

# **Issue Brief**

## **Insights and Recommendations From the National Academies' Report on Building Resilience** in the Nation's Medical Product Supply Chain

## Background

The Healthcare Distribution Alliance (HDA) is the national organization representing primary pharmaceutical distributors the vital link between the nation's pharmaceutical manufacturers and pharmacies, hospitals, long-term care facilities, clinics and others nationwide. HDA advocates on behalf of pharmaceutical wholesalers and distributors, leads the sector on relevant policy and fosters relationships across partner organizations. Healthcare distributors ensure the safe, efficient and reliable delivery of medications, vaccines and other critical medical products. As the backbone of the pharmaceutical supply chain, distributors handle approximately 95 percent of medicines moved across the United States, and they deliver medications and supplies to nearly 330,000 locations daily.<sup>1</sup> HDA's members find the safest and most efficient ways to get products where patients need them the most in a continuous and reliable manner.



The COVID-19 pandemic presented an unprecedented challenge for HDA's members and the healthcare sector. HDA and its members' response<sup>2</sup> to the pandemic centered on principles of communication, coordination and cooperation. Distributors' primary aim throughout the crisis was to move products globally to communities with the greatest need. HDA members communicated<sup>3</sup> with manufacturers and providers to monitor product availability and allocate supplies, while also assessing and mitigating shortages. Additionally, HDA and its members partnered closely with federal agencies and state governments to respond to the crisis and improve access to supplies, medications and vaccines.

In 2021, the National Academies of Sciences, Engineering and Medicine (NASEM) convened the Committee on Security of America's Medical Supply Chain to examine the root causes of medical product shortages and identify ways to enhance supply chain resilience. In its report<sup>4</sup>, "Building Resilience into the Nation's Medical Product Supply Chains," the Committee provides seven recommendations and presents a framework of protection measures related to awareness, mitigation, preparedness and response. Table 1 provides a summary of the NASEM report recommendations. Following the report's publication, study committee members authored <u>supporting commentary</u><sup>5</sup> in the health policy journal *Health Affairs*. The commentary synthesized prior work on supply chain resilience and recommendations for strengthening the supply chain. This document presents HDA's reflections on the NASEM report and commentary, focusing on data transparency and illumination, product ratings and public-private partnerships.

Healthcare Distribution Alliance Research Foundation. 94th Edition HDA Factbook: The Facts, Figures and Trends in Healthcare (2023–2024), October 2023.

https://hda.org/publications/94th-edition-hda-factbook-the-facts\_figures-and-trends-in-healthcare/. Healthcare Distribution Alliance. "Pharmaceutical Distributors Respond to the COVID-19 Pandemic." Accessed January 25, 2023. https://www.hda.org/getmedia/27f224d2-736c-4f85-b134-1aad3a8761b4/HDA-COVID-19-Fact-Sheet-Final.pdf. Healthcare Distribution Alliance Research Foundation. "How the US biopharmaceutical and medical product supply chain adapted to disruptions – and plans to build strategies for the

 <sup>4</sup> National Academies of Sciences, Engineering and Medicine. Building Resilience into the Nation's Medical Product Supply chains database of Sciences, Engineering and Medicine. Building Resilience into the Nation's Medical Product Supply Chains. Accessed November 20, 2022. <u>https://www.hda.org/publications/covid-19-after-action-report/</u>.
 4 National Academies of Sciences, Engineering and Medicine. Building Resilience into the Nation's Medical Product Supply Chains. Accessed November 20, 2022. <u>https://nap.nationalacademies.org/catalog/26420/building-resilience-into-the-nations-medical-product-supply-chains</u>.
 5 Park, Minje, Rena M. Conti, Marta E. Wosńska, Ergun Ozlem, Wallace J. Hopp, Erin R. Fox, "Building Resilience Into US Prescription Drug Supply Chains." *Health Affairs*, January 20, 2023. https://www.healthaffairs.org/content/forefront/building-resilience-into-us-prescription-drug-supply-chains

#### TABLE 1 - NASEM SUPPLY CHAIN SUMMARY OF RECOMMENDATIONS — CONSENSUS STUDY REPORT<sup>6</sup>

#### Awareness



#### **Public Transparency**

Make sourcing, quality, volume and capacity information publicly available for all medical products approved or cleared for sale in the United States.



#### Public Database

Establish a public database for the supply chain information acquired for medical products.

