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April 26, 2023

Senator Stacy Brenner, Senate Chair
Joint Standing Committee of Environment
Natural Resources
3 State House Station
Augusta, ME 04333

Representative Lori Gramlich, House Chair
Joint Standing Committee of Environment and
Natural Resources
2 State House Station
Augusta, ME 04333

RE: LD 1214 - An Act to Clarify the Laws to Combat Perfluoroalkyl and Polyfluoroalkyl Substances Contamination

Dear Chair Brenner, Chair Gramlich, and Honorable Members of the Committee,

The Advanced Medical Technology Association (AdvaMed) submits this letter in support of LD 1214 along with a request for clarification regarding FDA regulated medical devices. 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.

Currently, the PFAS in Products law bans access by 2030 to FDA regulated devices for all patients in Maine. These products include insulin pumps, catheters, pacemakers, infusion drugs, prosthetics, syringes, and MRI, CT, and mammography machines among other lifesaving technology. AdvaMed's goal is to work with the legislature to ensure the changes proposed in LD 1214 make Maine a leading steward of these complex chemicals and maintains the state's commitment to patient access and health equity across the state.

To mitigate the risk of the law unreasonably and unnecessarily restricting access to FDA regulated medical devices and medical products, we respectfully request that the committee support LD 1214 and include an exemption for FDA regulated medical devices and medical products

Background

It is critical to note that the PFAS categories tied to environmental contamination and bioaccumulation are not what are used in medical devices and technology. The non-water soluble PFAS (fluropolymers) used in medical devices are not bioavailable and do not biodegrade; they inherently do not actively or passively pass through cell membranes and are not considered toxic to human health or an environmental hazard. PFAS regulations should target unsafe products and supply chain practices of non-essential products that contain water-soluble PFAS and LD 1214 helps achieve this.

PFAS are a broad class of 12,000 chemistries, characterized by the strong bond between fluorine and carbon. Because of this strong bond, PFAS provides products with strength, durability, stability, and resilience required for the safe functioning of a broad range of products including medical devices and technology. PFAS are defined based on small chemical structural elements with such diverse properties and effects that it is not scientifically accurate to regulate them as a single class. The very distinct physical and chemical properties of PFAS demonstrate how varied they are and how imposing a new reporting requirement regardless of these differences would be scientifically inappropriate.

FDA Approval for Human Health & Safety

The U.S. Food and Drug Administration (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'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.

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 Maine is most 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. Any blanket regulation of PFAS places at risk the ability of companies to manufacture and provide lifesaving and life-enhancing fluoropolymer containing medical devices to patients across the U.S. and the globe. LD 1214 will help address this with its proposed change to the PFAS definition.

Essential for Human Health

The biocompatibility standards and testing required by the FDA considers factors such as neurotoxicity, local and systemic effects, carcinogenic properties, pathological, physiological, reproductive and developmental effects among many other factors before approving a product safe to human health. No other consumer product undergoes this level of scrutiny and oversight.

Here are a few examples of the essential medical technology that include PFAS fluoropolymers:

- Circuit boards, leads, and foil in large equipment made up of hundreds of components such as MRI, CT, and mammography machines
- Prosthetics

- Pacemakers and other implantables
- Syringes
- Contact lenses
- Blood collection bags, suction devices used in respiratory therapy and for anesthesia, I.V. solution bags, enteral nutrition, and premixed infusion drugs used in a hospital setting.
- Wireguides and delivery systems used in procedures to navigate through a patient's anatomy.

Reporting Compliance Challenges

The law currently has gaps in reporting requirements and Maine's Department of Environmental Protection (DEP) has failed to provide appropriately detailed guidance for accurate compliance. Basic questions like how to calculate the concentration of PFAS; what the burden of proof is to demonstrate the "exact quantity of PFAS"; and whether a de minimis will be implemented" have gone unanswered. By supporting LD 1214, the legislature will provide DEP better direction on how to implement the law more effectively.

In a supply chain that is eight to ten layers deep, often, a component material supplier views their component design as *their* intellectual property (IP), including the specific material used. In those instances, the FDA has a regulatory approach for those suppliers to divulge information to the FDA but not to the manufacturer. As a result, medical device manufacturers will never be able to achieve 100% disclosure to DEP. 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 is highly regulated by the FDA.

It may take device manufacturers upwards of several years to even identify where in the supply chain regulated substances 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 that no cross contamination, bleed-through or residuals are present. Any changes in the device or the package would then subject the item to re-submission to the FDA, further restricting patient access to proper healthcare and preventing providers from treating their patients appropriately.

Federal Action

Furthermore, Congress and the Biden Administration recently authorized significant legislation with new rules regulating PFAS.[3] Subsequently, under the Toxic Release Inventory (TRI) program companies or federal facilities that release 100 or more pounds of the 179 identified PFAS substances must collect and publicly report information on the amount that is released into the air, water, or land, and the quantities managed through disposal, energy recovery, recycling, or treatment. Additionally, the EPA is undergoing rulemaking under the Toxic Substances Control Act (TSCA) Section 8 that would require those who manufacture (including import) any identified PFAS to report information regarding PFAS uses, disposal, exposures, hazards, and production volumes.[4]

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.

Testing for and identifying what is defined as PFAS is already a complex process. Additional reporting requirements at the state level will lead to multiple testing requirements with multiple definitions of PFAS. At a minimum, Maine can utilize the TRI data to better inform and prioritize DEP's focus. We urge the committee to avoid the redundant use of state resources, support the EPA's efforts to comprehensively identify PFAS substances, and support the changes proposed in LD 1214.

Conclusion

AdvaMed strongly urges the committee to take prudent, decisive, and necessary steps to ensure patients have certainty in law that they will have access to the life-saving medical devices they depend on. AdvaMed respectfully requests that the committee consider all the reasons discussed above in order to support LD 1214 and further clarify whether FDA regulated medical devices will be safeguarded in the bill. We propose the following language:

This article does not apply to any of the following:

a) ***A product regulated as a drug or medical device by the United States Food and Drug Administration.***

b) ***Medical equipment or products used in medical settings, that are used for infection prevention or regulated by the United States Food and Drug Administration.***

c) ***Medical equipment or products intended for Research Use Only as defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C., Sec. 360, etc. seq).***

d) ***A product intended for animals that is regulated as animal drugs, biologics, parasiticides, medical devices, and diagnostics used to treat or are administered to animals under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.), the federal Virus-Serum-Toxin Act (21 U.S.C. Sec. 151 et seq.), or the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. Sec. 136 et seq.).***

We look forward to working with you on this important matter throughout the remainder of the legislative session.

Sincerely,

Roxy Kozyckyj
Director, State Government & Regional Affairs
AdvaMed