P. O. Box 936
Sheffield, MA 01257
Telephone (413) 229-3390
Fax (413) 229-3391

Elaine B. Panitz, MD MPH

Fax

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To	NIOSH Docket Officer	**From**	Elaine B. Panitz, MD MPH
Fax	513 533 8285	**Date**	5.19.10
Phone	513 533 8611	**Pages**	14 (including cover page)
Re	NIOSH 099-C	**CC**	

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•Comments

To Karen Bacon,

Attached please find my written comments regarding NIOSH 099-C: NIOSH Current Intelligence Bulletin – Asbestos Fibers and Other Elongate Mineral Particles: State of the Science and Roadmap for Research, Version 4 (January 2010).

Thank you for your kind assistance.

Yours truly,

Elaine B. Panitz, MD MPH

Elaine B. Panitz MD MPH

Occupational and Environmental Medicine
P. O. Box 936, Sheffield, MA 01257
Email: epanmd@yahoo.com
Tel: 413 229 3390
Fax: 413 229 3391

May 19, 2010

Diane Miller
NIOSH Docket Officer (niocindocket@cdc.gov)
Robert A. Taft Laboratories
4676 Columbia Parkway (M/S C34),
Cincinnati, Ohio 45226
Telephone (513) 533 8611

Re: Docket number 099-C (Comments on the Draft NIOSH Current Intelligence Bulletin on Asbestos Fibers and Other Elongate Mineral Particles: State of the Science and Roadmap for Research Version 4 January 2010)

Background

I am a physician and internist, licensed to practice medicine in the state of New Jersey, and specializing in occupational and environmental medicine for the past 35 years. I received a BA degree, with a major in biology and a minor in chemistry, from Vassar College in 1968; an MD degree from Harvard Medical School in 1972; and an MPH degree from the Medical College of Wisconsin in 1998. I am certified by both the American Board of Internal Medicine and the American Board of Preventive Medicine as an occupational and environmental disease specialist.

I am currently living in Massachusetts and, from time to time, serve as a consultant in occupational and environmental medicine. I have over thirty-five years of experience as an occupational disease specialist and have personally evaluated hundreds of individuals with asbestos-related diseases. I am intimately familiar with the peer-reviewed scientific literature relating to asbestos exposures and the risks of asbestos-related diseases.

I have recently been asked by plaintiff attorneys to evaluate the illness and death of a ceramics teacher from mesothelioma. Her major exposure was to ceramic dust containing fibrous talc from upstate New York. In evaluating this matter, I have reviewed most of the extensive literature surrounding asbestos-like diseases from elongate mineral particles (EMPs).

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Reason for Critique

I am writing to express concern over inconsistent and inaccurate statements in the Roadmap – statements that add additional confusion to an already confused arena. The Roadmap proposes to create broader and clearer understanding of the important determinants of toxicity for asbestos and other EMPs. Yet, in many sections of the Roadmap, NIOSH appears to restrict the discussion to asbestos and its non-asbestiform analogs only, and not to other EMPs. In other sections, NIOSH often seems to exclude some or all of the other EMPs, even though they habve been heavily associated with known asbestos-like health effects (e.g. fibrous talc, winchite, richterite, erionite, fluoro-edenite).

Below please find a detailed discussion of what, in my view, are inconsistent, inaccurate, or confusing comments that hinder the Roadmap's stated goal of broader and clearer understanding of an admittedly very difficult problem. Suggestions are made in the spirit of lending greater clarity and understanding to the Roadmap effort.

Forward

The Foreword by John Howard, MD (Page i) clearly states the mission for the Roadmap. The Work Group is trying to "summarize NIOSH's understanding of occupational exposure and toxicity issues concerning asbestos fibers and other EMPs... that will provide a broader and clearer understanding of the important determinants of toxicity for asbestos and other EMPs". Dr. Howard, in my view, has properly framed the issue with this terminology.

Executive Summary

The Executive Summary, however, introduces major confusion to Dr. Howard's clear terminology of the Foreward.

Paragraph 2 of Page vii, correctly points out that the term "mineral fiber" has been used by non-mineralogists to encompass thoracic-size EMPs that include a) asbestiforms, b) non-asbestiforms, and c) cleavage fragments. It correctly states that asbestiform EMPs are clearly of substantial concern, and that the non-asbestiform and cleavage fragment EMPs are less clearly of concern. Having broached the topic of EMP habit, however, the paragraph should then mention the substantial and fractious debate concerning the determination of EMP fiber habit (i.e. asbestiform v. nonasbestiform). The paragraph should point out that, regardless of EMP habit determination, other EMPs should be studied further if they have already been associated with asbestos-like disease.

Paragraph 3 of Page vii discusses NIOSH's 1990 recommendation to include only asbestos and its non-asbestiform analogs in regulatory efforts.

