

"Tuberculosis in the Workplace," that Congress had commissioned in 1999. (Exs. 184; 185; 186; 187)

Rulemaking participants represented diverse constituencies, including public health organizations such as the CDC, the American Lung Association's American Thoracic Society, the Infectious Disease Society of America, the National TB Controller's Association, and state and local health departments; labor unions such as the American Federation of State, County, and Municipal Employees and the Service Employees International Union; safety and health professionals and employees working in hospitals, correctional facilities, TB clinics, nursing homes, drug treatment centers and homeless shelters; and professional and trade associations such as the Society of Healthcare Epidemiologists of America, the American Hospital Association and the Association for Professionals in Infection Control and Epidemiology. These groups have extensive experience in TB control, and provided a broad range of perspectives on the issues involved in the rulemaking.

II. Reasons for Withdrawal of the Proposed Standard

OSHA has decided not to promulgate a standard addressing occupational exposure to TB because it does not believe a standard would substantially reduce the occupational risk of TB infection. Many commenters argued forcefully that the proposed rule was based on an overestimate of this risk. In addition, existing TB control efforts, initiated by the Federal government in concert with other public health agencies, have led to a dramatic decline in TB over the past decade, greatly reducing the risk of occupational exposure to TB. Because of these TB control efforts, effective infection control measures are already in place, particularly in hospitals, which is where the occupational risk of TB exposure would be most severe.

Moreover, much of the current occupational transmission appears to occur when workers do not realize that a patient, client, or other contact has infectious TB. An OSHA standard is unlikely to be more effective than the CDC guidelines in eliminating this risk. OSHA believes that workers in many situations, particularly those with limited medical qualifications and resources, will not be able to identify or diagnose currently undiagnosed TB cases frequently and rapidly enough to prevent this transmission from occurring. Risk to workers encountering undiagnosed cases will be reduced most

effectively by reducing even further the incidence of TB in the population as a whole, and therefore in their client populations. OSHA will use technical assistance, outreach, and cooperative activities to assist employers and their workers in implementing infection control measures. In addition, OSHA will continue to use its existing enforcement tools, as appropriate, with employers who are not taking adequate action to protect their workers from exposure to TB.

TB in the United States has declined significantly since OSHA decided to propose a TB Standard.

Until 1985, the number and rate of TB cases in the United States had declined steadily for more than 30 years. Unexpectedly, however, the incidence of TB started to increase in 1986. At the peak of this resurgence in 1992, CDC reported 26,673 TB cases (10.5 per 100,000 population)—an increase of 20% over the number of cases, and of more than 12% over the case rate, reported in 1985. The situation was especially pronounced in states with historically high TB rates. In 1992, when the rate of TB for the nation as a whole was 10.5 cases per 100,000 population, New York, Florida, California, Texas and Illinois, had rates ranging from 10.9 to 25.2 per 100,000, and accounted for 58% of the total cases. In addition, by 1991 there had been a seven-fold increase in the percentage of multidrug-resistant TB (MDR-TB), TB that is resistant to both isoniazid and rifampin, the two major drug treatments for the disease. (Ex. 187, p. 13)

The Federal agency with primary responsibility for responding to the TB crisis is the CDC. In 1989, CDC published its "Strategic Plan for the Elimination of Tuberculosis in the United States." (Ex. 6–19, pp. 1–25) This plan, which had been under development since 1984, called for a comprehensive governmental and public health effort to address TB transmission. In 1992, it was supplemented by the CDC's National Action Plan to Combat Multidrug-Resistant Tuberculosis. (Ex. 7–65) These plans provided the framework for the Federal response to the TB resurgence of the late 1980s and early 1990s.

The plans prescribed a broad and multifaceted attack on TB, including infection control guidelines describing methods to reduce transmission in a number of settings; physician education programs and practice guidelines to ensure effective treatment; research into new and faster methods of identifying TB, particularly MDR-TB; the implementation and maintenance of

community-based TB control programs, and the development of alternative TB treatments. (Ex. 187, pp. 17–23) As well as beginning work on its TB proposal, OSHA's contribution to this national effort included the enforcement activities described in its 1993 directive, as well as outreach and educational activities directed at employers with workers at risk of occupational exposure to TB. As a result of all of this coordinated activity, starting in 1993, the incidence of TB began to decline again.

By 1996, as OSHA noted in the preamble to its 1997 proposal, both the number and the rate of TB cases were lower than they had been in 1985, before the resurgence began. This decline has continued, and for 2002 CDC reported 15,078 TB cases (5.2 per 100,000 population). These numbers represent a reduction of more than 50% in the rate of TB since the 1992 peak, and of 43.5% in the number of cases. (Table 1) The number of reported TB cases and the national TB case rate are now at their lowest levels since TB reporting began in 1953, with significant decreases occurring in the states where the resurgence was most severe. The most dramatic decline occurred in New York, which in 1992 had the highest TB rate in the Nation, 25.2 cases per 100,000 population. By 2002, it had experienced a 70% decline in the case rate, to 7.5 per 100,000. New York, California, Florida, Texas, and Illinois together account for fully 65% of the decrease in the number of cases since 1992. The number of TB cases in these five states was reduced by about 50% over this period, 7% more than the Nation as a whole. The number and percentage of MDR-TB cases have also declined dramatically over this period. In 2002, 138, or 1.3%, of culture-positive TB cases were resistant to isoniazid and rifampin, down from 468, or 2.7% reported in 1993, a reduction of more than 70% in the number, and 50% in the percentage, of cases that are MDR-TB. (Centers for Disease Control and Prevention, Trends in Tuberculosis Morbidity, (United States, 1992–2002), MMWR 2003; 52: 217–222).

CDC has noted, however, that even though TB is declining in all demographic groups studied, there remains substantial variation in disease incidence among these groups. (MMWR 2003; 52: 217) In 2002, for the first time, more than half of all TB cases occurred in individuals who were born outside of the United States, and CDC believes that the majority of these cases are the result of infections also incurred outside of this country. This suggests that TB transmission in the U.S. may be even