AMDR
Association of Medical Device Reprocessors

April 29, 2005

BY HAND DELIVERY

Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Alleged Adverse Events Associated With Reprocessed Devices

Submitted to: Docket No. 03N-0161: Medical Devices; Reprocessed Single-Use Devices; Termination of Exemptions from Premarket Notification; Requirement for Submission of Validation Data; and

Docket No. 02N-0534: Medical Device User Fee and Modernization Act (MDUFMA).

Dear Sir or Madam:

The Association of Medical Device Reprocessors (AMDR)[1] respectfully submits the following comments to the above-referenced dockets in response to a letter, dated September 29, 2004, from the Advanced Medical Technology Association (AdvaMed) to Dr. Daniel Schultz, Director of the Center for Devices and Radiological Health,[2] regarding alleged adverse events

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[1] AMDR is a trade association representing the legal and regulatory interests of third-party reprocessors of medical devices labeled for "single use." It is estimated that AMDR members perform approximately 95% of the third-party reprocessing done in the United States.

[2] AdvaMed's September 29, 2004 letter was addressed directly to Daniel Schultz, MD, Director, Center for Devices and Radiological Health, FDA, 9200 Corporate Blvd, HFZ-01, Rockville, and not to Dockets Management. While the document includes in its header the words "submitted to" and then both docket numbers "03N-0161" and "02N-0534," our search of these two dockets indicates that the letter was never entered into either docket. The Dockets Management Office confirmed this on April 21, 2005. Further, AdvaMed's letter references

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associated with a reprocessed heart positioner and a reprocessed endoscopic vein harvesting system.[3]

AdvaMed's letter to Dr. Schultz indicates that it is aware of "actual serious injury associated with the use of reprocessed, single use devices." First, AdvaMed asserts that an (unidentified) OEM received a report of a heart positioner that failed to function properly, resulting in "laceration, exposing the patient to excessive bleeding and a prolonged procedure." This failure is asserted to have occurred because a "foam gasket" on the device "had decomposed due to reprocessing." AdvaMed's letter also describes a case involving an endoscopic vein harvesting system that allegedly failed because the "shrink tubing" had deteriorated due to multiple sterilization cycles.

Unfortunately, AdvaMed's letter provides no further information about these events. The letter does not identify the OEMs who received the reports, the hospitals where the events allegedly took place, the dates that the events occurred, or the companies that reprocessed the devices. Indeed, the letter does not even provide substantiation for the assertion that the devices were in fact reprocessed. AdvaMed's letter does assert that the original manufacturer of one of the reprocessed devices in question will be submitting further information about the events to FDA, but our search of FDA dockets and FDA's website (as of April 21, 2005) has found no such information. For this reason, it is impossible for AMDR or its members to address the specific allegations that a heart positioner and a vein harvesting device failed due to reprocessing.

However, AMDR does wish to address the more general issues raised by AdvaMed's letter. AdvaMed asserts that when the heart positioner in question failed, "the hospital contacted the OEM rather than the reprocessor, as required by MDUFMA." The letter asserts that this situation highlights two serious concerns. First, AdvaMed suggests that "additional education within user facilities is needed on this subject." Although FDA has been clear that adverse events involving reprocessed devices should be reported to the reprocessor,[4] AMDR is

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comments that it submitted to FDA on August 13, 2004, which are also absent from the docket. Finally, while AdvaMed's letter indicates that "the OEM plans to provide additional information to FDA regarding these [incidents involving actual serious injury]," to the best of our knowledge, no follow up reports have been filed with either docket.

[3] The second half of AdvaMed's letter concerns the "independent testing of reprocessed heart stabilizers." AMDR takes issue with many of AdvaMed's assertions with respect to that testing, but will submit a detailed response to those assertions separately.

