

A decorative arc of gold stars curves from the top center towards the bottom right corner of the cover.

NATIONAL STRATEGY FOR A RESILIENT PUBLIC HEALTH SUPPLY CHAIN

JULY 2021



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Foreword



The Coronavirus Disease 2019 (COVID-19) pandemic has illustrated the devastating effects that a global pandemic can have on all facets of our society. We must do better to prepare for and respond to future pandemics and biological incidents. This work includes creating a more resilient and sustainable public health supply chain—encompassing drugs, biological products, medical devices, personal protective equipment, and ancillary supplies—to ensure all Americans have access to critical supplies and effective health care. Doing so is essential to maintaining the national health security of the United States.

Per Executive Order (EO) 14001, “On a Sustainable Public Health Supply Chain,” the enclosed public health supply chain resilience strategy aims to design, build, and sustain a long-term capability in the United States to manufacture supplies for future pandemics and biological threats. The strategy outlines the vision, goals, and objectives for a resilient public health supply chain, and the path for implementation. It was developed in coordination and collaboration among the Departments of Health and Human Services, Defense, Homeland Security, Commerce, State, and Veterans Affairs, and the White House Office of the COVID-19 Response.

We look forward to continuing the work to execute this strategy so we can systematically protect the health and security of Americans by maintaining a public health supply chain that is resilient against disruptions from pandemics and other biological threats. Together, we can ensure that the United States is moving forward to a more brilliant future.

Respectfully,

A handwritten signature in black ink, appearing to read "Lloyd Austin".

Lloyd Austin
Secretary of Defense
Department of Defense

A handwritten signature in blue ink, appearing to read "Xavier Becerra".

Xavier Becerra
Secretary of Health and Human Services
Department of Health and Human Services

A handwritten signature in blue ink, appearing to read "Alejandro Mayorkas".

Alejandro Mayorkas
Secretary of Homeland Security
Department of Homeland Security

A handwritten signature in blue ink, appearing to read "Denis McDonough".

Denis McDonough
Secretary of Veterans Affairs
Department of Veterans Affairs

Table of Contents



Foreword	4
Executive Summary	9
Introduction	14
Defining Public Health Supply Chain Resilience	17
What the Public Health Supply Chain Encompasses	17
What the Public Health Supply Chain Protects Against	18
What Resilience Means	19
What Defines a Resilient Public Health Supply Chain	20
Robustness	21
Agility	21
Visibility	22
The Path to Resilience	23
Problem Statement and Solutions to Employ	23
Public Health Supply Chain Resilience Today	25
Medical Supply Chains are Complex Global Ecosystems	25
During COVID-19, the Role of the U.S. Government in the U.S. Medical Supply Chain Evolved Significantly	25
COVID-19 Illuminated Vulnerability and Opportunity	27
Our Vision, Values, and Goals for Public Health Supply Chain Resilience	29
Goal 1: Build a diverse, agile public health supply chain and sustain long-term U.S. manufacturing capability for future pandemics	30
Objective 1.1: Build and sustain a strong domestic industrial base for MCMs that is complemented by strategic near- and allied-shoring.	31

Objective 1.2: Safeguard supply chain diversity through policy, incentive, regulation, and other tools to reduce dependence on a single region, source, or product.	32
Objective 1.3: Reinforce supply chain agility to ensure that supply chain partners can better respond to supply chain disruptions and increased demand.	33
Objective 1.4: Achieve ethical, sustainable sourcing that includes high standards on labor and environment, while combatting unfair trade.	33
Objective 1.5: Build robustness into the supply chain at the SLTT level through partnership, policy, procurement, and regulation.	34
Objective 1.6: Create good jobs through the public health supply chain and invest in skills development so that we have the talent needed to invent and make critical supplies.	35
Goal 2: Transform the U.S. Government’s ability to monitor and manage the public health supply chain through stockpiles, visibility, and engagement.	35
Objective 2.1: Maintain the visibility and analytics needed to anticipate, prevent, mitigate, and respond to supply chain shortages and disruptions.	37
Objective 2.2: Enhance supply chain transparency and coordination with and among private-sector partners on supply chain status.	38
Objective 2.3: Enhance supply chain transparency and coordination with and among SLTT partners on the status of supply chain and stockpile levels.	38
Objective 2.4: Optimize the shelf-life, distribution, and allocation of stockpiled supplies through targeted stockpiling approaches.	39
Goal 3: Establish standards, systems, and governance to manage the supply chain and ensure fair, equitable, and effective allocation of scarce resources.	40
Objective 3.1: Establish transformative business practices that ensure long-term end-to-end MCM readiness.	41
Objective 3.2: Improve coordination across relevant stakeholders and incorporate new tools and technologies into public health preparedness, response, and recovery operations.	42

<p>Objective 3.3: Leverage data-informed decision-making to guide domestic pharmaceutical and medical supply chain and infrastructure requirements.</p>	42
<p>Objective 3.4: Position the federal government to respond quickly and equitably to emergency public health supply chain needs of SLTT authorities through strengthened governance, planning, and preparedness.</p>	43
<p>Resilience Recommendations</p>	44
<p>Robustness and Industry Sustainment</p>	44
<p>Agility and Innovation</p>	47
<p>Visibility and Engagement</p>	50
<p>Governance and Management</p>	53
<p>Conclusion</p>	56
<p>Appendix I: Acronyms</p>	57
<p>Appendix II: Challenges and Opportunities from the COVID-19 Response</p>	59
<p>Observed Problems in the Operating Environment</p>	59
<p>Supply Chain Data and Visibility</p>	61
<p>Interagency Public Health Supply Chain Coordinating Structures</p>	63
<p>Planning, Stockpiling, and Preparedness</p>	64
<p>SLTT Support and Engagement</p>	66
<p>Private-Sector Support and Engagement</p>	67
<p>International Support and Engagement</p>	70
<p>Deep Dive: Ensuring Quality of PPE and Effective Coordination through the Supply Chain Life Cycle</p>	71
<p> Current State</p>	71
<p> Immediate Need</p>	73
<p> The Path Forward</p>	74
<p>Appendix III – References</p>	77

Executive Summary



The COVID-19 pandemic of 2020 and 2021 has laid bare the fragility of the public health supply chain. Throughout the response, shortages of key material and challenges in quickly ramping up domestic production have resulted in additional disease spread and further illness and mortality. From the early shortages in testing needed to identify and arrest the spread, and of personal protective equipment (PPE) needed to allow critical workers to safely carry out their missions; to the subsequent challenges of scaling global vaccine production—poor supply chain resilience negatively impacted the response.

Effective response requires a resilient public health supply chain, anchored in domestic manufacturing capabilities, so that care and preventive measures can reach patients. Sustaining the resilience of this supply chain is critical for national security. However, the United States (U.S.) public health supply chain—comprised of medical countermeasures such as drugs, biological products, devices, diagnostics, PPE, and ancillary supplies—is vulnerable during pandemics.

During the COVID-19 pandemic, the supply chain saw significant disruption when global demand for critical material increased and manufacturing levels simultaneously decreased. These trends resulted in competition for limited quantities of needed supplies. The U.S. did not have what it needed to respond to the pandemic, whether in stockpiles or quickly scalable industrial capacity. It also lacked the national policies to support the allocation and distribution of scarce resources, and to support rapid and sustained manufacturing. Decades of globalization and lean, just-in-time supply chains had led to a supply chain that could not meet U.S. or global demand during the COVID-19 pandemic. COVID-19 supply chain challenges exposed the U.S.'s reliance on foreign manufacturing and lack of domestic manufacturing capabilities.

Today, the public health supply chain is much stronger. The U.S. Government and American industry have worked tirelessly to increase production of supplies ranging from surgical gowns to ventilators. The Strategic National Stockpile is much better positioned than it was at the beginning of the COVID-19 pandemic. Yet, the U.S. public health supply chain remains vulnerable to future pandemics without transformational, long-term investment. We, the U.S. Government, must continue the work of building

back a public health supply chain that can protect Americans from the next pandemic and other biological incidents. Doing so requires both critical reflection on the challenges experienced during COVID-19, and forward-looking preparedness and response planning for future threats.

Accordingly, as directed by Section 4 of Executive Order 14001 “On a Sustainable Public Health Supply Chain,” this National Strategy for a Resilient Public Health Supply Chain provides a strategic approach to design, build, and sustain a long-term capability in the United States to manufacture supplies for future pandemics and biological threats. This strategy outlines the U.S. Government’s vision to protect the health and security of Americans by ensuring a supply chain for PPE, medical devices, medicines, and other public health supplies that is consistent with our values and resilient against disruptions from pandemics and other biological threats.

THIS VISION IS SUPPORTED BY THREE STRATEGIC GOALS:

Goal 1: Build a diverse, agile public health supply chain and sustain long-term U.S. manufacturing capability for future pandemics;

Goal 2: Transform the U.S. Government’s ability to monitor and manage the public health supply chain through stockpiles, visibility, and engagement; and,

Goal 3: Establish standards, systems, and governance to manage the supply chain and ensure fair, equitable, and effective allocation of scarce resources.

Realizing these goals—through mechanisms that increase the resilience of the public health supply chain—will enable a more ethical, equitable, environmentally sustainable, innovative, and constructive U.S. public health supply chain. Such a supply chain would support the U.S.’s preparedness and response for future pandemics and biological threats. It would entail stronger products, people, and systems that we rely on in a public health emergency. This strategy rests on a tailored definition of resilience, focusing on three key elements of public health supply chain resilience: **robustness, visibility, and agility**. Together, capability in these areas results in a supply chain in which the U.S. can have confidence during and in-between crises.

Improved robustness involves mitigating risk in the supply chain before a crisis happens. Above all, robustness requires an expanded U.S. public health industrial base. Domestic manufacturing of critical supplies helps ensure the U.S. has what it needs when it needs it. Robustness also entails greater supplier diversity in order to reduce dependence on a single region, source, or product. Robustness applies not only to finished products, but also to the raw materials, equipment, and ancillary supplies needed to make and use that product.

Improved agility rests on the ability to adapt and scale up in time of crisis. No matter the strength of a supply chain, crises do occur, so the supply chain must be able to react to limit the scale of disruption and prevent shortages. In a crisis, such agility means that the supply chain has enough stockpiled materials so that end users can get the supplies they need until production can scale upward to meet increased demand. “Warm,” ready-to-scale manufacturing can help make that adjustment period as quick as possible. Agility also means that the U.S. Government and relevant private-sector actors can make smart, data-informed decisions to move the supply chain where it needs to go to respond to a disruption. Such response requires effective collaboration among public- and private-sector actors so that actions can occur in a coordinated manner.

Improved visibility means that the U.S. Government has a comprehensive understanding of the public health supply chain. To manage the supply chain, the U.S. Government must be able to monitor it. In times of calm, visibility enables strategic decision-making to shore up areas of risk and maintain confidence in the resilience of the supply chains for various items. In crisis, visibility enables smart, effective response. Deep supply chain data and intelligence—as well as powerful analytics—are needed to manage such a complex and dynamic ecosystem. Close engagement with industry and other groups makes this information sharing possible.

Achieving the above goals and qualities requires unprecedented investment in the public health industrial base as a national security asset—so that Americans have the supplies they need when they need them. The U.S. Government must make sustained investments in domestic manufacturing, as well as incentivize pandemic preparedness in the U.S. health care system. The U.S. Government must also continue to grow capabilities in supply chain intelligence, engagement, and management. Only through these collective actions can the U.S. public health supply chain be better situated to respond to future pandemics.

THIS STRATEGY LAYS OUT RECOMMENDATIONS TO ACTUALIZE THESE REQUIREMENTS, AMONG THEM:

Make bold investments in the American public health industrial base: The U.S. should sustain investments over the long term in a durable, resilient American industry and workforce—able to scale quickly—to ensure PPE, diagnostics, and other medical countermeasures remain at the ready when we need them. The U.S. Government faces an opportunity to build on the past year’s reinvigoration of the U.S. public health industrial base, recognizing the public health industrial base as a specific sector requiring dedicated U.S. Government management, oversight, and sustainment as a national strategic imperative. Over the next ten years, the U.S. needs to make significant investments in industrial base expansion and sustainment. This funding would support extended long-term contracts, on-hand inventory, vendor-managed inventory, and other actions, many of which would be managed through an expanded Strategic National Stockpile.

Build a more capable and robust Strategic National Stockpile: The U.S. Government should build a larger, broader, and smarter Strategic National Stockpile (SNS) that is linked with State, local, Tribal, and territorial (SLTT) capabilities—continuing current momentum—so that the U.S. is prepared for intentional, natural, and emerging pandemic threats. This capability means focusing on not only the SNS’s mission, but also all aspects of domestic preparedness including industrial base and supply chain solutions. Constituting a more capable medical countermeasures enterprise will require increased and sustainable funding, authorities, and coordination. It requires leveraging all available solutions, required resources, and tools—including solutions outside the SNS. Examples include centralized, SLTT, and vendor-managed-inventory stockpiling needed to ensure that the U.S. Government is ready to respond to future pandemics as well as intentional threats. To identify critical areas to meet future public health demands, the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) should lead an assessment of COVID-19 SNS-specific lessons learned. The PHEMCE can use insights and broader assessments of public health supply chain gaps to identify priorities for capability development.

Maintain end-to-end public health supply chain visibility: Supply chain visibility is critical to the U.S. Government’s ability to anticipate, prepare for, and respond to potential disruptions, particularly during a public health emergency. The U.S. Government is prepared to implement new supply chain situational awareness capabilities and authorities as well as establish a rhythm of regular supply chain illumination, analysis, and mapping. Expanding current supply chain visibility into critical public health and other all-hazard-scenario supplies requires 1) identifying and prioritizing the list of critical medical supplies/products for a pandemic response, and 2) prioritizing mapping and analysis of those products’ supply chains, to include raw materials, components, manufacturers, distributors, and end users. Visibility should also extend to stockpiles, including federal, SLTT, and private-sector stores. These capabilities will allow the U.S. Government to identify vulnerabilities, predict and prevent supply chain disruptions, and mitigate risks.

This strategy also outlines other recommendations in support of resilience; they include—expanding the purchase of American-made public health supplies across government and the U.S. health care sector; using trade tools to counter unfair trade practices; sustaining the public health supply chain workforce; developing capabilities to manage demand for supplies; launching a new public health supplies innovation center; streamlining coordination with the private sector; instituting an annual resilience “report card”; bolstering U.S. Government interagency oversight and coordination; improving plans for the allocation of constrained resources; and revamping global governance of the public health supply chain.

Collectively, these efforts will improve pandemic preparedness for future threats by ensuring that the public health supply chain can continue to deliver needed medical countermeasures even in the worst of circumstances. By maintaining a focus on supply chain resilience to achieve the objectives described in this strategy, the U.S. Government can build a public health supply chain that is responsive and resilient to public health emergencies—and therefore protective of American lives and livelihoods.

Introduction



Pandemics—widespread disease outbreaks with sustained human-to-human transmission across multiple countries and populations—and other biological incidents lead to deleterious health impacts and cause great suffering as well as negative psychological, social, political, economic, and national security impacts. Mitigating these impacts requires a robust public health supply chain encompassing drugs, biological products, personal protective equipment (PPE), and medical devices—including diagnostic and testing devices—as well as ancillary supplies required to deliver these countermeasures. However, market realities that have driven the globalization and evolution of lean, just-in-time supply chains have created public health supply chains brittle to periodic disruptions. During times of extremely high demand, such as during the Coronavirus Disease 2019 (COVID-19) pandemic, those weak points can break—hindering the United States’ (U.S.) ability to deliver effective health care and preventive measures to the public.

