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February 13, 2023

Senator Janeen Sollman, Chair
Senator Lynn P. Findley, Vice Chair
Senate Committee on Energy and Environment
900 Court St. NE, S-207
Salem, Oregon 97301

Re: SB 544 Establishing a Program for Single Use Plastic Source Reduction - Oppose

Dear Chair Sollman,

On behalf of the Consumer Healthcare Products Association (CHPA), the Washington, D.C. based national trade organization representing the leading manufacturers of over-the-counter (OTC) medicines, dietary supplements, and consumer medical devices, I'm writing to express opposition to SB 544 as it is currently drafted. This legislation seeks to implement a source reduction program for single-use packaging including the packaging of Food and Drug Administration (FDA) regulated consumer healthcare products. The source reduction goals outlined in the legislation, however, conflict with existing FDA regulated product packaging rules. Since FDA regulated products are not exempt from this legislation, we are forced to register in opposition.

FDA Regulates Consumer Healthcare Product Packaging

Manufacturers of consumer healthcare products take very seriously the types of packaging used to transport, store, and safely deliver OTC products to consumers seeking to address minor health ailments. A very complex, and highly regulated federal framework for OTC consumer healthcare packaging has been in place for decades and serves to ensure safety, efficacy, and stability of products for consumers. State action on packaging for these products likely conflicts with federal laws and regulations already in place, and could compromise safety and stability of the products themselves.

FDA regulates drug product packaging under Good Manufacturing Practices regulations (GMPs) (21 C.F.R. Part 211, Subpart G), including material examination and usage criteria (§211.122), packaging and labeling operations (§ 211.130), tamper-evident packaging (§ 211.132), and expiration dating (§ 211.137).

Certain drugs are also regulated by the Consumer Product Safety Commission (CPSC) under the Poison Prevention Packaging Act (PPPA), which requires child-resistant packaging. Manufacturers are required to test and certify compliance with the PPPA and, in fact, are deemed misbranded under the Food, Drug, and Cosmetic Act (21 U.S.C. § 352(p)) when the packaging does not comply with PPPA and labeling regulations. In addition, the Food and Drug Administration (FDA) has offered industry guidance stating specifically that recycled plastic should not be used for primary drug or dietary supplements packaging.

Amendment Recommendation

The existing extended producer responsibility (EPR) for packaging law currently in place in Oregon (SB 582) aptly exempts FDA regulated drugs. The legislature recognized the uniqueness of the industry's packaging and the need to exempt drugs, dietary supplements, and consumer medical devices from any form of state specific packaging mandate. We respectfully request that same exemption be extended in SB 544 as well by including the following language:

any material that is used in the packaging of a product that is regulated as a drug, medical device or dietary

supplement by the U.S. Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 et seq., sec. 3.2(e) of 21 U.S. Code of Federal Regulations is exempt.

Conclusion

CHPA and its members are committed to the health and welfare of consumers and the global environment. We applaud the Committee on Energy and Environment for taking on this important issue, but unfortunately, we cannot support the legislation in its current form. We look forward to continued dialogue with the hope we can come to an equitable resolution.

Respectfully submitted,

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cc: Members of the Senate Committee on Energy and Environment