#### Mitigation



#### **Resilience Contracting by Health Systems**

Deliberately incorporate quality and reliability, in addition to price, in contracting, purchasing and inventory decisions.

#### Preparedness

**Stockpiling** Modernize and optimize inventory stockpiling management to respond to medical product shortages at the national and regional levels.



#### Capacity Buffering

Cultivate capacity buffering for supply chain critical medical products where such capacity is a costeffective complement to stockpiling.

#### Response

 International Treaty
 Negotiate an international treaty with other major medical product exporters that rules our export bans on key components of global medical product supply chains.

7.

#### Last-Mile Management

Establish a working group to examine last-mile and end user issues regarding medical product supply chains.

Source: National Academies of Sciences, Engineering and Medicine, 2022.

## **Reflections on Resilience During a Global Pandemic**

Distributors experience strain when a disruption exceeds their capacity to maintain continuity in the supply chain using existing infrastructure and resources. Supply chain disruptions can be characterized by their origin, scope and scale. Disruptions can result from natural and human-made disasters, legislative and regulatory shifts or social-political phenomena, such as worker strikes. These disruptions can subsequently threaten one or multiple parts of the supply chain.

The types of events at the upstream end of the supply chain (i.e., sourcing and manufacturing processes) include raw material shortages and import or export bans. Demand-side disruptions occur at the downstream

<sup>6</sup> National Academies of Sciences, Engineering and Medicine. "Building Resilience into the Nation's Medical Product Supply Chains." Accessed November 20, 2022. https://doi.org/10.17226/26420.

end of the supply chain (i.e., consumers, patients). Extrinsic or societal factors typically induce them (e.g., changes in public awareness or sentiment about a product, increase in demand, medical surge, panic purchasing). Disruptions can be acute or chronic. Acute disruptions are sudden and limited in duration, whereas chronic disruptions (e.g., ongoing fuel shortages, workforce shortages, unexpected competition) can develop into longstanding issues that are not easily resolved. Finally, disruptions can be confined to a small region (e.g., conflict zone, power outage) or transcend borders (e.g., global pandemic).

The COVID-19 pandemic demonstrated how a global public health emergency can lead to complex shifts in customer/patient demand, work environments, inventory management, logistics management and political context. These shifts can then disrupt the global healthcare supply chain. Notably, as the pandemic unfolded, a short-term shutdown for non-essential workers morphed into chronic workforce shortages across many sectors, including distribution.<sup>7</sup> Global demand for healthcare products disrupted the normal flow of products in the U.S. Furthermore, the understanding of a novel pathogen led to public health recommendations, changes in workplace safety protocols and emergency use authorizations, which influenced how and when medications and medical supplies were used.<sup>8</sup>

The healthcare sector is reviewing the lessons from the COVID-19 pandemic response to identify ways to enhance supply chain resilience further. Healthcare distributors have valuable information and experience to contribute to these discussions. Distributors recognize their crucial role in distributing medical products throughout the country, particularly during crisis conditions, equips them to shed light on the dynamics that result in true resilience, especially at the last mile and last inch. In addition to their operational experience from navigating the pandemic, distributors can share lessons learned from collaboration with trading partners, including suppliers, customers and providers. Due to their unique role, distributors have insight into supply availability and demand surges.

It is the position of HDA and its membership that supply chain resilience efforts should focus on more than just preparing for and responding to adverse events. Instead, resilience-building endeavors should also enhance the efficiency and effectiveness of everyday operational capabilities. In addition, building and strengthening existing infrastructure will increase resilience for any potential disruption, regardless of scale, scope or origin.

In 2022, HDA released guiding principles for improving supply chain resilience,<sup>9</sup> informed by what healthcare distributors and their partners learned throughout the COVID-19 pandemic (Table 2). These principles support an approach to improving supply chain resilience that engages all stakeholders by leveraging their existing workforce and infrastructure to identify and prepare for various disruptions.

#### **TABLE 2. PRINCIPLES FOR IMPROVING** SUPPLY CHAIN RESILIENCE

- 1. Leverage distributor insight and expertise to inform public sector decision-making;
- 2. Encourage meaningful public-sector collaboration with private-sector health partners and infrastructure;
- 3. Prioritize protecting the supply chain workforce; and,
- 4. Recognize the connection between environmental sustainability and disaster mitigation and response.

Source: Healthcare Distribution Alliance, 2022.

