

The American Burn Association's Positions on the Current & Future Classification of FRO Wound Care Dressings

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Background: The A.B.A.

- Founded in 1967
- Largest organization of burn providers in the world
 - membership is widely multidisciplinary
 - >3500 members from 4 continents
- Advocates for burn survivors and providers to advance burn care and insure optimal outcomes.



A.B.A. Positions on Current FRO Product Classification

- The FRO classification is a very crowded “space” involving widely different devices, which produces wide-spread confusion for all stakeholders.
- A.B.A. agrees with the agency that reclassification of certain FRO devices is warranted.
- A.B.A. agrees with the agency that general controls alone are insufficient to assure safety and efficacy of FRO wound dressings.



A.B.A. Positions on Antimicrobials in FRO Wound Care Dressings

- Metal-based, polymer-based, quaternary ammonium compound, and oxidizing agent antimicrobials do not meet the definition of a “drug”.
- For topical silver, it has been used medically for millennia, has a clearly demonstrated safety profile, and there has never been any evidence of *clinically* significant resistance.



A.B.A. Positions on Reclassification of FRO Wound Care Dressings

- The wound care dressings currently classified as FRO products that contain metal-based, polymer-based, quaternary ammonium compound, and oxidizing agent antimicrobials should be reclassified as Class II devices.
 - The antimicrobials are not drugs
 - Special controls will be sufficient to assure safety and efficacy.



Closing Comment

- Burn care in the US is currently strained on a daily basis, exceeding local capacity on many days.
- Burn wound care options are actually limited when compared to treatment options for other diseases.
- Reclassification of current FRO Wound Care Dressings to Class III status would potentially have a dramatic effect on burn patients by limiting care options and increasing morbidity and mortality.

