



Medical Device Reprocessing in the News

March 24, 2008

WALL STREET JOURNAL - *The Informed Patient* – Hospitals Reuse Medical Devices to Lower Costs

In a well-balanced [article](#) in its March 19 issue, the Wall Street Journal reported that "in January, after reviewing eight years of FDA data, the Government Accountability Office weighed in with a report concluding there is **no evidence** that reprocessed single use devices create an elevated health risk for patients." The article noted that the GAO report tilts the debate strongly in favor of reprocessing and opens the door to more widespread use.

The article also acknowledged the significant environmental and cost-savings possibilities with reprocessed devices. Dr. Kenneth Kizer, former undersecretary for health at the U.S. Department of Veterans Affairs, said, "Single-use labeling is a real scam for a lot of devices, and by not using reprocessed devices where possible it is wasteful and not environmentally responsive...The reuse of medical devices that are labeled for single-use only is a well-established and safe practice regulated by the FDA and utilized by most of the top-ranked hospitals in the country." And Dean Edwards, vice president and chief procurement officer for Kaiser Permanente Health Care, said that Kaiser shaved about \$3.5 million from its device costs in 2007 and eliminated about 45.7 tons of medical waste through its use of reprocessed devices.

GAO report finds that reprocessing is safe and stringently regulated

In its second report on the reprocessing industry in eight years, the Government Accountability Office (GAO) again affirmed AMDR's long-held position that there is no increased risk to patients with the use of reprocessed devices, there is no pattern pointing to reprocessed SUD use resulting in higher risk to patients, and there is no reason to question the FDA's analysis of these facts. The [report](#) was made public on March 3, 2008.

The GAO report also noted that FDA regulation of reprocessing is stringent. Third-party reprocessors are more stringently regulated than original equipment manufacturers and have a history of more frequent FDA-inspections than the overall medical device industry.

Waxman reassured by GAO report: "The Gray Sheet" March 10, 2008

Rep. Henry Waxman, D-California - "It's time to put the issue of reprocessed devices to

(over)

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." As chair of the Committee on Government Reform, Waxman, along with ranking minority member Rep. Thomas Davis, called for the GAO study in 2005.

AMDR notes that FDA's adverse event reporting database, as documented in the GAO report, showed a rate of less than one tenth of one percent (65 reports out of 320,000) of all adverse events reported between 2003 and 2006 possibly involved a reprocessed device. This is much lower than might be expected, since reprocessing may impact as much as five percent of all OEM devices marketed.

AMDR members serve 77% of top rated patient safety hospitals

On March 17, 2008 Thomson Health care released their [Top 100 Hospitals](#) list based on their National Benchmarks for Success study. Hospitals chosen for this honor are evaluated on eight measures of clinical quality, operating efficiency and financial performance. AMDR member companies reprocess medical devices for 77 of those named to the top 100 list including 86% of the teaching hospitals and 75 % of the large community hospitals. This demonstrates that hospitals recognized by Thomson for safe patient practices also embrace reprocessing as a means of controlling costs and reducing waste.