Shortages of critical medical supplies and drugs were occurring with increasing frequency before the COVID-19 pandemic. In response, work to shore up the medical product supply chain had been underway. However, this work took on new urgency with the pandemic, which placed unprecedented stress on the availability of critical medical supplies and drug availability in the U.S. The pandemic highlighted several areas in which public health experts have long recognized a major U.S. reliance on foreign supplies. It reinforced the need to have better understanding of U.S. import trends and domestic production capacity in certain industries considered essential to U.S. public health and national security.

A strong public health system is a cornerstone of national security; ensuring a robust and resilient supply chain to support that system is equally critical. Continued access to essential medicines and supplies is crucial for ensuring a healthy workforce, continuity of education, and economic prosperity. Health care workers deserve access to adequate surge supply of critical items to meet increased demand and to remain safe in order to provide lifesaving care during relief and recovery efforts. Failure to ensure this access

¹ The term nation in the context of national health security is inclusive of American citizens, non-U.S. citizens, and visitors who may be at risk of adverse health effects in event of a public health emergency or disaster.

erodes the nation’s public health and costs lives. To save lives and protect the nation¹ from these public health risks, action must be taken to ensure the public health supply chain is able to withstand shocks and provide adequate surge capacity. Such resilience improves the U.S. Government’s ability to counter public health threats such as natural disasters, human-caused incidents, emerging and pandemic infectious diseases, and acts of terrorism.

This National Strategy for a Resilient Public Health Supply Chain charts a vision, goals, and recommendations to maintain resilience for the COVID-19 pandemic and future ones. The strategy builds upon and is consistent with the 2019–2022 National Health Security Strategy²—one of the goals of which is to leverage the capabilities of the private sector, and, in so doing, foster the creation of a resilient medical product supply chain. The pandemic response has promoted a collective reconsideration of the U.S. Government’s approach to developing, purchasing, storing, and distributing needed supplies, as well as ensuring those supplies are used effectively. The vulnerabilities in America’s public health supply chains exposed by the pandemic response—including inadequate domestic manufacturing capacity and capabilities—led to numerous supply chain interruptions amid over-reliance on foreign manufacturing, unprecedented excess global demand, and temporary closures of manufacturing and other supply chain related businesses following community mitigation measure implementation.

To address these challenges, this strategy outlines steps for the United States to invest boldly in public health preparedness. These actions include expansion of the domestic public health industrial base (PHIB), which is the system of industrial assets able to meet public health response needs with medical countermeasures (MCMs).³ They also include medical product stockpiling beyond the current pandemic.⁴ The U.S. Government should

² “[National Health Security Strategy \(NHSS\) 2019–2022](https://www.phe.gov/Preparedness/planning/authority/nhss/Documents/NHSS-Strategy-508.pdf),” Assistant Secretary for Preparedness and Response (ASPR), accessed May 21, 2021, <https://www.phe.gov/Preparedness/planning/authority/nhss/Documents/NHSS-Strategy-508.pdf>.

³ Medical countermeasures include both pharmaceutical interventions (e.g., vaccines, antimicrobials, antidotes, and antitoxins) and non-pharmaceutical interventions (e.g., medical devices—including diagnostics—ventilators, personal protective equipment, and patient decontamination) as well as other needed medical products that may be used to prevent, mitigate, or treat the adverse health effects of an intentional, accidental, or naturally occurring public health emergency. They include (but are not limited to) qualified countermeasures as defined in section 319F–1(a)(2) of the Public Health Service Act (42 U.S.C. § 247d–6a(a)(2)); qualified pandemic or epidemic products as defined in section 319F–3(i)(7) of the Public Health Service Act (42 U.S.C. § 247d–6d(i)(7)), and security countermeasures as defined in section 319F–2(c)(1)(B) of the Public Health Service Act (42 U.S.C. § 247d–6b(c)(1)(B)).

⁴ The [Public Health Emergency Medical Countermeasures Enterprise \(PHEMCE\) Multi-Year Budget](https://www.phe.gov/Preparedness/mcm/phemce/phemce-myb/FY2018-2022/Pages/future-challenges.aspx) notes, “The primary challenge faced by the PHEMCE is the sustainability of the MCM response capabilities and capacities of the SNS built through PBS. Successful procurement of an MCM obligates SNS to expend additional funding for sustainment. First, SNS faces replenishment requirements upon expiration for products added to the SNS by BARDA through PBS contracts. *PBS funding used for initial MCM procurement rarely supports ongoing maintenance and replacement of the products after it is approved by FDA. In the past, the PHEMCE SNS Annual Review recommended tradeoffs when available SNS funds were insufficient to both maintain current capabilities and absorb additional products. These tradeoffs translated to increasing levels of risk across the threat portfolios potentially jeopardizing the nation’s ability to realize the full benefits of prior research and development investments.*” (emphasis added). Accessed April 21, 2020, <https://www.phe.gov/Preparedness/mcm/phemce/phemce-myb/FY2018-2022/Pages/future-challenges.aspx>.

support the expansion and maintenance of the PHIB’s supply chain capabilities and mitigation of emerging vulnerabilities. In doing so, the United States would grow the MCM enterprise by leveraging novel approaches to processes, policies, material characteristics, and infrastructure critical to the timely and quality development, deployment, and use of MCMs.

Achieving this strategic vision to realize a resilient public health supply chain will require a whole-of-government⁵ approach, led by the U.S. Department of Health and Human Services (HHS). This approach involves gathering supply chain intelligence, making investments in domestic MCM manufacturing, identifying gaps and shortages, addressing vulnerabilities proactively, and incentivizing pandemic preparedness at the federal level; at the State, local, Tribal, and territorial (SLTT) levels, and across the U.S. health care system. Through committed efforts—advancing upon progress made during the COVID-19 pandemic—the U.S. Government can build a public health supply chain that is responsive and resilient to public health emergencies. Doing so will protect American lives and livelihoods.

⁵ See the ASPR Blog on the National Health Security Strategy, “[The purpose of the whole-of-government approach is to create a culture that facilitates a shared vision between federal agencies both within the U.S. Department of Health and Human Services and across all federal departments. Inter and intra agency coordination and cooperation strengthens departments’ abilities to operate as one system rather than a collection of separate components. It establishes a unified effort between government agencies to maximize all available resources—personnel, funding, and equipment and supplies—in a collaborative effort.](https://www.phe.gov/ASPRBlog/Lists/Posts/Post.aspx?ID=329)” Accessed May 27, 2021, <https://www.phe.gov/ASPRBlog/Lists/Posts/Post.aspx?ID=329>.

Defining Public Health Supply Chain Resilience



What the Public Health Supply Chain Encompasses

A supply chain is a system of organizations, people (including workers, producers, and importers), activities, information, and resources involved in providing a product or service to a consumer.⁶ The public health supply chain is the system that produces and delivers critical medical supplies to support the health care and public health (HPH) sector and other critical infrastructure (CI) sectors.⁷ These supplies include PPE, diagnostics, and other medical devices; as well as pharmaceuticals—therapeutics, biologics, and vaccines (see Figure 1, below).

Figure 1, Public Health Supply Chain



⁵ See the ASPR Blog on the National Health Security Strategy, “[The purpose of the whole-of-government approach is to create a culture that facilitates a shared vision between federal agencies both within the U.S. Department of Health and Human Services and across all federal departments. Inter and intra agency coordination and cooperation strengthens departments’ abilities to operate as one system rather than a collection of separate components. It establishes a unified effort between government agencies to maximize all available resources— personnel, funding, and equipment and supplies—in a collaborative effort.](#)” Accessed May 27, 2021, <https://www.phe.gov/ASPRBlog/Lists/Posts/Post.aspx?ID=329>.

⁶ As highlighted in the [National Critical Functions \(NCFs\)](#) outlined by the Department of Homeland Security’s Cybersecurity and Infrastructure Security Agency (CISA). Efforts to bolster the discussion between private- and public-sector entities frequently fall within the authorities of the Critical Infrastructure Partnership Advisory Council (CIPAC) and is a central point of communication between government and industry partners who manage their individual supply chains. The NCFs are divided into sections of Distribute, Connect, Manage and Supply. Accessed April 8, 2021, <https://www.cisa.gov/national-critical-functions-set>.

⁷ There are 16 critical infrastructure sectors whose assets, systems, and networks, whether physical or virtual, are considered so vital to the United States that their incapacitation or destruction would have a debilitating effect on security, national economic security, national public health or safety, or any combination thereof. For a [list of the CISA critical infrastructure sectors](#) <https://www.cisa.gov/critical-infrastructure-sectors>, accessed April 8, 2021. Also note that the 2021 National Defense Authorization Act renamed the Sector Specific Agencies into the Sector Risk Management Agencies (SRMAs) who coordinate critical infrastructure protection activities in line with the National Infrastructure Preparedness Plan. Accessed April 8, 2021, <https://www.cisa.gov/sector-risk-management-agencies>.

These supplies support public health in the face of pandemics and other public health threats and are a critical part of national health security. The interconnected nature of multiple supply chain tiers varies greatly among these categories of items. Furthermore, the raw materials and components of the public health supply chain overlap with those of non-health-related products, such that the public health and animal health supply chains are fully intertwined and draw from the same basic materials and supplies. For example, an animal health emergency may contribute to a shortage in laboratory supplies—as a result, addressing animal health emergencies or zoonotic emergencies requires coordination of supply chain needs.

What the Public Health Supply Chain Protects Against

Threats to the health and well-being of a nation’s population—and that of the entire globe—come from a variety of sources, in particular, naturally occurring and human-caused spread of diseases, both accidental and intentional. The onset of a disease can be from well-known and traditionally researched pathogens, from emerging or re-emerging infectious diseases, or from novel strains of bacteria and viruses to which human hosts have no previous immunity. Pathogens can and do mutate as part of their life cycle. Outbreaks of disease can come from seasonal influenza that undergoes genetic drift to become a strain of pandemic influenza. Bacterial diseases can develop resistance to the antibiotics that we use to control an infection. Novel strains of virus can jump from animals to humans. The rise of genetic engineering could lead to a “designer pathogen” that is specifically tailored to evade our immune systems.

Humans can encounter these pathogens through a variety of ways. The loss of habitat and the expansion of human developments and agricultural practices means that humans are increasingly coming into close contact with wildlife, and with them the zoonotic pathogens that may spread to us.⁸ Laboratory accidents, although rare, can occur, requiring continued emphasis on health security and biosafety practices so that the research community can continue to learn and grow. The possibility also exists for malicious actors to attempt purposeful exposure of vulnerable populations to pathogens with the intent to cause harm. Countering these threats requires an interwoven response across research disciplines, communities, government agencies, and the global community.

⁸ NHSS 2019–2022

Once sustained human-to-human transmission of a causative agent of disease takes hold in a community, and between communities, we have a pandemic. As mentioned above these events can occur with little or no warning. Successfully confronting the threat of one disease does not guarantee that another might not arise. Therefore, robust detection and preparedness activities are essential to respond to and quell a new outbreak of disease rapidly. Detecting and mitigating the transmission of disease early requires vigilance—including sustained funding of a public health cadre that is trained to communicate good health practices to the communities threatened by possible pandemic spread.

These mitigation activities require a resilient public health supply chain. Epidemiological curves are best flattened early, but once begun they are bent with only a collective response that includes a portfolio of detection, protection, and therapeutic and prophylactic countermeasures. Ongoing research, development, and manufacturing of medical countermeasures are essential to ensuring we are ready to respond to an unforeseen public health emergency (PHE).

What Resilience Means

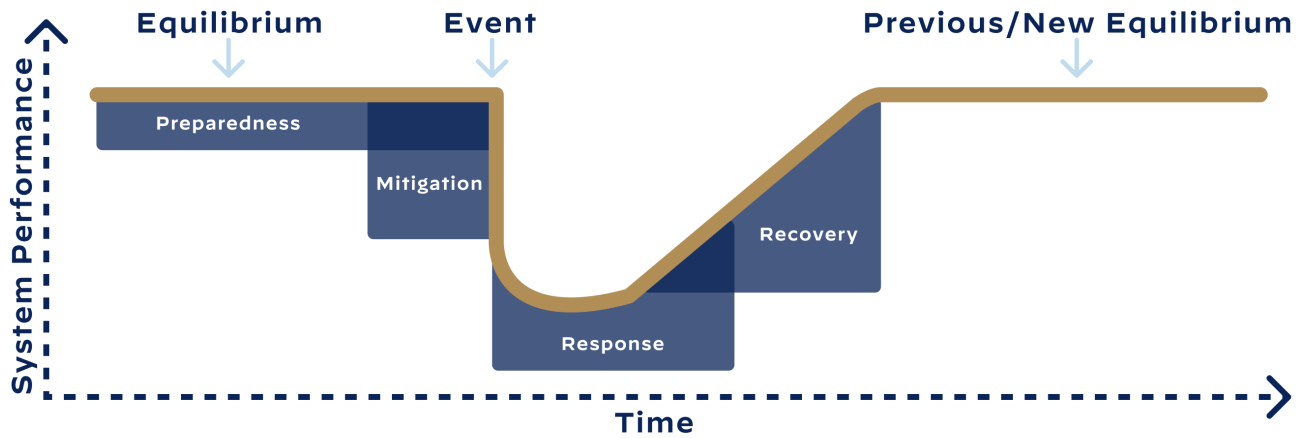
Resilience in emergency preparedness is the ability to prepare for and adapt to changing conditions and withstand and recover rapidly from disruptions. These disruptions include deliberate attacks, accidents, or naturally occurring threats or incidents.⁹ At its heart, resilience involves human behavior¹⁰ within and among systems with the ability to bend so that a catastrophic loss of function is avoided, and to do so by flexibly employing a variety of solutions to mitigate, respond to, and recover from an event (see Figure 2, below). Behaviorally, resilient systems have a sensing–adapting–learning component that includes the way that information is taken in and reacted to by the participants. The sum outcome of resilience is the ability to confront unforeseen events successfully.¹¹

⁹ A “[Presidential Policy Directive – Critical Infrastructure Security and Resilience](https://obamawhitehouse.archives.gov/the-press-office/2013/02/12/presidential-policy-directive-critical-infrastructure-security-and-resil),” The White House, accessed April 8, 2021, <https://obamawhitehouse.archives.gov/the-press-office/2013/02/12/presidential-policy-directive-critical-infrastructure-security-and-resil>.

¹⁰ Susan Spierre Clark, Thomas P. Seager, and Mikhail V. Chester, “[A capabilities approach to the prioritization of critical infrastructure](https://doi.org/10.1007/s10669-018-9691-8),” *Environ Syst Decis* 38, 339–352 (2018), <https://doi.org/10.1007/s10669-018-9691-8>.

¹¹ Paul Michelman and Yossi Sheffi, “[Building a Resilient Supply Chain](https://hbr.org/2007/08/building-a-resilient-supply-ch),” *Harvard Business Review*, accessed April 8, 2021, <https://hbr.org/2007/08/building-a-resilient-supply-ch>20May%2011.

Figure 2, Conceptual Resilience Diagram,¹² depicting a degradation in the system performance that initiates the return to function throughout the phases of preparedness, mitigation, response, and recovery



What Defines a Resilient Public Health Supply Chain

This strategy rests on a tailored definition of resilience: the three elements of public health supply chain resilience are robustness, agility, and visibility (see Figure 3, right). Together, capabilities in these areas forge a supply chain in which the U.S. can have confidence during and in-between crises. A resilient public health supply chain brings MCMs and other necessary supplies together to save lives and support human health before, during, and after a PHE—in a way that can adapt to spontaneous, varying, and extended shocks.

