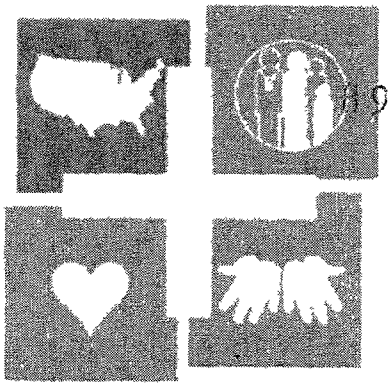

CENTER FOR
PATIENT ADVOCACY

00 '03 DEC -9 P1:41

November 3, 2003

Division of Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2003N-0422

Dear Sir/Madam:

I am writing to register for the December 3, 2003 Annual Stakeholders Meeting on the Implementation of the Medical Device User Fee and Modernization Act (MDUFMA). I also request to make an oral presentation as part of the Panel 5 discussion on the reuse of single use medical devices. Per the instructions provided in the *Federal Register* notice of September 29, 2003, an abstract of the presentation and my contact information are below.

Neil Kahanovitz, M.D.
Founder
Center for Patient Advocacy
1350 Beverly Road, Suite 207
McLean, VA 22101
Phone: (703) 748-0400
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E-Mail: patrickwildman@patientadvocacy.org

Abstract of Presentation (Docket No. 2003N-0422)

The Center for Patient Advocacy is a private, non-profit grassroots organization representing the interests of patients nationwide. With a membership of more than 100,000 individuals from all walks of life, the Center is dedicated to ensuring that American patients have timely access to

2003N-0422

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quality and safe medical care. The Center is extremely concerned about the safety and efficacy of reused single use medical devices (SUDs); whether certain SUDs can be safely reprocessed; and the appropriate regulation of medical device reprocessors by the Food and Drug Administration.

Information – MDUFMA Labeling Requirements:

As an organization dedicated to patient empowerment, the Center believes that patients have a right to know whether a reprocessed SUD will be used in the course of their treatment. We have conducted research that demonstrates the vast majority of patients are not aware of the practice of reprocessing SUDs, nor do they know whether those devices are being used during their surgeries. Because of this, we supported provisions of MDUFMA that required reprocessed SUDs to be clearly and prominently labeled with the name of the reprocessor. We believe this labeling requirement is an important factor that *may* help health care providers to distinguish between a reprocessed SUD and an original one. However, it may only help health care providers, not patients. Therefore, the implementation of this requirement by FDA is one area we intend to address in further detail during our presentation.

Safety and Efficacy – MDUFMA Requirements for Critical and Semi-Critical Reprocessed SUDs:

As previously mentioned, the Center is extremely concerned about the safety and efficacy of reprocessed SUDs. The potential risks to patient health posed by the use of reprocessed SUDs may include infection, transmission of disease, diminished device performance and malfunction. Our research has found that both patients and health care providers are concerned about the safety of reprocessed SUDs and majorities of both are opposed to the practice because of these concerns. In an effort to minimize the risks of reprocessed SUDs, the Center supported MDUFMA's requirements calling for stricter FDA regulation of reprocessors to ensure the safety and efficacy of reprocessed SUDs and their substantial equivalence to predicate devices. However, we are concerned about FDA's implementation of these provisions. For example, we are concerned that FDA may not have fully identified those *critical* reprocessed SUDs, whose exemption from premarket notification requirements will be terminated and for which reprocessors must submit validation data and other required elements of 510(k)s to ensure their substantial equivalence to predicate devices. Similar concerns exist with the identification of reprocessed SUDs already subject to 510(k) submission requirements. We also would like to submit our comments and concerns as FDA works to identify, by April 26, 2004, those *semi-critical* reprocessed SUDs whose 510(k) exemptions will be terminated.

In our oral presentation, the Center also intends to discuss concerns we have about the implementation of requirements for reprocessors to submit validation data regarding cleaning, sterilization, and functional performance of reprocessed SUDs. Specifically, we are concerned that the validation data may not provide sufficient evidence that reprocessed SUDs are substantially equivalent to their predicate devices.

The concerns outlined above represent some of the issues we intend to address in our presentation. 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 vigor as original equipment manufacturers.

Should you have any questions or require additional information regarding this registration, please do not hesitate to contact me or Pat Wildman of the Center at (703) 748-0400, ext. 28, or patrickwildman@patientadvocacy.org.

Sincerely,

Neil Kahanovitz, M.D.
Founder