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Advanced Medical Technology Association

MEDICAL ALLEY ASSOCIATION

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March 6, 2023

Representative Zack Stephenson
Commerce Finance and Policy, Chair
449 State Office Building
St. Paul, MN 55155

Representative Carlie Kotyza-Witthuhn
Commerce Finance and Policy, Chair
449 State Office Building
St. Paul, MN 55155

RE: HF 1000, PFAS in Certain Products Prohibition

Dear Chair Stephenson, Vice Chair Kotyza-Witthuhn, and Members of the Committee,

The Advanced Medical Technology Association (AdvaMed) submits this letter to provide comments on House File 1000. 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. The Medical Alley Association is our State MedTech Alliance member, the leading Minnesota healthcare industry association that supports and advances the industry globally. Medical devices made by AdvaMed and Medical Alley members help patients stay healthier longer, expedite recovery, allow earlier detection of disease, and improve effectiveness and efficiency of treatment. Minnesota is the second-biggest med tech center nationwide in revenue, jobs and payroll – generating an $8 billion dollar industry and creating over 26,000 high-paying jobs in the state.

To mitigate the risk of HF 1000 unreasonably and unnecessarily restricting patient access to FDA regulated medical devices and medical products, we submit that the committee recognize the essential use of life-saving FDA regulated medical devices and medical products, and instead focus scrutiny on those products which make up a larger share of the PFAS that contribute to bioaccumulation and environmental contamination.

We respectfully believe leaving any exemptions to rulemaking will result in unnecessary confusion and complications and 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.

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.

Federal Action

Congress and the Biden Administration recently authorized significant legislation with new rules regulating PFAS.[3] Subsequently, under the Toxic Release Inventory (TRI) program companies or federal facilities that release 100 or more pounds of the 179 identified PFAS substances must collect and publicly report information on the amount that is released into the air, water, or land, and the quantities managed through disposal, energy recovery, recycling, or treatment. Additionally, the EPA is undergoing rulemaking under the Toxic Substances Control Act (TSCA) Section 8 that would require those who manufacture (including import) any identified PFAS to report information regarding PFAS uses, disposal, exposures, hazards, and production volumes.[4]

The EPA's recent PFAS Roadmap recognizes the broad class of PFAS and outlines additional efforts to define, subcategorize, assess, and regulate this important class of compounds. The Administration and EPA agreed to a targeted approach and to regulate by groupings of chemicals rather than regulate as one big class.

Testing for and identifying what is defined as PFAS is already a complex process. Additional reporting requirements at the state level will lead to multiple testing requirements with multiple definitions of PFAS. At a minimum, Minnesota can utilize the TRI data to better inform and prioritize any necessary policy options. We urge the committee to avoid the redundant use of state resources and support the EPA's efforts to comprehensively identify PFAS substances.

Proposed Amendment

To mitigate the risk of Hf 1000 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.***

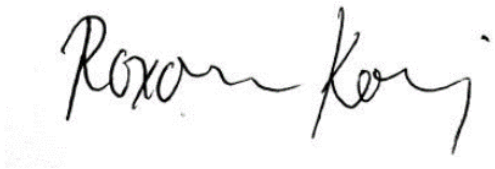
(c) ***A product intended for animals that is regulated as animal drugs, biologics, parasiticides, medical devices, and diagnostics used to treat or are administered to animals under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.), the federal Virus-Serum-Toxin Act (21 U.S.C. Sec. 151 et seq.), or the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. Sec. 136 et seq.).***

Conclusion

AdvaMed and Medical Alley respectfully request that the committee consider all the reasons discussed above and recognize the essential use of medical devices as well as their vetted safety for human health. Given the complexity and extensive supply chain involvement that goes into the manufacturing and approval of FDA regulated medical devices and medical products, we respectfully request to amend Hf 1000 to exempt medical devices with the proposed language above.

We look forward to working with you on this important matter. AdvaMed appreciates the opportunity to provide these comments. Enclosed are additional materials on the critical nature of PFAS in medical devices and the complexity of reporting. Please contact me at rkozyckyj@advamed.org if you have any questions.

Sincerely,



Roxolana Kozyckyj

Director, State Government & Regional Affairs

Michael C. Morton

Senior Advisor, Policy & Advocacy

Medical Alley

PFAS Data Reporting: Medical Devices & Technology

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.

The following points illustrate why applying PFAS (Per- and Polyfluorinated Substances) data reporting to FDA regulated medical devices and technology products would be duplicative and provide no added value or information for increased safety.

FDA Approval

- **Human Health:** The FDA considers human health and safety risks, optimal product quality, and assessment of who will be utilizing the device in their approval process of medical devices and packaging.
- **Unmatched Safety Standards:** The biocompatibility standards and testing required by the FDA are routinely the most scrutinized factor in a medical device's approval.
    - FDA regularly requests additional data and evidence of biocompatibility from a manufacturer over multiple rounds of verification and review before granting approval for the device. No other consumer product undergoes this level of scrutiny and oversight to ensure safety of human health.

