



# MASSACHUSETTS MEDICAL SOCIETY

*Every physician matters, each patient counts.*

**Testimony of  
The Massachusetts Medical Society  
Before the Joint Committee on Public Health  
In Opposition to House Bill 2233 and Senate Bill 1338  
An Act Relative to a Patients' Right to Know of the Re-Use of Certain Medical Devices  
Manufactured for a Single Use  
September 26, 2007**

The Massachusetts Medical Society wishes to be recorded in opposition to House Bill 2233 and Senate Bill 1338, "An Act Relative to a Patients' Right to Know of the Re-Use of Certain Medical Devices Manufactured for a Single Use," identical measures which would require physicians and other health care providers to inform patients if they intend to use reprocessed medical devices originally intended for single use and gain written consent to such use. The legislation would also establish civil liability for failure to secure such consent – even though the health care provider might not even know that the device was reprocessed! This would effectively limit the use of safe and effective reprocessed devices by raising unwarranted patient concerns about the safety of such devices, generate significant unnecessary paperwork, and increase the cost of health care.

The use of reprocessed durable medical equipment by physicians and hospitals is a long-standing practice that is already heavily regulated by the U. S. Food and Drug Administration (FDA). No significant patient safety problems are evident as a result of the use of reprocessed devices; however, what *is* evident is a significant savings in cost to the entire health care system. This bill's patient notification provision would allow patients to refuse to accept reprocessed devices, which would result in increased costs while affording no improvement to the quality of patient care.

Medical device reprocessors are regulated by the FDA and are subject to all of the same regulations as original equipment manufacturers – and then some! Like manufacturers, they must obtain FDA approval or clearance before marketing certain devices and comply with FDA's quality system regulation. They must register with the FDA and are subject to agency inspection. Device-related adverse events must also be reported to the FDA. Indeed, since 2002, reprocessors have been subject to additional requirements for FDA review and clearance that even original manufacturers need not comply with. *The major difference occurs not in patient safety but in cost.* Reprocessed devices cost, on average, half of what an original device costs. Thus, their use allows Massachusetts physicians and hospitals to achieve substantial cost savings while maintaining the highest standards of patient care.

We urge the Committee to report out this legislation as "ought not to pass."