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COMMENT:

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Date: DECEMBER 3, 1999

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

**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 14<sup>th</sup> 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 PRACTICING GASTROENTEROLOGIST, and I work in THOMAS hospital in FREDERICK, MD. 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.

