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August 18, 2014

The Honorable David S. Michaels  
Assistant Secretary of Labor  
Occupational Safety and Health Administration  
U.S. Department of Labor  
200 Constitution Avenue, N.W.  
Washington, DC 20210

c/o OSHA Docket Office  
Docket No. OSHA-2010-0034

**SUBMITTED ELECTRONICALLY:** [www.regulations.gov](http://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**

**Post-Hearing Brief**

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, many of which will be directly affected by OSHA’s proposed rule on silica. The public hearing testimony of the Chamber panel, including scientific, technical, and economic expert witnesses, along with their prior written comments, unequivocally demonstrate the flaws in the proposed rule. Furthermore, OSHA’s rulemaking fails to satisfy key requirements of the Occupational Safety and Health Act of 1970, and the Administrative Procedure Act. Finally, OSHA’s conduct of the hearing was overtly biased and prevented interested parties from having an adequate opportunity to question OSHA’s panel of technical experts, while those who were critical of the proposal were subjected to extensive and, at times, unrestricted questioning. For all these reasons, the proposed rule must be withdrawn.

- I. OSHA used an incorrect risk model to assess silica exposures.**
  - a. OSHA has rejected compelling evidence of a dose-response threshold.**

In the preamble to the proposed rule, OSHA stated:

OSHA has relied upon risk models using cumulative respirable crystalline silica exposure to estimate the lifetime risk of death from occupational lung cancer, silicosis, and NMRD [Nonmalignant Respiratory Disease] among exposed workers.... Is cumulative exposure the correct metric...?

Some of the literature OSHA reviewed indicated that the risk of contracting accelerated silicosis and lung cancer may be non-linear at very high exposures and may be described by an exposure dose rate health effect model. OSHA used the more conservative model of cumulative exposure that is more protective to the worker. Are there any additional data to support or rebut any of these models used by OSHA?<sup>1</sup>

Experts have made clear that while cumulative exposure can be a helpful analytical tool, it does not properly address crystalline silica risks. Rather, the science and expert testimony, including comments from OSHA's own peer reviewer, Dr. Kenny Crump, demonstrate that consideration of dose rates and minimum threshold exposures must be used to address silica risks.<sup>2</sup>

The cumulative exposure model is used to allege risk at low exposure levels that is not supported by empirical evidence, only by statistical extrapolation. Yet, overwhelming evidence demonstrates that the exposure-response relationship between silica and silica related disease requires a threshold level of exposure prior to causing disease,<sup>3</sup> and is impacted by the dose rate of the exposure. Critically important to silica risk assessment is accounting for the threshold level of exposure needed to cause disease. OSHA's risk assessment does not do so, even though the threshold concept is supported by several lines of evidence, including mechanist considerations, animal toxicology, and epidemiology studies.<sup>4</sup> Mechanist studies indicate that silica inhalation leads to a dose-related inflammatory response in the lungs.<sup>5</sup> The dose-related inflammatory response is a persistent inflammatory state which develops when the inhalation of silica dust exceeds the lung's ability to clear the deposited particles and to neutralize free radicals and cytokines that were released by cells in response to the particles retained on the lung surfaces.<sup>6,7</sup> As Dr. Valberg discussed during the hearings, whether the inflammatory

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<sup>1</sup> 78 Fed. Reg. 56274, 56285 (Sept. 12, 2013).

<sup>2</sup> U.S. Chamber of Commerce Comments and Appendices submitted February 11, 2014 (OSHA Docket No. OSHA-2010-0034-2288 (revised at 4194), 2368, 2376, 2330, 2285, 2264, 2263, 2332, 2259, 2364, 2283); Crump, K. 2011. Review Article: Use of Threshold and Mode of Action in Risk Assessment. Critical Reviews of Toxicology, OSHA Docket No. OSHA-2010-0034-3575.

<sup>3</sup> Appendix 3 to the U.S. Chamber of Commerce Comments submitted February 11, 2014, OSHA Docket No. OSHA-2010-0034-2330.

<sup>4</sup> *Id.*

<sup>5</sup> *Id.*

<sup>6</sup> Transcripts of the informal public hearings appear at OSHA Docket Nos. OSHA-2010-0034-3579 (Mar. 18, 2014), 3576 (Mar. 19, 2014), 3577 (Mar. 20, 2014), 3578 (Mar. 21, 2014), 3580 (Mar. 24, 2014), 3581 (Mar. 25, 2014), 3582 (Mar. 26, 2014), 3583 (Mar. 27, 2014), 3584 (Mar. 28, 2014), 3585 (Mar. 31, 2014), 3586 (Apr. 1, 2014), 3587 (Apr. 2, 2014), 3588 (Apr. 3, 2014), and 3589 (Apr. 4, 2014). References to transcript testimony will be designated hereinafter as "Tr." with 4-digit docket number.

<sup>7</sup> Tr.3576, 310-311 (Dr.Valberg testifying). For example, when laboratory rats are exposed to poorly soluble particles, such as silica, the lab rats have been shown to reach a lung condition called lung overload that is characterized by persistent inflammation. *Id.* This lung overload state is characterized by neutrophil influx, macrophage influx, oxidant and cytokine release, and increased pulmonary epithelial cell hyperplasia. *Id.* The biological mechanisms of crystalline silica exposure in rat lungs was also discussed by Dr. Dale Porter and others in *Progression of Lung Inflammation and Damage in Rats After*

response can become persistent and result in nonmalignant or malignant lung disease is governed by threshold considerations.<sup>8</sup>

The scientific evidence also demonstrates that the exposure level necessary to cause silica-related disease is likely more than twice the current permissible exposure level (“PEL”) of 100  $\mu\text{g}/\text{m}^3$ . For example, in a 2005 study, Professor Euro Pukkala and others sought to understand alternative exposure metrics for crystalline silica by examining 43,433 lung cancer cases in Finland.<sup>9</sup> Their analysis of a possible relationship between crystalline silica concentrations and lung cancer risk found strong evidence of a threshold, since lung cancer excesses were limited to exposure concentrations of at least 200  $\mu\text{g}/\text{m}^3$ .<sup>10</sup> Additionally, in an article entitled *Threshold Value Estimation for Respirable Quartz Dust Exposure and Silicosis Incidence Among Workers in the German Porcelain Industry*, Dr. Peter Morfeld and others studied approximately 17,000 workers from porcelain manufacturing plants in Germany where the workers were screened for silicosis between 1985 and 1987.<sup>11</sup> The workers were then observed for mortality and silicosis morbidity through 2005 and the authors found a threshold concentration of 250  $\mu\text{g}/\text{m}^3$  below which the lung responses did not progress to silicosis.<sup>12</sup>

Empirical evidence of a threshold associated with the onset of disease above the current PELs (100  $\mu\text{g}/\text{m}^3$  for general industry and 250  $\mu\text{g}/\text{m}^3$ ) is demonstrated by CDC and OSHA data, particularly when viewed together. CDC data show a dramatic declining trend of silica related mortality rates from almost 1200 in 1968 to 123 in 2007 with the current PELs. Despite the overwhelming empirical evidence that indicates a threshold of exposure above current PELs is required to cause risks of lung disease, several rulemaking parties suggested that the threshold response function is very low or non-existent. Others concluded, without supporting evidence, that workers exposed to respirable crystalline silica at or below the current PEL are at risk of increased risk of respiratory diseases.<sup>13</sup> None of these parties produced empirical evidence to support their propositions,<sup>14</sup> which clearly are contradicted by the evidence described above.<sup>15</sup>

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*Cessation of Silica Inhalation*, where he noted that the response of the rat lung to inhaled crystalline silica particles is biphasic, meaning that below a certain threshold, pulmonary inflammation in the lungs of the rat increased but was controlled. Porter *et al.* (2004). He concluded from his research that: “Pulmonary defense mechanisms were initially able to compensate and control silica-induced pulmonary inflammation and damage, but after a certain threshold lung burden was exceeded, these control mechanisms no longer were adequate to prevent the progression of silica-induced pulmonary disease.” *Id.*; See also Tr.3576 at 314.

<sup>8</sup> Tr.3576, 310, 318.

<sup>9</sup> Pukkala *et al.* (2005).

<sup>10</sup> Tr.3576, 320.

<sup>11</sup> Morfeld *et al.* (2013).

