

ENHANCING RESILIENCE:

Recommendations
To Achieve a
Safer and Secure
Pharmaceutical
Supply Chain

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The Healthcare Distribution Alliance (HDA) represents primary pharmaceutical distributors — the vital link between the nation’s pharmaceutical manufacturers and pharmacies, hospitals, long-term care facilities, clinics and others nationwide. Since 1876, HDA has helped members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently. The HDA Research Foundation, HDA’s nonprofit charitable foundation, serves the healthcare industry by providing research and education focused on priority healthcare supply chain issues.

EXECUTIVE SUMMARY

The pharmaceutical supply chain is a complex network of stakeholders that supports the healthcare ecosystem. The Healthcare Distribution Alliance (HDA) and its members recognize the importance of supply chain resilience to ensure that patients and providers can access lifesaving medications, vaccines and other medical supplies during steady-state and crisis conditions.

As pharmaceutical distributors, HDA's members play a vital role in the supply chain by connecting approximately 1,500 manufacturers to nearly 330,000 sites of care while maintaining a 0.4 percent profit margin (after taxes).¹ Distributors purchase prescription medicines, take legal ownership, manage inventory and assume credit risk for supply chain partners. They also support timely access for patients; approximately 95 percent of prescription medicines move through HDA-member healthcare distributors.

To achieve supply chain resilience, distributors partner with the government and trading partners to encourage public-private collaboration and joint decision-making as well as maximize private-sector resource utilization and capabilities. HDA and our distributor members believe this combination of private-public stakeholder expertise is critical.

HDA consulted with subject matter experts and distribution members to create a comprehensive report highlighting pharmaceutical supply chain resilience considerations. Looking forward, HDA and our members are committed to working with all stakeholders to ensure patients can access medications and medical supplies.

Key Concepts

- **Supply Chain Resilience:** [Supply chain resilience](#) is the ability of the supply chain to manage disruptions and shocks without significant interruption to patient care and healthcare delivery.²
- **Importance of Supply Chain Resilience:** Supply chains without resilience are vulnerable. When the healthcare supply chain is disrupted, sites of care (for example, dispensers, such as pharmacies and hospitals) and patients cannot receive necessary medicines and products.
- **Supporting Supply Chain Resilience:** The pharmaceutical supply chain continuously works to increase resilience by enhancing flexibility, creating redundancy, fostering collaborative relationships, increasing supply chain agility, and developing and implementing preparedness and response plans. As part of these efforts, distributors monitor and manage disruptions daily and maintain plans that acknowledge the importance of ensuring supply chain continuity throughout all phases of the monitoring process.³

Enhancing supply chain resilience, mitigating disruptions and ensuring the availability of medicines during steady-state or crisis conditions are essential. With collective efforts, healthcare supply chain stakeholders, including distributors, can create a robust healthcare supply chain that can withstand challenges.

INTRODUCTION

The healthcare delivery infrastructure is highly regulated and includes many trading partners and supply chains, including the pharmaceutical supply chain, hospitals, health systems, pharmacies, pharmaceutical quality standards developers, drug manufacturers, distributors and ultimately, patients. To meet the needs of consumers, manufacturers must research, develop, produce, market and sell healthcare products. A distributor's role is to purchase medicines from manufacturers, take legal ownership, manage inventory and manage credit risk to ensure that healthcare products are delivered on time and safely to pharmacies, providers, other sites of care and ultimately, consumers.

This report will define supply chain resilience, explain the considerations behind a resilient pharmaceutical supply chain and demonstrate the role of distributors in maintaining resilience.

¹ HDA Research Foundation. *94th Edition HDA Factbook: The Facts, Figures and Trends in Healthcare*. 2023. <https://www.hda.org/publications/94th-edition-hda-factbook-the-facts-figures-and-trends-in-healthcare/>.

² Healthcare Distribution Alliance. "Healthcare Supply Chain Resilience and Data Illumination." 2023. <https://www.hda.org/getmedia/38b4ad3e-1164-4ef5-9516-963f7dbfb048/HDA-Data-Illumination-Report.pdf>.

³ Healthcare Distribution Alliance. "HDA Guiding Principles for Increasing Supply Chain Resilience." 2023. <https://www.hda.org/getmedia/2d816602-0c28-46c6-a52f-d1d36c094cd9/Resilience-Report.pdf>.

SUPPLY CHAIN RESILIENCE

Supply chain resilience is managing disruptions and shocks without significantly interrupting patient care and healthcare delivery.⁴ As the supply chain is interconnected, all stakeholders must work cooperatively to ensure the right products reach patients at the right time. Healthcare distributors — organizations that buy medications and healthcare products from manufacturers, inventory and warehouse those products in a network of secure facilities, and deliver them safely and efficiently to dispensers — play an essential role in maintaining supply chain resilience.

Distributors enhance their operational resilience as part of the industry's efforts to ensure a steady supply of medical products.⁵ **Operational resilience involves an organization's ability to withstand, adapt to and recover from disruptions. This includes quickly implementing preparedness and response strategies to maintain operations amid diverse threats.**⁶ Lack of resilience can affect healthcare supply chain partners, so distributors strive to sustain a flexible and functional supply chain in all scenarios.

What Is Needed To Achieve Supply Chain Resilience?

A resilient supply chain at all levels must be robust, agile and transparent to achieve maximum effect.⁷ This will allow stakeholders to address any risk or disruption in the supply chain. To achieve resilience, the supply chain must be:

- Able to handle surges;
- Agile to respond to disruptions; and,
- Able to monitor threats that could cause supply chain disruptions.

Why Is Supply Chain Resilience Important?

