American Association of Tissue Banks®

February 27, 2024

Dockets Management Staff
Food and Drug Administration
5630 Fishers Lane
Room 1061, (HFA-305)
Rockville, MD 20852

In Re: Docket No. FDA-2023-N-3392, Medical Devices; General and Plastic Surgery Devices; Classification of Certain Solid Wound Dressings; Wound Dressings Formulated as a Gel, Creams, or Ointment; and Liquid Wound Washes

Dear Madams and Sirs:

The American Association of Tissue Banks (AATB or Association) and the American Association of Tissue Banks' Tissue Policy Group (AATB TPG or TPG) submit these comments related to the Food and Drug Administration (FDA) proposed rule titled "Medical Devices; General and Plastic Surgery Devices; Classification of Certain Solid Wound Dressings; Wound Dressings Formulated as a Gel, Creams, or Ointment; and Liquid Wound Washes." The AATB and TPG are concerned that the Agency's plan to limit the use of the term "wound management" in product labeling could unintentionally reduce payment for, and access to, important wound care products.

The American Association of Tissue Banks (AATB) is a professional, non-profit, scientific, and educational organization. AATB is the only national tissue banking organization in the United States, and its membership totals more than 120 accredited tissue banks and over 7,000 individual members. These banks recover tissue from more than 70,000 donors and distribute in excess of 3.3 million allografts for more than 2.5 million tissue transplants performed annually in the US. The overwhelming majority of the human tissue distributed for these transplants comes from AATB-accredited tissue banks.

The AATB TPG includes Chief Executive Officers and senior regulatory personnel from U.S. tissue banks that process donated human tissue. The purpose of the TPG is to drive policy in furtherance of the adoption of laws, regulations, and standards that foster the safety, quality, and availability of donated tissue. The TPG's membership is responsible for the vast majority of tissue available for transplantation within the U.S.

FDA states in the proposed rule that the term "wound management" could be interpreted broadly and that manufacturers should instead use more specific descriptions like "to protect and cover a wound" to describe products (if that is the function of the product). According to the Federal Register notice, manufacturers that continue to use the term "wound management" will not benefit from this proposal and could instead be required to submit their product to the Agency for review via an alternative marketing authorization, such as for a combination product or drug.

Rather than taking this approach, the AATB and TPG encourage FDA to better define the term "wound management," while maintaining a distinction between products that serve as wound supplies such as

gauze. Without this distinction, manufacturers may be required to modify product labels to state "wound covering" or "wound barrier" – terms that may, in fact, resemble wound supplies, and lead to reduced payment for such products.

This is not a hypothetical concern. Many skin substitute manufacturers, to fulfill FDA's requirements for "361 human cells, tissues, and cellular and tissue-based products (HCT/Ps)" have used the terms "wound covering," "wound barrier," or similar terms like "barrier membrane" to describe their product(s). However, under three recently rescinded payment policies, several Medicare Administrative Contractors (MACs) would have excluded many skin substitutes from separate coverage and payment based on a determination that the skin substitutes are considered wound coverings or wound dressings, rather than skin substitutes. The AATB and TPG disagreed with this assertion, as the excluded products are often provided in the form of a sheet that is anchored to the wound with sutures, adhesive strips, or other similar mechanisms and provide 'scaffolding' for the wound site by providing a temporary extracellular matrix framework for new skin cells to attach and grow into during the healing process, even if their primary purpose is to serve as a barrier or covering. In practice, the term "wound management" reflects the difference between certain devices and "361 HCT/Ps," and wound supplies. The Agency's proposal to discourage the use of "wound management" may unintentionally reduce coverage and payment for, and access to, these wound care products.

For these reasons, the AATB and TPG believe that FDA should work with device and HCT/P industry stakeholders to further define "wound management" – to reflect these distinctions from wound supplies – rather than reducing them to "wound barriers" or "wound coverings." This will help these innovative products reach patients in need while maintaining coverage and payment.

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We hope that you will find this information useful in your deliberations. The AATB and the TPG stand ready and willing to assist the FDA with its deliberations in any way that you deem appropriate.

Respectfully,

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American Association of Tissue Banks

Doug Wilson
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