Public Health Supply Chain and Industrial Base

One-Year Report

In Response to Executive Order 14017

February 2022

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

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Foreword

The Coronavirus Disease 2019 (COVID-19) pandemic has significantly tested the U.S. public health supply chain and industrial base. It has strained global supply chains and exposed critical vulnerabilities in the Nation's ability to deliver effective health care during times of high demand. Despite the challenges encountered since early 2020, the United States has made great progress to strengthen the public health supply chain and to address concerns regarding domestic manufacturing and supply chain surge capabilities.

One year ago, President Joseph R. Biden issued Executive Order (EO) 14017, "On America's Supply Chains." In response to EO 14017, the Department of Health and Human Services is proud to report what it has done to help make our public health supply chain and industrial base more resilient, diverse, and secure. This report identifies the successes and practical strategies that HHS is implementing to further the U.S. Government's goals for America's public health supply chain and industrial base.

Despite these great strides towards a more resilient public health supply chain, challenges remain. The actions outlined in this report ensure the U.S. is better prepared for the next public health emergency. We look forward to working towards a stronger and more resilient public health supply chain and industrial base so we can better protect the health of the Nation during public health emergencies.

Respectfully,

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

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Introduction

On February 24, 2021, President Joseph R. Biden, Jr. issued Executive Order (EO) 14017 on America's Supply Chains to help the United States ensure its prosperity, public health, and national security.[i] As we approach the one-year anniversary of the issuance of this order, the Department of Health and Human Services (HHS) is proud to report what it has done to help make our public health supply chains and biological preparedness industrial base more resilient, diverse, and secure. This report identifies the successes and practical strategies that HHS is implementing to further the U.S. Government's goals for America's public health supply chain and industrial base.

This report explores the public health supply chain and industrial base's vulnerabilities. It outlines HHS's existing and growing role and ongoing activities to strengthen the public health supply chain and industrial base and the importance of partnering with external stakeholders. It addresses personal protective equipment (PPE) and durable medical equipment (DME), testing and diagnostics, and pharmaceuticals—including therapeutics, vaccines, and active pharmaceutical ingredients (APIs); describes the status of these supply chains and industrial bases; and explains HHS's current and planned actions to address challenges.

In 2022 and beyond, HHS will take additional decisive actions to strengthen the U.S. public health supply chain and industrial base to address evolving coronavirus disease 2019 (COVID-19) challenges and to prepare for future public health emergencies and complex public health challenges. This report highlights planned and future actions the U.S. Government can take to further protect the public health supply chain.

This report relies and builds on the following U.S. Government analyses, which are all a part of the Biden Administration's ongoing efforts to build and sustain U.S. preparedness and response capabilities for future pandemics:

- *National Strategy for a Resilient Public Health Supply Chain* (the *National Strategy*)
- American Pandemic Preparedness Plan: Transforming Our Capabilities
- *Building Resilient Supply Chains, Revitalizing American Manufacturing, and Fostering Broad-Based Growth* (the 100-Day Report)

Definitions

A supply chain is the means for providing supplies and equipment to end-users. The public health supply chain system produces and delivers medical supplies to support the healthcare and public health (HPH) sector and includes both domestic and international suppliers and manufacturers. It provides PPE, DME, diagnostics, other medical devices, and pharmaceuticals (therapeutics and vaccines) to the American people.[ii] The public health supply chain and industrial base are primarily within the purview of the private sector. However, the U.S. Government has a role to play to ensure the foundations of our market economy provide for resilient and transparent supply chains, which are critical to the economic prosperity and national security of the United States. In addition, the U.S. Government has a continued interest in ensuring needed supplies are available to address the current COVID-19 pandemic, future

public health emergencies, and its internal needs.[1] The public health supply chain is, therefore, of great importance to the U.S. Government.

The public health industrial base (PHIB) includes all entities manufacturing or producing medical products and medical countermeasures (MCMs)[2] including medical devices, medical equipment, pharmaceutical products, and other products designed to improve patient outcomes. The PHIB also includes associated workforces, including research and development facilities, which help produce essential medicines[3], MCMs, and critical inputs for the HPH sector. It does not include the ability of distributors to source medical products from foreign sources to distribute within the U.S. healthcare system. Unlike the defense industrial base,[4] the PHIB is driven by the private market, which creates unique challenges, such as incentivizing domestic industry to maintain capacity which might be less economical than foreign competitors.

Support to the Supply Chain and Industrial Base During the COVID-19 Pandemic

HHS took decisive actions to address the COVID-19 pandemic. HHS is supporting the public health supply chain and the PHIB and providing crucial assistance to frontline workers and the American people. In 2021:

[1] For example, the National Institutes of Health's (NIH) Clinical Center is the nation's largest hospital devoted entirely to clinical research and therefore is an important government consumer of products from the public health supply chain and industrial base. NIH Clinical Center, accessed February 16, 2022.

[2] MCMs 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)), accessed February 16, 2022.

[3] "Generally, the essential medicines we identified are those that are most needed for patients in U.S. acute care medical facilities, which specialize in short-term treatment for severe injuries or illnesses, and urgent medical conditions. The medical countermeasures we identified are FDA-regulated products (biologics, drugs and devices) that meet the definition of a 'medical countermeasure' provided in the executive order and that we anticipate will be needed to respond to future pandemics, epidemics, and chemical, biological and radiological/nuclear threats. When identifying essential medicines and medical countermeasures, we focused on including those that are medically necessary to have available in adequate supply which can be used for the widest populations to have the greatest potential impact on public health," FDA Publishes List of Essential Medicines, Medical Countermeasures, Critical Inputs, Required by Executive Order, accessed February 13, 2022.

[4] "The Defense Industrial Base Sector is the worldwide industrial complex that enables research and development, as well as design, production, delivery, and maintenance of military weapons systems, subsystems, and components or parts, to meet U.S. military requirements," Defense Industrial Base Sector, accessed February 16, 2022.

HHS allocated $76B in COVID-19 emergency supplemental funding, including investing

- $3B to accelerate production of rapid tests, expand production capacity, and lead the Administration's procurement of 500 million over-the-counter COVID-19 diagnostic tests;
- $250M in PPE manufacturing;
- $65M in vaccine vial manufacturing.

Since the beginning of the COVID-19 response in 2020, **the Strategic National Stockpile (SNS) has utilized approximately $12B from COVID-19 supplemental appropriations to acquire approximately**

- 747 million N95 respirators (59 times pre-pandemic levels);
- 274 million surgical and procedure face masks (8.5 times pre-pandemic levels);
- 19.6 million face shields (two times pre-pandemic levels);
- 59.6 million gowns and coveralls (12.5 times pre-pandemic levels);
- 4 billion gloves (240 times pre-pandemic levels);
- 158,000 ventilators (10 times pre-pandemic levels).[5]

HHS has strengthened capabilities to monitor and manage supply chain bottlenecks by issuing 66 priority ratings under the Defense Production Act[6] (DPA) for U.S. Government contracts for health resources, eight priority ratings for industrial expansion, three priority ratings for non-U.S. Government contracts to support the production of resins for diagnostics and infusion pumps, and the manufacture of closed suction catheters for treatment of patients with COVID-19. These ratings allow the U.S. Government to ensure priority is given to urgently needed items, helping to prevent supply bottlenecks from halting production of needed goods.

As a result of all these actions, it was possible to

- administer 600 million COVID-19 vaccines doses and provide 78.4 percent of the U.S. population (ages 5+) at least one dose of a COVID-19 vaccine as of the beginning of January 2022;[iii]
- donate and deliver 327.5 million vaccines to other nations;[iv]
- procure 30 million treatment courses, distribute over 3.3 million monoclonal antibody (mAb) doses and 182 million diagnostics kits, and administer 2.9 million treatment courses;
- ship over 40 million rapid antigen tests and 2.3 million point-of-care polymerase chain reaction tests to the most vulnerable populations, including nursing homes, federally qualified health centers, and long-term care facilities since May 2021;
- place 1.5 billion doses of vaccine under contract and award contracts for 78 MCM projects to aid the COVID-19 response, including 16 therapeutics, 55 diagnostics, and seven vaccine candidates.

[5] Figures accurate as of December 29, 2021.

[6] Section 101 of the DPA authorizes the President to require acceptance and priority performance of contracts or orders and to allocate materials, services, and facilities to promote the national defense or to maximize domestic energy supplies. The President's priorities and allocations authority is delegated, in E.O. 13603, to the Departments of Agriculture, Energy, Health and Human Services, Transportation, Defense, and Commerce (referred to as "Resource Departments") with respect to resources within each department's jurisdiction, accessed January 26, 2022.

Supply Chain Vulnerabilities

The COVID-19 pandemic has strained global supply chains and exposed critical vulnerabilities in the Nation's ability to deliver effective health care during times of high demand. Offshore manufacturing and just-in-time inventory management, combined with the increased demands of the pandemic, have stretched the PHIB's supply chains beyond their capacities and created shortages, resulting in significant disruption for manufacturers and consumers. Although the U.S. Government has made great strides in addressing these vulnerabilities, challenges remain. The U.S. Government needs to help create adequate domestic stockpiles and capable domestic suppliers with surge capacity. The first step towards doing this is to identify vulnerabilities within the public health supply chain. Factors contributing to the insecurity of public health supply chains include:

> The COVID-19 pandemic drastically reduced international travel and trade. Lockdowns also forced workers in the United States and beyond to stay home as part of the pandemic response, greatly decreasing the extraction and production of raw materials crucial for items such as PPE and vaccines. Social distancing practices—due to labor shortages and/or limitations on onsite personnel capacity—also reduced the speed at which raw materials could be converted into finished goods.

Foreign Dependencies: The United States relies on foreign sources for components of its public health supplies. This can affect patient outcomes in the United States whether or not there is an ongoing public health emergency and limits the Nation's ability to implement prevention strategies that help maintain crucial operations. In addition:

- Foreign reliance puts the U.S. public health supply chain at risk of disruptions from **logistical challenges**, such as shipping and regulatory delays as well as port congestion. This can lead to production shortages when coupled with increased demand and just-in-time delivery processes.[v]
- Foreign **labor shortages** due to the COVID-19 pandemic, shifting demographics, natural disasters, conflicts, government regulations, or other origins can also disrupt supply chains.
- **Ethical considerations**, such as avoiding the products of forced labor, can limit the overall number of suppliers.
- **Single source suppliers** exacerbate foreign dependency challenges. Due in part to inconsistent international standards, it may be difficult to find sources of some medical-grade components that comply with FDA requirements. These challenges may lead to the sourcing of many medical-grade components solely from one country of origin. As a result, source material in the country of origin may become difficult to obtain, especially when national interests are prioritized, such as during increased demand periods, a localized event that disrupts the supply chain, or a public health emergency.
- Foreign sourcing makes the United States vulnerable to other countries' **export restrictions and other trade-restrictive measures.** Such measures can disrupt the supply of critical public health supplies, thereby posing a risk to national health security.
- Product constraints have been exacerbated by **limited access to raw materials** produced overseas and shortages of subcomponents, like aluminum capacitors, which directly impact the medical device industry.

