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Secretary James Kenney
New Mexico Environment Department
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Submitted via Public Comment Portal

Secretary Kenney,

On behalf of the Consumer Healthcare Products Association (CHPA), the national trade association representing manufacturers of over-the-counter medicines, dietary supplements, and OTC medical devices, I am submitting the following comments in response to the New Mexico Environment Department's (NMED) public comment solicitation to inform the reports required under House Joint Memorial 3 (HJM 3). These comments address the current exemption for products regulated as drugs, medical devices, and their packaging in the PFAS Protection Act (HB 212) and subsequent rulemaking relating to warning labels. CHPA strongly recommends that NMED preserve this exemption in its current form and presents the scientific basis for that position.

The scientific evidence demonstrates that an exemption for OTC medicines, medical devices, and associated packaging systems is warranted because (1) these products serve essential public health functions, (2) PFAS-containing materials often provide unique and difficult-to-replace performance characteristics, (3) available risk-assessment data demonstrate that exposure levels can be far below health-based thresholds even under conservative assumptions, and (4) these products are already governed by comprehensive United States Food and Drug Administration (FDA) regulatory frameworks. A risk-based essential-use exemption is therefore more scientifically justified than a categorical prohibition.¹

Current Statutory Exemption for Drugs and Medical Devices

Section 3(A) of the PFAS Protection Act explicitly exempts a "product regulated as a drug or medical device by the United States Food and Drug Administration" from the Act's prohibitions. This exemption reflects a legislative determination that the FDA already regulates the safety, efficacy, and composition of these products within a comprehensive federal framework, one that governs everything from raw material specification to manufacturing controls to post-market surveillance. CHPA's members manufacture a wide range of these FDA regulated products, including pain relievers, allergy medications, incontinence products, menstrual products, thermometers, blood

¹ U.S. Food and Drug Administration. (2026, August). *Container closure systems for human drugs and biological products: Guidance for industry (Draft guidance)*. U.S. Department of Health and Human Services. <https://www.fda.gov/media/194220/download>

glucose monitors, and others, all of which serve everyday and essential health functions for New Mexico residents.

This exemption has already been tested and confirmed once in New Mexico's own rulemaking process. In earlier comments to the Environmental Improvement Board on NMED's proposed implementing rules, CHPA urged that the exemptions be extended explicitly to the state's PFAS labeling proposal, on similar grounds that a product exempted from the Act's substantive prohibitions should not simultaneously be subject to a labeling requirement premised on the presence of a prohibited substance. The Department's final adopted rule applied the exemption to drugs, medical devices, and their packaging, an outcome that was the product of a full public comment and technical review process and represents NMED's own considered judgement on how exemptions in HB 212 should operate. CHPA appreciates the opportunity to comment again at this early stage of NMED's technical review under HJM 3 and urges the Department to recommend the preservation of the exemption that has already been carefully constructed for drugs, medical devices, and their packaging.

The Drug and Medical Device Exemption Rests on a Different Foundation Than the Fluoropolymer Exemptions

HJM 3 directs particular attention to the current fluoropolymer exemptions, which is described as having been adopted based on "limited scientific literature". That description should not apply to, and should not be extended to, the current drug and medical device exemption. The fluoropolymer exemptions rest on an evolving scientific record about the behavior and risk profile of a broad chemical class. The drug and medical device exemption rests instead on the existence of a comprehensive, product-specific federal regulatory regime. This includes the FDA review of individual products for safety and efficacy, ongoing agency oversight of manufacturing and labeling, and an established mechanism, through FDA itself, for revisiting any product's safety profile if new evidence emerges. These are two different kinds of exemptions, justified by two different kinds of facts, and HJM 3's critique of the scientific basis for one has no logical bearing on the other.

To consider the two exemptions as interchangeable would substitute categorical convenience for the individualized analysis that the Legislature performed. Section 3(A) exempts, without further qualification, products regulated by the FDA as drugs or medical devices. That unqualified language, combined with its reinforcement throughout the Act's reporting, testing, packaging provisions, and NMED's extension of the exemption to the labeling provision in rulemaking, reflects a deliberate and repeatedly confirmed legislative and regulatory decision. CHPA respectfully urges NMED to evaluate the drug and medical device exemption on its own terms in the report, rather than as a component of the review aimed at a different exemption with a different rationale.

