THE VOICE FOR MEDICAL INNOVATION
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Via Electronic Submission

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

RE: EIB 25-61 (R) – Proposed Rule to Adopt 20.13.2 NMAC (PFAS in Consumer Products)

Dear Chair Suina:

On behalf of the Medical Device Manufacturers Association (MDMA), I am submitting comments in response to the New Mexico Environment Department (NMED) proposed rule, per- and poly-fluoroalkyl (PFAS) in Consumer Products. On October 8, 2025, NMED submitted a petition to the New Mexico Environmental Improvement Board (EIB) to grant a hearing for, and then adopt, the proposed rule, which implements provisions under HB 212 related to the proposed rule. Since the proposal has the potential to place a unique and exceptional large burden on medical device manufacturers, we request that EIB deny NMED's petition to adopt the proposed rule. As it is currently proposed, NMED's rule conflicts with federal law and regulation, extends extremely burdensome administrative obligations and labeling requirements to the very products that the legislature exempted from the law's core provisions, and – as a result – jeopardizes New Mexico's access to medical devices and cost-effective health care. Furthermore, when HB 212 was enacted, the legislature specifically exempted medical devices and fluoropolymers from restriction and reporting provisions, signaling that these products were not considered to pose the same risks as other PFAS. As such, requiring a warning label on these products would be inconsistent with the statute's intent.

MDMA

The Medical Device Manufacturers Association members share NMED's commitment to public health. MDMA is a national trade association that provides educational and advocacy assistance to approximately 300 innovative companies in the field of medical technology. Our members, the majority of which are small to mid-sized medical device companies, have a strong record of delivering breakthrough therapies to treat chronic diseases and life-threatening conditions while lowering the cost of care. MDMA's mission is to ensure that patients have timely access to the latest advancements of safe and effective medical technologies that improve health outcomes. MDMA has many members that manufacture, develop, and sell medical devices in New Mexico.

ISSUES WITH THE PROPOSED RULE

In accordance with statutory requirements under HB 212 Section 3.A, the proposed rule exempts medical devices from the product prohibition (20.13.2.9), currently unavoidable use (20.13.2.11), reporting requirement (20.13.2.12), and product testing (20.13.2.14) provisions. However, there is no explicit or guaranteed exemption for medical devices under the labeling provision (20.13.2.13). Instead, manufacturers of products like medical devices may apply and be granted waivers from the labeling requirements if they demonstrate that consumers will not come into direct contact with PFAS while the product is being used as intended and throughout the product's useful life. We believe the waiver process is extremely limiting, creates a quasi-reporting obligation in conflict with the exemption pursuant to 20.13.2.12, and may unfairly impact numerous medical devices since their effectiveness often relies on interacting directly with the user or patient.

This approach alongside NMED's other proposed option for complex devices are unworkable for the reasons described below.

CONFLICTS WITH FEDERAL LAW AND REGULATIONS

To offer protections for all Americans, Congress prohibited states from setting their own standards for medical devices. States can only enact a state-specific requirement if FDA "grant[s] an exemption from preemption if the State requirement is more stringent than the Federal requirement and is required by compelling local conditions."[1] Since medical devices are not likely sources of significant PFAS releases and exposure in New Mexico, there is no compelling local condition concerning medical device management that could justify a state-specific standard under federal law.

Moreover, even if NMED proposed labeling requirements is found not to be preempted under federal law, medical devices, their chemical composition and characteristics, their packaging, and their labeling are regulated by FDA. FDA has already reviewed a device's composition and durability and biocompatibility, including the leachability of fluoropolymers and other fluorinated compounds. If a medical device manufacturer must apply the labeling in the proposed rule, manufacturers must submit this change to FDA for review. The product cannot be marketed or sold in New Mexico until FDA approves the change. This is especially concerning because, in this instance, the New Mexico labeling mandate would compel manufacturers to make a state-imposed safety statement that the FDA has not reviewed or approved. To the contrary, FDA has already concluded that comprehensive studies on many fluoropolymers like PTFE "found no conclusive evidence of patient health issues."[2] Since FDA has not found the NMED proposed information necessary for the safety and the effectiveness of the product, FDA may find the applicant's information conflicts with federal regulation. This uncertainty raises the substantial risk that New Mexico citizens will not have timely access to life saving medical devices.

EXTENSIVE BURDENS

The proposed approach also presents three unnecessary burdens on medical device

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[1] U.S. Food and Drug Administration, *Exemptions from Federal Preemption of State and Local Medical Device Requirements*, 21 C.F.R. § 808.20(a) (2025).

[2] U.S. Food and Drug Administration. (2025, August 6). PFAS in medical devices. https://www.fda.gov/medical-devices/products-and-medical-procedures/pfas-medical-devices

manufacturers. First, manufacturers in the medical device sector will have to file thousands of labeling waiver applications for devices that already meet the labeling exemption criteria. Therefore, manufacturers and NMED are unnecessarily burdened with significant paperwork and administrative requirements to carry out NMED's proposed case-by-case exemption mechanism. Like New Mexico, Congress and other U.S. states have exempted medical devices from PFAS reporting requirements. Unlike many other manufacturing sectors, medical device manufacturers would have to gather the extensive and detailed information from a complex supply chain of components and materials sourced from all over the globe in order to confirm whether compliance with the labeling provision is required.

