

Date: _____

Mr. Larry Spears
Food and Drug Administration
Office of Compliance
2094 Gaither Rd.
Rockville MD 20850
FAX # (301) 594 - 4672

7881 '99 DEC 13 A9:53

RE: Sterility of Reprocessed Single Use Medical Devices

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 the town meeting but I would like to submit my comments. 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 ~~in~~ at University of Florida hospital in Gainesville, FL. 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 both a failure of the device as well as the spread of infectious diseases. These are not theoretical concerns. Published articles in *US News & World Report*, the *NY Times*, the *LA Times* and *Forbes Magazine* describe actual patient injuries. I also believe that many infections are under-reported due to insufficient patient tracking and that many injuries due to device failure are under-reported due to legal liability concerns.

Although many reprocessors claim that reprocessing has been going on for twenty years, the fact is that this was with respect to reusable devices and opened but unused single use devices. In today's cost cutting environment, it is proper to look at all possible areas to save money, but reprocessing complex, plastic, single used devices such as biopsy forceps, sphincterotomes, electrophysiology catheters and angioplasty catheters 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 will be used on them. Without such knowledge, patients cannot protect themselves. As a healthcare professional, I want to speak out on their behalf.

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