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The Healthcare Supply Chain and U.S. National Security

Policy Considerations for
Investing in Resilience

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EXECUTIVE SUMMARY

Healthcare distributors are the center of gravity in the United States healthcare system in steady-state and during national crises, providing a vital link between manufacturers, providers and patients. Distributors routinely deliver 10.5 million medicines, vaccines and medical products to over 450,000 sites of care,¹ connecting patients with essential medical supplies despite growing threats from natural and human-caused disruptions. Healthcare distributors prevent and manage public health emergencies by supplying critical medicines to communities across the country. The resilience of the healthcare supply chain is also a critical element of U.S. national security, as distributors provide critical medical supplies to maintain continuity of care for U.S. troops at home and abroad. Healthcare distribution is part of the U.S. critical infrastructure and investments in its resilience must be a national security priority comparable to defense industrial base preparedness. Policies that enhance healthcare supply chain resilience will prepare the U.S. to better manage routine and catastrophic risks to public health.

Supply chain must be resilient to the full spectrum of potential threats, from normal, seasonal supply and demand fluctuations to unpredictable geopolitical conflicts. Healthcare supply chain are a known point of vulnerability for U.S. national security and potential targets in strategic competition between the U.S. and near-peer adversaries. To bolster healthcare supply chain resilience and ensure adequate supplies of critical medicines, policymakers should address potential challenges from natural and human-caused disasters, enhance coordination across critical infrastructure and military, modify disruptive national economic policies, and minimize gaps in information sharing and stockpiling processes. Investments in healthcare supply chain resilience will allow manufacturers, distributors and providers to maintain public health preparedness and national security despite the increasing frequency and severity of threats.

Policymakers can take specific actions to increase pharmaceutical supply chain resilience and enhance U.S. national security. These recommended actions, explained in further detail throughout this policy paper, offer opportunities for government and pharmaceutical distributors to collaborate to ensure the steady supply of critical medicines despite the threats facing supply chain:

- + **Invest** in increased supplies of critical medicines in the U.S. healthcare supply chain;
- + **Develop** and **test** crisis playbooks;
- + **Address** supply chain dependencies;
- + **Enhance** public and private sector coordination mechanisms between critical infrastructure sectors;
- + **Re-authorize** the Pandemic and All-Hazards Preparedness Act (PAHPA);
- + **Exempt** pharmaceutical products from broad tariffs;
- + **Invest** in domestic production for prioritized critical products; As a complement to existing supply chain resilience
- + **Ensure** national policies account for impacts to pharmaceutical distributors;
- + **Establish** clear definitions of “steady-state” and “incident” conditions;
- + **Leverage** and **expand** existing public-private partnerships;
- + **Establish** clear data sharing agreements;
- + **Implement** market-based incentives and payment reforms to diversify supply chain; and,
- + **Enhance** supplies in the Strategic National Stockpile and **expand** stockpiling investments in partnership with the private sector.

¹ Healthcare Distribution Alliance. “96th Edition HDA Factbook: The Facts, Figures and Trends in Healthcare.” 2025. <https://hda.org/publications/96th-edition-hda-factbook-the-facts-figures-and-trends-in-healthcare/>.

I. U.S. HEALTHCARE DISTRIBUTION SUPPLY CHAIN RESILIENCE AS A SECURITY IMPERATIVE

Supply chain resilience is defined as the ability to manage disruptions and shocks without significantly interrupting patient care and healthcare delivery.² Healthcare supply chain are resilient but face significant challenges from human-caused threats and natural disasters. The COVID-19 pandemic demonstrated healthcare supply chain's ability to adapt to unforeseen disruptions. However, the combination of threats from international trade disruptions, exploitation of supply chain in geopolitical conflicts, more frequent and more severe cyberattacks, global shipping disruptions and persistent risks from natural disasters represent significant challenges for the industry. Supply chain disruptions from any of these threats could affect U.S. public health, including the health of U.S. critical infrastructure operators and military personnel. Such impacts could cascade across critical infrastructure sectors and affect the operation of systems providing electric power to homes and businesses, processing clean drinking water, and supporting everyday communications over mobile phones and internet. More critically, disruptions of supplies of critical medicines and medical countermeasures to U.S. troops could limit the military's ability to project power around the world. The linkages between healthcare supply chain and U.S. national security make increased resilience of supply chain a critical priority for U.S. policymakers.

U.S. National Security Depends on Pharmaceutical Supply Chain

Pharmaceutical supply chain are an essential element of the overall system of U.S. critical infrastructure, with dependencies and interdependencies across multiple sectors that both rely on and support the healthcare and public health sector.³ Distributors serve as critical infrastructure enablers, ensuring that medicines reach providers across all 50 states, including during emergencies. Their ability to maintain continuity of operations during times of national distress is essential to national security and public health preparedness. Pharmaceutical distributors are particularly dependent on the "lifeline" infrastructure sectors — transportation, communications, energy and water — and have second and third-level dependencies on all other sectors.^{4, 5} Those infrastructure sectors, jointly managed by private companies and U.S. government agencies, are essential partners for the healthcare and public health sectors, and healthcare distributors.

All U.S. critical infrastructure systems also depend on the pharmaceutical supply chain, especially to ensure the health and wellness of the workers who operate and maintain infrastructure facilities. In 2020, the U.S. Department of Homeland Security identified the sectors and categories of employees that are "essential" to continued infrastructure operations so that state and local governments could appropriately prioritize response activities during the COVID-19 pandemic. The pharmaceutical supply chain supported those essential functions with vaccines and routine medicines during the pandemic and continues to support the health and safety of those functions during steady-state operations.⁶ Disruptions to the pharmaceutical supply chain would directly affect the health and safety of workers and quickly spread across all critical infrastructure sectors, potentially disrupting core functions.

The health and safety of U.S. military personnel and civilian employees are vital to the ability to project power around the world and ensure U.S. national security. U.S. military and veterans are especially vulnerable to disruptions in the pharmaceutical supply chain. Distributors supply essential medicines to U.S. troops both domestically and overseas—including both chronic care medicines for steady-state care and medical countermeasures required to treat injuries suffered in conflict—and to veterans through the Department of Veterans Affairs. Because the U.S. military relies on all other critical infrastructure sectors, it has interlinked

² Healthcare Distribution Alliance. "Enhancing Resilience: Recommendations to Achieve a Safer and Secure Pharmaceutical Supply Chain Report." 2024. <https://www.hda.org/getmedia/f8a57f40-49d1-419b-b595-db0ba83c878d/Supply-Chain-Resilience-Report.pdf>.

³ Department of Homeland Security. "Healthcare and Public Health Sector-Specific Plan." 2016. <https://www.cisa.gov/sites/default/files/publications/nipp-ssp-healthcare-public-health-2015-508.pdf>.

⁴ Ibid.

⁵ The U.S. Department of Homeland Security defines "lifeline sectors" as those functions that are "essential to the operation of most critical infrastructure sectors" in the 2013 National Infrastructure Protection Plan. <https://www.nist.gov/system/files/documents/cybercommission/-DHS- National Infrastructure Protection Plan -NIPP.pdf>.