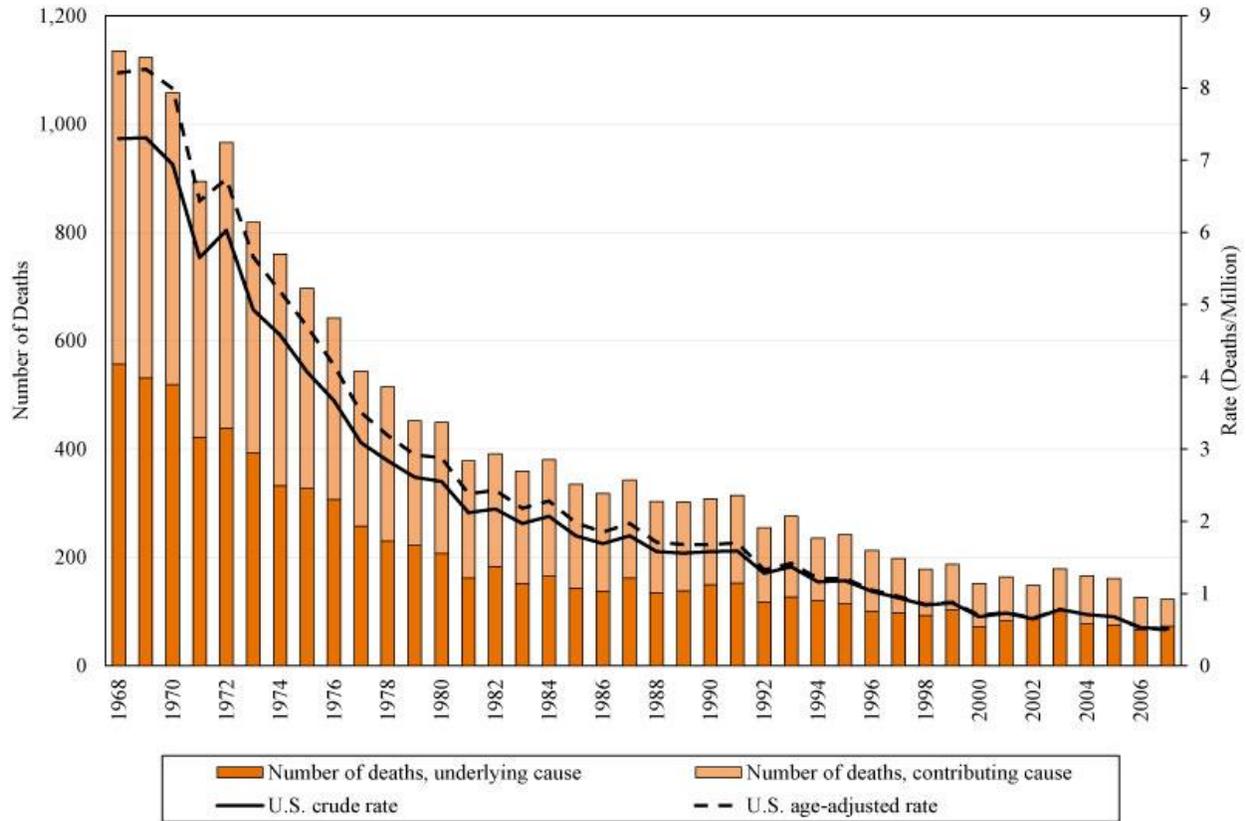
<sup>12</sup> Tr.3576, 322.

<sup>13</sup> Comments of the American Thoracic Society, the Association of Occupational and Environmental Clinics, the Council of State and Territorial Epidemiologists, and the American College of Chest Physicians at pg. 3 (OSHA Docket No. OSHA-2010-0034-2175). Comments of the American Public Health Association at pg. 2 (OSHA Docket No. OSHA-2010-0034-2178).

<sup>14</sup> Dr. Franklin Mirer, testifying on behalf of the AFL-CIO, when asked if there is evidence of a threshold for lung cancer or other silica effects, stated that a threshold cannot be demonstrated, but did not provide evidence to support his proposition. Dr. Mirer was correct when he said that animal studies have been used to demonstrate a threshold-no-effect level effect, but he failed to acknowledge that human studies and CDC / OSHA data support the proposition as well. Tr.3578, 986.

<sup>15</sup> Dr. Robert Park, NIOSH mentioned two studies that involved a pooling of populations in Europe with one looking at lung cancer and the other looking at silicosis. He surmised from these studies that if there is a threshold, it is very low. But, Dr.

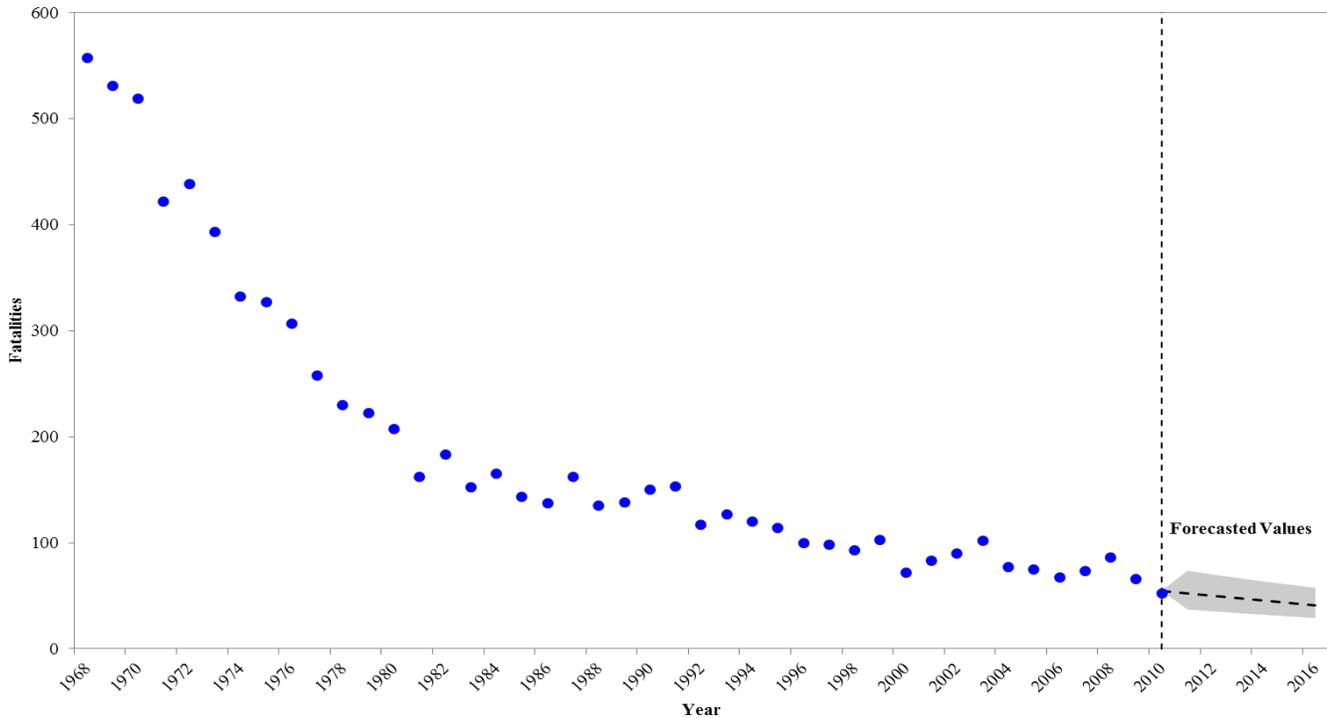
Silicosis: Number of deaths, crude and age-adjusted death rates, U.S. residents age 15 and over, 1968-2007<sup>16</sup>



Park did not explain how he reached this conclusion, nor did he produce any evidence to support this opinion. Similarly, Dr. Rosemary Sokas testified there were adverse health effects at levels below the proposed PEL, but also did not provide evidence to support this conclusion. Further, no expert purported to explain why low levels of silica in beach or desert areas do not result in adverse health effects. Tr.3579, 249-251.

<sup>16</sup> Mortality multiple cause-of-death data from National Center for Health Statistics, National Vital Statistics System. Date Posted: March 2012.

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.

**b. OSHA confuses a compliance problem for an exposure limit problem.**

OSHA data demonstrate a long term, 30% noncompliance rate with current exposure limits and significant exposures, far in excess of current limits, for decades. Such documented exposures could not possibly produce the CDC documented trend of steeply declining mortality data, unless the threshold for disease was far in excess of current OSHA limits. Indeed, whatever silica mortality remains within the CDC documented declining trend, can only be ascribed to the very high exposures documented by OSHA, as described by Dr. Borak in his testimony.<sup>17</sup>

In 1996, OSHA conducted a Special Emphasis Program (“SEP”) directing resources at enforcement inspections for silica.