Supply chain resilience does not prevent shocks and disruptions from occurring, but diminishes the impact of shocks and disruptions within the healthcare supply chain. Public and private stakeholders responsible for maintaining supply chain resilience collectively work to enhance flexibility, create redundancies and foster collaborative relationships and partnerships to increase the strength of the supply chain.

SUPPLY CHAIN DISRUPTIONS

The supply chain may operate differently during a crisis, unforeseen circumstances, events like production delays, a reduced supply of medical products or natural disasters, among other extreme pressures. While the causes of supply chain disruptions may differ, the effects can be similar.

What Is a Supply Chain Disruption?

Healthcare distributors and supply chain stakeholders experience strain when a disruption exceeds their capacity to maintain continuity using existing infrastructure and resources. Disruptions vary by origin, severity, scope and scale — and can result from natural and human-made disasters, legislative and regulatory shifts and geopolitical events.⁸ Stakeholders at the upstream end of the supply chain (for example, sourcing and manufacturing processes) may experience disruptions like raw material shortages, quality control issues, and import or export bans.⁹

Downstream disruptions (such as extrinsic or societal factors like increased demand or hoarding behavior) occur at the end of the supply chain and impact patients.¹⁰ Upstream and downstream disruptions can be acute or chronic. They can be sudden and limited in duration or develop into longstanding issues that are not quickly resolved. Disruptions can also be confined to a small region (for example, a conflict zone, a localized area impacted by a power outage) or transcend borders (like a pandemic or geopolitical event).



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⁴ Healthcare Distribution Alliance. "Healthcare Supply Chain Resilience and Data Illumination." <https://hda.org/getmedia/38b4ad3e-1164-4ef5-9516-963f7db-fb048/HDA-Data-Illumination-Report.pdf>.

⁵ Healthcare Distribution Alliance. "Bolstering Disaster Preparedness and Operational Resilience in the Healthcare Supply Chain." 2023. <https://www.hda.org/getmedia/f13bb354-88eb-494e-81ca-2456ea4d795c/Bolstering-Disaster-Preparedness-and-Operational-Resilience-in-the-Healthcare-Supply-Chain.pdf>.

⁶ Ibid.

⁷ Ibid.

⁸ Ibid.

⁹ Ibid.

¹⁰ Ibid.

Types of Supply Chain Disruptions

Climate change and workforce shortages are common contributors to supply chain strains and disruptions.¹¹ The increasing severity and **frequency** of weather events due to climate change have strained critical infrastructure, reducing time for mitigation and preparedness across all sectors, including healthcare.¹² For example, Hurricane Maria devastated Puerto Rico's infrastructure and the pharmaceutical manufacturing located on the island. The disruption of **medical device and pharmaceutical manufacturing**, affected the healthcare supply chain locally and globally.¹³ Puerto Rico provides approximately 8 percent of the medicines used in the U.S. healthcare system.¹⁴ Meanwhile, Hurricane Fiona caused widespread power outages throughout Puerto Rico in 2022 and again disrupted the supply chain. These recent examples demonstrate the vulnerability of the pharmaceutical manufacturing industry to weather events.

Drug Shortages

“DISTRIBUTORS WORK TO MITIGATE SUPPLY-DRIVEN SHORTAGES BY BUILDING REDUNDANCY INTO THEIR BUSINESS PRACTICES”

Often, entities and policymakers measure supply chain resilience through the lens of drug shortages. Overall, the pharmaceutical supply chain is successful; however, a percentage of medicines continue to experience shortages. Drug shortages pose challenges to both providers and patients. Drug shortages are a type of disruption that the pharmaceutical supply chain experiences that affects the overall resilience of the supply chain.

Mitigating and managing drug shortages, which are a type of disruption in the supply chain, is part of maintaining overall supply chain resilience. Drug shortages occur when the available supply does not meet the current demand. Drug shortages are caused by a myriad of factors and the drivers behind the demand differ with each shortage.

Drug shortages fall into two categories: **supply-driven shortages** and **demand-driven shortages**. **Supply-driven shortages are often rooted in upstream disruptions to manufacturing processes, quality issues and raw material or active pharmaceutical ingredient (API) shortages.**¹⁵ **Demand-driven shortages occur because of downstream pressures such as disaster or non-disaster related medical surge.** Demand-driven shortages often result in a sudden uptick in ordering.¹⁶ The causes of supply-driven and demand-driven shortages significantly differ.

Distributors work to mitigate supply-driven shortages by building redundancy into their business practices, such as purchasing from multiple manufacturers to ensure supplier diversification.¹⁷ Distributors manage demand-driven shortages by using tools such as ongoing public-private partnerships, stockpiling and vendor-managed inventory. All of those tools reduce supply chain disruptions, including drug shortages.

To avoid significant disruptions in the pharmaceutical supply chain, distributors work to enhance supply chain resilience and maintain operational resilience. Drug shortages along with the shifts in manufacturing, customer demand, work environments, inventory and logistics management caused by the pandemic, in addition to the political ramifications, have the potential to disrupt the pharmaceutical supply chain.¹⁸

Managing the Supply Chain Today

Whether in normal or crisis conditions, a robust supply chain is critical to ensuring continuity of care for patients. Accordingly, it is important to enhance the resilience of the supply chain to better prepare for events impacting public health. Doing so will benefit public-private partnerships, data and information sharing, and emergency preparedness. Additionally, enhancing supply chain resilience will lead to more informed conversations about domestic manufacturing and quality manufacturing.