Improving public health supply chain resilience requires wide participation. Only multi-solver approaches and partnerships can contend with the complex, interdependent nature of the interactions among producers, purchasers, and users in the supply chain. Only collaboration up and down the supply chain can enable effective preparation for unforeseen disruptions. Only public and private partnerships can make the needed investments in a sustainable way.

¹² Adapted from CISA's 2020 Regional Resilience Assessment Program, Methodology For Assessing Regional Infrastructure Resilience Lessons Learned

Figure 3, Three Elements of Resilience for the Public Health Supply Chain

Robustness	Agility	Visibility
<i>The U.S. Government is actively mitigating the risk and severity of potential supply chain shocks to prevent shortage and disruption</i>	<i>The U.S. Government is prepared to respond to shocks when they occur to limit shortage and disruption</i>	<i>The U.S. Government can monitor the supply chain against defined targets, foresee threats, and make data-informed decisions</i>
<ul style="list-style-type: none"> ● Manufacturing on-/near-shoring level ● Raw material and equipment on-/near-shoring level ● Manufacturer multi-sourcing ● Raw material and equipment supplier multi-sourcing ● Supply chain security 	<ul style="list-style-type: none"> ● Stockpiling status ● Warm Manufacturing capacity availability ● Product standardization and simplification ● Decision-making strength and readiness 	<ul style="list-style-type: none"> ● Existence of supply target(s) or targeted capabilities ● Manufacturer visibility ● Raw material and equipment visibility ● Scenario analytics capability ● Market awareness ● Private-sector engagement

Robustness

A major component of resilience is mitigating risk before a crisis happens. The U.S. and the private sector must actively reduce risk of disruption and shortage. Robustness involves geographic diversity of sources of critical items, raw materials, and equipment. Such diversity means access to reliable supply on- or near-shore, as well as strategic geographic variability domestically to mitigate risks of environmental or other location-based shocks. Robustness also involves supplier diversity. The U.S. and broader users of MCMs must take steps to add redundancy and multiplicity to their sourcing. Additionally, the manufacturers of MCMs can do the same for their own raw material and equipment sourcing. Such efforts help eliminate the potential for single sources of failure.

Agility

No matter the strength of a supply chain, crises do occur, so the supply chain must be able to react to limit the scale of disruption and prevent shortages. Tactically, agility for MCMs means that the supply chain has enough stockpiled materials and scalable, “warm” manufacturing capacity to bridge any production gaps in a crisis. Agility also means that the U.S. Government and certain private-sector actors can make smart, data-informed decisions that can move the supply chain where it needs to go to respond to a disruption. Finally, manufacturers and users of MCMs can also take steps to improve the interchangeability of supplies and components to enable greater flexibility in an emergency.

Visibility

To manage the supply chain, the U.S. Government must be able to see and understand it. Doing so allows the U.S. to make strategic decisions to shore up areas of risk and have confidence that certain targets or capabilities are met. For each type of public health supply such as medicines or PPE, true visibility requires a clearly defined target—whether a set quantity of items (e.g., how many N95 respirators must be available); or a scenario-based capability (e.g., the ability to produce enough two-dose vaccines within six months to inoculate against a novel viral threat). With a target set, the U.S. must then have adequate visibility into the supply chain of that item. Such visibility entails data regarding what existing and scalable manufacturing capacity exists for both finished products from manufacturers and inputs from suppliers. It also means close engagement with these companies to understand the latest trends in the market. Finally, visibility is enhanced by powerful analytical capabilities so that the U.S. and manufacturers can generate scenarios, quantify risks, and react accordingly. Diagnostic and testing devices play a unique and instrumental role in this element of resilience because a robust supply of tests is paramount in accurately assessing the state of an emerging and evolving biological threat. Early assurance of nationwide diagnostic capabilities can better inform an active response through analytical models that help to define target levels of needed MCMs.

The Path to Resilience



Problem Statement and Solutions to Employ

In summary, a resilient public health supply chain is central to any pandemic response. The U.S. public health supply chain remains vulnerable to significant disruption during widespread public health emergencies. The COVID-19 pandemic strained global supply chains and exposed critical vulnerabilities in the nation's ability to deliver effective health care in times of high demand.

Strong market forces and economic reality will naturally continue to drive the global supply model toward potentially non-resilient traits such as specialization, centralized manufacturing, and just-in-time efficiency. The U.S. can reshape some of these underlying market conditions that create vulnerabilities for the public health supply chain. Such actions include cultivating market dynamics that disfavor certain types of sourcing concentrations outside the United States. Some market forces, however, are inevitable, so the U.S. must also buttress the supply chain through adequate resiliency measures. Such measures include stockpiles and domestic surge manufacturing capacity.

Even before COVID-19, vulnerabilities existed in the public health supply chain; consistent potential points of failure include:

- ⇒ Just-in-time and lean practices without resilience mitigation;
- ⇒ Export and import disruptions impacting distribution and product delivery;
- ⇒ Lack of visibility into sub-tier suppliers, including raw material availability and labor conditions;
- ⇒ Rigid end user human behavior, including conservation of critical items; and
- ⇒ High cost of market entry, which can limit how many participants can respond.

The U.S. can employ a toolkit of actions to prevent, mitigate, and respond to these points of failure that includes:

- ⇒ Investment in the industrial base;
- ⇒ Procurement, including the setting of long-term requirements;

- ⇒ Trade policy, regulatory actions, and incentives;
- ⇒ Stockpiles and surge capacity;
- ⇒ Supply chain intelligence and analytics; and
- ⇒ Collaboration and engagement to ensure a more rapid and robust industry response.

This National Strategy for a Resilient Public Health Supply Chain comprises a vision that underpins a collection of goals, objectives, and recommendations. These components deploy the above toolkit to address the vulnerabilities exposed by COVID-19 as well as enduring potential points of failure.

Public Health Supply Chain Resilience Today



Medical Supply Chains are Complex Global Ecosystems

The medical supply chain ecosystem is complex. Market dynamics vary across categories of medical supplies and raw materials. The ecosystem includes private-sector companies, trade associations, governments and their regulatory authorities, and non-governmental organizations such as standards development organizations and conformity assessment bodies—many of which operate within the United States and internationally. Consequently, supply chains are subject to shifting geopolitical forces and nation-state decision-making that impact production and distribution.

For many critical medical supplies, suppliers compete based on low costs and economies of scale—resulting in overseas production and foreign dependence for both raw materials and inputs (e.g., resins, fibers, and active pharmaceutical ingredients), and finished goods (e.g., PPE and drugs). This focus on costs and scale has resulted in consolidation and lack of diversification across the supply chain—in some cases only a few suppliers exist globally for a finished good or component part. (For instance, prior to the COVID-19 pandemic, over 90 percent of medical gloves and their inputs were made in Asia by a small number of manufacturers.) These supply chains also have ethical hazards; for example, some have faced reports of forced labor and other exploitative labor practices associated with the production of goods.

During COVID-19, the Role of the U.S. Government in the U.S.

Medical Supply Chain Evolved Significantly

Prior to COVID-19: As mentioned, public health supply chains have been shaped by a focus on low costs, economies of scale, and efficiency that resulted in just-in-time practices and a high dependency on foreign sources of supply, leaving our supply chains vulnerable to disruption. In the years before COVID-19, these critical supply chains have

been subject to varied levels of monitoring, which is sometimes limited. For instance, while the Food and Drug Administration (FDA) has actively tracked and managed shortages of drugs, some supplies such as PPE and critical raw materials and inputs have historically had little ongoing supply chain monitoring from the U.S. Government.

Early to Peak COVID-19: At the beginning of the COVID-19 pandemic, public health supply chains faced severe disruption by lockdowns and demand spikes driven by real clinical needs and widespread stockpiling. The United States responded by distributing supplies from the SNS, replenishing those supplies, investing in domestic manufacturing capacity, and improving supply chain visibility and monitoring. Even with those actions, our supply chains remained vulnerable. For some supplies, such as N95 respirators, the U.S. did not have enough of a domestic manufacturing capacity to alleviate shortage. Other supplies struggled to scale rapidly to meet demand; for example, the testing and diagnostics supply chain was unable to ramp up production in the early months of the pandemic, in part because of the costs and risks associated with ramping production and assay development—as a result, the U.S. experienced long delays before the commercial production of test kits. These delays led to the underestimation of case counts and accurate modeling and analytics on the early state of the COVID-19 pandemic.

Currently: Today, both demand and supply are stabilizing, in part due to a marked decrease in acute demand for PPE—however, vulnerability remains. Fortunately, the SNS, SLTT partners, and hospital systems have built up significant inventories, and industry partners are reporting that demand for PPE and other supplies has dropped significantly from COVID-19’s peak. Supply for certain items, such as N95s and diagnostic test kits, has increased significantly as domestic manufacturing has come online; however, other items, including vaccine production materials, face a continuing increase in demand that outstrips regular annual supply by many orders of magnitude. The focus now is on active monitoring and management of key supply chains to mitigate the impact of new COVID-19 variants and any potential resurgence in cases—as well as support the ongoing vaccination campaign and the global community. The U.S. Government is also focused on long-term sustainment of industrial base expansion (IBx) investments, and preparation for future public health emergencies.

COVID-19 Illuminated Vulnerability and Opportunity

In 2020, the national response to the COVID-19 outbreak surfaced a set of complex and novel factors related to preparedness and response resilience. COVID-19 was the first time all States, territories, and the District of Columbia made major disaster declarations under the Stafford Act at the same time—presenting challenges not faced before.

Vulnerabilities were evident across all three areas of supply chain resilience. The supply chain did not have the robustness it needed. Earlier efforts to improve supply chain diversity could have been spearheaded by integrated public–private partnerships across all levels of government and different components of health care and other industries. Agility could have been improved through stronger partnership with the global community to evaluate signals to rapidly scale-up production of consumables and other critical inputs in manufacturing vaccines and therapeutics without hindering the production of other lifesaving medicines and vaccines. Supply chain visibility was degraded without a common operating picture or engagement among supply chain actors. A single source of information for both government-produced and external data could have allowed for a more unified response. Multiple perspectives and coordination are essential to making the most effective and impactful solutions, while recognizing that in the moment, no perfect solutions exist.

Effects of the pandemic on public- and private-sector organizations included shortages in personnel needed to maintain operations, occurring due to illnesses, social distancing policies, transportation system constraints, lack of well-defined workplace protections, concerns for personal safety, as well as limited supplies of PPE. Additionally, the restricted operations or closure of ancillary supporting businesses, such as food services, laundry, and childcare, impacted those responding to the pandemic. All the while, global supply chains that underpin delivery of essential services experienced disruption, and key commodities and infrastructure systems saw unexpected surges in supply and demand patterns.

The disease progression and the public health response to it affected the system’s function and created interdependencies that differed from historical experiences. First, the actual effects experienced by critical systems generally were not related to physical damage to the infrastructure itself. In events such as hurricanes, earthquakes, and floods, the physical hardware is often damaged or destroyed, degrading operations, and putting a

premium on rapid repair and restoration. The challenges experienced during the COVID-19 response were rooted more in personnel availability and supply–demand disconnects that have endured. Second, the geographic scope of the disruptive effects was significantly larger than a typical disaster—this disaster was experienced globally—thus relief from other regions was less available. Third, because of the previous two factors, COVID-19 affected communities that were responding and yet were impacted by the events in a global context, which created unique and complex dynamics among systems and partners.

These challenges and observations have played an integral role in the development of this reflective yet forward-looking strategy. Additional themes and observations are detailed in Appendix II: Challenges and Opportunities from COVID-19 Response.

Our Vision, Values, and Goals for Public Health Supply Chain Resilience



The U.S. Government’s vision is to protect the health and security of Americans by maintaining a public health supply chain that is consistent with our values and resilient against disruptions from pandemics and other biological threats.

The U.S. Government should partner with the private sector and international partners and allies to sustain deep visibility up and down the supply chain, forge sustainable robustness against risk, and cultivate agility to respond to inevitable biological events. Such a supply chain will help ensure Americans have adequate access to MCMs needed for rapid response to pandemics or other biological events, so as to mitigate the negative impacts of those events. The U.S. Government must protect this supply chain as a national security asset.

The U.S.’s public health supply chain should also imbue certain values. It should be ethical, equitable, and environmentally sustainable. These values entail promoting strong environmental and labor standards and having processes in place to identify and mitigate sourcing risks such as child labor, forced labor, and human trafficking; environmental damage; and corruption and fraud. They also require processes to ensure that the most vulnerable Americans have access to the supplies they need. These values also include a supply chain that is innovative and constructive. It should empower the creative and scientific innovation of American research and the industrial base, and it should create jobs and prosperity for Americans.

TO ACHIEVE THIS VISION AND THESE VALUES, THIS STRATEGY SETS THREE GOALS. THE U.S. SHOULD:

Goal 1: Build a diverse, agile public health supply chain and sustain long-term U.S.

Goal 2: Transform the U.S. Government’s ability to monitor and manage the public health supply chain through stockpiles, visibility, and engagement; and

Goal 3: Establish standards, systems, and governance to manage the supply chain and ensure fair, equitable, and effective allocation of scarce resources.

Objectives with accompanying actions and milestones underpin these goals. A new public health supply chain governance body should lead U.S. Government execution and external engagement to achieve these goals.

GOAL 1

Build a diverse, agile public health supply chain and sustain long-term U.S. manufacturing capability for future pandemics

Changing our approach to purchasing and producing needed products will improve our capabilities against future threats.

Global supply chains are optimized for moving goods at the lowest price during stable economic conditions. The logistics networks and the processes necessary to bring these products to the U.S. market are not always easy to scale rapidly. Pharmaceuticals, medical devices, and their components often come from international origins, are assembled in diverse locations, and are funneled into a large network of health care distributors. These stakeholders include third-party delivery providers that transport the product to the facility, and then coordinate the ordering and distribution of products into the health care system. During periods of sustained surges, these vulnerable systems become stressed as critical inputs become increasingly unavailable. New approaches are needed to build diversity and flexibility into the public health supply chain to ensure health security during future pandemics.

The U.S. Government should increase resilience by investing in domestic manufacturing capabilities and capacity that add greater flexibility and ability to respond rapidly to a public health emergency like a pandemic. Developing an appropriate level of enhanced domestic capacity available to the U.S. Government requires significant, sustained, and flexible sources of funding. During the COVID-19 response, the U.S. Government recognized the need to expand industrial base capacity for increased production of critical medical supplies. The resulting IBx strengthened the PHIB and delivered innovative solutions to respond to 21st-century health threats. These efforts are the first steps toward increased domestic production through incentivizing domestic manufacturing, improving situational awareness, building innovative partnerships, and transforming the workforce.

To meet future needs, a sustained approach to strengthening the PHIB should start with expansion of domestic manufacturing, but must also consider human capital and training requirements, including the technical expertise needed in advanced manufacturing with a foundation on science, technology, engineering, and math education. This approach must also consider ongoing innovations in advanced manufacturing that may increase domestic manufacturing competitiveness. The U.S. Government must also consider geography and product diversity in a successful portfolio mix of value and priority to support national pandemic response. Finally, expanding partnerships across the industrial base is essential to ensuring broad participation in PHE preparedness.

Sourcing critical materials from just one location or supplier increases supply chain vulnerability should that supplier be impacted by an unforeseen emergency. Diversifying supply chain sources according to geographic location and supplier type builds redundancy into the system that reduces the risk of single points of failure. Additionally, innovation is critical to adding variation among the product types in the MCM armamentarium and our future response options. Key to this approach are the expansion and reinvigoration of domestic manufacturing of key materials.

