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Kerri Malinowski Farris
Maine Department of Environmental Protection (DEP)
Office of the Commissioner
17 State House Station
Augusta, Maine 04333-0017

RE: Comments on Concept Draft Rule – Maine PFAS in Products Program

Dear Ms. Farris and the Maine Department of Environmental Protection,

The Advanced Medical Technology Association (AdvaMed) submits this letter to provide comments to the concept draft rule for implementation of 38 M.R.S. 1614 (the "Law"), which passed in 2021. AdvaMed is the largest national trade association representing nearly 450 of the world's leading innovators and manufacturers of medical devices, diagnostic products, digital health technologies, and health information systems. Medical devices made by AdvaMed members help patients stay healthier longer, expedite recovery, allow earlier detection of disease, and improve effectiveness and efficiency of treatment.

The Law's preamble states that "…it is imperative to collect information regarding the use of PFAS in and to phase out the sale of certain non-essential products containing PFAS, as proposed in this legislation." As innovators of the most critical lifesaving and life-enhancing medical devices and medical products in the United States and globally, AdvaMed's members are essential to the health, safety, and well-being of patients of Maine and are regulated by the Food and Drug Administration (FDA). AdvaMed believes FDA regulated medical devices and products fall under the exemption language in §1614.4(A) and are explicitly exempt from the Law. In conjunction with this, we ask that the Department of Environmental Protection (the "Department") use its statutory authority to determine by rule that FDA regulated

medical devices and medical products qualify under the Law's definition of "Currently unavoidable use."

Today, in many cases, medical devices that use fluoropolymers, one type of PFAS, are the "standard of care." Banning access to FDA regulated medical devices and medical products can result in significant decreases in clinical success, including higher morbidity and mortality rates and can place thousands of patients' lives at risk, unnecessarily, for lack of available treatments and life-saving options.

To mitigate the risk of the Law unreasonably and unnecessarily restricting patient access to FDA regulated medical devices and medical products, we request that the Department apply the statutory exemption in §1614.4(A) to FDA regulated medical devices and medical products. Alternatively, the Department should use its statutorily delegated authority to explicitly exempt FDA regulated medical devices and medical products in the rule under the Law's definition of currently unavoidable use. Applying either of these approaches allows the Department to focus on their intended goal of non-essential products making up a larger share of the PFAS that ends up in the waste stream.

Background

PFAS are a broad class of synthetic compounds, with each compound within the class containing different physical and chemical properties and different uses. It is not scientifically accurate or appropriate to group all of these substances together or treat them all the same. PFAS are defined based on small chemical structural elements that apply to a broad range of substances with such diverse properties and effects that it is impractical to regulate them as a single class. While some low molecular weight PFAS and some fluorinated polymers are being phased out by the medical device industry, working with the FDA, certain other distinct fluoropolymers are critical to the production of lightweight, flexible materials for medical devices and medical products. There are no commercially available alternatives to these fluoropolymers, so banning their presence in products and packaging would necessitate reverting to outdated and inefficient technologies that would not meet modern environmental standards.

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 this, FDA takes care not to cross over into EPA jurisdiction on environmental considerations that may include PFAS. The EPA's recent PFAS Roadmap recognizes

the broad class of PFAS and outlines additional efforts to define, subcategorize, assess, and regulate this important class of compounds. The Administration and EPA agreed to a targeted approach and to regulate by groupings of chemicals rather than regulate as one big class. And we understand that Congress has not contemplated including medical devices and medical products in any PFAS proposals for this reason.

In addition, in August 2021, the EPA published its final scope document outlining the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the agency will consider in its risk evaluation of PFAS. As the EPA continues to move through the risk evaluation process, states should heed the work being done at the federal level and avoid any future confusion that preemption will cause. Ultimately, a prohibition on the inclusion of PFAS places at risk the ability of companies to manufacture and provide lifesaving and life-enhancing medical devices and medical products to patients in Maine and across the U.S.

Use in Medical Technology

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's meant to be sold and distributed. Some devices like surgical tools, implantables, and syringes that need to be sterilized, require all their packaging and the product itself to withstand melting, breaking, becoming brittle or otherwise degrading during the critical sterilization process. 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.

Due to the complexity of the supply chain (8-10 layers deep for complex medical systems), it can take years for information to propagate up the supply chain, and to become aware of the occurrence of newly regulated substances by the medical device manufacturer. Manufacturers are beholden to the information that their suppliers provide, which is not always a consistent or standard read out of the materials in the product. Even with already established environmental regulations on certain chemicals, it may take device manufacturers upwards of several years to even identify where in the supply chain those occur before they can attempt to mitigate and change their processes. Substitutions or changes require extensive and costly compatibility studies to ensure no cross contamination, bleed-through or residuals are present. Any changes in the device or the package would then be subject the item to re-submission to the FDA, further restricting patient access to proper healthcare and preventing providers from treating their patients appropriately.

A few examples of the numerous FDA regulated medical devices and medical products or packaging that include PFAS:

- Circuit boards, leads, foil in large equipment such as MRI, CT, and mammography machines.
- Instruments and equipment (shears, cutters, staplers) used in minimally invasive, endoscopic surgical procedures
- Blood collection bags, suction devices used in respiratory therapy and for anesthesia, IV solution bags, Peritoneal Dialysis solutions, premixed drugs (drugs that are in a plastic bag ready for infusion in the hospital setting/no need for compounding, diluting, etc.), enteral nutrition.
- Wireguides and delivery systems used in minimally invasive procedures to navigate through a patient's anatomy.

Conclusion

AdvaMed believes FDA regulated medical devices and medical products are subject to the existing statutory exemption and also qualify under the Law's definition of products with currently unavoidable use of PFAS. Either approach will help the department better achieve the intent of the Law by focusing on the non-essential products containing PFAS.

We look forward to working with you on this important matter. AdvaMed appreciates the opportunity to provide these comments. Please contact me at rkozyckyj@advamed.org if you have any questions.

Sincerely,

Roxolana Kozyckyj

Director, State Government and Regional Affairs
AdvaMed