Economic Pressures: Competition for economies of scale[7] and the lowest available cost have contributed to offshoring production of many raw materials and finished products, reducing diversity across the supply chain.

- Companies operating overseas can often outcompete companies with U.S.-based production because of **lower overhead costs, fewer regulatory requirements, and lower taxes**. These advantages help expand foreign companies' market share, leading to further consolidation through sole source manufacturing.
- **Foreign anticompetitive practices** – such as state subsidies to businesses and labor, price fixing, or state-ownership of raw materials – provide further economic advantages to foreign locations over U.S. locations. The consolidation of the global container shipping industry into a small number of dominant foreign-owned lines and alliances can disadvantage U.S. exporters.
- **Consumers, both individuals and wholesale purchasers, prefer low-cost goods**, which are often foreign made, as opposed to more expensive goods produced domestically. This preference may cause existing suppliers to halt operations and new suppliers to lose interest in entering the domestic market.
- Industry **emphasis on cost-cutting** has led to a large-scale acceptance of just-in-time inventory management, which leads to limited stock on hand to help withstand disruptions.
- **Unpredictable fluctuations in demand** stress supply chains' financial stability and reduce manufacturers' willingness to scale up production for peak demand periods. To be resilient and manage the demand fluctuation, a supply chain needs to balance a push-and-pull strategy.[8]

Workforce Challenges: Challenges filling entry-level and non-entry level positions and heightened training needs, resulting from lengthy machine operating training and certification requirements, increase the risk of suboptimal production and capacity for some public health supplies. Difficult jobs with poor working conditions contribute to high turnover and prolonged job openings. When coupled with port congestion, this creates problems with receiving products from overseas manufacturers. Insufficient production supplies, prolonged job openings, absences due to illness, or a lack of technical skills can cause downstream delays of materials and ultimately production scarcity, leading to systemic disruptions.[vi] COVID-19 has also affected workers through policies related to onsite personnel capacity, vaccine mandates, and conditions for returning to work.

Barriers to Entry and Expansion: For some U.S. companies, complex and expensive startup costs, including those associated with infrastructure and lengthy regulatory and approval processes, are challenges to building or expanding manufacturing capabilities. Some manufacturers face reduced incentives to upgrade equipment, improve supply chains, or expand capacity,[vii] which contributes to dependency on a limited group of suppliers. Critical domestic environmental protections that safeguard public health and welfare, including the health and welfare of communities adjacent to manufacturing facilities, do not always exist in foreign supply chains. Subpar environmental and public health protections result in lower production costs that allow offshore competitors to undercut U.S. products.

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[7] "Economies of scale exist when increased size of production capacity results in lower unity costs," Daniel J. Alesch and L. A. Dougharty, Economies-of-Scale Analysis in State and Local Government, accessed February 10, 2022.
[8] Push-based supply chains ship products from the manufacturing site to retailers based on anticipated demand. Pull-based supply chains are demand-driven rather than prediction-based, *National Strategy for a Resilient Public Health Supply Chain*, accessed February 10, 2022.

In addition, equipment for capital expansion of production lines is often produced overseas, which complicates rapid industrial expansion.

Lack of Visibility and Coordination: Federal and state, local, tribal, and territorial (SLTT) authorities need to better understand supply chain networks and improve coordination, including in storage and transportation, to mitigate supply chain challenges in the future. Suppliers and private industry constitute a complex web that make up part of the public health supply chain. Purchasers do not always know the origins of all goods.[viii] Various factors can contribute to the maldistribution of finished drug and PPE products, including wholesale distributors and manufacturers not knowing whether purchases reflect clinical need or are being made in anticipation of possible shortage in the future. As a result, purchasers may acquire drug and PPE products in excess of clinical need, thereby exacerbating or creating unnecessary shortages. The lack of coordinated efforts can also lead to purchasing without a wide range of efficacy and reliability, resulting in increased supply chain risks due to counterfeit products, unvetted suppliers, and more.

Strengthening the Supply Chain & Industrial Base

HHS performs a vital role in the public health supply chain and industrial base. It does this in part by leveraging its convening power to bring stakeholders together to monitor and improve public health supply chains. HHS agencies and offices work, often in collaboration with other departments, such as the Departments of Defense (DoD), Commerce (DOC), and Labor (DOL), to address cross-cutting supply chain challenges and to strengthen the public health supply chain to ensure the United States has the resources it needs to prepare for and respond to public health emergencies. HHS accomplishes these responsibilities by contributing to the advanced development of critical MCMs; acquiring, stockpiling, and distributing needed public health supplies; implementing regulatory standards; and partnering and communicating with industry and other stakeholders to enhance supply chain visibility and to develop solutions to supply chain challenges.

In addition, HHS, ensures medical products are safe for the American public to use. The Centers for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health (NIOSH) tests and approves respirators to ensure they meet regulatory standards and conducts studies on other PPE types to inform implementation guidance and performance specifications for voluntary consensus standards.[ix] The Food and Drug Administration (FDA) ensures medical devices, drugs, and biological products, including vaccines, are safe and effective before they are approved for use by the public. FDA's shortage prevention programs and generic review processes help ensure that essential medical products are available and accessible to the people who need them. FDA advances public health by helping to speed innovations that make public health products more effective, safer, and affordable, by bringing efficiencies to the drug development and review process and promoting robust competition for established drugs, and by providing accurate, science-based information to the public.

Current Actions to Build Public Health Supply Chain Resilience

HHS's role in the public health supply chain has grown and is increasing as part of the COVID-19 response. Efforts under EOs 14017 and 14001 (A Sustainable Public Health Supply Chain, issued January 21, 2021) have already galvanized a large part of the interagency to fully implement HHS and national strategies. For example, HHS is expanding the PHIB and developing innovative solutions to address critical deficiencies in the public health supply chain by working across the U.S. Government and with academia and the private sector.[x] Since the COVID-19 pandemic began, HHS and DoD have

Themes within the National Strategy for a Resilient Public Health Supply Chain include

- manufacturing and industrial base expansion (IBx) investments;
- stockpiling, allocation, and coordination;
- innovation;
- trade policy and Buy American;
- regulations, policy, and standards;
- workforce development;
- global partnerships and standards;
- governance;
- external stakeholder engagement and coordination.

collaborated on more than $4B of investments to increase domestic production of MCMs to provide a reliable supply chain of medical products and to reduce risk to industry partners by connecting their products with actual customers in the government and the private sector. Stability is essential if the Nation is to count on the private sector to invest in innovations, new facilities, and an expanded workforce. These improvements in domestic manufacturing must occur across the entire supply chain; the companies involved want to know there will be enough demand now and in the future to sustain these expansions.

HHS is implementing recommendations outlined in the *National Strategy* to address critical gaps in the public health supply chain. Each recommendation is tied to specific interagency actions to mitigate root causes and bolster domestic manufacturing resilience. Recommendations that affect the entire public health supply chain—including PPE and DME, testing and diagnostics, and pharmaceuticals and vaccines—and related activities are outlined below.

Manufacturing and Industrial Base Expansion Investments

Create Public Health Industrial Base and Supply Chain Management Program: HHS is consolidating IBx and DPA-related activities into a new program office in 2022 to align resources and strategic intent to build domestic manufacturing capacity. This new IBx office will work with industry to identify levers to support domestic manufacturing. Subsequent efforts will focus on industrial base partnerships, emphasizing a sustainable and diverse manufacturing portfolio to mitigate a future public health emergency.

Establish DPA Title III[9] Program to build domestic industrial resources: HHS's DPA Title III Program will launch in Summer 2022 as part of broader Departmental efforts to strengthen the public health supply chain and to enhance industrial base capabilities. Dedicated to ensuring the timely availability of essential domestic industrial resources to support national defense, homeland security, and emergency preparedness requirements, the DPA Title III Program will target investments to sustain critical production, commercialize research and development investments, and scale emergency technologies to enhance or expand domestic PHIB capabilities.

The program will work in partnership with key internal and external stakeholders—including HHS offices, interagency partners, and industry—to identify areas where critical industrial capacity is lagging or non-existent. It will help reduce the Nation's reliance on foreign supply chains, ensure the integrity of materials supplied to the American people, and enhance national defense. The program is one of the key investment tools for HHS and the U.S Government to prepare for and respond to future public health and other threats to the national defense.[10]

[9] DPA Title III is dedicated to ensuring the timely availability of essential domestic industrial resources to support national defense and homeland security requirements, accessed January 24, 2022.
[10] For the purposes of the DPA, the definition of national defense includes military and energy production, military or critical infrastructure assistance to any foreign nation, homeland security, space, stockpiling, emergency preparedness activities under The Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C 5195 et seq.), and critical infrastructure protection and restoration, accessed February 16, 2022.

Identify Mechanisms for Sustainable Funding: HHS is building sustainable funding streams for IBx and supply chain activities. For example, the Critical Supply Chain Resilience Program (CSCRP) at DOC provides HHS with additional financing mechanisms to promote resilience for designated critical products in the face of supply chain risks. The DPA Title III Program will establish the necessary authorities and mechanisms to allow the CSCRP to be used for PHIB management. This funding will support extended long-term contracts, on-hand inventory, vendor-managed inventory, and ensure sufficient manufacturing capacity such that the U.S. Government could trigger procurement or production of critical supplies at the start of a public health emergency.

Build Visibility: HHS is building and improving end-to-end visibility of the supply chain, including through the Supply Chain Control Tower (SCCT)[11] and the FDA's Resilient Supply Chain and Shortages Prevention Program, administered by the Center for Devices and Radiological Health.[12] Enhancing supply chain surveillance and monitoring will enable earlier identification of concerns, issues, and challenges and help bring this information to leadership and relevant agencies sooner than might have been possible before. HHS is developing conceptual frameworks to support informational needs, recruiting staff with supply chain and data analytic skillsets, and employing technical integration of existing data platforms and designs for future growth.

Currently, the SCCT has eight distributors who voluntarily provide limited data about the supply of five PPE categories, 30+ pharmaceuticals, and other medical products on a near-daily basis. The SCCT receives data from distributors who represent 80 to 85 percent of the volume for the commodities it is tracking, and the total number of distributors varies by commodity. HHS Protect ingests and normalizes the data to create reports and dashboards that provide unprecedented visibility into commercial supply chains. The SCCT has also integrated supply status from around 5,000 hospitals and 15,800 long-term care facilities. The SCCT works closely with federal partners to share information, develop capabilities, and support decision making.[13] HHS will share industry insights with the Office of Management and Budget's Made in America Office and work with procurement category managers to promote domestic sourcing in Federal procurement pursuant to Executive Order 14005 (Ensuring the Future Is Made in All of America by All of America's Workers, issued January 25, 2021).

