

**Executive Summary**  
**Open Meeting: FDA's Proposed Strategy on Reuse of Single-Use Devices**  
**Tuesday, December 14, 1999**

**Opening Remarks – Linda Kahan, JD, Deputy Director, CDRH**

This meeting is one of a series of efforts to solicit input FDA can use to help us make a decision about the best way to regulate re-use. As many of you know, we broadcast a nationwide video teleconference on this subject in November to provide information about the various options FDA is considering. At that time, there was a limited opportunity for industry and consumer groups to express their initial reactions to FDA's strategy paper. This meeting is designed to expand that process and provide a wider forum for consumers, health care providers, manufacturers, and reprocessors to share their experience with us so that we can make an informed decision about the right strategy to adopt. We've already established a docket to take written comments and we're also planning to set up additional interactive opportunities using the world wide web.

We hope it's obvious from all this that we're taking great pains to keep the process as transparent as possible. We realize that the re-use of single use devices is a complicated issue, with medical, legal, ethical, and economic ramifications. We also realize that a simple "yay or nay" approach to regulating re-use won't work, because different devices may pose different safety questions when they're re-used. And to complicate matters, we don't have all of the scientific information we need to decide those safety questions.

Given the complexity of the issue, we think it's important that all the parties affected by re-use get to share their experience and expertise with us, and to let us know what actions they think we should take in order to protect public health. That's what this meeting is all about.

There are a number of things we already do know. First, we appreciate the need to change the way we have been regulating re-use. We recognize that the re-use of single use devices appears to be a growing trend, and that an increasing variety of products labeled "single use" are being used more than once. We also believe that we can probably identify a group of single-use devices that can be re-used safely following tested and validated cleaning and sterilization processes. Conversely, we think there are products out there whose re-use probably poses significant risk, in spite of efforts to clean and disinfect. And finally, we're sure there are products for which we simply don't have enough data to determine the risks, if any, that would be associated with re-use.

With that in mind, we've developed a regulatory approach that uses risk as its primary focus. Which means that we'd apply different enforcement strategy to different devices, depending on the potential risk those devices may pose if they're re-used. That's not a new concept. The whole regulatory structure for approving medical devices is based on risk—we don't subject a new wheelchair to the same regulatory scrutiny that we devote to a new heart valve.

Under our proposal, we'd use a three-tiered system to categorize single-use devices as high, moderate, or low risk. This system would be based on our regular classification system and, in addition, factor in what we know about the risk of infection and the complexity of reprocessing procedures associated with different devices. One of the workshops this afternoon will be devoted to getting feedback on this risk categorization proposal, which we posted on the web last week. We're also interested in other ideas for how to determine risk associated with re-use so we can implement an enforcement policy that will provide the maximum protection for patients and the minimum disruption in delivery of health care.

Other workshops this afternoon will explore the use of consensus standards to address the safety, effectiveness, and performance of re-used devices, and we'll be looking to you for ideas about how such standards can be developed to streamline data requirements. In fact, at the close of today's workshop on research and standards, we hope we'll be able to match up interested people with contacts at organizations that specialize in developing consensus standards.

So what do we want from you today? First, we want you to listen to an explanation of our proposed strategy. That won't take very long. Most of the morning will be devoted to us listening to you and to you listening to each other. Just as important, we want you to spend this afternoon participating in the various break-out sessions, where more interaction and feedback will be possible. And if you don't get a chance to share your opinions at this meeting, please submit your comments in writing to the docket. The address is listed in one of the handouts in your registration packet.

We understand that decisions we make about re-use will affect not only the original equipment manufacturers and third-party reprocessors, but also the hospitals and clinics that engage in this practice, and, most importantly, the individual consumers who seek health care at those facilities. The more we understand your different perspectives and the facts and data that support your viewpoints, the closer we'll come to a sound and sensible regulatory system.

We all want to ensure that any re-used device is safe and effective for patients. The American public is counting on us and we appreciate your willingness to help. Thank you for coming.

## **Public Oral Presentations**

Twenty-eight people presented their views during the formal presentation period of the meeting. The names of these speakers and their affiliations are listed at the end of this summary. The comments are summarized by topic, according to the sections of the strategy document.

### **1. Current policy on establishments that reprocess**

The comments on this area of the proposed strategy dealt with regulating hospital reprocessors and third party reprocessors of SUDs. Some speakers stated that anyone who reprocesses SUDs should be considered a manufacturer and therefore subject to all the regulations applicable to a manufacturer. Others stated that only third party reprocessors should be considered manufacturers and not hospitals. One person commented that third party reprocessors more

closely resemble servicers and should be regulated similarly to servicers. It was also suggested that following the Quality Systems Regulation was sufficient to ensure the safety of reprocessed SUDs.

