

10^{-8}) and concluded that "this indicates that the assumption implicitly made by OSHA of a constant ratio is not universally valid" [Ex. 237A, p. 41]. Using Crump's preferred estimate of risk for K_M (0.023) gives a ratio of 9.5×10^{-8} , approximately 10 times smaller than the average K_M/K_L used in OSHA's determination of an overall K_M .

TABLE 4.—NUMBER OF MESOTHELIOMA DEATHS AND ABSOLUTE RISK BY YEARS FROM FIRST EXPOSURE, DEMENT ET AL. (1983)*

Years since first exposure (Avg)	Observed mesotheliomas	Person-years	Absolute risk *
10 (5)	0	11,380	0
10-20 (15)	0	10,621	0
20-30 (25)	0	8,055	0
30 + (35)	1	2,775	0.3604
Total	1		

* From Crump (Ex. 237A, Table 4).

* Absolute risk = (number of deaths/person-years) $\times$ 1,000.

TABLE 5.—Number of Mesothelioma Deaths and Absolute Risk by Years From First Exposure, Weill et al. (1972)*

Years since first exposure (Avg)	Observed mesotheliomas	Person-years	Absolute risk *
10-15 (12.5)	0	31,160	0
15-20 (17.5)	2	29,473	0.0678
20-25 (22.5)	0	25,080	0
25-30 (27.5)	0	14,018	0
30-35 (32.5)	0	3,832	0
35 + (37.5)	0	1,565	0
Total	2		

* From Crump (Ex. 237A, Table 4).

* Absolute risk = (number of deaths/person-years) $\times$ 1,000.

Table 5 gives the results of the calculation of K_M for the Weill et al. study. Data from the Weill et al. cohort gives, by far, the smallest values of K_M . The OSHA model shows an inadequate fit to the data ($P=0.001$) with a K_M of 7.0×10^{-10} . The three-stage multistage model showed excellent fit to the data ($P=0.90$) and gave a K_M of 1.6×10^{-10} , almost 100 times smaller than the overall K_M calculated by OSHA in the proposal.

Dr. Crump pointed to the calculation of K_M for the six studies, three with mixed exposures (Selikoff et al., Seidman et al., and Finkelstein) and three with predominantly chrysotile exposures (Peto et al., Dement et al., and Weill et al.) and observed that:

What one sees here is a large difference between the potency estimates in the upper three studies involving the mixed exposures and those in the lower three involving exposures primarily to chrysotile. . . . [I]f you look at the geometric mean, there is about a 20-fold difference in the risk. Although there is more uncertainty in the numbers in the lower group because of smaller numbers of mesotheliomas, these values are still not consistent with the ones in the upper group. I feel that, taken together, they do show a pattern of a smaller risk experienced by the

workers—based upon exposure measurements—workers exposed predominantly to chrysotile.

The value of potency used by OSHA was 1, which is smaller than the estimates for the upper studies, but as you can see, it is considerably greater than the estimates made for populations exposed mainly to chrysotile [Tr. 7/9, p. 87].

However, during questioning, Dr. Crump admitted that—

* * * [T]he chrysotile estimates I was making, I was thinking about exposures which are today predominantly chrysotile. I wasn't thinking of necessarily applying those in situations where the exposures were to mixed fibers in removal operations [Tr. 7/9, p. 119].

Although the asbestos manufacturing industry may confine itself primarily to the use of chrysotile fiber in its products, OSHA believes now, as it did at the time of the proposal, that the major sources of exposure to asbestos workers in the next 20 to 40 years will be in the demolition, renovation, and removal of asbestos products (for example, insulation) which were installed 30 to 40 years ago. These products generally contain amphiboles. This was brought out by Dr. Nicholson during cross-examination, when he noted that:

I should make the point though we are concerned in much of the regulation of the future with exposures that will be to materials that have already been put in place, in the insulation materials, the sprayed on asbestos materials, all these loosely friable [sic] insulation materials that have been applied over the years.

Virtually all of the those exposures to those materials will be of a mixed fiber type. And so I think that's what we have to deal with. You can find in some circumstances, some manufacturing circumstances, pure fiber exposure. I don't know what their risk started at, as the discussion has indicated, because of the variabilities inherent in those studies.

But most of the exposures that we have in the future will be mixed fiber exposures [Tr. 6/19, p. 1-144].

Hence, OSHA believes it is wholly correct in using estimates of K_M from studies of mixed exposures as well as single-fiber type exposures in determining an overall estimate of mesothelioma risk.

Moreover, in a post-hearing submission, Dr. Nicholson gave some additional analysis of the carcinogenic response to different asbestos fiber types [Ex. 303A]. In an effort to make a broader comparison of mesothelioma according to exposure by mineral type, Dr. Nicholson compared the risk of pleural and peritoneal mesothelioma with that of lung cancer in a variety of studies. After various appropriate adjustments, the ratio of mesothelioma as a percentage of adjusted excess lung

cancer was calculated for four studies of interest. This analysis showed reasonable agreement with the analysis done by OSHA. Dr. Nicholson concluded:

In comparing the different ratios of pleural mesothelioma to adjusted lung cancer for all studies in which the major exposure was to one fiber type, one can see that there are roughly comparable ratios for chrysotile, amosite and mixed exposure. Crocidolite has approximately a two-fold greater number of mesotheliomas as percent of excess adjusted lung cancer. However, as noted previously, the untraced individuals in the various crocidolite cohorts may lead to an overestimate of this ratio. Though some greater potency may be considered for crocidolite regarding mesothelioma (a factor of two perhaps), the uncertainty associated with other factors in a given exposure circumstance lead to much greater differences. For example, as was seen in the case of lung cancer, different exposure circumstances with the same fiber led to nearly 100-fold differences. Thus, the suggestion that there are dramatic differences between different asbestos varieties has no basis in fact. Much greater differences would appear to be related to process, to fiber size distribution effects within a single asbestos variety (note the difference between textiles and mining, e.g.), or to methodological differences in cohort studies (e.g., the asbestos cement studies of Weill et al. and of Finkelstein) [Ex. 303A, p. 6].

In addition to the data from occupational cohorts, Nicholson also pointed to some evidence of environmental exposures as supportive evidence. He noted that:

Mesothelioma has been documented in a variety of non-occupational circumstances; including among family contacts of asbestos-exposed individuals. . . . Notable is that family contact cases are seen with exposure to chrysotile, amosite and crocidolite. Relative to the risk at work, there appears to be little difference in the family contact risk by fiber type.

Animal studies substantiate the above analysis and suggest that all varieties of asbestos should be considered equally potent with respect to the production of either lung cancer or mesothelioma. Table 6 [of Ex. 303A] lists the data of Wagner et al. (1974) [Ex. 84-98] from inhalation studies using different forms of asbestos. Canadian chrysotile produced as many mesotheliomas as crocidolite and more than amosite or anthophyllite. Further, it produced lung cancer with a single day's exposure [Ex. 303A, p. 6-7].

The addition of the Weill et al. study and the Dement et al. study to the data base used for the overall calculation of K_M raises several points. First, the small number of mesothelioma deaths in the two studies makes the estimates of risk much less reliable. Dr. Nicholson