers and the company has added a “Masks for School” initiative. For every mask purchased, JOANN Fabric will donate a mask to a school in need.²⁷⁶

- As discussed above in Section II B (a), major health care distributors are working with the federal government to increase the availability of PPE and other supplies to the U.S., and expedite PPE shipments to hotspot areas. There may be the potential for industry to build on these efforts in advance of a future resurgence of cases.
 - **In preparation for a potential resurgence in cases, health care distributors should examine data and their experiences thus far in responding to the COVID-19 pandemic to be able to better understand and match the supply needs of their customers, evaluate surges in demand in outbreak areas, and, if necessary, prioritize customers accordingly in the months ahead.**
 - **Where possible, distributors should evaluate current agreements with manufacturers and transportation companies, shift production to more resilient locations, and invest in people and processes to meet customer needs without interruption.**
 - **Congress, the Executive Branch, and the private sector should consider how to most effectively and efficiently increase the technology-based capabilities for medical supply chain management, such as modernizing government supply chain digital inventory systems and increasing secure data exchange platforms for real-time monitoring supply needs in private sector digital supply chain inventory systems.**
- COVID-19 also caused significant shortages in certain types of medications. For example, COVID-19 is particularly damaging to kidneys. As a result, the increased demand for renal failure treatment caused a national shortage of dialysis equipment.²⁷⁷ Two companies make more than 75 percent of dialysis equipment in the U.S.²⁷⁸
 - In April 2020, Fresenius reported that the need for dialysis machines by patients with COVID-19 could increase demand as much as three to five times the usual need. Fresenius formed a National Intensive Renal Care Reserve, which “includes the creation of a pool of approximately 150 pieces of equipment that are already located in hospitals across the country. The

²⁷⁵ *Id.*

²⁷⁶ JOANN, Make To Give Response, JOANN & Co, *available at* <https://www.joann.com/make-to-give-response/> (last visited Aug. 17, 2020).

²⁷⁷ Concentration Crisis, *America’s Concentration Crisis: An Open Markets Institute Report*, Open Markets Institute, *available at* <https://concentrationcrisis.openmarketsinstitute.org/industry/dialysis-equipment-manufacturing/> (last visited June 18, 2020).

²⁷⁸ *Id.*

equipment can be redeployed to other areas as needed within a week’s notice.”²⁷⁹ The plan also “doubles its tubing set and filter capacity, as well as increases its premixed dialysate fluid capacity by 75%.”²⁸⁰

- Baxter International, Inc. also increased supply and distribution of several products related to dialysis, including blood purification systems, drug delivery systems, and IV administration sets and solutions, increased air freight capacity and frequency of transport to allow essential equipment and medicines to be delivered to the U.S., and is hiring 800 new staff in the U.S., among other actions.²⁸¹
- **The Executive Branch should consider evaluating essential medicines and devices for which one or two suppliers exist, and either pursue alternative sources or consider using available authorities, such as the DPA, to help existing companies expand and/or diversify production.**

F. How can the U.S. increase domestic manufacturing of critical medical products?

- The COVID-19 pandemic has demonstrated the fragility of global supply chains. The pandemic has also brought to bear the need for additional collaboration with our allies to stabilize and diversify these supply chains, as well as increasing domestic manufacturing for certain products relevant not only to the COVID-19 response, but to care for Americans in general.
- As discussed above, the Trump Administration has used DPA authority to priority-rate orders and provide resources to certain private sector companies to increase their domestic production of needed supplies.
 - **Congress and the Executive Branch should consider how to incentivize additional production of critical health supplies, diversify production, address other supply chain dependencies that impact the health care supply chain, fill information and data gaps, and promote U.S. leadership on global health and trade issues.**
- BARDA has announced a number of contracts to increase domestic manufacturing of key supplies necessary to the COVID-19 response. For example:
 - In March 2020, BARDA launched Rapid Aseptic Packaging of Injectable Drugs (RAPID USA), a public-private partnership between ASPR, the SNS and ApiJect Systems America, to enable the SNS to rapidly fill and finish

²⁷⁹ Bill Vaile, *Fresenius, Baxter act on national dialysis machine, supply shortage during COVID-19 pandemic*, Healio (Apr. 20, 2020), available at <https://www.healio.com/news/nephrology/20200420/fresenius-baxter-act-on-national-dialysis-machine-supply-shortage-during-covid19-pandemic>.

²⁸⁰ *Id.*

²⁸¹ *Id.*

hundreds of millions of prefilled syringes to respond quickly to emergencies, like the COVID-19 outbreak.²⁸²

- The RAPID consortium was launched to build a surge capacity network of up to eight domestic facilities for the manufacturing of prefilled syringes using Blow-Fill-Seal (BFS) technology.²⁸³
 - HHS authorized funding of up to \$456 million to ApiJect Systems America for research and development of BFS prefilled syringes, rapid prototyping, and stability testing of select MCMs from the SNS in these devices.²⁸⁴
 - In May 2020, HHS and DoD awarded up to \$138 million to ApiJect Systems, and RAPID USA to support “Project Jumpstart,” an initiative designed to create a domestic supply chain for prefilled syringes with the use of a BFS aseptic plastics manufacturing technology. The goal of Project Jumpstart is to enable the manufacture of more than 100 million prefilled syringes for distribution across the U.S. by the end of 2020, and more than 500 million in 2021.²⁸⁵
- As previously mentioned, in June 2020, BARDA announced a partnership with DoD’s Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense and Corning Incorporated for the rapid expansion of domestic capacity to manufacture high-quality Corning Valor Glass tubing and vials/cartridges to reduce supply chain risk and ensure rapid delivery of MCMs in response to the COVID-19 pandemic.²⁸⁶ A

²⁸² U.S. Department of Health and Human Services, *HHS Announces New Public-Private Partnership to Develop U.S.-Based, High-Speed Emergency Drug Packaging Solutions* (Mar. 18, 2020), available at <https://www.hhs.gov/about/news/2020/03/18/hhs-announces-new-public-private-partnership-to-develop-us-based-high-speed-emergency-drug-packaging-solutions.html>.

²⁸³ ApiJect Systems Corp., *ApiJect Awarded HHS-DOD Title 3, Defense Production Act (DPA) Contract of \$138 Million in Support of a Joint Federal Agency Accelerated Build-out of Domestic Surge Capacity for a High-Speed, Population-Scale Emergency Drug Injection Solution* (May 12, 2020), available at <https://www.prnewswire.com/news-releases/apiject-awarded-hhs-dod-title-3-defense-production-act-dpa-contract-of-138-million-in-support-of-a-joint-federal-agency-accelerated-build-out-of-domestic-surge-capacity-for-a-high-speed-population-scale-emergency-drug-injecti-301058125.html>; Rapid USA, *Bridging the Gap in Pandemic Response*, available at <https://www.rapidusa.com/> (last visited Jun. 17, 2020).

