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October 21, 2009

The Honorable Jordan Barab
Acting Assistant Secretary for
Occupational Health & Safety
U.S. Department of Labor, Room S2315
200 Constitution Avenue, NW
Washington, DC 20210

Re: Concerns of the Brick Industry Association on OSHA's Peer Review of Its Preliminary Health Effects Analysis and Quantitative Risk Assessment for Occupational Exposure to Crystalline Silica

Dear Mr. Secretary:

This letter is written on behalf of The Brick Industry Association ("BIA"). [1] The primary purpose of this letter is to discuss unique factors related to silica exposure in the brick industry that we believe the Occupational Safety and Health Administration ("OSHA") must consider during the silica rulemaking process. In addition, we need to raise serious concerns with the closed-door manner in which OSHA is carrying out the peer review of the preliminary health effects analysis and quantitative risk assessment underway for OSHA's rulemaking on occupational exposure to crystalline silica. We ask that you take immediate action to make the preliminary health effects analysis and quantitative risk assessment public and

1 The BIA is the national trade association representing the brick industry, consisting of companies that manufacture and distribute quality clay brick products (both face and paver brick) across the United States. Thirty-five manufacturer members of the BIA produce between 80 to 85 percent of all 10 billion bricks produced annually. Most of these manufacturers are small businesses. The approximate number of workers employed in our industry (production, distribution, professional services, masons, etc.) is 215,000. All told, the brick industry contributes more than $20 billion annually to the U.S. economy.

that you place this letter in the public docket and provide copies of it to the peer reviewers for the silica quantitative risk assessment. As we explain more fully below, there are three main points for you to consider:

1. crystalline silica-bearing materials, ***silicosis caused by exposure to crystalline silica is essentially non-existent in the brick industry's workers***. The BIA strongly believes, therefore, that the current OSHA PEL for crystalline silica is amply protective of brick manufacturing workers and should not be reduced for our industry.

2. OSHA has the statutory authority to maintain the current PEL for brick manufacturing workers, even should OSHA reduce that PEL for industry in general.

3. OSHA's decision to carry out this peer review without providing an opportunity for the BIA and other members of the interested public to comment on it violates the principles of transparency and open government espoused by President Obama. This decision is also contrary to the fundamental tenet of this Administration that the public must be able to trust the science and scientific process informing public policy decisions.

I. An Enormous Body of Scientific Data Exists Demonstrating that No Significant Workplace Risk Exists at Current Exposure Levels Necessitating Any Reduction in the Crystalline Silica PEL for Brick Industry Workers.

Mortality and morbidity from silicosis across industry, in general, has declined significantly over the past several decades (in 1968 — 1168 silicosis-related deaths were reported; in 2002 — 148 silicosis-related deaths were reported). Nevertheless, cases of silicosis continue to occur in the quarrying and cutting of stone, in mining of metallic and nonmetallic ores, in iron and steel foundries, and in construction[2, 3] However, cases of silicosis among brick workers in the United States, and elsewhere, are sharply less prevalent than the cases of silicosis in the

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2 NIOSH, Work-Related Lung Disease Surveillance Report 2002, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, DHHS (NIOSH) Number 2003-111, May 2003. (Available at: http://www.cdc.gov/niosh/docs/2003-111/2003-111.html).

3 Bang KM, Mazurek JM and Attfield MD. Silicosis Mortality, Prevention, and Control — United States, 1968-2002, MMWR 54(16); 401-405, 2005. (Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5416a2.htm).

other industries mentioned above. We have carried out a thorough review of the medical literature and published reports of studies of silicosis in the brick industry. The leading work in this area is discussed below. Copies are enclosed with this letter as Attachment 1 through 9. The following table summarizes the results of these studies.

Study (Reference)	No. of Plants in Study	Workers Examined	No. of Silicosis Cases
1939 WVa State Health Dept (4)	20	325	2
1941 Trice NC Brick (8)	48	1555	0
1947 Merritt Study (Building Brick) (10)	120	~ 15000	3 [a]
1949 English Brickworks (12)	3	73	1
1978 NIOSH NC Brick Workers Study (14)	7	518	0
1980 NIOSH NC Brick Workers Study (15)	5	541	0
1972 Ontario Structural Clay Brick Study (23)	10	1116	0
1999 English and Scottish Brick Plant Study (27)	18	1831	0
2006 BIA Study (30)	13	701	0

[a]The Merritt Study focused on compensable silicosis cases in the heavy clay industry. The numbers in this table for building brick, sewer pipe, and drain tile denote the number of cases reported out of the total estimated number of workers in the industry.

In sum, what the data show is that while the older studies found a small prevalence of silicosis in the brick industry, the incidence of those case bears no resemblance to what was occurring within this time period in the aforementioned industries as a result of worker exposures to crystalline silica, either in terms of the numbers of cases or severity of findings. In succeeding years, as dust exposures in the 1960s and 70s were reduced across many industries, silicosis, while still a significant occupational illness, began to decline in cases reported and severity. The reductions of silicosis in brick workers were even more dramatic. To further illustrate this point, we look to the Institute of Occupational Medicine study conducted in Edinburgh, Scotland. Details of this report are provided below, but in summary the study concludes that the brick workers of England and Scotland had the lowest increase in the risk of developing silicosis when compared to hard rock miners, granite workers, gold miners, and coal miners subjected to the same cumulative quartz exposure.

Based on this evidence, it is our position that the brick industry should not be regulated based on quantitative risk assessments derived from exposure-response data from other industries handling silica-containing materials, but rather risk estimates limited to data from modern day brick operations.

Detailed assessments of each of the studies presented in this summary are provided below.