¹¹ Healthcare Distribution Alliance. "HDA Guiding Principles for Increasing Supply Chain Resilience." <https://hda.org/getmedia/2d816602-0c28-46c6-a52f-d1d36c094cd9/Resilience-Principles.pdf>.

¹² House Committee on Ways and Means, Majority Staff. "Health Care and the Climate Crisis: Preparing America's Health Care Infrastructure. II. Extreme Weather Events & Health Care Delivery." 2022. <https://web.archive.org/web/20220922063646/https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/RFI2.pdf>.

¹³ Aton, Adam. "Hurricane Maria Takes a Toll on Global Medical Supplies." *Scientific American*. October 25, 2017. <https://www.scientificamerican.com/article/hurricane-maria-takes-a-toll-on-global-medical-supplies/>.

¹⁴ Ibid.

¹⁵ Healthcare Distribution Alliance. "Understanding Drug Shortages: An Overview and Recommendations." 2023. <https://www.hda.org/getmedia/dd890154-f8fa-48c0-9c8f-ce75b81cfd82/Understanding-Drug-Shortages.pdf>.

¹⁶ Healthcare Distribution Alliance. "Insights and Recommendations From the National Academies' Report on Building Resilience in the Nation's Medical Product Supply Chain." 2022. <https://hda.org/getmedia/7290a259-5893-4fbb-9391-d8a91aa3eb85/Insights-and-Recommendations-From-the-National-Academies-Supply-Chain-Report.pdf>.

¹⁷ Healthcare Distribution Alliance. "Mitigating and Managing Drug Shortages: The Role of Healthcare Distributors." <https://hda.org/getmedia/984131d4-5163-411a-b74b-f3467113146b/Mitigating-and-Managing-Drug-Shortages.pdf>.

¹⁸ Ibid.

PUBLIC PRIVATE PARTNERSHIPS AND SUPPLY CHAIN RESILIENCE

Public-private partnerships (PPPs) bolster efforts toward supply chain resilience. PPPs are collaborations between public, private and nonprofit stakeholders to split resources and decision-making abilities to achieve specific outcomes in steady-state and crisis scenarios.¹⁹ Mutual benefits of engaging in PPPs include extending program and message reach and workforce training support. Moreover, PPPs assist in developing a more robust understanding of local issues and circumstances for targeted work, allowing partners to identify areas for innovation and form meaningful connections.²⁰ PPPs offer significant benefits by integrating the strengths of both public and private stakeholders. For a PPP to be effective, it should have mutually beneficial goals, collaborative decision-making, non-hierarchical structures, trust-based relationships, synergistic interactions and shared accountability.²¹

The **National Institutes of Health’s ACTIV program** was a PPP to support the expedited development of multiple COVID-19 vaccine candidates through Operation Warp Speed. Through ACTIV, government, industry (drug manufacturers) and nonprofits coordinated to prioritize and speed up the development of promising treatments and vaccines.²² PPPs support supply chain resilience because they offer the public and private sectors an opportunity to identify and address disruptions or potential disruptions. When a disruption strains the supply chain, PPPs can provide surge protection and procurement.²³

Another PPP addressing supply chain resilience is the **Supply Chain Control Tower (SCCT)**, which was launched amid the COVID-19 pandemic.²⁴ The SCCT was coordinated between the Department of Health and Human Services (HHS), other federal agencies and private-sector companies, including distributors. The program relied on a data-sharing agreement, which provided visibility into 90 percent of the U.S. pharmaceutical distribution market. While the SCCT provides federal stakeholders with supply chain visibility, private partners lack access to critical SCCT data. Specifically, distributors desire clear and limited parameters for SCCT operations. Distributors felt that SCCT outputs were too high-level or redundant, with missed opportunities in management and analysis.²⁵

HOW DATA AND INFORMATION SHARING SUPPORTS RESILIENCE

Adequate data and information sharing enhance supply chain resilience by providing visibility into product availability, supply chain capacity, patient needs and areas with increased demand.²⁶ **Data transparency, which is the use of data necessary to understand circumstances or provide clear information, involves using these essential data to answer questions related to resilience.** Data transparency offers a broader picture and may include involuntary data sharing and reporting mechanisms without clear plans for action.

Data illumination, which is the process of highlighting and sharing specific information within a meaningful timeframe, can be used to take explicit action, such as supporting public health needs, is often voluntary and focuses on providing critical information to address specific situations. Data illumination can be particularly valuable in supply chain coordination, where data sharing can help identify areas of need and ensure that resources are distributed quickly and efficiently.

The healthcare supply chain **depends on interconnected data sets**, such as inventory trends, acquisitions, supply chain information, and location-based and product-use data to support informed decision-making, emergency planning and incident response. While there is a growing need to share data, each organization and sector in the healthcare industry manages information sharing differently, which is compounded by the lack of clarity about who owns which data, where they originate and how they are used. Although data sharing doesn’t guarantee a more resilient healthcare supply chain, it can increase visibility, mitigate redundancies,²⁷ improve public-private coordination,²⁸ drive purposeful action and encourage investments in resilience.

Proactive plans for data collection and sharing between the public and private sectors are essential for successful supply chain communication strategies. Effective communication between public and private partners should be structured and consistent, ensuring accurate and timely coordination.

¹⁹ Healthcare Distribution Alliance. “The Importance of Public-Private Partnerships.” 2023.

<https://www.hda.org/getmedia/ecf2c869-91e8-4190-a419-36fa3542df45/The-Importance-of-Public-Private-Partnerships.pdf>.

²⁰ Ibid.

²¹ Brinkerhoff, Derick W., and Jennifer M. Brinkerhoff. “Public-private partnerships: Perspectives on purposes, publicness, and good governance.” ResearchGate. February 2011. https://www.researchgate.net/publication/227724894_Public-private_partnerships_Perspectives_on_purposes_publicness_and_good_governance.

