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Representative David A. Bennett, Chair
Environment and Natural Resources Committee
82 Smith Street
Providence, RI 02903

RE: HB 7619 – Toxic Packaging Reduction Act

Chair Bennett and Members of the Committee,

The Advanced Medical Technology Association (AdvaMed) submits this letter in respectful opposition to HB 7619. AdvaMed is the largest national trade association representing nearly 450 of the world's leading innovators and manufacturers of medical devices, diagnostic products, digital health technologies, and health information systems. Medical devices made by AdvaMed members help patients stay healthier longer, expedite recovery, allow earlier detection of disease, and improve effectiveness and efficiency of treatment.

While the bill is written to narrowly exempt PFAS from food packaging, it takes a broad approach to banning PVC from *all* packaging. PVC has been used safely in medical devices and their packaging for over 70 years allowing optimal technical performance and safety for both patient and practitioner. Furthermore, many medical devices are themselves considered packaging and would fall under the scope of this bill. Without an exemption for medical devices, this would unnecessarily restrict access to life-saving medical devices and technology.

FDA Approval for Human Health & Safety

The U.S. Food and Drug Administration (FDA) considers human health and safety risks, optimal product quality, and assessment of who will be utilizing the device (practitioner or patient) in their approval processes for medical devices and medical products. The health risks of these medical devices are thoroughly assessed by the FDA before they make it on the market and must undergo multiple tests to prove biocompatibility in compliance with the international biocompatibility standard, ISO 10993.

As part of FDA's regulatory process for medical devices coming to market, materials of the product as well as the packaging may be considered a component of the device itself or it could be a part of the final design specifications of the device as it's meant to be sold and distributed. In order to create the most optimally functioning product, some plasticizers and additives are required to create the very specific material properties for the product and it's packaging, which can be one and the same in some cases.

FDA must validate these products as safe, non-toxic, and resilient enough to withstand sterilization, transport, storage, and normal use so that it can function as intended without any damage or harm to the patient.

Examples of medical device packaging as a product includes 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.

We propose the following amendment to ensure that life-saving medical devices and their packaging is kept safe and accessible for the residents of Rhode Island:

This article does not apply to any of the following:

- *A product, including its peripheral accessories, and the packaging or packaging components for any product regulated as a drug or medical device by the United States Food and Drug Administration.*
- *Medical equipment or products, and the packaging or packaging components for any products used in healthcare settings, including hospitals and clinics that are regulated by the United States Food and Drug Administration or used for dispensing of medication.*
- *Medical equipment or products, and the packaging or packaging components for any product intended for Research Use Only as defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C., Sec. 360, etc. seq)*

Thank you for considering our concerns and proposed amendment. We look forward to working with you on this important matter throughout the remainder of the legislative session.

Sincerely,

Roxy Kozyckyj
Senior Director, State Government & Regional Affairs
AdvaMed