From August 1 to December 31, 1996, OSHA conducted 182 enforcement inspections under the program. Eighty-three were in construction, 78 in general industry, 3 in maritime, and 18 in other types of establishments. Inspections showed some significant overexposures, mostly in abrasive blasting or construction-related work. In some, worker overexposures were 60 to 80 times the OSHA permissible exposure limit. OSHA

<sup>17</sup> Tr.3576, 281-282.

compliance personnel have been submitting between 100 and 150 employee exposure samples per month to the OSHA Laboratory for analysis. About one-third of these have been above the permissible exposure limit. The inspections resulted in issuance of citations for 228 serious violations of OSHA standards relating to silica.<sup>18</sup>

In 2003 OSHA examined enforcement data from 1997 to 2002 and again “identified high rates of noncompliance.”<sup>19</sup> More specifically, this examination revealed a 42% noncompliance rate in construction and a 34% noncompliance rate in general industry.<sup>20</sup> Within these noncompliance rates, 24% and 13% of noncompliance was three times or higher than the construction and general industry PELs respectively.<sup>21</sup> OSHA readily acknowledges that current data “shows that considerable noncompliance with the PEL continues to occur.”<sup>22</sup> Enforcement data reviewed for the years 2003 through 2009 demonstrate a noncompliance rate of 25% for construction and 30% for general industry.<sup>23</sup>

Dr. Borak reviewed the CDC data and exposures documented by OSHA and concluded that remaining cases of silica related disease, within the context of the reduced CDC mortality rates, result from the high exposure levels documented by OSHA, far above current PELs.<sup>24</sup> In short, the evidence overwhelmingly suggests that OSHA proposes a drastic change to the silica standard based on compliance and enforcement problems that cannot be addressed with its proposed rule. OSHA has not demonstrated there is significant risk at the current PELs, or significant benefits at the proposed PEL and Action Level (“AL”).

While there were witnesses at the hearing who testified that they had been diagnosed with silica related disease or who knew people that suffered from silica related disease, their mere presence does not bolster OSHA’s case for the proposed lower PEL or the cumulative exposure approach. The Chamber and its members are committed to the elimination of silica related disease and encourage OSHA to obtain details from these witnesses about the circumstances of their exposure. Such details are needed to help the agency focus on the very high exposure conditions that create risk, demonstrated by OSHA’s own exposure data, in addition to practical, effective protections such as personal protective equipment.

Based on the testimony of these witnesses, however, there is no basis to assume or predict that a lower PEL would have prevented the diseases and symptoms reported by them. In fact, the descriptions of exposures presented in connection with these cases appear to far exceed the current OSHA PEL of 100  $\mu\text{g}/\text{m}^3$ . Many witnesses discussed working in environments where there was high exposure to silica dust without access to personal protective equipment such as respirators. For example, one witness discussed his experience working in a foundry for 14 years in unhealthful conditions doing

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<sup>18</sup> *The Campaign to End Silicosis*, Kane F. Job, Safety & Health Quarterly (JSHQ). 1997 Winter/Spring.

<sup>19</sup> 78 Fed. Reg. at 56293.

<sup>20</sup> *Id.*

<sup>21</sup> *Id.*

<sup>22</sup> *Id.*

<sup>23</sup> *Id.*

<sup>24</sup> Tr.3576, 281-282.

every job in the foundry over the years.<sup>25</sup> This witness indicated that he never received any type of protection from the heavy silica dust that was in his work environment.<sup>26</sup> Without knowing more, there is no way to conclude that those with a silica related disease would not have suffered from the disease if the PEL was lower.

As Dr. Borak stated during the hearing, “there is a lot of data showing that the exceedances and noncompliance with the current PEL seem to be most commonly found in those industries that are associated with the highest rates of silicosis.”<sup>27</sup> OSHA should have undertaken or sponsored a study of the CDC reported silica related mortality cases, and its own exposure data base, to help focus its resources on significant risks, as opposed to adding regulatory burdens where they are not needed and do not address risks.

**c. OSHA’s cumulative exposure model does not account for ambient exposures.**

Those who argued against the existence of a threshold fail to acknowledge that their inability to detect a threshold in some studies does not mean that no threshold exists.<sup>28</sup> As Dr. M. Alice Ottoboni wrote in her book *The Dose Makes the Poison: A Plain-language Guide to Toxicology*, “Despite the fact that thresholds in individuals cannot be determined precisely, the existence of thresholds is generally accepted as fact. The threshold concept is of great importance to the understanding of the toxic action of chemicals.”<sup>29</sup>

If the existence of a silica threshold is rejected, then *every individual* irrespective of occupational exposure would be at risk of silica related diseases due to silica being ubiquitous and contained in ambient air. The blowing of sand on a golf course, a beach, or from a child’s sandbox creates silica inhalation risks. Simply denying a threshold necessary for disease risk does not establish there is no threshold. Such a proposition ignores evidence of ambient air levels of silica and the infinitesimally small amount of silica OSHA proposes to regulate. The slide below, entered into the public hearing record during the Chamber testimony provides pictorial representations of OSHA’s proposed PEL and the current general industry PEL.<sup>30</sup>

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<sup>25</sup> Tr.2327-2328.

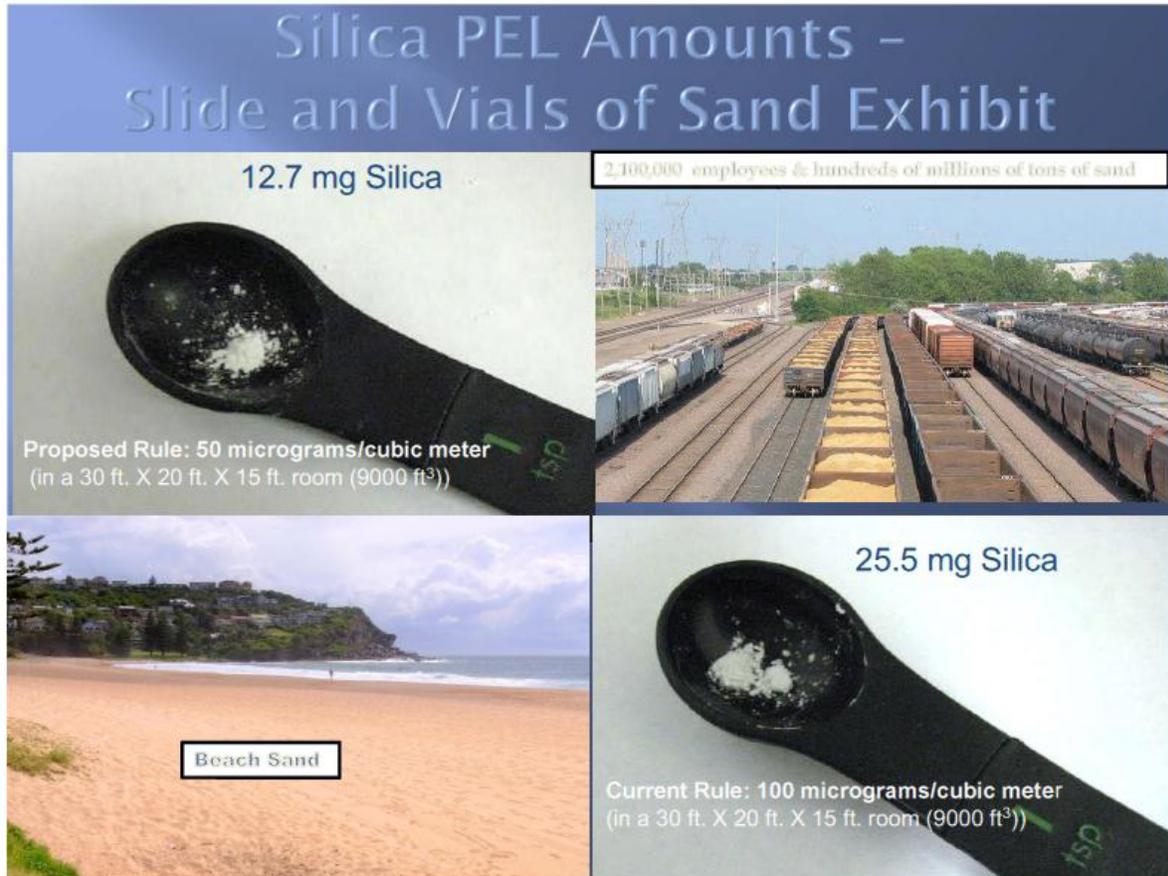
<sup>26</sup> *Id.*

<sup>27</sup> Tr.3576, 369.

<sup>28</sup> Tr.3576, 302.

<sup>29</sup> Ottoboni, 1991.

<sup>30</sup> Hearing Exhibit 36 (OSHA Docket No. OSHA-2010-0034-3436).



In 1996, the Environmental Protection Agency (“EPA”) reported, “there is enough indirect evidence to indicate that average ambient level [of crystalline silica]...in the U.S. metropolitan areas generally have ranged between 1 and 3  $\mu\text{g}/\text{m}^3$  and, in most circumstances, are not likely to exceed an 8  $\mu\text{g}/\text{m}^3$  annual average.”<sup>31</sup> However, the OSHA cumulative exposure model fails to reconcile how individuals, with a lifetime of exposures to ambient air levels of silica, do not develop silica related diseases.