Paragraph 1 of Page viii properly notes that this NIOSH 1990 recommendation inappropriately excluded other EMPs, and cites as examples winchite, richterite, and erionite. All three are EMPs that have been associated with substantial asbestos-like disease in humans. For the same reason, NIOSH should include upstate New York and

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Vermont talc[1], and fluoro-edenite[2] in its examples of other EMPs associated with substantial asbestos-like disease in humans. It is recognized that fluoro-edenite was not yet known as a health threat when NIOSH made its recommendations in 1990, but it should now be grouped with winchite, richterite, erionite, and fibrous talc as other EMPs of substantial concern.

Paragraph 2 of Page viii correctly notes that its 1990 recommendations created confusion, causing many to infer that the nonasbestiform minerals included in the NIOSH definition are asbestos. However, Paragraph 2 should also mention that NIOSH's 1990 recommendations caused many to infer that non-asbestos other EMPs do not need to be regulated. Epidemiologic studies have made it abundantly clear that richterite, winchite, erionite, fluoro-edenite, and fibrous talc cause asbestos-like disease and should be under active consideration for regulation.

Similarly, Paragraph 2 of Page ix discusses the epidemiology relating only to asbestos and its non-asbestiform analogs, and not to other EMPs. Although the paragraph suggests interest in epidemiologic studies of workers in upstate New York talc mines, it then states that talc exposures involve "predominantly nonasbestiform EMPs". This comment fails to reflect the fact that determination of EMP habit, especially in relation to upstate New York talc, is a hotly-debated (and unsettled) issue. In this Executive Summary, NIOSH should avoid making judgments in the contentious issue of whether other EMPs are non-asbestiform or asbestiform. NIOSH should focus on which of the other EMPs have shown epidemiologic evidence of disease potential, and therefore deserve further epidemiologic study, regardless of EMP habit.

NIOSH should completely remove the sentence beginning "Populations of interest...". NIOSH should simply amend the next sentence to read, "Populations of interest for possible epidemiologic studies include workers and others exposed to EMPs in relation to a) talc mining in upstate New York and Vermont, b) vermiculite mining in Libby, MT, c) taconite mining in northeastern Minnesota, d) gold mining in South Dakota, e) erionite contamination in Turkey, f) fluoro-edenite contamination in Sicily, and f) any other

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[1] Fibrous talc: a) Kleinfeld M, Messite J, Kooyman O, et al. Mortality among talc miners and millers in New York State. AEH 1967 May; 14: 663-667; b) Kleinfeld M, Messite J. Mortality experience among talc workers: a follow-up study. J Occup Med 1974 May; 16(5): 345-349; c) NIOSH Technical Report: Occupational exposure to talc containing asbestos. US DHEW, PHS, CDC, NIOSH, 1980; d) NIOSH HHE Report, HETA 90-390-2065. R. T. Vanderbilt Company, Gouverneur, New York, 1990; Selevan SG, Dement JM, Wagoner JK, et al. Mortality patterns among miners and millers of non-asbestiform talc: preliminary report. J Environ Pathol Toxicol 1979; 2: 273-284.

[2] Fluoro-edenite: a) Comba P, Gianfagna A, Paoletti L. Pleural mesothelioma cases in Biancavilla are related to a new fluoro-edenite fibrous amphibole. Arch Environ Health 2003; 58(4):229-232. b) Biggeri A;Pasetto R;Belli S;Bruno C;Di Maria G;Mastrantonio M;Trinca S;Uccelli R;Comba P. Mortality from chronic obstructive pulmonary disease and pleural mesothelioma in an area contaminated by natural fiber (fluoro-edenite). Scand J Work Environ Health 2004 Jun;30(3):249-52; c) Bruno C;Comba P;Zona A. Adverse health effects of fluoro-edenitic fibers: epidemiological evidence and public health priorities. Ann N Y Acad Sci 2006 Sep;1076:778-83.

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EMPs exposure that may show epidemiologic evidence of asbestos-like disease in the future. Note that the term "and others" should be included, to reflect the growing evidence for asbestos-like disease in the general populations around workplaces exposed to other EMPs (e.g. Libby, MT[3], northeastern MN[4], and upstate New York[5]).

The remaining paragraphs of the Executive Summary correctly return to the scientific evaluation of asbestos and other EMPs.

Introduction
Page 1, Paragraphs 1-2, of the Introduction correctly reiterates NIOSH's interest in the study of asbestos and other EMPs. Paragraph 3 correctly notes that health effects of other non-asbestos EMPs have not been studied as much as asbestos. However, Paragraph 3 then cites as examples of other EMPs a) the amphiboles in Libby, MT, b) those encountered in hardrock mining, and c) erionite in Turkey. For clarity and consistency, NIOSH should also list the health effects of the EMPs in upstate New York and Vermont talc mining, and e) the EMPs in the quarry near Biancavilla, Sicily. The remainder of the Introduction correctly refers to both asbestos and other EMPs.

