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June 24, 2014

The Honorable David S. Michaels
Assistant Secretary of Labor for
Occupational Safety and Health
U.S. Department of Labor
Room N-2625
200 Constitution Avenue NW.
Washington, DC 20210
c/o OSHA Docket Office
Docket No. OSHA-2010-0034

SUBMITTED ELECTRONICALLY: www.regulations.gov

Re: Occupational Safety and Health Administration Proposed Rule on Occupational Exposure to Respirable Crystalline Silica, Docket No. OSHA-2010-0034, 78 FR 56274, September 12, 2013

Dear Dr. Michaels:

The U.S. Chamber of Commerce (Chamber) is the world's largest business organization representing the interests of more than 3 million businesses of all sizes, sectors, and regions. Our members range from small businesses to large multi-national corporations and local chambers to leading industry associations. The Chamber's members include businesses in every market sector and every region throughout the United States. Many of them will be directly affected by OSHA's proposed rule. As these comments will demonstrate, the proposed rule does not address significant risks, nor provide significant benefits, and is neither technologically nor economically feasible. Accordingly, the Chamber believes the proposed rule must be withdrawn.

TABLE OF CONTENTS

Appendixes

SUMMARY

The Chamber and its member companies are committed to protecting employees and developing and implementing sound government policies that advance health and safety and at the same time enhance the nation's economy. The Chamber has a longstanding interest in silica policies given the ubiquitous nature of quartz on the Earth's crust. Silica has a critical role in a wide spectrum of the economy, including energy, manufacturing, consumer goods, agriculture, transportation, and technology. This is one of OSHA's farthest-reaching rulemakings ever and the first one to cover something as common as beach sand, gravel, rocks, and the thousands of processes that disturb them or use them for products and materials (*e.g.*, cement, glass, computers, cell phones, paints and coatings, hand tools, factory molds, brick, tile, roofing, farms, roads, buildings, rail roads, oil and gas production, and manufacturing of cars, ships, and airplanes).

Crucially, occupational disease mortality related to silica has declined dramatically in the United States over the last 45 years. The most recent and reliable U.S. government data, from the U.S. Centers for Disease Control and Prevention ("CDC"), documents that there were 123 deaths from silica-related disease in the U.S. in 2007, a 93% reduction in mortality since the 1960s. Even this low number of silica related deaths must, can, and will be prevented in the future. However, there is no need for, or benefit from, this OSHA rulemaking. As Federal District Court Judge Janice Graham Jack concluded when she sanctioned plaintiffs' lawyers responsible for some of the 20,000 false silica health-related lawsuits filed in Mississippi from 2002 to 2004, "this appears to be a phantom epidemic…" Litigation Order No. 29, *In Re: Silica Product Liability § MDL*, Docket No. 1553 (S.D. Tex. Jun. 30, 2005).

If there is any need to improve upon current protective practices, OSHA has two immediate, effective means, which are ignored in the proposed regulation: (1) providing compliance assistance for current exposure limits, for which OSHA documents a roughly 30% non-compliance rate; and, (2) supporting new technology and policies favoring effective, comfortable, respirators and clean filtered air helmets, which provide full protection but are not favored by OSHA's outdated "hierarchy of control" policy. Unfortunately, the Agency prejudged this issue by announcing in the Federal Register that it would not consider changing that policy, no matter how effective, efficient and economical the protective devices.[1]

The Chamber urges OSHA to reconsider impacting critical U.S. economic sectors, which OSHA estimates to employ about two million people, with new costs in the billions of dollars.[2] The businesses that create these jobs are still struggling to recover

[1] 78 FR 56278: " OSHA would like to draw attention to one possible modification to the proposed rule, involving methods of compliance, that the Agency would not consider to be a legitimate regulatory alternative: To permit the use of respiratory protection as an alternative to engineering and work practice controls as a primary means to achieve the PEL."

[2] See Dr. Ron Bird's economic analysis at Appendix 1.

from the recession. They will find it difficult to withstand a massive new regulation that increases U.S. costs with mandates not applicable to foreign competitors, particularly when the regulations are not needed, do not provide benefits, and are not feasible, as our comments, supported by scientific, engineering, economic and medical experts will demonstrate.

I. OSHA SHOULD EXTEND THE COMMENT PERIOD, EXPAND HEARINGS, AND INITIATE A NEW SBREFA PROCESS

Given the importance and complexity of this rulemaking, which has been under development at OSHA for more than a decade and underwent Office of Information and Regulatory Affairs ("OIRA") review for more than two years, the Chamber has urged OSHA to extend the comment period. We urge that OSHA postpone the planned public hearings and also schedule them around the nation to permit participation throughout the United States. We also request that OSHA initiate a new SBREFA review to consider current economic conditions and the particular impacts on and circumstances of the hydraulic fracturing ("fracking") industry, which were not considered during the 2003 SBREFA review.

The vast majority of U.S. industry and those companies affected by this proposal do not reside in Washington, D.C. and the Department of Labor has an obligation to provide meaningful opportunities for regulated parties to participate in rulemaking proceedings, particularly one as far reaching as this silica proposed rule. Moreover, we suggest that Congress did not intend for a more than ten year-old SBREFA review that left out key industries and data, to satisfy its concern for providing small business with meaningful input.

In the more than a decade since the SBREA panel met, the recession changed the world and our economy. At the same time, the energy industry changed dramatically and is now predicted to make the U.S. energy independent and the world's largest energy producer. Hydraulic fracturing evolved in that decade and is estimated by OSHA to be one of the most impacted industry segments of the economy under the new proposed rule on silica.

Millions of tons of sand (silica) are used by the fracking industry yearly, and the proposed rule's impact on employers will be massive. In the last five years, our oil and gas producers, hydraulic fracturing companies, and their suppliers and contractors vastly increased recoverable reserves, and produced new inexpensive domestic energy. The lower costs for energy produced by the energy industry have become critical to helping the struggling manufacturing industry compete with a world offering a lower wage structure while concurrently reducing the U.S. trade imbalance. Similarly, the abundance of hydrocarbon feedstocks has revitalized industries using them in their manufacturing processes.

As set forth by the experts, OSHA's last-minute analysis of this critical industry and the impact of its proposed rule are woefully inadequate. These failures demonstrate a

complete lack of understanding of the industry that must be cured through expanded public input and a new SBREFA review process.

OSHA identified the construction industry as the other segment of the economy most impacted by the proposed rule. The nation is relying on construction to help lead us out of the recession, but the industry continues to struggle and is far from returning to its pre-recession job levels. Regional hearings and an expanded comment period are necessary to ensure an adequate opportunity for the construction community and others to provide the detailed, meaningful input this rulemaking demands.[3]

The OSHA preamble to the proposed silica rule acknowledges its significant impact on small businesses while ignoring the vocal opposition to the rule expressed through the small business review process that occurred more than a decade ago, under far more favorable economic conditions. The 2003 Small Business Regulatory Enforcement Fairness Act ("SBREFA") panel even recommended that OSHA pursue non-regulatory options to reducing exposure to silica and associated disease and mortality rates. [4]

Before moving to impose the billions in costs of the proposed rule on the nation, OSHA must prove the proposal is justified and needed. We believe these comments make a compelling case that the proposal is neither, and the only responsible action is for OSHA to abandon this rulemaking in favor of a more logical, data driven approach to OSHA's goals. These comments will demonstrate that OSHA has not met its threshold burdens for regulation of showing significant risk, feasibility (both technical and economic) and significant benefits from its proposed rule. In fact, OSHA has attempted to treat a compliance issue with an unjustified massive regulatory program.

II. ANALYSIS OF EXPERTS SUPPORT WITHDRAWING THE RULE

To analyze the proposed rule and OSHA's supporting materials the Chamber engaged a panel of some of the nation's most distinguished scientists, physicians, engineers, and experts on occupational health, led by Dr. Jonathan Borak of the Yale Medical School, as well as leading experts on regulatory economic and statistical analysis, led by Dr. Ron Bird.[5]

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[3] The Chamber supports the comments of the Construction Industry Safety Coalition.

[4] SBREFA Report (2003) at 77, stated: "The Panel recommends that OSHA (1) carefully consider and solicit comment on the alternative of improved outreach and support for the existing standard; (2) examine what has and has not been accomplished by existing outreach and enforcement efforts; and (3) examine and fully discuss the need for a new standard and if such a standard can accomplish more than improved outreach and enforcement." OSHA did not properly address the SBREFA Report conclusion and supporting information, choosing instead to propose the provisions rejected by the SBREFA Panel.

[5] Dr. Ron Bird (Appendix 1); Dr. Jonathan Borak (Appendix 2); Dr. Peter Valberg and Dr. Christopher Long (Appendix 3); Dr. Thomas Hall (Appendix 4A, Appendix 4B); Dr. Gerhard Knutson (Appendix 5); Dr. Faten Sabry (Appendix 6); Dr. Patrick Hessel (Appendix 7A, Appendix 7B); Robert Lieckfield, CIH (Appendix 8); Greg Sirianni, MS, CIH (Appendix 9); and Dr. William Bunn (Appendix 10).

