

as low as 37 f-y/cc (this level produced a 1% prevalence of crepitations) and is consistent with the predictions made above. During the hearings, several witnesses stressed the range of physical and mental disability/impairment which may occur long before even radiologic evidence of disease appears. Typical of these comments were those made by Dr. Irving Selikoff of the Mount Sinai School of Medicine. He stated:

So, what you're seeing on x-ray is always very much less than is really present pathologically. So that, when you see a positive x-ray, there's a fair amount there in the lung . . . I've seen people with comparatively little on x-ray, who can't walk across a room. But by and large, all it means is that there's been scarring [TR. 7/2, p. 170].

While several participants commented in general on the risk of asbestosis, there was little direct comment on OSHA's quantitative estimates of risk. Hence, for these revised rules, OSHA has relied on the models developed for the proposal to predict the risk of asbestosis at the new PEL of 0.2 f/cc. Using OSHA's best estimate of risk, that from the Finkelstein data, OSHA predicted that exposure over a working lifetime to the 2 f/cc level will result in approximately a 5% incidence of asbestosis. Reducing the exposure to 0.2 f/cc would result in a lifetime incidence of asbestosis of 0.5%. While OSHA did not make predictions of risk at levels below 0.5 f/cc in the proposed rules, testimony received during the rulemaking increases OSHA's confidence that the Agency's estimates of risk at 0.2 f/cc are valid and reasonable. This is due primarily to the comments noting the validity of the model in the low dose region. Given the difficulties in accurately diagnosing cases of asbestosis and the fact that OSHA's estimates only take the risk of disabling asbestosis into account, OSHA believes that the Agency's estimates may be underestimates of the true risk of asbestosis to exposed workers.

VI. Significance of Risk

As discussed above in Section III (Pertinent Legal Authority), the Supreme Court in the Benzene case (*Industrial Union Department, AFL-CIO v. American Petroleum Institute* 448 U.S. 601 (1980)) ruled that, prior to the issuance of a new or revised standard regulating occupational exposures to toxic materials, OSHA must make a determination that a "significant" health risk exists and that the new standard will reduce or eliminate that risk. OSHA's analytical approach to making a determination that a significant risk of material impairment exists from

exposure to hazardous workplace chemicals takes into consideration a number of factors that are consistent with recent court interpretations of the OSH Act and rational, objective policy formulation. As prescribed by Section 6(b)(5) of the Act, OSHA examines the body of "best available evidence" on the toxic effects of hazardous chemicals to determine the nature and extent of possible health consequences resulting from exposure to the hazardous agent in question. Quantitative risk assessments are conducted, where possible, and the results are considered along with other relevant information, such as the nature and severity of the health consequences, to determine whether a hazardous agent poses a significant risk to workers at the current permissible exposure level. The Agency also determines whether a reduction in the permissible exposure level for the hazardous agent will substantially reduce that risk.

The Court gave some general guidance to the Agency for arriving at findings of the significance of an occupational health risk. It recognized that the Agency's determination that a particular level of risk is "significant" will be based largely on policy considerations (*UD v. API*, 448 U.S. 655, 656, n. 62). To illustrate how one may make a determination from quantitative information that a health risk is significant, the Court stated as follows:

It is the Agency's responsibility to determine in the first instance what it considers to be a "significant" risk. Some risks are plainly acceptable and others are plainly unacceptable. If, for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal, a reasonable person might well consider the risk significant and take appropriate steps to decrease or eliminate it (*UD v. API* 448 U.S. at 655).

Although the Court's example is based on a quantitative expression of the risk, the Court indicated that the significant risk determination required of OSHA is not "a mathematical straitjacket," and that "OSHA is not required to support the finding that a significant risk exists with anything approaching scientific certainty." "A reviewing court [is] to give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge [and] . . . the Agency is free to use conservative assumptions in interpreting the data with respect to carcinogens, risking error on the side of overprotection rather than underprotection" (448 U.S. at 655, 656).

OSHA has followed these guidelines in making a determination that the risk of material health impairment resulting from occupational exposure to asbestos is significant. The epidemiological and toxicological evidence and testimony presented in the November notice and in Section IV (Health Effects) of this preamble clearly show that exposure to asbestos is carcinogenic to humans and additionally causes disabling fibrotic lung disease. Lung cancer constitutes the greatest health risk to asbestos workers; in some occupational cohorts, this disease has been responsible for more than half of the excess mortality from asbestos exposure. Malignant mesotheliomas of the pleura and peritoneum, which are extremely rare among non-exposed persons, have been conclusively linked with asbestos exposure. Some studies of asbestos-exposed workers have also shown increases in mortality from gastrointestinal and other types of cancer. It has been known for years that exposure to asbestos is the only known cause of asbestosis, a progressive, fibrotic lung disease causing effects ranging from shortness of breath during exertion to complete disability, respiratory and cardiac failure, and death. OSHA's determination that the health risks from asbestos exposure is significant is based, in part, on the irreversible and ultimately fatal nature of these diseases, particularly of lung cancer and mesothelioma.

The finding that a significant risk exists is primarily supported by OSHA's quantitative risk assessment, which is based on studies of asbestos-exposed worker populations. OSHA's risk assessment (discussed in Section V of this preamble) estimates that 64 excess cancer deaths (including those from lung and gastrointestinal cancer and mesothelioma) will occur among 1,000 workers exposed at the existing permissible exposure limit of 2 f/cc for 45 years, a working lifetime. The estimates of mortality risk from mesothelioma, lung cancer, and gastrointestinal cancer are 16, 44, and 4 excess deaths, respectively, per 1,000 workers exposed for 45 years at 2 f/cc.

OSHA also estimated the risk of lung cancer, mesothelioma, and gastrointestinal cancer for 20-year and 1-year durations of exposure to asbestos at 2 f/cc. From this analysis, OSHA estimates that the risk from all asbestos-related cancers among workers exposed from 20 years to 2 f/cc is 44 excess deaths per 1,000 workers. The estimated cancer risk from all cancers among workers exposed to 2 f/cc for one year