Overview of Current Issues
2.1 Background
Paragraph 2 of Page 4 states that interest in EMPs other than asbestos fibers has been "focused primarily on fibrous minerals exploited commercially (e.g. wollastonite, sepiolite, and attapulgite)". This comment omits mentioning the other commercially exploited substances that contain fibrous minerals (e.g. fibrous talc and vermiculite

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[3] ATSDR. Mortality review. Mortality in Libby, Montana, 1979 to 1998. August 8, 2002: www.atsdr.cdc.gov/asbestos/sites/libby_montana/mortality_review.html; Peipins LA, Lewin M, Campolucci S, et al. Radiographic abnormalities and exposure to asbestos-contaminated vermiculite in the community of Libby, Montana, USA. EHP 2003 Nov; 111(14): 1753-1759; Horton DK, Bove F, Kapil V. Select mortality and cancer incidence among residents in various US communities that received asbestos-contaminated vermiculite ore from Libby, Montana. Inhal Toxicol 2008; 20: 767-775.

[4] Minnesota Department of Health. Cancer incidence rates in northeastern Minnesota with an emphasis on mesothelioma. MCSS Epidemiology Report 03:1. February 2003;
Minnesota Department of Health. Mesothelioma in Northeastern Minnesota and Two Occupational Cohorts: 2007 Update. Center for Occupational Health and Safety, Chronic Disease and Environmental Epidemiology Section, Minnesota Department of Health, St. Paul, MN. December 7, 2007: http://www.health.state.mn.us/divs/hpcd/cdee/mcss/documents/nemeso1207.pdf.

[5] Vianna NJ, Maslowsky J, Roberts S, et al. Malignant mesothelioma. Epidemiologic patterns in New York State. New York State J Med 1981 Apr: 735-738; Enterline PE, Henderson VL. Geographic patterns for pleural mesothelioma deaths in the United States, 1968-81. JCNI 1987 Jul; 79(1): 31-37; NIOSH. Work-Related Lung Disease (WoRLD) Surveillance System: Malignant mesothelioma: mortality. http://www2.cdc.gov/drds/WorldReportData/SectionDetails.asp?ArchiveID=1&SectionTitleID=7; NIOSH. Work-Related Lung Disease (WoRLD) Surveillance System: All pneumoconiosis: mortality, and Asbestosis: mortality. http://www2.cdc.gov/drds/WorldReportData/FigureTableDetails.asp?FigureTableID=500&GroupRefNumber=F01-03b;

containing winchite and richterite), and omits the major interest in EMPS occurring as contaminants in central Turkish (erionite) and Sicilian (fluoro-edenite) rocks and soils.

Paragraph 2 of page 4 goes on to note that the asbestos minerals, as well as "other types of fibrous minerals", are typically associated with other minerals in geologic formations at various locations in the United States, citing Van Gosen 2007. NIOSH should name the other types of fibrous minerals, especially since the main types of other fibrous minerals discussed by the cited Van Gosen 2007 article are fibrous talc and vermiculite containing winchite and richterite. Paragraph 2 continues on to state that "the biological significance of occupational exposure to airborne particles remains unknown for many of these minerals". This is simply untrue for the two major "other types of fibrous minerals" mentioned by Van Gosen 2007 (fibrous talc and vermiculite containing winchite and richterite). This sentence should be removed or clarified.

Paragraph 3 of Page 4 states "the lack of uniformity in the use of terms and the lack of precision in the definitions of many of the scientific terms remain issues which cannot be resolved in this Roadmap". This unfortunate comment suggests that NIOSH is not striving for precision in its use of certain key terms, such as other EMPs. I would argue that until NIOSH resolves its lack of consistency and clarity in the definition and use of the term asbestos and other EMPs, it will not succeed in creating a broader and clearer understanding of the Roadmap issues.

Minerals and mineral terminology

Section 2.2 Paragraph 4 of Page 5 states that "both asbestiform (fibrous) and nonasbestiform (massive) versions (i.e. analogs) of the same mineral can occur in juxtaposition or matrixed together". This sentence implies that the term fibrous can substitute for the term asbestiform. While all asbestiform particles are certainly fibrous particles, not all fibrous particles are asbestiform particles. It also implies that all nonasbestiform fibers are massive. Nonasbestiform fibers can occur in a range of habits, from massive to prismatic to acicular to very fibrous, up to but not including asbestiform fibers. This unfortunate sentence therefore implies that all nonasbestiform EMPs are massive and do not occur in fibrous forms. The sentence should be removed and replaced with the following: "Nonasbestiform fibers can occur in a range of habits, from massive or platy or tabular, to prismatic, to acicular, to very fibrous, up to but not including asbestiform. Both asbestiform and nonasbestiform habits of the same mineral can occur in juxtaposition or matrixed together, often within a narrow geological formation".

