

Healthcare Supply Chain Resilience and Data Illumination

Spring 2023

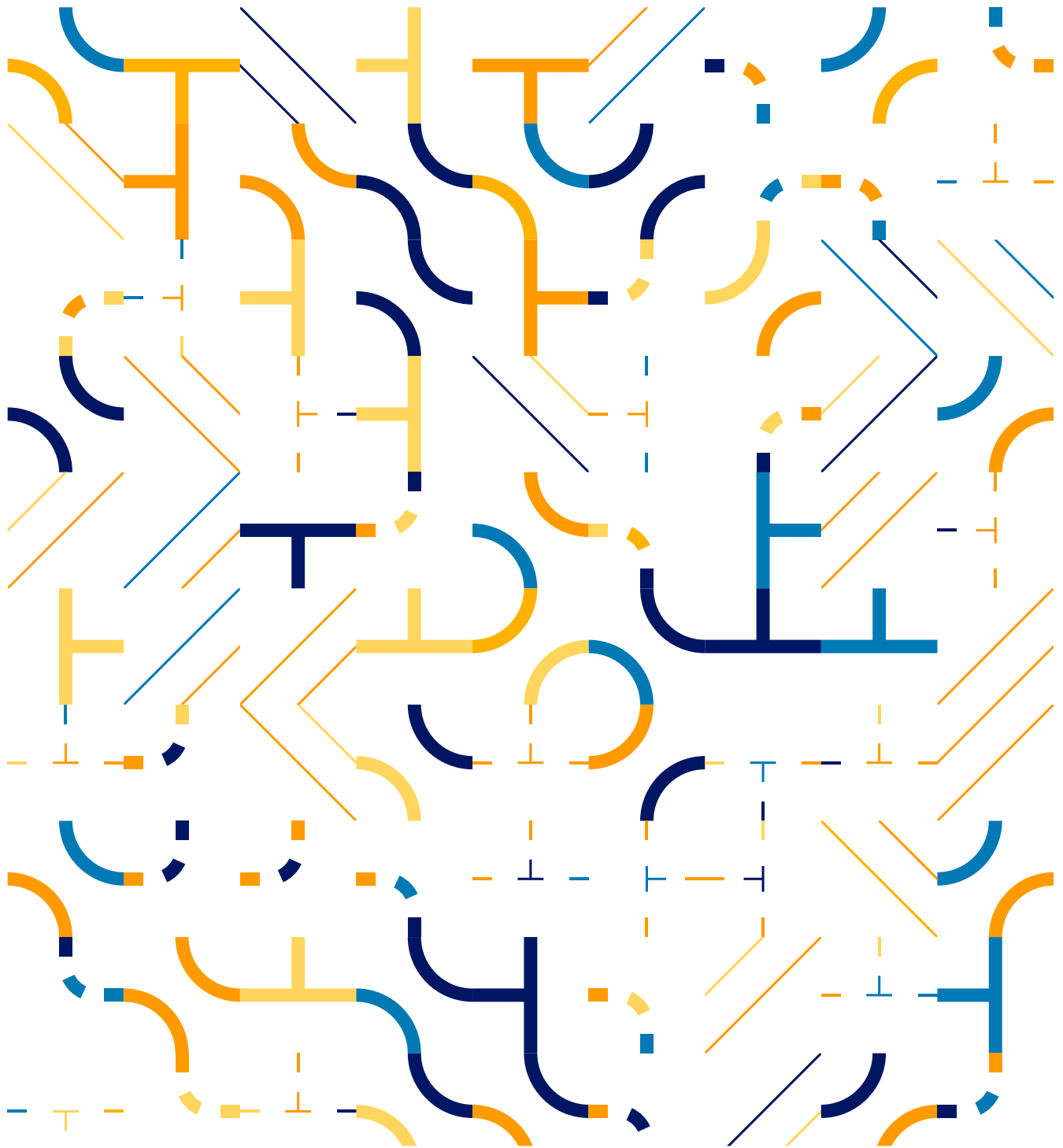


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EXECUTIVE SUMMARY

The Healthcare Distribution Alliance (HDA) and its members believe that data transparency and illumination play a role in bolstering the integrity and resilience of the healthcare supply chain, especially during public health emergencies. Additionally, HDA believes that measures taken by the public and private sector to increase data transparency must be done carefully to avoid redundancy and unnecessary reporting burdens, while ensuring the value and usability of the data exchanged. HDA believes that certain measures can be improved by incorporating feedback from private-sector partners.

In developing this report, HDA requested input from its distributors and subject matter experts, individually and as groups, to gain insights into current data and information sharing amongst the healthcare sector; the parameters for data and information sharing; and the value to industry and the federal government. Member respondents contributed to a common definition of healthcare supply chain resilience, highlighted lessons learned from the COVID-19 pandemic and provided recommendations to increase resilience and mutually beneficial solutions around data-sharing between public and private partners.

KEY FINDINGS

- **Define Resilience:** A proposed consensus definition for healthcare supply chain resilience is as follows - Healthcare supply chain resilience is the capability to prepare for, respond to and recover from planned and unplanned disruptions, and it is closely linked to U.S. critical infrastructure security and stability.
- **Increase Specificity of Data Requests:** Healthcare distributors collect a wide range of data, including, but not limited to, supply availability, shipping statistics, distribution and sales information. Federal partners should set targeted data requests with specific goals in mind to determine the exact needs from their private-sector partners. To ensure a clear data-sharing process, both parties should prioritize communication and understanding of the data that are needed and available.
- **Establish a Bidirectional System for Data-Sharing and Feedback:** Government data requests may be excessive and often do not articulate a desired outcome or benefit to industry. Increased visibility on data use and output would be beneficial to determine proper interpretation of the data and provide insight for further analysis.
- **Increase Efficiency of Government-Industry Data-Sharing:** The public sector should play a clear role in supporting industry and understanding the potential burdens when requiring data-sharing during an emergency response. For example, the government could consider automating data requests as part of data-sharing agreements to increase collaboration with regular working groups, as opposed to only during incident response.
- **Bolster Bidirectional Benefits:** The public sector should more clearly define and publicize the benefits to industry of data requirements. Decision makers must consider how data-sharing should co-benefit with industry rather than being one directional.
- **Define and Acknowledge Partnership Roles:** Both government and industry must gain a better understanding of each other's capabilities. The public sector would benefit from a better understanding of the marketplace and the differences between industry stakeholders. Likewise, industry would benefit from a better understanding of the challenges federal and state partners face to help prioritize what data should be shared and subsequent actions to take based on those data.

Greater communication, collaboration and coordination between healthcare supply chain industry partners and the public sector will be required for building supply chain resilience and enhancing data transparency and illumination. Important next steps for strengthening these areas include enhancing the bidirectional data system for data collection and information sharing, addressing existing technological barriers and taking steps to increase cooperation between the private and public sectors. Accordingly, this report can be used as an initial roadmap to achieve this goal.

INTRODUCTION

Effective communication is critical in today's complex healthcare environment. As the nation emerges from the COVID-19 pandemic's most severe impacts, we must prioritize communication, collaboration and coordination along the health supply chain to address residual impacts and ensure long-term healthcare supply chain resilience. However, building a more resilient supply chain is an ongoing process that requires partnership and shared investment. HDA understands that strong communication and data and information sharing played vital roles in bolstering the U.S.' response to the COVID-19 pandemic.¹ According to many of the interviewees across the sector, the healthcare sector's embracing of data-sharing practices during the pandemic ensured that the healthcare supply chain could meet surges in demand.

Data transparency is the use of data (*data necessary to understand the circumstances or provide a clear use*) to help answer questions related to resilience.

