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For further information
Dan Vukelich, Executive Director/AMDR
202-518-6796
Cindy Gordon/Anne Burns
Insight Communication
609-252-1300

Health care professionals oppose legislation limiting use of reprocessed medical devices

Charge OEMs with using scare tactics to mislead legislators

Sueanne Kyle, RN, Director of Supply Chain Services of **The Lahey Clinic** voiced its opposition to the legislation, stating in written testimony, "third party reprocessed devices meet the same standards and must comply with the same regulations as brand new devices. In fact, the current FDA requirements actually demand a higher level of due diligence than is required of brand new devices.... If the purpose of these bills is to provide more transparency to the patient...maybe we should be focusing on higher risk devices like stents or pacemakers that are in fact proven to cause patient deaths and injuries. This is bad legislation."

"Medical device manufacturers are trying to scare legislators into passing a bill that will needlessly increase healthcare costs and add to medical waste in Massachusetts," said Daniel J. Vukelich, executive director of the **Association of Medical Device Reprocessors** yesterday.

Testifying at a hearing of the Massachusetts legislature's Public Health Committee in Boston, Vukelich described the benefits of medical device reprocessing and noted that the industry has a stellar safety record. "In testimony before Congress in September 2006, FDA stated that reprocessed devices 'are as safe and effective as a new device,'" he said.

Brian Sullivan, CEO of **SterilMed**, one of the nation's leading commercial reprocessors of medical devices, said the proposed legislation "was an insult to the health care profession. To suggest that the finest hospitals in the United States would make choices that would put their patients at risk in order to save money is unimaginable," Sullivan said.

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Their comments were delivered in opposition to HB 2233/SB1338, which would, in practice, restrict the use of reprocessed medical devices, an initiative championed by the original device manufacturers, which stand to lose money if reprocessors continue to provide reprocessed devices in a safe, cost effective and environmentally responsible manner.

Karen Nelson, Senior Vice President, Clinical Affairs at the **Massachusetts Hospital Association**, noted that in her 25 years of hospital experience, she has made numerous complaints to FDA and manufacturers for faulty or broken medical equipment received directly from manufacturers. But in her 25 years she has never had to report a reprocessed medical device failure.

"We oppose this legislation because once you strip away the rhetoric, economics are the driving force behind it, not patient safety or the quality of patient care," said Marita Prater, president of **Massachusetts Organization of Nurse Executives**. "This legislation represents an attempt by medical device manufacturers to gain market share by limiting the ability of Massachusetts hospitals to access safe and cost effective processed medical devices."

In his testimony, Bill Ravenesi, MA, MPH, Boston Regional Director of **Health Care without Harm**, noted "having the choice of purchasing reprocessed devices has been one important strategy for waste minimization and cost containment for hospitals. He also stated that the decision by 63 Commonwealth hospitals to use reprocessed medical devices "has diverted 26 tons of medical waste from landfills, including landfills located in Massachusetts."

Vukelich also highlighted inaccuracies in medical device manufacturers' testimony before the committee.

- Manufacturers misled the committee into thinking that hypodermic needles and ophthalmic knives are reprocessed. These items are not reprocessed by any FDA-regulated company in the United States
- Device manufacturers do indeed sell as "single use" both invasive and non- invasive devices made of titanium, steel and carbon fiber, in addition to other durable materials
- Original equipment manufacturers have even reprocessed their own "single use" medical devices, the best evidence yet that "single use" does not always mean "single use."

The **Massachusetts Orthopaedic Association** and the **Massachusetts Medical Society** also submitted testimony in opposition to the legislation.

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Attachments