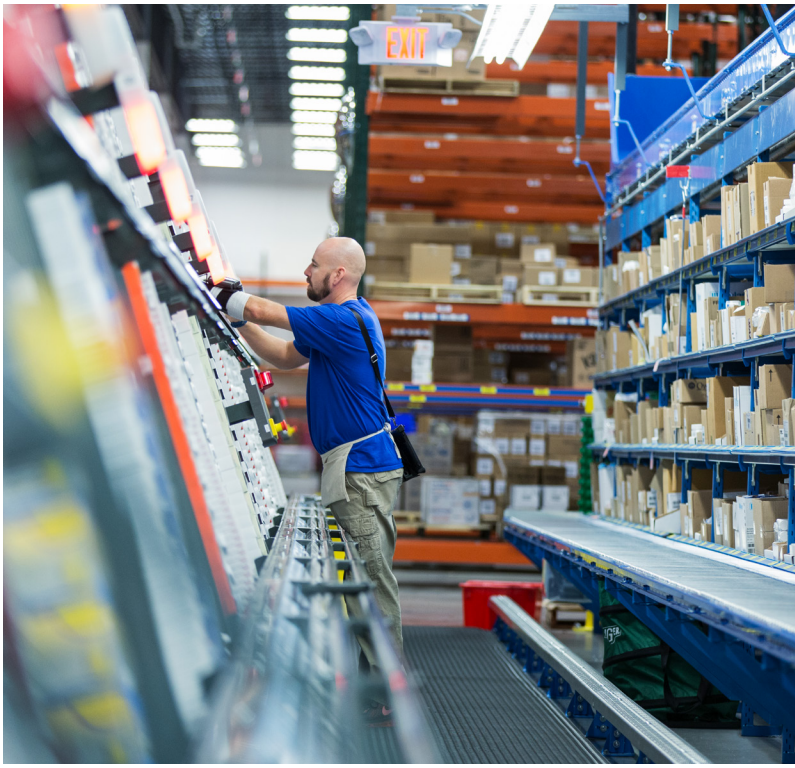
HDA
Healthcare Distribution Alliance

Issue Brief

Supply Chain Resilience Assessment: High-Level Summary and Recommendations

Introduction



As the backbone and logistics experts of the supply chain, resilience is a core tenet of healthcare distribution. The COVID-19 pandemic and other large-scale events have highlighted the need to focus on supply chain resilience and enhancing resilience to daily disruptions and catastrophic disasters. The nation's primary healthcare distributors, represented by the Healthcare Distribution Alliance, define supply chain resilience as *the ability to manage disruptions and shocks without significant interruption to patient care and healthcare delivery.* Recognizing the critical role of distributors, which serve as the vital link between the nation's pharmaceutical manufacturers and pharmacies, hospitals, long-term care facilities and others nationwide, the sector believes we have an essential role to play in supply chain resilience. Healthcare distributors desire to serve as a leader and partner on this issue, leveraging the industry's capabilities and technical know-how to address vulnerabilities and build on existing strengths.

We believe that steady-state resilience and resilience during crises require different capabilities and investment, and are certain that distributors have a role to play. We seek opportunities to share the knowledge and experience of distributors in the effort to enhance supply chain resilience.

Background

The White House's Executive Order 14017 – America's Supply Chains directed the Department of Health and Human Services (HHS) to identify risks in the supply chain for pharmaceuticals and active pharmaceutical ingredients (API), specifically those affecting critical medications on the FDA's Essential Medicine List. In May 2022, the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) released the first *Essential Medicines Supply Chain and Manufacturing Resilience Assessment*, a product of the National Forum to Secure America's Supply Chain for Essential Medicines (National Forum). The National Forum is a public-private consortium tasked with developing an action plan to address pharmaceutical supply chain vulnerabilities. The assessment report summarizes the main challenges affecting pharmaceutical supply chain resilience regarding essential medicines and proposes various strategies to improve that resilience.

