HHS DRAFT ACTION PLAN FOR ADDRESSING SHORTAGES OF MEDICAL PRODUCTS AND CRITICAL FOODS AND STRENGTHENING THE RESILIENCE OF MEDICAL PRODUCT AND CRITICAL FOOD SUPPLY CHAINS

2025-2028

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Acknowledgements

The HHS Draft Action Plan for Addressing Shortages of Medical Products and Critical Foods and Strengthening the Resilience of Medical Product and Critical Food Supply Chains ("Draft Action Plan") was developed by the Department of Health and Human Services (HHS) Supply Chain Resilience and Shortage Coordinator, in collaboration with federal partners across the U.S. Government. Its development was informed by the efforts and perspectives of a wide range of individuals, and these contributions played a key role in shaping the Draft Action Plan's goals, objectives, and strategies.

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Public Domain Notice

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List of Abbreviations

AHRQ	Agency for Healthcare Research and Quality
API	Active Pharmaceutical Ingredient
ARMI	Advanced Regenerative Manufacturing Institute
ARPA-H	Advanced Research Projects Agency for Health
ASPE	Office of the Assistant Secretary for Planning and Evaluation
ASPR	Administration for Strategic Preparedness and Response
BARDA	Center for the Biomedical Advanced Research and Development Authority
CBRN	Chemical, Biological, and Radiological/Nuclear
CDC	Centers for Disease Control and Prevention
CDRH	Center for Devices and Radiological Health
CHIP	Children's Health Insurance Program
CMS	Centers for Medicare & Medicaid Services
COVID-19	Coronavirus Disease 2019
CY	Calendar Year
EML	Essential Medicines List
EO	Executive Order
FDA	Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
HHS	Department of Health and Human Services
IPPS	Inpatient Prospective Payment System
KSM	Key Starting Materials
MCM	Medical Countermeasure
OGA	Office of Global Affairs
OGC	Office of the General Counsel
OPPS	Outpatient Prospective Payment System
PHE	Public Health Emergency
PPE	Personal Protective Equipment
R&D	Research and Development
SCCT	Supply Chain Control Tower
SLTT	State, Local, Tribal, and Territorial
SNS	Strategic National Stockpile

Executive Summary

The 2025–2028 Draft Action Plan for Addressing Shortages of Medical Products and Critical Foods and Strengthening the Resilience of Medical Product and Critical Food Supply Chains ("Draft Action Plan") presents coordinated and strategic actions that the Department of Health and Human Services ("HHS," or "Department") plans to take from 2025 through 2028.

This Draft Action Plan builds on current HHS activities and goals. It includes refined objectives, strategies, and targets aimed at improving insights into medical product and critical food supply chains, enhancing the agility of response capabilities, building stronger and more resilient medical product and critical food supply chains, and strengthening coordination, communication, and partnerships. This Draft Action Plan also reflects the next phase of the "2021 National Strategy for a Resilient Public Health Supply Chain" and related executive orders.[1,2] The Draft Action Plan includes a companion Draft Research Plan that describes research priorities to support the Draft Action Plan's goals. Specifically, this Draft Action Plan presents HHS's four goals for strengthening the resilience of medical product and critical food supply chains.

Goal 1. COORDINATE. Strengthen HHS's integrated approach to coordination, communication, and partnerships focused on improving the resilience of medical product and critical food supply chains.

Goal 2. ASSESS: Increase availability and utilization of actionable insights into critical medical product and food supply chains for HHS.

Goal 3. RESPOND. Strengthen HHS response to shortages and supply chain disruptions.

Goal 4. PREVENT. Incentivize investment in supply chain resilience through increased supply chain diversification, redundancy, and other strategies.

HHS has worked with industry partners and across government to mitigate the effects of shortages and supply chain disruptions and to increase investments that build redundancy and further diversify medical product and critical food supply chains. HHS remains committed to identifying risks and vulnerabilities in medical product and critical food supply chains, incentivizing resiliency within them, and improving communication and coordination within government and with key partners.

Achieving these goals and objectives requires significant funding and resources as well as continued efforts across the U.S. Government, the private-sector, and other stakeholders to overcome anticipated and as yet unknown challenges. These efforts must remain a priority to

[1] The White House (2021). National Strategy for a Resilient Public Health Supply Chain. Retrieved from: https://www.phe.gov/Preparedness/legal/Documents/National-Strategy-for-Resilient-Public-Health-Supply-Chain.pdf
[2] See Appendix E for a list of the executive orders.

protect the nation's public health and to increase national economic sustainability and competitiveness.

When the HHS Draft Action Plan is finalized, HHS plans to report annually on its website on the progress made toward the goals and objectives.

HHS Draft Action Plan At-A-Glance

This At-A-Glance section briefly summarizes the Goals, Objectives, and Actions that are discussed in detail in the narrative that follows.

Goal 1. COORDINATE: Strengthen HHS's integrated approach to coordination, communication, and partnerships focused on improving the resilience of medical product and critical food supply chains.

1.1 Strengthen HHS's internal communication and coordination of supply chain ecosystem information to increase supply chain resiliency.

1.1.1 Improve communication and coordination within HHS agencies to increase visibility into the supply chains, address shortages and strengthen supply chain resilience.

1.2 Strengthen HHS's integrated approach to external partnerships to prepare, mitigate, and respond to shortages and U.S. supply chain disruptions.

1.2.1 Improve connectedness, relationships, and communication of relevant information between HHS agencies and external domestic stakeholders to address shortages and increase supply chain visibility.

1.2.2 Generate and implement a coordinated strategy for communication and collaboration with international partners to increase visibility into the supply chains through increased monitoring and mapping activities.

1.2.3 Advance U.S. supply chain resiliency priorities through multilateral and bilateral engagements and partnerships.

Goal 2. ASSESS: Increase availability and utilization of actionable insights into critical medical product and food supply chains for HHS.

2.1 Expand availability of supply chain data, including on strategic intelligence and economics of market intermediaries, into critical medical product and food supply chains for HHS.

2.1.1 Conduct regular assessments to align current data needs with existing supply chain and shortage data needs, including identifying users, within and external to HHS, to identify cross-cutting capabilities and purposes.

2.1.2 Refine criteria and process for identifying medical products, critical foods, and raw materials that require enhanced visibility for HHS.

2.1.3 Improve data utilization, data-sharing, integration, and standardization across the supply chains for medical products and foods.

2.2 Expand HHS capacity for data analytics and other capabilities to transform available data into actionable insights with clear use cases for addressing shortages.

2.2.1 Formalize and implement a plan to transform how supply chain data are shared and integrated across HHS, as maximally allowable within existing authorities.

2.2.2 Conduct supply chain mapping for prioritized medical products identified for enhanced visibility.

2.2.3 Expand capacity for next generation integrated supply chain predictive tools for critical medical products.

2.2.4 Expand research and evaluation of strategies to enhance supply chain visibility and analytics to improve measurement of supply chain resilience.

Goal 3. RESPOND: Strengthen HHS response to shortages and supply chain disruptions.

3.1 Prioritize an effective response to a shortage or supply chain disruption through building and maintaining capacity and capabilities.

3.1.1 Proactively develop and maintain resources, protocols, plans, and processes to expand HHS's ability to surge and adapt during a response.

3.1.2 Accelerate development and adoption of technologies or approaches that enable rapid scaling and efficient supply chain management practices.

3.1.3 Promote inventory management practices, including buffer stock, vendor-managed inventory, and stockpiling in routine care and in the stockpiles.

3.2 Maintain and enhance the resilience, safety, and security of HHS workforce, facilities, and assets to ensure long-term viability of effective response capabilities related to shortages and/or supply chain disruptions.

3.2.1 Audit, maintain, and bolster a highly competent, diverse workforce to facilitate implementation of an effective response to address shortages and supply chain disruptions.

3.2.2 Maintain the safety and security of facilities and assets to ensure readiness during a response focused on shortages and/or supply chain disruptions.

Goal 4. PREVENT: Incentivize investment in supply chain resilience through increased supply chain diversification, redundancy, and other strategies.

4.1 Implement supply-side investments that reward supply chain resilience.

4.1.1 Identify new approaches and promote policies that expand the capacity of the industrial base and enhance supply chain resilience.

4.1.2 Speed innovation and adoption of advanced technologies to expand domestic capacity and supply chain diversification and redundancy.

4.1.3 Maintain and increase the competitiveness of the U.S. through human capital investments.

4.2 Implement demand-side investments that reward supply chain resilience.

4.2.1 Continue to refine existing demand-side programs to increase their use and effectiveness.

Section 1: Introduction and Background

About the Draft Action Plan

This Draft Action Plan describes activities that HHS plans to undertake from 2025 through 2028 to prevent shortages and supply chain disruptions of medical products and critical foods when possible and to mitigate their impacts on the nation when they occur. The development of this Draft Action Plan reflects a concerted effort to apply and expand upon existing strategies, workgroup results, research, and lessons learned during the COVID-19 pandemic and other responses. This Draft Action Plan builds on these current efforts and catalyzes new or revised goals, objectives, strategies, and targets. When appropriate, this Draft Action Plan may be revised to ensure alignment and coordination with other documents.

For the purpose of this Draft Action Plan, *medical products* include drugs, biological products, and medical devices, as well as active pharmaceutical ingredients (APIs) and raw materials, plus the parts, components, or ingredients used to manufacture them; this Draft Action Plan also discusses critical foods.[3,4] Medical countermeasures (MCMs) include a subset of certain drugs, biological products, and medical devices needed to respond to a public health emergency (PHE).[5] The strategies to address shortages and enhance resilience may differ across and within product areas because of the unique characteristics of their supply chains, development and approval processes, underlying authorities, market structures, and other factors.

This Draft Action Plan was developed by the HHS Coordinator in collaboration with the HHS Supply Chain Resilience in Shortage Working Group. The Working Group is co-chaired by the Food and Drug Administration (FDA) and the Administration for Strategic Preparedness and Response (ASPR). The member organizations of this HHS Working Group are listed below.

- Food and Drug Administration (FDA)—Co-chair
- Administration for Strategic Preparedness and Response (ASPR)—Co-chair
- Office of the Assistant Secretary for Financial Resources
- Centers for Medicare & Medicaid Services (CMS)
- Centers for Disease Control and Prevention (CDC)
- Office of Intergovernmental and External Affairs
- Office of Global Affairs (OGA)
- Immediate Office of the Secretary

[3] Section 201(ss) of the Federal Food, Drug, and Cosmetic Act defines critical food as "a food that is— (1) an infant formula; or (2) a medical food, as defined in section 5(b)(3) of the Orphan Drug Act." Section 201(z) of the Federal Food, Drug, and Cosmetic Act defines infant formula as "a food which purports to be or is represented for special dietary use solely as a food for infants by reasons of its simulation of human milk or its suitability as a complete or partial substitute for human milk." Section 5(b)(3) of the Orphan Drug Act defines a medical food as a "food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation."

[4] Although not in the scope of this Draft Action Plan, other foods besides infant formula also face similar challenges with respect supply chain vulnerabilities and visibility, and resource and authority needs as those products covered in this Draft Action Plan.

