

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

From: Glenn, Robert [RGlenn@crowell.com]
Sent: Monday, November 03, 2008 9:43 AM
To: Miller, Diane M. (CDC/NIOSH/EID)
Cc: Kalish, Paul; Behrens, Mark (SHB); Mark Ellis; Hearl, Frank J. (CDC/NIOSH/OD)
Subject: NIOSH Asbestos Roadmap Comments
Attachments: Coalition Comments NIOSH Asbestos Roadmap 10-1-08.pdf

Dear Ms. Miller,

I just got through speaking with Mark Ellis regarding comments not being received in the NIOSH Docket related to the Asbestos Roadmap. Mark has informed me that the comments he sent on behalf of the IMA-NA were not received. Below is the text of my email which transmitted the comments of the Coalition for Litigation Justice which were sent on October 1, 2008. I was unable to get them submitted by the deadline of September 30 because of it being a Jewish holiday and I was unable to get approval from the head of the Coalition due to observance of the holiday. I corresponded with Frank Hearl regarding our problem with obtaining formal approval and Frank granted me a one-day extension. I can forward our e-mail correspondence if necessary. You will find our comments attached. I would appreciate a reply to this e-mail regarding receipt of our comments. Because of them being a month late, will they receive consideration by the working group revising the Current Intelligence Bulletin?

Sincerely,
Bob Glenn

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<<Coalition Comments NIOSH Asbestos Roadmap 10-1-08.pdf>>

Please find attached the comments of the Coalition for Litigation Justice on the NIOSH Revised Draft - Current Intelligence Bulletin - Asbestos Fibers and Other Elongated Mineral Particles: State of the Science and Roadmap for Research. We appreciate consideration of our comments in finalizing your report.

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**COALITION FOR LITIGATION JUSTICE
COMMENTS ON THE REVISED DRAFT**

**CURRENT INTELLIGENCE BULLETIN – ASBESTOS FIBERS AND OTHER
ELONGATED MINERAL PARTICLES: STATE OF THE SCIENCE AND ROADMAP FOR
RESEARCH**

The Coalition for Litigation Justice, Inc. (Coalition) appreciates the opportunity to comment on the revised draft National Institute for Occupational Safety and Health (NIOSH) Current Intelligence Bulletin – Asbestos Fibers and Other Elongated Mineral Particles: State of the Science and Roadmap for Research.¹ The Coalition was formed in 2000 by insurers as a nonprofit association to address and improve the toxic tort litigation environment.² The Coalition has been interested in this issue since the publication of the NIOSH initial report, Asbestos and Other Mineral Fibers: A Roadmap for Scientific Research.³ To provide insight for practitioners in the occupational health into the topic of the proper nomenclature for asbestos and nonasbestiform minerals, the Coalition helped prepare a paper published this year. See Robert Glenn et al., *Asbestos: By Any Other Name, Is It Still?*, 38:22 *Occup. Safety & Health Reporter* (BNA) (May 29, 2008). A copy of the paper is attached for your review and consideration in finalizing the NIOSH Roadmap.

¹ NIOSH, *Revised Draft NIOSH Current Intelligence Bulletin - Asbestos Fibers and Other Elongated Mineral Particles: State of the Science and Roadmap for Research*, June 2008.

² The Coalition includes Century Indemnity Company; Chubb & Son, a division of Federal Insurance Company, CNA service mark companies, Fireman's Fund Insurance Company, Liberty Mutual Insurance Group, and the Great American Insurance Company.

³ Paul Middendorf, Ph.D., et al., *Asbestos and Other Mineral Fibers: A Roadmap for Scientific Research* iii (NIOSH Mineral Fibers Work Group Feb. 2007).

NIOSH apparently recognizes that confusion has been created among health scientists studying asbestos as a result of NIOSH continuing its long held practice of including nonasbestiform minerals in its definition of asbestos.

NIOSH recognizes that its descriptions of the REL since 1990 have created confusion and caused many to infer that the additional covered minerals were included by NIOSH in its definition of "asbestos." NIOSH wishes to make clear that such nonasbestiform minerals are not "asbestos" or "asbestos minerals." NIOSH also wishes to minimize any potential future confusion by no longer referring to particles from the nonasbestiform analogs of the asbestos minerals as "asbestos fibers." In a clarified REL presented in this Roadmap, NIOSH avoids referring to particles from such nonasbestiform minerals as "asbestos fibers" and clarifies that particles meeting the specified dimensional criteria remain countable under the REL even if they are derived from nonasbestiform minerals.⁴

It remains to be seen whether the change adds clarity to the issue, however, it might have been better for NIOSH to conform with the nomenclature accepted and used by mineral scientists when discussing asbestiform and nonasbestiform habits rather than choose to introduce two new terms, "elongated mineral particle" and "covered mineral", into the discussion.

