Healthcare Distribution Alliance
HEALTH DELIVERED

**Chester "Chip" Davis, Jr.,** President and Chief Executive Officer

March 28, 2025

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

*Submitted via email*

Dear Commissioner Makary:

On behalf of the Healthcare Distribution Alliance (HDA), congratulations on your confirmation as Commissioner of the Food and Drug Administration (FDA). We look forward to working with you and your team over the coming years to protect and preserve the U.S. pharmaceutical supply chain.

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.

As the backbone of the pharmaceutical supply chain, HDA members safely and securely distribute 95 percent of medicines sold in the United States to approximately 330,000 sites of care daily, including local community and retail pharmacies, health systems, physician clinics, and many others.[1] In doing so, pharmaceutical distributors provide a wide array of supporting services that enable the supply chain to function efficiently and safely. Importantly, pharmaceutical distributors' 360-degree view of the healthcare supply chain enables them to respond to the most pressing issues facing the nation, including drug shortages, as well as the safety and security of the supply chain. Our industry is committed to improving access to safe, affordable pharmaceutical products for patients regardless of their address, providing an estimated $63 billion in cost savings to the U.S. healthcare ecosystem each year.[2]

***We look forward to continuing our work with FDA to secure, strengthen, and safeguard the nation's healthcare infrastructure and pharmaceutical supply chain.***

## I. Securing America's Supply Chain Through Implementation of the Drug Supply Chain and Security Act

Pharmaceutical distributors prioritize the security and integrity of the supply chain against dangerous counterfeit and substandard medicines. In advancing that priority, HDA members have played a leading role in prescription drug traceability and licensure matters for two decades. Included in this work was the support for, and passage of, the Drug Supply Chain Security Act (DSCSA), which fundamentally changed the way pharmaceutical products and their associated data move in tandem

[1] HDA, *available at* https://www.hda.org/.
[2] HDA, Ensuring Safe and Affordable Healthcare for All Americans, *available at* https://www.hda.org/drug-pricing/#:~:text=Cost%20Savings%20for%20the%20U.S.%20Healthcare%20Ecosystem&text=With%20pharmaceutical%20distributors%20providing%20an,patients%20regardless%20of%20their%20address.

through the pharmaceutical supply chain, establishing a mechanism to more efficiently identify and prohibit counterfeit medicines in the supply chain.[3]

In advancing the implementation of this law, FDA's decision to grant exemptions over the next year to eligible trading partners for the final traceability requirements has provided stakeholders with critical flexibility to refine their data exchange processes. Yet, as the implementation deadlines approach, continued collaboration and open communication with the FDA will be essential to ensure a smooth and effective implementation of the law.

The DSCSA also provides a mechanism to establish important standards by which pharmaceutical distributors are licensed to handle Americans' medicines. To that end, distributors continue to anticipate the finalization of the National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers Proposed Rule,[4] recognizing its critical role in establishing uniform regulatory requirements across the supply chain. We are committed to leading efforts for high-quality standards for distributors and urge FDA to finalize the proposed rule so that those efforts can progress.

Importantly, we are prepared to continue advancing this work with FDA, building on HDA's long-standing collaboration with FDA leadership and personnel in Center for Drug Evaluation and Research (CDER), including the Office of Compliance and Office of Drug Security, Integrity, and Response (ODSIR). These teams play a crucial role in our shared efforts, supporting the significant investments our members have made over the years to enhance supply chain security and patient safety.

## II. Strengthening and Safeguarding America's Supply Chain Through Addressing Drug Shortages

Drug shortages pose one of the more acute challenges to the U.S. pharmaceutical supply chain. Shortages can often be categorized as either manufacturer/supply-driven or consumer/demand-driven. Supply-driven shortages are triggered by unavailability of raw materials or active pharmaceutical ingredients, manufacturer disruptions, or quality issues at the manufacturer facility. Recent shortages in treatments for COPD (albuterol) and certain cancers (cisplatin) are examples of supply-driven shortages caused by quality issues. In contrast, demand-driven shortages are caused by increases in demand that create a sudden uptick in ordering. For example, a recent surge in telemedicine prescribing for stimulants often used to treat ADHD has led to a sharp spike in demand and a corresponding shortage over the past couple of years.

Unfortunately, there are no immediate or simple solutions to these shortages. Still, pharmaceutical distributors play an integral role in helping to mitigate the impact of drugs shortages. HDA members invest in business strategies and capabilities that help maintain continued provider and patient access. These capabilities include: facilitating the purchase of additional inventory ("buffer stock") for customers, aiding customers with inventory management, identifying, sourcing, and securing product alternatives available to customers, and forecasting future demand of specific products.[5] While these programs do not prevent shortages, they play a significant role in helping providers and patients access the medicines they need.