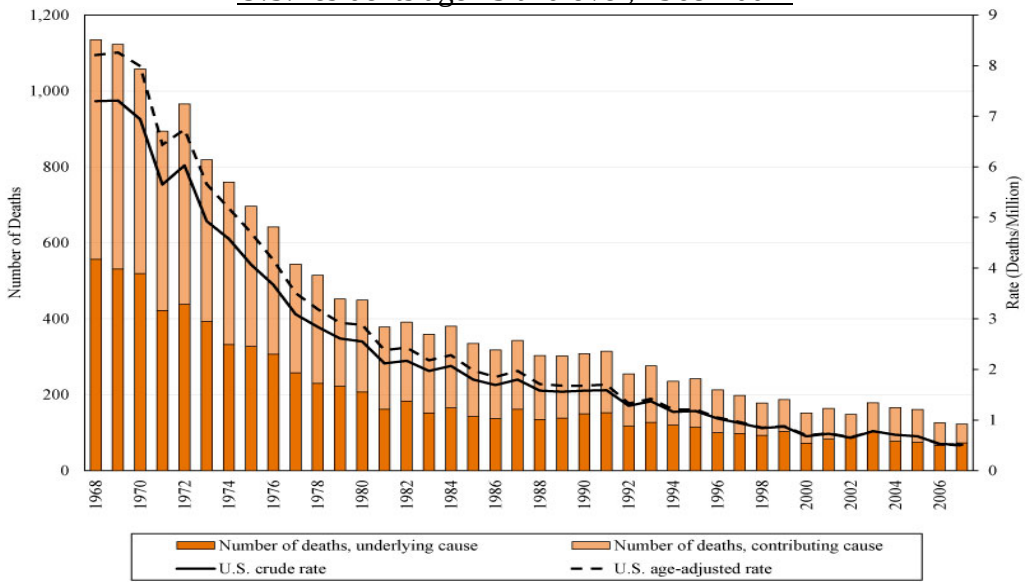
The curriculum vitae of each expert is appended to their comments, which are set forth as appendixes to these comments. The comments of the experts also were submitted independently by them, to OSHA, for inclusion in the rulemaking record. Their analysis and comments, along with the input of our members and our affiliated associations, leads us to the conclusion that OSHA should withdraw the proposed rule for a number of important reasons, including those set forth below.

III. OSHA FAILED TO UTILIZE OR RELY ON TRUSTWORTHY CURRENT DATA

(a) Steeply Declining Trend of CDC Silicosis Mortality Data

The rule seeks to portray conditions and define risks, using data more than a decade old and calling it "current," while ignoring the critical nature of actual current data that OSHA has at its fingertips.

Silicosis: Number of deaths, crude and age-adjusted death rates, U.S. residents age 15 and over, 1968-2007[6]



Among the more than 2.1 million employees exposed to silica,[7] CDC reports 123 cases of silica related mortality in 2007 (this equals 0.00585 % of the exposed

[6] Source: Mortality multiple cause-of-death data from National Center for Health Statistics, National Vital Statistics System. Date Posted: March 2012.

[7] "OSHA estimates that a total of 2.1 million employees in 550,000 establishments and 533,000 firms (entities) are potentially at risk from exposure to respirable crystalline silica. This total includes 1.8 million employees in 477,000 establishments and 486,000 firms in the construction industry and 295,000 employees in 56,000 establishments and 47,000 firms in general industry and maritime." OSHA Preliminary Economic Analysis, Section VIII. 78 FR 56274, 56337

population), down from nearly 1,200 cases in 1968. As OSHA admits, this declining trend of silica-related mortality represents a 93% decline in cases since 1968.[8]

OSHA's simplified conclusion in this rulemaking - that the current silica regulation is not protective and that the nation needs new regulations - is based on speculative statistical analysis and modeling, contrasted with actual data available from CDC. Even if OSHA's criticism that the CDC Data may suffer from under-reporting in any given year is legitimate, there is no contradicting the reality of the clear and welcome steep trend towards eliminating silica-related mortality.

OSHA's scientific justification for the new PEL and Action Level (AL) are wholly inadequate to support the new proposed rule. There are significant flaws in OSHA's analysis of the data and OSHA has failed to take into considerations fundamental issues like whether workers were exposed before the implementation of the current PEL in deciding whether the current PEL is adequately protective. The following points make clear OSHA has not provided sufficient scientific support for the proposed new PEL and AL:[9]

- There is substantial evidence that the exposure-response relationship between silica and silicosis is a threshold function. Evidence also indicates a likely threshold response function for silica-related lung cancer. OSHA fails to adequately consider the weight of evidence for a response threshold and also fails to consider the threshold-obscuring effects of exposure measurement errors.

- OSHA fails to adequately consider the magnitude and implications of sampling and analytical method errors. Those errors are of such magnitude that the analytical methods described in the NPRM are unlikely to meet OSHA's method performance requirement.

- The OSHA risk assessments are limited by exposure misclassification and errors, and OSHA has failed to consider numerous sources of such error and uncertainty. As a result, OSHA does not provide adequate scientific justification for its risk assessment conclusions.

- "Baseline" conditions described by OSHA indicate widespread

[8] "Unlike most occupational diseases, surveillance statistics are available that provide information on the prevalence of silicosis mortality and morbidity in the U.S. The most comprehensive and current source of surveillance data in the U.S. related to occupational lung diseases, including silicosis, is the National Institute for Occupational Safety and Health (NIOSH) Work-Related Lung Disease (WoRLD) Surveillance System; the WoRLD Surveillance Report is compiled from the most recent data from the WoRLD System (NIOSH, 2008c). . . . [hereafter "CDC Data"] For each of these sources, data are compiled from death certificates reported to state vital statistics offices, which are collected by the National Center for Health Statistics (NCHS). . . ." 78 FR 56274, 56298.

[9] Comments of Dr. Jonathan Borak, Appendix 2.

noncompliance and overexposure, within a generally declining trend of national exposures, but do not include the most recent inspection data. Silica exposures prior to 1990 were often substantially greater than corresponding "baseline" exposures. Because the latency of chronic silicosis is generally longer than the "10 to 30 years" cited in the NPRM, most of the silicosis cases and deaths noted by CDC and SENSOR were exposed historically to levels generally much higher than current OSHA PEL.

- The industries most often associated with silica-related morbidity and mortality have been distinguished by widespread exposure to respirable crystalline silica at levels greater than 100 $\mu g/m^3$. Reports of silicosis and related diseases in those industries provide no basis for OSHA to conclude that the current PEL is not protective.

- Most of the silicosis-related deaths cited in CDC reports and silicosis cases reported by SENSOR were first exposed prior to the adoption of exposure controls and work practices necessary to comply with the current OSHA PEL. Those reports provide little or no basis for OSHA to conclude that the current PEL is not protective.

- The OSHA performance-based definition of "respirable crystalline silica" would yield variable results depending on the sampler used, and may under-protect some workers while some employers may be wrongly judged non-compliant. OSHA should adopt a definition based on particle size, not sampler design and performance.

Unfortunately, while OSHA criticizes the completeness of the CDC Data (using two flawed studies that experts find not credible[10]), the Agency did not rely on the best

[10] From the comments of Dr. Patrick Hessel, Appendix 7A, describing an OSHA cited study by Rosenman et al (1997): "presented a summary of the data from the same Michigan surveillance program for the period 1987 through 1995. There were 577 individuals in the system at that time. The authors presented data on the time exposure began for 568 of these cases (year of initial exposure was unknown for nine cases).

It is clear that the vast majority (more than 95 percent) of the cases were exposed to silica before the introduction of the present OSHA PEL and 85 percent were exposed in the 1950s and earlier. Again, this raises questions about the relevance of the data presented by Rosenman et al (2003) to the present discussion of the adequacy of the existing standard which was initiated in 1970."

Appendix 7B describes the second study (Goodwin et al, 2003) relied upon by OSHA to criticize the CDC data: "The authors stated that their objective was "to estimate the extent of previously undetected silicosis." It is not clear what this means. The authors identified a relatively small subgroup of all death certificates, based on cause of death and usual industry. As noted above, most of these deaths were related to smoking. Three-quarters of the target group were then excluded; some were excluded on the basis of their usual industry. There can be no claim that the remaining group of 177 people who died from (largely) smoking-related causes is representative of the general population or the population occupationally exposed to silica. If the authors wanted to "estimate the extent of previously undetected silicosis" (emphasis added), then it was necessary for them to study a group that was representative of some target population so they could give some quantitative estimate of the extent of undetected silicosis. The group studied by Goodwin

available evidence or analyze the 123 cases reported by CDC for 2007 to determine their industry relationship, the length and initiation of exposure, the age at death, the extent of exposure, the latency and severity of the disease, or the impact of any confounding factors, such as smoking. OSHA also failed to analyze the relationship of the historical exposure levels that led to the 2007 cases to actual, *current* exposures. This is a particularly capricious approach to a public data set from a trustworthy source of such relevance to this rulemaking, involving a disease risk acknowledged to have a long exposure time frame (latency period), as described by experts[11] and OSHA itself.

