

HEALTH DELIVERED

March 3, 2025

U.S. Department of Health & Human Services Hubert H. Humphrey Building 200 Independence Avenue, SW Washington, D.C. 20201

Submitted via email

Dear Secretary Kennedy:

On behalf of the Healthcare Distribution Alliance (HDA) and our members we offer our congratulations to you on your confirmation as Secretary for the U.S. Department of Health and Human Services (HHS). 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 points of care across the United States. 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.¹ Pharmaceutical distributors purchase prescription medicines, take legal ownership, store and manage inventory, and assume credit risk for supply chain partners. In doing so, pharmaceutical distributors provide the logistics expertise, inventory capacity and technology required to keep pharmacy and hospital shelves stocked with the medicines that patients need. Distributors also 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 working with HHS and the numerous agencies that are essential to securing, strengthening, and safeguarding to the nation's healthcare infrastructure and pharmaceutical supply chain, including the Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services and the Administration for Strategic Preparedness and Response.

Securing America's Supply Chain

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 through the

¹ HDA, available at https://www.hda.org/.

² HDA, Ensuring Safe and Affordable Healthcare for All Americans, available at <a href="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

pharmaceutical supply chain, establishing a mechanism to more efficiently identify and prohibit counterfeit medicines.³ The DSCSA also provides for a mechanism to establish important standards by which pharmaceutical distributors are licensed to handle Americans' medicines. We are prepared to continue advancing this work with your teams within the FDA.

Strengthening America's Supply Chain

Distributors invest in business strategies to prepare and strengthen their capabilities to manage disruptions in the supply chain such as drug shortages by leveraging 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.⁴ These market-based solutions play a significant role in America's continued access to medicines. We value the opportunity to continue discussions with your teams in various agencies on these efforts to further strengthen the U.S. pharmaceutical supply chain.

Safeguarding America's Supply Chain Resiliency

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.⁵ As the logistics experts of the supply chain, 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. Long-term resiliency should be safeguarded through the encouragement and investment of inventory and manufacturing capacity, especially those that promote domestic manufacturing.

As you work to Make America Healthy Again, HDA emphasizes the importance of securing, strengthening, and safeguarding America's pharmaceutical supply chain. 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 Doving.

Chester "Chip" Davis, Jr.

CC: Hannah Anderson, Deputy Chief of Staff, Policy, Department of Health & Human Services Lee Stevens, Office of Intergovernmental and External Affairs

³ HDA, Leading the Industry on Federal Traceability Issues, available at https://www.hda.org/pharmaceutical-traceability/.

⁴ HDA, Ensuring Safe, Effective Drugs Are Available to Patients, available at https://www.hda.org/pharmaceutical-traceability/.

⁵ HDA, Bolstering Resilience to Mitigate Delivery Challenges, available at https://www.hda.org/supply-chain-resilience/.