At this point, the most serious shortcoming of the present NIOSH Roadmap is the failure to conduct either a qualitative or quantitative risk assessment for the nonasbestiform analogs of the asbestos minerals. Rather than attempt to determine through quantitative risk assessment what levels, if any, of exposure to nonasbestiform analogs of asbestos might be associated with the asbestos-related disease endpoints, NIOSH chose to simply apply the 0.1 fiber per cubic centimeter (f/cc) exposure limit that had been established based on epidemiology studies for asbestos minerals. It is helpful to review the development of the 0.1 f/cc limit and how it was passed on to apply to the nonasbestiform analogs of the asbestos minerals.

⁴ See *supra* note 1.

The revised NIOSH Roadmap on page 27 attributes the 0.1 f/cc recommended exposure limit (REL) to the NIOSH Revised Recommended Asbestos Standard published in 1976.^{5,6} It is the opinion of the Coalition that the authors of the 1976 document did not establish this level for the nonasbestiform analogs of asbestos because there is no discussion of human health studies of actinolite and tremolite, and the only discussion of anthophyllite is of the experience in Finland of a commercial form of anthophyllite asbestos. Moreover, there is no discussion in the 1976 NIOSH Revised Recommended Asbestos Standard of the health studies of the New York state talcs which have been at the center of attempts to regulate the nonasbestiform analogs of asbestos. The only study discussed with implications for the nonasbestiform analogs is the Gillam study of Homestake gold miners which found a threefold increase in the mortality from both malignant and nonmalignant respiratory diseases.⁷ The 1976 NIOSH Revised Recommended Asbestos Standard defined asbestos to be:

Asbestos is defined to be chrysotile, crocidolite, and fibrous cummingtonite-grunerite including amosite, fibrous tremolite, fibrous actinolite, and fibrous anthophyllite. The fibrosity of the above minerals is ascertained on a microscopic level with fibers defined to be particles with an aspect ratio of 3 to 1 or larger.⁸

⁵ See *supra* note 1.

⁶ NIOSH [1976]. Revised Recommended Asbestos Standard. National Institute for Occupational Safety and Health, Cincinnati, OH, DHEW (NIOSH) Publication No. 77-169.

⁷ Gillam JD, Dement JM, Lemen RA, Wagoner JK, Archer VE, Blejer HP, *Mortality Patterns Among Hard Rock Gold Miners Exposed to an Asbestiform Mineral*, 271 ANNALS NY ACAD. SCI. 336-344 (1976). The Gillam study was an initial study of a population of gold miners at the Homestake mine in Lead, South Dakota. The study was of only 439 individuals who had participated in an earlier U.S. Public Health Service silicosis study. The excess mortality was not reproduced in later larger studies with complete ascertainment of the cohort and longer follow-up (McDonald, 1978; Steenland and Brown, 1995).

⁸ See *supra* note 6.

The term fibrous was not defined in the document. Further evidence that the 1976 NIOSH Revised Recommended Asbestos Standard was not intended to apply to the nonasbestiform analogs of asbestos was NIOSH's comment that::

The standard was designed only for the processing, manufacturing, and use of asbestos and asbestos-containing products as applicable under the Occupational Safety and Health Act of 1970.⁹

It is thus clear that NIOSH that the NIOSH REL of 0.1 f/cc published in the 1976 NIOSH Revised Recommended Asbestos Standard was not meant to be a health-based exposure limit for the nonasbestiform analogs of asbestos.

The next important chapter in the regulation of asbestos, which could have potentially impacted the nonasbestiform analogs of asbestos, was the OSHA rulemaking that took place from 1984 until 1986. It was during this rulemaking that the asbestos definition took a particularly baffling turn that has not been explained fully to this day. In its proposed rule published in the Federal Register, OSHA made note that no other federal agencies, including the Mine Safety and Health Administration (MSHA), the Environmental Protection Agency (EPA), the Consumer Product Safety Commission and the Department of Education, regulated the nonasbestiform varieties of actinolite, tremolite and anthophyllite (herein referred to as ATA or nonasbestiform ATA) as asbestos.¹⁰ OSHA made it clear in the proposal that it intended to add the adjective "asbestiform" as a qualifier to the definition of ATA:

OSHA anticipates that it will change its definition by adding the adjective "asbestiform" in front of the nouns "tremolite, anthophyllite, and actinolite" in the current definition, or adopt similar language bring OSHA's definition into conformity with that of other federal agencies.

⁹ See *supra* note 6.

¹⁰ 49 Fed. Reg. 14,121 (Apr. 10, 1984).