²⁸⁴ U.S. Department of Health and Human Services, *HHS Announces New Public-Private Partnership to Develop U.S.-Based, High-Speed Emergency Drug Packaging Solutions* (Mar. 18, 2020), available at <https://www.hhs.gov/about/news/2020/03/18/hhs-announces-new-public-private-partnership-to-develop-us-based-high-speed-emergency-drug-packaging-solutions.html>.

²⁸⁵ U.S. Department of Defense, *DOD Awards \$138 Million Contract, Enabling Prefilled Syringes for Future COVID-19 Vaccine* (May 12, 2020), available at <https://www.defense.gov/Newsroom/Releases/Release/Article/2184808/dod-awards-138-million-contract-enabling-prefilled-syringes-for-future-covid-19/source/GovDelivery/>.

²⁸⁶ U.S. Department of Health and Human Services, *Operation Warp Speed ramps up U.S.-based manufacturing capacity for vials for COVID-19 vaccines and treatments* (June 11, 2020), available at <https://www.hhs.gov/about/news/2020/06/11/operation-warp-speed-ramps-up-us-based-manufacturing-capacity-for-vials-for-covid-19-vaccines-and-treatments.html>.

shortage of glass vials would impact the ability to deliver vaccines, so the manufacturing of the glass vials is an important step towards being prepared for vaccination distribution once a COVID-19 vaccine is authorized or approved by FDA.

- In addition, and as discussed in more detail below, BARDA has awarded a contract valued up to \$812 million to a team led by Phlow Corporation to increase domestic manufacturing of pharmaceutical products, including finished doses and APIs.²⁸⁷
- **The Executive Branch should examine whether there are other products necessary for the COVID-19 response that should be manufactured domestically. If so, the Executive Branch should work with Congress and the private sector to enable and support these efforts.**
- As discussed above, the federal government used the DPA to increase domestic manufacturing of ventilators in the short term. This is in addition to separate private sector initiatives. Efforts are also underway to create lower-cost ventilators.
 - To address ventilator shortages and the high cost of the devices, on March 18, 2020, DoD assembled a rapid-reaction team of medical professionals and engineers to compete in the “Hack-a-Vent” Challenge.²⁸⁸ Teams had to create prototypes using exclusively commercial-off-the-shelf items and/or 3D printed parts. Eight weeks later, the finalists submitted five distinct, low-cost ventilators for FDA approval that are operational for under \$500, and are small enough to be portable and provide a solution to rural communities.²⁸⁹
 - **Congress and the Executive Branch should evaluate other items that are critically needed, and consider additional initiatives similar to the “Hack-A-Vent” competition for ventilator design and RADx for diagnostic testing developments that maximize innovation, speed, and expand domestic manufacturing for cost-effective equipment or other supplies that are necessary for the COVID-19 response.**
- The COVID-19 response has further highlighted the need for more resilient supply chains and increased domestic manufacturing of pharmaceutical products, including those relevant to the COVID-19 response, as well as products necessary to care for Americans in general.

²⁸⁷ Phlow Corp., *Phlow Corporation Awarded \$354 Million HHS/ASPR/BARDA Contract to Manufacture Essential Medicines in Shortage* (May 19, 2020), available at <https://www.prnewswire.com/news-releases/phlow-corporation-awarded-354-million-hhsasprbarda-contract-to-manufacture-essential-medicines-in-shortage-301061648.html>.

²⁸⁸ U.S Department of Defense, *DOD Ventilator Challenge: Innovative Response to the Nation’s Need for Rapid Prototyping* (June 12, 2020), available at <https://www.defense.gov/Newsroom/Releases/Release/Article/2217983/dod-ventilator-challenge-innovative-response-to-the-nations-need-for-rapid-prot/>.

²⁸⁹ *Id.*

- FDA lists 118 drugs in shortage as of August 17, 2020, including dexamethasone sodium phosphate injection, a corticosteroid currently used in treating COVID-19 patients.²⁹⁰ GoodRx tracks drug shortages for those used to treat COVID-19 and, as of July 13, 2020, there are 27 COVID-19 treatment-related drugs listed as being in shortage.²⁹¹
- The federal government could encourage domestic drug manufacturing by identifying and prioritizing the pharmaceuticals to manufacture domestically, assessing the supply chain, and streamlining regulatory processes.²⁹² Through prioritizing essential medicines, increasing regulatory efficiencies and providing market-based incentives, the federal government could galvanize U.S. firms to domestically produce priority medicines.²⁹³
- The federal government could choose to enter long-term contracts with a smaller number of generic drug manufacturers, allowing them to enjoy cost advantages through increased production and lowered costs because the costs could be shared by the manufacturers and the government.²⁹⁴ Long-term contracts can include manufacturing innovation and automation funding to reduce costs, with increased consistency and fewer firms for FDA to inspect.²⁹⁵
- There are a number of factors to consider when evaluating proposed policy solutions to accomplish the goal of a secure pharmaceutical supply chain.
 - Medical supply chains are complex and vary by product. For example, there are differences between branded and generic drug supply chains. Companies selling branded drugs have more resources and can therefore implement additional flexibilities within their supply chains to reduce the risk of shortages of materials needed to manufacture drugs.²⁹⁶ The variations in medical product supply chains should be considered as any new policies are developed.

²⁹⁰ U.S. Food and Drug Administration, *FDA Drug Shortages, Current and Resolved Drug Shortages and Discontinuations Reported to FDA* (Aug. 17, 2020), available at <https://www.accessdata.fda.gov/scripts/drugshortages/>.

²⁹¹ Tori Marsh, *Live Updates: Which Drugs Are in Shortage Because of COVID-19?*, GOODRX (July 13, 2020), available at <https://www.goodrx.com/blog/covid-19-drug-shortages-updates/>.

²⁹² Association for Accessible Medicines, *A Blueprint for Enhancing the Security of the U.S. Pharmaceutical Supply Chain* (Apr. 2020), available at <https://accessiblemeds.org/sites/default/files/2020-04/AAM-Blueprint-US-Pharma-Supply-Chain.pdf>.

²⁹³ *Id.*

²⁹⁴ Peter Kolchinsky, *It's time to bring generic drug manufacturing back to the U.S.*, STAT (June 2, 2020), available at <https://www.statnews.com/2020/06/02/bring-manufacturing-generic-drugs-back-to-u-s/>.

