

October 10, 2010

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Dear Dr. Weston:

Thank you for the opportunity to serve as a reviewer for the NIOSH Current Intelligence Bulletin entitled "*A review of information published since 1995 on coal mine dust exposures and associated health outcomes.*" Based on your letter of September 8, 2010, I understand that the purpose of this review is to obtain opinions that may improve the quality of the current intelligence bulletin document and will be used in your revision of the document. I understand that the review should address issues of comprehension, scientific accuracy, appropriateness of the material, and depth of scope. Specifically, you requested four areas of commentary, and my responses follow.

1) Assessment of whether the Current Intelligence Bulletin has fully included all relevant material in its evaluation that is pursuant to its aims.

A principal intent of this document is to determine whether the 1995 *Criteria for a Recommended Standard -- Occupational Exposure to Respirable Coal Mine Dust* remains valid in light of new findings, and whether the document needs updating or supplementation. Based on available scientific information at the time, the 1995 NIOSH document recommended that the federal coal mine dust limit be reduced to 1 mg/m³ and that a separate limit for respirable crystalline silica be developed for more effective exposure monitoring and control.

Since the 1995 publication, there is compelling epidemiological evidence showing a reversal of the previous downward trend in CWP prevalence, both for all pneumoconiosis cases and for progressive massive fibrosis (PMF). Research summarized in the 2010 Bulletin shows that coal miners are developing severe CWP at younger ages, concentrated in hot spots in central Appalachia, and occurring mainly in miners who began working after 1969, when exposure levels were mandated by the Coal Mine Health and Safety Act.

Given these recent trends in health outcomes of US coal miners, there is no doubt that the 1995 document needs updating and supplementation. The 2010 review lists 80 peer-reviewed

published references since 1995 focused on health effects associated with coal mining, including relevant articles from international peer-reviewed publications. The 2010 literature review is comprehensive and well-summarized. The document reviews and updates findings on the spectrum of health outcomes associated with exposure to coal mine dust including coal workers' pneumoconiosis, silicosis, overall mortality, lung and stomach cancer, chronic airways obstruction, bronchitis, and emphysema. Particular weight is appropriately given to research publications with information on quantitative exposure assessment. For example, the investigation by Kuempel et al (2009, *Am Rev Resp Crit Care Med*) provides quantitative measures of both smoking and coal mine dust in predicting emphysema severity, a substantial contribution to the body of scientific information needed to guide policies for exposure control.

The updated document does not provide a complete compendium of the relevant literature over the past 15 years related to health effects from coal mine dust exposure, focusing mainly on the literature relevant to the NIOSH recommendations. For example, there are a number of pathology/autopsy studies describing dust exposure and emphysema that are not cited (including Vallyathan V, Green FHY, Brower P, Attfield MD, 1997, *Ann Occ Hyg*; Hnizdo E, Murray J and Davison A, 2000, *Int. Arch Occup Environ Health*). Additionally, peer-reviewed publications describing diffuse interstitial fibrosis as a manifestation of coal mine dust exposure are not discussed in the document (eg, Brichet A, et al, 2002, *Sarcoidosis Vasc Diffuse Lung Dis*). I am not aware of any peer-reviewed published literature relevant to the aims of the Current Intelligence Bulletin that have not been included in this review and that do not support the NIOSH recommendations.

The Bulletin also provides a brief but helpful summary of recent publications and efforts related to dust exposure assessment (eg, the real time personal dust monitor), exposure levels and control, and compliance policy and procedures. Notably, though overall coal mine dust levels have declined over time, there has been no significant longitudinal change in exposure to crystalline silica levels in underground mines. This thoughtful summary of the peer-reviewed published literature further substantiates the importance of developing a separate exposure standard for respirable silica, and it may be helpful to supplement the Current Intelligence Bulletin by providing additional and more specific recommendations for such a standard.

