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Via Electronic Submission — NMED Public Comment Portal

New Mexico Environment Department
Attn: House Joint Memorial 3 Public Comment
Harold L. Runnels Building
1190 St. Francis Drive, Suite N4050
Santa Fe, NM 87505
NMED-PFAS@env.nm.gov

RE: House Joint Memorial 3 (2026) — Comments on the Public Health, Environmental, and Economic Risks of the Medical Device and Fluoropolymer Exemptions Codified in the Per- and Poly-Fluoroalkyl Substances Protection Act

To the New Mexico Environment Department:

On behalf of the Medical Device Manufacturers Association (MDMA), I submit these comments to inform the report the New Mexico Environment Department (NMED) is preparing under House Joint Memorial 3 (HJM 3), which the Legislature passed on February 18, 2026.¹ The HJM 3 requests that NMED, in consultation with other state agencies, assess the public health, environmental, and economic risks of the exemptions codified in the Per- and Poly-Fluoroalkyl Substances Protection Act (the Act)² and recommend to the Legislature whether those exemptions should be continued, modified, or removed. MDMA appreciates the opportunity to contribute to that record.

MDMA respectfully recommends that NMED report to the Legislature that the exemption for medical devices and drugs regulated by the U.S. Food and Drug Administration (FDA) and the exemption for fluoropolymers should be continued without modification.

The HJM 3 recites that the Act exempts certain products from the phaseout and prohibition “based on limited scientific literature regarding chemical degradation, environmental mobility and persistence, potential human exposure pathways and possible health impacts.” For the two exemptions addressed in these comments, that premise does not hold. The evidentiary record specific to fluoropolymers in medical devices is unusually deep. It includes a federally commissioned systematic review of the most widely used fluoropolymer in devices, two peer-reviewed critical reviews applying internationally recognized polymer-of-low-concern criteria, published explanted-device chemical data, and a formal FDA determination — reaffirmed as recently as September 1, 2026 — that there is no reason to restrict the continued use of fluoropolymers in medical devices. These comments summarize that record and then address each of the three risk categories HJM 3 identifies.

MDMA

¹ House Joint Memorial 3, 2026 Reg. Sess. (N.M. 2026), <https://www.nmlegis.gov/Sessions/26%20Regular/final/HJM003.pdf>.

² Per- and Poly-Fluoroalkyl Substances Protection Act, 2025 N.M. Laws ch. 102 (H.B. 212), codified at NMSA 1978, §§ 74-15-1 et seq. Product and material exemptions appear at Section 3 of the Act.

MDMA 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.

I. THE EXEMPTIONS REST ON A SUBSTANTIAL SCIENTIFIC RECORD

A. FDA has evaluated this precise question and reaffirmed its conclusion this month.

On September 1, 2026, FDA updated its public webpage *PFAS in Medical Devices: What You Need to Know*.³ The update added a Key Takeaways summary, a new section describing how FDA evaluates devices before and after market, and a six-question FAQ. Three determinations on that page bear directly on HJM 3.

First, FDA states that the fluoropolymers used in medical devices are not the same as the PFAS linked to environmental contamination or health concerns since they differ in chemical structure, in molecular size, and in interactions with the body. Second, FDA identifies fluoropolymers as critical components of life-saving devices — including catheters, cardiovascular implants, tubing, and wound dressings — because of biocompatibility, durability, electrical resistance, and lubricity and states that no other materials currently exist that can perform the same critical roles. Third, FDA states that its determination based on available scientific studies is that “*there is no reason to restrict the continued use of fluoropolymers in medical devices.*”⁴

