AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 5178 OFFERED BY MR. BALLENGER

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Needlestick Safety and Prevention Act.''

SEC. 2. FINDINGS.

The Congress finds the following:

(1) Numerous workers who are occupationally exposed to bloodborne pathogens have contracted fatal and other serious viruses and diseases, including the human immunodeficiency virus (HIV), hepatitis B, and hepatitis C from exposure to blood and other potentially infectious materials in their workplace.

(2) In 1991 the Occupational Safety and Health Administration issued a standard regulating occupational exposure to bloodborne pathogens, including the human immunodeficiency virus, (HIV), the hepatitis B virus (HBV), and the hepatitis C virus (HCV).

(3) Compliance with the bloodborne pathogens standard has significantly reduced the risk that workers will contract a bloodborne disease in the course of their work.

(4) Nevertheless, occupational exposure to bloodborne pathogens from accidental sharps injuries in health care settings continues to be a serious problem. In March 2000, the Centers for Disease Control and Prevention estimated that more than 380,000 percutaneous injuries from contaminated sharps occur annually among health care workers in United States hospital settings. Estimates for all health care settings are that 600,000 to 800,000 needlestick and other percutaneous injuries occur among health care workers annually. Such injuries can involve needles or other sharps contaminated with bloodborne pathogens, such as HIV, HBV, or HCV.

(5) Since publication of the bloodborne pathogens standard in 1991 there has been a substantial increase in the number and assortment of effective engineering controls available to employers. There is now a large body of research and data concerning the effectiveness of newer engineering controls, including safer medical devices.

(6) 396 interested parties responded to a Request for Information (in this section referred to as the ''RFI'') conducted by the Occupational Safety and Health Administration in 1998 on engineering and work practice controls used to eliminate or minimize the risk of occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps. Comments were provided by health care facilities, groups representing healthcare workers, researchers, educational institutions, professional and industry associations, and manufacturers of medical devices.

(7) Numerous studies have demonstrated that the use of safer medical devices, such as needleless systems and sharps with engineered sharps injury protections, when they are part of an overall bloodborne pathogens risk-reduction program, can be extremely effective in reducing accidental sharps injuries.

(8) In March 2000, the Centers for Disease Control and Prevention estimated that, depending on the type of device used and the procedure involved, 62 to 88 percent of sharps injuries can potentially be prevented by the use of safer medical devices.

(9) The OSHA 200 Log, as it is currently maintained, does not sufficiently reflect injuries that may involve exposure to bloodborne pathogens in healthcare facilities. More than 98 percent of healthcare facilities responding to the RFI have adopted surveillance systems in addition to the OSHA 200 Log. Information gathered through these surveillance systems is commonly used for hazard identification and evaluation of program and device effectiveness.

(10) Training and education in the use of safer medical devices and safer work practices are significant elements in the prevention of percutaneous exposure incidents. Staff involvement in the device selection and evaluation process is also an important element to achieving a reduction in sharps injuries, particularly as new safer devices are introduced into the work setting.

(11) Modification of the bloodborne pathogens standard is appropriate to set forth in greater detail its requirement that employers identify, evaluate, and make use of effective safer medical devices.

SEC. 3. BLOODBORNE PATHOGENS STANDARD.

The bloodborne pathogens standard published at 29 C.F.R. 1910.1030 shall be revised as follows:

(1) The definition of ''Engineering Controls'' (at 29 C.F.R. 1910.1030(b)) shall include as additional examples of controls the following: ''safer medical devices, such as sharps with engineered sharps injury protections and needleless systems''.

(2) The term ''Sharps with Engineered Sharps Injury Protections'' shall be added to the definitions (at 29 C.F.R. 1910.1030(b)) and defined as ''a non-needle sharp or a needle device used for withdrawing body 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) The term ''Needleless Systems'' shall be added to the definitions (at 29 C.F.R. 1910.1030(b)) and defined as ''a device that does not use needles for (A) the collection of bodily fluids or withdrawal of body 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) In addition to the existing requirements concerning exposure control plans (29 C.F.R.

1910.1030(c)(1)(iv)), the review and update of such plans shall be required to also—

(A) ''reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens''; and

(B) ''document consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure''.

(5) The following additional recordkeeping requirement shall be added to the bloodborne pathogens standard at 29 C.F.R. 1910.1030(h): ''The employer shall establish and maintain a sharps injury log for the recording of percutaneous injuries from contaminated sharps. The information in the sharps injury log shall be recorded and maintained in such manner as to protect the confidentiality of the injured employee. The sharps injury log shall contain, at a minimum—

''(A) the type and brand of device involved in the incident,

''(B) the department or work area where the exposure incident occurred, and

''(C) an explanation of how the incident occurred.''.

The requirement for such sharps injury log shall not apply to any employer who is not required to maintain a log of occupational injuries and illnesses under 29 C.F.R. 1904 and the sharps injury log shall be maintained for the period required by 29 C.F.R. 1904.6.

(6) The following new section shall be added to the bloodborne pathogens standard: ''An employer, who is required to establish an Exposure Control Plan shall solicit input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation, and selection of effective engineering and work practice controls and shall document the solicitation in the Exposure Control Plan.''.

SEC. 4. EFFECT OF MODIFICATIONS.

The modifications under section 3 shall be in force until superseded in whole or in part by regulations promulgated by the Secretary of Labor under section 6(b) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655(b)) and shall be enforced in the same manner and to the same extent as any rule or regulation promulgated under section 6(b).

SEC. 5. PROCEDURE AND EFFECTIVE DATE.

(a) PROCEDURE.—The modifications of the bloodborne pathogens standard prescribed by section 3 shall take effect without regard to the procedural requirements applicable to regulations promulgated under section 6(b) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655(b)) or the procedural requirements of chapter 5 of title 5, United States Code.

(b) EFFECTIVE DATE.—The modifications to the bloodborne pathogens standard required by section 3 shall—

(1) within 6 months of the date of enactment of this Act, be made and published in the Federal Register by the Secretary of Labor acting through the Occupational Safety and Health Administration; and

(2) at the end of 90 days after such publication, take effect.