This report aims to illustrate the importance of data within the healthcare supply chain ecosystem and further study the relationship between data transparency, data illumination and supply chain resilience. Data illumination is defined as the continuous process of highlighting and sharing specific information in a meaningful timeframe which can be used to take clear action (in this case, to support public health needs). Data illumination differs from data transparency in that the latter provides a broader picture (often over a longer time period) and includes involuntary data-sharing and reporting mechanisms, with unclear plans for action. Meanwhile, the former is often a voluntary effort and is often used to provide information critical to addressing specific circumstances.

Additionally, the report aims to inform future data- and information-sharing practices between the public and private sectors. Doing so will require increased and intentional cross-sector coordination to establish a data-sharing framework that enhances their collective abilities to make informed decisions, and to take decisive action during incident response. The report also provides recommendations to improve communication, collaboration and coordination between the healthcare industry and the public sector. Further, the report examines the role of data illumination in private-public coordination. Finally, the report aims to shed light on the different perspectives of the HDA members within the total healthcare supply chain. From the different industry segments represented in our research, each had different perspectives on:



Data Ownership



Data-Sharing Logistics



Data Utilization



Desired Outcomes for their Industry

¹ Healthcare Distribution Alliance Research Foundation. *The First 90 Days: US Biopharmaceutical Finished Goods Supply Chain Response to COVID-19*. September 2020. <https://www.hda.org/publications/the-first-90-days-us-biopharmaceutical-finished-goods-supply-chain-response-to-covid-19/>.

METHODOLOGY

In developing this report, HDA conducted a series of interviews from several industry members to gain insights into current data and information sharing, the parameters for data and information sharing, and the value to industry and the federal government.

The team conducted informed interviews and group interviews with data- and policy-focused experts across several sectors in the healthcare distribution supply chain. Twenty experts were interviewed within the (1) supplier, (2) distributor, (3) manufacturing, (4) shipping and logistics and (5) policy and research industries.

Additionally, targeted interviews were held with staff belonging to governmental and non-governmental organizations. This included staff belonging to the Administration for Strategic Preparedness and Response (ASPR) with Health and Human Services (HHS) and The National Academies of Sciences, Engineering and Medicine (NASEM). The team specifically focused on two aspects of data illumination and supply chain impacts, including both COVID response (emergency response) and steady state (both pre- and post-COVID response). The respondents discussed their steady-state experiences in their industries, as well as the challenges and issues they faced in the onset and throughout the COVID response and recovery. Additionally, many respondents spoke directly to their specific agreements with the government in the wake of the COVID-19 pandemic, the public health emergency, and the COVID-era policies that will impact them moving forward.



1 | Healthcare Supply Chain Resilience

HDA defines supply chain resilience as the ability to manage disruptions and shocks without significant interruption to patient care and healthcare delivery. Supply chain resilience is closely linked to U.S. critical infrastructure security and stability.² While prioritizing mitigation considerations for common supply chain disruptions may significantly reduce shocks and recovery time, it is important to note that shocks and disruptions of larger magnitude may be unavoidable despite robust planning efforts.

Recognizing the critical role of pharmaceutical 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 it can play an essential role in ensuring supply chain resilience.³ The definition takes into account elements of HDA members' perspectives on what supply chain resilience is, as evidenced from the input received through our research:



Getting the **right** products to the **right** customers at the **right** time.
-Healthcare Distributor

Ability to **withstand stresses to the system** that cause a bend in the demand curve and **respond** across a wide range of existing resources to locate additional support and supplies and **recover** quickly

Being able to flex to changing situations and **meeting customer needs**
-Healthcare Distributor

-Operations Expert

There are two kinds of supply chains – **manufacturing** and **distribution**. Resilience is different and has different impacts between the two.

-Policy Expert

Good logistics and geographically **diverse distribution networks**.

-Healthcare Distributor

WHAT IS SUPPLY CHAIN RESILIENCE?

The quotes above represent a sample of the impactful definitions of supply chain resilience from across different parts of the healthcare supply chain sector. These statements come from personnel representing logistics managers, supply chain data experts, distributors and suppliers. Overall, the statements demonstrate that although HDA members with different roles within the healthcare supply chain have varying missions and customers, they are all dedicated to their end customers or users to ensure that they have reliable, steady

² Healthcare Distribution Alliance. "HDA Guiding Principles for Increasing Supply Chain Resilience." 2022. <https://www.hda.org/getmedia/2d816602-0c28-46c6-a52f-d1d36c094cd9/Resilience-Principles.pdf>.

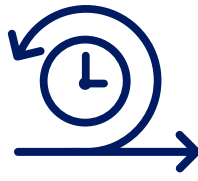
³ Healthcare Distribution Alliance. "Supply Chain Resilience Assessment: High-Level Summary and Recommendations." 2022. <https://www.hda.org/getmedia/92505331-5f7d-401b-b099-3b05359ae280/Supply-Chain-Resilience-Assessment-High-Level-Summary-Recommendations.pdf>.

service. This shows that there is significant consistency in priorities among HDA members and incentive for them to coordinate to ensure a healthy and resilient supply chain. Further, healthcare supply chain resilience includes three major elements:⁴



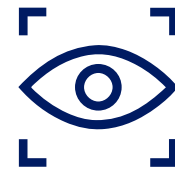
ROBUSTNESS

preparedness for and the ability to mitigate disruption



AGILITY

the ability to respond to a disruption



VISIBILITY

the ability to monitor threats, to make data-driven decisions and recover from disruptions

ROBUSTNESS

Robustness is defined as having an inherently diverse supply chain with the ability to surge capacity. A robust supply chain, when possible, prepares for and attempts to mitigate risks and disruption before they occur. However, there are varying levels of disruption (acute, regional and calamity) that can vary based on severity, frequency and lead time. An acute disruption, for example, may include theft, counterfeiting or a common cyberattack. Regional disruptions could include but are not limited to terrorism, a financial crisis, or a major climate-related disaster. Cataclysmic disruptions could consist of global military conflicts, pandemics (such as COVID-19), or an extreme meteorological or solar event. Supply chains and the organizations in them, regardless of how robust or prepared they are, cannot be expected to absorb shocks from and mitigate every disruption — especially those at the catastrophic level. The associated risks of an event are dependent on the level of disruption, although specific sectors within the healthcare supply chain may be more vulnerable or potentially see more risks from specific disruptions. The levels of disruption and the risks they carry, must be evaluated to determine the potential shocks to organizations on the supply chain, as well as the supply chain's ability to absorb them.

Outlining the elements of robustness can support the production of high-quality healthcare products for the U.S. market. Some elements of robustness include leveraging a diverse set of manufacturers or having multiple source options for each product and its predecessor.⁵ By using robust organizational maturity, organizations can bolster their infrastructure as needed to address and mitigate potential risks. To increase the U.S. healthcare supply chain's capacity to develop products, some government officials advocate for increasing the on- or near-shoring of medical supplies, and HDA believes that these solutions should be explored further with the supply chain to determine what investments would be necessary to sustain these proposed changes.

One element to achieve robustness is multi-sourcing raw materials, product manufacturing and equipment procurement. By diversifying and prioritizing strategic geographic variability of suppliers, the risk of location-based disasters halting the supply chain diminishes, as well as the exposure to inevitable shocks to the system. A robust healthcare supply chain should include well-developed data security infrastructure to increase its resilience to cyberattacks. Additionally, a robust supply chain should ensure a safe space for



Aim to build a diverse supply chain with the ability to surge capacity

⁴ "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>.

⁵ "Building Resilient Supply Chains, Revitalizing American Manufacturing, And Fostering Broad-Based Growth, 100-Day Reviews under Executive Order 14017. The White House - Reports." June 2021. <https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf>.

suppliers, distributors and customers to communicate more efficiently and with complete transparency. This will help to insure increased data transparency across the sector and with the government as well as increase sector wide efficiency.