[5] MCMs can be used to diagnose, prevent, protect from, or treat conditions associated with chemical, biological, radiological, or nuclear (CBRN) threats, or emerging infectious diseases. MCMs include biological products such as vaccines, blood products and antibodies, drugs such as antimicrobial or antiviral drugs, and medical devices (diagnostic tests and PPE such as gloves, respirators, and ventilators). The Strategic National Stockpile provides MCMs needed to states, tribal nations, territories, and the largest metropolitan areas during public health emergencies.

- Office of the General Counsel (OGC)
- Office of National Security
- Advanced Research Projects Agency for Health (ARPA-H)
- Agency for Healthcare Research and Quality (AHRQ).

HHS would also like to acknowledge input from others in HHS, including but not limited to the Assistant Secretary for Administration and the Office of Climate Change and Health Equity.

HHS Supply Chain Vision

As described above, shortages of critical medical products and foods in recent decades have frequently strained the U.S. healthcare system and significantly affected patient care. To address these issues, HHS has set supply chain goals centered around addressing vulnerabilities affecting the future availability of medical products and critical foods by strengthening the resilience of medical product and critical food supply chains. Ultimately, progress toward these goals will help HHS achieve its mission to improve the health and well-being of all Americans by helping to ensure that critical medical products and foods are available when and where they are needed.

Measuring and Reporting Progress and Establishing Accountability

This Draft Action Plan includes actions or targets, many of which are composites of multiple activities pursued by multiple agencies. When the Draft Action Plan is finalized, it will include the name of the department or agency responsible for each action. It will also discuss plans for reporting on progress, as well as process for updating targets.

While there is consensus that having resilient medical product and critical food supply chains is the ultimate goal, HHS recognizes the importance of establishing metrics to measure progress toward achieving resilience. Some metrics that could be considered include:

- Fewer new shortages.
- Decreased volume of APIs or finished dosage forms originating from a concentrated set of foreign countries.
- Increased funding allocated toward expanding and sustaining the industrial base.
- Decreased number of patients affected by shortages.
- Briefer duration of shortages.

Most or all metrics will be influenced by factors outside of HHS's control. This makes it nearly impossible to distinguish the impact of HHS efforts alone. Existing research also indicates that using different metrics can lead to different investment decisions, which further highlights the importance of selecting the correct metric.[6] When this Draft Action Plan is finalized, HHS will consider further steps to define these metrics, while balancing noted challenges.

[6] Behzadi, G., O'Sullivan, M.J., Olsen, T.L. (2020). On metrics for supply chain resilience, *European Journal of Operational Research*, Volume 287, Issue 1,2020: 145-158, https://doi.org/10.1016/j.ejor.2020.04.040.

Background

More resilient and sustainable medical product and critical food supply chains are central to protecting the nation's public health, national security, and economic well-being. The COVID-19 pandemic highlighted vulnerabilities in U.S. and global medical product and critical food supply chains, in some cases leading to shortages or supply constraints of certain life-saving medicines, medical devices, critical foods, and other vital components, including manufacturing materials.[7] Manufacturing delays, natural disasters, product discontinuations, and many other supply chain disruptions have threatened patient care and further emphasize the need to ensure dynamic, adaptable, and resilient supply chains.

Medical product and critical food shortages during the COVID-19 pandemic were exacerbated by intense demand but were also the product of market dynamics contributing to a lack of supply chain resilience. Intense downward pressure on price and concentration among supply chain intermediaries has contributed to supply chain disruptions stemming from manufacturing quality concerns, market exits by manufacturers, and limited supplier diversification. In addition, pharmaceutical and medical device supply chains are increasingly relying on manufacturers and suppliers outside the U.S., largely driven by lower production costs. Relying on a concentrated set of foreign manufacturing facilities and countries can increase the risk of disruptions and shortages. While this has not yet been a common cause of shortages, in emergencies, some foreign manufacturers may prioritize supplying their homeland over the U.S. market. Such actions, as well as potential export and travel restrictions, could exacerbate future supply shortages.[8]

Shortages of drugs, biological products, medical devices, and critical foods can be detrimental to individuals, families, communities, clinicians, and health systems across the U.S. They can lead to delays in patient care, increased costs for both patients and hospitals, and deleterious impacts on patient health—particularly among vulnerable and underserved populations. Previous research suggests that drug shortages cost hospitals $600 million or more annually, while patients face rising costs for drugs that are in shortage.[9] In addition to monetary costs, consumers face potential health impacts from medication rationing, delayed or discontinued treatment, higher risk of medication errors, switching to less effective medications, not receiving the standard of care treatment, and potentially higher mortality rates.[10,11] Consumers also face indirect costs resulting from additional time spent finding alternative medications, dealing with other consequences of shortages, and experiencing negative mental health effects.[12]

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[7] While the scope of the Draft Action Plan focuses on human medical products, as of January 13, 2025, FDA reported 13 ongoing shortages of animal drugs, some of which have been in shortage since before 2020. Further, other foods that are not critical foods are considered strategic commodities, and their supply chains may face similar risks and vulnerabilities as those of medical products and critical foods. U.S. Food and Drug Administration, "Current Animal Drug Shortages." https://www.fda.gov/animal-veterinary/product-safety-information/current-animal-drug-shortages.

[8] Chen, P.G., Chan, E.W., Qureshi, N., Shelton, S., & Mulcahy, A.W. (2021). Medical Device Supply Chains: An Overview and Description of Challenges during the COVID-19 Pandemic. Rand Corporation. Retrieved from: https://aspe.hhs.gov/reports/medical-device-supply-chains

[9] Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services (2023). Impact of Drug Shortages on Consumer Costs. Retrieved from: https://aspe.hhs.gov/reports/drug-shortages-impacts-consumer-costs

[10] Beleche, T., and Kolbe, A. (2024). Medical Product Shortages in the United States: Demographic and Geographic Factors and Impacts. Washington, D.C. Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. Retrieved from: https://aspe.hhs.gov/reports/medical-product-shortages

[11] Vail E, Gershengorn HB, Hua M, Walkey AJ, Rubenfeld G, Wunsch H. (2017). Association Between US Norepinephrine Shortage and Mortality Among Patients With Septic Shock. JAMA. 2017;317(14):1433–1442. doi:10.1001/jama.2017.2841

[12] Institute for Safe Medication Practices (2023). Medication, Supply, Equipment Shortages are Harming Patients. New Survey Reveals Shortages are Negatively Affecting Patient Care, Causing Harm. October 13, 2023. https://home.ecri.org/blogs/ismp-news/medication-supply-equipment-shortages-are-harming-patients

Shortages of medical products and supply chain disruptions have been a public health concern for decades (See Appendix A for a description of HHS agencies and their roles in addressing supply chain disruptions and shortages). For example, there were 123 ongoing shortages in January 2024.[13] Of these products, approximately 25 percent were first reported in shortage before 2020, suggesting prolonged challenges for patients. New drug shortages hit a high of 250 in 2011, while in 2023 there were 55 new shortages.[14] Shortages occur across a range of therapeutic areas, with analgesics/anesthetics (17 percent), anti-infectives (12 percent), and cardiovascular products (13 percent) comprising 42 percent of all drug shortages. At any time, the ongoing shortages may include shortages reported in a previous year.

Shortages of medical devices have also been an issue. From 2010 to 2019, approximately five shortages of medical devices were voluntarily reported annually. The number of medical devices in shortage increased fourfold in the first half of 2020.[15] Pre-COVID-19, there were reported shortages of intravenous bags and critical pediatric devices (e.g., tracheostomy tubes). At the beginning of the COVID-19 PHE, medical devices (e.g., ventilators, tests and diagnostics, and personal protective equipment (PPE)) were the first medical products to go into shortage. Acute increases in demand led to shortages of critical devices required to deliver care to COVID-19 patients. By October 2022, there were 34 product codes on FDA's medical device shortages list, each representing a different class of devices. Each product code in shortage can equate to thousands of devices that were not available for patient care. As of December 2024, FDA had six product codes listed on the medical device shortage list.[16] Shortages also impact critical foods (i.e., medical foods and infant formula). For example, in 2022, the U.S. encountered a severe shortage of infant formula, posing a unique challenge for parents, the U.S. Government, and the healthcare system.[17,18,19] (See Appendix B and the Draft Research Plan for more information on the causes of these shortages.)

Resilient supply chains are less likely to face disruption and can withstand and mitigate disruptions so that, when they do arise, their impacts are limited. A resilient supply chain relies on robust strategies for preparedness, mitigation, response, and recovery. Resilience requires an expanded industrial base and is based on diversified sourcing—including both redundant manufacturing capacity and a balance of domestic and diversified foreign sources—and investment in reliable, efficient, and sustainable manufacturing practices. Mitigation and prevention tools such as buffer inventory, excess capacity, and risk mitigation plans are also essential supply chain strategies. Resilience also depends on reliable, efficient, and sustainable

[13] U.S. Food and Drug Administration (2024). FDA Drug Shortages. Retrieved from: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
[14] U.S. Food and Drug Administration (2023). Tenth Annual Report to Congress on Drug Shortages for Calendar Year 2022 (2023). Retrieved from: https://www.fda.gov/media/169302/download
[15] Beleche, T., Kuecken, M., Sassi, A., Toran, K., Galloway, E., & Henry, T. (2022). Characteristics of Medical Device Shortages in the US, 2006–20: Study examines the characteristics of medical device shortages in the US from 2006–20. *Health Affairs*, 41(12), 1790-1794.
[16] U.S. Food and Drug Administration (2024). Medical Device Shortages List, Update: December 19, 2024. Retrieved from: https://www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/medical-device-shortages-list#shortage.
[17] The White House (2022). President Biden Announces Twenty-Fourth Operation Fly Formula Mission. Retrieved from: https://www.whitehouse.gov/briefing-room/statements-releases/2022/09/16/president-biden-announces-twenty-fourth-operation-fly-formula-mission/
[18] Damian-Medina, K., Cernioglo, K., Waheed, M., DiMaggio, D.M., Porto, A.F., & Smilowitz, J.T. (2024). Cross-Sectional Analysis of Infant Diet, Outcomes, Consumer Behavior and Parental Perspectives to Optimize Infant Feeding in Response to the 2022 US Infant Formula Shortage. Nutrients, 16(5), 748.
[19] U.S. Food and Drug Administration (2023). Status Update on FDA's Infant Formula Response Activities. Retrieved from: https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/status-update-fdas-infant-formula-response-activities

purchasing, distribution, and manufacturing practices. Moreover, proactive monitoring, assessment, and communication of risks and vulnerabilities to prevent or mitigate shortages or supply chain disruptions are crucial, especially for those products at highest risk of supply chain disruptions, such as generic drugs. Building a resilient supply chain requires strong partnerships with industry and other stakeholders to facilitate and promote collaboration and actions to address vulnerabilities and risks. It also requires creating a system in which all actors have adequate incentives and responsibility to respond to relevant information and support more resilience and diversification across the supply chain. This means developing a system in which the private sector competes not just on price but also on strengthening supply chain resilience.