Objective 1.1: Build and sustain a strong domestic industrial base for MCMs that is complemented by strategic near- and allied-shoring.

One of the most essential components of robustness is the existence of a strong domestic industrial base for public health supplies—helping ensure the U.S. has the supplies it needs when it needs them. The U.S. Government must grow and sustain this industrial base. The U.S. can also build resilience through strategic partnerships with neighbors and allies who

also produce public health supplies. Such cooperation can enhance resiliency and foster collective economic and national security. Ensuring that necessary supplies are available to U.S. and international partners and allies in a timely fashion will strengthen the capacity to respond to disasters and emergencies.

Sub-objectives:

1. Build, maintain, and sustain domestic public health industrial base capacity for essential raw materials and finished MCMs through coordinated federal procurement and interagency investment.
2. Sustain reliable domestic manufacturing capacity over the long term by fostering “Buy American” practices among government and non-government consumers of critical MCMs and medical devices.
3. Leverage strategic international partnerships with neighbors and allies to expand public health industrial base capacity and to ensure shared access to needed supplies in public health emergencies.
4. Review U.S. free trade agreements (FTA) to consider possible revisions that support U.S. supply chain capacity and resiliency.

Objective 1.2: Safeguard supply chain diversity through policy, incentive, regulation, and other tools to reduce dependence on a single region, source, or product.

The U.S. Government is committed to supply chain diversity as a risk management strategy to broaden the base of suppliers for critical medical goods. Using a variety of tools such as regulatory policies and tax incentives, the U.S. Government should seek to make domestic manufacturing more attractive.

Sub-objectives:

1. Incentivize the sourcing diversity of finished goods and components using targeted production subsidies, tax incentives, strategic federal procurement, and, when appropriate, the trade tools available to the U.S. Trade Representative and the Department of Commerce.
2. Create requirements for how critical MCMs are made with respect to limiting externalities associated with foreign production and processing methods.
3. Emphasize public health supply chain needs through negotiation and application of specific provisions in trade agreements, including the manufacturing of MCMs that

would incentivize building supply chain nodes.

4. Support innovation and corporate diversity through policy, incentive, and focused federal procurement designed to support small and medium enterprises.
5. Use regulatory authority to embed supplier diversity requirements into private-sector procurement, particularly in the health care sector.

Objective 1.3: Reinforce supply chain agility to ensure that supply chain partners can better respond to supply chain disruptions and increased demand.

Resilient systems can adapt to unforeseen challenges and, in so doing, enable a proactive response. The U.S. Government should help maintain warm-based manufacturing capacity that can ensure rapid response to a public health emergency. In a pandemic, this capability means the U.S. Government can trigger production or procurement at the start of an outbreak. Agility can also be realized through improved product design and advanced manufacturing processes that emphasize interchangeability, flexibility, and rapid scalability.

Sub-objectives:

1. Enable rapid scaling at the start of a public health emergency by encouraging flexible manufacturing that can alternate between products and scale rapidly, including the use of warm- and cool-base sites—as appropriate to the product type.
2. Engage with manufacturers and consumers to increase product standardization and interchangeability.
3. Support efficient manufacturing practices related to product design, such as the use of modular or “bolt-on” components (i.e., uniform but with multiple separate aspects of functionality).
4. Develop mechanisms to allow suppliers of a product to coordinate to fill contracts during times of acute shortage.
5. Promote advanced manufacturing approaches that enable quick transition between products, such as rapid-response platform technologies.
6. Promote business models that support sustainability, flexibility, and resilience in the domestic industrial base and supply chain.

Objective 1.4: Achieve ethical, sustainable sourcing that includes high standards on labor and environment, while combatting unfair trade.

HHS should continue to work with the interagency and international organizations to create resiliency for medical device supply chains to promote coordination that will help ensure a resilient medical device supply chain. Partnering should focus on improving standards for fair and ethical production and trade of MCMs, including labor and environmental standards.

Sub-objectives:

1. In collaboration with trusted international partners, work to promote adoption and enforcement of ethical production and trade standards to mitigate risks caused by forced labor, counterfeits, and deficient product quality in the public health supply chain.
2. Ensure equitable labor conditions by promoting best practices and U.S. adherence to child labor and forced labor laws and regulations in supply chains.
3. Use U.S. trade remedy laws to address dumping and the unfair use of government subsidies, especially in regard to non-market economies.
4. For low-margin products with higher labor costs, position the U.S. to out-compete competition economies through investments in automation and increased manufacturing efficiencies.
5. Promote environmentally sustainable manufacturing practices to limit environmental impacts to the planet and communities located near manufacturing facilities.

Objective 1.5: Build robustness into the supply chain at the SLTT level through partnership, policy, procurement, and regulation.

Increasing emergency preparedness across the system includes working with SLTT partners to improve their preparedness for a future PHE. The U.S. Government should work with SLTT authorities to incentivize increased stockpiling and preparedness for local governments, NGOs, and businesses.

Sub-objectives:

1. Incentivize emergency essential businesses' use of federal purchasing vehicles to support individual business pandemic preparedness and SLTT risk mitigation.
2. Work with SLTT governments to incentivize local domestic manufacturing capacity.
3. Revise regulatory and reimbursement practices to promote the cost-efficient maintenance of inventories at multiple points in the supply chain.

4. Create SLTT-level supply buffer through regulatory changes that require emergency essential businesses to maintain a specified level of pandemic preparedness.
5. Create SLTT-level supply buffer through regulatory changes that limit participation of health care system components (e.g., hospitals, hospital systems, skilled nursing facilities) in federal programs without first proving pandemic preparedness.

Objective 1.6: Create good jobs through the public health supply chain and invest in skills development so that we have the talent needed to invent and make critical supplies.

At the core of manufacturing is the workforce that facilities employ, and with those jobs come the potential for new innovations and increased productivity. By attracting, training, and retaining skilled workers, the U.S. Government can establish the foundation for renewed competitiveness in the bioeconomy.

Sub-objectives:

1. Ensure that skilled workers are available to work in the supply chain through investment in training and skills development.
2. Incentivize skilled workforce recruiting and retention for domestic manufacturers.
3. Coordinate hubs of production based on quality of life, locating production in areas that have low cost of living and desirable conditions.
4. Pursue immigration policies that promote domestic manufacturing of critical health care products through targeting skilled foreign service providers and instructors.
5. Maintain sufficient U.S. Government public health supply chain talent by advancing workforce models that attract and retain talent in biopharmaceutical industry operations and practice; acquisitions and contracting staff; biotechnology development and deployment; and logistics, operations, and sustainment.

GOAL 2

Transform the U.S. Government’s ability to monitor and manage the public health supply chain through stockpiles, visibility, and engagement.

Improving the U.S. Government’s approach to stockpiles, supply chain intelligence, and engagement with supply chain stakeholders will enhance its ability to manage risk in the public health supply chain.

The scope of medical product stockpiling to prepare for future public health emergencies varies significantly across jurisdictions and facilities in the types, quantities, and distribution of products stockpiled. Historically, the SNS’s role has been to supplement SLTT supplies during public health emergencies by providing products as a short-term stopgap “buffer” when the material supply may not be immediately available, or by providing unique MCMs for which no commercial market exists. HHS should continue to replenish and expand the SNS, while engaging key partners and stakeholders to meet supply needs. The SNS should also expand to address identified gaps and other inefficiencies in medical and public health preparedness and response activities.¹³

HHS coordinates federal capabilities with SLTT public health officials, health care systems, and emergency medical service systems to ensure effective integration of federal public health and medical assets during a PHE.¹⁴ Coordination with SLTT partners on prioritization and allocation helps the U.S. Government identify the CI assets, systems, and networks needed for the proper functioning of the HPH sector that must be maintained through an emergency or disaster. These include entities capable of assisting with, responding to, and mitigating PHE effects. As an example of this coordination, in partnerships with the Department of Defense (DoD) and through Biomedical Advanced Research and Development Authority (BARDA) and HHS’s IBx activities, the U.S. Government is bolstering the domestic capacity for producing critical pharmaceuticals and medical supplies—reducing America’s vulnerabilities stemming from reliance on overseas suppliers and manufacturers.

By transforming our approach to supply chain risk management, the U.S. Government can expand access to needed MCMs and to information regarding the status of those products’ delivery, and partner with private-sector providers central to the supply chain. Achieving this goal requires changing the way U.S. Government thinks about:

- **Stockpiles:** Ensuring that stockpiles can meet critical supply needs during disruptions to prevent shortages by enhancing supply acquisition, production, distribution, and dispensing;
- **Visibility:** Improving the U.S. Government’s ability to monitor and manage the supply chain by understanding status, and increasing situational awareness across the supply chain ecosystem; and,

¹³ 42 U.S. Code § 300hh-10 (b)(4)(E)

¹⁴ 42 U.S. Code § 300hh-10 (b)(4)(B)

- **Engagement:** Improving coordination and engagement in our approach to manufacturing and distribution, with an emphasis on collaboration using public-private partnerships (PPPs) with respect to planning, manufacturing, distribution, and allocation.

Supply chain intelligence and a robust information consolidation system are needed to assure visibility of these different inventories, to anticipate shortages, and to provide the opportunity to prevent or mitigate supply chain disruptions. Although the SNS can replenish stocks in advance of another PHE, future demand events occur with little warning.

Objective 2.1: Maintain the visibility and analytics needed to anticipate, prevent, mitigate, and respond to supply chain shortages and disruptions.

The U.S. Government must prepare and deploy information technology assets and capabilities that enable improved situational awareness of the public health supply chain. These tools should extend to private-sector and SLTT partners, allowing for a more streamlined process for sharing data with the U.S. Government. Such tools must include appropriate information sharing and cybersecurity protections for business-sensitive or proprietary data.

Sub-objectives:

1. Establish deep U.S. Government visibility into the medical supply chain through end-to-end supply chain data access—to include U.S. Government supply chain data—in a centralized HHS-managed technology platform that can be tied to epidemiological data.
2. Maintain constant awareness of supply chain status, risks, and trends by maintaining the tools and talent needed to conduct and commission research, data analytics, predictive modeling, demand modeling, mitigation strategies, and forecasting.
3. Develop the analytical capabilities to conduct risk assessments on the health of the supply chain that assess current levels of stockpiling and warm and hot manufacturing capacity relative to supply targets.
4. Develop situational awareness of external threats to the medical supply chain, including naturally occurring, man-made, and cyber events.
5. Obtain and sustain supply chain visibility to the raw material level by requiring a

manufacturing bill of materials report to obtain and retain MCM licensure, approval, and clearance.

6. Invest in mechanisms to encourage increased supply chain visibility and data sharing, thus supporting and incentivizing private-sector participation.

Objective 2.2: Enhance supply chain transparency and coordination with and among private-sector partners on supply chain status.

HHS has a variety of responsibilities to incentivize flexible, nimble, and stable PPPs in stated strategy and policies. Partnering and engaging with industry remains “a cornerstone of our MCM approach.”¹⁵

Sub-objectives:

1. Engage manufacturers, labor management partnerships, health care associations, and other private-sector entities on supply chain challenges, vulnerabilities, and risks.
2. Establish a PPP to guide input, development timelines, and product portfolios for MCMs.
3. Conduct combined exercises and planning efforts among public- and private-sector entities to prepare for PHEs.
4. Partner with distributors and purchasers to establish reciprocal sharing agreements.
5. Use market research and engagement to collect information on trends and capabilities to improve operational understanding, resource management, and alignment of effort with industry before, during, and after PHEs.

Objective 2.3: Enhance supply chain transparency and coordination with and among SLTT partners on the status of supply chain and stockpile levels.

Emergency management principles often posit that disaster response is best when locally executed, State-managed, and federally supported. Information regarding supply availability is critical to this process. To that end, SLTT partners need an improved ability to see the supplies available to them, to coordinate on distribution and dispensing, and to offer assistance to other impacted regions through information systems that facilitate sharing of critical supplies.

¹⁵ NHSS 2019–2022

Sub-objectives:

1. Engage public-sector partners on supply chain challenges, vulnerabilities, and risks.
2. Develop analytics and predictive modeling tools tailored to support the needs of SLTT partners, emergency essential business, and health care system components.
3. Develop mechanisms to coordinate supply chain distribution activities both vertically and laterally to ensure greater coordination across sectors and between federal and SLTT caches to inform distribution and ensure equitable access to resource limited areas.
4. Obtain visibility into SLTT-level supply chain buffer by incentivizing health care system components (e.g., hospitals, hospital systems, skilled nursing facilities) and emergency essential businesses with regulatory changes to require reporting of essential data.

Objective 2.4: Optimize the shelf-life, distribution, and allocation of stockpiled supplies through targeted stockpiling approaches.

Federal stockpiling should shift to better align with industry best practices related to procuring, storing, and dispensing MCMs. This shift would include product rotation to HPH-sector partners and end users, as well as the use of virtual stockpiles and pre-staged distribution centers.

Sub-objectives:

1. Ensure the portfolio of the SNS evolves to include the raw materials, inputs, and supplies needed to counter pandemics and other biological threats.
2. Expand the use of vendor-managed inventory, virtual stockpiles, and other methods to pre-stage supplies when beneficial to do so.
3. Develop new approaches to rotate SNS products with a commercial market or humanitarian need, when feasible, into regular use with partners before their expiration.

GOAL 3**Establish standards, systems, and governance to manage the supply chain and ensure fair, equitable, and effective allocation of scarce resources.**

Transformed governance can position the U.S. Government to build and sustain resilience in the public health supply chain, and to improve supply chain coordination with SLTT and global stakeholders.

Building, maintaining, and managing a resilient public health supply chain requires coordinated leadership and governance. The U.S. Government should develop a new framework and leverage the existing governing bodies through the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) to focus on these activities. The PHEMCE should expand to focus on guiding and integrating a whole-of-government approach on scarce resource planning domestically and globally for all pandemic preparedness. The PHEMCE should develop a transformative overarching business framework and strategy, with a focus on building long-term, end-to-end capabilities that ensure future readiness of the nation's public health supply chain while prioritizing diverse manufacturing and logistics strategies. This work includes advising on building public health readiness; enhancing engagement with pharmaceutical and biotechnology industries to develop and ensure emergency access to novel MCMs; developing requirements and acquisition processes that ensure new MCMs will meet the needs of the American public (especially those on the front lines in public health and the medical community); and prioritizing a comprehensive approach that maximizes fiscal responsibility through cost-effective strategies by implementing a "planning, programming, budget, evaluation" life-cycle framework that harmonizes PHEMCE partner missions focused on MCM preparedness.

The PHEMCE includes representation of senior leadership from across the federal government including HHS, DoD, the Department of Homeland Security (DHS), and the Department of Veterans Affairs (VA). The PHEMCE is expanding its partnerships to include SLTT jurisdictions, industry, academia, professional societies, and associations—as well as the American public and international collaborators. The PHEMCE should coordinate with relevant stakeholder groups to build and strengthen communication, identify and close gaps, and build collaborative solutions that more efficiently leverage

Government resources and stabilize private-sector investment. With these stakeholders, the PHEMCE can expand its solution-set to build a resilient supply chain that is strategically postured for response to current and future PHEs.

Objective 3.1: Establish transformative business practices that ensure long-term end-to-end MCM readiness.