⁶ Cybersecurity and Infrastructure Security Agency. "Guidance on the Essential Critical Infrastructure Workforce: Ensuring Community and National Resilience in COVID-19 Response." 2020. <https://www.cisa.gov/sites/default/files/publications/CISA-Guidance-on-Essential-Critical-Infrastructure-Workers-1-20-508c.pdf>.

dependencies on pharmaceutical distributors to provide medical supplies that support those sectors as well. Just as the U.S. military is dependent on the full U.S. defense industrial base, including manufacturers, logistics and services from a diverse set of private sector partners, the military is dependent on the medical industrial base that includes manufacturers, distributors and providers. Impacts to public health from disruptions in the pharmaceutical supply chain would directly affect the U.S. military's ability to keep troops healthy and degrade the broader industrial base that provides materiel and operational support.

The U.S. Departments of Defense and Veterans Affairs are significant purchasers in the U.S. domestic healthcare market. Their consistent procurement of pharmaceutical products contributes to the demand needed to support investments in every component of the healthcare industrial base, including manufacturers and distributors, and ensure a steady supply of products like generic pharmaceuticals in the broader U.S. healthcare system. Their purchase of pharmaceutical products for troops supports the projection of U.S. power around the world and supports investments in the overall U.S. supply of generic drugs and other critical products, ensuring their availability during public health emergencies.

Threats to the Healthcare Supply Chain are Threats to National Security

The pharmaceutical supply chain is already resilient against many potential disruptions that distributors encounter every day. Distributors have already invested in resilience against steady-state challenges and are thus able to scale up support during national crises. Resilience across every component of pharmaceutical supply chain against such large-scale events ensures that the U.S. can maintain public health and national security preparedness during disruptions from man-made or natural disasters.⁷ As the federal government re-evaluates and re-aligns the national approach to resilience, preparedness and national security, the role of private sector partners like pharmaceutical distributors is more critical than ever.⁸

The pharmaceutical supply chain is well-positioned to manage annual fluctuations in demand for pharmaceuticals for flu, RSV and other respiratory illnesses. Exceptionally high demand for any product may trigger temporary shortages, but manufacturers and distributors have invested significant time and resources into sophisticated planning processes to ensure adequate supply and distribution of the products required to address anticipated annual demand increases.⁹ The industry also invests in innovative cold-chain packaging and transportation capabilities and provides medicines to treat chronic, complex and rare diseases via specialty distributors. A disease outbreak that falls outside the expected seasonal illnesses could present a more significant challenge to the pharmaceutical supply chain through unanticipated, extremely high demand for medical supplies. The COVID-19 pandemic strained global supply chain for pharmaceutical products but the supply chain responded with extraordinary efforts such as Operation Warp Speed and Project Airbridge to meet unprecedented demand for COVID-related pharmaceuticals and maintain access to regular medicines.^{10, 11}



⁷ Healthcare Distribution Alliance. "Supply Chain Resilience Assessment: High-Level Summary and Recommendations." <https://www.hda.org/getmedia/b2d8fb6b-e26f-4773-9c4a-649858abc25f/Supply-Chain-Resilience-Assessment-Summary.pdf>.

⁸ The White House. Executive Order 14239, "Achieving Efficiency through State and Local Preparedness". 2025. <https://www.whitehouse.gov/presidential-actions/2025/03/achieving-efficiency-through-state-and-local-preparedness/>.

⁹ Ibid.

¹⁰ Healthcare Distribution Alliance. "Bolstering Disaster Preparedness and Operational Resilience in the Healthcare Supply Chain." <https://hda.org/getmedia/f13bb354-88eb-494e-81ca-2456ea4d795c/Bolstering-Disaster-Preparedness-and-Operational-Resilience-in-the-Healthcare-Supply-Chain.pdf>.

¹¹ Healthcare Distribution Alliance Research Foundation. "The First 90 Days: US Biopharmaceutical Finished Goods Supply Chain Response to COVID-19." 2020. <https://www.hda.org/publications/the-first-90-days-us-biopharmaceutical-finished-goods-supply-chain-response-to-covid-19/>.

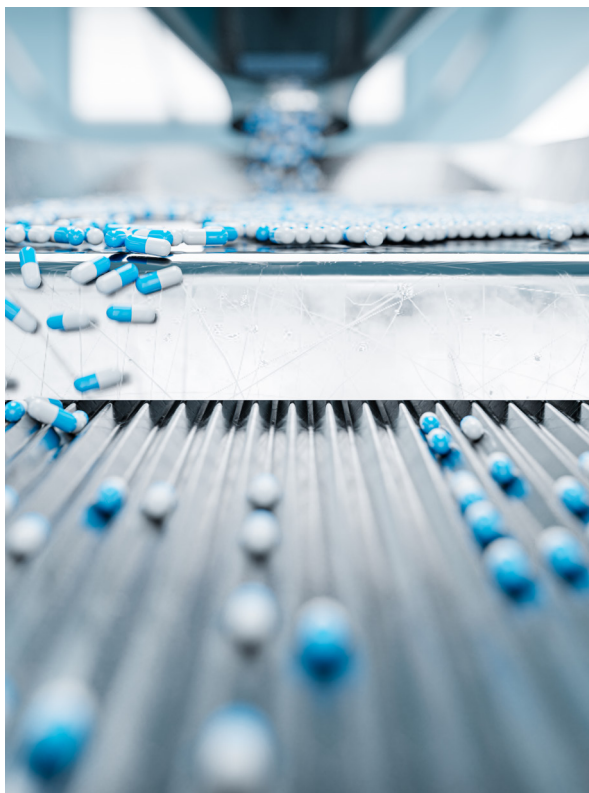


Cybersecurity in the Healthcare Sector

Multiple noteworthy cyberattacks against healthcare supply chain led to disruptions in the supply of blood products and blood plasma to hospitals in the U.S. in 2024. In April 2024, the blood plasma provider Octapharma suffered a ransomware attack that forced the closure of over 190 plasma donation centers, multiple manufacturing facilities and exposed the sensitive information of donors.¹²

A similar ransomware attack in July 2024 targeted OneBlood, a Florida-based blood product supplier. This attack caused a software outage that disrupted shipments of blood products to more than 250 hospitals, leading to a supply shortage.¹³

Distributors are addressing cyber risks and organizing both security and resilience efforts using industry standards and frameworks such as the National Institute of Standards and Technology (NIST) Cybersecurity Framework, the International Organization for Standardization (ISO) standard for information security management systems (ISO 27001) and the HITRUST Cybersecurity Framework.^{14 15 16} Leading distributors are improving their cybersecurity programs by applying these standards and other cybersecurity best practices, including training and awareness programs for employees, structured risk management programs, audits and evaluations, and cyber incident response plans.



Despite the resilience that pharmaceutical distributors demonstrated during the pandemic, supply chain remain vulnerable to growing threats from human-caused disruptions, such as cyberattacks, terror attacks, global shipping disruptions, international trade policies and cascading impacts from geopolitical conflicts. Some incidents may only affect healthcare supply chain indirectly or coincidentally (e.g., indiscriminate ransomware attacks), but other incidents could specifically target healthcare supply chain.