This change in definition would mean that mineral products such as tremolite in talc products that are now regulated as asbestos under the OSHA standard would no longer be specifically regulated under the asbestos standard. OSHA requests and encourages public comments on whether the mineralogic definition of asbestos fibers should be adopted in OSHA's definition for asbestos.¹¹

NIOSH in its June 21, 1984, testimony did not object or offer any comment regarding the change in the asbestos definition to add the adjective "asbestiform" to actinolite, tremolite and anthophyllite with the end result being that the nonasbestiform analogs of asbestos would not be regulated under the asbestos standard. A further indication of OSHA's intent not to regulate the nonasbestiform analogs of asbestos was the fact that the quantitative risk assessment prepared by Dr. Nicholson of the Mt. Sinai School of Medicine did not use any of the studies of the nonasbestiform analogs in developing risk estimates for lung cancer, mesothelioma or asbestosis.¹²

Against this backdrop, it was surprising to some involved in the rulemaking when in its final rule OSHA reversed its position regarding the nonasbestiform analogs expressed in its proposed rule.¹³ Instead of following through with its earlier assessment regarding the health risks associated with the nonasbestiform analogs, the agency changed course and in less than a page discussion in the Federal Register justified its decision to include the nonasbestiform analogs. In doing so, it is not apparent from the rulemaking record as to what new information was submitted that provided a sufficient scientific foundation to cause OSHA to reverse its position even though the 1984 proposal invited the public to provide comment on this issue.

¹¹ 49 Fed. Reg. 14,122 (Apr. 10, 1984).

¹² OSHA Docket H-033C, Exhibit 84-392, *Quantitative Risk Assessment for Asbestos Related Cancers*, William J. Nicholson, Mount Sinai School of Medicine, New York, NY, Oct. 1983.

¹³ *Preamble to OSHA 1986 Final Asbestos Standard*, 51 Fed. Reg. 22,612 (June 20, 1986).

Indeed, after modifying its asbestos definition to include the nonasbestiform analogs, OSHA failed to return to the risk assessment from the 1984 proposal used to support its permissible exposure limit of 0.1 f/cc and include studies of exposure to the nonasbestiform analogs. OSHA simply swept the nonasbestiform analogs into the asbestos regulation and the promulgated PEL of 0.1 f/cc without quantitative or qualitative risk assessment. OSHA supported its decision by stating:

The Agency recognizes that the minerals tremolite, actinolite and anthophyllite exist in different forms. Further, the Agency has concluded that all forms of these minerals should continue to be regulated for the reasons stated above. Therefore, OSHA is amending the definition of asbestos in recognition that different mineral forms exist and adding a definition for tremolite, anthophyllite and actinolite to make it clear that all of the mineral forms come under the scope of the standard.¹⁴

In its final rule OSHA defined asbestos as:

"Asbestos" includes chrysotile, amosite, crocidolite, tremolite asbestos, anthophyllite asbestos, actinolite asbestos, and any of these minerals that have been chemically treated and/or altered.¹⁵

OSHA then went on to define tremolite, actinolite and anthophyllite as:

"Tremolite, anthophyllite, or actinolite" means the non-asbestos form of these minerals, and any of these minerals that have been chemically treated and/or altered.¹⁶

On October 17, 1986, OSHA granted an administrative stay of the asbestos standard related to occupational exposure to nonasbestiform ATA and decided to conduct supplemental rulemaking limited to the issue of whether nonasbestiform ATA should continue to be regulated in the same standards and to the same extent as asbestos, or whether it should be treated in some

¹⁴ 51 Fed. Reg. at 22,679 (June 20, 1986).

¹⁵ *Id.* at 22,733.

¹⁶ *Id.*

other way.¹⁷ The stay was granted to allow OSHA to review a letter from the Director of NIOSH and certain related NIOSH staff memoranda which were brought to OSHA's attention, as well as submissions from other stakeholders concerning the appropriateness of regulating nonasbestiform ATA in the revised asbestos standards. OSHA noted in granting the stay that the post-rulemaking submissions and in particular, the documents generated by NIOSH, raised serious questions about the nature and extent of the hazards posed by these non-asbestiform minerals.

In 1990, NIOSH decided to revise its recommendation concerning occupational exposure to airborne asbestos fibers over concerns about the potential health risks associated with worker exposure to the nonasbestiform analogs of asbestos and the inability of the analytical method routinely used for airborne asbestos fiber analysis (i.e., phase contrast microscopy) to differentiate between the nonasbestiform analogs of asbestos from the asbestiform varieties. To address these concerns, NIOSH defined "airborne asbestos fibers" to encompass not only fibers from the six previously listed asbestos minerals (chrysotile, crocidolite, amosite, anthophyllite asbestos, tremolite asbestos, and actinolite asbestos), but also to include the nonasbestiform analogs of these minerals. NIOSH continued with phase contrast microscopy as the recommended analytical method and retained its counting rules of particles with an aspect ratio of 3:1 or greater and a length greater than 5 micrometers. NIOSH also retained its REL from its 1976 Revised Asbestos Standard of 0.1 f/cc.