AGILITY

Agility for the healthcare supply chain is a measurement of its ability to quickly react to, limit the scale of and prevent product shortages during disruptions.⁶ For example, during supply disruptions like drug shortages, distributors can predict shortages, track existing shortages and recommend drug alternatives using internal data analytics until that drug shortage is resolved. One aspect of healthcare supply chain agility is the capacity to disseminate critical medical devices and products to key locations, such as hospitals. Agility may vary from organization to organization and by the magnitude of the disruption. While procedures for addressing a novel cyberattack may be codified and standardized, addressing a global military conflict may involve adjusting an organization's strategic approach based off an evolving situation and new information. This process requires transparency for the demand of regional and local providers to meet need and reduce potential for over-delivering. Once a bottleneck in production or shortage is identified, rapid-scaling manufacturing, or shifting the production of a product to a shortage manufacturing site to address demand, can help pivot production at the onset of national or regional health emergencies.

One way to gauge supply chain agility is to invest in analytical capabilities, both technological and staff, to evaluate its manufacturing and delivery performance. These gauges can help identify vulnerabilities on either end of production or delivery to end-users. For example, as digitalization becomes increasingly important to the healthcare supply chain, transitioning to a fully integrated Digital Supply Networks (DSN) may be a priority for some distributors.⁷ However, before making significant investments, distributors may consider a holistic review of vulnerabilities to cater their approach to address pertinent concrete challenges. While DSNs may add value to managing both steady-state and incident response operations for some distributors, for others it may be duplicative to other systems/capabilities currently in place. To invest in staff capabilities for resilience, distributors could address known labor shortages within the supply chain, empower team members at all levels of the organization to flag vulnerabilities, or increase both top-down and bottom-up collaboration opportunities to improve communication channels.⁸ Investments in a single form of technology or resource should not be considered a panacea for all resilience concerns.



Agility is successfully mobilizing during disruption response

Keeping in mind that shocks to the supply chain are inevitable, a certain level of financial liquidity could help private sector partners mitigate disruptions, ramp-up production, or pivot to production needs in the event of a major global disturbance. This could also mean diversifying their company portfolio or products for production. Diversifying products could have co-beneficial solutions for flexibility and efficiency of production. Companies can prepare for disruptions by maintaining a level of corporate credit or liquidity even during extended periods of steady-state normalcy.

⁶ "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>.

⁷ Coleman, Tom, et al. "Key determinants for resilient health care supply chains." April 2022. <https://www2.deloitte.com/us/en/insights/industry/health-care/healthcare-supply-chain.html>.

⁸ Farivar, Samira, Amirmohsen Golmohammadi and Alejandro Ramirez. "Analytics Capability and Firm Performance in Supply Chain Organizations: The Role of Employees' Analytics Skills." *Analytics*, Volume 1, Issue 1. May 2022. <https://www.mdpi.com/2813-2203/1/1/1>.

VISIBILITY

Visibility into the healthcare supply chain sector enables decision-makers to address risks and ensure target capabilities are accomplished in the event of disruption. Data-driven transparency should provide an end-to-end view of pharmaceutical and medical suppliers.⁹ This can be achieved by mapping suppliers by tier to identify vulnerabilities within the supply chain and pinpoint potential risk exposures in the ways that products are developed, delivered or stored. By employing data from both internal and external sources and evaluating them against resilience metrics in the areas of data security, finance, operations, organizational maturity, regulation, reputation and structure, both the visibility of the supply chain and resilience against disruption can be strengthened.

Visibility in this sense does not pertain to real-time data on where supplies are at any given time. Supplies are constantly being shifted from manufacturing sites to storage facilities to other warehouses before being delivered to the consumer. Visibility between the data and clearly defined targets (e.g., geographical need for the product), are interdependent to achieve one aspect of resilience. For example, the capabilities of medical supply companies are defined by the amount of product that can be produced and delivered in the given amount of time to improve visibility. So, the private and public sectors can collaborate to create analytic models and diagnostic testing to generate disruption scenarios, quantify risks associated and devise appropriate responses for visibility into the supply chain.

By doing so, private and public stakeholders can help to improve existing risk mitigation and response efforts while also providing an opportunity for public-private collaboration that can be used to inform future information partnerships. Additionally, this effort can help to shape policymakers; ideas of what investing in supply chain resilience entails and the importance of and perspectives on data-sharing in related policy. As previously noted, members of the healthcare supply chain have a vast range of ideas of what supply chain resilience entails. Policymakers will likely not be as well informed about supply chain issues or efforts to improve its resilience. A pilot project emphasizing displaying the importance of joint visibility measures can demonstrate the complexity and importance of information coordination on the supply chain.



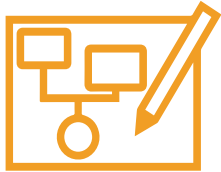
U.S. GOVERNMENT PERSPECTIVE

The Biden administration stated, “A resilient supply chain is one that recovers quickly from an unexpected event.”¹⁰ Although there is a shared understanding regarding resilience across the healthcare supply chain between the private and public sector, the inherent challenge concerns the role of data and data transparency — and how all parties can use data properly to satisfy the converging needs of the private and public sectors. The federal government is especially concerned with the interplay of data transparency and the healthcare supply chain in the wake and aftermath of the COVID-19 response. Therefore, because of the recent COVID response experience, it can be concluded that the federal government views resilience from a lens of emergency/disaster response capability — that is, the ability to respond to the health needs due to a medical surge or public health response event.

⁹ McKinsey & Company. “Four ways pharma companies can make their supply chains more resilient.” September 2021. <https://www.mckinsey.com/industries/life-sciences/our-insights/four-ways-pharma-companies-can-make-their-supply-chains-more-resilient>.

¹⁰ The White House. “Building Resilient Supply Chains, Revitalizing American Manufacturing, And Fostering Broad-Based Growth, 100-Day Reviews under Executive Order 14017. The White House - Reports.” June 2021. Retrieved December 5, 2022, from <https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf>.

Based on interviews with federal personnel as well as industry members who work closely with the federal government, this limited perspective has been pervasive. Despite this, members of the healthcare supply chain community have experienced short and long-term disruptions to their supply chains and have been forced to adapt to ensure their businesses are resilient. Although the private sector wants to ensure quick recovery from an “event,” the definition of “event” can often differ among private sector supply chain members and between industry and the government. This key distinction has impacted the capability and willingness of the private sector to effectively share data with the federal government in response operations. Therefore, collaboration between the government and industry should be structured and defined during “steady-state” as well as during an “event” necessitating a response so that there is an adjustable framework for all parties to effectively work together. One of the interviewees accurately characterized this as a framework without “light-switch transparency.”



Clearly Define Steady State and Event State Sharing Practices



Establish Bidirectional Communication



Establish Structured, Routine Collaboration

Additionally, the National Academies prioritizes the interdependencies of transparency, analytics and communication for a resilient supply chain.¹¹ Clearly the lack of any of these dependencies will reduce the ability of the supply chain to flex to meet the dynamic needs of the complex market, but the National Academies of Sciences (NAS) has provided several recommendations that increase the one-way data-sharing burden on industry. The NAS recommends increased reporting of application programming interfaces (APIs) and raw materials, increased visibility on manufacturing locations, and enhanced data-sharing on manufacturing production and capacity. Although these recommendations would increase the one-way data-sharing that currently occurs and increase the overall communication, there are some current policy and industry barriers to this type of data-sharing.

Structured, routine collaboration between the public and private sectors serves as the foundation for ensuring long-term supply chain resilience. During the COVID-19 response, HDA and its members supported the Biden administration’s efforts to increase private-public collaboration for improving data transparency across the supply chain. The industry supported this effort because the federal government expressed specific needs and the major outcomes were clearly communicated. The U.S. Department of Health and Human Services (HHS), the U.S. Department of Homeland Security (DHS), the Cyber and Infrastructure Security Agency (CISA), and the Healthcare and Public Health Sector Coordinating Council (HPHSCC) organized the flow of information, requirements and distribution networks during the COVID-19 response. This group convened specifically to address healthcare supply chain challenges and was built on the infrastructure of the HHS/ASPR Critical Infrastructure Protection Program (CIP) working groups to create resources for government and industry use.