To accomplish the PHEMCE and HHS mission for MCM readiness, the U.S. Government should implement business practices that encourage and incentivize private-sector engagement, thereby promoting a more durable, sustainable, and robust MCM enterprise from end to end. The PHEMCE should build partnerships among federal, SLTT, and international MCM stakeholders to ensure close and transparent collaboration as the PHEMCE expands its scope to include industrial base and commercial supply chain solutions as part of MCM preparedness. Moreover, the PHEMCE should refine reporting requirements that ensure Congress remains informed and educated about the state of MCM preparedness. These reporting requirements, supplemented by budgetary analysis, will help lay the foundation for justifying and obtaining necessary resourcing. The PHEMCE should make recommendations to the Secretary of HHS regarding budget strategies and mechanisms to advance MCM preparedness in a fiscally responsible manner, industrial base expansion, commercial supply chain and inventory solutions, and the SNS. More effective business practices will ensure the PHEMCE and its federal partners present complementary budget proposals that best articulate funding requirements and implementation of MCM capabilities to protect America’s public health and national security.

Sub-objectives:

1. Implement a “planning, policy, budget, evaluation” framework that harmonizes MCM preparedness missions and investments across the enterprise to ensure sustainable MCM readiness.
2. Establish budget and funding strategies and implement cost-effective, sustainable solutions that ensure the U.S. Government is a predictable and reliable long-term partner for the MCM industrial base.
3. Strengthen relationships among MCM stakeholders within and beyond the U.S. Government, and improve communication of MCM preparedness activities, requirements, and analysis to Congress.

Objective 3.2: Improve coordination across relevant stakeholders and incorporate new tools and technologies into public health preparedness, response, and recovery operations.

Improved information sharing across various stakeholders within the public- and private-sector entities (including the federal interagency, SLTT, NGOs, industry, academia, and research communities) is central to pandemic preparedness and response. The U.S. Government should invest in new mechanisms (and reinvigorate existing ones) for coordination and sharing of information—including best practices and technologies for improved supply chain operations.

Sub-objectives:

1. Develop an integrated approach and communications mechanism for coordinating, tracking, and sharing public health supply chain information among federal departments and agencies.
2. Develop and periodically exercise logistics support and operational plans and procedures for optimized acquisition and use of MCMs and PPE during response.
3. Facilitate testing of new technologies or novel supply chain solutions with key stakeholders and interagency partners.

Objective 3.3: Leverage data-informed decision-making to guide domestic pharmaceutical and medical supply chain and infrastructure requirements.

The U.S. Government should establish and invest in information technology resources to improve decision-making regarding the public health supply chain. An assessment of the providers of raw materials, manufacturers, and end users allows for a “stress test” of the system. Such a transparent assessment of sector performance, capacity, and needs—created in partnership with the HPH Sector Risk Management Agency (SRMA)—is essential to improving planning and exercises.

Sub-objectives:

1. Continuously maintain data-informed industry requirements for all critical public health supply chain items and their critical raw materials and equipment.
2. Perform regular quantitative and qualitative assessments of supply chain resilience for all critical public health supplies.
3. Use insights from supply chain assessments to determine actions and investments

to improve the domestic and global supply chains as well as identify areas that are at risk of collapse due to economic recession, global competitiveness, conflict, and other disruptive events.

Objective 3.4: Position the federal government to respond quickly and equitably to emergency public health supply chain needs of SLTT authorities through strengthened governance, planning, and preparedness.

Responding to emergency supply needs of SLTT partners involves proactive, well-established, and coordinated lines of effort to better assess, prioritize, and respond to SLTT requests for assistance. Anticipating—rather than reacting to—supply chain shortages improves overall readiness and response to PHEs. The U.S. Government should improve governance, planning, and preparedness to prioritize requests in a way that balances ethics and needs-based concerns to ensure equitable and targeted distribution of critical supplies to all affected populations.

Sub-objectives:

1. Maintain the two-way communications and engagements with SLTT authorities to ensure efficient communication outward and escalation of regional issues upward.
2. Develop, test, and maintain equitable processes and approaches for emergency allocation of MCMs to SLTT authorities.
3. Maintain the technical and analytical tools and capabilities needed to operationalize emergency allocation.
4. Hone the preparedness of the U.S. Government to respond during PHEs through rigorous exercises, talent development, and continual workforce training.
5. Provide developmental support to SLTT authorities to improve their public health supply chain resilience capabilities and foster continuous planning and preparedness.
6. Enable and incentivize SLTT partnership development agreements to enable cross-leveling of supplies among SLTT authorities to address local and regional supply shortages.

Resilience Recommendations



Table 1. Recommendations on how the U.S. Government can support a resilient public health supply chain

Robustness and Industry Sustainment	Agility and Innovation	Visibility and Engagement	Governance and Management
<ul style="list-style-type: none"> ● Bold Investments and incentives for the American industrial base: <ul style="list-style-type: none"> ★ Significant investments to sustain the U.S. public health industrial base ★ Buy American and Berry Amendment rules expansion to all agencies and grantees ★ Support for American-made supplies in the U.S. health care sector ★ Use of trade tools to counter unfair trade practices and strengthen the public health industrial base needed for national security ★ A supply chain workforce with the people and skills needed for pandemic preparedness 	<ul style="list-style-type: none"> ● A more capable and robust Strategic National Stockpile and expanded SLTT stockpiling ● Preemptive supply chain demand management capabilities to modulate demand before shortages occur ● A new public health supplies innovation center and product standardization task force 	<ul style="list-style-type: none"> ● End-to-end supply chain visibility through expanded and continuous supply chain surveillance ● Streamlined U.S. Government-private sector coordinating body for sustained public health supply chain private-sector engagement ● An annual resilience “report card” 	<ul style="list-style-type: none"> ● Interagency oversight of the public health supply chain and a strong U.S. Government public health supply chain workforce ● Revisions to EO 13603 on “National Defense Resources Preparedness” ● National framework for allocation of constrained resources ● Revamped global governance of the public health supply chain

Robustness and Industry Sustainment

1. Drive bold investments and incentives for the American industrial base

⇒ **Make significant investments** to sustain the U.S. public health industrial base

The U.S. Government faces an opportunity to build on the past year’s reinvigoration of the U.S. public health industrial base—recognizing the public health industrial base as a sector requiring dedicated U.S. Government management, oversight, and sustainment as a national strategic imperative. This sustainment requires investment and responsibility at HHS under the Assistant Secretary for Preparedness and Response (ASPR) to build

out the workforce, authorities, industrial relationships, and programmatic plans requisite to ensure resilience and expand the industrial base. Investments from several sources have helped build parts of the industrial base over the past year. Over the next ten years, however, the U.S. needs to make additional significant investments in industrial base expansion and sustainment. The American Rescue Plan (ARP) has provided some funding, and additional funding has been requested through the American Jobs Plan (AJP). Additional resources will be considered as part of the President’s Budget. This funding would help sustain the public health industrial base so the U.S. remains prepared for future pandemics. A wide range of supplies and raw materials are relevant, from meltblown and resins and nitrile rubber to vials and bioreactor bags.

This funding would support extended long-term contracts, on-hand inventory, vendor-managed inventory, and other actions, many of which would be managed through an expanded SNS. These investments would help ensure sufficient manufacturing capacity such that the U.S. Government could trigger procurement or production at the start of a public health emergency. HHS should leverage PPP and conduct analyses to determine the appropriate financial incentives—including the use of Defense Production Act (DPA) authorities for industrial base expansion—needed to onshore or nearshore the production capacity of critical parts, raw materials, and final product.

⇒ **Expand Buy American¹⁶ and Berry Amendment¹⁷ rules** to all agencies and grantees

While business incentives are important for spurring greater investment into the growth of American industrial workforce skills and the medical industrial base, critical public health manufacturing also needs a stronger demand signal from the U.S. Government. As the U.S. replenishes stockpiles and acquires material needed for ongoing operations and future responses, investment with public funds should recognize the national security implications for the long-term resilience of those supply chains. To do so, the U.S. should expand several actions to incorporate critical public health supplies—namely, expanding the application of the Buy American Act, extending Berry Amendment–style rules (including for “wholly made” American goods), and applying the intent of EO 14005, “Ensuring the Future Is Made in All of America by All of America’s Workers.” These rules

¹⁶ 41 U.S. Code § 8301–8305

¹⁷ 10 U.S. Code § 2533a

and requirements should apply to procurement of critical public health supplies across the U.S. Government—as well as procurement by grantees using funds provided by federal grants and cooperative agreements for such purpose. Long-term requirements planning, combined with a thoughtful waiver process consistent with EO 14005, can help ensure these requirements are supportive of missions requiring urgent deployment of public health supplies. As a result, these changes would ensure that U.S. Government–supported purchases of public health supplies contribute to the resilience of the supply chains for those items.

- ⇒ **Support the use of American-made public health supplies** in the U.S. health care sector

Federal government procurement is only one small piece of the U.S. market for public health supplies. Sustaining a strong domestic industrial base requires the U.S. health care sector to buy more American products as well. A reliable domestic industrial base is critical for patient and health care worker outcomes during supply disruptions—pandemic or otherwise. Health care providers, however, may face challenges purchasing domestic supplies due to higher cost or unavailability. To help, HHS, including the Centers for Medicare & Medicaid Services, should explore strategies to strengthen the domestic supply chain, stimulate resiliency, and safeguard patient and worker access in times of crisis. Whether through education, outreach, or other mechanisms within its authority, HHS can encourage hospitals, nursing homes, community health centers, and other providers to procure domestically made PPE and other public health supplies as part of a broader quality and risk mitigation strategy. By supporting American manufacturers in times of calm, health care providers can have more assurance they can turn to American manufacturers in the next crisis.

- ⇒ **Use trade tools** to counter unfair trade practices and strengthen the public health industrial base needed for national security

The distortive effects that non-market economies have on global trade—as well as the impact of vastly different regulatory requirements for intellectual property, labor, environmental, and consumer protection—require the United States to deploy targeted trade policies to protect critical supply chains. Public health supply chain resilience should be incorporated into U.S. trade policy, including in the ongoing review of U.S.–China trade policy. The U.S. Government should identify and address unfair foreign trade practices

that have eroded U.S. supply chains needed for pandemic resilience, and it should consider the use of all available tools to address the impact of imports that could pose risks to the health security of Americans. Trade policy action needs to be complemented by targeted investments and other incentives that support domestic production of critical supplies.

- ⇒ **Sustain a supply chain workforce** with the people and skills needed for pandemic preparedness

The U.S. Government must bolster the public health supply chain workforce and implement new training and preparedness processes to include exercises. The U.S. Government should conduct capabilities-based assessments to outline the necessary skills and training for the next generation of American researchers, engineers, and users who will work in science, technology, engineering, arts, and mathematics (STEAM). The U.S. Government should establish apprenticeships, skills programs, and education programs to ensure that American workers, including federal employees, gain expertise in these technical fields and facilitate pursuits in legal, policy, business, and trade areas to take full advantage of public health supply chain–related opportunities. Such training helps provide the knowledge, resources, standards, reporting, and quality management necessary for execution and oversight of public health supply chain resilience efforts.

Agility and Innovation

- 2. Build a more capable and robust Strategic National Stockpile** and expand SLTT stockpiling

The U.S. Government is committed to building a more capable and robust SNS prepared to respond to intentional, natural, and emerging pandemic threats. To meet this objective, ASPR must ensure that any SNS expansion is reviewed and validated through the PHEMCE. The validated requirements ensure that the SNS constitutes the adequate and essential commodities and materials to respond to the full range of public health threats including pandemics; chemical, biological, radiological, nuclear, and high-yield explosives (CBRNE) threats; and natural disasters. The PHEMCE should focus on enterprise-wide harmonization of priorities and budgeting focused on life-cycle and sustainment of MCM preparedness posture. This objective means focusing on not only the SNS's mission, but also all aspects of domestic preparedness, including industrial base and supply

chain solutions. Constituting a more capable MCM enterprise will require increased and sustainable funding, authorities, and partnerships, to leverage all available solutions, including those outside the SNS, needed to ensure that the U.S. Government is ready to respond to future public health emergencies. Such resources and tools include centralized, SLTT-managed, and vendor-managed inventory stockpiling. To identify priorities for capability development to meet future public health demands, the PHEMCE should lead an assessment of COVID-19 SNS-specific lessons learned and combine those insights with the latest supply chain data.

The U.S. Government should also promote the expansion of SLTT stockpiling. This work should include development of new stockpiling standards and processes for the private sector and SLTT partners, as well as an increase in their capacity for warehousing and distribution. Such expansion would require examining and expanding funding opportunities for SLTT stockpiling activities. The U.S. Government should also sustain and enhance planning, training, exercise, and evaluation activities to support SLTT stockpiling efforts—as well as improve SLTT access and utilization of SNS supplies.

3. Develop preemptive supply chain demand management capabilities to modulate demand before shortages occur

The U.S. Government has several opportunities to improve supply chain data and visibility to prevent critical supply shortages before they occur, ensuring that supplies are available when and where they are needed during a pandemic. Demand management is a planning methodology used to forecast and manage the demand for products and services. This methodology includes creating a common operating picture of key supplies in the public health supply chain; increasing visibility in supply distribution systems; working with SLTT and federal entities to account for various approaches to utilization; expanding the ability to view, model, and account for inputs across the entire supply chain; and working with stakeholders on the ground to understand best practices and utilization rates in the field.

These activities, along with a centralized system, would allow for hospitals and other consumers to better manage inventories of critical supplies; advise federal and SLTT resource allocation and planning; and inform manufacturing needs. Through analysis of trigger points in the supply chain created by fluctuations in demand, the U.S. Government would be able to provide guidance to end users to alter behaviors in order to conserve items in high demand to be used in other geographic areas. In addition, in order to gain a

greater visibility into demand during the pandemic, the U.S. Government should work with manufacturers, group purchasing organizations, health care delivery organizations, labor organizations, and other stakeholders to model demand. The U.S. Government should work to create models that are capable of predicting demand for MCMs in a variety of scenarios.

4. Launch a new public health supplies innovation center and product standardization task force

To speed the development of advanced technologies and ensure product standardization, the U.S. should invest in the creation of an innovation center for public health supplies. This innovation center would link manufacturers with appropriate federal counterparts to receive guidance on an appropriate regulatory process, obtain early regulatory feedback on their proposed advanced technology from relevant FDA subject matter experts through the appropriate process in support of product and technology development and implementation, and ensure priority authorization and quality control approvals. The innovation center would also provide a match-making platform for new products that have received FDA approval for associated products to connect with SLTT end users seeking reliable supplies of quality products during surge events when normal distribution channels are limited. By leveraging financial incentives or investments (both public and private), the U.S. can spur private-sector willingness to develop domestic production capacity, as well as identify and provide skills-based training for American workers to meet the needs of production.

To improve the efficacy, usage effectiveness, safety, supply stability, and accessibility of PPE designed for use in U.S. health care settings for infection prevention and control (IPC), the U.S. Government should establish a workgroup for PPE innovation in health care. The workgroup would gather information and assess relevant issues and facts to support decision-making related to innovations in design, construction, materials, production, distribution, and oversight related to PPE—producing written summaries, as needed. This group would recommend PPE standards to minimize multiple options and complexity of manufacturing, and to attain insight into issues and opinions among experts from the health care, industry, research, and government sectors regarding needs, opportunities, barriers, and potential solutions to current PPE limitations. Finally, the workgroup would also seek to share information and support dialogue among the above sectors, including frontline health care personnel, to ensure effective and acceptable

solutions are identified. The membership should include representatives from the federal government, industry associations and group purchasing organizations, clinical organizations, trade unions, and other relevant stakeholders.