U.S. dependence on geographically concentrated sources of key starting materials (KSMs), active pharmaceutical ingredients (APIs) or finished dosage forms (FDFs)—including suppliers located in China, India, and other countries—can create vulnerabilities if limited supply chain redundancy exists.¹⁷ A 2023 assessment found that 97 percent of antibiotics, 92 percent of antivirals and 83 percent of the top 100

¹² Health-ISAC and American Hospital Association. Joint Threat Bulletin. 2024. <https://www.aha.org/advisory/2024-08-01-american-hospital-association-and-health-isac-joint-threat-bulletin-tlp-white>.

¹³ Ibid.

¹⁴ National Institute for Standards and Technology. Cybersecurity Framework. 2024. <https://nvlpubs.nist.gov/nistpubs/CSWP/NIST.CSWP.29.pdf>.

¹⁵ International Organization for Standardization. ISO 27001: Information security, cybersecurity and privacy protection: Information security management systems, Requirements. 2022. <https://www.iso.org/standard/27001>.

¹⁶ HITRUST. "HITRUST CSF: Our Cybersecurity Framework". 2025. <https://hitrustalliance.net/hitrust-framework>.

¹⁷ API Innovation Center. "A Bold Goal: Reshoring 25% of Small Molecule API to the U.S. in Five Years." 2024. https://apicenter.org/wp-content/uploads/2024/01/White-Paper_2024.pdf.



generic drugs consumed in the U.S. have no domestic source of APIs.¹⁸ For example, China manufactures 80 percent of the global supply of para-aminophenol (PAP), a precursor for painkillers such as acetaminophen, including 46 percent of global supply from one Chinese company. The closure of a single facility in China in 2021 led to a brief increase in acetaminophen prices.^{19 20} India, another major supplier of APIs, KSMs and FDFs to the U.S., has its own significant dependencies on China, including 80 to 100 percent dependencies on China for the APIs required to manufacture several essential medicines such as acetaminophen, amoxicillin and ciprofloxacin.²¹ Geopolitical developments and export controls have highlighted the importance of understanding potential supply chain vulnerabilities and ensuring sufficient diversification to reduce reliance on any single source for critical pharmaceutical inputs.²²

Pharmaceutical distribution is also vulnerable to the ripple effects from cyber or physical disruptions outside the healthcare sector, including disruptions to global shipping routes, such as the 2021 blockage of the Suez Canal by a container ship and multiple cyberattacks against maritime ports and shipping companies.^{23 24} Such disruptions could strain pharmaceutical supply chain and force distributors to activate emergency response plans to manage limited inventory and turn to stockpiles for critical products. Despite significant efforts by industry to find alternative providers and ration existing supplies, a long-term disruption could eventually exhaust stockpiles and cause shortages with wide-ranging impacts on U.S. public health and national security.

Natural disasters remain a significant concern for distributors and can threaten the pharmaceutical supply chain in many ways, including direct impacts to manufacturing facilities, closure of transportation routes used by distributors, and power outages or other disruptions to providers such as hospitals and clinics. While “notice” events such as hurricanes allow for evacuations, facility hardening, and other measures to avoid significant impacts, other “no-notice” events like earthquakes and rapidly spreading wildfires can cause severe damage without warning. Regardless of what preventive and protective measures are in place, natural disasters often have lasting cross-sector impacts to affected communities, including pharmaceutical manufacturers, distributors

¹⁸ Sardella, Anthony. “U.S. Generic Pharmaceutical Industry Economic Instability.” 2023. Washington University in St. Louis. <https://wustl.app.box.com/s/zhY8hbl8wmi8nawqy4lfcytl0epijxr>.

¹⁹ Sardella, Anthony. “The US Active Pharmaceutical Ingredient Infrastructure: The current state and considerations to increase US Healthcare Security.” 2021. https://www.uscc.gov/sites/default/files/2025-11/2025_Executive_Summary.pdf.

²⁰ CNBC. “High paracetamol prices to be a blip over a quarter or two: Granules Pharma.” 2021. <https://www.cnbc18.com/healthcare/see-high-paracetamol-prices-to-be-a-blip-over-a-quarter-or-two-granules-pharma-8696011.htm>.

²¹ The Economic Times. “Budget 2023: ‘Pharmacy of the World’ has a Chinese Achilles heel.” 2023. <https://economictimes.indiatimes.com/small-biz/sme-sector/budget-2023-pharmacy-of-the-world-has-a-chinese-achilles-heel/articleshow/97046291.cms>.

²² U.S.-China Economic and Security Review Commission. “2025 Report to Congress.” 2025. https://www.uscc.gov/sites/default/files/2025-11/2025_Executive_Summary.pdf.

²³ U.S. Department of Transportation, Bureau of Transportation Statistics. “Suez Canal Blockage by Ever Given Will Affect U.S. Ports, Businesses, Consumers.” 2021. <https://www.bts.gov/data-spotlight/ever-given-suez-canal>.

²⁴ U.S. Department of Homeland Security. “U.S. Maritime Trade and Port Cybersecurity.” 2024. <https://www.dhs.gov/sites/default/files/2024-09/2024aepphasellusmaritimetradeandportcybersecurity.pdf>.

and providers. Distributors are critical partners to help communities recover, but also vulnerable to cascading impacts from disruptions to manufacturers or providers. Distributors have developed emergency response plans and activate them during disruptions of steady-state operations to provide a critical linkage between manufacturers and providers. Distributors have updated these plans with lessons learned from previous disruptions, that have strained supply chain operations. and other major supply chain disruptions. Nonetheless, distributors remain vulnerable to natural disasters, especially those affecting the energy and transportation sectors. As these natural disasters become more frequent and more severe, distributors and other stakeholders in pharmaceutical supply chain will continue to face potential disruptions.

Distributors and other components of the pharmaceutical supply chain have planned carefully to ensure resilience against the effects of human-caused incidents and natural disasters. Despite efforts to prevent and mitigate potential disruptions, however, a catastrophic event such as military conflict between the U.S. and another nation-state, a large-scale cyber incident, or a natural disaster such as a major earthquake, would have widespread and significant consequences for the whole country and require months or years to fully recover.^{25, 26} Those consequences would affect healthcare distributors and likely cause temporary drug shortages because of impacts to manufacturers and supply chain logistics that enable distribution. U.S. recovery from such catastrophic incidents would also depend on pharmaceutical distribution to enable medical care for survivors and responders. The critical medicines that pharmaceutical distributors supply to providers during steady-state operations would be even more essential during times of national crisis. Investments in resilience against known and recurring threats like cyberattacks and natural disasters will not prevent shortages during catastrophic incidents but will facilitate long-term recovery and shorten the timeframe for any pharmaceutical shortages.

Recommendations



Invest in increased supplies of critical medicines in the U.S. healthcare supply chain. Leverage existing, unused capacity in domestic manufacturing facilities to increase U.S. government spending on supplies of generic pharmaceuticals and distribution capacity to increase overall domestic supply chain resilience.



Develop and test crisis playbooks. Develop emergency response playbooks to specifically test healthcare supply chain capacity and capabilities and test those playbooks in realistic, government-facilitated tabletop and functional exercises with participation from manufacturers, distributors and all relevant federal, state and local governments. Include scenarios featuring supply chain disruptions in the U.S. and overseas.