The “Essential Medicines Supply Chain and Manufacturing Resilience Assessment” reports offer prioritized strategies and implementation actions to increase supply chain resilience — by addressing challenges and constraints — for the essential medicines supply chain.¹² Offered strategies include increased supply chain coordination, security and transparency, expand production capacity, advance manufacturing capabilities, and purchasing, stockpiling and distribution approaches. The “Essentials Medicines Supply Chain and

¹¹ “Building Resilience into the Nation’s Medical Product Supply Chains.” National Academies of Sciences, Engineering, and Medicine. 2022. <https://doi.org/10.17226/26420>.

¹² U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR). “Essential Medicines Supply Chain and Manufacturing Resilience Assessment.” May 2002. https://www.armiusa.org/wp-content/uploads/2022/07/ARMI_Essential-Medicines-Supply-Chain-Report_508.pdf.

Manufacturing Resilience Assessment” report is a result of Executive Order 13944,¹³ which required the U.S. Food and Drug Administration (FDA) to identify a list of medical countermeasures to protect Americans during events that cause supply chain disruptions. The federal government’s review of the pharmaceutical supply chain and availability of key medicines also extended to Executive Orders 14001¹⁴ and 14017.¹⁵

In response to these reports, HDA and the members drafted the “Supply Chain Resilience Assessment: High-Level Summary and Recommendations”¹⁶ to assess each of the recommendations put forth by the federal government. HDA’s primary recommendations that were in line with the federal government’s findings and recommendations that centered around increasing supply chain coordination, security and transparency and improving purchasing, stockpiling and distribution strategies. Although the Essential Medicines Supply Chain and Manufacturing Resilience Assessment identified the key priorities, these reports did not map out the industry-focused mechanisms for sharing data. HDA identified roadblocks with this highly regulated space that decrease overall public-private collaboration. Additionally, HDA identified supply chain infrastructure in need of large-scale investment as well as redundancies that were not apparent to federal agencies. Although HHS presented strategies for making the supply chain more resilient, the HDA response showed that significant gaps still exist in the implementation of these strategies towards enhanced supply chain resilience.

EFFECTIVE DATA-SHARING DURING STEADY STATE AND INCIDENT RESPONSE

Strong steady-state and incident response postures are closely tied to overall, long-term supply chain resilience. While the postures and strategies that support a catastrophic event, such as a biological disaster (e.g., COVID-19, etc.) would require different capabilities, such disasters are ultimately supported by a strong supply chain. Based on HDA’s research, data-sharing should become more routinized during steady-state conditions and significantly attributed based on need and use of the data — so healthcare supply chain stakeholders can be ideally positioned before an incident occurs. Reliable data that can help better inform analysis and trends emerge from a consistent and predictable data collection process. Additionally, enhanced data collection allows for response organizers to quickly pinpoint and communicate with supply chain organizations that are either in need of assistance or have resources that can provide emergency relief.



Consider the lessons that can be learned from the COVID-19 Pandemic when planning for future incident response posture.

However, during the COVID-19 pandemic, the level and volume of data-sharing requests was unprecedented compared to previous shock events (e.g., H1N1, Ebola, Hurricane Maria) due to the widespread nature of the incident. While the ad hoc nature of data-sharing was necessary during the pandemic, as no prior data-sharing agreement existed, the inconsistency of data requests heavily burdened the industry. Real-time data were being requested during a time when industry members were responding to their own disruption — leaving little-to-no resources to respond to more data demands. During times of declared public health emergencies, HDA supports a consolidated point of contact within the federal government to serve as a conduit to provide guidance to and interact with the healthcare industry. This coordination will help leverage existing supply chain resources and expertise.¹⁷

¹³ Executive Order 13944 Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States.” August 6, 2020. <https://www.federalregister.gov/documents/2020/08/14/2020-18012/combating-public-health-emergencies>.

¹⁴ “Executive Order 14001 A Sustainable Public Health Supply Chain.” January 26, 2021. <https://www.federalregister.gov/documents/2021/01/26/2021-01865/a-sustainable-public-health-supply-chain>.

¹⁵ “Executive Order 14017 America’s Supply Chains.” February 24, 2021. <https://www.federalregister.gov/documents/2021/03/01/2021-04280/america-supply-chains>.

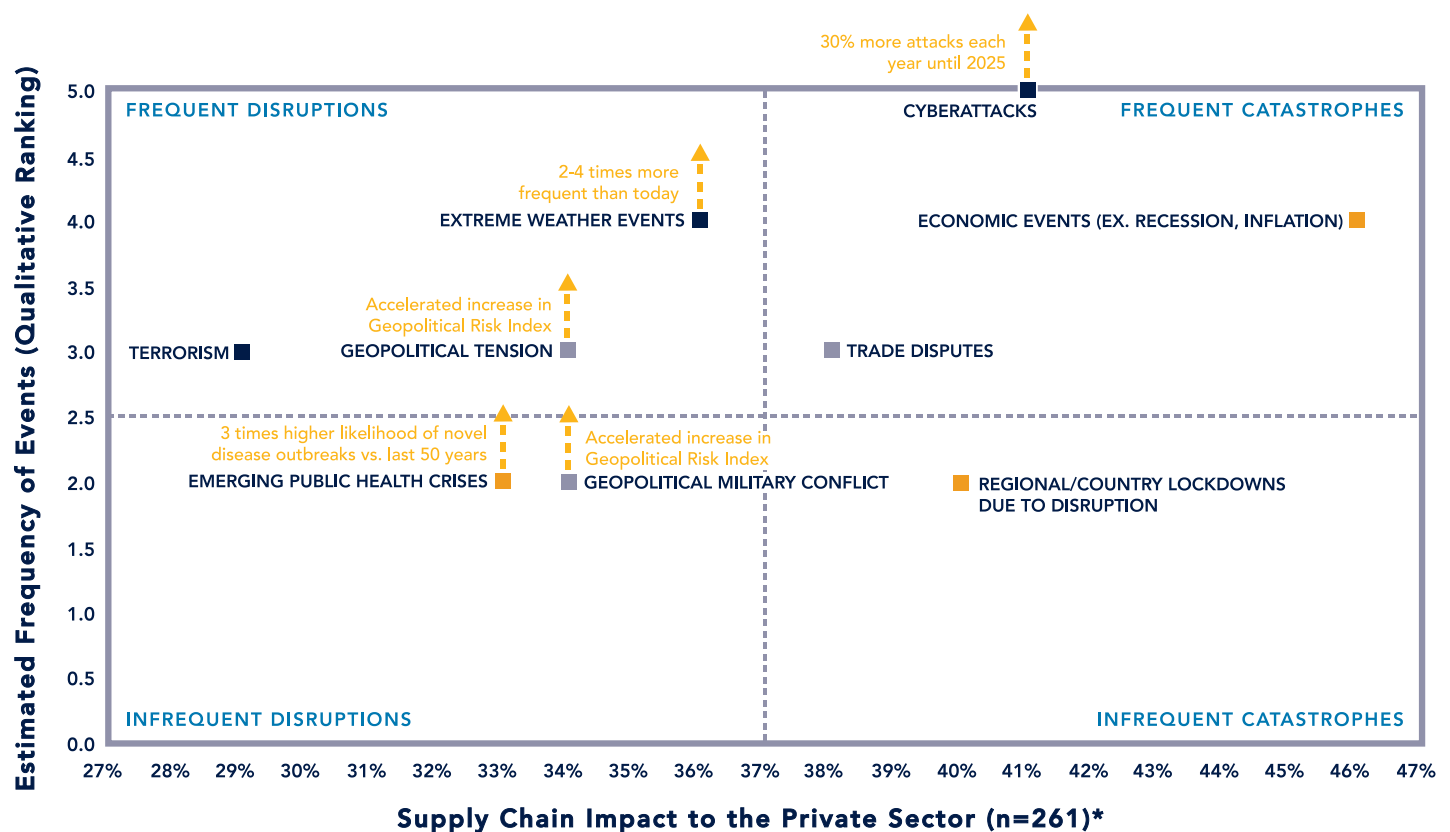
¹⁶ Healthcare Distribution Alliance. 2022.

