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NASPE's Mission Statement

The mission of the North American Society of Pacing and Electrophysiology, an organization of physicians, scientists, and allied professionals throughout the world dedicated to the study and management of cardiac arrhythmias, is to improve the care of patients by promoting research, education and training, and providing leadership toward optimal healthcare policies and standards.

Executive Director
Carol J. McGlinchey

June 22, 1999

The Honorable Richard J. Durbin
Senate Russell Building
Room 364
Washington, DC 20510

Dear Senator Durbin:

The North American Society of Pacing and Electrophysiology (NASPE) is very concerned with your proposed amendment to Senate Bill 1233, titled "Reprocessed Medical Devices". This amendment would restrict the re-processing of medical devices labeled for single-use. The current medical practice of re-sterilizing medical devices, such as cardiac catheters, is not only common, but has been proven safe and effective in the care and treatment of patients with cardiac rhythm problems, also known as arrhythmias.

NASPE is an organization of physicians, scientists and allied health professionals dedicated to the study and management of cardiac arrhythmias and to improving the care of patients by promoting research, education and training. NASPE members diagnose and treat patients with cardiac rhythm problems.

There has been considerable peer-reviewed published research into the effect on patient care using re-sterilized cardiac catheters. A brief list of references is attached. After studying thousands of patients who have undergone cardiology procedures with re-sterilized catheters, findings indicate there is no increased risk of infection for patients. Re-sterilization of cardiac catheters for electrophysiology studies has been an ongoing practice for over twenty years with no known adverse patient outcomes. In addition, the Food and Drug Administration permits re-sterilization of catheters provided that a meticulous quality assurance program documents the structural integrity of the catheters, and that sterility and chemical residuals are monitored.

NASPE members foremost priority is to provide quality medical care to patients. Appropriate medical device re-processing is a safe and effective way to achieve health care cost savings without compromising patient care. These savings can be directed towards improving patient access and medical care.

Legislation, which would add new and unnecessary regulatory requirements for the reprocessing of medical devices, would hinder the practice of cardiac electrophysiology in this country. NASPE encourages you to research this topic further before passing a legislative mandate that would, in essence, ban a medically acceptable and safe practice. Hearings on this topic could include

experts in the field of medical device reprocessing, representatives of the Food and Drug Administration, physicians, as well as patient representatives.

NASPE would be pleased to provide you with additional information on this critical issue. Please feel free to call me at the Hershey Medical Center at 717-531-3907 or Amy Melnick, Director, Government Relations at NASPE. Thank you for your attention.

Sincerely,

A handwritten signature in cursive script that reads "Gerald V. Naccarelli M.D." with a stylized flourish at the end.

Gerald Naccarelli, MD
President
North American Society of Pacing and Electrophysiology

References:

- 1) O'Donoghue S, Platia EV. Reuse of Pacing Catheters: A Survey of Safety and Efficacy, PACE 1988;11:1279-1280.
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- 3) Avitall B, Khan, Krum D, Jazzayeri M, Hare H. Repeated Use of Ablation Catheters: A Prospective Study. American Journal of Cardiology 1993;22:1367-1372.
- 4) Aton EA, Murray P, Frase V, Conaway L, Cain ME. Safety of Reusing Cardiac Electrophysiology Catheters. American Journal of Cardiology 1994;74:1173-1175.