Address supply chain dependencies. Identify and assess dependencies for prioritized pharmaceutical products, including APIs, KSMs, and FDFs, to identify vulnerabilities, reduce single points of failure, and inform risk-based resilience investments.



Enhance public and private sector coordination mechanisms between critical infrastructure sectors. Hold regional government-led workshops to identify and address cross-sector supply chain vulnerabilities and strengthen steady-state and incident coordination among U.S. critical infrastructure Sector Risk Management Agencies (SRMAs), relevant state and local partners, and private sector manufacturers and distributors.



Re-authorize the Pandemic and All-Hazards Preparedness Act (PAHPA). The PAHPA framework provides the foundation for the resilience of the U.S. healthcare system. A comprehensive reauthorization of PAHPA would ensure the long-term stability of the federal programs that support public health during crises and the national security functions that depend on resilient healthcare services.

²⁵ Healthcare Distribution Alliance. "Bolstering Disaster Preparedness and Operational Resilience in the Healthcare Supply Chain." <https://hda.org/getmedia/f13bb354-88eb-494e-81ca-2456ea4d795c/Bolstering-Disaster-Preparedness-and-Operational-Resilience-in-the-Healthcare-Supply-Chain.pdf>.

²⁶ Federal Emergency Management Agency, Region 10 Cascadia Subduction Zone Earthquake and Tsunami Plan. 2022. <https://mil.wa.gov/asset/68404ea51bc02/FEMA-Region-X-CSZ-Earthquake-and-Tsunami-Plan.pdf>.

II. NAVIGATING POTENTIALLY DISRUPTIVE ECONOMIC POLICIES

National economic policies could disrupt pharmaceutical supply chain by reducing federal healthcare spending and disincentivizing private sector investment in manufacturing, distribution and provider spending. Decreased demand for healthcare services (including pharmaceutical products) due to policy changes will ripple across the healthcare sector and destabilize supply chain. Increased costs will deter patients from seeking care and decreased demand for care (especially compensated care) will cascade to cause financial challenges for providers. Those providers will



consolidate or close facilities, thereby reducing access to care and continuing a downward spiral of decreasing demand and decreased system resilience. Policymakers can adjust economic policies to either avoid these detrimental effects or gradually phase-in changes to allow time for the private sector to adapt. It is critical to U.S. national security that policymakers account for the potential downstream effects of these policies and choose to invest in a more resilient healthcare supply chain.

Broad Tariffs Affecting the Prices of Pharmaceuticals, API and KSM

The complex dependencies and interdependencies in the global healthcare supply chain mean that broad tariffs on imported pharmaceutical supplies such as APIs, KSMs and FDFs could have unintended consequences for the supply chain, including significantly higher prices for patients and providers or the inability of small domestic manufacturers to remain viable in the highly competitive market.²⁷ Tariffs may incentivize increased investment in domestic production, but take years to show their full effect. The negative financial impacts, however, take effect immediately through increased prices and strain on the supply of critical pharmaceutical products. Upstream cost increases can lead to volatility in pricing and supply, complicating inventory planning and contractual obligations with providers. These price increases and potential shortages will have cascading impacts on the healthcare supply chain during steady-state and become especially acute during national crises, thereby threatening U.S. national security.

The pharmaceutical supply chain currently relies on geographical diversity to provide redundancy



Tariffs Could Increase Drug Prices by 12.9 Percent

A report by Ernst & Young found that a 25 percent proposed tariff on pharmaceutical imports would increase drug prices for patients by 12.9 percent and increase domestic U.S. pharmaceutical manufacturing costs by 4.1 percent.²⁸ The report did not account for potential retaliatory tariffs.

²⁷ Healthcare Distribution Alliance. "HDA Statement on Proposed Tariffs of Pharmaceutical Products." 2025. <https://www.hda.org/newsroom/2025/february/hda-statement-on-proposed-tariffs-of-pharmaceutical-products/>.

²⁸ Becker's Hospital Review. "Pharma Tariffs Would Raise Drug Costs By \$51b: Report." 2025. <https://www.beckershospitalreview.com/pharmacy/pharma-tariffs-would-raise-drug-costs-by-51b-report/>.



and mitigate single points of failure that are vulnerable to natural and human-caused disruptions. Strategic investments in domestic production capacity will add further redundancies and enhance the overall resilience of the U.S. healthcare supply chain but should not come at the expense of the existing network of global suppliers.²⁹ Some KSMs and APIs are available only from foreign suppliers and will remain foreign dependencies regardless of how much domestic manufacturing capacity for finished medicines increases.³⁰ Additionally, the U.S. supply chain for several generic drugs consists entirely of foreign companies without U.S.-based competitors because domestic production is not financially viable. Developing U.S. production capacity for these high-volume, low-margin products would require significant U.S. government intervention to make pricing viable for domestic U.S. manufacturers, take several years to implement, and would still require KSMs and APIs sourced from foreign suppliers. Tariffs that disrupt the supply of these medicines before U.S. manufacturing capacity is fully operational will lead to drug shortages and negative outcomes for patients. Policies intended to increase domestic production should include U.S. government investments to incentivize production of low-margin products and supplement total supply chain capacity rather than replace the resilient, diverse supplier networks currently in place.

Cost increases from tariffs will affect stakeholders at every step in the pharmaceutical supply chain — manufacturers, distributors, providers and patients. Generic pharmaceutical manufacturers and distributors already face slim margins (0.2 percent net profit margin after taxes³¹) and cannot absorb cost increases from tariffs.³² Similarly, hospitals—continue to face significant financial pressures and would also face cost increases of up to 15 percent from tariffs.^{33 34}

These cost increases would have especially severe impacts to rural and critical access hospitals. Increased costs for these providers could lead to consolidation or closures, thereby reducing or eliminating healthcare access for patients.³⁵ Finally, higher prices would likely lead to higher costs for patients through increased premiums, deductibles and out-of-pocket expenses.³⁶ These increased financial pressure points all lead to greater potential disruption in the healthcare supply chain, with higher prices at every node in the system triggering lower demand and lower supply. The resilience of the supply chain depends on consistent demand signals for suppliers to provide products and pricing that enable production and distribution as well as policies that decrease demand and will decrease overall supply chain resilience.

²⁹ Healthcare Distribution Alliance. “HDA Guiding Principles for Drug Shortages.” 2024. [HDA-Drug-Shortages-Guiding-Principles.pdf](https://www.hda.org/publications/96th-edition-hda-factbook-the-facts-figures-and-trends-in-healthcare/).

³⁰ Iqvia Institute for Human Data Science. “U.S.–India Medicine Partnership.” 2024. [IQVIA-US-India-Medicine-Partnership.pdf](https://www.iqvia.com/insights/industry/US-India-Medicine-Partnership).

³¹ Healthcare Distribution Alliance. “96th Edition HDA Factbook: The Facts, Figures and Trends in Healthcare.” 2025. <https://www.hda.org/publications/96th-edition-hda-factbook-the-facts-figures-and-trends-in-healthcare/>

³² Healthcare Distribution Alliance. “HDA Statement on Proposed Tariffs of Pharmaceutical Products.” 2025. <https://www.hda.org/newsroom/2025/february/hda-statement-on-proposed-tariffs-of-pharmaceutical-products/>.

