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Representative David A. Bennett, Chair
Environment and Natural Resources Committee
82 Smith Street
Providence, RI 02903

RE: HB 7356 – Comprehensive PFAS Ban Act of 2024

Chair Bennett and Members of the Committee,

The Advanced Medical Technology Association (AdvaMed) submits this letter in respectful opposition to HB 7356. 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.

As drafted, the definitions of "Covered Product" and "Product" and as they are used interchangeably in this bill despite differing definitions create confusion as to whether medical devices are exempt from Section 2-18.18-4, Prohibition on use of PFAS. This is further made more confusing since the bill explicitly exempts medical devices from Section 12-18.18-5 Disclosure of PFAS in certain products. We ask that this be clarified as we believe the intent of the bill is to exempt medical devices entirely.

Without such a clarification, any ban would impact patients using products such as insulin pumps, catheters, pacemakers, infusion drugs, prosthetics, syringes, and MRI, CT, and mammography machines among other lifesaving products. Furthermore, it may take device manufacturers upwards of several years to even identify where in their global supply chain regulated substances occur before they can attempt to report the required data outlined in the bill. Recognizing that all patients and providers trust and rely on this critical medical technology, we want to help Rhode Island become a responsible steward of these complex compounds, without unnecessarily restricting access to life-saving medical devices and technology.

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 (fluoropolymers) 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.

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 Massachusetts 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.

Med Tech is 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.

Conclusion

As many states look to regulate PFAS in products more broadly, AdvaMed is working closely with legislators across the country to ensure medical devices are held harmless from any product bans. Cognizant of the risk to patient access of lifesaving, life-enhancing medical devices and products and the challenges that exist for reporting data on such products, AdvaMed urges the committee to clarify this language and ensure that medical devices are clearly exempt as it appears they are intended to be.

Thank you for considering our concerns and proposed amendment. We look forward to working with you on this important matter throughout the remainder of the legislative session.

Sincerely,

Roxy Kozyckyj
Senior Director, State Government & Regional Affairs
AdvaMed