Advance Manufacturing Technologies to Build Domestic Manufacturing Capacity: HHS recently launched efforts to enable, engage, and enhance domestic supplies of and improved access to critical drug substances and drug products, which would be subject to future review and approval. It has done this by developing and commercializing advanced manufacturing technologies to reduce overall production costs to ensure price competitiveness with foreign industry while maintaining appropriate quality standards consistent with current good manufacturing practice (cGMP). These advances include development and deployment of 1) platform technologies that enable on-demand, continuous practice (cGMP)-compliant production of pharmaceuticals, and 2) a platform technology that enables distributed

[11] The Office of the Assistant Secretary for Preparedness and Response runs the SCCT.
[12] FDA's Resilient Supply Chain and Shortages Prevention Program will enhance Center for Devices and Radiological Health's capacity to enable rapid intervention to prevent and mitigate supply chain interruptions, accessed February 16, 2022.
[13] The SCCT does not control the number of participating hospitals and long-term care facilities. It is based on the number reporting through teletracking and the CDC's National Healthcare Safety Network.

on-demand production of cGMP-compliant intravenous saline solution and other supportive care fluids. Continuing innovation, development, and commercial deployment of these platforms, including through coordination with the Made in America Office and the Manufacturing Extension Partnership, will enable distributed domestic drug substance and drug product manufacture. At the same time, these platforms will help strengthen supply chain resilience, grow the bioeconomy, and deploy increasingly renewable and sustainable pharmaceutical resources capable of immediately responding to surges in demand caused by public health emergencies.

Ensure Safe Waste Management Strategies: HHS is investing in research and development efforts to deliver safe and effective long-term waste management strategies to protect human health and the environment. HHS will work in partnership with other federal agencies to design and execute this work.

Stockpiling, Allocation, and Coordination

Transform the SNS: HHS is transforming the SNS to create a larger, more diverse, and interlinked supply chain with SLTT and private partner capabilities, which are critical to the Nation's ability to prepare for and respond to public health emergencies. This transformation requires focusing on the SNS's contents and ensuring the SNS has access to additional supplies of MCMs by expanding the domestic PHIB and integrating comprehensive supply chain solutions. HHS is leveraging creative acquisition strategies and targeted stockpiling approaches that optimize shelf-life, enhance distribution, enable product rotation strategies with health delivery facilities, and account for scarce resource allocation decisions. The SNS teams are working to increase and sustain funding and promote horizontal coordination across government, SLTT, and industry stakeholders to improve supply chain situational awareness and analytics for manufacturers.

Develop MCMs Stockpiling Plan: HHS is developing a *United States Medical Countermeasures Stockpiling Plan* to transform the U.S. Government's ability to monitor, manage, and grow the public health supply chain through stockpiles, visibility, and engagement. This plan will recommend enhancements to information sharing and ensure jurisdictional stockpiles, which are maintained by SLTT and private sector entities, employ coordinated and complementary stockpiling strategies to those maintained by the U.S. Government and private sector. This information sharing and coordination will ensure MCMs that are necessary to prevent, diagnose, and treat diseases are readily available and deployable, if needed in the future. The plan will explore alternative approaches to stockpiling MCMs, including vendor-managed inventory, as well as build strategies to develop a common operating picture of MCM stockpiles. These changes will build stronger, more resilient stockpiles across all sectors and levels of government.

National Framework for Allocation of Constrained Resources: The establishment of a national framework for SLTT planning, preparedness, and response is essential to ensure fair, equitable, and effective allocation of constrained resources. The framework would establish a shared understanding of roles, responsibilities, risks, processes, and systems required for pre-, intra-, and post-pandemic governance and management. The framework will facilitate coordinated information sharing, enable cross-jurisdictional support during public health emergencies, and ensure consistent and coordinated continuity of support.

Innovation

Speed Innovation and Development of Public Health Supplies: HHS is in the early stages of launching a virtual innovation center that will serve as a hub to speed the pace and direction of innovation for public health supplies and facilitate the processes and approvals required for manufacturing products. The innovation center will incorporate an effective organizational design, leverage novel public-private partnerships, and sustain interagency collaboration that will invigorate an underfunded sector and catalyze new technological advances in PPE and broader MCMs. A key purpose of the innovation center is to facilitate expedition of the processes and approvals required for domestic manufacturing of these products. The innovation center will provide a platform for entrepreneurs, manufacturers, and product developers to obtain early regulatory feedback, and serve as a multi-sided matchmaking platform for new domestic manufacturers to connect with SLTT and private sector end-users seeking reliable supplies of quality products, particularly during surge events when normal distribution channels are limited.

Regulations, Policy, and Standards

Promote Environmentally Sustainable Manufacturing Practices: HHS, in consultation with the Environmental Protection Agency (EPA) and the Department of Energy (DOE), will promote environmentally sustainable manufacturing practices that protect the environment and public health, including for communities adjacent to manufacturing facilities. This effort will draw on COVID-19 lessons learned to strengthen the PHIB and address the interests and needs of communities with environmental justice concerns.

Promote Ethical Production and High-Quality Product Standards: To promote adoption and enforcement of ethical production and high-quality product standards, HHS is supporting other agencies, including the Department of State (DOS), in mitigating risks caused by forced labor, counterfeits, and deficient product quality in the public health supply chain.

Workforce Development

Train and Build the Supply Chain Workforce: HHS is making strides to audit the U.S. Government's public health supply chain workforce talent and build strategies to address demands for a skilled workforce. This effort will include close coordination and collaboration with DOL to catalogue opportunities and understand functional competencies needed to train and build the workforce.

Specifically, DOL is implementing efforts to bolster the U.S. supply chain workforce with the people and skills needed for pandemic preparedness. Planning is underway to expand apprenticeships alongside the private sector to ensure a steady pipeline of talent into the industry. Additional investments support expanding existing workforce grants and programs across the interagency to strengthen job training and skill and knowledge development programs.

Global Partnerships

Leverage Global Partnerships: HHS and DOS are building a framework to leverage global partnerships to strengthen and expand the regional PHIB that complements domestic manufacturing expansion efforts to ease supply chain barriers and promote near-shore production of essential products.

Trade Policy and Buy American

Strategic Near-Shoring and On-Shoring: The Made in America Office and the DOC are coordinating efforts to foster the use of domestic sourcing, including Buy American and Berry Amendment policies, in the public and private sectors to sustain reliable domestic manufacturing capacity for critical MCMs over the long term. This requires sustaining a reliable manufacturing base, leveraging partnerships with industry and international neighbors and allies, and reviewing domestic sourcing and international procurement commitments to ensure they support U.S. supply chain capacity and resiliency. Further efforts are underway to bolster the resiliency of the healthcare sector through emergency preparedness, which the COVID-19 pandemic has shown deserves renewed focus.

Increase Competitiveness of the U.S. Economy: The U.S. Government recognizes the critical importance of producing PPE in the United States, and towards this end, is implementing Buy American provisions to expand the industrial base for domestic PPE production capacity. It is also working to increase the competitiveness of the U.S. economy through the Infrastructure Investment and Jobs Act's (IIJA) Made-in-America requirements aimed at bolstering domestic manufacturing and manufacturing supply chains.[xi] Section C of the IIJA, the "Make PPE in America Act," establishes a PPE production program requiring the Department of Homeland Security (DHS), HHS, and the Department of Veterans Affairs (VA) to secure long-term contracts (of at least two years) for domestically manufactured PPE (e.g., powered air purifying respirators, protective eyewear, and gloves) to help ensure the sustainment and expansion of domestic PPE production.

Governance

The National Security Council and National Economic Council will lead interagency efforts to coordinate existing programs that address national supply chain efforts.

Transform the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE): Efforts are under way within HHS to transform and reinvigorate the PHEMCE as a coordinating body across the interagency entities that govern or otherwise influence the supply chain to address public health supply chain issues. The PHEMCE will guide implementation of resilient public health supply chain processes based on adaptive and responsive inventory management practices for the SNS.

Develop Annual Report: HHS is actively monitoring progress of implementation for each activity within the *National Strategy* through an annual report that summarizes and assesses ongoing activities intended to increase the public health supply chain's resilience. The report will outline key recommendations to mitigate vulnerabilities and provide updates on current implementation and mitigation measures. The first annual report is expected in July 2022.

External Stakeholder Engagement

External stakeholders—including the HPH sector, regulated industry and trade groups, academia and other researchers, SLTT authorities, and non-governmental organizations—play a pivotal role in pandemic preparedness and response efforts. To realize a resilient domestic public health supply chain, the U.S. Government must continue to build partnerships with external stakeholders.

HHS aims to improve coordination and information sharing to increase government visibility into the public health supply chain. Several public-private partnership mechanisms enable transparent, real-time dialogue and data sharing between government and industry partners. HHS is engaging supply chain industry experts to partner directly with HHS and DHS to strengthen supply chain resilience. HHS is also working with external stakeholders to better identify and understand the impact of cyber vulnerabilities on supply chain and critical infrastructure functionality.

HHS will remain active and flexible to respond to dynamic supply chain priorities and support long-term viability of U.S. Government investments in supply chain industry owners and operators. For example, the Office of the Assistant Secretary for Preparedness and Response (ASPR) is promoting business models supporting sustainability in the domestic MCM enterprise and taking significant steps to protect U.S. Government capacity investments made in the last 18+ months in response to the COVID-19 pandemic. These efforts will help to strengthen and build the resilience of the public health supply chain beyond the COVID-19 pandemic. Additional activities for engaging with external stakeholders include:

Streamline U.S. Government External Engagement: HHS is coordinating across the interagency to streamline U.S. Government engagements with external stakeholders on the public health supply chain. The efforts will outline pathways to engage with external stakeholders about supply chain issues during a public health emergency and identify and address potential gaps in existing engagement platforms. HHS and FDA will coordinate with the Made in America Office and the Manufacturing Extension Partnership to connect stakeholders with domestic manufacturing support programs.

Launch 'IBx Connect' Platform: HHS values the longstanding history of the U.S. Government's connection with external stakeholders to accelerate success, as illustrated through existing platforms between the Biomedical Advanced Research and Development Authority (BARDA) at HHS, academia, and industry. HHS is reimagining the BARDA electronic platform and applying its principles to PHIB expansion and supply chain efforts through IBx Connect. IBx Connect will provide a fair and equitable platform to keep HHS and the broader U.S. Government apprised of valuable industry innovations and insights that will shape the broader IBx strategy and provide opportunities to engage with and inform industry. Beyond the IBx Connect platform, HHS is actively evaluating and identifying new ways to engage external stakeholders to promote innovations and potentially shape new policies to support domestic manufacturing capacity.

Build Capacity to Test and Evaluate Public Health Supply Chain: HHS is building capacity to test and evaluate preparedness within the public health supply chain across the whole community, including all levels of government and the private sector.