³³ American Hospital Association. “Executive Summary: Tariffs and Their Impact on the U.S. Health Care Supply Chain.” 2025. <https://www.ahmm.org/system/files/media/file/2025/06/Tariffs-Impact-Health-Care-Supply-Chain-PDF.pdf>.

³⁴ Becker's Hospital Review. “Hospital Finance, Supply Leaders Predict 15% Increase In Tariff-Related Costs.” 2025. <https://www.beckershospitalreview.com/supply-chain/hospital-finance-supply-leaders-predict-15-increase-in-tariff-related-costs/>.

³⁵ Health Affairs. “Tariffs: Added Strain on the U.S. Health Care System.” 2025. <https://www.healthaffairs.org/content/forefront/tariffs-added-strain-us-health-care-system>.

³⁶ Ibid.

Recommendations



Exempt pharmaceuticals products from broad tariffs. Exempt pharmaceuticals, APIs and KSMs from broad tariffs to avoid supply disruptions and gradually phase-in potential tariffs on healthcare products in alignment with increased domestic production capacity for prioritized products.



Invest in domestic production for prioritized critical products. Increase federal investment in domestic production for specific, prioritized APIs, KSMs and FDFs that are critical to support national security and public health during a potential public health emergency, while complementing existing global supplier networks, accounting for existing foreign dependencies, and strengthening overall supply chain resilience.



Ensure national policies account for impacts to pharmaceutical distributors. Ensure that economic policies account for downstream impacts on distributors, including how reimbursement and demand shifts affect their ability to maintain inventory, logistics capacity and emergency response readiness.

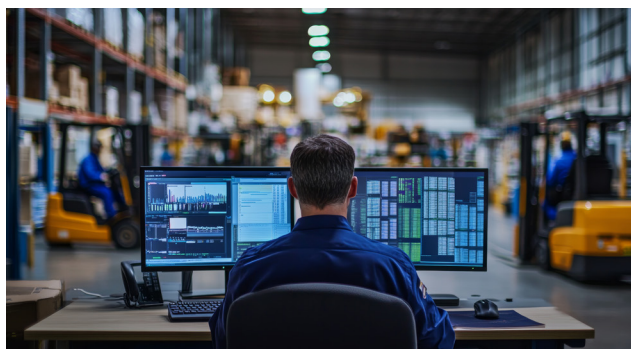


III. IMPROVING INFORMATION SHARING AND SUPPLY CHAIN MONITORING PROCESSES

Information sharing between the government and industry partners is a cornerstone of effective supply chain resilience and public health disaster response capacity. Public-Private Partnerships (PPPs) play an important role in giving the government insight on the state of play in the industry to enable informed policymaking that creates more resilient supply chain. Current information sharing structures lack elements that could make them more effective, both in steady-state operations and emergency scenarios. The lack of two-way information sharing significantly limits industry visibility and responsiveness while impeding trust growth between partners. Policymakers should prioritize changes to the information sharing framework to improve their own visibility and enable quicker industry response.

Steady-State Information Sharing

Steady-state operations represent the bulk of supply chain activities, and establishing a robust information sharing framework for normal operating conditions is required to maintain resilience and provide awareness in advance of potential supply chain disruptions. Distributors and other industry players can provide qualitative information to the U.S. government during steady-state operations to inform national strategy and build understanding of future challenges. PPPs enable partners to overcome hurdles such as business sensitivities, antitrust concerns, data privacy laws and data volume, facilitating a more robust private sector response capacity. Existing PPPs, such as the Supply Chain Control Tower (SCCT) framework, provide a blueprint for success and a foundation to build additional information sharing capacity.³⁷



Access to accurate information concerning the state of supply chain and response capabilities is critical for the maintenance of supply chain resilience during steady-state operations. Actors across the healthcare industry can access important data necessary to inform a holistic view of the supply chain's current state, including purchase, shipping and sales data, site-level inventory reporting, and location-based data.³⁸ During the COVID-19 pandemic, the SCCT framework made significant progress to collect this information to inform policymakers. Partners shared information on a weekly basis, enabling a consolidated approach to supply chain stability and enhancing end-to-end visibility for industry partners. Information sharing under these programs has been discontinued since the return to steady-state operations; however, significant opportunity exists to use the SCCT framework and its complementary PPPs to enhance information sharing and supply chain resilience.

PPP development and resourcing should be a focus during steady-state operations to facilitate the sharing of vital information and build an integrated network to support supply chain resilience. Effective PPPs require sustained funding, jointly agreed upon goals, collaborative decision making, nonhierarchical structures and horizontal processes, strong cooperation and transparency, and shared accountability.³⁹ PPPs should leverage these tenets to improve information transfer during steady-state operations. The SCCT framework could also be improved by tailoring outputs to industry players to ensure they are filling blind spots, sharing the nuances of healthcare data with federal staff, and creating a central repository for data flows backed by standardized universal product codes.⁴⁰

³⁷ Healthcare Distribution Alliance. "Enhancing Resilience: Recommendations to Achieve a Safer and Secure Pharmaceutical Supply Chain." 2024. <https://www.hda.org/getmedia/f8a57f40-49d1-419b-b595-db0ba83c878d/Supply-Chain-Resilience-Report.pdf>.

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

³⁹ Healthcare Distribution Alliance. "Leveraging Public-Private Partnerships to Strengthen the Nation's Healthcare and Public Health Sectors." 2023. [Leveraging-PPPs-to-Strengthen-Nations-HC-and-PH-Sectors_Oct2025.pdf](https://www.hda.org/getmedia/38b4ad3e-1164-4ef5-9516-963f7dbfb048/HDA-Data-Illumination-Report.pdf).

⁴⁰ Healthcare Distribution Alliance. "Healthcare Supply Chain Resilience and Data Illumination." 2023. [HDA-Data-Illumination-Report.pdf](https://www.hda.org/getmedia/38b4ad3e-1164-4ef5-9516-963f7dbfb048/HDA-Data-Illumination-Report.pdf).



Enhanced Information Sharing in a Public Health Emergency

While information sharing is important during steady-state operations, it becomes more critical during public health emergencies. Access to up-to-date data is essential for decision makers, distributors and industry partners to maintain supply chain resilience and respond quickly to disruptions. During the COVID-19 pandemic, PPPs such as Project Airbridge and the SCCT framework were created to address urgent shortages. These PPPs should be expanded and codified to ensure a prompt response to supply chain disruptions caused by future public health emergencies. Currently, the SCCT does not facilitate two-way communication or collect information from direct care providers, API manufacturers, managed care organizations and non-hospital healthcare facilities. These functions would be critical during a national health emergency. Industry partners require clarity on expectations, data use and reciprocal benefits to ensure beneficial partnerships.

Existing PPPs could be expanded to ensure processes for increased information sharing are in place in case of a public health emergency. This expansion must include robust data sharing agreements (DSA) between the government and key industry players. Recent public health emergencies illustrated the importance of pre-established DSAs to govern information sharing, as a lack of pre-existing agreements led to more ad-hoc data requests and impromptu supporting agreements that heavily burdened the industry.⁴¹ DSAs established in advance could mitigate these issues by clearly outlining the types of data needed during a public health emergency, enabling more rapid coordination between the government, distributors, and industry partners and lessening supply chain disruptions.

