



## 2008 Annual Report *Reprocessing Industry Update*

### **Federal**

A long-anticipated Government Accountability Office (GAO) report on reprocessed medical devices, released in January, effectively put to rest any lingering Congressional concerns over the safety of reprocessed medical devices. After nearly a decade of federal legislation, hearings and studies focused on the subject, the third-party reprocessing (TPR) industry faced no major federal legislative or regulatory threat in 2008. In a dramatic role-reversal, original equipment manufacturers (OEMs), on the other hand, have been on the defense, the subject of intense Congressional scrutiny fueled by continuing safety and/or regulatory problems with new devices and illegal activity by some OEMs.

### ***Legislative Activities***

In 2008, Congress focused its attention toward further regulation of the device industry. While TPRs are always at risk of being swept up into any device-related legislation, none of the proposals has had an adverse effect on reprocessors. In fact, a number of the proposals may have the potential effect of promoting the use reprocessed devices. We anticipate that most of the issues discussed in 2008 will be reintroduced in 2009, including the *Unique Device Identification Act*, *Drug and Medical Device Company Gift Disclosure Law*, *Drug and Device Accountability Act*, *Physician Payment Sunshine Act*, *Comparative Effectiveness Research Act*, and the *BPA-Free Kids Act*.

Additionally, the Senate has been actively investigating kickback allegations against Medtronic and direct-to-consumer advertising of medical devices. The House, particularly Rep. Waxman, has been critical of FDA's priorities, post-market surveillance efforts, and has sought to overturn the Supreme Court's preemption ruling in *Riegel vs. Medtronic* with the *Medical Device Safety Act of 2008*. At the request of Congress, GAO will also soon release a report on the appropriateness of the 510(k) process in determining substantial equivalence for Class II devices, the conclusions of which are of enormous concern to OEMs and could affect reprocessors. The GAO's conclusions will likely become part of the 2009 legislative agenda.

### ***GAO Reports***

In January, the U.S. Government Accountability Office (GAO) released its long-awaited report on "single-use" device (SUD) reprocessing. The report is perhaps the most thorough and positive independent report on reprocessing to date. Entitled, [\*\*Reprocessed Single-Use Medical Devices: FDA Oversight Has Increased, and Available Information Does Not Indicate That Use Presents an Elevated Health Risk\*\*](#), the report confirmed that reprocessing is safe, stringently regulated, and supported by America's hospitals.

With the release of GAO's report, Congressman Waxman, one of the report's requesters said, "It's time to put the issue of reprocessed devices to rest and to move on to making sure that FDA has the authority and resources it needs to make sure that all medical devices are as safe and effective as they can be."

In another victory for the reprocessing industry, GAO issued a report in September on [\*\*Health-Care-Associated Infections\*\*](#) (HAIs). In legislation from 2007, Congress explicitly instructed GAO to consider reprocessed SUDs as a possible source of HAIs. In the final report, GAO concluded that "none of the experts [GAO] interviewed cited the use of reprocessed single-use devices as a factor contributing to HAIs in hospitals." With these reports, GAO has studied and reported on reprocessed SUDs 3 times since 2000 and has consistently found no increased risk to patients with the use of reprocessed devices.

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## **FDA**

In 2008, Congress instructed FDA to implement a Unique Device Identification (UDI) system for all medical devices. FDA has expressed concern as to how the TPR industry should be treated as FDA implements a UDI program. AMDR has been in touch with FDA's UDI team to share details of the reprocessing industry's existing 100% device tracing system, and to encourage fair implementation of an industry-wide program.

## **State Legislative Activities**

### ***Massachusetts***

In a first for the reprocessing industry, AMDR helped to defeat the OEM-sponsored anti-reprocessing bill in Massachusetts in the spring of 2008. The bill, referred to "study," effectively died in the spring and, unless it is reintroduced by the OEMs in the next session, reprocessing will likely no longer be debated in the Massachusetts State House. Massachusetts also passed a bill giving authority to the Department of Public Health to promulgate a code of conduct based on industry standards, requiring drug and device companies to report to DPH the nature and reason of all gifts to doctors valued above \$50. This has put OEMs on the defensive in Massachusetts and federally, as they seek to undue or minimize these requirements.

### ***Michigan***

In response to inappropriate syringe reuse by a local doctor, two Michigan legislators have introduced bills identical to the OEM-introduced bills in Massachusetts and New Jersey. AMDR staff has met with proponents of these bills and is working to assisting in crafting legislation that will address the objectives of the sponsors to protect patients against inappropriate device reuse.

### ***New Jersey***

Originally, three members of the New Jersey legislature co-sponsored anti-reprocessing bills, but now just one bill remains. Due, in part, to strong support from the state Hospital Association, no formal action has been taken to advance the remaining bill. Additionally, the New Jersey Department of Health and Senior Services issued, as part of a larger rulemaking, very strong language dismissing OEM calls for informed consent, additional reporting requirements, and additional liability for reprocessed devices.

### ***Rhode Island***

AMDR provided testimony at a hearing in Rhode Island in early 2008, opposing anti-reprocessing legislation there that mimicked Massachusetts bill. Though the bill lacked sufficient votes to pass out of Committee, the legislature commissioned a study of reprocessing to commence in November. AMDR is working diligently to ensure a fair review.

### **AMDR Public Relations Accomplishments:**

- A number of balanced articles, including the *Wall Street Journal*
- Developed new brochure, "The Facts about Medical Device Reprocessing"
- Responded to several trade journal inquiries (*Claims Rx*, *Journal of Bone and Joint Surgery*, *Materials Management in Healthcare*, and *Mass High Tech Journal*)

### **2008 Speaking Engagements:**

- Club Espanol de Esterilizacion, Cordoba, Spain
- CleanMed, Pittsburgh, Pennsylvania
- Heart Rhythm, San Francisco, California
- Minimally Invasive Surgery event, Williamsburg, Virginia
- Regulatory Affairs Professionals Society (RAPs), Boston, Massachusetts
- New Jersey Healthcare Central Sterile Association (NJHCSA), Somerset, New Jersey
- Kellogg Business of Health Conference, Northwestern University, Evanston, Illinois (over)

***AMDR Outreach Accomplishments:***

- *AAMI*
- *ASHRM*
- *Practice GreenHealth*
- *Product Stewardship Institute*