## **Commentary on NASEM Recommendations for Building Resilience**

#### **Expand the Scope of Supply Chain Resilience**

The NASEM report and commentary define the goal of supply chain resilience as avoiding shortages of medical products, thereby preventing negative impacts on public health. While product shortages are an important consideration, this definition oversimplifies supply chain complexities and the interplay between

Luscombe, Richard. "Covid Caused Huge Shortages in US Labor Market, Study Shows." The Guardian, September 13, 2022, sec. US news. https://www.theguardian.com/us-news/2022/

sep/13/us-labor-shortage-long-covid. Tran, Allan, and Theodore J. Witek. "The Emergency Use Authorization of Pharmaceuticals: History and Utility During the COVID-19 Pandemic." Pharmaceutical Medicine 35, no. 4 (2021): 203-13. https://doi.org/10.1007/s40290-021-00397

Healthcare Distribution Alliance. "HDA Guiding Principles for Increasing Supply Chain Resilience." Accessed January 25, 2023. https://www.hda.org/getmedia/2d816602-0c28-46c6-a52f-d1d36c094cd9/Resilience-Principles.pdf.

physical, economic, political, regulatory and social forces. Resilience is more than the ability of the supply chain to anticipate and avoid all shortages. Even a resilient supply chain with forecasting capabilities, threat awareness and preparedness and mitigation measures can still experience product shortages. These forces are often outside the supplier's control and can include novel diseases, demand surges, hoarding behavior or unanticipated regulatory burdens.

HDA and its members understand supply chain resilience to be the capability to prepare for, respond to and recover from anticipated and unanticipated disruptions. In this view, resilience is more closely linked to national critical infrastructure security and stability. As such, HDA supports expanding discussions about the goals of resilience to reflect the dependencies within and across sectors. Additionally, these discussions should include efforts to minimize the impacts of disruptions on all stakeholders who play a role in how medical products flow through the supply chain.



#### Improve Data Transparency and Illumination

The NASEM report and commentary recommend high data transparency for all medical products through a publicly available database. The rationale is that the healthcare and public health communities can analyze the detailed data on supply chain processes (e.g., manufacturing location, sourcing practices, volume produced and available production capacity) to proactively identify potential areas of concern and design or activate mitigation measures. HDA acknowledges the value of data aggregation and proactive, predictive analysis for both general operations and adverse event preparedness and response. Moreover, HDA members have demonstrated that commitment by contributing to the federal government's Supply Chain Control Tower (SCCT) program during the pandemic to provide visibility into crucial products during a medical surge (e.g., COVID-19, baby formula shortages, RSV and flu season).10

However, universal data disclosure is not infallibly or inherently beneficial to supply chain resilience. Decisions about data transparency must be informed by an analysis of the risks of disclosure, the burden

on reporting entities and the fit for purpose of the requested information. For HDA and its members, universal data disclosure surfaces concerns about supply chain security and the potential for interference in its operations. Public disclosure of sourcing, manufacturing and distribution information makes the supply chain vulnerable to foreign actors seeking to undermine national security by harming the production and availability of critical supplies or medications. In addition, HDA and its members question if the data requested will be sufficient to inform decision-making. For example, requiring distributors to report on inventory figures for a specific drug would not provide a complete picture of the actual availability and production capability for that medication. Finally, HDA and its members are concerned about the anticipated burden on reporting entities. The healthcare supply chain is a complex and dynamic system, with little capacity to absorb burdensome reporting requirements that do not support operations or continuity. For this reason, additional reporting burdens may further strain supply chain operators. Smaller distributors particularly feel these burdens, as their organizations are likely to be leaner and already stretched to comply with existing requirements.<sup>11</sup>

Administration for Strategic Preparedness & Response, U.S. Department of Health and Human Services. "Strengthening the Supply Chain & Industrial Base - Public Health Supply Chain and Industrial Base One-Year Report." Accessed February 16, 2023. <u>https://aspr.hbs.gov/MCM//Bx/2022Report/Pages/Strengthening-the-Supply-Chain-and-Industrial-Base.asp</u>.
 Health Care Distribution Alliance and Partner Forces. *Healthcare Supply Chain Resilience and Data Illumination*. March 2023. <u>https://hda.org/getmedia/38b4ad3e-1164-4ef5-9516-963f7dbfb048/HDA-Data-Illumination-Report.pdf</u>.

