HDA
Healthcare Distribution Alliance

Issue Brief
Summary

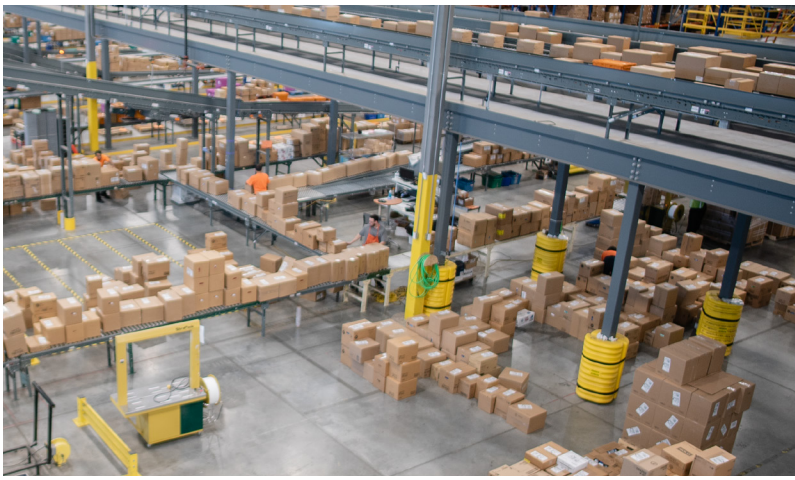
Supply Chain Resilience Assessment: *High-Level Summary and Recommendations*

The Healthcare Distribution Alliance (HDA), the national association representing primary pharmaceutical distributors, welcomes the *Essential Medicines Supply Chain and Manufacturing Resilience Assessment*, a report from the National Forum to Secure America's Supply Chain for Essential Medicines. This assessment outlines the consortium's vision as follows:

"[A] resilient and robust U.S. supply chain can ensure **that essential medicines are available in the event of a pandemic or crisis as well as for typical acute patient care.** The reliable availability of these medicines can help **to alleviate strains on hospital resources**, resulting in more lives saved and improved patient care."

The report identifies a number of challenges to a secure and resilient supply chain: market structure, global competition, labor and workforce, manufacturing processes, supply chains and distribution, and regulations. The report also lays out a number of strategies to address these challenges. These strategies are grouped into the following categories:

1. Increased supply chain coordination, security and transparency
2. Expanded onshore or nearshore production capacity
3. Advanced manufacturing capabilities, research and development
4. Purchasing, stockpiling and distribution approaches



HDA has a unique perspective on the supply chain and the many factors that can enhance — or hinder — resilience. HDA's members have acute knowledge of the various factors that may impact the resilience and reliability of the supply chain, as well as the strategies that can provide meaningful improvements or solutions to those issues.

It is important to note the existing operating principles that healthcare distributors use as a guide on supply chain resilience:

The owners and operators of the healthcare supply chain (private sector) should be engaged at every step as critical partners in enhancing supply chain resilience.

- **Steady-state resilience** is the ability of the supply chain to absorb small scale or regional shocks and disruptions that could impact the flow of medical products on a daily basis.
    - Steady-state resilience requires a different level of investment and different set of strategies to properly build.

- It also includes supply chain security measures and relies on rigorous enterprise planning, which exists in programs along the supply chain.
- **Crisis resilience** requires a different set of capabilities than steady-state resilience. Crisis resilience describes the ability of the supply chain to pivot to meet the demands caused by a large scale (national, global) medical surge event.
- This could be caused by many different types of hazards, but ultimately results in a bolus of product being needed in multiple geographic locations. Crisis resilience may shift based on the event — that is crises with no notice that require novel medical countermeasures are different than events with notice or existing medical countermeasures.
- While healthcare distributors have plans to account for crisis resilience, it is impossible to fully prepare for a sustained catastrophic event with product on the shelves. Large scale, no-notice events require an investment in long-term capability and capacity, not just product on shelves.

