Additional SHEA Submission to OSHA on Bloodborne Hazards

On October 18, 1989, Dr. Michael Decker testified on behalf of SHEA regarding the Occupational Safety and Health Administration's (OSHA) proposed rules for occupational exposure to bloodborne pathogens (29 CFR 1910), published in the *Federal Register* of Tuesday, May 30, 1989 (pages 23042-23139). A summary of Dr. Decker's original comments was published in the March *Newsletter.*

In response to requests from the OSHA hearing panel for the Bloodborne Hazard standard, Dr. Decker submitted supplementary comments in April addressing two related issues: the standard of care defined in the proposed regulation and how that standard ought to be applied to the technical details of an immunization program. A summary of those comments follows.

STANDARD RECOMMENDATIONS FOR MEDICAL PRACTICE

In our previously submitted comments, it was recommended that OSHA revise Section (f)(1)(iii), changing the phrase "standard recommendations for medical practice" to "acceptable standards of medical practice."

Our concern is that the current phrasing seems to imply the existence of a single standard, which would have to be divined and then adhered to. However, in general, there is no single standard for medical care. There are many areas that are unsettled, and in which equally authoritative but conflicting recommendations exist. In addition, medical care constantly evolves, and new understandings and new developments are adopted in "standard recommendations" at an irregular and unpredictable pace.

An example can be found in current recommendations for a second dose of measles vaccine. The Immunization Practices Advisory Committee of the Public Health Service has recommended administering this injection at 5 years of age. The *Red Book* Committee of the American Academy of Pediatrics has recommended administering this injection at 11 years of age. Within the medical community, the two bodies are considered equally authoritative with respect to their recommendations regarding immunization. Absent evidence as to the superiority of one recommendation, which would you select to give the force of law? And why do so, absent evidence of superiority?

As we said previously, "A rigid adherence to recommendations of the U.S. Public Health Service (USPHS) should not be required." Evolution in USPHS recommendations flows out of innovation that would never occur if every program was prohibited from deviating from the existing "standard recommendations."

INTRAMUSCULAR vs INTRADERMAL IMMUNIZATION

It has been suggested that the "standard recommendation for medical practice" would require that immunization against hepatitis B be delivered by the intramuscular route and that the intradermal injection of vaccine would be prohibited. We believe such a requirement would be inappropriate for two reasons: it likely would put an end to legitimate research that ought to be encouraged, and it well might result in fewer persons being offered immunization against hepatitis B.

We do not believe that the proper role of intradermal immunization against hepatitis B is a settled issue. It may be that carefully designed, conscientious intradermal programs can provide equal protection to more persons at lower cost than can intramuscular programs. Futhermore, nearly all the research regarding intradermal immunization is being done within medical centers, using medical students and employees. A prohibition by OSHA against intradermal immunization of healthcare workers likely would end any research in this area.

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At this point, it is not known if persons immunized against hepatitis B (by any route) will require booster doses. If boosters are required, they may be required sooner in those immunized by the intradermal route, but this may nonetheless be the most resource-efficient approach; the vaccine cost of an intradermal booster every five years is still only one-f&h that of an intramuscular booster every ten years.

CONCLUSION

In light of the above considerations, we would urge OSHA to: select language for the "standard of care" paragraph (Section [f] [1] [iii] that does not imply there is only one legitimate standard; not prohibit legitimate research involving the diagnosis, treatment or prophylaxis of healthcare workers; and permit (with appropriate safeguards) immunization programs that wish to select the intradermal route, particularly as such programs then offer free vaccination to more persons than regulations would otherwise require.

Brief items of interest for the SHEA Newsletter may be sent to Robert A. Weinstein, MD, SHEA Newsletter Editor, Division of Infectious Diseases, Michael Reese Hospital, Lake Shore Drive at 31st St., Chicago, IL 60616. Copy must be typed, doublespaced and may not exceed five pages.

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