



July 7, 2008

Vivian Turner  
Designated Federal Official  
EPA Science Advisory Board (1400F)  
US Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460

**Re: OSWER Interim Method to Assess Asbestos-Related Carcinogenic Risk**

Dear Ms. Turner:

The American Association for Justice (AAJ), formerly known as the Association of Trial Lawyers of America (ATLA®), hereby submits comments in response to the proposal of the Office of Solid Waste and Emergency Response (OSWER) for an interim method to assess asbestos-related carcinogenic risk.

AAJ, with members in the United States, Canada and abroad, is the world's largest trial bar. It was established in 1946 to safeguard victims' rights, strengthen the civil justice system, promote injury prevention, and foster the disclosure of information critical to public health and safety. Members of AAJ represent thousands of mesothelioma victims and their families. OSWER has proposed a revised method for estimating the potency of asbestos fibers. OSWER suggests that its intent is simply to improve risk estimates for Superfund sites, but AAJ believes the proposed methods will likely be used by asbestos producers and users to deny compensation to mesothelioma victims and their families.

For more than two decades, asbestos producers and users have argued chrysotile either does not cause cancer or causes cancer so infrequently that they should not be held liable for damages to mesothelioma victims. Government agencies for two decades have rejected this theory. The Science Advisory Board (SAB) should do so as well. OSWER simply has not shown an adequate scientific basis for its dramatic departure from established government policy nor has it adequately explained how this exercise will better protect the public health. The uncertainties in the proposed methods make it particularly ill-suited for speculating about what caused an individual's mesothelioma. Victims have suffered enough while the asbestos industry delayed accepting responsibility for the public health epidemic caused by asbestos exposure. The SAB should reject efforts to embolden asbestos producers and users even more.

**I. For Two Decades, Government Agencies Have Rejected The Theory That Public Health Policy Should Be Based on Claim That Chrysotile is a Less Potent Carcinogen Than Amphiboles.**

The asbestos industry first proffered the theory that chrysotile is less potent than other forms of asbestos in response to the Occupational Safety and Health Administration's (OSHA) proposal to regulate asbestos cancer risks. In 1984, Dr. Crump, EPA's current risk assessment consultant who was then testifying on behalf of the asbestos industry, argued that there was a risk differential by asbestos fiber type and OSHA should take that differential into account in assessing asbestos risks and setting its workplace exposure standard. The effect of this argument would have been to provide less protection to workers exposed to asbestos. OSHA rejected the argument.

Human epidemiology studies have suggested that occupational exposure to amphiboles is associated with a greater risk of mesothelioma than is exposure to chrysotile. No clear risk differential for lung cancer or other asbestos-related disease has been demonstrated by epidemiological studies. Animal experiments, however, have indicated that chrysotile is a more potent carcinogen than amphiboles when administered by inhalation or intrapleural injection, thus conflicting with the findings of human epidemiology studies.... OSHA agrees with [rulemaking experts] that epidemiological and animal evidence, taken together, fail to establish a definitive risk differential for the various types of asbestos fiber. Accordingly, OSHA has, in its Quantitative Risk Assessment [ ] and in the establishment of a permissible exposure limit [ ] recognized that all types of asbestos fiber have the same fibrogenic and carcinogenic potential. 51 Fed. Reg. 22612 (1986).

EPA also decided, in its 1986 asbestos risk assessment, to assume that all asbestos fibers posed similar risks. EPA noted "[t]here is no evidence" in the studies it considered "that would suggest a substantially different relative mesothelioma hazard for the different types of asbestos varieties." EPA Risk Assessment at 93 (1986).

