

HDA Policy Agenda on Drug Shortages

(Updated 2/23/24)

As the vital link in the healthcare supply chain, distributors ensure the safe, efficient and reliable delivery of medications, vaccines, and other critical medical products. Every day, distributors continuously and reliably connect [1,500 manufacturers to 330,000 sites of care](#),¹ while maintaining a [0.4 percent net profit margin \(after taxes\)](#).² Because pharmaceutical distributors handle [95 percent](#) of the medicines that move through the supply chain to patients,³ they are uniquely positioned to understand the issues affecting supply chain resilience, such as drug shortages. Overall, the supply chain is highly efficient and effective with drug shortages only occurring in one percent of products. When considering the issue of drug shortages, policies must protect the integrity of the 99 percent of the supply chain that is working.

While only a small fraction of drugs are impacted by shortages, when they do occur, drug shortages pose challenges to the entire supply chain, including healthcare systems and patients. The Healthcare Distribution Alliance (HDA) and its members have developed the following policy agenda to address drug shortages.



Federal Coordination

Distributors have some insight into upstream availability and downstream provider needs, but it is by no means comprehensive. Other private sector stakeholders in the supply chain as well as federal regulatory authorities hold insights that can complement distributor insights to provide more visibility into the pharmaceutical supply chain. Federal agencies such as the U.S. Food and Drug Administration (FDA) and the Administration for Strategic Preparedness and Response (ASPR), along with health-system group purchasing organizations (GPOs) and manufacturers can complement the insights distributors have into the supply chain. Supply chain partners working collaboratively with federal agencies could help improve understanding and visibility of supply and demand challenges and work together to mitigate the impact of drug shortages.

Early Warning Partnership: Bolster a voluntary partnership between supply chain stakeholders and relevant federal partners (FDA, ASPR), to better detect and coordinate responses to identified drug shortages. An early warning partnership would increase visibility into the pharmaceutical supply chain to anticipate future drug shortages. This partnership would complement the work distributors already do with the FDA and ASPR to provide insights into the supply chain.

- The parameters of this partnership would be established with supply chain stakeholders to define and ensure the scope of the partnership, expected actions and indications of a potential shortage.

- All information exchanged would be confidentially held by federal partners until there is agreement across all partners to share information within the pharmaceutical supply chain. (This avoids the risk of sharing information prematurely, which may trigger disruptive purchasing behaviors such as hoarding.)
- The partnership should employ a [bidirectional system](#)⁴ for data-sharing, collaboration and information. This will enhance data flow and transparency for all partners.
- This partnership should leverage existing systems and utilize data analysis as needed.

Support Appropriations: Advocate for necessary FDA, Centers for Disease Control and Prevention (CDC) and ASPR appropriations.

- Support for these appropriations will enhance the abilities of the CDC, FDA and ASPR to fund programs to inspect foreign manufacturing facilities, mitigate drug shortages and support programs to provide advanced warning to demand-driven shortages. It is crucial that federal agencies have the appropriate resources to safeguard and ensure the safety of the nation’s pharmaceutical and medical supply chains.

Strategic Investment

Strategic federal investments will help diversify the pharmaceutical supply chain for products that support national security while decreasing the risk of a drug shortage.

Federal Investment in Manufacturing: Federal investments to address drug shortages should focus on products with a strategic interest in reshoring production capabilities for active pharmaceutical ingredients, key starting materials and finished dose medicines to the United States.

- These federal investments should be enduring, with a plan to ensure buyers of the product through available federal programs (U.S. Department of Defense, U.S. Department of Veterans Affairs or federal stockpiles).
- Federal investments should include investments in domestic manufacturing to create supply chain redundancies and proactively address geopolitical risks.

Strategic Inventory: Federal investments employing public-private partnerships (PPPs) to strategically increase inventory of medicines should be considered as a tool to increase supply of product on hand, specifically for products that would need to be used during medical surges, such as the seasonal cold and flu season. Strategically increasing inventory through vendor managed inventory (VMI) contracts can help mitigate the impact of drug shortages, in addition to helping [stabilize prices and addressing national security](#) issues. Federal investments in strategic inventory expansion would be beneficial in the following ways:

- Strategic inventory should allow products to be rotated through the commercial supply chain using the existing operations of pharmaceutical distribution channels as VMI to acquire, manage product expirations and replenish the supply of medicines that have historically been in shortage.
- Investments in strategic inventory bolster the role and effectiveness of PPPs and expand the strategic inventory capacity.
- Creating additional strategic inventories to utilize when supply-driven shortages arise would complement, rather than duplicate, the existing Strategic National Stockpile (SNS). Distributors can operate highly efficient perpetual inventory models to cycle medicines, prevent expiration and ensure supply chain disruptions.