(b) OSHA Failed to Publish, Analyze, and Rely on Its Own Critical Exposure Data

Equaling the severity of OSHA's failure to conduct a meaningful analysis of the CDC-established silica mortality rate, incidents, trends and accomplishments, OSHA similarly failed to analyze its own latest silica sampling results (from its inspectors and regulated parties), which number in the thousands and were collected from a broad spectrum of the economy resulting from OSHA's silica emphasis programs.

Instead of publishing and evaluating *actual*, *current* conditions from data within its sole control, OSHA defines 2002[12] and older sampling results as "current" and uses them to define risk in this rulemaking. Since only OSHA has access to its sample data, it prevented impacted parties from analyzing and commenting on the meaning of this important, withheld data, as well.

What is known from the available exposure data and from the published literature is that silica exposure levels generally have fallen, significantly over time, at least partially explaining and correlating with the CDC recorded trend towards elimination of silica-related mortality.

> IARC reports on an analysis of 7,209 personal sample measurements collected during 2,512 OSHA inspections during 1988–2003, which suggest that geometric mean crystalline silica exposure levels declined in some high-risk construction industries during the period under study, and revealed a significant decline when compared with silica exposure levels found in a previous study by Stewart & Rice (1990). Geometric mean airborne silica exposure levels among workers in various construction industries were *significantly lower* in 1988–2003 than in 1979–1987. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, "Silica Dust, Crystalline, in the Form of Quartz or Cristobalite" Vol. 100C, *available in*

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et al (2003) is not representative of any group outside itself. Given the lack of representativeness, and considering the points raised above, especially those related to false-positive [x-ray] readings, it is not possible to look at these results and estimate the number or percent of unrecognized silicosis cases in any identifiable group.

[11] Comments of Dr. Jonathan Borak, Appendix 2.

[12] "ERG contractor reports primarily relied on information sources published from 1990 through 2001, updated with some information through 2007." (PEA IV-3) (emphasis added)

http://monographs.iarc.fr/ENG/Monographs/vol100C/mono100C-14.pdf. (emphasis added)[13]

However, OSHA historical data also demonstrates some significant exposures,[14] far above the current PEL, even though the exposures occurred during forty years of steeply declining silica-related mortality and exposures. Experts draw the rational conclusion that such historical high exposures produced the remaining (but declining) silica-related mortality exemplified by the CDC data; OSHA incorrectly concludes that resulting silica-related cases are the result of a PEL that is too high.

This OSHA conclusion is inconsistent with the data, particularly since the more than a decade-old OSHA exposure data, described in the preamble and the ERG report, demonstrates that about 30% of OSHA silica samples were above current OSHA exposure limits yet the trend of disease continued to decline. OSHA is thus attempting to convert a compliance issue to a PEL/regulatory problem.

IV. OSHA MADE IMPROPER AND FALSE RISK/BENEFIT ASSUMPTIONS AND ESTIMATES

Further undermining the validity of this rulemaking are the OSHA application of 1960s concepts to a 2014 rulemaking, and the lack of consideration of the latest and most reliable scientific evidence. A few examples demonstrate the need for OSHA to abandon its inapplicable, erroneous approach.

(a) False Exposure Estimates and OSHA Policy Create False Risks and Benefits

OSHA defines the risks of exposure using a "45-year" working lifetime of exposure. 78 FR 56274, 56311. No such 45-year career silica exposures exist in today's working world, particularly in construction, energy production, and other short term work-site industries, where work crews are active for limited times, change locations often, and expect careers in these jobs closer to 6 years rather than the 45 years assumed by OSHA "policy."[15]

OSHA has not undertaken any analysis of these actual working life time exposures in the impacted industries. Instead, under Section 6(b)(5)of its statute, OSHA improperly inflates risk estimates with its false 45-year policy, contradicting the Act,

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[13] *See* Susan E. Dudley and Andrew P. Morris, The George Washington University Regulatory Studies Center, The Occupational Safety and Health Administration's Proposed Standards for Occupational Exposure to Respirable Crystalline Silica, Docket No. OSHA-2010-0034 RIN: 1218-AB70, December 4, 2013.

[14] Comments of Dr. Jonathan Borak, Appendix 2.

[15] OSHA's contractor, ERG, estimates a 27.2 % annual turnover rate for general industry and maritime, and a 64% rate for construction, but OSHA does not analyze the potential massive impact of these rates on its risk assessment. 78 FR 56274, 56364. See also Comments of Dr. Ron Bird, Appendix 1.

which requires standards based on actual, "working life" exposures –not dated hypotheticals.

The OSHA preamble also demonstrates the agency's reflexive and strident commitment to its "hierarchy of controls" policy, regardless of nearly a half-century of technological advances, economic changes, and massive workplace changes since the idea was adopted by the industrial hygiene community decades ago. The hierarchy policy requires the use of all feasible engineering controls before personal protective equipment ("PPE") can be used to achieve compliance and protection, and it prohibits rotation of personnel to reduce exposures below the PEL. 78 FR 56274, 56278.

The hierarchy results in false OSHA risk estimates that provide no protection credit for large numbers of protected employees who are actually protected. Through its hierarchy policy, OSHA vastly inflates risk and benefit estimates, as OSHA's data demonstrates.[16] OSHA data also inflate hydraulic fracturing exposures, using a small number of samples and inaccurate unconventional, high bias, air sampling equipment, again inflating OSHA risk and benefits.[17]

At regulated sites, the antiquated OSHA hierarchy policy mandates experimenting with the most expensive, unproven engineering controls and workplace modifications before trying the most effective and economical protections, such as new technology PPE. The OSHA preamble goes to great lengths to reinforce OSHA's strident bias towards this policy, pre-judging its refusal to consider changes.[18]

Forcing expensive engineering control trials and experiments repeatedly throughout the nation, one industry after another, one company after another, using often ineffective retrofits to seek to meet new OSHA limits, misuses vast resources that can be applied to beneficial health and safety efforts, contributes to job losses to foreign competition, and still requires the use of personal protective equipment after massive and costly engineering experiments have failed to reduce exposure levels adequately. An example of this is the foundry industry as it continues to struggle to meet the current PEL in an industry heavily impacted by foreign competition and this rulemaking.[19]

The proposed silica rule both prohibits effective respirator use as a primary control and discourages the use of new technology, such as clean filtered air helmets, that

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[16] For example, OSHA's contractor, ERG estimates 98% use of respiratory protection by the hydraulic fracturing industry. OSHA ERG Report at 44. Comments by Dr. Faten Sabry, Appendix 6.

[17] See comments of Dr. Thomas Hall, Appendix 4; Dr. Faten Sabry, Appendix 6.

[18] OSHA also prohibits rotation of employees to reduce individual employee exposures: Paragraph (f)(5) of the construction proposed rule, and Paragraph (f)(4) of the general industry/maritime proposed rule specify that the employer must not rotate workers to different jobs to achieve compliance with the PEL. OSHA proposes this prohibition because silica is a carcinogen, and the Agency assumes that any level of exposure to a carcinogen places a worker at risk. 78 FR 56466.

This conclusion ignores the overwhelming evidence that there is a significant threshold of exposure needed to cause silica related disease, as described by Drs. Valberg and Long in their comments at Appendix 3.

[19] "OSHA's examples demonstrate that compliance is not feasible." Request to Appear at Public Hearing by American Foundry Society, December 11, 2013 OSHA ID: 2010-0034

do not cause breathing resistance or respirator face seal discomfort, and do not require fit testing or medical exam clearance for effective use and protection. OSHA should incentivize their further use and continuous improvement by recognizing that they are not traditional respirators, but effective, wearable, micro-engineering controls that protect employees. The provisions of the proposed rule, and OSHA policy generally, that apply the antiquated hierarchy of controls to air helmets and improved respirators are not justified and should be reversed.

(b) OSHA Ignores the Basis, Purpose and Protective Nature of Its PEL

Newly published and highly reliable studies confirm the opinion of one of the authors of the 1968 ACGIH silica TLV (which is the same as today's OSHA PEL, 100 $\mu g/m^3$).[20] Dr. Howard E. Ayer, of the University of Cincinnati, published an article describing the origin of the TLV, which he helped develop. He concluded that due to the method used to develop the limit, it was twice as protective as intended and should have been the equivalent of 200 $\mu g/m^3$.[21]

In proposing the new silica standard, OSHA did not analyze the origin of its current PEL to determine and understand its basis, so that it could properly determine its effectiveness, before abandoning one of the most successful standards in U.S. history.