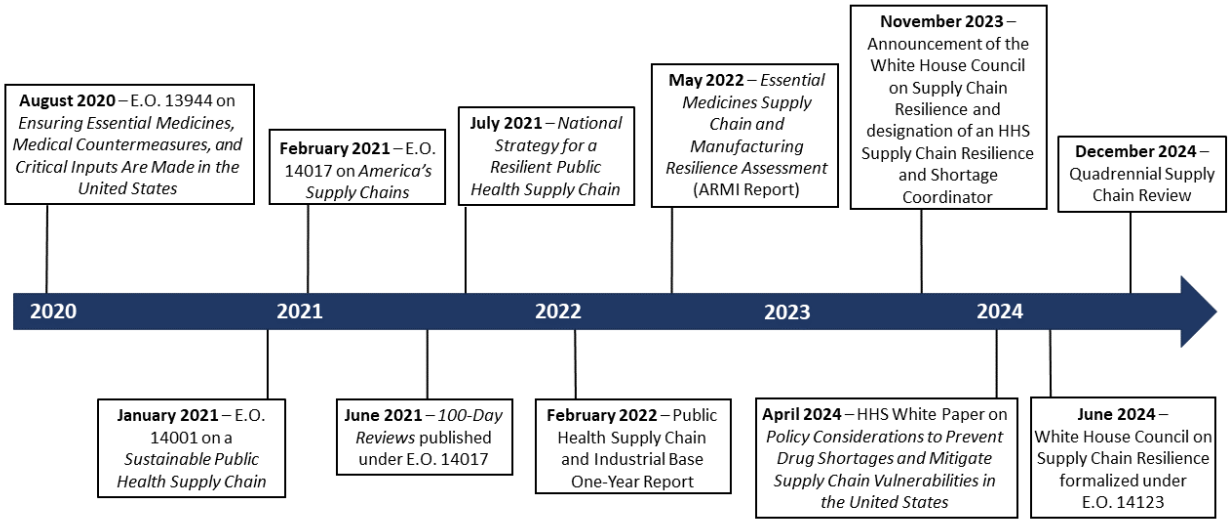
A central component of strengthening the medical product and critical food supply chains and limiting the impact of shortages or supply chain disruptions is the public health industrial base, which includes all entities manufacturing, producing, or distributing medical products, including MCMs, and critical foods. This also includes the associated workforces, such as those in research and development (R&D) facilities, manufacturing facilities producing essential medicines,[20] MCMs, and critical inputs for the healthcare and public health sectors. The public health industrial base is a critical sector for the U.S., not only because of its contribution to the gross domestic product and labor market, but also given its vital role in maintaining the health of the U.S. population and, therefore, to national security. ASPR plays an important role in preparing for, responding to, and recovering from public health emergencies and strengthening the industrial base. For additional information see the Quadrennial Supply Chain Review's chapter on the public health and biological preparedness industrial base.[21]

Efforts to Date

Figure 1 summarizes U.S. Government milestones aimed at strengthening supply chains in the U.S. since 2020. These efforts include executive orders (E.O.s) directing agencies to develop strategies to respond to threats through increased domestic production of essential supplies, and assessments of the resilience of supply chains. The assessments include the development of a 100-Day Review, a One-Year Report, and a Quadrennial Supply Chain Review for critical sectors. In response, HHS developed, in collaboration with other agencies, a National Strategy to build a resilient public health supply chain, and has since reported on progress made to address supply chain vulnerabilities, identify essential medicines, and increase supply chain resilience (see Appendix C for additional details on these specific efforts).

[20] For purposes of this report, "essential medicines" is broadly defined as priority life-saving products. This may include among others, medicines in the Executive Order 13944 List of Essential Medicines, Medical Countermeasures, and Critical Inputs published in October 2020, as well medicines in the Essential Medicines Supply Chain and Manufacturing Resilience Assessment report published by ARMI in May 2022.
[21] The White House. National Economic Council and National Security Council. (2024). 2021-2024 Quadrennial Supply Chain Review. Retrieved from: https://www.whitehouse.gov/wp-content/uploads/2024/12/20212024-Quadrennial-Supply-Chain-Review.pdf.

Figure 1: U.S. Government Milestones to Increase Supply Chain Resilience and Ability to Address Shortages



Within HHS, efforts to strengthen medical supply chains and improve the nation's ability to respond to future threats continue to grow. In November 2023, new actions were announced to strengthen America's supply chains across sectors, including the establishment of a White House Council on Supply Chain Resilience and, for the health and medical sector, the designation of a new HHS Supply Chain Resilience and Shortage Coordinator ("the Coordinator"). The HHS Secretary designated the Coordinator to reside in the Office of the Assistant Secretary for Planning and Evaluation (ASPE).

Establishing an official Coordinator and an HHS Working Group underscores the importance of identifying and mitigating supply chain vulnerabilities, and ensuring that HHS is better prepared to address future shortages and supply chain disruptions. Consolidating efforts across the Department improves coordination of activities, such as the development and implementation, when finalized, of HHS's Draft Action Plan. One of the first activities of the Coordinator was to lead HHS in the development of a white paper ("HHS White Paper") discussing factors underlying shortages and HHS's actions to address them.[22] The HHS White Paper, published in April 2024, noted lack of transparency, market concentration, and price competition as driving forces of shortages. The HHS White Paper also presented several policy considerations to avoid or mitigate future supply chain disruptions and strengthen resilience in the pharmaceutical supply chains. In June 2024, E.O. 14123 was issued to strengthen domestic and global supply chain resilience and coordinate U.S. Government efforts to address supply chain threats and vulnerabilities.[23] To achieve these goals, agencies are required to recommend best practices for cooperation and coordination, identify resources needed to support supply chain resilience, and recommend administrative actions to accomplish these goals. Additionally, the White House

[22] U.S. Department of Health and Human Services (2024). Policy Considerations to Prevent Drug Shortages and Mitigate Supply Chain Vulnerabilities in the United States. Retrieved from: https://aspe.hhs.gov/reports/preventing-shortages-supply-chain-vulnerabilities
[23] Executive Order No. 14123 (2024). White House Council on Supply Chain Resilience, 89 *Fed. Reg. 51949* (June 14, 2024). Retrieved from: https://www.federalregister.gov/documents/2024/06/21/2024-13810/white-house-council-on-supply-chain-resilience

Council on Supply Chain Resilience coordinated the development of a Quadrennial Supply Chain Review released on December 19, 2024.

More recently, HHS described additional efforts to increase resilience in the pharmaceutical and API supply chains, and in the industrial base. For example, actions to expand the industrial base include investing over $3 billion dollars across 61 contracts to increase domestic production of PPE (including nitrile gloves, gowns, surgical masks, and N95 respirators, among other items) and testing capacity. HHS distributed nearly two billion at-home COVID-19 test kits directly to U.S. homes, and it shipped over 285 million antigen tests to nursing homes, federally qualified health centers, and long-term care facilities since the COVID-19 PHE declaration expired on May 11, 2023. HHS also increased interagency and industry coordination and enhanced supply chain visibility to strengthen the domestic industrial base. HHS made additional strides to improve the pharmaceutical and API supply chains by developing an essential medicines list to inform domestic production strategies and expanding domestic manufacturing of key starting materials (KSMs) and APIs. Since 2023, HHS, through the new Industrial Base Management and Supply Chain Office, has invested hundreds of millions of dollars in advanced manufacturing capabilities to lower the cost of domestic manufacturing and reduce foreign dependency, as well as promote global competitiveness for these KSMs and APIs. These actions are described in more detail in the Quadrennial Supply Chain Review's chapters on the public health and biological preparedness industrial base, and pharmaceuticals and APIs.

Section 2: Goals, Objectives, and Actions

This HHS Draft Action Plan lays out four goals designed to achieve HHS's supply chain vision:

Goal 1: COORDINATE. Strengthen HHS's integrated approach to coordination, communication, and partnerships focused on improving the resilience of medical product and critical food supply chains.

Goal 2: ASSESS. Increase availability and utilization of actionable insights into critical medical product and food supply chains for HHS.

Goal 3: RESPOND. Strengthen HHS response to shortages and supply chain disruptions.

Goal 4: PREVENT. Incentivize investment in supply chain resilience through increased supply chain diversification, redundancy, and other strategies.

Goal 1: COORDINATE. Strengthen HHS's integrated approach to coordination, communication, and partnerships focused on improving the resilience of medical product and critical food supply chains.

The medical product and critical food supply chains comprise a complex, multifaceted ecosystem of many entities providing finished products and raw materials, many of which may not be in regular communication, nor have integrated information systems. This ecosystem encompasses many thousands of products that may have their own unique supply chains. Sustained engagement with the various stakeholders underpins HHS's ability to gain insights into supply chain constraints or delays. Improving coordination and communication of actionable information among HHS agencies, across the U.S. Government, and with all relevant supply chain stakeholders will strengthen the Department's capacity to proactively prevent, mitigate, and prepare for shortages of medical products and critical foods that are critical for public health. Greater HHS insight into the medical product and critical food supply chains will also improve the U.S. Government's ability to link domestic and global supply chain data and work effectively with industry and other partners to enhance visibility across the supply chain ecosystem. This requires building on existing partnerships and establishing new ones to ensure all key stakeholders affected by supply chain vulnerabilities and shortages can play a role in solving current and future challenges. Achieving a resilient supply chain will require setting specific and measurable supply chain targets and evaluating the progress of supply chain policies toward achieving these objectives. Strengthened coordination can also enable continuous scanning for gaps in the strategic approach and making adjustments, as needed, to achieve supply chain objectives.

Statement of the Problem

Currently, several HHS divisions implement a range of activities related to supply chains and shortages. There are also numerous efforts led by other parts of the U.S. Government, non-government entities inside and outside the U.S., and international partners. Until the recent establishment of the HHS Supply Chain Resilience and Shortage Coordinator, there was no formal coordinating structure to oversee HHS-wide responses and strategies. This limited the capability of HHS and the U.S. Government to mitigate and respond to shortages and strengthen supply chain resilience. The HHS Coordinator and the White House Council on Supply Chain Resilience were established to improve alignment of existing engagement mechanisms with U.S. Government strategic objectives and forge a direct line of communication between the government and the private sector.[23,24] Their roles include coordinating and promoting efforts to strengthen supply chain resilience and U.S. competitiveness, and facilitating collaboration between various agencies, allies, and partners to foster greater global supply chain resilience. The nascent nature of the HHS Coordinator and the White House Council on Supply Chain Resilience creates challenges (and opportunities) to improve communication and coordination

[24] The White House (2023). Fact Sheet: President Biden Announces New Actions to Strengthen America's Supply Chains, Lower Costs for Families, and Secure Key Sectors. Briefing Room, November 27, 2023. Retrieved from: https://www.whitehouse.gov/briefing-room/statements-releases/2023/11/27/fact-sheet-president-biden-announces-new-actions-to-strengthen-americas-supply-chains-lower-costs-for-families-and-secure-key-sectors/

across HHS and with relevant stakeholders, which can further enhance the U.S. Government's visibility into the supply chains more broadly and strengthen supply chain resilience and response. Gathering the diverse set of stakeholders within and outside of government that represents the complex supply chains presents a unique opportunity to solve the issues of shortages and supply chain vulnerabilities, build trust, promote equity and inclusion, and optimize skills and resources that would be unavailable if these stakeholders were working separately. The breadth of stakeholders' expertise covers regulatory matters, economics, manufacturing, payment, contracting, healthcare delivery, and other areas. This diverse expertise is crucial to developing enduring solutions to medical supply chain issues. However, diverse stakeholders will have varying goals, which makes identifying common objectives and outcomes a challenge. Nevertheless, building strong partnerships is a crucial step to improving supply chain resilience and addressing shortages, but can take time to build trust and effective processes.

