JOURNAL of MEDICAL DEVICE REGULATION

May 2011 SPECIAL REPRINT

LETTER TO THE EDITOR Setting the Record Straight: The Debate over Reprocessing Should Focus on Facts and Science, Not Scare Tactics and Innuendo

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LETTER TO THE EDITOR

Setting the Record Straight: The Debate over Reprocessing Should Focus on Facts and Science, Not Scare Tactics and Innuendo

Hospitals and stressed government budget officials are clamouring for safe and effective ways to lower healthcare costs and to reduce responsibly unnecessary environmental waste in one of the largest polluting industries[1-3]. The third-party reprocessing industry has a long, documented history of providing safe, effective, lower-cost and environmentally-friendly medical devices to hospitals - contrary to the picture painted by Peter Schroeer of Eucomed's Reuse Task Force (and of Johnson & Johnson) in his February 2011 article entitled *Reprocessing Single-Use Medical Devices: A Risky Business*[4].

The Association of Medical Device Reprocessors (AMDR), the trade association representing third-party reprocessors in the USA, believes that Mr Schroeer, in an effort to cast doubt over reprocessing in Europe, conveniently disregarded numerous facts. It is imperative that people examine all of the facts and scientific evidence, so that readers and policymakers recognise the unsubstantiated claims, scare tactics or innuendo being advanced by companies with an economic and environmental agenda that differs from current reprocessing customers.

That said, the AMDR agrees with Mr Schroeer and Eucomed that 'Europe needs to prioritise patient-safety unambiguously'. We agree that European patients deserve to know that reprocessed medical devices are just as safe and as effective as original equipment. In fact, the AMDR urges international legal and regulatory bodies, including the European Union, to consider implementing legislative and regulatory requirements to ensure that all reprocessed devices are safe and effective for patients.

As the name of this Journal implies, regulation is key. Reasonable regulation of reprocessing is necessary to ensure that reprocessing is safe and effective. In determining specifically what regulations are necessary, it is of critical importance that clinicians, legislators and regulators have access to scientifically sound, truthful and complete information when making healthcare decisions for patients. Listed below are some facts that the AMDR believes Mr Schroeer should have considered:

The 'single use' label is a designation chosen by the medical device manufacturer, not by the US Food and Drug Administration (FDA) or European regulatory entities.

In fact, over time, some manufacturers simply shifted the labels on certain devices from 'reusable' to 'single use'[5,6], or provided cleaning instructions to hospitals so they could reuse single-use devices (SUDs)[7], and some have even marketed 'remanufactured' or 'recycled' SUDs to hospitals[8,9] - all behaviour that has eroded the credibility of the 'single use' label. According to a report by the US Government Accountability Office (GAO), an independent investigative arm of the US Congress:

> 'The decision to label a device as single-use or reusable rests with the manufacturer. If a manufacturer intends to label a device as reusable, it must provide data demonstrating to FDA's satisfaction that the device can be cleaned and sterilized without impairing its function. Thus, a device may be labeled as single-use because the manufacturer believes that it cannot be safely and reliably used more than once, or because the manufacturer chooses not to conduct the studies needed to demonstrate that the device can be labeled as reusable'[10].

As in the USA, in Europe, the decision to market a device as reusable or single use is the manufacturer's responsibility, not regulators. Mr Schroeer argues that so-called 'single use' devices are designed that way because 'an

appropriate method to clean and reuse the devices has not been established'; however, he is only partially correct. While some original equipment manufacturers (OEMs) choose not to establish adequate cleaning protocols for their products, this does not necessarily mean appropriate cleaning and sterilisation methods have not been established by another responsible entity. In many cases, it simply means that the OEM chose not to undertake such validations[11]. As the American Academy of Orthopaedic Surgeons has noted, 'it is obviously in the best financial interest of the manufacturer to label every device for single use in order to sell more units of devices'[12].

While mischaracterised in Mr Schroeer's article, in the USA, the FDA regulates the reprocessing of SUDs and has determined that 'reprocessed SUDs that meet FDA's regulatory requirements are as safe and effective as a new device'[13].