²⁹⁵ *Id.*

²⁹⁶ University of Michigan, *From the Conversation: Medical supply chains are fragile in the best of times and COVID-19 will test their strength* (Mar. 25, 2020), available at <https://ihpi.umich.edu/news/conversation-medical-supply-chains-are-fragile-best-times-and-covid-19-will-test-their>.

- Patient access and drug costs must also be considered. Policies that would require federal programs to purchase American-made pharmaceuticals are well-intentioned and aim to encourage domestic manufacturing. However, these requirements could disrupt patient access to needed medications and increase drug costs.²⁹⁷
 - There are benefits of a diverse, secure supply chain. The sourcing of materials and finished medical products from multiple suppliers helps prevent and mitigate the risk of shortages.²⁹⁸ If a natural disaster or a public health emergency strikes and interrupts manufacturing at one facility, a diverse supply chain allows manufacturers to pivot to alternative sourcing until the interruption can be resolved. The need for diverse supply chains has been evidenced by the manufacturing disruptions caused by Hurricane Maria that led to widespread saline shortages and the numerous shortages currently being experienced during the COVID-19 outbreak, such as swabs and PPE. Additionally, the U.S. may not have access to all of the raw ingredients or components necessary to manufacture the medical products Americans need, such as certain rare-earth minerals.
 - Finally, policies that aim to promote government take-over of manufacturing could disrupt private sector manufacturing and innovation.
 - **Congress should promote policies to encourage domestic production of critical medical supplies and pharmaceutical products. Increased domestic manufacturing can be achieved by creating additional market-based incentives without imposing sweeping government mandates or controls.**
 - **Such policies should promote transparency into the pressure points in supply chains and what countries we are most reliant on for critical supplies, increase information available to Congress and federal agencies, and diversification of supply chains, such as encouraging the use of advanced manufacturing, creating additional markets for private sector businesses, and making regulatory processes more efficient.**
- Congress has begun to develop and pass legislation to effectuate these policy goals. For example:

²⁹⁷ Wayne Winegarden, *The Trump Administration's Buy American Drug Mandate is a Costly Mistake*, FORBES (Mar. 16, 2020), available at <https://www.forbes.com/sites/waynewinegarden/2020/03/16/the-trump-administrations-buy-american-drug-mandate-is-a-costly-mistake/#163f70de3c62>.

²⁹⁸ USP Global Public Policy Position, *Key Elements to Building a More Resilient Supply Chain*, available at <https://www.usp.org/sites/default/files/usp/document/our-impact/covid-19/global-policy-supply-chain.pdf> (last visited Aug. 1, 2020).

- Section 3101 of the CARES Act requires the National Academies, with input from federal agencies, to examine and issue a report on U.S. medical product supply chain security. This study will conduct an assessment on U.S. dependency on foreign entities for critical drugs and medical devices, identify information gaps needed to analyze supply chain security, and evaluate the pros and cons of domestic manufacturing. The report will also provide recommendations to improve supply chain resiliency and address vulnerabilities.²⁹⁹
- Section 3112 of the CARES Act requires drug manufacturers to annually report on the volume of drugs and APIs being manufactured.³⁰⁰
- H.R. 4866, the “National Centers of Excellence in Continuous Pharmaceutical Manufacturing Act,” would direct FDA to designate National Centers of Excellence in Continuous Pharmaceutical Manufacturing to work with the agency and industry to craft a national framework for continuous manufacturing implementation.³⁰¹
- H.R. 6670, The “Prescription for American Drug Independence Act,” would require the National Academies to establish a committee of drug supply chain experts and convene a public symposium to analyze the impact of U.S. dependence on foreign manufacturing of critical drugs and to recommend strategies to reduce dependency on foreign manufacturing while still ensuring a diversified supply chain.³⁰²
- H.R. 6930, the “Manufacturing API, Drugs, and Excipients (MADE) in America Act,” would require a GAO study to assess whether the differing regulatory requirements across countries creates inefficiencies in drug manufacturing, enhance transparency of facility inspection timelines, codify FDA’s advanced manufacturing technologies program, and provide tax credits for pharmaceutical and medical product manufacturers that locate to distressed zones within the U.S.³⁰³
- Efforts are also underway within the Executive Branch to increase and incentivize domestic manufacturing of key pharmaceuticals and APIs.
 - BARDA has existing authorities under the Public Health Service Act to support the manufacturing of products needed in public health emergencies and for bioterrorism response through the Centers for Innovation in Advanced Development and Manufacturing (CIADM). The CIADMs are public-private

²⁹⁹ Coronavirus Aid, Relief, and Economic Security Act (P.L. 116-136), enacted on March 27, 2020.

³⁰⁰ *Id.*

³⁰¹ H.R. 4866, *National Centers of Excellence in Continuous Pharmaceutical Manufacturing Act of 2019* (Oct. 28, 2019), 116th Cong. (2019-2020).

³⁰² H.R. 6670, *Prescription for American Drug Independence Act of 2020* (May 1, 2020), 116th Cong. (2019-2020).

³⁰³ H.R. 6930, *MADE in America Act of 2020* (May 19, 2020), 116th Cong. (2019-2020).

partnerships that provide domestic infrastructure in the U.S. capable of manufacturing MCMs on a commercial scale, as well as vaccines and therapeutics for the prevention and treatment of pandemic influenza and other infectious diseases.³⁰⁴

- Two CIADMs (Texas A&M University System and Emergent BioSolutions) are currently reserved to produce COVID-19 vaccine candidates.³⁰⁵
- As previously mentioned, BARDA recently awarded a four-year, \$354 million contract to a team of private industry partners led by Phlow Corporation to provide domestic pharmaceutical manufacturing of finished dosage forms and APIs needed to make critical medicines to help relieve drug shortages, particularly during the COVID-19 pandemic.³⁰⁶ The contract also includes additional options for long-term sustainability, bringing the total value of the contract up to \$812 million.³⁰⁷
 - The Phlow-led team, which also includes Civica Rx, Virginia Commonwealth University’s Medicines for All Institute, and AMPAC Fine Chemicals, will use advanced manufacturing processes, including continuous manufacturing, to provide the U.S. health care system with finished generic medicines that are at risk of shortages.³⁰⁸
 - The partnership “immediately enabled Phlow, with the help of its partners, to deliver over 1.6 million doses of five essential generic medicines used to treat COVID-19 patients to the [SNS], including medicines used for sedation to help patients requiring ventilator

³⁰⁴ U.S. Department of Health and Human Services, Public Health Emergency, *U.S. Department of Health and Human Services’ Centers for Innovation in Advanced Development and Manufacturing*, available at <https://www.medicalcountermeasures.gov/barda/core-services/ciadm/> (last visited Aug. 1, 2020).