²² National Institutes of Health. “Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV).” Accessed October 30, 2023. <https://www.nih.gov/research-training/medical-research-initiatives/activ>.

²³ Ibid.

²⁴ Healthcare Distribution Alliance. “U.S. Healthcare Supply Chain Monitoring Structure: Issues and Recommendations.” 2023.

<https://www.hda.org/getmedia/3f1f79ea-5d32-4897-b81b-899d290732ec/HDA-FactSheet-US-HC-Supply-Chain-Monitoring-Structure-FINAL.pdf>.

²⁵ Healthcare Distribution Alliance. “Healthcare Supply Chain Resilience and Data Illumination.” <https://hda.org/getmedia/38b4ad3e-1164-4ef5-9516-963f7dbfb048/HDA-Data-Illumination-Report.pdf>.

²⁶ Healthcare Distribution Alliance. “Creating a More Resilient Supply Chain by Enhancing Public-Private Sector Information Sharing.” 2023. <https://www.hda.org/getmedia/33103a51-ea4a-44c5-ae1e-e0d62ec3ae85/HDA-FactSheet-Enhancing-Public-Private-Info-Sharing-FINAL.pdf>.

²⁷ Ibid.

²⁸ Ibid.

UNDERSTANDING UPSTREAM FACTORS

Another potential strategy to bolster resilience in the healthcare supply chain is the shift of manufacturing essential medications, supplies or their components (for example, active pharmaceutical ingredients [API] and raw materials) to domestic locations or sites closer or with better relations to the U.S. These efforts are also known as onshoring, near-shoring or friend-shoring.

Onshoring Federal Strategy

Some policymakers believe that onshoring may provide greater control of quality, safety and supply chain visibility. As a result, **more than 50 federal and state bills have been introduced** to increase onshoring to decrease drug shortages.²⁹ One of those proposals is **S. 1176**, the Onshoring Essential Antibiotics Act, introduced by Sen. Tina Smith (D-Minn.) in the 117th Congress. That legislation seeks to create grants for three drug manufacturers to manufacture generic antibiotic drugs or their APIs in the U.S. Also, the **American Rescue Plan Act** included a \$60 million Defense Production Act appropriation to increase domestic manufacturing capabilities for API.³⁰ Drug manufacturers have publicly stated that they are open to increasing domestic manufacturing if appropriate investments are made to support the pharmaceutical industry.³¹

Federal actions to increase onshoring include using the **Defense Production Act** (DPA) to expedite and expand the domestic production of healthcare products and supplies needed to respond to the COVID-19 pandemic. The DPA is a presidential authority that can be used during a national emergency to accelerate and expand the U.S. industrial base. More recently, President Biden and his administration announced **new actions to strengthen the U.S. supply chains**. The Biden administration will broaden HHS authorities under the DPA to invest in domestic manufacturing of essential medicines and medical countermeasures. HHS has allocated \$35 million for domestic production of key materials for sterile injectable medicines.³² A new Supply Chain Resilience and Shortage Coordinator will be designated to strengthen medical and food supply chains. These efforts align with the Administration's broader goal of enhancing access to essential medicines and medical products. To better understand the DPA's past and future use, HDA and its members recommend conducting a Government Accountability Office (GAO) study on the use of the DPA to address the healthcare supply chain during **catastrophic events**.

In addition, the White House has forged partnerships to bolster supply chain monitoring and strategy.³³ For instance, the Department of Commerce's groundbreaking Supply Chain Center integrates industry expertise and data analytics to create innovative risk assessment tools. It conducts deep-dive analyses on critical supply chains and collaborates with various sectors. This includes partnering with the Department of Energy for clean energy supply analyses and with HHS to assess industry and import data, addressing foreign dependency vulnerabilities for critical drugs.

Furthermore, President Biden has signed **Executive Order 14017 – America's Supply Chains** into law. This Executive Order mandated HHS to evaluate and pinpoint vulnerabilities in the supply chain for API and pharmaceuticals, specifically focusing on critical medications listed on the Food and Drug Administration's (FDA) Essential Medicine List. This review, summarized in the **Essential Medicines Supply Chain and Manufacturing Resilience Assessment**, emphasizes the importance of ensuring the availability of essential medicines and maintaining high standards of healthcare product manufacturing for the market. To achieve this goal, a resilient supply chain system is crucial, which may include multiple sources or diverse manufacturers for each product and its precursor.

In addition to the above actions and proposals, the **"Building Resilience into the Nation's Medical Product Supply Chains"** report found that onshoring can be expensive and time-consuming, and it would not be feasible to quickly increase the production of medical products on U.S. soil during a crisis.³⁴ Therefore, it is important to explore other strategies to ensure that medical product supply chains are secure and reliable.



²⁹ Association for Accessible Medicines. "The Quickest Route to U.S. Essential Medicines Production: Existing and Idle Production Sites." February 9, 2023. <https://accessiblemeds.org/resources/blog/quickest-route-us-essential-medicines-production-existing-and-idle-production-sites>.

³⁰ The White House. "FACT SHEET: Biden-Harris Administration Announces Supply Chain Disruptions Task Force to Address Short-Term Supply Chain Discontinuities." June 8, 2021. <https://www.whitehouse.gov/briefing-room/statements-releases/2021/06/08/fact-sheet-biden-harris-administration-announces-supply-chain-disruptions-task-force-to-address-short-term-supply-chain-discontinuities/>.