- We encourage any strategic inventory investments to also ensure equitable access to products. If policies such as establishing and maintaining a buffer inventory to increase the amount of product on hand for facilities (such as physician offices, pharmacies, hospitals and health-systems) are considered, we encourage the proposals to include input and considerations from the pharmaceutical supply chain, specifically distributors and manufacturers. Buffer inventory must require coordination and transparency to ensure it does not exacerbate existing shortages or create further supply chain disruptions.

Stabilizing the Generic Supply Chain From End to End

Economic policies to address drug shortages must acknowledge the financial strain stakeholders face. Financial pressures affect the entire pharmaceutical supply chain and in some cases, in an unsustainable way. Upstream (manufacturers, distributors) and downstream (healthcare facilities, providers) stakeholders operate in a complex environment with ongoing pressure from trading partners and payers to lower expenditures.

Preventing Market Failures: It is imperative that policies intended to lower the price of medicines for patients do not do so at the expense of a viable generic manufacturing industry. While the last four decades of policy have effectively lowered the cost of medicines, some products are now priced too low, resulting in an unsustainable market for manufacturers and greater instability in the global supply chain. Any policies put forward to address drug shortages should:

- Review the outcomes of the current policy to lower drug prices and increase the number of generic medicines (i.e., Generic Drug User Fee Amendments [GDUFA] II) in the market. Also, review opportunities for additional federal investment for the FDA

to conduct foreign inspections of generic facilities. A National Academy of Medicine study should be conducted to review the impact of policies to increase the number of abbreviated new drug applications (ANDAs) on the generic market.

- Centers for Medicare and Medicaid Services (CMS) and FDA should coordinate to review the number of suppliers for any given generic drug to determine if additional manufacturing entrants would potentially destabilize the marketplace and push price beyond sustainable levels.

Rebates: Alleviate rebate obligations and inflation penalties for generic drugs prone to shortages and specific medical products deemed vulnerable to shortage or disruption.

- Alleviating rebate obligations in certain federal programs will increase revenues for multi-source drugs at risk of shortage faced in a highly competitive market. This relief will reduce deflationary pressures on manufacturers and create a more sustainable market for those products.

Reimbursement: Adjust reimbursement policies to increase provider reimbursement to alleviate downward pressure on healthcare facilities.

- Higher reimbursement for providers may remove upstream pressure that affects downstream stakeholders while acknowledging complexities in provider reimbursement.
- Higher reimbursement may also help alleviate drug shortages by allowing providers to consider factors outside of price when purchasing. Low reimbursement drives providers to seek the lowest price possible when buying medicines.

For additional HDA materials and information on drug shortages, visit:
<https://www.hda.org/drug-shortages/>.

Endnotes

- 1 Healthcare Distribution Alliance. "Delivering Value Across Healthcare." 2023. <https://www.hda.org/getmedia/807f7717-3a3a-4e8a-9011-2c8a91502dec/hda-factsheet-deliveringvalueacrosshealthcare-2023.pdf>.
- 2 HDA Research Foundation. *94th Edition HDA Factbook: The Facts, Figures and Trends in Healthcare*. 2023. <https://www.hda.org/publications/94th-edition-hda-factbook-the-facts,-figures-and-trends-in-healthcare/>.
- 3 Healthcare Distribution Alliance. "Delivering Pharmaceuticals and Value to Healthcare." 2023. https://www.hda.org/getmedia/4e490d25-762b-433a-aea4-9622e6b7d826/hda-factsheet_delivering-pharmaceuticals-and-value-to-healthcare-v7.pdf.
- 4 A bidirectional system would increase visibility for both private sector and government stakeholders. In a bidirectional system the private sector and government would transmit and receive information.

About the Healthcare Distribution Alliance

The Healthcare Distribution Alliance (HDA) represents primary pharmaceutical distributors — the vital link between the nation's pharmaceutical manufacturers and pharmacies, hospitals, long-term care facilities, clinics and others nationwide. Since 1876, HDA has helped members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently. The HDA Research Foundation, HDA's nonprofit charitable foundation, serves the healthcare industry by providing research and education focused on priority healthcare supply chain issues.