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Senator John Marty, Chair
Finance Committee
3235 Minnesota Senate Bldg.
St. Paul, MN 55155

Senator Nick Frentz, Vice-Chair
Finance Committee
3109 Minnesota Senate Bldg.
St. Paul, MN 55155

RE: SF 2438, PFAS in Certain Products Prohibition

Dear Chair Marty, Vice Chair Frentz, and Members of the Committee,

The Advanced Medical Technology Association (AdvaMed) submits this letter to provide comments on Senate File 2438. 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. Understanding the complexity and importance of this issue, our goal is to work with the sponsors to ensure that these bills make Minnesota a leading steward of these complex chemicals and maintain its commitment to patient safety and health equity across the state.

As is currently written, this bill recognizes the need for an exemption for children. Therefore, it stands to reason that this legislation should ensure all patients in Minnesota have the same certainty in the bill for access to FDA regulated medical devices.

To mitigate the risk of SF 2438 unreasonably and unnecessarily restricting access to FDA regulated medical devices and medical products for all patients, we respectfully request that FDA regulated medical devices and medical products be exempt from both the reporting requirements and the ban mandated in the bill.

Background

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 inappropriate.

It is important to note that The PFAS categories of concern tied to environmental contamination and bioaccumulation are not what are used in medical devices and technology. Targeting the concerning water-soluble PFAS categories and excluding the non-water soluble PFAS (polymers), would overwhelmingly ensure legislation efficiently targets unsafe products and supply chain practices.

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 this bill 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. 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.

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.

Due to the complexity of the supply chain (8-10 layers deep for complex medical systems), it can take years for information to propagate upstream for suppliers 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 discussed above, 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 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.

Proposed Amendment

To mitigate the risk of SF 2438 unreasonably and unnecessarily restricting patient access to FDA regulated medical devices and medical products, we request that the committee adopt the following amendment, exempting medical devices from the reporting requirements and the ban:

This article does not apply to any of the following:

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

(b) ***A medical equipment or product used in medical settings that is regulated by the United States Food and Drug Administration.***

(c) ***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.).***

Conclusion

AdvaMed respectfully request that the committee consider all the reasons discussed above and apply the exemption for all patients in Minnesota. By continuing to group FDA regulated medical devices, that

have been tested and approved for human health and safety over many decades of clinical trials and research, with products whose safety and components are unknown, the state undermines FDA authority and most importantly casts unnecessary and harmful skepticism on these life-saving products that patients and providers trust and rely on.

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

Sincerely,

Roxolana Kozyckyj

Director, State Government & Regional Affairs

Michael C. Morton

Senior Advisor, Policy & Advocacy

Medical Alley