DEPARTMENT OF HEALTH & HUMAN SERVICES

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STATEMENT OF

DANIEL SCHULTZ, M.D., DIRECTOR

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
FOOD AND DRUG ADMINISTRATION
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM
HOUSE OF REPRESENTATIVES

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INTRODUCTION

Mr. Chairman and Members of the Committee, I am Dr. Daniel Schultz, Director, Center for Devices and Radiological Health (CDRH) at the Food and Drug Administration (FDA or the Agency). I consider device safety to be of utmost importance and appreciate your invitation and the opportunity to discuss this issue. Let me say at the outset that I believe FDA currently has many tools to ensure the safety, effectiveness, and manufacturing quality of reprocessed, single-use devices (SUDs).

FDA has been actively engaged in the SUD reuse issue for some time, and our efforts have included research, outreach, pre-market review, inspections, and compliance investigations. We have held numerous public meetings and conferences with industry, healthcare professionals, and consumers over the years to determine the extent, magnitude, and changing nature of this practice. FDA has carefully evaluated and conducted research to develop the scientific basis for addressing SUD reprocessing. We have inspected third party reprocessors, evaluated and investigated reports of patient injuries, and reviewed numerous pre-market submissions. Taken together, the Agency believes that these efforts have provided, and will continue to provide, reasonable assurance of safety and effectiveness of reprocessed SUDs for patients.

BACKGROUND

I will begin with a brief overview of our regulatory authorities for medical devices. A medical device as defined by Federal law encompasses several thousand health products, from simple articles such as tongue depressors and heating pads, to cutting-edge and

complex devices such as implantable defibrillators and robotic equipment for minimally invasive surgery.

The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic (FD&C) Act gave FDA specific authority to regulate the safety and effectiveness of medical devices. Medical devices are assigned to one of three "classes." Class I is the lowest risk category of device and includes items such as adhesive bandages. Class II, or medium-risk category of device, includes devices such as intravenous catheters and powered wheelchairs. Class III is the highest risk category of device and includes devices such as heart valves and coronary stents.

THE REGULATION OF REPROCESSED SINGLE USE MEDICAL DEVICES

The reprocessing of SUDs is legally permissible in the United States under the FD&C Act. Currently, only Class I and II SUD device types have been cleared by FDA for reprocessing. No Class III SUDs have been cleared/approved for reprocessing.

In August 2000, FDA issued a guidance document for industry and staff entitled "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals." This document set forth FDA's priorities for enforcing pre-market submission and post-market requirements for manufacturers who wished to market reprocessed SUDs. The guidance document stated that any third party or hospital reprocessor should comply with requirements pertaining to: registration and listing, medical device reporting, medical device tracking, medical device corrections and

removals, the quality system regulation, labeling, and pre-market submission.

- Essentially, third party firms and hospitals reprocessing SUDs were placed in the same regulatory framework as original equipment manufacturers (OEMs).

Prior to issuance of this guidance, reprocessing of SUDs was frequently performed by hospital personnel without regulatory oversight or regard to the level of device risk. In addition, many third party reprocessors contracted with hospitals to perform similar tasks and these contractors did not consistently adhere to FDA's Good Manufacturing Practice Requirements.

CHANGES ENACTED WITH MDUFMA

In 2002, with enactment of the Medical Device User Fee and Modernization Act (MDUFMA), Congress mandated a number of new requirements for SUD reprocessors including, for certain SUDs, the pre-market submission of data to the Agency that exceeded the requirements for OEMs. In addition to the requirements specified in our 2000 Guidance Document, certain reprocessed SUD types that potentially could pose the greatest risk of infection and inadequate performance following reprocessing and that were previously exempt from any pre-market submission requirements, are no longer exempt.

MDUFMA also created a new type of pre-market submission, called a "pre-market report" (PMR), for Class III reprocessed SUDs that otherwise would have required a pre-market approval application. Among other information, a PMR must include validation

data regarding cleaning, sterilization, and functional performance of the reprocessed device to ensure it is substantially equivalent to a legally marketed device. To date, only one PMR has been submitted to the Agency and it was later withdrawn by the firm.

In addition, MDUFMA required a change to FDA's MedWatch voluntary and mandatory reporting forms (Forms 3500 and 3500A, respectively) to facilitate the reporting of adverse events involving reprocessed SUDs.

Finally, MDUFMA required, as of August 1, 2006, that reprocessed SUDs prominently and conspicuously bear the name, abbreviation, or symbol of the reprocessor on the device itself, on an attachment to the device, or on a detachable label, depending on the physical characteristics of the device and whether the device has been marked by the OEM.

