

**Testimony of Daniel J. Vukelich, Esq,
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before the
Joint Public Health Committee
of the
Massachusetts Legislature
on the
Reprocessing of Medical Devices (SB 1338/HB 2233)**

September 26, 2007

Mr. Chairman, members of the Committee:

Good morning. My name is Dan Vukelich and I am the Executive Director of the Association of Medical Device Reprocessors, or AMDR. AMDR represents the third-party medical device reprocessing industry, which serves the majority of hospitals in the U.S. and in Massachusetts. Reprocessing plays a crucial role in helping hospitals control spiraling health care costs, reduce regulated medical waste, and preserve financial resources that are better spent on hiring more nurses, buying new medical technology, or providing indigent care.

Today I'd like to briefly provide you with a description of the U.S. Food and Drug Administration's stringent regulations for device reprocessors, including a discussion of the "single use" label. And in the limited time we have, I'll briefly address what the legislation proposes, and how that would needlessly drive up the cost of health care, and increase medical waste, in Massachusetts.

Reprocessing is Stringently Regulated by FDA

Reprocessors of medical devices labeled for “single use” are stringently regulated by the U.S. Food and Drug Administration (FDA). In fact, pursuant to federal legislation enacted in 2002, reprocessors are now more stringently regulated than even original equipment manufacturers (OEMs). Medical device reprocessors are treated by FDA as device manufacturers, and reprocessors not only must meet all the same requirements as the OEMs, but also must provide additional data to FDA that ensures reprocessed devices are clean, functional and sterile. In testimony before Congress in September, 2006, FDA stated, and I quote, “reprocessed [single use devices] that meet FDA’s regulatory requirements are as safe and as effective as a new device.”¹

In the past ten years of regulated third-party reprocessing, and after reprocessing over 50 million devices, there have been no deaths caused by a failed reprocessed device and no lawsuits filed against device reprocessors for failed product or injury to patient. This safety record is stellar. Indeed, FDA’s own data of adverse events associated with all medical devices shows fewer absolute errors associated with reprocessed devices, than with original devices. The safety record of reprocessing is well-documented and overwhelmingly supported by the clinical community.

¹ Emphasis added. See Testimony of Dr. Daniel Schultz, Director, Center for Devices and Radiological Health, Food and Drug Administration, September 26, 2006.

The “Single Use” Label

I’d like to briefly address the meaning of the “single use” label because I think this is the source of most of the misinformation about reprocessing. The single use label is not an FDA requirement. Rather, it is a designation that is chosen by the manufacturer, and that choice frequently represents a business strategy to sell more devices -- not to enhance patient safety. The best evidence of just how meaningless the “single use” label can be is that some OEMs offer hospitals reprocessing programs on their own “single use” devices, and, in fact, some OEMs partner with AMDR companies to do the reprocessing—reprocessing devices that the OEM has labeled as “single use.”

I’ve had the opportunity to meet with many of you on this committee in the last several weeks. I have shown you some of the devices these manufacturers label for “single use.” They include titanium clamps, stainless steel surgical blades, and even tourniquet cuffs. It becomes obvious just looking at these devices that they do not belong in a landfill after just one use when current technology allows them to be safely reused.

Legislative Analysis

The provisions of the legislation being considered are designed to burden reprocessing to such an extent that hospitals will be forced to limit or cease their use of reprocessed devices. SB 1338 and HB 2233 would do three things. First, it would require health care providers and reprocessors to report to the Department of Health adverse events associated with reprocessed devices. This provision is redundant of current federal requirements and would add to the paperwork burdens of health care providers without providing a corresponding benefit to patients. Further, AMDR believes that such a provision would be pre-empted by federal law.

Second, the legislation would require health care providers to obtain “informed consent” before using a reprocessed device. The purpose of informed consent is to advise patients when a procedure involves an increased risk. However, reprocessed devices are as safe and effective as original equipment and are, in fact, more stringently regulated. They are not experimental or investigational products. Therefore, there is no legal or ethical basis for imposing an informed consent requirement on reprocessed devices, but not on original devices.

Finally, the proposed legislation would immunize original device manufacturers from all liability associated with their devices if the device happens to be reprocessed, even from liability attributable to problems caused by the manufacturer’s own acts or omissions. This is contrary to well-settled principles of tort law. Indeed, the subsequent alteration of a product has never, by itself, absolved the original

manufacturer of liability for injuries caused by its own actions– even if the original manufacturer clearly cautions against such alteration.

Conclusion

U.S. health care facilities derive significant cost savings from reprocessed devices – on average a 50% cost savings as compared to purchasing a new device, and these savings help pay for important patient care improvements, like adding more nursing jobs, investing in new medical technology, or providing indigent care. In addition, reprocessing has significant environmental benefits. Reprocessors were responsible for diverting over 27 tons of medical waste from landfills in Massachusetts alone last year.

Thank you for the opportunity to speak with you about this important topic. *[I urge this committee to limit its evaluation of the proposed bill to the facts and science, not scare tactics, or unsubstantiated allegation.] I extend an invitation to you to visit one of our reprocessing facilities. Thank you. I would be happy to answer any questions.*

* * *

For use if the dirty picture show is given:

Facts and Science Versus Scare Tactic and Innuendo

Let me now briefly address the pictures you see here. First, let me ask you, would the finest hospitals in the country put their patients at risk to save money? The photos you see here are the same photos that have been shown around the country for nearly a decade in an effort to scare hospitals from reprocessing. The study was initiated and paid for by one of the OEMs - a company which has been very active in promoting anti reprocessing legislation in MA and other states. In that time period, AMDR reprocessors have reprocessed over 50 million devices with no increased risk to patients. After investigation, we found that devices in these pictures were not even reprocessed by third-party reprocessors, but were reprocessed inside a hospital located overseas – something never mentioned when these photos are displayed. The bottom line is this dirty picture show lack credibility. It is put forth by an industry with a tremendous economic incentive to cast reprocessing in a negative light.