MedicalAlley

02/21/24

RE: SF 3561

Members of the Senate Environment, Climate, and Legacy Committee,

Medical Alley represents a global network of more than 800 leading health technology and care companies in all corners of this state. Our mission is to activate and amplify healthcare transformation.

Minnesota, recognized globally as a leader in healthcare innovation, sets a standard for excellence, which not only impacts local communities, but extends its influence worldwide. With access, affordability, and quality as top priorities, Medical Alley and our partners are committed to developing solutions which drive meaningful change and save lives.

It is with this these guiding principles that we express concern about Senate File 3561's impact on access to care from medical devices, medical drugs, medical equipment, medical products, infant formula, medical food, and nutritional supplements.

For medical devices, FDA requirements govern the methods, facilities, and controls used in the design, manufacturing, packaging, labeling, storage, installation, and servicing of all finished devices. This is to ensure that the products are safe and effective for patients and consumers.

Medical devices must remain sterile, free from contamination, and protected from any mechanical damage throughout the supply chain process. Packaging must be designed to meet these requirements in order to protect the medical devices and help ensure their effective delivery.

Manufacturers have very little control over the type of packaging available from their suppliers to meet these standards and therefore cannot easily change it. Any additional requirements by individual states risk compliance with the FDA.

Once a medical device has been given approval by the FDA and is through the supply chain process, it is made available to patients, hospitals, and consumers through various distribution channels.

Products and equipment typically remain in service with the end user until they reach the stage for disposal, at which time some hospitals operate recycling programs or participate in partnerships with manufacturers and other organizations to recycle or repurpose constituent materials.

Many medical device manufacturers have specific sustainability goals and support recycling programs for their products and packaging. Some even operate stewardship and partnership

programs to reclaim materials – including products and packaging – from consumers and hospitals to divert material from the waste stream and support the circular economy.

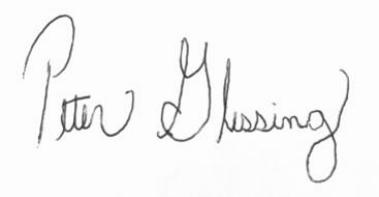
The medical technology industry is working to develop and redesign packaging to be more sustainable and use less materials while still meeting the rigorous standards of the FDA.

Several companies are members of the Healthcare Plastics Recycling Council (HPRC), which is a consortium of the health care and recycling industry working to improve recycling of the plastic products that are vital to medical technology. HPRC partners with hospitals to create recycling programs and identify common challenges of recycling throughout the supply chain and potential solutions.

As it pertains to specialized nutrition products like infant formula and medical food, the selection of packaging material is an important consideration. The multilayer containers used today must withstand processing and heat treatment conditions while maintaining product integrity and nutrient levels throughout the product shelf life. Specialized nutrition products support nutritional needs of individuals with health conditions such as illness, disease, injury, and malnutrition. Further research is needed on functional and sustainable packaging options, but those may be slower to develop because of the many important packaging considerations for specialized nutrition products.

We ask committee members to ensure this legislation prioritizes access to medical care while allowing for environmental stewardship to be carefully managed by federal regulators and the industry to ensure a consistent process and stable supply of life-saving medical equipment.

Sincerely,



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Medical Alley