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March 13, 2025

The Honorable Representative John Lively
Chair, House Climate, Energy, and Environment Committee
900 Court Street NE
Salem, OR 97301

RE: Oppose – HB 3512 – relating to PFAS restrictions.

Chair Lively,

On behalf of the Consumer Healthcare Products Association (CHPA)[1], I'm writing to express opposition to House Bill 3512 as currently drafted. This legislation would ban the sale of certain healthcare products containing "intentionally added" per- and polyfluoroalkyl (PFAS) chemicals, including menstrual products, dental floss, and their packaging.

We share lawmakers' concerns about the health and environmental risks of certain PFAS chemicals, however our industry has concerns regarding specific language in HB 3512. The bill's overly broad definition of "intentionally added" PFAS and absence of exemptions for drugs – particularly those that are also cosmetics - creates potential complications for both manufacturers and consumers. To better balance consumer safety with practical implementation, we offer the following specific recommendations for your consideration prior to advancing this legislation.

Definition of "Intentionally Added PFAS" Should be Amended

The current "intentionally added" definition in the bill creates ambiguity regarding trace PFAS that emerge during manufacturing processes rather than through deliberate addition. Modern industrial operations involve complex chemical reactions where PFAS compounds can appear as contaminants or byproducts without being deliberately incorporated into finished products.

The definition's use of "should have known" terminology lacks clear parameters for interpretation, creating inconsistency in enforcement standards. This ambiguity presents compliance challenges for manufacturers.

Verification poses technical difficulties, as many manufacturers lack the specialized analytical equipment necessary for detecting trace PFAS compounds. These testing requirements may increase production costs that could ultimately be passed on to consumers.

While trace PFAS may be detected during manufacturing, their presence typically results from incidental exposure rather than intentional formulation and likely poses minimal public health risk. A more targeted regulatory approach—focusing specifically on PFAS compounds

[1] Consumer Healthcare Products Association is the Washington, D.C. based national trade association representing the makers of over-the-counter medicines, dietary supplements, and medical devices

deliberately added for functional purposes—would better balance environmental protection, consumer safety, and manufacturing feasibility.

Based on these considerations, CHPA recommends the following amendment to House Bill 3512:

Strike Section 1, Subsection 10, and replace with:
"Intentionally added perfluoroalkyl or polyfluoroalkyl substance" means a perfluoroalkyl or polyfluoroalkyl substance (PFAS) that a manufacturer has intentionally added to a product and that have a function or technical effect on the product."

Food and Drug Administration (FDA) Regulated Drug Products Should Be Exempt

The current language of HB 3512 regarding PFAS regulation in cosmetics may unintentionally encompass drug products that also function as cosmetics. These essential healthcare products—such as sunscreens that prevent cancer, medicated dandruff shampoos, anti-cavity toothpastes, and therapeutic skincare treatments—fall primarily under FDA drug regulations, with their cosmetic attributes being secondary. Without modification, this legislation risks limiting patient access to medically necessary products and creating regulatory confusion between state and federal frameworks. We urge amending the bill to explicitly exempt all FDA-regulated drug products, including those with dual drug-cosmetic status. This critical exemption would allow the bill to effectively regulate cosmetics as intended while maintaining the established regulatory pathway for drug products that ensures their safety, efficacy, and availability to consumers. Many state legislatures have already recognized the importance of this distinction and included similar exemptions in their PFAS legislation, creating precedent for maintaining regulatory clarity while still protecting consumers from unnecessary PFAS exposure in purely cosmetic products. To exempt FDA regulated drug products from this legislation we recommend the following change:

In Section 1, Subsection 6, add new section (c) and include:

"'Cosmetic'" does not include any product regulated as a drug by the United States Food and Drug Administration pursuant to 21 U.S.C. 321 (g)."

Exemptions for Consumer Healthcare Product Packaging Should be Included

Non-prescription drug packaging should be exempt from PFAS regulation due to the comprehensive regulatory framework already in place at the federal level. The FDA rigorously governs consumer healthcare product packaging through Good Manufacturing Practices regulations (21 C.F.R. Part 211, Subpart G), which establish stringent standards for material examination, usage criteria, packaging operations, tamper-evident requirements, and expiration dating. Similarly, dietary supplement packaging falls under separate GMP regulations (21 C.F.R. Part 111, Subpart L) designed to ensure product quality and prevent contamination. Additional oversight comes from the Consumer Product Safety Commission through the Poison Prevention Packaging Act, mandating child-resistant packaging with required compliance testing and certification. Products failing to meet these standards can be deemed misbranded under the Federal Food, Drug, and Cosmetic Act. State-level PFAS regulations, while well-intentioned, risk creating a patchwork of inconsistent requirements that could compromise the carefully engineered stability profiles of these products,

potentially jeopardizing safety and efficacy. The specialized nature of healthcare product packaging, developed to maintain stability across varying environmental conditions and ensure proper dosing, makes broad state mandates often impractical and potentially counterproductive to consumer safety when imposed upon an already comprehensively regulated sector.

To accommodate these FDA regulated healthcare products in the legislation, we respectfully recommend the following exemption be added to the bill within the definition of "packaging":

"'Packaging' does not include packaging for products that are regulated as a medical device, drug, or dietary supplement by the United States Food and Drug Administration under the federal Food, Drug, and Cosmetic Act, 21 U.S.C. Sec. 321 et seq."

Access to affordable healthcare through OTC products is vital for Oregonians. Without the suggested modifications to this bill, their access to these essential FDA-regulated healthcare products could be jeopardized. Thank you for considering our concerns.

Respectfully submitted,

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cc: House Climate, Energy, and Environment Committee
The Honorable Representative Mark Gamba, Vice Chair
The Honorable Representative Bobby Levy, Vice Chair