Personal Protective Equipment & Durable Medical Equipment

During a public health emergency, PPE and DME serve vital roles in protecting patients, healthcare workers, and the public. Ensuring PPE and DME are readily available for patients and healthcare workers may help prevent a public health concern from evolving into a public health emergency. In the early months of the COVID-19 response, the United States faced challenges procuring sufficient supply and effective distribution of PPE. Private, federal, and SLTT acquisition organizations struggled to procure PPE because of increased global demand. With the rush to procure supplies from a limited market, many purchasers made decisions based on PPE availability rather than on performance and quality, which resulted in delivery of incorrect or substandard products.[xii] Investments in increasing industrial base capacity has enhanced the ability to produce and acquire effective PPE.

PPE supply chain challenges extend to DME such as: oxygen equipment, continuous positive airway pressure and bilevel positive airway pressure machines, nebulizers, and other respiratory assistive devices. Most notably, ventilators were initially in short supply during the spring of 2020. By November 2020, ventilators had reached target threshold levels, and the SNS currently has more than 158,000 ventilators on hand (a ten-time increase over pre-pandemic levels) and ~25,000 high flow nasal cannula kits available for deployment, which it did not previously stock.

Current Overview

The U.S. Government's investments in key domestic manufacturing capabilities have improved the U.S. posture significantly since the COVID-19 pandemic began, both in quantities of PPE and DME stored in the SNS and domestic industrial manufacturing capacities. The most notable gaps were in raw materials, such as nitrile butadiene rubber (NBR) for pharmaceutical and medical glove manufacturing and man-made fiber for gowns and surgical masks. HHS reports and strategies highlighted the lack of raw materials, and the Department continues taking steps to address this problem.

The United States has sustained and expanded the PHIB through recent investments to ensure its viability during public health emergencies. This includes a $250M investment in expanding and sustaining the public health supply chain and industrial base to reduce dependency on foreign markets for all PPE including gloves, gowns, respirators, and raw materials. FDA has taken actions to get PPE and DME to patients and those impacted by COVID-19, including

- issuing 28 guidance documents (including 21 revisions) outlining policies to help expand the availability of medical devices needed in response to COVID-19;
- issuing Emergency Use Authorizations (EUA) or granting marketing authorization to nearly 2,000 medical devices for COVID-19-related uses;
- reviewing nearly 13,500 applications for medical product approval, clearance, or authorization between March 2020 and September 2021;
- authorizing the use of 269 PPE devices, including 51 surgical masks, 205 filtering facepiece respirators, and issuing 13 EUAs for face shields and other barriers intended to protect the user from bodily fluids, liquid splashes, or other potentially infectious materials.[xiii]

Respirators and Masks

Early in the COVID-19 pandemic, a large influx of imported respirators led the CDC to develop an abbreviated filtration efficiency test for imported non-NIOSH-approved respirators. Testing revealed that approximately 60 percent of more than 780 international respirators performed below U.S. standards. These reports helped federal, state, and user communities identify substandard and counterfeit products. CDC and FDA continue their efforts to ensure availability of respirators and masks despite the emergence of the highly contagious Omicron variant.

During the pandemic, FDA has identified and implemented agile regulatory approaches including assigning additional staff to PPE premarket reviews, issuing EUAs, and releasing guidance. FDA also continues to actively engage public health and industry stakeholders to monitor respirator supply and demand and to communicate the status of supply and mitigation actions undertaken to facilitate access. Currently, the inventory of NIOSH-approved respirators and surgical masks are higher than at the start of the COVID-19 pandemic. Globally, there are approximately 90 NIOSH-approved N95 manufacturers; most masks are produced overseas, but largely by companies headquartered in the United States. However, vulnerabilities and the possibility of sub-standard or counterfeit goods still exist.

N95 filtering facepiece respirator levels remain reactive to COVID-19 case surges. Currently, no conservation strategies are in effect and, assuming COVID-19 mitigation protocols stay in place, current models project steady demand for surgical and procedural masks in the future. Assuming max production capacity continues, monthly N95 filtering facepiece respirator production requirements can be met domestically. If industry is unable to provide additional capacity in the case of another demand surge, federal and state stockpiles can provide time for manufacturers to ramp up production. Of note, N95 filtering facepiece respirator demand is vulnerable to changing CDC guidelines and additional modeling efforts are required to visualize the impact of changes in use among the general public.

Gloves

Commercial inventories of medical-grade nitrile gloves across major distributors have risen over the last 12 months; volumes are now much higher than at the start of the pandemic. The supply chain for nitrile gloves depends on international sources for both manufacturing and key raw materials. Key medical-grade glove manufacturing is concentrated in Southeast Asia,[14] which is geographically close to the precursor raw material supply chains, such as natural rubber. The United States cannot cost effectively produce sufficient supply to meet its own demand.

Gowns

There are several types of surgical and non-surgical gowns, each with their own kind of barrier protection, complexity in manufacturing, and regulatory requirements. The global supply of medical-grade gowns could grow by billions of gowns per year due to greater supply and cost competitiveness from Asia and Europe. For certain gowns, these expansion efforts will likely satisfy U.S. demand in the

[14] The four manufacturers with the highest share of the global nitrile glove market are based in Malaysia.

near and long-term.[15] U.S. demand is expected to decrease from approximately 3.5 billion (2021) to approximately 1.4 billion gowns (ongoing demand), which is an increase from 2019 levels but a decrease from 2020-2021 levels.

Approximately 80 to 90 percent of global manufacturing of finished gowns happens in Asia and some nearshore, but companies headquartered in the United States dominate, which provides opportunities to shape industry by increasing domestic production and decreasing international reliance.

DME

DME encompasses a wide range of products that include any equipment and supplies ordered by a healthcare provider for everyday or extended use (e.g., oxygen equipment, testing equipment, wheelchairs, ventilators). Resin, a component of DME plastic equipment, experienced supply chain constraints during 2021. A series of natural disasters, including a winter storm and fires, caused power outages and plant shutdowns across the petrochemical industry in Texas and Louisiana. These shutdowns resulted in a marked decrease in the production of medical-grade resins, reducing allocations to the medical device industry. Demand fluctuations have compounded supply chain vulnerabilities created by limited suppliers and mitigation delays. Overall, resin availability for medical device and component manufacturing appears to have stabilized but will remain extremely fragile in 2022. A current exception applies to medical device packaging manufacturing, where resin-based adhesive or heat seal coating is used to create sterile barrier systems.

Current Actions to Address Supply Chain Vulnerabilities

The PHIB remains vulnerable without sustained commitment; the demand for PPE and DME will eventually decline as the threat from COVID-19 subsides, and with it the customer base for the PHIB. However, the U.S. Government has a vested interest in U.S. companies' continued marketplace viability and has made significant investments to expand PPE production capacity.

Since the start of the COVID-19 pandemic, the U.S. Government has made large investments to expand domestic industrial base capacity to meet vital PPE needs, including investments in N95 respirators (filtering facepiece and elastomeric half facepiece), surgical and isolation gowns, gloves, and raw material inputs for these items. Ongoing activities to address PPE and DME supply chain vulnerabilities and to strengthen the industrial base include:

Growing the Nation's Stockpiles: HHS works with industry and government partners to stabilize stockpile levels and enhance storage capabilities to improve the function, composition, and accessibility of the SNS. HHS led an interagency effort to address the early pandemic PPE supply shortage and resultant purchasing based on availability rather than quality or performance. The SNS, the Federal Emergency Management Agency, and SLTT governments have stockpiled more than one year's supply of N95 respirators. In addition, since the onset of the COVID-19 pandemic, NIOSH has added 30 new domestic approval holders, which have significantly added to the national inventory of respirators. The

[15] There are four levels (L1-L4) and two types (surgical and non-surgical) of gowns. The gowns market is expanding with many entrants in L2 isolation gowns and global expansion efforts in L2 and L3 disposable gowns.

SNS has awarded contracts for additional gloves, which will meet or exceed its stockpiling target by May 2022. In the future, additional PPE standards will facilitate broader access to higher quality PPE.

Advancing Domestic Raw Material Manufacturing: HHS is assessing opportunities to advance nitrile and key chemical manufacturing in the United States. In addition, HHS is seeking opportunities to facilitate warm-base manufacturing opportunities. Warm-base manufacturing refers to the capacity to be operationally ready quickly to manufacture MCMs during a response.

FDA is working to address silicone shortages. Silicone is a new area of concern in the supply chain because it is essential to medical technology manufacturing. It is in great demand because it is used to produce medical device components, on-device printed ink, and as a bonding agent in device component sealing and assembly. FDA has received and is currently investigating several silicone shortage signals. It is working to identify key silicone suppliers and will work with suppliers and manufacturers to better understand the supply chain.

Expanding PPE Research and Innovation: CDC has developed plans to expand the Nation's capabilities and capacity for PPE research and innovation via a nationwide network of personal protective technologies (PPT) Centers of Excellence (COE). It has identified PPT priority topic areas for the COEs and defined the structure for their core components: planning and evaluation, research, and outreach.

CDC has also developed plans for an aggressive Broad Agency Announcement (BAA) Program for PPT. Based on a socio-technical systems approach, the BAA uses technology developers, engineering firms, research scientists, suppliers, and manufacturers to develop and evaluate innovative designs and test methods to improve the availability, acceptability, comfort, fit, and usability of domestically produced PPE.

Improving PPE and DME Comfort, Utility, and Protective Capability: ASPR, in partnership with NIOSH and the National Institute of Standards and Technology, created the Mask Innovation Challenge to improve the comfort, utility, and protective capabilities of masks for the public to combat COVID-19 and to reduce the transmission of influenza and other common infectious diseases in non-medical settings. During the first phase, the Challenge identified 10 innovative concepts for next-generation face coverings to protect against respiratory disease pathogens.[xiv] The next phase will accelerate the development of next generation masks that have multi-hazard protection.[xv]

Preventing Counterfeit Products from Entering the U.S. Market: FDA, in coordination with NIOSH and the Occupational Safety and Health Administration (OSHA), communicated the transition away from crisis capacity strategies, such as respirator decontamination and use of non-NIOSH approved respirators.[16] NIOSH has worked to identify possible counterfeit respirators and to coordinate with federal partners such as the U.S. Customs and Border Protection Agency (CBP) and the U.S. Patent and Trademark Office to establish strategies to manage counterfeit products, such as registering the "N95"

[16] This transition ultimately resulted in the revocation of EUAs for respirator decontamination systems and for non-NIOSH approved respirators, the withdrawal of immediately in effect guidance (IIEs) related to respirator decontamination, updates to the NIOSH-approved respirator EUA, and the continued evolution of the respirator and facemask IIE.

trademark. FDA has also worked to identify possibly counterfeit PPE and works with device manufacturers and other government partners to communicate about these issues. FDA, CDC, and OSHA continue to coordinate their overlapping responsibilities and authorities about PPE, particularly respirators. A draft memorandum of understanding has been established to coordinate activities among these agencies. FDA, OSHA, NIOSH, and the CBP have worked closely together to detect and prevent counterfeit medical products from entering the market and have continued discussions as to how the agencies can continue to effectively work together to eliminate counterfeit and substandard products from entering the U.S. market. Regulations and laws, such as the Make PPE in America Act, can be used to expand domestic production and promote greater use of PPE made in the United States. Addressing the problem of counterfeit and substandard products offered for sale within the United States will ensure the domestic consumer is able to access high-quality PPE.

