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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 Second 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 second 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.

Exemption for FDA Regulated Medical Devices

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. Notwithstanding 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" and under the second concept draft's designation of "Essential for the Health, Safety, or the Functioning of Society."

Today, in many cases, medical devices that use fluoropolymers, one type of PFAS, are the "standard of care." Moreover, the common PFAS materials (fluoropolymers) used in medical devices are not responsible for the water and soil contamination with which this law is concerned. 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.

Cognizant of the complexity and extensive supply chain involvement that goes into the manufacturing and approval of FDA regulated medical devices and medical products, we request:

- **The Department apply the statutory exemption in §1614.4(A) from notification to FDA regulated medical devices and medical products.**

To mitigate the risk of the Law unreasonably and unnecessarily restricting patient access to FDA regulated medical devices and medical products, we request:

- **The Department use its statutorily delegated authority in §1614.5(D) to explicitly exempt FDA regulated medical devices and medical products in the under the Law's definition of currently unavoidable use**
- **The Department designate FDA regulated medical devices and medical products essential for health, safety, or functioning of society as the second Concept Draft authorizes.**

Applying these approaches allows the Department to focus on their stated goal of regulating and removing non-essential products, which make up a larger share of the PFAS that ends up in the waste stream.

Clarifications for Implementation

While we feel the information above outlines a very clear exemption for FDA regulated medical devices, AdvaMed requests better clarity on the following details for implementation while the department pursues formal rulemaking.

- AdvaMed requests better clarity on the definition "Significant change" because 10% is a very low threshold to have obligations to report. For example, if the concentration of PFAS is lower in a product, the 10% change can happen more easily because you could easily have fluctuations in the PFAS concentration of a product. In addition, often, the concentration of any substance cannot be precisely controlled within a 10% accuracy level and may differ from item to item (especially if concentrations are lower).

- We also point out that "Concentration" is not defined, and it is therefore impossible to report against. Does it mean the grams of PFAS as percent of the total weight of the product? Or as percent of the weight of the Product's component? Or as percent of the weight of the lowest level Product component? Or the percent of weight of the article as defined by EU REACH? Or percent of weight of the homogeneous material as defined by EU RoHS? Finally, there are many PFAS compounds not tracked in the chemical abstract registry (CAS), are companies only required to disclose CAS tracked compounds?

- Related to the requested clarity on the definition of "Concentration," we request clarity on the following clause: See 3.A.(1)(c): "*The amount of each of the PFAS as a concentration, identified by name and its chemical abstracts service (CAS) registry number, of each PFAS in the product or any product component reported as an exact quantity determined using commercially available analytical methods, or as falling within a range approved by the Department; and*".

It is unclear if companies need to report to total amount or concentration of PFAS. This sentence contradicts. First it says to report PFAS as a concentration (e.g., 1%), but the second half of the sentence says to report the exact quantity (e.g., 1 mg), but the third part again mentions range, without specifying if those ranges cover a concentration or quantity. Currently industry works in concentrations (% w/w), but the FAQ mentions Maine wants to know which are the biggest sources of PFAS. It is not possible to know that from concentrations (if you don't know the weight of the component it is in). But the total amount per product is not reportable as this information is not tracked in the supply chain.

- What is the Department's intended 2023 rulemaking timeline for determining which products fall under unavoidable use? How will the Department enforce notification and levying fees if some products are under review for unavoidable use in 2023? When will companies be notified that their products are under review? If these products have already been reported and paid for, will there be refunds issued?

- When will products be designated essential for health, safety, or functioning of society? When will companies be notified that their products fall under this category? If these products have already been reported and paid for, will there be refunds issued?

- We request a better understanding of how the fees were determined. Many medical device companies sell thousands of products into the state and would therefore be liable for a significant payout to the Department, not proportional to the amount of PFAS waste produced by their devices and level of risk associated.

- AdvaMed members are concerned about what the DEP will do to protect confidential business information (CBI), including but not limited to in the event of a Freedom of Information Act (FOIA) request. Much of the information required to be disclosed is extremely sensitive proprietary information for medical device manufacturers and the concept draft rule does not address how it will be protected from discovery or disclosure.