Two-way communication represents a key component of effective information sharing during a public health emergency, as it enables private sector partners to access information pertaining to demand surges and end-to-end tracing of healthcare products.⁴² Current gaps in PPPs lead to information blind spots for distributors and private partners that reduce visibility of potential supply chain disruptions and lengthen response times. DSAs that support two-way communication would produce more agile private partners empowered by government assessments on supply chain threats and vulnerabilities. Information from across the healthcare industry is also crucial for bolstering supply chain resilience during a public health emergency, and currently, significant gaps exist in the information collected from direct care providers, API manufacturers, managed care organizations and non-hospital healthcare facilities.⁴³ These gaps lead to blind spots for both policymakers and private partners, harming decision-making and reducing the efficacy of coordinated responses to supply chain disruptions. DSAs put into place with these organizations prior to a public health emergency would enable policymakers and private partners to predict and address supply chain disruptions more efficiently.

⁴¹ Iqvia Institute for Human Data Science. "U.S.-India Medicine Partnership." 2024. <https://www.ipa-india.org/sites/default/files/2025-07/IQVIA-US-India-Medicine-Partnership.pdf>.

⁴² Healthcare Distribution Alliance. "96th Edition HDA Factbook: The Facts, Figures and Trends in Healthcare." 2025. <https://hda.org/publications/96th-edition-hda-factbook-the-facts-figures-and-trends-in-healthcare/>.

⁴³ Healthcare Distribution Alliance. "HDA Statement on Proposed Tariffs of Pharmaceutical Products." 2025. <https://www.hda.org/newsroom/2025/february/hda-statement-on-proposed-tariffs-of-pharmaceutical-products/>.

Clarifying expectations, data use and the reciprocal benefits of PPPs during public health emergencies is essential to building trust with private partners and ensuring mutually beneficial collaborations that strengthen supply chain resilience. Establishing DSAs in advance would support this clarity, and publishing federal analyses of vulnerabilities, threats and issues identified through PPP data would further enhance transparency and visibility.⁴⁴ Opportunities exist to remove or reduce other cumbersome barriers to effective collaboration on data sharing, such as provisions in the Sherman Antitrust Act that impede information sharing.⁴⁵ Acting to eliminate or reduce impediments by modifying existing regulations would facilitate increased inter-industry collaboration and benefit government and industry partners.

Recommendations



Establish clear definitions of “steady-state” and “incident” conditions. Clear definitions enable data sharing agreements that identify thresholds for enhanced information sharing procedures between the U.S. government and private sector partners.



Leverage and expand existing public-private partnerships. Use existing government-led working groups to examine existing information sharing mechanisms and update procedures as needed to ensure clear expectations for private sector partners to share data in emergency situations and what the U.S. government will provide back to industry.



Establish clear data sharing agreements. Data sharing agreements put in place prior to public health emergencies significantly improve the speed and quality of data sharing. They can also facilitate two-way communication that improves visibility for industry partners.

⁴⁴ Ibid.

⁴⁵ United States National Archives. “Sherman Anti-Trust Act (1980).” 2022. <https://www.archives.gov/milestone-documents/sherman-anti-trust-act>.

IV. COORDINATING STOCKPILING AND NATIONAL EMERGENCY RESPONSE EFFORTS

Coordination between the government and industry players is important to maintain a robust national emergency response capacity. Distributors, manufacturers, providers and other key industry players play crucial roles in the aftermath of a public health emergency. Integrating these partners into federal, state and local emergency response via PPPs can improve response times and outcomes. Industry guidance and cooperation are also key to long-term disaster planning, such as stockpiling. Distributors have the expertise to source critical medical supplies on regular intervals, enabling larger stockpiles that are rotated regularly to ensure medications are up to date. Policymakers should establish agreements to integrate industry players into these processes to improve efficiency and response capacity.

Integration of Distributors into Federal, State and Local Emergency Response

Integrating distributors into emergency response mechanisms is crucial to successfully addressing supply chain disruptions. These disruptions can be supply-side, rooted in upstream disruptions to manufacturing processes, quality issues and raw material or API shortages, or demand side, stemming from legitimate demand or “hoarding” practices related to disaster or non-disaster-related medical surges.⁴⁹ Healthcare distributors play a critical role in ensuring pharmaceuticals and medical products get from the supplier to the point of care when suppliers are particularly vulnerable to disruptions caused by natural disasters, cyberattacks and geopolitical events. Cross-sector working groups and information sharing are useful mechanisms for fostering integration. Distributors and their suppliers should be integrated into specific, actionable response plans.⁵⁰

Supply-side supply chain disruptions can arise quickly from unforeseen events and stress the entire supply chain. Production capability for critical medical products is often concentrated in one geographic location, making disruptions stemming from crises in these regions particularly critical. For example, Hurricane Maria devastated Puerto Rico in 2017, which had significant impacts for U.S. medical supply chain as a number of critical medical products were produced solely or primarily on the island.⁵¹ At the time, around eight percent of medicines taken



Hurricane Helene

In late September 2024, Hurricane Helene made landfall in the southeastern U.S. and progressed along the East Coast, eventually causing severe flooding in Western North Carolina. Floodwaters permeated Baxter's North Cove, N.C. facility, which produced 60 percent of the U.S. supply of IV fluid and peritoneal dialysis solutions.⁴⁶ Flooding closed production and damaged supplies held in the facility, triggering a national shortage.⁴⁷

Baxter coordinated with the FDA and the Department of Health and Human Services (HHS) to temporarily import products from five international facilities. The North Cove facility was not fully operational until February 2025. The FDA announced in August 2025 that the national shortage of saline products had ended.⁴⁸

⁴⁶ HealthExec. “Fda Confirms End To Iv Saline Shortage Caused By Hurricane Helene.” 2025. <https://healthexec.com/topics/healthcare-management/healthcare-logistics/fda-confirms-end-iv-saline-shortage-caused-hurricane-helene>.

⁴⁷ U.S. Food and Drug Administration. “A Statement from FDA Commissioner Marty Makary, M.D., M.P.H.: Announcing Resolution of the IV Saline Solutions Shortage.” 2025. <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-marty-makary-md-mph-announcing-resolution-iv-saline-solutions-shortage>.

⁴⁸ U.S. Food and Drug Administration. “Update on Baxter's North Cove, NC Facility.” 2024. <https://www.fda.gov/media/182564/download>.

⁴⁹ Healthcare Distribution Alliance. “Understanding Drug Shortages: An Overview and Recommendations.” 2024. https://www.hda.org/getmedia/2d816602-0c28-46c6-a52f-d1d36c094cd9/Understanding-Drug-Shortages-D2_110824.pdf.

⁵⁰ Healthcare Distribution Alliance. “HDA Guiding Principles for Increasing Supply Chain Resilience.” 2023. <https://www.hda.org/getmedia/2d816602-0c28-46c6-a52f-d1d36c094cd9/Resilience-Principles.pdf>.

⁵¹ Healthcare Distribution Alliance. “Bolstering Disaster Preparedness and Operational Resilience in the Healthcare Supply Chain.” 2023. <https://www.hda.org/getmedia/f13bb354-88eb-494e-81ca-2456ea4d795c/Bolstering-Disaster-Preparedness-and-Operational-Resilience-in-the-Healthcare-Supply-Chain.pdf>.



by Americans by dollar value were manufactured in Puerto Rico, in addition to critical medical devices like insulin pumps and pacemakers.⁵² Dependencies like this highlight the need for a well-formulated disaster response plan that integrates distributors.

