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

2025–2028

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Preparation Notice

This Draft Research Plan for the 2025-2028 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 was prepared by the Department of Health and Human Services.

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Executive Summary

HHS has a decades-long history of working on policy research and analysis of medical product[1] and critical food supply chains and related topics. For the purpose of this Draft Research Plan, *medical products* include drugs, biological products, and medical devices, as well as active pharmaceutical ingredients (APIs) and raw materials, parts, components, or ingredients used to manufacture them. This Draft Action Plan also discusses critical foods.[2,3] Research topics include, among others, understanding the root causes and impacts of shortages and supply chain disruptions, studying the domestic and global supply chains of medical products, and critical foods, reviewing and assessing policy levers that affect supply chain resilience, and understanding the role of supply chain intermediaries and contracting practices on supply chain risks and vulnerabilities.

While HHS continues to contribute to the research on medical product and critical food supply chain resilience and shortages, much more must be done to fill research gaps and advance collective understanding of, and insights into, medical product and critical food supply chains. This Draft Research Plan is an annex to the 2025–2028 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"). This Draft Research Plan describes a targeted call to action across all sectors of research, both public and private, including academia, to accelerate research that can inform decisions to improve supply chain resilience and address shortages of essential medical products and critical foods. This Draft Research Plan describes priorities across the four goals in the Draft Action Plan, which are summarized below.

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

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

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

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

About the Draft Research Plan

Background

The 2025–2028 Draft Research Plan for Addressing Shortages of Medical Products and Critical Foods and Strengthening the Resilience of Medical Product and Critical Food Supply Chains ("Draft Research Plan") complements the 2025–2028 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"). The Draft Action Plan and the Draft Research Plan represent coordinated and strategic actions that the Department of Health and Human Services (referred to herein as HHS or the Department) plans to promote, support, or undertake in the next four years to improve the health and wellbeing of all Americans.

This Draft Research Plan aims to orient research priorities to support the four goals in the Draft Action Plan:

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

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

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

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

Purpose of the Draft Research Plan

- This Draft Research Plan provides an overview of the current research in this area, including work within HHS, by other U.S. Government agencies, and by external entities and researchers.
- This Draft Research Plan builds on ongoing research supported or conducted within and outside the U.S. Government. This Draft Research Plan aims to accelerate and expand these efforts and calls for more action by external researchers.

Partner Input

This Draft Research Plan was developed with input from key public and private partners. In addition to gathering input from HHS agencies, HHS interviewed researchers with expertise and active research portfolios in the major topical research areas. These researchers are affiliated with universities, think tanks, and nonprofit patient advocacy organizations. The interviews focused on understanding the available evidence, research gaps and priorities, and challenges to

accelerating research. This Draft Research Plan reflects the input obtained from these interviews.

Meaningful input is important throughout research projects, to help guide researchers and to translate findings into effective policy and practice. HHS will continue these conversations to gather feedback and revise the Draft Research Plan moving forward, as needed.

Introduction

This Draft Research Plan provides a high-level summary of current research on medical product and critical food shortages and supply chains, including their components and factors affecting supply chain resilience and vulnerability. It focuses on four areas delineated in the HHS Draft Action Plan: coordination, assessment, response readiness, and prevention through supply chain resilience. A targeted review of the literature (see Appendices B1-B4) and input from stakeholders contributed to this Draft Research Plan; it is not an exhaustive review of all the U.S. Government or external research on supply chain resilience and shortages.

Broadly, the research presented in this document highlights current gaps in the literature, presents opportunities to improve understanding, and examines the potential for applying certain findings to policy. For example, the identified need for a unified understanding of supply chain terminology, intermediaries, underlying structures, and root causes of risks to resilience highlights opportunities to improve and expand the tools that monitor supply chains in real time, visualize or quantify potential supply chain risks, and facilitate predictions or assessments of disruptive events—such as natural disasters or cybersecurity attacks—to improve resource allocation and other decision making. Current and future research priorities are important to providing evidence that informs the implementation of the HHS Draft Action Plan, including strategies related to stockpiling and inventory management, supply chain vulnerability assessments, novel technologies, workforce talent, and other key areas.

This Draft Research Plan also summarizes research aimed at increasing domestic manufacturing capacity, diversifying existing supply chains, and incentivizing medical product and critical food supply chain resilience. Where possible, this Draft Research Plan discusses research gaps and evidence examining the unintended consequences of some strategies, including environmental and health equity considerations. This Draft Research Plan also presents findings from the gray and peer-reviewed literature discussing the benefits of improved coordination, communication, and partnerships to increasing resilience, specifically aligning needs with resources, improving trust in government regulatory bodies, and enabling faster, more agile responses to supply chain disruptions.

Finally, this Draft Research Plan presents a summary of the priority research areas that aim to generate evidence to inform development, implementation, and evaluation of the goals in the HHS Draft Action Plan. It also identifies challenges and opportunities to engage the broader U.S. research enterprise[4] to facilitate advancement of evidence that informs pressing public health issues.

Current HHS Research Portfolio on Supply Chain Resilience and Shortages

The Draft Research Plan builds on ongoing research supported or conducted by HHS, aims to accelerate and expand these efforts, and calls for more action by the private sector, including academic and nonprofit organizations. The current HHS research portfolio on supply chains and shortages, developed over decades, has been innovative, and emphasizes the role of collaboration between the public and private sectors.

This section is intended to be a summary which highlights current HHS research. It is not an exhaustive inventory of all U.S. Government supported research on supply chain resilience and shortages. Appendix A provides a summary of recent publications. Major policy areas or topics that are covered in this portfolio include:

- **Increasing visibility into domestic and global supply chains.** This is done through assessments of the need for additional data, analytics, and mapping, as well as performing risk assessments. Most of the work in this space is regarding finished drug products, but there has been an increasing recognition of the importance of active pharmaceutical ingredients (APIs) and key starting materials (KSMs). This body of research aligns with Goal 2 of the Draft Research Plan.
- **Understanding the root causes and impacts of shortages of critical products.** Critical products include drugs, biological products, medical devices, and infant formula. While the focus has been on human drugs, specifically generics, there has been increasing interest in understanding factors and root causes of other product shortages, including medical devices, animal drugs, over-the-counter-drugs, foods other than infant formula, etc. This body of research is foundational and most closely aligns with Goal 2 of the Draft Research Plan.
- **Understanding the role of supply chain intermediaries.** Supply chain intermediaries include distributors, group purchasing organizations (GPOs), and pharmacy benefit managers (PBMs). Analyses of their roles in shortages and supply chain vulnerabilities include examination of the various types of contractual arrangements and other market dynamics, such as concentration of suppliers and profit margins. This body of research is foundational and most closely aligns with Goal 2 of the Draft Research Plan.
- **Assessing and developing strategies to enhance supply chain resilience.** These strategies include:
    - Examining policies that provide additional payments for buying N95 respirators that are domestically made, and for establishing and maintaining a buffer stock of essential medicines.
    - Expanding the domestic industrial base through investments by the Administration for Strategic Preparedness and Response (ASPR)**.**
    - Increasing transparency of manufacturing quality issues and promoting adoption of advanced manufacturing technologies.