The 1939 West Virginia State Health Department Study

The first study of silicosis among brick workers in the United States was a 1939 report by the Bureau of Industrial Hygiene of the West Virginia State Health Department.[4] The study was based on inspections in 20 brick plants throughout the state. The type of brick products described and number of plants were common and face brick (13); building tile (3); paving brick (3); farm drain tile (2), acid brick (1); sewer brick (1); floor and wall tile (1); fire brick (2), ladle brick (2) and insulating brick (1). The last three plants listed were refractory brick products with very differing processing; namely, the raw materials used and elevated firing temperatures. This and other early studies were important in differentiating the striking disparity in silicosis between refractory brick and structural brick (e.g., common face brick). According to census figures 1,111 employees in West Virginia were engaged in production of brick at the time of the 1939 study. The average total silica in the raw materials was 54 percent (30-85 percent) and the free silica or quartz ranged from 2-20 percent. The report explains that since the quartz is harder and resists crushing and grinding compared to the clays and other minerals used in the manufacturing process, there is less quartz in the fine dust than there is in the raw clay or shale itself. Thus, as the particle size becomes smaller the percentage of quartz becomes less. Particle size measurements from four of the plants found a small median size diameter of 1.2 micrometers indicating a highly respirable dust. Dust exposures ranged from 3 to 242 millions of particles per cubic foot (mppcf). Highest average exposures were found in the grinding (92-242 mppcf), and manufacturing (28-80 mppcf). Lower exposures were found in the pit (4 mppcf)

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4 Anon, (1939). Preliminary Report of a Study in the Brick and Tile Industry in West Virginia, Bureau of Industrial Hygiene, West Virginia State Health Department.

and mine (15 mppcf), in brick setting (11 mppcf) and wheeling (7 mppcf). Jobs in yard operations ranged from 3-50 mppcf with all below 10 mppcf except for brick shed workers with an average of 50 mppcf. To provide some perspective on the magnitude of these levels, in 1936 the Vermont Health Department adopted an exposure limit of 10 mppcf to protect workers in granite quarries and carving sheds from silicosis.

In addition to analysis of the raw materials and the manufacturing process itself, a medical study was conducted on 325 workers (299 men and 26 women) at four of the 20 total brick plants. Average age of those studied was 36 years and average length of employment was 10.7 years.[5] Chest X-ray interpretations were based on a scheme by Dreessen and Jones.[6, 7] Of the 325 films, 19 (5.9%) were read as abnormal. Nine were read as G-1, indicating the presence of "granular" or "ground glass" markings, but linear markings still existed. Two of the nine had brief employment in the brick industry and histories of long employment in another dusty industry. Eight were classified as G-2 indicating a "granular" or "ground glass" appearance with linear markings obliterated. Of the eight, one had long exposure in another dusty industry and brief exposure in the brick industry. Two were read as N and both men had nodulation of about 2 millimeters in diameter scattered throughout the lung parenchyma.

<u>**The 1941 North Carolina Brick Industry Study**</u>

Another important early study was conducted by Trice in the North Carolina brick industry and was published in 1941.[8] The study involved 48 brick plants manufacturing structural brick from alluvial clays or shale. Dust samples were taken with midget impingers and the dustier jobs were selectively over-sampled. A total of 183 impinger counts of dust were made in 28 of those same plants. Trice and his colleagues performed health exams, including chest x-rays, on 1,555 workers. The chest x-rays were read independently by two physicians who were experienced film readers with the North Carolina Dusty Trades Program, an early prevention program that conducted routine medical examinations of workers in asbestos textile plants, quarries, sand plants, and clay operations in the state. Both of the physicians reported no evidence of silicosis in any of the workers. Average

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5 *Ibid.*

6 Dreessen WC and Jones RR. Anthracosilicosis. JAMA 1936, 10:1179-1185.

7 Flinn RH, Dreessen WC, et al. Silicosis and Lead Poisoning Among Pottery Workers. Public Health Bulletin No. 244.

8 Trice MF. Health of Brick and Tile Workers in North Carolina. Bulletin of the American Ceramic Society. 20(4); 130-134, 1941.

dust exposures ranged from 2 to 138 mppcf and 11 of the 31 jobs had average exposures above 20 mppcf.

It is apparent that these negative findings were quite unexpected. As the author wrote:

> The examination of the workers in brick and tile plants was expected to reveal the existence of pulmonary pathology that could be attributed to the inhalation of dust.

As a result, further analyses of the medical data were made to determine whether some effect of dust inhalation were present by analyzing for higher incidences of the more common respiratory disorders. [9] No appreciable differences in the incidence of various parameters were found between examinations of workers for pre-employment compared with the brick workers.

The lack of any silicosis or other respiratory disorders among the brick workers prompted Trice to conclude:

> The total absence of silicosis and other serious pulmonary pathology and the low incidence of other respiratory diseases among 1555 brick and tile plant workers indicate that exposure to dust in the North Carolina industry does not constitute a serious menace to health.

This early experience in North Carolina is also noteworthy in that studies by the National Institute for Occupational Health and Safety ("NIOSH") in the 1970s, over 30 years later, came to a similar conclusion regarding silicosis and respiratory diseases among North Carolina brick workers (*see infra* at pp. 13-15).

The 1947 Merritt Study

In another early work, Merritt reported on a study of silicosis in the heavy clay industry in a 1947 Ohio Industrial Commission publication. [10] The heavy clay industry is described as building brick and clay refractories. Merritt contrasted the silicosis experience in heavy clay with the ceramic whiteware

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9 *Ibid.*

10 Merritt LM (1947) Silicosis Hazard in Heavy Clay Products. Ohio Industrial Commission Monitor, Vol. 20, Page 89-90, 1947.

industries over a ten-year period beginning in 1937 when silicosis became a compensable disease in Ohio.