PRE-MARKET REVIEW OF REPROCESSED SUDs

Under the FD&C Act, before introducing a device to market, manufacturers must submit a Notification of Intent to Market a Device (510k) and obtain FDA clearance, unless the device has been exempted. MDUFMA required FDA to identify previously 510(k)-exempt device types that, if reprocessed as a SUD, would now require 510(k) pre-market review, including the submission of validation data. In addition, MDUFMA required that FDA identify SUDs that were already subject to 510(k) pre-market requirements, but that would now also require the submission of validation data. Required validation data include cleaning and sterilization data, and functional performance data demonstrating

that each SUD will remain substantially equivalent to its predicate device after the maximum number of times the device is intended to be reprocessed.

The criteria used to determine which reprocessed SUD types would no longer be exempt from pre-market notification requirements and would require 510(k)s with validation data, and which reprocessed SUDs already subject to the 510(k) requirements also would now be subject to the additional requirement of validation data are available on the Internet at: *http://www.fda.gov/OHRMS/DOCKETS/98fr/03-10413.html.*

Using these criteria, FDA identified all previously exempt "critical" and "semi-critical" devices that were high-risk. These devices would no longer be exempt from 510(k) requirements and SUD reprocessors of these device types would be required to submit 510(k)s with validation data and receive clearance in order to continue marketing these devices.

In addition, the requirements and the lists of devices that were newly subject to these requirements were published in the *Federal Register*. FDA has added other reprocessed SUD types to these lists as we become aware of information that warrants their inclusion.

On June 1, 2004, FDA issued a revised "Guidance for Industry and FDA Staff; Medical Device User Fee and Modernization Act of 2002, Validation Data in Pre-market Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices." This

document describes the types of validation data that FDA recommends be submitted on cleaning, sterilization, and functional performance of certain reprocessed SUDs to ensure that they are substantially equivalent to the predicate device. Additionally, this document describes the timeframe for FDA's reviews of these validation data submissions, and what actions the Agency intends to take if it finds a reprocessed SUD to be Not Substantially Equivalent (NSE) to the predicate device.

As of September 2006, FDA has received nearly 200 pre-market notification 510(k) submissions for reprocessed SUDs. These submissions cover from one, to as many as several hundred, device models. Of the almost 200 submissions, approximately 67 percent have been cleared by FDA. The remaining were not cleared for such reasons as inadequate validation data, lack of necessary information from the reprocessor, withdrawal of the application by the submitter, or lack of response to FDA's request for data. (Approximately 88 percent of 510(k)s for all other devices are cleared and approximately 3.4 percent are found NSE to the predicate device.)

COMPLIANCE ACTIVITIES

FDA's inspectional program serves as a bridge between pre- and post-market activities. Since 2000, on average, FDA has conducted inspections of reprocessor firms once every two years, a rate considerably higher than the one inspection in four years for OEMs. Of the seven firms currently known to be reprocessing, all have been inspected within the last two years. FDA continues to evaluate newly registered firms to confirm whether they are performing SUD reprocessing and updates its inspectional plan as required.

POST-MARKET SURVEILLANCE FOR REPROCESSED SUDs

Post-market monitoring of device-related adverse events (AEs) and product problems is accomplished through the Medical Device Reporting (MDR) system. MDR reports include deaths, serious injuries, and device malfunctions. Healthcare facilities are required to report deaths suspected to be device-related to both FDA and the manufacturer/reprocessor. They are required to report serious injuries to the manufacturer/reprocessor.

FDA also receives voluntary reports, generally from healthcare professionals, through its MedWatch reporting system. As previously mentioned, under MDUFMA, the MedWatch reporting form 3500A was revised to include a data entry field (D8) to ask if the device associated with the reported event was a reprocessed SUD. This question was added to the form to enhance the Agency's ability to quickly identify and investigate reports of problems associated with reprocessed SUDs.

FDA responds to reports of death or serious injury by investigating the report and taking appropriate follow-up actions as needed. Follow-up actions may include enforcement actions and/or the issuance of a public health notification to alert the healthcare community of the Agency's concerns.

As you know, on January 24, 2006, I and others briefed this Committee about SUD reprocessing. At that time, we provided background information including the current

regulatory framework and AE data. Specifically, we searched our Manufacturer and User Facility Device Experience (MAUDE) database for reports from October 22, 2003, to December 13, 2005, that were coded as adverse events associated with reprocessed SUDs. The search produced 176 reports of death, serious injury, and/or device malfunction; however, analysis of these reports did not disclose a clear causative link between a reprocessed SUD and subsequent patient injury or death.