  This body of research aligns with Goal 4 of the Draft Research Plan.

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While HHS continues to contribute to the research on supply chains and shortages, much more must be done to fill research gaps, improve our understanding, and provide better insights into medical product and critical food supply chains and their impacts, particularly their effects on patients. The next section presents a summary of HHS's understanding of the existing research and gaps, and the identified priorities that can accelerate research in this space.

Fully understanding global medical product and critical food supply chains requires a comprehensive and multi-disciplinary approach that combines the resources of the U.S. research enterprise, collaborative efforts across the federal government, and strong public and private partnerships.

Goals and Future Priorities

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

Appendix B1 summarizes the reviewed literature on the topics of coordination, communication, and partnerships. Current research underscores the critical role of partnerships with private industry and other stakeholders in improving visibility and facilitating coordination and collaboration within the U.S. and with allied countries. There is also recognition that advancing relationships and collaboration can incentivize diversification and information sharing.

Future Research Priorities to Strengthen Coordination, Communication, and Partnerships

- Consider research to understand the role of various stakeholders in strengthening coordination and communication, and increasing supply chain visibility and resilience.
- Expand research to understand effective practices that build trust across the various participants of the supply chain.
- Consider research to develop frameworks and processes through which information can be effectively shared for cross-sector communication and collaboration.
- Consider research to assess the feasibility of establishing international agreements that facilitate cooperation during crises.

Anticipated Impacts. A robust understanding of the barriers to strengthening communication and coordination; and a similarly robust understanding of the facilitators of communication and coordination. Both are essential, within and outside the U.S. Government, to building strong and collaborative partnerships.

Goal 2. ASSESS. Increase Availability and Utilization of Actionable Insights into Critical Medical Product and Food Supply Chains for HHS

Existing work recognizes the paucity of empirical evidence for identifying strategies to address supply chain vulnerabilities, due in part to limited visibility into medical product and critical food supply chains.[5] End-to-end visibility for the U.S. Government and others into the physical and digital components of the supply chains are important to identify risks and other unknown factors[6] needed for characterization of shortages, including their frequency and persistence,[7] and models to improve supply chain efficiency.[8] See Appendix B2 for additional details.

Future Research Priorities to Increase Insights into the Supply Chains

- Promote research using real-world evidence or other sources to assess the full effect of shortages and allocations on patients and patient outcomes—particularly on vulnerable populations—and on health care delivery and health care system costs, and how these may differ by types of products in shortage.
- Facilitate the development of a data repository related to medical product supply chains from government agencies and other entities.
- Develop unified terminology (e.g., definitions of shortage, resilience, criticality, etc.) and data quality standards to facilitate insights into the medical product supply chains, including the upstream supply chains (APIs, KSMs, and excipients), the last mile, and the various product delivery mechanisms.
- Expand research on criticality of medical products and strategies for updating lists of critical medical products and their raw materials.
- Facilitate research that increases the ability of the U.S. Government and supply chain entities (e.g., suppliers, manufacturers, hospitals, distributors, providers, etc.) to identify and assess risks and vulnerabilities facing domestic and global medical product supply chains. These might include the effects of climate change and cybersecurity risks on the nation's economy, on other supply chain ecosystems, and on infrastructure and public health.
- Advance research to understand the role of intermediaries and their various prevalent contracting practices, in building and improving supply chain resilience, including examination of market dynamics such as market concentration and product discontinuations.
- Advance research to understand the ways in which increased transparency and predictability of potential medical product shortages can support improved supply chain resilience and functionality.
- Expand research into how to estimate demand more accurately (e.g., considering commitments to other buyers), and how to improve surveillance and forecasting capabilities, including through the use of artificial intelligence.
- Develop evidence to identify and assess technologies, platforms, or capabilities for analyzing vulnerability and predictions, and how they support improved supply chain resilience.

- Expand research to increase insights through collaborative approaches, such as data sharing and assessments by trusted third parties.
- Explore the identification of potential research areas on supply chain issues related to critical foods and animal medicines.

Anticipated Impacts. Improved insights will enable the U.S. Government, manufacturers, and other intermediaries in the supply chain to identify vulnerabilities promptly, make informed decisions (including selection of more reliable suppliers), and coordinate responses to supply chain disruptions. This can lead to more proactive risk management, reducing the risk or likelihood of shortages during crises. Effective risk assessment tools will enable the U.S. Government and other organizations to allocate resources efficiently, prioritize critical areas for intervention, and develop contingency plans. This proactive approach can minimize the impact of disruptions on patients' health care delivery.

Goal 3. RESPOND. Strengthen HHS Response to Shortages and Supply Chain Disruptions

The COVID-19 pandemic opened opportunities for increased understanding of the Strategic National Stockpile (SNS), inventory management practices, and novel technologies that can play a significant role in facilitating an agile response and ensuring that medicines and critical foods are available to those who need them. Some of the existing information came from lessons learned and a recognition that there is room to innovate in the way that private and public inventories are managed, and with respect to the technologies and techniques to produce medical products more efficiently. The existing literature also acknowledges the importance of ensuring that there is a skilled workforce to facilitate a response and to keep up with novel manufacturing technologies. See Appendix B3 for a summary of the findings on this topic.

Future Research Priorities to Strengthen HHS Response to Shortages and Supply Chain Disruptions

- Promote research to develop and assess strategies, including clinical guidance, that ensure adequate and equitable access to and distribution of essential medicines during a shortage or supply chain disruption, especially those involving vulnerable communities or rural areas.
- Expand research to understand inventory management practices, including, but not limited to, hospital inventories, state local, and national stockpiles, that facilitate or hinder access to critical inventory during a supply chain disruptions or shortages.
- Research into product shelf life, including the impact of extending shelf life, on the feasibility of buffer stocks and other inventory management practices, and exploring strategies to support longer product shelf life.
- Advance research to better understand where advanced manufacturing technologies (AMTs) are most beneficial, to identify the barriers to AMT adoption, and to develop potential solutions to incentivize the use of AMTs more widely, where appropriate.
- Conduct research to assess workforce needs and develop strategies to maintain and enhance a cadre of well-trained individuals to facilitate an agile response to shortages and supply chain disruptions, as well as to meet the requirements to adopt novel technologies.
- Promote research to assess the impacts of oversight and regulatory measures aimed at ensuring quality and reliability, and how these measures affect manufacturer and consumer behavior, supply chain dynamics, and overall product quality.