Distributors possess advanced knowledge of supply chain operations, which are critical for rapid disaster response and mitigation. They offer a streamlined, secure and highly efficient supply chain experience by acting as a single point of contact for multiple manufacturers, simplifying procurement and reducing administrative burden.⁵³ The ability to rapidly source medical supplies from alternative suppliers in the wake of a disaster ensures that there is no disruption

in care. After Hurricane Maria, the FDA sourced alternative intravenous (IV) solutions and antibiotics from other nations, such as Australia and Ireland.⁵⁴ Integrating distributors into disaster response plans — such as Climate Action Preparedness Plans (CAPPs) — leverages their expertise in sourcing from broad supplier networks, enabling rapid and cost-effective procurement of replacement medical supplies.

Investing in Domestic Production and Maintaining Diverse Supply Chain

Domestic production capacity of key MCMs is essential to maintaining resilient supply chain in the face of potential disruptions. Geopolitical events, natural disasters and economic instability can have devastating impacts on offshore partners' ability to meet demand, and a robust domestic production capability offers increased flexibility. In 2021, 87 percent of facilities manufacturing generic APIs for the U.S. market were outside of the country.⁵⁵ This represents a significant concentration of pharmaceutical production outside the United States, highlighting the importance of strengthening domestic capacity while maintaining geographically diverse supplier networks. Despite the need for increased domestic production, key challenges remain. Significant investment is needed to produce the specialized facilities, personnel and manufacturing equipment required to produce APIs, KSMs and MCMs.

Increased domestic production capacity can still be supplemented by diverse international suppliers. Relying on a mix of suppliers is key to maintaining supply chain resilience, as it reduces the impact that any event can have and enables rapid pivots to alternative suppliers when capacity is damaged in one area.⁵⁶ Economic incentives can encourage a broader and more geographically diverse supplier base for critical medical supplies, reducing single points of failure while strengthening overall supply chain resilience.

⁵² Scientific American. "Hurricane Maria Takes a Toll on Global Medical Supplies." 2017. <https://www.scientificamerican.com/article/hurricane-maria-takes-a-toll-on-global-medical-supplies/>.

⁵³ Healthcare Distribution Alliance. "2025 Specialty Pharmaceutical Distribution Facts, Figures and Trends." 2025. [HDA Publications - 2025 Specialty Pharmaceutical Distribution Facts, Figures and Trends | HDA](#)

⁵⁴ Ibid.

⁵⁵ Mitchell, Andrew. "The Geography of Health: Onshoring Pharmaceutical Manufacturing to Address Supply Chain Challenges." World Trade Review. 2024. <https://www.cambridge.org/core/journals/world-trade-review/article/geography-of-health-onshoring-pharmaceutical-manufacturing-to-address-supply-chain-challenges/120B2E49D4D0CA475F00944F9ACE6172>.

⁵⁶ Healthcare Distribution Alliance. "Enhancing Resilience: Recommendations to Achieve a Safer and Secure Pharmaceutical Supply Chain." 2024. <https://www.hda.org/getmedia/f8a57f40-49d1-419b-b595-d80ba83c878d/Supply-Chain-Resilience-Report.pdf>.

Support for the Strategic National Stockpile (SNS), Regional and State-level Stockpiles

The SNS provides a crucial lifeline for suppliers and distributors to adjust during national emergencies. The MCMs contained in the SNS can be used as a short-term solution when supply chain are facing a catastrophic health emergency, as they have during major public health emergencies and other disasters.⁵⁷ In addition to providing stop-gap capacity, the SNS is a critical provider of MCMs that do not have a commercial market, such as the smallpox vaccine.⁵⁸ This combination of capabilities makes the SNS an essential component of supply chain resilience. Distributors have the expertise to bolster the SNS and ensure it remains capable of supporting a coordinated response to public health emergencies.

In addition to optimizing the SNS, the federal government should prioritize the development of the Strategic Active Pharmaceutical Ingredients Reserve (SAPIR) with APIs and critical drug components. Currently, only roughly 10 percent of APIs are manufactured domestically, creating a key foreign dependency.⁵⁹ Distributors could help identify which critical APIs should be stocked and adopt a model that extends inventory levels from the current 28-day standard to six months for MCMs.⁶⁰ Expiration concerns could be managed by fulfilling new orders with stockpiled products and replacing them concurrently.

Regional and state-level stockpiles can help mitigate localized supply chain disruptions or disasters that do not require SNS intervention. Distributors have the expertise to manage these stockpiles, continually rotate products and maintain a reliable supply of important medical supplies and devices.⁶¹ Government investment will be required to leverage this expertise, as stockpiling is extremely resource intensive and requires specialized facilities and equipment. Partnerships between distributors, other supply chain actors (such as manufacturers and providers), and the government could produce a reliable network of stockpiles ready to meet the need for medical supplies during public health emergencies.

Recommendations



Implement market-based incentives and payment reforms to diversify supply chain. Existing manufacturers' capacity should be expanded and made more economically viable, particularly for low-margin but essential medicines.



Enhance supplies in the SNS and expand stockpiling investments in partnership with the private sector. This includes maintaining SAPIR and exploring innovative technological solutions to provide connectivity between the U.S. government and private sector partners.

⁵⁷ Administration for Strategic Preparedness and Response. "Stockpile Responses." 2025. <https://aspr.hhs.gov/SNS/Pages/Stockpile-Responses.aspx>.

⁵⁸ Healthcare Distribution Alliance. "The Strategic National Stockpile: Safeguarding Rx Supply Chain Resilience for National Security." 2025. <https://www.hda.org/getmedia/e36e8ad4-377b-483d-9498-8a1ef2d20165/HDA-Factsheet-The-Strategic-National-Stockpile.pdf>.

⁵⁹ The White House. "President Donald J. Trump Ensures American Pharmaceutical Supply Chain Resilience by Filling the Strategic Active Pharmaceutical Ingredients Reserve." 2025. <https://www.whitehouse.gov/fact-sheets/2025/08/fact-sheet-president-donald-j-trump-ensures-american-pharmaceutical-supply-chain-resilience-by-filling-the-strategic-active-pharmaceutical-ingredients-reserve/>.

⁶⁰ Healthcare Distribution Alliance. "Strengthening the Strategic National Stockpile for the Future." 2025. <https://www.hda.org/perspectives/2020/strengthening-the-strategic-national-stockpile-for-the-future/>.

⁶¹ Healthcare Distribution Alliance. "Enhancing Resilience: Recommendations to Achieve a Safer and Secure Pharmaceutical Supply Chain." 2024. <https://www.hda.org/getmedia/f8a57f40-49d1-419b-b595-d60ba83c878d/Supply-Chain-Resilience-Report.pdf>.

