AdvaMed
Advanced Medical Technology Association

1301 Pennsylvania Avenue, NW
Suite 400
Washington, D.C. 20004
P :: 202.783.8700
F :: 202.783.8750
W:: AdvaMed.org

February 20, 2024

Senator Virginia Lyons, Chair
Senate Committee on Health and Welfare
115 State Street, Room 17
Montpelier, VT

RE: Senate Bill 197 – An act relating to the procurement and distribution of products containing perfluoroalkyl and polyfluoroalkyl substances and monitoring adverse health conditions attributed to perfluoroalkyl and polyfluoroalkyl substances

Dear Chair Lyons and Members of the Committee,

The Advanced Medical Technology Association (AdvaMed) submits this letter to provide comments on Senate Bill 197. 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 help patients stay healthier longer, expedite recovery, allow earlier detection of disease, and improve effectiveness and efficiency of treatment.

To mitigate the risk of S. 197 unreasonably and unnecessarily restricting patient access to essential FDA regulated medical devices and medical products, we request that the committee focus it's efforts on the PFAS of concern and also insert an exemption for FDA regulated medical devices and medical products.

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 ban or any 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.

Use in Medical Technology

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. 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 and bacterial or viral contaminants. 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.

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.

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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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.

AdvaMed Requested Amendments:

Strike and replace § 3746. (b)(1) with the following:

"Perfluoroalkyl or polyfluoroalkyl substance" or "PFAS" means any chemical listed in [a rule that shall be promulgated by the [relevant environmental agency] no later than [XX] days after enactment of this section] "PFAS" does not include (1) chemicals without Chemical Abstract Service Registry Numbers, (2) fluoropolymers or perfluoropolyethers, or (3) any other chemical substances that the [relevant environmental agency] determines present low environmental and human health risks based on anticipated conditions of use.

Add:

This article does not apply to any of the following:

- *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.*
- *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.*
- *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)*

Conclusion

AdvaMed respectfully request that the committee consider all the justification discussed above and move to both target the concerning water-soluble PFAS categories excluding the non-water soluble PFAS

(polymers), and recognize the essential use of PFAS in medical devices as well as their vetted safety for human health. 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.

We urge the committee to exempt FDA regulated medical devices and medical products and ensure that that patients in Vermont continue to have access to these life-saving technologies. Please contact me at rkozyckyj@advamed.org if you have any questions.

Sincerely,

Roxolana Kozyckyj
Senior Director, State Government & Regional Affairs
AdvaMed

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PFAS in Medtech

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.

Why are PFAS chemicals used for medical device products and packaging?

- PFAS has unique properties that cannot be substituted like: flexibility, rigidity, sterility, penetrability, thermal stability, resiliency, ergonomic, degradation proof, chemical resistance, and low friction coefficient.
- 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.

PFAS Used in Medical Devices

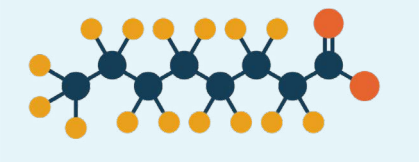
- Water insoluble PFAS (e.g. fluoropolymers) are a larger, higher molecular weight PFAS molecule that are inherently stable, insoluble in water, and less bioavailable. Given their size, molecular weight, and water/lipid insolubility they are too large and too water/lipid repelling to cross cell membranes and therefore pose minimal risk to human and ecological health relative to water-soluble PFAS. Due to their unique properties of thermal stability, lubricity, and chemical resistance, fluoropolymers are essential in medical devices.

PFAS Found in the Environment

- Low molecular weight PFAS have many applications in other industries and are water-soluble. Due to their low molecular weight and water/lipid solubility, these PFAS can permeate water, soil, and cells. The most studied and regulated of this class are PFOA and PFOS, as examples. These types of PFAS have been demonstrated to accumulate in the human body and cause adverse health effects through consumption of drinking water, fish, crops, breast milk, in utero, and through exposure to certain food packaging or carpeting.

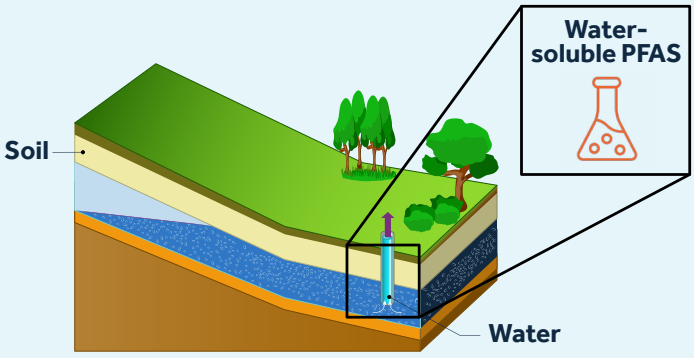
PFAS

Water-soluble - small molecule



Water insoluble - fluoropolymer, a long-chain of repeated monomer units

WATER-SOLUBLE PFAS IN THE ENVIRONMENT



*Source: EPA Multi-Industry Per- and Polyfluoroalkyl Substances (PFAS) Study – 2021 Preliminary Report

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What is the alternative to PFAS?

At this time, there is no material that can substitute PFAS or its unique properties necessary to meet FDA standards for a medical device and its packaging.

- **FDA Review Process:** The FDA must validate medical device products as safe and resilient enough to withstand sterilization, transport, storage, and normal use so that the products can function as intended without any damage or harm to the patient. PFAS is critical to the design and production of high performance devices. The medical device package must pass the FDA's "shake, rattle, and roll" product test.
- **Patient Safety:** The FDA considers human health and safety risks before a device can make it on the market. The device must undergo multiple tests to prove biocompatibility and toxicological safety in compliance with international biocompatibility standard ISO 10993.
- **Supply Chain:** The complexity of the supply chain means information can take years to disseminate to the manufacturer, and substitutions or changes to product design require extensive and costly compatibility studies. Any changes in the device or package would then subject the item to resubmission to the FDA, further restricting patient access to proper healthcare and treatment.

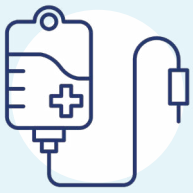
FDA Regulated Medical Devices and Products that Rely on PFAS:

Implantable devices

Prosthetics

Circuit boards, leads, foil in large equipment such as MRI, CT, and mammography machines

Instruments and equipment (shears, cutters, staplers) used in minimally invasive, endoscopic surgical procedures



Blood collection bags, suction devices used in respiratory therapy and for anesthesia, IV solution bags

Guide wires and delivery systems used in minimally invasive procedures to navigate through a patient's anatomy

Bottom Line

Banning the use of all PFAS in medical devices and products would effectively ban access to lifesaving technology and medical devices for patients. Acknowledging the extensive federal oversight and approval process of medical devices, state legislation should exempt medical devices and products and instead focus on products that contribute to a larger share of PFAS bioaccumulation and environmental contamination.