Reports have shown that the pharmaceutical supply chain experienced challenges, but held up fairly well during the pandemic. Understanding the investments and strategies that enabled this would be valuable before adding additional capabilities that do not actually improve resilience.

Healthcare distributors do not solely rely on a "just-in-time" system, but have robust plans and strategies in place to ensure continuity of medicines. While we cannot solely rely on just-in-time, we should depend on the knowledge and experience of distributors to determine how to ensure availability of critical medicines during times of surge.

The majority of healthcare distributors' infrastructure is spread across the United States and North America, with significant geographical redundancy. While policymakers are pushing for the near-shoring and onshoring strategy, we urge a focus on the infrastructure, investments and workforce to sustain these resilience strategies long-term.

The report provides an overview of four (4) categories with 21 strategies to address supply chain resilience, to which we have responded with the following. HDA applauds the consortium's effort and appreciates the opportunity to collaborate on these issues in greater detail.

1 Increased supply chain coordination, security, and transparency

The healthcare supply chain is a highly regulated space that already requires frequent reporting to multiple federal agencies, most notably, the U.S. Food and Drug Administration (FDA). The standardization of metrics across the supply chain may be beneficial and should be explored further with strong input from industry organizations, with parameters for timing (near-time, periodic, as needed) and scope (steady-state versus in a crisis or public health emergency) and desired outcomes.

However, any data collection should be evaluated in aggregate of what is already being submitted to avoid redundancy and burden. It is important to also balance the reporting burden with the scope of necessary and actionable data that should be transmitted.

Regarding public-private collaboration, there is a need to better clarify the roles of federal agencies in supply chain coordination — especially during emergency responses and public health emergencies (e.g., ASPR, FEMA, FDA, CDC, etc.). Healthcare distributors (and the private sector, broadly) would benefit from the use of centralized coordination functions to manage governmental responses through a single coordinating entity. The need for coordination, however, does not require control. Manufacturers and distributors are organizations with deep expertise in their operations who should continue to operate independently, even during healthcare crises.

2 Expanded onshore or near-shore production capacity

While expanding domestic production capacity is a laudable goal, onshore production has significant cost barriers which can be a long-term challenge to sustain. Distributors support financial incentives that will enable supply chain organizations' investments into the domestic production, while noting that distributors maintain the capacity to move finished product securely and efficiently within the U.S., regardless of origin.

When considering onshoring and near-shoring capabilities for healthcare distribution sector, it is important to note the significant geographic redundancy that exists across the U.S. Most HDA member companies have a distribution center or warehouse in most states across the country.

3 Advanced manufacturing capabilities, research and development

Supply chain organizations support investments in workforce recruitment and training. These investments should not only encompass science, technology, engineering and mathematics (STEM) positions, but should also include assistance with recruitment and training for other key sectors. Strong investments in the education system and workforce pipeline are core to the ability to maintain critical infrastructure in the U.S.

4 Purchasing, stockpiling and distribution approaches

The proposed purchasing and distribution strategies presented do not fully account for the complexities of healthcare distribution. The real-time reporting of stock levels and other inventory data would be onerous and would not guarantee increased coordination or improved resilience. HDA recommends that the federal government commission an independent study to determine the various flows of data and information on supply chain status and operations, and the uses of this data and information.

The recommendation and benefits for a "vendor-managed" stockpile/vendor managed inventory (VMI) are not fully defined, but HDA supports the concept and expansion of the VMI model as a tool to increase the capabilities of the national stockpile. There should also be additional effort made to determine if the VMI/product rotation model is the only sustainable model recommended to increase the buffer of available product for health crises.

Lastly, HDA encourages discussion regarding the role and scope of the federal government in overseeing purchasing or allocation decisions, in steady-state and during a public health emergency. There are opportunities for public-private partnerships in this space — which required clearly established plans and investments.

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 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.