

Darbi Gottlieb

Please see attached for comments on behalf of AdvaMed.

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September 17, 2026

Secretary James Kenney
New Mexico Environment Department
1190 St. Francis Dr., Suite N4050
Santa Fe, NM 87505

Re: Feedback on House Joint Memorial 3

Dear Secretary Kenney:

On behalf of AdvaMed, the Medtech Association, I am writing today to share feedback as the department works to implement the requirements in House Joint Memorial 3.

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 650 members are device, diagnostic, medical imaging, and digital health technology companies that range from the smallest to the largest medical technology innovators.

The medical device industry shares New Mexico's commitment to protecting public health and the environment. We appreciate the collaboration with the Department and legislature as you've worked to implement the PFAS Protection Act.

We strongly encourage NMED to recommend maintaining the exemption for FDA-regulated medical devices in the PFAS Protection Act. The exemption reflects both the unique nature of the PFAS materials used in medical technology and the critical role those materials play in safe and effective patient care. The available scientific evidence does not support treating medical devices containing fluoropolymers in the same manner as products associated with exposure to certain nonpolymeric PFAS. Moreover, eliminating or narrowing the exemption could jeopardize access to essential medical technologies without providing a corresponding public health benefit.

Safety of Fluoropolymers in Medical Products

PFAS refers to a very broad group of over 10,000 chemicals that have significantly different physical, chemical, toxicological, and exposure profiles. Not all PFAS are

the same, and only a small subset of these chemicals have been associated with potential environmental or health effects. A scientifically sound PFAS policy must recognize those differences. 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 resource page 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 fluoropolymers used in medical device have a long history of use and the exposure pathways that underpin concerns regarding other types of PFAS are not present in the fluoropolymers used in medical technology. 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.

In addition to their safety record, fluoropolymers provide a unique combination of performance characteristics that make them essential to modern medicine, such as thermal stability, chemical resistance, low friction, biostability, and compatibility with sterilization processes. These characteristics make them essential to a wide range of medical technologies including catheters, pacemakers, wire coatings, implantables, surgical tools and syringes. There are currently no materials that can replace them without compromising safety or effectiveness. Any material substitution would require extensive validation and regulatory review to demonstrate equivalent performance. For these reasons, we believe the decision to exempt fluoropolymers and medical devices regulated by the FDA from HB 212’s restrictions is consistent with both scientific understanding and patient care needs.

The Department’s leadership has also stated that fluoropolymers are “not as risky” as other PFAS.² 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

¹ <https://www.fda.gov/medical-devices/products-and-medical-procedures/pfas-medical-devices>

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



those using the products.”

Medical Devices Are Subject to Strict Federal Oversight

Medical devices are 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.). 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 evidence-based information.

FDA-regulated medical devices undergo extensive review to ensure that materials and packaging are safe, biocompatible, and capable of withstanding sterilization, transportation, storage, and normal clinical use. Medical devices must undergo biocompatibility assessments consistent with internationally recognized standards, including ISO 10993, before they can be marketed to patients. As a result, material selection is directly tied to product safety and performance and cannot be modified without careful validation and, where appropriate, additional regulatory review.

Medical devices are manufactured through highly complex supply chains that may extend through multiple layers of suppliers, often eight to ten layers deep. Even a single component substitution may require extensive design validation, compatibility studies, and regulatory review. These complexities should be considered when evaluating whether alternative materials are reasonably available for FDA-regulated devices.

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. Without a medical device exemption, the ban on PFAS containing products in HB 212 could lead to significant delays and risk access to critical lifesaving and life enhancing devices for New Mexico 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. Without a medical device exemption, it would not only affect patients access to existing critical treatments it could also discourage



development of next generation medical technologies that rely upon fluoropolymers to achieve performance, safety and durability requirements.

We appreciate the opportunity to provide comments as you work to review the exemptions provided in the PFAS Protection Act. We remain committed to working with the Department on this important issue. Please do not hesitate to reach out with any additional questions.

Sincerely,



Senior Director, State Government and Regional Affairs
AdvaMed

