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

Jeffrey W. Shupp, MD
Chair, Research Committee
American Burn Association
Director, MedStar Washington Hospital Center—Burn Center
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 widespread 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.