

# COOK<sup>®</sup>

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September 17, 2002

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

Re: Docket No. 01P-0120—June 20, 2002 Advanced Notice of Proposed Rulemaking, Needle-Bearing Devices

Dear Sir or Madam:

FDA issued the above-referenced Advanced Notice of Proposed Rulemaking regarding Needle-Bearing Devices in order to determine what additional actions, if any, the agency should take to protect healthcare workers from needlestick injuries from medical devices. *See* 67 Fed. Reg. 41,890 (June 20, 2002). The notice was issued in part to respond to a petition submitted jointly by Public Citizen's Health Research Group (HRG) and the Service Employees International Union (SEIU), which requested that FDA take certain actions the petitioners believed would further reduce the risk of needlestick injuries to healthcare workers. Specifically, the petition requested that FDA ban a number of devices, establish performance standards for certain devices and require a labeling statement on conventional syringes advising against use for standard blood draws. For the reasons detailed below, we oppose all three requests. However, if FDA decides that it is appropriate to pursue establishing a performance standard for devices that pose a danger of needlestick, we request the opportunity to participate in the process.

**I. Banning Certain Medical Devices in an Effort to Eliminate Needlestick Injuries is Inappropriate**

Numerous device bans, or even a single device ban, is not a remedy well suited to address needlesticks as it would unnecessarily deprive healthcare professionals and patients of access to effective medical devices and thereby adversely affect the public health. Further, the banning process is cumbersome and inefficient and not the best use of the agency's resources to address the petitioners' concerns. Moreover the legal standard for initiating a ban has not been met substantively and will be very difficult to meet procedurally. Finally, an alternative remedy, OSHA's amended bloodborne pathogens standard, has been promulgated and should be given time to take effect before draconian solutions are implemented.

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**A. The Proposed Ban Would Deprive Patients of Effective Care**

The petitioners propose that the following devices be banned, if they do not meet certain design criteria: catheters, needles, tube holders, butterfly syringes, capillary tubes and IV infusion equipment. Banning these large categories of devices would remove from use many effective devices that are widely used as the standard of care without first ensuring that appropriate alternatives exist. Such a ban would be detrimental to patients and the public health. In contrast, in the only device ban regulation ever promulgated, relating to prosthetic hair fibers, FDA made a specific finding that the device was not and could not be effective for its intended purpose and provided no benefit to the public health. *See* 48 Fed. Reg. 25,126, 25,127 (June 3, 1983). Further, FDA has many other more efficient enforcement tools at its discretion, such as mandatory and voluntary recall, correction and removal, and seizure authorities, that are more specifically targeted and would not result in as much disruption to patient care. Given how the device ban authority has been employed in the past, and the accumulation of enforcement options at the FDA's disposal particularly since the Safe Medical Devices Act of 1990, initiating a ban should be an action of absolutely last resort.

**B. The Standard for Initiating a Banned Device Proceeding Has Not Been Met**

Section 516 of the Food, Drug, and Cosmetic Act ("Act") provides that FDA may "initiate a proceeding to promulgate a regulation" to ban a device when it finds, "on the basis of all available data and information, that –

- (1) a device intended for human use presents substantial deception or an unreasonable and substantial risk of illness or injury; and
- (2) in the case of substantial deception or an unreasonable and substantial risk of illness or injury which the Secretary determined could be corrected or eliminated by labeling or change in labeling and with respect to which the Secretary provided written notice to the manufacturer specifying the deception or risk of illness or injury, the labeling or change in labeling to correct the deception or eliminate or reduce such risk, and the period within which such labeling or change in labeling was to be done, [and] such labeling or change in labeling was not done within such period

Section 516(a) of the Act.

Importantly, the petitioners do not argue that the types of devices present substantial deception. We agree. In the only case of a banned device, discussed above, FDA found substantial deception because prosthetic hair fibers could not be used safely or effectively for their intended purpose regardless of the labeling. 48 Fed. Reg. at 25,127, 25,134. Here, the

devices at issue are effective for their intended uses, and as found by FDA, professionals are acutely aware of the danger such devices present.

**1. Petitioners have not made a showing that the devices they seek to ban present a substantial and unreasonable risk of illness or injury**

The petitioners have failed to demonstrate an unreasonable and substantial risk of illness or injury. They do not provide specific data that are sufficient to determine the unreasonableness and substantiality of the risk of illness or injury for each or indeed for any of the types of devices they seek to ban. The regulations provide that in determining whether the risk posed by continued marketing is substantial, the benefits to the public health must be compared. 21 C.F.R. § 895.21(a)(1). Specifically, the regulations make clear that before FDA may initiate a proceeding to ban a device, the agency must find that the continued marketing of the device presents a risk that is important, material, or significant in relation to the benefit to the public health from the continued marketing of the device. The reasonableness of a risk posed by a device is also customarily evaluated by comparing the risk to anticipated benefits from the device. Such analyses for the devices at issue will differ depending upon the patient group, type of facility, type of procedure and possibly a number of other variables. Moreover, an analysis must be done for each specific device, because different features of devices within a type may change a device's risk profile. The petition did not show, as FDA properly recognized, which specific types of devices were used, how many devices of that type were used during the relevant time period surveyed, what the design characteristics of those devices were, or whether the devices met any or all of the design criteria listed. 67 Fed. Reg. at 41,892. Thus, insufficient data and information were presented in order to analyze each type of device.