Anticipated Impacts. Increased understanding of strategies that foster an agile response can improve capabilities for planning and response, which can in turn increase access to essential medicines.

Goal 4. PREVENT. Incentivize Investment in Supply Chain Resilience Through Increased Supply Chain Diversification, Redundancy, and Other Strategies

Existing research suggests that the COVID-19 pandemic incentivized many entities to rebalance the tradeoff between manufacturing cost efficiency and low supply chain resilience (See Appendix B4 for details). Strategies aimed at reshoring production to increase domestic manufacturing capacity gained significant attention in the wake of the supply chain disruptions that occurred during the COVID-19 pandemic. The primary motivation was to reduce dependency on foreign suppliers. The current research acknowledges that increasing domestic manufacturing and diversification are important, though reshoring may not be a cure-all.

Future Research Priorities to Incentivize Supply Chain Diversification and Investment in Supply Chain Resilience

- Promote research on the resilience of medical product and critical food supply chains, including methods to measure or track supply chain resilience.
- Examine the role of controlled substance quotas and related policies on supply chain resilience.
- Advance research to identify and develop effective strategies to increase domestic capacity and supply chain diversification, including an examination of the socioeconomic, demographic, and environmental impacts on supply chain resilience and the U.S. population.
- Advance research to identify steps such as demand-side incentives that can be used to sustain investments in industrial base expansion over time.
- Investigate policy frameworks that promote both domestic resilience and international collaboration, including trade policies, mutual recognition agreements, and shared stockpiling strategies.
- Explore the scalability, cost-effectiveness, and integration of AMTs into existing manufacturing infrastructures, particularly in domestic settings.
- Gather evidence that informs the development of effective procurement, investment, and regulatory strategies that increase supplier diversification.
- Encourage research to understand the role of trade policies such as tariffs on diversifying medical product and critical food supply chains, including examining the impacts on availability and affordability of medical products and critical foods.
- Promote research that examines the effectiveness of economic and regulatory incentives meant to encourage diversification of supply chains without imposing excessive costs on manufacturers and purchasers.
- Investigate the environmental implications of reshoring and diversifying supply chains, including research to assess the carbon footprint of different supply chain configurations and exploration of sustainable practices in manufacturing and distribution.

Anticipated Impacts. A deeper understanding of effective strategies to promote the adoption of advanced manufacturing technologies and increased domestic capacity could facilitate policy advancement and industry participation to diversify the medical product and critical food supply chains and increase resilience.

Implementing the Draft Research Plan

This Draft Research Plan is a call to action to the U.S. research enterprise—both federal and private sectors, including academic and non-academic organizations—that will require commitment, engagement, and investments.

HHS intends to conduct research on select topics that will build on the portfolio of ongoing research described above. HHS calls upon non-governmental entities to contribute to the evidence base as outlined in this document. Evidence generated by research from the entire U.S. research enterprise that addresses the gaps described in this Draft Research Plan will inform researchers, health care personnel, payers, patients, hospitals, manufacturers, suppliers, and policymakers. The research will inform the development and assessment of strategies, such as investment decisions, to enhance insights into the medical product and critical food supply chains and strengthen their resilience. Evidence from improved surveillance, modeling, and mapping will be used to understand the risks and threats, and to make informed decisions that prevent and mitigate shortages.

Anticipated Challenges

There are various challenges to conducting the research priorities presented in this Draft Research Plan. Below, we summarize the most salient issues discussed during interviews with stakeholders.

- **Funding**: Discussions with various researchers revealed that one of the key barriers to conducting research is funding to obtain data and field a research team to perform and sustain research activities in this space. For external researchers, funding opportunities such as grants or contracts are essential, and in many cases are the only way to conduct research. Within the U.S. Government, research is also limited by availability of resources.
- **Access to Data**: Researchers noted that in many cases, the types of research questions that can be addressed are largely determined by data availability. Even in cases where researchers are available to examine a particular issue, the data do not exist (e.g., data to understand impacts on patient outcomes). Even when data are available, challenges related to the cost, quality, and licensing of the data can hinder the research. Additionally, some data may only be available to the federal government (e.g., data on the 340B program, data on drug volume, etc.). In some cases, the data exist but are not shared due to various issues including trust or prevailing practices to limit data sharing. Within the U.S. Government, providing access to data for external use often requires resources which may already be constrained, and in some cases, it may not be possible to share because it is considered confidential, commercial, or trade secret information.
- **Awareness in the Research Community**: Many researchers emphasized how the complexity and global nature of medical product and critical food supply chains requires expertise that can take time to acquire or that may limit general awareness in the research community. This in turn can pose a challenge when disseminating the work through peer-reviewed journals or conferences, where reviewers may not be able to fully assess the contribution of the research. In addition, there is some recognition that many do not know what others in the research community are working on, or what data may be

available, in what format, and where. This limits the ability for collaboration or sharing of information.

- **Complexity of Supply Chains**: The evolving, complex, and global nature of medical product and critical food supply chains creates challenges for researchers trying to advance mapping capabilities. This requires prioritizing products to map and the resources required. Even when prioritization can be achieved, the diversity of databases and their uneven quality can challenge mapping and inhibit further assessments of the direct and indirect consequences of events or policies affecting supply chains.

Appendices

Appendix A. Recent HHS Publications on Supply Chains and Shortages

Study Title	Agency	Research Areas
API supply chain assessment	ASPR/ DOC	Strategies for supply chain resilience; mapping; APIs
ASPE Report to Congress: Impact of Drug Shortages on Consumer Costs	ASPE	Impact of drug shortages; supply chain economics
Assessing Relationships between Drug Shortages in the U.S. and Other Countries	ASPE	Supply chain economics
Characteristics of Medical Device Shortages in the US, 2006–20	ASPE	Root causes and impact of medical device shortages
Drug Shortages Prior to and During the COVID-19 Pandemic	AHRQ	Increasing visibility; impacts of drug shortages
Economic Analysis of the Causes of Drug Shortages	ASPE	Root causes of drug shortages
Effects of the valsartan recall on heart failure patients: A nationwide analysis	AHRQ	Increasing visibility; impacts of drug shortages
Impacts of Climate Change on Health and Drug Demand	ASPE	Increased visibility; impacts of drug shortages;
Impact of COVID-19 on Drug Shortages	AHRQ	Impacts of drug shortages
Impacts of Drug Shortages on Patients in the United States: A Case Study of Three Drugs	ASPE	Impacts of drug shortages
Impacts of a Nonprofit Membership-Based Pharmaceutical Company on Volume of Generic Drugs Sold and Drug Prices: A Case Study	ASPE	Supply chain intermediaries
Linking Medical Product Manufacturing Locations with Natural Hazard Risk: Implications for the Medical Product Supply Chain	ASPE	Risk Assessment; increasing visibility; mapping
Major Shifts in Acid Suppression Drug Utilization After the 2019 Ranitidine Recalls in Canada and United States	AHRQ	Impact of drug shortages
Medical Product Shortages in the United States: Demographic and Geographic Factors and Impacts	ASPE	Impacts of drug shortages
Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships	ASPE	Supply chain intermediaries; Increasing visibility
The Potential Role of the Nonprofit Pharmaceutical Industry in Addressing Shortages and Increasing Access to Essential Medicines and Low-Cost Medicines	ASPE	Supply chain intermediaries

