American Hospital Association

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January 29, 2004

John L. Henshaw
Assistant Secretary of Labor
Occupational Safety and Health Administration
200 Constitution Avenue, NW
Washington, DC 20210

Dear Assistant Secretary Henshaw:

We are writing in response to the Occupational Safety and Health Administration's (OSHA) decision to withdraw the proposed tuberculosis (TB) rule, revoke the respiratory protection interim rule currently being used to enforce the Centers for Disease Control and Prevention (CDC) TB guidelines (1971 29 CFR 1910.139), and simultaneously apply the General Industry Respiratory Protection Standard (1910.134) for occupational exposure to *M. tuberculosis*. The American Hospital Association (AHA) represents nearly 5,000 hospitals, health care systems, networks and other health care providers, as well as more than 28,000 personal members, including many health care professionals who would have been covered by OSHA's proposal.

We applaud the agency's decision to withdraw its proposed TB rule, recognizing the effectiveness of many organizations and individuals to reduce TB exposures over the past decade. We believe that initiatives undertaken by the AHA and others have contributed to the reducing the prevalence of TB in the United States to its lowest level in recorded history. In testimony provided to an Institute of Medicine committee reviewing occupational exposure to TB[1], the AHA attributed the reduction in TB exposure to the high percentage of employee health programs in hospitals, the increased attention to the environment, and the current efforts of hospitals to incorporate American Institute of Architects guidelines or state regulatory engineering controls. We further noted that requirements for an infection control risk assessment are in place and that new construction or major renovation of health care facilities requires negative airflow in triage and waiting areas of emergency rooms and radiology suites – protecting health care workers, patients and visitors from individuals with unidentified TB disease. The Joint Commission on Accreditation of Healthcare Organizations requires these same standards and emphasizes ventilation and engineering controls in their revised standards.

[1] Testimony of the American Hospital Association before the Institute of Medicine Committee on Regulating Occupational Exposure to Tuberculosis, August 2000.

Continued efforts are critical, because even with the most rigorous respiratory protection program, TB can still be transmitted from the unsuspected case – a fact noted in OSHA's withdrawal notice. TB transmission may occur in health care facilities and the community when it is not recognized and properly treated. The AHA remains committed to supporting effective and proven efforts to reduce the risk of transmission of tuberculosis to workers, patients and visitors in the health care setting, sustaining important gains made in public health for patients and health care personnel.

In light of the nation's current success in controlling TB in health care settings, and for reasons discussed below, **the AHA strongly recommends that OSHA rescind its decision to apply the General Industry Respiratory Protection Standard (1910.134) to occupational exposure to TB. OSHA should instead provide the public with an opportunity to address this important issue through a formal open comment period.**

We have several concerns. First, the General Industry Respiratory Protection Standard is not applicable to occupational exposure to biologic agents or to patients with communicable infectious diseases. Susceptibility to many infectious diseases varies considerably. The dynamics of exposure and transmission for biologic agents contrast dramatically with the airborne chemical contaminants or particulate matter (e.g., asbestos) for which the General Industry Respiratory Protection Standard was developed. In health care facilities, even in the face of community-based resurgence of TB, outbreaks of tuberculosis were (and are today) controlled and prevented by early identification of cases, prompt isolation and appropriate treatment. These early outbreaks were controlled during a period prior to the use of particulate respirators and fit testing, when masks were the standard for protecting health care personnel.

Second, the decision to impose this new mandate was issued as a final rule without the opportunity to review or provide public comment. This decision is a substantially different action than merely withdrawing the proposed TB standard. We strongly disagree with OSHA's assertion that it has met the requirement to permit public comment during the comment period provided for the proposed TB standard.

The decision to publish this mandate as a final rule violates OSHA law. The Occupational Safety and Health Act requires that, prior to the issuance of a new standard, a determination must be made, based on substantial evidence in the record considered as a whole, that there is a significant health risk under existing conditions and that issuance of a new standard will significantly reduce or eliminate that risk. The AHA and others addressed a similar question in the context of OSHA's TB rulemaking process. That is, does enough evidence exist to support the promulgation of a final TB standard? OSHA subsequently agreed that such evidence did not exist and that the agency's proposed standard is unlikely to reduce the remaining health risk from TB. As a result, OSHA withdrew the proposed TB standard. Our concern is that OSHA has now used selected information taken from this process to justify imposing something

different than the proposed rule for which the data were originally gathered. **To now apply the General Industry Respiratory Protection Standard intended for chemical aerosols to biologic agents, such as TB, constitutes a significantly different action, and as such OSHA must provide an opportunity for public comment to examine the scientific basis required for such an action.**

Finally, it is counterintuitive for OSHA to apply the General Industry Respiratory Standard to TB in the face of its own assessment that "the rate of TB has declined steadily and dramatically" and "[h]ospitals…have come into substantial compliance with Federal guidelines for preventing the transmission of TB." The CDC's guidelines on preventing transmission of TB in health care settings, to which OSHA is referring, include respiratory protection recommendations that hospitals have adopted. These recommendations are in the process of being updated to reflect current scientific evidence and practices. OSHA offered no rationale for now instituting a new and costly respiratory protection standard unproven for application to a disease that OSHA has acknowledged is declining and for which effective protective measures already exist.

OSHA is required by its own mandate to provide a comment period for such a significant policy change in order to examine the science for the most effective methods for protecting health care workers from biological agents such as TB. **To that end, we request OSHA immediately withdraw its decision to make TB respiratory protection subject to the General Respiratory Protection Standard (1910.134), and we also urge OSHA to re-evaluate the appropriateness of applying this standard to TB. If OSHA feels compelled to move forward, a public comment period regarding this issue is required through a notice of proposed rulemaking process.**

If you have questions concerning our comments, please contact myself or Roslyne Schulman, senior director of policy, at (202) 626-2273.

Sincerely,

Rick Pollack
Executive Vice President