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Reprocessing Single-Use Medical Devices: The State of the Debate

by Mark Herrmann and Brian Ray

“In one instance, an electrode from a catheter broke off in a patient’s heart. In another, a patient’s eyeball was impaled.”¹ Through a series of articles highlighting injuries like these allegedly caused by the reuse of medical devices labeled for single-use, *The Washington Post* has re-ignited the debate over the safety of the practice known as “reprocessing.”

Responding to congressional concerns raised by these articles, the General Accountability Office (GAO) recently announced that it will investigate the safety of reprocessed single-use devices (SUDs) and the Food and Drug Administration’s (FDA’s) oversight of reprocessors. FDA has responded that the agency strictly enforces existing regulations of the reprocessing industry and that reprocessing is a widespread, legal practice that greatly reduces hospital and healthcare facility costs.² Reprocessing companies, hospitals, and other healthcare facilities agree and accuse medical device manufacturers of raising unfounded safety concerns in the interest of driving up profits. At least one thing is clear: reprocessing is a growing but controversial industry subject to an increasingly complex and fast-developing set of regulations and a wide range of unresolved legal issues.

Background

This is not the first time GAO has looked at the safety of reprocessed SUDs. In 2000, GAO issued a report titled “Single-Use Medical Devices: Little Available Evidence of Harm From Reuse, but Oversight Warranted.”³ As described by GAO, the core of the problem was that medical device manufacturers seek approval to market a device labeled for a single use, and the FDA cannot require those manufacturers

to test whether those devices can be reused safely.⁴ The single-use designation thus meant only that the device *could* safely be used *once*; the designation was not an affirmative determination that *reuse* was *unsafe*. As a result, the GAO report found that hospitals “distrust the single-use label for some devices because (1) FDA cannot require manufacturers to support the designation of a device as single-use, [and] (2) they perceive that manufacturers have an economic incentive to market devices as single-use that could just as well be sold as reusable ...”⁵

GAO concluded that, while SUD reprocessing poses some theoretical risks, at least some SUDs can be reprocessed safely.⁶ At the same time, GAO found that there was insufficient information to properly assess the safety concerns raised by reprocessing and recommended that FDA implement its proposed plan to regulate reprocessors more closely and to gather better safety data on the use of reprocessed SUDs.⁷

Not content to leave FDA on its own, in 2002 Congress passed the Medical Device User Fee and Modernization Act (MDUFMA),⁸ which amended the Federal Food, Drug, and Cosmetic Act, among other things, to create specific requirements for reprocessed SUDs. First, section 302 of MDUFMA required FDA to develop a list of reprocessed



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devices that would be subject to enhanced clearance requirements to ensure that they remain substantially equivalent to the original device after a specified number of uses. This was a significant new requirement for reprocessed products.

Second, for reprocessed low and moderate risk (i.e., Class I and II) devices, section 302 required FDA to review within a set time the existing exemptions from premarket clearance requirements to determine which devices should be subject to enhanced requirements. Third, for high-risk (i.e., Class III) devices, section 302 requires reprocessors to submit premarket approval applications that are identical in scope to those submitted by the original device manufacturers and to provide validation data on the maximum number of times a device can safely be reprocessed.

MDUFMA made two other changes related to reprocessed SUDs. First, section 303 of MDUFMA modified the MedWatch forms that are used to report patient injuries to provide more information related to reprocessing. Second, section 301 of MDUFMA requires reprocessors to attach a label to all devices that “prominently and conspicuously” identifies the reprocessor and states that the device is reprocessed.

Since MDUFMA’s enactment, FDA has issued a series of regulations and guidance documents implementing MDUFMA’s requirements for reprocessed SUDs. The most recent guidance, issued June 1, 2004, explains in detail MDUFMA’s requirements, outlines a process for reprocessors to submit validation data to FDA, and makes specific recommendations for reprocessing procedures.⁹ FDA also has developed a list of Frequently Asked Questions about reprocessed SUDs that addresses issues ranging from where to obtain information about third-party reprocessors to the requirements for hospital compliance with MDUFMA for in-house reprocessing.¹⁰

The Debate Continues

Despite the substantial increase in oversight produced by MDUFMA and FDA’s implementation measures, *The Washington Post* series demonstrates that the debate over the safety of reprocessed SUDs continues unabated. The lines of the debate are fairly clear. On one side, medical device manufacturers assert that it is difficult, if not impossible, to guarantee the safety of reprocessed SUDs because the devices were designed and originally tested only for one-time use. The manufacturers disclaim any responsibility, therefore, for the malfunction of a reprocessed SUD.

Medical device manufacturers also cite surveys demonstrating that patients generally expect to be informed if a reprocessed device is going to be used in a procedure and note the lack of uniform standards among hospitals for obtaining patient consent to using reprocessed devices.¹¹ As a result, device manufacturers claim, use of reprocessed SUDs may increase the risk of liability for hospitals and physicians.