³⁰⁵ U.S. Department of Health and Human Services, *HHS Reserves and Rapidly Expands Manufacturing Capacity for COVID-19 Vaccines at Texas Center for Innovation in Advanced Development and Manufacturing* (July 27, 2020), available at <https://www.hhs.gov/about/news/2020/07/27/hhs-reserves-and-rapidly-expands-manufacturing-capacity-for-covid-19-vaccines-at-texas-center.html>; U.S. Department of Health and Human Services, *HHS Adds \$628 Million to Contract with Emergent BioSolutions to Secure CDMO Manufacturing Capacity for Operation Warp Speed* (June 1, 2020), available at <https://www.hhs.gov/about/news/2020/06/01/hhs-adds-628-million-contract-emergent-biosolutions-secure-manufacturing-capacity-operation-warp-speed.html>.

³⁰⁶ Peter Kolchinsky, *It’s time to bring generic drug manufacturing back to the U.S.*, STAT (June 2, 2020), available at <https://www.statnews.com/2020/06/02/bring-manufacturing-generic-drugs-back-to-u-s/>.

³⁰⁷ Phlow Corp., *Phlow Corporation Awarded \$354 Million HHS/ASPR/BARDA Contract to Manufacture Essential Medicines in Shortage* (May 19, 2020), available at <https://www.prnewswire.com/news-releases/phlow-corporation-awarded-354-million-hhsasprbarda-contract-to-manufacture-essential-medicines-in-shortage-301061648.html>.

³⁰⁸ *Id.*; “Continuous processing is an alternative manufacturing method involving flow reactors that allow chemical reactions to run on a smaller scale over and over again until the entire volume of API is produced. This maximizes throughput, increases product quality and reproducibility, and has significantly lower labor requirements since most of these systems are highly automated.” Phlow Corp., *What We Do, Advanced Continuous Manufacturing*, available at <https://www.phlow-usa.com/what-we-do/> (last visited July 31, 2020).

support, medicines for pain management, and certain essential antibiotics.”³⁰⁹

- Phlow is also building the U.S. Strategic Active Pharmaceutical Ingredients Reserve, “a long-term, national stockpile to secure key ingredients used to manufacture the most essential medicines on U.S. soil, reducing America's dependency on foreign nations to support its drug supply chain.”³¹⁰
- The President signed an Executive Order on May 14, 2020, to encourage domestic medical supply production by granting DPA Title III loan authority to the U.S. International Development Finance Corporation (DFC).³¹¹ The Executive Order authorizes the DFC to “make loans, make provision for purchases and commitments to purchase, and take additional actions to create, maintain, protect, expand, and restore the domestic industrial base capabilities, including supply chains within the United States and its territories (“domestic supply chains”), needed to respond to the COVID-19 outbreak.”³¹²
 - **Congress should conduct oversight into the effectiveness of DFC’s loan authority in encouraging domestic medical supply production, and depending on the findings, should consider codifying this program.**
- In July 2020, the DFC signed a letter of interest to provide a \$765 million loan to Eastman Kodak Company to support the launch of Kodak Pharmaceuticals, a new part of the company that will produce critical pharmaceutical components.³¹³
 - This was the first use of authority delegated by President Trump’s Executive Order that enables DFC and DoD to collaborate in support of the domestic response to COVID-19 under the DPA.³¹⁴
 - Kodak Pharmaceuticals will produce critical pharmaceutical components identified as essential and in chronic shortage, as defined by FDA. Once fully operational, Kodak Pharmaceuticals will have the

³⁰⁹ Phlow Corp., *Phlow Corporation Awarded \$354 Million HHS/ASPR/BARDA Contract to Manufacture Essential Medicines in Shortage* (May 19, 2020), available at <https://www.prnewswire.com/news-releases/phlow-corporation-awarded-354-million-hhsasprbarda-contract-to-manufacture-essential-medicines-in-shortage-301061648.html>.

³¹⁰ *Id.*

³¹¹ The White House, *EO on Delegating Authority Under the DPA to the CEO of the U.S. International Development Finance Corporation to Respond to the COVID-10 Outbreak* (May 14, 2020), available at <https://www.whitehouse.gov/presidential-actions/eo-delegating-authority-dpa-ceo-u-s-international-development-finance-corporation-respond-covid-19-outbreak/>.

³¹² *Id.*

³¹³ U.S. International Development Finance Corporation, *DFC to Sign Letter of Interest for Investment in Kodak’s Expansion into Pharmaceuticals* (July 28, 2020), available at <https://www.dfc.gov/media/press-releases/dfc-sign-letter-interest-investment-kodaks-expansion-pharmaceuticals>.

³¹⁴ *Id.*

capacity to produce up to 25 percent of the APIs used in non-biologic, non-antibacterial, generic pharmaceuticals and will support more than 1,500 jobs.³¹⁵

- The loan from DFC will support startup costs to repurpose and expand existing facilities in Rochester, New York, and St. Paul, Minnesota, including the incorporation of continuous manufacturing and advanced technology capabilities.³¹⁶
 - In its second quarter Securities and Exchange Commission (SEC) filing, Eastman Kodak Company stated that it is “involved in investigations being conducted by several congressional committees and the SEC stemming from events related to the announcement of the potential DFC Loan and Pharmaceutical Initiative” to manufacture pharmaceutical ingredients for essential generic drugs.³¹⁷ DFC subsequently announced that the loan will not proceed unless recent allegations of wrongdoing are cleared.³¹⁸
- Additional initiatives to increase domestic manufacturing of critical supplies or products across the federal government and the private sector could create innovative ways to expand this capacity.
 - For example, Manufacturing USA is a network comprised of 14 public-private institutes and their federal sponsoring agencies, and over 1,900 member organizations that include manufacturers of all sizes and academia. Each institute focuses on a unique advanced manufacturing technology area but with the same goal to secure America's future through manufacturing innovation, education, and collaboration. Institutes connect member organizations, work on major research and development collaboration projects to solve industry's toughest challenges, and train people on advanced manufacturing skills.³¹⁹
 - An example of a project resulting from one of the Manufacturing USA network institutes is the American Institute for Manufacturing Integrated Photonics (AIM Photonics) work to develop highly scalable COVID-19 testing that can distinguish between influenza and COVID-19 in minutes.³²⁰

³¹⁵ *Id.*

³¹⁶ *Id.*

³¹⁷ U.S. Securities and Exchange Commission, *Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934*, Eastman Kodak Company (June 30, 2020), available at https://www.sec.gov/Archives/edgar/data/31235/000156459020039315/kodk-10q_20200630.htm.

