CHPA® | CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

Taking healthcare personally.

April 23, 2025

The Honorable Senator Denise Tepler, Co-Chair
Joint Committee on Environment and Natural Resources
Legislative Information Office
100 State House Station
Augusta, ME 04333

The Honorable Representative Victoria Doudera, Co-Chair
Joint Committee on Environment and Natural Resources
Legislative Information Office
100 State House Station
Augusta, ME 04333

RE: LD 1423 - An Act to Improve Recycling by Updating the Stewardship Program for Packaging (Support)

Dear Chair Tepler and Chair Doudera,

On behalf of the Consumer Healthcare Products Association (CHPA)[1], I am writing to express strong support for L.D. 1423, legislation which proposes critical amendments to Maine's packaging stewardship program by exempting consumer healthcare product packaging from the law's scope.

While the Maine Legislature has acknowledged the unique challenges faced by producers of FDA-regulated consumer healthcare products under the current Packaging Stewardship Law, the program still has the potential to conflict with federal standards. The existing law directs the Department of Environmental Protection (DEP) to review packaging materials for these products and consider their exclusion from the definition of "packaging material." This provision is essential because nonprescription drugs, dietary supplements, and medical devices are subject to rigorous federal regulations that dictate specific content and construction standards for their packaging.

Despite our detailed exemption request submissions to the DEP highlighting these regulatory conflicts, our requests have not been approved. It's worth noting that Maine stands alone as the only state with a packaging stewardship law that fails to provide any exemptions for consumer healthcare product packaging.

Existing Federal Packaging Rules for Consumer Healthcare Products

The Food and Drug Administration (FDA) regulates consumer healthcare product packaging under Good Manufacturing Practices regulations (GMPs) (21 C.F.R. Part 211, Subpart G), including material examination and usage criteria, packaging and labeling operations, tamper-evident packaging and expiration dating. Similarly, FDA regulates dietary supplement

[1] Consumer Healthcare Products Association is the Washington, D.C. based national trade organization representing the manufacturers of over-the-counter (OTC) medications, dietary supplements, and OTC medical devices

product packaging under separate GMP regulations (21 C.F.R. Part 111, Subpart L) so that the condition of the packaging will ensure the quality of the dietary supplements (§ 111.410); and that it will protect against contamination, particularly airborne contamination (§ 111.415). Other consumer healthcare products are also regulated by the Consumer Product Safety Commission under the Poison Prevention Packaging Act (PPPA), which requires child resistant packaging. Manufacturers are required to test and certify compliance and products can be considered misbranded under the Federal Food, Drug, and Cosmetic Act when packaging does not comply with PPPA packaging and labeling regulations.

FDA's Guidance on Recycled Packaging Materials

In 1999, the FDA issued guidance regarding the use of recycled materials in packaging for regulated products. This guidance highlighted significant concerns about potential contamination and the impact on product stability when recycled materials are used in packaging for sensitive healthcare products.

The guidance emphasized that recycled materials can introduce unknown and potentially harmful contaminants into packaging that may migrate into products. For drugs, dietary supplements, and medical devices, such contamination could pose serious health risks to patients and consumers.

This FDA guidance effectively discourages or prevents the use of many recycled materials in packaging for these regulated healthcare products. This creates a direct conflict with Maine's EPR law, which encourages the use of recycled content in packaging. Manufacturers caught between these conflicting directives face an impossible choice between state and federal compliance.

Packaging for Stability, Efficacy, and Safety

The packaging of drugs, medical devices, and dietary supplements fundamentally differs from typical consumer product packaging due to its critical role in ensuring product stability, efficacy, and safety.

Stability Protection: Packaging for healthcare products must prevent degradation from environmental factors such as light, moisture, oxygen, and temperature fluctuations. This often requires specialized barrier materials that may not be easily recyclable.

Efficacy Preservation: Many active pharmaceutical ingredients and biological products are highly sensitive and require packaging that maintains their therapeutic effectiveness throughout the product's shelf life.

Contamination Prevention: Healthcare product packaging must prevent microbial contamination and maintain sterility where required. This necessitates materials and designs that create effective antimicrobial barriers.

Dosage Accuracy: For many drugs, the packaging is integral to proper dosing (e.g., metered-dose inhalers, pre-filled syringes). The materials used must maintain precise functionality that directly impacts therapeutic outcomes.

Unlike conventional consumer goods, alterations to healthcare product packaging to comply with state EPR requirements could compromise these critical functions, potentially putting consumers at risk and violating federal requirements and recommendations.

Industry Commitment to Sustainable Packaging Innovation

CHPA and our members are firmly committed to environmental sustainability and actively pursuing innovations in packaging when such innovations do not compromise product safety, stability, or efficacy. The healthcare products industry is not resistant to sustainable practices—quite the opposite. Our members invest significant resources in research and development of more environmentally friendly packaging solutions that still meet the rigorous standards required by federal regulations.

Many of our member companies have established comprehensive sustainability programs with specific targets for reducing packaging waste, increasing recyclability, and minimizing environmental impact. These initiatives include exploring alternative materials, reducing packaging volume, and redesigning packaging systems to be more environmentally friendly while maintaining compliance with FDA requirements.

However, these sustainability efforts must be balanced with the paramount concern for consumer safety. When safety and sustainability objectives appear to conflict, our industry must prioritize consumer protection in accordance with federal mandates. An exemption from Maine's EPR law would not indicate a lack of commitment to sustainability, but rather would acknowledge the complex regulatory framework in which these products exist and allow manufacturers to continue developing sustainable solutions that do not compromise patient safety.

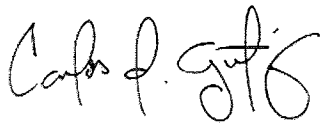
Aligning Maine with National Practices While Supporting Sustainability

While the consumer healthcare product industry shares a commitment to sustainability and environmentally friendly packaging, the unique regulatory landscape for our products necessitates special consideration. We believe oversight of packaging for medications, dietary supplements, and medical devices should remain under federal jurisdiction to ensure consistent safety standards and avoid potential conflicts with state-level requirements.

Of the five states to pass broad EPR packaging laws to date, Maine remains an outlier as the only state that has adopted a stewardship law for product packaging that does not exempt any consumer healthcare product packaging. Laws in California, Colorado, Minnesota, and Oregon all exempt at least one category of consumer healthcare products. Additionally, New Jersey and Washington have passed mandatory post-consumer recycled content for product packaging laws and exempt packaging for nonprescription drugs, dietary supplements, and medical devices. LD 1423 will align Maine's Stewardship Program for Packaging with the growing practices in other states by exempting all FDA-regulated consumer healthcare products to maintain product safety standards and minimize potential risks to consumers.

We appreciate your consideration of our concerns and urge your support of LD 1423.

Respectfully submitted,



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