A Retrospective Cohort Study of the 2018 Angiotensin Receptor Blocker Recalls and Subsequent Drug Shortages in Patients With Hypertension	AHRQ	Impacts of drug shortages
Market & Economic Analysis (MEA) Project	ASPR/ IBMSC	Strategies for supply chain resilience
Measuring Preparedness for Public Health and Health Care Emergencies	ASPE	Strategies for supply chain resilience
Medical Device Supply Chains: An Overview and Description of Challenges During the COVID-19 Pandemic	ASPE	Strategies for supply chain resilience; impacts of drug shortages
Policy Considerations to Prevent Drug Shortages and Mitigate Supply Chain Vulnerabilities in the United States	ASPE	Strategies for supply chain resilience
Strategic Utilization of Pharmaceutical Product Location and Identification (SUPPLI)	ARPA-H	Strategies for supply chain resilience; increasing visibility; mapping
Characteristics of Part D Drugs in Shortage	ASPE	Root causes of drug shortages
Characteristics of Part B Drugs in Shortage	ASPE	Root causes of drug shortages

Appendix B1. Summary of Research on Goal 1. COORDINATE.

Collaborating with Industry, the Community, Patients, and Allied Partners

The impact of partnerships and supply chain collaborations on improving visibility and resilience of medical product and critical food supply chains is significant and multifaceted. Health systems, particularly those with a disproportionately high share of hospitals and high burden systems, are increasingly integrating or redesigning strategies to address supply chain challenges. Collaboration with new partners, such as start-ups, is less prevalent but can present growth opportunities. High coordination and collaboration among suppliers, hospitals, and government entities can positively influence supply chain performance, potentially improving patient outcomes and health care service quality.[9] Further, public-private partnerships (PPPs) combine the expertise and efficiency of various organizations while avoiding duplication of effort, facilitate rapid procurement of products, and enhance credibility and buy-in from the community and government through the involvement of established organizations.[10,11,12,13,14]

Community and patient involvement can also affect medical product and critical food supply chains by identifying local health priorities, aligning program activities with community needs, and providing feedback on the effectiveness and accessibility of medical products and critical foods. There is also recognition that enhancing supplier relationships and collaboration can incentivize diversification. For example, research suggests that bridging measures within the health care supply base, such as offering procurement support for suppliers or calling upon long-term buyer-supplier relationships, are more effective for securing medical supplies than buffering measures.[15] By collaborating closely with multiple suppliers, purchasers can encourage suppliers to develop diversified sourcing strategies and share best practices, thereby improving overall supply chain resilience. Building strong, collaborative relationships between manufacturers, suppliers, and purchasers can also enhance reliability, as demonstrated in Nova Scotia.[16] By centralizing procurement and fostering collaboration across their supply chains, purchasers were able to better monitor and manage supply quality and reliability.

Targeted strategies at the national and international level can provide incentives for diversification and better coordination of monitoring activities. For instance, the Organisation for Economic Co-operation and Development (OECD) recommends that stakeholders work together to define lists of critical products and mechanisms to monitor international and regional flows.[17] Collaborative efforts can lead to agreements that discourage hoarding and export restrictions, facilitating more diversified and stable supply chains. Global coordination can also help manage risks and ensure fair and continuous supply during public health emergencies.

To maximize the positive impact of partnerships on medical product and critical food supply chains, organizations may consult with stakeholders at various levels to identify health priorities, integrate partners with diverse technical skills, establish clear roles and responsibilities, maintain regular communication, develop conflict resolution strategies, plan for financial sustainability, support workforce development, and ensure integration with national health programs. **Additional research is needed to understand the roles of various stakeholders in enhancing coordination, communication, and increasing supply chain visibility and resilience.**

The Role of Trust in Coordination and Partnerships

Existing research suggests that public trust in the government significantly impacts medical product and critical food supply chains and influences supply chain resilience, as greater trust enables smoother implementation of policies to strengthen the system. In contrast, low trust can lead to resistance against government interventions, even when they aim to enhance stability and prevent shortages. Trust also plays a key role in facilitating information sharing between government agencies and private-sector manufacturers. Improved transparency through trust in turn allows for better anticipation and mitigation of potential supply chain disruptions. Public behavior is also affected, as low trust can lead to panic buying and hoarding during crises, disrupting typical supply and distribution patterns.[18] Conversely, higher trust can result in more stable and predictable demand, and the public is more likely to follow government guidelines on medication use and procurement.[19]

Trust in government also shapes interactions between manufacturers and authorities. Higher trust encourages voluntary reporting of potential shortages or supply chain vulnerabilities, facilitating better coordination and preemptive action. It also strengthens public-private partnerships, leading to more resilient supply networks and improved responses to disruptions.[20]

In the regulatory environment, public trust influences compliance with regulatory requirements, including supply chain management. Greater trust typically results in better compliance, enhancing overall transparency and reliability. Trust also promotes more collaborative policy development between government and industry stakeholders, leading to more effective regulations that strengthen the supply chain. The benefits of trust have been cited widely. **More research is needed to understand effective practices that build trust across the various participants of the supply chain**.

Cross-Sector Communication and Information Sharing

Proactive and early engagement with local health authorities, manufacturers and other relevant entities can prevent or mitigate shortages through enhanced collaboration.[21] Research has shown that high levels of coordination, collaboration, and integration can positively influence hospitals' health care service quality and patient outcomes.[22] Community and patient involvement can help identify local health priorities, align program activities with community needs, and provide feedback on the effectiveness and accessibility of medical products and critical foods. High coordination and collaboration among suppliers, hospitals, and government entities positively influences supply chain performance. Digital platforms and technologies are also important in facilitating coordination, information sharing, and building trust, while also ensuring data integrity and automated transfer of data to various entities, including regulatory agencies.[23] However, researchers also acknowledge that to reap the full potential of digital solutions, standards are needed to establish parameters that allow for data sharing and interoperability among various digital platforms and users. **More research is needed to develop frameworks and processes through which information can be effectively shared for cross-sector communication and collaboration.**

Appendix B2. Summary of Research on Goal 2. ASSESS

Facets of Visibility

Defining Terminology is an Important First Step to Facilitate Analyses, Surveillance, and Data Collection

Existing research has recognized the importance of defining key terms to facilitate analyses, surveillance, and data collection.[24,25,26,27] Most of this research has discussed the differences in defining a shortage and how that may affect comparisons across databases. As the research expands to broader issues of supply chain resilience, more research is needed to identify key terms (e.g., "supply chain resilience," "essential medicine") that affect the ability to gain further insights into supply chains and assess them more fully.