Analyzing Semiconductor Shortages and its Impact on Medical Devices: FDA has been working with medical device manufacturers to gain greater visibility into the semiconductor supply chain. U.S. Government outreach to device manufacturers is ongoing. In addition, FDA is actively working with ASPR and DOC to analyze the semiconductor shortage and its impact on the medical device industry, patients, and U.S. healthcare systems.

Updating PPE Standardization System: Through NIOSH, HHS is addressing and updating the U.S. PPE product standardization system to improve the efficacy, usage, effectiveness, safety, supply stability, and accessibility of PPE designed for use in U.S. healthcare settings, by critical infrastructure workers, and for general public protection to protect workers and reduce exposure to infectious diseases in workplaces and community settings. NIOSH is establishing a Product Standardization Task Force to promote innovative approaches and technologies to streamline PPE manufacturing and to address availability and standardization gaps and limitations for PPE and the technical methods, processes, techniques, tools, and materials that support PPE development.

Establishing Essential Medical Device List: FDA is leading an interagency effort that includes broad representation from public health experts and clinicians in the government, non-profit, and private sectors to develop recommendations for an essential medical device list (including device materials, components, parts, or accessories) that are clinically essential for patients, healthcare workers, and the U.S. public.

Increasing Visibility to Prevent Disruptions and Shortages: FDA is currently building a data analytics and predictive modeling platform to support visibility and prevention of supply chain disruptions and shortages of medical devices.

Planned Actions to Address Supply Chain Vulnerabilities

HHS is incentivizing domestic raw materials production of NBR and key chemicals for gloves and of man-made fiber for gowns and N95 filtering facepiece respirators through investment, public-private partnerships, collaboration with industry, regulation, and proposed legislation in order to onshore or near-shore production capacities and reduce reliance on foreign production.

The risks associated with a lack of medical-grade PPE and DME directly impact the Nation's ability to protect frontline medical professionals. The PHIB must be able to sustain operations as PPE demand drops post-COVID-19. The following are additional actions that could support these goals:

Increase Capacity Using Emerging Technologies: Invest in artificial intelligence, robotics, and automated assembly practices and technologies (e.g., shelf-life extension) for existing manufacturers, including extruders for increasing production of man-made fibers and computer numerical control/robotic automation assets for sewing and finishing gowns, and advanced humanlike headforms to expedite respirator development timelines. Industry can also use new and emerging technologies to address potential domestic and foreign manufacturing shortages and to develop a conformity assessment scheme for protecting the public during a pandemic.

Optimize Industry Collaboration: Collaborate with industry to identify untapped domestic manufacturing potential or strategies to spread end-to-end risk across manufacturers and address the lack of vertically integrated domestic manufacturers.

Stimulate and Sustain Demand: Investigate other avenues to establish domestic demand through U.S. Government partnerships, increasing stockpile inventory, and establishing a revolving fund for SNS with Buy American provisions.

Collaborate with the Interagency: Collaborate with other departments to share market intelligence or shape procurement strategies. FDA will continue to work collaboratively with U.S. Government partners, such as DOC, to stay informed about semiconductor supply chain vulnerabilities, risks, and shortages, and their impact on manufacturing of life-sustaining and life-supporting medical devices. FDA can also collaborate with other U.S. Government agencies to assess potential scalability of domestic foundries and semiconductor chip producers identified in the public DoD Trusted Foundries Program.

Ensure Strategic Contracting: Incorporate language into new contracts to require scale up of production in a specified number of days in the event of a public health emergency or other contingency response. Partner with industry to ensure continuity of distribution and delivery that anticipates supply chain disruptions in the event of a public health emergency or other contingency response.

Incentivize and Invest: Invest in and incentivize reshoring of raw materials processing, such as NBR and its key starting chemicals. Assess the potential to invest in mitigation strategies targeting the resin and semiconductor chip shortages. Planned improvements to PPE raw materials capacity include investments in key chemicals for NBR, N95 respirators (filtering facepiece and elastomeric half facepiece types), and medical gown production. These strategies and investments have the potential to greatly strengthen the PHIB, ensure a viable economic base, and could be quickly executed.

Testing & Diagnostics

The supply chain for testing, including diagnostics, is complex and global, requiring materials from both domestic and foreign sources, thereby risking possible disruption. Once shipped to the United States, raw materials are utilized to generate test kits and other reagents for use in both closed and open diagnostic systems. Early in the pandemic, shortages of a few common raw materials (e.g., swabs, test reagents) gave way to more widespread shortages of a variety of testing components and consumables (e.g., pipette tips, antigen test strip), secondary to resin and nitrocellulose shortages. Many companies manufacture testing instruments and consumables internationally and ship them to the United States for assembly and kitting. Shipping logistics and skilled labor challenges are exacerbating supply chain issues for testing and diagnostic materials.

When the pandemic first began, no tests for COVID-19 existed. CDC and the private sector worked quickly to meet rapidly growing demand, and as of January 2022, there are two categories of tests—diagnostic and antibody tests—produced by several different manufacturers. FDA has authorized the use of a number of tests under EUA, including individual EUAs for molecular, antigen, antibody and other adaptive immune response tests for COVID-19.[xvi] Different tests may be conducted in a laboratory, healthcare setting, or completed at home and may vary in accuracy and speed. As the pandemic has evolved, the demand for tests has also changed. Since the beginning of the COVID-19 pandemic, the testing and diagnostic supply chain has been stressed and some of these challenges remain with acquiring, producing, and distributing almost all components of the testing supply chain.[xvii]

Current Overview

Testing supply chain limitations have largely arisen from molecular tests carried out in central laboratories. These tests are highly complex and require specialized equipment. They also involve numerous steps, including sample collection, storage, and transport; sample preparation, including extraction of nucleic acid; and sample analysis and processing. The number of end-to-end steps and actions involved with these tests illustrates the complexities and challenges associated with the testing supply chain.

In vitro diagnostic devices (IVDs), for both COVID-19 and other diseases, are made by a variety of test developers, including conventional manufacturers and laboratories. Manufacturers are in a variety of locations, including in the United States, Europe, China, India, and other countries. IVDs cover a wide range of devices spanning different diseases, conditions, and patient populations.

Despite the current challenges and limitations, HHS has achieved notable successes. As of January 2022, FDA has authorized 423 tests and sample collection devices for SARS-CoV-2 under EUA, including

- 291 molecular tests and sample collection devices;
- 87 antibody and other immune response tests;
- 45 antigen tests;
- 1 molecular and 3 antigen prescription at-home tests;
- 69 molecular and 1 antibody authorization that can be used with home-collected samples;
- 14 antigen and 3 molecular over-the-counter at-home tests;

- 25 antigen tests and 9 molecular tests for serial screening programs.

FDA has also authorized 783 revisions to SARS-CoV-2-related EUA authorizations.

Current Actions to Address Supply Chain Vulnerabilities

To stabilize test production rates and related supplies and to reduce vulnerabilities associated with import delays, increased costs, and offshore sourcing, the U.S. Government has

- funded capital purchases to build, expand, and improve production of test kits and supplies, such as swabs and reagents;[17]
- improved coordination and information sharing with test suppliers to help sync production capacity with demands;
- funded test manufacturers and their supply chain to onshore production of tests, test kit components, and reagents from non-domestic manufacturing plants.

HHS is working to expand U.S.-based manufacturing of point-of-care molecular tests to avoid importing the supplies and materials used in the tests. This work supports jobs for American workers, boosts the U.S. economy, and increases access to point-of-care molecular tests.

Modeling Testing Demand: As of March 2021, the Pandemic Testing Board's Work Group on Supply and Distribution has been defining principles and strategies to achieve sufficient testing and upstream supply production. Since then, their demand model has been enhanced to explore simultaneous scenarios, such as high and low vaccination rates, high and low screening, high and low transmissibility, and high and low vaccine escape. Over-the-counter testing supply and demand are explored separately from laboratory testing supply and demand.

Increasing Testing Capability: Since June 2020, the U.S. Government has invested in increasing the production of COVID-19 tests from 40 million per month to 257 million tests per month in September 2021 to over 400 million per month in December 2021. Demand for COVID-19 tests continued to rise in the last quarter of 2021 coinciding with the Omicron surge. U.S. Government investments in rapid antigen test production have incentivized the market to produce more tests. With COVID-19 case surges and testing mandates, HHS investments are addressing the demand for lab-based tests, point-of-care tests, and at-home tests.

Expanding At-Home Testing: Beginning in February 2021, the U.S. Government has used the DPA, industrial mobilization, and advance purchase commitments to ramp up supply of testing, including at-home, rapid tests. Advance purchase commitments allowed domestic testing manufacturers to increase production, add factory lines, increase staffing, and move up manufacturing timelines. As a result, the United States went from 24 million at-home, rapid tests on the market in August 2021, to 46 million in

[17] The Small Business Administration continues to reexamine its current suite of loan products designed to support small businesses in facing supply chain challenges. It currently offers 7(a) and microloan programs, which provide businesses with up to $5 million for working capital and capital purchases such as equipment and real estate. It also offers the 504 program which can support larger real estate and equipment purchase beyond the $5 million 7a program limit.

October, to 100 million in November, to over 300 million in December, to 375 million in January 2022. U.S. Government investments in at-home tests guarantee a specific number of tests will be bought and paid for, which provides stability to the supply chain.

In December 2021, the U.S. Government announced plans to expand free at-home testing by purchasing one billion tests to be distributed to the U.S. population. In January 2022, the U.S. Government made 500 million at-home tests available for order online at no cost to the customer. It also announced employment-based group health plans and private health insurance companies will be required to expand coverage of at-home COVID-19 tests without cost sharing. In February 2022, the Administration announced Medicare will cover over-the-counter tests. The U.S. Government also plans to distribute 50 million at-home tests through neighborhood sites, community providers, and rural clinics. These actions provide much needed assistance to those who lack the financial means to pay for testing or for whom accessing testing sites is difficult. The United States is on track to quadruple the supply of rapid at-home tests as compared to Summer 2021 levels. [xviii]

Accelerating Diagnostics: The National Institutes of Health (NIH), in conjunction with other U.S. Government agencies, established the Rapid Acceleration of Diagnostics (RADx®)/Advanced Technology Platforms. The purpose of this program is to speed innovation in the development, commercialization, and implementation of technologies for COVID-19 testing. [xix] The program funds the development and maturity of COVID-19 diagnostic technology up to the point when it is ready to be accelerated to market and supports the validation and scale-up of manufacturing capacity.