A number of speakers stated that hospitals are not equipped to meet FDA regulations applicable to manufacturers. It was suggested that standards for reprocessing be developed and then hospitals could declare conformance to the standards. It was also suggested that FDA could work with outside organizations to better inspect the reprocessing in hospitals. Some stated that hospitals already receive sufficient oversight. Several people voiced the concern that doctors' offices should be held to the same reprocessing standards as hospitals because the same instruments are used and reprocessed.

## 2. Development of device risk categorization system

Most of the comments on the device risk categorization system were in favor of such a system, but not all thought that FDA's proposal was the best way. The comments on the device categorization included:

- the proposal is confusing;
- FDA has not taken into account whether the device can be reprocessed (including disassembly, cleaning, sterilization, reassembly, etc.);
- the criticality of the device should be taken into account;
- the broad risk categories do not take into account the vast differences from model to model within a device class;
- there should only be two categories – high and low; and
- FDA should not develop an additional categorization system but use the device classification system already in place.

Comments regarding specific devices include that

- biopsy forceps should remain a high risk, critical device because they break the mucosal barrier, and
- EP catheters do not have a lumen so they are easier to reprocess than other types of cardiovascular catheters.

## 3. Comments on list of frequently reprocessed SUDs

There were no comments on the list of frequently reprocessed SUDs.

## 4. OEMs provide information on their labeling about risks associated with reuse

Some in the hospital environment thought that it would be good to have information about the risks associated with reuse on the device labeling. Others were troubled by the idea that a manufacturer should provide negative information about reuse of the device on the label. They stated this would be too inflammatory. Many of the manufacturers thought additional labeling

on their devices was unwarranted. A number of speakers said that OEMs should have to justify their claim that the device was a single use only device and could not be safely reprocessed.

#### 5. Working definitions for terms

Very few comments were made about the definitions in the strategy document. There was agreement that the terminology in the document should be clarified.

#### 6. Explore how consensus standards can be applied to reprocessing

Most of the speakers stated that the use of consensus standards was appropriate. It was suggested that the standards should include guidance on the process as well as minimum acceptance levels of sterility and performance.

#### 7. Consider developing research program

The level of available data was disputed. Many of the speakers stated that additional research is needed – both to determine what devices can be safely reprocessed as well as in support of the development of consensus standards. Some of the speakers referred to specific research conducted already.

#### 8. General comments

General comments, not specific to the strategy document, included:

- there is no direct patient benefit to the reprocessing of single use devices. It is done purely for economic reasons;
- conserving scarce health care dollars can benefit the public health in a more general way;
- single use only devices are labeled as single use purely for economic reasons; and
- alternatives to single use devices can be used.

### **Workshop Sessions**

Four workshop sessions were held in the afternoon. The following are the highlights of each session.

#### **Workshop A: Enforcement Issues**

Larry D. Spears, Director, Division of Enforcement III, Office of Compliance, CDRH  
Lillian J. Gill, Director, Office of Compliance, CDRH

Much of the discussion centered on the issue of timeframes for submitting data to FDA and the enforcement of those timeframes. Many people thought that six months was too soon,

particularly for hospitals, to submit data related to the reprocessing of high risk devices. Many also thought that two years was too long a time period for the submission of data on the reprocessing of moderate risk devices. A few people thought that hospitals should have longer timeframes, in general, to submit.

### **Workshop B: Outreach Program and Educational Issues**

Al W. Thomas, Chief, Systems Analysis and Human Factors Branch III, Division of Device User Programs and Systems Analysis, Office of Health and Industry Programs, CDRH  
Debra Y. Lewis, OD, Deputy Director, Office of Health and Industry Programs, CDRH

Attendees at this workshop discussed their expectations for what information they would like from FDA as well as how that information should be disseminated. There was agreement that there should be broad access to information and that the website and list server are good ways to accomplish this for industry. The attendees would like periodic updates on significant steps that are being taken by the Agency. Hospitals and health care providers are best reached through a “multiplier network” of associations. They need regulatory education now. There was also agreement that consumers needed to be made aware of this issue, and FDA’s role, through the lay press. It was agreed that consumer education should start now.

### **Workshop C: Device Risk Categorization Issues**

Barbara C. Zimmerman, Chief (Acting), Diagnostic and Surgical Branch, Division of Ophthalmic Devices, Office of Device Evaluation, CDRH  
Timothy A. Ulatowski, Director, Division of Dental, Infection Control, and General Hospital, Office of Device Evaluation, CDRH

Most of the attendees at this workshop stated that the risk categorization scheme has potential but needs work. There were many questions about how this scheme works with our current classification system. Suggested changes to the scheme were discussed. There was also discussion about who will do the categorization, when it will be done, and how this information will be communicated to the parties involved.