Defining key terms is foundational to facilitating visibility into medical product and critical supply chains. Having well-understood and harmonized (to the extent possible) definitions can help develop performance indicators and other measures needed to surveil supply chain activities, identify risks, and predict disruptions.

Data Quality and Standardization Play a Crucial Role in Improving Visibility

Survey data from 2022 suggests that 90 percent of supply chain leaders from nearly every sector have invested in new digital technologies.[28] Establishing common standards for those entities to collect, share, and evaluate data could enhance supply chain visibility.[29,30] These standards or frameworks could center on shared systems already widely used in accordance with U.S. law, such as product identification systems (e.g., North American barcodes, radio frequency identification tags, European article numbers, etc.), shipping container identifiers, transaction information (e.g., purchaser, price, final destination). However, feasibility and implementation are limited by a shortage of qualified personnel to transform the existing digital infrastructure, as well as varying costs and reporting requirements.[31,32]

One of the critical areas for future research is the development of comprehensive systems for real-time monitoring and transparency in supply chains. Researchers have highlighted the absence of systematic monitoring and global coordination to manage risks and ensure equitable supply continuity during public health emergencies.[33] To achieve these tasks may require standardized data collection methods that apply technologies like blockchain and advanced analytics to track APIs, manufacturing capacities, and distribution networks.[34]
More research is needed on the implementation of data quality standards, domestically and globally. An examination of unintended competition and security issues is also needed.

Prioritizing the Depth and Breadth of Visibility

Limited resources highlight the importance of prioritizing the depth and breadth of supply chain visibility. **Determining criteria, processes, or thresholds of when, how, and who should use lists** of critical, essential, and/or life-saving medicines is another research question that has remained unanswered. These questions include: (1) understanding or developing best practices for creating or maintaining fit-for-purpose lists; (2) determining a process to identify the scope of

products to prioritize for supply visibility; (3) gathering evidence to inform the purpose and applications of the various lists (e.g., coordinate inventory stockpiling and capacity buffering policies, investment decisions, clinical guidance, etc.); and (4) assessing the various lists.[35]

Greater Visibility of Key Inputs Can Illuminate Resilience and Vulnerability of Supply Chains

Existing research on APIs has identified how heavily China and India influence the supply chain. In 2021, 48 percent of API Drug Master Files (DMFs) voluntarily submitted to the FDA were from manufacturers in India, and 13 percent were from China. By comparison, the U.S. accounts for 10 percent of submitted API DMFs.[36] Indian-produced drugs, including some generics, may still rely on APIs and KSMs from China, though confidentiality agreements limit transparency.[37] Further, DMFs do not indicate volume, making it impossible to infer how these values relate to the influence of individual manufacturers or countries. While HHS has taken a proactive approach to fund the production of such materials domestically, more research is needed to supplement policy development that encourages manufacturing by allies and in the U.S., and to identify and mitigate supply chain vulnerabilities.[38,39]

Identifying and Understanding the Diverse Entities Comprising Complex Supply Chains

Ongoing U.S. Government efforts aim to improve the visibility of all entities within the complex medical product and critical food supply chains, specifically those most poorly understood. For example, pharmacy benefit managers (PBMs) and group purchasing organizations (GPOs) are both perceived as powerful intermediaries in the medical product supply chains.[40] Several reports and proposals demonstrate the growing interest in understanding and gaining greater visibility into the practices of PBMs and GPOs.[41, 42, 43] Additionally, there is limited insight into the various supplier tiers of certain products, especially for some medical devices. **More research is needed on the prevailing practices of these and other intermediaries.**[44]

Understanding the Potential Threats to Shortages and Supply Chain Disruptions Is Important to Increase Visibility into the Supply Chains

Identifying and understanding the root causes of medical product and critical food shortages and supply chain disruptions have been important steps to developing potential solutions. Prior to the COVID-19 pandemic, drug shortages and supply chain disruptions were typically associated with manufacturing quality issues.[45,46] While these vulnerabilities remain a concern, other causes have been emerging, such as increased demand due to pandemics, natural or human-made disasters, unavailability of API, coordination failure (disruption in transportation and delivery), geopolitical issues, and a lack of transparency and information sharing.[47,48] Market behavior that rewards the lowest price without rewarding supply chain resilience is a contributing factor to the increased risk and vulnerability of supply chains.

Past and current research has focused mainly on understanding the factors that affect shortages in pharmaceutical markets. For example, one line of research has explored the broader impacts of shortages on health systems or consumers, while a another body of research has focused on the impacts on select populations (e.g., specific health systems, cancer patients, or specific shortages).[49,50,51,52,53] There is an emerging body of work that has examined the causes of shortages of medical devices, infant formula, and other products.[54,55,56,57,58] However, there has

been little research in understanding how shortages of animal drugs may disrupt not just veterinary practice and animal health, but also looks at the downstream consequences to human health.[59,60] Recent supply chain disruptions highlighted that food commodities are also vulnerable to the threats faced by medical products.[61] More research to better understand the risks that affect these supply chains is also needed. There has also been increasing interest in understanding how shortages in the U.S. affect other countries and vice-versa.[62,63,64,65,66] These studies have uncovered various challenges, including lack of standardized data, variation in definitions, and differing regulatory and policy environments. There is greater recognition that the global nature of supply chains calls for a global approach that engages all relevant actors and looks beyond the health care sector alone.[67]

Cybersecurity also plays a critical role in protecting supply chains as well as infrastructure from threats that could disrupt operations, compromise patient safety, and lead to shortages. The increasing integration of digital technologies in medical devices and health care systems has introduced new vulnerabilities that can be exploited by cybercriminals, making them susceptible to significant economic, political, and social impacts.[68] Cybersecurity breaches in the supply chain can result in data theft, ransomware attacks, and disruptions in health care services. Human vulnerabilities, such as lack of awareness and training, contribute significantly to cybersecurity risks in health care organizations.[69,70] Social engineering attacks, such as phishing, are increasingly targeting health care professionals, necessitating better awareness programs and training activities.[71] **Further studies are required to assess how breaches of cybersecurity affect medical product and critical food supply chains as well as the health care sector**.