During the period the ceramic whiteware industries had 241 claims allowed which accounted for 21.8 percent of all silicosis claims allowed by the Industrial Commission. The heavy clay industry experienced just 51 claims or 4.6 percent of the total allowed. Of the 51 compensable cases allowed, only three (5.9%) came from 120 plants representing the building brick, sewer pipe and drain tile plants. The remaining 48 cases (94.1%) were distributed as shown in Table 1. It is interesting to note that the 120 brick plants accounted for just three compensable cases, whereas the great majority of the cases (48) came from the remaining 33 plants using silica-containing materials in the manufacture of products.

Table 1. Compensable Silicosis Cases in the Ohio Heavy Clay Products (1937-1947)

	No. of Plants	Silicosis Claims Allowed 1937-1947
Building brick, sewer pipe & drain tile	120	3
Fire brick and other clay refractories	26	8
Silica Brick	3	12
Insulating	1	8
Glass house refractories	3 [11]	20
	153	51

Merritt noted that it was common to find dust counts of 100 mppcf, and not rare to find counts as high as 300 mppcf, near the dry pan where grinding takes place. He estimated that 15,000 workers were employed in the 120 building brick plants. Merritt concluded for the structural clay products that:

> The dusts produced in the manufacture of building brick, sewer pipe, drain tile and clay refractories do

11 One glass house refractory plant closed in 1944.

> not produce silicosis as readily as those from the compounded bodies used in other ceramic industries.

The 1949 English Brickworks Study

In 1949, Keatinge and Potter reported on a health and environmental study in three of four brickworks in England described as typical of the brick-producing industry. [12] Two measurements of respirable-sized dust taken during removing brick from the kilns after firing (brick-drawing) and cleaning out the kiln were quite high with mass concentrations of 0.12 g/1000 ft^3 (equal to 4.2 mg/m^3), and with corresponding count data of 326 and 340 particles/cm^3 <5.5μ (equal to 9.2 and 9.6 mppcf <5.5μ). Whole dust samples taken during brick-drawing and cleaning out the kiln ranged from 1.2 – 7.2 g/1000 ft^3 (42.4-254.4 mg/m^3).

The dust in the screening areas of the plants were also quite high with the respirable fraction ranging from 0.06 to 0.16 g/1000 ft^3 (2.1-5.7 mg/m^3), and the whole dust range being 0.9 to 4.8 units g/1000 ft^3 (31.8-169.6 mg/m^3). The particle counts ranged from 105 to 601 particles/cm^3 <5.5μ (3.0-17.0 mppcf). The authors refer to a paper by Gardner and suggest that while dust levels are high that the inhalation risk of free silica is not a hazard due to the alumina in the brick clays inhibiting fibrosis.

Of a total employment of 144 workers in the brickworks 100 were examined medically and 73 of the 100 underwent a chest radiograph. [13] Of the 73, only one new entrant to brick-making was reported as having changes consistent with silicosis (Class V, second-stage silicosis), and he had previously been a bricklayer's laborer. The authors note that they had previously observed early dust changes in the lungs of bricklayers and their laborers. In conclusion, notwithstanding the measurement of extremely high respirable and total dust exposures, silicosis did not appear to be a problem in the workforce of these English plants.

The 1978 and 1980 NIOSH North Carolina Brick Worker Studies

Following the 1941 Trice study, North Carolina again became the focus of interest in silicosis in the brick industry when the North Carolina Department of Health asked NIOSH to assist in two medical studies of brick workers in the

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12 Keatinge GF and Potter NM. Health and Environmental Conditions in Brickworks. Brit. J. Industr. Med. 1:31-44, 1949.

13 *Ibid.*

1970s.[14, 15] The 1978 NIOSH studies was conducted of 518 brick workers from seven plants and 592 controls from occupations without exposure to dust. The 1980 NIOSH study was conducted of 541 workers in five brick plants and 253 workers in two clay pipe plants, and 785 non-dust exposed control workers. The North Carolina Health Department had been conducting annual medical surveys of brick workers for ten years, to include chest X-rays, and they had failed to show an excess of silicosis or any other chest disease. [16] Along with its mobile health surveys in 1969-70, the Department conducted an industrial hygiene study of dust exposures. [17] The Health Department dust study found that the free silica content of the respirable dust samples ranged from 13.1% to 48.8%. Respirable dust concentrations ranged from 0.07 mg/m^3 to 26.2 mg/m^3 with average values for the various operations ranging from 0.88 to 2.49 mg/m^3. In spite of these high dust levels, the chest X-ray survey did not turn up any evidence of silicosis in these plants. In actual fact, no cases of silicosis were found in the round of chest X-ray examinations of an estimated 2000 brick workers statewide. These findings were similar to the findings that Trice had reported 30 years prior. This prompted the Health Department in 1973 to request NIOSH to make an epidemiological study of the brick industry to explain the lack of silicosis in brick workers when the study conducted by the Health Department showed the workers to be exposed to levels which greatly exceeded OSHA's permissible exposure limit for free silica. [18]

Stringer and Anderson of NIOSH reported on a respiratory medical study of 770 brick workers and 776 controls. [19] Excluded from analyses were workers with missing questionnaires, workers who had worked more than one year in another dusty trade, and those whose tests were unsatisfactory. The final study population

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[14] NIOSH [1978]. North Carolina Brick Industry Respiratory Disease Morbidity Study, 1978. Cincinnati, OH. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health.

[15] NIOSH [1980]. North Carolina Brick Industry Industrial Hygiene and Respiratory Disease Morbidity Survey, 1974-1975, 1980. Cincinnati, OH. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health.

[16] Deubner DC. State of North Carolina Health Surveys within the Brick Industry, 1969-1971. Unpublished data.

[17] Carstens CJ. Silicosis Potential in North Carolina Brick Industry. Raleigh, NC, North Carolina Department of Human Resources, State Board of Health, Occupational Health Section, 1972, 10 pp.