³¹⁸ DFCgov (Aug. 7, 2020), available at <https://twitter.com/DFCgov/status/1291853877168558086>.

³¹⁹ Manufacturing USA, *About Us*, available at <https://www.manufacturingusa.com/about-us> (last visited July 31, 2020).

³²⁰ Ford Burkhart, *AIM Photonics collaborations targeting Covid-19 tests on a global scale*, OPTICS.ORG (May 12, 2020), available at <https://optics.org/news/11/5/8>.

- The U.S. Department of Commerce’s National Institute of Standards and Technology (NIST) has funding opportunities for rapid, high-impact projects that support the nation’s response to the COVID-19 pandemic. Using CARES Act appropriations, NIST will award these grants through the NIST Manufacturing USA National Emergency Assistance Program to eligible Manufacturing USA institutes.³²¹
 - One such award was announced by the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) on June 24, 2020, for \$8.9 million to nine projects including: advancing serological testing by making recombinant virus proteins; rapid development of diagnostic testing capabilities to assist regional hospital systems; enhancing domestic supply chains related to testing and PPE manufacturing; testing of approaches for rapid sanitization; and testbeds to accelerate agile manufacturing of MCMs and rapid release testing of biopharmaceuticals and vaccines.³²²
 - The award recipients and NIIMBL project partners are:
 - Development of a SARS COV-2 Polyvalent Microbead Immunoassay led by Wadsworth Center, New York State Department of Health;
 - Increased Throughput for COVID-19 Diagnosis Utilizing the Roche cobas® 6800 Real-Time PCR and Detection System led by the University of Delaware;
 - Designing a Test Kit Supply Chain led by North Carolina State University;
 - Emergency Production of COVID-19 Spike Protein for Therapeutic Antibodies and Diagnostics led by Texas A&M University;
 - Biomanufacturing and Implementation of Sensitive Quantitative COVID-19 ELISA Platform to Identify Sera Needed for Plasma Therapy led by Johns Hopkins University;

³²¹ U.S. Department of Commerce, National Institute of Standards and Technology, *NIST Funding Manufacturing Institutes to Support Pandemic Response* (Mar. 31, 2020), available at <https://www.nist.gov/news-events/news/2020/03/nist-funding-manufacturing-institutes-support-pandemic-response>.

³²² The National Institute for Innovation in Manufacturing Biopharmaceuticals, *NIIMBL Announces Nine Project Recipients of \$8.9M in Pandemic Response Efforts* (June 24, 2020), available at <https://niimbl.force.com/s/news/a0a3u000005jNQ6AAM/niimbl-announces-nine-project-recipients-of-89m-in-pandemic-response-efforts>.

- Validation of the Use of Vapor-Phase Hydrogen Peroxide as a Rapid Viral Decontamination Agent for Clinical and Public Space led by PMT LLC; and
 - Production of N95 and Surgical Masks led by North Carolina State University.³²³
- **Congress and the Executive Branch should consider whether to expand Manufacturing USA to include HHS as a sponsoring agency either for already-existing institutes, or to create or expand an institute focused on manufacturing health care products to include innovative health care devices, health care supply chain data technologies, or more efficient manufacturing of laboratory equipment, among other areas.**
- Small business innovation research and small business technology transfer grants provide another mechanism to increase domestic manufacturing of critical health resources and technologies to address COVID-19 for small businesses seeking commercialization and contract support. While the federal government does not typically award grants for starting or expanding businesses, it does provide grants to support small business research and development in order to bring innovative solutions to public health challenges and facilitate the commercialization of technologies and medical biotechnologies, such as developing COVID-19 MCMs, through small business innovation research and small technology transfer grants.³²⁴
 - **Congress and the Executive Branch should continue to examine innovative ways to increase domestic production of critical supplies that are needed to respond to COVID-19.**
 - For example, FDA’s EUAs for the 3D printing of face shields and respirator decontamination and sterilization systems have increased domestic manufacturing of PPE.
 - **Congress and the Executive Branch should consider what incentives and regulatory changes are needed to increase domestic manufacturing of critical products.**
 - **Congress and the Executive Branch should consider what existing laws and regulations are impeding domestic manufacturing of critical products and determine whether any such laws or regulations should be changed or eliminated.**
 - A global medical supply chain offers the benefits of diversity, resiliency, and sourcing materials. However, the COVID-19 pandemic has highlighted the risks and

³²³ *Id.*

³²⁴ Small Business Association, *Small Business Innovation Research and Small Business Transfer Technology* (July 8, 2020), available at <https://www.sbir.gov/>.

challenges that result from a supply chain relying too heavily on one country as a primary supply source, especially when that source is strained by a high global demand or abruptly stops shipments.

- **Congress and the Executive Branch should give careful consideration to the medical products that are needed to safeguard public health and the safety of health care workers, such as PPE and certain biologics and drugs, and strategically prioritize the development of manufacturing those products domestically, and/or focus on more secure and diverse global supply chains as necessary.**

G. How will the upcoming influenza season impact supplies of critical medical supplies?

- An essential strategy to minimize the effects of COVID-19's potential resurgence or a second wave on the health care supply chain in the fall is to increase the rate of influenza vaccination in the U.S.
 - Between 12,000 to 61,000 people die from influenza or influenza-related complications during a typical influenza season.³²⁵ During the 2018-2019 influenza season, 45.3 percent of adults were vaccinated against influenza and 34,200 influenza-related deaths were reported, which was less than the 61,000 influenza-related deaths the previous season when 37.1 percent of the adult population was vaccinated.³²⁶ CDC set a target for 70 percent of adults to be vaccinated against influenza in 2020.³²⁷
 - In addition to preventing influenza, the influenza vaccine can also decrease the severity of illness, for example, it has the potential to prevent 40 percent of influenza-associated hospitalizations during pregnancy.³²⁸
 - **The Executive Branch should create a robust influenza vaccination campaign to reduce the spread of influenza, which will reduce the number of people seeking health care for influenza-like symptoms, alleviate pressure on our nation's health care system, and help preserve medical supplies.**

³²⁵ Claire Gillespie, *This Is How Many People Die From the Flu Each Year, According to the CDC*, HEALTH.COM (Mar. 26, 2020), available at <https://www.health.com/condition/cold-flu-sinus/how-many-people-die-of-the-flu-every-year>.

