



AMERICAN SOCIETY OF ANESTHESIOLOGISTS

SECTION ON CLINICAL CARE

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

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September 10, 2002

To Whom It May Concern:

This letter is written on behalf of the American Society of Anesthesiology (ASA) in response to the Food and Drug Administration's (FDA) call for comments on "Medical Devices; Needle-Bearing Devices; Request for Comments and Information (21 CFR Part 880, [Docket No 01P-0120], RIN 0910-ZA20). The ASA's members are front line healthcare workers with regard to concerns related to bloodborne pathogens. Needlestick injuries are of vital interest to our members and we have undertaken extensive educational and practical efforts to improve safety in this area. This specific issue is followed closely by our society and we wish to take this opportunity to respond to the FDA's advance notice of proposed rule making.

ASA has been and remains supportive of engineered sharps injury protection (e.s.i.p.) needleless systems, and the other elements of the Bloodborne Pathogens Standard (29 CFR 1910.1030). However, we also recognize that there must exist the possibility of utilizing alternatives to the "safe" items specified in the Standard when available needleless systems or sharps devices with e.s.i.p. would compromise the patient's care or safety.

As anesthesiologists, we are often called to start IVs when others have failed. Frequently "safety catheters" are not the best tool for a specific clinical situation. This is particularly true in the operating room, emergency room, intensive care units, and labor and delivery areas, where intravenous access is often an emergency and the equipment with the highest chance of success must be immediately available. Safe patient care mandates that a variety of equipment be available to permit the health care worker on the "front lines" to make the decision of which is most appropriate to use. It is our view that banning of all of the listed devices, in particular IV catheters and certain blood collection needle sets ("butterfly syringes"), has the potential of compromising patient care in these circumstances.

We would further note that there are numerous tasks required for the practice of anesthesia, for which there are no practical safety devices. Examples of such tasks include spinal, epidural, and other regional anesthesia techniques, and various arterial and central venous access procedures. In order to provide good patient care, we must use the devices available and practice stringent safety techniques. It would be inappropriate to ban these instruments, tools or techniques, as requested in the petition from HRG and SEIU

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In addition, we would like to voice our support of the FDA's response to the petition that there was insufficient information to constitute a legal basis for banning because the devices do not present a "substantial risk of illness or injury."

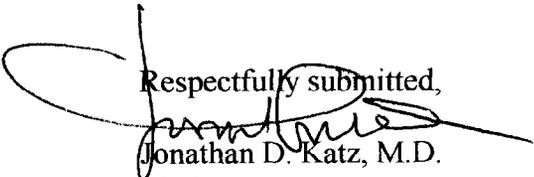
Finally, we agree with FDA that it is unnecessary to label all syringes with the disclaimer mentioned. This information is well known to health care professionals.

As a professional society with a strong stake in occupational safety, we will continue to reduce our use of equipment or techniques that are "unsafe" with regards to the risks of bloodborne pathogens. We look forward to changes in technology that will continue to provide improvements in safety without compromising patient care. We support the use of e.s.i.p. devices where appropriate. However, we can not support the banning of equipment that can be vital in specific settings.

We urge the FDA to consider careful testing and evaluation of new products with regards to claims of "safety". When doing so, we hope that a broad representation from all specialties be included needs may differ among the various groups. This will better protect healthcare workers as well as our patients.

Thank you for the opportunity to comment on this matter.

Respectfully submitted,


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Chair

Committee on Occupational Health
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Task Force on Infection Control
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