¹⁷ Healthcare Distribution Alliance. “HDA Principles for Pandemic and Public Health Emergency Response.” 2020. <https://www.hda.org/getmedia/51158d66-3859-45a3-beac-8d1e9753b28a/HDA-Principles-for-Pandemic-and-Public-Health-Emergency-Response.pdf>.

Incident response involves understanding that the differing levels of disruption (acute, regional and calamity events) can vary based on their severity, frequency, lead time and needs. Acute disruptions can occur at any given time. These disruptions can range from a distributor’s truck breaking down and delaying delivery to small-scale surges that result from floods or power outages in the area. Distributors are prepared to work through and around normal day disruptions on a regular basis, and often require minimal contingency planning. Regional disruptions, such as a statewide power grid failure or essential staff shortage due to a strike, require detailed contingency planning, though these events are usually within the scope of the current capacity of the healthcare supply chain to absorb and manage. Finally, calamities, such as the outbreak of a pandemic or a large-scale earthquake, can cause disruptions nationwide and require extensive response and contingency planning. By maintaining adequate levels of preparedness plans, actors can anticipate, respond to and mitigate the ramifications of these disruptions. Figure 1 provides examples of disruptions that can occur effecting the healthcare supply chain at varying levels.¹⁸


Understanding potential supply chain bottlenecks during disruption and establishing an early warning system can reduce more significant impacts to the end customer. Effective data-sharing and specifying the data types needed during steady-state times would allow forecasting to indicate an early warning signal (such as data indicating increased demand of therapeutics across certain geographies or within certain age groups) and set forth a more proactive rather than reactive response during and after a disruption. Doing so will greatly improve overall supply chain resilience and mitigate disruption impacts before they get too extreme.

Figure 1: Supply chain disruptions vary based on their severity, frequency, and lead time¹⁹



¹⁸ Healthcare Distribution Alliance Research Foundation. *How the US biopharmaceutical and medical product supply chain adapted to disruptions — and plans to build strategies for the future*. December 2022. <https://www.hda.org/publications/covid-19-after-action-report>.

¹⁹ Healthcare Distribution Alliance Research Foundation.



2 | Healthcare Supply Chain Data

The healthcare industry is an expansive ecosystem with an extensive supply chain. That supply chain is composed of unique segments that source essential raw materials, manufacture pharmaceuticals and healthcare products, and distribute those medicines and products to sites of care and businesses that, ultimately, dispense or sell them to the patient. Various segments have their own internal processes to manage their in-house analytics, which require a range of staffing and resources. Distributors have internal analytics teams, which can consist of smaller teams of one to five people, as well as larger analytics departments that help forecast, plan, identify impacts to customers and more. To maintain awareness of business operations, many organizations will invest in data warehouse repositories, proprietary data analytics software and teams dedicated to mining data to answer specific business questions.

Because distributors maintain robust internal analytics capabilities, the industry is frequently called upon by governments during healthcare emergencies to enter into data-sharing agreements for better coordination and industry response. For healthcare distribution, data-sharing can include sales history, industry positions, requirements data for state and federal licensing, inventory levels and pricing information. The information governments ask distributors to share can vary from state to state and by federal agency.

Fulfilling government data requests comes with its own set of challenges. For example, distributors' internal systems differ from company to company. Some companies may not have end-to-end interoperable systems and many will adhere to an internal system that may not export data that directly correlate to others. Furthermore, distributors can only provide data that is within their purview of the supply chain. The disconnect of which data is requested and which is available points to an opportunity to establish a shared understanding with federal partners on the types of data healthcare distributors can readily provide and the optimal process for collecting that data.

The primary outlets for sharing healthcare distributor data with the federal government are through voluntary agreements with agencies. Interviewees shared that currently data requests come from the Federal Emergency Management Agency, DHS, HHS, U.S. Drug Enforcement Administration (DEA) and FDA although voluntary agreements are not in place in all cases. Requests also vary in size and cadence. While some recurring data requests ensure a consistent flow of data, other requests are ad hoc in nature. Distributors noted that such ad hoc requests typically have had a vague purpose on a more frequent basis and would not include a follow up to share final outcomes.

While interviewees noted that government data-driven products have illuminated trends in the general marketplace, distributors consistently expressed a lack of understanding on the use of data points they provide or visibility into final products that include the data. Furthermore, distributors stated that when the government did share information with HDA members, private-sector partners often saw limited value in the products. Specific feedback on products produced by groups such as the Supply Chain Control Tower (SCCT) established by HHS follows in the next section.

DATA-SHARING

Across all sectors of the healthcare industry, companies desire to support informed decision-making. Each sector has different, but interrelated, data sets that may help inform steady-state intelligence, emergency planning and incident response operations. Industry has several data types that it can share, from inventory trends and acquisitions to site-level inventory reporting. Some organizations have very specific purchase, shipping and sales data linked to a significant number of products. Other organizations have extensive supply chain data (from product inputs to sales data) for one or two specific products. Additionally, some distributors and transportation companies provide a wide range of location-based data for products and can analyze where shortages will be geographically and temporally. Sales history and inventory data for manufacturers is also a data subset integral to industry decision-making and shared with the federal government.

From pharmaceuticals to personal protective equipment (PPE), sharing these types of data sets within a central database to aggregate this information can help compare stockpiles against industry partners and distributors, as well as help determine where demand is surging. That way, an overall view of the health of the supply chain can aid in analysis to meet the goal of resilience. Although distribution partners have a significant amount of data, hospitals and primary care offices also collect and maintain different, but equally useful, data to support decision-making. These can include emerging threats and requests for products, supply chain disruptions and product usage data. Each of these specific data sets allows an organization to understand: (1) what is being developed, (2) what is being shipped and (3) when and where it is going. Aggregating these data across all sources can also shine a light on the delta between supply and demand and the need to flex accordingly by getting a broader view of the supply chain.

Although the healthcare industry has common goals — to support customer needs — each organization and sector manages data collection, maintenance and sharing differently. Sectors have different perspectives on who owns what data, who is the appropriate originator and how these data inform decision-making. This can lead to confusion within the federal government about sources for specific data requests and how to use that data appropriately. Additionally, confusion can exist within data illumination. For example, distributor purchase data are different from manufacturer sales data, so using and interpreting these data require clear parameters and industry knowledge. Overall, while data-sharing does not inherently lead to a more resilient healthcare supply chain, it can lead to increased visibility, which may result in purposeful action and help drive resilience investments.



*It's building less towards specificity and requirements...and [building] more toward **long term investments** in supply chain actors.*

-Healthcare Expert

*Any type of **early warning system** of where...the bottleneck might be... will set us [distributors] up for success in terms of how we support our customers.*

-Healthcare Distributor

*It would be great if we had a **collaborative effort**, a working group [or] **steering committee**...that looks at data, how data requirements are used and at data-sharing efforts.*

-Federal Partner

WHAT DO YOU RECOMMEND?

SUPPLY CHAIN CONTROL TOWER

The COVID-19 pandemic prompted a major incident response effort across the healthcare supply chain. During the pandemic, the U.S. Department of Health and Human Service's ASPR launched the Supply Chain Control Tower (SCCT). The SCCT is a private-public-partnership that enabled a consolidated approach to data-sharing in order to monitor healthcare supply chain stability. As part of the effort, major distributors supplied weekly data to the SCCT.²⁰ In exchange, the SCCT aimed to create and provide end-to-end visibility across the supply chain on inventory levels and manufacturing capacities, provide insights for demand forecasting and gap scenario modeling and inform capacity planning and product shortage responses.