Overview of Effort

The National Forum conducted assessments by gathering input through a series of stakeholder engagement activities, including interviews with pharmaceutical supply chain representatives, material suppliers, pharmaceutical manufacturers, group purchasing organizations (GPOs), wholesale distributors, healthcare providers, and pharmacies. In addition, the National Forum hosted a series of workshops involving clinical and industry stakeholders. This process resulted in a prioritized list of 86 essential medications, as well as a list of "industry-vetted" strategies that could be used to increase resilience in the pharmaceutical supply chain. This brief summarizes the proposed strategies presented in the report and presents potential impacts and next steps from the healthcare distributor perspective.

Vision: A Resilient Pharmaceutical Supply Chain

The 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.

To build resilience in the pharmaceutical supply chain, the report presents a three-pronged strategy consisting of:

(1) Anticipating potential supply chain issues through the use of a centralized data clearinghouse receiving information from across the supply chain;

(2) Preparing for potential disruptions through strategies such as redundancy, emergency inventory, contingency measures; and,

(3) Responding to emergencies by shifting resources such as workforce and distribution capacity.

Challenges Identified by Consortium

The assessment identified a set of vulnerabilities that make the pharmaceutical supply chain susceptible to disruption.

Market Structure

- The market for manufacturing generic medicines (representing most essential medicines) maintains a low margin, driving manufacturers out of the market and making it difficult for current manufacturers to consistently meet demand. A low margin market creates a high-risk, low-reward outlook for potential market entry.
- Downward pressure on cost can make it difficult to maintain profitability and quality management, increasing vulnerability and impact of potential disruptions.
- Just-in-time inventory practices limit on-hand inventory. The report couples the definitions of just-in-time manufacturing (rapid production of small batches of product) and just-in-time distribution (low levels of on-hand inventory) and expresses concern about disruption risks from these practices.
    - The report noted the COVID-19 pandemic as an example of the risks posed by just-in-time, due to sudden spikes of demand, facility closures and import delays.
    - The HDA Research Foundation report, *The First 90 Days: US Biopharmaceutical Finished Goods Supply Chain Response to COVID-19*, refutes these claims with a review in the performance of pharmaceutical supply chain in the first 90 days, and the adjustments used to avoid shortages. This report shows that while the pharmaceutical supply chain experiences significant challenges due to the initial global surge from COVID-19, the supply chain avoided catastrophic shortages.

Global Competition

- A dependence on the global supply chain (e.g., global competitors and strategic foreign direct investment) has created a lack of sustainability for U.S.-based businesses. This dependency is particularly pronounced for essential medicines as their raw materials, APIs and finished doses are largely sourced from overseas.
- However, as noted in the HDA Foundation report, U.S.-based businesses have benefited from global supply chain robustness. Further, the global supply chain has provided a variety of contingency options for obtaining medical products during times of domestic or regional supply chain stress. Shifting to domestic production would not serve to remedy existing vulnerabilities, but instead create challenges with production, geographical diversity and transportation.
- A globalized supply chain results in additional vulnerabilities during times of crisis, when export limits could result in essential product becoming unavailable for U.S. markets.
- The report noted that some production of key source materials (KSMs) domestically may be unrealistic due to components that are exclusively sourced from other countries based on natural resources or assets.

Labor and Workforce

- Shortages in the technical workforce limit the ability for the U.S. to absorb pharmaceutical manufacturing. The science, technology, engineering and mathematics (STEM) workforce's needs do not match the trained workforce available to operate these facilities.
- The report does not include discussion of recent shortages of non-STEM workers that can also impact the supply chain, such as warehouse workers, truck drivers and last-mile delivery couriers.

Manufacturing Processes

- Certain generic manufacturing considerations (e.g., need for redundancy, lack of incentives for innovation and technology and quality issues) present a clear limitation and challenge to building supply chain resilience.
- The ability for generic manufacturers to maintain production or even meet medical surge will likely pivot back to a focus on their business model and low margins, which make redundancy and other expanded resilience measures difficult to attain. This conversation could shift toward the purchasing consortia and their impact on the generic market.