As Europe embarks on a discussion on how to regulate the reprocessing of SUDs, there is no reason to ignore the experiences of other countries, including the USA and Germany, where reprocessing has been regulated successfully and has resulted in no evidence of increased risk to patients[14].

Mr Schroeer's discussion of the reports by the European Commission and the Scientific Committee on Emerging and Newly Identified Health Risks was incomplete and misleading. While highlighting the public health, ethical and liability concerns raised in the studies, he noted, though briefly (as the reports did) that the number of documented incidents [of harm] is 'very small'. However, Mr Schroeer neglected to highlight that the Commission's work also found that 'in the existing inventory in the US, no evidence of an increased risk was noted for patients from reprocessed devices', and this is likely due to the regulations the FDA has in place for reprocessors[15].

In the USA, where all reprocessors are held to the same high standard, there has been no evidence of harm to patients[10]. In fact, like all devices in the USA, a reprocessed device is subject to pre-market review by the FDA, unless the Agency has, by regulation, declared the device to be exempt from pre-market requirements[16]. Indeed, reprocessors are subject to more stringent regulation by the FDA than OEMs[17] because, pursuant to provisions added in 2002 by the *Medical Device User Fee and Modernization Act* (MDUFMA), the FDA has withdrawn the exemptions from the pre-market notification requirement for a significant number of previously exempt reprocessed devices, even though the 'original' devices remain exempt from pre-market review[18-19].

Further, reprocessors must, in many cases, include in their pre-market submissions a whole category of data that OEMs are not required to submit[17,20]. Specifically, reprocessors are, in many cases, required to include 'validation data…regarding cleaning and sterilization, and functional performance' to show that the reprocessed device 'will remain substantially equivalent…after the maximum number of times the device is reprocessed as intended'[20], thus demonstrating that reprocessing produces devices that are equivalent to 'original' devices. In short, the 'FDA believes that reprocessed SUDs that meet FDA's regulatory requirements are as safe and effective as a new device'[13].

In the USA where SUD reprocessing is federally regulated, independent sources have also noted the absence of any evidence, from any source, indicating an increased risk to patient safety from the reprocessing of SUDs.

The FDA and GAO independently concluded 'no causative link between reported injuries or deaths and reprocessed SUDs'[10]; '[n]one of the experts…cited the use of reprocessed single-use devices as a factor contributing to [hospital acquired infections]'[21]; and 'studies have shown both that reprocessed procedures can be safely accomplished and that patient outcomes are not adversely affected by the use of SUDs'[6].

In addition to the wide body of independent, peer-reviewed literature, clinical groups have long supported FDA-regulated reprocessing of select SUDs. These groups include the American Academy of Orthopaedic Surgeons, the American College of Cardiology, the American Hospital Association, the American Medical Association, the Association for peri-

Operative Registered Nurses, the Association for Professionals in Infection Control and Epidemiology, Heart Rhythm, and the nation's leading medical centres such as Johns Hopkins, the Cleveland Clinic and the Mayo Clinic[22].

Mr Schroeer went out of his way to ignore nearly all of the evidence and wide-ranging support for regulated reprocessing, in order to disparage all reprocessing of so-called SUDs. In his characterisation of reprocessing as a 'shortcut' whose benefits are unproven, Mr Schroeer, for example, completely ignored the fact that, according to the most recent US *News & World Report* ranking of America's best hospitals, AMDR's members serve all the 'honor roll' hospitals, or the top 14 institutions in the USA. While Mr Schroeer attempts to cast doubt on reprocessing, a majority of US hospitals have employed the practice to reduce costs and waste while still delivering top level healthcare.

Third-party reprocessors consistently deliver reprocessed SUDs at prices 40-60% less than the cost of buying new devices, including what Mr Schroeer defines as 'hidden costs'.

Healthcare providers support the practice of reprocessing in large part because of the cost savings. Reprocessed devices are as safe and effective as original devices but cost much less - typically about half of the cost of an original device[6]. In 2000, the GAO found that facilities using reprocessed devices saved, on average, between US$200,000 and US$1 million annually[6]. The savings enable hospitals to hire additional nurses, upgrade technology, treat indigent persons, and make other patient care improvements.