The primary incentive to participate in the SCCT program was that the information provided by SCCT gave individual distributor companies visibility into aspects of the supply chain that they would not otherwise have had access to. Ideally, the control tower would use Artificial Intelligence (AI) modeling to link data from across industry-wide partners to help anticipate shortages and mitigate impacts on consumers.²¹ At the height of the pandemic, data was transmitted weekly with SCCT. Today, data continue to be sent to SCCT, but they have been reduced to be shared monthly.

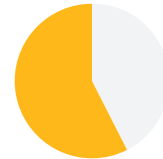
During interviews with healthcare distributors, participants expressed their desire to be more involved in planning processes for future SCCT operations, indicating the SCCT succeeded in engaging and intriguing the private sector but could improve operations. Distributors believe that because of their strong understanding of the goal for data analysis, they can more effectively recommend data points/metrics and more efficiently share that information. Interviewees expressed it was unclear how the government used the data and information from the SCCT and noted some of the data that were requested had "nothing to do with pandemic response."

Many participants outlined what they viewed as missed opportunities with SCCT management and outputs and provided feedback for future programming. For example, participants pointed to how SCCT outputs provided to their organizations failed to achieve the intended result to inform the health of the supply chain. This was because they were either too high-level to have value or they would provide distributors with insights that distributors already knew from their own internal data analytics. Since many healthcare distributors have internal teams conducting similar analyses, SCCT leadership should consider co-beneficial opportunities for timely, distribution network-wide insights through proper management and analysis of the SCCT. While some respondents pointed to a need for a central government repository for data flows, many distributors expressed that to make a central database successful, standardization of universal product codes (UPCs) is needed to increase the efficacy of such a program.

Moving forward, the role of SCCT is still unclear for industry partners. While the flow of information has slowed from the previous level of urgency from the pandemic, the scope of the control tower has grown beyond COVID-19 for use in other epidemics, such as Mpox and baby formula shortages. Aside from scope, healthcare distributors also raised concerns about the federal resources required to properly analyze the data being provided. Educating federal staff on the nuances of healthcare data would increase value to all parties and improve the collective approach to incident response. Overall, a healthy partnership between the public and private sectors is imperative to successfully implement SCCT in future response efforts.

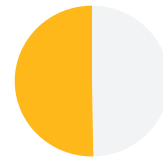
²⁰ Administration for Strategic Preparedness and Response. "Information Management Division." Accessed November 18, 2022. <https://aspr.hhs.gov/AboutASPR/ProgramOffices/ICC/Pages/IM-Division.aspx>.

²¹ SAP. "Supply Chain Control Towers: End-to-End Visibility: SAP Insights." Accessed November 18, 2022. <https://www.sap.com/insights/supply-chain-control-tower.html#:~:text=A%20supply%20chain%20control%20tower%20is%20a%20cloud-based%20solution,to%20proactively%20manage%20supply%20chains>.



Utilize data analytics to prioritize products and locations in high demand

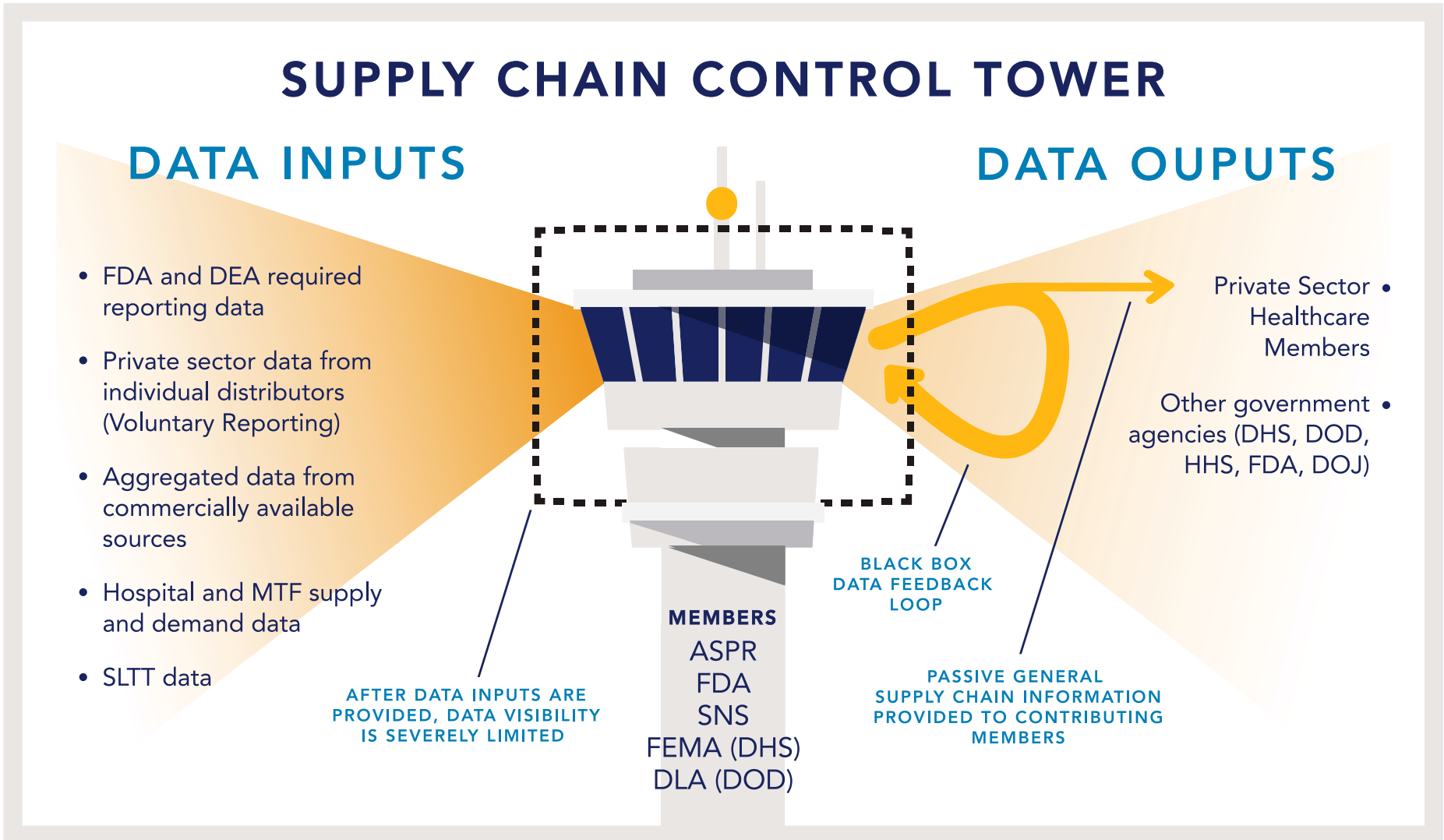
Over 57% of respondents valued obtaining usage data from customers and relaying inventory and availability information to them.



Minimize barriers for more effective communication

Over 50% of respondents are willing to share information regarding disruptive events and supply chain inventory with government agencies.

Figure 2: Perceived inputs and outputs of the Supply Chain Control Tower based on interviews



| | | | |
|-------------|--|-------------|--|
| FDA | U.S. Food and Drug Administration | FEMA | Federal Emergency Management Agency |
| DEA | Drug Enforcement Agency | DHS | Department of Homeland Security |
| MTF | Multi-Time Frame | DLA | Defense Logistics Agency |
| SLTT | State, Local, Tribal, and Territorial Governments | DOD | Department of Defense |
| ASPR | Administration for Strategic Preparedness and Response | HHS | U.S. Department of Health and Human Services |
| SNS | Strategic National Stockpile | DOJ | U.S. Department of Justice |

DRUG SUPPLY CHAIN SECURITY ACT

The Drug Quality and Security Act (DQSA) was enacted by President Obama on November 27, 2013. Title II of DQSA, the Drug Supply Chain Security Act (DSCSA), outlines steps to achieve interoperable, electronic tracing of pharmaceuticals at the package level to identify the movement of certain prescription drugs as they are distributed in the United States.²² This will enhance FDA's ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated or otherwise harmful. While DSCSA will increase transparency regarding supply chain integrity and security of medical products within the healthcare supply chain, it will not increase broader data transparency across the sector.