Supply Chains and Distribution

- Pharmaceutical supply chain complexity and multi-factorial system was noted as a challenge for identification of suppliers, diversification of suppliers and managing downstream costs.
    - The report specifically identifies middlemen, and in particular wholesale distributors, as a confounder to the complexity of the supply chain, with their role described as "introduc[ing] a markup and increas[ing] medicine costs."
    - Healthcare distributors have been demonstrated to reduce cost and increase efficiency in the supply chain.
    - Pharmacy Services Administration Organizations (PSAOs) are mentioned alongside payers, pharmacy benefit managers (PBMs) and group purchasing organizations (GPOs) as a mechanism within purchasing and insurance practices that may impact available supply of medicines. The unintended consequences of the consolidation offered by GPOs and PSAOs is noted, specifically on the potential impact of limiting available suppliers while driving down cost (and ultimately [generic] manufacturer margin).

    - » HDA has refuted this — primarily at the state level — and offered clarification on the role of PSAOs. The mention of PSAOs here is lumped into the analysis with other players in the supply/payment chain. PSAOs, based on their function, play no role in the supply chain resilience discussion.

- The report amplifies the argument that data transparency could enable diversification of raw material suppliers and could highlight areas where the supply chain is vulnerable. Furthermore, the report argues that data transparency could assist purchasers in identifying the vulnerability of their suppliers and could help coordinate purchasing behaviors across the industry to avoid hoarding and eliminate waste.
    - While data transparency is referenced as a need, the many existing entry points for data (from the private sector to the federal government/public sector, and bidirectionally) are not clarified. HDA recommends that there be an assessment of current (pre-COVID and during-COVID, steady-state and in crisis) data and information-sharing mechanisms by the Government Accountability Office (or a similar group) before other points of reporting are established.
    - Stockpiling is identified as a difficult redundancy method to implement due lack of coordination of whether items should be stockpiled at the federal or state level. The limited shelf life of pharmaceuticals and resource-intensive needs for maintenance, as well as the lack of standardization in pharmaceutical products (e.g., vials) make effective stockpiling even more challenging.
    - HDA recommends an expansion of the Strategic National Stockpile (SNS) capabilities to include: vendor-managed inventory (VMI) models, cooperative agreements and investments in dedicated rotated stock by healthcare distributors. Recognizing that the SNS may need to have expanded authorities to accomplish this, HDA supports legislation to expand the authorities, capabilities and funding of the Strategic National Stockpile.

Regulations

- A highly regulated pharmaceutical environment poses difficulties for manufacturers to be nimble and increase production or use new suppliers in the event of emergencies.
- U.S. environmental regulations are also stated to cause unintended consequences for supply chain resilience. The report argues that by highly regulating and penalizing the production of pharmaceuticals with high levels of polluting byproducts, the agency may inadvertently encourage manufacturers to produce these items offshore, creating additional vulnerabilities.

Assessing Suggested Strategies and Recommendations

The National Forum report presents a set of strategies meant to increase the resilience of the supply chain. 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; and,
4) Purchasing, stockpiling and distribution approaches.

HDA's primary equities are reflected in strategies 1 and 4. Regarding strategies 2 and 3, HDA notes our members' commitment to working with the government and manufacturers to deliver medicines to patients — regardless of where they are made.

Each category includes a subset of recommendations for a total of 21 strategies, with those that were prioritized by industry stakeholders deemed "high priority." This brief includes a summary of each of the four strategy areas as well as an assessment of those recommendations.

Increased Supply Chain Coordination, Security and Transparency

The report highlights the need to improve data and information sharing, integration and standardization across all elements of the supply chain. To achieve those aims, the authors recommend implementing various strategies revolving around:

- Collecting data from all participants in the supply chain;
- Building the infrastructure to analyze these data; and,
- Empowering governmental organizations to either collaborate with or, in times of emergency, exert control over supply chain organizations.