[18] NIOSH [1980], *op. cit.*

[19] *Ibid.*

consisted of 1,110 persons (518 brick workers and 592 controls). The NIOSH researchers concluded that there was a lack of statistical evidence to support the hypothesis of increased respiratory disease among this group of brick workers compared to the non-dust exposed control group. Spirometry, chest X-rays and respiratory disease questionnaire data provided no indication of excess disease associated with the brick workers. Results of the chest X-rays found few abnormal films and there was no significant difference ($p>0.05$) in the number of abnormal between the brick workers and controls.

The 1980 medical study conducted by NIOSH was of 541 brick workers from five plants and 253 clay pipe workers from two plants compared to a control group of 785 non-dust exposed workers. [20] A dust study was included with this evaluation and the brick plants were found to have higher respirable free silica levels ranging from 0.4 $\mu g/m^3$ to 692 $\mu g/m^3$, compared to the pipe plants with levels ranging from 8 $\mu g/m^3$ to 200 $\mu g/m^3$. After excluding some workers from analyses for the same reasons as in the Stringer and Anderson study, a study group of 1289 persons were studied (336 brick workers, 246 pipe workers, and 707 unexposed controls). The results of this study were remarkably similar to the 1978 NIOSH study and the 1939 Trice study.[21, 22] Pulmonary function data, chest X-rays, respiratory questionnaires and sputum cytology gave no indication of excess respiratory disease among the brick workers and pipe maker study group compared to the control population. The authors stated they found no compelling evidence to support the hypothesis of increased respiratory disease among this group of brick and pipe workers in relation to the comparison group.

The 1972 Ontario Structural Clay Brick Study

Around this same time, similar to the negative North Carolina studies discussed above, negative results for silicosis and respiratory diseases were found in a 1972 study in Canada of workers manufacturing structural clay bricks in Ontario.[23] Extremely high dust levels were documented, some more than 100 times the prevailing occupational limits. The study by Rajhans and Buldovsky included eight brick and two tile plants with a total of about 1,166 production workers. A total of 77 impinger counts were taken in the plants. The free silica percentages of the total airborne dusts varied from 13.2 to 24.8, while the raw materials contained

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[20] *Ibid.*

[21] NIOSH [1978], *op. cit.*

[22] Trice, *op. cit.*

[23] Rajhans & Buldovsky J. Dust Conditions in Brick Plants of Ontario. Am Ind Hyg Assoc J, 33: 258268, 1972.

from 22% to 32% free silica in the clays and shale. The total silica in the raw materials varies from 40% to 68%. Mean dust counts range from 12 mppcf to 1026 mppcf. Two counts in one plant that were not included in the study were above 10,000 mppcf, the highest ever recorded by the Ontario Occupational Health Laboratory. Data is not given for specific operations, however, plant conditions were extremely dusty across all plants with mean impinger counts exceeding the TLV from 1.26 to 114 times. As seen in the table below, six of the 10 plants exceeded the TLV by more than a factor of 10 and no plants were below the established TLV.

Table 4. Impinger Count Measurement and Exceedances of the TLV for Ontario Brick Plants.

Plant No.	% Free Silica (Resp.)	Impinger Count (mppcf)	TLV (mppcf)	TLV Exceedance [24]
1	15	271	8.8	30.79
2	21	580	8.5	68.23
3	14.7	1026	9.2	114
4	20	128	8.5	15.05
5	7.5	19	13.7	1.39
6	20	175	8.6	20.34
7	19	322	8.7	37.01
8	18	67	8.1	8.27
9	12.5	12	8.4	1.43
10	10	12	9.5	1.26

Regular chest x-rays were taken on employees beginning in 1959 and were conducted every 18 months.[25] The films were read according to a system developed by Drs. A. R. Riddle and J. H. Brennan in 1935. The system is explained as Code number 1 designating normal lung markings; Codes 2 and 3 denoting heavier markings; and code 4 characterizing as reticulation of the lungs. Codes 5 through 9 designated pneumoconioses with increasing amount and quality of nodulation. With the exception of one film that showed diffuse miliary nodulation (code 5), no chest x-ray patterns consistent with silicosis were found. The one case was a worker who had worked in an iron mine for 13 years and for 2 years in a tile plant.

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24 TLV exceedance is the multiple of how many times the exposure was above the TLV and is calculated as TLV Exceedance = Impinger Count (mppcf) ÷ TLV (mppcf).

25 Rajhans, *op. cit.*

The authors attributed his changes to his former work and he was removed from the study. The authors attempted to find a relationship of the chest x-ray interpretations with the seniority of the workers and dust exposures but did not find any correlation with total dust counts nor with respirable dust concentrations.

The authors concluded that even though the workers were exposed to dust concentrations considerably in excess of the TLVs (8 to 114 times), nevertheless, radiological signs of silicosis among the workers were not present. [26] Moreover, they questioned whether the ACGIH TLVs at the time of the study were applicable to the brick industry.

The 1999 English and Scottish Brick Plant Study

In a more recent study published in 1999, more than 1,900 workers from 18 brick plants in England and Scotland participated in a respiratory medical study that included chest x-rays, respiratory symptom and smoking questionnaires, and lifetime occupational histories [27, 28] A total of 1407 personal dust samples were taken at the same time. The average dust concentration was reported to be 1.3 mg/m^3 and average quartz concentrations were 0.11 mg/m^3.

Cumulative exposures to mixed respirable dust and to quartz were calculated by combining estimates of dust and quartz concentrations within occupational groups, and time worked in these groups. [29] For 1831 workers, in whom exposure-response was investigated, the mean of cumulative exposure to quartz was 1.51 mg/m^3-years. Of these, 120 workers had 4.0 mg/m^3- years exposure or higher. X-rays were read by three physicians, and an average category of radiological abnormality was derived by using the median of the three readings. The prevalence of category 1/0+ small rounded opacities was 1.4%. A multiple logistic regression analysis showed a statistically significant relation between radiological abnormality (1/0+) and cumulative exposure to quartz, allowing for age and smoking. Predicted prevalences (%) in non-smoking workers, initially aged 20, exposed to a respirable quartz concentration of 0.1 mg/m^3 for 10 and 20 years respectively, were 0.2 (95%CI

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26 *Ibid.*

27 Love RG, Waclawski ER, Maclaren WM, Wetherill GZ, Groat SK, Porteous RH, & Soutar CA. Risks of Respiratory Disease in the Heavy Clay Industry. Occup Environ Med, 56, 124-133, 1999.

