

December 9, 1999

8 2 1 9 '99 DEC 14 P 1 57

Dockets Management Branch  
Division of Management Systems and Policy  
Office of Human Resources and Management Services  
Food and Drug Administration  
5603 Fishers Lane, Room 1061 (HFA-305)  
Rockville, Maryland 20852

**Re: Docket Number 99N-4491**  
**FDA's Proposed Strategy on Reuse of Single-Use Devices**

Dear Sir or Madam:

The Medical Device Manufacturers Association (MDMA) appreciates this opportunity to comment upon the FDA's "proposed strategy" for regulating the reprocessing and reuse of single-use medical devices. MDMA is the national voice for the entrepreneurial sector of the medical technology industry and represents 130 independent manufacturers of medical devices, diagnostic products, and health care information systems. As such, MDMA seeks to improve the quality of patient care by encouraging the development of new medical technology and by fostering the availability of beneficial innovative products in the marketplace.

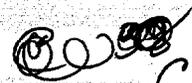
### **Background**

Single-use medical devices have been developed as a result of three primary influences: the clamor by health professionals and healthcare facilities for devices that are less expensive than reusable devices but still safe and effective, the effort to control hospital-acquired infections, and the need for more intricate devices to support the ongoing development of more advanced and minimally invasive surgical techniques. However, the downward cost pressures faced by hospitals and health professionals in today's highly competitive marketplace have led many institutions and practitioners to attempt to cut costs by reprocessing and reusing single-use devices on new patients. While the medical device industry can sympathize with the pressures to cut costs, we cannot condone a practice that places patients at an increased and unnecessary risk of physical harm or infection.

### **Position**

MDMA believes the reprocessing and subsequent reuse of medical devices intended for "single use only" is dangerous to the public health and deceives the patient, and therefore should be banned. Accordingly, we have formally petitioned the FDA to commence regulatory proceedings that would determine whether such a ban is appropriate for all reprocessed single-use medical devices.

99N-4491

  
C 61

Dockets Management Branch  
December 9, 1999  
Page 2 of 7

While the resolution of MDMA's petition is pending, we recognize that the FDA's issuance of a "proposed strategy" on the reuse of single-use devices signals that the FDA intends to disregard most or all of our petition. While MDMA still fully advocates acceptance of this petition, we nevertheless have developed in good faith these comments on the FDA's "proposed strategy."

Short of banning reprocessed single-use devices, the FDA, at the very least, must hold reprocessors of single-use devices, including both commercial reprocessing firms and healthcare facilities, to the same legal and regulatory requirements that original equipment manufacturers (OEMs) must satisfy with respect to reusable devices. This includes submitting premarket notification submissions or premarket approval applications to provide the public with a reasonable assurance of the continued safety and effectiveness of the reprocessed single-use devices, and adhering to the good manufacturing practices required under the FDA's Quality System (QS) regulation.

Secondly, MDMA believes that an OEM must not be required to demonstrate affirmatively that there is no conceivably safe way to reprocess and reuse a device before the OEM is allowed to label that device for single use only. To require an OEM to discover and study all possible or theoretical means for reprocessing a device would be highly impractical, if not impossible. The responsibility for ensuring that a single-use device can be reprocessed and reused safely and effectively, and the liability for the subsequent failure or other hazard caused by the reprocessed device, should rest squarely upon the "remanufacturer" of the allegedly reusable device, i.e., the company or healthcare facility that reprocesses the product. These remanufacturers should be required to delete the name and all copyrighted marks of the OEM from such devices to ensure that customers are not misled and that OEMs will not be forced to incur liability for injuries resulting from the unintended use of such reprocessed devices.

Thirdly, MDMA believes that until the FDA properly regulates reprocessed single-use devices based on safety and effectiveness, the federal government should require healthcare facilities and health professionals to obtain informed consent from patients prior to the commencement of procedures that involve reprocessed single-use devices. Medical ethics require healthcare providers to disclose material risks that would influence a patient's decision whether or not to proceed with medical treatment. Unless and until the FDA can provide a reasonable assurance of the safety and effectiveness of reprocessed single-use devices, patients must have the right to choose between a reused device and a new single-use device.