¹⁷ 51 Fed. Reg. at 37002 (Oct. 17, 1986).

In the same year OSHA reopened its asbestos rulemaking on the stayed portion of the standard regarding the regulation of nonasbestiform ATA.¹⁸ In the preamble to the proposal OSHA noted that after a review of all the available evidence that it believes that there is insufficient evidence to conclude that nonasbestiform ATA cleavage fragments present a health risk similar in magnitude or type to fibers of their asbestiform counterparts. OSHA went on to state:

OSHA believes that the health evidence is unclear as to the carcinogenicity of non-asbestiform cleavage fragments of tremolite, anthophyllite and actinolite. For these reasons OSHA believes that it may be inappropriate to include these minerals under the scope of the revised standards for asbestos for which a significant risk to workers has been clearly established. It may be more appropriate to address these non-asbestiform minerals with a different regulatory approach or to regulate the substances as "particulates not otherwise regulated" under Table Z-1-A of the Air Contaminant Standard. Thus OSHA proposes not to include non-asbestiform tremolite, anthophyllite and actinolite under the revised standards for asbestos.¹⁹

OSHA established a separate docket for the nonasbestiform ATA portion of the rule, and after receiving public comment and holding days of public hearings published its Final Rule in the Federal Register on June 8, 1992. The final standard defined asbestos as "chrysotile, amosite, crocidolite, tremolite asbestos, anthophyllite asbestos, actinolite asbestos, and any of these minerals that have been chemically treated and/or altered."²⁰ This definition explicitly excluded minerals of the same chemical composition that did not grow in the asbestiform habit.²¹ OSHA chose not to include these non-asbestiform minerals in its updated regulation because

¹⁸ 55 Fed. Reg. 4938 (Feb. 12, 1990).

¹⁹ *Id.* at 4949.

²⁰ *Preamble to OSHA 1992 Final Asbestos Standard*, 57 Fed. Reg. 24310 (June 8, 1992).

²¹ *Id.* at. 24310-01.

there was not conclusive evidence that these mineral forms posed the same health risks as those growing in the asbestiform habit:

OSHA's determination to remove non-asbestiform ATA [anthophyllite, tremolite, and actinolite] from the scope of the asbestos standards, is based on the insufficiency of evidence to support determinations that their further inclusion would protect exposed employees from a risk of disease which was the equivalent in incidence and gravity to asbestos related disease, and that removing coverage would pose a significant risk to exposed employees. The Agency also finds that the evidence is insufficient to regulate non-asbestiform ATA as presenting a significant health risk to employees other than as a physical irritant. . . .²²

Most importantly, OSHA recognized that asbestos and non-asbestiform ATA were "distinguishable mineral entities" and, that "the characteristics which differentiate them generally appear to correspond to the properties which may dictate biological response."²³ In other words, OSHA recognized not only that a different structural form of the same mineral made it distinguishable for identification purposes, but also that the different structural forms had different potential health consequences.²⁴ OSHA concluded that the available toxicological evidence relating specifically to non-asbestiform ATA was either negative or inconclusive regarding the health effects from exposure. For the human evidence, OSHA relied on three different cohort studies of mine workers exposed to non-asbestiform cleavage fragments to determine if they had increased mortality from lung cancer and mesothelioma. The three cohorts were of workers exposed to (1) a grunerite-cummingtonite ore in the Homestake gold mine in

²² *Id.* at 1.

²³ *Id.* at 2.

²⁴ Glenn RE, Lee RJ, Jastrem LM, Bunker KL, Van Orden DR, and Strohmeier BR, *Asbestos: By Any Other Name, Is It Still?*, 38:22 *Occup. Safety & Health Reporter* (BNA) (May 29, 2008).

South Dakota;²⁵ (2) grunerite and other non-asbestiform amphiboles in the Minnesota taconite mines;²⁶ and (3) non-asbestiform ATA in an industrial talc mine in New York.²⁷

Indeed, OSHA found that most of the studies of non-asbestiform ATA failed to show a statistically significant positive response to exposure.²⁸ Therefore, OSHA determined that from a regulatory perspective, the evidence was insufficient to support regulating non-asbestiform ATA as presenting a risk similar in kind and to the extent of asbestos. Further, OSHA determined that workers exposed to non-asbestiform varieties of regulated asbestos would not face a significant risk if these varieties were excluded from the asbestos standard. (Additional studies following the 1992 OSHA rulemaking in the Homestake gold mine cohort and the New

²⁵ Gillam JD, Dement JM, Lemen RA, Wagoner JK, Archer VE, Blejer HP, *Mortality Patterns Among Hard Rock Gold Miners Exposed to an Asbestiform Mineral*, 271 *Annals NY Acad. Sci.* 336-344 (1976); McDonald JC, Gibbs GW, Liddell FDK, McDonald AD, *Mortality After Long Exposure to Cummingtonite-grunerite*, 118(2) *AM. REV. RESP. DIS.* 271-277 (1978); Brown DP, Kaplan SD, Zumwalde RD, Kaplowitz M, Archer VE, *Retrospective Cohort Mortality Study of Underground Gold Mine Workers, Silica, Silicosis, and Lung Cancer* 335-349 (Goldsmith D, Winn D, Shy C (Eds): New York: Praeger 1986).