HDA supports data illumination, a strategy that streamlines the flow of currently available data from multiple sources to collectively analyze data and interpret information to achieve mutually agreed-upon goals. Rather than increasing data disclosure requirements or calling for universal data transparency, HDA recommends examining the existing disclosure requirements. A clear understanding of the current reporting mechanisms, how the data they produce are already being used and how reporting could be better coordinated is necessary before additional reporting requirements are imposed. HDA supports working with HHS, especially FDA and ASPR, to identify opportunities to streamline reporting and increase cooperation and data sharing across federal agencies.

#### **Expand Supply Chain Capacity**

Supply chain resilience discussions often focus on building resilience through increasing domestic production capacity and increasing the amount of product suppliers have available to respond to an emergency. For example, the inventory companies will stock "just-in-case" to avoid running out of product due to a sudden increase in demand.

Before the pandemic, most supply chain partners adopted lean business models and a combination of just-in-time and just-in-case inventory management, maximizing efficiency and cost savings and minimizing environmental footprint and waste. These strategies are based on moving product only as needed, requiring a low inventory and rapid, routine delivery of product. The just-in-time strategy is especially important for healthcare facilities with little capacity to hold large volumes of medical products. Another strategy to avoid running out of product due to increased demand is stockpiling. Stockpiling for major disruptions was viewed as a separate strategy, occurring at the health system, regional, state and federal levels as part of the preparedness enterprise. Stockpiling critical healthcare supplies and medications is an important component of an emergency preparedness strategy. Recommendations that supply chain partners carry additional inventory to mitigate potential shortages have direct



implications for business operations. This is particularly true for low-margin sectors (e.g., generic medicines), where requirements to carry additional inventory would only compound resilience issues.

Calls to increase domestic production capacity stem from what some policymakers and policy experts may see as the healthcare sector's overdependence on foreign-manufactured products. The NASEM report and commentary caution against an overreliance on domestic production given the potential for increased costs. Rather than calling for a blanket shift away from global production chains, the NASEM report recommends working with ASPR and FDA to fund research and development in advanced manufacturing techniques that may bring about more competitive onshore production for critical medical products through public-private partnerships. HDA and its members support such initiatives as a strategy for diversification of manufacturing in cases where this strategy enhances resilience. Distributors maintain they will distribute FDA approved products intended for use in the U.S. regardless of the manufacturing country. The supply chain diversification process will be a lengthy and costly process that will require significant, sustained federal investment and support from organizations across the healthcare sector.

#### **Establish Product Ratings**

The NASEM report calls for establishing independent, third-party quality management systems that grade the quality of medications and medical products. Because such a system would require access to data currently held only by the FDA, this recommendation is tied to the push for data transparency.

This quality rating system could contribute to confusion among consumers and patients. Under the current regulatory system and Hatch-Waxman, FDA-approved medicines are deemed of equivalent quality and safe for consumers. Thus, FDA approval conveys a connotation of quality to the public. As has been the case in other sectors, the creation of one independent rating system may lead to the development of multiple rating systems (e.g., hospital quality rating scales), each with its own mission and metrics. Consumers and patients would be left to interpret potentially conflicting ratings for the same or similar products.

Generic medicines come to market under the bioequivalence principle, using the equivalent brand product's safety and efficacy data. Introducing a rating system where a brand and generic medicine could receive a different quality rating would challenge the notion that the generic and brand medicines are equivalent, and may violate the Hatch-Waxman Act. Moreover, given <u>over 90 percent of prescriptions</u> in the U.S. are filled with generics, a third-party rating system would create confusion among purchases and patients,<sup>12</sup> ultimately destabilizing the generics market.<sup>13</sup>

[Establishing a] quality rating system could contribute to confusion among consumers and patients. Under the current regulatory system and Hatch-Waxman, FDA-approved medicines are deemed of equivalent quality and safe for consumers. Thus, FDA approval conveys a connotation of quality to the public.

Further, recommendations related to implementing a proposed quality management maturity (QMM) system,<sup>14</sup> whether it is controlled by a third party or the FDA, could pose challenges for supply chain stakeholders. A QMM system would rank manufacturers based on the transparency of their operations rather than being focused on the quality of their products. While the FDA's QMM program is only in its early stages, HDA believes that such a rating system would negatively impact the industry without accomplishing FDA's intended goals for the program — namely, bolstering supply chain resilience and reducing quality-related drug shortages.