Finally, the FDA should require healthcare facilities and health professionals to monitor their use of reprocessed single-use devices, including the number of times such devices are reused, and to report any injuries or infections that occur during or after the use of reprocessed single-use devices. Such tracking will enable more informed research into the link between reprocessed single-use devices and patient injuries and infections.

**Comments on the FDA's "Proposed Strategy on Reuse of Single-Use Devices"**

In reviewing the FDA's "proposed strategy" on reuse of single-use devices, MDMA has identified seven aspects of this strategy upon which the FDA has requested comments or that otherwise deserve further comment. We have identified each particular section in italics in the following paragraphs.

*"Risk-based Classification System"*

Without question, the FDA must reevaluate the safety and effectiveness of single-use medical devices once reprocessing and reuse has changed the original intended use of these devices. For instance, single-use devices used in beating-heart coronary bypass procedures have been classified into Class I by the FDA (21 CFR 870.4500) and are exempt from premarket notification. However, subjecting such used devices to reprocessing or repeated sterilization cycles may compromise product performance and increase the risk of transmitting infections to subsequent patients, which supports the reclassification of reprocessed devices following review by an advisory panel in accordance with statutory classification procedures. MDMA believes it is unreasonable to expect that the FDA currently has or could accumulate rapidly all of the relevant data necessary to make an informed decision regarding the specific risks posed by the various categories of single-use devices that are apparently reprocessed and reused.

However, the FDA's proposed establishment of a new "risk-based categorization system" for reprocessed single-use devices would directly contradict the procedures established by Congress and specified in Section 513 of the Federal Food, Drug, and Cosmetic Act, as amended (21 USC 360c). Simply put, there is no legal basis or precedent for the FDA's proposal to develop a wholly new classification scheme for regulating certain discrete categories of medical devices.

The Medical Device Amendments of 1976 clearly established three regulatory classes for devices intended for human use. MDMA can not find any suggestion in the statute or its legislative history that this classification scheme should be replaced or discarded at the sole discretion of the FDA. Furthermore, the FDA has not even demonstrated the need for developing a separate classification scheme. We do not see, therefore, how the FDA's proposed categorization system accords with either the law or the intent of Congress.

MDMA also believes the development of a risk-based classification system is impractical and unnecessary. One can reasonably expect that the characteristics, performance capabilities, or sterility of a device designed for single use are altered to some extent each time that device is reprocessed or reused. However, the FDA currently considers all of these factors and more in its regulation of reusable devices under the current statutory classification system. Since reprocessing turns a single-use device into an allegedly reusable device, the FDA should simply regulate reprocessed single-use devices under the same rubric it employs to regulate reusable devices.

Rather than establishing a wholly new categorization scheme that is neither practical, necessary, nor supported by law, the FDA should utilize the statutory device classification process mandated by Congress to determine the safety and effectiveness of reprocessed single-use devices. MDMA urges the FDA to use the panels of experts created by statute to assist the FDA in sorting through the available scientific data to determine what controls are necessary for reprocessed single-use devices. Unless the FDA and its advisory panels decide to exempt a reprocessed single-use device from premarket requirements, the FDA must require individual submissions from reprocessing companies or healthcare facilities and must review them based on their appropriate classification.

*Proposed List of "Frequently Reprocessed SUDs"*

At this time, MDMA does not have any additions or subtractions to the list of "Frequently Reprocessed SUDs" (single-use devices) delineated by the FDA. However, we suggest that the title of the list should be changed to "Frequently Reprocessed and/or Reused SUDs" or a similar title, since certain single-use devices (e.g., syringes) may be reused without undergoing any cleaning or sterilization that even would rise to the level of "reprocessing." Additionally, MDMA requests that the FDA disclose the process it applied to develop this list and produce for the public record all documents and the identity of all parties associated with the process.

