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AdvaMed
Advanced Medical Technology Association

July 15, 2022

Re: Feedback on Preliminary Action Plan Scope for Advisory Committee Review

Members of the State of Washington Phthalates Action Team & Advisory Committee:

Thank you for the opportunity for Advanced Medical Technology Association (AdvaMed) to provide feedback on the Washington Departments of Ecology and Health Phthalates Action Team's ("Action Team") *Preliminary Action Plan Scope for Advisory Committee Review* ("Draft Scope"). AdvaMed recognizes and thanks the Action Team for its significant work to date and welcomes ongoing opportunities for engagement throughout the process.

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.

The Draft Scope covers several topic areas and is intentionally broad within each. One of these topic areas is "medical applications" which includes medical devices. Within this, the Draft Scope acknowledges the critical role the United States Food and Drug Administration (U.S. FDA) has in regulating medical devices, including assessing the health risks.

The U.S. 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. As part of FDA's assessment and approval 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. To help create optimal functionality for products, some plasticizers and additives are required to create the very specific material properties for the product and its packaging, which can sometimes be one and the same.

AdvaMed is grateful for the recognition of the U.S. FDA's regulatory role in this space, as well as the Action Team's continued consideration of this in the development of any final recommendations.

Thank you again for the opportunity to provide feedback. AdvaMed looks forward to working with the Action Team as it finalizes the scope for its work.

Sincerely,

Bobby Patrick, III

Bobby Patrick
Vice President, State Government and Regional Affairs
Advanced Medical Technology Association (AdvaMed)