³²⁶ U.S. Centers for Disease Control and Prevention, *Influenza (Flu) 2017-2018 Season, Estimates of Influenza Vaccination Coverage among Adults* (Nov. 5, 2018), available at https://www.cdc.gov/flu/flu_vax_view/coverage-1718estimates.htm.

³²⁷ U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion, Healthy People 2020 Topics & Objectives, *Immunization and Infectious Diseases*, IID-12.12 available at healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases/objectives (last visited June 18, 2020).

³²⁸ Centers for Disease Control and Prevention, CDC Newsroom Releases, *Flu vaccine reduces risk of flu hospitalization among pregnant women* (Oct. 11, 2018), available at <https://www.cdc.gov/media/releases/2018/p1011-flu-vaccine-reduces-risk-pregnant-women.html>.

- Because of the similarity of symptoms between COVID-19 and seasonal influenza, health care workers will need to treat all those presenting with influenza- or COVID-19-like symptoms as COVID-19 patients until a person's illness can be appropriately diagnosed. As a result, health care workers may use higher volumes of PPE and other supplies than they would typically use for a patient with influenza until a suspected case is deemed to not be COVID-positive.
 - As discussed in an earlier Second Wave Preparedness report, rapid, point-of-care tests that quickly distinguishes between influenza and COVID-19 are critical. A quick diagnosis will allow health care institutions, such as hospitals, to separate patients and utilize PPE and other critical supplies accordingly.
 - **Given the large numbers of people who have been tested for COVID-19 at Community Based Testing Sites and other dedicated COVID-19 testing sites, Congress, the Executive Branch, and the states should consider supplying dedicated COVID-19 testing locations with tests that diagnose both influenza and COVID-19, to preserve testing supplies and so that those with symptoms can be appropriately treated.**
- Accordingly, increasing the availability of, and access to, the influenza vaccine will be critical for the upcoming influenza season. Many Americans get their influenza shots from pharmacies; another significant portion of Americans get their influenza shots at work and may still be working from home during the influenza season.
 - **To conserve resources and to facilitate outreach to the teleworking population and rural communities, Congress and the Executive Branch should consider supporting creative outreach venues to administer the influenza vaccine, such as mobile influenza vaccine sites arranged through collaboration with mobile health care groups such as blood bank organizations that have blood mobiles; mobile mammogram vans; mobile medical tents stationed in pre-announced locations for set periods of time and variable hours; and drive-thru vaccine stations.**
- A strategy to increase influenza vaccination rates in the U.S. must also consider the increased need for ancillary supplies such as glass vials, needles, and syringes to manufacture and administer the vaccine.
 - A recent Reuters poll found that about 60 percent of U.S. adults surveyed plan to get the influenza vaccine this fall, which indicates an increase from prior years.

- Flu vaccine manufacturers plan to increase production by about ten percent, to approximately 189 million doses from 170 million doses manufactured last year.³²⁹
- CDC purchased seven million doses directly from manufacturers to be distributed to states for adult vaccination. Typically, CDC purchases about 500,000 doses for adults.³³⁰
- Rite-Aid pharmacy has ordered 40 percent more vaccine doses to meet the anticipated demand this year. CVS Health Corp. and Walgreens also anticipate that more Americans will get influenza shots than in a typical year.³³¹
- **The Executive Branch should work with the states to create an influenza distribution plan in anticipation of the higher volume of people who will seek the vaccine this year, and in future years. A comprehensive plan to increase influenza vaccine distribution will also help establish a framework to distribute and administer a COVID-19 vaccine to millions of people when a vaccine becomes available.³³² This will help address any operational complications before the COVID-19 vaccine roll-out, including potential ancillary supply challenges.**
- **Congress and the Executive Branch should work with stakeholders on an educational campaign to encourage as many people as possible to get vaccinated, and to direct people to a variety of available non-health care based locations where they can get an influenza shot, including pharmacies, to prevent the health care system from getting overwhelmed.**
- **As a subsidiary part of the national educational campaign to increase influenza vaccination coverage generally, the Executive Branch should consider implementing an influenza vaccination strategy targeted towards increasing availability and accessibility of influenza vaccines for COVID-19 high-risk patient categories.³³³ For example, the Executive Branch could work with faith-based organizations and minority community leaders to launch educational campaigns about the benefits of**

³²⁹ Lena Sun, *CDC and drugmakers boost flu vaccine doses amid fears of an unprecedented respiratory illness season*, THE WASHINGTON POST (June 24, 2020), available at <https://www.washingtonpost.com/health/2020/06/24/cdc-drugmakers-boost-flu-vaccine-doses-amid-fears-an-unprecedented-respiratory-illness-season/>.

³³⁰ *Id.*

³³¹ Caroline Humer and Julie Steenhuisen, *Fears of coronavirus second wave prompt flu push at U.S. pharmacies, drugstores*, WKZO (May 26, 2020), available at <https://wkzo.com/news/articles/2020/may/26/fears-of-coronavirus-second-wave-prompt-flu-push-at-us-pharmacies-drugmakers/1022093/>.

³³² Max Nisen, *To Fight Covid-19, Get a Flu Shot*, BLOOMBERG (June 15, 2020), available at <https://www.bloomberg.com/opinion/articles/2020-06-15/to-fight-covid-19-this-fall-get-a-flu-shot>.

³³³ Centers for Disease Control and Prevention, *Coronavirus Disease (COVID-19), People Who Are at Increased Risk for Severe Illness* (June 25, 2020), available at <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-at-increased-risk.html>.

influenza vaccines targeted toward specific groups such as COVID-19 high-risk patients or children. In addition, the Executive Branch should ensure an adequate supply of high-dose and adjuvanted influenza vaccines for individuals 65 years and older.

- **The Executive Branch should explore options for increasing awareness of, availability of, and access to the free Vaccine Finder application that allows users to search for locations that offer immunizations and track potential vaccine shortages.**³³⁴
- Efforts to modernize influenza vaccine production have been discussed for more than a decade.
 - Most influenza vaccines are still produced in chicken eggs (a method started in the 1940s), and a little under 50 percent the U.S. supply of egg-based influenza vaccine is made overseas.
 - In September 2019, President Trump signed an Executive Order to modernize influenza vaccines by promoting domestic, non-egg-based vaccine manufacturing. This prioritization will decrease the amount of time it takes to manufacture influenza vaccines, which allow experts more time to match vaccines to actively circulating viruses, making them more effective to treat seasonal influenza.³³⁵
 - **The Executive Branch should consider whether it is necessary to source alternative international suppliers for influenza vaccines to ensure redundancy while working towards the goals to strengthen and diversify the influenza vaccine supply chain set forth in the National Influenza Vaccine Modernization Strategy, including increasing domestic manufacturing capabilities.**³³⁶

III. Recommendations

A. The Strategic National Stockpile

- States should consider building independent medical supply stockpiles to be better prepared to manage critical shortages of medical resources.
- Congress and the Executive Branch should clarify the role of the SNS during a global pandemic or biological event which affects the whole country, including mechanisms

³³⁴ HealthMap Vaccine Finder, available at <https://vaccinefinder.org/>.