Development and negotiation of agreements with the appropriate partners, including allied countries, pose various challenges. For instance, evidence shows that in a time of crisis or when they perceive their national interests to be at odds with the interests of the larger group, nations have a strong tendency to put their own interest first.[25] This means that finalizing multilateral agreements can take many years. Enhanced coordination and collaboration can drive improvements across all components of the supply chain but will require sustained commitment, engagement, and leadership from all involved.

Objective 1.1. Strengthen HHS's internal communication and coordination of supply chain ecosystem information to increase supply chain resiliency.

- *Action 1.1.1.* Improve communication and coordination within HHS agencies to increase visibility into the supply chains, address shortages, and strengthen supply chain resilience.

    ✓ Strengthen existing supply chain resilience and shortage coordination, communication, and collaboration within HHS.

Objective 1.2. Strengthen HHS's integrated approach to external partnerships to prepare, mitigate, and respond to shortages and U.S. supply chain disruptions.

- *Action 1.2.1.* Improve connectedness, relationships, and communication of relevant information between HHS agencies and external domestic stakeholders to address shortages and increase supply chain visibility.

    ✓ Develop strategy for communicating information between HHS and domestic non-governmental partners and stakeholders, including a plan to identify whom to engage and when, and to develop infrastructure that facilitates engagement, potentially including through public-private partnerships.

[25] National Academies of Sciences, Engineering, and Medicine (2022). *Building Resilience into the Nation's Medical Product Supply Chains*. Washington, DC: The National Academies Press. https://doi.org/10.17226/26420

- ✓ Engage with patients and communities to understand how they are affected by supply chain vulnerabilities and shortages and ensure that coordination and communication strategies incorporate their perspectives.
- ✓ Evaluate strategy for communicating information and ensuring that communications are effective, consistent and appropriately tailored for specific domestic audiences.
- ✓ Establish flexible contracting mechanisms, such as through coordinated federal procurement contracts or agreements to sustain domestic private sector partnerships, for increased supply chain visibility and rapid responding.

- *Action 1.2.2:* Generate and implement a coordinated strategy for communication and collaboration with international partners to increase visibility into the supply chains through increased monitoring and mapping activities.

  - ✓ Expand supply chain collaboration efforts that are ongoing across HHS and the U.S. Government, including through public-private partnership models, to monitor global threats and enable coordination and information sharing, as allowable within existing authorities, across the global supply chain.
  - ✓ Collaborate with international partners on identifying critical items for end-to-end mapping and assessments of other aspects of supply chain resiliency.

- *Action 1.2.3*. Advance U.S. supply chain resiliency priorities through multilateral and bilateral engagements and partnerships.

  - ✓ Develop strategy to leverage opportunities within partnerships and multilateral relationships to ensure shared access to needed supplies during a response or supply chain disruption.
  - ✓ Promote regulatory harmonization, convergence, and reliance with regulatory counterparts through bilateral and multilateral partnerships to encourage adoption of relevant international standards, improve quality, facilitate access, and help reduce the root causes of shortages.
  - ✓ Develop and implement a strategy to leverage opportunities in partnerships and multilateral relationships to promote investments in new technologies and expansion of the industrial base, including adoption of environmentally sustainable and ethical practices and development of eco-friendly manufacturing practices for KSMs and APIs that are cost-competitive with traditional methods.

Anticipated Implementation Challenges, Including Gaps in Resources and Authorities

While improved coordination and collaboration can help facilitate resilient responses to supply chain disruptions, funding limitations pose a barrier to expanding HHS's coordination and communication activities, both internally and in partnership with domestic and international stakeholders. Securing additional funding may also be necessary to incentivize meaningful engagement, and uncertainty about sustained funding may pose a barrier to achieving some of these targets. While leveraging multilateral opportunities is key to increasing domestic manufacturing capacity, some partners may be hesitant to collaborate due to concerns about

staffing, trade secrets, regulatory actions, and trust. Appendix E lists budget requests and legislative proposals that seek to fill these gaps and would, if passed, support achievement of this goal.

Goal 2. ASSESS. Increase availability and utilization of actionable insights into critical medical product and food supply chains for HHS.

America's medical product and critical food supply chains are complex and involve many actors, including regulators, suppliers, manufacturers, distributors, wholesalers, group-purchasing organizations, pharmacy benefit managers, pharmacies, and healthcare providers (e.g., hospitals, physicians, and emergency responders). A crucial element for addressing shortages is supply chain visibility, which requires identifying and collecting data from all links in the supply chain.[26] Specifically, this includes identifying the medical products and critical foods for which visibility should be prioritized, and specifying the level of data required and the process for gathering the information.[1] HHS has taken steps in recent years to improve supply chain visibility and to enable improved decision-making, including through implementation of manufacturer volume reporting requirements and connecting with medical product distributors to collect inventory and shipment data through the Supply Chain Control Tower (SCCT). Greater supply chain visibility through increased availability and utilization of data across HHS could promote early identification of supply chain risks and vulnerabilities.

Statement of the Problem

During the COVID-19 pandemic and recent shortage response efforts, manufacturers, distributors, group purchasing organizations, pharmacies, hospitals, retailers, industry associations, and other private sector stakeholders have voluntarily provided HHS with crucial production, inventory, and demand data. These data have helped facilitate a stronger response to supply disruptions and kept industry and consumers more informed. However, manufacturers, distributers, and other industry stakeholders are not required to provide FDA with all the data necessary to achieve end-to-end manufacturing supply chain visibility for all—including critical medical products.[25] For example, the CARES Act of 2020 mandated registrants of drug establishments to report annually the amounts of each listed drug manufactured for commercial distribution, but the lack of linkage between API production quantities and amounts allocated to specific finished dosage form manufacturers limits the usefulness of the reports.[27] In addition, the CARES Act added Section 506J to the Food, Drug, and Cosmetic Act (FD&C Act). Section 506J requires manufacturers of certain medical devices to notify FDA about interruptions and discontinuances likely to lead to a meaningful supply disruption, but only during or in advance of a PHE.[28] FDA does not have the statutory authority to collect information on drug manufacturers' production capacity. It was not until 2022 that the FD&C Act was amended to require risk management plans and notifications from manufacturers about potential shortages of

[26] Harbert, T. (2020). Supply chain transparency explained. MIT Sloan School of Management. Retrieved from: https://mitsloan.mit.edu/ideas-made-to-matter/supply-chain-transparency-explained
[27] U.S. Food and Drug Administration (2023). Letter to Committee on Energy and Commerce. https://docs.house.gov/meetings/IF/IF14/20230511/115917/HMTG-118-IF14-20230511-SD006.pdf
[28] U.S. Food and Drug Administration (2023). Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act. Guidance for Industry and Food and Drug Administration Staff. November 2023. Retrieved from: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/notifying-fda-permanent-discontinuance-or-interruption-manufacturing-device-under-section-506j-fdc

critical foods (i.e., medical foods and infant formula).[29] There is still no requirement for risk management plans for medical devices. Further, the lack of investment into quality management maturity of the manufacturing process for medical products and critical foods means that the market lacks information to reward manufacturers that invest in supply chain resiliency.[30] The 2024 HHS White Paper discussed potential policy solutions to increase data collection and disclosure to assess the reliability of drug manufacturing practices. Similar solutions are relevant for other types of medical products. Data needs include:[25,22]

- Manufacturing production capacity, inventory, and site information to identify suppliers, site locations, inspection information for compliance, and to define available supplies.
- Distributor inventory and order data to understand buffer inventory levels and national demand, and to facilitate shortage detection and resolution efforts.
- Prescription volume and sales information to provide insights into market diversity and demand projection modeling.
- Product-specific data that provide granular lists of raw materials, APIs, or components to identify origin sources and suppliers.
- Logistics data such as listings of cold chain and other supply locations and volumes.
- Purchaser information to provide visibility into infield supply.

Gaps in the demand data for medical products also limit identification and predictability of potential shortages driven by surges in demand. For example, lack of real-time inventory or purchasing data limits the capacity for purchasing coordination during a crisis. Further, inadequate information on expected demand—due to factors such as lack of long-term purchasing contracts—can weaken supply chain redundancy because uncertainty regarding demand can make manufacturers unwilling to invest in expanded capacity.

Availability of resources, the variety and complexity of medical product and critical food supply chains, and other challenges discussed above mean that limited visibility will always be an issue. This predicament necessitates innovative, cost-effective, equitable, and efficient approaches to determine the best method to gather actionable insights for various use cases. For example, industry stakeholders have recently developed supply chain resiliency assessment programs designed to help medical product purchasers identify and select more resilient suppliers, thus helping to incentivize manufacturers and others to invest in costly resiliency steps.[31] Insights from these assessment programs could also help HHS evaluate supply chain vulnerabilities and take preventive actions to reduce future shortages.

Objective 2.1. Expand availability of supply chain data, including on strategic intelligence and economics of market intermediaries, into critical medical product and food supply chains for HHS.

[29] U.S. Food and Drug Administration (2024). Status Update on FDA's Infant Formula Response Activities. Updated February 12, 2024. Retrieved from: https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/status-update-fdas-infant-formula-response-activities

[30] FDA Drug Shortages Task Force (2020). Drug shortages: Root causes and potential solutions. Retrieved from: https://www.fda.gov/drugs/drug-shortages/report-drug-shortages-root-causes-and-potential-solutions

[31] Healthcare Industry Resilience Collaborative (undated). A Badge Built on the Science of Resiliency. Retrieved from: https://hircstrong.com/resiliency-badge/

- *Action 2.1.1*. Conduct regular assessments to align current data needs with supply chain and shortage data needs, including identifying users, within and external to HHS, to identify cross-cutting capabilities and purposes.

    - ✓ In consultation with relevant internal and external experts, identify data and research needs.

- *Action 2.1.2*. Refine criteria and process for identifying medical products, critical foods, and raw materials that require enhanced visibility for HHS.

    - ✓ Assess animal drugs and APIs to determine the need to prioritize animal drugs and their APIs for enhanced visibility.
    - ✓ Assess the need and feasibility to prioritize foods for enhanced visibility.
    - ✓ Support efforts to identify and prioritize the list of MCMs needed for potential threats, including a PHE.

- *Action 2.1.3* Improve data utilization, data sharing, integration, and standardization across the supply chains for medical products and foods.