³¹ Association for Accessible Medicines. "A Blueprint for Enhancing the Security of the U.S. Pharmaceutical Supply Chain." Published October 2021. Accessed June 2, 2023. <https://accessiblemeds.org/sites/default/files/2020-04/AAM-Blueprint-US-Pharma-Supply-Chain.pdf>.

³² <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/>. ³³ <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/>.

³⁴ National Academies of Sciences, Engineering, and Medicine. "Building Resilience into the Nation's Medical Product Supply Chains." 2022. <https://doi.org/10.17226/26420>.

PROPOSED MEASURES OF RESILIENCE

Proposed quality ratings programs include the Quality Management Monitoring (QMM) system in [development by the FDA](#), a publicly available supply chain database [recommended by a committee of the National Academy of Sciences, Engineering, and Medicine \(NASEM\)](#), and annual [resilience report cards or reports](#). The central concept behind these proposals is to establish increased transparency to strengthen supply chain resilience efforts.

The proposed QMM system would score companies on various tenets of quality manufacturing. The hope for the program is to use those scores to encourage purchasers only to procure medicines from highly rated manufacturers. The expectation is that this would serve as an incentive for manufacturers to improve their quality manufacturing.³⁵ The QMM system would rank drug manufacturers based on the transparency of their operations instead of the quality of their products.³⁶ Despite the QMM system being in its early stages, there are concerns surrounding the ranking because it is believed that the quality of prescription medications will be confusing to the public compared to the FDA-approval system of a product. HDA believes that the QMM system would negatively impact the pharmaceutical industry and would not accomplish the goal of increasing quality.³⁷

The 2021 [“National Strategy for a Resilient Public Health Supply Chain”](#) report recommends an annual “report card” to assess the resilience of the public health supply chain based on robustness, agility and visibility.³⁸ The report card would analyze supply chain capabilities, vulnerabilities, preparedness for public health emergencies and the role of foreign supply chains in the U.S. public health supply chain.

In the [2022 report](#), NASEM’s Committee on Security of America’s Medical Supply Chain suggested that the FDA and other U.S. government organizations collaborate to establish a publicly available supply chain database.³⁹ The public supply chain database intends to provide information on healthcare products to improve the FDA’s understanding of potential vulnerabilities and weaknesses. However, the benefits are limited because universal data disclosure is not infallibly or inherently beneficial to supply chain resilience.⁴⁰ Without the proper systems, it can be challenging to classify and identify critical data and information that should remain secure and confidential. Additionally, the lack of a comprehensive understanding of the supply chain could lead to ineffective and inefficient processes. Supply chain stakeholders must feel comfortable sharing data for the FDA and other government agencies to benefit from data sharing.

Purchasing, Stockpiling and Distribution Solutions During Disruptions

Purchasing, stockpiling and distribution approaches to supply chain resilience involve developing and implementing strategies and tactics to ensure a stable and reliable supply of essential goods, particularly during emergencies or disruptions. These approaches focus on building robust, agile, responsive supply chains that withstand various challenges. Some critical purchasing, stockpiling and distribution solutions include vendor-managed inventory (VMI), supporting the SNS, sourcing from multiple suppliers, establishing long-term contracts and partnerships, and creating an inventory buffer.

VMI allows distributors to manage and replenish their customers’ inventory levels. This approach enables better coordination between suppliers and customers, reduces stockouts and ensures a more efficient supply chain. HDA supports the VMI model as a tool to increase national stockpile capabilities.

The SNS, established in 1999, is a large-scale reserve of medical supplies, equipment, and pharmaceuticals the government and distributors maintain for use during public health emergencies or other crises. It ensures the availability of critical resources when they are needed most. HDA and its members are longtime partners of the SNS and support further strengthening the SNS.

When possible, distributors source from multiple suppliers, particularly from different geographical locations. Sourcing from multiple suppliers can mitigate the risk of supply chain disruptions caused by localized events or supplier-specific issues. Distributors have established long-term contracts and partnerships with key suppliers to ensure a more stable and predictable supply chain. These arrangements can facilitate better communication and collaboration and increase operational resilience, enabling both parties to respond effectively to unexpected events.

To minimize the effects of a supply chain disruption, distributors need to maintain buffer inventory or safety stock when possible. Buffer inventory or safety stock can help absorb fluctuations in demand or supply, reducing the risk of running low or out of stock during disruptions.

³⁵ Silverman, Ed. “FDA Considers a Rating System for Manufacturing Facilities as a Way to Fight Drug Shortages.” *STAT News*. October 28, 2019. <https://www.statnews.com/pharmalot/2019/10/28/fda-shortages-rating-system/>.

³⁶ Healthcare Distribution Alliance. “Insights and Recommendations From the National Academies’ Report on Building Resilience in the Nation’s Medical Product Supply Chain.” <https://www.hda.org/getmedia/7290a259-5893-4fbb-9391-d8a91aa3eb85/Insights-and-Recommendations-From-the-National-Academies-Supply-Chain-Report.pdf>.

³⁷ Ibid.

³⁸ U.S. Department of Defense et. al. *National Strategy for a Resilient Public Health Supply Chain*. July 2021. <https://www.phe.gov/Preparedness/legal/Documents/National-Strategy-for-Resilient-Public-Health-Supply-Chain.pdf>.

³⁹ National Academies of Sciences, Engineering, and Medicine. “Building Resilience into the Nation’s Medical Product Supply Chains.” <https://nap.nationalacademies.org/catalog/26420/building-resilience-into-the-nations-medical-product-supply-chains>.

⁴⁰ Ibid.