(c) OSHA Ignores Higher Exposure Levels Needed to Create Silica Risk

The latest and best scientific evidence demonstrates that the exposure level necessary to cause silica-related disease is likely more than twice the current PEL of 100 $\mu g/m^3$.[22] This higher level explains why there are so few reported cases of silica mortality, even with 30% of the OSHA sampling results exceeding the 100 $\mu g/m^3$ PEL. It also suggests why there are no environmental, ambient air silica risks. The evidence for this higher threshold directly contradicts the proposed OSHA PEL and Action Level. Moreover, the higher threshold also protects against the lung cancer risk OSHA alleges as support for its risk assessment and hierarchy of controls, as explained by expert comments submitted herewith, including the lack of a medical mechanistic process to cause lung cancer in the absence of silicosis, which is prevented by keeping exposures below the threshold.

(d) OSHA Failed To Properly Analyze Exposure Variability and Threshold Impact in Its Risk Assessment

In assessing silica risk using epidemiological studies OSHA did not take into account the extensive variability of the underlying exposure assessments and exposure group assignments. The resulting high bias in the OSHA risk assessment renders it incapable of justifying the OSHA proposed exposure limit. In addition, the OSHA risk

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[20] Comments of Drs. Valberg and Long Appendix 3 and Dr. Jonathan Borak, Appendix 2.

[21] Ayer, H.E.: Origin of the U.S. Respirable Mass Silica Standard. Appl. Occup. Environ. Hyg. 10 (12): 1027-1930; 1995.

[22] Comments of Drs. Valberg and Long, Appendix 3.

analysis failed to account for the threshold exposures necessary to cause silica related disease.

The review and analysis of OSHA's risk assessment by Dr. Christopher Long and Dr. Peter Valberg highlight some of its critical flaws: [23]

- The OSHA proposed crystalline silica rule relies on a risk assessment that is inherently limited by its dependence on epidemiologic findings derived from uncertain exposure assessments:

- OSHA believes that uncertainty in the exposure assessments that underlie each of the 10 studies included in the pooled analysis is likely to represent one of the most important sources of uncertainty in the risk estimates. (OSHA, 2010, p. 292)

- OSHA's assessment of exposure measurement error is limited by its failure to consider the potential for a number of likely sources of exposure measurement error to obscure and bias estimates of threshold concentrations:

  > [E]xposure-response threshold estimates are imprecise and appear to be highly sensitive to measurement errors. (ToxaChemica, 2004)

- OSHA's analyses of the occupational data as to respirable crystalline silica exposure fail to adequately consider the weight of evidence for a response threshold, which our review suggests is supported by results from animal toxicology studies, mechanistic analysis, and epidemiologic studies.

- Because of its failure to consider the potential for a number of sources of exposure measurement error to contribute bias to epidemiologic risk estimates and estimates of threshold concentrations, OSHA does not provide adequate scientific justification for the conclusions of its risk assessments.

(e) OSHA's Proposed Definition of the Regulated Substance Is Wrong

Importantly, by not analyzing and understanding the basis of its current PEL, OSHA also failed to define properly the regulated substance, "respirable crystalline silica" (RSC), consistent with the underlying scientific studies. While OSHA understands that the risk of silica-related disease is limited to, and dependent upon, very small particle

[23] *Id.*

sizes of a specific substance, identifiable by lab analysis, it fails to so define the regulated substance in its definition and procedures, nor does it adequately account for the measurement and exposure assessment uncertainties inherent in its risk and feasibility assessments.[24]

Instead, OSHA seems to favor vagueness by defining the regulated substance as particles, *determined* to be collected by an expanded list of samplers, "*containing* silica."[25] This definition encourages and condones inaccurate measurements, and permits the regulation of, and enforcement against, non-respirable particles that contain materials that are not silica. In addition, excessive particles of a size that are not respirable interfere with actual silica identification, do not pose silica risks, and can render the measurement of samples infeasible. The OSHA proposal is better understood as regulating dust that may contain RSC, rather than specifically regulating RSC. In addition, by adopting the ISO sampler specifications, OSHA essentially reduces the PEL by another 20% by the use of samplers that produce higher RSC results.[26] The OSHA proposed definition is inconsistent with accepted science and must be rejected as unrelated to the proposed regulated substance.

(f) OSHA's Review of the Term "Respirable" and Sampling Methodologies Leaves Many Questions Unanswered

Dr. Thomas Hall analyzed OSHA's review in the Preliminary Economic Analysis of the available scientific literature regarding the definition of "respirable" (American Conference of Governmental Industrial Hygienist (ACGIH)/International Organization for Standardization (ISO)/European Committee for Standardization (CEN)) and the aerosol sampling equipment—five commercially available cyclone separation devices.[27] Based on its review, OSHA concluded that cyclone size pre-separators operate with an acceptable level of bias at their prescribed flow rates. However, the Agency failed to define what it means when it refers to an "acceptable level of bias." The "comprehensive" review of cyclone technology in the PEA paints a somewhat rosy picture for sampling with cyclones as meeting the requirements necessary for compliance with the newly proposed quartz PEL and AL. Moreover, there are questions regarding their impact on sampling method variability that have not been addressed. These issues include:

- Does the adoption of a new particle penetration convention, ACGIH/ISO/CEN, with a differing D_{50}[28], from the previously

[24] Comments of Dr. Jonathan Borak, Appendix 2, Dr. Peter Valberg and Dr. Christopher Long, Appendix 3.

[25] 78 FR at 56445: "Under the proposed definition of respirable crystalline silica in paragraph (b), respirable crystalline silica means airborne particles that contain quartz, cristobalite, and tridymite and whose measurement is determined by a sampling device designed to meet the characteristics for particle-size-selective samplers specified in International Organization for Standardization (ISO)."

[26] Comments of Dr. Tom Hall, Appendix 4.

[27] Comments from Dr. Jonathan Borak, Appendix 2; Dr. Tom Hall, Appendix 4; Robert Lieckfield, CIH, Appendix 8.

[28] DM_{50} - 50% collection cut off

accepted convention, 4.0 vs. 3.5 µm, result in different collected respirable quartz dust masses?

The adoption of the ACGIH/ISO/CEN particle penetration convention results in an approximately 30% increase in the dust, e.g. quartz, mass collected. The adoption of the new ACGIH/ISO/CEN convention for particle sampling can result in citations for over exposure to quartz dust where none would have been issued prior to the adoption of this convention.

- Does the use of a cyclone pre-separator add additional error to the estimation of the recognized sampling and analytical error for quartz?

  As reviewed above, there is substantial evidence that the use of cyclone pre-separators is associated with potential sampling errors and that these errors are compounded by the variability of sampling pumps. NIOSH does not include an estimate of the potential error in their analysis of the sampling and analytical error for Method 7500 and OSHA has ignored this error in its feasibility assessment. The only error OSHA does account for includes that imparted by variation in sampling pump flow and X-Ray analysis.

- Does the use of a cyclone pre-separator add any bias to the OSHA or NIOSH methods for determining quartz exposure?

  As discussed earlier, dependent on the D_{50} and GSD[29] of the aerosol sampled and the specific cyclone used, e.g. GK2.69, bias can have a significant effect on the variability observed for the collection and analysis of quartz using NIOSH 7500. For aerosol clouds with a DM_{50} greater than 10 µm, the expected absolute bias can range be between 20 and 60%. Given an overall expected error = 26% for the quartz analytical method reported by NIOSH, the total variability for the method SAE[30] can be as large as 85-90%. This would mean that regulatory samples that are at or slightly above the AL of 25µg/m^3 could be interpreted as exceeding the PEL, i.e., wrongly seen non-compliant.

- In the proposed rule, OSHA does not specifically recommend any one of the commercially cyclones: Dorr-Oliver 10 mm (nylon or metal), the BGI GK2.69, aluminum SKC, multi-inlet sampler, or the Higgins-Dewell cyclone. Does this mean they produce identical results?

[29] Geometric Standard Deviation (GSD)

[30] Sampling and Analytical Error (SAE)

> The published literature makes clear that sampling results differ depending on the choice of sampler used. The commercially available cyclone pre-separators have been evaluated under a variety of test conditions, and those tests make apparent that they have different collection efficiencies, specifically with respect to particle collection in aerosol clouds with large DM_{50}'s, > 10µm. The GK2.69 has been clearly demonstrated to over sample large particulate resulting in biased aerosol mass determination. Gorner specifically addressed this issue –"the values of D_{50} can vary considerably from one sampler to another. This does not mean that some of them are not well designed. They were designed at different periods when the sampling conventions were also different. Their flow rates were optimized to bring their D_{50} values closer to the existing ACGIH/ISO/CEN respirable aerosol sampling convention." This does not indicate that the proposed pre-separators provide consistently similar results.[31]

Clearly, the changes proposed by OSHA have not been adequately analyzed for their impact on risk determinations, compliance determinations, and accuracy and precision of sampling results.