Climate change poses other significant risks to supply chains, stemming from extreme weather events, resource scarcity, and disruptions in transportation and logistics. Understanding and mitigating these risks is crucial to ensuring the availability of essential products in the face of climate-related threats. Climate change can lead to a reduction in the availability of natural resources and raw materials, causing stockouts, increased inventory costs, and bottlenecks in procurement, manufacturing, and logistics functions.[72,73,74] They can also impact food production, natural resources, and transportation, which cascades into other interlinked global supply chain networks. The health care sector's supply chain is highly vulnerable to climate change, with significant emissions stemming from energy consumption, transportation, and product manufacture, use, and disposal.[75] Climate change affects defense medical logistics as well, including vulnerabilities in the cold supply chain, medical device functionality, air conditioning needs, and fresh water supplies.[76] Understanding the strategies that are most effective to resolve shortages may facilitate improvement of response capabilities. **Further research is needed to understand the multifactorial threats to the domestic and global medical product and critical food supply chains, particularly those associated with climate change and cybersecurity.**

Enhancing Insights into the Impacts of Shortages and Supply Chain Vulnerabilities

Data gaps in medical product and critical food supply chains may hamper the ability to understand the direct and indirect impacts of shortages and supply chain vulnerabilities on suppliers, manufacturers, distributors, other intermediaries, and end-users – especially vulnerable populations including economically disadvantaged people, racial and ethnic minorities, and the uninsured, among others. Previous research showed that gaps in Drug Enforcement Agency

(DEA) pharmacy data were exploited by purchasers, ultimately leading to disproportionate, increased dispensing of opioids to non-white communities.[77] Other research suggests that diabetes drugs are less likely to reach non-white patients during shortages.[78] Unfair practices by supply chain intermediaries that increase drug costs could also impact the most vulnerable, especially regarding new drugs, as uninsured patients must pay full price, compared to insured patients who benefit from rebate structured pricing.[79,80] Even short-term, regional disruptions—such as that of oxytocin—spur equity concerns where Black mothers already face a disproportionately higher risk of maternal morbidity and poor birth outcomes.[81] The COVID-19 pandemic further exposed the vulnerability of medical product supply chains, where global shortages of essential supplies like PPE, testing materials, and pharmaceuticals increased risks to patient care and safety.[82] Some of these impacts are further complicated by institution-specific considerations. For example, hospitals that participate in the 340B program may need to meet certain requirements for the types of medicines that they can purchase or administer, and may face challenges when a specific product is in shortage. This could lead to market exit or increased dependence on foreign sources. In addition, real world data (RWD), data related to patient health status and/or data on the delivery of health care that are routinely collected from various sources outside of traditional clinical settings, have shown potential for analysis that can improve patient outcomes.[83] To our knowledge, there is no evidence on the use of RWD to understanding the impacts of shortages on patient outcomes. **More research is needed to further understand the impacts of shortages or supply chain disruptions on those affected, especially vulnerable populations and communities.**

Health equity also plays a significant role in supply chains and infrastructure, potentially affecting access, distribution, and outcomes across vulnerable or rural populations. Health equity considerations can influence how medical products and critical foods are distributed and accessed, but there is no systematic process to establish allocations in an equitable manner. For example, health insurance coverage can impact equity in accessing medical products, but benefit coverage often differs across populations.[84] Geographical variations in health outcomes suggest state-level factors and social determinants of health should be considered in supply chain design and distribution.[85] Additionally, factors contributing to disparities often differ by disease or type of care, requiring targeted interventions rather than general provisions.[86] While implementation research has been proposed as a framework that can consider equity and health outcomes, research aimed at understanding health equity's role in supply chains is still developing.[87]

Understanding How Medical Product Supply Chains Intersect with Other Supply Chains

The medical product supply chain intersects with multiple other systems and supply chains, such as non-medical product manufacturing, energy and natural resources, transportation.[88] This was recently highlighted by the temporary shutdown of the U.S. East Coast and Gulf Coast ports due to a work stoppage that threatened shortages of many products, from bananas to auto parts.[89] **More research is needed to understand overlapping risks and their impacts on medical product supply chains and other supply chain ecosystems**.

Surveillance and Analytics

Mapping and Measuring Complex Supply Chains

The complexity of—and need to understand—each node of the medical product and critical food supply chains has been well established, but more research is needed to increase insight into the entire network of stakeholders. This type of research is commonly referred to as "mapping," which would assist in increasing visibility into the ways in which geographic (i.e., environmental, geopolitical) factors and economic factors (i.e., tariffs, taxes, and rebates), as well as private sector participants (i.e., transportation, health care delivery, EMS services, etc.) integrate and influence one another.[90,91]

Some mapping tools are also risk assessment models that incorporate diverse data sources, including weighting, decision-making and forecasting, but may not include geopolitical risks, natural disasters, and market dynamics. To date, no comprehensive mapping or measurement tool is yet available, but efforts have been made to map different aspects of the supply chain. For example, the Department of Commerce announced its SCALE Tool, which uses various sets of indicators to assess supply chain risks across the U.S. economy.[92] Additionally, U.S. Pharmacopeia uses various databases to map the supply chain of pharmaceuticals and conduct risk assessments, including estimating the likelihood and duration of shortages.[93] There are also collaborative efforts to maintain uninterrupted access to seven pre-selected critical pediatric cancer medications, and to assess supply chain resiliency.[94,95] Moreover, mapping and risk assessment can support supply chain market surveillance that is critical for monitoring and preventing shortages.[96,97] However, these tools are proprietary and not publicly available.[98,99,100,101,102] **More research is needed to understand the benefits, methodology, and limitations of mapping tools and measures to assess supply chain resilience**.

Modeling and Analytical Capabilities, Including the Role of Artificial Intelligence (AI)

Modeling needs differ across the various components of the supply chain and models usually take a particular point of view. For example, some aim to predict the timing and scale of disruptions or shortages, estimate cost implications, and recommend agile responses.[103,104,105] Predictive models rely on cross-linking databases that are shared voluntarily, and their lifespan is not known.

AI has played a key role in supply chain management and modeling. For example, AI and machine learning algorithms can analyze historical data and market trends to predict demand for medical products more accurately.[106,107] This allows for improved inventory management, reduced stockouts, and more efficient allocation of resources. AI-powered supply chain control towers can provide real-time visibility into the entire supply chain by collecting and analyzing data from different systems. This allows for proactive identification and resolution of bottlenecks or disruptions, better coordination between different supply chain partners, and improved tracking of products throughout their lifecycle.

AI can also be used for validating product legitimacy, tracking counterfeit products, monitoring manufacturing processes (to predict and prevent quality issues), and analyze data on product defects to identify potential quality problems. To facilitate optimizing infrastructure, AI can be used to analyze patient flow data to optimize the allocation of staff, equipment, and facilities across health care systems.[108,109] While AI is not a one-fix-all tool, its use may improve the speed, accuracy, and decision-making of current capabilities.[110] Further, these types of analytic tools hold promise to implement stress testing as a means to identify vulnerabilities.[111] As

mentioned in a previous section, data and reporting standards could greatly improve modeling capabilities, but **more work is needed on what type of model is best suited to meet the needs of the various components of the supply chains**.