FDA also addresses the mechanism that would be necessary for harm to occur. The fluoropolymers used in medical devices are typically comprised of molecules too large to cross through cell membranes and, as a result, are very unlikely to cause toxicity to patients. On the empirical record, FDA explains that fluoropolymers have been used as materials of construction in medical devices since the 1950s, are now used in many thousands of devices from catheters to pacemakers, and that no toxicity issues have been connected to their use in devices. FDA reaches that conclusion on the strength of its post-market monitoring program and an independent study it commissioned from Emergency Care Research Institute (ECRI), which collected data from more than 1,800 health care provider organizations and more than 1,750 published, peer-reviewed articles relevant to the safety profile of polytetrafluoroethylene (PTFE) in medical applications, and which found no conclusive evidence of patient health issues associated with PTFE as a material.⁵

B. Independent peer-reviewed reviews reach the same conclusion.

The scientific literature on fluoropolymers is not limited, and it is not confined to industry submissions. Henry et al. (2018) assembled fluoropolymer toxicity data, human clinical data, and physical, chemical, thermal, and biological data, and concluded that fluoropolymers satisfy widely accepted criteria for classification as polymers of low concern. The review reports that fluoropolymers exhibit thermal, chemical, photochemical, hydrolytic, oxidative, and biological stability, have negligible residual monomer and oligomer content and low to no leachables, are practically insoluble in water and not subject to long-

³ U.S. Food & Drug Admin., *PFAS in Medical Devices: What You Need to Know* (updated Sept. 1, 2026), <https://www.fda.gov/medical-devices/products-and-medical-procedures/pfas-medical-devices-what-you-need-know>.

⁴ Id. (Key Takeaways; “What Types of Devices Use Fluoropolymers?”).

⁵ Id. (FAQ 2, “What does the evidence say about the safety of PFAS in medical devices?”). The referenced study is ECRI, *Medical Device Material Performance Study: PTFE Safety Profile* (2021), commissioned by FDA.

range transport, and, at molecular weights well above 100,000 Da, cannot cross the cell membrane. Of particular relevance here, the review reports that clinical studies of patients receiving permanently implanted PTFE cardiovascular devices demonstrate no chronic toxicity or carcinogenicity and no reproductive, developmental, or endocrine toxicity. Its conclusion is that fluoropolymers are distinctly different from other polymeric and non-polymeric PFAS and should be separated from them for hazard assessment and regulatory purposes.⁶

Korzeniowski et al. (2023) extended that analysis to fluoroplastics and fluoroelastomers and concluded that commercial fluoropolymers representing approximately 96 percent of the global commercial fluoropolymer market meet the polymer-of-low-concern criteria.⁷ Together, these two peer-reviewed critical reviews are the principal published application of internationally recognized regulatory criteria to this material class, and both support the distinction the New Mexico Legislature drew in 2025.

C. Device-specific data show no measurable release after years of implantation.

Beyond the material-class literature, there is direct device-level evidence. A peer-reviewed extractables study co-authored by an FDA scientist examined cardiac leads explanted after periods of implantation ranging from approximately three months to nearly eleven years. The study found no PFAS-related extractables traceable to the leads' fluoropolymer components at a detection sensitivity of 100 nanograms per milliliter.⁸ A companion clinical review reaches consistent conclusions and notes that regulatory attention in this area is properly focused on minimizing exposure to small-molecule PFAS rather than on the polymeric materials of device construction.⁹ This is precisely the category of evidence — degradation behavior and human exposure pathways under real conditions of use, over clinically meaningful durations — that HJM 3 identifies as missing.

D. FDA premarket review independently generates the degradation and migration evidence HJM 3 seeks.

Before a medical device may be legally marketed in the United States, the manufacturer must generally submit a premarket submission — a 510(k) notification, De Novo request, or premarket approval application — for a determination on whether marketing will be permitted. As part of that submission, the manufacturer must identify the materials used to construct the device, including materials that directly or indirectly contact the patient and packaging components that could affect the safety of the device or its materials.¹⁰ FDA therefore has a complete picture of which materials, including any fluoropolymer, are present in a device before any review of safety data begins.

