General and Plastic Surgery Devices Advisory Panel Meeting

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United States Food & Drug Administration
September 21, 2016
Gaithersburg, MD
Disclosure

• Regulatory/Legal Counsel to Argentum Medical, LLC

• Supporting Argentum Medical LLC contract with BARDA, for development of silver nylon burn dressings for radiation, mustard gas and other mass casualty use
Comments on the Overall Process

• We greatly respect what FDA is trying to accomplish
• We recognize the concerns FDA has with this therapeutic category but the effort to regulate must be
  – balanced against the benefits;
  – data driven; and
  – given enough time for medical and scientific input
    • only six weeks notice to hearing
    • limited format for input/discussion
The Scope and Timing of the Process are Concerning—one-size fits all

• We are tasking this Panel with monumental societal/medical/scientific decisions affecting a great number of patients, physicians and commercial entities
• Based upon problems that have not been firmly established
• And based on evidence the Agency admits is equivocal
• The solutions being proposed are broad-based and not tailored to individual therapy categories or even individual products within those categories
The FDA’s “Executive Summary” Data Are Not Compelling

- Page 28 “...difficult to assess the efficacy of wound dressings combined with topical antimicrobials for chronic wounds and to compare results across studies”
- Page 29 “...authors found no RCTs that reported a study of a silver dressing or topical agent to treat diabetic foot ulcers, although the use of such products is common for these wounds”
- Page 30 “...mixed findings related to wound dressings and results from two additional studies”
- And many, many more such references through the entire report attesting to the equivocal state of the data
The Big Picture

• Burn patients, physicians, and health care facilities already face numerous challenges with the resources (including wound dressings) that are available today.

• Classification must take into consideration that Class III designations will limit the wound dressings availability in the future.

• Safety and efficacy of devices need to be considered for a huge range of patients, wounds, environments, and health care providers.
Don’t make the problem worse

- Appears to be a case of “ready, fire, aim”—FDA is a data-driven Agency, let’s operate on data
- Regulatory decisions that push devices into Class III or require additional data for marketing are the wrong decisions
- Seems to be a presumption that the medical community does not know what it is doing
- Topical dressings actually DECREASE the use of antibiotics overall
  - Fewer IV antibiotics
  - Fewer oral antibiotics
Challenges for Proposed Panel Decisions

• The issues are too broad
• The data at hand is inconclusive at this scale
• The ingredients involved are too numerous
• Safety and efficacy varies widely for each ingredient
• The questions to be answered require a governmental study, not precipitous anecdotal action
• Why the hurry?
Challenges (continued)—Too Much Variability

• The Agency wants to lump decisions for
  – hundreds of cleared devices
  – all different kinds of wounds
  – a myriad of microbes
  – into a handful of big questions

• What is the answer?
THE ANSWER SHOULD BE...

“IT DEPENDS”

• It Depends Upon
  – Dose
  – Indications for Use
  – Materials used and how constructed
  – Clinical needs
  – Patient
  – Environment
  – Concomitant therapies

• And it depends upon more data than we have today and the time to analyze it, debate it and draw conclusions
THANK YOU