discussed the advantage of additional information, but remarked that—

* * * [T]he total number of cases involved in those two studies is three. So it would be a very large uncertainty of any estimates made with those. And when one averaged it with the much higher levels of the four studies, would not substantially alter the lower value which was chosen in the OSHA document.

That is, we would now be using an average of six studies rather than four. . . . [I]f those additional two studies were utilized there may not have been the need to artificially lower the average that was obtained using the four studies that were cited here. . . . [i]n essence, what I'm saying is that if you take account of all the data, I don't think it would change the estimate of K_M substantially. And, in fact, the correction that was made to lower the estimate is an appropriate one. It fits most of the data that do exist [Tr. 6/19, p. I-138].

Dr. Crump also noted the added uncertainty associated with the use of studies containing small numbers of deaths [Ex. 7/9, p.87].

OSHA has computed the arithmetic and geometric means of the K_M's of the six studies for both the values of K_M from the OSHA model (including Dement et al. and Weill et al. as computed by Crump) and for the "best fit" model using the K_M from the multistage model with one, two or three stages. As Dr. Nicholson suggested, the inclusion of the Dement et al. and Weill et al. data may "eliminate the need to artificially lower the average" by looking at the ratio of K_M to K_L, since these two studies represent the lower end of the mesothelioma risk. Using the data in Table 3, the OSHA model gives an arithmetic mean of the K_M of 2.73×10^{-8}, (almost three times that proposed) and a geometric mean of 0.82×10^{-8}, approximately equal to OSHA's best estimate of K_M given in the proposal.

The mean values of the estimates of K_M from each of the six studies from the multistage model with the best fit are astonishingly high, with an arithmetic mean of 64.26×10^{-8} to 70.92×10^{-8}, (up to 70 times larger than OSHA's preferred estimate of K_M) and a geometric mean of the six K_M's of 2.45×10^{-8} to 7.2×10^{-8}. Further inspection of Table 3 demonstrates that using several values of K_M from models with only slightly poorer fit (e.g., .097 vs. 0.99) would produce estimates of risk several orders of magnitude larger. Hence, according to this analysis, OSHA's original choice of a best estimate of K_M of 1×10^{-8} is by no means an overestimate, as Dr. Crump apparently contends; indeed, his own calculations show that 1×10^{-8} in fact, greatly underestimates the mesothelioma risk which may be experienced by asbestos-exposed workers.

In addition, OSHA has examined several alternate combinations of the data, including computing the best estimate of K_M from the ratio of K_M/K_L. As in the lung cancer data, these calculations produce estimates which bracket the 1×10^{-8}.

Dr. Crump's preferred estimate of K_M of 2×10^{-9} [Ex. 237A, p. 48] was based solely on the studies of predominantly chrysotile-exposed workers and was meant to represent the mesothelioma risk of workers exposed predominantly to chrysotile; his preferred estimates was not meant to characterize the risk of mesothelioma faced by workers in a variety of workplaces—including the major exposures to mixed fibers that will occur in asbestos removal, demolition, and renovation operations [Tr. 7/9, p. 119].

OSHA has therefore determined that Dr. Crump's approach is not adequate to address the question of the total risk posed by asbestos exposure, and the Agency has chosen instead to base its best estimate of risk on the six studies with sufficient data to quantify the excess risk of mesothelioma. Hence, OSHA concludes that its best estimate of K_M remains at 1×10^{-8}, as proposed. The addition of the two studies with small numbers of deaths adds some uncertainty to this estimate but, as indicated, this estimate is likely to represent a substantial underestimate of the risk of mesothelioma actually experienced by asbestos-exposed workers.

III. Estimates of Risk for Other Cancers

As discussed in Section IV, OSHA has concluded that workers exposed to asbestos are likely to be at an increased risk of gastrointestinal cancer. Though an excess of GI cancer has not been observed consistently in every study of asbestos workers, and while the ratio of gastrointestinal cancer to lung cancer varies considerably from study to study, there appears to be sufficient evidence to roughly estimate the excess gastrointestinal cancer risk in asbestos-exposed populations. A number of submissions to the record recognized the relationship between asbestos and gastrointestinal cancer [see, e.g., Exs. 91-40, 116, 163e, 158, 261A, 277, 297, 321]. In general, the risk ranges from about 5 to 20% of the excess lung cancer risk.

The AIA/NA commented that:

Although excess GI cancers have been found in some heavily exposed worker studies, no such excesses have been found in many other studies. Of the twenty-one studies reviewed by OSHA (in each of which there was a minimum of 10 observed or expected GI cancers), only seven had statistically significant excess GI cancers (Ex. 84-392 at 13) [Ex. 328, p. 1-21].

However, Dr. Nicholson pointed out at the rulemaking hearing that:

* * * [Ex. 84-392] said 21 studies were listed. Twelve demonstrated an excess gastrointestinal cancer, and eight demonstrated a deficit. One was even.

Many of those—several of those—actually were studies in which there was also no excess lung cancers. So there were circumstances where the excess risk to be expected was a very low one. And, thus, one would be within the range of statistical fluctuations no matter what the risk was; since the GI cancer . . . risk is never expected to be equal to that of the excess lung cancer risk.

I think, of these 21 studies . . . only 13, if I'm not mistaken, would demonstrate an excess lung cancer risk.

And the ones that do not [demonstrate an excess lung cancer risk] are largely the negative ones [for GI cancer] [Tr. 6/19, p. I-117].

In addition, OSHA believes the finding of a statistically significant excess of GI cancer in seven studies of worker populations to be a substantial body of evidence. As pointed out by Dr. Nicholson, many of the studies in which GI cancer was not observed were unable to detect lung cancer as well. This points perhaps to methodological problems in the studies as well as low exposures.

It was also suggested that the observed excesses could conceivably be due to a misdiagnosis of peritoneal mesothelioma. While OSHA believes it is unreasonable to totally account for these excesses (some as large as 60% of the lung cancer risk) by misdiagnosis, to the extent that the incidence of mesothelioma has been underobserved in these studies, then OSHA's predictions of the risks of mesothelioma are also underestimated.

In an attempt to quantify the risk of gastrointestinal cancer, OSHA considered a simple risk model in which gastrointestinal cancer risk was assumed to be equal to 10% of the lung cancer excess risk. As Dr. Nicholson noted:

Based upon the rough finding and given the fact that there are different dose-response relationships, that overall, considering an increase over lung cancer of 10 percent for gastrointestinal cancer would give an underestimate of possible asbestos-related GI cancers.

One finds that the relationship that I just mentioned, comparing excess GI cancer with excess lung cancer to be such that some studies demonstrated an increase of GI cancer about 50-60 percent that of lung cancer, a very high correlation. Others show,