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."

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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

provider. If neither of those, then whom do they benefit?

The fact of the matter is that our healthcare delivery system simply can no longer afford the luxury of using some things once and then throwing them away. That having been said, rather than a requiem and wake for the reuse of SUDs in hospitals as Dr. Favero suggested, perhaps the requiem and wake should be held for what appears to be the unjustified FDA reprocessing regulations.

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The author declines to reply.

Leading a Horse to Water: Are Crucial Lessons in Endoscopy and Outbreak Investigations Being Learned?

To the Editor:

In 1999, the Centers for Disease Control and Prevention (CDC) reported an outbreak of *Pseudomonas aerguinosa* that occurred in 1998 in a hospital in Flushing, New York.[1] This outbreak, referred to as cluster 3, was investigated by officials from the New York State Department of Health, the CDC, and the Food and Drug Administration (FDA). Eighteen infections and 1 death were reported.[1,2] This cluster 3 outbreak was discussed in greater detail by Sorin et al.[2] and Weber et al.[3] in the July 2001 issue of *Infection Control and Hospital Epidemiology*. Sorin et al.[2] agreed with the CDC that improper connection of both Olympus (Olympus America, Inc., Melville, NY) and Pentax (Pentax Precision Instrument Corp., Orangeburg, NY) bronchoscopes to a specific automated endoscope reprocessor (AER) model was primarily responsible for this *P. aeruginosa* outbreak. The editorial by Weber et al.[3] discussed in part lessons that may have been learned from this and other outbreak investigations.

Several questions and unresolved issues remain after reviewing these two articles. If, as Sorin et al.[2] concluded, this cluster 3 outbreak was due at least in part to hospital personnel improperly connecting bronchoscopes to the AER, what does this reprocessing mishap portend for gastrointestinal endoscopes? Because they are more difficult to clean and have many more internal and complex channels and connectors, gastrointestinal endoscopes would then seem to be even more susceptible to improper connection to an AER, and therefore to patient infection, than bronchoscopes, the simplest flexible endoscopes to reprocess. If true, the implications of Sorin et al.'s conclusion are far-reaching and clinically significant.

In short, Sorin et al. concluded that, due to "faulty connections" of the AER to the bronchoscope, "inadequate" flow of the AER's peracetic acid sterilant through the bronchoscope's instrument channel resulted in "incomplete sterilization," which contributed to, if not caused, the cluster 3 outbreak.[2] Although their conclusion may have merit, the authors did not publish the flow and pressure data necessary to support it. Moreover, although faulty connections between any AER and endoscope can no doubt raise serious infection control concerns, the authors' conclusion requires that the bronchoscopes remained contaminated with *P. aeruginosa* despite being repeatedly (1) precleaned manually with a brush and detergent solution (the authors noted that the bronchoscope's suction valve was also thoroughly cleaned); (2) completely immersed in a liquid sterilant (although possibly being connected improperly to the AER); (3) rinsed with 70% alcohol followed by purging with forced air; and (4) hung vertically to dry in a dedicated storage cabinet. Although this conclusion is plausible, human error is unlikely to have been solely responsible. Reports have demonstrated for years that *P. aeruginosa* infection is rare when the endoscope's channels are thoroughly dried using 70% alcohol.[4,5] These reports suggest that some other factors possibly unrelated to connecting the bronchoscope to the AER may have contributed to this cluster 3 outbreak.[5]

The well-recognized contribution of the environment to *P. aeruginosa* outbreaks raises several questions. What was the source of the *P. aeruginosa*? To what extent might the environment have contributed to this outbreak? During the investigations of the cluster 3 outbreak,[1,2] was the filtered rinse water (0.2 μm rated) sampled microbiologically? And if so, was it immediately tested for *P. aeruginosa*? In general, epidemiologic investigations of similar types of outbreaks routinely sample the environment[6] and relevant water sites to identify the outbreak's source. Indeed, several reports have linked contaminated water supplies to nosocomial infections.[7-9] One report linked contaminated filtered rinse water to an outbreak following gastrointestinal endoscopy.[9]

It is unclear whether Sorin et al. or the CDC's investigators sampled the filtered rinse water microbiologically for *P. aeruginosa*, as these data were not published.[1,2] Sampling the AER and its filtered rinse water, among other sites, is crucial to investigating and identifying the source of this cluster 3 (or any other) outbreak. In one scenario, if the filtered rinse water was not sampled, then it cannot be ruled out as a possible source of the cluster 3 outbreak. As a consequence, the conclusion that improper connection of the AER to bronchoscopes was primarily to blame for the *P. aeruginosa* outbreak may be incomplete.[5]

In another scenario, as pointed out previously by Muscarella,[5] if the filtered rinse water, which by the AER's design contacts the endoscope *after* chemical immersion, was sampled and found to be contaminated with *P. aeruginosa*, then the bronchoscope could have been recontaminated by the rinse water prior to bronchoscopy and the outbreak might