Planned Actions to Address Supply Chain Vulnerabilities

The United States needs continued innovation, research, and development in testing and diagnostics. This includes advances in at-home testing and data collection and analysis, which could be leveraged now and during future large-scale infectious disease outbreaks. [xx] There is a need to encourage and enable greater innovation to improve testing technology and lower the cost of testing, so tests will be available to all who want them.

Invest in Testing Kit Research and Development: Investing in test kit research and development may increase test availability. Lowering the cost of the starting components through development of new manufacturing processes could help reduce test kit costs. Research into improving the shelf-life of tests and their reagents could lead to a shelf-life extension, allowing unused tests and materials to remain on shelves longer.

Increase Test Component Interchangeability: The interchangeability of non-patented test components would assure vendors are producing interchangeable supplies, increase volume of common components, and reduce spot shortages. Improving human capital through training and education, while a difficult challenge, could improve test production, and warrants further investigation.

Ensure COVID-19 Testing Capacity: The U.S. Government will continue to invest to ensure sufficient COVID-19 testing capacity. It will accomplish this through stockpiling tests and testing supplies while simultaneously working closely with the industrial supply chain. HHS will prioritize warm-base production capacity that will allow test, component, and reagent suppliers to quickly scale up

production during surges in demand. The U.S. Government is also planning investments to help reduce the costs of tests, broaden detection capabilities to include multiple viruses and pathogens, increase production, and make tests more widely available. The U.S. Government plans to invest further in training and human capital.

Fortifying a robust testing and diagnostics supply chain will ensure that tests and diagnostics are ready to be developed, deployed, and analyzed during future public health emergencies.

Pharmaceuticals & Vaccines

Pharmaceuticals and vaccines play key roles in protecting the U.S. public's health. Disruptions to the pharmaceutical and vaccine supply chains can affect the United States' ability to reduce morbidity and mortality during public health emergencies by reducing access to critical drugs needed to treat patients and preventing effective partnerships with the private sector to develop and distribute vaccines. The United States must develop and implement strategies to mitigate risks and vulnerabilities in these supply chains and strengthen domestic manufacturing capabilities to ensure patients have access to lifesaving treatments, especially during public health emergencies.

Current Overview

A robust pharmaceutical supply chain should include

- the capability to domestically manufacture certain high-quality products for U.S. consumption;
- diversification of the drug supply chain;
- redundancy of the supply chain (e.g., having multiple manufacturers for each product and its precursors).[xxi]

At present, the U.S. Government has limited visibility into the supply chain for most pharmaceuticals. Locations of API manufacturers for FDA-approved or authorized prescription drugs are better known than those for over-the-counter products. Information about the volume of pharmaceuticals and APIs manufactured is hard to come by because not all approved sites are continuously active. Therefore, data is not collected in a way that clearly describes current end-to-end production.

Key Starting Materials (KSM): The U.S. Government has relatively limited information about KSM supply chains. Little KSM manufacturing takes place in the United States; in addition to wage differences, certain foreign suppliers are not subject to the same environmental and public health protections as manufacturers in the United States and can produce KSM at lower costs than U.S.-based manufacturers. Overall, insufficient data are available to the U.S. Government, due to confidentiality practices among API manufacturers and KSM suppliers, so it is difficult to properly understand and assess supply chain vulnerabilities.

Finished Dosage Form (FDF): Some FDF manufacturing occurs in the United States. HHS expanded industrial base capacities for many drugs facing bulk production and fill-finish bottlenecks by examining the market influences across pharmaceutical supply chains and initiating direct investments in platform technologies and additional fill-finish capacity. HHS established on-demand manufacturing capabilities for API and fixed-dose formulation drugs.

Therapeutic Development: During the COVID-19 response, new therapeutic development focused in part on mAb therapeutics. These require some of the same resources—such as glass vials—as vaccines to produce. Although there are currently no problems producing mAbs themselves, production is limited because of the difficulty in acquiring the glass vials required to deliver and administer these therapeutics to patients. This results in mAb shortages for the public.

In addition to mAbs, there are several other COVID-19 treatments being studied, including

- 50+ antivirals;
- 60+ cell and gene therapies;
- 130+ immunomodulators;
- 60+ neutralizing antibodies;
- 110+ other single agent treatments;
- 40+ combination agent treatments.

Vaccines: Although not unique to vaccines, building capacity to manufacture biologic products, including messenger RNA vaccines and mAbs, has led to the development of innovative manufacturing platform technologies that improve flexibility, mitigate cross-contamination risk, and reduce time and cost of cleaning between manufacturing campaigns.

FDA continues to use every tool available to help facilitate the development and availability of vaccines and other biological products to combat the COVID-19 pandemic expeditiously and safely. FDA is working on many efforts to address the COVID-19 pandemic, such as

- helping to expedite development programs for vaccines and certain therapeutic biological products that hold promise to prevent or treat COVID-19 by providing timely interactions, scientific advice, and recommendations for individual sponsors and through issuance of guidance documents;
- supporting product development and facilitating the scaling up of manufacturing capacity for high priority products to treat COVID-19 and conducting timely reviews;
- expediting the review of EUA requests and Biologics License applications for vaccines and other critical medical products to address COVID-19, including the evaluation of booster doses of COVID-19 vaccines and the use of COVID-19 vaccines in certain pediatric populations;
- helping to ensure an adequate and safe blood supply;
- providing information to healthcare providers and researchers to help them submit expanded access investigational new drug application requests to permit the use of the FDA-regulated investigational products for patients with COVID-19.[xxii]

Current Actions to Address Supply Chain Vulnerabilities

Investments to address API and KSM supply chain vulnerabilities include domestic, direct production of APIs, including fine chemicals and catalysts, both more prevalent in U.S. pharmaceutical production, and biologically derived APIs produced for antibiotics. HHS investments to date stand at $105M resulting in prototypes for increased capacities for drug products at more than 600 million doses for six medicines in shortage. HHS is working to identify current product shortages, anticipate future shortages, and determine where and by whom the products are manufactured. HHS will then institute mitigation measures to ease or eliminate the shortages through investments to bolster domestic production.

Developing Essential Medicines List: In 2021, HHS assembled several consortia of public health experts and clinicians in the government, non-profit, and private sectors to review the FDA Essential Medicines

List[18] and recommend 50 to100 drugs that are most critical to have at all times due to clinical need and lack of therapeutic redundancy. An evaluation of the critical drugs list is underway to identify vulnerabilities for those items, which will define strategies to ensure domestic supply and production of essential medicines.

HHS is working with interagency partners, through industrial-based assessment and inquiries, to identify APIs that are at risk and critical to drug manufacturing. HHS is also investing in technology and infrastructure development to improve domestic capacity to produce APIs for a variety of essential medicines.

Partnering with the National Academies: Congress directed HHS to partner with the National Academies of Sciences, Engineering, and Medicine to assess the security and resilience of the U.S. medical products supply chain. The Committee on Security of America's Medical Product Supply Chain was tasked with assessing U.S. reliance on critical drugs and devices sourced or manufactured outside the United States and making recommendations to strengthen the medical products supply chain by addressing these dependencies.[xxiii] To examine critical dependencies within the supply chain, the committee held information-gathering sessions throughout 2021. The purpose of these sessions was to understand the end-users' definitions of essential medical devices, the formula for creating essential medical devices lists, and the impact these lists have on decision-making in order to inform strategies to mitigate the impact of failures in the medical product supply chain.[xxiv] Further exploration of this topic is now ongoing.

Partnering with the Interagency: In partnership with the Defense Advanced Research Projects Agency and the U.S. Air Force, two efforts are underway for drug substance and drug product production. The combined investments of approximately $105M are enabling advanced continuous synthesis of APIs, in support of cGMP-compliant manufacture of sterile injectable analgesics and sedative medications. The filing of an abbreviated new drug application with the FDA is planned during Q1 2022 for producing one of these drugs using these new methods.

Advancing Manufacturing Capabilities: HHS is investing in the development of advanced manufacturing capabilities to lower the cost of domestic manufacturing of critical supplies. Additional innovations will spur development and deployment of novel manufacturing platforms; the scale-up of these technologies will help develop the domestic pharmaceutical industry. This work will address the critical need to onshore the production of drug products and drug substances. Once established, it will be critical to sustain this new domestic pharmaceutical ecosystem. HHS will try to catalyze domestic pharmaceutical development by enabling factors to enhance competitiveness. These efforts include, but are not limited to, increasing technological efficiencies (e.g., automation) in pharmaceutical processes to decrease costs in production, enabling process intensification and scale-up, and improving data sharing and security to maximize collaboration and minimize redundancy in research and development efforts. To accomplish these goals, it is necessary to strengthen partnerships with private partners and within

[18] FDA Publishes List of Essential Medicines, Medical Countermeasures, Critical Inputs, Required by Executive Order, accessed on January 24, 2022.

government, including those presently engaged in fostering development and deployment of advanced manufacturing platforms.

Gains in automation and improvements in efficiencies will not reduce the need for skilled labor, but instead will create employment opportunities throughout the supply chain. The gains and improvements will also enhance workers' safety by reducing exposure to hazardous environments and ensuring an enterprise that is safe, highly productive, and sustainable. Although these activities will expand the ability to produce critical medicines domestically and increase competitiveness, without further effort vulnerabilities will persist.

In addition, ASPR[19] has begun to establish a consortium with partners across the drug and vaccine manufacturing supply chain, including manufacturers of raw materials and consumables and suppliers of fill-finish services, to transform and build core capabilities for biodefense. The initial effort focuses on MCM manufacturing and the role that public-private partnerships can play in strengthening the Nation's biomanufacturing infrastructure. It will support ongoing efforts to expand the industrial supply chain for MCM production, manufacturing, and implementation. The consortium's goal is to establish the physical infrastructure, manufacturing platforms, and supply chains capable of producing enough vaccines for the entire U.S. population within 130 days and the global population within 200 days after recognition of a potential emerging pandemic threat. It expands the ability to domestically produce the therapeutics and vital supplies to halt future pandemics.[xxv]

Creating a Rating System for Quality Management Maturity (QMM): HHS and FDA are constructing a program for a rating system to incentivize drug manufacturers to invest in achieving QMM and sustainable compliance.[20] The program's purpose is to recognize manufacturers that develop mature quality management practices, which focus on continuous improvement, business continuity plans, and early detection of supply chain issues. To build this program, FDA has engaged with purchasers, pharmacies, and other federal agencies. FDA has executed two pilot programs, one for domestic manufacturers producing FDFs and one for foreign manufacturers producing API, to develop an assessment framework that can be used to rate the maturity of observed quality management practices at participating sites.

Detecting and Managing Supply Chain Disruptions: FDA continues to build on current drug shortage initiatives by leveraging available data, improving its visibility across business partners, and identifying data gaps needed to improve supply chain oversight. FDA's Center for Drug Evaluation and Research (CDER) has recently established the Pharmaceutical Supply Chain Governance Board to facilitate and coordinate all supply chain initiatives across CDER and provide strategic guidance on major supply chain issues.