Paragraph 1 of Page 6 addresses itself to the habits of amphibole EMP minerals only. For greater clarity, NIOSH should address itself to a more inclusive term, such as hydrous magnesium silicates, in order to address the habits of other important but non-amphibole EMPs, such as fibrous talc and erionite. Although not amphiboles, fibrous talc (see reference 1) and erionite (see Roadmap 2.6.2, p. 35) have been associated with significant asbestos-like human disease, and should be included in any listing of important EMPs.

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Paragraph 2 of Page 6 continues the confusion by equating the terms fibrous and asbestiform, and suggesting that acicular fibers are not fibrous. The final sentence again excludes non-asbestos EMPs from the discussion.

Geological Definitions

In Sectioin 2.3.1, NIOSH states that, in addition to asbestos, there is interest in "related materials that may resemble asbestos (e.g. fibrous antigorite, richterite, and winchite), unrelated fibrous minerals (e.g. the zeolites erionite and mordenite, the clay materials sepiolite and palygorskite, etc.), and individual particles or fragments of the nonasbestiform asbestos minerals". Again, it is unclear why fibrous talc and fluoro-edenite (both "unrelated fibrous minerals") are not included in the listing, when erionite (another "unrelated fibrous mineral") is listed. All three non-asbestos materials (erionite, fibrous talc, and fluoro-edenite) have been heavily associated with asbestos-like health effects.

The NIOSH Recommendation for Occupational Exposure to Asbestos

Section 2.6 In 1990, NIOSH recommended microscopic methods be used to define fibers as particles having 1) an aspect ratio of 3 to 1 or greater, 2) the mineralogic characteristics of the asbestos minerals and their nonasbestiform analogs, and 3) cleavage fragments from the nonasbestiform analogs of the serpentine minerals antigorite and lizardite, and the amphibole minerals in the series cummingtonite-grunerite, tremolite-ferroactinolite, and glaucophane-riebeckite. This paragraph should also note that NIOSH 1990 excluded non-asbestos <u>other EMPs</u>, such as fibrous talc, erionite, winchite, and richterite (fluoro-edenite had not yet declared itself in terms of human disease).

Amphibole Asbestos and Other Fibrous Minerals

Section 2.6.1.2 Paragraph 2 of Page 19 cites concerns over the fact that current OSHA and MSHA asbestos definitions cover only the asbestiform varieties of the six commercially important asbestos materials. NIOSH specifically cites the problem of OSHA and MSHA regulations not including the asbestiform amphiboles winchite and richterite in Libby, MT vermiculite exposures, and the asbestiform amphibole fluoro-edenite in the Biancavilla, Sicily exposures. NIOSH should also mention the failure of OSHA and MSHA to include exposure to Turkish erionite and upstate New York talc, both of which have been found to contain asbestiform fibers by at least some investigators (see below).

Epidemiologic Studies

Section 2.6.1.3.1 On Pages 23-27, the NIOSH discussion of the epidemiology of upstate New York talc workers assumes that the talc EMP exposures are "nonasbestiform", and groups the talc epidemiology discussion with that on gold and taconite miners. Such a grouping suggests that the results of epidemiologic findings in talc workers have been similar to those in gold and taconite miners. In fact, studies of talc workers have demonstrated a clear pattern of asbestos-like disease, including increased risk for pleural plaques and pneumoconiosis, a three-fold increased risk for lung cancer, and a number of reports of malignant mesothelioma in miners (see below). Studies of gold and taconite workers have shown little or no evidence of asbestos-like disease (see below).

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Upstate New York talc workers

No explanation is given for designating the fibrous talc exposures of upstate New York as "nonasbestiform", other than mentioning that the exposures have been reported to be nonasbestiform by RT Vanderbilt (Kelse 2005). NIOSH does state that the NIOSH 1980 industrial hygiene analysis of RT Vanderbilt talc showed 4.5-15% anthophyllite, some of which was asbestiform. But, because the NIOSH 1980 study proved to be "the subject of debate", NIOSH suggests that the asbestiform anthophyllite fibers may have been "transitional minerals" – as if the fibers were therefore no longer asbestiform, and were not to be considered biologically significant. NIOSH should clarify that a number of independent investigators and organizations, over a period of some 50 years, have found the EMPs in upstate New York talc to be asbestiform in habit (see below).

