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May 1, 2024

Senator Virginia Lyons, Chair
Committee on Health and Welfare
115 State Street
Montpelier, VT 05633

Senator David Weeks, Vice Chair
Committee on Health and Welfare
115 State Street
Montpelier, VT 05633

RE: SB 25 – AdvaMed Request to Exempt Medical Devices from PPE

Dear Chair Lyons and Members of the Committee,

The Advanced Medical Technology Association (AdvaMed) submits this letter to provide comments on Senate Bill 25. AdvaMed is the largest national trade association representing nearly 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 help patients stay healthier longer, expedite recovery, allow earlier detection of disease, and improve effectiveness and efficiency of treatment.

We commend the author for recognizing the life-saving products and technology that the medical device industry provides and appreciate the exemption placed under the definition of juvenile products. However, to mitigate the risk of SB 25 unreasonably and unnecessarily restricting provider, hospital, and patient access to essential FDA regulated PPE, we request that the existing exemption for FDA regulated medical devices and medical products apply to the definition of PPE as well**.** New Hampshire has amended their bill, HB 1649, to reflect this.

There are many masks on the market that are neither medical grade nor FDA regulated and therefore not considered PPE, like simple face masks. If the bill exempts medical devices from PPE, you will ensure that only equipment and PPE labeled as a medical device, which are critical to healthcare settings and infection control, are protected, but still capture PPE that is not medical grade.

Background

PFAS are a broad class of 14,000 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.

Essential Use in PPE

In the case of personal protective equipment (PPE), gloves, helmets, face shields, goggles, facemasks, and/or respirators or medical gowns are designed specifically according to FDA regulations and are essential to protect the patient and healthcare provider from injury or the spread of infection. PPE is also used as barrier between infectious materials such as viral and bacterial contaminants and your skin, mouth, nose or eyes, blocking transmission of contaminants from blood or various bodily fluids and secretions. PFAS in PPE makes it more durable, waterproof, flexible, and provides chemical resistance properties.

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.

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.

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.

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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.

Alternatives and Supply Chain Concerns

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.

Conclusion

AdvaMed respectfully request that the committee consider all the reasons discussed above and recognize the essential use of PFAS in PPE as medical devices as well as their vetted safety for human health. We encourage the committee to align with other states who have focused on PPE and exempted medical devices, most recently, New Hampshire.

We urge the committee to exempt medical devices from PPE in SB 25, not just from juvenile products. Please contact me at rkozyckyj@advamed.org if you have any questions.

Sincerely,

Roxolana Kozyckyj
Senior Director, State Government & Regional Affairs
AdvaMed