Appendix B3. Summary of Research on Goal 3. RESPOND

Stockpiling and Inventory Management Practices

Stockpile Management

Holding inventory can be complex, with problems related to demand visibility, monitoring of stock, product expirations, and other management details that hinder preparedness. However, the SNS and other public inventories can improve effectiveness by applying evidence-based approaches, such as calculating optimal inventory levels by considering the demand rate, order lead time, setup cost, proportional order cost, and inventory holding cost to ultimately prevent hoarding and overstocking.[112]

Currently, there are no set requirements or guidance for state, local, tribal, and territorial (SLTT) governments to maintain their own stockpiles for PHEs. Some have proposed pushing more responsibility to regional networks to allow for greater flexibility as local health officials and health systems have better knowledge about inventory patterns, distribution plans, and communication strategies unique to their circumstances. However, others have cited lack of funding and lack of clear responsibility for addressing shortages as challenges to developing regional or state stockpiles.[113]

In response to increasing shortages of medical products, several strategies have been proposed or developed to increase buffer capacity. Under the Medicare Hospital Inpatient Prospective Payment System (IPPS), CMS provides separate payment to certain hospitals that voluntarily establish and maintain a six-month buffer stock of one or more of 86 essential medicines. Small, independent hospitals, that is hospitals with 100 beds or fewer, and that are not part of a chain organization, are eligible for these payments and can establish their buffer stock(s) directly, or through contractual arrangements with a pharmaceutical manufacturer, distributor or intermediary.[114] Another mechanism involves "crisis prices" auctions in which the U.S. Government solicits bids for specific products to supplement stockpile inventories. Other proposals include the creation of a government-funded buffer inventory that would include a list of high value generic injectable drugs that could not otherwise be accessed from the SNS.[115] Other countries have established national reserves or requirements for suppliers to stockpile certain medicines to create buffer capacity.[116] **Research is needed to assess the strategies required to ensure adequate availability of essential medicines during a shortage or supply chain disruption.**

Inventory Management Practices

Existing research points to alternative approaches other than the standard "just-in-time" model to improve inventory management for the SNS and health systems. These include vendor-managed inventories (VMI) and consignment inventories (CI).[117] A VMI model supports end users in health care to reduce demand uncertainty and inventory costs by having the manufacturer assume full responsibility for maintaining an agreed-upon inventory level of a product or its components at the end user's location. Under this model, the supplier determines a reorder point to provide sufficient stock, as well as a replenishment quantity to balance the costs of shipping and

inventory storage. Key considerations of VMI are reliance on the supplier to track products in stock, reduced visibility by health systems into their future inventory and increased risk of shortage within a health system. When using CIs, suppliers maintain an end user's committed inventory at the supplier's site or other designated location. Here, inventory purchases occur only when used. The SNS and health systems could use CIs to reduce working capital and overall expenses, as CIs allow the supplier to conduct regular product rotation, which reduces the risk of expiration and waste. Potential limitations of this model include the lack of direct management and transparency for end users. **More research is needed to understand the inventory management practices that facilitate or hamper the ability to access needed inventory during a supply chain disruption or shortage.**

Novel Technologies and Approaches to Facilitate Agile Manufacturing

Advanced manufacturing technologies (AMTs) is a collective term for new and innovative applied manufacturing technologies that are used to upgrade or replace existing systems and improve product quality and process performance. They often integrate novel approaches, innovate existing techniques, and expand production methods where there is no defined best practice.[118,119,120] AMTs have been cited as important when considering reshoring drug manufacturing, as they may help prevent drug shortages, produce better quality products, and improve emergency preparedness.[121,122,123] Within HHS, FDA supports AMTs in several ways, including issuing guidance, reviewing products made with AMTs, and advancing regulatory science to proactively address challenges.[124] Ongoing FDA initiatives include the following:

- Develop a regulatory framework to support adoption and use of AMTs.[125]
- Examine the effects of AMTs.[126]
- Support the adoption and use of advanced manufacturing for both new and existing drugs.[127,128]
- Promote dialogue, training, and visibility among staff, prospective innovators, developers, and external stakeholders.[129]
- Fund extramural stakeholders to advance the knowledge needed (and identify gaps) to develop and adopt emerging technologies.**Error! Bookmark not defined.Error! Bookmark not defined.**
- Increase hands-on experience and training in various novel technologies.[130]

AMTs considered through these programs include end-to-end continuous manufacturing, distributed manufacturing, artificial intelligence, 3D printing, digital product lifecycles, and smart manufacturing, among others. AMTs may not only facilitate modular automation, but also offer new avenues toward process intensification, and in-line analytical monitoring from raw materials to packaged goods.[131]

One of the largest barriers to industry adoption of AMT is the perception of risk and anticipation of significant up-front investments required by manufacturers.[132] This is especially evident with manufacturers of generics operating on a slimmer profit margin than branded drugs.[133] Other challenges include the uncertainty posed by intellectual property and regulatory challenges, and technical difficulties in evaluating complex systems. **Additional research is needed to further understand where AMTs are most beneficial, the barriers to AMT adoption, and the development of potential solutions to incentivize the use of AMTs, where appropriate.**

Workforce Development and Capacity

A well-trained workforce, including pharmacists, logisticians, and supply chain managers, and those that are part of the HHS response, are crucial for maintaining the availability and quality of medical products and critical foods, and to effectively prevent, respond to, and contain threats to the supply chains.[134,135] For example, workforce shortages have been associated with frequent stock-outs of essential medical supplies, particularly in low- and middle-income countries, where vacancy rates in public sector roles can reach up to 71 percent.[136,137] Multiple strategies are needed to maintain and strengthen the workforce that prevents and responds to shortages. This includes improving forecasting, planning, education, deployment, retention, and performance management. Specific interventions include improving public sector pay, establishing rural education pipelines, reforming education strategies, and professionalizing supply chain roles through dedicated training programs.[138] **Additional research is needed to assess workforce needs and develop strategies to maintain and enhance a cadre of well-trained individuals to facilitate an agile response to shortages and supply chain disruptions**.

