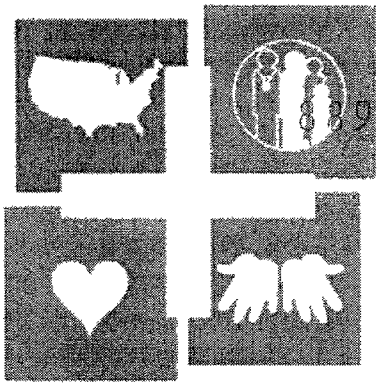

CENTER FOR
PATIENT ADVOCACY

'03 DEC -9 P1:10

Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2003N-0422
Annual Stakeholder Meeting on the Implementation of the Medical Device User Fee and Modernization Act of 2002

Dear Sir/Madam:

My name is Dr. Neil Kahanovitz and I am a practicing orthopedic surgeon and the founder of the Center for Patient Advocacy, a nonprofit, grassroots organization representing the interests of patients nationwide and dedicated to ensuring that American patients have timely access to *safe* and *quality* health care. I am pleased to present our comments and concerns on the implementation of the reuse provisions of the Medical Device User Fee and Modernization Act (MDUFMA).

As an organization representing patients across the country with an active membership of approximately 100,000 patients from all walks of life, the Center is extremely concerned about the safety and efficacy of reprocessed single use medical devices (SUDs). We believe the use of reprocessed SUDs is an inherently risky practice and that reprocessors should be regulated in the same manner and with the same scrutiny as original equipment manufacturers (OEMs). This is absolutely critical to minimize the risks of these devices and help ensure patient safety.

In addition to being the founder of the Center, I am a practicing orthopedic surgeon with more than 25 years of experience treating patients and participating in the clinical research that leads to the development of innovative single use medical devices. As a surgeon, I know first-hand the benefits these products bring to patients. I also know that these devices often are intricate in their design, complex, and are manufactured in a way that does not allow them to be easily cleaned, refurbished, or resterilized. These devices also are composed of materials and component parts that may not safely hold up to more than one use and may not be able to withstand the rigors, including exposure to heat and chemicals, experienced during the reprocessing process. In short, single use devices are not designed to be used again and again.

2003N-0422

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One of the panelists shared an example of how reprocessing can render an SUD unusable and unsafe for patient use. I too have first-hand knowledge of the dangers that can result from reprocessing. I have had a reprocessed SUD malfunction during surgery and some of my colleagues have as well. So I know the dangers these products pose to patients. Patients, however, do not.

A survey conducted for the Center for Patient Advocacy last year found that the overwhelming majority of patients are not aware of reprocessing, nor do they know whether reprocessed SUDs are used during their surgery. That is why the Center for Patient Advocacy launched a nationwide grassroots campaign to educate the public about the practice of reprocessing. It is also why we supported the provisions of MDUFMA that required reprocessed SUDs to be prominently and clearly labeled with the name of the reprocessor. Although I will not go into further detail regarding this provision since it is the subject of a different panel, we believe that it is an important factor that may help patients and their physicians to distinguish an original SUD from a reprocessed one. We also believe this provision will help ensure proper accountability should a reprocessed SUD fail or cause harm to a patient.

Patients and Health Professionals Share Concerns About Reprocessing

Majorities of patients and health care professionals share our concerns about reprocessing. They worry that reprocessed SUDs expose patients to risks that include infection, transmission of disease, diminished device performance and malfunction. In fact, the survey conducted on reprocessing for the Center found that:

- 74% of surgeons believe that single use only medical devices should not be reprocessed.
- 79% of nurses believe that the use of reprocessed SUDs should be discontinued.
- 77% of patients are uncomfortable with the idea of reprocessed SUDs being used in their surgery.

These concerns – from patients and health care professionals alike – help demonstrate why the reuse provisions of MDUFMA were enacted and why it is incumbent upon the agency to see that they are fully implemented and enforced.

Validation Requirements

To help ensure that reprocessed SUDs are substantially equivalent to predicate devices, MDUFMA requires that 510(k)s for certain reprocessed devices include validation data, including cleaning, sterilization, and functional performance data. Validation data also are required for PMA devices subject to reprocessing. We believe it is critically important that the agency implement and enforce its validation guidance in a way that ensures that reprocessed SUDs are held to the same rigorous safety and efficacy standards as are original SUDs. Validation requirements for reprocessed SUDs must be comprehensive. This is especially vital since SUDs are not designed or manufactured by OEMs to be reused. Therefore, the burden of demonstrating whether an SUD can, in fact, be safely reprocessed must fall on the reprocessor.

Moreover, reprocessors should be required to ensure that reprocessing techniques can accommodate design changes made by OEMs. This will require that SUDs subject to reprocessing be evaluated to determine whether design changes have been made and, if so, whether they can be reprocessed safely.

