COALITION OF

Wound Care Manufacturers

February 28, 2024

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

Re: Docket No. FDA–2023–N–3392 – Proposed Rule; 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

Docket No. FDA-2023-N-3275 – Proposed Amendment; Proposed Order; Effective Date of Requirement for Premarket Approval Applications for Certain Solid Wound Dressings; Wound Dressings Formulated as a Gel, Cream, or Ointment; and Liquid Wound Washes Containing Medically Important Antimicrobials

Submitted electronically to www.regulations.gov

To the Food and Drug Administration:

On behalf of the Coalition of Wound Care Manufacturers ("CWCM"), I am submitting comments on FDA's Proposed Rule, *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* (Docket FDA-2023-N-3392) and its companion proposed amendment and order (Docket FDA- 2023-N-3275). Founded in 2000, the Coalition represents leading manufacturers of wound care products used by Medicare and commercially insured beneficiaries for the treatment of wounds; including the products that are the subject of this proposed rule and proposed amendment.

The Coalition is a member of the Alliance of Wound Care Stakeholders and agrees with and supports the very detailed comment letter they submitted. We agree with the issues raised as well as the recommendations provided in their letter and encourage the FDA to adopt their recommendations. The Coalition, however, would also like to underscore the following issues, concerns, and recommendations:

1. We submit that the proposed classification rule should be withdrawn. We believe that finalizing the proposal could significantly reduce availability of critical dressing and wash products for the vulnerable wound patient population.

2. Wound dressings and washes containing antimicrobials are safe and beneficial products that are a critical part of wound care. Maintaining access to these products is also critical to patients. However, FDA's proposed rule, if finalized, will cause the withdrawal of many

5225 Pooks Hill Rd | Suite 627S
Bethesda, MD 20814
T 301.530.7846 | C 301.802.1410
www.woundcaremanufacturers.org

safe and beneficial products from the market. For example, the proposed classification currently excludes (and would prompt withdrawal of):

- 510(k)-cleared foam and powder wound dressings;
- 510(k)-cleared gel, cream, ointment antimicrobial dressings containing silver, hypochlorous acid, and other safe antiseptics to prevent microbial growth within the dressing; and
- 510(k)-cleared antiseptic wound washes that are indicated for wetting gauze and other bandages to create an antimicrobial barrier.

4. FDA's proposed rule lacks many critical details regarding special controls that manufacturers need to know for commenting purposes. For instance, the proposed rule does not account for its true costs as the result of the tremendous burden it could create in terms of time, testing, expense, and potentially, need for product reformulation. When weighed against the speculative benefits of the proposed rule, there is no reason to proceed with the proposal with respect to dressings containing "other chemicals" and/or antimicrobials with low or moderate antimicrobials resistance concerns.

5. In regards to product labeling, the proposed rule provides restrictions which changes decades of precedents and prohibits truthful and accurate discussion of organisms used in antibacterial effectiveness testing. In addition, banning the use of terms like "wound management" and "biofilm removal," and creating other restrictions **serves no public health purpose**, and will unnecessarily burden and confuse discussions between manufacturers and clinicians.

   The FDA has proposed a 6-month timeline for manufacturers of cleared products to get new clearances, after which FDA could remove products from the market if they haven't received a new clearance. We believe that this proposal is not realistic. The process to develop data, submit for FDA review, and get a clearance could take years, not months given the volume of affected products, limited testing capacity of labs, lack of clear standards, and the potential need for product reformulations, relabeling, etc. based on the proposed classification requirements. This proposal is not workable. A 3 to 5 year timeline starting from publication of a final rule and final guidance regarding new requirements, is a more reasonable and risk-based timeline to phase in any new requirements.

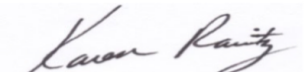
6. If the FDA moves forward with the language in this proposed rule, we submit that it could disrupt access to these important products for patients We believe that FDA hasn't adequately addressed that potential impact. In addition to the direct harm this would do to patients, limiting access to these products could lead clinicians to prescribe more systemic antibiotics, which will adversely affect antibiotic resistance and stewardship initiatives. Furthermore, if FDA wants to proceed, in addition to the impact analysis, we request that it publish a new proposed classification rule and companion guidance with details regarding special controls and test standards that are currently lacking, estimates of the true cost of the proposed rule so as to ensure currently marketed products stay on the market with their current indications and without the need to submit new 510(k)s.

The Coalition appreciates the opportunity to submit our comments. The proposed rule as written can have devastating effects on patients and should be withdrawn. Should you require additional

information, please feel free to contact me.

Thank you for your consideration.

Sincerely,



Karen Ravitz, JD
Health Policy Advisor
Coalition of Wound Care Manufacturers
301 807 5296
Karen.ravitz@comcast.net