ATTACHMENT K

June 23, 1999

The Honorable Thad Cochran
United States Senate
326 Russell Senate Office Building
Washington, DC 20510

Dear Chairman Cochran:

The American Hospital Association (AHA), which represents nearly 5,000 hospitals, health care systems, networks, and other providers of care, wants to raise our serious concerns about an amendment that Senator Richard Durbin (D-IL) is preparing to offer to the Agriculture Appropriations bill when it comes to the Senate floor this week. The amendment would restrict reprocessing of medical devices, and could seriously affect both the quantity and quality of health care we offer our patients.

The clinical use of reprocessed medical devices is safe, effective, and efficient. Hospitals have reprocessed devices labeled "single use" or "disposable" for years with excellent success. In our view, the real issue is not whether reuse is appropriate, but whether the single use label is a complete and accurate representation of the device. With this in mind, it is the general practice for hospitals to rely on physicians, nurses, sterile processing professionals and infection control specialists to deliberate carefully before deciding to reprocess any device and ensure that proper safeguards exist in the reprocessing procedure. In-hospital reprocessing is also subject to Joint Commission on Accreditation of Healthcare Organizations oversight.

For hospitals, proper reprocessing is a safe and effective way to deliver the highest quality patient care. There is an extensive body of research demonstrating that reprocessing of certain medical devices is appropriate and poses no significant risk to patients. If the Durbin amendment is adopted, it would result in devices being disposed of after only one use, even if the device could still be used safely and effectively, contributing unnecessarily to the waste streams generated by health care facilities.

Finally, the Food and Drug Administration (FDA), whose jurisdiction includes oversight of reprocessed devices, has indicated that it shares some of our concerns regarding Sen. Durbin's amendment. The FDA agrees that more research needs to be done to determine the prevalence of reprocessing and the ability of reprocessors to maintain quality.

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There is no quick and easy solution to this issue. The Durbin amendment is at best premature and at worst would have a far-reaching negative impact on what is a safe and standard medical practice. The whole issue deserves a much more thoughtful review before legislation is enacted. We respectfully ask that this amendment not be included in the Agriculture Appropriations bill when it comes to the Senate floor.

Thank you for your attention to this matter.

Sincerely,

Rick Pollack

Rick Pollack
Executive Vice President

AMERICAN COLLEGE of CARDIOLOGY

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June 25, 1999

The Honorable
Richard Durbin
364 Russell Senate Office Building
Washington, D.C. 20510

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Dear Sen. Durbin:

It has come to the attention of the American College of Cardiology (ACC) that you are considering offering an amendment to the Agriculture, Rural Development, and Related Agencies Appropriations bill that would severely restrict the use of reprocessed medical devices. On behalf of more than 24,000 cardiovascular specialists, I wish to express the ACC's deep opposition to your amendment.

When it comes to treating patients, our number one concern is safety. The reprocessed medical devices used in diagnosing and treating cardiac patients are in fact safe and effective. In particular, the ACC is concerned about the effect your amendment will have on the use of reprocessed catheters, such as those used in electrophysiology. Solid, rigid catheters are used by cardiovascular specialists in electrophysiology for the placement and removal of pacemakers and implantable defibrillators. Generally, between two and six catheters are used during a single procedure, but it is not uncommon for as many as eight to be used. New, these catheters cost between $150 and $1000 each. Reprocessed catheters are not only safe and effective, they are also cost efficient.

The catheters used in electrophysiology can be used safely, following sterilization, as many as five times, thereby greatly reducing costs. Concerns that reprocessed catheters could cause serious injury to patients are completely unfounded. There are cardiovascular specialists who have been using reprocessed catheters in their labs for more than 20 years and cannot cite a single instance where a reprocessed catheter has broke or caused infection. Simply stated, your amendment will unnecessarily increase health care costs and could potentially result in the closing of electrophysiology labs.

Generally speaking, your concern for patient safety is appreciated. The ACC simply questions the claims that reprocessed medical devices, particularly those used in cardiovascular medicine pose a danger to patients. Therefore, the ACC must oppose your amendment, as it will unjustifiably increase costs, and urges you not to seek its passage until a more detailed discussion about the issue can occur.

Sincerely,

Arthur Garson, Jr., M.D., F.A.C.C.
President

Cc: Sen. Edward Kennedy
Sen. William Frist
Sen. Jim M. Jeffords

NASPE North American Society of Pacing and Electrophysiology

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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 electrophysiolgy 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,

Gerald V. Naccarelli M.D.

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

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Stephen C. Hammill, M.D.
Cardiovascular Diseases
& Internal Medicine

June 23, 1999

The Honorable Paul Wellstone
United States Senate
Washington DC 20510

Dear Senator Wellstone:

As Professor of Medicine and Director of Electrophysiology at Saint Marys Hospital and Mayo Clinic, I am writing to express my concern about reports that Senator Richard Durbin may propose legislation to restrict the reprocessing of medical devices labeled for single use. Such legislation would have a seriously negative economic impact on our Electrophysiology Program at Saint Marys Hospital.

The Electrophysiology Program at Mayo has sought to provide the highest quality care while maintaining a cost-efficient approach. For more than 20 years, the catheters used in electrophysiology procedures have been reprocessed at Mayo and have continued to function normally without any evidence of infection. Reprocessing the catheters has allowed us to use each catheter five or six times, greatly decreasing the cost of the procedures. During electrophysiologic testing, we use between two and eight catheters per study with total catheter costs approaching $300-$4000. Reprocessing of the catheters has proven to be a safe and effective technique and has allowed us to gain the most use from the catheters, making them as cost efficient as possible.

I am greatly concerned that any legislation to add new and unnecessary regulatory requirements for the reprocessing of medical devices would add tremendous costs to the electrophysiology study and achieve no benefit for patients. I would appreciate you not supporting this type of legislation, and I would be happy to provide any additional information you might desire.

Sincerely,

Stephen C. Hammill, M.D.
Professor of Medicine
Director, Electrocardiography
and Electrophysiology Laboratories

SCH:mp