The risk analysis necessary before initiating a proceeding to ban a device should also take into account what alternative devices are legally available to maintain the benefits to the public health provided by the device to be banned. In the case of the prosthetic hair fiber ban, the analysis was simple because the ineffective fibers were found to provide no public health benefit. This is a very different case. The petitioners do not allege that the catheters, needles, tube holders, butterfly syringes, capillary tubes and IV infusion equipment are ineffective or that they fail to provide a public health benefit. Further, it is not clear that the alternatives touted as being superior are actually so. As HRG and SEIU acknowledge, there have been numerous reports implicating needleless IV systems in patient bacterial infections. *See* HSG/SEIU Petition at section 3. OSHA has explicitly recognized that "safer" alternatives need to be evaluated in specific situations before they can be adopted as a solution. *See* 29 C.F.R. § 1910.1030(c)(1)(iv)(B); 66 Fed. Reg. 5318 (January 18, 2001). In sum, part of the ban determination is a balance of risk and benefits – if the alternatives also present significant risks, the calculus may shift in favor of the device sought to be banned. Insufficient information has been presented to make a risk/benefit determination for each device, and thus it has not been demonstrated that the devices present a substantial and unreasonable risk of illness or injury.

**2. The Commissioner should consult with an expert panel before initiating a proceeding to ban a device.**

FDA has the discretion to consult a panel that has expertise in the type of device being considered for banning before proposing a banned device regulation. 21 C.F.R. § 895.21(b). The panel need not approve the proposal, but should be consulted beforehand and given the opportunity to respond to a banning proposal. Even though a panel consult is discretionary, given the draconian nature of a ban FDA should avail itself of this resource to ensure that its decision is as well informed as possible.

**3. No attempt has been made to address any alleged unreasonable and substantial risk of illness or injury with labeling changes**

Under the statute, the Secretary must determine whether the deception or risk can be addressed with labeling before initiating a ban.<sup>1</sup> If it can, the Commissioner must notify the person responsible for labeling the device of the required change in labeling. Only if the relabeling is not accomplished within a reasonable time may the Commissioner initiate a ban and take further steps as appropriate. Here labeling, including emphatic warnings, would appear reasonable, assuming such warnings are necessary to avoid needle sticks. Given the public health implications of removing so many effective and widely utilized devices from use, it is especially important that the procedural dictates of the statute and regulations be followed with regard to these products.

In sum, it is clearly premature to initiate a banned device procedure because a determination of substantial and unreasonable risk cannot be made on the basis of the data and information presented, and no determination about whether labeling can address the risk of needlestick for each type of device has been considered, let alone made.

**C. The Procedure for Banning a Device is Cumbersome, Expensive and Not Likely to be an Efficient Means of Addressing the Needlestick Issue.**

HRG and SEIU's apparent view is that the procedure for banning a device is a simpler, faster means of addressing the needlestick issue than what it calls "OSHA's process-heavy approach" which, it argues, "will not result in the immediate removal of unsafe devices from the market, even where there are well-recognized, safer alternatives." HSG/SEIU Petition at section 5. As demonstrated by the required steps for initiating the proceeding to ban a device, outlined above, their view is misguided. Even assuming that there is a health risk, initiating a proceeding to ban a device should not be FDA's first choice for addressing health risks presented by devices. In the case of the ban on prosthetic hair fibers, which occurred almost twenty years ago, the administrative record shows that numerous regulatory actions were taken first, *i.e.*, detentions,

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<sup>1</sup> This reasonably clear language of the statute is reinforced by the legislative history which states that FDA "must make a positive determination that labeling changes would not be sufficient to correct or eliminate the substantial deception or unreasonable and substantial risk of illness or injury associated with use of the device." H.R. Rep. 94-853 at 19 (1976).

seizure, injunctions, and a nationwide investigation of all manufacturers of the device before the proceeding to ban the device was initiated. FDA was clearly alarmed and took a substantial number of actions prior to even pursuing a ban. Any proceeding involving the devices petitioners wish to ban will be even more cumbersome and expensive given the sheer number of types of products, their effectiveness and necessity, and the relatively small number of needlestick injuries reported. If any individual device or type of device is determined to be a hazard, FDA has a number of more efficient enforcement options at its disposal, such as mandatory and voluntary recalls, and seizures to remove a hazardous device from the market more quickly and efficiently.