²⁶ Higgins IT, Glassman JH, Oh MS, Cornell RG., *Mortality of Reserve Mining Company Employees in Relation to Taconite Dust Exposure*, 118(5) *AM. J. EPIDEMIOLOGY* 710-719 (1983); Cooper WC, Wong O, Graebner R, *Mortality of Workers in Two Minnesota Taconite Mining and Milling Operations*. 30 *J. OCCUP. MED.* 506-510 (1988); Cooper WC, Wong O, Trent LS, Harris F, *An Updated Study of Taconite Miners and Millers Exposed to Silica and Non-asbestiform Amphiboles*, 34 *J. OCCUP. MED.* 173-180 (1992).

²⁷ Brown DP, Dement JM, Wagoner JK, *Mortality Patterns Among Miners and Millers Occupationally Exposed to Asbestiform Talc, Dusts and Disease* 317-324 (Lemen R, Dement JM (Eds) Pathotox Publisher, Park Forest South, IL 1979); Lamm SH, Levine MS, Starr JA, Tirey SL, *Analysis of Excess Lung Cancer Risk in Short-term Employees*, 127 *Am. J. Epidemiology* 1202-1209 (1988); Dement JM, Zumwalde RD; Gamble JF, Fellner W, DeMeo MJ; Brown DP, Wagoner JP, *Occupational Exposure to Talc Containing Asbestos, Morbidity, Mortality, and Environmental Studies of Miners and Millers*, I. Environmental Study, II. Cross Sectional Morbidity Study, III. Retrospective Cohort Study of Mortality, NIOSH Tech. Rep., DHEW (NIOSH) Pub. No. 80-115 (Feb. 1980); Stille WT, Tabershaw IR, *The Mortality Experience of Upstate New York Talc Workers*, 24 *J. Occup. Med.* 480-484 (1982); Gamble J, OSHA Docket # H033D, *Asbestos*, Exh. 478-8, No. 1221571, 237 (1990), available at <http://dockets.osha.gov/vg001/V023A/00/99/01.PDF>.

²⁸ See *supra* note 24.

York talc mine cohort have failed to show a positive relationship between exposure to non-asbestiform cleavage fragments and either lung cancer or mesothelioma.²⁹⁾

In short, OSHA did not conclude that the non-asbestiform varieties should not be regulated at all, but rather that these varieties should be regulated under OSHA's standard for particulates presenting a risk as a physical irritant (fifteen milligrams per cubic meter total dust or five milligrams per cubic meter respirable dust), instead of under the asbestos rubric. OSHA decided that due to the lack of evidence that non-asbestiform ATA should be regulated in the asbestos standard, or in a separate health standard based on specific related disease endpoints, the workers would not be subjected to a risk greater than those caused by particulates not otherwise regulated.

In so doing, OSHA rejected NIOSH's recommendation that it regulate the non-asbestiform ATA as "asbestos."³⁰ Specifically, NIOSH urged that cleavage fragments from non-asbestiform minerals be considered as equally hazardous as the same size fragments from asbestiform minerals.^{31, 32} OSHA found no evidentiary basis to support NIOSH's contention.

Indeed, OSHA noted that:

...available data show that asbestos containing dusts have much greater potency than non-asbestos containing dusts. Nor is there

²⁹ Gamble JF, *A Nested Case Control Study of Lung Cancer Among New York Talc Workers*, 64 INT'L ARCH. OCCUP. ENVTL. HEALTH 449-456 (1993); Honda Y, Beall C, Delzell E, Oestenstad K, Brill I, Matthews R, *Mortality Among Workers at a Talc Mining and Milling Facility*, 46 Annals Occup. Hyg. 575-85 (2002); Oestenstad K, Honda Y, Delzell E, Brill I, *Assessment of Historical Exposures to Talc at a Mining and Milling Facility*, 46 Annals Occup. Hyg. 587-596 (2002); Steenland K, Brown D, *Silicosis Among Gold Miners: Exposure-Response Analyses and Risk Assessment*, 85 Am. J. Pub. Health 1372-1377 (1995).

³⁰ Preamble to OSHA 1992 Final Asbestos Standard, 57 Fed. Reg. 24310-01, at 5.

