ORAL ARGUMENT NOT YET SCHEDULED

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 16-1105(L)
(consolidated with Nos. 16-1113, 16-1125, 16-1126, 16-1131, 16-1137, 16-1138, and 16-1146)

NORTH AMERICA'S BUILDING TRADES UNIONS,

Petitioner,

v.

OCCUPATIONAL SAFETY & HEALTH ADMINISTRATION, AND UNITED STATES DEPARTMENT OF LABOR,

Respondents.

On Petitions for Review of a Final Rule of the United States Occupational Safety and Health Administration

JOINT REPLY BRIEF OF INDUSTRY PETITIONERS

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GLOSSARY

ACC	American Chemistry Council
AFS	American Foundry Society
COPD	Chronic obstructive pulmonary disease
Doc.ID.	Document Identification Number
ERG	Eastern Research Group
FEA	Final Economic Analysis and Final Regulatory Flexibility Analysis
FTE	Full time equivalent employee
JA	Joint Appendix
µg/m³	Micrograms per cubic meter of air
NIOSH	National Institute for Occupational Safety and Health
NMRD	Non-malignant respiratory disease
OIS	OSHA Information System
OSHA	Occupational Safety and Health Administration
OSH Act	Occupational Safety and Health Act of 1970
PEL	Permissible exposure limit
PLHCP	Physician or other licensed health care professional

STATUTES AND REGULATIONS

All applicable statutes and regulations are contained in the addenda to the Joint Opening Brief for Industry Petitioners ("Ind.Br.") and the Joint Brief of Union Petitioners.

SUMMARY OF ARGUMENT

The burden was on the Occupational Safety and Health Administration ("OSHA") in the rulemaking to demonstrate, through substantial evidence, that replacing the prior permissible exposure limit ("PEL") with the drastically more stringent 50 $\mu g/m^3$ PEL was "reasonably necessary and appropriate to remedy a significant risk of material health impairment." *See Indus. Union Dep't, AFL-CIO v. American Petroleum Inst.*, 448 U.S. 607, 639 (1980) ("*Benzene*"). OSHA fails at all points to support its determination that significant risk existed at the prior PEL or that the new PEL is justified.

OSHA's conduct of the rulemaking was a textbook exercise in confirmation bias. With respect to each of the disease endpoints at issue in this rulemaking, OSHA picked its way through the record, selecting only evidence that might support a more stringent PEL. At the same time, OSHA rejected (or ignored altogether) all evidence that was contrary to that foreordained goal.

Of particular significance, OSHA fails to justify its refusal to account in any meaningful way for the reality that considerable scientific uncertainty exists about

whether there is a level of exposure to respirable crystalline silica ("silica") – a threshold – below which no one suffers any ill effects. This failure alone condemns the final Rule.

Additionally, OSHA provides no justification for its arbitrary decision to subject the brick industry to the new standard, while simultaneously declining to subject the nearly identically-placed sorptive minerals industry to the standard, and should be rejected as an arbitrary and capricious action. OSHA has failed altogether to address the brick industry's arguments regarding the economic infeasibility of the new PEL. As the new standard poses potentially catastrophic consequences for the brick industry, OSHA's abuse of discretion demands *vacatur*.

As with its analysis of significant risk, OSHA has completely failed to meet its burden of demonstrating that the Rule is feasible in the foundry, hydraulic fracturing, and construction industries. Of particular importance, OSHA ignores key evidence of exposure variability in certain industries, variability that makes the revised PEL unattainable in most operations most of the time. OSHA also cherry-picks information from the record that supports its preordained feasibility conclusions, while ignoring the best available evidence provided by experts in the affected industries. Further, for both its technological and economic feasibility analyses, OSHA adopts assumptions that do not reflect the real world at all.

The Agency's failings in the critical areas of significant risk and feasibility emerge from a backdrop of rulemaking procedural errors that run afoul of OSHA's own authorizing statute and deprived affected parties of notice and a fair opportunity to rebut information in the rulemaking record. These errors coupled with OSHA's unwillingness to consider the best available evidence in the rulemaking record on significant risk and feasibility require that the Rule be vacated by this Court.

ARGUMENT

I. OSHA HAS FAILED TO SHOW THAT A SIGNIFICANT RISK OF MATERIAL HEALTH IMPAIRMENT EXISTS AT A PEL OF 100 µg/m^3 AND THAT A PEL OF 50 µg/m^3 IS JUSTIFIED.