Data collection from the supply chain is identified as a critical priority. Desired data elements include manufacturer and distributor inventory levels, provider usage levels and electronic health record data. The report suggests that collection of this additional information could be achieved through more frequent mandated federal reporting as well as data standardization across the supply chain. There is an acknowledgement that safeguarding these data is critical to reporting organizations to preserve the competitiveness of supply chain organizations. Once this information is obtained, the report proposes conducting periodic risk assessments of the essential medicine supply chain to identify vulnerabilities (e.g., limited suppliers of raw materials, few facilities manufacturing a specific medication). In particular, the report proposes assigning resilience scores to each API for the essential medicine list, which would help prioritize resilience efforts. (Note: this connects to the FDA's Risk Management Guidance to Promote a Stronger, Resilient Drug Supply Chain, currently in draft and under comment until August 31, 2022, at the time of this analysis).

Lastly, under this category the report outlines a set of initiatives aimed at increasing collaboration between the U.S. government and private organizations in the supply chain. One end of the spectrum involves initiatives that promote public-private collaboration, such as the ongoing review of the essential medicines list with industry input, as well as the creation of an essential medicine consortium where supply chain stakeholders advise governmental resilience efforts. HDA supports the role of public-private coordination and ongoing collaboration between the sectors toward supply chain resilience. While our industry supports this as an ongoing strategy on all supply chain resilience activities, we note that similar mechanisms existed prior to COVID-19. Additional mechanisms (public-private partnerships, ongoing working groups, etc.) have been stood up during COVID-19. Based on the number of convened groups stood up at this point, we believe it is important to avoid duplication of efforts in these activities — this ensures that the right conversations are happening with the right partners in a manner that minimizes burden on all. Existing consortia include the Healthcare and Public Health Sector Coordinating Council (and its Supply Chain Resilience Working Group), the Defense Production Act Section 708 working groups and the National Academies' Forum on Medical and Public Health Preparedness for Disasters and Emergencies. Further, HDA and its members are encouraged by the reestablishment of the Public Health Emergency Medical Countermeasures Enterprise and engaging all components of the supply chain would create another valuable forum for such discussions.

The report proposes "control" strategies that propose the creation of centralized platforms to aggregate data as well as the possibility of designating U.S. pharmaceutical industry and supply chain as critical infrastructure, paving the way for governmental coordination and control of the industry during crises. HDA recommends appropriate scoping and parameters of this approach, including a review of the ways existing information-sharing and visibility have been used to activate levers in the federal government to avoid disruption (as appropriate).

Distributor assessment: The healthcare supply chain is a highly regulated space that already requires frequent reporting to multiple federal agencies, including the FDA. Standardizing 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.

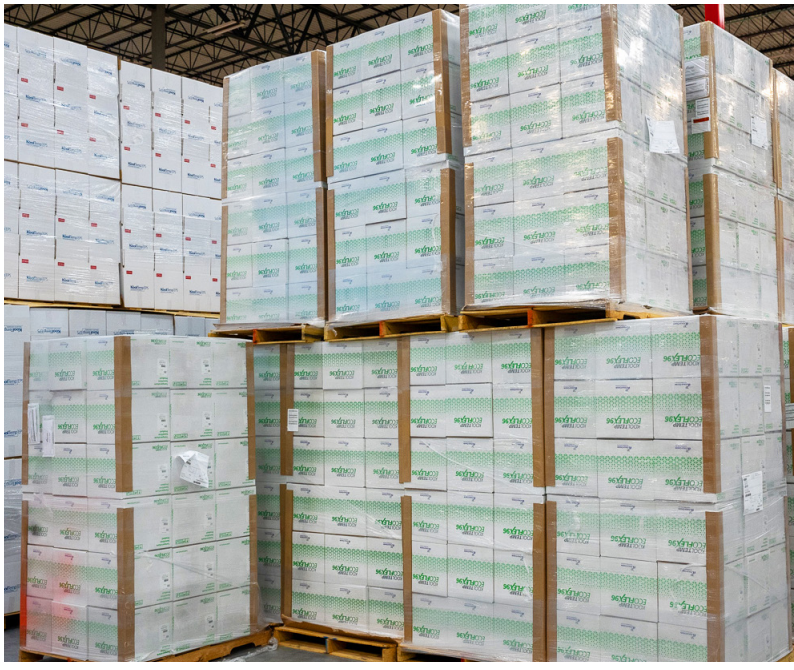
However, any data collection should be evaluated in aggregate of what is already being submitted by supply chain organizations, so that changes are made to the current reporting mechanisms, rather than merely overlayed on top of the existing structure. It is important to also balance the reporting burden with the scope of necessary and actionable data that should be transmitted.