³¹ *Id.*

³² *See supra* note 24.

direct evidence showing fiber equivalency for asbestos and asbestiform ATA.³³

The promulgation of OSHA's final rule in 1992 deciding against regulating the nonasbestiform analogs of asbestos was in sharp contrast to the NIOSH 1990 revised recommendation which encompassed not only fibers from the six previously listed asbestos minerals but also the nonasbestiform analogs of these six minerals. Over the intervening years, concerns were raised with the revised recommendation and NIOSH came to recognize that its description in the 1990 REL had created confusion and caused many to infer that the additional covered minerals were included by NIOSH in its definition of "asbestos" or "asbestos minerals."³⁴ The concerns NIOSH discussed in the Revised Draft Current Intelligence Bulletin were: inclusion of the elongated mineral particles (EMPs), the lack of inclusion of other asbestiform amphiboles and other fibrous minerals (e.g., winchite, richterite and erionite), the dimensional criteria may not be protective of worker health, other physiochemical properties of EMPs, and confusion caused by NIOSH's incorrect use of the term "fiber".

In the Asbestos Roadmap, NIOSH maintains that its rationale for recommending that nonasbestiform analogs of the asbestos minerals be encompassed within the policy definition of airborne asbestos fibers was first articulated in NIOSH comments and testimony to OSHA.^{35, 36} In that testimony, NIOSH based its recommendation on three elements:

³³ See *supra* note 24; see also John Kelse, *The Long and Short of It: Flawed Arguments Dog Asbestos Identification*, *Indus. Minerals* 66-74 (Feb. 2008).

³⁴ See *supra*.

³⁵ NIOSH [1990a]. Comments of the National Institute for Occupational Safety and Health on the Occupational Safety and Health Administration's Notice of Proposed Rulemaking on Occupational Exposure to Asbestos, Tremolite, Anthophyllite, and Actinolite. Docket No. H-033d, Apr. 9, 1990.

- The first element comprised results of epidemiologic studies of worker populations with mixed exposures to asbestos fibers and other EMPs from nonasbestiform mineral analogs of the asbestos minerals or with exposures solely to EMPs (e.g., cleavage fragments) from the nonasbestiform analogs. The testimony characterized the existing evidence as equivocal for excess lung cancer risk attributable to exposure to such nonasbestiform EMPs.
- The second element comprised results of animal carcinogenicity studies involving experimental intrapleural or intraperitoneal administration of various mineral particles. The testimony characterized the results of the studies as providing strong evidence that carcinogenic potential depends on particle length and width and reasonable evidence that neither chemical composition nor mineralogic origin are critical factors in determining a mineral particle's carcinogenic potential.
- The third element comprised the inability to adequately distinguish between airborne exposures to particles from asbestiform and nonasbestiform minerals.³⁷

The Coalition disagrees with the first element above that the epidemiologic studies of worker populations exposed to nonasbestiform analogs of asbestos are inconclusive. In fact, after holding a two-year rulemaking which compiled an overabundance of docket submissions and public testimony on this very subject, OSHA was left with what it considered no evidentiary basis to support NIOSH's contention that cleavage fragments (aka EMPs) from nonasbestiform minerals were equally as hazardous as the same size fragments from the asbestiform minerals. More importantly, since the 1990 NIOSH testimony and the 1992 OSHA rulemaking, the justification for not regulating the nonasbestiform analogs of asbestos there has been

(continued)

³⁶ NIOSH [1990b]. Testimony of the National Institute for Occupational Safety and Health on the Occupational Safety and Health Administration's Notice of Proposed Rulemaking on Occupational Exposure to Asbestos, Tremolite, Anthophyllite, and Actinolite. Docket No. H-033d, May 9, 1990.

³⁷ NIOSH, *Revised Draft NIOSH Current Intelligence Bulletin - Asbestos Fibers and Other Elongated Mineral Particles: State of the Science and Roadmap for Research*, June 2008.

strengthened by important follow-up studies of the Homestake gold miners and the New York talc miners with more rigorous exposure-response analyses and these too have failed to show a positive relationship between the nonasbestiform analogs of asbestos and lung cancer.

As for NIOSH's second element, given the strength of the epidemiologic studies that have failed to show an exposure-response relationship for lung cancer in the cohorts of gold miners, talc workers and taconite workers; it is unreasonable for NIOSH to fallback on the animal experimental literature as justification for regulating the nonasbestiform analogs of asbestos. NIOSH should closely examine the mineral characterization of the materials used in the animal carcinogenic studies that are cited as evidence for a relationship between the nonasbestiform analogs of asbestos and disease outcomes. The Coalition urges NIOSH to give careful consideration to the comments of the National Stone, Sand and Gravel Association regarding the characterization of the materials used in animal testing and the differing results seen with asbestiform minerals and the nonasbestiform analogs of asbestos.

