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Regulation

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ABSTRACT

In Volume 4, Number 1 of The Journal of BioLaw and Business, we reported on the status of various federal and state legislative initiatives designed to force hospitals and other health care providers to implement needlestick reduction technologies at their work sites. Since that article went to print, significant developments have occurred at the federal level that will impact the selection of engineering controls used to eliminate or minimize the risk of occupational exposure to bloodborne pathogens. This article discusses the Needlestick Safety and Prevention Act ("NSPA") that President Clinton signed into law last fall and the Occupational Safety and Health Administration's ("OSHA") implementing regulations that were promulgated earlier this year. Although employers are still afforded flexibility in selecting appropriate engineering and work practice controls, the new regulations require them to formally consider the use of certain needlestick prevention technologies. Companies that market sharps will need to understand the current requirements facing their customers and to appreciate the impact that the new regulations are likely to have on the market.

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INTRODUCTION: FEDERAL LEGISLATION IMPACTING BIOTECH AND LIFE SCIENCE COMPANIES

On November 6, 2000, President Clinton signed the NSPA into law.[1] The bill received wide bi-partisan support as an alternative to more prescriptive legislation introduced by Congress in the spring of 1999, which was summarized in our first article. The bill also received strong backing by unions including the SEIU. OSHA's Bloodborne Pathogen Standard (the "BBP Standard") has always required employers to protect employees from exposure to bloodborne pathogens through the use of engineering controls. The NSPA requires OSHA to revise the BPP Standard by May 6, 2001 to require employers to review and update their exposure control plans to "reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens" and to "document annually consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure."[2]

The statute also requires OSHA to revise the definition of "engineering controls" in the BBP Standard to include as additional examples of engineering controls "safer medical devices, such as sharps with engineered sharps injury protections and needleless systems." Sharps with

engineered sharps injury protections ("ESIP") are nonneedle sharps or needle devices "used for withdrawing bodily fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident."[3] Needleless systems are devices that do not use needles for "(A) the collection of bodily fluids or withdrawal of bodily fluids after initial venous or arterial access is established; (B) the administration of medication or fluids; or (C) any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps."[4]

Although Congress singled out the use of "safer medical devices," such as needleless systems and sharps with ESIP as having the potential to be extremely effective in reducing "accidental sharps injuries," Congress also made it clear that other appropriate safer devices (and engineering controls, generally) may be used to reduce the risk of needlestick injuries in the workplace.[5] In a Joint Statement of Legislative Intent on the bill, Congress emphasized that "[t]he citing of these examples should not be considered an endorsement or preference of a specific product or assurance of a specific product's effectiveness. Rather, it is the intent of this legislation to reflect innovation and evolving technology in the marketplace [...] [T]he legislation's reference to the consideration and implementation of safer medical devices is hinged upon the 'appropriateness' and the 'commercial availability' of such devices."[6]

OSHA'S IMPLEMENTING REGULATIONS

On January 18, 2001, OSHA published a final rule in the Federal Register[7] to revise the BBP Standard (hereinafter the "Needlestick Regulation") as directed by Congress to implement the requirements of the NSPA. The Federal Register announcement states that the Needlestick Regulation becomes effective on April 18, 2001, though it is possible that the effective date may be slightly delayed by the new Administration. By June 18, 2001, the 23 "state plan" states that have their own, federally-approved OSHA plans, must amend their regulations to adopt comparable requirements. In the mean time, federal OSHA will "provide interim enforcement assistance, as appropriate" in the state plan states, and directly enforce the OSHA rule in non-state plan states.

To meet the new requirements in the BBP Standard regarding exposure control plans, employers subject to the standard will have to:

- *Step 1:* Identify any "safer medical devices" that are commercially available. Employers will need to comply with the requirement to identify safer medical devices by soliciting information on safer medical devices from vendors, from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps (as required by section 1910.1030(c)(1)(v) of the Needlestick Regulation), and from other viable sources.

