General and Plastic Surgery Devices Advisory Panel Meeting

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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