V. THE PROPOSED RULE IS NOT TECHNOLOGICALLY FEASIBLE

(a) The Silica Measurement System Is Not "Accurate" and Not Feasible

OSHA and NIOSH created a definition for the term "accurate" as it applies to sampling and lab analysis: plus or minus 25% of the true value, 95% of the time. While that definition alone demonstrates the arbitrary and capricious nature of the proposed rule and its lack of a reasonable basis, OSHA's inability to meet even its own, "flexible" definition is shocking and demonstrated by "round robin" AIHA testing reported in the PEA at IV-41: "the … range of 55 to 165 percent (of the reference value). A total of 71 samples (81 percent) were in the range of ±25 percent of the reference mean."

The entire proposed rule rests on the presumption that employers can conduct sampling and monitoring and know with certainty whether their exposure levels trigger the various requirements of the rule. Robert Lieckfield, CIH reviewed OSHA's testing tolerances and concludes that the proposed rule is not technologically feasible due to the high variability of testing results that will mean employers will not be able to tell with certainty whether they are in compliance or need to take further measures: [32]

- OSHA has not demonstrated the feasibility of its sampling and analysis procedures to produce "accurate" (as defined by OSHA)

[31] Comments of Dr. Thomas Hall Appendix 4 (footnotes omitted).

[32] Comments of Robert Lieckfield, CIH, Appendix 8

results for respirable crystalline silica at the proposed exposure limit of 50 µg/m^3 or at the proposed action level of 25 µg/m^3. The existing documentation, using either internal laboratory quality control samples or external proficiency testing samples, show the need for further method evaluation at these lower mass loadings. The OSHA XRD method has an overall accuracy of ±26% at levels greater than 50 µg silica, failing to meet the ±25% criteria. The limited amount of data reported at levels between 20 µg and 40 µg, using laboratory prepared samples, also showed that the current method would not meet the accuracy criteria at 20 µg.

- Lowering the PEL and Action Level before validating that the current analytical methods can reliably measure silica at those lower concentrations, with the required degree of accuracy and precision, could potentially result in underestimating or overestimating individual exposure levels. The result would be to call into question the validity of exposure data impacting industry compliance with the standard, as well as the OSHA enforcement process.

- The current analytical methods used for evaluating occupational exposures to crystalline silica — XRD and IR — are well established in the industrial hygiene laboratory community. There is no doubt that these methods are capable of measuring quartz and cristobalite from air samples collected on 37-mm filters. The proposed change in the OSHA PEL for crystalline silica requires measurement of crystalline silica mass below levels that are supported by current published data in terms of acceptable accuracy and precision criteria required by OSHA of ±25%. Although the methods can generally achieve the required LOD[33] and LOQ,[34] the more relevant discussion is the accuracy and precision at the lower silica concentrations required with the proposed PEL. The key question is whether these methods meet the OSHA method performance requirement of ±25% (95% Confidence Level) at silica concentrations between 10 µg and 50 µg, since these silica concentrations would be required under the proposed PEL of 50 µg/m^3 and Action Level of 25 µg/m^3.

- Since the proposed PEL encompasses all three polymorphs — quartz, cristobalite, and tridymite — an X-ray diffraction analytical method would be required to produce exposure assessment data. The infrared method could be substituted only in instances where the potential exposure is well characterized and where only one

[33] LOD - Limit of Detection

[34] LOQ – Limit of Quantitation

polymorph is known to be present. The IR method would not be applicable to mixed polymorph exposures since specific quantitation of individual polymorphs cannot be accomplished. Therefore, the focus of this document is the X-ray Diffraction (XRD) analytical method. In addition, the XRD method is the only published methodology used by the OSHA Salt Lake Technical Center.

- Further evaluation of the methodology must be conducted to define method performance at the concentration levels required to meet the proposed OSHA PEL. In the NIOSH Manual of Analytical Methods, Chapter R, it was noted that, "Current analysis methods do not have sufficient accuracy to monitor below current exposure standards." Further supporting this position, Mr. Peter Stacey, UK Health and Safety Laboratory, published an article in the JOEH, January 2007 (an elaboration of an article published by the United Kingdom Health and Safety Commission, Advisory Committee on Toxic Substances (ACTS) in November 2006) regarding the ability of the XRD method to measure crystalline silica masses at levels required by the proposed standard. Mr. Stacey examined method performance data at silica concentrations needed for the proposed PEL, and concluded that the proposed PEL of 50 $\mu g/m^3$ and Action Level of 25 $\mu g/m^3$ represent levels that are at the limit of what can be reliably measured using existing methods and techniques, before taking into account interferences and variability of the sampling environment. Mr. Stacey's data showed that at mass levels corresponding to the proposed PEL, the RSD_{95} was between 23 and 36%, and at the Action Level of 25 $\mu g/m^3$ a RSD_{95} of 39%. These data are consistent with method performance statistics in AIHA PAT data using matrix based performance samples.[35]

- As cited in the Preliminary Economic Analysis feasibility study, OSHA's own performance on industry-accepted proficiency samples – AIHA PAT – demonstrates that the OSHA SLTC could report underestimated exposure data as low as 45% below the actual value, to as much as a 65% overestimate. The RSD_{95} shows that any individual data point could vary by ±38% — well in excess of OSHA's own method performance criteria. The PAT data summary for the OSHA SLTC specific performance, showed that only 81% of their results were within ±25% of the reference mean, which further corroborates that the XRD method, as implemented by OSHA, would have a potential error rate greater than OSHA method performance requirements.

[35] *Id.*

- Additional studies are needed to validate the XRD method for measuring silica concentrations at lower levels than currently supported by established analytical methods. The results of these studies should be subject to the peer-review process and formally presented or published, enabling the laboratory industry to benchmark their performance using the XRD method. The proposed studies/clarifications include:
    - Measurement of method accuracy and precision at mass loadings between 10 and 50 micrograms quartz and cristobalite, using a real-world matrix and a select group of laboratory participants.
    - Define the mass concentration, and the precision and accuracy at those concentrations, where secondary diffraction angles are valid for qualitative confirmation.
    - Verification of the LOD and LOQ across a select group of laboratory participants.
    - Determine whether the variance seen in PAT samples is related to methods or participants.
    - Define the methodology required to establish LOD/LOQ for crystalline silica.
    - Provide direction (OSHA) on how exposures are calculated when more than one polymorph (quartz, cristobalite, and tridymite) is present in the same sample and in particular, the mathematical treatment of non-detected polymorphs. According to the proposed standard, when more than one is present in a collected sample, the concentrations of each polymorph detected are added together to evaluate the exposure against the proposed PEL. The laboratory industry convention, as required by AIHA accreditation policy, is to report a non-detectable quantity as a "less than" value.[36]

OSHA failed to satisfy the feasibility requirement of Section 6(b)(5) for its proposed PEL and Action Level. OSHA admits that a PEL of 25µg/m^3 would not be feasible from a control perspective, but it is also is not feasible because measurement errors are unacceptably high at 25µg/m^3. 78 FR 56274, 56354. Notwithstanding these reservations, OSHA still mandates air monitoring based on this value that cannot be measured accurately. Moreover, contrary to OSHA's feasibility conclusion, the same is true at 50µg/m^3: accurate measurement is impossible,[37] and the various programmatic mandates triggered by the PEL and Action Level, are thus not feasible as well.

[36] *Id.*

[37] *Id.*

OSHA's high sampling and analysis inaccuracy eviscerate the proposed self-monitoring and enforcement scheme because neither regulated parties nor OSHA will be able to know when they have reached or exceeded the Action Level or the PEL.

(b) OSHA Proposed Silica Dust Controls Are Not Technologically Feasible and OSHA Did Not Determine Feasibility in Specific Critical Industries

An overwhelming flaw in OSHA's feasibility analysis is the Agency's failure to meaningfully test for feasibility, industry-by-industry. [38] Importantly, "the undisputed principle that feasibility is to be tested industry-by-industry demands that OSHA examine the technological feasibility of each industry individually."[39]

For example, OSHA did not conduct a proper analysis of the hydraulic fracturing ("fracking") industry,[40] or of many other impacted industries. As a substitute for a feasibility analysis and a SBREFA review of the fracking industry, OSHA's findings and conclusions are summarized in Appendix 1, to the Preliminary Economic Analysis. The Appendix uses information from a very limited study of 11 non-representative sites,[41] as a baseline to determine feasibility. Dr. Thomas Hall's review of the key study upon which OSHA relies reveals several critical flaws: [42]

- This publication does not provide data that were collected from randomly selected sites within the large population of available sites using a fracking methodology, therefore, these data cannot be construed to represent quartz exposures across petroleum and gas fracking operations.

- The exposure information collected was targeted to specific occupations without regard to potential exposure distributions.