In the case of testing and diagnostics, early innovation and rapid deployment of tests are essential to maintain accurate visibility of transmission and collect epidemiological data. Novel testing capabilities and sufficient testing capacity should be available within a timely manner after identification of a pathogen of concern. Continued innovation and support for modernizing data infrastructure and reporting for all point-of-care and at-home tests are also a priority to improve and maintain epidemiological data collection and analysis.

Visibility and Engagement

5. Maintain end-to-end supply chain visibility through expanded and continuous supply chain surveillance

Supply chain visibility is critical to the U.S.'s ability to anticipate, prepare for, and respond to potential disruptions, particularly during a public health emergency. Such visibility is even relevant for threats such as hurricanes and other natural disasters that may not ever rise to the level of a public health emergency, but for which medical device shortages could significantly impact patient care.

Accomplishing this effort would require sustained U.S. Government funding to support activities in supply chain surveillance, analytics, and modeling, and an expansion of engagements with private-sector stakeholders that would allow for enhanced partnerships, transparency, and data sharing. Accordingly, the U.S. Government is prepared to implement new supply chain situational awareness capabilities and authorities, as well as establish a rhythm of regular supply chain illumination, analysis, and mapping for federal, SLTT, and private-sector stockpiles. Expanding current supply chain visibility into critical public health and other all-hazard-scenario supplies requires 1) identifying and prioritizing the list of critical public health supplies for a pandemic response, and 2) prioritized mapping and analysis of those products' supply chains—to include raw materials, components, manufacturers, distributors, and end users. Mapping is a critical step to detect hidden relationships and interdependencies that may impede resilience efforts. HHS should work closely with interagency and industry partners to collect data and information, in a targeted way, that would enable it to gain visibility over,

monitor, and assess supply chain risks and vulnerabilities. This capability would better allow HHS to identify vulnerabilities, predict and prevent supply chain disruptions, and mitigate risks.

This level of visibility also requires enhancing the U.S. Government’s ability and authorities to collect additional data. HHS should develop and deliver recommendations to Congress, seeking statutory authorization to increase HHS’s ability to collect such information. Such authorities would also require close consultation with industry and other stakeholders. HHS should also make recommendations regarding FDA’s authorities to collect such information. To assure a more resilient domestic supply chain and help reduce dependence on foreign production, FDA requires expanded authorities including (but not limited to)—specification that organizations should notify FDA any time a potential for a shortage exists; the inclusion of production volume information; fuller oversight of supply chain disruptions, including requiring manufacturers to perform risk assessments, implement risk management plans, and identify alternate suppliers and manufacturing sites; the authority to request records in advance or in lieu of an inspection; permission to allow temporary importation of unapproved devices, with appropriate scientific and regulatory controls, when in the interest of the public health; clarification as to which entities should notify FDA, including contract terminal sterilizers of medical devices; and permission for FDA to allow devices to be distributed past their labeled shelf life (with appropriate, supportive scientific data) when needed to prevent or mitigate a shortage.

6. Streamline U.S. Government–private sector coordination for sustained public health supply chain private-sector engagement

The complex public health supply chain ecosystem is multifaceted with a swath of private sector entities that engage across global supply chains to provide finished products and raw materials to support acute and non-acute care settings. The ecosystem encompasses many hundreds of products that have their own unique supply chains. Sustained engagement with the private sector underpins of our ability to gain visibility over supply chain constraints or delays. Leveraging the existing coordination mechanisms and relationships formed through the interagency body Critical Infrastructure Protection Advisory Council (CIPAC) and the CIPAC Government Coordinating Council, the U.S. Government is linked with voluntary end users from 16 sectors to engage on priority public health supply chain concerns and situations as they arise. Sustaining and better aligning this engagement mechanism with U.S. Government strategic objectives would forge a direct line of communication between the government and private sector during PHEs to prepare for and respond to supply chain

shortages and disruptions. In addition, the administration, in coordination with HHS, as recommended recently,¹⁸ should advise on improving domestic manufacturing capacity for critical drug substances and drug products—including any ancillary devices required for their delivery. ASPR has leveraged an existing public–private partnership to establish a consortium, co-chaired by the FDA, to prioritize drug products on the essential medicines list, and how best to produce and deliver them to those in need. The consortium is garnering insights from leaders in government, the private sector, academia, industry and trade associations, nonprofits, and health coalitions to provide these recommendations in coming weeks. These insights should be provided to sub-committees established under the recently approved DPA 708 “Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Drug Products, Drug Substances, and Associated Medical Devices to Respond to COVID-19,”¹⁹ in order to build domestic pharmaceutical manufacturing resiliency.

Leveraging the successes of this consortium, we anticipate that the DPA 708 engagements will transition from the Federal Emergency Management Agency (FEMA) to HHS and be co-administered by ASPR and FDA. The Section 708 process provides a conduit to engage across the entire supply chain, enabling the U.S. Government and industry stakeholders who volunteer to participate to share information, build a common operating picture, perform analysis, and solve problem sets necessary to ensure a resilient domestic public health industrial base. ASPR and FDA should establish a meeting cadence and work with government agencies and industry to identify problem sets needing to be addressed that would delay providing support in response to U.S. medical emergencies, and develop sustainable solutions. The CIPAC and DPA 708 process should complement each other and work synchronously together to provide a holistic picture from manufacturer to end user to gain situational awareness and recommendations to correct supply chain constraints before they can impact national support to public health emergencies. Both mechanisms are needed to capture as many voluntary private industry participants as possible, and strong coordination between ASPR and FDA would avoid duplication of efforts, while providing a thorough market overview of any supply chain challenges. Moreover, the U.S. Government should consider other mechanisms to support public–private partnerships such as the medical device information and analysis sharing (MDIAS) partnership that incentivizes data sharing and transparency that would ultimately result in an improved ability to predict and respond to public health supply chain disruptions.

¹⁸ “[Building Resilient Supply Chains, Revitalizing American Manufacturing, and Fostering Broad-Based Growth, 100-Day Reviews under Executive Order 14017](https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf)” The White House, accessed June 8, 2021, <https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf>.

¹⁹ “[Notice Pursuant to the Defense Production Act of 1950; Review of Plans of Action](https://www.federalregister.gov/documents/2021/05/24/2021-10874/notice-pursuant-to-the-defense-production-act-of-1950-review-of-plans-of-action),” Federal Register, accessed May 24, 2021, <https://www.federalregister.gov/documents/2021/05/24/2021-10874/notice-pursuant-to-the-defense-production-act-of-1950-review-of-plans-of-action>.

7. Institute an annual resilience “report card”

An annual resilience “report card” should be instituted to facilitate regular assessment of the resilience of the public health supply chain. Resilience should be measured based upon the framework of robustness, agility, and visibility—as well as consider the values laid out in this strategy. This analysis should include an assessment of current capacities; an evaluation of potential points of failure in the supply chain system to prepare and respond to a PHE; and continued analysis of the role of foreign supply chains in America’s public health supply chain. The report card should include recommended courses of action to mitigate any gaps or risks, and, where relevant, updates on ongoing mitigation efforts.

This work should be conducted in coordination with the HPH SRMA, and use existing analytic capabilities of the U.S. Government, to include the National Labs, the National Risk Management Center, the National Infrastructure Simulation and Analysis Center (NISAC), and the National Center for Epidemic Forecasting and Outbreak Analytics called for in the *National Strategy for the COVID-19 Response and Pandemic Preparedness*.²⁰

Governance and Management

8. Bolster interagency oversight of the public health supply chain, and sustain a strong U.S. Government public health supply chain workforce

The ASPR is the lead federal official for directing and coordinating MCM development, staging, and deployment, and does so through the PHEMCE. Accordingly, the U.S. Government must strengthen interagency coordination of public health supply chains through reinvigorated support of the PHEMCE and by transforming the PHEMCE to deliver governance recommendations and sustained oversight of the supply chain. Expanding upon its current focus, the PHEMCE should identify existing supply chain governance bodies and coordinate across them to ensure cohesive implementation of a renewed PHEMCE strategy on managing the supply chain and ensuring an adequate workforce. The PHEMCE should guide implementation of resilient supply chain processes based on adaptive and responsive inventory management practices and systems. Then it can promote national preparedness activities that are adaptive to known and unknown threats to the public health supply chain. To ensure a workforce capable of supporting a resilient supply chain, the PHEMCE should

²⁰ “[National Strategy for the COVID-19 Response and Pandemic Preparedness](https://www.whitehouse.gov/wp-content/uploads/2021/01/National-Strategy-for-the-COVID-19-Response-and-Pandemic-Preparedness.pdf),” The White House, accessed January 22, 2021, <https://www.whitehouse.gov/wp-content/uploads/2021/01/National-Strategy-for-the-COVID-19-Response-and-Pandemic-Preparedness.pdf>.

coordinate a comprehensive public health supply chain talent and capability study to identify U.S. Government gaps in skilled labor.

9. Revise EO 13603 on “National Defense Resources Preparedness”

Executive Order 13603 on “National Defense Resources Preparedness” was issued in 2012 and, among other actions, delegated authorities under the Defense Production Act of 1950 (DPA). The EO established the Defense Production Act Committee to coordinate and advise on the effective use of the act, made up of the departments and agencies to which the President delegated authority. The committee was to advise on the effective use of the authorities under the DPA. A revision to this Executive Order should be considered to expand representation on the Defense Production Act Committee to include all departments and agencies with significant relation to the public health supply chain and industrial base, as well as any potential additional delegations needed to provide for pandemic preparedness. For example, the Department of Veterans Affairs (VA) oversees the largest integrated health care system in the U.S. and, consequently, serves as a national defense component for response to natural disasters, public health emergencies, and other national emergencies. Having representation as a full member of the Defense Production Act Committee would help ensure such departments and agencies are recognized as equal participants in national public health planning, preparedness, and response. Other revisions could include expanding consideration of authorities beyond DPA Title I. Doing so could help the U.S. Government leverage the DPA to the extent needed to safeguard national health security.

10. Establish a national framework for allocation of constrained resources

The establishment of a national framework for SLTT planning, preparedness, and response is essential for ensuring fair, equitable, and effective allocation of constrained resources. The framework would foster a shared understanding of roles, responsibilities, risks, processes, and systems required for pre-, intra-, and post-pandemic governance and management. The framework would facilitate coordinated information sharing, enable cross-jurisdictional support during PHEs, and ensure consistent and coordinated continuity of support.

The SNS’s role is to supplement state and local supplies during public health emergencies by providing products as a short-term stopgap “buffer” when the material supply may not be immediately available or by providing unique MCMs for which no commercial market exists. A national framework for SLTT allocation would allow the SNS to distribute supplies effectively and equitably to meet this mission. The allocation framework should be informed

by demand modeling and the supply chain data—and it should leverage increased visibility into the supplies that are available outside of its own warehouses—including product held in SLTT stockpiles and existing manufacturing capacity. Access to these data would help inform supply allocation strategies. This framework should also outline vertical and lateral communication channels to SLTT authorities during public health surge events, allowing SLTT to better understand how to request supplies from the SNS, and helping to prevent competition for scarce resources. Additionally, this framework should create mechanisms to give SLTT authorities advance notice of the supplies they receive, and to ensure they have the ability to use those supplies once received.

11. Revamp global governance of the public health supply chain

Domestic production is only one aspect of driving resilience in the public health supply chain since it is not feasible or realistic to expect every product needed for American patients to be produced domestically. The U.S. Government should leverage and strengthen existing international partnerships as well as build new ones to enhance visibility of the public health supply chain during and in-between public health emergencies. The U.S. Government should work with international partners to develop and strengthen globally focused systems capable of scaling up during surge events such as a pandemic by assessing the current global supply chain landscape and identifying key levers that are critical to ensuring supply chain functionality. International partnership discussions help illuminate risks to the global public health supply chain and can enable collaboration to manage those risks. Through focused collaboration with partner nations, international organizations, and other stakeholders, the U.S. Government can evaluate current and future global capabilities to manufacture critical public health supplies and build complementary strategies that create additional production without unnecessary duplication. The U.S. should also work with international partners to support use of international standards, develop a market intelligence platform that includes demand and supply information for both manufacturers and API suppliers, and promote manufacturing quality across all parties. This work should leverage ongoing and planned U.S. and global efforts to enhance supply chain visibility.

Conclusion



Sustaining resilience in the public health supply chain is critical for protecting Americans against future public health emergencies. This concept of resilience does not entail building a flawless system—although an improved system is certainly the intent of this work—but rather one that can be responsive to a variety of possible shocks and disruptions. Doing so acknowledges that the effects of “unknown unknowns” cannot be entirely accounted for in any design, particularly one that is called on during a dynamic, complex process such as a public health emergency. Furthermore, although resilience is enabled by the capacities and capabilities of systems, it is the behavioral element of the actors within and across those systems that creates resiliency. Information sharing, risk management, and training and exercising will be as essential to resilience as any supplies or tools. To paraphrase the approach adopted by CISA’s National Critical Functions program: resilience is not what you are; it is what you do.

Resilience can be expressed through a variety of lenses, although this strategy has defined resilience around three elements: **robustness**, the ability of a system to resist and absorb a shock, in this case through improved diversity of supply sources; **agility**, the responsive ability to return to function and pivot operations; and **visibility**, the ability of actors and organizations to sense and increase awareness of the status of the system. All of these measures contribute to regaining equilibrium in the system below, at, or above previous levels.

This strategy, through its goals, objectives, and recommendations, aims to forge a public health supply chain that embodies all these elements of resilience. Achieving this vision will require significant, continued efforts across U.S. Government, SLTT, private-sector, and other stakeholders. This work is crucial for helping ensure that future pandemics or other biological incidents are met by an integrated and responsive public health supply chain. Such a supply chain is achievable and must remain a priority so that the U.S. Government can protect the health and security of Americans.

Appendix I: Acronyms



- API – Active Pharmaceutical Ingredient
- ASPR – Assistant Secretary for Preparedness and Response
- BARDA – Biomedical Advanced Research and Development Authority
- CBRNE – Chemical, Biological, Radiological, Nuclear and High-yield Explosives
- CDC – Centers for Disease Control and Prevention
- CI – Critical Infrastructure
- CIPAC – Critical Infrastructure Partnership Advisory Council
- CISA – Cybersecurity and Infrastructure Security Agency
- COVID-19 – Coronavirus Disease 2019
- DHS – U.S. Department of Homeland Security
- DLA – Defense Logistics Agency
- DoD – U.S. Department of Defense
- DPA – Defense Production Act
- DPAC – Defense Production Act Committee
- EO – Executive Order
- EUA – Emergency Use Authorization
- FDA – Food and Drug Administration
- FEMA – Federal Emergency Management Agency
- FTA – Free Trade Agreement
- HHS – U.S. Department of Health and Human Services
- HPH – Health Care and Public Health
- IBx – Industrial Base Expansion
- ICT – Information and Communication Technology
- IPC – Infection Prevention and Control
- MCM – Medical Countermeasure
- MDIAS – Medical Device Information and Analysis Sharing
- NCF – National Critical Function
- NGO – Non-Governmental Organization
- NHSS – National Health Security Strategy
- NIH – National Institutes of Health
- NIOSH – National Institute for Occupational Safety and Health

- NISAC – National Infrastructure Simulation and Analysis Center
- NIST – National Institute of Standards and Technology
- PHE – Public Health Emergency
- PHEMCE – Public Health Emergency Medical Countermeasures Enterprise
- PHIB – Public Health Industrial Base
- PPD-21 – Presidential Policy Directive – Critical Infrastructure Security and Resilience
- PPE – Personal Protective Equipment
- PPP – Public–Private Partnership
- SLTT – State, Local, Tribal, and Territorial
- SNS – Strategic National Stockpile
- SRMA – Sector Risk Management Agency
- STEAM – Science, Technology, Engineering, Arts, and Mathematics
- USDA – U.S. Department of Agriculture
- VA – U.S. Department of Veterans Affairs

Appendix II: Challenges and Opportunities from the COVID-19 Response



This section expands upon public health supply chain resilience themes observed since the beginning of the COVID-19 response—observations and considerations which helped inform the development of this strategy and its recommendations. Themes include challenges and opportunities that exist both inside and outside of government. These reflections are not exhaustive and will continue to evolve beyond the publication of this document as the response to the COVID-19 pandemic continues.

