The authors reply.

We greatly appreciate Dr. Daschner's comments on our article and his interest about this topic. However, to our knowledge, one major difference between the European and the U.S. markets is that in the European Union, the use of medical devices is generally regulated by European or national law, whereas the Food and Drug Administration does not regulate home care institutions.

It was the intention of our article to demonstrate the problems and hazards of reprocessing single-use devices. Problems originating from reprocessing of complex reusable devices have been described previously.[1] These problems have led some European countries to change their regulations (eg, France no longer allows the reuse of biopsy forceps, even if they are classified as reusable by the manufacturer).

Manufacturers should prove the reusability of their products by suitable methods, as they have been described in our study. The label "reusable" and the fact that a device is not destroyed in the autoclave are not enough! We expect the release of EN ISO 17664 describing the information to be provided by the manufacturer for the reprocessing of re-sterilizable devices.

Finally, according to *Webster's Dictionary*, an oxymoron is an epigrammatic effect of the combination of contradictory or incongruous words, such as "reuse of single-use devices."

REFERENCE

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If It Is Reusable, Why Not Reuse It?

To the Editor:

On the basis of his editorial "Requiem for Reuse of Single-Use Devices in US Hospitals,"[1] there seems to be little doubt that Dr. Favero is convinced that the reuse of single-use devices (SUDs) is at best a short-term situation. As he states, the issues regarding the reuse of products that are labeled as allegedly being SUDs are indeed controversial. However, in commenting on the demise of their reuse, Dr. Favero failed to include the most important consideration that supports the need for their being reused. Specifically, it is for the economic welfare of healthcare providers and our nation's entire healthcare delivery system. As a quality-oriented, cost-conscious healthcare consumer who retired 11 years ago following a 40-year career in the industry, I believe that that element warrants being brought to attention.

Those reading this commentary who were not around during those good old days may not know that the thought of using a device once and discarding it initially was not readily accepted by healthcare providers. Although the items were promoted as being easy to use, highly efficient, worry free, and labor saving, they were viewed as being unduly expensive and wasteful. What then accelerated their popularity? The truth of the matter is that it had nothing to do with their desirable attributes; rather, it was skewed by a reimbursement system that permitted the healthcare provider to charge Medicare for the product's cost—plus another 35% to 40% markup labeled as a "handling charge." Thus, as a line item charge, the SUD became a revenue generator. Although an item processed in-house may have been known to be less expensive, the difference in cost was irrelevant.

Also not to be overlooked is the fact that, to this day, identifying an item as being "for single-use only" is not a requirement of the U.S. Food and Drug Administration (FDA). The use of that descriptive language actually originated prior to the formation of the agency and has self-perpetuated. Actually, the decision to describe an item in that manner is left to the manufacturer.

The suitability for reuse of a myriad of the alleged SUDs is a matter of public record. It has recently been reported that for a period of approximately 3½ years, the FDA's Medical Device Reporting system documented only 245 adverse events associated with the reuse of SUDs.[2] Compared with the literally thousands of reports that are received on an annual basis (FDA, personal communication, 2001), the nominal number of those on reprocessed SUDs is exemplary.

Why then is it necessary for the FDA to impose its regulations on those facilities for the items that they have been reprocessing? Rather than the FDA's considering them the same as it does the original equipment manufacturer,[3] why can't they simply be "grandfathered" in the same way as items that were made before 1976, when the agency first came into being? For example, the Cleveland Clinic retrospectively studied 3,000 electrophysiology mapping and 2,000 reference ablation procedures, of which 97% used one or more reprocessed nonlumen catheters, and found not one infection![4] If any one of the members of their professional clinical staffs had any reason to even be suspicious of an adverse outcome as a result of their reuse, would they have continued to reprocess them? Why should the facility be required to sacrifice any of the sorely needed financial benefits it has been accruing all this time?

The fiscal condition of our nation's healthcare delivery system has been said to be attributable to the implementation of the Balanced Budget Amendment of 1997 that reduced the rate of reimbursement for its services. The fact is that a recent report from the Robert Wood Johnson Foundation indicates that one-third of all hospitals in the United States are failing financially. The report further indicates that another one-third are on the other end of the scale and that the remaining one-third are barely making it.[5]

According to a report from the General Accounting Office, a hospital's costs for an in-house reprocessed device are less than 10% of the cost of a new one.[4] Interestingly enough, an FDA official recently remarked that it is the high cost of the agency's rules "that more and more hospitals are getting out of it."[6] Is it the intent of the FDA's regulations to deprive healthcare providers of the financial relief that could be theirs by reprocessing SUDs? From what we have seen here, they don't seem to contribute to either the patient's welfare or the financial interest of the healthcare