28 Love RG, Waclawski ER, Maclaren WM, , Porteous RH, Groat SK, Wetherill GZ, Hutchinson PA, Kidd MW, Soutar CA (1994). Cross-Sectional Study of Risks of Respiratory Disease in Relation to Exposures of Airborne Quartz in the Heavy Clay Industry. Edinburgh: Institute of Occupational Medicine (IOM Report TM/94/07).

29 Love [1999], *op. cit.*

0.1 -0.8) and 0.9 (0.4 -2.1). The prevalence among these brick and tile workers of 1.4% of 1/0 or greater was much lower than other dust-exposed populations they had studied with a finding of 4.4% in surface mine workers and 4.7 % in workers quarrying hard rock. Interestingly, a group of postal and telecommunication researchers, not exposed to dust, that were used as a control population for the studies above had a prevalence of 2.8%, twice that of the brick and clay workers. Thus, the prevalence finding in the brick and clay workers of 1.4% is within what could be considered as background for a normal population.

The 2006 BIA Study

To develop a better understanding of the risk of silicosis in the United States brick industry, the BIA sponsored a Study, completed in May 2006, entitled "The Prevalence of Silicosis in the Brick Industry," to determine the prevalence of radiographic signs of silicosis among current workers in the U.S. brick industry. [30] We chose as the Study leader Dr. Patrick Hessel, an epidemiologist with great experience in occupational and environmental lung diseases, who has conducted extensive research on silicosis, asbestosis, and lung cancer. Dr. Hessel and his colleagues studied workers at thirteen plants producing structural clay brick from 94 facilities operated by members of the BIA. These workers were selected through a random process, which took account of company size, geographic location, and employee age. Radiographs from 701 workers were read by two NIOSH-certified B-readers. When the two primary readers disagreed on the interpretation of a film, the chest x-ray was read by a third B-reader. Very importantly, none of the chest x-rays of the 701 workers was consistent with silicosis. These results are consistent with the previous studies mentioned of brick workers from the United States, the United Kingdom and Canada. A copy of Dr. Hessel's Study is enclosed with this letter as Attachment 10.

We are pleased that Dr. Hessel's research shows our brick workers appear not to be at risk for silicosis at today's exposure levels. Our industry will continue to look for opportunities to sponsor research to fill the critical knowledge gaps regarding the uniqueness of the silica particles found in the brick industry.

It is evident from this review of the medical studies of brick workers that the risk of developing silicosis from exposure to quartz in brick clays and shale is insignificant at exposure levels that exist in our modern industry today. It is important to understand that we do not take the position that quartz in brick clays and shale is benign, or incapable of producing silicosis, but that the fibrogenic

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[30] Glenn RE, Hessel P., Silicosis in the Clay Brick Industry. Chest 132, Suppl. 4, 599S, 2007.

potency of the quartz in brick clays and shale necessary to produce scarring of the lungs characteristic of silicosis differs from that of quartz found in other industrial settings. Indeed, it has been recognized for some time that there are multiple factors that affect the potency of crystalline silica; that these factors may interact in multifaceted ways to either intensify or diminish the biological response; and our understanding of these factors continues to grow. We will be pleased to develop our comments on this subject in future submissions, but for now we choose to concentrate on the fact that the risk of developing silicosis among brick workers is simply nowhere near as sharp as the exposure-response for other industries handling silica-containing materials. Consequently, the brick industry should not be regulated based on quantitative risk assessment derived from exposure-response data from these other industries. The basis for risk estimates for our industry should be limited to studies conducted in modern day brick operations.

The 1996 IOM Report

To illustrate this point we rely on an eloquent report from researchers at the Institute of Occupational Medicine ("IOM") in Edinburgh, Scotland. This prestigious research unit was also responsible for the study described above by Love, et al. of brick workers in England and Scotland.[31, 32] Pilkington and colleagues prepared a detailed report with one of the objectives being to examine the risk of silicosis in the range of exposure limits under discussion today and to determine what evidence there might be to support an absence of an effect at low concentrations. [33]

In the IOM report, the researchers carefully examined six radiographic studies of silicosis for which there were suitable data for comparison of exposure-response relationships. The six studies were of Canadian hardrock miners in Ontario, of granite quarry workers in Hong Kong, of white South African gold miners, of Vermont granite quarry and shed workers, of Scottish coal miners who experienced high quartz exposures due to geologic conditions, and the brick workers in the study of Love.[34, 35, 36, 37, 38, 39] Pilkington and his colleagues prepared the

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31 Love [1997], *op. cit.*

32 Love [1994], *op. cit.*

33 Pilkington A, Maclaren W, Searl A, Davis JMG, Hurley JF, Soutar, CA, Pairon JC, Bignon J. (1996). Scientific Opinion on the Health Effects of Airborne Crystalline Silica. Edinburgh: Institute of Occupational Medicine (IOM Report TM/95/08).