**d. Courts reject OSHA’s theory.**

Courts have discredited expert witnesses claiming that any exposure or cumulative exposure, without a threshold level, causes disease<sup>32</sup> and they are increasingly skeptical of scientific theories based on “cumulative dose,” “no safe dose,” or “no threshold dose,” and have excluded such expert testimony for not being based on generally accepted scientific methodologies.<sup>33</sup> Particularly, courts are

<sup>31</sup> U.S Environmental Protection Agency, Office of Research and Development, *Ambient Levels and Noncancer Health Effects of Inhaled Crystalline Silica and Amorphous Silica: Health Issue Assessment* (November 1996), pp. 3-30.

<sup>32</sup> See *Betz v. Pneumo-Abez*, 615 Pa. 504, 44 A.3d 27 (2012) (addressing expert’s discrepancy between any exposure to an asbestos fiber causes disease and admission of a lifetime of background exposures does not.).

<sup>33</sup> See, *Bartel v. John Crane Inc.*, 316 F. Supp. 2d 603(N.D. Ohio, 2004)(holding the no safe dose theory was not supported by medical literature), *Parker v. Mobil Oil Corp. et al.*, 857 N.E.2d 1114 (N.Y. 2006) (upholding Appellate Division’s decision to exclude expert testimony where in part, the expert concluded that for exposure to benzene there is no threshold

cautious of those experts who ignore generally accepted science of toxicology.<sup>34</sup>

Likewise, OSHA should give no weight to studies relying on the theory that if high dose, prolonged exposure to crystalline silica creates a risk of silica related diseases, so does low dose exposure.<sup>35</sup> The “extrapolation down theory” has been criticized as not conforming to generally accepted science.<sup>36</sup> As Judge Colville stated in context of an asbestos case:

[t]he fallacy of the “extrapolation down” argument is plainly illustrated by common sense and common experience. Large amounts of alcohol can intoxicate, larger amounts can kill; a very small amount, however, can do neither. Large amounts of nitroglycerine or arsenic can injure, larger amounts can kill; small amounts, however, are medicinal. Great volumes of water may harmful, greater volumes or an extended absence of water can be lethal; moderate amounts of water, however, are healthful. In short, the poison is in the dose.<sup>37</sup>

## II. OSHA lacks evidence to support the technological feasibility of the proposed rule.

An evaluation of the testimony and the data provided supporting the feasibility of proposed rule in the hydraulic fracturing industry demonstrates that the industry cannot achieve compliance. For example, SandBox Logistics LLC (“Sandbox”) provided commentary and testimony that it offers technology that will allow the fracking industry to meet, if not surpass, the proposed PEL through the use of their Sandboxes, which they claim eliminate silica exposure during the supply chain process, through total substitution of equipment used in the process.<sup>38</sup>

SandBox submitted post-hearing data of silica exposure monitoring that took place at a well site near Dickinson, North Dakota using its technology.<sup>39</sup> Although their technology reduced the amount of airborne dust in the work environment at the well site, the *reduction did not lower exposure to the proposed PEL*.<sup>40</sup> This data illustrate that even with projected advances in technology and total substitution with new, unproven equipment, at unknown costs and during an unknown time frame needed for industry-wide deployment, compliance with the proposed PEL is not technologically feasible.

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below which leukemia would not occur for “the scientific reliability of th[at] methodology has flatly been rejected as merely a hypothesis”), *Nelson v. Tennessee*, 243 F.3d 244 (6th Cir. 2001) (excluding experts testimony as to injury from PCB exposure where no actual dose was determined therefore the reasoning and methodology underlying testimony is not scientifically valid).

<sup>34</sup> *McClain v. Metabolife International, Inc.*, 401 F.3d 1233 (11th Cir. 2005) (“the relationship between dose and effect (dose-response relationship) is the hallmark of basic toxicology.”) *Id.* at 1242 (internal citation omitted).

<sup>35</sup> Similarly, hearing witnesses testified that OSHA’s risk assessment uses an evaluation “based on extrapolation of modified, unrelated data and not on direct evidence” (that also was inapplicable to the U.S. population). Tr.3589, 4353 -4354.

<sup>36</sup> *In re Toxic Substances Cases*, 2006 Pa. Dist. & Cnty. Dec. LEXIS 581 (excluding plaintiff’s experts testimony regarding extrapolating down because it was not generally accepted methodology to support their contention that high dose exposure can cause disease so can low dose exposure).

<sup>37</sup> 2006 Pa. Dist. & Cnty. Dec. LEXIS 581, \*23.

<sup>38</sup> Tr.3589, 4136-4147.

<sup>39</sup> OSHA Docket No. OSHA-2010-0034-3589, posted June 4, 2014.

<sup>40</sup> *Id.*

In addition to SandBox, NIOSH mentioned during the hearing and also submitted post-hearing comments regarding a patent-pending engineering control technology for sand movers that it is working on for hydraulic fracking operations.<sup>41</sup> It is clear that the technology is still in the research stage since NIOSH admitted that it had only done preliminary testing and that the data had not yet been analyzed.<sup>42</sup> Further, in its post-hearing comments, NIOSH explained that although their new technology has undergone some field evaluation and proof of concept design testing, it still does not have information regarding costs, such as the cost of the product and the estimated cost of and time for implementation by hydraulic fracturing companies.<sup>43</sup> Tellingly, NIOSH provided no information regarding how effective the product will be in reducing exposure down to OSHA's proposed PEL.

Clearly, neither of these participants has offered evidence to show feasibility of compliance by the hydraulic fracking industry. Rather, the testimony and data presented show that engineering controls technology for the fracking industry is only in the conceptual stages.

Moreover, the evidence OSHA relies on to support its technological feasibility analysis is inapposite to the hydraulic fracking industry in the United States. First, OSHA relies on a study by Abdul Rahman Bahrami of rock crushing operations in Iran to support technological feasibility of achieving the proposed PEL. As the Chamber's expert Dr. Knutson demonstrated, hydraulic fracking does not include rock crushing and even the unsuccessful controls used in the Bahrami study are not applicable to conveying sand in hydraulic fracturing because the material handling systems are different, the equipment (except the conveyors) are different and the location of where operators perform their work in relation to the crushing operation is different.<sup>44</sup> But more importantly, the data from this study did not provide evidence of compliance with OSHA's current or proposed PEL. As Dr. Knutson points out in his written comments, OSHA uses this study to support technological feasibility of meeting the proposed PEL for hydraulic fracturing when the study itself fails to support technological feasibility of meeting the proposed PEL for stone crushing, because exposure levels on average were twice the current PEL.<sup>45</sup>

Similarly, the second study OSHA relies on by Perry Gottesfeld is of a water spray operation in India. In Dr. Knutson's written comments he explains precisely why drawing a comparison between Indian stone crushing and hydraulic fracking is questionable, including differences in material handling systems, in the process of delivering rock to the crusher and in the location of the operators. Similar to the Bahrami study, the Gottesfeld study failed to demonstrate compliance with OSHA's current or proposed PEL and therefore failed to support a conclusion that the proposal is technologically feasible.

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<sup>41</sup> Tr.3579, 177-78; OSHA Docket No. OSHA-2010-0034-3998, posted June 4, 2014.

<sup>42</sup> Tr.3579, 178.

<sup>43</sup> OSHA Docket No. OSHA-2010-0034-3998, posted June 4, 2014.

<sup>44</sup> Appendix 5 to the U.S. Chamber of Commerce Comments submitted February 11, 2014, OSHA Docket No. OSHA-2010-0034-2264.

<sup>45</sup> *Id.*

### **III. The accuracy and reliability of the sampling method in the proposed rule renders it not technologically feasible.**

Sampling and analytical methods that can accurately measure respirable crystalline silica concentrations at the proposed PEL and AL are essential to establishing the technological feasibility of the rule. If the measurement methods do not provide accurate measurements of respirable silica to which employees are exposed, there will be no way to determine either compliance or the existence and effectiveness of engineering controls needed to meet the proposed rule.

As indicated in earlier comments and expert testimony, OSHA has not demonstrated the feasibility of its sampling and analysis procedures to produce “accurate” results for respirable crystalline silica at the proposed exposure limit of 50  $\mu\text{g}/\text{m}^3$  and at the proposed action level of 25  $\mu\text{g}/\text{m}^3$  rendering the proposed rule not feasible, and therefore not in compliance with the mandates of the Occupational Safety and Health Act of 1970 (“OSH Act”) and the Administrative Procedure Act (“APA”).<sup>46</sup>

In an Orwellian twist of the English language, NIOSH and OSHA have taken the ordinary meaning of “accurate” and converted it to permit impermissible rulemaking error. In plain English, “accurate” means: (1) free from mistakes or errors, and (2) able to produce results that are correct.<sup>47</sup> The accurate, true value of 100  $\mu\text{g}$  of silica, provided by the Office of Weights and Measures of the National Institute of Standards, is 100  $\mu\text{g}$ . Instead of accurate measurement, OSHA and NIOSH seek to measure silica by a standard that includes and accepts massive error: +/- 25% of the true value, 95% of the time.<sup>48</sup>

OSHA seeks to impose a rule that accepts anywhere between 75 cents to 125 cents, as accurate change for one dollar, except for 5% of the time when the change is even more inaccurate. Nothing in the OSH Act or any other governing authority permits the agency to satisfy feasibility mandates with massively inaccurate measurement techniques and a new definition.