Tracking Reprocessed SUDs/MedWatch Form

"Do You Know Where That's Been?" That is the title of an information packet the Center for Patient Advocacy has made available to patients about reprocessing. Prior to the enactment of MDUFMA, there was really no way for a patient or provider to determine the answer to that question. Equally of concern is that patients and providers – and even reprocessors -- do not know how many times an SUD has been used or reprocessed. However, MDUFMA's tracking provisions and the changes it requires for MedWatch Forms, if appropriately implemented, will help answer these questions. They also will help the agency, and patients and providers alike, to gather adverse event information about reprocessed SUDs – information that has been lacking in part because reports currently do not identify whether a device has been reprocessed. It also is information that could be used to prevent future injuries to patients and could help patients injured by a reprocessed SUD to accurately identify the party responsible for the injury.

While the Center firmly believes that reprocessing inherently poses risks to patients, we also believe that these risks increase each time an SUD is reprocessed. Because of this concern, it is absolutely crucial that reprocessors have controls in place to track the number of times an SUD has been reprocessed. After all, they are required to specify the number of times an SUD can be safely reprocessed in order to market the device in the first place. Reprocessors also should have systems in place to remove devices from the market when they have reached their maximum number of uses.

Bundling

As is the case with reprocessing in general, the Center is concerned about the practice of bundling In short, bundling should not be allowed because not all SUDs are the same. SUDs, even those in the same device class, that are manufactured by different OEMs may include unique biomaterials and component parts. They may be designed and manufactured differently and they may have other technological characteristics that prevent a particular SUD from being safely reprocessed in the same manner as another SUD in the same device class. However, bundling **presumes** SUDs are the same. It presumes, without scientific or clinical evidence, that one size fits all. As a physician, I can tell you that the practice of medicine based on presumptions is dangerous. Medicine, and the development of medical devices, is based on sound science and an examination of the clinical evidence. There is no room for guessing and false assumptions. It is not tolerated. Nor should FDA tolerate assumptions and guessing when it comes to reprocessing. Unless a reprocessor can demonstrate that SUDs made by multiple OEMs are the same or similar with respect to their design, component parts, manufacturing processes and other technological characteristics, bundling must not be permitted.

Promotion/Misbranding

As we at the Center for Patient Advocacy have continued our efforts to educate the public and the press about the practice of reprocessing SUDs, it has come to our attention that the reprocessing industry may be engaged in a coordinated campaign of misinformation -- a campaign that makes

unsubstantiated and false claims about reprocessed SUDs to patients, providers, hospitals and the public.

For example, we are aware of claims that reprocessed SUDs are in some way "better" or "safer" than original SUDs. That they are "reprocessed in an FDA-approved facility" or "meet higher quality standards than original devices." In fact, an executive of one of the largest reprocessors in the country recently was quoted in a news story as saying that reprocessed SUDs are "as clean or cleaner" than original SUDs. We are disturbed that these claims could be allowed. They are false and misleading and constitute misbranding. The FDA has authority to regulate these claims just as it does with claims made by OEMs and pharmaceutical manufacturers. We request that the agency take appropriate action to help ensure that patients and their health care providers are not misled, but afforded the accurate information about their health care they need to make informed decisions.

Perhaps the most alarming effect of these claims is their effect on informed consent. The Center strongly believes that patients have a right to know whether reprocessed SUDs will be used during their surgery and they have a right to refuse the use of these devices. In fact, we have produced a consent form patients can use to request that a reprocessed SUD not be used in their surgery. Unfortunately, false and misleading statements – whether provided directly to patients or to the physicians and hospitals who treat them -- violate the principle of informed consent and must be stopped.

I would like to close by telling you about something recently brought to our attention about our patient consent forms. Although this is anecdotal, we understand that some hospitals may be attempting to avoid complying with these patient consent forms by claiming that reprocessed SUDs are original SUDs because they now are subject to the additional requirements of MDUFMA, including validation data and 510(k) submission requirements. If true, this development is indeed very troubling and I am concerned that hospitals may be taking this action because they are receiving false assurances from the reprocessors themselves about the regulation of the industry and the safety and efficacy of reprocessed SUDs. Again, these types of misleading statements, if they are occurring, must be stopped and appropriate action should be taken to ensure that they do not continue.

Conclusion

Although the Center for Patient Advocacy believes that the reprocessing of SUDs inherently poses health risks to patients, strict FDA oversight of the practice is necessary to minimize those risks and help ensure patient safety. We hope that by working with concerned stakeholders, including patients, providers and manufacturers, the Agency will exercise its statutory authority to ensure that reprocessors are regulated in the same manner and with the same scrutiny as original equipment manufacturers.

Sincerely,

/s/
Neil Kahanovitz, M.D.
Founder