

AMDR TAKES ISSUE WITH FDA OVER DEVICE REUSE PROMOTIONAL STATEMENTS

The Association for Medical Device Reprocessors (AMDR) is taking issue with a recent FDA letter it received, asking the group to stop making claims about the safety and effectiveness of reprocessed single-use devices and saying that certain statements AMDR made were false and misleading. AMDR says its characterization of the status of reprocessed single-use devices has always been appropriately characterized, and cites passages from previous FDA correspondence to support its argument.

In the FDA letter, reprinted below, FDA says that an AMDR letter misleads readers by implying that reprocessors' use of the Quality Systems Regulation (QSR) assures safety and effectiveness. "The safety and effectiveness of a device is not determined through a Quality Systems inspection." But, FDA says, adherence to QSR offers a level of assurance that the firm has controls in place to make a product that meets established specifications.

AMDR argues that FDA's response to a device trade group's petition last year shows that FDA believes the regulation provides reasonable assurance that QSR ensures that the firm is following standards to guarantee a device's safety and performance. It is unclear whether AMDR has decided to stop using the claims.

FDA Letter to AMDR on Reprocessed Device Promotion

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Dear Mr. Terman:

This letter is written to express concern regarding false and/or misleading statements attributed to representatives of the Association of Medical Device Reprocessors (AMDR) with respect to the safety of reprocessing medical devices labeled as "single use only." As you serve in the capacity of legal counsel for AMDR, I urge you to ensure that AMDR representatives and its affiliate members and representatives immediately cease making such unfounded representations. This letter follows telephone conversations I recently had with you and Ms. Pamela Furman, Executive Director of AMDR, regarding this matter. Specific examples of false and/or misleading statements follow.

The December 1998 OR Manager Vol. 14, No. 12, referenced FDA's October 19, 1998 letter, signed by me, to you with the headline, "Third party reprocessing is lawful, FDA says." In the OR Manager article, AMDR "called the letter(s) a victory," referring to FDA's response to the 1997 HIMA Citizen Petition and the October 19, 1998 letter, and were quoted as saying [the letters], "confirmed the safety and regulatory soundness of medical device reprocessing." The statement regarding safety is false in that the FDA letters addressed the regulatory status and legality of reprocessing. Neither letter stated that FDA has determined that reprocessing is safe; whereas, the AMDR statement of "regulatory soundness" is misleading in that it implies that third party reprocessing in general is somewhat actively regulated and that there are no significant regulatory problems in the industry. The reality is that relatively few inspections have been conducted of third party reprocessors (approximately half of the known reprocessors have been inspected) while several Warning Letters have been issued. Also, in the November 1998 issue of Materials Management in Health Care, the headline reads, "Reprocessing is OK, says FDA" referring to the October 19, 1998, letter.

Likewise, in a March 1, 1999, letter from Pamela Furman to James McGee, M.D., Chairman and Medical Director of Radiation Oncology of the St. Francis Medical Center, Peoria, Illinois, Ms. Furman made at least two statements that are false or misleading with respect to the safety of reprocessing. That letter was written as the AMDR response to Written and Oral Testimony taken at the December 10, 1998, Illinois State Board of Health Board Meeting and Public Hearing regarding the reprocessing of devices la-

beled for single use. The most glaring false statement was made on page 6 of that letter and is as follows, "Significantly, FDA's stated position regarding the safety of third-party reprocessing is that, when done properly, third-party reprocessing is safe." The letter goes on to say that this FDA policy was included in the FDA letter denying the HIMA Citizen Petition. However, the letter to HIMA states that, "FDA notes the general absence of evidence of adverse patient outcomes attributed to the reuse of single-use devices." This is in no way a statement that FDA considers reprocessing safe. On the contrary, FDA has not reviewed sufficient data to make a determination regarding the safety of the practice. On page 19 of Ms. Furman's letter, she makes a statement, "In order to comply with the QSR, a third party reprocessor must establish and maintain systems to ensure that its reprocessed devices are safe and effective and in full compliance with applicable FDA law and regulations." This implies devices reprocessed by third party reprocessors are, in fact, safe and effective if the firm complies with the QSR (Quality System Regulation). This is misleading. The safety and effectiveness of a device is not determined through a Quality System inspection. Rather, adherence to that regulation provides some level of assurance that the firm has sufficient controls to consistently produce a product that meets established specifications.

After careful evaluation of the issues raised by AMDR's actions and their misuse of my October 19, 1998, letter, I have, in conjunction with the Office of Chief Counsel, re-examined the letter and decided to rescind it. The statement, "Third-party reprocessing of devices labeled for single use is lawful in the United States provided that the reprocessing firm complies fully with all regulatory requirements currently imposed on them," is an error. In the revised letter, I am hereby rescinding that statement and replacing it with, "Third-party reprocessing of devices labeled for single use is unlawful unless those engaged in this practice comply with all regulatory requirements for manufacturers, including premarket notification requirements. However, FDA has exercised and will continue to exercise regulatory discretion for all premarket notification requirements, until a new FDA reprocessing position is adopted." Please destroy all copies of the October 19, 1998, letter and cease the distribution of and reference to that letter.

If you have any questions regarding the issues raised in this letter, I can be reached at 301-594-4646.

Sincerely yours,

Larry Spears
Director, Division of Enforcement III, Office of Compliance
Center for Devices and Radiological Health