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Mr. Larry Spears
Food and Drug Administration
Office of Compliance
2094 Gaither Rd.
Rockville, MD 20850

Via Telefax: 301-594-4672

Dear Mr. Spears:

Recently, I learned that the FDA has proposed a new policy to regulate reprocessors of single use medical devices and will hold a "town meeting" on December 14th in Maryland to receive input on this new policy. Unfortunately, I am unable to attend this meeting. Please accept this letter as my formal comment on the proposed new policy. While I strongly support the FDA's efforts to increase regulation of reprocessors of single use medical devices, I do not believe the new FDA policy is sufficient.

I am a gastroenterologist, and I work at the Scottsdale Healthcare North Campus in Scottsdale, Arizona. I have been and continue to be concerned with the reuse of used disposable medical devices. I am concerned about the potential for patient injury from either device failure or the spread of infectious diseases

In today's cost cutting environment, it is proper to look at all possible areas to save money, but reprocessing complex, plastic, single use devices such as biopsy forceps & sphincterotomes is simply not a safe avenue to pursue until these reprocessed devices receive FDA approval for reuse.

This practice also poses many ethical questions. There is no medical benefit to the patient, and, it is my understanding, that the patient does not receive lower healthcare costs. It is also my understanding that patients are not told that used disposable devices may be utilized on them. **Without such knowledge, patients are unable to give proper "informed consent" for their procedures and are helpless to protect themselves.**

It seems clear that if clinical tests were set up to prove whether or not a reprocessed used disposable device was safe for reuse, informed patient consent would absolutely be required. **Without sufficient data or approval from the FDA, the practice of utilizing previously used disposable devices on patients is akin to human experimentation without patient consent.**

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Lastly, reprocessing a single use device for reuse changes the device's classification into a "reusable" device. Therefore, **reprocessors should be considered manufacturers and should be regulated in the same manner as the original equipment manufactuers using the existing FDA regulations for reusable devices.** To create a new policy is a waste of government time and resources and most importantly, it places patients at risk.

Sincerely,

Daniel Meline, M.D.

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