CHPA® | CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

Taking healthcare personally.

May 9, 2021

The Honorable Senator Stacy Brenner (Senate Chair)
The Honorable Representative Ralph Tucker (House Chair)
Joint Committee on Environment and Natural Resources
Maine State Legislature.
100 State House Station
Augusta, ME 04333-0100

RE: **Concerns with L.D. 1471** – An Act to Establish a Stewardship Program for Packaging
Opposition to L.D. 1541 – An Act to Support and Improve Municipal Recycling Programs

Dear Chairs Brenner and Tucker:

On behalf of the Consumer Healthcare Products Association (CHPA), the national trade association representing the leading manufacturers of over-the-counter (OTC) medications, dietary supplements, and consumer medical devices, I'm writing to express strong opposition to L.D. 1541, and minor concerns with L.D. 1471. As currently drafted, L.D. 1541 penalizes consumer healthcare product manufacturers whose packaging is bound by already existing federal rules and regulations. Shifting recycling and disposal costs of packaging from local government to critical healthcare products threatens the affordability of these products at a time when consumers can least afford it.

Healthcare Product Packaging Is Regulated by the Federal Government

Packaging for consumer healthcare products is very complex and highly regulated by the Food and Drug Administration (FDA) and other federal agencies to ensure product safety, quality, and stability. 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 and dietary supplements 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 their packaging and certify compliance. In addition, drug products for which packaging does not comply with PPPA packaging and labeling regulations are misbranded under the FDCA (21 U.S.C. § 352(p)).

In 1994, the Dietary Supplement Health and Education Act (DSHEA) was enacted as an amendment to the Federal Food Drug and Cosmetic Act (FFDCA). DSHEA explicitly defines dietary supplements as a category of food. Therefore, all the safety concerns regarding the use of plastic materials made from post-consumer resins in food-contact articles as described in the FDA guidance entitled, *Recycled Plastics in Food Packaging* apply to dietary supplements.

A federal framework guiding the industry's packaging is already in place, and for decades has served the public interest well.

As Maine considers a post-consumer recycling program for packaging, it is important to understand the impact this program will have on healthcare product manufacturers, which in turn will adversely impact costs of healthcare for Maine residents.

Consumer Healthcare Products Play A Critical Role in American Healthcare

Millions of Americans rely on OTC consumer healthcare products as an accessible and effective first line of defense solution for commonly occurring conditions, so any impact on their affordability give us great concern. OTC medicines enable the healthcare system to utilize its limited resources on the diagnosis and treatment of more serious diseases and medical conditions that necessitate the direct involvement of a physician, while at the same time providing safe, effective, and accessible treatment for a range of conditions to consumers and their families. The COVID-19 pandemic has illustrated the importance of self-care achieved in part by utilizing OTC medications and dietary supplements. Now more than ever, consumers have been empowered to address their health by relying on OTC treatments and limiting unnecessary visits to primary care centers and hospitals. OTC medications save the U.S. healthcare system $146 billion annually and provide $34 billion in annual workplace productivity savings.[1] Most importantly, consumer healthcare products greatly expand access to healthcare solutions because they are readily available without a prescription at local outlets, drug stores, and retailers.

The ENR Committee This Year Passed Mandatory Manufacturer Funded Drug Disposal

Earlier this year, the Joint Committee on Environment and Natural Resources passed L.D. 8 – legislation which will implement a manufacturer funded drug take-back law. L.D. 8 is well on its way to final passage and if signed into law will require every manufacturer of medicine (both prescription and nonprescription) to implement and fully pay for a statewide drug disposal program. No state in the country has required medicine manufacturers to pay for both drug disposal and recycling efforts at the same time. If L.D. 8 and L.D. 1541 are passed as currently drafted, Maine will become the most prohibitive state for consumer healthcare product affordability in the entire United States of America, as no state in the Union requires both a drug take-back law and an EPR for packaging mandate at the same time.

Consumer Healthcare Products Should Be Granted an Exemption from Packaging EPR

Last year, the Joint Committee on Environment and Natural Resources conceded the importance of an exemption from this proposal for FDA approved drugs, and medical devices. States like New York, Maryland, Colorado, and Washington have included an expanded exemption for all FDA approved healthcare products including dietary supplements in packaging EPR bills they've considered and/or are considering this legislative session. CHPA respectfully requests that same exemption be granted in both L.D. 1541 and L.D. 1471. This exemption can be accomplished by including the language pasted below:

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

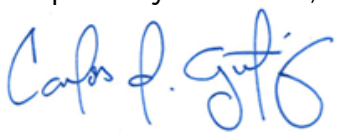
[1] https://www.iriworldwide.com/IRI/media/Library/Publications/CHPA_IRI_OTC-Value_WhitePaper.pdf

Food, Drug, and Cosmetic Act, 21 U.S.C. 321 et seq., sec. 3.2(e) of 21 U.S. Code of Federal Regulations or the Dietary Supplement Health and Education Act is exempt.

Conclusion

On behalf of CHPA, I thank you for the opportunity to comment on both L.D. 1541 and L.D. 1471. We respectfully request you give careful consideration to our concerns as these bills will have a profound impact on the affordability of consumer healthcare products for Mainers for years to come. Please feel free to contact me directly with any questions or concerns.

Respectfully submitted,



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cc: The Joint Committee on Environment and Natural Resources
Sabrina Carey