MedicalAlley

03/10/24

RE: HF 3577

Members of the House State and Local Government Finance and Policy Committee,

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

Recognized worldwide as a leader in healthcare innovation, Minnesota sets a standard for excellence – impacting local communities and influencing global health outcomes and advancements. 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 House File 3577's impact on access to care from medical devices, medical drugs, medical equipment, and medical products.

Packaging for medical devices is highly regulated and subject to FDA validation and requirements. Medical device and drug manufacturers are obligated to create packaging according to certain specifications to maintain safety and functionality of life-saving of medical devices and medical products used in thousands of routine and complex healthcare procedures every day. Some medical devices are themselves considered packaging – such as a blood bag, a saline drip bag, and an ostomy bag. The packaging used to seal and deliver medical devices is tested to ensure it will protect the sterility of instruments and implants. This is to ensure that the products are safe and effective for patients and consumers.

Packaging for devices may not meet the proposed state standards because of the need for certain surface coatings and gas permeability. Packaging specifications and materials are part of the regulatory submission process. Manufacturers have very little control over the type of packaging available from their suppliers to meet these standards and therefore cannot easily change it. Should the state mandate these packaging requirements on medical device packaging, that would subvert the approved use as found in the FDA approval, create a compliance risk with FDA, and potentially a patient safety issue if sterilization were compromised.

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.

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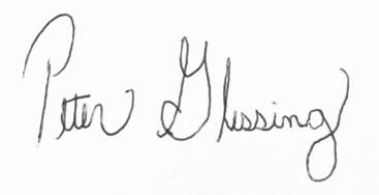
Many medical device manufacturers have specific sustainability goals and support recycling programs for their products and packaging. Some even operate stewardship and partnership programs to reclaim materials – including products and packaging – from consumers and hospitals to divert material from the 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.

Medical Alley appreciates Representative Jordan's willingness to discuss and consider our concerns as this process moves forward.

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,



Peter Glessing
Senior Director of Policy and Advocacy
Medical Alley