Regulated third parties, like AMDR's members, are able to employ much more sophisticated cleaning and sterilisation techniques than hospitals and, thus, can achieve better, consistent results - albeit for a more limited set of medical devices. Third-party reprocessors, however, as verified by independent parties like the GAO, have consistently provided savings of 40-60% of the price of buying a new device. The 40-60% of cost savings include all the third-party 'hidden' costs (i.e. research and development, equipment and materials, staff, and the cost of recycling SUDs when they have reached the end of their life, among many other operational costs).

Hospital use of reprocessed medical devices does NOT violate ethical standards, nor does it necessitate patient informed consent.

In its report[15], the European Commission raised ethical and liability concerns that have not yet been addressed by most health authorities in Europe because reprocessing is not regulated. However, these concerns were addressed in 2000 - the same year reprocessors became fully regulated in the USA - when improvements to specific labelling, marking, quality systems, and pre-market requirements were put in place to ensure that reprocessed devices are safe, effective and readily identifiable. In the USA, reprocessed devices are legally marketable devices subject to all FDA device manufacturer requirements, including pre-market clearance and approval requirements[23]. The FDA does not require a physician to obtain informed consent when a device that has been cleared or approved by the Agency will be used during a procedure[24], nor is it standard medical practice to obtain informed consent to use legally marketed medical devices. Reprocessed devices comply with FDA requirements and are as safe and effective as original devices[13]. Therefore, there is no legal, medical or ethical basis for requiring informed consent for reprocessed devices but not for original devices.

Patient safety should never be compromised in an effort to save money; but if done right, Europe is poised to establish a system that will promote the highest quality healthcare while simultaneously mitigating, to some degree, the economic concerns facing hospitals. A recent report by Tessarolo, *et al* includes an excerpt that poignantly addresses this ongoing ethical dilemma:

> 'In an era of enormous restriction of resources in the healthcare system, the incentive to save money is a legitimate claim. From an ethical perspective, any wastefulness is unjustifiable in a healthcare system where a patient may be denied a service because of a lack of resources. As

such, reuse may not be unethical so long as it is established that the quality of care is maintained and there is no significant loss of device effectiveness and no unreasonable increased risk of harm to the patients'[25].

Conclusion

These facts are inconvenient for those who stand to gain economically at the expense of their customers by preventing the further adoption of third-party reprocessing in Europe. However, the AMDR is confident that, after evaluating all the facts and evidence, the European Community studying the reprocessing of SUDs will conclude that the practice - when appropriately regulated - is safe and effective, lowers healthcare costs and assures that patients receive the care they need.