Engel (1962), of the USGS, describes the talc of upstate New York as "highly striated, fibrous bundles of anthophyllite and talc"[6]. Rohl and Langer (1974) note the presence of at least three asbestiform minerals (tremolite, anthophyllite, and chrysotile) in upstate New York talcs.[7] IARC (1987), after extensive review and analysis of the world's literature, found that certain talcs (primarily from upstate New York) contain asbestiform fibers and meet the criteria for a Group 1 human carcinogen[8]. Beard (2001) at Research Triangle Institute, in an independently funded analysis, found RT Vanderbilt talc from upstate New York to contain more than 20% asbestiform fibers, including asbestiform talc (.81%), asbestiform anthophyllite (4.4%), and asbestiform transitional fibers (16%)[9]. The 2005 USGS dataset on asbestos sites in the Eastern United States notes that the Arnold talc mine in upstate New York contains "asbestiform anthophyllite" and "asbestiform tremolite"[10]. The dataset cites as references Ross (1968)[11], Van Gosen (2004)[12], and Webber (2004)[13], as well as Engel (1962) and Beard (2001). Van Gosen (2007) reports that regional metamorphism of dolomitic marbles in Gouverneur talc mining district created fibrous varieties of talc, tremolite, and anthophyllite, as well as unusual transitional fibers[14].

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[6] Engel AEJ. The precambrian geology and talc deposits of the Balmat-Edwards district, northwest Adirondack Mountains, New York. US Geological Survey, Open File Report, preliminary, 1962.
[7] Rohl AN, Langer AM. Identification and quantitation of asbestos in talc. EHP 1974; 9: 95-109.
[8] IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Silica and some silicates (talc) 42: 185-224, 1987.
[9] Beard MR, Crankshaw OS, Ennis JT, et al. Analysis of crayons for asbestos and other fibrous materials, and recommendations for improved analytical definitions. Center for Environmental Measurements and Quality Assurance, Research Triangle Institute, 2001 Feb 28.
[10] Van Gosen BS. Reported historic asbestos mines, historic asbestos prospects, and natural asbestos occurrences in the Eastern United States. US Geological Survey Open-File Report 2005-1189 Version 2.0 (http://pubs.usgs.gov/of/2005/1189/pdf/Plate.pdf).
[11] Ross M, Smith WL, Ashton WH. Triclinic talc and associated amphiboles from Gouverneur mining district, New York. The American Mineralogist 1968 May-Jun; 53: 751-769.
[12] Van Gosen BS, Lowers HA, Sutley SJ, et al. Using the geologic setting of talc deposits as an indicator of amphibole asbestos content. Environmental Geology 2004; 45: 920-939.
[13] Webber JS, Jackson KW, Parekh PP. Reconstruction of a century of airborne asbestos concentrations. Environ Sci Technol 2004; 38: 707-714.
[14] Van Gosen BS. The geology of asbestos in the United States and its practical applications. Environ & Engineer Geoscience 2007 Feb; XIII(1): 55-68.

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Webber, et al. (2004) (see footnote 14), of the New York State Department of Health, analyzed samples of talc ore from upstate New York and reported that 15% of crushed Arnold pit ore was respirable. The respirable fraction contained a large proportion of asbestiform fibers, "typified by aspect ratios exceeding 10 (often in the hundreds), curved fibers, and fibers terminating in frayed ends". When the crushed ore samples were aerosolized, the airborne fibers were found to be anthophyllite (40%), tremolite (6%), "intermediate" (48%), and talc (2%). The authors then reconstructed air concentrations of anthophyllite asbestos near the talc mines from 1846 to 1967, using nearby lake sediment samples. They demonstrated that airborne anthophyllite asbestos concentrations a) increased more than five times over the studied time period, b) correlated significantly ($p < .01$) with annual production of local talc, and c) were much higher ($p = .004$) than concurrent concentrations in a control lake located upwind of the mines and mills.

As discussed on Page 23, an excess of pulmonary fibrosis and pleural plaques is well recognized to have occurred among workers exposed to fibrous talc (Siegel 1943[15], Kleinfeld 1955[16]). NIOSH should emphasis, however, that lung cancer mortality has been consistently reported to be elevated in studies of New York talc miners (Kleinfeld 1967, Kleinfeld 1974, Brown 1980, and NIOSH 1990[17]; Stille 1982[18], Lamm 1988[19], Gamble 1993[20], Honda 2002[21]), despite various study weaknesses that make dose-response evaluations difficult. NIOSH should mention that there have been a number of mesothelioma cases reported among NY talc workers, including Kleinfeld 1955[22]; Kleinfeld 1967 and 1974, and NIOSH 1980 (see footnote 1); Vianna 1981 (see footnote 5), Honda 2002[23]; Hull 2002[24], and Rubin 2006[25]. At least some of the cases included reports of other markers of asbestos-like disease, including pleural plaques, asbestosis or pneumoconiosis, asbestos bodies, and asbestos-like fibers in lung tissue (Kleinfeld 1955, Hull 2002, Rubin 2006).