The Coalition is somewhat in agreement with NIOSH that the differentiation between asbestiform and nonasbestiform minerals is difficult for the inexperienced analyst. However, analyst can be trained and through experience become proficient in identifying the different habits. We find more agreement with OSHA's conclusion that asbestos and non-asbestiform ATA are "distinguishable mineral entities" and, further that "the characteristics which differentiate them generally appear to correspond to the properties which may dictate biological response."³⁸ In other words, OSHA recognized not only that a different structural form of the

³⁸ See *supra* note 37, at 2.

same mineral made it distinguishable for identification purposes, but also that the different structural forms had different potential health consequences.

NIOSH's additional concern is that by deregulating nonasbestiform ATA, OSHA will leave unprotected workers who may be exposed to asbestos, as a contaminant of a nonasbestiform mineral deposit or product to which they are exposed. (See Tr. 5/9, pp. 10-14). In this regard OSHA notes that available evidence indicates that significant contamination of nonasbestiform mineral deposits is identifiable and thus amenable to regulations under applicable asbestos standards. Thus, OSHA does not believe that potential asbestos contamination of nonasbestos minerals, including nonasbestiform ATA, is sufficient reason to include such nonasbestiform minerals in the asbestos standard. If the presence of asbestos is known, it should be evaluated for extent and exposure potential. The definition of asbestos in the asbestos standards, and the counting criteria therein are sufficiently broad so as to cover all identifiable asbestos fibers. As discussed later in this document, OSHA has not changed these provisions. If an identification error is made, it is likely to be a false positive for asbestos rather than a false negative.³⁹

In regulating workplace exposure to toxic substance, OSHA must demonstrate that the substance poses a significant health risk and that a new, lower standard is necessary to protect exposed workers. The determination of significant risk, when possible, is established on the basis of an analysis of the best available evidence through methods of quantitative risk assessment. Therefore, a critical but essential part of the issue of whether to regulate the nonasbestiform analogs of asbestos as if they were asbestos is whether they produce the same, or some of the same, disease endpoints, and are they equally potent for equivalent doses. The Coalition is not aware of any quantitative risk assessments that have been conducted for the nonasbestiform analogs of asbestos. For both the 1986 and 1994 OSHA asbestos standards, the Agency relied on the quantitative risk estimates developed in conjunction with its 1984 proposal

³⁹ *Preamble to OSHA 1992 Final Asbestos Standard*, 57 Fed. Reg. 24311, June 8, 1992.

for lung cancer, mesothelioma and asbestosis.^{40, 41, 42} Eight studies were used to determine the quantitative risk level for lung cancer and five were used for mesothelioma risk with some overlap of these studies for the two disease endpoints.⁴³ The cohorts involved were exposed solely to commercial forms of asbestos mainly to chrysotile, mixed exposures to chrysotile and crocidolite, chrysotile contaminated with tremolite asbestos, and amosite asbestos. The studies included exposures in asbestos cement pipe production, asbestos textiles, friction product production, asbestos sheet production, in the production of asbestos insulation products, and insulators installing and removing asbestos insulation. For the asbestosis risk assessment, two studies were used of chrysotile exposed asbestos textile workers and one study of asbestos cement pipe workers exposed to a mixture of chrysotile and crocidolite.⁴⁴ Importantly, none of the studies for any of the asbestos-related diseases was from exposures to nonasbestiform

⁴⁰ 59 Fed. Reg. 40964 (Aug. 10, 1994).

⁴¹ See *supra* note 40, at 24318.

⁴² 49 Fed. Reg. 14116 (Apr. 10, 1984).

⁴³ Berry G, Newhouse ML. 1983. Mortality of workers manufacturing friction materials using asbestos. *Br J Ind Med* 40:1-7; Dement JM, Harris RL Jr., Symons MJ, Shy C. 1982. Estimates of dose-response for respiratory cancer among chrysotile asbestos textile workers. *Ann Occup Hyg* 26: 869-887; Henderson VL, Enterline PE. 1979. Asbestos exposure: Factors associated with excess cancer and respiratory disease mortality. *Ann NY Acad Sci* 330:117- 126; Selikoff IJ, Hammond EC, Seidman H. 1979. Mortality experience of insulation workers in the United States and Canada, 1943-1976. *Ann NY Acad Sci* 330:91-116; Peto J. 1980. Lung cancer mortality in relation to measured dust levels in an asbestos textile factory. *IARC Sci Pub* 30:829-836; Weill H, Hughes J, Waggenspack C. 1979. Influence of dose and fiber type on respiratory malignancy risk in asbestos cement manufacturing. *Am Rev Respir Dis* 120:345-354; Finkelstein MM. 1983. Mortality among long-term employees of an Ontario asbestos-cement factory. *Br J Ind Med* 40:138-144; OSHA Docket H-033C, Exhibit 84-261A, Short-Term Asbestos Work Exposure and Long-Term Observation - July 1984 Updating, Herbert Seidman, American Cancer Society, New York, NY.

