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August 26, 2024

Maine Department of Environmental Protection
17 State House Station
32 Blossom Lane
Augusta, Maine 04333-0017

RE: *Revised* Draft Rule Chapter 428; EPR Program for Packaging, Routine Technical

To Whom It May Concern,

AdvaMed, the Medtech Association, submits these comments for the Draft Rule of the EPR Program for Packaging to the Department of Environmental Protection ("the Department"). AdvaMed is the largest association that represents over 500 of the world's leading innovators and manufacturers of medical devices, diagnostic products, digital health technologies, and health information systems.

AdvaMed appreciates the opportunity to provide these comments in conjunction with our comments on the exemption request for FDA regulated healthcare products that the Department received. We look forward to working with you on this matter in a future major substantive rulemaking where an explicit exemption for FDA regulated healthcare products (such as that appended below), including medical devices and their packaging, can be fully considered and promulgated.

AdvaMed is engaged on legislative and regulatory EPR efforts nationwide working with state regulators so that broad EPR laws account for the complexity and strict Food and Drug Administration (FDA) regulation of packaging for medical devices, and medical products, and their components. In 2024, Minnesota passed a comprehensive product stewardship law that created a robust exemption for packaging of FDA regulated healthcare products. In 2023, Colorado's broad EPR law also provided for such an exemption. We urge the Department to mirror these exemptions, as explicitly encouraged by the Maine legislature in Section 13(D) of 38 M.R.S. 2146, for FDA regulated healthcare products for better alignment and standardization across the country.

The purpose of EPR regulations is to provide an incentive for producers to reduce packaging volume and improve circularity. However, producers of FDA regulated healthcare products are obligated to create packaging according to certain specifications to maintain safety and functionality of life-saving medical devices and medical products used in thousands of routine and complex healthcare procedures every day. Without

making a clear exemption under "packaging material", medical device manufacturers will be subject to the material goals and fees of this EPR law, effectively penalizing them for using packaging that must first comply with FDA regulations to keep patients and healthcare providers safe.

Thank you for the opportunity to provide this comment. In addition, we ask for a dedicated meeting with the Department of Environmental Protection to discuss the issues with this draft rule and provide technical assistance for major substantive rulemaking where possible. Please contact me at rkozyckyj@advamed.org if you have any questions.

Sincerely,

Roxy Kozyckyj
Senior Director, State Government and Regional Affairs
AdvaMed

MN EPR for packaging law (passed 2024) – HF3911(omnibus bill – EPR language p.108

Exempt materials. "Exempt materials" means materials, or any portion of materials, that:

(4) are packaging for a product regulated as a drug or medical device by the United States Food and Drug Administration, including associated components and consumable medical equipment;

(5) are packaging for a medical equipment or product used in medical settings that is regulated by the United States Food and Drug Administration, including associated components and consumable medical equipment;

(6) are drugs, biological products, parasiticides, medical devices, or in vitro diagnostics that are used to treat, or that are administered to, animals and are regulated by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act, United States Code, title 21, section 301 et seq., by the United States Department of Agriculture under the federal Virus-Serum-Toxin Act, United States Code, title 21, section 151 et seq.;

(7) are packaging for products regulated by the United States Environmental Protection Agency under the Federal Insecticide, Fungicide, and Rodenticide Act, United States Code, title 7, section 136 et seq.;