The manufacturer must then demonstrate that those materials remain stable under the conditions of use and will not break down or degrade in ways that could compromise device performance or introduce new safety risks over the device's intended period of use. That demonstration includes mechanical testing and chemical

⁶ Henry, B.J., et al., A Critical Review of the Application of Polymer of Low Concern and Regulatory Criteria to Fluoropolymers, 14 Integrated Env'tl. Assessment & Mgmt. 316 (2018), <https://doi.org/10.1002/ieam.4035>.

⁷ Korzeniowski, S.H., et al., A Critical Review of the Application of Polymer of Low Concern Regulatory Criteria to Fluoropolymers II: Fluoroplastics and Fluoroelastomers, 19 Integrated Env'tl. Assessment & Mgmt. 326 (2023), <https://doi.org/10.1002/ieam.4646>.

⁸ Long, E.K., Hassler, J.F., Saylor, D.M., Gitsov, I.P.I., Jolliffe, L., Witkowski, A., Alkatout, J.A., Haugstad, G., & Chaffin, K.A., End of Life Biocompatibility Assessment for Chronically Implanted Cardiac Leads, 113 J. Biomedical Materials Rsch. Part A e37932 (2025). One co-author is affiliated with FDA's Center for Devices and Radiological Health; the publication carries an express disclaimer that it does not represent FDA endorsement or policy.

⁹ Vatterott, P.J., et al., The Role of Per- and Polyfluoroalkyl Substances in Medical Devices and Delivery Systems: Why the Electrophysiologist Should Care, 22 Heart Rhythm 2151 (2025).

¹⁰ 21 C.F.R. § 807.87 (device description requirements, premarket notification); 21 C.F.R. § 814.20(b)(4) (device description requirements, premarket approval); 21 C.F.R. § 860.220(a)(4) (device description requirements, De Novo classification requests). Most class I devices and some class II devices are exempt from premarket notification under sections 510(l) and 510(m) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360(l), (m), but remain subject to FDA's general controls.

characterization of the material's composition and of substances it may contain as a result of manufacturing. Where release into the patient is possible, the manufacturer must evaluate the device's extractables — substances that can be released under deliberately aggressive laboratory conditions — and, where warranted, its leachables, the substances actually shown to migrate under clinical use conditions. For each identified substance, a tolerable intake or tolerable contact level is derived and compared against a health-protective, worst-case estimate of patient exposure, accounting for the duration of contact, the surface area of the body involved, and the route of contact.¹¹ If the resulting data package is inadequate, FDA may request additional data, decline to clear or approve the submission, or otherwise prevent the device from being marketed until the deficiency is resolved.¹²

The practical consequence for NMED's report is straightforward. For FDA-regulated devices, the chemical degradation, environmental mobility, and human exposure questions HJM 3 poses have already been answered device by device, under a federal framework, before the product entered the New Mexico market. Removing the exemption would not generate new information about those questions. It would layer a state process on top of an existing federal one that has already produced the answers.

II. PUBLIC HEALTH RISK OF CONTINUING THE EXEMPTIONS

The public health question HJM 3 asks is whether continuing the exemptions creates risk to New Mexicans. For medical devices, the relevant exposure pathway is patient contact, and that pathway is assessed for every device before marketing under the framework described in Section I.D. The record after roughly seventy-five years of clinical use contains no signal of harm attributable to fluoropolymers as device materials, and FDA has stated it is not aware of any evidence that fluoropolymer PFAS materials in medical devices have harmful public health effects.

It is also worth stating plainly what removing the exemption would and would not accomplish. Applying the Act's labelling requirement to a catheter or a vascular graft would not change its composition and would not reduce any New Mexican's exposure to PFAS. It would hamper access to medical devices for New Mexico residents. Since device manufacturers would need to seek FDA approval for any state-mandated change to the already approved label, manufacturers could not offer affected devices in New Mexico until FDA acts.