⁴⁴ Berry G, Gilson JC, Holmes S, et al. 1979. Asbestosis: A study of dose- response relationships in an asbestos textile factory. *Br J Ind Med* 36:98- 112; Berry G, Lewinsohn HC. 1979. Dose-response relationship for asbestos-related disease: implications for hygiene standards. Part I. Morbidity. *Ann N Y Acad Sci* 330:185-194; Finkelstein MM. 1982. Asbestosis in long-term employees of an Ontario asbestos-cement factory. *Am Rev Respir Dis* 125:469-501.

analogues of the asbestos minerals. Indeed, in the 1992 preamble to the final rule removing ATA from its asbestos standard, OSHA stated that:

...various uncertainties in the data⁴⁵ and a body of data showing no carcinogenic effect, do not allow the Agency to perform qualitative or quantitative risk assessments concerning occupational exposures. Further, the subpopulations of nonasbestiform ATA which, based on mechanistic and toxicological data, may be associated with a carcinogenic effect, do not appear to present an occupational risk. Their presence in the workplace is not apparent from the record evidence.⁴⁶

Even NIOSH acknowledges in the draft Asbestos Roadmap that a critical knowledge gap is whether the nonasbestiform amphibole analogues have the same potential health risks as the asbestiform amphiboles.⁴⁷

It will also be important to authoritatively determine whether EMPs from nonasbestiform amphiboles pose the same potential health risks as those observed in workers exposed to fibers from asbestiform amphiboles. Animal and *in vitro* studies have indicated a potential risk for exposed humans, and results from completed epidemiologic studies of workers exposed to amphibole cleavage fragments have to date failed to resolve this major area of current controversy. 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.

On page 62 NIOSH further admits that the nonasbestiform analogues have a lower potential of producing related lung disease.⁴⁸

Asbestos fibers are clearly carcinogenic and cause asbestosis. However, the biological relevance of other EMPs remains uncertain. The results of epidemiological studies remain inconclusive, but taken together with

⁴⁵ OSHA was making reference to the scientific data on which NIOSH based its own carcinogenic health effect recommendation to OSHA.

⁴⁶ Occupational Exposure to Asbestos, Tremolite, Anthophyllite and Actinolite, Preamble to Final Rule, Section 5 - V. Health Effects, 57 Fed. Reg. 24310 (June 8, 1992).

⁴⁷ See *infra* p. 77.

⁴⁸ NIOSH, *supra*, p. 62.

animal tests and *in vitro* test results, EMPs from nonasbestiform minerals have generally lower aspect ratios than asbestos fibers and appear to have generally lesser potential to produce lung pleural and lung [sic] disease.

OSHA excludes non-asbestiform analogs from its asbestos definition because of the lack of scientific evidence demonstrating a significant risk from exposure to nonasbestiform analogs or any benefits to worker health by including them. Thus, if NIOSH is correct that the nonasbestiform analogs of certain dimensions produce the same disease endpoints and at equal potency as asbestos, NIOSH should consider abandoning its guilt by association strategy and instead develop a health-based recommendation using methods of quantitative risk assessment for those minerals with appropriate mineralogical terminology but separate from the terminology used to define asbestos.

Our Coalition members, who have been involved in not only asbestos litigation but also in the control of asbestos hazards through assisting companies we insure, know all too well of the dangers of asbestos exposure and the need for OSHA, MSHA and NIOSH to regulate and strictly enforce asbestos standards in our workplaces. However, based on the lack of scientific evidence regarding the carcinogenicity of the nonasbestiform analogs of asbestos, we feel certain that after NIOSH carefully considers the scientific evidence on this issue that they too will agree with OSHA that it is inappropriate to include these mineral forms in a standard for asbestos because they don't pose the same health risks as those growing in an asbestiform habit. If NIOSH wishes to regulate the nonasbestiform analogs of asbestos then NIOSH needs to concentrate on a review of studies of workers exposed for the most part to nonasbestiform fibrous particles and mineral cleavage fragments for comparison to cohorts exposed to commercial asbestos or to minerals containing a significant percentage of asbestos. If such studies of workers exposed to nonasbestiform fibrous particles and cleavage fragments are not available or are inconclusive

(despite OSHA's apparent reliance on current data as sufficient), then NIOSH needs to set about to define appropriate cohorts of such workers with acceptable exposure information to examine exposure-response relationships for the disease endpoints of interest and in turn develop quantitative risk assessments to demonstrate that not regulating such mineral entities would pose a significant risk to exposed workers. Only if a particular exposure risk is established (though this would be contrary to currently existing evidence) can accurate and appropriate remedies be applied, and only then can the negative consequences of lumping such vastly different mineral forms under a broad definition be avoided.