Such a list would be unnecessary, of course, if the FDA were to adhere to the intent of Congress by classifying reprocessed single-use devices according to the statutory classification scheme established by Congress for medical devices.

*Labeling by Original Equipment Manufacturers to Identify the "Potential Risks" of Reuse*

MDMA advises against any efforts to require OEMs to alter the labeling of their devices to include "any information" of which they are aware regarding the "potential risks" associated with reuse. With so many variables involved, no manufacturer can develop, with any certainty, a complete list of all potential risks associated with the reuse of their single-use devices. Such a list may mislead customers into thinking these are the only possible risks, and the omission of an unforeseen risk by the manufacturer could become the basis for a product-liability lawsuit for a variety of reasons, including allegations that the device's labeling is false or misleading.

The labeling of a device as being "single use only" should be sufficient to warn the prudent user that, in the view of the original manufacturer, reuse of the device must not be attempted under any circumstances. As an alternative, MDMA recommends use of the following clarification:

"The reprocessing and/or reuse of this device is not authorized by (company name). Such unauthorized use is the responsibility of those who reprocess and/or reuse a product for which the intended use has been accomplished or

Dockets Management Branch

December 9, 1999

Page 5 of 7

compromised. Liability for any possible adverse event is the responsibility of those who reprocess and/or reuse this product.”

*Working Definitions of “Single-Use Device”, “Reuse”, “Reprocessing”, and “Resterilization”*

The FDA should define a “single-use device” as “a device intended by the manufacturer for use on one patient during a single procedure”. Further elaboration is unnecessary. In addition, the FDA should not differentiate between used and unused single-use devices. Many unused single-use devices whose sterility has been breached may be unsuitable for resterilization. Unless a manufacturer provides users with proper protocols for resterilizing an unused single-use device, the reprocessor of the device should be required to demonstrate to the FDA that the reprocessed device is still safe and effective and to validate the protocols used in the reprocessing.

The other definitions are acceptable as working definitions, although the FDA may need to refine them before putting them into use as regulatory definitions.

*Use of Consensus Standards*

Certainly, reprocessors of single-use devices, like original equipment manufacturers, should be permitted where appropriate to declare conformity to recognized standards as part of the premarket review process. However, the FDA undoubtedly recognizes that verification of conformance to standards is most appropriate when undertaken in controlled environments with as few variables as possible. By its very nature, the reprocessing of hundreds of different types of used medical devices – devices which vary widely in complexity, are subjected to varying degrees of stress and to different infectious organisms during their use, and experience various physical and chemical conditions during reprocessing – does not lend itself to the development of and compliance with uniform standards.

*FDA Research Program on Reuse of Single-Use Devices*

While MDMA agrees with the FDA that more research on the effects of reprocessing single-use devices is warranted, we question whether the FDA, with its limited resources, is the proper agency to conduct such research. Moreover, MDMA believes the FDA has confirmed its bias toward reprocessing of single-use devices by its failure to enforce existing provisions of law, its unwillingness to release data it has developed on adverse events related to reprocessed single-use devices, and its disregard of data submitted by manufacturers and third parties that demonstrate the risks of reuse.

The FDA should review premarket submissions for reprocessed devices and increase its oversight of reprocessing facilities, both of which are tasks that fall within the FDA’s mandate and core competencies. General research on the effects of reprocessing single-use devices, on

Dockets Management Branch

December 9, 1999

Page 6 of 7

the other hand, would best be conducted by the federal Centers for Disease Control or independent contract research organizations.

*Third-Party Inspections of Healthcare Facilities that Reprocess Devices Themselves*

MDMA supports the FDA's proposal to contract with accredited third-party organizations or other federal agencies to inspect the reprocessing systems of healthcare facilities that reprocess single-use medical devices themselves. MDMA expects that the FDA will hold healthcare facilities responsible for complying with the FDA's QS regulation (in addition to applicable premarket review requirements), and that the third-party organizations will be trained to conduct their inspections in accordance with the QS regulation.

