

**Beth Israel Deaconess
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December 3, 1999

**Larry Spears
Food and Drug Administration
Office of Compliance
2094 Gaither Road
Rockville, MD 20850**

RE: Sterility of reprocessed single use medical devices

Dear Mr. Spears:

Recently, I have been informed that the FDA has proposed a new policy to regulate reprocessors of single use medical devices, and will hold a town meeting on December 14, 1999 in Maryland. I will be unable to attend this meeting, however, I would like to submit my comments for your review. I certainly endorse the FDA's efforts to increase regulation of reprocessors of single use medical devices. However, I do not believe that the new FDA policy will be sufficient.

I am the co-director of endoscopy at the Beth Israel Deaconess Medical Center in Boston, Massachusetts. I have been and continue to be concerned with the reuse of used disposable medical devices. I am very concerned about the potential for patient injury due to failure of the device as well as for the potential of spread of infectious disease from patient to patient.

I have reviewed much of the data regarding reprocessing of the medical devices that we use today in gastrointestinal endoscopy. I am specifically concerned about the reprocessing of single use disposable biopsy forceps. The data that I have reviewed clearly demonstrates that these devices cannot be cleaned adequately with the current reprocessing techniques. With the inability to clean these devices properly, the rate of malfunction will increase proportionately. In addition, as these devices cannot be cleaned

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Larry Spears, M.D.

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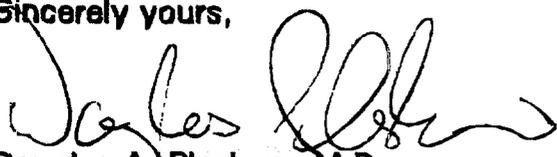
adequately the risk of infection will increase greatly as well. I am very concerned about the transmission of bacteria and viruses, but I think we also need to be concerned about the potential for spreading infectious agents that may not be as yet identified, that may not be susceptible to the reprocessing solutions. I am also extremely concerned about the reuse of disposable polypectomy snares and sphincterotomes. These studies I have reviewed again do not clearly demonstrate that these devices can be cleaned adequately, therefore increasing the risk of transmission of infectious disease from patient to patient. I am also concerned about the lack of any data from the reprocessing companies regarding the electrosurgical characteristics of the instruments after they have been reprocessed. I imagine that reprocessing procedures must change some of the electrosurgical properties of these devices, thereby influencing the effects of these devices on our patients. When asked specifically, the reprocessing companies suggest that these devices work to the same specifications of the manufacturer. However, when I ask specifically for data to review that these devices work in the same fashion, they are unable to provide me with any data. They also have no plans to investigate whether these devices work in the same fashion. The procedures that we do, carry an inherent risk. When we potentially increase the risk to our patients due to potential cost-saving measures, ie reprocessing, I feel that we are putting them in severe jeopardy. Without sufficient data or approval from the FDA, the practice of reusing disposable devices on patients is similar to human experimentation without patient consent.

I am very glad that the FDA is considering increased regulation of the reproprocessors, but again I do not believe that the current new policy is adequate.

Reprocessors of single use devices claim to have the equipment and expertise necessary to properly reprocess single use devices. They are therefore manufacturers in the eyes of health care workers and patients. In addition, reprocessing a single use device for reuse changes the device into a reusable device. Accordingly, reproprocessors should be regulated in the same manner as the original equipment manufacturer who is using the existing FDA regulations for reusable devices. They therefore need to be held to the same standard as the original manufacturers.

Thank you very much for reviewing these comments.

Sincerely yours,



Douglas A. Pleskow, M.D.

Co Director of Endoscopy, Beth Israel Deaconess Medical Center

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