HDA
Healthcare Distribution Alliance
HEALTH DELIVERED

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Maine Department of Environmental Protection
17 State House Station
32 Blossom Lane
Augusta, Maine 04333-0017

HDA Comments re: Rulemaking for Maine's Packaging Stewardship Law, § 2146

On behalf of the Healthcare Distribution Alliance (HDA), we appreciate the opportunity to provide further comments during the rulemaking for the Packaging Stewardship Law § 2146.

HDA is the national trade association representing healthcare wholesale distributors, the vital link between the nation's pharmaceutical manufacturers and more than 200,000 customers- pharmacies, hospitals, long-term care facilities, clinics and others nationwide. In Maine, our members serve 261 customers.

In their role as a wholesale distributor, HDA members do not research, develop, manufacture or market pharmaceutical products. Their primary role is to purchase pharmaceutical products from manufacturers, securely store, and safely deliver them to state and federally licensed healthcare providers. Simply put, wholesale distributors are logistics experts that ensure pharmacies and hospitals keep their shelves stocked with medications their patients need.

On behalf of our member companies, HDA would like to thank the Department for the continued conversation on this topic, and for expressing agreement with our interpretation that wholesale distributors should not be considered producers within the statute. **To ensure there is no ambiguity as the program is implemented, we respectfully request that when the Department issues rules, the rules do explicitly state that distributors are exempt from the definition of producers.**

While we appreciate the Department's understanding that wholesale distributors should not be considered producers, we would again request the Department consider a similar position for entities that repackage or relabel pharmaceutical products in which they do not manufacture. We believe the legislative intent is for the definition of "producer" to apply to the actual manufacturer who manages the FDA approval of their products and are the intellectual property owners of FDA- approved drugs. Repackers and private label distributors are not the intellectual property owners of FDA-approved drugs, and including them in the definition of producers would create programmatic ambiguity and burden on the state as to which entity is ultimately responsible for compliance.

Furthermore, should Maine ever coordinate Packing Law § 2146 with the state's Drug Take- Back Stewardship Program, § 1612, ensuring the definition of "producer" and "manufacturer" are aligned would be critical, and § 1612 does explicitly exclude wholesalers from the definition of manufacturer:

K. "Manufacturer" means: (1) A person that has legal ownership of the brand of a covered drug sold in or into the State; or (2) If the person to which subparagraph (1) applies has no physical presence in the United States, a person that imports a covered drug that is branded by the person to which subparagraph (1) applies.

"Manufacturer" does not include a wholesaler that sells or offers for sale in the State at wholesale a covered drug if the covered drug is manufactured by a manufacturer that is a participant in a stewardship program.

In summary, HDA would first like to thank the Department for agreeing with our interpretation of the law and confirming that wholesale distributors do not meet the definition of producer under the law. We would like to respectfully request that rule making provide a more explicit exclusion of wholesalers to ensure clarity as the program is implemented. We would also like to reemphasize our belief that the Department consider a similar stance on repackaging and private label distribution entities since the original manufacturers are in the best position to manage product stewardship activities and to reduce waste, rather than those entities in the middle of the pharmaceutical supply chain which "handle" products. Adding such clarifying exemption language would prevent misalignment between the EPR and Stewardship laws, reduce administrative burdens for the state, and ensure that a single product is not taxed or tracked multiple times as it passes through the healthcare supply chain.

Thank you again, and please feel free to contact me for any further discussion at kmemphis@hda.org or 443.375.6541

Sincerely,

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