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Advanced Medical Technology Association

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

Dear Ms. Pryor and the Department of Environmental Protection,

The Advanced Medical Technology Association (AdvaMed) submits these comments for the first stakeholder meeting on Producer Exemptions for the EPR Program for Packaging. AdvaMed is engages on legislative and regulatory EPR efforts nationwide that do not recognize the significant importance of the Food and Drug Administration (FDA) in regulating packaging of medical devices and combination products and seeks to educate states on the complexity of these products and their packaging.

AdvaMed is a trade 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. 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.

The FDA doesn't just monitor and control the medical devices and drugs used in the U.S.—it 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. The resilient packaging must also meet rigorous labeling standards which let the FDA trace devices in use.

We respectfully ask the language below to be added to a list of exemptions in the proposed rule under "Producer Exemptions":

Medical devices and covered materials and products regulated as a drug, medical device, or dietary supplement by the US Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act, 21 USC 321 et SEQ Sec. 3.2 (E) of 21 US Code of Federal Regulations or the Dietary Supplement Health and Education Act.

Currently, the law allows the Department of Environmental Protection (DEP) to "determine if packaging for certain federally regulated products should be excluded" and if "federally regulated products are required to conform to specific packaging content or construction standards that may preclude or significantly diminish the producers' ability to modify packaging to increase recyclability or reduce volume." For medical products, this represents a challenge for DEP. AdvaMed believes that this type of review of medical products would require a significant amount of time and resources for the department. This determination would also represent a challenge for the FDA or the Environmental Protection Agency (EPA). There are associations and international standards organizations (ISOs) groups that exist in order to avoid confusion stemming from disparate regulatory structures and to ensure standardization wherever possible in global industries such as medical technology.

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

Sincerely,

Roxy Kozyckyj
Director, State Government and Regional Affairs
AdvaMed