Regarding public-private collaboration, the supply chain could benefit from efforts to outline clear roles of all federal agencies that touch the supply chain — especially during emergency responses and public health emergencies (e.g., ASPR, FEMA, FDA, CDC). The recent COVID-19 pandemic highlighted the need for clearer coordinating plans, and 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. While HDA notes the successes of the FEMA Supply Chain Task Force, Operation Warp Speed, the National Business Emergency Operations Center, and other similar entities, most were stood up during the pandemic and functioned as separate entry points.

The need for coordination, however, does not require control. Manufacturers and distributors are organizations with deep expertise in their operations that should continue to operate independently, even during healthcare crises. Balancing the coordination with expectations regarding likely (and necessary) actions should be considered and established from the outset.

Expanded Onshore or Nearshore Production Capacity

The report focuses on offshore manufacturing and single points of failure as a supply chain vulnerability. The report explains the current rigidity in the supply chain by focusing on single points of failure or lack of geographic redundancy in manufacturing. Offshore sourcing and manufacturing, particularly when it relies on a single location (e.g., China), makes the supply chain vulnerable to events like export bans, shipping delays, and geopolitical disruptions. The report emphasizes the hypothesis that the pharmaceutical supply chain will be less vulnerable to disruption by increasing domestic production. However, generics manufacturers operate under very slim margins, and to remain economically viable, have moved production overseas. The report proposes improving the capacity and diversifying the sourcing of the pharmaceutical supply chain through a combination of strategies on the supply and demand end of the chain. Supply-end strategies include financial incentives for domestic



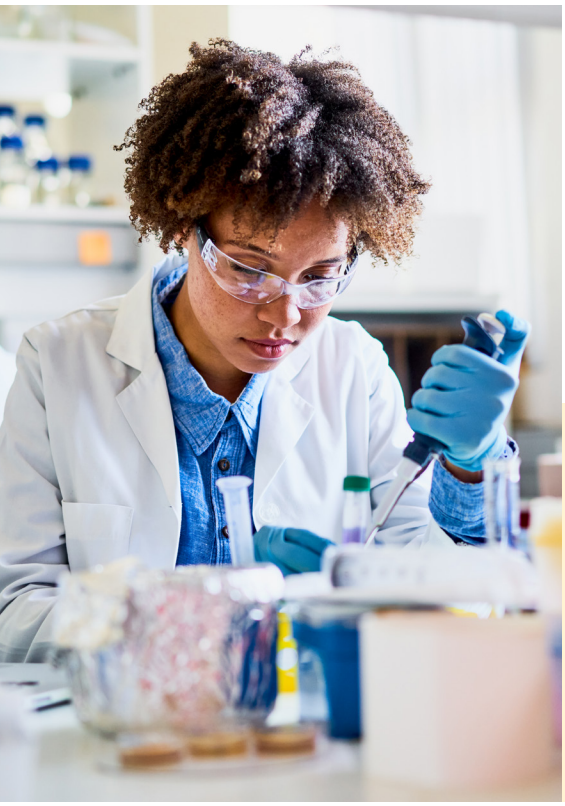
manufacturing of essential medications and reevaluating industry regulation. Demand-side strategies focus on maintaining a stable demand for essential medications through agreements with hospitals and health systems while also employing regulatory mechanisms like price floors.

The report proposes providing direct government investment dollars and tax breaks to encourage domestic pharmaceutical production. Other incentives could support manufacturers that have invested in additional production capacity for essential medicines. These funds could mitigate the costs of setting up and maintaining extra production capacity that remains idle during steady state operations. Additionally, the authors discuss reevaluating the nature of pharmaceutical regulations and the capacity of regulatory agencies to approve new suppliers or facilities more quickly.