Distributors see value in metrics and standards for risk and reliability across the supply chain. HDA supports creating and equitably applying such standards, recognizing that these metrics should improve supply chain resilience rather than drive market performance. The development of a third-party quality management and rating systems should focus on reliability rather than quality to enhance resilience. To the extent there are concerns regarding the ability of the FDA to monitor quality, HDA proposes working with trading partners and the FDA to quantify those challenges and push for adequate federal funding for the agency to fulfill its mission. Further, HDA recommends exploring the potential impact of a quality management program on the healthcare system, as manufacturers with low margins may be unable to invest in changes without some incentive or inflow of resources.

- Pharmaceutical Research and Manufacturers of America. "Fact Sheet: What Is Hatch-Waxman? June 2018." Accessed November 20, 2022. <u>https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PhFMA-Org</u>
- Office-generic-drugs-2021-annual-report.
  U.S. Food and Drug Administration. Once of Generic Drugs 2021 Annual Report. Teordary 14, 2022. <u>https://www.da.gov/drugs/generic-drugs-2021-annual-report.</u>
  U.S. Food and Drug Administration, Quality Management Maturity: Essential for Stable U.S. Supply Chains of Quality Pharmaceuticals, 2022. Office of Pharmaceutical Quality, Center for Drug Evaluation and Research. Accessed February 3, 2023. <u>https://www.fda.gov/media/157432/download.</u>
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#### Strengthen Public-Private Partnerships in the Healthcare Sector

The NASEM report proposes optimizing and modernizing the Strategic National Stockpile (SNS), including convening working groups. HDA has advocated for strengthening the SNS, including several provisions in the Prepare for and Respond to Existing Viruses, Emerging New Threats (PREVENT) Pandemics Act. Portions of this bill were recently enacted as part of the 2023 Consolidated Appropriations Bill (Omnibus), which among other measures, strengthens the SNS and pandemic response supply chain.<sup>15</sup> Additional policies regarding SNS modernization may be included in the upcoming Pandemic and All-Hazards Preparedness. Act (PAHPA) reauthorization. As these pieces of legislation are implemented, HDA and its membership stand ready to collaborate with public sector stakeholders and trading partners. Distributors have the capacity and expertise to help expand the stockpile. Each company can use its existing distribution capacity, its capability to rotate product and established organization-wide inventory management protocols to achieve this goal. Additionally, if given the opportunity, distributors can leverage their networks and industry connections to streamline the stockpiling strategy and replenishment process further.

Tapping private sector networks to support the modernization and expansion of the SNS can bolster response and stockpile management efforts. Public-private partnerships that employ private-sector expertise, capabilities, networks, infrastructure and public-sector information and management can improve each sector's capabilities and resilience while simultaneously helping to address complex problems. In the case of supply chain resilience, suppliers and distributors have capabilities the public sector can and should use, including distributing essential products during emergencies and maintaining and ramping up production during times of crisis. Additionally, the private sector constantly enhances its capabilities, including investing in technologies to improve manufacturing and delivery and developing strategies to best combat short-term and extended crises.

HDA also strongly supports the recommendation to establish mechanisms for stakeholders to share best practices and expertise.<sup>16</sup> This will allow for a more robust understanding of the capabilities and insights of the industries and actors uniquely qualified to assist.

## **Next Steps**

Healthcare distributors have taken significant steps to improve the supply chain's resilience to cope with the significant and unprecedented disruptions brought about by the COVID-19 pandemic. These strategies have included reassessing, diversifying and reconstructing supply processes; relocating manufacturing sites; increasing inventory; implementing digital analytics to refine allocation processes; using alternative delivery routes; and implementing workforce initiatives to combat labor shortages.<sup>3</sup> HDA believes efforts to improve supply chain resilience must balance that goal while also ensuring continued supply chain security. Such balanced efforts include employing existing private-sector infrastructure and bolstering public-private partnerships to maximize effective communication and cooperation between both sectors. HDA welcomes the opportunity to partner in designing and implementing novel efforts that strengthen the supply chain.

Association of American Medical Colleges. "Pandemic Preparedness Measures Passed as Part of FY 2023 Omnibus." Accessed February 14, 2023. <u>https://www.aamc.org/advocacy-policy/washington-highlights/pandemic-preparedness-measures-passed-part-fy-2023-omnibus</u>.
 Healthcare Distribution Alliance. "The Importance of Public-Private Partnerships." March 2023. <u>https://hda.org/getmedia/ecf2c869-91e8-4190-a419-36fa3542df45/The-Importance-of-</u>

Public-Private-Partnerships.pdf.

## About the Healthcare Distribution Alliance

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.