However, MDMA does not support the FDA contracting with the Joint Commission for Accreditation of Healthcare Organizations (JCAHO) to conduct these inspections. First, JCAHO reviewers are not trained in process validation or any other procedural or theoretical elements of the QS regulation. Second, a July 1999 report from the Health and Human Services Office of Inspector General found that JCAHO surveys are "unlikely to surface patterns, systems, or incidents of substandard care" and are "unlikely to reveal problems or patterns that might take a more thorough examination to uncover" [The External Review of Hospital Quality: The Role of Accreditation (OEI-02-97-00051), July 20, 1999].

The FDA has developed courses for training European conformity assessment bodies in the QS regulation for purposes of the mutual recognition agreement on medical devices between the United States and the European Union. To train third-party inspectors of healthcare facilities, the FDA could open these courses to or hold additional sessions for appropriate third-party organizations, such as organizations accredited to participate in the FDA's third-party premarket-review pilot program.

**Summary**

MDMA believes the reprocessing and subsequent reuse of medical devices intended for "single use only" is dangerous to the public health and deceives the patient, and therefore should be banned. However, MDMA is willing to consider the application of appropriate legal and regulatory controls over the practice as a substitute for banning, provided that these controls are applied fairly and consistently. As a result, we neither support the establishment of a separate categorization system for reprocessed single-use devices, nor do we endorse the use of untrained or unqualified third-party organizations to inspect hospital-based reprocessing facilities.

Instead, MDMA believes the FDA must hold reprocessors of single-use devices, including both commercial reprocessing firms and healthcare facilities, to the same legal and regulatory standards to which OEMs are held. Furthermore, once a single-use device has been reprocessed or reused, it no longer is the device released by the OEM for its intended use. All references to

Dockets Management Branch

December 9, 1999

Page 7 of 7

the identity of the OEM and prior OEM representations must be eliminated, as they are no longer applicable, and the user must be advised that the reprocessed device is not the OEM's device. Consequently, the responsibility for ensuring that a single-use device can be reprocessed and reused safely and effectively, and the liability for the subsequent failure or other hazard caused by the reprocessed device, must rest squarely upon the "remanufacturer" of the allegedly reusable device, i.e., the company or healthcare facilities that reprocesses the product.

MDMA appreciates this opportunity to comment upon the FDA's proposed strategy, and we hope our recommendations will assist the FDA in carrying out its responsibility to protect patients from the unsafe reprocessing and reuse of single-use medical devices.

Very sincerely yours,



Stephen J. Northrup  
Executive Director

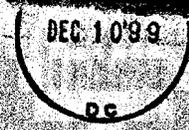
2 LB. POSTAGE RATE  
DOMESTIC USE ONLY



2.75  
U.S. POSTAGE



U.S. POSTAGE



U.S. POSTAGE

OR PICKUP C/

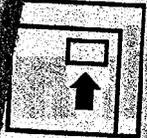


UNITED STATES POSTAL SERVICE™

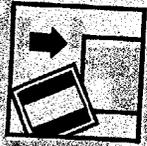
HOW TO USE:



1. COMPLETE ADDRESS LABEL AREA  
Type or print required return address and addressee information in customer block (white area) or on label (if provided).



2. PAYMENT METHOD  
Affix postage or meter strip to area indicated in upper right hand corner.



3. ATTACH LABEL (if provided)  
Remove label backing and adhere over customer address block area (white area).

**MDMA** MEDICAL DEVICE MANUFACTURERS ASSOCIATION  
 1900 K STREET, N.W. / SUITE 300 / WASHINGTON, D.C. 20006 / 202-496-7150

---

TO: Dockets Management Branch  
 Division of Management Systems and Policy  
 Food and Drug Administration  
 5603 Fishers Lane, rm 1061  
 HFA-305  
 Rockville MD 20852

The efficient FLAT RATE ENVELOPE.