- *Step 2:* Conduct a review to determine whether the commercially available safer medical devices are (a) appropriate; and (b) effective. A medical device is considered "appropriate" only if its use, based on reasonable judgment in individual cases, will not jeopardize patient safety or be medically contraindicated. A medical device is "effective" if, based upon reasonable judgment, it will make an exposure incident involving a contaminated sharp less likely to occur in the application in which it is used.[8] Again, the Needlestick Regulation requires that certain non-managerial employees be included in this evaluation process.

- *Step 3:* Decide which products will be used in the workplace based on the results of the review.

- *Step 4:* Document Steps 1-3. Describe, in writing, (A) the safer devices identified as candidates for adoption; (B) the method or methods used to evaluate devices, including the means used to solicit the input of non-managerial employees; (C) the results of the evaluations; and (D) the justification for selection decisions.[9]

Accordingly, employers will be required to:

- Maintain copies of correspondence or phone records reflecting the solicitation of information on alternative devices pursuant to Step 1;
- Identify in writing the procedures and criteria applied to determine whether a product was appropriate and effective (which may include the results of pilot testing, employee interviews, etc.);
- Identify in writing the employees who were involved in the review process;
- Maintain copies of meeting minutes of persons evaluating devices, records of responses from vendors and employee's whose input on devices was solicited, such as reports evaluating the effectiveness of a safer device in trial applications; and
- Prepare a document setting forth the results of the product review and the justification for the selections made.

If there are no commercially available alternatives in Step 1, in Step 4, the employer should include in the final document justifying its product selection decisions a statement that there are no commercially available ESIPs or needleless systems that can be used as alternatives to the traditional sharp product. However, a company's technology that is determined to be suitable today (because there are no commercially available alternative safer devices) may no longer be appropriate if a competing technology with sharps injury protection emerges. For example, if a manufacturer markets a spinal needle that does not have a built-in sharps injury protection feature, the firm's product may become obsolete if a competitor develops a similar needle with sharps injury protection.

SUMMARY

The enactment of the NPSA has increased awareness about the risks of occupational exposure to bloodborne pathogens and the availability of technologies developed over the last decade that can be used in the workplace to help prevent accidental needlesticks. While not mandating the use of specific technologies, the legislation and implementing regulations show a clear preference for the use of ESIPs and needleless systems in the workplace, where such technologies are "appropriate" and "available." Notwithstanding this preference, there is a clear recognition by Congress that other engineering controls that are currently available or that may become available; also may be effective in reducing the risk of needlestick injuries and should not categorically be excluded from consideration.

The Needlestick Regulation's vague standards will require employers to address some difficult questions as they implement or revise their exposure control plans. For example, is a particular safer medical device "appropriate" if it costs twice as much as the current technology? Does cost play any role in deciding which technologies are selected? Does an employer have to use more expensive safer devices even if it has never had an exposure incident while using its existing technology and its employees favor the old technology? Could an employer continue to use traditional pre-filled syringes even though the same medication could be transferred into empty syringes with ESIPs on site, on the grounds that the traditional devices play a critical role in ensuring that medication is administered in the proper dose?

These are difficult questions with enormous consequences for the industry and employers. In the past, OSHA has tended to resolve interpretative issues like these through ad hoc guidance letters in response to specific inquiries. Left to its own devices, OSHA may not appreciate the ramifications of its decisions on these issues.

The change in Administration presents an important opportunity to shape OSHA guidance and policy on these matters for years to come. Employers and manufacturers and their counsel would be well-advised to work with the new Administration to ensure that employers are not facing enforcement actions and medical devices are not facing obsolescence because of an unduly restrictive reading of the NSPA and the Needlestick Regulation. JB&B

ENDNOTES

1. Pub. L. No. 106-430.
2. *Id*.
3. *Id*.
4. daily ed. October 3, 2000.
5. daily ed. October 26, 2000.
6. 146 Cong. Rec. S11042-11043.
7. See 66 Fed. Reg. 5318, 5325 (Jan. 18, 2001) (final rule).
8. Id. at 5319.
9. 66 Fed. Reg. at 5319 (preamble).

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