

December 8, 1999

David Feigal, MD
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Re: Risk to Patient Safety from Reprocessed Used Single Use Medical Devices

Dear Dr. Feigal,

I am writing to you as a United States patient that has been injured by the reuse of a single use medical device. In 1993, I was admitted to the hospital for cataract surgery. Unbeknownst to me, this hospital regularly reprocessed single use tips of reusable surgical probes used in cataract surgery. Unfortunately, I did not get a new single use tip and, during my procedure, a reused tip was used and failed. As a result, I am virtually blind in my right eye, and due to constant and severe pain, I will likely have my eye replaced with a glass eye later this year. You cannot know the anguish this has caused both me and my family.

We felt strongly enough that we brought suit against the hospital. The jury found that my injury was a result of a failed reprocessed used single use device and assessed compensatory damages of \$100,000 against the hospital for negligence and exemplary damages of \$150,000 against the hospital for gross negligence. The judge defined gross negligence as a total want of care for the patient. The Texas Appeals Court recently overturned the jury's verdict indicating that there was not sufficient evidence that the injury was a result of the tip being reprocessed. Obviously we disagree and so did the jury. It is clear that the tip must have worked at least the first time or it would have been thrown away. It was never intended to work more than that one time and was not FDA approved for multiple uses. Yet it was reused on me, failed and now I'm blind in one eye. We are appealing to the Texas Supreme Court.

I do not believe patients in the United States should be put in the position of determining whether only FDA approved devices are being used on them. This is the type of practice that one associates with third world countries not the United States. I want to know why the FDA is allowing this practice to continue.

It is my understanding that the FDA has publicly stated that reprocessors are "manufacturers" under the law and subject to all the regulations that the original manufacturer of these devices is subject to. Unfortunately, I also understand that FDA is not enforcing some of the most important regulations - that is requiring reprocessors to prove to the FDA that these devices are safe and effective for multiple uses before the devices are reused in patients. Such enforcement may have prevented my injury!

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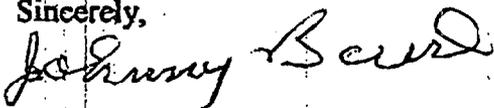
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I cannot understand why the FDA has chosen to ignore an issue that is so important to public safety. United States patients rely on the FDA, and we have clearly been let down. The hospital did not tell me that they were going to use these unapproved and unlawful devices on me, nor did the hospital charge me less for my procedure. This was not done with me, the patient, in mind. No one is claiming that my best interests were served by using a reused tip. Furthermore, I cannot think of how I might have protected myself. I had no idea that this type of practice even existed. I was not, therefore, in a position to question the doctor. In my mind, this type of unapproved activity is exactly what FDA is supposed to protect me from.

Lastly, I understand that the FDA recently proposed a new policy to regulate/reprocessed single use devices. Why? Doesn't reprocessing a single use device simply make it a reusable device and hasn't the FDA regulated these devices for years under the existing regulations? I'm afraid that FDA is again trying to avoid full regulation of reproprocessors, and I cannot understand why. I was injured, I understand that a 32 year old woman in Kansas was injured when an electrode fell off and became lodged in her heart, and I understand from articles in *US News & World Report*, *USA Today*, *Forbes*, the *NY Times*, the *LA Times* and others that there are many other injuries. What is the FDA waiting for?

Unfortunately, I cannot make it to your December 14th town meeting. I would truly like to but my health will not permit me at this time. I would ask you, though, to please have this letter read into the record at that meeting to provide at least some comment from the patients' perspective.

Sincerely,



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