AdvaMed
Advanced Medical Technology Association

1301 Pennsylvania Avenue, NW
Suite 400
Washington, D.C. 20004
P :: 202.783.8700
F :: 202.783.8750
W:: AdvaMed.org

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Phoebe Suina
Chair
New Mexico Environmental Improvement Board (EIB)
1190 St. Francis Dr. Suite N4050
Santa Fe, NM 87505

Re: PER- AND POLY-FLUOROALKY SUBSTANCES IN CONSUMER PRODUCTS 3 PART 2 PROHIBITIONS

Dear Chair Suina:

On behalf of AdvaMed, the Medtech Association, I am writing today to share feedback on the draft Per and Poly-Fluoroalkyl Substances in Consumer Products Prohibitions on Products Containing Per- Or Poly-Fluoroalkyl Substances; Currently Unavoidable Use; Reporting; Labeling; Testing' Fees and Penalties rulemaking.

AdvaMed is the largest medical technology association, representing the leading innovators and manufacturers transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Our over 600 members range from emerging companies to large multinationals, and include device, diagnostic, medical imaging, and digital health technology companies.

The medical device industry shares New Mexico's commitment to protecting public health and the environment. However, we are deeply concerned that the proposed PFAS labeling requirements, particularly as applied to rigorously regulated FDA-regulated medical devices, could have significant unintended consequences for patient safety, create serious regulatory inconsistencies, and harm access to critical medical technologies.

Concerns with Proposed Labeling Requirement

As drafted, the labeling provision would require products containing PFAS, including FDA regulated medical devices made with fluoropolymers, to include the following statement warning of the potential consequences of using the product:

> *"This product is made with PFAS or contains component parts made with PFAS. PFAS are a family of chemicals, exposure to which are associated with negative*

health and environmental effects. For more information on the location of components made with PFAS, review the product's operation and maintenance manual."

The labeling requirement implies a health risk that neither the FDA has identified nor does scientific research substantiate for fluoropolymers used in medical devices. This would require manufacturers to place a state mandated safety warning on medical devices whose risks have already been rigorously evaluated by the FDA for safety and efficacy.

As such, the proposed rule creates three major concerns:

- **Conflict with FDA labeling standards and federal preemption:** The warning proposed by NMED would constitute a safety claim subject to additional FDA review. The FDA sets national comprehensive standards to ensure consistency, scientific accuracy, and consumer protection. The review covers everything from premarket review of products for safety and effectiveness to product labeling and claims. Imposing a state-specific requirement could create federal compliance challenges and risk violating federal labeling preemption.
- **Operational and supply chain challenges:** A New Mexico-specific label will likely require a host of new submissions to FDA across the industry on vital medical technologies for patients, triggering redesigns, additional biocompatibility and packaging testing, recertification, and distribution challenges. These changes are resource-intensive and importantly will delay and limit access to critical medical devices for patients and impact industry sustainability goals.
- **Potential for patient and provider confusion:** The FDA has repeatedly stated these materials have a long history of safe use and are "very unlikely to cause toxicity to patients." Introducing additional state-specific labels suggesting a health risk with FDA regulated products may cause unwarranted concern, hesitation in treatment, or misinterpretation of device safety.

Legislative Intent

Based on the final legislative text, it is unclear why the Department has included exempted product categories, including FDA-regulated medical devices, within the labeling requirement. Every other substantive provision of HB 212 (product bans, testing, and reporting) explicitly exempts FDA-regulated products. This strongly indicates that the legislature did not find FDA-regulated products to present the same risks as other PFAS. Medical devices were exempted from the bill because they are essential, heavily regulated,

and not associated with environmental or human health concerns that were motivating factors behind the law.

Applying a warning label to these same products now contradicts the statute's original intent. We believe the labeling provisions were intended to be applied narrowly to carry out the core provisions of the legislation -- not to broadly affect all products. Further, the use of permissive language "may" in the labeling provision suggests that the entire section is optional and may be limited.

Lastly, the intent of HB 212 focuses on traditional consumer products, whereas most medical devices are purchased by health systems or providers. Many devices, like implantables, guidewires, and catheters, are never handled or even seen by the traditional consumer. Applying consumer-facing labeling requirements to a professional-use medical product is inconsistent with the realities of the healthcare system and the intent of the law.

Robust FDA Oversight

Medical device labeling is comprehensively regulated by the U.S. Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §360c et seq.). Under this federal framework:

- All written, printed, or graphic material that accompanies a medical device is considered labeling and is subject to FDA review. Labeling statements are treated as claims about a product's safety, effectiveness, or risk profile, requiring extensive review and validation.
- States are expressly preempted from imposing additional or differing labeling requirements under 21 U.S.C. §360k(a).

This labeling requirement would fundamentally contradict the preeminent role that the FDA has long held in regulating the labeling of its regulated products. The FDA being the sole authority for medical device and pharmaceutical products is grounded in what is best for patients: a single, unified approach to patient safety ensures that patients have a consistent, prudent approach to disclosing the most necessary, evidence-based information. State based labeling could distract patients and providers from the critical information conveyed in an FDA label, including proper usage/dosing, contraindications, etc. It could also imply that the device or drug are inherently unsafe, a statement that could contradict the FDA's determinations as well as undermine the practice of medicine and erode confidence in the safety and effectiveness of FDA-regulated products.