34 Muir DCF, Verma DK et al. (1989). Silica exposure and silicosis among Ontario hardrock miners: III. Analysis and risk estimates. American Journal of Industrial Medicine; 16:29-43.

figure below which points out the disparate exposure-response relationships from these five diverse mining industries and the brick making industry of England and Scotland. It should be noted that although the studies differed in ways of design and definition of the radiographic category of silicosis, nonetheless, the figure show the extreme variability in silicosis risk for exposure to what could be considered by some to be the same agent, namely quartz. Differences include that the Canadian study, the South African study and the study from Hong Kong considered radiographic evidence of silicosis to be small rounded opacities of ILO category 1/1 or greater, whereas the Vermont study, the Scottish coal study and the Love study of brick workers considered silicosis to be small rounded or small irregular opacities of ILO category 1/0 or greater. A second difference is that the Canadian and South African studies analyzed the incidence of silicosis using a life-table method with cumulative exposure acting as the "time" variable, whereas the other authors modeled the prevalence of silicosis at a single time point, using logistic regression. Therefore, the figure has a number of simplifications and assumptions but as long as these are kept in mind, the illustration is useful, and draws attention to the difficulty of setting exposure limits for quartz.

(continued)

35 Ng TP, Chan SL. (1994). Quantitative relation between silica exposure and development of small opacities in granite workers. Annals of Occupational Hygiene; 38:857-863.

36 Hnizdo E, Sluis-Cremer GK. (1993). Risk of silicosis in a cohort of white South African Gold Miners. American Journal of Industrial Medicine; 24:447-457.

37 Graham WGB, Ashikaga T, Hemenway D, Weaver S, O'Grady RV. (1991). Radiographic abnormalities in Vermont granite workers exposed to low levels of granite dust. Chest; 100:1507-1514.

38 Miller BG, Hagen S, Love RG, Cowie HA, Kidd MW, Lorenzo S, Tielemans ELJP, Robertson A, Soutar CA. (1995). A follow-up study of coalminers exposed to unusual concentrations of quartz. Edinburgh: Institute of Occupational Medicine, 1995 (IOM Report TM/95/03).

39 Love [1994], *op. cit.*

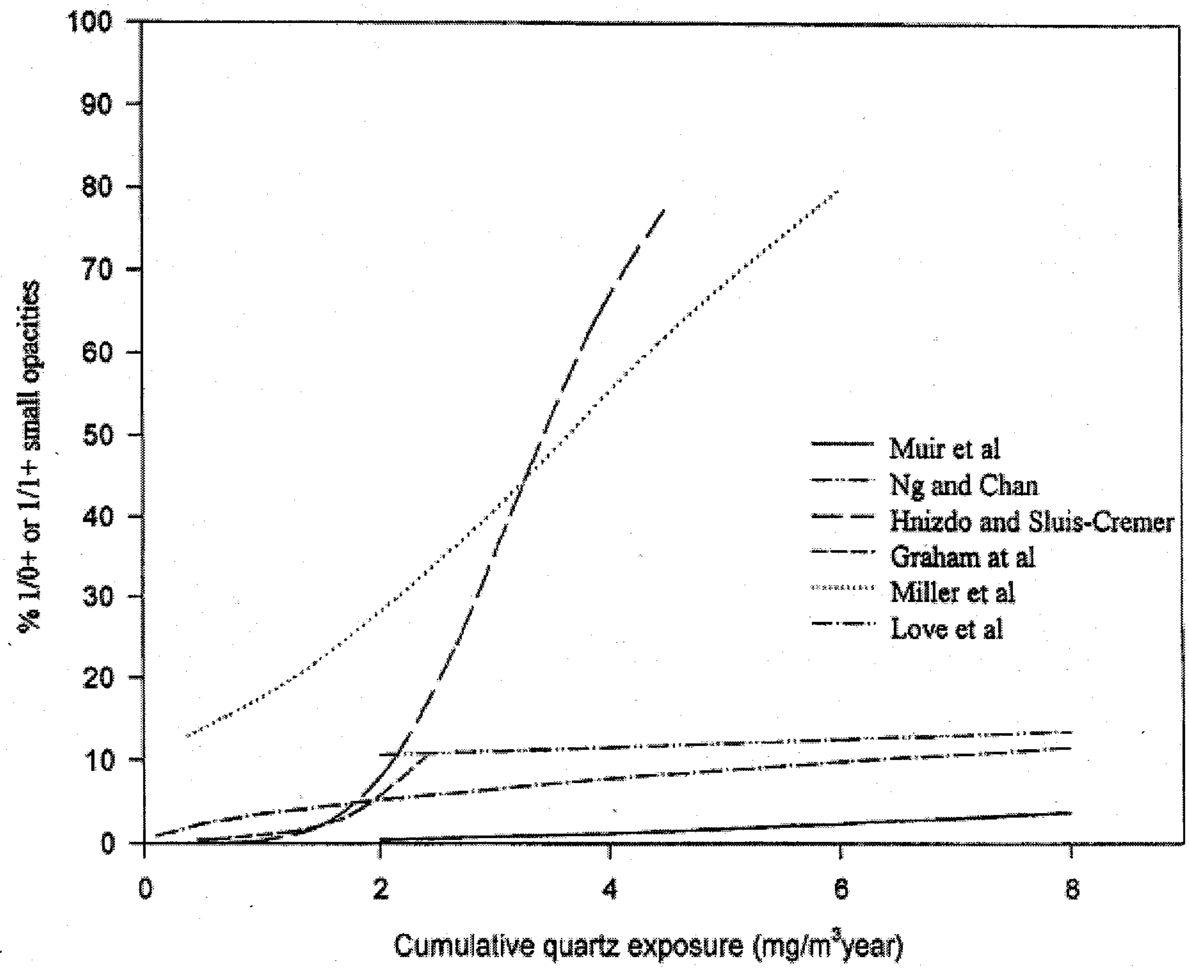

Figure 1. Risks of Silicosis in Relation to Cumulative Exposure to Quartz (From IOM Report TM/95/08, Figure A4.4.1, page 48).