A. OSHA Relies Impermissibly on Selective Evidence to Support Its Finding of Significance Risk for Each Disease Endpoint.

Industry Petitioners observed in their opening brief that the final rule was a "solution in search of a problem." Ind.Br. p.13. From 1968 to 2010, silicosis mortality rates declined by more than 90 percent in this country, reflecting the introduction and implementation in 1971 of a general industry PEL of 100 µg/m^3 and a construction industry/shipyard PEL of between 250 µg/m^3 and 500 µg/m^3, which standards the final rule has now replaced. OSHA has itself conceded that many of the silica-related deaths that did occur over that time were among those workers whose principal exposure to respirable crystalline silica "probably occurred" before those 1971 standards were introduced. 81 Fed. Reg. 16,285, 16,306 (Mar. 25, 2016) ("Silica Rule" or "Rule") (JA ____, ___). OSHA has further

acknowledged that its own enforcement data show that over the past decades exposures in excess of the prior PEL have been widespread in both general industry and construction, and that, in many cases, these overexposures have been quite severe. 81 Fed. Reg. at 16,296-297 (JA __-__).

In light of this, better enforcement on OSHA's part of the prior standards, and not much more stringent standards, would be the reasonable way to address those harms to worker health, attributable to silica exposures, which may still remain. As its own recitation of the history of the silica standards betrays, however, OSHA has long been eager to replace the 1971 standards, even if more stringent standards are not "reasonably necessary and appropriate to remedy a significant risk of material health impairment." *See Benzene*, 448 U.S. at 639. Lacking solid evidence to justify the new standards, OSHA has been driven to embrace confirmation bias – *i.e.*, selectively relying on information in the record, picking and choosing between various studies to support its finding of significant risk, and arbitrarily rejecting evidence contrary to that finding.

Industry Petitioners in their opening brief provided numerous examples of this confirmation bias. OSHA argues that "[t]hese same criticisms were a focus during the rulemaking," and contends that the Agency "carefully evaluated and disposed of petitioners' criticisms in the preamble" to the final rule. Respondent's Brief

("Resp.Br.") p.52.[1] OSHA's claim that it has already "carefully … disposed" of Industry Petitioners' challenges in this regard does not survive scrutiny.

OSHA opens its defense with a truism: "The so-called 'flaws' highlighted by petitioners affect all retrospective epidemiological studies to varying degrees." Resp.Br., p.52. Perhaps so, but this observation fails to respond to the charge that OSHA's biases led it to ignore the high degree of flaws in the studies on which it relied, leaving the final Rule unsupported by substantial evidence.

OSHA further protests that the "'best available evidence' standard does not expect the studies OSHA relies on to achieve a level of perfection or certainty that does not exist in the real world." Resp.Br. p.54, *citing Benzene*, 448 U.S. at 656. This statement is true, but it provides no defense to Industry Petitioners' objection that OSHA began its risk assessment with the conclusion it wished to reach already in view and then cobbled together evidence to support it. The "best available evidence" standard *does* demand more from the Agency than that. *See, e.g.*,

[1] OSHA also looks to smuggle in the wrong standard of review, asserting that it is "entitled to 'an extreme degree of deference' when it is 'evaluating scientific data within its technical expertise.'" Resp.Br. p.20, *quoting Nat'l Mining Ass'n v. Sec'y, U.S. Dep't of Labor*, 812 F.3d 843, 883-84 (11th Cir. 2016). OSHA's claim that its evaluation of "scientific data" deserves "extreme … deference" is based on cases arising under the federal Mine Safety & Health Act. By contrast, under the OSH Act, OSHA is required to support its standards with "substantial evidence," which provides for more rigorous scrutiny on the part of the reviewing court. *See* Ind.Br. pp.1-2.

Benzene, 448 U.S. at 656 (the "best available evidence" standard affords OSHA "some leeway where its findings must be made on the frontiers of scientific knowledge," with the Agency being allowed to "use conservative assumptions in interpreting data," provided that those assumptions "are supported by a *body of reputable scientific thought*." (emphasis added)). OSHA cannot credibly claim that findings are supported by a "body" of "scientific thought" where, as here, the Agency culled out certain favorable studies and at the same time failed to justify the rejection of studies deemed contrary to its preordained conclusion.[2]

OSHA's more specific defenses of its work fare no better. First, OSHA notes that it commissioned a separate quantitative analysis by ToxaChemica to "study the possible effects of exposure uncertainty … on OSHA's risk estimates." Resp.Br. p.54. According to OSHA, with respect to the risk estimates for lung cancer derived from the pooled data in Steenland *et al.* (2001), this analysis "found that neither random error in the underlying exposure estimates nor hypothetical systematic errors

