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Senator Bill Ingebrigtsen
Chair, Environment and Natural Resources Finance
3207 Minnesota Senate Bldg.
St. Paul, MN 55155

Representative Rick Hansen
Chair, Environment and Natural Resources Finance and Policy
407 State Office Building
St. Paul, MN 55155

RE: Senate File 4062, Sec.6 (Disclosure of PFAS in Products)

Chairman Ingebrigsten and Chairman Hansen:

The Advanced Medical Technology Association (AdvaMed), is a trade association that leads the effort to advance medical technology in order to achieve healthier lives and healthier economies around the world. AdvaMed's membership is made up of over 400 members ranging from the largest to the smallest medical technology innovators and companies. AdvaMed is the common voice for companies producing medical devices, diagnostic products and digital health technologies. We are OPPOSED UNLESS AMENDED to Senate File 4062, due to our concern relating to the reporting of perfluoroalkyl and polyfluoroalkyl substances (PFAS.) Additionally, we oppose the arbitrary and vague fee that the commissioner could levy on manufacturers who report based on volume of PFAS, volume of sales, and types of PFAS. Specifically, we are respectfully requesting amendments to SF 4062 that would exempt the application of SF 4062 to the life sciences as follows:

Sec.6, Subd. 2(5)(b) This subdivision does not apply to the sale or resale of used products; or medical devices approved or authorized by the federal Food and Drug Administration, or medical equipment and products used in medical settings.

Background of PFAS in the life sciences industries

PFAS generally describes a broad and diverse group of chemistries (per US EPA around 600) that assist in providing strength, durability, and resilience to certain products. For this reason, regulatory efforts relating to PFAS have been more targeted as opposed to generally applying to all chemicals that may be characterized as PFAS. Medicines and medical technology are highly regulated products that are extensively reviewed for safety efficacy by existing entities like the U.S. Food and Drug Administration (FDA.) Any changes to FDA approved products and packaging by the producer are highly scrutinized by the FDA and require prior regulatory approval. Some examples of FDA regulated and approved products whose packaging includes PFAS and phthalates include:

- Blood collection bags, suction devices used in respiratory therapy and for anesthesia, IV solution bags, Peritoneal Dialysis solutions, premixed drugs (drugs that are in a plastic bag ready for infusion in the hospital setting/no need for compounding, diluting, etc.), enteral nutrition
- Devices such as contact lens packages need enough space for the patient to hold the package and open it properly and remove the device
- EpiPen packaging must maintain the integrity of the technology so it is safe to operate when it is needed
- Injectables and implantables require packaging to be both strong and flexible as there zero room for error during usage

SF 4062 potential to disrupt the supply and availability of necessary medicines and medical devices that are currently extensively regulated for safety

- SF 4062 ignores the existing complex federal regulatory efforts already impacting the use of PFAS.
    - As mentioned earlier, the FDA has an extensive regulatory process for the regulation of medical devices. Any changes are highly scrutinized by the FDA and require prior approval which can be time consuming. This process includes an environmental assessment.
    - The U.S. Environmental Protection Agency (EPA) has already recently authorized significant new legislation and rules governing the use of PFAS.
- New broadly drafted and potentially conflicting regulatory requirements on medicines and medical devices can provide significant access and supply issues for patients and providers and disrupt the highly regulated medicine and medical device supply chain. This is not only harmful to patients, but also has the potential of increasing overall costs to Minnesota's health care delivery system and overall quality of care.

For the reasons stated above we must respectfully OPPOSE SF 4062, unless it is amended to exempt the life sciences industries and the critical medicines and medical devices that they provide to Minnesota patients.

Sincerely,

Roxolana Kozyckyj

Director, State Government & Regional Affairs

AdvaMed