DYNAMICS AND CONSIDERATIONS FOR ACHIEVING SUPPLY CHAIN RESILIENCE

HDA and our members are working toward enhancing the resilience of the pharmaceutical supply chain. By working with PPPs, the industry can ensure the efficient distribution of essential medical products during emergencies and steady-state conditions. HDA identified several areas for achieving supply chain resilience.

Dynamics:

- **Public-private partnerships:** Collaboration between the public and private sectors has been crucial in responding to crises and ensuring the efficient distribution of essential medical products.⁴¹ Mutual benefits include extending program and message reach, providing workforce training support, helping entities gain a more robust understanding of local issues and circumstances for future work within an area, identifying areas of integration and forming meaningful connections.
- **Emergency preparedness and response strategies:** Improved planning and coordination have enhanced the supply chain's ability to manage disruptions and deliver medical products during emergencies.
- **Global competition:** Dependence on the global supply chain has diminished the sustainability and predictability of U.S.-based businesses, especially regarding essential medicines, as raw materials, APIs and finished doses are primarily sourced from overseas.

Considerations:

- **Market structure:** The low-margin market for manufacturing low-cost generic medicines, which constitute many essential medicines, drives manufacturers out of the market and hampers their ability to meet demand consistently. This low-margin market presents a high-risk, low-reward outlook for potential market entrants.⁴²
- **Labor and workforce:** Shortages in the technical workforce hinder the country's capacity to increase domestic pharmaceutical manufacturing, as the need for a science, technology, engineering and mathematics (STEM)-trained workforce does not align with the workforce currently available to operate these facilities.⁴³
- **Manufacturing processes:** Generic manufacturing considerations can lead to over-reliance on a single supplier, creating supply chain disruptions if the supplier fails to deliver.⁴⁴ Additionally, low-quality production methods can lead to delays and unreliable delivery times, compromising the supply chain's resilience.
- **Regulations:** The highly regulated pharmaceutical environment makes it difficult for manufacturers to be agile and increase production or use new suppliers during emergencies.⁴⁵
- **Security:** The healthcare industry anticipates a **30 percent increase** in cybersecurity measures over the next two years.⁴⁶ Healthcare distributors, due to their frequent interactions with various companies and systems, are well-positioned to **enhance their cybersecurity defenses**, mitigating the risks associated with potential cyberattacks.⁴⁷

RECOMMENDATIONS FOR BOLSTERING SUPPLY CHAIN RESILIENCE

HDA members are dedicated to employing their expertise and capabilities to strengthen supply chain resilience. As logistics experts responsible for delivering more than 10 million medicines, healthcare products, vaccines and other supplies, distributors play a critical role in the healthcare supply chain.⁴⁸ Ensuring the efficiency and reliability of the pharmaceutical supply chain is a vital aspect of healthcare delivery.

Besides managing daily disruptions, supply chain resilience is crucial to emergency preparedness and disaster planning for catastrophic events and public health emergencies.



HDA
SUPPORTS
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CAPABILITIES.

⁴¹ Healthcare Distribution Alliance. "The Importance of Public-Private Partnerships." <https://www.hda.org/getmedia/ecf2c869-91e8-4190-a419-36fa3542df45/The-Importance-of-Public-Private-Partnerships.pdf>.

⁴² Healthcare Distribution Alliance. "Supply Chain Resilience: High-Level Summary and Recommendations." 2022. <https://hda.org/getmedia/92505331-5f7d-401b-b099-3b05359ae280/Supply-Chain-Resilience-Assessment-High-Level-Summary-Recommendations.pdf>.

⁴³ Ibid.

⁴⁴ Ibid.

⁴⁵ Ibid.

⁴⁶ HDA Research Foundation. "COVID-19 After Action Report." <https://hda.org/publications/covid-19-after-action-report/>.

⁴⁷ Healthcare Distribution Alliance. "Pandemic and All-Hazards Preparedness Act Reauthorization: Background and Opportunities To Enhance Resilience." 2023. <https://www.hda.org/getmedia/c77c0197-674d-46cf-a870-8017ac070ae0/PAHPA-Background-and-Opportunities-to-Enhance-Resilience.pdf>.

⁴⁸ Healthcare Distribution Alliance. "HDA Guiding Principles for Increasing Supply Chain Resilience." <https://hda.org/getmedia/2d816602-0c28-46c6-a52f-d1d36c094cd9/Resilience-Principles.pdf>.

Supply Chain Resilience

As HDA continues to prioritize our commitment to supply chain resilience, we recommend several ways to improve efficiency and reliability within the pharmaceutical supply chain. These measures are crucial for both steady-state and crisis scenarios.

- Involve private-sector and industry experts in the policymaking process to better inform decision-making;⁴⁹
- Use private-sector networks and infrastructure to bolster public-sector capabilities;⁵⁰
- Support and invest in the healthcare workforce;⁵¹ and,
- Acknowledge the connection between environmental sustainability and disaster preparedness.⁵²

Operational Resilience

As distributors work to strengthen supply chain operations, HDA members are uniquely qualified to offer robust recommendations to enhance preparedness and response efforts during disasters.

- Develop working groups that include private sector representatives and climatologists to inform extreme weather contingency planning decision-making;⁵³
- Sponsor PPPs for researching, developing and distributing new medical countermeasures modeled after the National Institute of Health's private-sector partnerships for developing COVID-19 vaccines and treatments;⁵⁴
- Increase the number of community-level PPPs and grants to bolster communal trust, knowledge and preparedness for disasters;⁵⁵
- Partner with private sector vendors, such as distributors, to strengthen and expand the capacities of the SNS using an expanded VMI model authorized in the PREVENT Pandemics Act;⁵⁶ and,
- Invest in initiatives that bolster the healthcare supply chain workforce's resilience, particularly targeted efforts around worker safety and mitigating workforce shortages.⁵⁷

Drug Shortages

Distributors work with regulators, policymakers and other pharmaceutical supply chain stakeholders to ensure the availability of safe and effective medicines. To mitigate drug shortages and the disruptions they cause, HDA recommends implementing policies to prevent future drug shortages.

