

less common than the numbers in Table 1 would indicate. Even among the U.S. born population, there are substantial disparities among racial, ethnic, and economic groups, with higher TB rates

associated with lower socioeconomic status. (MMWR 2003: 52: 218) Well over half of all TB cases are in individuals who are not in the workforce, so the TB rates for workers are substantially lower

than the overall population rates. (Ex. 187, pp. 153, 154 citing MMWR 2003: 52: 222)

TABLE 1.—U.S. TUBERCULOSIS CASES AND CASE RATES PER 100,000 POPULATION

Year	Number	Rate	Percent change number	Percent change rate
1992 .....	26,673	10.5	+1.5	+1.0
1993 .....	25,287	9.8	−5.2	−6.7
1994 .....	24,361	9.4	−3.7	−4.1
1995 .....	22,860	8.7	−6.2	−7.4
1996 .....	21,337	8.0	−6.7	−8.0
1997 .....	19,851	7.4	−7.0	−7.5
1998 .....	18,361	6.8	−7.5	−8.1
1999 .....	17,531	6.4	−4.5	−5.9
2000 .....	16,377	5.8	−6.6	−9.4
2001 .....	15,989	5.6	−2.4	−3.4
2002 .....	15,078	5.2	−5.7	−7.1

From CDC: "Reported Tuberculosis in the United States, 2001"; "Trends in Tuberculosis Morbidity—U.S., 1992–2002."

*The occupational risk of TB infection is lower than that reflected in OSHA's proposed standard.*

The proposed standard was based on OSHA's preliminary assessment that workers occupationally exposed to TB were at substantially greater risk of TB infection, and therefore of active TB disease and death, than was the general population. Both OSHA's preliminary risk assessment, and the revision released in 2000 were based in large part on published data on the number of workers in different health care and prison settings with skin tests indicating recent TB infection (the conversion rate), and on comparisons of those data to estimates of background conversion rates among comparable populations without occupational exposure. In order to determine the estimated background conversion rates, OSHA used calculations derived from the number of active TB cases reported to CDC in a given year. OSHA assumed that about 10% of infected individuals who do not undergo prophylactic treatment would eventually develop active TB, 40% of them in the first year after infection, 20% in the second year, and the remaining 40% distributed equally through the remainder of their lifetimes. The revised risk assessment estimated that, based on the existing frequency of prophylactic treatment, active TB would occur in only about 6.5% of infected individuals. OSHA also assumed that 7.8% of active TB cases would be fatal.

As both OSHA's peer reviewers and many commenters pointed out, however, there are several uncertainties associated with these calculations, and the risk assessments likely overstated the occupational risk. (Exs. 185; 186;

187, p.153; 189–21; 189–20; 189–32; 189–28; 189–25) First, for a number of reasons ranging from imprecise testing protocols to poor availability of appropriate study populations, data on conversion rates are of less than ideal reliability and estimates of increased risk among occupationally exposed workers are necessarily imprecise. Second, a number of participants pointed to data indicating that far less than 10% of infected individuals, possibly even less than 5%, will develop active TB. (Exs. 185; 187 pp. 152–153, 216–220) This most obviously affects OSHA's estimate of the number of occupationally-acquired infections that will develop into active TB. In addition, because background infection rates were derived in large part by applying this assumption about disease development to actual data on the number of active cases, the assumptions also affect the calculation of excess occupational risk of infection. If only half the assumed percentage of infected individuals develop active TB (5% instead of 10%), the number of TB infections leading to a given number of active TB cases (the background rate) would be twice as high as calculated, meaning that the excess risk of infection attributed to occupational exposure would be lower than originally assumed.

Similarly, even though the fatality rate was not a major basis for OSHA's preliminary determination of significant risk, many participants criticized the assumption that 7.8% of TB cases would be fatal. The IOM report stated that, for healthcare workers who are not immunocompromised or infected with MDR-TB, the risk of death is negligible.

(Ex. 187, pp. 154, 222). Several participants noted that the 7.8% mortality rate was derived from 1989 to 1991 data, and that the death rate for those years was much higher than it has been since; in fact, for 1999 and 2000, the death rate was 3%. (Exs. 187, p. 153; 185, p.12; 189–13, p. 3; 189–22, p. 3; 189–25, p. 7; 189–28, p.3)

In any event, whatever may have been the case when the proposal was issued in 1997, there is no dispute that occupational risk has declined as the incidence of TB in the population as a whole has declined. This is demonstrated by the fact that there has been a decline in TB among occupationally exposed workers that mirrors the decline in the population at large. The proposal noted that in the early 1990s, when the record shows that few employers were using infection control measures to protect their workers from exposure to TB, workplace exposures resulted in TB infections, disease and, in some cases death. (Exs. 187, pp. 95–96, 7–3; 5–16; 151–3; 151–15; 5–3; 7–136; 6–25) Healthcare workers represent the largest group of TB-exposed workers, and in the early years of TB recordkeeping, they were more likely than other workers to develop TB. (Exs. 187, pp. 105–107; 7–3; 5–16; 5–11; 151–3; 151–15) As the Society for Healthcare Epidemiologists of America (SHEA) noted, more recent data indicate that healthcare workers "represent a small proportion of all cases and are not disproportionately represented in the TB caseload compared to their presence in the workforce" (Ex. 183–15, p.1–2). IOM reported that for 1998, although healthcare workers accounted for 9% of