

September 13, 2002

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

RE: RIN 0910-ZA20

Dear Sir:

The University of Iowa Hospitals and Clinics is pleased to have the opportunity to provide comments on the notice of proposed rulemaking regarding needle-bearing devices published in the June 20, 2002 *Federal Register* (pages 890-892). It is our belief that the ultimate goal of these rules should be to enhance and promote utilization of the correct product in the appropriate clinical situation.

Our specific comments with respect to (A) banning, (B) performance standards, and (C) labeling are as follows:

**A. Banning**

IV Catheters

Standard Teflon and polyurethane over the needle catheters are used for procedures other than peripheral IVs. Syringes are placed on the end and the needles are used as chest tubes in neonates, paracentesis, arterial lines, etc. There are times that IV access in very small neonates is difficult with the safety IV catheters and standard IVs are needed. To eliminate them totally would impede medical procedures. Also, as more institutions change to safety products, there is a learning curve to consider. Not being able to gain IV access in a patient could result in a negative patient outcome.

OIP-D120

Blood Collection Devices (needles and tube holders)

Standard blood draw needles (those with a rear latex-covered needle to puncture the blood tubes) are used for solely one purpose. There are a number of safety needles available for drawing blood. As long as the manufacturers of these safety blood draw needles are able to supply the entire nation, standard blood draw

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needles are not needed. Blood tube holders do not cause injuries, the needles do. Not removing needles from standard holders should decrease the risk of a needlestick.

Blood collection needle sets  
("butterfly syringes")

There are butterfly needles (steel needle with wide wings), but not butterfly syringes. Butterfly needles are used for both blood draws and for short-term IV infusions. Before standard butterflies are eliminated, safety butterflies need to be developed to meet user needs. There are currently four products available. Not all can brands can be used for infusion and even the safety butterflies do not eliminate injuries.

Glass capillary tubes

We have been unable to find mylar-coated capillary tubes with balanced heparin in them. These are used for blood gases and allow for a number of additional lab tests to be performed on the same blood sample.

IV infusion equipment that does not use needleless technology or recessed needles

Standard IV infusion sets with y-sites can be used without a needle per the 4/16/1992 FDA safety alert. The y-sites can be accessed safely by either using a protected recessed needle or by adding a needlefree adaptor to the y-site. Many companies make these adaptors which work on standard IV tubing for both giving IV push medication or for connecting one IV line to another. Other institutions may choose to use stopcocks for IV connections or IV push. Heparin lock (intermittent IV) access with a needle is not necessary. Its use can be eliminated (per FDA 4/16/1992 alert) by using a needlefree dead-end cap. Heparin locks **cannot** be eliminated until all pharmaceutical companies make prefilled syringes with a needle. Users of needlefree IV tubing may need to use a heparin lock to administer a drug that comes in a prefilled syringe with a needle that is fixed (not removable). Although rare, it is a very real possibility and could affect the timely and safe administration of live-saving drugs.

### General comments:

- Before standard products are eliminated from all use, it must be evaluated whether or not there are adequate safety-engineered substitutes and if there is adequate supply for the entire United States.
- Epinet data for 1998 included 3,180 injuries. Of those, 1,070 (34%) occurred “before use” or “during use”. Safety products will not eliminate the risk of injuries as long as sharp items are required for medical procedures. 333 (19%) of injuries were “between steps,” and it is questionable whether or not a safety-engineered sharp would have prevented the injury.
- Regarding Epinet data supporting the HRG/SEIU request:  
**Syringe injuries:** 33% of injuries were with syringes – (1) disposable syringes accounted for 919 (29%) injuries (syringes do not cause injuries, it is the needle that is placed on the syringe that is the risk); (2) prefilled cartridge syringe accounted for 70 (2%) of injuries. Prefilled cartridge syringes are drug-filled syringes produced by pharmaceutical companies over which institutions often times have no control; and (3) blood gas syringes accounted for 46 (1%) of injuries. These are specialty syringes.  
**Capillary tubes:** There were 4 out of 3,180 injuries related to capillary tubes, use of which are minimal in the healthcare setting.

### B. Performance Standards

Each device is unique and, as technology advances, it is difficult to identify one set of criteria for all products that pose a possible risk.

### C. Labeling

Request that the FDA require that the labeling for “conventional syringes” state: “TO PREVENT POSSIBLE EXPOSURE TO HIV AND HEPATITIS, DO NOT USE FOR STANDARD BLOOD DRAWS.”

Syringes do not cause injuries. It is estimated that only 25-30% are even used with a needle that will be contaminated with blood or other infectious body fluid.

Syringes (usually 10 cc or larger) are often used when drawing blood from central lines and arterial lines. Syringes attached to safety butterflies are how blood cultures and blood draws in children < 1 year old are routinely performed. These are very common, frequently performed tasks. Once the blood draw is complete, the blood is transferred to a blood tube. It is the transfer of the blood into the blood tube that poses a hazard. There are transfer devices available for this purpose.

If HRG/SEIU are referring to blood draws using a standard needle attached to a syringe, that is a highly uncommon practice. Blood draw needles and butterflies as noted in “A” above are most commonly used. Safety needles are available in the size a user would need if they did draw blood this way.

Most conventional syringes are used for various other procedures and mandating a label that only referred to a minimally used application does not seem effective.

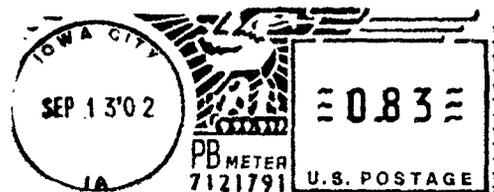
Your consideration of these comments will be sincerely appreciated. Please do not hesitate to contact me if additional information is desirable.

Sincerely,

A handwritten signature in black ink, appearing to read 'DKB', written in a cursive style.

Donna Katen-Bahensky  
Director and Chief Executive Officer

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