Observed Problems in the Operating Environment

The U.S. public health supply chain is vulnerable to significant disruptions during widespread PHEs. A sustainable public health supply chain is central to any pandemic response. The practice of offshoring manufacturing, combined with globalization and the practicality of “just-in-time” operations, helped create a supply chain that was stretched beyond capacity. There are strong market forces and economic rationales that support a global supply model that allows for increased specialization, manufacturing dispersed across multiple countries, and just-in-time transportation of goods. The model’s resiliency, however, must be augmented through adequate domestic stockpiles and capable domestic suppliers with built-in surge capacity. Moreover, the underlying conditions that created the vulnerabilities for the public health supply chain could also be mitigated, to some degree, through cultivation of market dynamics that disfavor certain types of sourcing concentrations outside the U.S. The CISA Information and Communication Technology (ICT) Supply Chain Risk Management Task Force²¹ produced a report on “Building A More Resilient ICT Supply Chain: Lessons Learned During the Covid-19 Pandemic” that noted:

²¹ Although information and communication technology focused, the supply chain insights in the report are true of medical products as well, and of supply chains generally. [Building A More Resilient ICT Supply Chain: Lessons Learned During The COVID-19 Pandemic](https://www.cisa.gov/publication/ict-supply-chain-lessons-learned-covid-19), accessed May 24, 2021, <https://www.cisa.gov/publication/ict-supply-chain-lessons-learned-covid-19>.

The typical approach to supply chain management emphasized the need to strike a balance between efficiency and resiliency. While these concepts are often at odds with one another, effective supply chains are those that strike the right balance between the two. Moreover, companies also need to seamlessly integrate supply chains with many different components and a large, human workforce supporting and serving as its backbone. Increased competition and often-compressed profit margins have driven supply chain managers to emphasize cost reduction, just-in-time deliverables, and days of supply inventory management.

While the supply chain is generally efficient in moving goods during stable economic conditions, responses to rapid fluctuations in supply and demand during a PHE sometimes do not occur in time to prevent shortages. A variety of factors drive supply shortages; the list below elaborates on these supply chain issues:

- ⇒ *Production Scarcity* is the problem of not having enough needed supplies or workforce. Scarcity in the public health supply chain is inclusive of raw materials, API, and finished dosage form (FDF), medical device components, and other products needed to get goods to market such as glass vials and syringes. When material is scarce, downstream entities must wait for material to be available or locate alternative sources—leading to inefficiencies and shocks to the system. Further impacting production is a decrease in qualified labor due to health conditions and insufficient technical skills; this decline also helps increase risk of forced labor and harmful operational shortcuts.
- ⇒ *Order-to-Delivery Time* is the issue of moving goods from place to place and includes all of the logistical considerations associated with product distribution, including regulatory actions (e.g., withhold release orders²² seizing imported goods produced by forced labor). Just-in-time delivery processes are optimized to reduce dwell time in the system; however, factory closures or backlogs at critical nodes like trans-shipping ports can accumulate to such an extent that the system seizes up, exacerbating shortage conditions and creating a supply chain disruption that can last months to years.

²² "[Withhold Release Orders and Findings](https://www.cbp.gov/trade/programs-administration/forced-labor/withhold-release-orders-and-findings)," Customs and Border Protection, accessed April 21, 2021, <https://www.cbp.gov/trade/programs-administration/forced-labor/withhold-release-orders-and-findings>.

- ⇒ *Marketplace Access* includes the ability to order from the full marketplace as well as the knowledge of what products are available. Purchasers' lack of transparency to goods' origins creates an asymmetry of information for consumers. Hoarding behavior, duplicate and cancelled orders, and delivery of unusable supplies are some of the effects that can occur during a crisis response.
- ⇒ *Allocation and Prioritization* are linked and are part of the last-mile problem. Ensuring supplies are allocated to points of greatest need requires the ability to route and re-route supplies among customers. To be effective, established allocation and prioritization criteria and participation from all stakeholders is essential to ensure a needs-based prioritization of supplies.
- ⇒ *Balancing "Push" and "Pull" Supply Chain Strategies to Manage Risk.* Push-based supply chains ship products from the manufacturing site to retailers based on anticipated demand. In contrast, pull-based supply chains are demand-driven rather than prediction-based. To be resilient, a supply chain must use a hybrid approach. For instance, a PPE manufacturer might choose to increase its raw material inventory as a means to buffer shortages in the event of a PHE.

Each of these elements varies in importance for different products and different emergencies. However, resolving or even mitigating the root causes faced in PHEs generally, and experienced in the COVID-19 pandemic acutely, is this strategy's focus.

Supply Chain Data and Visibility

- ⇒ *Need for a common operating picture of supplies in the public health supply chain.* During the COVID-19 pandemic, multiple sources of both government-produced and external information existed. Individual agencies and subunits of agencies relied on their own datasets, at times augmented by non-harmonized open-source media reports. Where more rigorous systems were employed, they used differing calculations of epidemiologic data.
 - The lack of a common operating picture or uniformly recognized "single source of truth" from front-line staff to top-level leadership, between regions, and between communities (manufacturers, distributors, and supply managers) resulted in a range of differing perceptions—from adequate levels of PPE to acute shortages.

- The front-line staff realities and perspectives on PPE supply health are important for the credibility of future systems.
 - A single supply chain management system that tracks shared metrics of performance would enable effective supply chain assessments, analysis, and implementation.
- ⇒ *Need for greater transparency in distribution systems.* Lack of visibility into supply availability constrained the ability of end users to secure supplies through their (non-pandemic) established distribution systems—using planned advanced purchasing through a small number of distribution channels and from a limited number of manufacturers. When demand surged during COVID-19, the visibility and data sorting requirements overwhelmed distributors who had limited to no visibility into source material productions.
- ⇒ *Need for the ability to view information across the entire supply chain.* Early in the pandemic, the U.S. Government identified the importance of a consolidated and integrated information system for increased visibility, data collection, analytics, and sharing across the entire supply chain, from raw materials suppliers to end users of the products and services. The response highlighted the importance of flexibility and agreed-upon assumptions with demand modeling, as well as current product inventories to predict shortages.
- ⇒ *Need to reduce large buyers' impacts on data volatility.* When established supply chains were challenged with excess demand, larger, better-connected buyers were better able to purchase outside of normal distribution channels, which not only drove up prices for smaller entities but also introduced extreme volatility into inventory data.
- ⇒ *Need to revisit Strategic National Stockpile operating assumptions.* Before COVID-19, the SNS had very limited supply chain data and visibility, as that role had not been required under previous mission operating assumptions. Understanding market shortages and commercial constraints plays a large role in when and how much the SNS procures supplies, as the SNS makes every effort to not disrupt the commercial market. Understanding the levels of various supplies going to different regions, states, and providers would allow the SNS to target undersupplied requestors more effectively.

Interagency Public Health Supply Chain Coordinating Structures

- ⇒ *Synchronization of procurement actions.* At the outset of the pandemic response, coordination of government procurement was very limited. The lack of an existing structure to synchronize federal procurements often led agencies to inundate the supply chain with multiple requests. Industry partners had to determine which agency or requests to prioritize.
 - Initial distribution prioritization under the rated orders did not give VA equal priority with other health care systems and required the direct engagement of the VA Secretary with HHS and DHS. Subsequently, VA requirements received a higher priority for critical supplies.
 - The use of DPA authorities for public health response to a pandemic in the United States was a novel application of DPA. Originally, Congress intended DPA to support civil defense and war mobilization and expanded the intent to include homeland security and other domestic requirements through amendments in 1994, 2003, and 2009. Inclusion of the VA as a member of the DPA Committee would ensure the VA is recognized as an equal participant in national public health planning, preparedness, and response.²³

- ⇒ *Expedition of the import of MCMs.* The U.S. import and customs processing system is designed to expedite and facilitate trade involving entities with a trusted or historically compliant status, resulting in rapid entry of large volumes of cargo through a predominantly automated clearance process—while simultaneously pinpointing cargo risk and enforcing U.S. laws at the border. However, at the beginning of the COVID-19 crisis, multiple non-traditional importers and new foreign suppliers entered the customs process, adding to the existing cargo volumes, and creating transactions the system was not calibrated to clear rapidly. This volume drove a significant increase in vetting efforts and further strained the import clearance processes; it was especially difficult for public health supply chain items that required regulatory approval from multiple agencies to be sold in the U.S. market.

²³ “[Veteran Health Administration \(VHA\) Coronavirus Disease 2019 \(COVID-19\) Response Report](https://www.va.gov/HEALTH/docs/VHA_COVID-19_Response_Report.pdf),” Veterans Affairs, October 27, 2020, https://www.va.gov/HEALTH/docs/VHA_COVID-19_Response_Report.pdf.

- ⇒ *Need for increased interagency coordination.* Federal agency personnel easily recognized the necessity to coordinate needs and leverage expertise across domains and disciplines, but a formally designated mechanism for doing so was not apparent. Agencies added value by working together under designated leads to address shared challenges in supply chain disruptions. Going forward, need and emphasis for this kind of collaboration is essential.
 - The U.S. Government should consider expanded use of the HPH Sector Government Coordinating Council structure for interagency coordination. Co-chaired by the FDA and ASPR, membership includes HHS, VA, DoD, DHS, and others.
 - The U.S. Government should also reinvigorate medical countermeasures development, distribution, and coordination through the PHEMCE.

Planning, Stockpiling, and Preparedness

- ⇒ *Increase of testing equipment and supplies.* Early global shortages of testing equipment and supplies made it difficult for the U.S. Government to conduct regular surveillance testing to accurately estimate infection rates and to track the spread. The shortages in supplies, in part due to just-in-time supply chains, made testing, contact tracing, and isolation efforts less robust than desired. Given these challenges, future pandemic planning should seek to increase capacity to integrate and institutionalize logistics and contracting support approaches that limit competition and increase coordination among interagency and SLTT entities.
- ⇒ *Reduction of reliance on the SNS.* The national supply chain, including the supply chain for the SNS, was unable to meet demand. The SNS was never intended to meet every contingency requirement. To bridge this gap, HHS and FEMA turned to DoD to take advantage of its acquisitions and logistics expertise to support nearly all facets of the national supply chain.
 - The SNS is historically underfunded for pandemic response and needs clear, long-term, stockpiling goals for pandemic preparedness aligned with annual appropriations to successfully prepare for the next pandemic. Before COVID-19, the SNS's primary mission had been for regional CBRNE responses and natural disasters. Now expanded to include response to

national pandemics, the SNS quickly implemented partnerships with large, geographically diverse distributors to enhance its preparedness and distribution capabilities over the long term.

- Certain federal agencies were not funded to support pandemic readiness and resulted in early demand for SNS support that compounded SNS challenges. Going forward, each agency must maintain some level of operational inventory to prevent U.S. Government competition with SLTT authorities at the start of a pandemic.
- Stockpiled products must be stored properly, maintained according to manufacturer recommendations, and rotated into the supply chain to avoid expiration. Rotating products into the active supply chain also can ensure end-user familiarity and experience. Collaboration with the industry will further increase efficiency and reduce risk.

⇒ *Incentivization and funding of SLTT pandemic preparedness.* The U.S. Government should incentivize SLTT pandemic preparedness—including hospitals, hospital systems, and emergency essential businesses—by developing a plan for providing material at the federal level in support of large-scale PHEs and aligning that plan with the many SLTT plans. A plan must be built to describe how pieces of the national supply chain will interact with the whole, and how decisions will be made. The data systems that now exist have not been complemented with role definition, rule definition, and how supply would be matched with demand (i.e., if the data shows a shortage, what is the threshold to release product from the SNS versus the commercial supply chain or a state stockpile?).

⇒ *Incorporation human behavioral considerations into planning efforts.* User-side behavioral constraints should be included in crisis preparedness planning, which should include the demands associated with model and size selection and fit-testing of respirators available on the market during a crisis that were not previously used in a respiratory protection program. Hospitals resisted having to use multiple new types of approved respirators as they increased management burden and because clinical staff trusted their product of choice. Difficulties existed regarding coordination with hospitals on deliveries of medical supplies and visibility into the supply chain on their end.

- Policymaking must address potential deviations in the anticipated need. These estimates must not be limited to health care and must take crisis behaviors into. These requirements will not be static and must be reassessed and updated regularly.
 - Allocation must understand and consider the level of response SLTT partners will face, especially behavioral aspects of using alternate PPE supplies (e.g., reuse vs. disposal, fit testing, brand loyalty, etc.).
- ⇒ *Need to conduct a whole-of-government pandemic exercise.* The U.S. Government should hold an annual or bi-annual table-top exercise to assess national medical emergency supply chain preparedness and resiliency. This exercise should be conducted expressly to test interagency integrated communications mechanisms, processes, and procedures; identify gaps in capability, logistics, supply, processes, understanding, relationships; and inform future improvements. Exercises should be scenario-driven; underpinned by modeling and simulation and data analytics; and collaborative with government, industry, and academia both domestic and international.
- The U.S. Government’s national public health supply chain should be treated as a national asset and therefore include all stakeholders in its care. It should establish expectations for its supply chain and SLTT partners to ensure supply chain resiliency.

SLTT Support and Engagement

- ⇒ *Need for the ability to distribute supplies.* There were significant coordination issues between the supplies requested by state governments, and the actual needs faced by front-line public health professionals.
- SLTT partners reported that processes and protocols for requesting materials from the SNS were challenging, partly because the long-established process was changed at the beginning of the pandemic response.
 - The U.S. Government response observed the need for clear activators, thresholds, and mechanisms for SLTT partners to access supplies and/or

request assistance from federal agencies during a PHE. However, requests for information from the U.S. Government to SLTTs allowed for greater visibility into the supply chain and better coordination for supply deliveries through the development of situational awareness tools.

- Investments in SLTT capabilities through Public Health Emergency Preparedness funding were fundamental to preparing some localities to receive delivered supplies. Without the established history of sustained funding (15 years), the U.S. could have experienced severe shortages of logistics and warehousing capabilities and facilities needed to receive the emergency supplies.

- ⇒ *Need to establish coordinated prioritization plans.* Prioritization of PPE contracts, supply chain logistics, and order fulfillment should to be established, across regions, so that industry, SLTT authorities, and the federal government are not competing for purchasing supplies during a PHE.
- ⇒ *Need to establish a regionalized approach.* Significant work is needed to explore opportunities for a regionalized approach for supply chain needs and implementation, ensuring products can be ordered, surged, and shared across areas of need.
- ⇒ *Need for supply chain assurance to reduce local hoarding behavior.* A fair amount of hoarding at the local level occurred. To address this hoarding, some hospitals established a horizontal sharing system. Meanwhile, states became the supplier for all the nontraditional medical facilities that needed PPE during COVID-19.
 - In DPA Section 708 conversations, industry raised that SLTT authorities and even hospital-level officials were stockpiling respirators during the COVID-19 pandemic when availability of supplies was still limited. This local stockpiling reduced available supplies on hand and meant that some end users went without needed PPE.

