



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,

A handwritten signature in black ink that reads "Rick Pollack". The signature is written in a cursive, slightly slanted style.

Rick Pollack

Executive Vice President