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[15] Siegal W, Smith AR, Greenburg L. Report on study of talc miners and millers in St. Lawrence County. The Industrial Bulletin 1943 Nov: 434-437, 468.
[16] Kleinfeld M, Messite J, Tabershaw IR. Talc pneumoconiosis. AMA Arch Indust Health 1955; 66-72.
[17] See reference 1.
[18] Stille WT, Tabershaw IR. The mortality experience of upstate New York talc workers. J Occup Med 1982 Jun; 24(6): 480-484.
[19] Lamm SH, Levine MS, Starr JA, et al. Analysis of excess lung cancer risk in short-term employees. Am J Epidem 1988; 127(6): 1202-1209.
[20] Gamble JF. A nested case control study of lung cancer among New York talc workers. Int Arch Occup Environ Health 1993; 64: 449-456.
[21] Honda Y, Bealk C, Delzell E, et al. Mortality among workers at a talc mining and milling facility. Ann Occup Hyg 2002; 46(7): 575-585.
[22] Kleinfeld M, Messite J, Tabershaw IR. Talc pneumoconiosis. AMA Arch Indust Health 1955; 66-72.
[23] See footnotes above _____.
[24] Hull MJ, Abraham JL, Case BW. Mesothelioma among workers in asbestiform fiber-bearing talc mines in New York State. Ann occup Med 2002; 46(Suppl 1): 132-135.
[25] Rubin E. Letter to J. Kelse, RT Vanderbilt Company, Inc., dated November 8, 2006 (http://www.cdc.gov/niosh/docket/pdfs/NIOSH-099/0099-053007-kelse_sub.file3.pdf).

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Given the dramatic findings of Webber (2004) above, it is important for NIOSH to mention that the residents of St. Lawrence County are also exhibiting evidence suggestive of asbestos-related diseases. The mortality rate for all pneumoconioses in St. Lawrence County was 5-10 times higher than NYS rates from 1975 to 2004 (NIOSH WoRLD 2007, see footnote 5). Mortality from asbestosis specifically was 4 times higher than the NYS rate from 1995 to 2004 (NIOSH WoRLD 2007, see footnote 5). The incidence of lung and bronchus cancer for 2003-2007 in St. Lawrence County is 43% higher than in New York State in both men and women[26]. There is a higher than expected number of lung cancer cases for 2002-2006 in over half the zip codes of St. Lawrence County, including the Gouverneur zip code (37 cases v. 17.2 predicted)[27]. The lung cancer incidence in Jefferson County is also elevated in both men (38%) and women (36%), compared to New York State rates[28]. These elevated lung cancer rates do not appear related to increased smoking rates in the local populations. Smoking rates in St. Lawrence and Jefferson counties are similar to those in the rest of NYS excluding NYC (22.2% v. 22.1% of adults)[29]. Mesothelioma rates from 1966 to 1981 were significantly elevated in Jefferson County, the site of some of the talc industry in New York, and located only a few miles from the concentration of talc mines in adjacent St. Lawrence County (Vianna 1981, Enterline 1987, see reference 5). In more recent years (1999-2004), the mesothelioma mortality rates in St. Lawrence and Jefferson counties appear to be only slightly higher than NYS (13% and 35% respectively, see reference 5).

Vermont talc workers

On Page 27, NIOSH discusses the cohort study of Vermont talc workers (Selevan 1979), and states that "available evidence indicates that Vermont talc is free of asbestos fibers", without citations. In addition to indicating sources for this statement, NIOSH should mention that several investigators have reported asbestos in Vermont talc. Zodac (1940) describes "radiating masses of fibrous actinolite" in the talc quarry in Chester, VT[30]. Van Gosen (2004) (see reference 13) of the USGS reports that Vermont talc deposits in some areas host "well-developed chrysotile asbestos", citing Bain (1942)[31] and Cady (1963)[32].

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[26] New York State Cancer Registry. Cancer incidence and mortality by county and gender, St. Lawrence County, 2003-2007 (http://www.health.state.ny.us/statistics/cancer/registry/vol1/v1cst.lawrence.htm and http://www.health.state.ny.us/statistics/cancer/registry/pdf/volume1.pdf).

[27] New York State Cancer Registry. Lung and bronchus cancer incidence by zip code, St. Lawrence County, 2002-2006 (http://www.health.state.ny.us/statistics/cancer/registry/zipcode/lung/stlawrence.htm).

[28] New York State Cancer Registry. Cancer incidence and mortality by county and gender, Jefferson County, 2003-2007 (http://www.health.state.ny.us/statistics/cancer/registry/vol1/v1cjefferson.htm)

[29] New York State Department of Health. St. Lawrence County Indicators for Tracking Public Health Priority Areas (http://www.health.state.ny.us/prevention/prevention_agenda/indicators/county/stlawrence.htm and http://www.health.state.ny.us/prevention/prevention_agenda/indicators/county/jefferson.htm).