    - ✓ Leverage existing authorities, data sources, and analytical capabilities to enhance visibility into prioritized list of essential medicines, which may include products on the Advanced Regenerative Manufacturing Institute's (ARMI) essential medicines list (EML) or other prioritized products, including through collaboration with interagency and external stakeholders.
    - ✓ Leverage existing authorities, data sources, and analytical capabilities to enhance visibility into a prioritized list of critical medical devices, including raw materials and components.
    - ✓ Enhance availability and utilization of actionable insights into investments and assess their impacts on economic sustainability and supply chain resilience.
    - ✓ Support initiatives that develop and maintain the workforce talent needed to improve availability, utilization, integration, and validation of data.
    - ✓ Assess data needs and gaps to enhance availability and utilization of actionable insights into food supply chains.
    - ✓ Leverage technology and horizon scanning tools that can be used by U.S. Government agencies.
    - ✓ Leverage existing partnerships and mechanisms to expand the utility of the Supply Chain Control Tower (SCCT) for data monitoring and sharing.

Objective 2.2. Expand HHS capacity for data analytics and other capabilities to transform available data into actionable insights with clear use cases for addressing shortages.

- *Action 2.2.1* Formalize and implement a plan to transform how supply chain data are shared and integrated across HHS, as maximally allowable within existing authorities.

- ✓ Based on data needs, assess the feasibility of integrating and sharing certain supply chain data across HHS, as allowable within existing authorities, to increase visibility into the supply chain for relevant components of HHS.
- ✓ Support investments, collaborations, and convenings to encourage exchange of information and data between the U.S. Government and external stakeholders, as allowable within existing authorities.
- ✓ Develop and execute a plan to share information with state, local, tribal, and territorial (SLTT) partners and to build visibility into SLTT-level supply chain buffer inventories.

- *Action 2.2.2* Conduct supply chain mapping for prioritized medical products identified for enhanced visibility.

  - ✓ Complete mapping of PHE medical products previously prioritized for enhanced visibility, including raw materials, components, manufacturers, distributors, and end users.
  - ✓ Map prioritized medical devices for enhanced visibility, including components, and other relevant data.
  - ✓ Assess feasibility of extending supply chain mapping to the Strategic National Stockpile (SNS).
  - ✓ Support initiatives that develop and maintain workforce talent needed to facilitate analytical capacity.

- *Action 2.2.3* Expand capacity for next generation integrated supply chain predictive tools for critical medical products.

  - ✓ Complete assessment of ability to assess risk of drug supply chain disruptions.
  - ✓ Complete development of data analytics and predictive modeling platform to increase visibility into medical devices.
  - ✓ Identify and assess next generation supply chain predictive tools to increase visibility into prioritized medical products.
  - ✓ Explore procurement mechanism of analytical tools that can facilitate improvements in modeling and other analytical capabilities.

- *Action 2.2.4* Expand research and evaluation of strategies to enhance supply chain visibility and analytics to improve measurement of supply chain resilience.

  - ✓ Facilitate research to address gaps and further understand the role of key factors or actors affecting supply chain vulnerability and shortages, including, but not limited to, understanding the role of economic health, measuring and evaluating supply chain resiliency and visibility.

Anticipated Implementation Challenges, Including Gaps in Resources and Authorities

Many causes of disruptions are unpredictable or occur at nodes in the supply chain where HHS may have limited visibility, resources, or authority. Although HHS has insight into some aspects of the supply chains for certain finished products and APIs and actors, there are limitations to

resources, statutory authority, data quality, data reliability, reporting requirements, confidentiality and disclosure protections, that inhibit the ability to share data widely and to enhance visibility into the domestic and global supply chains. Appendix D lists budget requests and legislative proposals that seek to fill these gaps and, if passed, would support implementation of this goal.

In addition to legislative authorities, current HHS funding levels limit activities that would enhance visibility into medical product and critical food supply chains, including identification and assessment of vast data sources; conduct of comprehensive surveys of data collections regarding APIs and KSMs required to detect threats; and comprehensive and regular assessments of threats and vulnerabilities, such as those associated with cybersecurity and natural disasters, among others. HHS will continue to develop and make recommendations to Congress seeking statutory authorization and funding to increase HHS's ability to collect and share information, as well as to expand its predictive and surveillance capacity to enhance supply chain visibility.

Goal 3. RESPOND. Strengthen HHS response to shortages and supply chain disruptions.

An effective response rests on the ability to adapt and scale up in times of crisis to limit disruptions and prevent shortages due to any of a wide variety of threats.[1,Error! Bookmark not defined.] Preparedness, mitigation, response, and recovery are key activities that determine the resilience of supply chains. Mitigation strategies reduce the likelihood or magnitude of supply disruptions or shortages, and include actions that help prevent them or blunt their impacts. Preparedness includes actions that are taken before a supply chain disruption or shortage, and is meant to prevent an event or reduce the risk to public health and safety if the event occurs. Preparedness means ensuring there are processes, plans, protocols, assessments, and governance in place to manage known or unanticipated threats introduced by a disruption or shortage. It also involves readiness, which builds capabilities for managing scenarios and threats without specific plans made in advance. Preparedness as a process involves a continuous cycle of planning, organizing, training, equipping, exercising, evaluating, and taking corrective action to ensure an effective response. Response measures include actions taken after a disruption or shortage occurs to prevent or reduce public harm. An effective response is coherent, agile, and relies on robust preparedness and mitigation activities that return the supply chain to a state of normalcy (recovery), while minimizing harm.

Statement of the Problem

The complexity of medical product and critical food supply chains introduces many opportunities for shortages and supply chain threats to affect the health and well-being of Americans. Shortages may be triggered by a supply chain disruption such as a natural disaster, insufficient supply to meet increasing demand, or business decisions by industry, such as minimizing quality-related investments or discontinuing a product or set of products. Some shortages (e.g., of manufacturing materials) can create an additional challenge to quickly ramp up domestic production of life-saving medical products and critical foods. Further, threats such as pandemics and disasters (e.g., fires, hurricanes, other extreme weather events, infectious diseases, and deliberate chemical, biological, and radiological/nuclear (CBRN) threats, or security attacks) are difficult or impossible to predict. This diverse set of threats poses many challenges to HHS as well as to suppliers, purchasers, and other stakeholders that play a crucial role in facilitating an effective response.

While the overall framework for response remains the same for every shortage or disruption, the risks and resources needed will vary (e.g., data, analyses, policy tools, coordination), and each response must be evaluated along these dimensions. A risk-based approach is established on multiple criteria including, but not limited to, the cause of the shortage or disruption, the public-health risk associated with the shortage or disruption, logistics and distribution considerations, and the authorities or other actions available to HHS or its partners. Further, development and regular maintenance of protocols, plans, and processes for identifying threats and implementing a response will require establishing processes for strategizing, evaluation, distribution,

procurement, funding, administration, and other response activities that need to be nimble in a time of crisis.

Objective 3.1. Prioritize an effective response to a shortage or supply chain disruption through building and maintaining capacity and capabilities.

- *Action 3.1.1* Proactively develop and maintain resources, protocols, plans, and processes to expand HHS's ability to surge and adapt during a response.

    - ✓ Identify, develop, monitor, and update resources needed to expand HHS ability to surge and adapt during a response.
    - ✓ Identify current HHS and other U.S. government risk assessment efforts to identify critical risks to public health and develop a risk management plan to address potential risks.
    - ✓ Implement HHS's long-term strategy to strengthen the resilience of the U.S. infant formula supply chains.
    - ✓ Conduct regular tabletop exercises to assess current or developing capabilities in preparedness and response within and outside HHS, and update plans and capabilities.
    - ✓ Facilitate research to identify threats, including (where appropriate) those to animal drugs and foods, that affect HHS's ability to surge and adapt during a response.
    - ✓ Enhance inspection and enforcement to prevent counterfeit products from entering the U.S. market.

- *Action 3.1.2* Accelerate development and adoption of technologies or approaches that enable rapid scaling and efficient supply chain management practices.

    - ✓ Identify advanced manufacturing technologies, novel technologies, or other approaches that facilitate rapid scale-up of production and delivery through guidance, procurement and investment requirements, and other available tools.

- *Action 3.1.3* Promote inventory management practices, including buffer stock, vendor-managed inventory, and stockpiling in routine care and in stockpiles.

    - ✓ Develop and implement strategy to innovate the SNS to optimize shelf-life and distribution.
    - ✓ Identify inventory management practices that minimize the impacts of shortages or supply chain disruptions and build resilience into the supply chain, including, but not limited to, automation, alternative stockpiling modalities, sustainable measures, machine learning, artificial intelligence, and centralized distribution.
    - ✓ Promote inventory management practices in routine care and in the SNS that mitigate the impacts of shortages or supply chain disruptions and strengthen the resilience of the supply chain through investments, acquisition methods, and reimbursement policies.

Objective 3.2. Maintain and enhance the resilience, safety, and security of HHS workforce, facilities and assets to ensure long-term viability of effective response capabilities related to shortages and/or supply chain disruptions.

- *Action 3.2.1* Audit, maintain, and bolster a highly competent, diverse workforce to facilitate implementation of an effective response to address shortages and supply chain disruptions.

    - ✓ Develop strategy to improve recruitment and retention practices that attract the best talent to support HHS response capabilities.

- *Action 3.2.2* Maintain the safety and security of facilities and assets to ensure readiness during a response focused on shortages and/or supply chain disruptions.

    - ✓ Develop strategy to adopt best practices in safety and security of all HHS facilities and assets.

Anticipated Implementation Challenges, Including Gaps in Resources and Authorities

Current budget authority is not sufficient to sustain certain existing HHS activities, many of which were supported by COVID-19 supplemental funding. In many cases, especially for acute responses, engagement of other HHS and U.S. government partners, industry, and other external stakeholders is critical for an effective response, and some capabilities, such as funding to purchase licenses to access proprietary market data or to build and maintain a central hub of current distributor data through the SCCT, require sustained funding or new authorities to continue. Likewise, FDA's Center for Devices and Radiological Health, Office of Supply Chain Resilience requires additional base funding to sustain the medical device supply chain data analytics and modeling capabilities that were built with COVID-19 supplemental funding. These capabilities have been used to inform decisions and mitigate impacts from systemic supply chain issues not related to COVID-19 (e.g., ethylene oxide and medical device sterilization capacity, Chinese manufactured syringe recalls, per-and-polyfluoroalkyl substances, supplier market exits, and disruptions due to natural disasters).

HHS's ability to accelerate development and adoption of technologies that enable rapid scaling is also limited by funding available for investment and procurement. Stable investment and funding opportunities for industry are critical in order to incentivize building, expanding, and maintaining response capabilities in partnership with HHS. Further, improving flexibility in contracting mechanisms and requirements can allow HHS to guide vendors to shift production priorities to help sustain the supply chain during a crisis and to ensure a rapid response. Appendix D lists legislative proposals that seek to fill these gaps and, if passed, would support achievement of this goal.

Amid the increasing complexity of global supply chains and a diverse set of threats, HHS must continually strengthen its capacity to act swiftly and decisively in the face of medical product and critical food shortages and supply chain disruptions; swift and decisive action can, in turn, prevent or mitigate the most adverse impacts to public health.

