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

RE: Proposed Chapter 428 Rule; EPR Program for Packaging, Routine Technical

To Whom It May Concern,

The Advanced Medical Technology Association (AdvaMed) 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 MedTech association that represents over 400 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 as a precursor to the exemption request forms that the Department will be issuing soon. We look forward to working with you on this matter in major substantive rulemaking where an explicit exemption for 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.

While the Department's draft rules do not address the definition of packaging specifically, we believe it is the most critical definition in the law to clarify in rulemaking. 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 to maintain safety and functionality of life-saving medical devices and medical products used in thousands of routine and complex healthcare procedures every day.

We request that primary and secondary packaging for medical products and products defined as devices or drugs, as specified in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Secs. 321(g), 321(h), and 353(b)(1)) be expressly

exempt through major substantive rulemaking in the definition of "Packaging material".

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. The FDA also ensures the packaging used is safe and effective at keeping the contents clean and germ-free. The packaging used to seal and deliver medical devices is tested to ensure it will protect the sterility of instruments and implants. This resilient packaging must also meet rigorous labeling standards which let the FDA trace devices in use.

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 complies with FDA regulations and keeps patients and healthcare providers safe.

We would welcome a dedicated meeting with the Department of Environmental Protection once the exemption forms are issued to better understand your goals with respect to packaging of FDA regulated devices and products 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