Given these constraints, imposing a New Mexico specific label would create significant operational burdens, trigger packaging redesigns, and may require new product submissions including additional biocompatibility and packaging testing. These changes would be resource-intensive, time-consuming – taking anywhere from 3-5 years to fully effectuate -- and disrupt national supply distribution systems without providing any additional health benefits for patients.

Safety of Fluoropolymers in Medical Products

PFAS refers to a very broad group of over 10,000 chemicals that vary widely in structure and properties. Not all PFAS are the same, and only a small subset of these chemicals have been associated with potential environmental or health effects. Polymeric PFAS used in medical devices, such as fluoropolymers, are chemically distinct. These materials are stable, inert, non-bioavailable, and have been used safely for decades in critical healthcare applications, including catheters, pacemakers, and surgical instruments.

A recent publication by the FDA indicates that fluoropolymers used in medical devices are not linked to toxicity or adverse health effects. Because of their high molecular weight and chemical stability, these materials do not migrate, dissolve, or cross cell membranes. FDA reviews – including an extensive 2021 study in partnership with ECRI – found no evidence of patient harm or degradation from fluoropolymer-based devices. As the FDA states, "The PFAS used in medical devices are not the same as those identified as being potentially harmful to people in other contexts." [1] The FDA goes on to say " the FDA's evaluation is that currently there is no reason to restrict their continued use in devices." The PFAS materials used in medical devices (known as fluoropolymers) have a long history of use.

In addition to their safety record, fluoropolymers provide unique performance characteristics that make them essential to modern medicine, such as chemical resistance, biostability, and low friction. There are currently no materials that can replace them without compromising safety or effectiveness. For these reasons, the decision to exempt fluoropolymers from HB 212's restrictions was consistent with both scientific understanding and patient care needs.

[1] https://www.fda.gov/medical-devices/products-and-medical-procedures/pfas-medical-devices

Additionally, the Department's leadership has stated that fluoropolymers are "not as risky" as other PFAS. [2] Also, the NMED website specifically claims that "The legislation includes important exemptions and enforcement provisions – such [as] medical devices and electronic – where PFAS is essential and does not pose serious harm to those using the products." To now compel labeling that directly links fluoropolymer-containing products to negative health and environmental impacts undermines the legislature and department's own rationale for the exemption.

Potential Effects on Healthcare Access and Patient Outcomes

Medical devices are essential for patient care, with many critical technologies — such as cardiovascular stents, pacemakers, vascular grafts, guidewires, blood collection bags, instruments and equipment, and many more — relying on the unique properties of fluoropolymers. The proposed rule will inevitably lead to significant delays and limit the availability of medical devices—including through unusable medical device inventory —as manufacturers will be required to create and implement a standalone compliance and distribution program dedicated to this new process. This could create significant practical and financial challenges for companies and risk access to critical lifesaving and life enhancing devices for New Mexico patients.

Operationally, creating New Mexico-specific product streams would create significant challenges, and require major system overhauls to segregate, track, and label products. This change would not only impact packaging, but distribution and IT systems across the supply chain. This burden may ultimately force some manufacturers to limit or withdraw products from the New Mexico market, reducing access to life-saving technologies, poorer clinical outcomes, and increased morbidity and mortality.

A state-specific PFAS warning label on medical devices also risks confusing patients and providers who rely on the longstanding track record of FDA-reviewed products and information. Introducing additional state-specific labels suggesting a health risk may cause unwarranted concern about the safety and efficacy, hesitation in treatment, or misinterpretation of device safety.

We encourage NMED to take a balanced approach that maintains alignment with FDA oversight and scientific evidence, protects patient access and safety while meeting environmental objectives.

[2] Hearing on HB 212 Before the Senate Conservation Committee (Mar. 8, 2025) (testimony of Secretary Kenney, timestamp 10:28 AM).

NMED Should Expressly Exempt Medical Devices

Under the proposed waiver process, exempted product categories may only apply for a waiver if no intentionally added PFAS comes into contact with a consumer. This arbitrary threshold will capture nearly all medical devices and may not provide any additional protections for patients.

Over the last thirty years, advancements in medical device technology have transformed treatment pathways. Minimally invasive procedures, like leading cardiac surgeries, rely on flexible, fluoropolymer-coated guidewires to navigate the body safely and effectively. Many of these devices and procedures rely on PFAS. These materials have enabled lifesaving procedures, increased patient access, and improved patient outcomes.

Furthermore, there is no scientific data to suggest these products are unsafe or more harmful to the consumer than products not containing PFAS. Medical products containing PFAS have been available to patients for over 50 years, with tens of millions of devices used without demonstrating adverse health effects. Yet, the waiver process does not recognize this longstanding track record of safety and federal oversight. The process remains unclear, overly burdensome, and misaligned with the FDA's existing regulatory framework. The waiver process also creates significant uncertainty for manufacturers, as the department has no criteria for how and when a waiver will be granted.

Recommendations

We respectfully recommend that the Environmental Improvement Board:

1. Clarify that any labeling requirements under HB 212 do not apply to FDA-regulated medical devices or their packaging.
2. Maintain the statutory exemption for fluoropolymers from all requirements of HB 212, consistent with scientific and regulatory findings.

We appreciate the opportunity to provide comments on the draft rule and its potential impact on the medical device industry.

Sincerely,

Senior Director, State Government and Regional Affairs
AdvaMed