EPA reaffirmed its approach to asbestos risk assessment in 1989, when it adopted a ban on asbestos products. 54 Fed. Reg. 29467. EPA noted that "a number of commenters argued that chrysotile is far less carcinogenic than other forms of asbestos." EPA recognized that there is some epidemiological evidence suggesting that crocidolite is more potent than chrysotile for inducing pleural mesothelioma. "However, definitive conclusions concerning the relative potency of various fiber types in inducing meothelioma cannot be made on the basis of epidemioligcal information.... Available information indicated that the combined epidemiological and animal evidence fail to establish conclusively difference in mesothelioma hazard for the various types of asbestos fibers. In view of the inconsistencies and uncertainty regarding this issue, EPA believes that it is prudent and in the public interest to consider all fiber types as having comparable carcinogenic potency." 54 Fed. Reg. 29470 (1989).

OSHA again looked at the issue of whether different asbestos fibers had different potencies in 1994 when the asbestos industry claimed a scientific consensus that "chrysotile

carries a reduced carcinogenic risk.” OSHA rejected the claim again, finding that “the scientific community has not achieved consensus on these issues.” The National Institute of Occupational Safety and Health (NIOSH) agreed that there was not enough scientific evidence to conclude different asbestos fibers had different potencies. Based on this evidence, “OSHA believes that there is insufficient evidence to show that chrysotile does not present a significant mesothelioma risk to exposed employees.”

OSWER’s proposed approach must be viewed against this background. For the past two decades, government agencies, urged by the asbestos industry, have considered whether there were adequate data to conclude that chrysotile asbestos was a less potent carcinogen than other types of asbestos fibers. And, for more than two decades, those government agencies have rejected the idea, consistently finding that the human data suggesting chrysotile was less potent was inconsistent and incompatible with animal data suggesting the opposite. Because the data was inconsistent and uncertain, EPA has found that it would be unwise to rely on data suggesting different potencies for public health purposes.

It remains unwise to do so. OSWER has offered no explanation for the dramatic shift in policy implicit in its proposed methods. It must do so persuasively before the SAB approves its approach. Thus, the SAB should conclude, in response to Charge Question 1, that there is not adequate data to support the proposed method.

## **II. The Process OSWER Is Relying on is Inconsistent with EPA’s Cancer Risk Assessment Guidelines.**

EPA’s cancer risk assessment guidelines require that a weight of evidence narrative precede development of a dose-response assessment. This narrative is supposed to weigh all evidence of a cancer hazard, including both animal studies and human studies. According to the guidelines, “the narrative explains the kinds of evidence available and how they fit together in drawing conclusions, and it points out significant issues/strengths/limitations of data and conclusions. Because the narrative also summarizes the mode of action information, it sets the stage for the discussion of the rationale underlying a recommended approach to dose-response assessment.” Pages 1-12.

Both EPA and OSHA have previously done a comprehensive review of the animal and human data on the carcinogenicity of asbestos. Both agencies have previously found that the human data suggests that amphiboles may be more potent than previously assumed for mesothelioma (not for lung cancer), but that animal evidence suggests that chrysotile may be more potent. Because of the inconsistency between the human and animal evidence on fiber potency, neither agency has articulated a coherent explanation of how the data fit together. Despite industry efforts to suggest a consensus exists in the scientific community that chrysotile is less potent for mesothelioma than are amphiboles, OSHA and NIOSH disagree that such a consensus exists. Because no rationale has been agreed upon to explain these inconsistencies, both agencies have refused – at least until now – to assume a lower potency for chrysotile-induced mesothelioma for risk assessment.

OSWER's proposed methods represent a dramatic change in government policy. This change flies in the face of the requirement, in EPA's cancer risk assessment guidelines, that a comprehensive analysis of scientific data precedes and guides development of dose-response models. It is particularly remarkable that OSWER has developed potency factors which assume asbestos risk varies by fiber type when both EPA and OSHA have consistently rejected arguments for such an approach. It has not explained why this change of policy is justified. Such an explanation is required before the SAB supports a method for calculating potency factors fundamentally at odds with established government policy.

OSWER acknowledges that a full assessment of the scientific data is needed. The Integrated Risk Information System (IRIS) says it is ongoing. Nevertheless, OSWER is moving forward with potency formulas which presuppose the outcome of the still to be announced weight of evidence review. Why rush to implement potency factors based on interpretation of scientific data previously rejected by EPA? Why allow potency formulas to implicitly resolve disputed scientific issues? OSWER has offered no explanation.

