The Reuse of Single-Use Devices

FDA Proposed Strategy: Concept in Development

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Beginning of Practice

- Reuse of reusable devices started in 1960s
- Advent of single use devices (SUDs) early 1980s: Determination of label from the Original Equipment Manufacturer (OEM)
- Economics is driving force for reprocessing
- In the US, most reprocessing done by hospitals
- Growth in third party reprocessing companies
FDA’s Position Historically

- Reprocessing in hospitals/clinics
  (Compliance Policy Guide 300.500)
- Any person engaged in single use device reprocessing is a “manufacturer”
- Premarket submissions have not been requested
FDA’s Position Historically
(continued)

• Requirements of 3rd Party Reprocessing Firms:
  – Device Registration and Listing, 21 CFR, Part 807
  – Good Manufacturing Practice (GMP) Inspection, 21 CFR, Part 820
  – Medical Device Reporting, 21 CFR, Part 803
  – General Labeling Requirements, 21 CFR, Part 801

• Reuse Policy Documents & Correspondence on FDA Web Page (www.fda.gov/cdrh/reuse)
Simple Solutions?

• One voice in the debate suggests calling for identical regulatory controls for reprocessing as for OEMs - call for 510(k)s and PMAs

• An opposing voice suggests we leave General Controls in place as sufficient: Registration and Listing, GMP (Quality System Requirements), Labeling, and Medical Device Reporting

• Neither approach is satisfactory
Problems to Solve

• Minimal evidence of public health problems does not mean that the current practice is safe and effective

• This system inside hospitals and in third parties has grown over time with FDA tacit acceptance

• Reuse is basically a problem of economics and ethics: both are outside of FDA mandate!
Some Guiding Principles

- Capitalize on what we do best: understanding of regulatory control and devices
- Our constraints suggest the importance of partnering/outside leveraging: show leadership but do not solve all by ourselves
- Do not let the perfect serve as the enemy of the good
Regulatory Strategy by Risk

- Develop a risk categorization scheme
- Use this to determine the timing of submitting premarket notification
- Determine how to judge safety and effectiveness of SUD reprocessing
- Work with hospitals and others to educate widely concerning FDA requirements
- Develop enforcement strategy
- Promote research to obtain better data base
Risk Categorization Scheme

• Establishes a way to evaluate the level of risk associated with the reuse of a SUD
• Assumes that reprocessing or reuse adds to the inherent risk of the SUD
• Begins with the inherent risk associated with the classification of a device into Class I, II, or III
• Evaluates the additional risk that may result from reuse
Critical Premarket Issues

- How to establish device specifications to ensure device is (as) safe and effective
- How to detect changes to devices by OEM and the need for revalidation
- Ability to perform thorough process definition and validation studies given facility and sterilizer limitations
Enforcement Issues

• Timeframe for submitting data, including registration and listing, depends on what data agency will require

• Huge education and terminology problem
  – Hospitals and physician’s offices have little experience with FDA

• FDA should have one set of requirements for OEMs, 3rd party reprocessors, hospitals, physician offices
The Potential Role of Standards

• Three dozen existing standards may apply: mostly in cleaning, sterilizing
• Some new horizontal standards needed
• Issues that need to be covered include verification of sterility after reprocessing
• New product specific vertical standards will be needed, but
  – these will take time and considerable cooperation from clinical community
The Role of Research

• Continued wide support for more research
• Research needed to develop meaningful endpoints such as residuals
• Research needed on the performance endpoints for device specific standards
• Need to develop worst case scenario to narrow amount of testing
Vision for the Future

Current Reality

- Widespread practice with little data on safety or effectiveness
- Single use labels not clearly meaningful
- Single use labels don’t identify vulnerabilities
- Patients are not informed - experimentation?

Future Vision

- FDA regulatory approach will be RISK and SCIENCE based
- Single use labels will have clinical relevance
- Single use labels will identify vulnerabilities
- Horizontal and vertical standards critical
- Leverage outside parties
Time for Action and a Bit of Magic!

- FDA now taking all comments into consideration
- FDA will begin to issue guidance early in 2000 and changes to the reuse of SUDs will happen soon after
- Magic? How to do this with clearly inadequate resources!
- Although consensus has not been achieved, we are much closer; we will get there!