Goal 4. PREVENT. Incentivize investment in supply chain resilience through increased supply chain diversification, redundancy, and other strategies.

Supply chain resilience involves fostering processes that are robust and less likely to face disruption, as well as establishing the ability to withstand and mitigate disruptions so that their impacts—when they occur—are limited. As noted in Goal 3, a resilient supply chain rests on robust preparedness, mitigation, response, and recovery strategies. Resilience requires an expanded industrial base and is built by diversification in sourcing—both in terms of redundancy in manufacturing capacity and balance of domestic and diversified foreign sourcing. Resilience relies on the presence of reliable, efficient, sustainable and robust purchasing, distribution, and manufacturing practices. Resilience applies to finished products, raw materials, and components used to make finished products. Further, other supply chains (e.g., energy, fuel, durable goods, and agriculture) that often intersect with medical product and critical food supply chains warrant careful consideration in building resilience into medical product and critical food supply chains.

Both supply-side and demand-side incentives can increase supply chain resilience. Supply-side incentives typically target manufacturers, whereas demand-side incentives are typically targeted toward purchasers. Supply-side incentives can be used to diminish risk or decrease upfront capital investment needed to enter a market, such as through a contract for building manufacturing capacity. Demand-side incentives can be used to influence purchaser behavior, such as by encouraging purchasers to identify and remove risks in their supply chain. Supply-side incentives can spur more direct and immediate actions by manufacturers, but the impact on patient care may be delayed or uncertain. Demand-side incentives can be more easily tied to steps that improve healthcare providers' ability to improve patient outcomes, but the impact on manufacturers may be delayed or uncertain. Improving patient care is HHS's ultimate goal, and challenges to the economic viability of medical manufacturers have been consistently identified as a root cause of shortages (see accompanying Draft Research Plan for details). For these reasons, HHS is employing both supply-side and demand-side incentives to address supply chain challenges.

HHS, through the new Industrial Base Management and Supply Chain Office, has since 2023 invested hundreds of millions of dollars in advanced manufacturing capabilities to lower the cost of domestic manufacturing of KSMs and APIs, thereby reducing foreign dependency and promoting global competitiveness for U.S.-made products. HHS is also using its tools to align certain incentives, including through its payment policies, to bolster supply chain resilience and further promote adoption of supply chain practices. For example, in the calendar year (CY) 2023 Hospital Outpatient Prospective Payment System (OPPS) final rule, CMS finalized a policy to provide separate payment to hospitals for the Medicare share of the additional cost of domestic surgical N95 respirators approved by the National Institute for Occupational Safety and Health (NIOSH)(87 FR 72037-47). CMS also included a request for comment in the CY 2025 OPPS proposed rule on other types of PPE, such as nitrile gloves and medical devices, that could be appropriate for a payment adjustment similar to the existing payment adjustments for domestic, NIOSH-approved surgical N95 respirators (89 FR 59396-99). In the CY 2025 OPPS final rule, CMS summarized these comments and stated their intention to propose a new payment

methodology for these adjustments and to propose to expand the payment adjustments to domestic non-surgical N95 respirators and domestic nitrile gloves in 2026 rulemaking (89 FR 94290-95).

In the CY 2024 OPPS final rule, CMS solicited public comment on providing separate payment under the Medicare Inpatient Prospective Payment System (IPPS)—and potentially the OPPS—for establishing and maintaining access to buffer stock of essential medicines (88 FR 82127-30). In the FY 2025 IPPS and Long-Term Care Hospital Prospective Payment System final rule, CMS, to foster a more reliable, resilient supply of essential medicines, adopted a policy to provide separate payment under the IPPS to small, independent hospitals for the IPPS shares of the additional resource costs to voluntarily establish and maintain a six-month buffer stock of one or more essential medicines (89 FR 69387-400). CMS stated that in future years, as it gains additional experience under this policy, it plans to assess the program's impact and consider program expansion and other revisions, where appropriate, to help ensure availability of essential medicines for patients. CMS also noted in the CY 2024 OPPS final rule that, as part of the agency's initial efforts, CMS intended to propose new Conditions of Participation in a future notice and comment rulemaking addressing hospital processes for pharmaceutical supply (88 FR 82130).

In addition, the April 2024 HHS White Paper describes policy concepts and two programs that would require Congressional action to develop and implement: a Manufacturer Resiliency Assessment Program and a Hospital Resilient Supply Program.[22] These programs would provide increased payments to hospitals that take costly steps to identify and reduce risks in their supply chains such as by contracting with more reliable suppliers, diversifying their supply chains, and holding buffer inventories. By targeting demand-side incentives that improve patient care, these programs can help HHS ensure that any increased costs are better matched with corresponding benefits to patients, in line with HHS's mission.

Statement of the Problem

The resilience of supply chains is highly influenced by the level of dependence on foreign countries for certain critical foods and medicines, APIs, and their manufacturing materials, as well as for medical devices, their key components, and manufacturing materials. Market factors, such as cost pressures, play a key role and tend to diminish diversification, redundancy, and investments in infrastructure and advanced manufacturing technologies and systems. Domestic production is often not competitive due to higher labor or production costs, including the costs of compliance with U.S. environmental and occupational regulations and codes compared to other countries.

U.S. and allied drug manufacturers, especially of generics and common drugs, are often undercut by low-cost competition, particularly competitors from India and China. Similarly, U.S. manufacturers of medical devices face intense competition from lower-cost imports, particularly from China, that are capable of flooding the market through traditional distribution streams as well as through e-commerce marketplaces. As seen early in the COVID-19 PHE and recently with Chinese manufactured syringes, some foreign-sourced products can pose significant safety risks to patients. Further, concentration in medical product and critical food markets adds to the negotiating power of certain intermediaries, resulting in lower costs for purchasers, but also

lower margins for manufacturers. While advanced manufacturing technologies have the potential to lower production costs and improve efficiency, their adoption is low due to perceived financial risks, lack of awareness, and regulatory concerns.

Increasing economic sustainability of resilient supply chains requires greater predictability in production costs, pricing, and sales volume. It also requires increasing government and private sector flexibility in contracting and sourcing of raw materials and finished products, and assessing the sectors and mechanisms that are in place to support diversification. Building resilience through supplier diversification involves exploring ways to support and reward increasing domestic capabilities for manufacturing essential medicines, medical devices, and other critical medical products and foods. This includes substantial investments to support domestic manufacturing of key ingredients and drugs, and innovative advanced manufacturing solutions to enable scalable, cost-effective, and environmentally sustainable solutions. It also involves leveling the playing field for medical device manufacturers so they can compete with lower cost, foreign sourced medical devices. In addition, it requires strengthening links with partner and allied nations that use supply chain management practices that support resilience. Given the likelihood that cost differentials between domestic and foreign medical products will continue, innovation in manufacturing is likely to be a key component of the strategy to diversify manufacturing and increase domestic supply.

Objective 4.1. Implement supply-side investments that reward supply chain resilience.

- *Action 4.1.1* Identify new approaches and promote policies that expand the capacity of the industrial base and enhance supply chain resilience.

    - ✓ Refine and implement the industrial base expansion plan for medical products, including plans to ensure sustainment of products and materials.
    - ✓ Continue to refine the quality management maturity protocol assessment as a tool that can be used to increase transparency on resiliency in the pharmaceutical supply chain.
    - ✓ Promote strategies such as onshoring, ally-shoring, and "Buy in America" to expand the domestic industrial base and enhance supplier diversification.
    - ✓ Coordinate the promotion of administrative and legislative options that enhance quality management maturity and supply chain resilience practices.
    - ✓ Adopt acquisition practices that incentivize industry's engagement in approaches that promote domestic sourcing and supply chain resilience (e.g., proof of concept, supply chain resilience plan development).

- *Action 4.1.2* Speed innovation and adoption of advanced technologies to expand domestic capacity and supply chain diversification and redundancy.

    - ✓ Promote adoption of new and sustainable manufacturing technologies to stimulate domestic production and diversified sourcing and strengthen supply chain resilience.
    - ✓ Invest in infrastructure to expand domestic capacity for manufacturing vials, fill-finish, consumables, and raw materials.

- ✓ Promote manufacturing processes to improve the agility, flexibility, cost, and reliability of product manufacturing, including vaccines and cell and gene therapies; continue working intramurally and through extramural award(s) to foster innovation, development, and creation of more modern, U.S.-based advanced manufacturing; and build off a demonstration project for messenger RNA focusing on best practices in integrated and continuous vaccine manufacturing.
- ✓ Engage with manufacturers and blood centers to identify novel pathogen reduction technologies for whole blood; to encourage R&D of innovative blood products; and to expand diversification and manufacturing quality improvements.

- *Action 4.1.3* Maintain and increase the competitiveness of the U.S. through human capital investments.

  - ✓ Develop strategy to improve recruitment and retention practices to train and retain the HHS workforce needed to implement policies and initiatives that strengthen supply chain resilience.

Objective 4.2. Implement demand-side investments that reward supply chain resilience.

- *Action 4.2.1* Continue to refine existing demand-side programs to increase their use and effectiveness.
  - ✓ Assess the impacts of CMS buffer stock payment policy and consider revisions in future rulemaking as needed to help ensure availability of essential medicines for patients.
  - ✓ Continue to refine the quality management maturity protocol assessment as a tool that can be used to increase insights into the resiliency of the pharmaceutical supply chain.
  - ✓ Assess feasibility of developing a quality management maturity framework to increase transparency on resiliency in the medical device supply chains.

Anticipated Implementation Challenges, Including Gaps in Resources and Authorities

While HHS is using its capabilities to create incentives to bolster supply chain resilience, the tools currently available are limited in scope and can take time to implement given established timelines or budget requirements (e.g., budget neutrality). Achieving the stated goal requires significant investment and changes in HHS's budget and statutory authority. Current budget and legislative authority are not sufficient to incentivize investment levels or the supply chain diversification and redundancy required to enhance supply chain resilience in a timely, meaningful, or sustainable manner. The HHS White Paper provides a policy proposal that could enable adequate budget and legislative authority. Appendix D lists budget requests and legislative proposals that seek to fill these gaps and, if passed, would support achievement of this goal. These and other proposals would incentivize investments in practices that increase supply chain resilience.

Section 3. Conclusion

The COVID-19 pandemic highlighted significant vulnerabilities in the U.S. medical product and critical food supply chains, and historic efforts were made to mitigate and resolve these disruptions and shortages. The HHS Draft Action Plan (2025–2028) outlines four overarching goals to further address existing supply chain vulnerabilities and better position the U.S. Government to respond to future shortages and supply chain disruptions. These goals include increasing supply chain visibility and capacity to identify risks and vulnerabilities, strengthening the response to shortages and supply chain disruptions, building a more resilient public health supply chain by incentivizing investments in resilient practices, and improving communication and coordination within government and with key partners. While the Draft Action Plan describes the roles and responsibilities of various agencies and HHS offices in addressing supply chain vulnerabilities, a detailed description of HHS efforts to increase resilience in the pharmaceutical and API supply chains, as well as the industrial domestic base, are outlined in the Deep Dive: Pharmaceuticals and APIs and the Industrial Base chapters of the Quadrennial Supply Chain Review.