DSCSA requires tracking at the unit level, but mechanisms for reporting are case by case. For example, if product contamination is suspected, DSCSA would ensure the pedigree of where the drug changed buyers and sellers. In other words, DSCSA requires a recorded trail of receipts to show exactly where a product has been. This audit system brings a high level of visibility to protect consumers from faulty products. However, the data are not reported or aggregated to the federal government; doing so would create an operational burden on the private sector and still leave significant gaps in data transparency. While DSCSA will provide clarity on where a product has been and where it is going, it does not offer insight into overall inventory.



DSCSA

Enacted in 2013, the **Drug Supply Chain Security Act (DSCSA)** is a multi-phased approach to end-to-end pharmaceutical product traceability. DSCSA aims to protect consumers from counterfeit, stolen, contaminated or otherwise harmful medical products. DSCSA is enforced by the FDA and the final implementation phase is set to take effect in November 2023. With this final phase, supply chain trading partners will be required to provide transaction data along with serialized product upon a change of ownership.

²² "Drug Supply Chain Security Act (DSCSA)." Accessed December 1, 2022. <https://www.gpo.gov/fdsys/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf>.

3 | RECOMMENDATIONS FOR DATA-SHARING BETWEEN INDUSTRY AND GOVERNMENT

Proactive and robust plans for data collection — and information sharing between actors across the public and private sectors — are the foundation of successful supply chain information communication strategies. Currently, many organizations have formal agreements or a memorandum of understanding agreement (MOUs) with the FDA and DEA regarding their data, including what is collected, what is aggregated and what is industry proprietary. Throughout the COVID-19 pandemic, ASPR established temporary MOUs with various interagency organizations, including the SCCT and the Testing and Diagnostics Working Group (TDWG). Industry partners interpret these requests as intelligence gathering to identify suspected impacts to the supply chain. These COVID-19 public-private partnerships were voluntary and requests could be ad hoc. While this framework was effective during the immediate COVID-19 pandemic response, a more structured data-sharing arrangement is needed to achieve a sustainable data illumination process. These recommendations are further elaborated in the sections below.



Communication should be structured and consistent, to ensure the availability of accurate, complete, realizable, relevant and timely data to illuminate trends for resilience.



Direct engagement with industry when policies, programs and processes are set to establish a shared alignment on inputs and critical products/supplies.



Increase specificity of data requests with specific goals to determine the exact needs from private sector partners.



Establish a better understanding of the types of data valuable to the federal government and an approach to sharing meaningful data that is minimally burdensome to collect and analyze.



Improve technology solutions, such as increased automation, streamlined processes, secure databases and staffing resources.



Create more collaboration opportunities across different sectors to form communication channels.

BIDIRECTIONAL SYSTEM FOR DATA COLLECTION AND INFORMATION SHARING

Both industry and the federal government would benefit greatly from a shared, data-driven understanding of the path to achieve a resilient healthcare supply chain. To enhance data flow and transparency, HDA supports implementing mutually agreed upon bidirectional information sharing initiatives between the healthcare entities and the federal government, as well as state governments. Information-sharing agreements offer many benefits, such as enabling in-depth risk assessments and inventory counts across the supply chain. These agreements can also help rapidly identify product gaps and potential provider or manufacturer vulnerabilities across the private sector and offer immediate support for public sector partners.

Additionally, the private sector can gain deeper visibility into public sector capacities. However, the parameters of these agreements require clear definitions to ensure the protection of sensitive and confidential information

between parties, while also ensuring full privacy for the private sector partners. This will ensure that private sector capacities are not diminished because privacy protections will allow the private sector to be fully transparent with their information and analyses in order to respond to crises. A trusting public-private relationship will also allow the public sector to be more direct with the requirements and requests, outline the preferred outcome and allow private sector to conduct their proprietary analysis as needed. This will also allow private sector partners to fully use government information to better their own response.

When government undertakes data transparency or illumination efforts without input from distributors (or other healthcare-sector actors), the impact of those efforts may be limited, and cooperation made more difficult. For example, interviewees noted that while data-sharing in the height of the pandemic was justified and acknowledged by all parties as necessary, in a non-pandemic time period, sharing became less supportive. Interviewees expressed concern with what the federal government does with the data. As a result, distributors commented on a loss of control over data flows and use, and which agencies/parties have access

PUBLIC SECTOR BENEFITS



Provide Direct Requests



Establish Desired Outcomes



Fully Leverage Government Data



Run Proprietary Data Analysis

PRIVATE SECTOR BENEFITS

to data. One common concern with legislation, such as those outlined in DSCSA, is the data reporting requirements. Some of the data reported risk exposing company trade secrets and other confidential information. In other cases, distributors and manufactures must report the same data via cumbersome processes, creating needless overlap and challenges with adhering to legislation.

Additionally, industry has prioritized inter-company data-sharing as well. The Healthcare Transparency Initiative is a current, cross-industry collaboration put in place to improve supply chain transparency and visibility across a singular platform.²³ This platform aims to connect various stakeholders across healthcare supply chain sectors and ensure that data can be shared consistently and rapidly. This is just one effort that will allow the private sector to more effectively cross-talk and ensure that the data being shared with the government is comprehensive.

Prioritizing private-sector feedback and operational independence should be made to optimize private-public collaborations and data transparency efforts. Additionally, a clear scope of necessity would reduce reporting burdens and redundancies that impose on healthcare supply chain industry resources, especially during crises. Furthermore, federal agencies should better organize and clarify federal supply chain coordination roles and responsibilities.²⁴ Doing so would benefit the healthcare sector and boost national disaster relief efforts through increased government response efficiencies.

TECHNOLOGICAL BARRIERS

Current data-sharing approaches are time sensitive and time intensive. They often involve a manual process for gathering data, documenting data collected and manually sharing with the federal government through established portals. An automated, secure technology solution would help the federal government gather data while minimizing the burden on industry — a mutually beneficial solution to a complex problem. Both the public and private sectors can simplify data illumination through clearly defined data parameters, technology solutions such as increased automation, streamlined processes and a consistent mechanism for communication and information sharing before an incident or disruption occurs.

Additionally, several IT-related barriers obfuscate direct connections with federal partners. These barriers relegate organizations to manual practices for information sharing, which are inefficient, create significant time lags and do not offer a nuanced view of the data being shared. Increased IT connectivity would greatly improve data-sharing capabilities. Cybersecurity concerns are also a critical and constant consideration when discussing IT barriers. Industry is aware that data can never be “unshared,” and organizations want increased automation and more precise data inquiries. One suggested framework positions the government similarly to an industry client, i.e., granting access to portals for quick access to data.

23 Healthcare Transparency Initiative. <https://healthcare.resilinc.com/>

24 U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR). May 2002.

DATA-SHARING AUTOMATION

Industry members shared that automation of data-sharing processes would further enhance effectiveness and connection. A well-coordinated data-sharing process would provide a consistent data flow to industry organizations; this would enable better forecasts so they can proactively mobilize for public health requests and requirements. During steady state, data-sharing is about communicating regular insights about supply chain health and availability of supplies. With clear and open lines of communication on data-sharing between industry and government, industry can be involved in planning and exercise phases for incident response. When disaster strikes, the government can leverage this integrated system for fast, easy, safe and transparent data-sharing during incident response.

