

elimination.” (Ex. 183–15, p. 1) The effectiveness of all of these measures is demonstrated by a decline in TB among occupationally exposed workers that has exceeded the decline in the population at large. (Exs. 7–147; 7–148; 7–149; 7–173; 7–167; 151–15; 18–49A; 181–3; 18–53; 187, p. 89)

An OSHA standard would not substantially reduce transmission of TB from undiagnosed sources.

Finally, evidence in the rulemaking record indicates that, with the current level of compliance with CDC guidelines, the “primary risk” of occupational exposure to TB is from individuals with unsuspected and undiagnosed infectious TB. (Ex. 187, p. 2) One commenter, St. Joseph Mercy Hospital, called these exposures the “Achilles heel” of TB control efforts. (Ex. 17–881, p. 3) Although OSHA’s proposed standard called for early identification and isolation of infectious TB patients, this early identification can be extremely difficult. (Exs. 5–4; 5–18; 6–27; 7–76; 7–77; 7–78; 7–79; 5–12) An OSHA standard must substantially reduce a significant risk, and OSHA believes it is unlikely that employers will identify enough of the currently undiagnosed TB cases their workers come in contact with to reduce the remaining occupational risk of TB infection substantially. *Industrial Union Department, AFL–CIO v. American Petroleum Institute, et al.*, 448 U.S. 607, 642, 653 (1980).

The record shows that there are a number of reasons that a client’s or patient’s infectious TB may not be recognized. (Exs. 17–11; 17–12; 17–36; 17–458) In some situations, the infectious person may not manifest evident signs and symptoms of TB. And even after receiving training, a worker who is not expecting to see TB, which is especially likely in an area where the disease is uncommon, may not recognize the significance of TB signs and symptoms. In other cases, an exposed employee may lack the clinical expertise or resources to identify a patient or client as a suspect TB case and make a referral for diagnosis.

Lack of recognition may also occur where a worker has contact with many patients or clients who have coughs or other possible TB symptoms. Also, workplaces such as drug treatment centers and homeless shelters operate with unique limitations, and rarely possess either the resources or the clinical expertise to identify and isolate TB cases in a timely manner. (Exs. 187, p. 132; 17–53; 17–76; 17–58; 17–12; DC TR, pp. 2019–2020, 2113, 2131; NY TR, pp. 610, 612; LA TR, pp. 598, 600, 601, 617, 630) They are also less likely to be

able to distinguish between active TB disease and other medical conditions with similar symptoms.

As the Association for Professionals in Infection Control and Epidemiology (APIC) put it:

Obviously, protecting workers against exposure to TB from patients is contingent upon suspecting that the patients have TB in the first place. Patients may initially enter a hospital for a different reason or show only vague symptoms of TB. Until diagnosed, these patients unwittingly expose probably dozens of individuals to their illness. (Ex. 17–671, p. 3)

APIC then reported on 17 outbreaks since 1960 where transmission to healthcare workers was reported, pointing out that 75.6% of the workers were infected by an undiagnosed and unsuspected TB patient. (Id.) The Home Health Services and Staffing Association (HHSSA) also asserted that 75% of TB transmissions from patients to healthcare workers are not preventable because, at the time of transmission, the patient’s TB could not be readily identified or even suspected. (Ex. 17–673, p. 3) To the extent that these reports do not reflect advances made in infection control over the last decade, they may overstate the percentage of undiagnosable cases, but HHSSA’s and APIC’s conclusions about the significance of these cases are consistent with those of the IOM. Moreover, the case reports APIC submitted describe situations where transmissions have occurred, and OSHA’s own review of these reports indicates that, even with a modern TB infection control program, a number of the source patients would still not have been diagnosed before healthcare workers were exposed to them.

These reports also show that occupational exposures to undiagnosed TB and potential disease transmission can occur in all settings, including hospitals that have implemented the CDC Guidelines. The IOM pointed out that, in locations such as hospital emergency rooms, exposure may occur before infectious individuals are recognized and isolated, and that infectious individuals may remain asymptomatic for some time. (Ex. 187, p. 135) Consistent with CDC guidelines, the proposal called for treating contacts as having suspected infectious TB if they had both a persistent cough lasting at least three weeks, and at least two of the following additional symptoms: bloody sputum, night sweats, weight loss, fever, and anorexia. (62 FR 54292–3).

First, for workers in residential settings such as nursing homes and correctional facilities, this criterion does

not provide any protection in the first three weeks that a resident has symptoms and is not recognized as having TB. In some other settings, identification of infectious individuals depends on the self-reports of patients or clients to determine whether almost any of the symptoms are present. Several participants pointed out that, outside of health care settings, potentially infectious individuals who fear they will be denied a benefit (such as a shelter bed or substance abuse treatment), or be compelled to enter a coercive treatment situation, may feel a strong incentive not to respond honestly to questions about symptoms. (Exs. 18–22A, 18–57A; 183–15, p. 4; NY TR, p. 615; DC TR, pp. 2009; 2034; 2069)

Homeless shelters are a prime example of a population where many clients have the coughs, fevers, night sweats, weight loss, and other symptoms associated with TB. (NY TR, pp. 607–608; Chicago TR, pp. 710–711, 768, 789) These non-hospital settings do not diagnose, treat, or isolate individuals with active TB disease; at most, they screen clients for symptoms of infectious disease and transfer or refer those with suspect symptoms to facilities with appropriate diagnostic and isolation capabilities. (Exs. 17–50; NY TR, p. 697; Chicago TR, pp. 789–790; DC TR, pp. 1867–1868) They rarely possess any means to identify asymptomatic individuals. They often lack the resources even to provide all the services they believe their clients need, and may well resist transferring any of their limited resources to a TB screening program, particularly when, as noted above, the screening may engender fear or hostility in their clients. (Exs. 18–22A, 18–57A; 17–50; 183–15, p. 3, NY TR, p. 703; Chicago TR, pp. 701–702, 713; DC TR, pp. 1910, 2046, 2069)

The bottom line is that no infection control regime, including that in OSHA’s proposed standard, would have much effect on workplaces where the greatest source of exposure and risk is unsuspected and undiagnosed active TB disease.

The Need for an OSHA Standard

The major issue in the rulemaking was whether, in light of the ongoing decline in the national incidence of TB, the steps that employers were already taking, and the difficulty in identifying many infectious TB patients, there is a current justification for an OSHA rule on occupational exposure to TB. Many participants argued that the rule would not result in a meaningful additional reduction in risk. According to these commenters, the problem addressed by