[38] OSHA concedes that a PEL below 50µg/m^3 is not feasible. 78 FR 56283, 56337, 56406. OSHA does not posit any solutions that would reduce silica concentrations below the action level of 25 µg/m^3 to eliminate its proposed periodic exposure assessments triggered by this level of exposure. Moreover, the expert comments of leading CIH Robert Lieckfield confirm that accurate OSHA sampling and analysis at the Action Level, and at the proposed PEL, are not possible and therefore not technologically feasible.

[39] *See* Color Pigments Mfgrs. Assn. v. OSHA 16 F3d 1157, 1161-64 (11th Cir. 1994). Examples are the hydraulic fracturing industry described below, the construction industry described in the Construction Industry Safety Coalition comments, and the foundry industry described in the comments of the American Foundry Society.

[40] OSHA estimates that the exposure level of nearly 75% of fracking workers exceeds the current 100µg/m^3 PEL, A-49, but ignores successful respiratory protection use that negates these exposures and eliminates the alleged risks. 78 FR 56283.

[41] Comments of Dr. Thomas Hall, Appendix 4, reviewing Esswein EJ, Breitenstein M, Snawder J, Kiefer M, Sieber WK. Occupational exposures to respirable crystalline silica during hydraulic fracturing. *J Occup Environ Hyg* 2013;10:347-356. See also Dr. Faten Sabry, Appendix 6.

[42] Comment of Dr. Thomas Hall, Appendix 4.

- For a large fraction of the monitored populations an insufficient number of samples were collected to adequately describe the exposure distribution.

- By combining the exposure measurements from a variety of sites (11) and drilling methodologies, the authors of this study have potentially obscured important results. This has resulted in a biased view of quartz exposures occurring within the petroleum and gas fracking sites.

- The sampling method, GK2.69, has been demonstrated to have significant bias that is unaccounted for in analysis by Esswein, et al. This bias could result in grossly inflated exposure measurements.

(c) OSHA Did No Fracking-Specific Analyses to Determine Feasibility of Controls in One of the Industries Most Affected by This Proposal [43]

OSHA does not offer any fracking-specific engineering control studies or research to support its conclusions. Instead, OSHA impermissibly relies on reasoning by analogy that engineering controls studied at two vastly different and primitive industrial sites, in India and Iran, will be effective in the U.S. fracking industry. OSHA impermissibly relies on sheer conjecture for its feasibility analysis.[44]

For example, Local Exhaust Ventilation ("LEV") systems are the main way OSHA proposes to reduce exposure levels to or below 50µg/m^3. It proposes implementing systems at various points on sand-handling equipment used in the fracking industry. According to OSHA, LEV systems would capture dust at emission points on conveyor belts, sand movers and blender hoppers. A-49. Importantly, the Agency admits that it did not identify any studies demonstrating that LEV systems would be effective in controlling silica exposure in the fracking industry. A-30; A-31.

Yet, OSHA concludes that companies can reduce exposure levels by 50% using LEV controls on fracking industry "thief hatches," [45] based solely on the Agency's "best available evidence," namely its "visual impression" from photographs of fracking operations. A-32. In other words, OSHA *surmises* from *photographs* that about half the respirable dust (not visible to the human eye) at fracking sites is attributable to emissions from thief hatches. A-31. As demonstrated by the comments of leading ventilation expert Knutson, this position does not survive scrutiny. Moreover, even if OSHA is correct, it acknowledges that the LEV systems at fracking sites are "unproven." A-32.

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[43] Comments of Dr. Gerhard Knutson, Appendix 5.

[44] *See* National Maritime Safety Ass'n v. OSHA, 649 F.3d 743, 753 (D.C. Cir. 2011) (refusing to uphold rule due to lack of analysis).

[45] "thief hatches" are access ports on sand moving equipment.

Similarly, OSHA concludes that enclosed operator booths are a "practical option" for those workers whose estimated exposure levels would still exceed the proposed 50 $\mu g/m^3$ PEL after implementing LEV and wet methods. A-40; A-50. OSHA has no data regarding the use or availability of enclosed booths in the fracking industry, or other industries where employees must be mobile to conduct their work. Instead, it analogizes to control booths used in the structural clay industry, A-41, regardless of a completely different set of conditions, operations and exposures.

The Agency asserts that "[p]ortable booths positioned on pallets or a truck bed are also an option." A-40. Yet, OSHA does not cite to any instances where such portable operator booths have been used at all, much less in working environments similar to those in the fracking industry. Similarly, OSHA's assertion that a worker can spend 50% of the time in a clean air booth, reducing exposure by 45%, and still accomplish his job duties is similarly unsupported by any evidence and is pure speculation and conjecture. *See* A-50. Additionally, "OSHA emphasizes that there is considerable uncertainty in the cost estimate because most of the relevant engineering controls have not yet been deployed in oil field or on the types of mobile equipment used in oil fields." A-55-56. Consequently, any attempt to estimate the costs of the booths raises more than "considerable uncertainty" making any cost estimates purely speculative.[46]

VI. OSHA TREATS A COMPLIANCE ISSUE WITH AN UNJUSTIFIED REGULATORY SOLUTION AND FAILED TO PROVE SIGNIFICANT RISKS AND BENEFITS

A well-established requirement for OSHA to issue a health standard, such as this proposal, is that it must demonstrate a "significant risk" to regulate, with "feasible" solutions that will provide "significant benefits." Yet OSHA never properly analyzes nor addresses how its proposal will decrease the 30% non-compliance rate with the current PEL, nor result in feasible engineering measures to achieve compliance with its proposed PEL, nor produce benefits beyond those that would be produced by achieving full compliance with the current PEL. OSHA cannot explain the CDC data demonstrating a trend of vanishing silica-related mortality, particularly in light of recorded high exposures. OSHA simply cannot meet its initial regulatory burden to justify its proposed mandates under applicable law.

OSHA states that:

> The Supreme Court has held that before the Secretary can promulgate any permanent health or safety standard, she must make a threshold finding that significant risk is present and that such risk can be eliminated or lessened by a change in practices. *Industrial Union Dept., AFL-CIO v. American Petroleum Institute,* 448 U.S. 607, 641-42 (1980) (plurality opinion) *("The Benzene case").* Thus, section 6(b)(5) of the Act requires health standards to reduce significant risk to the extent feasible. *Id.*

[46] Comments of Dr. Gerhard Knutson, Appendix 5.

> The Court further observed that what constitutes "significant risk" is "not a mathematical straitjacket" and must be "based largely on policy considerations." *The Benzene case,* 448 U.S. at 655. The Court gave the example that if,
>
> > . . . the odds are one in a billion that a person will die from cancer . . . the risk clearly could not be considered significant. On the other hand, if the odds are one in one thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal, a reasonable person might well consider the risk significant. *(Id.)* 78 FR 56274, 56293.

Even if the CDC data and graph reproduced above suffer from under-reporting, as alleged by OSHA (based on two limited and contradictory studies that our expert[47] shows are flawed and unreliable), OSHA has no analysis of the impact of the conceded lack of compliance with the current standards on current or future risks and benefits:

> A recent analysis of OSHA enforcement data from January 2003 to December 2009 (covering the period of continued implementation of the Special Emphasis Program and the first two years of the National Emphasis Program) shows that considerable noncompliance with the PEL continues to occur. These enforcement data, presented in Table 2, indicate that 14 percent of silica samples from the construction industry and 19 percent for general industry were at least three times the OSHA PEL during this period. The data indicate that 70 percent of the silica samples obtained during inspections in general industry were in compliance with the PEL, and 75 percent of the samples collected in construction were in compliance. 78 FR 56274, 56294.

With such a large population of workers historically and currently exposed beyond the PEL, several questions arise that OSHA has not answered:

> (1) Why has there not been an epidemic of silica disease, and indeed why have silica related fatalities fallen dramatically?
>
> (2) What factors protect the population that was exposed beyond the PEL?
>
> (3) What impact would achieving full compliance with the current PEL have with respect to silica related disease and mortality?

If more than 2 million silica-exposed employees are currently being protected from silica-related risks under current conditions and standards, with the significant PEL overexposures demonstrated by CDC and OSHA data, OSHA must demonstrate how its high statistical risk and benefit calculations relate to low recorded government mortality data. OSHA sets forth its understanding of the law as follows:

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[47] Comments of Dr. Patrick Hessel, Appendix 7.

> The Agency's burden to establish significant risk derives from the OSH Act, 29 U.S.C. 651 et seq. Section 3(8) of the Act requires that workplace safety and health standards be "reasonably necessary and appropriate to provide safe or healthful employment." 29 U.S.C. 652(8). The Supreme Court, in the "benzene" decision, stated that section 3(8) "implies that, before promulgating any standard, the Secretary must make a finding that the workplaces in question are not safe." *Indus. Union Dep't, AFL-CIO v. Am.* Petroleum Inst., 448 U.S. 607, 642 (1980). Examining section 3(8) more closely, the Court described OSHA's obligation to demonstrate significant risk… is not the equivalent of "risk-free." A workplace can hardly be considered "unsafe" unless it threatens the workers with a significant risk of harm. Therefore, before the Secretary can promulgate any permanent health or safety standard, he must make a threshold finding that the place of employment is unsafe in the sense that *significant risks are present and can be eliminated or lessened by a change in practices.* 78 FR 56322 (emphasis added).