Similarly, applying the Act's 2032 prohibition to devices would reduce exposure only by removing the devices from New Mexico residents — and, because no substitute materials with equivalent performance are currently available, by removing entire categories of care. FDA's own explanation of why fluoropolymers are used illustrates the trade-off: biostability is a design requirement precisely because degradation is the hazard, and FDA notes that degradation of a device in the body could lead to pieces breaking off and potentially causing life-threatening medical issues for patients. A policy that displaced fluoropolymers from implants without a validated substitute would introduce the very acute health risk that the material was selected to prevent.

Fluoropolymer-containing devices are used daily in cardiovascular and structural heart procedures, in electrophysiology, in neurovascular intervention, in diabetes management, and in minimally invasive surgery. Delay or loss of access to these technologies would directly impact procedure success rates,

¹¹ Int'l Org. for Standardization, ISO 10993-18:2020, Biological Evaluation of Medical Devices — Part 18: Chemical Characterization of Medical Device Materials Within a Risk Management Process; ISO 10993-17:2023, Biological Evaluation of Medical Devices — Part 17: Toxicological Risk Assessment of Medical Device Constituents.

¹² This description of premarket review is MDMA's own, drawn from the regulatory provisions and consensus standards cited in this Section. It is not a quotation of, or paraphrase of, any published FDA policy statement. FDA's public-facing PFAS webpage describes its evaluation factors in general terms and does not currently set out the materials-disclosure or extractables and leachables methodology at this level of detail; MDMA has separately recommended that FDA add such content to that page.

treatment outcomes, and the quality of care available to patients in New Mexico. The public health risk of continuing these exemptions will be substantial if the exemption was removed.

III. ENVIRONMENTAL RISK OF CONTINUING THE EXEMPTIONS

MDMA recognizes that the most substantive published challenge to the fluoropolymer exemption is a life-cycle argument, and we address it directly rather than leaving it to the record by implication. Lohmann et al. (2020) argue that fluoropolymers should not be treated as low concern when their full life cycle is assessed, on the grounds that production of some fluoropolymers has been closely linked to the use and emission of legacy and novel PFAS as polymer processing aids, and that fluoropolymers are extremely persistent. The authors recommend that fluoropolymer production and use be curtailed except in cases of essential use.¹³

Two observations follow, and MDMA respectfully urges NMED to reflect both in its report.

First, that critique is directed at manufacturing and end-of-life management, not at the in-use behavior of the finished polymer in a patient. It supplies no basis for removing an exemption that governs the sale of finished, FDA-regulated devices in New Mexico. Processing-aid emissions occur at polymer production facilities, none of which are located in New Mexico, and are addressed through federal authorities including the Toxic Substances Control Act and the Clean Air Act. Removing the New Mexico exemption would not reduce those emissions by any measurable increment; it would relocate the compliance burden onto New Mexico hospitals, clinicians, and patients without touching the source the critique identifies. The appropriate instruments for that concern are manufacturing controls and chemical management authorities directed at the facilities where the emissions occur, not sales restrictions on finished, FDA-regulated devices downstream of them.

Second, the essential-use carve-out that Lohmann et al. themselves preserve is the paradigm case for implanted and interventional medical devices. Removing New Mexico's medical device exemption would go further than the leading published critique of fluoropolymers recommends.

On disposal, the device categories at issue here — cardiovascular implants, catheters and guidewires, surgical instruments, and clinical tubing — are predominantly used in clinical settings and enter regulated medical waste streams that are managed separately from municipal solid waste and household disposal. They are not a documented contributor to the residential product disposal pathways that the Act's consumer product provisions were designed to address.

Finally, MDMA respectfully suggests that NMED state affirmatively in its report whether it has identified any New Mexico-specific data attributing measurable PFAS loading in the state's drinking water, wastewater, septic systems, or solid waste infrastructure to medical devices. MDMA is aware of none. The State's documented PFAS contamination, including the contamination NMED is actively litigating, is dominated by aqueous film-forming foam releases at military installations.¹⁴ A report that distinguishes documented sources from undocumented ones will be considerably more useful to the Legislature than one that treats all PFAS-containing products as equivalent contributors.