Appendix B4. Summary of Research on Goal 4. PREVENT

Increasing Domestic Capacity

Policies aimed at increasing domestic manufacturing capacity for pharmaceuticals and medical supplies have gained significant attention, especially in the wake of supply chain disruptions caused by the COVID-19 pandemic. While these policies intend to enhance supply chain resilience and national security, research suggests that they may have complex and unintended effects.[139]

One of the primary motivations for increasing domestic capacity is to reduce dependency on foreign suppliers, particularly for critical medical products. Research suggests that the pandemic incentivized U.S. firms to rebalance the trade-off between manufacturing cost efficiency and supply chain resilience.[140] The initial shortages of PPE and APIs highlighted vulnerabilities in global supply chains, prompting calls for reshoring manufacturing capabilities.[141]

However, reshoring manufacturing processes may not be a cure-all, and the global nature of supply chains means that diversification and regional cooperation might also be effective strategies. Further, policies promoting international diversification can sometimes be more beneficial than reshoring, depending on the elasticity of demand and the nature of supply chain risks.[142]

Potential cost escalations and reduced global cooperation are some of the challenges facing strategies seeking to establish fully domestic supply chains. Domestic manufacturing often involves higher production costs compared to low-cost countries such as China and India. These increased costs can lead to higher prices for medical products, burdening health care systems and patients.[143] API manufacturing is heavily concentrated in China and India; only a small share of APIs for generic drugs being made in the U.S.[144,145] Increased domestic API manufacturing can also have unintended environmental outcomes, such as increased contamination of the nation's waters, which may or may not be harmful to humans.[146,147] Further, policies aimed at increasing domestic capacity might inadvertently reduce global cooperation, which is essential during global health crises. For example, the pandemic saw numerous countries imposing export restrictions on medical supplies, which exacerbated shortages worldwide.[148,149]

Some have proposed alternative strategies to enhance supply chain resilience without solely relying on increasing domestic capacity, including strengthening long-term buyer-supplier relationships and offering procurement support to suppliers.[150] Such strategies may improve supply security without the substantial costs associated with reshoring. Others recommend improving multinational cooperation on supply chain resilience and incentivizing quality and resilience across the supply chain.[151] To do so may involve approaches that enhance transparency, diversify sourcing, and adopt advanced manufacturing technologies to make domestic production more competitive and flexible. **Further research is needed to identify and develop effective strategies to increase domestic capacity and supply chain diversification, including an examination of the socioeconomic, demographic, environmental, and trade impacts, and how to ensure that demand-side support can sustain industrial base investments in domestic manufacturing over-time**. More research is also needed to estimate the value of domestic manufacturing relative to foreign manufacturing, and

where the manufacturing gaps are located to better understand the competitiveness in these markets.

Incentivizing Purchasing Behavior that Rewards and Promotes Resilience

Many recommendations or proposed solutions aim to promote market competition based on supply chain resilience. These include developing frameworks or measures to gain insights into supplier reliability and resilience, and for purchasers to incentivize quality and resilience by considering these factors in their purchasing decisions.[152,153] These metrics would provide a consistent framework for assessing manufacturers, enabling purchasers and regulators to make informed decisions based on quantifiable quality metrics. Prioritizing quality and resilience in procurement criteria can motivate suppliers to diversify their supply chains. For example, suppliers that demonstrate diversified sourcing, robust risk management plans, and transparent operations can be rewarded with preferred supplier status or long-term contracts. Others have noted the importance of risk assessment, forecasting, and decision-making tools to help purchasers identify vulnerabilities and opportunities for diversification, as well as to quantify and manage potential risks. By systematically assessing risks, purchasers can develop strategies that encourage diversification and reduce reliance on high-risk suppliers. **Additional work is needed to develop and assess effective measures of supply chain resilience.**

While the method or process may vary, there is consensus that implementing criteria for strategic purchasing and procurement beyond lowest cost is a critical part of diversifying suppliers and improving resilience, not just in the U.S. but in OECD countries. For example, OECD recommends that procurement approaches should consider factors such as quality, sustainability, and supply security.[154] Where applicable, cross-country pooled procurement has also been noted as a way to improve demand predictability and encourage suppliers to diversify their production and sourcing strategies. For instance, the PanAmerican Health Organization (PAHO) has a revolving fund for vaccine purchases that exemplifies how pooled procurement can secure supply for smaller markets and reduce dependency on single suppliers. This collaborative approach makes markets more attractive to a broader range of suppliers, promoting diversification.

Investing in and incentivizing advanced manufacturing technologies, such as continuous manufacturing, can also facilitate diversification. Continuous manufacturing allows for flexible, scalable, and efficient production processes, enabling manufacturers to respond swiftly to supply chain disruptions.[155] Supporting regional and local production can also reduce dependence on global suppliers and encourage diversification. Purchasers can incentivize this by including regional sourcing requirements in their procurement policies or offering incentives to suppliers that establish local production facilities. Regulatory interventions can also promote diversification by increasing transparency and accountability. Mandating that manufacturers disclose their raw material sources and manufacturing locations enhances visibility into the supply chain. This transparency allows purchasers to assess the diversification of suppliers and make informed decisions that favor those with more resilient and diversified supply chains. **More research is needed to gather evidence that informs the development of effective procurement, investment, and regulatory strategies that increase supplier diversification.**

Trade Policy, Including Tariffs, Import or Export Bans

Over-dependence on foreign sources gives trade policies such as tariffs and import/export bans a significant role in shaping the availability and affordability of medical supplies and critical foods, affecting health care systems worldwide.[156] With the U.S. importing roughly 80 percent of APIs, any disruption in trade could severely impact drug availability. National security experts have warned that China could use its pharmaceutical exports in a trade conflict, potentially leading to shortages in critical medications in the U.S. This dependence underscores the need for more resilient and diversified supply chains.

The COVID-19 pandemic and tensions in China-U.S. trade have significantly affected the global supply chain for medical products. Early in the COVID-19 pandemic, a global shortage of PPE caused widespread panic. China initially reduced its PPE exports, which led to severe shortages in the EU and U.S. In response, both regions imposed export controls and took extraordinary measures to secure supplies. [157] By April 2020, China's PPE exports surged but at much higher prices. The situation prompted the U.S. to invest over $1 billion to boost domestic PPE production, highlighting the need for better pandemic preparedness and international cooperation.

Tariffs have been used for centuries, often to protect domestic industry or to raise revenue for central governments, among other reasons.[158] Research suggests that tariffs may reduce labor productivity in manufacturing by weakening import competition and by inducing entry of smaller, less productive firms.[159] Tariffs can also increase import costs, lead to higher prices or reduced profit margins, cause supply delays and reduce exports or availability of affected goods.[160,161] **Additional research is needed to understand the role of trade policies on diversifying the medical product and critical food supply chains, including examining the impacts on availability and affordability of medical products and critical foods.**

References and Notes

[1] For purposes of this Draft Research Plan, "medical products" includes pharmaceuticals, biological products, medical devices, critical foods, and other vital components, including manufacturing materials.
[2] 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."
[3] Although not in the scope of this Draft Research Plan, other foods besides critical foods may face similar challenges with respect to supply chain vulnerabilities and visibility, and resource and authority needs as those products covered in this Draft Research Plan.
[4] For purposes of this Draft Research Plan, the "research enterprise" includes the U.S. government, universities, research institutions such as think tanks, nonprofit organizations, and other private or public entities conducting qualitative or quantitative studies, evaluations, assessments, or other work on supply chain and shortages; the work may be commissioned, self-funded, or conducted intramurally.
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