Comments and testimony that sought to dismiss this critical rulemaking problem by pronouncing the proposal feasible, using this definition, were both unsubstantiated and factually wrong.<sup>49</sup> These witnesses and commenters failed to provide evidence supporting their accuracy claim or refute the evidence to the contrary demonstrating that OSHA could not even meet its own revisionist definition.

Repeated statements at the public hearing demonstrated the lack of accuracy of the OSHA measuring system, even using OSHA’s definition. First, a NIOSH witness admitted, when asked by the Chamber’s Counsel, that the OSHA lab produced highly variable, inaccurate results: “There are additional sources of error in real world samples. Pump rates, for example, operator error, things like that... You need to have 75 percent or greater acceptable results to pass the PT [Proficiency Analysis Testing] round.”<sup>50</sup> “You could be off 25 percent on one of the four samples.”<sup>51</sup>

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<sup>46</sup> 29 U.S.C. 655(b), 5 U.S.C. 553, 5 U.S.C. 706.

<sup>47</sup> *Accurate Definition*, MERRIAM-WEBSTER.COM, <http://www.merriam-webster.com/dictionary/accurate> (last visited July 17, 2014).

<sup>48</sup> Comments of the U.S. Chamber of Commerce, OSHA-2010-0034-2288 (revised at 4194), p. 17.

<sup>49</sup> *See e.g.*, Rosa Key-Shwartz at Tr.3579, 148-223, Dr. Paul Shulte at Tr.3579, 124-43, Peg Seminario at Tr.3578, 915-33, Franklin Mirer at Tr.3578, 933-49, Bill Walsh at Tr.3586, 3281-94, and Rami Katrib at Tr.3584, 2532-37, 2585-2586.

<sup>50</sup> Tr.3586, 3290.

Second, an OSHA panel member responded to actual, documented evidence and data demonstrating the inaccuracy of the OSHA silica measurement system, presented by Chamber of Commerce witness Mr. Robert Lieckfield by stating: “[b]ut would you also be interested or surprised to know that I have done statistical calculations like that with internal OSHA data, and the lower spike samples actually have a better accuracy and precision than the sample set as a whole.”<sup>52</sup> While the Chamber sought release of this undisclosed data, it was not forthcoming or available for public comment. And, despite assurances from OSHA during the hearing that “[w]e will make the data from Salt Lake City Lab that was referred to, we’ll put that in the record”<sup>53</sup> to date, the Chamber has been unable to locate this information in the docket.

Third, the organization which operates and manages the Proficiency Analysis Testing (“PAT”) program, comparing many lab results of standardized samples, including the OSHA lab, admitted that they had to “winsorise” round robin testing results by not using the high readings, even to produce the PAT results showing very high variability of analysis results: “we do a process called winsorising the data, and that is where the outliers, and I am not a statistical expert and I cannot speak to it in greater detail, but that will help us to remove and identify the outliers... Winsorizing is our standard process.”<sup>54</sup>

During the hearing on March 18, 2014, a NIOSH witness indicated that, “[t]he current proposal by OSHA ... is measured by techniques that are valid, reproducible, attainable with existing technologies, and available to industry and government agencies.”<sup>55</sup> Without providing any discussion or data about the actual accuracy of the results, methods and technology, Ms. Rosa Key-Shwartz from NIOSH indicated that technologies NIOSH was referring to were: 1) the NIOSH 7500 method utilizing X-ray diffraction, and 2) the Dorr-Oliver, the SKC and the aluminum cyclone, Higgins-Dewell.<sup>56</sup> Yet, Dr. Paul Shulte from NIOSH admitted that “additional laboratory requirements are needed to increase reliability and reduce inter-laboratory variability.”<sup>57</sup>

As discussed in testimony outlined below from Dr. Thomas Hall, Robert Lieckfield, Paul Scott, Kelly Bailey and Dr. Richard Lee, the variability and errors associated with the sampling system and analyses demonstrate that the OSHA analytical method will not even meet the OSHA revisionist definition of accuracy at the OSHA PEL and AL.

We emphasize that for a feasibility analysis and determination, the rulemaking issue is not the “limit of detection” (LOD) for silica, which some witnesses confused with accurate measurements of exposure at regulated levels. The LOD is the smallest quantity of crystalline silica that can be detected with the laboratory equipment in use, with accepting a certain degree of error.<sup>58</sup> Comments and testimony that confuse the detection limit with “accuracy” are misleading and irrelevant to the PEL and

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<sup>51</sup> *Id.*, 3292.

<sup>52</sup> Tr.3576, 516.

<sup>53</sup> Tr.3576, 518.

<sup>54</sup> Tr.3586, 3295-96.

<sup>55</sup> Tr.3579, 126.

<sup>56</sup> Tr.3576, 219-20.

<sup>57</sup> Tr.3579, 133.

<sup>58</sup> Silica PEA, Chapter IV, p. IV-4.

AL, which require “accuracy” to determine if a quantity of respirable silica, collected and measured to represent an employee’s exposure meets or exceeds the PEL and AL. In other words, a lab’s ability to detect 10µg of silica, more than 50% of the time, does not render an exposure estimate at 25 µg/m<sup>3</sup> or 50 µg/m<sup>3</sup> accurate (even for purposes of OSHA’s revisionist definition of 25% of its true value, 95% of the time).<sup>59</sup>

**a. Variability attributed to analysis methods**

In his oral testimony presented at the April 1, 2014 hearing, Bill Walsh from the Analytical Accreditation Board of the AIHA Laboratory Accreditations Program (LAP) addressed silica sample analysis:

[t]he AIHA LAP has reviewed OSHA’s analysis in the proposed rule on sampling and analytical methods that can be used to measure airborne crystalline silica and agrees with OSHA that the x-ray diffraction and infrared spectroscopy methods of analysis are both sufficient to quantify levels of quartz and cristobalite that would be collected on air samples taken from concentrations at the proposed PEL and action levels. We have also reviewed the data from OSHA’s Salt Lake City Technical Center on lower filter loadings which has shown an acceptable level of precision analyzing samples at 40 µg and 20 µg. *While that data show acceptable precision and analysis, we recognize that more work needs to be done to prove analytical methods for silica especially if labs are going to be able to produce reliable data at or below the proposed action level of 25 µg/m<sup>3</sup>.*<sup>60</sup>

However, Mr. Walsh and his colleagues, while endorsing OSHA methods and precision (repeated inaccurate results are precise, but still inaccurate), did not testify to accuracy (the true value of the exposure versus the OSHA results). Moreover, Mr. Walsh agreed that “[t]here are additional sources of error in real world samples. Pump rates, for example, operator error, things like that.”<sup>61</sup> None of these error factors, and sampling location and time variations, were taken into account in the endorsement testimony for the OSHA lab performance.

While Mr. Walsh is correct that additional sources of error exist, he improperly implied the feasibility of accurately analyzing silica samples for compliance with the PEL and AL. As Mr. Lieckfield indicated in his comments, the NIOSH Manual of Analytical Methods, Chapter R, specifically notes that, “Current analysis methods do not have sufficient accuracy to monitor below current standards.” In addition, he noted that the “AIHA PAT – [round robin lab tests] 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<sub>95</sub> 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....”<sup>62</sup>

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<sup>59</sup> Tr.3576, 444-446.

<sup>60</sup> Tr.3586, 3284-85 (emphasis added).

<sup>61</sup> Tr.3579, 329 (emphasis added).

<sup>62</sup> Appendix 8 to the U.S. Chamber of Commerce Comments submitted February 11, 2014, OSHA-2010-0034-2259, p. 2.

Overall, none of the participants at the hearing offered evidence to show that technological feasibility has been achieved in measuring and analyzing respirable silica dust accurately at the proposed PEL and AL. Rather, the testimony and data presented provides valid, credible, overwhelming evidence of the deficiencies in the proposed rule and OSHA's analysis.<sup>63</sup>

**b. Issues pertaining to high rate sample collection and particle size**

Responding to a question from Mr. Scott Schneider from the Laborers' Health and Safety Fund of North America, Mr. Walsh noted that "the greater the air volume the lower the measured amount. As long as the cyclones pulling at the four micron cut point, it's irrelevant as far as the analysis is concerned."<sup>64</sup> Yet, Mr. Walsh's confidence was not anchored by sound science.