Second, the application mechanism presents significant uncertainty to applicants. NMED only states that eligible manufacturers may apply for the labeling waiver and includes the two aforementioned eligibility prerequisites. NMED does not guarantee exemption should manufacturers meet these or other criteria that NMED would use to make decisions on applications. Importantly, NMED's proposed rule does not establish a timeframe within which NMED must act to respond to such labeling waiver request. Manufacturers will, consequently, have to wait for an indeterminate period of time for individual outcomes to each application without certainty. Furthermore, NMED's proposed rule states that a product containing an intentionally added PFAS is banned unless labeled by January 1, 2027. For medical devices, as just one category of products exempted from product prohibitions pursuant to 20.13.2.9, this presents a direct and impermissible conflict with the statute's intent.

Third, medical device distribution channels are complex and nationally integrated. Requiring a state-specific PFAS warning label for New Mexico would introduce significant operational challenges for manufacturers. Shipping devices to different states would require a state-specific distribution process for New Mexico, involving tracking, separating, and labeling products. This change would impact packaging, distribution, and IT systems, and increase both delivery time and costs. Moreover, doctors often order multiple sizes and/or configurations of the same medical device for a single patient so that the doctor can fit the patient with the best device for the patient's situation. For the devices not used, the doctor then returns the others back to the manufacturer/distribution center. For returns from New Mexico, there would be additional cost to repackage or remove the labels at the distribution center. The complexity, investment, and resources needed to create and manage this state-specific labeling system may outweigh the economic benefits of serving the New Mexico market, making it possible that some manufacturers would choose not to offer their products in the state.

For complex medical devices, there is further risk to confidential business information. The proposed rule requires disclosure for complex durable goods in manuals and specification sheets of each PFAS-containing component. If NMED denies a waiver for a complex medical device, the manufacturer would be obligated to disclose proprietary information and release sensitive design information. As mentioned previously, our members include approximately 300 innovative companies in the field of medical technology. The risk to intellectual property is a considerable concern.

SCIENTIFIC AND FUNCTIONAL BASIS FOR EXEMPTING FLUOROPOLYMERS

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. Fluoropolymers used in medical devices 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.

The aforementioned 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's review – 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. The PFAS materials used in medical devices (known as fluoropolymers) have a long history of use. The best-known of these materials is polytetrafluoroethylene (PTFE), which is used in multiple consumer products, and was first used in a medical device in the 1950s" and "The FDA's evaluation is that currently there is no reason to restrict their continued use in devices".

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 known alternatives with equivalent technical performance as fluoropolymers. For these reasons, the decision to exempt fluoropolymers from HB 212's requirements was consistent with both scientific understanding and patient care needs.

PROPOSED ACTION

All these consequences of NMED's proposed labeling requirements for medical devices raise barriers and costs that will discourage innovative companies like MDMA members from serving the New Mexico market. MDMA's small businesses face substantial hurdles to bring novel, cost saving therapies to market. The proposed labeling requirements raises another, unnecessary obstacle and risk to better health care in New Mexico.

We note that HB 212 gives EIB discretion not to apply the product labeling regulations to medical devices: "[EIB] *may*…adopt rules to carry out [HB 212], including requiring the labeling of products" (emphasis added). HB 212 does not include a compliance timeframe for labeling nor does it frame labeling as a necessary regulatory tool. Rather, the statutory language indicates that labeling is an optional measure that should be implemented only to the extent that it support the law's core intentions. Product prohibitions, reporting requirements, and product testing, on the other hand, are statutorily mandated mechanisms and included categorical exemptions for medical devices. Furthermore, NMED's proposed rule states that a product containing an intentionally added PFAS is banned unless labeled by January 1, 2027. For medical devices, as just one category of products exempted from product prohibitions pursuant to 20.13.2.9, this presents a direct and impermissible conflict with the statute's intent. HB 212

does not direct NMED or EIB to expand the statute's scope by applying the optional labeling implementation measure in a way that undermines and conflicts with (instead of complementing) the exemption framework incorporated into the statute's core provisions.

For these reasons, we ask EIB to deny NMED's petition to approve the proposed rule unless it is amended to include language explicitly exempting medical devices and fluoropolymers from the labeling requirements. Extending labeling obligations and requiring waiver applications for otherwise exempt products and materials contradicts legislative intent, imposing regulatory uncertainties and compliance burdens that can risk undermining patient safety without advancing consumer protection.

Thank you for your attention to our comments. If we can provide additional information, please contact me at mleahey@medicaldevices.org or (202) 354-7171.

Sincerely,

Mark Leahey
President & CEO
MDMA