On the other side, reprocessors and hospitals, many of which do their own reprocessing for certain devices, point to long track records and clinical studies supporting the safety of reprocessed devices. Supporters of the practice also emphasize that FDA began regulating reprocessed SUDs well before MDUFMA and that reprocessed devices are now subject to the same requirements and meet the same standards as new medical devices. Citing the tremendous cost savings that result from reprocessing, supporters argue that original device manufacturers are motivated more by profit than safety concerns.¹²

Reprocessors also assert that the rigorous approval measures now required by FDA for reprocessed SUDs render the informed consent issue moot. According to reprocessors, FDA approval for most reprocessed SUDs now requires evidence that the device is the substantial equivalent of a new device; consent is not required to use a new device and, therefore, should not be required to use the substantial equivalent of a new device.

The relative merit of these competing arguments is clouded by the economic interests that motivate each side. The 2000 GAO report found that reprocessed devices not only present a lower cost option for hospitals, but also that the very existence of reprocessed alternatives often decreases the prices for new devices.¹³ By the same token, reprocessors are motivated to minimize costly compliance measures and make reprocessing legal for the broadest range of devices. Hospitals and other healthcare facilities have a similar interest in protecting the cost savings provided by reprocessing.

Further confounding the debate is the lack of reliable data on the safety of reprocessed SUDs. The MDUFMA-mandated revisions to MedWatch forms have been implemented only since February 2004 so little data is yet available to analyze the role of reprocessed SUDs in patient injuries. This dearth of information makes it difficult to assess objectively the safety-related claims central to the reprocessing debate. As a result, the debate has continued to center largely on anecdotal evidence and assessments that predate the new regulations.

Sweeping Changes Unlikely but Risks Remain

Despite the active debate over reprocessed SUDs, it appears likely that the practice is here to stay. Yet, significant questions about the safety and legal risks of reprocessing remain unanswered. GAO has not released any information regarding the precise questions it intends to address in its new investigation of the reprocessing industry. Given FDA's sustained focus on the issue and the lack of any significant new data on the safety of reprocessed SUDs since GAO's 2000 report, it seems unlikely that the investigation will result in recommendations for sweeping changes to the current regulations. Regulatory change is more likely to occur on an incremental basis and to be driven by the results of FDA's new effort to collect more accurate data on injuries caused by reprocessing.

While increased regulation may help clarify the safety status and legal risks posed by reprocessed SUDs, the present reality is that all of the players in the reprocessing industry—physicians, hospitals, reprocessors, and manufacturers—are operating in a quickly changing and uncertain environment. The uncertainty that surrounds the reprocessing of SUDs poses real compliance and litigation risks, and requires close attention to regulatory and legal developments. ▲

The views expressed in this article are those of the authors and not necessarily of their clients or firm.

- ¹ Alec Klein, *Hospitals Save Money, but Safety Is Questioned*, WASH. POST, Dec. 11, 2005, at A1.
- ² Alec Klein, *GAO to Probe Reprocessing of Single-Use Medical Devices*, WASH. POST, Jan. 10, 2006, at A2.
- ³ GAO, *SINGLE-USE MEDICAL DEVICES: LITTLE AVAILABLE EVIDENCE OF HARM FROM REUSE, BUT OVERSIGHT WARRANTED* (GAO/HEHS-00-123) (2000), available at <http://www.p2pays.org/ref/10/09819.pdf>.
- ⁴ *Id.* at 7.
- ⁵ *Id.* at 11.
- ⁶ *Id.* at 4-5.
- ⁷ *Id.* at 5.
- ⁸ Pub. L. No. 107-250, 116 Stat. 1588 (2002).
- ⁹ FDA, *Guidance for Industry and FDA Staff, Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices* (June 1, 2004), available at <http://www.fda.gov/cdrh/ode/guidance/1216.html>.
- ¹⁰ FDA, *Reuse of Single-Use Devices, Frequently Asked Questions*, <http://www.fda.gov/cdrh/reuse/reuse-faq.html> (last visited Feb. 28, 2006).
- ¹¹ See, e.g., Kelly M. Pyrek, *Reprocessing of Medical Devices: Government Intensifies Scrutiny as Clinicians Debate Patient-Safety Issues*, ICT, Mar. 2006, available at <http://www.infectioncontroltoday.com/articles/321inside.html> (last visited Mar. 17, 2006).
- ¹² See, e.g., Pamela J. Furman, *The Reprocessing of Medical Devices Labeled for "Single Use" in the US—An Historical Overview*, MED. DEVICE MFG. & TECH. 2 (2002).
- ¹³ GAO REPORT, *supra* note 3, at 19.