Definition Broadness

- **12,000+ PFAS:** PFAS is a broad class of over 12,000 substances, all with very different physical and chemical properties and very different uses. It is not scientifically accurate or appropriate to group all these substances together or treat them the same when considering hazard or risk.
    - There is no commercially available test that could sufficiently identify all 12,000+ types PFAS by substance and concentration in a product, its component, or packaging. The type of PFAS would have to be specified to be identified in any test findings.

- **Polymers Aren't the Problem:** 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.

Threshold Criteria

- **Intentionally Added PFAS:** There needs to be recognition that complex products may contain components that are not specified by the "manufacturer" or "brand owner" and even if the product were tested for the presence of PFAS it wouldn't be known whether the PFAS was intentionally added.
- **Numbers Matter:** An additional definition for "de minimis concentration" that would not restrict or prohibit products that contain extremely low levels of PFAS, particularly in complex articles would be a prudent step in obtaining data on the PFAS that leaches out.
- **Reporting Unfeasibility:** Without a threshold, reporting is impossible as minute traces of the substance cannot be avoided or detected. (Compare EU REACH: only above 0.1% w/w). On the other hand, very low thresholds are not practically feasible if they are beyond the limit of the measurement.
    - If a threshold is set, it should be clear against which component scope the weight is measured (entire product, homogeneous material (EU RoHS) or article (EU REACH).

Recognition of Essential Use

- **Patient Access:** Since there is no suitable material that can substitute PFAS that can ensure the essential sterility, rigidity, flexibility, and durability of a medical device or its packaging, including FDA approved devices would be ineffective, duplicative and provide no added value or information for increased safety.

Today, in many cases, medical devices that use fluoropolymers, one type of PFAS, are the "standard of care."

The common PFAS materials (fluoropolymers) used in medical devices are not responsible for the water and soil contamination that is at issue.

Cognizant of the complexity and extensive supply chain involvement that goes into the manufacturing and approval of life-saving FDA regulated medical devices and medical products, legislation should exempt these and focus scrutiny on those products which make up a larger share of the PFAS that contribute to bioaccumulation and environmental contamination.

AdvaMed
Advanced Medical Technology Association

PFAS in Medical Devices & Technology

Background

Medical devices and medical technology that contain Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS), have been available to patients for over 50 years, with tens of millions of devices used without demonstrating adverse health effects.

Some devices like surgical tools, implantables, and syringes that need to be sterilized, require the product and often it's packaging to withstand melting, breaking, becoming brittle or otherwise degrading during the critical sterilization process. FDA must validate these products as safe 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.

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The industry has been and is currently taking steps to phase out some PFAS in paper and coating used in medical device packaging. However, certain other distinct PFAS are critical to the production of lightweight, flexible devices and packaging that must possess a host of other essential properties to pass the FDA's "shake, rattle, and roll" product test.

Unique, Unsubstitutable Properties of PFAS:

- **Flexibility**
- **Rigidity**
- **Sterility**
- **Penetrability**
- **Hot/cold temperature resiliency**
- **Ergonomic**
- **Degradation proof**

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 and toxicological safety in compliance with international biocompatibility standard, ISO 10993. 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 their packaging.

Furthermore, manufacturers and the FDA, in compliance with the FDA Quality System Regulation, continue to monitor the safety of these products even after they are marketed.

Use in Medical Technology

Levels of PFAS can be highly variable and are at times hard to ascertain and report in part due to complexity of the supply chain and their use in components developed by much further downstream suppliers as well as third party packaging suppliers. This can render compliance near impossible where trace amounts are unintentionally introduced as part of a complex supply chain. This would make compliance very challenging for any reporting requirements or prohibition.

The complexity of the supply chain means information can take years to propagate to the manufacturer, and substitutions or changes require extensive and costly compatibility studies to ensure no cross contamination, bleed-through or residuals are present.

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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.

Some Medical Devices Containing PFAS:

- **Circuit boards, leads, foil in large diagnostic equipment.**
- **Covers for electrical wiring**
- **Instruments and equipment (shears, cutters, staplers) used in minimally invasive, endoscopic surgical procedures**
- **Catheters (including balloon)**
- **Guidewires**
- **Grafts**
- **Stents**
- **Contact Lenses**
- **Syringes**
- **Blood collection bags**
- **IV solution bags and tubing**
- **Infusion drugs**
- **Peritoneal dialysis solutions**
- **Enteral nutrition**
- **Surgical Kits**
- **Injectables, autoinjectors**
- **Implantables**

Patients First

As innovators of critical lifesaving and life-enhancing medical devices and medical products in the United States and globally, AdvaMed's members produce medical technologies essential to the health, safety, and well-being of patients.

Our innovations are helping patients lives longer, healthier, and more productive lives. Advancements in medical technologies have been vital to public 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.