References

1. Gifty Kwakye, MD, MPH; Gabriel A Brat, MD, MPH; Martin A Makary, MD, MPH: *Green Surgical Practices for Health Care*. *Archives of Surgery*, 2011, **146**(2), 131-136, which states, 'health care is the second leading contributor to waste in the United States'.
2. Gifty Kwakye MPH; Peter J Pronovost MD, PhD; Martin A Makary MD, MPH: *A Call to Go Green in Healthcare by Reprocessing Medical Equipment*. *Academic Medicine*, 2010, **85**(3), 398-400, stating, 'it is estimated that American health care facilities continue to dispose of over four billion pounds of waste annually in landfills and commercial incinerators, making the health industry the second largest contributor to landfills after the food industry'.
3. J Diconsiglio: *Reprocessing SUDs Reduces Waste, Costs*. *Materials Management in Healthcare*, 2008, **17**, 40-42.
4. *Journal of Medical Device Regulation*, 2011, **8**(1), 8-12 (February 2011).
5. For example, Marketing letter from Brian Dowling, Product Manager, USCI Cardiology & Radiology Products to hospital customers (24 July 1980) explaining that, although USCI was changing the label on its intracardiac electrodes from 'reusable' to 'single use', its 'manufacturing processes…have not changed. These electrodes are made with the same materials and in the same manner as they have been in the past'.
6. *Single-Use Medical Devices: Little Available Evidence of Harm From Reuse, but Oversight Warranted*, GAO/HEHS-00-123, US Government Accountability Office, June 2000.
7. For example, Marketing letter from Geoffrey M Allen, Boston Scientific Corporation, Microvasive Division to hospital customers (1 May 1987), informing a hospital that its 'BICAP® Hemostatic Probes are recommended for single use only. However, this recommendation does not prohibit reuse under certain specific conditions'.
8. For example, *OEM Moves into Reprocessing*, *Medical Design Technology*, 1 March 2006. Orthopaedic device manufacturer Synthes offered/offers hospitals the option to purchase previously-used external fixation components as part of its own reprocessing programme. 'The U.S. division of this Swiss firm is reprocessing over a dozen of its fixation devices, including single use devices such as its 'combination clamp' and 'tube to tube clamps'.' *See also*, Synthes External Fixation Reprocessing Program Corporate Marketing Material (2004). *See also*, 510(k) K033158, Synthes, USA: Reprocessed External Fixation Devices, cleared by the US FDA on 5 November 2003.
9. Daniel S Horwitz MD; Kathryn LS Schabel, MD; Thomas F Higgins, MD: *The Economic Impact of Reprocessing External Fixation Components*. *The Journal of Bone and Joint Surgery*, 2007, **89**, 2132-2136, stating that 'Stryker Orthopaedics applied for, and was granted, United States Food and Drug Administration (FDA) 510(k) approval of this recertification process'.
10. *Reprocessed Single-Use Medical Devices: FDA Oversight Has Increased, and Available Information Does Not Indicate That Use Presents an Elevated Health Risk*, GAO-08-147, US Government Accountability Office, January 2008.
11. 2000 GAO Report which found that, 'in effect, because FDA can only evaluate a device relative to the use intended for it by its manufacturer, *its approval of a device as single-use means that a device can be used safely and reliably once, not necessarily that it cannot be used safely and reliably more than once if it is appropriately reprocessed*' [emphasis added].
12. Letter from William W Tipton Jr, MD, Executive Vice President, American Academy of Orthopaedic Surgeons/American Association of Orthopaedic Surgeons, to Bernard Schwetz, DVM, PhD, Acting Principal Deputy Commissioner, Food and Drug Administration, 30 August 2001.
13. Testimony of Dr Daniel Schultz, Director, Center for Devices and Radiological Health, US FDA, before the US House Committee on Government Reform, 26 September 2006. For a more detailed discussion of the FDA's requirements for medical device reprocessors, the 'single use' label, and the safety record of reprocessed devices, *see* AMDR's *Best Clinical Practice* background paper (www.amdr.org.php5-15.websitetestlink.com/wp-content/uploads/2009/12/bp_bkgrnd_doc_rev.pdf).