These are not the only efforts to address supply chain vulnerabilities and shortages. Indeed, HHS has proposed several complementary legislative initiatives to improve the Department's capabilities in achieving each of the four goals in the Draft Action Plan. These proposals span several HHS agencies and would provide them with new or additional authorities to better address potential supply chain disruptions and protect public health. Some of these changes would require new or additional information sharing between industry and FDA under certain conditions. Such conditions include when there is an interruption or discontinuance in the manufacture of critical devices or critical foods; positive test results for relevant pathogens; or when drug manufacturers will, collectively, be unlikely to meet an increase in demand. Similarly, it would require that key partners such as healthcare providers, laboratories, pharmacies, suppliers, service organizations, and SLTT agencies submit additional data to improve health threat detection and distribute MCMs and critical supplies.

Another proposed solution entails granting new authorities for FDA to conduct remote interactive evaluations of facility inspections, and separately to ensure that the data supporting medical products are reliable and verifiable. Other proposals would permit FDA to share information with the public, such as the disclosure of impurities in drugs, as well as sharing certain non-public information with SLTT partners to protect public health. Authorities to improve FDA's risk identification and supply chain tracking, as well as expanding the agency's recall authority, would allow it to more quickly respond to poor quality products and collect a fixed fee from the responsible party. Several proposals would advance ASPR's efforts to increase the supply of essential medicines, including acquiring innovative commercial products, funding development and large-scale manufacturing of a product, and acquiring or constructing non-federally owned facilities. In the HHS White Paper, HHS describes policy concepts that would require Congressional action to develop and implement two programs: a Manufacturer Resiliency Assessment Program and a Hospital Resilient Supply Program. Each would bring transparency into the market, better align purchasing and payment decisions with supply chain resilience practices, and incentivize investments in supply chain resilience and diversification. HHS is also aware of many additional ideas under consideration, which would further improve

supply chain data collection, increase competition, and ensure that fraudulent products are identified and removed from the market.

Accomplishing the goals in this Draft Action Plan, when finalized, will increase investments in technologies and practices that help create more robust and resilient supply chains. Doing so will mitigate or prevent future shortages and supply chain disruptions, improve the overall health and wellbeing of Americans, and increase the economic sustainability and competitiveness of the U.S. as a whole. Achieving these goals and outcomes requires significant funding and resources as well as continued efforts within HHS, across the U.S. Government, SLTT partners, the private-sector, and other stakeholders, and must remain a priority to protect the health of Americans.

Appendices

Appendix A. HHS Agencies and Their Roles in Addressing Supply Chain Disruptions and Shortages

Within HHS, FDA leads the response effort for shortages of products that it regulates. The various components within FDA (e.g., the Center for Biologics Evaluation and Research, the Center for Drug Evaluation and Research, the Center for Devices and Radiological Health, the Human Foods Program) each have established structures and procedures to respond to shortages of drugs, biological products, medical devices, and critical foods (i.e., medical foods and infant formula). These capabilities center on information gathering to determine whether a shortage exists, planning and implementing strategies to mitigate or prevent shortages, and assessing manufacturers' compliance with various reporting requirements. Other HHS agencies maintain a constant watch for potential and emerging public health threats. The Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology coordinates health information technology activities across the Department, ensuring patients' continued access to their health information and providing early detection of health information to clinicians and public health entities across the country. Within ASPR, the HHS Secretary's Operation Center is the focal point for information collection and sharing within the Department. Further, ASPR supports and coordinates and sustains targeted expansion of domestic manufacturing of essential medical products,[32] invests in next-generation MCM manufacturing and ancillary suppliers, and coordinates the acquisition and distribution of select COVID-19 vaccines and therapeutics through the Center for Industrial Base Management and Supply Chain, the Center for the Biomedical Advanced Research and Development Authority (BARDA), and the Center for the HHS Coordination Operations and Response Element. ASPR also manages the Center for the SNS and the SCCT, enabling it to acquire and distribute certain medical countermeasures and monitor the medical supply chain for COVID-19 products from participating distributors onwards.

In addition to these efforts, CDC provides critical support, in the form of surveillance and analytical modeling in mitigating the health impacts of supply shortages by through, as well as developing clinical guidelines and communication with stakeholders. CDC also works through interagency partnerships, and with SLTT health agencies, and provides information to clinical and public health professionals, policymakers and the public.

CMS facilitates preparedness for both natural and other disasters and emergencies by designing national emergency preparedness requirements for Medicare and Medicaid providers. For example, CMS may provide flexibilities or waive certain requirements under Medicare, Medicaid, and Children's Health Insurance Program (CHIP) during a PHE to ensure that beneficiaries have the healthcare items and services they require. CMS also administers programs that provide health coverage, such as Medicare, Medicaid, and CHIP programs, and

[32] As footnoted above, for purposes of this report, "essential medicines" are broadly defined as priority life-saving products. This may include among others, medicines in the Executive Order 13944 List of Essential Medicines, Medical Countermeasures, and Critical Inputs published in October 2020, as well medicines in the Essential Medicines Supply Chain and Manufacturing Resilience Assessment report published by ARMI in May 2022.

the Health Insurance Marketplace.®[33] To develop promising treatments and vaccines, the National Institutes of Health both conducts and supports research through various centers and institutions. ARPA-H invests in high-impact solutions to health challenges and is generally interested in research efforts in supply chain data analytics, medical logistics and advanced manufacturing innovation to support supply chain resilience. ARPA-H investments are program manager driven. AHRQ produces, disseminates, and implements evidence to improve healthcare, including supporting health services research to make healthcare safer, higher quality, more accessible, equitable, and affordable, which could include research that explores strategies and solutions to improve supply chain resilience. Additionally, AHRQ has identified supply chain disruption as the focus of a forthcoming Making Healthcare Safer report.[34] The Office of Intergovernmental and External Affairs (IEA) establishes and supports intergovernmental and external partner relationships and communication channels, including on supply chain disruptions and shortages. IEA advises HHS on SLTT issues, facilitates communication between HHS and external partners, and coordinates the HHS regional offices when disruptions and shortages arise. Finally, OGC is the legal team for HHS, providing representation and legal advice, including issues related to shortages and the COVID-19 pandemic. While individual response efforts are undertaken within these HHS agencies, additional actions include coordination across multiple HHS offices, as well as more broadly with agencies outside HHS.

[33] Health Insurance Marketplace® is a registered service mark of the U.S. Department of Health and Human Services.
[34] AHRQ (2024). Making Healthcare Safer IV: Supply Chain Disruption Monitoring Programs. Retrieved from: https://effectivehealthcare.ahrq.gov/products/monitoring-programs/protocol

Appendix B. Examples of Causes of Shortages of Medical Products and Critical Foods

Drug shortages are often driven by manufacturing delays caused by quality concerns. An analysis of drugs newly in shortage from 2013-2017 found that 62 percent were caused by manufacturing or product quality issues.[35] While increased price competition among generic manufacturers has produced low-cost generic drugs, the accompanying reliance on a small number of manufacturers increases the possibility of a shortage occurring. Additionally, the low margins make it difficult to invest in buffer stock, as well as manufacturing maintenance and upgrades.

For medical devices, all six medical device product codes in shortage in December 2024 were due to discontinuation or shortage of a component, part, or accessory of the device, with one also listing an increase in demand. This is consistent with the reasons for shortages experienced through much of the COVID-19 PHE. A study examining data from 2016-2020 found that pre-2020, most shortages of medical devices stemmed from regulatory and enforcement actions related to product quality and manufacturing issues, while shortages in early 2020 were due to an acute increase in demand.[36]

On February 17, 2022, Abbott Nutrition—one of the largest U.S. manufacturers whose Sturgis, Michigan facility supplies 40 percent of the nation's infant formula—issued a voluntary recall of certain infant formula products manufactured in Sturgis and temporarily ceased production. The recall was voluntarily expanded on February 28, 2022, by Abbott Nutrition to cover additional products. While necessary to safeguard public health, the recall and pause in production further stressed a supply chain already strained by the COVID-19 pandemic and preceding market concentration issues. While the underlying causes of shortages vary within and across product type, some overlapping issues relate to limited diversity in suppliers and manufacturing practices that increase the risk of supply chain interruptions.

[35] U.S. Food and Drug Administration (2020). Drug Shortages: Root Causes and Potential Solutions 2019. Retrieved from: https://www.fda.gov/media/131130/download

[36] U.S. Food and Drug Administration (2024). Medical Device Shortages List. Retrieved from: https://www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/medical-device-shortages-list#shortage

Appendix C. Select U.S. Government Milestones to Increase Supply Chain Resilience and Address Shortages

In August 2020, E.O. 13944 was issued to strengthen domestic supply chains and protect the public from infectious diseases and other threats.[37] This action directed FDA to identify a list of essential medicines, MCMs, and critical inputs that are most needed in acute care medical facilities or anticipated to respond to future pandemics, epidemics, and CBRN threats. It also directed relevant federal agencies, including or in consultation with FDA, to develop strategies to procure these products, accelerate domestic manufacturing, and identify and address supply chain vulnerabilities. In response, in 2020 FDA released a list of regulated products determined to be in need during a national emergency and which were expected to have the greatest impact on public health ("E.O. 13944 EML").[38] The E.O. 13944 EML included certain human drugs and biological products, MCMs (including medical devices), and critical inputs, which included APIs, starting materials, or other ingredients or parts. The inclusion criteria for the E.O. 13944 EML varied by product (medicines, MCMs, medical devices) and inputs.[39] As part of a separate, more recent action discussed in the "Efforts to Date" section, ARMI and ASPR prioritized 86 medicines from the E.O. 13944 EML. The ARMI EML included medicines that were considered to be the most critically needed for typical acute care.

In 2021, two executive orders were issued to further strengthen supply chains. Executive Order 14001 focused primarily on preparedness. It directs agencies to develop a strategy to respond to future pandemics and threats through increased domestic production of key supplies for sustainable public health supply chains.[40] To accomplish this task, HHS, in collaboration with the departments of Defense, Homeland Security, Commerce, State, Veterans Affairs, and the White House Office of the COVID-19 Response, developed the National Strategy for a Resilient Public Health Supply Chain ("National Strategy") in 2021.[1] The National Strategy contains several overarching goals related to public health to be achieved over 10 years. These include building an agile public health supply chain for future pandemics, improving the government's ability to monitor and manage the supply chain, and establishing standards, systems, and governance in a fair, equitable, and effective way. To accomplish these tasks, the National Strategy calls for improving the robustness, agility, and visibility of finished products and the raw materials, equipment, and ancillary supplies needed to make and use these products. Additional efforts include training requirements and investments in human capital to sustain additional domestic manufacturing. Over the long term, this requires the U.S. Government to remain focused on sustaining industrial base expansion investments and preparedness. E.O. 14001 also requested the establishment of a quadrennial supply chain review, including processes and timelines regarding ongoing data gathering and supply chain monitoring. The majority of the Plans of Action and Milestones, as part of the National Strategy for a Resilient

[37] Executive Order No. 13944 (2020). Combating Public Health Emergencies and Strengthening National Security by Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States, 85 *Fed. Reg. 49929* (August 14, 2020). Retrieved from: https://www.federalregister.gov/documents/2020/08/14/2020-18012/combating-public-health-emergencies-and-strengthening-national-security-by-ensuring-essential

[38] U.S. Food and Drug Administration, Executive Order 13944 List of Essential Medicines, Medical Countermeasures, and Critical Inputs (2020). Retrieved from: https://www.fda.gov/about-fda/reports/executive-order-13944-list-essential-medicines-medical-countermeasures-and-critical-inputs#

[39] U.S. Food and Drug Administration, Criteria for Identifying Human Drug and Biologic Essential Medicines, Medical Countermeasures, and Critical Inputs for the List Described in Section 3(c) of the Executive Order (EO) 13944. Retrieved from: https://www.fda.gov/media/143407/download.