V. CONCLUSION

Pharmaceutical supply chain are critical to U.S. national security and face a growing number of threats. They require support from policymakers to ensure distributors and their counterparts can maintain and enhance supply chain resilience. It is critical that policymakers account for the complexities and nuances of healthcare supply chain when shaping national security and economic policies. These recommended actions can address several existing challenges facing healthcare distributors and their partners in healthcare supply chain. Policymakers should consider these actions to be investments in U.S. public health and U.S. national security and a shield against an increasingly unpredictable threat environment.

POLICY RECOMMENDATIONS

- 1 **Invest in increased supplies of critical medicines in the U.S. healthcare supply chain.** Leverage existing, unused capacity in domestic manufacturing facilities to increase U.S. government spending on supplies of generic pharmaceuticals and distribution capacity to increase overall domestic supply chain resilience.
- 2 **Develop and test crisis playbooks.** Develop emergency response playbooks to specifically test healthcare supply chain capacity and capabilities and test those playbooks in realistic, government-facilitated tabletop and functional exercises with participation from manufacturers, distributors and all relevant federal, state and local governments. Include scenarios featuring supply chain disruptions in the U.S. and overseas.
- 3 **Address supply chain dependencies.** Identify and assess dependencies for prioritized pharmaceutical products, including APIs, KSMs, and FDFs, to identify vulnerabilities, reduce single points of failure, and inform risk-based resilience investments.
- 4 **Enhance public and private sector coordination mechanisms between critical infrastructure sectors.** Hold regional government-led workshops to identify and address cross-sector supply chain vulnerabilities and strengthen steady-state and incident coordination among U.S. critical infrastructure Sector Risk Management Agencies (SRMAs), relevant state and local partners, and private sector manufacturers and distributors.
- 5 **Re-authorize the Pandemic and All-Hazards Preparedness Act (PAHPA).** The PAHPA framework provides the foundation for the resilience of the U.S. healthcare system. A comprehensive reauthorization of PAHPA would ensure the long-term stability of the federal programs that support public health during crises and the national security functions that depend on resilient healthcare services.
- 6 **Exempt pharmaceutical products from broad tariffs.** Exempt pharmaceuticals, APIs and KSMs from broad tariffs to avoid supply disruptions and gradually phase in potential tariffs on healthcare products in alignment with increased domestic production capacity for prioritized products.
- 7 **Invest in domestic production for prioritized critical products.** Increase federal investment in domestic production for specific, prioritized APIs, KSMs and FDFs that are critical to support national security and public health during a potential public health emergency, while complementing existing global supplier networks, accounting for existing foreign dependencies, and strengthening overall supply chain resilience.
- 8 **Ensure national policies account for impacts to pharmaceutical distributors.** Ensure that economic policies account for downstream impacts on distributors, including how reimbursement and demand shifts affect their ability to maintain inventory, logistics capacity and emergency response readiness.

- 9 **Establish clear definitions of “steady-state” and “incident” conditions.** Clear definitions enable data sharing agreements that identify thresholds for enhanced information procedures between the U.S. government and private sector partners.
- 10 **Leverage and expand existing public-private partnerships.** Use existing government-led working groups to examine existing information sharing mechanisms and update procedures as needed to ensure clear expectations for private sector partners to share data in emergency situations and what the U.S. government will provide back to industry.
- 11 **Establish clear data sharing agreements.** Data sharing agreements put in place before public health emergencies significantly improve the speed and quality of data sharing. They can also facilitate two-way communication that improves visibility for industry partners.
- 12 **Implement market-based incentives and payment reforms to diversify supply chain.** Existing manufacturer capacity should be expanded and made more economically viable, particularly for low-margin but essential medicines.
- 13 **Enhance supplies in the SNS and expand stockpiling investments in partnership with the private sector.** This includes creating a Strategic Active Pharmaceutical Ingredient Reserve (SAPIR) and exploring innovative technological solutions to provide connectivity between the U.S. government and private sector partners.



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GLOSSARY

Active Pharmaceutical Ingredients (APIs): Any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body.

Cold Chain: A temperature-controlled supply chain that includes all vaccine-related equipment and procedures. The cold chain begins with the cold storage unit at the manufacturing plant, extends to the transport and delivery of the vaccine and proper storage at the provider facility, and ends with administration of the vaccine to the patient.

Critical Infrastructure: The assets, systems and networks, whether physical or virtual, that are considered so vital to the U.S. that their incapacitation or destruction would have a debilitating effect on security, national economic security, national public health or safety, or any combination thereof.

Data Sharing Agreements (DSAs): A legally binding agreement that outlines the conditions under which data is exchanged between two or more parties.

Finished Dosage Forms (FDFs): A tablet, capsule or solution that contains at least one active pharmaceutical ingredient, generally, but not necessarily, in association with other ingredients in finished package form suitable for distribution to pharmacies, hospitals, or other sellers or dispensers of the drug product to patients or consumers.

Incident: An occurrence, natural or manmade, that necessitates a response to protect life or property. Examples include, major disasters, emergencies, terrorist attacks, terrorist threats, wild and urban fires, floods, hazardous materials spills, nuclear accidents, aircraft accidents, earthquakes, hurricanes, tornadoes, tropical storms, war-related disasters, public health and medical emergencies, cyberattacks and other occurrences requiring an emergency response.

Key Starting Materials (KSMs): Chemical compounds used early in the synthesis of APIs.

Medical Countermeasures (MCMs): FDA-regulated products (biologics, drugs, devices) that may be used in the event of a potential public health emergency stemming from a terrorist attack with a biological, chemical, or radiological/nuclear material, or a naturally occurring emerging disease.

Medical Industrial Base: The extensive and interconnected network of entities involved in the delivery of healthcare, including pharmaceutical manufacturers, distributors and healthcare providers.

Pharmaceutical Supply Chain Resilience: The capability among entities in the pharmaceutical supply chain (manufacturers, distributors and providers) to prepare for, withstand, respond to and recover from planned and unplanned disruptions to the supply chain for pharmaceutical production, distribution and use.

Public-private Partnerships (PPPs): Cooperative efforts between public, private and nonprofit actors to split resources and decision-making abilities and work toward specific outcomes in both steady-state and crisis conditions.

Sector Risk Management Agencies (SRMAs): A federal department or agency with responsibility for providing institutional knowledge and specialized expertise as well as leading, facilitating or supporting the security and resilience programs and associated activities of its designated critical infrastructure sector in the all-hazards environment.

Steady-state: Routine pharmaceutical supply chain operations, including seasonal fluctuations in influenza, RSV, and respiratory infections in the absence of a specific, acute increase or decrease in supply or demand for pharmaceutical products.

Strategic Active Pharmaceutical Ingredient Reserve (SAPIR): A federal program established to stockpile APIs to ensure domestic supply of essential medicines, strengthen domestic supply and to mitigate supply chain vulnerabilities.

Strategic National Stockpile (SNS): A federal program designed to provide medical supplies and pharmaceuticals during public health emergencies, ensuring that states have access to critical resources when local supplies are insufficient.

Supply Chain Control Tower (SCCT): A public-private partnership between the Department of Health and Human Services (HHS), other federal agencies and private-sector companies. It was developed during the COVID-19 pandemic to facilitate supply chain visibility, inform decision-making — and was a key tool used to ensure that the pharmaceutical supply chain remained resilient under the pressures of a global pandemic. The SCCT aggregates voluntarily shared data and commercially available distribution information.