



Healthcare Distribution Alliance

PATIENTS MOVE US.

November 16, 2020

President-Elect Joseph R. Biden
Presidential Transition Headquarters
Attention: Former Senator Ted Kaufman
1401 Constitution Ave NW
Washington, D.C., U.S.

Dear Senator Kaufman:

On behalf of the Healthcare Distribution Alliance (HDA), I write to congratulate President-elect Joe Biden and Vice President-elect Kamala Harris on their historic victory. We look forward to working with the new administration at this pivotal moment for our country.

HDA is the national trade association representing primary pharmaceutical distributors — the vital link between the nation’s pharmaceutical manufacturers and more than 180,000 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 nation’s primary pharmaceutical distributors play a vital role in the healthcare system. Every day HDA members work around the clock to safely and efficiently ship millions of healthcare products (medicines, medical supplies, durable medical equipment, et al.) to pharmacies, hospitals and other healthcare providers in order to keep their shelves stocked with the medications and products they need to treat and serve their patients. Distributors are unlike any other supply chain participants – their core business is not engaged in manufacturing and they do not prescribe medicines or dispense to patients. Their key role is to serve as a conduit for medicines to travel from manufacturer to patient while making sure the supply chain is fully secure, functional, and as efficient as possible.

There are many challenges that our nation faces, none more immediate than the COVID-19 public health crisis. It has become abundantly clear that our nation’s ability to effectively respond to this crisis depends on the public and private sectors joining forces, maintaining constant coordination, and working together to identify operational and regulatory barriers impeding access to medicines and medical supplies. To date, three of our largest members have been selected by the Federal government to play important roles in ensuring a safe and effective distribution of vaccines as they become available in the coming months. Further, many HDA members have significant expertise and capabilities in ensuring the availability and equitable

distribution of personal, protective equipment (PPE) which we understand to be a priority issue for the incoming Biden Administration. HDA and all of our members are committed to working with the federal government and states to deploy our logistics expertise and relationships in support of their efforts.

As you lead the transition and determine priority issues, we welcome the opportunity to serve as a resource to you on matters related to the safety and security of the pharmaceutical supply chain. HDA has several priority issues which are highlighted below.

COVID-19 Response

We encourage the federal government to utilize the capabilities of the nation's existing pharmaceutical distribution infrastructure to expedite and streamline efforts in the continuing COVID-19 response. Distributors already have warehousing facilities across the United States, established relationships with healthcare providers, sophisticated ordering systems that their customers have and use daily, and efficient shipping networks to swiftly reach those customers. Specifically, distributors' expertise in transporting cold chain products will play a critical role in distributing COVID-19 treatments and vaccines. With the industry's investments in cutting-edge, temperature-controlled supply chain protocols, distributors are well-equipped to preserve the integrity of these groundbreaking products.

HDA [recently released policy principles](#) reaffirming the pharmaceutical distribution industry's commitment to ensuring – in partnership with federal and state governments – the safe and efficient distribution of COVID-19 vaccines and treatments once they are approved by the Food and Drug Administration (FDA). Among these principles, HDA recommends that the federal government partner with and provide detailed guidance to pharmaceutical distributors on how these essential medicines should be distributed. In addition, it is critical that federal and state authorities work together to designate priority populations, localities and eligible facilities, and communicate that information to the supply chain to ensure these products are distributed as safely and expeditiously as possible.

Supply Chain Resiliency

A report recently published by the Healthcare Distribution Alliance (HDA) Research Foundation and Deloitte Consulting LLP found that during the first 90 days of the COVID-19 pandemic, the biopharmaceutical finished goods industry quickly adapted and adjusted to deliver medicines safely and efficiently to patients, with only minimal disruptions.

As noted in the report, [The First 90 Days: US Biopharmaceutical Finished Goods Supply Chain Response to COVID-19](#), pharmaceutical distributors, manufacturers and other stakeholders in the biopharmaceutical supply chain leveraged their strong relationships and prior emergency response experience to get medicines safely and efficiently to patients. Pharmaceutical distributors closely collaborated with manufacturers and hospitals, pharmacies, providers and other partners to anticipate changes in demand, respond to evolving patient needs and mitigate disruptions, including handling surges for critical medicines. The [evaluation of the industry's performance](#) in response to these challenges found the distribution industry was resilient, adaptable, and responsive.

Supply Chain Security

Working directly with manufacturers, pharmaceutical distributors ensure that they are purchasing legitimate, FDA-approved medicines and preventing the introduction of counterfeit medicines into the supply chain. They also maintain secure facilities that are both FDA and Drug Enforcement Administration (DEA) inspected and approved.

As medicines move through the supply chain, distributors have procedures in place to safeguard products from theft and diversion. These include:

- Advanced physical security systems that feature surveillance cameras, alarms and perimeter controls;
- Established practices to safely store and transport medical products;
- Monitoring and reporting suspicious orders to the DEA to help mitigate the diversion of prescription medicines; and,
- Information-sharing programs with local law enforcement and supply chain security coalitions, such as HDA's Pharmaceutical Cargo Security Coalition, to share best practices on securing the nation's healthcare supplies.

Implementation of the Drug Supply Chain Security Act (DSCSA)

As noted above, HDA members focus significant resources on the safety and security of the supply chain. Historically, HDA and our members have worked across the country to raise standards for wholesaler licensure and strengthen the security of the supply chain. In 2013, Congress enacted the Drug Supply Chain Security Act (DSCSA), Title II of the Drug Quality Security Act (Public Law 113-54), which sets a framework for unit level traceability of prescription medicines by 2023. The law preempted a 50-state patchwork of pedigree requirements with one federal traceability solution for prescription medicines. In addition, the law:

- Clarified and consolidated supply chain regulations, increasing the efficiency and safety of the supply chain;
- Strengthened distributor licensure standards across the United States; and,
- Established new processes for identifying suspicious and illegitimate products in the supply chain.

HDA, along with the entire supply chain, strongly advocated for enactment of PL 113-54 and is working diligently to ensure it is fully implemented. The pharmaceutical supply chain continues to make steady progress to comply with DSCSA; however, some implementation priorities have shifted amid the initial industry response to the COVID-19 pandemic.

Additionally, as the industry works to implement the DSCSA, we remain concerned with the Trump administration's drug importation policies. HDA and its members share FDA's commitment to ensuring patients across the nation have access to safe, effective and affordable medicines, but believe drug importation will lead to [additional costs](#) for the healthcare system, regulators and patients and undermine the supply chain's collaborative efforts to implement the DSCSA.

[HDA is ready to partner with President-elect Biden and Vice President-elect Harris](#) to leverage the logistics expertise of pharmaceutical distributors, advocate for policies that support a strong

and resilient supply chain in response to COVID-19 and beyond, while also continuing to apply the innovations and supply chain efficiencies created by our members that meaningfully impact healthcare affordability and access. We welcome the opportunity to serve as a resource to you and your team.

Sincerely,

A handwritten signature in cursive script that reads "Chester W. Davis, Jr.".

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