- Regarding "Notification," AdvaMed would petition the Department to limit the reportable data filed to those currently defined in international standards of supply chain communication, such as IPC1754A or 62747 (for electronic products and similar standards for other product categories). For example, sales volume, intended use, and why intentionally added PFAS is used, are not typical data fields. The requested information should be limited to the data fields which are included in those standards. Additionally, supplier declaration should be sufficient data provided by "end manufacturers", instead of analytical test results that would be more appropriate for a supplier to provide.

- In keeping with international reporting standards, we request that DEP allow other internationally used product classification codes such as TARIC code (as used by EU SCIP database), as alternative to GPC brick code. Many companies use these other reporting codes and not GPC. To ease reporting burden, companies should use an international product classification code but not be required to use one verses

another. Without allowing currently used reporting systems, the burden becomes even more immense on companies.

- Finally, we request clarity on what happens with products where either the presence of PFAS or the exact concentration is unknown at the time of notification. Since Maine is the first jurisdiction in the world to require this level of detail, it is unreasonable to expect companies that have complex global supply chains with eight or more suppliers can obtain this level of detail quickly. For example, the EU typically provides a couple years for compliance.

During the stakeholder meeting in October, the response that products cannot be sold into the state until and unless notification is provided is unreasonable and unrealistic, especially for products that are considered to have unavoidable PFAS and are essential for safety, health, or functioning of society. This will effectively make the law restrict supply of critical medicines, medical devices, and diagnostics to residents of Maine.

Background

The EPA currently includes 12,034 substances that fall into the PFAS classification, 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 are being phased out by the medical device industry, working with the FDA, certain other distinct fluoropolymers are critical to the production of medical devices and medical products to achieve a low coefficient of friction (nothing sticks to it) and high chemical resistance (nothing within the human body breaks it down).

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. **Under Maine's law, 70% of medical device products will not be able to be distributed to the state of Maine.**

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.

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 an October 20, 2022 Chemical Watch article on PFAS, an FDA official states that the agency cannot review PFAS as a class because "We look at safety based on a specific substance, so we don't agree with lumping all PFAS together," Sharon Koh-Fallet, chief of the FDA's regulatory review branch, said at a Keller and Heckman seminar recently. The agency must make determinations informed by toxicity data for individual compounds, she said.

Finally, the Department should heed the August 2021, the EPA 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. There is no "commercially available" technique that can assess for all 12,034 chemicals at one time. Analytical techniques can only assess what can be extracted out of a device, it becomes near impossible to identify what is present rather than what can leach out. 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:

- Implantable devices
- 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.
- Wire guides and delivery systems used in minimally invasive procedures to navigate through a patient's anatomy.
- Pipette tips, gaskets, seals, tubing, and reagent cartridges/containers that require precise dispensing quantities to ensure accurate patient dosing or diagnostic results.

- Various packaging of medical devices and instruments including tape, film (packaging): clear films, that require specific types of unsubstitutable qualities to withstand sterilization.
- O ring materials, mechanical seal, adhesives/solvents; wound drains.

Without an exemption, this law will affect approximately 70% of resins with plastics and may effectively shut down the shipment of medical devices and products due to their packaging.

Conclusion

AdvaMed believes FDA regulated medical devices and medical products are subject to the existing statutory exemption and qualify under the Law's definitions of products with currently unavoidable use of PFAS and products that are essential to the health, safety, or functioning of society. Making these designations will help the department better achieve the intent of the Law by focusing on the non-essential products containing PFAS the preamble references. As the Department formulates its draft rule, we hope it strongly considers the information outlined in this letter to better accomplish the intent of this Law.

Additionally, we would like to point to Maine's Extended Producer Responsibility Program for Packaging, 38 M.R.S. §2146 that passed the legislature in 2021 as well. The Department makes clear in it's guidance that during formal rulemaking it will consider product exclusions including material associated with a medical device. AdvaMed believes the Department should remain consistent in it's reasoning for exempting FDA regulated medical devices and medical products when thinking through the complex lifecycle of a medical device.

In the interim, we request clarity on the aforementioned questions regarding implementation to better understand compliance for those member companies that may need to report their data beginning January 1, 2023.

We look forward to further guidance before January 1, 2023 and to working with you on this important matter as the Department drafts the official proposed rule. 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