Distributor assessment: While expanding domestic production capacity is a laudable goal, onshore production has significant cost barriers. 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 within the United States.

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. The investment in domestic capacity could extend to distributors, which would enable a range of infrastructure investments to address resilience (including toward climate adaptation). These incentives should not only be designated for building new facilities but should also provide operational funding to defray organizational costs incurred as result of maintaining extra production or transportation capacity to deal with catastrophic events or similar large-scale emergencies.

Advanced Manufacturing Capabilities & Innovative Research and Development



The report notes that the pharmaceutical supply chain could benefit from new technologies, research and development to improve production efficiency and remain competitive. The authors promote a hub-and-spoke model for pharmaceutical manufacturing that decentralizes production from one large plant (and potentially one single point of failure) to multiple regional facilities, all with the same production processes and standards. This decentralized model would have implications for healthcare distributors, who would be responsible for managing the logistical complexities of multiple production points for a single medication.

Distributor assessment: Supply chain organizations support investments in workforce recruitment and training. These investments should not only encompass STEM positions but should also include assistance with recruitment and training for non-STEM positions that are critical to supply chain operations (e.g., warehouse workers, packing associates, inventory specialists, transpiration workers). These positions are also critical to the uninterrupted supply of essential medicines. Shortages for qualified personnel to fill these roles continue and must be addressed in order to avoid staffing shortages.

Purchasing, Stockpiling and Distribution Approaches

This set of strategies comprises actions around purchasing and distributing healthcare products. The report proposes leveraging the federal government's purchasing power to drive change by incentivizing the purchase of products made domestically through higher purchase prices. The report implies that healthcare products of lower quality are more likely to experience supply chain disruptions (e.g., contamination, recall issues), while higher quality products may not experience the same supply chain vulnerabilities. The authors propose implementing a "quality rating" for pharmaceutical products to allow purchases to include quality as a purchasing factor. The report proposes that this quality rating could also be used as a factor when determining federal contracts. HDA welcomes the opportunity to discuss this approach with policymakers, as well as any cascading impacts from this strategy.

On the question of stockpiles, the authors propose creating regional stockpiles in place of a national stockpile. Supply chain stakeholders are presented as possible managers for these regional stockpiles, with the idea that manufacturers and distributors could be in a better position to continually rotate product prior to expiration. These regional stockpiles could be managed by supply chain stakeholders, rather than the federal government. HDA strongly supports this approach, noting the extensive capabilities that distributors (including regional distributors) maintain which can be leveraged toward this goal. In-depth briefings have been provided to the federal government (upon request), and HDA is happy to provide additional information or briefings on the capacity that exists within the distribution sector to support this objective.

Finally, the report suggests that federal oversight of stock levels, allocation methodologies and logistics contingency plans could result in improved resilience. This strategy area suggests that regulators exert a strong amount of control over the core competencies of distributor organizations, without acknowledging the complexities of distribution, and the expertise that distributor organizations bring to the table to make these decisions.

Distributor assessment: The purchasing and distribution strategies presented in the report do not fully account for the complexities of healthcare distribution. As previously discussed, 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.

In many cases these data could be deemed a trade secret, which would impede the implementation of a federal stock reporting mechanism. In other cases, the data reporting paths already exist and flow into the regulatory agency (FDA).

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 SNS and our nation's national security assets. Manufacturer and distributor organizations will continue to partner with federal and state governments to replenish the stockpile, but the management of that stockpile requires significant resources and cannot be absorbed by supply chain stakeholders without financial resources allocated to this end. Additional input from stakeholders should be gathered to determine if the VMI/product rotation model is the only model recommended to increase the buffer of available product for health crises.

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 models of success that reflect a role for partnership and coordination, which HDA welcomes as a strategy to navigate the initial stages of a public health emergency or a similar catastrophic event.

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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.