[2] For this reason, Union Petitioners-Intervenors' reliance on *Public Citizen Health Research Group v. Tyson*, 796 F.2d 1479 (D.C. 1986) is misplaced. Quoting *Tyson*, they assert that OSHA should be seen as having acted "reasonably where, as here, it looks at a body of scientific literature on a substance's health effects and concludes that it 'paints a striking portrait of serious danger to workers.'" Union Pet.-Int. Br. at 9. If any "striking portrait of serious danger" is on display here, it is not derived from the "body" of scientific evidence but, rather, is the work of OSHA's hand, the Agency's having picked through that evidence in order to present a misleading picture.

in exposure estimation is likely to have substantially influenced" those risk estimates. *Id.*

OSHA misses the point completely. As was explained in comments on the proposed standard, the ToxaChemica analysis was fatally flawed because it was "based on inappropriate methods" to determine the effects of uncertainty on risk estimates and reflected "personal beliefs and unjustified assumptions." Doc.ID.2307, p.70 (JA __). As a consequence of those flaws, the "likely effects of exposure estimations errors" in the studies on which OSHA relied had not been addressed using "relevant, validated, technically appropriate, or biologically plausible models and methods." *Id.*

With respect to silicosis mortality, OSHA concedes that its modeling of errors in exposure estimates did have "more of an effect." Resp.Br. p.54. It was for this reason, OSHA says, the Agency "incorporated the simulated error into its risk estimates, based on Mannetje *et al.* (2002), for this [disease] endpoint." *Id.* Even after accounting for potential errors in its exposure estimates, OSHA's reliance on the Mannetje *et al.* study is misplaced. As was pointed out in the American Chemistry Council("ACC") Comments, there is "no statistically significant difference in the odds ratios for silicosis mortality associated with different estimated cumulative exposures" in the Mannetje pooled analysis. Doc.ID.2307, p.114 (JA __). Indeed, "despite order-of-magnitude differences between high and

low estimated exposures, their confidence intervals all overlap" and the "exposure-response relation is not even fully monotonic." *Id.* For that reason, the Mannetje study cannot provide a "reliable basis for estimating the risk of silicosis mortality." *Id.* at 115 (JA __).

In short, while OSHA claims that, "to the extent possible," it "analyzed and accounted for exposure estimation error in its risk estimates," and "conclud[ed] that such error did not substantially affect the results in the majority of studies examined," Resp.Br. pp.54-55, the Agency fails to appreciate the serious flaws in those studies on which it relies. For that reason alone, OSHA cannot plausibly claim that its risk assessment is grounded in substantial evidence.

Second, with respect to the Park, *et al.* (2002) study, on which OSHA places great weight in support of its projection of nonmalignant respiratory disease ("NMRD") mortality risks at exposure levels below 100 $\mu g/m^3$, a principal concern voiced by Industry Petitioners is that OSHA had failed in the rulemaking to address the ACC's assertion that the Agency had wrongly assumed that cumulative exposure is the only relevant metric. Short-term, high-level exposure should have also been considered. In response, OSHA simply repeats that it "continues to believe, as stated in the preamble, that 'the ACC's characterization of exposures in the Park *et al.* study as vastly higher than the final and former PELs is incorrect.'" Resp.Br. p.55, *citing* 81 Fed. Reg. at 16,318.

OSHA's defense of the Park *et al.* study on this basis flows from its claim that the Agency's exclusive reliance on a cumulative exposure model for its risk assessment was proper. This claim fails, as is explained in part B below. Further, as was explained in the ACC Comments, the Vacek *et al.* (2011) study of the Vermont granite worker cohort had found no positive association between cumulative silica exposure and NMRD mortality except in the highest exposure category – and, even there, only a non-significant elevated odds ratio was observed – and the "trend test was far from being significant." Doc.ID.2307, p.106, *quoting* Morfeld Comment, p.29 (JA__).

Further, OSHA simply ignores the update by Cherry *et al.* (2012) of the Stoke-on-Trent pottery workers cohort, which found a lack of dose-response between cumulative silica exposure and mortality from chronic obstructive pulmonary disease ("COPD"). Doc.ID.2307, p.106 (JA __). The authors observed that the "lack of dose-response lung COPD in more recent periods, or for [chronic non-malignant respiratory disease] at any period, require some consideration." *Id.* at 106-107 (JA__-__), *quoting* Cherry *et al.* The point is, the results of studies such as Vacek *et al.* and Cherry *et al.* – which OSHA disregards – cast serious doubt on the validity of the finding in Park *et al.* that there is an association between silica exposure and NMRD mortality.

