MedicalAlley

4/10/2023
House Ways and Means Committee

RE: HF 2310: Products Containing PFAS

Chair Olson 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.

Medical Alley is deeply committed to advancing health equity and improving patient outcomes for everyone. Our partners understand the significant challenges facing healthcare — with affordability and reducing health disparities as top priorities.

With that important goal in mind, Medical Alley has strong concerns that this legislation as it is currently written would increase barriers to patient access and would impede the path toward stronger health equity in the state. Under the current language, legislation restricting the use of PFAS would force patients to travel outside Minnesota for treatment or lose access to care altogether.

It is because of this perspective and expertise that we respectfully ask to amend House File 2310, 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, recognize the need to drive 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 House File 2310 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 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.

Patients and healthcare providers may lose access to the following devices and more, should this bill pass unamended:

- Contact lenses
- Stents
- IV solution bags and tubing
- Surgical kits
- Injectables, autoinjectors
- Implantables
- Catheters
- Syringes
- Instruments and equipment (shears, cutters, staplers) used in minimally invasive surgical procedures
- Guidewires
- Circuit boards, leads, foil in large diagnostic equipment
- Covers for electrical wiring
- Blood collection bags
- Peritoneal dialysis solutions
- Enteral nutrition

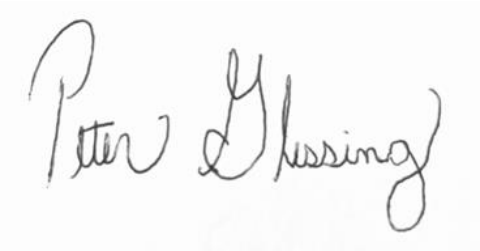
In 2022, the California legislature passed a near identical bill that exempted medical devices, but the bill was ultimately vetoed by Governor Gavin Newsom due to high implementation costs and other complications. With this complexity in mind and the vast array of life-saving products that would fall under the reporting of this bill, we request the following amendment under Section 35 of Article 3 of the bill:

This section 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 House File 2310 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,



Peter Glessing
Director, Government Affairs & Policy
Medical Alley