

February 19, 2026

House Environment and Natural Resources Finance and Policy Committee  
Minnesota House of Representatives  
Capitol G3  
658 Cedar Street  
Saint Paul, MN 55155

RE: MPCA presentation on PFAS to the House Environment and Natural Resources Finance and Policy Committee

Dear Chair Heintzeman, Chair Fischer, and Members of the Committee,

On behalf of AdvaMed, the MedTech Association, we are writing with respectful concerns regarding the Minnesota Pollution Control Agency's (MPCA) implementation of PRISM, the PFAS Product Reporting and Information System for Manufacturers.

AdvaMed is the largest medical technology association, representing the innovators and manufacturers transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Our nearly 650 members range from emerging companies to large multinationals, and include traditional device, diagnostic, medical imaging, and digital health technology companies.

Without a doubt the implementation of Amara's Law is extremely complex and we appreciate MPCA's engagement with this committee on the implementation of PRISM. However, we are concerned that PRISM is not ready to receive the required data by the July 1, 2026, deadline.

Based on feedback from members who had access to the preview and who accessed the system after the formal launch, we would like to raise concerns regarding the technical portions of PRISM. These include PRISM being unreliable, inconsistent, and needing additional information and flexibility. For example, it was not initially clear that a reporting template could be downloaded. The template was slow to validate and the macros within the downloaded template are unstable and can cause crashes. Additionally, there are areas where flexibility would be welcome. For example, some products may not have a brand name or product model and may only have a company part number so those fields being optional would help



reporting. It would not be unusual for one of our member companies to report 5,000, 10,000, or more SKUs so a responsive reporting platform would be very helpful.

AdvaMed is also concerned about data security for the information reported. There is an extraordinary amount of information that is being reported through PRISM, some of which is confidential business information. We are concerned that there has not been clear communication about what happens to data between when it has been entered into PRISM and MPCA makes its determination whether it should be considered private data. Additionally, there is also no mechanism for companies to appeal the decision whether something is private data or not. It would also be helpful for companies to understand what information could be gathered through a formal request for information by third parties.

Further, we are concerned about how the information is disseminated once it has been collected. Releasing information without context could lead to assumptions and misinformation. This could lead to the unintended consequence of patients delaying or not seeking care out of the misunderstanding or concerns over the use of fluoropolymers in medical devices.

Per- and polyfluoroalkyl substances, known as PFAS, are a broad class of over 12,000 substances that are found in a variety of consumer, commercial and industrial products, including medical devices and their packaging. PFAS can essentially be divided into two separate classes: water-soluble PFAS and water insoluble PFAS. PFAS used in medical devices is water insoluble. Water insoluble PFAS (e.g., fluoropolymers) are a larger, higher molecular weight PFAS that are inherently stable, insoluble in water, and less bioavailable. Due to their unique properties of thermal stability, chemical resistance, and low friction, devices like catheters, pacemakers, and wire coatings in radiological machinery rely on PFAS, as well as packaging for surgical tools, implantables, and syringes that require sterilization. These unique properties make fluoropolymers essential in medical devices and medical products regulated by the FDA.

The FDA considers human health and safety risks, optimal product quality, and assessment of who will be utilizing the device (practitioner or patient) in their approval processes for medical devices and medical products. The health risks of these medical devices are thoroughly assessed by the FDA before they make it on the market and must undergo multiple tests to prove biocompatibility in compliance with the international biocompatibility standard, ISO 10993.



As part of FDA's regulatory process for medical devices coming to market, materials of the product as well as the packaging may be considered a component of the device itself, or it could be a part of the final design specifications of the device as it is meant to be sold and distributed. FDA must validate these products as safe, non-toxic, and resilient enough to withstand sterilization, transport, storage, and normal use so that it can function as intended without any damage or harm to the patient.

Finally, AdvaMed would welcome an additional extension from July 1, 2026, to July 1, 2027. This additional extension would allow MPCA to continue to develop and receive comments on PRISM.

Thank you again for the opportunity to provide comments for this hearing and I am happy to provide additional information or answer any questions.

Sincerely,



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