

**Healthcare Distribution Alliance (HDA)  
Testimony  
Oregon Senate Committee on Healthcare  
January 30, 2019**

Good Afternoon Chairwoman Monnes Anderson, Vice Chair Linthicum and Members of the Committee,

On behalf of the Healthcare Distribution Alliance (HDA), the national trade association representing primary pharmaceutical wholesale distributors which serve as the vital link between the nation's pharmaceutical manufacturers and nearly 5,000 Oregon pharmacies and healthcare settings, we are writing in opposition to Senate Bill 409. We believe SB 409 would endanger the safety of the domestic pharmaceutical supply chain and conflict with the work Congress has done to secure our nation's drug supply and protect patients.

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, therefore 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. The FDA has no enforcement discretion in Canada and therefore could not require these standards to be met. Allowing the importation of drugs from Canada or other countries would impede the protections established by the DSCSA, and thereby increase the risk of illegitimate or counterfeit medications entering the U.S. market.

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.

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 nation and would violate the federal law established to protect the US pharmaceutical supply chain. Due to these concerns, we ask that you oppose Senate Bill 409.

Thank you,



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