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March 3, 2000

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Docket No. 99N-4491  
Docket Management Branch  
Divisions of Management Systems Policy  
Office of Human Resources and Management Services  
Food and Drug Administration  
5630 Fishers Lane, Room 1061 (HFA-305)  
Rockville, MD 20852

Dear FDA Staff:

I applaud your efforts to reevaluate the reprocessing, single use device, --- issue. This has been a confusing issue for too long and patient safety is at risk.

My nursing career has been concentrated in the perioperative area where this issue has been dealt with for a very long time. I have been active in my specialty organization (AORN) on both the local and national level for many years. Standards and Recommended Practices guide the decisions I make for my practice and practice within organizations. Attending your conference on December 14<sup>th</sup> was educational for me and also demonstrated the need for education within the FDA.

While there are many aspects of this topic that must be dealt with by each organization, for the purposes of this letter I will focus on patient safety and my experiences.

Yes, it is frustrating to have used a particular item for two years following manufacturers instructions on reusing and suddenly a new supply arrives with the stamp "Single Use". This was experienced with an ophthalmology product and I convinced the staff nurse who first noticed the new verbiage to do a study since the product number had not changed. This only demonstrates the need for manufacturers to be held accountable for making the determination of "Single Use".

Opened unused products must have some mechanism for reprocessing. Manufacturers must respond to this need and currently there is little inclination to address this problem. In my opinion this is where the real opportunity for economy lies with no impact on patient safety.

I must admit when the statement was made that anesthesia tubing was an example of an item that could easily be reprocessed, I gasped. A principle that has stood the test of time is, "*How easily can the item be cleaned?*". A smooth surface that is easily reached by cleaning agents can be cleaned easily. Anesthesia tubing is corrugated which makes surface cleaning extremely difficult. I encourage you to apply common sense principles when making determinations regarding ease of cleaning! If the item is not properly cleaned, sterilization cannot be accomplished.

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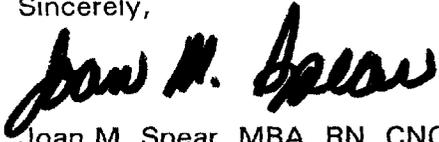
Cleaning and reprocessing is an area of patient safety and must be carefully considered.

Category creation lacking specific criteria is an area of high risk. There is an expected outcome that is not measurable. This has inherent serious patient safety risks. Much more delineation is required. Before the proposed categories can be safety operationalized. Make every attempt to eliminate the gray area before establishing policy.

The opinions expressed are my own and are made as a patient advocate only.

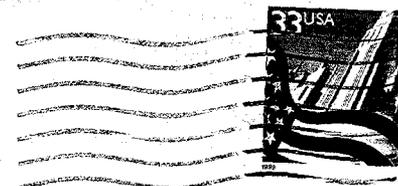
Thank you for providing the opportunity for me to express my opinion. I look forward to your successful deliberations in this matter.

Sincerely,

A handwritten signature in black ink that reads "Joan M. Spear". The signature is written in a cursive, flowing style.

Joan M. Spear, MBA, RN, CNOR

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