HDA
Healthcare Distribution Alliance
PATIENTS MOVE US.

March 1, 2021

The Honorable Stephen Casey
Chairman, House Committee on Health and Human Services
Rhode Island General Assembly
State House
Providence, Rhode Island 02903

Re: Healthcare Distribution Alliance (HDA) Opposition Letter on HB 5249, Establishing the Wholesale Prescription Drug Importation Program

Chairman Casey and Honorable Members of the House Committee on Health and Human Services:

On behalf of the Healthcare Distribution Alliance (HDA), I would like to thank you for the opportunity to provide written comments regarding HB 5249, which would establish a Wholesale Prescription Drug Importation Program. HDA is the national trade association representing primary pharmaceutical wholesale distributors — the vital link between the nation's pharmaceutical manufacturers and more than 200,000 pharmacies and other healthcare settings nationwide.

HDA offers this letter to summarize its concerns regarding the implementation of any Drug Importation program, and most importantly our concern that it increases the likelihood of allowing counterfeit or contaminated medications to enter the U.S. supply chain at a great risk to patient safety.

Canadian Importation Conflicts with the Drug Supply Chain Security Act (DSCSA)

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 2023. Once finalized, 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.

- Serialized product: DSCSA requires manufacturers to apply a unique identifier to prescription drugs at the unit and case level to improve the ability to trace products and identify illegitimate products in the supply chain.

- Streamlined regulatory framework: DSCSA included more stringent wholesaler licensing standards and a new federal ceiling for traceability requirements to improve safety and uniformity across the country.
- Establish and mandate Authorized Trading Partners: DSCSA requires supply chain participants to conduct business exclusively with "Authorized Trading Partners," or manufacturers regulated and approved by FDA working with wholesalers, third-party logistics providers, and pharmacies licensed and regulated by states.
- Establish data on all transactions: Once a product is serialized, exchange of transaction data will be possible. While the system will take time to mature as supply chain participants build their systems, the information can be leveraged to provide additional efficiency and safety benefits within the supply chain.

Drugs that are sold or designated for sale in Canada and other countries do not conform with these 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 Rhode Island to comply with the DSCSA to "the extent feasible," yet there remains no clarity or specifications as to how said compliance will be ensured.

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

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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

Again, HDA appreciates the inclusion of requirements for FDA safety and DSCSA traceability standards in this legislation. However, these provisions are moot under current federal law. When comparing the current structure and standards of the U.S. pharmaceutical supply chain with international standards, HDA does not see how meeting such requirements is possible. Verifying and tracking foreign product in the U.S. pharmaceutical supply chain to ensure patient safety and prevent diversion by the strict standards put forth within current federal law would be impossible, and requires vendors operating under the proposed program to assume substantial risk. Most importantly, it opens the door for bad actors and increases the likelihood of counterfeit or adulterated drugs entering the U.S. supply chain.

We appreciate the opportunity to share these concerns with you and look forward to an open dialogue on this topic during the legislative session. Please contact Will Dane at (571) 287-3020 or wdane@hda.org if you have any questions or would like to discuss this issue further.

Thank you,

Will Dane
Director, State Government Affairs
Healthcare Distribution Alliance

[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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