¹³ Lohmann, R., Cousins, I.T., DeWitt, J., Glüge, J., Goldenman, G., Herzke, D., Lindstrom, A.B., Miller, M.F., Ng, C.A., Patton, S., Scheringer, M., Trier, X., & Wang, Z., Are Fluoropolymers Really of Low Concern for Human and Environmental Health and Separate from Other PFAS?, 54 *Envtl. Sci. & Tech.* 12820 (2020), <https://doi.org/10.1021/acs.est.0c03244>

¹⁴ N.M. Env't Dep't, Legal Action Against U.S. Department of War, <https://www.env.nm.gov/pfas/legal-action-against-us-air-force-facilities/>.

IV. ECONOMIC RISK OF CONTINUING — AND OF REMOVING — THE EXEMPTIONS

In announcing this review, NMED cited a Minnesota Pollution Control Agency estimate that removing one pound of PFAS from municipal wastewater systems can cost between \$2.7 million and \$18 million.¹⁵ MDMA does not dispute that figure. We note only that it measures the cost of PFAS in the wastewater stream, and that medical devices have not been shown to be a contributor to that stream in New Mexico. Continuing the exemptions therefore imposes no identified cost on the State. The economic risk in this matter lies on the removal side of the ledger:

- **Compliance burden.** Medical device manufacturers source components and materials from complex, globally distributed supply chains. Determining PFAS content at the component level across thousands of catalogue items — for products the Legislature has already determined pose materially different risks — would require substantial supplier engagement, testing, and documentation before a single reporting or labelling determination could be made. The Act's implementing rule further imposes reporting fees and, for products seeking relief from labelling, waiver application fees of \$2,000 per product and \$5,000 per product class, with approvals expiring after three years and requiring renewal.¹⁶ For a manufacturer with a broad catalogue, the recurring administrative cost is significant and produces no corresponding public health benefit.
- **Distribution and returns.** Medical device distribution channels are nationally integrated. A New Mexico-specific label would require tracking, segregating, and labelling products for a single state, with downstream effects on packaging, distribution, and information systems, and on delivery time and cost. The returns pathway compounds this. Physicians routinely order multiple sizes or configurations of the same device for a single patient so that the best fit can be selected at the point of care, and return the unused units. Each New Mexico return would require repackaging or label removal at the distribution center.
- **Market access.** MDMA's membership is composed predominantly of small and mid-sized companies. Fixed compliance costs of this kind fall disproportionately on them. For a company with modest New Mexico volume, the investment required to build and maintain a state-specific labelling and distribution system may exceed the economic value of serving the market. The predictable result is that some manufacturers decline to offer certain products in New Mexico. In a state with substantial rural and frontier populations and existing access challenges, that outcome carries a real and measurable health cost.
- **Investment and future access.** The economic risk is not confined to products already on the market. Device development programs commit to materials years before launch, and uncertainty about whether a fluoropolymer-based design will remain lawful to sell in New Mexico weighs on those decisions. Where that uncertainty cannot be resolved, the rational response is to deprioritize New Mexico in launch planning or to avoid the material in next-generation designs. Both outcomes reduce the flow of new technology to New Mexico patients, and neither produces an offsetting reduction in PFAS exposure.
- **Absence of alternatives.** Because no materials are currently available that reproduce the combination of lubricity, electrical insulation, and biostability that fluoropolymers provide, a prohibition applied to devices in 2032 would not function as a substitution requirement. It would function as a withdrawal of the device categories themselves from the New Mexico health care

¹⁵ N.M. Env't Dep't, News Release, Public Input Sought on Future of PFAS Protections for Consumers (Aug. 7, 2026) (citing a 2023 Minnesota Pollution Control Agency estimate of \$2.7 million to \$18 million per pound of PFAS removed from municipal wastewater systems).