[19] BARDA's Biopharmaceutical Manufacturing Consortium (BioMaC) Industry Day held on January 20, 2022.
[20] QMM and cGMP compliance are distinct concepts, although sometimes correlated. QMM approaches align with cGMP compliance, but QMM also incorporates additional distinct elements.

Allocating and Distributing Pharmaceuticals: HHS, through the HHS Coordination Operations and Response Element (H-CORE)[21], is overseeing the allocation of mAbs on a state and territorial-level basis. Post allocation, HHS will continue to monitor therapeutic ordering and utilization at the facility and state levels to prevent excessive stockpiling and wastage of therapeutic inventory. HHS is planning for the distribution of molnupiravir [xxvi] and is monitoring inventory levels, which will allow for earlier detection of supply disruptions and shortages.

Stopping Unlawful Products: FDA has issued more than 260 warning letters on the selling of unlawful, unproven products billing themselves as effective for the treatment, diagnosis, or prevention of COVID-19. In coordination with CBP, FDA has destroyed almost 85,500 violative products, totaling over 15,050,242 capsules, tablets, and other dosage forms of violative drugs. [xxvii]

Coordinating Vaccine Supply Chain with Industry: Currently, three COVID-19 vaccines have been authorized by FDA for emergency use under EUAs, and two of these three have been licensed for use in certain populations. These vaccines require similar resources needed to manufacture other vaccine candidates that are still completing clinical testing. Balancing these priorities across the supply chain requires successful coordination between the federal government and private industry. Much of this activity has been channeled through the H-CORE. The Federal COVID-19 Response Team and HHS have formulation and fill-finish manufacturing models for each vaccine candidate aligned to known final package format across a network of U.S.-based capacities. Vaccine capacity is primarily domestically based; however, HHS monitors the supply chain for critical components. Overall, vaccine demand will depend on a number of factors, including the impact of variants.

Planned Actions to Address Supply Chain Vulnerabilities

HHS will continue to invest in technology and infrastructure development to improve domestic capacity to produce APIs used for a variety of essential medicines. This includes technologies that will result in more sustainable production techniques, more efficient manufacturing systems, and burgeoning research such as the use of biosynthetic pathways to potentially reduce the supply chain footprint. The workforce at all levels of research and development as well as manufacturing is limited and requires additional personnel.

Work with Global Partners: The U.S. Government is proposing conversations with global partners to ensure cooperative agreements and near-shore capacities are available to diversify and sustain the supply chain, especially in times of crisis.

Expand Manufacturing Capacity: HHS plans to further invest in infrastructure to expand manufacturing capacity for single-use assemblies and the capacity expansion of domestic raw materials and special

[21] Previously known as the Operation Warp Speed and the Countermeasures Acceleration Group.

enzymes. It will invest $2.65B across three portfolio areas: vials,[22] fill-finish,[23] consumables and raw materials. These investments will reduce risk to the vaccine supply chain and enable effective response to future public health emergencies without reverberation through existing biotherapeutic markets.

There is an opportunity to use end-to-end continuous manufacturing for both API and drug product manufacturing. Continuous manufacturing offers the potential to reduce drug shortages and increase or maintain quality standards, while keeping the industrial base globally competitive in this market. There are also a variety of novel analytical and drug production technologies that may be utilized in this area, including portable and modular manufacturing platforms (e.g., pharmaceuticals on demand), and using 3D-printing technologies for solid dosage forms.

Leverage Data: Provisions in the Coronavirus Aid, Relief, and Economic Security (CARES) Act will allow FDA to gather data related to quantities of API and FDF released for commercial distribution. This data may improve future analyses by increasing transparency into the upstream supply chain and provide a more complete understanding of key manufacturers based on market share. Although reported annually, this will improve FDA's awareness of potential issues before shortages arise, and domestic infrastructure investment could be prioritized based on criticality of an essential medicine as well as supply chain resiliency.

Although ongoing efforts address different parts of the vaccine supply chain, they do not address every tier of the component parts, such as suppliers of sand for glass and chemicals for lipids and nucleotide synthesis. In addition to stockpiling vaccine, there is opportunity to stockpile raw materials and other materials for vaccine development. Research is needed to determine feasibility of this approach, including additional factors that would need to be considered such as product expiration and usability of the stockpiled materials in different scenarios. Stockpiling consumables may prove more feasible than bioactive materials, although consumables have expiration dates. Vendor-managed inventory can also be considered, with vendors licensed to sell off supply at determined intervals. Consideration can also be given to alternatives to physical storage, including virtual stockpiles,[24] whereby regular inventory buffer distributed across the supply network can by shifted as needed during a contingency response.

[22] Biopharmaceutical surge capacity to enable production of 600 million vaccine doses within six to nine months requires a surge capacity of between 800 million and 1 billion vial containers.

[23] Seeks to expand existing domestic-based aseptic fill-finish manufacturing capacity for MCMs during a public health emergency. Expansion of fill-finish facilities enables development and scale-up of vaccine products during a public health emergency.

[24] "The idea of [virtual stockpile pooling] is to first integrate the stockpile into several locations' regular inventory buffers and then dynamically reallocate the stockpile among these locations in reaction to the demand realizations to achieve a kind of virtual transshipment," Fang Liu, Jing-Sheng Song, and Jordan D. Tong, "Building Supply Chain Resilience through Virtual Stockpile Pooling," May 2, 2016, accessed January 25, 2022.

Conclusion

The COVID-19 pandemic has significantly tested the U.S. public health supply chain and industrial base. At the beginning of the COVID-19 response, shortages of PPE and DME and an absence of testing and diagnostics hampered efforts to combat and contain the spread of the virus. These challenges highlighted pre-existing issues in the public health supply chain and industrial base, such as the lack of on- or near-shore manufacturing and sourcing for raw materials and finished medical products. Unless the U.S. Government takes action to create a more resilient public health supply chain, we may experience similar disruptions during a future public health emergency.

Despite the challenges encountered since early 2020, the United States has made great progress to shore up the public health supply chain and to address concerns regarding domestic manufacturing and supply chain surge capabilities. The U.S. Government has invested in efforts to fortify the domestic supply chain, rebuild the SNS, and expand and strengthen the PHIB. The increase in COVID-19 test production from 40 million per month in June 2020 to over 400 million per month in December 2021 is just one example of the success of these investments. The U.S. Government increased visibility and insight into the public health supply chain. Through collaboration and coordination with federal, SLTT, and private sector partners, the U.S. Government will continue to expand its visibility and awareness of potential public health supply chain challenges.

This report is a snapshot of where the public health supply chain stands as of February 2022. It complements earlier reports including the *National Strategy*, the *100-Day Report*, and the *American Pandemic Preparedness: Transforming Our Capabilities Report*. These documents outline the U.S. Government's efforts and commitment to ensuring that the United States has the critical resources it needs to protect the American people.

These reports are only meant to be a foundation for building public health supply chain's resiliency. The U.S. Government continues to work in this area. The White House is leading federal efforts to identify strategies to address supply chain vulnerabilities, including those described in the *National Strategy*. As part of that, ASPR is leading the development of an annual report, which will provide annual updates on the challenges, developments, and opportunities for the public health supply chain. In addition, as directed by the National Defense Authorization Act for Fiscal Year 2022, a progress report will be submitted by the President to Congress annually through 2025, providing updates and evaluations of the strategy on securing supply chains for medical materials.[xxviii] In a similar vein, a White House-led effort to establish Biodefense Goals will complement the work underway to address the *National Strategy* actions.

The actions outlined in this report will better ensure U.S. preparedness for the next public health emergency. Whether the public health supply chain is disrupted by another global pandemic, a weather event, or economic disruption, strengthening how the United States anticipates and manages challenges will make the Nation more resilient and better prepared for future public health emergencies.

List of Acronyms

API	Active Pharmaceutical Ingredient
ASPR	Assistant Secretary for Preparedness and Response
BAA	Broad Agency Announcement
BARDA	Biomedical Advanced Research and Development Authority
CARES	Coronavirus Aid, Relief, and Economic Security Act
CBP	U.S. Customs and Border Protection
CDC	Centers for Disease Control and Prevention
CDER	Center for Drug Evaluation and Research
cGMP	Current Good Manufacturing Practice
COE	Centers of Excellence
COVID-19	Coronavirus Disease 2019
CSCRP	Critical Supply Chain Resilience Program
DHS	Department of Homeland Security
DME	Durable Medical Equipment
DOC	Department of Commerce
DoD	Department of Defense
DOE	Department of Energy
DOL	Department of Labor
DOS	Department of State
DPA	Defense Production Act
EO	Executive Order
EUA	Emergency Use Authorization
FDA	Food and Drug Administration
FDF	Finished Dosage Form
H-CORE	HHS Coordination Operations and Response Element
HHS	Department of Health and Human Services
HPH	Healthcare and Public Health
IBx	Industrial Base Expansion
IIJA	Infrastructure Investment and Jobs Act
IVD	In Vitro Diagnostic
KSM	Key Starting Material
mAb	Monoclonal Antibody
MCM	Medical Countermeasure
NBR	Nitrile Butadiene Rubber
NIH	National Institutes of Health
NIOSH	National Institute for Occupational Safety and Health
OSHA	Occupational Safety and Health Administration
PHEMCE	Public Health Emergency Medical Countermeasure Enterprise
PHIB	Public Health Industrial Base
PPE	Personal Protective Equipment

PPT	Personal Protective Technologies
QMM	Quality Management Maturity
RADx	Rapid Acceleration of Diagnostics
SCCT	Supply Chain Control Tower
SLTT	State, Local, Tribal and Territorial
SNS	Strategic National Stockpile
VA	Department of Veterans Affairs

Bibliography

Alesch, Daniel J. and L. A. Dougharty, "Economies-of-Scale Analysis in State and Local Government," Santa Monica, CA, *RAND Corporation*, 1971. Accessed February 10, 2022. https://www.rand.org/pubs/reports/R0748.html.

Assistant Secretary for Preparedness and Response (ASPR). "ASPR Program Office for Innovation and Industrial Base Expansion (IBx)." Accessed January 3, 2022. https://www.phe.gov/about/offices/program/icc/sppr/apo-ibx/Pages/default.aspx.

ASPR. "COVID-19 Therapeutics." Accessed January 28, 2022. https://www.phe.gov/emergency/events/COVID19/therapeutics/Pages/default.aspx.

Biomedical Advanced Research and Development Authority (BARDA). "BARDA and HHS to host National Biopharmaceutical Manufacturing Consortium (BioMaC) Industry Day." Updated January 12, 2022. https://www.medicalcountermeasures.gov/newsroom/2022/biomac/.