[40] Executive Order No. 14001 (2021). A Sustainable Public Health Supply Chain, *86 Fed. Reg. 7219* (January 21, 2021). Retrieved from: https://www.federalregister.gov/documents/2021/01/26/2021-01865/a-sustainable-public-health-supply-chain

Public Health Supply Chain, are complete/resolved, with the remaining due to be complete by the end of 2025.

The second Executive Order, E.O. 14017, directed federal agencies to conduct a 100-day supply chain review ("100-Day Report"), as well as a subsequent report one year later ("One-Year Report") and established a quadrennial supply chain review ("QSCR") for a range of sectors.[41] HHS was directed to identify supply chain risks related to pharmaceutical products and APIs, provide policy recommendations to address these risks, and to discuss progress in making public health supply chains and the biological preparedness industrial base more resilient. The findings of the HHS section of the 100-Day Report highlighted several key components of a resilient pharmaceutical supply chain, including the ability to produce high-quality drug products for the U.S. market, a geographically diversified supply chain, as well as redundancy to ensure production volumes can change with market conditions.[42]

In June 2021, the 100-day review published in response to E.O. 14017 (February 2021) advised that a consortium of public health experts in the government, the non-profit sector, and the private sector assemble to review the E.O. 13944 EML and recommend 50-100 drugs that are most critical to have available to U.S. patients at all times. ASPR sponsored a report to identify critical medicines needed for acute patient care, as well as related supply chain vulnerabilities and actionable solutions.[38] This effort used as a starting point the E.O. 13944 EML from 2020 referenced above.[38] Over 80 essential medicines were identified, as were several strategies to increase drug supply chain resiliency. These strategies include increasing end-to-end supply chain visibility, expanding onshore or nearshore production capacity, implementing advanced technologies and manufacturing processes, and improving national stockpiling of essential medicines.

In the One-Year Report, HHS detailed the historic progress in production capacity and identification of numerous factors contributing to the supply chain vulnerabilities that were exposed and exacerbated during the COVID-19 pandemic.[43] These vulnerabilities included reliance on foreign manufacturing, the economic pressures driving production away from the U.S., workforce challenges, barriers to entry, and lack of visibility into, and coordination within, the supply chain system. The One-Year Report also outlined further actions the U.S. can take to address each of these existing challenges and further bolster the public health supply chain and industrial base. Specifically, the One-Year Report highlighted the difficulties in procuring PPE and durable medical equipment during the COVID-19 pandemic, while noting the accomplishments of distributing and administering millions of vaccine doses and making investments in domestic production of MCMs. In December 2024, the Quadrennial Supply Chain Review (the Review) was released. The Review represented the first-ever formal assessment of critical sectors, including the public-health and biological preparedness industrial base, the pharmaceuticals and active ingredients sector, and the agri-food supply chains. The

[41] Executive Order No. 14017 (2021). America's Supply Chains, 86 *Fed. Reg. 11849* (February 24, 2021). Retrieved from: https://www.federalregister.gov/documents/2021/03/01/2021-04280/americas-supply-chains

[42] The White House (2021). Building resilient supply chains, revitalizing American manufacturing, and fostering broad-based growth: 100-day reviews under Executive Order 14017. Retrieved from: https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf

[43] The White House (2022). Executive Order on America's Supply Chains: A Year of Action and Progress. Retrieved from: https://www.whitehouse.gov/wp-content/uploads/2022/02/Capstone-Report-Biden.pdf

Review also detailed progress made over 2021-2024 to bolster the resilience of the most critical supply chains.

Appendix D. Budget Requests and Legislative Proposals that Support Goals in the Draft Action Plan

Budget Requests and Legislative Proposals in President's Budget for Fiscal Year 2025	**Goal 1 Coordinate**	**Goal 2 Assess**	**Goal 3 Respond**	**Goal 4 Prevent**
$10M to coordinate Department-wide supply chain activities, acquire analytic and administrative support for related activities, and to expand research activities to further understand medical product supply chains. (ASPE)	X	X		
Expand ASPR's withholding authority to include protection against the release of certain sensitive information of BARDA-funded partners. (ASPR)		X		
Require drug manufacturers to notify FDA of an increase in demand that the manufacturer will likely be unable to meet for certain drugs, which would assist the FDA in its prevention and mitigation efforts. (FDA)		X	X	
Expand FDA's authority to publicly disclose and use information submitted related to impurities in drugs, including biological products, when determined by FDA to be in the interest of public health. (FDA)		X	X	
Require Site Master Files for drug manufacturing facilities, which will assist FDA with risk identification for sites for surveillance and for-cause inspections. (FDA)		X	X	
Require drug labeling to include the original manufacturer and supply chain information to enable FDA to identify the original manufacturer of an API more quickly, and to facilitate taking appropriate action related to poor quality products. (FDA)		X	X	
Require manufacturers to notify FDA when there is an interruption or		X	X	

Budget Requests and Legislative Proposals in President's Budget for Fiscal Year 2025	Goal 1 Coordinate	Goal 2 Assess	Goal 3 Respond	Goal 4 Prevent
discontinuance in the manufacturing of certain devices. This will help mitigate critical device shortages beyond PHE situations. Require manufacturers of certain medical devices to develop, maintain, and implement risk management plans. (FDA)				
Clarify that FDA can impose additional conditions on notifications submitted by manufacturers of critical foods, (i.e., medical foods and infant formula) when there is a permanent discontinuance or interruption in manufacturing, and new authority to designate additional categories of foods for notification of anticipated interruptions, as is appropriate during a declared PHE. (FDA)		X	X	
Require that, among other things, infant formula manufacturers report to FDA product positive test results for relevant pathogens, and conduct more frequent environmental monitoring in their facilities to identify relevant pathogens to facilitate early detection of potential issues. (FDA)		X	X	
Provide FDA authority to ensure that data supporting applications and non-application medical products are reliable and verifiable for as long as the product may be legally marketed. This will ensure that FDA has appropriate tools to act on findings of fraudulent or unreliable data or information.(FDA)		X	X	
Expand FDA's authority to request records or other information in advance of or in lieu of inspections to		X	X	

Budget Requests and Legislative Proposals in President's Budget for Fiscal Year 2025	Goal 1 Coordinate	Goal 2 Assess	Goal 3 Respond	Goal 4 Prevent
all FDA-regulated commodities and to any records or other information that FDA may inspect under the FD&C Act as a whole. (FDA)				
Expand FDA's authorities for non-application drugs to allow for a risk-based approach to determine if an inspection or other evaluation of the manufacturing facilities required to register under the FD&C Act is necessary before the drug can be distributed, and to conduct such inspection or other evaluation if it is necessary. (FDA)		X	X	
Grant CDC authority to require data from healthcare providers, facilities, suppliers, pharmacies, laboratories, service organizations, and SLTT agencies, for the purposes of public health threat detection and monitoring, evaluation, and distribution of MCMs and critical supplies, and connection of communities with resources and services. (CDC)	X	X	X	
Expand FDA's authority to share certain non-public information with state, local, and territorial authorities with counterpart functions related to FDA-regulated products to improve efficiency and promote collaboration to better protect human and animal health. (FDA)	X	X	X	
Require manufacturers to provide FDA data identifying the suppliers they relied on to manufacture their drug products and the extent of such reliance, which would help FDA to identify vulnerabilities in the supply chain. (FDA)		X		X
Expand FDA's mandatory recall authority under the SUPPORT Act so that it covers all drugs. (FDA)		X	X	

Budget Requests and Legislative Proposals in President's Budget for Fiscal Year 2025	Goal 1 Coordinate	Goal 2 Assess	Goal 3 Respond	Goal 4 Prevent
Require expiration dates to be lengthened, which will help FDA mitigate critical drug shortages. (FDA)			X	
Expand FDA's reinspection and recall fee authority to collect a fixed fee from the responsible party; grant FDA discretion to reduce fees for smaller food facilities under the Preventive Controls regulations and amend the definition of a "reinspection." (FDA)			X	
Provide ASPR authority to acquire innovative commercial products, services, processes, and/or methods, e.g., technology investment agreements, R&D activities, and other capabilities, needed to respond to a future outbreak(s). (ASPR)			X	
Provide authority for acquisition, construction, or alteration of non-federally owned facilities, which would allow ASPR to support efforts to develop domestic manufacturing capacity for MCMs and related products. (ASPR)			X	X
Expand ASPR's Other Transaction Authority to enable ASPR to fund development of a product and move directly into large-scale manufacturing of the product, whether for a response or for stockpiling. (ASPR)			X	X
Provide funding to advance ASPR's permanent industrial base management capabilities, as domestic manufacturing efforts to increase supplies of essential medicines are critical to ensuring the resilience of the national health supply chain. (ASPR)				X

Appendix E. Background Documents

Author	Title	Publication Year
Executive Order	E.O. No. 13944, Combating Public Health Emergencies and Strengthening National Security by Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the U.S.	2020
Executive Order	E.O. No. 14001, A Sustainable Public Health Supply Chain	2021
Executive Order	E.O. No. 14017, America's Supply Chains	2021
The White House	Building Resilient Supply Chains, Revitalizing American Manufacturing, and Fostering Broad-Based Growth: 100-Day Reviews under Executive Order 14017	2021
The White House	National Strategy for a Resilient Public Health Supply Chain	2021
Department of Health and Human Services	Public Health Supply Chain and Industrial Base One-Year Report	2022
The White House	Executive Order on America's Supply Chains: A Year of Action and Progress	2022
Administration for Strategic Preparedness and Response	Essential Medicines Supply Chain and Manufacturing Resilience Assessment	2022
Administration for Strategic Preparedness and Response	Public Health Emergency Medical Countermeasure Enterprise - Strategy and Implementation Plan	2022
U.S. Government Accountability Office	GAO-23-106467, Priority Open Recommendations: Department of Health and Human Services	2023
Department of Health and Human Services	Policy Considerations to Prevent Drug Shortages and Mitigate Supply Chain Vulnerabilities in the U.S.	2024
Executive Order	E.O. No. 14123, White House Council on Supply Chain Resilience	2024
Quadrennial Supply Chain Review	2021-2024 Quadrennial Supply Chain Review	2024