OSWER has put the cart before the horse. It then tries to throw the issue back to the SAB, asking in Charge Question 1 whether the data are adequate to support the method it proposes. But, OSWER has not provided the SAB with a qualitative narrative describing that data. EPA has previously found the data were so uncertain that it could not prudently adopt a risk assessment which relied on different fiber potencies. Why is it prudent to do so now?

### **III. The Data Does Not Support the Conclusion that Chrysotile is Less Potent Than Previously Thought.**

In 1982, Nicholson, et al., prospectively estimated future mesothelioma deaths in the United States as a result of occupational exposure. Nicholson made no effort to estimate future mesothelioma deaths from the type of community exposure with which OSWER must contend. Nicholson was also the primary author of the EPA 1986 Risk Assessment for asbestos. Nicholson's 1982 paper assumed, as did EPA, that all asbestos fibers are equally potent for causing mesothelioma. He based his 1982 projections of future mesothelioma deaths and the 1986 risk estimate, in large measure, on mesothelioma deaths observed by Selikoff and Seidman among workers exposed to significant chrysotile asbestos. Nicholson's predictions about the annual incidence of expected mesothelioma deaths have closely tracked actual mesothelioma deaths from 1982 to the present.

Any revised estimate of risk which suggests mesothelioma deaths from chrysotile have been overestimated would seem to be inconsistent with actual experience. Likewise, any method for estimating chrysotile potency which suggests it causes fewer mesotheliomas deaths than predicted by the 1986 model is incompatible with actual experience. Furthermore, any method which predicts lower chrysotile mesothelioma risk because it excludes the Selikoff/Seidman data from its potency estimates, is not credible, since, according to OSHA, the Selikoff/Seidman data represent over 84% of mesothelioma deaths observed in epidemiology studies.

#### **IV. Potency Factors Will Be Used To Deny Cancer Victims Compensation.**

OSWER's effort to develop specific cancer potency factors for amphiboles may be a useful way to decide whether sites contaminated with tremolite-laden vermiculite require more clean up, because they pose greater risks than previously thought. It does not follow, however, that in doing so OSWER should propose a method which will have the effect of so dramatically reducing the predicted mesothelioma risks from chrysotile. Whatever value these methods may have for gauging clean up responsibilities, mesothelioma victims would suffer a grave injustice if these methods are used in court to deny victims compensation. The SAB should ensure they are not used for that purpose.

For the reasons previously stated, the uncertainties associated with the potency factors make them particularly ill-suited for use in litigation to determine whether chrysotile caused an individual's mesothelioma. Yet, that is exactly how they will be used. Since OSWER first began developing fiber-specific potency factors, asbestos defendants have pointed to those analyses to argue that EPA agrees that chrysotile poses substantially less risk for mesothelioma than previously thought. But, since EPA has never formally agreed that chrysotile poses less risk, this defense strategy has had little success. If the SAB approves the OSWER method, its principal effect is unlikely to be felt at toxic waste sites. Rather, any SAB endorsement of OSWER's methods will be used to deny compensation to mesothelioma victims and their families. The SAB should ensure that this is not the case.

AAJ recognizes OSWER's desire to improve the process for determining clean up responsibilities for toxic waste sites. However, doing so by relying on potency factors which likely underestimate the risks from chrysotile exposure and are so uncertain is imprudent as a matter of public health policy and unfair to asbestos victims. Unless revised potency factors decrease the uncertainty inherent in risk assessment – which these do not -- and are based on all the animal and human data showing risk (rather than a skewed subset of the human data), they should not form the basis of EPA policy.

AAJ appreciates the opportunity to submit these comments in response to the OSWER interim method to assess asbestos-related cancer risk. If you have any questions or comments, please contact Gerie Voss, AAJ's Director of Regulatory Affairs at (202) 965-3500 ext. 748.

Sincerely,

Kathleen Flynn Peterson  
President  
American Association for Justice

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