2) Evaluation of whether the presentation and summarization of that material is fair and unbiased.

The Current Intelligence Bulletin provides an excellent discussion of relevant published data on health effects associated with coal mine dust exposure. It is presented in a fair and unbiased manner and, given recent trends in CWP prevalence and severity and the likely causal role of respirable silica exposure, perhaps even understates the importance of reducing the coal mine dust exposure standard to the 1995 recommendation and of modifying the exposure limit for crystalline silica.

The document summarizes findings from the Coal Worker's X-Ray Surveillance Program (CWXSP), an effort that led to recognition and further investigation of the central Appalachian "hot spots" of rapidly progressive CWP. The CWXSP observations prompted both an enhanced program to improve participation as well as a number of epidemiologic studies that have helped identify potential causes for disease resurgence, particularly in smaller mines, including increased exposure to crystalline silica through mining of narrower seams, mining of higher ranks of coal, longer working hours, and insufficient dust control. Mortality studies from the US and UK since 1995 continue to show that cumulative exposure to respirable coal mine dust and respirable quartz were each highly significant predictors of pneumoconiosis mortality. The analyses of increasing years of potential life lost (YPLL) due to CWP in the US since 2002 provides additional support for the NIOSH recommendations.

The Toxicology section provides insights into potential mechanisms for development of CWP, with brief discussions of the roles of silica and coal rank. Based on the available literature, including findings from risk analysis, the Current Intelligence Bulletin documents that minimizing exposure to respirable silica (particularly brief high exposures) through improved exposure monitoring and control would be prudent.

Notably, the Bulletin addresses the issue of participation bias as a possible explanation for the hot spots observations, and presents sufficient evidence to support the assertion that such bias is unlikely to explain these observed trends.

3) Determination of whether the overall conclusions are accurate and supportable, including those relating to support for the 1995 conclusions and recommendations.

As described in my previous responses above, it is clear that newer research efforts published in the peer-reviewed scientific literature since 1995 strengthen and augment the previous CCD conclusions and recommendations. Given the rather alarming increase in prevalence and severity of disease from coal mine dust exposure, the conclusions and recommendations of the updated review are, if anything, understated.

4) Evaluation of whether the organization and format of the material as presented is satisfactory for the intended purpose

The review provides excellent updated figures and tables illustrating recent trends in coal mine dust exposure (including operator compliance sampling data and increasing work hours), prevalence data for CWP and PMF (including longitudinal trends), mortality and YPLL for CWP, and lung function declines associated with work in the industry. The Executive Summary is particularly helpful, though it reiterates the Summary section verbatim. Overall, the organization, presentation and format of the material are excellent.

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5) Other comments you might have

a. Page 6, first sentence, remove the word “underground” as a modifier of coal miners, since exposures may affect both underground and surface coal miners.

b. Though exposure to diesel exhaust particulates in coal mining workplaces has raised concerns about potential risks, the report contains no mention of this exposure and possible associated health effects.

c. A few typos and areas of ambiguity were noted as follows:

(1) Page 2, item #6 - last sentence, “A major underlying problem may be achieving sufficient dust control in small coal mines.”

(2) Page 10, last paragraph, 4th sentence, “Although no existing epidemiologic data exist . . .” should be changed to say, “Although no epidemiologic data exist . . .”

(3) Page 12, 2nd full paragraph, last sentence, there is no verb.

(4) Page 13, 1st paragraph, 3rd sentence states, “This dichotomy, in the author’s presentation, was associated with more rapid development of silicosis (≥ 2 mg/m³) compared to chronic silicosis development (< 2 mg/m³).” The sentence is ambiguous, and seems to compare more rapid onset of silicosis to chronic silicosis, presumably of longer latency. But is the more rapidly developing disease clinical distinguishable from chronic silicosis, or is the only difference in latency? Please clarify.

(5) Page 14, 2nd paragraph, there should be a space between associated severe declines.

Sincerely,