The importance of particle size to accurate measurements of respirable silica dust exposure is critical. Only certain small sized particles are recognized to present inhalation hazards and excessive collection of "oversize particles" for a sample is recognized as contamination. Oversize particles also impact lab analysis techniques (e.g. interfere with X-ray diffraction analysis) which further contributes to sample contamination.

Several commenters testified to the limitations of the use of high-flow samplers. First, the need to evaluate accuracy with these samplers is important because studies by Lee et al. in 2010 and 2012 indicate that the high-flow rate samplers tend to collect a higher proportion of larger-size particles than the lower-flow rate samplers currently use. Lee et al. in 2010 found that the BGI GK 2.69 high-flow sampler had a large bias for particles with a large mass mean aerodynamic diameter. In general, all three high-flow samplers evaluated by Lee et al., 2010, tended to have a substantial bias towards collecting larger particulates than the low-flow samplers, collecting between 12% and 31% more mass than the low-flow samplers, thereby negating any relationship to the basis of the scientific literature on health risks and providing biased results that inaccurately increase reported dust levels above accurate exposure levels.

**IV. Serious notice and comment defects violate fundamental principles of due process and OSHA's rulemaking mandates.**

The process of notice and comment rulemaking is not to be an empty charade. It is to be a process of reasoned decision-making. One particularly important component of the

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<sup>63</sup> Problems created by measurement inaccuracy resulting from the proposed rule, go much further than the ones noted above. During the March 26, 2014 hearing, Paul Scott from Cardno ChemRisk, LLC, testified that "the use of the Salt Lake Technical Center evaluation to estimate analytical error by OSHA fails to account for several sources of analytical error that include the effective differences in particle sizes on the analysis of silica by x-ray diffraction and infrared methods; the effect of potential interferences on these two analytical methods; the effect of inter-laboratory differences in sample preparation methods, calibration standards, and the implementation of the x-ray diffraction and infrared methods; and, finally, the effect of inter-laboratory differences caused by differences in analysts and sample preparation methods, as well as variability in the actual analysis run. By failing to account for these additional sources of analytical error, OSHA calculates an overly optimistic value for precision based on artificially low value of analytical error." Tr.3581, 1970-71.

<sup>64</sup> Tr.3586, 3287.

reasoning process is the opportunity for interested parties to parties to participate in a *meaningful* way in the discussion and final formulation of rules.

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The purpose of the comment period is to allow interested members of the public to communicate information, concerns, and criticisms to the agency during the rulemaking process....<sup>65</sup>

OSHA has sought to rush this regulation, rather than develop a standard based on reasoned decision-making, using sound science, evidence and a transparent risk assessment. For example, an OSHA promised, outside, independent and public scientific peer review of the silica risk assessment<sup>66</sup> was canceled, in favor of a private, OSHA controlled alleged “peer review.” OSHA also refused to conduct a meaningful small business panel review under the Small Business Regulatory Enforcement Fairness Act, despite the fact the one in the record was done in 2003, under industry and economic conditions that have changed significantly since then.

In addition, the initial regulatory package submitted to OIRA on February 14, 2011 had no analysis of the impact on the hydraulic fracturing (fracking) industry, one of the industries most severely affected by this proposed rule. Only after short, inadequate and last minute reports were developed was the fracking industry discussed in the pending rule, and then in such a superficial and inadequate way as to make the analysis worthless.<sup>67</sup>

Further, the administrative hearings were extraordinarily biased, with dissent and scientific inquiry suppressed by OSHA ignoring objections, and limiting the availability of its personnel and rule supporters to questioning by industry representatives. Chamber counsel had prepared over 200 probing questions, but was granted only a single five minute time slot to question OSHA experts, with no succeeding rounds of questions, or an opportunity to submit written questions. Conversely, when the Chamber experts testified, they were subject to extensive and unlimited questions from agency representatives, and rule proponents of the rule were given multiple rounds of questioning to interrogate them.

As discussed below, a large tranche of documents was added to the docket by OSHA, after the rulemaking hearing. The documents included roughly 1000, mostly copyrighted articles that are not publicly available without cost (other than in OSHA’s DC office). The process and timing OSHA used to “salt” the record does not allow a reasonable and meaningful opportunity for review and comment. It is another example of OSHA’s rush to adopt the proposed rule, preventing legitimate questions from being raised.

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<sup>65</sup> *Connecticut Light and Power v. Nuclear Regulatory Comm’n*, 673 F.2d 525, 528 (D.C. Cir. 1982)(citations omitted).

<sup>66</sup> OSHA Peer Review Agenda, Last Updated February 2014 available at: [https://www.osha.gov/dsg/peer\\_review/peer\\_agenda.html](https://www.osha.gov/dsg/peer_review/peer_agenda.html).

<sup>67</sup> Tr.3576, 447-461.

**a. Comment Period Deficiencies**

1. *OSHA failed to provide interested parties adequate time to review, analyze and comment on its proposal and its evidence.*

On August 23, 2013 OSHA released a copy of the 757 pages of its proposed rule, which was published in the Federal Register on September 12, 2013. At the time of the release of the proposed rule, the docket contained roughly 1715 supporting materials and documents. While admittedly the timeframe for comments exceeded the minimum period under the OSH Act, the time permitted was inadequate given the magnitude and complexity of this rulemaking.

Moreover, hearing participants had inadequate time to prepare for the public hearings. The written comment period ended on February 11, 2014 and the public hearings began four weeks later on March 18, 2014. For these public hearings to have been a true open dialogue that elaborates, clarifies, responds to, and tests the validity of the initial comments, hearing participants should have been afforded more time to prepare their testimony and questions for other participants.

2. *Evidence relied upon by OSHA in this rulemaking has not been released to the public for comment.*

In order to allow for useful criticism, it is especially important for the agency to identify and make available technical studies and data that it has employed in reaching the decisions to propose particular rules. To allow an agency to play hunt the peanut with technical information, hiding or disguising the information it employs, is to condone a practice in which the agency treats what should be a genuine interchange as mere bureaucratic sport. An agency commits serious procedural error when it fails to reveal portions of the technical basis for a proposed rule in time to allow meaningful commentary.<sup>68</sup>

During the hearing, one of OSHA's chemists at the agency's Salt Lake Technical Center, Mr. B.J. Albrecht, made clear that data OSHA relied on was not available in the record: "[b]ut would you also be interested or surprised to know that I have done statistical calculations like that with internal OSHA data, and the lower spike samples actually have a better accuracy and precision than the sample set as a whole."<sup>69</sup> Since the accuracy of OSHA's measurement system is in debate, such data is crucial to this rulemaking and should have been made available for public comment. Failure to disclose this information is a fatal procedural error under the APA's notice and comment requirements.

Despite assurances from OSHA during the hearing that "[w]e will make the data from Salt Lake City Lab that was referred to, we'll put that in the record"<sup>70</sup> to date, the Chamber has been unable to locate this information in the docket.<sup>71</sup>

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<sup>68</sup> *Connecticut Light & Power*, 673 F.2d at 530-31.

<sup>69</sup> Tr.3576, 516.

<sup>70</sup> *Id.*, 518.

<sup>71</sup> *Hanover Potato Products, Inc., et. al.* 989 F.2d 123, 130 (3rd Cir. 1993)(making clear that the burden to determine the completeness of an administrative record is on the agency because interested parties would not "even known in which

## **b. Informal Public Hearing Deficiencies**

### *1. Insufficient opportunity to seek clarification and question OSHA's panel*

Although promoted as being open and neutral, the informal public hearing was biased and prohibited open dialogue and questions from the public. OSHA made clear that it was not interested in answering questions from interested and affected parties.<sup>72</sup> In short, the hearing served as a means for OSHA to seek to refute comments from opposition witnesses and develop a record to serve the Agency's pre-determined result.

Perhaps the most important segment of the hearing, the opportunity to question OSHA's panel of technical experts, was severely circumscribed. Participants were given only five minutes with no additional rounds of questions, despite repeated objections from many participants that this time was insufficient. For example, the Chamber's Counsel stated "I think I have enough questions to take probably an hour, but five minutes, I'll do my best to get as much as I can in."<sup>73</sup> Similarly, American Chemistry Council's attorney noted, "I also have too many questions to finish in a few minutes."<sup>74</sup> Even Mr. Eric Frumin with Change to Win (a supporter of the regulation) noted that he had "too many questions to cover in the time allotted. So I'd certainly like to be able to ask some more."<sup>75</sup>

Despite the insufficient time to question OSHA's panel, some participants were willing to reduce their questions to writing as the hearing judge suggested.<sup>76</sup> However, OSHA was insistent that questions to the panel be restricted to the scheduled period in the hearing which was essentially two hours the morning of the first hearing date, March 18, 2014. Despite repeated statements by OSHA that "the main purpose of this hearing is to develop the record" and "the main purpose of this hearing is to expand and improve the record so that OSHA can do, create the best rulemaking possible" OSHA was more interested in seeking support for its proposed rule by asking its own question, "because that's really important for developing the record."<sup>77</sup>

At times OSHA even refused to answer legitimate questions that came up during the testimony and questioning of hearing participants. For example, during testimony and questioning of NIOSH witnesses, the Chamber's Counsel directed a question to Ms. Key-Schwartz, a NIOSH representative. In response, Ms. Key-Schwartz, who did not appear to know the answer stated, "I'd like for OSHA maybe to address that." In response Mr. O'Connor, OSHA's Director of the Office of Chemical Hazards stated, "OSHA's questioning session has concluded."<sup>78</sup> These are not the actions of an Agency committed to

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instances it was required to look since the absence of key supporting documentation would rarely if ever be evidence from the record itself.")