BARDA. "BARDA-NIOSH Mask Innovation Challenge Selects 10 Winning Concepts for $10,000 Phase 1 Prizes." July 2, 2021. https://www.medicalcountermeasures.gov/stories/maskchallenge/.

BARDA. "BioMaP Consortia RFI Final Document." October 21, 2021. https://www.medicalcountermeasures.gov/media/38403/barda-rfi-biomap-consortium.pdf.

BARDA. "Mask Innovation Challenge: Phase 2." Accessed January 5, 2022. https://drive.hhs.gov/mask-innovation-challange.html.

Centers for Disease Control and Prevention (CDC). "COVID-19 Vaccinations in the United States." COVID Data Tracker. Accessed January 5, 2022. https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total.

CDC. "Personal Protective Equipment." The National Institute for Occupational Safety and Health. Accessed January 3, 2022. https://www.cdc.gov/niosh/ppe/default.html.

Cybersecurity & Infrastructure Security Agency. "Defense Industrial Base Sector." Critical Infrastructure Sectors. Accessed February 16, 2022. https://www.cisa.gov/defense-industrial-base-sector#:~:text=The%20Defense%20Industrial%20Base%20Sector,to%20meet%20U.S.%20military%20requirements.

Defense Production Act of 1950, 50 U.S. Code § 4552 (14), https://www.law.cornell.edu/uscode/text/50/4552.

Department of Defense. "Defense Production Act (DPA) Title III." The Office of Industrial Policy. Accessed January 24, 2022. https://www.businessdefense.gov/Programs/DPA-Title-III/.

Department of Defense, Department of Health and Human Services, Department of Homeland Security, Department of Veterans Affairs. *National Strategy for a Resilient Public Health Supply Chain*. July 2021. https://www.phe.gov/Preparedness/legal/Documents/National-Strategy-for-Resilient-Public-Health-Supply-Chain.pdf.

Executive Office of the President. "A Sustainable Public Health Supply Chain." Executive Order No. 14001 of January 21, 2021, 86 Fed. Reg. 7219 (January 21, 2021). https://www.federalregister.gov/documents/2021/01/26/2021-01865/a-sustainable-public-health-supply-chain.

Executive Office of the President. "Ensuring the Future Is Made in All of America by All of America's Workers." Executive Order No. 14005 of January 25, 2021, 86 Fed. Reg. 7475 (January 25, 2021). https://www.federalregister.gov/documents/2021/01/28/2021-02038/ensuring-the-future-is-made-in-all-of-america-by-all-of-americas-workers.

Executive Office of the President. "America's Supply Chains." Executive Order No. 14017 of February 24, 2021, 86 Fed. Reg. 11849 (February 24, 2021). https://www.federalregister.gov/documents/2021/03/01/2021-04280/americas-supply-chains.

Federal Emergency Management Agency. "Defense Production Act Authorities." Defense Production Act. Updated July 6, 2021. https://www.fema.gov/disaster/defense-production-act/dpa-authorities.

Food and Drug Administration. "FDA's Budget: Medical Device Supply Chain and Shortages Prevention Program." Current as of July 21, 2021. https://www.fda.gov/news-events/fda-voices/fdas-budget-medical-device-supply-chain-and-shortages-prevention program#:~:text=The%20RSCSPP%20will%20enhance%20CDRH's,providers%2C%20patients%2C%20and%20others.

FDA. "FDA Publishes List of Essential Medicines, Medical Countermeasures, Critical Inputs Required by Executive Order." Current as of November 9, 2020. https://www.fda.gov/news-events/press-announcements/fda-publishes-list-essential-medicines-medical-countermeasures-critical-inputs-required-executive.

FDA. "In Vitro Diagnostics EUAs." Updated November 15, 2021. https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas.

Kaiser Family Foundation. "U.S. International COVID-19 Vaccine Donations Tracker." Accessed January 5, 2022. https://www.kff.org/coronavirus-covid-19/issue-brief/u-s-international-covid-19-vaccine-donations-tracker/.

Liu, Fang, Jing-Sheng Song, and Jordan D. Tong. "Building Supply Chain Resilience through Virtual Stockpile Pooling." *Production and Operations Management* 25, no. 10 (2016): 1745-1762. Wiley Online Library. https://doi.org/10.1111/poms.12573.

National Academies of Sciences, Engineering, and Medicine (NASEM). "Security of America's Medical Product Supply Chain - Committee Meeting 2 and Public Workshop." December 1-3, 2020. https://www.nationalacademies.org/event/12-01-2020/security-of-americas-medical-product-supply-chain-committee-meeting-2-and-public-workshop.

NASEM. "Security of America's Medical Product Supply Chain." 2021. https://www.nationalacademies.org/our-work/security-of-americas-medical-product-supply-chain.

National Institutes of Health (NIH). "NIH Clinical Center." Accessed February 16, 2022. https://clinicalcenter.nih.gov/.

NIH. "Rapid Acceleration of Diagnostics (RADx)." Accessed February 14, 2022. https://www.nih.gov/research-training/medical-research-initiatives/radx.

Sarata, Amanda K. and Simi V. Siddalingaiah. "COVID-19 Testing Supply Chain," *Congressional Research Service*, February 25, 2021. https://crsreports.congress.gov/product/pdf/IF/IF11774.

The Public Health Service Act, 42 U.S.C. § 247d–6a(a)(2), https://www.law.cornell.edu/uscode/text/42/247d-6a.

The Public Health Service Act, 42 U.S.C. § 247d–6b(c)(1)(B), https://www.law.cornell.edu/uscode/text/42/247d-6b.

The Public Health Service Act, 42 U.S.C. § 247d–6d(i)(7), https://www.law.cornell.edu/uscode/text/42/247d-6d.

The White House. "American Pandemic Preparedness: Transforming Our Capabilities." September 2021. https://www.whitehouse.gov/wp-content/uploads/2021/09/American-Pandemic-Preparedness-Transforming-Our-Capabilities-Final-For-Web.pdf?page=29.

The White House. *Building Resilient Supply Chains, Revitalizing American Manufacturing, and Fostering Broad-Based Growth*. June 2021. https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf.

The White House. "President Biden Announces New Actions to Protect Americans Against the Delta and Omicron Variants as We Battle COVID-19 this Winter." December 2, 2021. https://www.whitehouse.gov/briefing-room/statements-releases/2021/12/02/fact-sheet-president-biden-announces-new-actions-to-protect-americans-against-the-delta-and-omicron-variants-as-we-battle-covid-19-this-winter/.

U.S. Congress, House of Representatives. "Infrastructure Investment and Jobs Act." HR 3864, 117th Congress, 1st sess.," November 15, 2021. https://www.congress.gov/bill/117th-congress/house-bill/3684/text.

U.S. Congress, House of Representatives. "National Defense Authorization Act for Fiscal Year 2022." HR 4350, 117th Congress, 1st sess.," December 2, 2021. https://www.congress.gov/bill/117th-congress/house-bill/4350/text.

U.S. Congress, Senate Committee on Health, Education, Labor, and Pensions, *Addressing New Variants: A Federal Perspective on the COVID-19 Response: Hearing before the U.S. Senate Committee on Health, Education, Labor & Pensions, Testimony of Janet Woodcock*, 117th Cong., 2nd sess., (2022). January 11, 2022. https://www.help.senate.gov/imo/media/doc/Woodcock7.pdf.

Endnotes

[i] Executive Order No. 14017 of February 24, 2021, America's Supply Chains, 86 Fed. Reg. 11849, Section 4(ii).
[ii] Department of Defense, Department of Health and Human Services, Department of Homeland Security, Department of Veterans Affairs, *National Strategy for a Resilient Public Health Supply Chain*, July 2021, 17.
[iii] "COVID-19 Vaccinations in the United States," COVID Data Tracker, Centers for Disease Control (CDC), accessed January 5, 2022.
[iv] "U.S. International COVID-19 Vaccine Donations Tracker," Kaiser Family Foundation, accessed January 5, 2022.
[v] *National Strategy for a Resilient Public Health Supply Chain*, July 2021, 70.
[vi] Ibid., 60-64.
[vii] The White House, *Building Resilient Supply Chains, Revitalizing American Manufacturing, and Fostering Broad-Based Growth*, June 2021, 208.
[viii] *National Strategy for a Resilient Public Health Supply Chain*, 60-64.
[ix] "Personal Protective Equipment," the National Institute for Occupational Safety and Health, CDC, accessed January 3, 2022.
[x] "ASPR Program Office for Innovation and Industrial Base Expansion (IBx)," ASPR, accessed January 3, 2022.
[xi] "H.R. 3864 - Infrastructure Investment and Jobs Act," U.S. Congress, House of Representatives, November 15, 2021, Sec. C.
[xii] *National Strategy for a Resilient Public Health Chain*, 71-72.
[xiii] U.S. Congress, Senate Committee on Health, Education, Labor, and Pensions, *Addressing New Variants: A Federal Perspective on the COVID-19 Response: Hearing before the U.S. Senate Committee on Health, Education, Labor & Pensions, Testimony of Janet Woodcock*, 117th Cong., 2nd sess., January 11, 2022, 4, 9, 12, 17.
[xiv] "BARDA-NIOSH Mask Innovation Challenge Selects 10 Winning Concepts for $10,000 Phase 1 Prizes," Biomedical Advanced Research and Development Authority (BARDA), July 2, 2021.
[xv] "Mask Innovation Challenge: Phase 2," BARDA, accessed January 5, 2022.
[xvi] "In Vitro Diagnostics EUAs," Food and Drug Administration, updated November 15, 2021.
[xvii] "COVID-19 Testing Supply Chain," Sarata, Amanda K. and Simi V. Siddalingaiah, Congressional Research Service, February 25, 2021.
[xviii] The White House, "President Biden Announces New Actions to Protect Americans Against the Delta and Omicron Variants as We Battle COVID-19 this Winter," December 2, 2021.
[xix] "Rapid Acceleration of Diagnostics (RADx)," National Institutes of Health, accessed May 13, 2021.
[xx] *National Strategy for a Resilient Public Health Supply Chain*, 50.
[xxi] *Building Resilient Supply Chains, Revitalizing American Manufacturing, and Fostering Broad-Based Growth*, 208.
[xxii] "Testimony of Janet Woodcock," January 11, 2022, 2-3.
[xxiii] "Security of America's Medical Product Supply Chain," The National Academies of Sciences, Engineering and Medicine (NASEM), accessed January 5, 2022.
[xxiv] Security of America's Medical Product Supply Chain - Committee Meeting 2 and Public Workshop, NASEM, December 1-3, 2020.
[xxv] "BioMaP Consortia RFI Final Document," BARDA, October 21, 2021.
[xxvi] "COVID-19 Therapeutics," ASPR, accessed January 28, 2022.
[xxvii] "Testimony of Janet Woodcock," January 11, 2022, 15.
[xxviii] "H.R. 4350 - National Defense Authorization Act for Fiscal Year 2022," U.S. Congress, House of Representatives, December 2, 2021, Sec. 109.