Notice the extremely sharp exposure-response relationship of the South African gold miner study and the Scottish coal study which are strikingly different than the others. The Love study of English and Scottish brick workers has the lowest slope of the six. This observation of the variability in the risk of developing silicosis for what could be considered equal cumulative exposure to quartz establishes why it is imperative that the brick industry not be regulated by the silicosis risk found in other exposure situations. The IOM Report and the reports referenced above are enclosed with this letter as Attachments 8, and 11 through 16.

In addition to the literature cited above, as we stated at the outset of this letter, an enormous body of additional scientific data exists demonstrating that no significant workplace risk exists necessitating any reduction in the crystalline silica

PEL for brick industry workers. As OSHA's crystalline silica rulemaking progresses, the BIA will discuss this additional scientific information.

II. OSHA has the Statutory Authority to Maintain the Current PEL for Brick Manufacturing Workers, Even Should OSHA Reduce the PEL for Industry in General.

Given the low health risk associated with silica exposure in the brick industry, as demonstrated by the leading studies discussed above, and the proactive nature of the industry to engage in the prevention of silica-related disease, the question becomes whether and to what extent this information must bear on OSHA's health effects analysis and quantitative risk assessment for occupational exposure to crystalline silica, and OSHA's authority to impose any new silica exposure standard on the brick industry (irrespective of the merits of imposing such a standard on other industries).

As you know, the extent to which OSHA must consider the scientific data from a particular industry in assessing the risk of occupational exposure to a particular toxic agent is not addressed in the OSH Act and, for the most part, has not been raised or addressed in the case law. OSH Act rulemaking case law has made it clear, however, that in regulating across a broad spectrum of industries, OSHA cannot ignore data as it relates to specific industries. For example, § 6(b)(5) of the OSH Act, 29 U.S.C. § 655(b)(5), requires that in setting exposure limits for toxic materials, OSHA's standard must be "feasible." In practice, courts have interpreted this to mean that OSHA must assure that any standard established be both technologically and economically feasible for *every industry* affected by the standard. *See United Steel Workers of Am, AFL-CIO v. Marshall,* 647 F.2d 1189, 1301 (D.C. Cir. 1981) (amended opinion), noting the "undisputed principle that feasibility is to be tested industry-by-industry." Although feasibility is not the issue we address in this letter, it is well established that before OSHA can promulgate a health standard for the workplace, the Agency must determine that there is a "significant risk of material health impairment" which the proposed standard is intended to remedy. *See Indus. Union Dept., AFL-CIO v. Am. Petroleum Inst,* 448 U.S. 607, 639, 642 (1980) (the *"Benzene" decision). Benzene* held further that OSHA first must find that the "workplaces in question are not safe," meaning that they are unsafe "in the sense that significant risks are present and can be eliminated or lessened by a change in practices." *Id. at 642.*

Where risk becomes "significant" turns in large part on policy considerations on which OSHA is accorded deference. *Id. at 655.* In the first instance, however, OSHA must be able to point to "a body of reputable scientific thought" to support its finding that a significant workplace risk exists. *See Public Citizen at 1497.* OSHA, therefore, must "must explain the logic and the policies underlying any legislative choice, . . . state candidly any assumption on which [the Agency] relies, and . . . present [its] reasons for rejecting significant contrary evidence and argument." *See Steelworkers at 1207.* In other words, not only must OSHA defend its own scientific findings, it must also defend its reasons for not following persuasive evidence that militates toward a different conclusion.

In light of the above, the BIA submits that because OSHA is required to address any evidence that contradicts its findings and conclusions that a lower exposure limit is necessary (certainly before a court, at least, if OSHA fails to do so earlier), it makes practical sense that OSHA adapt its rule to exclude the brick industry from the scope of its rulemaking at the outset if the empirical data does not evidence a "significant" health risk within the brick manufacturing industry. This is particularly so since OSHA is clearly empowered by the OSH Act to tailor its standards as it deems fit, including drawing distinctions between industries if the body of evidence so justifies. *See Industrial Union Dept., AFL-CIO v. Hodgson*, 499 F.2d 467, 480 & n.31 (D.C. Cir. 1974). In that case, the Court expressly rejected the notion that OSHA is obligated to create "a single uniform standard for reasons of practical administration." *Id.* The Court said:

> The statutory scheme is generally calculated to give [OSHA] broad responsibilities for determining when standards are required and what those standards should be. *If [OSHA] determines that meaningful distinctions between the compliance capabilities of various industries can be defined, [it] is authorized to structure the standards accordingly.*

Id. (Emphasis added.)

While the issue in *Hodgson* concerned the effective date of an asbestos PEL, the decision demonstrates that OSHA certainly has the discretion to craft its standards in a manner that reflects the distinctions between industries. Moreover, OSHA has the obligation to justify the necessity of any standard ultimately promulgated, which includes the obligation to explain why significant evidence to the contrary has not been followed. Given this, the BIA believes that OSHA *may* and *should* exempt the brick manufacturing industry from its crystalline silica rulemaking in light of the overwhelming evidence that no significant health risk exists in our industry from exposure to silica.

III. OSHA's Decision to Carry Out Peer Review of Its Preliminary Health Effects Analysis and Quantitative Risk Assessment for Occupational Exposure to Crystalline Silica Without Providing an Opportunity for Public Comment Violates the Principles of Transparency and Open Government Espoused by President Obama.

OSHA's decision to carry out a secretive, closed-door peer review of its preliminary health effects analysis and quantitative risk assessment for occupational exposure to crystalline silica constitutes a major setback for the efforts of the Executive Branch, including this Administration, to enhance the practice of peer review of government science documents. On December 16, 2004, the Director of the Office of Management and Budget ("OMB") issued a Memorandum for Heads of Departments and Agencies transmitting a bulletin entitled "Final Information Quality Bulletin for Peer Review."[40] In his Memorandum, the OMB Director stated:

> This Bulletin establishes government-wide guidance aimed at enhancing the practice of peer review of government science documents. Peer review is an important procedure used by the scientific community to ensure ... the quality of published information. Peer review can increase the quality and credibility of the scientific information generated across the federal government.