**D. Other Mechanisms, Such as OSHA's Bloodborne Pathogen Rule Are Likely to be More Efficient and Should be Given Time to Work**

OSHA's bloodborne pathogens ("BBP") standard was recently amended specifically to reduce needlestick injuries,<sup>2</sup> and FDA "provided input and comment to OSHA during the drafting of the standard."<sup>3</sup> The standard represents a thoughtful, deliberate approach and should be given a chance to be effectively implemented and evaluated before additional federal action is taken. The amended rule requires employers to annually review and update their Exposure Control Plans, specifically in order to "reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens." 29 C.F.R. § 1910.1030(c)(1)(iv). Employers must also annually document "consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure." Id.

The preamble to the standard states that this consideration and implementation of safer medical devices, "would include, but would not be limited to, newly available medical devices designed to reduce the risk of percutaneous exposure to bloodborne pathogens. Consideration and implementation of safer medical devices could be documented in the Exposure Control Plan by describing the safer devices identified as candidates for adoption; the method or methods used to evaluate devices and the results of evaluations; and justification for selection decisions." 66 Fed. Reg. at 5319. Further, the revised Exposure Control Plan requirements make clear that

employers must implement the safer medical devices that are appropriate, commercially available, and effective. No one medical device is appropriate in all circumstances of use. For purposes of the standard, an 'appropriate' safer medical device includes only devices whose use, based on reasonable judgment in individual cases, will not jeopardize patient or employee safety or be medically contraindicated. Although new devices are being continually introduced, OSHA recognizes that a safer device may not be available for every situation. . . . Furthermore, the revised requirements are limited to the safer medical devices that

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<sup>2</sup> The amendments to the regulation were mandated by the Needlestick Safety and Prevention Act, Pub. L. 106-430, signed November 6, 2000, by President Clinton.

<sup>3</sup> FDA's September 5, 2001 Response to HRG's Citizen Petition, page 5.

are considered to be 'effective.' For purposes of this standard, an 'effective' safer medical device is a device that, based on reasonable judgment, will make an exposure incident involving a contaminated sharp less likely to occur in the application in which it is used.

Id. at 5319. HRG/SEIU's petition lacks similar consideration for the effect upon patient care that completely removing from use and attempting to replace certain devices would have.

The BBP standard also acknowledges that employee input is critical to identifying, evaluating and selecting effective engineering and work practice controls, including new devices. *See* 29 C.F.R. § 1910.1030(c)(1)(v). It requires employers to solicit input on engineering and work practice controls from non-managerial workers responsible for direct patient care, who have the most potential exposure to needlestick injuries. While one reason for this view was employee resistance to new devices that may require a change in technique, two other reasons illustrate the problems with banning certain devices and expecting others to safely, effectively and instantaneously fulfill their roles. The other two barriers that "participation of frontline workers" can help to overcome are:

- Equipment compatibility problems. With the broad array of devices being used in healthcare settings, it is critical to ensure that devices will work together when necessary.
- The need for continued evaluation of devices and the allotment of sufficient time for adequate device evaluation. After initial use by employees, some facilities found it necessary to replace the device originally selected with a more suitable device.

66 Fed. Reg. at 5320. These issues indicate that a ban could be dangerous and jeopardize patient care because equipment compatibility problems and other issues could arise that render alternative devices unsuitable.

The new recordkeeping rule in the amended standard, which requires that employers maintain a sharps injury log, is intended to evaluate devices and add to the knowledge base as well. The log must contain at a minimum the type and brand of the device, the department or work area where the injury occurred and an explanation of how the incident occurred. 29 C.F.R. § 1910.1030(h)(5). This information will be critical in determining which devices in which situations present the most risk.

Clearly, this approach of making sure that "safer" substitutes for devices actually exist, are safe and effective for the patient care applications they are replacing, and will reduce the incidence of sharps injuries is preferable to a ban. The collection of data on such substitutes will ensure that usage decisions are more scientifically based. At this time, not enough data have yet been generated, collected, or analyzed to suggest that commercially available alternatives are suitable replacements for the devices that the petitioners seek to ban.

The BBP amendments should be given an opportunity to work. The amendments were effective April 18, 2001, and implementation is ongoing. 66 Fed. Reg. 5318 (January 18, 2001).<sup>4</sup> For example, OSHA issued an Instruction in November 2001 regarding enforcement of the standard. In addition, the rule requires annual updates to the employer's Exposure Control Plan. The effect of compliance with these requirements on sharps injury rates has not been systematically evaluated and should be done before any other major regulatory steps, such as a device ban, performance standard or labeling, are considered.

