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March 5, 2025

Delegate Luke Clippinger, Chair
Delegate J. Sandy Bartlett, Vice Chair
House Judiciary Committee
100 Taylor House Office Building
Annapolis, MD 21401

RE: House Bill 1112 -- PFAS Chemicals - Civil Actions and Prohibition on Consumer Product Sales

Dear Chair Clippinger, Vice Chair Bartlett, and Member of the Committee,

AdvaMed, the Medtech Association, submits this letter in respectful opposition to HB 1112. AdvaMed is the largest national trade association representing over 500 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.

We are proud of our med tech footprint in Maryland, where 40 AdvaMed members have a presence and where the medtech industry generates nearly $2 billion for the state.

AdvaMed respectfully opposes HB 1112 due to the broad nature of the ban mandated in the bill and it's fundamental misunderstanding of the complex chemical class, PFAS. Patients in Maryland will be at serious risk of losing access to thousands of critical medical devices like pacemakers, cardiac catheters, imaging equipment, stents, complex surgical equipment, and many other products that save and enhance patients' lives. We strongly urge the committee to adopt a more tailored definition of PFAS, offered below, if it moves forward with this legislation to ensure the bill more accurately focuses on what products contribute to bioaccumulation and environmental contamination.

Essential Use of PFAS in Medical Technology

As innovators of the most critical lifesaving and life-enhancing medical devices in the United States and globally, AdvaMed's members contribute to the health,

safety, and well-being of patients in the U.S. and around the world and are regulated by the Food and Drug Administration (FDA).

Many medical technologies rely on PFAS to provide the performance that supports the highest standard of care for patients by delivering safe, sterile, and effective products. Many PFAS materials have unique properties that cannot be easily substituted like flexibility, rigidity, sterility, penetrability, thermal stability, resiliency, degradation resistance, chemical resistance, lubricity and a low friction coefficient. Essential products like heart stents, cardiac catheters, pacemakers, glucose pumps, surgical tools, and diagnostic instruments use types of PFAS to serve vital functions that cannot readily be replicated with other currently available substances.

These products have been used safely over many years. The common PFAS materials (fluoropolymers) used in medical devices, accessories, and their packaging are not responsible for the water and soil contamination that is of concern to the law's original intent, due to their non-solubility in water. Fluorinated substances such as fluoropolymers are insoluble in water and cannot pass through cells membranes making their use safe for patient health. 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.

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.

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.

Proposed Amendments and Conclusion

The PFAS categories tied to environmental contamination and bioaccumulation are not what are used in medical devices and medical technology in addition to many products essential to human health and safety. We urge the bill use the following definition of PFAS, that is already in statute in Delaware, West Virginia.

"Perfluoroalkyl or polyfluoroalkyl substance" or "PFAS" or "PFAS chemicals" means: (1) a non-polymeric perfluoroalkyl substance; (2) a non-polymeric saturated polyfluoroalkyl substance; or (3) side-chain fluorinated polymers; a molecule of which contains at least two (2) fully fluorinated sequential carbon atoms.

(b) The term does not include gases and substances that become gases in use.

Due to the reasons outlined above, AdvaMed opposes the bill and urges you adopt our proposed changes that would reflect a more risk-based approach to regulating PFAS in products in Maryland and prevent a broad ban that would risk patient access to life-saving medical technologies.

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 Affairs
AdvaMed