The OMB Bulletin not only established peer review requirements for "influential" scientific information prior to its dissemination; but also established additional peer review requirements for "highly influential scientific assessments."[41] OSHA has determined that its preliminary health effects analysis

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40 Bulletin M-05-03, also published at 70 Fed. Reg. 2664 (Jan. 14, 2005).

41 The Bulletin provides:

> A scientific assessment is considered 'highly influential' if the agency or [OMB] determines that the dissemination could have a potential impact of more than $500 million in any one year on either the public or private sector or that the dissemination is novel, controversial, or precedent-setting, or has significant interagency interest.

Id. at 2671.

and quantitative risk assessment for occupational exposure to crystalline silica is likely to be a highly influential scientific assessment document.[42]

The Bulletin recognizes that public comments can be important in shaping expert deliberations; and in the case of highly influential scientific assessments, the Bulletin provides:

> Whenever feasible and appropriate, the agency shall make the draft scientific assessment available to the public for comment at the same time it is submitted for peer review (or during the peer review process) and sponsor a public meeting where oral presentations on scientific issues can be made to the peer reviewers by interested members of the public. When employing a public comment process as part of the peer review, the agency shall, whenever practical, provide peer reviewers with access to public comments that address significant scientific or technical issues. To ensure that public participation does not unduly delay agency activities, the agency shall clearly specify time limits for public participation throughout the peer review process.[43]

In this instance, the BIA does not believe that OSHA has provided any rationale for its decision to avoid this requirement of the OMB Bulletin. On the chance that OSHA's decision to skip this vital step was out of concern that public participation might unduly delay the agency's crystalline silica rulemaking, it would have been easy for OSHA to make the preliminary health effects analysis and quantitative risk assessment available for public comment and to specify a time limit for public participation, as the Bulletin requires.

As if the OMB Bulletin itself were not enough reason for OSHA to allow the BIA and other members of the interested public to comment on the preliminary health effects analysis and quantitative risk assessment, OSHA's decision is totally

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42 *See* OSHA Peer Review Agenda, Last Updated June 15, 2009, stating that the two reports under peer review, entitled "Health Effects Analysis and Quantitative Risk Assessment for Crystalline Silica" and "Models and Data Supporting the Preliminary Economic Analysis of Occupational Exposure to Crystalline Silica," are likely to be highly influential scientific assessments. http://www.osha.gov/dsg/peer_review/peer_agenda.html.

43 70 Fed. Reg. 2676.

contrary to the instructions of President Obama himself to the heads of executive departments and agencies.

In his Memorandum of January 21, 2009, entitled "Transparency and Open Government," the President instructed his executive department and agency heads as follows:

> My Administration is committed to creating an unprecedented level of openness in Government. We will work together to ensure the public trust and establish a system of transparency, public participation, and collaboration. Openness will strengthen our democracy and promote efficiency and effectiveness in Government.
>
> *Government should be transparent.* Transparency promotes accountability and provides information for citizens about what their Government is doing. Information maintained by the Federal Government is a national asset. My Administration will take appropriate action, consistent with law and policy, to disclose information rapidly in forms that the public can readily find and use. Executive departments and agencies should harness new technologies to put information about their operations and decisions online and readily available to the public. Executive departments and agencies should also solicit public feedback to identify information of greatest use to the public.
>
> *Government should be participatory.* Public engagement enhances the Government's effectiveness and improves the quality of its decisions. Knowledge is widely dispersed in society, and public officials benefit from having access to that dispersed knowledge. Executive departments and agencies should offer Americans increased opportunities to participate in policymaking and to provide their Government with the benefits of their collective expertise and information. Executive departments and agencies should also solicit public input on how we can increase and improve opportunities for public participation in Government.
>
> *Government should be collaborative.* Collaboration actively engages Americans in the work of their Government. Executive departments and agencies should

> use innovative tools, methods, and systems to cooperate among themselves, across all levels of Government, and with nonprofit organizations, businesses, and individuals in the private sector. Executive departments and agencies should solicit public feedback to assess and improve their level of collaboration and to identify new opportunities for cooperation.

President Obama's Memorandum was published in the Federal Register for January 26, and a copy is enclosed with this letter as Attachment 4.

Even more directly on point, in a March 9, 2009 Memorandum for the Heads of Executive Departments and Agencies entitled "Scientific Integrity," the President said:

> Science and the scientific process must inform and guide decisions of my Administration on a wide range of issues, including improvement of public health, protection of the environment, increased efficiency in the use of energy and other resources, mitigation of the threat of climate change, and protection of national security.
>
> The public must be able to trust the science and scientific process informing public policy decisions. Political officials should not suppress or alter scientific or technological findings and conclusions. If scientific and technological information is developed and used by the Federal Government, it should ordinarily be made available to the public. To the extent permitted by law, there should be transparency in the preparation, identification, and use of scientific and technological information in policymaking. The selection of scientists and technology professionals for positions in the executive branch should be based on their scientific and technological knowledge, credentials, experience, and integrity.

This memorandum was published in the Federal Register on March 11, 2009, and a copy is enclosed with this letter as Attachment 5.

Conclusion.

To conclude, the BIA urges you and your colleagues to carefully consider this letter. The BIA will continue to participate actively in OSHA's crystalline silica rulemaking. As we noted at the outset, we request that you place this letter in the public docket and provide copies of it to your peer reviewers. Should you have any questions about this letter, please feel free to contact Susan Miller, BIA Vice President Environment, Health & Safety at 703-674-1545 or smiller@bia.org or Bob Glenn at 202-624-2636 or rglenn@crowell.com.

Sincerely,

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Crowell and Moring LLP

Susan Miller
Vice President,
Environment, Health & Safety
The Brick Industry Association

Attachments

cc: Ed Green, Counsel to BIA