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[3] HDA, Leading the Industry on Federal Traceability Issues, *available at* https://www.hda.org/pharmaceutical-traceability/.
[4] 87 Fed. Reg. 6708 (Feb. 4, 2022), *available at* https://www.federalregister.gov/documents/2022/02/04/2022-01929/national-standards-for-the-licensure-of-wholesale-drug-distributors-and-third-party-logistics.
[5] HDA, Ensuring Safe, Effective Drugs Are Available to Patients, *available at* https://www.hda.org/pharmaceutical-traceability/.

Further, as the logistics experts of the supply chain, pharmaceutical distributors play a critical role in bolstering long-term resiliency within the pharmaceutical supply chain to combat ongoing and emerging threats, especially those that may impact or undermine national security. To that end, HDA supports federal investments that 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.[6]

Expanding domestic pharmaceutical manufacturing capacity will take time and require substantial investment, infrastructure growth, and corresponding workforce development. Given the long-term nature of these efforts, it is crucial to take a measured approach that supports continued sourcing and production capabilities to prevent further drug shortages. We appreciate the opportunity to engage with your teams and others to advance these initiatives and further strengthen the U.S. pharmaceutical supply chain.

## III. Safeguarding America's Supply Chain Resiliency Through Revising the National Drug Code Format and Adopting Other Label Modernizations

It is well understood that the industry is rapidly running out of available National Drug Codes (NDCs), a challenge that threatens to disrupt pharmaceutical manufacturing, distribution, and patient access to medicines.[7] FDA must move swiftly to finalize the proposal "Revising the National Drug Code Format and Drug Label Bar Code"[8] (the "NDC Rule"). Without timely action, the increasing demand for new drug codes will outpace availability, creating unnecessary bottlenecks in the supply chain.

Further, finalizing the proposal now is essential to safeguarding America's pharmaceutical supply chain resiliency, as it will provide manufacturers, distributors, and dispensers with the necessary time to update their operational systems, adapt labeling and data infrastructure, and ensure a seamless transition to the expanded NDC format. Delayed action will only compress implementation timelines, increasing the risk of operational disruptions and unintended consequences across the supply chain.

Further, outside of the NDC Rule, we urge FDA to promote supply chain resiliency through modernizing how prescribing information is conveyed to physicians and pharmacists. In alignment with the Alliance to Modernize Prescribing Information, we urge FDA to leverage digital platforms and electronic labeling to enable real-time prescribing information updates and reduce waste across the pharmaceutical supply chain.[9]

In sum, HDA emphasizes the importance of securing, strengthening, and safeguarding America's pharmaceutical supply chain. **At your earliest convenience, we would appreciate the opportunity to meet and introduce you to HDA's role in the aforementioned efforts**. Patrick Kelly, Chief Advocacy Officer (pkelly@hda.org), and Kala Shankle, Vice President of Regulatory Affairs (kshankle@hda.org), would be happy to coordinate this on behalf of HDA.

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[6] HDA, Bolstering Resilience to Mitigate Delivery Challenges, *available at* https://www.hda.org/supply-chain-resilience/.
[7] See Regulatory Focus, FDA Begins Preparations for New NDC Coding System, Nov. 5, 2018, *available at* https://www.raps.org/news-and-articles/news-articles/2018/11/fda-begins-preparations-for-new-ndc-coding-system (stating "[t]he NDC is a statutorily created FDA standard for uniquely identifying drugs in the US, and FDA anticipates it will run out of the 5-digit labeler codes in approximately 15 years.").
[8] 87 Fed. Reg. 44038 (July 25, 2022), *available at* https://www.federalregister.gov/documents/2022/07/25/2022-15414/revising-the-national-drug-code-format-and-drug-label-barcode-requirements#:~:text=The%20proposed%20rule%2C%20if%20finalized,a%202%2Ddigit%20package%20code
[9] Alliance to Modernize Prescribing Information, *available at* https://modernizeprescribinginfo.com/about-us/.

We welcome the opportunity to serve as a resource to you and your teams on a wide range of issues that impact the pharmaceutical supply chain. Please do not hesitate to contact me directly by email at cdavis@hda.org or on my direct line at (202) 963-0043.

Sincerely,

Chester “Chip” Davis, Jr.

CC: Jim Traficant, Chief of Staff, Office of the Commissioner