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Joan Claybrook, President

October 11, 2002

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

Re: Medical Devices; Needle-bearing Devices; Request for Comments and Information

Almost two years ago, on November 29, 2000, Public Citizen and the Service Employees International Union wrote to the Food and Drug Administration (FDA) petitioning you to (1) remove from the market all unsafe intravenous (IV) catheters, blood collection devices, blood collection needle sets ("butterfly syringes"), glass capillary tubes and IV infusion equipment; (2) issue performance standards to ensure that new unsafe devices of these kinds do not enter the market; and (3) issue a labeling requirement for syringes that do not adequately protect the user from bloodborne pathogens. The Advanced Notice of Proposed Rulemaking (ANPR) published in the Federal Register of June 20, 2002, is the agency's response to that petition.

In part, the agency is seeking device-specific needlestick rates, data that are notoriously hard to find. EPINet, coordinated by the University of Virginia, does not collect data for particular branded devices involved in needlestick injuries. It does collect information on the type of device (e.g., IV catheter) and whether it had a safety feature. Moreover, the data collection form designed by EPINET, available at <http://www.med.virginia.edu/medcntr/centers/epinet/forms/SOI2001.PDF>, does contain a space for the brand name of the device; it is likely that hundreds of hospitals are using this form, even though they do not report the brand name to EPINet. The Centers for Disease Control and Prevention (CDC) collect information on the type of device and the general type of safety feature (active/passive), if any, for the device implicated in the needlestick injury, although again not the specific brand name. There is thus an abundance of data on the types of devices associated with injuries, even if the data are not characterized by a particular company's product. If the FDA is serious about collecting device-specific data, it will contact these sources to get as much data as possible and urge them to collect the detailed device-specific data it wants.

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In submitting the comments below, we do not in any way endorse the ANPR as an adequate response to our petition. The limited nature of the agency's response calls to mind the comment of the D.C District Court in 1983 in a case involving the Occupational Safety and Health Administration's failure to adequately regulate ethylene oxide: by issuing only an ANPR, said the court, OSHA had "embarked on the least responsive course short of inaction."¹

Nonetheless, we have conducted a PubMed search of the literature published since our November 2000 petition to determine whether any additional information about this serious threat to the health of workers has come to light. We focused on studies that produced quantitative data on the efficacy of safety devices in reducing the incidence of needlestick injuries. Our review shows that not a single study published since our petition has directly evaluated the devices covered by our petition, and that the new studies address devices not mentioned in our petition. In the course of this research, we also identified older empirical studies of devices not mentioned in our petition and include descriptions of these as well, because the FDA notice was not restricted to the devices mentioned in our petition.

Evaluations of devices mentioned in our petition

In our search, we encountered a study of a self-capping IV catheter that had not come to our attention during the writing of our petition.² A self-capping IV catheter was introduced in an emergency medical service and needlestick rates examined for the ten months before and after the switch-over to the safer devices. The incidence of contaminated needlesticks per year decreased from 169/100,000 attempts to start an IV catheter to 0/100,000 ($P < 0.005$).

Evaluations of devices not mentioned in our petition

a. Retractable lancets

In another emergency medical system study, self-retracting glucometer lancets were implemented.³ Needlesticks related to these lancets decreased from 17/1,000 worker-years to 4/1,000 worker-years ($p < 0.05$).

b. Anesthetic syringes

Safer syringes for the administration of anesthesia in the dental setting have also been developed. In one study, there was no change in the rate of needlestick injury after the safer device was introduced.⁴ In another, the needlestick rate was reduced from 12/1,000,000 hours worked to 0/1,000,000 hours worked after a safer syringe was introduced; there was no change in a comparison unit.⁵

c. Blunt surgical needles

We examined two randomized studies in which blunt surgical needles were compared to standard

surgical needles. In one, there was a significant decrease in both needlestick injuries and instances of glove perforation during laparotomy closure in the blunt needle group compared to the sharper needle group.⁶ In another study, surgeons were similarly randomized to sharp or blunt needles during hip arthroplasty; the blunt needles had a statistically significantly lower rate of perforations (13% vs. 26% of outer gloves were perforated).⁷

d. Needle covers

One study evaluated the effectiveness of a needle cover system, which permitted one-handed recapping of used syringes.⁸ The rate of needlesticks that would be expected to be reduced by the needle cover was decreased by 60% (95% CI: 18%-82%), while the rate of needlesticks not susceptible to reduction by this device remained essentially constant.

Evaluations of multi-component interventions

Our search identified two new evaluations where more than one safer device was introduced. In the first of these, both safety syringes and needleless IV systems were introduced in a metropolitan hospital.⁹ Needlestick rates declined after the transition to the safer devices ($p < 0.001$ for before-after comparison). However, there was also a decline in needlestick rates prior to the transition and device-specific rates were not available.

In the second study, researchers surveyed 2,287 medical-surgical nurses in 22 U.S. hospitals (response rate: 56%) and asked them about their needlestick histories and also about workplace conditions, including use of safer devices.¹⁰ In logistic regression, use of safer blood-drawing equipment was associated with a 31% reduction in needlesticks. Capless valve IV systems and safer IV catheters were associated with decreased odds of “near-misses.”

Reviews of device effectiveness

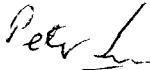
Our search also identified two review articles. The Cochrane Collaboration, which only synthesizes data from randomized trials, conducted one of these.¹¹ After reviewing such trials, some of which are included in these comments and others of which appear in our petition, the authors concluded: “Studies evaluating the effectiveness of engineering control interventions, particularly sheathed and self-capping needles, needleless intravenous systems, blunt suture needles, and needle covers, have shown significant reductions in [needlestick injuries]. Continued development of effective engineering approaches will be the best protection for the worker through elimination of needle exposure.”

The second review was conducted by the American Medical Association’s Council on Scientific Affairs.¹² The review concluded: “Scientific data now indicate that the appropriate use of needlestick prevention devices, especially in comprehensive prevention programs, significantly reduces the incidence of needlestick injuries.”

Conclusion

In sum, the data reviewed in this letter underscore the demonstrated effectiveness of a number of safer medical devices and suggest that at least some unsafe devices not subject to our petition, particularly non-retractable lancets, could now safely be removed from the market. Ordinary surgical needles should be relabeled to suggest to users that they use blunt needles whenever possible. Rather than using protracted information-gathering as a substitute for action, it is time for the FDA to act decisively and remove unsafe devices from the market wherever feasible.

Yours sincerely,



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Public Citizen's Health Research Group

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