OSHA goes on to assert that the agency should be given considerable latitude in making its significant risk determination, notwithstanding that the statute requires it to be supported by "substantial evidence":

> Because section 6(b)(5) of the Act requires that the Agency base its findings on the "best available evidence," a reviewing court must "give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge." *Benzene,* 448 U.S. at 656. Thus, while OSHA's significant risk determination must be supported by substantial evidence, the Agency "is not required to support the finding that a significant risk exists with anything approaching scientific certainty." *Id*.

The flexibility claimed by OSHA, however, does not permit it to brush aside reality in favor of speculative statistical analysis, particularly statistical analysis based on false assumptions[48] and suspect data,[49] that do not account for important uncertainties.[50]

In addition, OSHA should have analyzed the CDC Data and OSHA's own existing enforcement sampling data, in conjunction with its risk/benefit determinations. Why did OSHA not conduct an in-depth study to compare its risk assessment predictions, applied to 2 million exposed employees, to CDC recorded, actual mortality data? These questions and the absence of answers from OSHA make clear that the agency's risk analysis is not sufficient to support this regulation and that the proposal should therefore

[48] There are many examples of false or speculative assumptions in the OSHA rulemaking documents described in the comments of the experts, but two discussed herein are the use of a 45 year life time exposure factor, when the actual expected duration of silica exposures is about 6 years for temporary work site employees and, the OSHA refusal to credit its acknowledged use of effective, personal protective equipment in reducing exposures and risks. See Comments of Dr. Ron Bird, Appendix 1; Comments of Dr. Faten Sabry, Appendix 6.

[49] *Id*.

[50] Comments by Dr. Peter Valberg and Dr. Christopher Long, Appendix 3.

be withdrawn until OSHA can provide statistically valid answers to these fundamental questions.

The comments of Dr. William Bunn, attached as Appendix 10, present the views and opinions of one of the nation's most experienced occupational health executives and experts. Dr. Bunn is a leader in the field, with unparalleled expertise and experience in multiple industries preventing silica risks among thousands of employees. Dr. Bunn confirms the lack of need for the proposed rule and suggests that OSHA focus resources in a more effective manner.

VII. OSHA'S PROPOSAL IS NOT ECONOMICALLY FEASIBLE AND THREATENS JOBS

OSHA has not shown that the proposed rule is economically feasible, as demonstrated by experts.[51] At risk are the more than 2 million employees and their employers that OSHA estimates are exposed to silica and impacted by the proposed rule, which OSHA estimates will cost almost $1 billion but in reality is likely to cost many more billions.

(a) OSHA's Assessment of Compliance Costs Does Not Include Several Critical Elements

To demonstrate economic feasibility, OSHA must first produce a complete and accurate assessment of the costs of compliance with the proposed rule as the basis for comparisons to revenues and profits. Dr. Ron Bird's analysis identifies the ways in which OSHA has failed to do so:

- OSHA's analytical approach is fundamentally flawed by failure to consider the distribution of compliance costs across the spectrum of affected establishments in each industry sector and by OSHA's failure to conduct the necessary surveys to obtain data to accurately characterize the distribution of compliance costs.
- OSHA's Preliminary Economic Analysis is incomplete because OSHA entirely omitted significant compliance cost elements, omitted significant numbers of establishments that will incur costs, and ignored significant secondary economic impacts on the U.S. economy.
- OSHA's Preliminary Economic Analysis is not accurate as OSHA's compliance cost analysis is rife with instances where key cost computation parameters are given arbitrary values without any basis in fact, and in other instances OSHA relies on flimsy and unrepresentative observations to establish critical baseline conditions for determining the level and distribution of compliance costs.

[51] Comments of Dr. Ron Bird, Appendix 1and Dr. Faten Sabry, Appendix 6.

- OSHA failed to conduct the basic survey research and scientific experiments on which an analysis of economic impact and a determination of economic feasibility for such a complex and broad-reaching regulation must be based to ensure accuracy. The faster something has to be done, the higher the cost will be.

- OSHA failed to consider and assess the time dimension of compliance costs in relation to its proposed compliance schedule. OSHA's proposal would require employers to achieve complete compliance with the proposed PEL by retrofitting or rebuilding facilities to incorporate engineering controls within one year of the effective date of a final rule. Exposure assessment would be required within six months of the effective date despite the fact that OSHA's proposed laboratory testing standards may not be effective, if at all, until two years later.

- OSHA failed to examine the adequacy of the supply of occupational health professionals to meet the demand for professional services necessary for employers to comply with the proposed regulation. There is a significant risk that the lack of available service providers or the resulting escalation in cost of their services will render compliance with the proposed rule within the schedule proposed by OSHA technically and economically infeasible.

- There is a significant risk that OSHA's proposed rule will have serious adverse unintended economic consequences for the nation due to the flawed economic analysis.

  For example, in the context of an analysis of feasibility of controlling exposure to the proposed 50 $\mu g/m^3$ PEL in foundries, OSHA's contractor, ERG advised OSHA that:

  > operators in some foundries will not reach this level because casting size or the need to manipulate castings will make it more difficult to fully enclose this high energy operation . . . for some older, less modernized facilities, it might be more practical to replace existing open shakeout equipment with more modern, enclosed, or automated equipment for separating sand from castings. . . . In some of these cases, foundries would need to fully automate and rebuild the facility to reach exposure levels of 50 $\mu g/m^3$ or less.

The recovery of manufacturing is at the foundation of the President's agenda to restore the economic well-being of middle class Americans. The foundries described in the ERG report are critical elements of America's manufacturing infrastructure, and a regulatory action that would necessitate the total rebuilding (with the potential for further relocation of this industry outside the U.S.) would

have profound negative impacts on the economic resurgence that is just now getting underway. A January 2013 report prepared for the American Foundry Society by Environomics, Inc. states:

> If the estimated cost of $400 to $500 million per year for ancillary provisions at a PEL of 50 μg/m^3 were added to our previously estimated costs of more than $1.5 billion per year for engineering controls for such a PEL, the total compliance cost of roughly $2 billion per year for OSHA's potential new regulation would amount to about 6% of U.S. foundry industry revenues as of 2007. This regulatory cost burden would be very difficult for the industry to bear. We would expect a significant quantity of facility closures and job losses in the industry, as well as reduced competitiveness relative to foreign metalcasters.[52]

How prevalent are cases where engineering controls and ancillary mandates to achieve compliance with the proposed rule will force employers and industries to close, rebuild or move offshore? These questions go to the heart of the proposed rule's economic feasibility. OSHA must consider not only the economic feasibility for a single employer, but also the economic feasibility of the proposed rule for the nation.

OSHA has not and cannot answer the necessary questions about the distribution of economic impacts across facilities by age, design, operations, condition and region with available data. A full-scale national survey of baseline conditions, practices and exposures in the affected industry sectors is needed to reveal the full range of costs and economic impact of the proposed rule and to determine accurately and credibly the economic feasibility of the proposal.

(b) OSHA's Estimate of Benefits for the Fracking Industry Are Grossly Overstated and Not Reliable

In one of the industries that will be most affected by this rule, OSHA's benefits estimates and calculations are not reliable and are not adequately supported by data. Dr. Faten Sabry's analysis shows the various ways in which OSHA's benefits calculations are not acceptable:[53]

- OSHA's estimates of the benefits of the proposed PEL are unreliable and overstated [for the hydraulic fracturing industry]. OSHA's study hinges on its dose response assumptions and its exposure assumptions for the fracking workers. These assumptions lead to questionable results.
    - OSHA's extrapolated silica exposure estimates for fracking workers are unreliable because of the small samples used. OSHA reported that there were 200 fracking entities and

[52] Comments by Dr. Ron Bird, Appendix 1 citing http://www.afsinc.org/files/CoststoFoundriesPotentialSilicaAncillaryRequirements2013.pdf.

[53] Comments of Dr. Faten Sabry, Appendix 6. (citations omitted)

444 fracking establishments. However OSHA relied on NIOSH's sample data from only 11 fracking sites to develop its industry wide exposure profiles, which included between 2 to 34 data points per job category. OSHA acknowledged that the sites were not randomly selected and that they did not have the data to evaluate whether the sites are representative of the industry as a whole. Even if one assumes that the sampled sites are representative of all fracking sites, standard statistical tests document a high level of uncertainty in OSHA's estimates of silica exposure by job category. For example, OSHA relied on six observations for ancillary workers to extrapolate the exposure levels for 6,360 ancillary workers in the fracking industry, which resulted in unreliable extrapolation. The 95% confidence interval around OSHA's extrapolated estimate for ancillary workers ranges from 20 $\mu g/m^3$ to 8,088 $\mu g/m^3$.

