Healthcare Distribution Alliance

PATIENTS MOVE US.

February 8, 2022
Delegate Orrock
CC: Committee on Health, Welfare, and Institutions
Richmond, Virginia

Re: Healthcare Distribution Alliance (HDA) Position on HB 478, Wholesale Drug Importation Program

Dear Chairman Orrock

On behalf of the Healthcare Distribution Alliance (HDA), I would like to thank you for the opportunity to submit for the record our views regarding **HB 478**, which would establish a Wholesale Prescription Drug Importation Program in Virginia. HDA is the national trade association representing primary healthcare wholesale distributors — the vital link between the nation's pharmaceutical manufacturers and more than 180,000 pharmacies and other healthcare settings nationwide.

HDA offers this letter to respectfully express our concerns regarding the implementation of any Drug Importation program, and most importantly our concern that it would conflict with the United State's highly efficient and secure drug supply chain system, protected by federal law. This bill's proposed Drug Importation program would create compliance complications and significantly increase the likelihood of allowing counterfeit or contaminated medications to enter the U.S. supply chain, at great risk to patient safety.

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, commonly referred to as DSCSA. HDA and our member companies were extremely supportive of the enactment of this law, which will provide for a federal traceability solution for prescription medicines by next year, 2023. Approaching finalization, DSCSA will lead to the establishment of electronic, unit-level traceability requirements across the entire supply chain for prescription drug products. HDA and our members are working closely with supply chain partners –manufacturers, pharmacies, third party logistics providers and regulators – to ensure the law is implemented effectively and on time. The DSCSA adopted a comprehensive, practical approach to increase safety, continue efficiency, and minimize inconsistencies among competing state requirements.

Drugs that are sold or designated for sale in Canada and other countries do not conform with U.S. traceability regulations, nor would these countries be required to modify or change their regulations to comply with U.S. law. Allowing for the importation of drugs from Canada or other countries would impede the efforts of the DSCSA regulations in further securing the U.S. supply chain, and thereby

increase the risk of illegitimate or counterfeit medications entering the U.S. market. HDA recognizes this measure includes a provision for Virginia to comply with the DSCSA to "the extent feasible," yet there still remains no clarity or specifications as to how said compliance will be achieved.

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 ensuring good manufacturing practices, product authenticity, and 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

It should be noted that Canada has consistently expressed its unwillingness and incapability to become a supplier for the United States' demand for prescription medicines over the past two years, stating that Canada's market is too small to meet U.S. demands, importing drugs from Canada would not significantly lower U.S. prices, and Canada's priority remains ensuring a steady and affordable supply of pharmaceuticals for Canadians[1]. As recently as November 2019, fifteen Canadian patient and healthcare advocacy organizations wrote a multi-stakeholder letter to Prime Minister Justin Trudeau expressing their continued concerns regarding U.S. drug importation proposals and their impact on Canada's drug supply, strongly urging the Prime Minister to take swift action to prevent transferring Canada's drug supply to the United States through wholesale and bulk U.S. importation[2].

Conclusion

When comparing the current structure and standards of the U.S. pharmaceutical supply chain with international standards, HDA does not see how an international importation program could meet federal safety and traceability requirements. HDA does believe that sufficiently verifying and tracking

[1] "Canadian ambassador says drug imports would not lower U.S. prices", Reuters, (November 1, 2019) https://www.reuters.com/article/us-canada-health-supplies/canadian-ambassador-says-drug-imports-would-not-lower-u-s-prices-idUSKBN1XB55E

[2] Letter from Canadian advocacy organizations to Prime Minister Justin Trudeau, (November 6, 2019) https://buysaferx.pharmacy/wp-content/uploads/2019/11/Multi-Stakeholder-Letter-to-PM-Trudeau.Final_.110619.pdf

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foreign product in the U.S. pharmaceutical supply chain to ensure patient safety according to the strict standards put forth within current U.S. federal law would be impossible. This bill would open the door for bad actors and increases the likelihood of counterfeit or adulterated drugs entering the U.S. supply chain. Therefore, we respectfully request you oppose this bill.

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 Memphis
Director, State Government Affairs

CC: Vice Chair Head; Delegate Bell; Delegate Hodges; Delegate Edmunds; Delegate Robinson; Delegate Walker, Delegate Fariss; Delegate Cherry; Delegate Scott; Delegate March; Delegate Wachsmann; Delegate Hope; Delegate Price; Delegate Hayes; Delegate Delaney; Delegate Adams; Delegate Guzman; Delegate Trans; Delegate Willett; Delegate Hudson

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