In July 2006, the Agency updated the search to include all reports entered into the MDR, MAUDE, and MedWatch databases between December 2005 and July 2006. FDA has received a total of approximately 434 reports, including MedWatch forms, where the reprocessed SUD field was checked "yes." Our analysis of these reports determined that many of the devices were not reprocessed SUDs. Rather, they were implanted devices or devices that were designed to be re-usable and, therefore, were not reprocessed SUDs. Of the 434 reports, approximately 65 reports actually involved or were suspected to involve reprocessed SUDs, and were reviewed by FDA. The final analysis of the reports found that the types of adverse events reported to be associated with the use of SUDs were the same types of events that also are being reported for new, non-reprocessed devices. Therefore, it was unclear whether the device, the medical condition of the patient, the medical procedure, or other confounding factors caused or contributed to the adverse event.

FEEDBACK FROM A SAMPLING OF MEDSUN HOSPITAL FACILITIES THAT USE REPROCESSED SUDs

FDA's Medical Product Safety Device Network (MedSun) is comprised of over 350 hospitals that have been recruited and specifically trained to identify and report device problems. The hospitals in this program are broadly representative of U.S. healthcare facilities. FDA staff talked with representatives from more than 50 of these facilities to obtain feedback on their experience with using reprocessed SUDs.

The MedSun respondents who gave us feedback represented various occupations in hospitals, including materials management, biomedical and clinical engineering, risk management, infection control, surgical services, nursing staff, supply utilization, and equipment management. Staff being interviewed responded overwhelmingly that they view the use of reprocessed SUDs as providing a significant cost savings to their facilities and as being an environmentally sound practice.

There was considerable variation in the devices being reprocessed at the various facilities and the degree of acceptance of this practice by individual practitioners within the facilities. None of the participants we spoke with reported specific problems with SUD-related infections, but they also pointed out that, if an infection occurred, it would be difficult to discern whether the reprocessed SUD was the cause. It also is interesting to note that the participants did not report a greater concern with mechanical problems associated with reprocessed SUDs compared to un-reprocessed SUDs. In general, the participants had a favorable view of reprocessed SUDs used in their facilities. They also stated that they relied heavily on FDA oversight to ensure safety and effectiveness and to provide objective information on reprocessed SUDs.

ONGOING FDA ACTIVITIES

The Agency continues to review and assess the practice of reprocessing SUDs.

- CDRH established an active internal work group to ensure that review scientists remain current with the evolving scientific literature and new consensus standards that are relevant to the reprocessing of SUDs.
- CDRH has convened a second work group, called the "Post-market Issue Action Team," to develop a long-term strategy for monitoring, evaluating, and communicating information about reused SUDs.
- CDRH continues to submit reprocessor inspection requests to the Office of Regulatory Affairs to schedule inspections of reprocessor facilities to assess conformance with the Quality System Regulation.
- CDRH periodically updates its reuse webpage so that healthcare facilities and providers will have current information on legally marketed, reprocessed SUDs. Recently, easy-to-read tables listing FDA requirements for specific reprocessed SUD types were added to the website. In addition, we improved accessibility and added instructions to the publicly searchable FDA pre-market databases. These databases allow the user to search in real-time for recent and past clearances. (*http://www.fda.gov/cdrh/reuse/index.html*)
- CDRH regularly updates guidance to industry and FDA reviewers on validation data requirements for reprocessed SUDS.
- CDRH regularly updates the list of reprocessed SUDs subject to the additional pre-market requirements imposed by MDUFMA.

- CDRH is conducting research to develop/establish "acceptable" SUD cleaning criteria.
- CDRH is collaborating with two local healthcare facilities to help monitor changes in the design of some SUDs and identify new SUDs being reprocessed.

On September 25, 2006, FDA published two rules: the direct final rule for Medical Devices; Reprocessed Single-Use Devices; Requirement for Submission of Validation Data; and a proposed rule for Medical Devices; Reprocessed Single-Use Devices; Requirement for Submission of Validation Data; Companion to Direct Final Rule (proposed rule). These amendments will help ensure that reprocessors submit the data, including cleaning, sterilization, and functional performance data, needed to demonstrate that their device is substantially equivalent to the predicate device.

CONCLUSION

Available data show that SUDs can be reprocessed with a reasonable assurance of safety and effectiveness. FDA believes that reprocessed SUDs that meet FDA's regulatory requirements are as safe and effective as a new device. The law and regulations in place are designed to protect the public health by assuring that the practice of reprocessing and reusing SUDs is based on sound science. FDA continues to monitor the performance of these devices and to assess and refine our ability to regulate these devices appropriately.

Mr. Chairman, thank you again for the opportunity to address this important topic. I will be happy to answer any questions.