HDA
Healthcare Distribution Alliance

PATIENTS MOVE US.

April 9, 2019

Senator Heather Sanborn, Chair
c/o Legislative Information Office
100 State House Station
Augusta, ME 04333

Re: Healthcare Distribution Alliance (HDA) Opposition to LD 1272

Chairman and Members of the Joint Committee on Health Coverage, Insurance, and Financial Services,

The Healthcare Distribution Alliance (HDA) offers this letter to indicate our opposition to LD 1272, the 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. While we understand the intent behind the legislation, to reduce pharmaceutical costs for patients in Maine we believe the legislation would violate federal law and conflict with efforts to further secure our nation's drug supply chain. On behalf of the industry, HDA would like to express our concerns with the proposed budget due to the potential impact on pharmaceutical supply chain and risk to patient safety.

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. This law outlines steps to build an electronic, interoperable system to identify and trace prescription drugs as they are distributed in the United States. This will enhance the Food and Drug Administration's ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. The system will also improve detection and removal of potentially dangerous drugs from the drug supply chain to protect U.S. consumers.

Under the confines of DSCSA, any drug distributed in the U.S. must be distributed to and from an authorized trading partner. Further, any drug distributed within the U.S. must also be a serialized product, incorporating the National Drug Code, Serial Number, Lot Number and expiration date. Drugs that are sold or designated for sale in Canada as well as other countries do not conform with these U.S. traceability regulations, it would be a violation of federal law for any wholesaler or other trading partner to accept or distribute product within the U.S. that do not meet these standards. Allowing for the importation of drugs from Canada or other countries would render the DSCSA regulations useless, and thereby increase the risk of illegitimate or counterfeit medications entering the U.S. market and putting patient safety at risk.

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 a number of drugs available for sale in Europe, Canada or other countries that may be priced at a lower cost for a variety of reasons, it is important to recognize that other countries' regulatory agencies have different approval guidelines, dosage recommendations and quality assurances. At this point in time, the FDA cannot guarantee to an American consumer that a drug marketed and available abroad will be the same product his or her physician had written the prescription for, nor can it fully attest to its safety. [1] Further, the four most recent FDA Commissioners wrote an open letter to Congress in March 2017 expressing their continued concerns with a drug importation program stating that "such importation represents a complex and risky approach – one that the evidence shows will not achieve the aim, and that is likely to harm patients and consumers." [2]

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.

HDA appreciates the sponsor's decision to include federal approval requirements in the provisions of the proposed importation program, however HDA does not see how meeting traceability requirements is possible. Given the recent actions to enhance security within our pharmaceutical supply chain, allowing for importation of prescription drug products, even from a specific country, increases the likelihood of counterfeit or adulterated drugs entering the U.S. Patient safety and product integrity will suffer as a result of prescription medicine importation. Before considering importation of potentially dangerous products from other countries, we should consider the implications of introducing such risk to the pharmaceutical supply chain.

Due to these concerns, we ask that you oppose LD 1272. Please contact Bryan Lowe, bwlowe@hda.org if you have any questions or would like to discuss this issue further.

Thank you,

Bryan Lowe
Senior Director, State Government Affairs

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[1] Letter from William K. Hubbard, Associate Commissioner for Policy and Planning, FDA to Robert P. Lombardi, Esq., The Kullman Firm https://www.crowell.com/pdf/FDALetter.pdf

[2] Open letter to Congress authored by four FDA commissioners opposing drug importation, (March 2017)https://www.documentcloud.org/documents/3519007-FDA-Commissioners-Drug-Reimportation.html?utm_source=newsletter&utm_medium=email&utm_campaign=newsletter_axiosvitals

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