Miller, Diane M. (CDC/NIOSH/EID)

From: Randy Rabinowitz
Sent: Tuesday, December 30, 2008 1:32 PM
To: Miller, Diane M. (CDC/NIOSH/EID)
Cc: 'Duncan, Julia'; 'Voss, Gerie'
Subject: FW: 099-A NIOSH Revised CIB Roadmap
Attachments: AAJ Comments 9-30-08.pdf

I am forwarding a copy of an e mail submitting comments from the American Association of Justice to NIOSH's Docket on the Asbestos Roadmap. These comments were initially sent to NIOSH on September 30, 2008, but were not entered in the docket. Could you please enter these in the docket now. Thank you and Happy New Year.

From: Duncan, Julia [mailto:Julia.Duncan@justice.org]
Sent: Tuesday, December 30, 2008 10:20 AM
To: randy(Voss, Gerie
Subject: FW: 099-A NIOSH Revised CIB Roadmap

Here is the email I sent them with the date and time on it. I can't find anything they sent back to me.

Julia J. Duncan
Associate Director and Counsel, Federal Relations
American Association for Justice
Formerly the Association of Trial Lawyers of America
202-944-2819
Julia.Duncan@justice.org

From: Duncan, Julia
Sent: Tuesday, September 30, 2008 1:32 PM
To: nioshdocket@cdc.gov
Subject: 099-A NIOSH Revised CIB Roadmap

Please accept and file attached comments on behalf of the American Association of Justice relating to **NIOSH Docket Number 099-A.**

Thank you,

Julia J. Duncan
Associate Director and Counsel, Federal Relations
Public Affairs
American Association for Justice
Formerly the Association of Trial Lawyers of America
202-944-2819
Julia.Duncan@justice.org

September 30, 2008

NIOSH Mailstop: C-34
Robert A. Taft Lab.
4676 Columbia Parkway
Cincinnati, Ohio 45226

Re: Comments on NIOSH Asbestos Fibers and Other Elongated Mineral Particles: State of the Science and Roadmap for Research – Revised Draft, June 2008 (Docket No. NIOSH 099-A)

Dear Sir or Madam:

The American Association for Justice (AAJ), formerly known as the Association of Trial Lawyers of America, hereby submits comments in response to the agency's NIOSH Roadmap for Research.

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.

AAJ supports the premise stated in the proposed Roadmap's executive summary that a strategic plan for research in toxicology, exposure assessment, epidemiology and analytical methods is needed to reduce existing uncertainties and the help resolve current controversies about the risks of exposure to asbestos and other mineral fibers. AAJ is concerned, however, that several features of the revised draft might be misconstrued and we, therefore, suggest the following changes.

I. The roadmap should state that the definition of asbestos is being clarified, not changed.

The revised draft states that there has been confusion as to whether the "additional covered minerals" covered by NIOSH's REL since 1990 have been included in the definition of asbestos. It goes on to say that "NIOSH wishes to make it clear that such nonasbestiform minerals are not 'asbestos' or 'asbestos minerals.'" The revised draft should state explicitly that this clarifies existing policy.

Since at least 1990 NIOSH has made a distinction between asbestos minerals and other materials that are covered by the REL. For example, NIOSH's testimony in the 1990 OSHA rulemaking hearing was that "the asbestos minerals are defined as chrysotile, crocidolite, amosite (cummingtonite-grunerite), anthophyllite, tremolite, and actinolite. In addition, airborne cleavage fragments from the nonasbestiform habits of the serpentine minerals antigorite and

lizardite, and the amphibole minerals contained in the series cummingtonite-grunerite, tremolite-ferroactinolite, and glaucophane-riebeckite shall also be counted as fibers provided they meet the criteria for a fiber when viewed microscopically." This is also the current description of the REL in the NIOSH Pocket Guide.

Some individuals and organizations may have become confused, because in some places NIOSH has referred to the nonasbestiform materials covered by the REL as "asbestos fibers." But NIOSH has never referred to them as "asbestos" or "asbestos minerals" and a careful reading of NIOSH documents shows that NIOSH has consistently stated that the REL covers the limited list of "asbestos minerals" noted above along with other non-asbestos materials.

The revised draft sharpens the way this distinction is described, but it does not make any substantive change. Asbestos is now defined as "A generic term for silicate minerals occurring in the asbestiform habit, usually used to refer to those minerals that have been commercially exploited as asbestos, including chrysotile in the serpentine mineral group and tremolite asbestos, actinolite asbestos, anthophyllite asbestos, cummingtonite-grunerite asbestos (amosite), and riebeckite asbestos (crocidolite) in the amphibole mineral group." The revised draft also defines the materials covered by the REL as these six commercial forms of asbestos plus a list of other materials that are not covered by the asbestos definition, including "their nonasbestiform analogs (the serpentine minerals antigorite and lizardite, and the amphibole minerals contained in the cummingtonite-grunerite mineral series, the tremolite-ferroactinolite mineral series, and the glaucophane-riebeckite mineral series)."