[4] For example, in FDA's "Guidance on Adverse Event Reporting for Hospitals that Reprocess Devices Intended by the Original Equipment Manufacturer for Single Use," at 9, the

supportive of additional education of user facilities in this regard. AMDR's members are committed to providing hospitals with the safest devices possible, and they recognize that feedback from their hospital customers about device-related adverse events is critical to these efforts. AMDR therefore would strongly support any efforts by the agency to remind user facilities to report failures of reprocessed devices to the reprocessor. For example, it may be useful for FDA to add another question and answer to the Frequently Asked Questions (FAQs) section of FDA's reuse web-page[5] repeating the information in FDA's guidance on adverse event reporting for hospitals using reprocessed devices,[6] which should help make user facilities more aware that reprocessors are the proper recipient of information about adverse events associated with reprocessed devices.

Second, AdvaMed states that, because OEMs who receive reports of adverse events associated with reprocessed devices are not required to report the incident, the result may be "under-reporting or non-reporting of the failures associated with reprocessed devices."

AMDR is troubled by this assertion. AMDR notes that, in fact, OEMs are *required* to advise FDA of such an event. Specifically, although FDA's regulations state that when a "manufacturer or importer determines that the device was manufactured or imported by another manufacturer or importer," it is not required to file an adverse event report, the regulations *go on* to state that "any reportable event information that is erroneously sent to a manufacturer . . . shall be forwarded to FDA, with a cover letter explaining that the device in question was not manufactured . . . by that firm."[7] FDA's policy, as confirmed in a recent conversation with the Reporting Systems Monitoring Branch, is that when the agency receives such information, it will contact the actual manufacturer (unless it is unable to determine who the manufacturer is) and direct the entity to comply with its reporting obligations under the MDR regulation.

If it is true that there have been "serious injury events" with reprocessed devices of which AdvaMed or its members are aware, we strongly urge them both to comply with their regulatory responsibility to advise FDA of such information and to report the information to the reprocessor or, at the very least, to direct the hospital that has provided the information to report the event to the reprocessor. Patient safety is of paramount concern to AMDR's member companies, and

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agency states, "in this situation [where an SUD reprocessed by a third-party reprocessor is involved in a reportable event], the manufacturer of the reprocessed SUD is the third party reprocessor and not the OEM who originally manufactured the SUD."

5 http://www.fda.gov/cdrh/reuse/.

6 *Supra* footnote 4.

7 21 C.F.R. § 803.22(b)(2).

AMDR's members are intensely interested in learning of any problems that customers experience with their devices. AdvaMed and its members have repeatedly expressed the "concern" that adverse events associated with reprocessed devices are underreported. Thus, we fail to understand why, regardless of whether the regulations *require* it, an OEM receiving such a report would opt *not* to provide the information either to the reprocessor or to FDA, nor to direct the user facility to report the incident to the reprocessor. Nothing in the regulations prohibits an OEM from taking one of these steps and, in fact, the OEMs have every incentive to take one or more steps to ensure that the event is reported to FDA as an adverse event associated with a reprocessed device. Indeed, in the interest of patient safety, we urge any OEM who becomes aware of an adverse event associated with a reprocessed single-use device to report the event to the reprocessor and/or to FDA.

Finally, AMDR notes that, the issue of reprocessing aside, underreporting of device-related adverse events by user facilities is a widely-recognized problem. In 1997, the U.S. General Accounting Office (now the Government Accountability Office) reported that, since the 1990 enactment of the Safe Medical Devices Act, which first required user facility reporting, "FDA has received significantly fewer adverse event reports from user facilities than it expected. Moreover, much of the information that user facilities did provide was of poor quality and incomplete, in part because FDA did not . . . periodically educate user facilities about their responsibilities . . ."[8] AMDR would, therefore, fully support additional efforts by the agency to encourage user facilities to report all reportable device-related adverse events.

Respectfully submitted,

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cc: Dr. Daniel Schultz
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[8] GAO, "Medical Device Reporting: Improvements Needed in FDA's System for Monitoring Problems With Approved Devices" (1997) at 3.