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April 21, 2025

Senator Denise Tepler, Chair
Committee on Environment and Natural Resources
Cross Building, Room 216
100 State House Station
Augusta, ME 04333

Representative Victoria Doudera, Chair
Committee on Environment and Natural Resources
Cross Building, Room 216
100 State House Station
Augusta, ME 04333

RE: LD 1423 -- An Act to Improve Recycling by Updating the Stewardship Program for Packaging

Chair Depler, Chair Doudera, and Members of the Committee,

AdvaMed, the MedTech Association, and the Medical Device Manufacturers Association (MDMA), appreciate the opportunity to submit these comments on LD 1423. Our collective members represent the world's leading innovators and manufacturers of medical devices, diagnostic products, and digital health technologies. We support LD 1423 and are encouraged by the efforts of the Department of Environmental Protection working with a diverse coalition of stakeholders to clarify and improve the 2021 Stewardship Program for Packaging to a program that functions well and addresses recyclability where it is feasible. As part of this work, we strongly recommend that an exemption be made for FDA regulated medical devices in LD 1423 as California, Colorado, Minnesota, and Maryland have.

We have been engaged on legislative and regulatory EPR efforts nationwide working with state regulators so that broad Extended Producer Responsibility (EPR) legislation accounts for the complexity and strict Food and Drug Administration (FDA) regulation of packaging for medical devices and medical products. In the 2025 legislative session, Maryland was the most recent state to exempt medical devices from their Packaging EPR law.

While the purpose of EPR regulations is to provide an incentive for producers to reduce packaging volume and improve circularity. However, the drug and medical device industry

are obligated to create packaging according to certain specifications by the FDA. These specs maintain the safety and functionality of life-saving medical devices and medical products used in thousands of routine and complex healthcare procedures every day.

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. Medical devices and products are heavily regulated by the FDA and require many years or decades for a finished device to come to market.

Without an exemption for medical device packaging, medical device manufacturers cannot simultaneously be obligated to existing heavy regulation by the FDA to ensure safety and functionality of their product to remain on the market while also complying with the EPR packaging requirements. Furthermore, some medical devices are, themselves, considered packaging, such as blood bags, saline drip bags, ostomy bags, and enteral nutrition bags.

Medical device manufacturers will be subject to the material goals and fees of this EPR law, effectively penalizing them for using packaging that complies with FDA regulations and keeps patients and healthcare providers safe. This will risk many companies selling their critical medical devices into the state of Maine, and, as a result, Mainers' access to medical devices will be significantly disrupted.

Furthermore, it is important to note that the majority of the current exemptions in statute in Section 13(D) are all packaging for products for medical use including prescription drugs, propellants used for drug delivery, and for tamper-proof or poison-prevention purposes. This omits the need for considering the critical properties that medical device packaging requires to maintain safety and functionality for patients in Maine. We encourage DEP to use its authority set out in Section 13(D) to exemption medical devices.

We propose the following language for your consideration:

Packaging does not include:

(a) Medical devices and packaging which are included with products regulated as a drug, medical device, or dietary supplement by the United States food and drug administration under the federal food, drug, and cosmetic act, 21 U.S.C. 321 et seq., Sec. 3.2(E) of 21 U.S. code of federal regulations, or the dietary supplement health and education act;

AdvaMed and MDMA appreciate the opportunity to provide these comments, and we look forward to working with the sponsor and the committee on this matter. Please contact me at rkozyckyj@advamed.org if you have any questions.

Sincerely,

Roxy Kozyckyj
Senior Director, State Government and Regional Affairs
AdvaMed

Clayton Hall

EVP for Government Affairs