The definitions of asbestos and REL-covered materials from the 1990 documents and the new revised Roadmap draft are identical in substance although different in wording. Therefore, the Roadmap should note that this is a clarification, rather than a change to the definition of asbestos.

II. The roadmap should state that the listed concerns with NIOSH's 1990 recommendations are concerns held by some stakeholders and are not necessarily concerns of NIOSH itself.

The revised draft lists six "concerns" that have been raised through the years. The document should state which individuals and/or organizations have raised these concerns and make it clear that this is not an official list of NIOSH's "concerns."

III. The roadmap should qualify the potential use of short-term tests.

The revised draft states that the ideal outcome of a strategic research program would be to use the research results to develop recommendations for worker protection and that it would be "particularly advantageous" if this could be "based primarily on results from validated *in vitro* or short term *in vivo* assays." AAJ urges that NIOSH set this statement in proper context by stating clearly that there are no such tests that currently have sufficient sensitivity, specificity and predictive value to be used for such a purpose.

IV. The roadmap should state that NIOSH's position with regard to precautionary action in the face of uncertainty has been clarified but not changed.

The executive summary of the revised draft states on p. vii: "Due to various study limitations, NIOSH has viewed findings from relevant epidemiological studies as providing inconclusive, as opposed to either positive or negative, evidence regarding health hazards associated with exposures to EMPs from nonasbestiform amphiboles." Later in the document (p. 17) it is made clear that "based on inconclusive epidemiological evidence for lung cancer risk associated with exposure to cleavage fragments... NIOSH took a precautionary approach..." and included these materials among those covered by the REL.

NIOSH should state clearly in the executive summary that its view on this matter has not changed, that it still believes that precautionary action is often appropriate when the evidence is inconclusive, and that the existence of the Roadmap is not a retraction of past policy statements or documents. The executive summary should also state that while the scientific basis for public policy evolves over time, NIOSH's past statements and documents regarding asbestos have always been based on the best available evidence and continue to reflect the Agency's sound scientific judgment. Without such statements it will be difficult to understand the implications of statements on pp. 27-28[1] and p. 62.[2]

V. The roadmap should state more clearly that new analytic tools such as transmission electron microscopy (TEM) should not be used by regulatory agencies without first changing the exposure standards to which they are applied.

The revised draft on p. 54 states: "Care should be taken in developing or applying new analytical methods to the analysis of asbestos for standardized and compliance assessments. The use of new or different analytical methods to assess exposures must be carefully evaluated and validated to ensure that they measure exposures covered by the health protection standard." This is not a sufficient caution.

The Roadmap document should address the possibility that a new method applied to an older, existing health protection standard may inadvertently reduce worker protections. For example, the existing OSHA asbestos standard is based on PCM analysis, recognizing that this method is relatively insensitive and will measure fibers not covered by the standard. The standard, therefore, was set at a higher level than if the analytic technique had been more specific. For example, consider a workplace where the airborne fibers were 50% asbestos and 50% nonasbestiform. PCM sampling might show that workers were exposed to total fiber levels

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[1] "The results from studies of populations reportedly exposed to nonasbestiform EMPs do not provide clear answers regarding the toxicity of these EMPs...The findings from these studies should best be viewed as providing inconclusive as opposed to negative evidence regarding the health hazards associated with exposure to nonasbestiform EMPs."

[2] "...positive correlations between lung cancer and exposure to short asbestos fibers make it difficult to rule out a role for short asbestos fibers in the causation of disease."

just exceeding the standard of 0.1 f/cc. If TEM sampling were done in the same workplace and distinguished clearly between asbestos and nonasbestiform fibers and reported the exposure level just in terms of the covered asbestos, the result would be just more than half the PEL. The NIOSH roadmap document needs to state that if sampling and analytic methods for risk assessment become more sensitive and specific, the allowable standards for asbestos exposure will need to be revised downward.

VI. The suggestion to convene an expert panel to consider whether there is an adequate database to conduct a quantitative risk assessment for nonasbestiform amphibole EMP's should be deleted.

The revised draft states (p. 77) "If nonasbestiform amphibole EMPs are, in fact, associated with some risk, a quantitative risk assessment would be needed to understand whether the risks are similar to the risk associated with exposures to asbestos fibers. An expert panel could be assembled and charged with ascertaining if the existing epidemiological evidence could support development of a likely maximum risk estimate associated with exposure to nonasbestiform amphibole EMPs." While it would be useful to know the relative potency of various nonasbestiform vs. asbestos fibers, the expert asbestos panel recently assembled by the Science Advisory Board of the EPA has already considered this question and concluded that the existing epidemiological evidence is not sufficient to support quantitative asbestos risk assessment. AAJ therefore asks that this suggestion be deleted from the final Roadmap.

AAJ appreciates this opportunity to submit comments in response to the Agency's proposed Roadmap for Research regarding asbestos fibers and elongated material particles. If you have any questions or comments, please contact Gerie Voss, AAJ's Director of Regulatory Affairs at (202) 965-3500 ext. 748.

Sincerely,

Les Weisbrod

Les Weisbrod
President
American Association for Justice

/gv