[30] Zodac P. A talc quarry near Chester, VT/ Rocks and Minerals 1940; 15: 369-371.

[31] Bain GW. Vermont talc and asbestos deposits. In: Newhouse WH (ed). Ore deposits as related to structural features. Princeton University Press: Princeton University Press, 1942, pages 255-258.

[32] Cady WM, Albee AL, Chidester AH. Bedrock geology and asbestos deposits of the upper Missisquoi Valley and vicinity, Vermont. US Geological Survey Bulletin 1122-B, 1963, 78 pages, 1 plate.

However, NIOSH should also address whether Vermont talc contains asbestiform minerals other than asbestos per se. NIOSH should mention, for instance, that the companion NIOSH industrial hygiene study for Selevan (1979) found "talc shards and ribbons", both in bulk talc samples and in airborne dust samples (Boundy 1979)[33]. NIOSH should also mention that other studies of Vermont talc report the presence of asbestiform amphiboles, structurally and chemically intermediate between anthophyllite and talc, and similar to those reported in the Gouverneur talc mining district by Ross in 1968 (Veblen 1977 and Veblen 1978[34], Van Gosen 2004, see reference 13).

NIOSH notes that the mortality study of Vermont talc workers reveals significantly increased risk for non-malignant respiratory disease, with significantly increased risk among millers but not miners (Selevan 1979). NIOSH should also mention that a) most of the men who died of NMRD had radiographic readings consistent with pneumoconiosis, and b) the authors concluded that the x-ray evidence supported talc as the etiology of NMRD in the millers, but that data were too limited in miners to judge their true risk. NIOSH should also mention the subsequent Harvard School of Public Health PFT and x-ray study of Vermont talc workers, in which PFT abnormalities and small irregular opacities on chest x-ray were significantly related to years of employment and talc-years of exposure. The authors concluded that talc workers were being affected by their work exposures (Wegman 1982)[35].

Respiratory cancer risk in the Selevan (1979) study was significantly increased among miners and not millers, a pattern similar to that in RT Vanderbilt miners and millers. NIOSH notes that the authors suggest that their respiratory cancer findings might be due to non-talc exposures. NIOSH should also note that the authors also suggest that talc may be acting in combination with other factors to affect cancer risk.

Summary of EMP epidemiology

On Page 31, NIOSH then summarizes the epidemiologic studies of cohorts exposed to "nonasbestiform EMPs". The section heading and the ensuing discussion imply that NIOSH has been tasked to consider only the other EMPs that are nonasbestiform, rather than all other EMPs (including the asbestiforms). According to Dr. Howard's Foreward, this is not so (see Pages i-ii). This epidemiologic summary should include an even-handed review (see above) of all of the other EMPs that have been heavily associated with asbestos-like diseases, including upstate New York and Vermont talcs, Libby MT vermiculite, Cappadocian erionite, and Sicilian fluoro-edenite. It should then conclude

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[33] Boundy M. Occupational exposure to non-asbestiform talc in Vermont. Presented at Conference on Occupational Exposure to Fibrous and Particulate Dust and Their Extension into the Environment, Washington, DC, December 6, 1977. In: Lemen R, Dement JM, eds. Dusts and Disease. Park Forest South, IL: Pathotox Publishers; 1979.

[34] Veblen DR Buseck PR, Burnham CW. Asbestiform chain silicates: new minerals and structural groups. Science 1977; 198: 359-365. Veblen 78, Burnham CW. New biopyriboles from Chester, VT: I. Descriptive mineralogy. American Mineralogist 1978; 63: 1000-1009.

[35] Wegman DH, Peters JM, Boundy MG, et al. Evaluation of respiratory effects in miners and millers exposed to talc free of asbestos and silica. Br J Indust Med 1982; 39: 233-238.

with the more limited evidence of asbestos-like disease associated with South Dakota's gold mine, and the northeastern Minnesota's taconite mines.

Some Minerals of Potential Concern Not Covered by the NIOSH REL
This section belongs in the 2.6.1.3.1 Epidemiologic Studies section on Pages 22-32, as discussed above.

Some Minerals of Potential Concern Not Covered by the NIOSH REL
On Page 35, the Roadmap states, in reference to EMPs, that "only for erionite has the IARC made an assessment that the evidence was sufficient to determine that it is a human carcinogen". This is simply untrue, and NIOSH should correct this sentence to properly reflect IARC's findings on talc. In 1987, IARC opined that "there is sufficient evidence for the carcinogenicity to humans of talc containing asbestiform fibres"[36]. In fact, in 2007, IARC opined that "there is limited evidence for the carcinogenicity in experimental animals of talc not containing asbestos or asbestiform fibers", and classified such talc as Group 3 (not classifiable as to its carcinogenicity to humans)[37]

Summary of Key Issues
On Page 68, NIOSH attempts to summarize key issues developed by the Roadmap. But, once again, the paragraph begins by framing its first question around "fibers from the asbestos minerals", rather than asbestos and the other EMPs.

