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Taking healthcare personally.

May 15, 2023

The Honorable Stacy Brenner
Joint Committee on Environment and Natural Resources, Chair
Maine Senate
3 State House Station
Augusta, ME 04333

The Honorable Lori Gramlich
Joint Committee on Environment and Natural Resources, Chair
Maine House of Representatives
3 State House Station
Augusta, ME 04333

Re: L.D. 1908 – An Act to Enact the Safe Cosmetics Act

Dear Chairs Brenner and Gramlich,

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 opposition to L.D. 1908. As currently drafted, this legislation seeks to ban specific chemicals found in cosmetics but may inadvertently extend this same chemical ban to products found in Food and Drug Administration (FDA) approved drugs. CHPA opposes the legislation as it will ban the majority of sun factor protection (SPF) sunscreens, and additional drug products Maine families rely on for their everyday healthcare.

L.D. 1908 Impact Drugs, Not Just Cosmetics

L.D. 1908 targets cosmetics, but as currently drafted will also impact FDA regulated drugs. The Federal Food, Drug, and Cosmetic Act (FD&C Act) defines a "drug" as:

- 1) An Article "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease;"
- 2) Articles, other than food, that are "intended to affect the structure or any function of the body;" and,
- 3) Articles "intended for use as a component" of such drugs.

Unlike cosmetics and their ingredients (with the exception of color additives), drugs are subject to (FDA) approval before being introduced to the marketplace. Drugs must either:

- 1) Receive FDA premarket approval of a new drug application (NDA), or
- 2) Conform to a set of FDA requirements known as a monograph.

Monographs govern the manufacture and marketing of most over-the-counter (OTC) drugs and specify the conditions under which OTC drugs can be legally marketed in a particular category. A cosmetic, on the other hand, is defined as a product that is intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering

appearance. The term covers a broad range of FDA-regulated products that may be used externally, internally, and within orifices.

Finally, every OTC medicine available at retail must include a Drug Facts label. This label has information about what condition the medicine treats and how to use it safely. Therefore, any product with a Drug Facts label is first and foremost a drug, even if it has cosmetic uses.

Oxybenzone Is a Critically Important Sunscreen Ingredient

Oxybenzone is a safe, and effective ingredient approved by the FDA in 1978 and found in hundreds of personal care products on the market today including some of the most popular sunscreens, lip balms, and lotions designed to guard against sun damage. In fact, oxybenzone offers broad spectrum protection against both ultraviolet A (UVA) and ultraviolet B (UVB) rays that are the greatest contributors to skin cancer. Some popular sunscreen products containing oxybenzone include Coppertone, ChapStick, Blistex, Hawaiian Tropic Lotion Sunscreen, Aveeno Moisturizing Lotion, SoftLips Cube, Neutrogena lotions and countless other shampoos, conditioners, lipsticks, body washes, hairsprays, aftershaves, and more.

Importance of Oxybenzone Containing Sunscreen Protection Against Skin Cancer

The most common form of cancer is skin cancer. Every year there are more cases of skin cancer in the United States than the combined incidents of breast cancer, prostate cancer, lung cancer, and colon cancer combined. In fact, over the last 30 years, more people have experienced skin cancer than all other cancers combined. One out of five Americans will develop skin cancer in their lifetime, and one person dies of melanoma (the deadliest form of skin cancer) every hour. The vast majority of melanomas are caused by the sun, and a person's risk of melanoma doubles if he or she has had more than five sunburns. When used as directed, sunscreens containing oxybenzone on the market today have proven to be very effective in protecting skin against the sun's harmful rays. The FDA has acknowledged research that shows sunscreens aid in decreasing the risk of developing skin cancers and early skin aging. The FDA recommends use of a broad-spectrum sunscreen with sun protection factor (SPF) values of 15 or higher regularly and as directed to protect against ultraviolet A sun rays as provided by oxybenzone sunscreen products. In order to get ultra-high SPF, oxybenzone is required to serve as a stabilizer for other sunscreen ingredients in sunscreen. Without it, high SPF may not be achieved.

Unintended Consequences of L.D. 1908

Over-the-counter sunscreen containing oxybenzone is an affordable, accessible first line of defense for individuals seeking protection from the sun's cancer-causing UV rays. Banning the use of oxybenzone, an important UV filter ingredient, in Maine will drastically reduce the selection of sunscreen products available to residents and tourists. The combination of reduced choice and less effective products could have the dangerous consequence of Maine residents and tourists using less protective sunscreens or worse - not using sunscreen at all - thereby, causing more skin damage and potentially increasing skin cancer rates.

FDA Approved Drugs Should Be Exempt

Restricting the use of FDA approved ingredients in OTC drugs that are also regulated as cosmetics can cause unnecessary confusing and preventable health risks to consumers. To

address these concerns, CHPA respectfully requests the following amendment to exempt FDA regulated drugs from being subjected to the bill's ingredient/chemical bans:

Amend page 2, line 13-14 as follows:

“Cosmetic product” does not include soap, dietary supplements, or food and drugs approved by the United States Food and Drug Administration.

Conclusion

Thank you for taking the time to consider our concerns and feel free to contact me directly with any questions you may have.

Respectfully submitted,



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cc: Members of the Joint Committee on Environment and Natural Resources
The Honorable Representative Sophia Warren