14. 2008 GAO Report, which, among other things, concluded, 'After reviewing the available evidence - including FDA's process for identifying and investigating device-related adverse events reported to involve reprocessed SUDs, peer-reviewed studies published since 2000, and the results of our and FDA's consultations with hospital representatives - *we found no reason to question FDA's analysis indicating that no causative link has been established between reported injuries or deaths and reprocessed SUDs*. That is, the available information regarding safety, while not providing a rigorous safety comparison between reprocessed SUDs and other devices, does not indicate that reprocessed SUDs currently in use pose an increased safety threat' [emphasis added].
15. *Report from the Commission to the European Parliament and the Council; Report on the issue of the reprocessing of medical devices in the European Union*, European Commission, 27 August 2010, in accordance with Article 12a of Directive 93/42/EEC, which states, in part, 'in the existing inventory in the United States, no evidence of an increased risk was noted for patients from reprocessed devices. *This apparent lack of an increased risk may be associated in part with the limitations that the United States impose on the reuse of reprocessed medical devices*' [emphasis added]. *See also*, *The Risks are Controllable*, European Hospital, 1 October 2010, where German experts independent of the AMDR were quoted questioning the overall balance of the Commission reports on reprocessing. Professor Axel Kramer, spokesman of the Expert Group for Safety in Medical Devices and Director of the Institute for Hygiene and Environmental Medicine at the University Clinic of Greifswald, noted that 'it is good and important to allude to the risks, however, to be fair one has to say that *professional reprocessing service providers control those risks…that though, the European Commission did not do*' [emphasis added].
16. 21 United States Code (USC) §360(k).
17. Schultz Testimony, stating, '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 the original manufacturers (OEMs)*' [emphasis added].
18. Title III of MDUFMA amended the *Federal Food, Drug & Cosmetic Act* (Public Law 107-250). The law required the FDA to identify 'critical' and 'semi-critical' 510(k)-exempt devices for which the exemptions should be terminated when the devices are reprocessed, 'in order to provide a reasonable assurance of the safety and effectiveness of the devices' (21 USC §360(o)). For devices that lost exemption from the pre-market notification, reprocessors had to submit a 510(k) within 15 months of FDA's publication of a notice terminating the exemption, or the device in question could no longer be legally marketed (21 USC §360(o)(2)(B)).
19. *Federal Register*, 2003, **68**, 38071 (26 June 2003).
20. *Federal Register*, 2003, **68**, 23139 (30 April 2003), citing 21 USC §360(o). For a full description of the validation data reprocessors must submit on a pre-market basis, including more particular guidance on cleaning, functional testing and sterilisation data requirements, see *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 Medical Devices*, 25 September 2006.
21. *Health-Care-Associated Infections in Hospitals*, GAO-08-1091R, US Government Accountability Office, 26 September 2008.
22. *See*, for example, American Academy of Orthopaedic Surgeons, letter to Bernard Schwetz, DVM, PhD, Acting Principal Deputy Commissioner, FDA, 30 August 2001; American College of Cardiology, Position Statement, 2000; Testimony of Dr John Clough, Chair of Health Affairs, Cleveland Clinic Foundation, representing the American Hospital Association (AHA) before the Senate Committee on Health, Education, Labor and Pensions, 27 June 2000 ('[m]any medical products can be safely reused as evidenced through decades of hospital experience in reprocessing both reusable devices and those labeled 'for single use'. The AHA is unaware of any evidence to demonstrate a problem with reprocessing devices labeled 'for single use'.'); American Medical Association, Report 3 of the Council on Scientific Affairs, *Reprocessing of Single Use Medical Devices*, 2000; Association of Peri-Operative Registered Nurses, Position Statement, *Environmental Responsibility*, March 2006; Association for Professionals in Infection Control and Epidemiology, *Reprocessing of Single Use Medical Devices*, Position Statement, 31 August 2007; North American Society for Pacing and Electrophysiology (now Heart Rhythm), Letter to Senator Richard Durbin, 22 June 1999; Dr Stephen Hammill, Director of Electrocardiography and Electrophysiology Laboratories at the Mayo Clinic ('For more than 20 years, the catheters used in electrophysiology procedures have been reprocessed at Mayo and have continued to function normally without any evidence of infection. Reprocessing the catheters has allowed us to use each catheter five or six times, greatly decreasing the cost of the procedures…Reprocessing of the catheters has proven to be a safe and effective technique and has allowed us to gain the most use from the catheters, making them as cost efficient as possible'.); Association for Healthcare Resource and Materials Management, *Reprocessing Advisory* (undated); Hospitals for a Healthy Environment,

Regulated Medical Waste (undated).
23. *Guidance for Industry and for FDA Staff: Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals*, FDA, 14 August 2000.
24. *A Guide to Informed Consent - Information Sheet: Guidance for Institutional Review Boards and Clinical Investigators*, FDA, 1998.
25. Francesco Tessarolo; Iole Caola; Giandomenico Nollo: *Critical Issues in Reprocessing Single-Use Medical Devices for Interventional Cardiology*. *Biomedical Engineering, Trends, Research and Technologies*, edited by Malgorzata Anna Komorowska and Sylwia Olsztynska-Janus, ISBN: 978-953-307-514-3, InTech, January 2011.

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