In the next paragragh (Page 69), the summary shifts back briefly to "EMPs" and mentions erionite as well as the "asbestos minerals". It even mentions non-EMPs such as quartz, and yet does not mention important other EMPs, including upstate New York and Vermont talc, Libby vermiculite containing winchite and richterite, and Sicilian fluoro-edenite.

Unfortunately, this summary reflects the Roadmap's failure to define and use the term asbestos and other EMPs in a consistent manner, as intended by Dr. Howard in the Foreward (Pages i-ii).

Framework for Research
Fortunately, Page 70's Framework for Research returns to a clear and consistent use of the term asbestos and other EMPs, as stated by Dr. Howard in the Foreward (Pages i-ii).

Develop Information and Knowledge on Occupational Exposure to Asbestos Fibers and Other EMPs and Related Health Outcomes
On page 86, section 3.5.2, the Roadmap again reverts to the statement that "the body of knowledge concerning human health effects from exposure to EMPs consists primarily of

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[36] IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Silica and some silicates (including talc) 42: 185-224, 1987.
[37] Baan RA. Carcinogenic hazards from inhaled carbon black, titanium dioxide, and talc not containing asbestos or asbestiform fibers: recent evaluations by an IARC Monographs Working Group. Inhal Toxicol 2007; 19(Suppl 1): 213-228.

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epidemiologic studies of workers exposed to asbestos fibers and several other types of EMPs (e.g. wollastonite, attapulgite, erionite). As pointed out above, this listing of examples is incomplete and misleading. It cites two EMPs associated with very little epidemiologic evidence of asbestos-like disease (wollastonite, attapulgite), yet fails to cite other EMPs heavily associated with asbestos-like disease (upstate New York and Vermont talc, Libby vermiculite containing winchite and richterite, and Sicilian fluoro-edenite).

In the last sentence of the same paragraph, the Roadmap seeks to ensure a clear science base that might support a formal recommendation for control of occupational exposures to "all asbestiform amphibole fibers". This terminology is confusing and inappropriate. It limits the recommendation to only asbestiform EMPs, eliminating nonasbestiform EMPs. It further limits the recommendation to amphiboles, eliminating both erionite and upstate New York and Vermont talc, which are heavily associated with asbestos-like disease. NIOSH should change this terminology to all asbestos and other EMPs, in the interest of clarity and consistency with Dr. Howard's Foreward.

The next paragraph then speaks of "EMPs from nonasbestiform amphiboles" and seeks to compare their health risks to those of asbestiform amphiboles. Although it is important to consider the nonasbestiform EMPs, as well as the asbestiform EMPs mentioned above, the consideration should not exclude non-amphibole EMPS (such as erionite and upstate New York and Vermont talc). This entire section is crippled by its ever-changing terminology. It would be greatly strengthened if it used the terminology asbestos and other EMPs, in concert with Dr. Howard's Foreward, and the Framework for Research section on Page 70.

Conduct Selective Epidemiological Studies of Workers Exposed to Asbestos Fibers and Other EMPs

Section 3.5.3 Pages 87-90 categorize upstate New York and Vermont talc exposures as "EMPs from nonasbestiform amphiboles". As has been pointed out above, using the term "nonasbestiform" is inappropriate in relation to upstate New York and Vermont talc exposures (see above at page 3 of this commentary). Using the term "amphiboles" is also too limiting, in that the mineral talc, although a magnesium silicate, is not considered to be one of the amphiboles.

Summary of Critique

As stated in the Roadmap Executive Summary, this document is intended to define the scientific and technical research issues that need to be addressed to ensure that workers are optimally protected from health risks posed by exposure to asbestos fibers and other EMPs. To make its point more vivid concerning other EMPs, the cover of the Roadmap includes a remarkable USGS photograph of upstate New York talc fibers[38].

[38] Why has the cover photograph of upstate New York talc fibers, along with the acknowledgment of the USGS for its contribution, both previously part of the 2009 draft, been eliminated from the January 2010 draft?

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The Roadmap must now effectively frame its epidemiologic discussion to include all other EMPs – both asbestiform and nonasbestiform - beyond the six types of asbestos and their non-asbestiform analogues. The EMP health problems in Libby, MT (winchite, richterite), Cappadocia (erionite), Biancavilla (fluoro-edenite), upstate New York and Vermont (fibrous talc), northeastern MN (taconite), and perhaps others, cry out for proper overview, analysis, and further investigation. NIOSH must follow through on its promise to protect humans from asbestos and other EMPs - all of them - or it will miss, or misinterpret, current and future opportunities to prevent EMP disease.

Yours truly,

Elaine B. Panitz, MD MPH