## **II. Developing a Performance Standard for Each Type of Device at Issue is Premature.**

HRG/SEIU requested that FDA develop a performance standard for each of the types of devices at issue that incorporates the five design criteria set forth in FDA's 1992 Safety Alert. These criteria, as restated in the petition, are as follows:

- a. a fixed safety feature provides a barrier between the hands and the needle after use;
- b. the safety feature allows or requires the worker's hands to remain behind the needle at all times;
- c. the safety feature is an integral part of the device, and not an accessory;
- d. the safety feature is in effect before disassembly, if any, and remains in effect after disposal; and
- e. the device should be simple and easy to use, requiring little training.

HRG/SEIU Petition at Section A. Under section 514 of the Act, FDA may include a performance standard as a special control for a class II device if it determines that the standard is necessary to provide a reasonable assurance of the safety and effectiveness of the device. Section 514(a). In addition, 21 C.F.R. § 861.5 provides that when developing a performance standard, FDA's policy, to the maximum extent practical, will be to (1) use support available from other Federal agencies, (2) consult with other Federal agencies concerned with standard setting as well as recognized standard-setting entities; and (3) "invite participation, through conferences, workshops, or other means, by representatives of scientific, professional, industry, or consumer organizations who can make a significant contribution." 21 C.F.R. § 861.5. This should certainly include working with OSHA to obtain the data collected pursuant to the amendments to the BBP standard.

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<sup>4</sup> The revisions to the recordkeeping rule were not effective until January 1, 2002, *see* 56 Fed. Reg. 5917 (January 19, 2001), but employers were required to keep a separate sharps log from the effective date of the rule until the revised recordkeeping rule became effective. *See* 66 Fed. Reg. at 5321.

It is too soon to conclude that a performance standard incorporating the five design criteria listed above is necessary to provide a reasonable assurance of the safety and effectiveness of the instant devices. Data from the OSHA BBP standard should contribute greatly to an understanding of the devices and design features that provide a reasonable assurance of safety and effectiveness. Although the BBP standard is an OSHA standard, FDA provided input during its creation and FDA's own regulations advise the agency to use support available from other Federal agencies when considering a performance standard. Accordingly, prudence counsels that FDA work with OSHA to collect and analyze the information resulting from the implementation of the amendments to the BBP standard, to see if it provides insight as to whether a performance standard is advisable and, if so, what its requirements should be. To the extent that FDA has already been engaged in obtaining information regarding the advisability of a performance standard, we would be happy to contribute to that effort.

### **III. Labeling Requested for Conventional Syringes Is Not Required Under FDA's Regulations.**

We agree with FDA that the label requested by the petitioners for conventional syringes - **TO PREVENT POSSIBLE EXPOSURE TO HIV AND HEPATITIS, DO NOT USE FOR STANDARD BLOOD DRAWS** - restates the obvious and that the warning is commonly known by health professionals licensed by law to use these devices. Accordingly, the label statement is not required under FDA's regulations. See 21 C.F.R. § 801.109(c). Moreover, it is unclear why this one device would be singled out for that label. Finally, because no finding of unreasonable and substantial risk has been made, or could be made on the basis of information currently available, it is inappropriate to propose labeling under the device ban provisions of the Act and regulations.

### **IV. Conclusion**

The BBP amendments have taken a reasoned approach, acknowledging that devices currently in use cannot be immediately jettisoned and that "safer" devices must be evaluated for their safety and effectiveness for each particular situation. Banning certain devices would require facilities to immediately switch to devices that may be untried in certain situations and may adversely affect patient care. Such devices also may not decrease the incidence of injury to health care workers. Importantly, the record shows that inadequate information exists to satisfy the substantive standard for banning the devices referenced in the HRG/SEIU petition. Moreover, banning devices should be a remedy of last resort because FDA has a substantial arsenal of enforcement tools to protect the public health, most of which would be more efficient than pursuing a ban under the cumbersome procedures required by law.

In addition, data from the OSHA BBP standard should contribute greatly to an understanding of the devices and design features that provide a reasonable assurance of safety and effectiveness. Without such data, it is premature to conclude that a performance standard is

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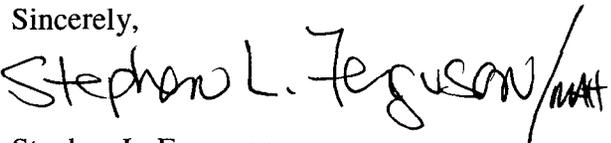
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necessary to provide a reasonable assurance of the safety and effectiveness of the devices at issue.

Finally, because there has been no finding, nor any data presented to find that conventional syringes present a substantial and unreasonable risk of illness or injury, and because professional users of such syringes are well aware of the potential for needlestick injury, the labeling proposed by petitioners for such devices is unwarranted and not required under the law.

Sincerely,

A handwritten signature in black ink that reads "Stephen L. Ferguson" followed by a stylized flourish or initials.

Stephen L. Ferguson  
Executive Vice President