DEPARTMENT OF VETERANS AFFAIRS

CARL T. HAYDEN VETERANS AFFAIRS MEDICAL CENTER
PHOENIX, ARIZONA

In Reply Refer To:

December 1, 1999

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 VA Medical Center in Phoenix, 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. 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. Patient injuries due to device failure may be under-reported due to 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 use devices such as biopsy forceps, sphincterotomes, electophysiology 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 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.

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As a practitioner in an institution actively participating in clinical research, I am keenly aware of what constitutes proper informed consent. 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.

I am thankful that the FDA is considering increased regulation of reprocessors, but I do not believe the new policy is appropriate. It is insufficient to protect patient safety. Data proving safety and effectiveness will only be required for "high risk" devices, and FDA officials have stated publicly that very few devices will be deemed high risk. Reprocessors of low risk devices will receive even less regulatory oversight than they do today. As one example, many biopsy forceps are Class I exempt devices and will likely be deemed low risk devices, despite studies by manufacturers showing that many reprocessed biopsy forceps sitting on hospital shelves are contaminated with drug resistant bacteria. Importantly, biopsy forceps are critical devices that break the mucosal barrier when samples are taken and, thus, can easily pass bacteria remaining on the device to the unsuspecting patient.

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 manufacturers using the existing FDA regulations for reusable devices. To create a new policy wastes valuable FDA resources and delays regulatory enforcement. This ultimately places patients at risk for an undetermined period of time.

Sincerely,

Michele Young, M.D.
Staff Physician, Department of Gastroenterology