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Federal hearing reveals that reprocessed medical devices are safe, stringently regulated

"Original devices - not reprocessed ones ... cause the largest numbers of death and injuries," says Rep. Henry Waxman.

Recent public statements and news accounts in New Jersey have questioned the safety of reprocessed medical devices, but comments from federal legislators on Capitol Hill Tuesday reflected the stellar safety record of the reprocessing industry which provides hospitals with a safe and cost effective alternative to the high priced "single use" medical devices that are filling the nation's landfills.

In his opening statement before the House Committee on Government Reform's hearing entitled, "Medical Device Safety: How FDA Regulates the Reprocessing of Supposedly Single-Use Devices," Representative Henry Waxman (D-CA) noted that under the law, reprocessed devices are actually more tightly regulated now than single-use counterparts. "The FDA is not doing a good job protecting Americans from the dangers of **new** devices. And it is the **original devices** - not reprocessed ones-that cause the largest numbers of deaths and injuries," said Waxman.

Waxman cited the recent manufacturing defects in brand-new implantable cardiac defibrillators as an example of the safety risks posed by original devices. "Even after one major manufacturer of defibrillators learned that some of its devices were flawed, the company did not inform physicians or the public, and the faulty defibrillators continued to be surgically implanted."

Committee Chairman Tom Davis (R-VA) expressed his disappointment in the original device manufacturing industry. "We have no device makers testifying today because they preferred to speak through their trade association. We would have preferred to have direct testimony from companies so they would be able to provide specific examples and commentary regarding their specific devices," Davis said.

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Dennis Toussaint, Director of Regulatory Affairs at SterilMed, Inc. and Don Selvey, Senior Vice President for Regulatory Affairs and Quality Assurance at Ascent Healthcare Solutions, representatives of the nation's two largest medical device reprocessing companies testified at the hearing.

"Our safety record is outstanding," said Selvey. "The FDA's adverse event database contains over 6,500 reports of patient deaths associated with original (unreprocessed) medical devices since 2004. According to that same database, **no deaths** have been associated with the use of reprocessed 'single use' medical devices."

Rep. Gil Gutknecht (R-MN) noted when questioning FDA that, "the evidence here is pretty scant that there is real harm" from reprocessing single-use devices.

Under the Federal Food, Drug and Cosmetic Act, reprocessors of medical devices are required to meet all the same regulatory requirements as the original manufacturers, plus some additional requirements applied only to reprocessors. Reprocessors must not only prove to FDA that their devices are clean, functional, and sterile, but must also label their devices as having been reprocessed, including marking the device itself or an attachment thereto, with the name or symbol that identifies the reprocessor. Additionally, every reprocessed device must be tested or inspected before reuse. By comparison, original devices labeled for single use are only sample tested.

In his testimony, Toussaint stated that 13 out of the 14 institutions ranked as the nation's "Honor Roll" hospitals by US News & World Report use reprocessed medical devices. These include the Mayo Clinic, the Cleveland Clinic and Massachusetts General Hospital. He noted that reprocessors serve all ten hospitals considered by US News & World Report to be the top ten heart and heart surgery hospitals in the country, and in at least nine of the top ten orthopedic hospitals nationwide.

In New Jersey, more than fifty hospitals use reprocessed medical devices including Hackensack University Medical Center, Morristown Memorial Hospital, Newark Beth Israel Medical Center and the St. Barnabas Health Care System.

"Reprocessing is safe, it makes economic sense for hospitals and it is good for the environment. We all know that many consumer products are deliberately designed to become obsolescent, forcing consumers to buy more goods than they need and to clog our landfills with this unnecessary waste. The same is true in the medical device field—throwing away a titanium rod after one use just doesn't make any sense. The reprocessing industry helped hospitals divert over 4,000 tons of medical waste from landfills in 2005," said Selvey.

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