- OSHA overestimated the benefits of the proposed rule for the fracking industry as it did not adjust for current respirator usage among workers. Notwithstanding the evidence of high respirator usage among fracking workers—98% compliance as reported by ERG, OSHA's own consulting expert on the regulation—OSHA estimated the benefits of reducing the permissible exposure level based on the assumption that there was no respirator usage in the fracking industry. By using exposure levels unadjusted for respirator usage, OSHA inflated the benefits of the proposed PEL.

- OSHA's dose response assumptions are unreliable because of the inclusion of a controversial study for lung cancer and the reliance on estimates for NMRD and renal diseases with wide confidence intervals. [H]ad OSHA excluded the controversial Attfield and Costello (2004) dose response model, with its outlier incidence estimates,… a 46% reduction [in mortality would result]. In addition, the dose-response models OSHA relied upon to predict NMRD and renal diseases are based on estimates with high level of uncertainty.

- OSHA focused on the [calculated] benefits of a new PEL, yet its own study suggests the bigger impact would result from increased compliance under the current PEL.

- Most of the [OSHA estimated] avoided fatalities in the fracking industry in OSHA's calculations of benefits were based on workers whose current [estimated] baseline exposure exceeded the current PEL. There is no basis to assume that all workers with exposure levels above the current PEL would experience a reduction in their exposure due to the proposed rule.

- Based on OSHA's own calculations for the fracking industry, achieving full compliance at the current PEL would result in [higher benefits] than reducing the PEL. OSHA's own calculations established that achieving full compliance at the current PEL is about 11 times more effective than reducing the PEL with respect to [OSHA calculated] avoided deaths and about 4 times more effective with respect to avoided illnesses. ….

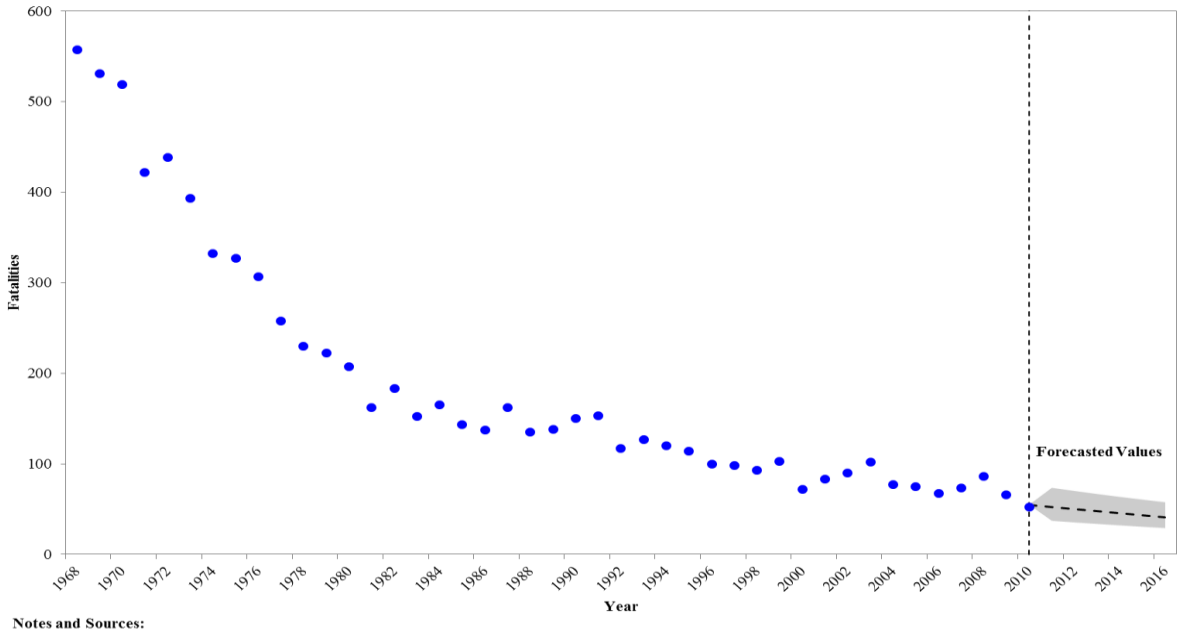
- Finally, OSHA's estimates are not supported by the historical data on silicosis-related deaths.

    - The decline in the number of silicosis-related deaths, according to data from the National Occupational Respiratory Mortality System ("NORMS"), is inconsistent with OSHA's estimates of silicosis-related deaths. According to NORMS, the number of deaths due to silicosis in the United States fell from a high of 557 in 1968 to a low of 52 in 2010. However, OSHA predicted the annual number of avoided silicosis-related deaths for all industries due to the proposed rule to be 102 once the proposed rule is fully effective, which is nearly twice the number of actual silicosis-related deaths in the 2010.

    - There is no historical evidence of *any* silicosis-related deaths for the fracking industry. OSHA estimated the annual number of deaths due to silicosis in the fracking industry at the current exposure levels to be 15.9 workers. However, while fracking is a process that has been used in the oil and gas industry since the late 1940s, the main database on the prevalence of silicosis mortality by industry in the U.S. reported a total of 1,445 fatalities due to silicosis between 1985 and 1999, ***none*** of which were attributed to the oil and gas extraction industry (which includes fracking).[54]

[54] *Id.* (citations omitted)

Fatalities in the United States with Silicosis as Underlying Cause of Death According to NORMS for the Period 1968 to 2010 with NERA Forecasts After 2010



Notes and Sources:
Data from CDC National Occupational Respiratory System (NORMS), aggregated across all states, races, ages, and genders.
Underlying Cause-of-Death data for the total number of fatalities with any of the following conditions: Silicosis (ICDA-8 codes 010 and 515.0, ICD-9 code 502, or ICD-10 code J62).
We estimated the number of fatalities and the corresponding 95% confidence interval (shown in gray) following 2010.

Presidential Executive Orders 12866 and 13563 require agencies to base rulemaking on full and accurate economic analyses using the best data that the agency can obtain. OMB/OIRA guidance in Circular A-4 encourages agencies to conduct surveys and experiments to obtain the data needed for a thorough and accurate analysis of regulatory costs and benefits. The criterion is not the data that happens to be already on hand but rather, the best data that is within the capacity of the agency to reasonably obtain, including by conducting surveys, field site visits, and controlled experiments to collect up-to-date and accurate information.

Given the more than ten years during which OSHA has been contemplating the proposed rule and the potential for disruption of the economy, the fact that OSHA has not devoted the necessary resources to design, obtain OMB clearance, and execute statistically valid surveys and experiments to provide an accurate and complete basis for its economic cost analysis is astonishing. This is what OSHA could have done and should have done, but OSHA chose not to do. The result of OSHA's negligent research planning is an analysis that cannot be relied upon as an accurate basis for determining the economic feasibility of the proposed rule and a proposed rule that could have devastating consequences for the nation.

OSHA should withdraw the current flawed Preliminary Economic Analysis and withdraw the current rulemaking action. Should it decide to proceed, the Agency needs to conduct a statistically reliable, industry-by-industry, representative sample-based survey of current facilities, conditions, exposures and facility-specific modifications or

replacements that are necessary to achieve both improved compliance with the existing standard and compliance with any contemplated new standards.

CONCLUSION

With silicosis in long-term decline, OSHA had a duty to explain clearly and logically how and why its proposed rule is necessary and the appropriate solution for the limited, remaining silica-related disease cases. Instead, OSHA built its proposed rule on a chain of assumptions, did not properly analyze the most recent and current mortality and exposure data, and it failed to research or analyze the impact and value of this proposal on the hardest-hit industries.

The agency has attempted to claim this proposal is both technologically and economically feasible based on conjecture, assumptions, and belief, rather than on readily developed statistical and empirical data. The proposal attempts to fix a compliance problem by creating a new standard. Based on nothing more than long-standing, outdated policy, it rejects the most effective and economical solutions in favor of unproven, infeasible ones.

Finally, OSHA has insisted on moving forward with this rulemaking in a hurried way. While two extensions to the comment period were granted, the total amount of time was far less than interested parties requested, and other relevant deadlines such as the start of the hearings were not extended in synch. With a docket that includes over 1700 highly technical documents, more time is needed to do the thorough analysis of these materials necessary to fully comprehend the data and supporting materials on which OSHA relies. OSHA also has declined to conduct a second small business panel review under SBREFA, preferring to rely on the more than 10 year old 2003 report, which did not even include the significantly impacted fracking industry. OSHA’s attempt to substitute an incomplete hydraulic fracturing industry analysis for conducting a second SBREFA panel with representatives from the industry was a wholly inadequate substitute.

For the foregoing reasons the Chamber urges OSHA in unequivocal terms to withdraw this proposed regulation. If OSHA believes a new RCS PEL and programmatic regulation are warranted, the agency must present appropriate medical, scientific, technological, and economic data to make that case. This proposal fails to satisfy any of those requirements.

Sincerely,

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