

February 29, 2024

Honorable Representative Donovan, Chair House Health and Human Services Committees Rhode Island State House 82 Smith St, Providence, RI 02903

Re: Healthcare Distribution Alliance (HDA) Letter of Opposition to H.7444

Dear Chair Donavan:

On behalf of the Healthcare Distribution Alliance (HDA), I am reaching out to share our **opposition to H.7444**, **establishing a Wholesale Prescription Drug Importation Program in Rhode Island**. HDA is the national trade association representing primary healthcare wholesale distributors — the vital link between the nation's pharmaceutical manufacturers and more than 360,000 pharmacies and other healthcare settings nationwide. In Rhode Island, our members serve over 830 sites of care. Across the nation, around 95% of pharmaceutical products are physically handled and delivered by our members.

HDA and our pharmaceutical distributor members support efforts to address the high cost of prescription drugs. However, we remain concerned that importing medicines not intended for distribution in the United States, as proposed in H.7444, will introduce additional challenges to the country's secure and reliable closed distribution system. Importation programs significantly increase the likelihood of counterfeit or substandard drugs entering the U.S. supply chain. Ultimately, this bill would unintentionally put Rhode Island patients' safety at risk.

Furthermore, while the FDA has recently authorized Florida's drug importation program, it is essential to note that Florida's ability to import drugs is contingent on the state meeting several costly and challenging conditions, such as comprehensive testing, reporting, relabeling requirements, and quarterly reports that demonstrate whether the program brings savings and outlines any safety concerns. HDA believes that states can best support the stability of the supply chain by waiting to review the results of Florida's reports before considering similar legislation- especially in light of the excessive expenses and challenges of implementing such a program.

HDA's 37 healthcare distributor members work every day to deliver efficiencies across the supply chain and protect patients. In our view, regulators and policymakers should consider workable long-term solutions to our country's access and affordability challenges — rather than quick fixes such as importing drugs not

intended for distribution in the U.S. HDA and our members are committed to collaborating with the state of Rhode Island and our industry partners to help ensure patient access to affordable medication.

We respectfully ask that based on the concerns we outline above and below, H.7444 not be given a favorable report in committee.

Canadian Importation Conflicts with US Federal Law (Drug Supply Chain Security Act)

The U.S. pharmaceutical supply chain is the most sophisticated, efficient, and highly secure drug supply chain system in the world. The security of the supply chain was further strengthened in 2013 by the passage of the federal Drug Supply Chain Security Act (DSCSA). For more than 10 years, pharmaceutical trading partners have been hard at work implementing the DSCSA traceability law and are preparing for the end of FDA's stabilization policy in November 2024. The DSCSA, once finalized, will establish a uniform national framework for tracing prescription medicines. Importing prescription drugs — not intended or labeled for distribution in the U.S. and not supported by manufacturer verification systems — will threaten the significant progress made by the public and private sectors to create an even safer and more secure supply chain through the DSCSA. HDA urges states to avoid disruption of this stabilization period by passing patchwork wholesale importation laws.

Increased Counterfeiting Potential

Drug approval by the FDA is contingent upon the strictest guidelines for product integrity, good manufacturing practices, scientific data analysis and public safety. Although there are drugs available for sale in Canada or other countries that may be priced at a lower cost for varying reasons, it is important to recognize other countries' regulatory agencies have different approval guidelines, dosage recommendations, and quality assurances.

Both branded and generic drugs are susceptible to counterfeiting, containing insufficient or too much of an approved medicine's active ingredient or to being contaminated by unsanitary manufacturing conditions. The U.S. supply chain, regulated by the FDA, devotes significant resources to ensure the safe and secure distribution of drugs through authorized parties from the point of manufacture to the point of dispensing. HDA members are an essential part of this closed distribution system, working daily with supply chain partners, law enforcement, and government regulators to help ensure prescription medicines are safely delivered to legal, licensed pharmacies within the U.S.

Canadian Opposition

HDA's counterpart in Canada, the Canadian Association for Pharmacy Distribution Management (CAPDM), represents Canada's leading national and regional pharmaceutical distributors, shares similar concerns, stating that "CAPDM and its members share the priority of ensuring a safe, high quality and stable supply of medications for Canadians. We are not supportive of any policy initiative or policy proposal that has the capacity to threaten the stability of medications available to Canadians, or worsen instances of already serious drug shortages."

Furthermore, due to the consideration of Canadian drug importation proposals in the US, the government of Canada, including Health Canada, has put in place regulations to safeguard Canada's drug supply to prevent these proposals from taking effect. These include specific licensing requirements for Canadian manufacturers and wholesalers as well as laws that prevent bulk exportation.

Conclusion

HDA's 37 healthcare distributor members work every day to deliver efficiencies across the supply chain and protect patients. Regulators and policymakers should be focused on workable solutions to our country's access and affordability challenges — rather than quick fixes such as importing drugs not intended for distribution in the U.S. HDA and our members are committed to collaborating with the state of Rhode Island and our industry partners to help ensure patient access to affordable medication.

We truly appreciate the opportunity to share these concerns with you. Please contact Kelly Memphis at (443) 375-6541 or at kmemphis@hda.org if you have any questions or would like to discuss this further.

Sincerely,

Kelly Memphia

Kelly Memphis
Director, State Government Affairs
Healthcare Distribution Alliance