

**MASSACHUSETTS
ORTHOPAEDIC
ASSOCIATION, INC**

167 Washington Street

**MOA TESTIMONY IN OPPOSITION TO H.2233/S.1338
“AN ACT RELATIVE TO A PATIENTS’ RIGHT TO KNOW OF THE RE-USE OF
CERTAIN MEDICAL DEVICES MANUFACTURED FOR A SINGLE USE”
SUBMITTED TO THE COMMITTEE ON PUBLIC HEALTH
SEPTEMBER 26, 2007**

The Massachusetts Orthopaedic Association wishes to be recorded in opposition to H.2233 and S.1338, “An Act Relative to a Patients’ Right to Know of the Re-Use of a Certain Medical Device Manufactured for a Single Use”, sponsored by Senator Susan Tucker. These identical bills would limit the use of safe and cost-effective reprocessed orthopedic devices.

The use of reprocessed medical devices by orthopedic surgeons is not new. The practice has been commonplace since the mid 1980’s, having derived from providers and facilities desire to reduce the cost of health care while maintaining patient safety and quality care. It is important to note that reprocessing does not affect the quality, physical characteristics or performance of all medical devices. In fact, if not for the stringent labeling requirements, most orthopedic surgeons would not even know that they were using a reprocessed medical device.

In preparation for this hearing, the MOA researched the regulation of reprocessed medical devices and found that reprocessing is subject to stringent federal regulation. Reprocessing is comprehensively regulated by the U.S. Food and Drug Administration (FDA). According to FDA, reprocessors are regulated as if they were original equipment manufacturers, and are subject to all of the same regulations and requirements, including the methods, facilities and controls used for the design, manufacture, packaging, labeling, storage, and installation and servicing of finished devices. Moreover, since 2002, reprocessors have been subject to additional requirements – above and beyond those with which original equipment manufacturers must comply with. Specifically, under the Medical Device User Fee and Modernization Act, reprocessors now have to submit for FDA review and clearance certain types of data that original equipment manufacturers do not. That law was further amended in 2005 to create even more requirements of reprocessors. Since that time, all reprocessed single use devices must be clearly marked as reprocessed on the device itself as well as on the packaging. Under such stringent federal guidelines, the MOA does not believe further state statutory controls are necessary at this time.

The MOA estimates that reprocessed devices cost, on average, half of what an original device costs. From the perspective of orthopedic surgeons, there are many reprocessed implants where there does not appear to be a difference between single use implants and reprocessed implants. When there is not difference in implant quality and the reprocessed implant is significantly less costly, the best interests of patients and the system are served by keeping medical costs down. Limiting either the availability or the use of reprocessed devices will only drive up health care costs without producing *any* corresponding benefit for Massachusetts patients.

The MOA urges the Committee on Public Health to report H.2233 and S.1338 out “Ought Not to Pass”.