



September 17, 2002

Lester Crawford, D.V.M., Ph.D.
Acting Administrator
Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 01P-0120 – Medical Devices; Needle-Bearing Devices; Requests for Comments and Information

Dear Dr. Crawford:

On behalf of the 1,600 leading not-for-profit hospitals and health systems allied in Premier, Inc., we appreciate the opportunity to respond to the Food and Drug Administration’s request for information on **Medical Devices; Needle-Bearing Devices**, as published in the June 20, 2002 *Federal Register*. Premier is a strategic alliance of approximately 215 independent, not-for-profit owner health systems that operate or are affiliated with more than 1,600 hospitals and healthcare sites nationwide. Premier is headquartered in San Diego, CA, with offices in Chicago, IL; Charlotte, NC; and Washington, DC.

Integral to the alliance’s goal of improving the health of communities, Premier offers a selection of sharps safety devices from 15 manufacturers to help protect healthcare workers from bloodborne infection stemming from percutaneous contact; i.e. sharps-related injuries. In doing so, Premier assists its allied hospitals in meeting the requirements of the Needlestick Safety Prevention Act, an initiative in whose crafting we were privileged to play a collaborative, advisory role. Premier also supports efforts to educate all frontline healthcare workers on strategies to reduce the risk of needlestick injuries. To that end, Premier’s Safety Institute Web site, at www.premierinc.com/safety, offers extensive resources and tools for implementing facility-based sharps injury prevention programs. The Web site is password-free and available to the public.

Please accept our comments with respect to the following issues, as outlined in the FDA request:

- Banning
- Performance Standard
- Labeling

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Banning

Premier believes that banning sharps devices that pose a significant occupational safety risk is appropriate and permissible *only* where and when sufficient alternative “safety” devices are readily available in the marketplace. For example, the marketplace currently supports sufficient alternatives to glass capillary tubes and conventional IV infusion equipment (i.e., non-glass or wrapped glass capillary tubes and needleless IV infusion systems). Therefore, we believe a ban on the former could conceivably contribute to healthcare worker safety without adversely impacting the performance of clinical or laboratory procedures. However, at present, the marketplace does not avail caregivers of sufficient devices *alternative* to IV catheters that are, in fact, appropriate for all patient populations, like low birth-weight neonates. A ban on all IV catheters that do not meet the criteria established in FDA’s April 16, 1992 safety alert could have the unintended effect of severely restricting or even eliminating the availability of such devices for use with specialized populations (i.e., newborns with low birth-weight). Consequently, clinical procedures could be compromised.

Regarding any bans on blood collection devices, we would urge the FDA to consider the multitude and diversity of such devices available in the marketplace, and how these devices are used in combination. Some use a standard, conventional needle with the “safety feature” built into the holder. In other devices, the “safety feature” is integral to the needle itself, and a standard holder is used. Since needles *and* tube holders may be engineered with “safety technology,” the demand and need for *both* standard/conventional needles *and* standard/conventional holders exist. A ban on either could conceivably limit the options for use of these safety devices. While we recognize that clinicians’ use of the standard needle and standard holder may pose a greater risk of injury, Premier believes that inappropriate device use ought to be an enforcement responsibility, incumbent upon OSHA. The agency’s attention to the reduction of sharps-injury risk during blood collection is evident in its recent ban on removal of contaminated needles from tube holders. Finally, we are concerned, in general, that safety alert language for needle-bearing devices that is highly prescribed cannot conceivably foresee or appreciate the nature of future technological advance, and could, therefore, have a hampering effect on innovation.

Performance Standard

Again, Premier believes that the establishment of specific criteria in the performance standard arena could inhibit new innovative technologies. We are committed to the promotion of innovation, and ensuring that our allied hospitals have access to the safest, most technologically advanced products. Between 1999 and 2001, Premier’s Safety Institute conducted field evaluations of sharps safety devices to identify performance considerations that would contribute to innovation in future product design (see attached summary). The results of our field evaluations and the performance considerations identified therein serve as guidance *only*, and do not identify any “best” devices. In that vein, Premier is concerned that the establishment of overly prescriptive standards that leave little room for amendment or flexibility could limit the introduction of new and innovative healthcare technology. However, we are eager to work with FDA to establish voluntary guidelines, under the assumption that no single device can conceivably be considered “best” or “safest.” As does FDA, Premier, too, recognizes the difficulty in developing specific performance criteria for safety devices, and the challenges of

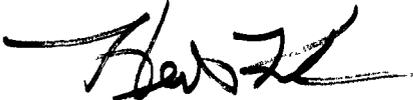
injury data collection to determine the efficacy of such devices in preventing needlesticks. (See the attached "Evaluating Sharps Safety Devices: Meeting OSHA's intent," *Infection Control and Hospital Epidemiology*; July 2001.)

Labeling

The labeling of devices with warnings about their intended use is appropriate only when and where sufficient alternatives exist. The Premier Safety Institute recently completed a field evaluation of 17,000 safety phlebotomy devices (from five different manufacturers), involving 580 clinicians and phlebotomists in 25 hospitals (see attached summary). A significant number of participants commented on the need for a "special" syringe for use in drawing blood from "difficult" patients (for example, those with collapsed veins) when vacuum blood tubes and phlebotomy needles were inappropriate and/or insufficient. Without appropriate alternatives, a warning against the use of conventional syringes could be problematic. Furthermore, future safety technologies that address this issue may not fit into the proposed "performance standards," such as features that prevent needlesticks, but are not an integral part of the device. Under the proposed rule, as written, such a device would be banned.

Finally, Premier supports all efforts to reduce the risk of accidental sharps injury and applauds FDA's actions to date, including its numerous guidance documents, safety alerts, and educational activities. We thank you for the opportunity to offer our perspective, and look forward to working with you on an issue so critical to the safety and wellbeing of both caregivers and patients. If you have questions or would like to discuss our comments further, please contact Gina Pugliese, vice president, Premier Safety Institute, at 630.891.4863.

Sincerely,



Herb Kuhn
Corporate Vice President
Premier

Attachments