³³⁵ The White House, *Executive Order on Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health* (Sept. 19, 2019), available at <https://www.whitehouse.gov/presidential-actions/executive-order-modernizing-influenza-vaccines-united-states-promote-national-security-public-health/>.

³³⁶ United States Public Health Service, *National Influenza Vaccines Modernization Strategy 2020-2030* (June 24, 2020), available at <https://www.phe.gov/Preparedness/planning/nivms/Documents/nivms-2020-2030.pdf>.

for coordinating health care resources to the states and territories, to provide a shared understanding of the SNS' role in that situation.

- Congress should consider whether the SNS should be allowed to accept donations of certain products.
- Congress and the Executive Branch should examine the use of the SNS in the first wave of the pandemic, the coordination of the SNS' response activities with FEMA, and potential overlaps in authorities and responsibilities among HHS, FEMA, and DoD, and put in place any needed changes or processes to most effectively replenish and manage the SNS.
- Congress should seek information on how DoD, the Veterans Health Administration, and state and local stockpiles are managed, and determine best practices for how the SNS can most efficiently and effectively supplement state supplies.
- Congress and the Executive Branch should explore whether any of the HHS plans for enhanced SNS IT communication and supply management can be expedited for implementation before the fall. With the forecasted increased medical supply demand, it will be important for SNS management to be able to detect and respond to any rapidly shifting conditions in the global supply chain through monitoring manufacturing capacity of key suppliers as well as import and export controls.
- Congress and the Executive Branch should review HHS' procurement and acquisition processes and staffing to assess if barriers prevent the SNS from using HHS DPA authorities, which provide mechanisms for priority rating SNS agreements and orders or allocate distribution of a contractor's stock inventory.
- Congress and the Executive Branch should clearly identify the criteria by which supplies from the SNS should be prioritized, if necessary, and clearly identify these criteria for the states.
- While Congress has provided additional funds for the SNS, Congress should consider whether additional funds are needed in both the short- and long-term to adequately stock and maintain the SNS.
- Congress and the Executive Branch should consider whether the SNS should maintain a broader array of MCMs and drugs critical to saving and preserving life, in addition to its historical supply of drugs.
- Congress and the Executive Branch should study whether APIs can and should be included in the SNS, as there are concerns with the feasibility of such a requirement.
- Congress and the Executive Branch should consider whether, and if so, what, potential therapeutics for COVID-19 should be included in the SNS once authorized or approved by FDA.

- The Executive Branch should consider whether similar “push packs” should be created and maintained for pandemic PPE supplies, such as masks and gloves.
- Congress and the Executive Branch should evaluate the most efficient and effective management strategies to modernize the SNS, and implement any needed legislative or regulatory changes to effectuate such a modernization.
- Congress should work with the Executive Branch and stakeholders to consider whether, and if so, how SNS 2.0 can optimize a national health care supply chain central leadership position to improve supply availability and visibility and facilitate the allocation of critical medical supplies for supplies that are stocked in the SNS 2.0 for the COVID-19 response.
- Congress should conduct oversight of the SNS 2.0 program and, depending on the findings, consider codifying the program if effective.
- Once the immediate wave of the COVID-19 pandemic has waned, ASPR and FDA should determine the extent to which relevant product in the SNS is expired and awaiting testing, and expedite testing under the Federal Shelf Life Extension Program.
- Congress should consider whether additional authorities are needed for the SNS to be able to cycle products through before expiration.

B. Additional Supply Chain Issues

- If air cargo capacity remains low, the Executive Branch should consider whether contract arrangements should be made to secure additional space for transportation of medical supplies to the U.S. through use of air cargo services with FedEx, UPS, and DHL which were the least disrupted during the initial outbreak.
- In order to ensure the stability of supply chains, Congress and the Executive Branch should evaluate how federal agencies coordinate contracting considerations, and ensure that they clearly communicate their actions and plans regarding medical supply chain coordination efforts to ensure process transparency.
- Congress and the Executive Branch should review critical medical equipment temporary tariff exclusions to determine if additional exclusions are needed, and if any approved exclusions need to be extended to assist in the response to the pandemic.
- Government contractors and suppliers, particularly those working with the federal government for the first time, should ensure that they are in compliance with all provisions of their agreements.

- Before a resurgence of COVID-19 cases, the Executive Branch should identify and coordinate response distribution roles and responsibilities and ensure agencies, and any other FEMA-facilitated third parties, avoid duplication of effort to ensure efficient operations.
- Congress and the Executive Branch should examine whether the procurement and supply distribution responsibilities among agencies should be more clearly delineated before any subsequent waves of the COVID-19 pandemic occur.
- The Executive Branch should consider what metrics will be used to determine if Project Air Bridge will be relaunched and how that coordination will occur if the Supply Chain Stabilization Task Force is no longer operational.
- Congress and the Executive Branch should consider whether procedures to replace any of the temporary and stopgap transport and delivery systems being used for the current outbreak should be established before a potential resurgence of cases in the fall, or in the event of future pandemics.
- Congress and the Executive Branch should consider how to leverage data and other information gathered by the Supply Chain Stabilization Task Force to best prepare for future demand surges.
- Congress and the Executive Branch should evaluate if additional authorities may be needed to support keeping ACS sites in a “warm” status so that they can be activated, if needed, during a resurgence of COVID-19 cases.
- Congress and the Executive Branch should consider whether the temporary telehealth flexibilities should be extended or made permanent to encourage a stable health care delivery platform on which innovative approaches to healthcare delivery can be built.
- Congress and the Executive branch should consider what, if any, continued streamlined contracting, production, other new emergency authorities, or funding should continue given the global need and increased customer base for critical supplies, such as PPE. For example, HHS could consider creating an entity similar to FedMall where vendors are pre-vetted, or join with DLA, to further expand the vendor and buyer capacity in FedMall.
- Congress and the Executive Branch should examine whether the collaboration efforts between HHS, FEMA, DoD, and other agencies were hampered by existing regulations or laws, and if so, consider whether the federal government would benefit from legislative or regulatory changes.
- The Executive Branch should continue to examine additional methods to extend testing supplies to meet the high demand.

