at . . . [this particular facility]. In fact, at this time, it is not possible to answer this question based on epidemiologic data alone, because the population available for study is small, the follow up period is relatively short . . . , data on smoking are lacking, and previous exposures in other neighboring talc mines and mills represents a confounding factor" (Ex. 84-218, p. 179).

Tabershaw and Thompson (Ex. 84-219, pp. 179-180) responded to the criticism of Brown et al., and disagreed with NIOSH's conclusion that the talc from the facility contained asbestiform minerals. They cited other studies in which analysis of talc from the facility failed to find any asbestiform fibers, and took exception to NIOSH claiming that asbestos was present based on only 10 atmospheric samples taken during the grinding of a single ore sample. In addition, Tabershaw and Thompson pointed out that, of the nine individuals reported by NIOSH to have died from lung cancer, 4 were employed for less than one year at the facility making it doubtful that exposure to talc at the facility was the likely cause of lung cancer mortality for those 4 workers.

As part of their post-hearing submission, Organization Resources Counselors, Inc., submitted a publication by the R.T. Vanderbilt Company, in which Dr. Selikoff offered opinion on these epidemiology studies. In this publication, Dr. Selikoff is quoted as follows:

"[Vanderbilt] . . . employees in many cases had worked in other New York State mines. Therefore, in the analysis of studies, a question could be raised whether . . . sufficient latency had existed . . . to determine that people who worked only with Vanderbilt talc has excessive cancers. The data can be looked at in various ways. It does create a problem because the ones with the longest latency were also the one who had worked in other mines and mills by definition. . . . I wish we had enough Vanderbilt workers who had begun work 50 years ago, to be able to tell us what happens ultimately to people who inhale Vanderbilt talc. There simply aren't enough such people, if there are any." (Ex. 123-A)

OSHA agrees with Dr. Selikoff's assessment that the epidemiological data are inconclusive with respect to the asbestos-related risk associated with exposure to talc at the Vanderbilt facility. Although the NIOSH studies (Exs. 84-029, 84-181) are suggestive of an increased risk from lung cancer mortality and non-malignant respiratory morbidity among workers at this facility, they are not definitive because of the confounding factor or prior exposure to talc at other facilities. In addition, OSHA agrees with Tabershaw and Thompson (Ex 84-218) that the inclusion in the cohort of workers with less than one year of work experience at the facility further complicates the analysis. On the other hand, OSHA does not believe that the study by Stille and Tabershaw (Ex. 84-196) indicates a lack of carcinogenic risk among workers at the facility; their analysis of the subcohort with no other prior work experience is inconclusive because of the small size of the cohort and the lack of an adequate follow-up period. An assessment of the implications of these studies is further complicated by the controversy regarding the presence of asbestiform minerals at this facility. OSHA therefore does not find that these studies shed new light on the issue of the carcinogenic or fibrogenic potential of the various forms of tremolite or anthophyllite.

In addition to the epidemology studies discussed above, OSHA described an animal study conducted by Smith et al. (Ex. 84-194) in which the authors administered intrapleural injections of four different tremolitic substances into hamsters. The ore samples tested included fibrous tremolitic talc from New York, tremolite prepared from talc ore at the facility studied by NIOSH, tremolite prepared from Western U.S. talc deposits, and asbestiform tremolite. Tumors and pleural fibrosis were observed only in animals injected with tremolite from western talc or asbestiform tremolite. Smith et al. suggested that the tremolite sample from the facility studied by NIOSH yielded negative results because of the generally short length of the fibers, despite its high tremolite content. They also suggested that the fibrous tremolite sample from New York failed to elicit a carcinogenic response because of the low content of fibrous talc (tremolite constituted only 35 percent of the sample by weight; in addition, only 25 percent of the tremolite was in fibrous form). Smith et al. concluded as follows:

Since [the two samples that yielded positive results] . . . contain at least 5% of material other than tremolite, we cannot be sure that their activity is due wholly, or even in part, to tremolite. If we assume that their activity is due to tremolite, then the experiments indicate that appropriately high doses of long, thin particles of tremolite induced tumors, whereas high doses of shorter particles did not. This would, of course, be consistent with previous findings by ourselves and others with other materials, such as chrysotile and glass fibers. (Ex. 84-194, p. 338).

In a post-hearing submission (Ex. 306-A), R.T. Vanderbilt Company submitted two additional studies by Smith that contain the same results report by Smith et al. (Ex 84-194) for the tremolite from New York talc, this submission also contained a report by McConnell et al. (1983) in which F-344 rats were given a diet consisting of one percent tremolite obtained from Vanderbilt's Gouverneur mine. The tremolite had no effect on survival or tumor development compared to that of control rats. OHSA does not find this study noteworthy since, as discussed earlier in this section, several feeding studies of asbestiform minerals known to be carcinogenic by other routes of exposure have failed to show carcinogenic activity by the oral route.

The evidence presented by the R.T. Vanderbilt Company (Exs. 123-A, 306-A), namely the epidemiology study by Stille and Tabershaw and the animal studies conducted by Smith et al. (Exs. 84-194, 306A), would suggest that there was no evidence for asbestos-related disease at their facility, which they maintain contains no asbestiform fiber. Based on these data, and other evidence submitted on the mineralogy of asbestos (Exs. 123-A, 228, 229-A), they have urged OSHA to revise its definition of asbestos to exclude non-asbestiform fibrous tremolite and anthophyllite. As discussed earlier in this section, the finding of asbestos-related disease and the existence of asbestiform minerals at the Vanderbilt site were highly controversial issues during this rulemaking and, as suggested by Dr. Selikoff, cannot be completely resolved at this time. OSHA therefore finds that there is insufficient evidence upon which to state with any degree of certainty that exposure to some forms of fibrous tremolite or anthophyllite is safe. For this and other reasons discussed in Section X of this Preamble (Summary and Explanation), OSHA has not revised its definition of asbestos to exclude certain fibrous forms of these minerals. The Agency believes that this decision comports with prudent public health policy.

## V. Quantitative Risk Assessment

### *Introduction*

OSHA's determination that currently exposed workers face a significant risk of asbestos-related disease is primarily based on the results of the quantitative risk assessment performed by the Agency, as discussed in the November proposal [48 FR 51122]. OSHA has critically evaluated the scientific evidence concerning the health risk from asbestos exposure. OSHA, as well as other scientific groups, believes that asbestos exposure causes lung disease, respiratory cancer, mesothelioma, and gastrointestinal cancer. OSHA has also examined evidence that indicates that

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