

February 21, 2024

Senator FOUNG Hawj  
Chair, Senate Environment, Climate, and Legacy Committee  
95 University Avenue, W  
Minnesota Senate Building, Room 3231  
St. Paul, MN 55255

Dear Chairman Hawj,

The Consumer Healthcare Products Association (CHPA) appreciates the opportunity to provide comments on SF 3561. While we support Senator Morrison's efforts to address packaging waste in Minnesota, we have concerns about the bill's unintended consequences for packaging required by Food and Drug Administration (FDA) regulations. As the trade association for over-the-counter medicine, dietary supplement, and consumer medical device manufacturers, CHPA aims to partner on practical solutions that reduce waste while still protecting product safety, stability, and efficacy.

The 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 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.

SF 3561, unlike most extended producer responsibility (EPR) bills considered in states around the country, does not exempt FDA regulated consumer healthcare products (drugs, dietary supplements, and medical devices) from the EPR or post-consumer recycled content (PCRC) sections of the legislation. This is unfortunate given the existing federal restrictions on packaging material use for these healthcare items.

To maintain uniformity with other states around the country and to avoid conflict with existing federal packaging requirements, we respectfully request FDA regulated drugs, medical devices, and dietary supplements be granted an exemption from this bill. Consumer healthcare products undergo rigorous packaging checks from the FDA and other federal agencies. The specialized packaging needs of these products make across-the-board state mandated packaging proposals unfeasible in many cases. Exempting these FDA regulated products from scope of the bill would preserve the overall intent of cutting excess packaging from landfills, while not unduly affecting the availability and affordability of these important healthcare products.

### **Amendment Request**

To accommodate FDA regulated consumer healthcare products in the legislation, we recommend the following exemption be added to the bill:

*This Act does not apply to 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.;*

### **Conclusion**

Packaging for pharmaceuticals, dietary supplements, and medical devices is a multi-faceted and highly regulated space that forces manufacturers to consider several factors beyond basic aesthetics of the package itself. A federal framework guiding the industry's packaging is already in place, and for decades has served the public interest well. For this reason, we respectfully request the exemption amendment be added to the legislation before final approval.

Thank you for taking the time to consider our concerns and feel free to contact me directly with any follow-up questions you may have. CHPA has a long track record of working collaboratively with state legislatures and we look forward to continuing that on this proposal and with this committee as well.

Sincerely,



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Cc: Members of the Senate Environment, Climate, and Legacy Committee