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Healthcare Distribution Alliance
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Healthcare Distribution Alliance (HDA)
Testimony
Oregon House Committee on Health Care
House Bill 2680
February 19, 2019

Good Afternoon Chairman Greenlick, Vice Chair Nosse, Vice Chair Hayden 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 House Bill 2680. While we understand the intent behind the legislation, to reduce pharmaceutical costs for patients in Oregon, we believe the legislation would violate federal law and conflict with efforts to further secure our nation's drug supply chain.

According to the U.S. Food and Drug Administration (FDA), the United States Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. section 331) prohibits the interstate shipment (which includes importation) of unapproved new drugs. The FFDCA was further strengthened by Congress in 2013 by the passage of the Drug Supply Chain Security Act (DSCSA, or Title II of the Drug Quality and Security Act). The Act provides for a federal traceability solution for prescription medicines, which by 2023, will lead to the establishment of FDA-regulated, electronic, unit-level traceability requirements across the entire supply chain for prescription drug products. Given the action Congress has taken to enhance supply chain safety and security, allowing for importation of prescription drug products will expose the domestic supply and patients to unnecessary risk.

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.

HDA firmly believes that allowing importation, even from a specific country, increases the likelihood of counterfeit or adulterated drugs entering the United States and will not ensure meaningful reductions in the cost of prescription drugs. Before considering importation of potentially dangerous products from other countries, it is essential to consider the implications of introducing such risk to the pharmaceutical supply chain. Due to these concerns, we ask that you oppose House Bill 2680.

Thank you,

Leah Lindahl
Senior Director, State Government Affairs
Healthcare Distribution Alliance
LLindahl@hda.org
(303) 829-4121