- The Executive Branch should monitor testing supplies for diagnostic and surveillance testing needs. In considering allocation and distribution, the Executive Branch should examine whether use of its DPA allocations authority or other mechanisms, such as voluntary agreements, are available and appropriate to allocate supplies based on outbreak areas and fluctuating testing needs.
- The Executive Branch should consider methods to systemically increase real-time communication and improve transparency of information regarding available testing supplies.
- Congress and the Executive Branch should consider how to best mobilize and increase this specialized laboratory workforce to improve the U.S.' laboratory test processing
- In preparation for a potential resurgence in cases, health care distributors should examine data and their experiences thus far in responding to the COVID-19 pandemic to be able to better understand and match the supply needs of their customers, evaluate surges in demand in outbreak areas, and, if necessary, prioritize customers accordingly in the months ahead.
- Where possible, distributors should evaluate current agreements with manufacturers and transportation companies, shift production to more resilient locations, and invest in people and processes to meet customer needs without interruption.
- Congress, the Executive Branch, and the private sector should consider how to most effectively and efficiently increase the technology-based capabilities for medical supply chain management, such as modernizing government supply chain digital inventory systems and increasing secure data exchange platforms for real-time monitoring supply needs in private sector digital supply chain inventory systems.
- The Executive Branch should consider evaluating essential medicines and devices for which one or two suppliers exist, and either pursue alternative sources or consider using available authorities, such as the DPA, to help existing companies expand and/or diversify production.
- Congress and the Executive Branch should consider how to incentivize additional production of critical health supplies, diversify production, address other supply chain dependencies that impact the health care supply chain, fill information and data gaps, and promote U.S. leadership on global health and trade issues.
- The Executive Branch should examine whether there are other products necessary for the COVID-19 response that should be manufactured domestically. If so, the Executive Branch should work with Congress and the private sector to enable and support these efforts.

- Congress and the Executive Branch should evaluate other items that are critically needed, and consider additional initiatives similar to the “Hack-A-Vent” competition for ventilator design and RADx for diagnostic testing developments that maximize innovation, speed, and expand domestic manufacturing for cost-effective equipment or other supplies that are necessary for the COVID-19 response.
- Congress should promote policies to encourage domestic production of critical medical supplies and pharmaceutical products. Increased domestic manufacturing can be achieved by creating additional market-based incentives without imposing sweeping government mandates or controls.
 - Such policies should promote transparency into the pressure points in supply chains and what countries we are most reliant on for critical supplies, increase information available to Congress and federal agencies, and diversification of supply chains, such as encouraging the use of advanced manufacturing, creating additional markets for private sector businesses, and making regulatory processes more efficient.
- Congress should conduct oversight into the effectiveness of DFC’s loan authority in encouraging domestic medical supply production, and depending on the findings, should consider codifying this program.
- Congress and the Executive Branch should consider whether to expand Manufacturing USA to include HHS as a sponsoring agency either for already-existing institutes, or to create or expand an institute focused on manufacturing health care products to include innovative health care devices, health care supply chain data technologies, and more efficient manufacturing of laboratory equipment, among other areas.
- Congress and the Executive Branch should continue to examine innovative ways to increase domestic production of critical supplies that are needed to respond to COVID-19.
- Congress and the Executive Branch should consider what incentives and regulatory changes are needed to increase domestic manufacturing of critical products.
- Congress and the Executive Branch should consider what existing laws and regulations are impeding domestic manufacturing of critical products and determine whether any such laws or regulations should be changed or eliminated.
- Congress and the Executive Branch should give careful consideration to the medical products that are needed to safeguard public health and the safety of health care workers, such as PPE and certain biologics and drugs, and strategically prioritize the development of manufacturing those products domestically, and/or focus on more secure and diverse global supply chains as necessary.

- The Executive Branch should create a robust influenza vaccination campaign to reduce the spread of influenza, which will reduce the number of people seeking health care for influenza-like symptoms, alleviate pressure on our nation's health care system, and help preserve medical supplies.
- Given the large numbers of people who have been tested for COVID-19 at Community Based Testing Sites and other dedicated COVID-19 testing sites, Congress, the Executive Branch, and the states should consider supplying dedicated COVID-19 testing locations with tests that diagnose both influenza and COVID-19, to preserve testing supplies and so that those with symptoms can be appropriately treated.
- To conserve resources and to facilitate outreach to the teleworking population and rural communities, Congress and the Executive Branch should consider supporting creative outreach venues to administer the influenza vaccine, such as mobile influenza vaccine sites arranged through collaboration with mobile health care groups such as blood bank organizations that have blood mobiles; mobile mammogram vans; mobile medical tents stationed in pre-announced locations for set periods of time and variable hours; and drive-thru vaccine stations.
- The Executive Branch should work with the states to create an influenza distribution plan in anticipation of the higher volume of people who will seek the vaccine this year, and in future years. A comprehensive plan to increase influenza vaccine distribution will also help establish a framework to distribute and administer a COVID-19 vaccine to millions of people when a vaccine becomes available. This will help address any operational complications before the COVID-19 vaccine roll-out, including potential ancillary supply challenges.
- Congress and the Executive Branch should work with stakeholders on an educational campaign to encourage as many people as possible to get vaccinated, and to direct people to a variety of available non-health care based locations where they can get an influenza shot, including pharmacies, to prevent the health care system from getting overwhelmed.
- As a subsidiary part of the national educational campaign to increase influenza vaccination coverage generally, the Executive Branch should consider implementing an influenza vaccination strategy targeted towards increasing availability and accessibility of influenza vaccines for COVID-19 high-risk patient categories. For example, the Executive Branch could work with faith-based organizations and minority community leaders to launch educational campaigns about the benefits of influenza vaccines targeted toward specific groups such as COVID-19 high-risk patients or children. In addition, the Executive Branch should ensure an adequate supply of high-dose and adjuvanted influenza vaccines for individuals 65 years and older.

- The Executive Branch should explore options for increasing awareness of, availability of, and access to the free Vaccine Finder application that allows users to search for locations that offer immunizations and track potential vaccine shortages.
- The Executive Branch should consider whether it is necessary to source alternative international suppliers for influenza vaccines to ensure redundancy while working towards the goals to strengthen and diversify the influenza vaccine supply chain set forth in the National Influenza Vaccine Modernization Strategy, including increasing domestic manufacturing capabilities.