



February 25, 2004

Tommy G. Thompson  
Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Secretary Thompson:

The American Nurses Association (ANA) would like to call to your attention a matter of great significance. The ANA represents the nation's 2.7 million registered nurses through its 54 constituent member associations. With health and safety as a core issue, the ANA advocates on behalf of the well-being of all healthcare workers by addressing occupational hazards encountered in healthcare settings and the delivery of health services. At the heart of the issue we wish to raise the question whether federal agencies, namely the U.S. Department of Health and Human Services (US-DHHS) and the Centers for Disease Control and Prevention (CDC) can be permitted to cause healthcare industry employers to violate a regulation set by another federal agency, the Occupational Safety and Health Administration (OSHA).

In light of current efforts to conduct and extend a federal smallpox vaccination program, DHHS along with CDC run the risk of disregarding the federal OSHA Bloodborne Pathogen Standard (29 CFR 1910.1030) and its modifications enacted by the Needlestick Safety and Prevention Act of 2000 (PL 106-430). These federal mandates explicitly require the consideration of using safer needle and sharps devices (types of engineering controls) as a means to eliminate or reduce the risk of occupational exposure to bloodborne pathogens (i.e., human immuno-deficiency virus and hepatitis C virus) and that frontline healthcare workers have direct input into the selection and evaluation of such devices.

As stated in 29 CFR 1910.1030(d)(2)(i):

Engineering and work practice controls shall be used to eliminate or minimize employee exposure. Where occupational exposure remains after institution of these controls, personal protective equipment shall also be used.

As stated in 29 CFR 1910.1030(c)(1)(v):

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.

Considering these stipulations, DHHS and CDC should not pre-package a traditional bifurcated needle not equipped or designed with a safety feature along with smallpox vaccine distributed through the federal program. Doing so effectively ignores the noted stipulations of the OSHA Bloodborne Pathogens Standard and raises significant concern with respect to the program's execution.

Inclusion of traditional bifurcated needles fails to recognize that bifurcated needles with safety features are currently available specifically for use with smallpox vaccine. To our knowledge, multiple manufacturers have now made available such safety devices that can reduce the risk of an occupational needlestick/sharps injury among healthcare workers administering the smallpox vaccine. Those administering smallpox vaccinations should not be denied access to these new safety products because federal agencies choose to impose the traditional bifurcated needle as part of the program. The use of safer needle devices captures the fundamental principle of prevention through the application of engineering controls as the OSHA Bloodborne Pathogens Standard requires.

Healthcare organizations and agencies charged with carrying out the federal smallpox program may face questions as to what is the appropriate action in using "unsafe" traditional bifurcated needles. They now must consider the potential threat of receiving an OSHA citation and fine for violating the Bloodborne Pathogen Standard requirements listed above. Further, healthcare facilities will be forced to resolve the problems imposed by the inclusion of a traditional bifurcated needle. To be in compliance with the OSHA standard they will have to discard the unsafe traditional bifurcated needles and bear the cost of replacing them with safety-engineered bifurcated needles. Additionally, the opportunity to receive input from front-line healthcare workers is completely eliminated. Extending decision-making authority to employers with, most importantly, input from frontline healthcare workers contributes to the acceptance and adherence to using available safer needle and sharps devices that matches their own needs and preferences.

As has been well documented, healthcare workers, particularly nurses, are at tremendous risk of occupational exposure to bloodborne pathogens and other potentially infectious

materials through needlestick and sharps injuries. Administration of the smallpox vaccination compounds this risk through the use of a needle without safety features in  
Tommy G. Thompson

February 25, 2004

addition to the potential unintentional exposure to the smallpox vaccine. DHHS and CDC must recognize that both the imposition of a needle device without safety features and the disregard of frontline worker input into the selection and evaluation of such devices do a tremendous disservice to this nation's healthcare workforce, particularly when they are asked to respond to a governmental call to action.

The ANA brings this matter to your attention with the request that you investigate this issue along with other federal agencies such as the Centers for Disease Control and Prevention (CDC), the National Institute for Occupational Safety and Health (NIOSH), and the Occupational Safety and Health Administration (OSHA) and take action to ensure that healthcare workers are not subjected to unsafe bifurcated needles. Further, the ANA would be very willing to work with you to come to a resolution for this concern. We look forward to your response. Should you have any questions or concerns, please feel free to contact Dr. Butch de Castro at [Bdecastro@ANA.org](mailto:Bdecastro@ANA.org) or (202) 651-7138.

Sincerely,

Barbara A. Blakeney, MS, APRN,BC, ANP  
President

cc: Julie L. Gerberding, MD, MPH, Director, Centers for Disease Control and Prevention  
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