- The FDA should work with the private sector to conduct a focused review of the challenges affecting specific product classes;⁵⁸
- Abbreviated New Drug Applications (ANDAs) and the number of suppliers on the market should be reviewed by the FDA, especially for high-risk products;⁵⁹
- Congress and the FDA should examine financial incentives and operational considerations for strategically investing in product development capacity and working with distributors to build safety stocks and buffers;⁶⁰
- As part of its mission to reduce potential drug shortages or mitigate the impact of current shortages, the Government Accountability Office (GAO) should conduct a study to explore additional possible solutions and partnerships, specifically with the FDA, HHS and ASPR;⁶¹ and,
- The Centers for Medicare and Medicaid Services should give generics and biosimilars preference in the Medicare formulary for Medicare and Medicaid Services.^{62 63}



⁴⁹ Ibid.

⁵⁰ Ibid.

⁵¹ Ibid.

⁵² Ibid.

⁵³ Healthcare Distribution Alliance. "Bolstering Disaster Preparedness and Operational Resilience in the Healthcare Supply Chain." <https://hda.org/getmedia/f13bb354-88eb-494e-81ca-2456ea4d795c/Bolstering-Disaster-Preparedness-and-Operational-Resilience-in-the-Healthcare-Supply-Chain.pdf>.

⁵⁴ Ibid.

⁵⁵ Ibid.

⁵⁶ Ibid.

⁵⁷ Ibid.

⁵⁸ Healthcare Distribution Alliance. "HDA RFI Submission on Drug Shortages." July 2023. <https://hda.org/getmedia/cc3658b0-cebe-47cd-a944-0af2504ece9a/HDA-RFI-Submission-Drug-Shortages.pdf>.

⁵⁹ Ibid.

⁶⁰ Ibid.

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⁶² Association for Accessible Medicines. "Drug Shortages: Causes & Solutions." Accessed July 14, 2023. https://accessiblemeds.org/sites/default/files/2023-06/AAM_White_Paper_on_Drug_Shortages-06-22-2023.pdf.

⁶³ Ibid.

Pandemic and All-Hazards Preparedness Act

As HDA navigates the post-COVID-19 healthcare landscape, a reliable and resilient healthcare supply chain is essential to ensuring the health and safety of patients. However, HDA recognizes there are challenges to data and information sharing within the supply chain coordination and tracking framework.

- The SCCT shall be fully operational during a public health emergency only. The SCCT may remain at a warm posture (with the ability to scale up for public health emergencies) between public health emergencies. The SCCT must consider antitrust regulations and laws regarding the industry data stakeholders submit to the SCCT. Additionally, the SCCT must include protections to maintain security for industry data stakeholders who submit to the SCCT.⁶⁴
- Address vaccine tracking and distribution reporting requirements by ensuring reporting system interoperability between the federal government and its U.S.-based healthcare distributor voluntary partners through annual testing and exercises.⁶⁵

Public-Private Partnerships

To ensure the success of a PPP, HDA focuses on key areas. By doing so, HDA can create sustainable, effective and scalable projects.

- Invest resources in establishing PPPs during steady-state and crisis conditions;⁶⁶
- Leverage previous collaboration between public-sector entities and private industry to build on existing relationships and infrastructure of earlier PPPs;⁶⁷
- Partner with the private sector to employ expertise, existing infrastructure, networks, relationships, manufacturing abilities and technologies whenever possible;⁶⁸ and,
- Solicit private-sector input in developing data-sharing efforts to bolster supply chain resilience.⁶⁹

Data and Information Sharing

As HDA works to enhance bidirectional data and information sharing between the public and private sectors, it's important to remember the many benefits such efforts can bring. By mitigating redundancies, increasing data illumination and improving public-private collaboration, the industry can identify and implement supply chain actions that will help better understand risk assessments and inventory counts.



- Incentivize private-sector partners.⁷⁰
- Provide clear data-request parameters.⁷¹
- Eliminate technological barriers and leverage automation.⁷²
- Improve information request management.⁷³
- Memorialize private sector stakeholder/government relationships.⁷⁴

Establishing official channels and working groups would facilitate a consistent cadence, expectation and context for data sharing. During the COVID-19 pandemic, the government's limited data-sharing framework resulted in missed opportunities. To build a robust data-sharing network, the government should implement more communication modes, expand its network and facilitate collaboration opportunities across different sectors. Formal and trusted communication channels would set firm expectations for the industry and help achieve a more resilient healthcare supply chain.

⁶⁴ Healthcare Distribution Alliance. "U.S. Healthcare Supply Chain Monitoring Structure: Issues and Recommendations." 2023.

<https://www.hda.org/getmedia/3f1f79ea-5d32-4897-b81b-899d290732ec/HDA-FactSheet-US-HC-Supply-Chain-Monitoring-Structure-FINAL.pdf>.

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⁶⁶ Healthcare Distribution Alliance. "Leveraging Public-Private Partnerships To Strengthen the Nation's Healthcare and Public Health Sectors." 2023.

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⁶⁷ Ibid.

⁶⁸ Ibid.

⁶⁹ Ibid.

⁷⁰ Healthcare Distribution Alliance. "Creating a More Resilient Supply Chain by Enhancing Public-Private Sector Information Sharing." 2023.

