

PATIENTS MOVE US.

December 11, 2019

Megan Garratt-Reed
Senior Advisor for Coverage and Affordability
Maine Department of Health and Human Services
11 State House Station, 109 Capitol Street
Augusta, Maine 04333
Megan.Garratt-Reed@Maine.gov

Re: Healthcare Distribution Alliance (HDA) Opposition to Proposed Major Substantive Rule: 10-144, Maine State Services Manual, Section 8, Wholesale Prescription Importation Program

Ms. Reed,

The Healthcare Distribution Alliance (HDA) offers this letter to communicate our continued opposition to the wholesale importation program as enacted by LD 1272. 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 Maine's proposed rules are only meant to create a process to inform the design the state's importation program, which will be developed later to achieve the intent of the law, they are predicated on the forthcoming federal "Safe Importation Action Plan" rules. When the Department of Health and Human Services (HHS) and the U.S. Food and Drug Administration (FDA) released this new plan, HDA issued a statement in opposition: "Pharmaceutical distributors support efforts to address the high cost of prescription drugs. But we firmly believe the administration should focus on policies that maintain the same high standards of safety that Americans have come to rely on. Importation runs directly counter to the efforts of many regulators, the pharmaceutical industry and congressional intent — and is simply not worth the risk." Therefore, HDA maintains that Maine's subsequent state rules will also violate the safety standards, put patient safety at risk, and not achieve any substantial cost savings due to their compliance with the fundamentally flawed "Safe Importation Action Plan".

It should be noted that since Maine passed LD 1272, Canada has publicly expressed its unwillingness and incapability to become a supplier for the United States' demand for prescription medicine. Canada's acting ambassador to the United States, Kristin Hillman, stated that Canada's market is too small to meet U.S. demands, that importing drugs from Canada would not significantly lower U.S. prices, and that Canada's priority remains ensuring a steady and affordable supply of pharmaceuticals for

¹ HDA Statement on HHS-FDA "Safe Importation Action Plan", Healthcare Distribution Alliance, (July 31, 2019) https://www.hda.org/news/2019-07-31-statement-on-hhs-fda-safe-importation-action-plan

Canadians.² 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.³

HDA believes that Maine's wholesale importation program will pose significant risk to patients and the supply chain, without any substantial cost savings for consumers, if the state rules intend to comply with the flawed approach outlined by HHS-FDA's "Safe Importation Action Plan". Please contact Roxy Kozyckyj@hda.org if you have any further questions.

Sincerely,

Roxolana Kozyckyj

Director, State Government Affairs

Healthcare Distribution Alliance

Roxan Konj

² "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

³ 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