<sup>72</sup> Tr.3579, 43, 91, 121.

<sup>73</sup> *Id.*, 31.

<sup>74</sup> *Id.*, 43.

<sup>75</sup> *Id.*, 53.

<sup>76</sup> *Id.*, 37.

<sup>77</sup> *Id.*, 43-44.

<sup>78</sup> *Id.*, 155.

developing an accurate, clear, fair, and complete record. Rather such obstinacy suggests that OSHA is “playing hunt the peanut with technical information.”<sup>79</sup>

OSHA’s position in this rulemaking is in stark contrast to how the Agency handled the rulemaking for the proposed Ergonomics Program rule.<sup>80</sup> Specifically, in that rulemaking OSHA allowed two full days for participants to question the OSHA panel.<sup>81</sup> “[E]ach member of the public had up to one hour and five minutes to question the OSHA panel.”<sup>82</sup> OSHA recognized that questioning by the public was part of “developing the record” and was an essential part of the rulemaking process even going so far as to “ced[e] some of its own time for questioning to industry and labor.”<sup>83</sup> Similar to the proposed rule for the Ergonomics Program, the proposed rule for regulating crystalline silica has major implications and impacts a wide array of employers in the United States. This is just as significant of a proposed rule as the Ergonomics Program and the disparity between the two hearings is unjustified.

Having a genuine dialogue involves the Agency being willing to undergo criticism of the rationale, evidence, data and studies used and relied upon in proposing the rule. It is precisely this criticism that allows the Agency to develop an accurate and complete record. The denial of sufficient time to ask questions encumbers participants in providing meaningful comments because participants are left to guess or speculate as to the Agency’s reasons, or draw assumptions which could be made clear through a simple exchange of questions and answers. Moreover, the purpose of the informal administrative hearing is not limited to gathering information. As with all informal hearings, the post-hearing procedures made clear that the proceeding is “intended for information gathering *and clarification*. This hearing is an adjunct to the written comment period, and is intended to provide interested persons with an additional opportunity to address the Agency.... These procedural rules governing the hearing are intended to facilitate the development of a clear, accurate and complete record, while assuring fairness and due process.”<sup>84</sup> “Moreover, a dialogue is a two-way street: the opportunity to comment is meaningless unless the agency responds to significant points raised by the public.”<sup>85</sup>

In addition to failing to provide sufficient time for questioning, many participants were cut off during questioning and/or prohibited from asking follow-up questions. Typically these participants were critical of the proposed rule and OSHA’s rationale and methodologies and were seeking clarification. For example, during the March 18<sup>th</sup> hearing the Chamber’s Counsel was questioning NIOSH’s Director of Division of Applied Research and Technology, Ms. Key-Schwartz, when Administrative Law Judge Solomon stated, “You’re at the end. You can answer the question, but this will be it. This is last one.”<sup>86</sup> The Chamber’s counsel noted for the record that “I have a lot more questions that I would like to ask but

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<sup>79</sup> *Connecticut Light & Power*, 673 F.2d at 530.

<sup>80</sup> The hearings for the Ergonomics Program standard allowed multiple rounds of questioning and in contrast to the silica hearings the Agency encouraged questions. “The OSHA Panel will be happy to answer your questions on the proposed rule and the supporting analyses underlying it.” Ergonomics Program Standard Committee, Volume 1, Monday, March 13, 2000 p. 1-26.

<sup>81</sup> 65 Fed. Reg. 68261 (Nov. 14, 2000)

<sup>82</sup> *Id.*

<sup>83</sup> *Id.*

<sup>84</sup> [https://www.osha.gov/silica/hearing\\_procedures.html](https://www.osha.gov/silica/hearing_procedures.html) (emphasis added).

<sup>85</sup> *Home Box Office v. FCC*, 567 F.2d 9, 35-36 (D.C. Cir. 1977).

<sup>86</sup> Tr.3579, 159.

I'm not being allowed to ask for answers....”<sup>87</sup> In contrast, the presiding administrative judge appeared to give leeway to labor participants where they exceeded their five minutes and sought to ask additional questions. For example, that same hearing day, when told that her five minutes were up, Ms. Chris Trahan, with the Building and Construction Trades Department (“BCTD”) stated, “Okay. Can I just ask a couple of more....”<sup>88</sup> ALJ Solomon allowed her to continue with additional questions.<sup>89</sup>

The record is replete with similar examples of leeway provided to labor participants and those generally supportive of OSHA’s proposed rule. During the March 24<sup>th</sup> hearing, the Construction Industry Safety Coalition (“CISC”) panel was questioned extensively by Ms. Elizabeth Nadeau with the International Union of Operating Engineers. After asking at least seven questions, which undoubtedly exceeded five minutes, Judge Solomon asked Ms. Nadeau “How much more do you have?”<sup>90</sup> To which she replied, “Just a couple more.”<sup>91</sup> And again, Judge Solomon allowed Ms. Nadeau to continue with an additional five questions. Similarly, the CISC was questioned by Ms. Trahan with the BCTD. Ms. Trahan asked more than twenty-one questions and, rather than abruptly end her questioning, Judge Solomon again asked, “How much more do you have?”<sup>92</sup> In comparison, Mr. Robert Matuga with the National Association of Home Builders was permitted to only ask four questions before Judge Solomon abruptly stopped him stating, “Okay. Mr. Schneider [with the Laborers’ Health and Safety Fund] has been waiting for quite some time.”<sup>93</sup> Mr. Matuga requested to ask one more quick follow-up question to which Judge Solomon responded, “No. No, you can’t. What can I say....”<sup>94</sup>

While the Chamber recognizes that the administrative law judge, was in part, needed to ensure that the hearing was conducted in an orderly manner, he was required to conduct the hearing in a fair and impartial manner. For significant and critical portions of the public hearings this was not the case. The bias displayed in allotting time for participants to ask questions hindered the public’s participation in these informal public hearings and served only to develop a record seeking to support the Agency’s pre-determined position and findings and deepen suspicion that OSHA is intent on pushing this regulation through the process regardless of the substantive issues presented during the rulemaking.

## *2. All hearings were held in one location - Washington, D.C.*

In accordance with Section 6(b)(3) of the OSH Act, OSHA must conduct public hearings when requested during the rulemaking process. Here, OSHA conducted three weeks of informal public hearings with each day of the hearings being held in Washington D.C. For such a significant rulemaking that has the potential to impact a significant number of employers across the nation, the lack of geographical diversity failed to accommodate all members of the public who sought to testify.

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<sup>87</sup> *Id.*

<sup>88</sup> Tr.3579, 98.

<sup>89</sup> *Id.*

<sup>90</sup> Tr.3580, 1391.

<sup>91</sup> *Id.*, 1392

<sup>92</sup> *Id.*, 1418.

<sup>93</sup> *Id.*, 1430.

<sup>94</sup> *Id.*

The Agency has frequently held informal public hearings in locations other than Washington D.C. to provide greater access for the impacted public to provide testimony. For example, the informal public hearings for the proposed rule on the Ergonomics Program standard not only lasted for nine weeks but were held in three locations – Washington D.C., Portland, OR and Chicago, IL.<sup>95</sup> Additionally, OSHA held informal public hearings for the revisions to the Hazard Communication standard in Pittsburgh, PA and Los Angeles, CA, as well as Washington D.C.<sup>96</sup> OSHA also held public hearings in locations other than Washington D.C. for its proposed rule on Occupational Tuberculosis including Chicago, Los Angeles, and New York City.<sup>97</sup>

The Agency's statement in the Tuberculosis proposed rule equally applies to the Crystalline Silica proposed rule.