### **Workshop D: Research and Standards Development Issues**

Katherine Merritt, PhD, Research Biologist, Division of Life Sciences, Office of Science and Technology, CDRH  
Donald E. Marlowe, Director, Office of Science and Technology, CDRH

It was agreed that standards are an important part of ensuring the safety and effectiveness of reprocessing. There needs to be consensus on what endpoints should be met to ensure safety and effectiveness. It is necessary to develop standard soils to use in the testing. There are already existing standards that deal with reprocessing of reusable devices that might be applicable to the reprocessing of single use devices, and these standards could be used now.

## **Summary of the Open Meeting and Where We Go From Here**

Larry Kessler, ScD, Director, Office of Surveillance and Biometrics, CDRH

Dr. Kessler provided an overview of what was discussed at the meeting and discussed next steps. He mentioned several issues that were brought up during the meeting that are not issues that fall within FDA's mission. These included the potential economic issues related to the reuse of single use devices, the ethics involved in reuse, and the global implications of reuse.

Dr. Kessler also provided a list of things that must be addressed before a comprehensive regulatory strategy can be put in place. These items include:

- clarify of our action plan;
- develop guidance on sterility validation;
- develop guidance on registration and listing for healthcare facilities;
- review the guidance on assessing the risk of single use devices;
- reach out to industry, healthcare facilities, clinicians, and the public;
- use quality systems in the context of reuse;
- develop auditing programs;
- develop regulation on labeling single use devices;
- continue to receive, catalog, and analyze scientific data;
- help develop horizontal and vertical standards relating to the reuse of single use devices.

He told the audience that work is ongoing and CDRH will make resolution of the reuse issue a priority in the coming year.

FDA documents related to the reuse of single use devices can be found on the CDRH web site at <http://www.fda.gov/cdrh/reuse/index.html>.

## List of Public Speakers

Mr. Stephen M. Kovach  
Manager, Central Supply  
Farmington Hills, MI

Ms. Anne Cofield  
International Association of Healthcare Central  
Service Materiel Management  
Dearborn, MI

David Greenwald, MD  
Chair, ASTM Subcommittee on GI Endoscopes  
Bronx, NY

David Berstein, MD  
Manhasset, NY

Mr. Will Shelton, M(ASCP), CIC  
Manager, Department of Epidemiology  
Swedish Medical Center  
Seattle, WA

Ms. Loretta Fauerbach  
Guidelines Committee, Association for  
Professionals in Infection Control and  
Epidemiology  
Gainesville, FL

Ms. Janet Schultz, RN, MSN  
President, Jan Schultz & Associates  
Roswell, GA

Mr. Louis Mazzaresse  
Independent Consultant  
Fairfield, CT

Mr. Craig Patnode  
CEO, SterilMed, Inc.  
Minneapolis, MN

Mr. Stephen Northrup, Esq.  
Executive Director, Medical Device  
Manufacturers Association  
Washington, DC

Ms. Pamela Furman, Esq.  
Executive Director, Association of Medical  
Device Reprocessors  
Washington, DC

Mr. Mark Bruley  
VP for Accident and Forensic Investigations  
ECRI  
Plymouth Meeting, PA

Mr. Charles Masek  
President & CEO, Vanguard Medical Concepts,  
Inc.  
Lakeland, FL

Mr. Patrick Lysaught  
Kansas City, MO

Mr. David Hambrick, RN  
Director, GI Lab  
Montclair Baptist Medical Center  
Birmingham, AL

Ms. Paula Graling  
Board of Directors, Association of periOperative  
Registered Nurses  
McLean, VA

Ms. Gwen Gampel  
VP of Government Relation, National Renal  
Administrators Association  
Washington, DC

Gerald Naccarelli, MD  
President, North American Society of Pacing  
and Electrophysiology  
Hershey, PA

Ms. Josephine Torrente, Esq.  
President, Association of Disposable Device  
Manufacturers  
Washington, DC

Michelle Alfa, PhD  
St. Boniface General Hospital  
Winnipeg, Manitoba, Canada

Mr. Richard Radford  
President & CEO, ClearMedical  
Bellevue, WA

Mr. Frank Seizmore, RCST  
President-Elect, American Society for  
Healthcare Central Service Professionals  
Winston-Salem, NC

Ms. Roslyne Schulman  
Senior Associate Director, American Hospital  
Association  
Washington, DC

Ms. Eugenia Tonca Matasa  
Owner, Ortho-Cycle Co.  
St. Louis, MO

Mr. Robert Bard, Esq.  
Chief Operating Officer, McKinley Medical  
Wheat Ridge, CO

Gina Pugliese, RN, MS  
Director, Premier Safety Institute  
Premier, Inc  
Westchester, IL

James Franks, MD  
President, American Society for Gastrointestinal  
Endoscopy  
Rockford, IL

Philip Grossman, MD  
Private Group Practice  
Miami, FL