Private-Sector Support and Engagement

- ⇒ *Maximization of the use of PPPs.* PPPs, offering a holistic, integrated approach across different industries in the supply chain, proved very useful. PPPs provide

natural venues for multiple perspectives and coordination essential to making the most effective and impactful solutions.

- All involved must “lean in” to their respective authorities, policies, and areas of responsibility. Each has various levers and is more effective when operating within their respective strengths.
- Lack of private-sector access to, and coordination with, federal partners resulted in an inability to usher products into the marketplace to fill shortfalls.
- U.S. Government response missed opportunities for innovative private-sector solutions and academia input. The U.S. Government should continue strategic engagement of the private sector through DPA Section 708 and the CIPAC on issues related to stockpiling strategies.
- In response to COVID-19 and in coordination with HHS, the Department of Justice, and the Federal Trade Commission, FEMA established a Voluntary Agreement under DPA Section 708 to coordinate and share information with the private sector. A Section 708 Voluntary Agreement allows for an affirmative defense against antitrust actions for participants for actions taken in accordance with an agreement or plan. The U.S. Government should consider whether additional, proactive, use of Voluntary Agreements under DPA Section 708 would strengthen PPPs and improve future preparedness and response.²⁴

⇒ *Need to identify and mitigate inherent vulnerabilities.* Overarching issues—more than just inflated prices—related to just-in-time supply procurement made it difficult to identify or locate vendors that had available supply, foreign-made international products eligible for emergency-use authorization, and counterfeit products. Cost was a driving factor as expenses increased due to high demand mixed with reduced supply.

- Shelf-life extension for SNS products created confusion for end users trained to note and use only those products with an existing shelf life based on expiration labeling.

²⁴ “[Voluntary Agreement Under Section 708 of the Defense Production Act; Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic](https://www.federalregister.gov/documents/2020/08/17/2020-18005/voluntary-agreement-under-section-708-of-the-defense-production-act-manufacture-and-distribution-of),” Federal Register, accessed June 24, 2021, <https://www.federalregister.gov/documents/2020/08/17/2020-18005/voluntary-agreement-under-section-708-of-the-defense-production-act-manufacture-and-distribution-of>.

- Well-established conformity assessment processes, if known and readily available, could have addressed some of the issues encountered during the pandemic response (e.g., PPE performance, post-market quality assurance testing, and product labeling).
- Vetting producers was increasingly difficult, leading to numerous unconventional processes used to protect purchasers at federal and SLTT levels from rogue sellers. The role of the federal government to filter supply “scammers” and transmit that information to the SLTT level added value with a clear process to vet manufacturers to ensure the quality of PPE; however, this role could be expanded and routinized.
- The U.S. Government must create a risk balance that counters the commercial sector attraction to return to just-in-time and lean practices when the pandemic ends.

⇒ *Need to address the emergence of threats through nontraditional channels and suppliers.* Global simultaneous demand for the same supplies exceeded capacity, which led to increased sales of counterfeit and unapproved products. Malign economic actors, both foreign and domestic, exploited such demand surges for imported products by selling counterfeit, unapproved, and otherwise deceptive products through e-commerce and other channels.

- For public health supply items, the uncertainty provided by this surge presented a two-fold threat. First, counterfeits and unapproved products are typically of lower quality and will not perform the intended function, causing harm to the individuals that use them. Second, the presence of increased numbers of such products increases the burden of inspecting shipments as they go through customs. Without a corresponding surge in targeting, inspection, and clearing capacities, the legitimate goods may be slowed from making entry into the U.S. economy.
- The increased availability of counterfeit and unapproved products created significant risk for traditional government vendors, especially small businesses.
- The inability to compete successfully in the international PPE market resulted in a high number of contract modifications and cancellations—forcing buyers to alternate channels—when small businesses were unable to deliver products according to contract requirements.

- ⇒ *Need to mitigate effects of global supply chains.* A significant percentage of products are produced on a global scale. Even U.S.-based companies require components or finished products from overseas. International surges, import–export restrictions, and policies within countries (including policies on “essential” businesses, transportation and curfew limitations, available workforce, etc.) will have an impact on U.S. supply chains.
 - The U.S. Government must work with the global community to evaluate levers to rapidly scale up production of consumables and raw materials, critical inputs in manufacturing vaccines and therapeutics, at surge levels of capacity without hindering the production of other lifesaving medicines and vaccines.

- ⇒ *Need to protect business-sensitive or proprietary information.* The U.S. Government must be sensitive to proprietary information on supply chains—such as sourcing, availability, throughput, and market share—which can be strongly protected and incredibly sensitive.

International Support and Engagement

- ⇒ *Need to improve international sharing of products and information.* Coordination with international stakeholders (both public- and private-sector) is needed to bring greater visibility on global availability of and demand for supplies during a response.
 - A mechanism to facilitate donations of health supplies from foreign governments to the U.S. Government exists. However, no equivalent exists for foreign governments or foreign private parties to donate directly to SLTT authorities without making a formal customs entry and incurring associated customs transaction fees.
 - Early engagement with international public and private-sector partners with multisectoral reach would facilitate deeper information sharing on the global picture and enhance coordination during a response.

- ⇒ *Need for international coordination of response resources.* The international response to COVID 19 did not have the same structure as the domestic response, impacting optimal coordination of resources. Individual federal agencies determined their priorities for assistance and messaging without a lead federal agency identified to coordinate priorities. If a U.S. Government component had been designated to prioritize and coordinate international resources in support of domestic response, then the lead federal agency for the international response could have assisted in providing more timely, efficient, and effective support to partners and allies.
 - The U.S. Government should designate an agency to coordinate the international response resources and work towards an effective mechanism for prioritizing and directing global resources for an incident in United States. When appropriate, the U.S. Government should do so by partnering with international organizations.
 - The consequences of a pandemic on the U.S. are enormous, and the threat posed by the spread of a global contagion should be more prominently addressed in national security strategies.

Deep Dive: Ensuring Quality of PPE and Effective Coordination through the Supply Chain Life Cycle

This section provides a detailed reflection on opportunities to improve coordination and distribution of PPE in public health emergencies.

Current State

During the early stages of the COVID-19 response, the federal government faced immense challenges in effectively coordinating sufficient supply—and effective distribution—of consumer-ready PPE such as respirators, gowns, and gloves.

Federal and SLTT acquisition organizations struggled to successfully procure PPE in an efficient or effective manner—in part because of reliance on intuition, lack of situational awareness, entrenched purchasing habits, and over-prioritization for immediate responses. In many cases, the acquisition process failed to identify the appropriate standards; or, in some cases, the appropriate standard did not exist. Moreover, in the rush to procure supplies from a supply-limited market, many purchasing decisions were

made based on the PPE available for purchase, rather than on performance and quality standards. This rushed purchasing resulted in delivery of sometimes substandard, mislabeled, and counterfeit products.

The U.S. imported 72 percent of its face masks from China in 2019 and closer to 85 percent in 2020, according to Congressional Research. However, the U.S. experienced large shares of imports from China for a broad range of medical supplies (nitrile gloves, disposable gowns, surgical masks, melt blown fiber to make masks and ventilators). Approximately one third of the nation's 6,300 hospitals operate at a loss, a third break even, and a third make a small profit. Our hospitals and hospital associations are driven to buy cheap PPE on price (meet minimum worker compliance) to balance expenses with managing a hospital.

In response to supply shortages and the purchase of substandard PPE, the National Institute for Occupational Safety and Health (NIOSH) researched and evaluated into conformity assessment protocols, which, in turn, informed CDC guidance, and FDA Emergency Use Authorizations (EUAs) on what type of PPE could be used. These assessments included a previously ongoing evaluation of expired stockpiled N95s, new evaluations of N95s currently being marketed, and decontaminated NIOSH-approved respirators. For example, NIOSH began evaluating test reports and technical requirements for gowns conforming to American Society for Testing Materials standards in November 2020. In March 2020, NIOSH initiated an assessment and evaluated over 780 non-NIOSH approved respirators that met international standards that were being recommended in a crisis capacity scenario.

NIOSH's research and evaluations—as well as subsequent CDC guidance and FDA EUAs—allowed qualified stockpiled respirators to be disseminated and used, even where such had expired. Without this review, PPE shortages would have likely continued. When policy makers were considering dissemination and use of expired stockpiled respirators from the SNS, leadership was able to validate that certain N95 respirators, which had been tested by NIOSH,²⁵ continued to perform in accordance with NIOSH performance standards.

²⁵ The [NIOSH PPE Conformity Assessment Studies and Evaluations \(PPE CASE\)](https://www.cdc.gov/niosh/npptl/ppcase.html) reports, published in 2020 after several years of research and evaluation, provided evidence that specific respirator products maintained performance after long-term storage, and the empirical data could be used to inform decisions of whether the products should be disseminated. The research and evaluation were necessary to ensure expired stockpiled products continued to conform to appropriate standards and provided the requisite level of personal protection to healthcare workers. More information can be found on the NIOSH website, accessed May 28, 2021, <https://www.cdc.gov/niosh/npptl/ppcase.html>.

These models were released from the SNS with a letter indicating that they should provide the expected level of protection to the wearer when used in conjunction with an Occupational Safety and Health Administration–compliant respiratory protection program, including training and fit testing.

N95 respirators exceeding their manufacturer-designated shelf life were only released from the SNS due to the potential urgent health care demand caused by the COVID-19 pandemic. In the face of this emergency, the U.S. Government believed that the N95 respirators past their manufacturer-designated shelf life would provide greater protection than surgical masks (i.e., medical masks), other masks not evaluated or approved by NIOSH, improvised mouth and nose covers (e.g., bandanas), or no protection at all. This recommendation was also made since health care services are essential and must continue in the face of the COVID-19 pandemic.

Early in the response, confusion persisted on the proper use and warnings for EUA-approved PPE and equipment. While CDC provided specifications in guidance,²⁶ certain federal, state and local acquisition organizations were unaware, and as such did not follow the guidance prior to making purchases.

Immediate Need

A durable process for assuring conformity of PPE with the relevant standards should be developed and deployed during stable planning conditions. This process would ensure the quality of, and appropriate use for the supply of products prior to the emergency arising. Federal agencies with overlapping authorities must plan future collaborations to establish this process and must ensure uniform implementation.

A declared strategy would ensure effective supply chain management into the future. Two primary issues observed were the quality of the products received and inconsistent coordination across federal and SLTT partners. Documented strategies for addressing these issues would support effective supply chain quality and coordination.

An effective supply chain starts with designating the required standards to which products must conform, coupled with a reliable means for demonstrating conformance. These

²⁶ “[Optimizing Personal Protective Equipment \(PPE\) Supplies](https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html),” CDC, accessed May 24, 2021, <https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html>.

standards inform the supply chain by identifying the performance, quality, and reliability of qualified products.

Expertise exists in the federal government to define PPE quality and to effectively coordinate supply chain issues associated with PPE. It is critical that the PPE supply chain experts be clearly identified and incorporated in the decision-making processes. These strategies need to be anticipated and developed in advance of the emergency event. There may be situations where some level of prioritization should be executed; however, if this plan is implemented, the country should be in a better position to adequately address surges in demand to ensure the protection of America’s workers and the general public during a pandemic or other national or global crisis.

The Path Forward

I. Quality of the PPE Products

- a. Ensure a diverse set of qualified domestic suppliers
 - i. During steady state operations, establish a robust set of suppliers and provide federal support to ensure sufficient capacity during a crisis scenario. To address the experience of inadequate capacity that occurred during the COVID-19 pandemic:
 1. Ensure there is a resilient, commercially sustained capacity base that can ramp up quickly for future operations and add federal support as needed. Ensure qualified suppliers maintain their capabilities through routine post market evaluations.
 2. Clearly inform potential suppliers about standards and acceptable conformity assessment approaches to assist in preparing for acquisitions.
 - ii. Apply the U.S. PPE Conformity Assessment Framework,²⁷ to establish a national process such as third-party certification of supplier qualifications. Engage federal agencies such as National Institute of Standards and Technology (NIST) and NIOSH to establish effective strategies to facilitate these selections.
 - iii. Establish a clear inspection and acceptance criteria and monitor supplier performance through on-going audits of supplier-required qualifications to provide needed assurances of qualified supplies.

²⁷ “[National Framework for Personal Protective Equipment Conformity Assessment – Infrastructure](https://www.cdc.gov/niosh/docs/2018-102/default.html),” CDC, accessed May 24, 2021, <https://www.cdc.gov/niosh/docs/2018-102/default.html>.

- iv. Design and manage the stockpiles to maintain adequacy and viability of supplies and handle surges in supply.
 - b. Conduct research on potential suppliers
 - i. During conventional operations, encourage potential key suppliers to complete the qualification process through on-site and remote site qualification audits.
 - ii. Gather information about second-tier or sub-tier suppliers. The U.S. PPE Conformity Assessment infrastructure has ample standards and accreditation processes to enhance and select qualified suppliers.
 - iii. Manage the suppliers by preventing the return of black-listed suppliers by informing all purchasers of suppliers who do not comply with requirements. A suppliers' qualification program will ensure only qualified suppliers participate.

II. Effective Coordination

- a. Within the federal government, agencies have been assigned responsibilities and given authorities for making definitive decisions about the quality requirements and conformity assessment management of specific types of PPE. For example, NIOSH has statutory authority for ensuring the quality of all respiratory protective devices used in U.S. workplaces, including health care settings. Similarly, for certain types of gowns FDA has clearance requirements and FDA and NIOSH have subject matter expertise. A comprehensive list of these agencies, the types of PPE for which each is responsible, and their authorities should be developed, including where split or joint authorities exist. Mechanisms for effective communication and coordination among these agencies, and those who will need their expertise (FEMA, the Defense Logistics Agency [DLA], stockpile managers, etc.) during both routine and emergency operations, must be developed and followed. The obligations within this integrated system of communication and coordination flow in both directions.
 - i. Experts within the listed agencies should be identified for each type of PPE to ensure the appropriateness of decision-making concerning PPE.
 - ii. Publish and make all affected agencies aware of these authorities and develop a system to ensure each component of the supply chain issue is coordinated.
 - iii. Create interagency awareness and leverage DPA authorities to address supply chain issues. DLA is responsible for developing a common operating picture of PPE for DoD. As interagency authorities are developed, DLA

could offer economies in consolidating requirements, assisting acquisition, and storage and distribution to support the interagency response.

- iv. Clearly identify PPE standards required for the various types of PPE and the appropriate conformity assessment declarations to ensure only approved products are supplied and used.
- b. Clearly communicate PPE requirements and use guidance to purchasers and ultimately to wearers.
- c. Assess and ensure supplier qualifications, assessments, and processes to sustain the performance of selected suppliers and monitor through a federal information management system to allow continual supply chain improvements that could model the electronic health care record systems and serve as a PPE supply chain management system.
- d. Develop consistent stockpile distribution and management requirements towards localized distribution and establish a modernized inventory and distribution system that coordinates, and tracks needs based distribution and subsequent follow-up effectiveness of utilized supplies. While some stockpiles have automated systems already in place, many states have no process for tracking inventory quantities, resulting in the inability to obtain necessary supplies. Therefore, a coordinated federal effort should be established to avoid these issues that should also include a process for end users to provide input on non-compliant products.
- e. Establish a new purchasing agreement framework to monitor and deploy approved supplies with greater agility. Develop an intergovernmental communication strategy based on where relevant competencies lie within the SLTT, and not solely based on the federal agency structure.

Appendix III – References



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