MedicalAlley

3/29/2023
Senate Environment, Climate and Legacy Committee

RE: SF 2438, Article 2, Section 57 (116.943): Products Containing PFAS

Chair Hawj and members,

Medical Alley and our network of more than 800 members represent one of the most diverse and influential healthcare communities in the world. We are a critical partner and connection point between companies, talent, and the broader Medical Alley community, which employs more than half a million Minnesotans. Our partners and investors understand the significant challenges facing healthcare — with affordability and access to care as top priorities.

It is because of this perspective and expertise that we respectfully ask to amend Minnesota Senate File 2438, Article 2, Section 57 (116.943) to include an exemption for medical devices and other products regulated by the Food and Drug Administration (FDA).

As a non-profit organization representing Minnesota's leading healthcare companies and manufacturers, we are committed to advancing healthcare innovation while also protecting the environment. Our partners embrace the responsibility of minimizing environmental impacts to ensure a healthy and sustainable future for all Minnesotans.

We believe that SF 2438 should include a medical device exemption that recognizes the critical role of PFAS in many medical products and equipment. PFAS are essential components in medical devices such as catheters, stents, and other lifesaving technologies that are necessary for effective patient care. Overly restrictive regulations could limit access to these critical devices and result in negative impacts on patient health.

It is important to note — 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.

In 2022, California passed a near identical bill that exempted medical devices, but the bill was ultimately vetoed by Governor Gavin Newsom due to high implementation costs and other complications. With this complexity in mind and the vast array of life-saving products that would fall under the reporting of this bill, we request the following amendment:

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.).***

We appreciate your attention to this important issue and urge you to consider our request to amend SF 2438 with an exemption for medical devices. Medical Alley is committed to working with policymakers to find a balanced approach that protects both public health and the environment while promoting innovation and economic growth in Minnesota.

Sincerely,

Michael Morton
Senior Advisor, Policy and Advocacy
Medical Alley