

January 26, 2026

The Honorable Representative Susan Donovan
Chair, House Committee on Health and Human Services
Rhode Island House of Representatives
Providence, RI 02903

Re: Opposition to H 7110 - The Personal Hygiene Product Safety and Toxic Metal Removal Act of 2026

Dear Chair Donovan:

On behalf of Consumer Healthcare Products Association (CHPA)¹, I write to respectfully express our strong opposition to H 7110, which would establish concentration limits for lead, cadmium, and arsenic in personal hygiene and care products. While we share the General Assembly's commitment to consumer safety, this legislation is flawed in its approach and would impose unworkable requirements that conflict with established federal regulatory frameworks without providing meaningful public health benefits.

Our opposition centers on four critical areas: the scientific inadequacy of the proposed metal concentration limits, conflicts with existing FDA regulations, impractical testing and labeling requirements, and the disproportionate nature of the enforcement mechanisms.

Scientifically Unsupported Concentration Limits

H 7110 establishes concentration limits of 0.1 ppm for lead, 0.05 ppm for cadmium, and 0.1 ppm for arsenic without any scientific justification or risk assessment to support these specific thresholds. These limits fail to account for a fundamental reality of manufacturing: many personal hygiene and menstrual products are made from natural materials such as cotton and other plant-based fibers that inevitably contain trace amounts of naturally occurring metals absorbed from soil and water during growth and processing.

These trace metals are not intentionally added contaminants but rather reflect unavoidable environmental exposure that manufacturers cannot control through their production processes. The Food and Drug Administration's (FDA) regulations for medical devices already recognize that trace levels of certain metals are unavoidable and have established risk-based standards accordingly. H 7110 ignores this scientific and regulatory reality by treating all detectable concentrations as if they were intentionally added adulterants.

Furthermore, the bill relies on the Environmental Protection Agency's (EPA) classification of "toxic metals," despite the fact that the EPA does not assess substances based on consumer exposure through personal care products. The EPA's classifications are designed for environmental contamination scenarios, not for evaluating the safety of trace amounts in consumer products used in the manner intended. Any enforceable limits on trace metals

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

must be grounded in science-based standards that account for real-world manufacturing conditions, actual exposure pathways, and established federal regulatory frameworks.

Conflicts with Federal Regulatory Authority

H 7110 creates direct conflicts with existing FDA jurisdiction in several respects. First, menstrual products are already regulated as medical devices under comprehensive FDA oversight. The bill's testing requirements would create unnecessary duplication and potential regulatory conflicts. Requiring manufacturers to comply with both FDA medical device requirements and Rhode Island's distinct testing and concentration standards would impose significant costs and complexity without corresponding public health benefits.

The conflict becomes even more problematic with respect to over-the-counter (OTC) drug products that also have cosmetic uses. Products such as anti-dandruff shampoo, fluoride-containing whitening toothpaste, and skin moisturizers with sunscreen active ingredients are drugs that have additional cosmetic uses. Under 21 CFR 201.66, the FDA has sole authority over OTC drug product labels. FDA labeling requirements include listing active ingredients, inactive ingredients, the product's purpose, warnings, expiration dates, and dosage instructions through the standardized Drug Facts label.

H 7110's requirement that personal hygiene products "include a label that certifies they have been tested and meet all federal safety standards concerning toxic metals" would require manufacturers to add state-specific compliance language to products already subject to comprehensive federal labeling requirements. For OTC drugs with cosmetic properties, this creates a direct conflict with FDA's exclusive labeling authority. Any product with a Drug Facts label is regulated first and foremost as a drug and adding additional state-mandated labeling requirements would conflict with federal regulations and confuse consumers about which regulatory framework applies.

Impractical Testing and Labeling Requirements

The bill's testing requirements lack the specificity necessary to ensure consistent, reliable results. While H 7110 mandates testing by "independent laboratories accredited by the FDA or an equivalent authority," it provides no detail regarding testing methodologies, sample sizes, frequency of testing, or acceptable margins of error. This ambiguity could result in widely varying analytical results across different laboratories, making compliance assessment arbitrary and inconsistent.

Moreover, the labeling requirements create substantial practical challenges for products distributed nationally. Uniformity in labeling and ingredient regulation is essential for maintaining efficient interstate commerce in these essential consumer products. Requiring manufacturers to create Rhode Island-specific labeling and compliance documentation fragments the national regulatory system, increases manufacturing costs, and creates supply chain complications without providing consumers with meaningful additional protection beyond what FDA regulation already provides.

The public reporting requirement in Section 23-18.20-6, which mandates that manufacturers submit testing reports to the Department of Business Regulation for public posting, raises

additional concerns about proprietary manufacturing information and creates administrative burdens for both manufacturers and the state agency.

Disproportionate Enforcement Mechanisms

The bill's mandatory recall authority represents a disproportionately severe enforcement mechanism given the undefined nature of many provisions and the fact that manufacturers cannot control naturally occurring trace metals in raw materials. Section 23-18.20-7 authorizes the Department of Business Regulation to order recalls at manufacturer expense for any product exceeding the concentration limits, coupled with civil penalties of up to \$250,000 per violation.

These enforcement provisions fail to recognize the FDA's longstanding acknowledgment that trace metals from environmental sources cannot be entirely eliminated from products made with natural materials. Imposing recall authority and substantial penalties under these circumstances would expose manufacturers to significant liability for conditions beyond their control, potentially forcing recalls of safe products that pose no actual health risk to consumers.

The combination of scientifically unsupported concentration limits, duplicative oversight, impractical compliance requirements, and severe penalties creates an enforcement regime that is fundamentally unworkable and unjust.

Recommended Amendments

If the Committee chooses to advance this legislation, we strongly urge the following amendments:

- Concentration limits should be developed through a science-based rulemaking process that considers actual health risks, exposure pathways, and the unavoidability of trace metals in natural materials, in consultation with FDA and relevant scientific experts.
- The bill should explicitly exempt all FDA-regulated drugs, including OTC drug-cosmetic combination products, from its scope to avoid conflicts with federal law.
- Testing requirements should specify accepted methodologies, quality assurance standards, and recognition that variation in naturally occurring metals is normal and expected.
- Labeling requirements should be eliminated or revised to avoid conflicts with federal requirements and interstate commerce concerns.
- Enforcement provisions should be modified to exclude liability for naturally occurring, unavoidable trace metals and to provide graduated enforcement mechanisms rather than immediate recall authority.
- The bill should include provisions harmonizing state requirements with existing FDA standards rather than creating a parallel regulatory regime.

Conclusion

CHPA shares the sponsors' goal of ensuring the safety of personal hygiene and care products. However, H 7110 pursues this goal through an approach that is scientifically unsupported, duplicative of existing federal oversight, impractical to implement, and likely to impose substantial costs on manufacturers and consumers without providing meaningful public health benefits.

We respectfully urge the Committee to reject H 7110 in its current form. We stand ready to work with the Committee and bill sponsors to develop alternative approaches that would genuinely enhance consumer protection while respecting established federal regulatory frameworks and scientific principles.

Thank you for your consideration of these concerns. I would welcome the opportunity to discuss these issues further or to provide additional technical information to assist the Committee's deliberations.

Respectfully submitted,

A handwritten signature in blue ink, reading "Carlos I. Gutiérrez".

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CC: Members of the House Committee on Health and Human Services
The Honorable Representative Karen Alzate