Because the proposed standard will impact employees and employers across the nation, the Agency believes that is appropriate to hold public hearings at additional sites in order to give parties who may not be able to attend the hearings in Washington, D.C., an opportunity to participate in the public hearing process. OSHA has found that the hearings provide an important forum for interested parties to submit their comments and concerns on OSHA's proposed rulemakings and that the hearings provide the Agency with valuable information in developing its final standards.<sup>98</sup>

Often, local Chambers of Commerce, small to mid-sized employers, and employees do not have the resources to travel to Washington D.C. to testify in response to a proposed rule. As such, the majority of commenters during these hearings were trade associations, unions, and manufacturers. While trade associations speak for the interests of members, they are not a substitute for the first-hand testimony of employers and employees directly impacted by the proposed rule who can speak directly to the implications on business, jobs, and the feasibility of compliance. By choosing to hold all three weeks of public hearings in Washington D.C., OSHA failed to provide countless interested parties an opportunity to participate in the public hearing process.

### **c. Post-Hearing Comment Period Deficiencies**

The hearing procedures established by OSHA allowed participants who filed notices of intent to appear to submit additional information and data through June 3, 2014, and final briefs, arguments, and summations are due on August 18, 2014, pursuant to a June 17, 2014, OSHA notice which stated:

Due to the volume of additional data and information added to the docket, the Assistant Secretary has determined that it is appropriate to offer participants additional time to prepare their post-hearing briefs. The period for submitting final briefs, arguments, and summations is being extended by 31 days. Therefore, participants who filed notices of intent to appear will be permitted to file final briefs, arguments, and summations through

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<sup>95</sup> 65 Fed. Reg. 68831.

<sup>96</sup> 77 Fed. Reg. 17574 (Mar. 26, 2012).

<sup>97</sup> 62 Fed. Reg. 65388.

<sup>98</sup> *Id.*

Monday, August 18, 2014.

While the Chamber appreciates the extension of 31 days, it falls short of adequately providing due process. The Agency recognizes and admits that a considerable amount of new data was added to the docket, but OSHA downplayed the extent and magnitude of the data and evidence it entered into the record since the closing of the administrative hearings.

From May 29 through June 10, 2014, almost 1,000 documents were added to the docket as additional evidence or data allegedly relevant to this rulemaking. Most of the roughly 1,000 documents submitted are scientific articles, silica dust control studies, medical surveillance studies and scientific evidence on health effects. Over 525 of these documents were posted as new “Supporting and Related Materials” by OSHA. Of these 525 documents more than 396 are copyrighted and are only viewable in the OSHA Docket Office/Technical Data Center.

Another approximately 415 documents were submitted as attachments to post-hearing evidence and data submissions. For example, on June 3, 2014, the AFL-CIO submitted a cover letter along with 73 documentary evidence attachments. These documents are not reflected individually in the docket but rather all fall under the initial submission. Similarly, the BCTD of the AFL-CIO submitted a cover letter along with 96 documentary evidence attachments. Thirty-two of the 96 documents are copyright protected, and one document alone lists 422 websites with links to alleged commercially available equipment-control options for specific construction related tasks such as abrasive blasting, cutting, sawing, grinding.

Additionally, the National Institute for Occupational Safety and Health (“NIOSH”) submitted a cover letter and 97 documentary evidence attachments. Again, a great majority of these documents are copyrighted, over 70 attachments, and are only available upon inspection in OSHA’s Docket Office.

Because of the vast amount of new material added to the docket and questions about its relevancy and how OSHA would rely on it, the American Chemistry Council, the American Foundry Society, and the Chamber requested that OSHA publish a Notice of Data Availability (NODA) in the Federal Register: (1) soliciting comments on the additional data and evidence submitted to the docket since the end of the administrative hearings; (2) reopen the docket for comments regarding this additional data and evidence.

NODAs are routinely used by the Environmental Protection Agency, the Department of Energy and other federal Agencies to announce the availability of data, how such data impacts a proposed rule and request public comment on such data. For example, in June 2012 the EPA issued an NODA on its proposed rule for cooling water intake structures the Agency had issued in April 2011.<sup>99</sup> In the NODA EPA explained that since issuing the proposed rule, it had received more than 80 studies providing additional data on cooling water intake structures at existing facilities.<sup>100</sup>

Unlike the EPA, OSHA claims that there will be no new findings as a result of the submission of

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<sup>99</sup> 77 *Fed. Reg.* 34315 (June 11, 2012).

<sup>100</sup> *Id.*

over 1000 new studies. In OSHA's response to the ACC, the agency acknowledged that the post-hearing submission of documents was "made in response to issues raised in public comments and testimony on the proposed rule, and to provide additional and updated evidence to inform the rulemaking."<sup>101</sup> But the Agency went on to claim, "[t]hese submissions do not represent any new findings by the Agency...."<sup>102</sup>

Without a full and public review and analysis of these submissions, OSHA cannot assert that the submissions do not represent any new findings. Such a statement suggests the Agency's own bias and implies that irrespective of what new evidence and data is submitted to the docket, the Agency will not adjust its findings accordingly. These are not actions of an agency open to opposing viewpoints. Rather, they suggest an agency that "in some measure adjudged the facts as well as the law...in advance of hearing it."<sup>103</sup>

The Agency's actions display a callous disregard of the entire notice and comment rulemaking process and are precisely the type of "play[ing] hunt the peanut with technical information, hiding or disguising the information" condemned by the courts.<sup>104</sup> Moreover, the Agency indicates that it "added documents from OSHA's hexavalent chromium rulemaking providing information on unit costs of certain engineering controls, as well as commercial catalogs with heavy construction equipment and dust control systems for updating estimates of engineering control costs."<sup>105</sup> Clearly these submissions represent new information and findings from an unrelated rulemaking that OSHA deemed useful and put in the record, but not in time for interested parties to evaluate and comment on.

Further, the U.S. Court of Appeals for the D.C. Circuit and the Fourth Circuit have made clear that a meaningful opportunity to comment involves "being aware of the information the agency finally decides to rely on in taking agency action."<sup>106</sup> "Notice must 'appris[e] the public of the nature and basis of the regulation or rule sufficiently to enable them to understand and identify the material issues relating to the justification for the regulation or rule so that they can comment thereon intelligently."<sup>107</sup>

OSHA's enormous document record dump did not apprise the public of what information the agency will rely on in taking final agency action or provide notice of what new evidence, if any, provides justification for the rule as currently drafted. While OSHA theoretically has made these documents available, they are meaningless without notification to the public about what information specifically the Agency considers relevant to the record and its decision making.<sup>108</sup>

The Agency's claim that these submissions do not represent any new findings or positions is

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<sup>101</sup> OSHA Docket No. OSHA-2010-0034-4193, posted June 18, 2014.

<sup>102</sup> *Id.*

<sup>103</sup> *United Steelworkers of Am. v. Marshall*, 647 F.2d 1189, 1209 (D.C. Cir. 1980).

<sup>104</sup> *Connecticut Light & Power*, 673 F.2d at 530.

<sup>105</sup> OSHA Docket OSHA-2010-0034-4193, posted June 18, 2014.

<sup>106</sup> *Ohio Valley Env'tl. Coal. v. United States Army Corps of Eng'gs*, 674 F. Supp. 2d 783, 803 (S.D. W. Va 2009) (citing to *Nat'l Asphalt Pavement Ass'n v. Train*, 539 F.2d 775, 779 n. 2 (D.C. Cir. 1976) and *Appalachian Power Co. v. EPA*, 579 F.2 846, 852-53 (4th Cir. 1978).

<sup>107</sup> *Id.*

<sup>108</sup> *Appalachian Power Co. v. EPA*, 579 F.2 846, 852-53 (4th Cir. 1978).

entirely disingenuous. This is particularly so when OSHA claims that “the Agency submitted documents in response to stakeholder comments on the costs, benefits, feasibility analysis, and underlying methodology in OSHA’s Preliminary Economic Analysis; health and risk analyses; and other aspects of the proposed rule.”<sup>109</sup> Clearly these documents are “new findings” supporting the Agency’s position.

Moreover, many of these documents, because of copyright issues, are only available in hard copy in the docket office, making access to them extremely restricted and burdensome. The only means of accessing most of this new data is either to purchase a copy or physically visit the docket office, which then requires an individual to sit and review the material, or a copy of the material, which must then be destroyed. OSHA’s actions and disregard for issuing an NODA have prevented “meaningful” comments and violate the notice and comment requirement of the OSH Act and the APA.

## V. Conclusion

The Agency’s actions throughout this rulemaking demonstrate a rush to issue a deeply flawed rule. The Agency’s predetermined results, and its denial of an opportunity for interested parties to submit full, complete meaningful comments and thus develop a complete and accurate record taint any residual sense of balance or benefit of the doubt OSHA would normally be due. As a result of these critical procedural shortcomings and the scientific, risk assessment, and feasibility flaws demonstrated earlier in this brief and the full comments submitted previously, the Chamber reiterates its strong belief that OSHA must withdraw this proposed rule as not meeting the requirements of the OSH Act and being arbitrary and capricious under the Administrative Procedure Act.

Sincerely,



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<sup>109</sup> OSHA Docket No. OSHA-2010-0034-4193, posted June 18, 2014.