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House Health Committee
Maryland House of Delegates
Lowe House Office Building
6 Bladen Street
Annapolis, MD 21401

RE: Oppose HB 1022, PFAS Chemicals – Product Phase Outs and Registration Requirements

Dear Chair Bagnall,

AdvaMed, the MedTech Association, is writing in respectful opposition of HB 1022, *PFAS Chemicals – Product Phase Outs and Registration Requirements*.

AdvaMed is the largest medical technology association, representing the innovators and manufacturers transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Our nearly 650 members include manufacturers across the full spectrum of medical technology, including traditional device, diagnostic, medical imaging, and digital health technology companies. 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.

Per- and polyfluoroalkyl substances, known as PFAS, are a broad class of over 12,000 substances that are found in a variety of consumer, commercial and industrial products, including medical devices and their packaging. PFAS can essentially be divided into two separate classes: water-soluble PFAS and water insoluble PFAS. PFAS used in medical devices is water insoluble. Water insoluble PFAS (e.g., fluoropolymers) are a larger, higher molecular weight PFAS that are inherently stable, insoluble in water, and less bioavailable. Due to their unique properties of thermal stability, chemical resistance, and low friction, devices like catheters, pacemakers, and wire coatings in radiological machinery rely on PFAS, as well as packaging for surgical tools, implantables, and syringes that require sterilization. These unique properties make fluoropolymers essential in medical devices and medical products regulated by the FDA.

The 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 is meant to be sold and distributed. 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.

We are concerned that medical devices and other medical technologies are being unintentionally captured in the product ban in HB 1022. Specifically, the overly broad definition of textile could inadvertently capture a range of medical devices. Therefore, we are asking for explicit language related to the product ban and registration requirements to ensure continued patient access to medical devices.

We respectfully propose the following language:

> An additional definition: "Medical device" has the same meaning as "device" in 21 USC 321(h).
>
> Under 6—1605. (A) this section does not apply to:
> (5) A product, including its peripheral accessories, and the packaging or packaging components for any product regulated as a drug or medical device by the United States Food and Drug Administration.
>
> (6) Medical equipment or products, and the packaging or packaging components for any products used in healthcare settings, including hospitals and clinics that are regulated by the United States Food and Drug Administration or used for dispensing of medication.
>
> (7) Medical equipment or products, and the packaging or packaging components for any product intended for Research Use Only as defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C., Sec. 360, etc. seq)

Colorado, Connecticut, Illinois, New Hampshire, New Mexico and Maine's amended law all have included similar patient protection language. These states have recognized the highly complex and regulated nature of medical technology and exempted medical devices from their PFAS bills. These states instead focused their resources on gathering PFAS data and information on products that are subject to their states' PFAS bans. Additionally, New Mexico exempted fluoropolymers from their law passed last year, recognizing not all PFAS is the same. A reporting exemption for medical devices, drugs, and their packaging would also allow Maryland to focus on PFAS-containing products that are not subject to the same rigorous regulatory scrutiny as medical technologies.

Further, we are concerned about how information will be disseminated once collected. Releasing information without appropriate context could lead to confusion and misinformation. This may result in unintended consequences, including patients delaying or foregoing necessary care due to misunderstandings about the use of fluoropolymers in medical devices.
For these reasons, we respectfully request language in HB 1022 to protect patient access to medical devices and drugs, which are critical for lifesaving care for patients.

AdvaMed appreciates the opportunity provide comments regarding HB 1022 and welcomes the opportunity to serve as a resource for this committee.

Sincerely,

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