¹⁶ 20.13.2.15 through 20.13.2.20 NMAC (reporting fees of \$2,500 initial and \$1,000 per subsequent significant change; label waiver application fees of \$2,000 per product and \$5,000 per product class, with approved waivers expiring three years after approval).

system. Even where a candidate substitute exists, substitution is not a procurement decision. It requires redesign, design verification and validation, biocompatibility testing, and in most cases a new premarket submission to FDA before the modified device may be sold. That sequence routinely takes years for a single device family.

V. LEGAL AND PRACTICAL CONSIDERATIONS

MDMA raises the following briefly, as context for the Legislature rather than as the primary basis for our recommendation.

Congress has preempted states from imposing device requirements that differ from or add to applicable federal requirements, and FDA may grant an exemption from that preemption only where the state requirement is more stringent than the federal requirement and is required by compelling local conditions.¹⁷ Medical devices are not a likely source of significant PFAS release or exposure in New Mexico, and MDMA is aware of no compelling local condition concerning medical device management that would support a state-specific standard.

Separately, a device's composition, packaging, and labelling are subject to FDA review. A state-mandated safety statement that FDA has not reviewed or approved would, in many cases, require a manufacturer to submit the labelling change to FDA before the product could be marketed in New Mexico, creating both a conflict risk and a timing risk for patient access.

Finally, the express medical device exemption is what provides regulatory certainty. The Act separately exempts products for which federal law pre-empts state authority, but that provision would require case-by-case determinations of pre-emption scope across thousands of device types. The express, standalone exemption avoids that uncertainty. The Environmental Improvement Board reached the same conclusion in adopting the final rule, which carries the medical device carve-out through to the labelling provision as well.¹⁸

VI. RECOMMENDATIONS

1. NMED publishes its recommendation that the Legislature continue, without modification, the exemption for medical devices and drugs, and the packaging of medical devices and drugs, that are regulated by the FDA, including prosthetic and orthotic devices.
2. NMED publishes its recommendation that the Legislature continue, without modification, the exemption for fluoropolymers consisting of polymeric substances with a per- or polyfluorinated carbon-only backbone or a perfluorinated polyether backbone that is solid at standard temperature and pressure.
3. NMED reports that the medical device exemption carried into the labelling provision of the final rule, at 20.13.2.13.B(4) NMAC was correctly decided on a full rulemaking record and should be preserved.
4. NMED distinguishes fluoropolymers from small-molecule PFAS throughout the report and treats production-phase processing-aid concerns as analytically separate from the question of whether

¹⁷ 21 U.S.C. § 360k(a); 21 C.F.R. § 808.20(a) (FDA may grant an exemption from preemption only where the state requirement is more stringent than the federal requirement and is required by compelling local conditions).

¹⁸ 20.13.2 NMAC, published at N.M. Register, Vol. XXXVII, Issue 9 (May 5, 2026), effective July 1, 2026. See 20.13.2.10 NMAC (Subsection C, medical devices and drugs; Subsection P, fluoropolymers); 20.13.2.13.B(4) NMAC (labelling exemption); 20.13.2.14.A NMAC (testing).

finished, federally regulated products should be exempt from New Mexico's consumer product provisions.

5. NMED identifies any New Mexico-specific evidence attributing measurable PFAS loading in state water, wastewater, or waste infrastructure to medical devices, and distinguishes that question from the State's documented aqueous film-forming foam contamination.
6. NMED consults FDA's Center for Devices and Radiological Health before recommending any modification to the medical device exemption so that the Legislature has the benefit of the federal agency's current assessment.

MDMA would welcome the opportunity to brief NMED staff on any of the technical material summarized above and can facilitate contact with FDA's Division of Industry and Consumer Education if that would assist the Department's literature review.¹⁹

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

Sincerely,

A handwritten signature in dark ink, appearing to read "Mark H. Leahey", with a stylized flourish at the end.

Mark Leahey
President & CEO
MDMA

¹⁹ U.S. Food & Drug Admin., Center for Devices and Radiological Health, Division of Industry and Consumer Education (DICE), <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>.