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June 24, 2002

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

RE: 21 CFR Part 880 [Docket number 01P-0120]

To Whom It May Concern:

I read with great concern the published notice requesting comments on the petition filed by Public Citizen's Health Research Group and the Service Employees International Union.

I implore you not to ban any currently marketed items from use. The Needlestick Prevention Act ("the Act") requires employers and employee representatives to jointly review all new sharps devices entering the market. Under the Act, employers must provide an engineered control device unless: 1) nothing is available, 2) safety of the patient is compromised, 3) safety of the employee is compromised or 4) the item is not as safe as what is on the market. Therefore, the petition before you would prohibit the use of devices that employees in the evaluation group may deem *safer* than the engineered controls. I encourage you to leave the decision-making with the clinical personnel performing the work.

Further, I would request that you not establish performance standards in relation to the five design criteria identified by the FDA safety alert. Clinical personnel are extensively trained in safe processes and procedures. These clinical personnel are able to readily identify risks and concerns as they apply in the clinical environment. I have a grave concern that the varying needs for different uses and specialties may be blurred in attempts to develop a single standard or set of immutable standards to apply across all specialties and uses. I encourage you make no changes in the current regulations, to allow nurses and physicians to select the right equipment for their patients.

Last, I hope that you will not impose warning labels on syringes. Most syringes are too small for the warning to be effective while allowing proper visualization of the dosage drawn. Additionally, the language proposed implies that proper use may create an exposure, whereas a needlestick is necessary to create the exposure. [As a matter of clarification, syringes often come without needles pre-attached. Therefore, labeling the syringe is inappropriate, as a needle with an engineered control may be attached prior to use. Therefore, it would be the needles that would have to be labeled, which is ludicrous.]

Thank you for the opportunity to provide this feedback.

Sincerely,



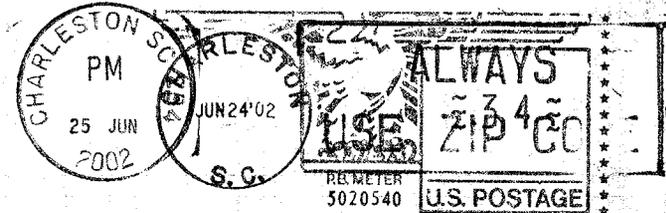
Amanda W. Smith, MBA
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