<https://www.hda.org/getmedia/33103a51-ea4a-44c5-ae1e-e0d62ec3ae85/HDA-FactSheet-Enhancing-Public-Private-Info-Sharing-FINAL.pdf>.

⁷¹ Ibid.

⁷² Ibid.

⁷³ Ibid.

⁷⁴ Ibid.

Onshoring, Near-shoring and Friend-shoring as Part of Supply Chain Resilience Efforts

HDA members work to weather unexpected disruptions in the supply chain and ensure we can continue providing essential products to patients.

- Distributors and the federal government should implement policies and incentives to bring production back to the country strategically.⁷⁵ This strategy has to be sustained with long-term funding in order to make this possible.
- Recognizing that domestic production is a part of the solution, but not the full solution, there should also be an effort to work with manufacturers abroad to invest in resilience and redundancy practices to increase the ability to respond to surges or changes in supply.

Purchasing, Stockpiling and Distribution Solutions During Disruptions

Reporting stock levels and other inventory data in real time would be onerous and not guarantee increased coordination or improved resilience. However, HDA recommends independent studies to help develop more effective strategies for addressing challenges.

- **Strategic National Stockpile (SNS)**
 - To support the SNS program and its partnerships, the SNS should receive a funding authorization that, at a minimum, maintains the appropriate funding level for Fiscal Year 2023.⁷⁶
 - The SNS should work with all voluntary U.S.-based healthcare distributors to maintain IT connectivity.⁷⁷
 - The SNS should review its management and reimbursement practices for medical products before procuring certain supplies with excess products.⁷⁸
- **Vendor Managed Inventory (VMI)**
 - There should be an established process to determine what products should be part of VMI. VMI increases stockpile capabilities.⁷⁹
- **Diversification of Suppliers**
 - Sourcing from multiple suppliers, a practice distributors maintain, will build redundancy and mitigate the risk of supply chain disruptions caused by local events or supplier-specific issues.⁸⁰

CONCLUSION

Enhancing supply chain resilience not only means mitigating disruptions, but ultimately ensuring essential medicines' availability when the worst happens. Disruptions threatening one or multiple parts of the pharmaceutical supply chain can stem from a wide range of natural and human-made causes — and it is crucial to consider the various factors behind those disruptions to enhance resilience for the future.

As logistics experts at the center of the pharmaceutical supply chain, HDA-member distributors work daily to promote a resilient supply chain and are uniquely positioned to recommend solutions. To this point, the industry believes supply chain resilience can be enhanced by:

- Leveraging public-private partnerships, investing in a robust healthcare workforce and improving emergency preparedness and response strategies.
- Promoting data transparency and visibility to understand the environment and provide clarity to answer questions.
- Considering a range of options to expand manufacturer capabilities, as certain plans to increase domestic production may present significant cost barriers and be a long-term challenge for companies to sustain.

With collective efforts, healthcare stakeholders can create a robust supply chain that can withstand challenges.

⁷⁵ Healthcare Distribution Alliance. "HDA Guiding Principles for Increasing Supply Chain Resilience." <https://hda.org/getmedia/2d816602-0c28-46c6-a52f-d1d36c094cd9/Resilience-Principles.pdf>.

⁷⁶ Healthcare Distribution Alliance. "Supply Chain Resilience Assessment: High-Level Summary and Recommendations." <https://hda.org/getmedia/92505331-5f7d-401b-b099-3b05359ae280/Supply-Chain-Resilience-Assessment-High-Level-Summary-Recommendations.pdf>.

⁷⁷ Ibid.

⁷⁸ Ibid.

⁷⁹ Ibid.

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APPENDIX:

HDA Supply Chain Resilience Resources

Issue Briefs

- [Healthcare Supply Chain Resilience and Data Illumination](#)
- [PAHPA: Background and Opportunities to Enhance Resilience](#)
- [Bolstering Disaster Preparedness and Operational Resilience in the Healthcare Supply Chain](#)
- [Insights and Recommendations from the National Academies Report on Building Resilience in the Nation's Medical Product Supply Chain](#)
- [The Importance of Public-Private Partnerships](#)
- [HDA Guiding Principles for Increasing Supply Chain Resilience](#)
- [Supply Chain Resilience Assessment: High-Level Summary and Recommendations](#)

Fact Sheets

- [Creating a More Resilient Supply Chain by Enhancing Public-Private Sector Information Sharing](#)
- [U.S. Healthcare Supply Chain Monitoring Structure: Issues and Recommendations](#)
- [Bolstering Disaster Preparedness and Operational Resilience in the Healthcare Supply Chain](#)
- [Leveraging Public-Private Partnerships To Strengthen the Nation's Healthcare and Public Health Sectors](#)

Policy Recommendations

- [PAHPA Reauthorization: High-Level Summary and Recommendations](#)
- [HDA RFI Submission on Drug Shortages](#)

- ¹ HDA Research Foundation. 94th Edition HDA Factbook: The Facts, Figures and Trends in Healthcare. 2023. <https://www.hda.org/publications/94th-edition-hda-factbook-the-facts-figures-and-trends-in-healthcare/>.
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- ⁷ Ibid.
- ⁸ Healthcare Distribution Alliance. "Bolstering Disaster Preparedness and Operational Resilience in the Healthcare Supply Chain."
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- ¹³ Aton, Adam. "Hurricane Maria Takes a Toll on Global Medical Supplies." Scientific American. October 25, 2017. <https://www.scientificamerican.com/article/hurricane-maria-takes-a-toll-on-global-medical-supplies/>.
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