DATA ILLUMINATION OPPORTUNITIES

FEDERAL GOVERNMENT RECOMMENDATIONS FOR WORKING WITH INDUSTRY

A more strategic approach to making data requests and meeting requirements would be helpful to all parties. The federal government should internally coordinate across agencies to reduce the volume of data requests and gain more useful information from the data they already have. Industry can assist government with conducting broader and deeper analyses on available data and with filtering data appropriately so that questions can be answered, and action can be taken, in a timelier manner.

Optimizing available data will reduce backlogs, increase response rates and improve overall efficiency. With data, more is not always better in terms of conducting analyses — too many inputs can cloud the bigger picture. Targeted data requests are the first step towards executing this more strategic approach.

Both government and industry must gain a better understanding of each other's capabilities and needs for this strategic approach to be achieved. Government would benefit from a better understanding of the marketplace and the differences between industry players. Likewise, industry would benefit from a better understanding of the challenges federal and state partners are facing to help prioritize what data should be shared and subsequent actions to take based on that data. Because formal collaboration between government and industry partners remains undefined in some aspects, industry has focused on customers and building resilience for the consumer base, not for the government. If the government wishes to collect data and streamline its utility, then it must incentivize industry to be elevated to the top of the priority list.

IMPROVED PARTNERSHIPS AND COMMUNICATION

The federal government and industry partners can build a stronger partnership for sharing supply chain data by addressing regulations at all levels to help organizations discuss data freely and transparently. Data-sharing requires more than increased regulations; it also necessitates improved communication. Examples of data-sharing identified by interviewees, such as federal seasonal flu data being used to craft a targeted approach and ensure surge needs are met, rely on standardized reports rather than active communication and collaboration with private partners. Currently, the FDA and SCCT are collecting data using both formal and informal relationships. These conversations have helped illuminate the state of the overall supply chain. Despite this, enhanced communication between government organizations, such as the Strategic National Stockpile, FDA and SCCT, would be beneficial for overall visibility. This would also streamline the data request process and ensure the right data sources are targeted.

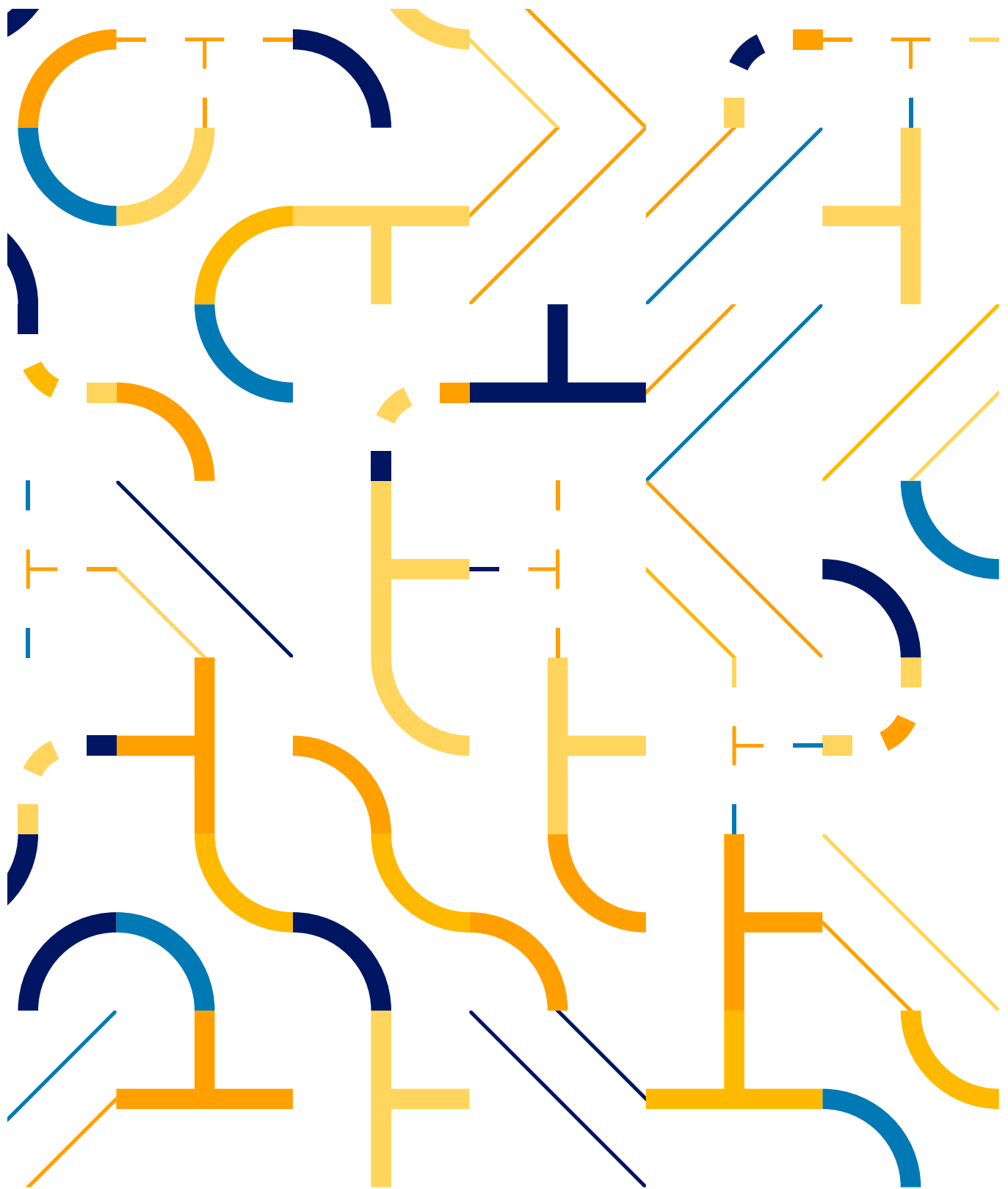
Additionally, industry has a clear and pressing desire to support informed government decision-making efforts. One interviewee cited proactive communication with federal partners about a potential product shortage to groups such as ASPR or the CDC and their response was that they either did not have information to share or that they were not at liberty to share any information. For industry to lend its expertise and advocacy, government must establish clear channels of communication through which industry can facilitate

data illumination. As mentioned previously, ad hoc requests and voluntary MOUs are not a sustainable approach for long-term resilience. Therefore, official channels and working groups would be helpful to facilitate a consistent cadence, expectation and context for data-sharing.

During the COVID-19 pandemic, industry partners attempted to communicate existing supply chain challenges, risks and implications, but the government was not amenable to information from outside sources; nor did it not have an adequate framework to facilitate data-sharing from the widest network. Instead, government reached out only to data suppliers they knew. To build a most robust data-sharing network, the government should implement more modes of communication to connect with both data suppliers and vendors. Expanding the network, in turn, would also spread the government's risk. The government must facilitate more collaboration opportunities across different sectors to establish a shared understanding of the desired cadence, requests, language and outcomes during incident responses. Formal and trusted communication channels would set firm expectations for industry so it can provide the most targeted and accurate information. By casting the widest net possible and keeping communication channels open, even during steady-state, the learning curve for industry during incident response will result in a more resilient healthcare supply chain.

CONCLUSION

Greater communication, collaboration and coordination between healthcare supply chain industry partners and the public sector is key to successfully building resilience and enhancing data transparency and illumination. Bolstering the SCCT and ASPR's MOUs has shown promise with data illumination leading to resilience, but we are far from an established framework that will aid in better decision making geared toward a more resilience healthcare supply chain. An enhanced bidirectional data system for data collection and information sharing, addressing technology barriers and improving partnerships and communication are only a few recommendations to help us reach a shared sense of mission between the public and private sectors. This report is only the start of the conversation and will inform future analysis and study into the depths of a building a more resilient healthcare supply chain.



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