The stakes of this distinction are not abstract. If NMED's report treated the drug and medical device exemption as part of a general reconsideration of PFAS exemptions and

elect to remove that exemption, some products that inadvertently fall within the definition of “intentionally added PFAS,” such as certain allergy nasal sprays that rely on fluorinated components for formulation stability or delivery performance, could become non-compliant based solely on their chemical composition, with no finding that they pose any actual risk to consumers. Manufacturers would then face a choice between reformulating products that have already been reviewed and approved by FDA, a process that itself requires new FDA authorization and can take years, or withdrawing them from New Mexico shelves altogether. Either outcome would reduce access to everyday OTC healthcare products for New Mexico consumers without any corresponding public health benefit, since the products in question would remain unchanged in their actual safety and performance characteristics. This is precisely the kind of result Section 3(A) was written to prevent.

Case for the Exemption

The scientific record independently supports maintaining the exemption for drugs, medical devices, and their packaging. Any PFAS containing materials used in these products are typically related to supply performance characteristics, like chemical resistance, barrier protection, and long-term stability, which are difficult or impossible to replace without compromising the product’s safety or effectiveness. Available risk assessment data indicates that resulting consumer exposure levels remain well below health-based thresholds, including under worse-case assumptions.² Since these products are already subject to comprehensive federal regulatory oversight, an additional layer of state-level substance restriction directed at these products only duplicates a framework that already exists and functions as designed. This distinction is most important regarding packaging. Any evaluation of PFAS in product packaging should depend on actual risk to end consumers, rather than the mere presence of a PFAS related compound. OTC medicine and medical device packaging may sometimes be fluorinated specifically to impart barrier properties that prevent moisture or gas permeation, preserve product potency, and maintain sterility. These are not cosmetic or convenience features, and are instead functional requirements that are tied directly to whether the product inside the packaging remains safe and effective for consumers. Migration testing has demonstrated that the presence of PFAS related compounds in this packaging does not, itself, equate to meaningful consumer risk. As these products are distinct from discretionary consumer products, policy approaches developed for cookware, textiles, cosmetics, or household products should not be automatically applied to products that serve essential public health functions. Further, the technical case against substitution reinforces the case for exemption. PFAS used in these applications are used because of specific and well documented performance properties, including chemical resistance, thermal stability, barrier protection, corrosion

² Racz, L., Gauthier, A., Bare, J., Heintz, M., Feifarek, D., Kennedy, S., & Panko, J. (2024). Assessment of perfluorocarboxylic acids in fluorinated high-density polyethylene containers and estimation of potential non-cancer risks associated with anticipated use scenarios. *Regulatory Toxicology and Pharmacology*, 147, 105560. <https://doi.org/10.1016/j.yrtph.2024.105560>

resistance, water resistance, and durability.³ OTC healthcare products face particular significant barriers to substitution, as material performance is not a matter of consumer preference, but needs to directly support safety, efficacy, sterility, stability, and basic functionality. The FDA has already reached this conclusion with respect to medical devices specifically. As the agency has stated, “The FDA's determination based on available scientific studies is that there is no reason to restrict the continued use of fluoropolymers in medical devices.”⁴

This has direct implications for how NMED should weigh the cost of considering altering exemptions. Requiring replacement of PFAS in healthcare products before alternatives are fully validated risks a set of specific and foreseeable consequences, reduced product performance, disruption to established supply chains, altered product stability profiles, and potential pulling of vital healthcare products from store shelves.

Conclusion

CHPA respectfully requests that NMED’s HJM 3 report recommend that the Legislature continue the current exemptions for FDA-regulated drugs, medical devices, and their packaging without further modification. CHPA will submit additional scientific comments as NMED’s technical review continues and looks forward to ongoing participation in this process.

Thank you for considering these comments.

Respectfully submitted,



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³ RTI International. (2023, June 20). Overview of per- and polyfluoroalkyl substances (PFAS) chemistries, sources, uses, regulatory trends, market dynamics, and potential health risks in U.S. and international markets: Final white paper prepared for the U.S. Consumer Product Safety Commission. U.S. Consumer Product Safety Commission, National Product Testing and Evaluation Center. <https://www.rti.org>

⁴ U.S. Food and Drug Administration. (2026, September 1). PFAS in medical devices: What you need to know. U.S. Department of Health and Human Services. FDA PFAS in Medical Devices webpage