Industry Petitioners also challenged OSHA's reliance on the Park *et al.* study because the results may reflect confounding by smoking. OSHA agrees that "comprehensive smoking data would be ideal," but claims Park had "performed 'internally standardized analyses,' which are 'less susceptible to confounding by smoking'" than some other studies. Resp.Br. p.56, *quoting* 81 Fed. Reg. at 16,318. OSHA concluded that Part *et al.*'s study "suggested that the risk of death from non-malignant respiratory disease 'based on this cohort are not likely to be exaggerated due to cohort members' smoking habits." *Id.*

OSHA reaches this convenient conclusion notwithstanding the Agency's acknowledgment that, while studies such as Park *et al.* suggest that "respirable crystalline silica increases the risk for mortality from nonmalignant respiratory disease (not including silicosis) in an exposure-related manner," it "appears that the risk is *strongly influenced* by smoking, and the effects of smoking and silica exposure may be synergistic." Doc.Id.1711, p.207 (emphasis added). This being true, OSHA's acceptance of the validity of the Park *et al.* findings, where the smoking habits for some 67 percent of the workers who died from non-malignant respiratory disease were unknown, is particularly problematic.

To prop up its position that there is a statistically significant link between silica exposure and lung cancer, in the absence of silicosis, OSHA defends its reliance on the older, smaller Attfield and Costello (2004) study of the Vermont

granite workers cohort (which found such a link) and its rejection of the more recent, larger, and more comprehensive study of the same cohort by Vacek *et al.* (which found no such link). OSHA's defense of its choice between these studies is illustrative of OSHA's inconsistent, results-oriented approach to data analysis.

OSHA begins by observing that "Petitioners' brief does not disclose that the Vacek study was financed by the ACC's Crystalline Silica Panel, an organization that vehemently opposes OSHA's Silica Rule." Resp.Br. p.57. With respect, this comment appears to be a calculated effort by OSHA's counsel to cast aspersions on the legitimacy of what was an independent, peer-reviewed scientific study. OSHA itself had noted in the preamble that the ACC Crystalline Silica Panel had funded the Vacek study, but nowhere did the Agency call into question the study's credibility on that basis. *See* 81 Fed. Reg. at 16,335 (JA__).

OSHA claims that it "comprehensively addressed the attributes and drawbacks of both Vacek *et al.* and Attfield and Costello in the preamble to the final rule." Resp.Br. p.57, *citing* 81 Fed. Reg. at 16,335-38. Not quite: an examination of the portion of the preamble to which OSHA makes reference reveals that the Agency addressed *only* what it identified as the "attributes" of Attfield and Costello and *only* what it perceived to be the "drawbacks" of Vacek *et al.* While OSHA does recite a few of the criticisms raised by commenters on the inferiority of the older Attfield and Costello study compared to the Vacek study, *see* 81 Fed. Reg. at 16,355

(JA__), at no point does OSHA respond to, much less actually attempt to rebut, any of those specific challenges.

To give but one example, after acknowledging comments that "Attfield and Costello's exposure estimates for sandblasters … were too low compared to Vacek *et al.*'s estimates," OSHA observes that Attfield and Costello had derived their estimates from another, much earlier study, and that, in turn, those estimates "were based on six published industrial hygiene measurement studies." 81 Fed. Reg. at 16,335 (JA__). Be that as it may, nowhere does OSHA respond to the pertinent point of the comment in question, which is that the values upon which Attfield and Costello relied "are simply not credible." *See* Doc.ID.2307, pp.39-40 (JA __-__).

Ultimately, OSHA "decided not to reject the Attfield and Costello study (2004) in favor of the Vacek *et al.* study as a basis for risk assessment," with the Agency maintaining that it had "performed an objective analysis" of the two studies. 81 Fed. Reg. at 16,338 (JA__). Yet nowhere has OSHA even attempted to engage the objections raised to the Agency's reliance on the older, smaller study, or address the flaws that commenters have identified.

OSHA's failure to do so is concerning. In the view of Dr. Cox, "using Attfield and Costello (2004) in preference Vacek *et al.* (2011) … appear[s] to reflect OSHA's own study selection, data selection, and confirmation biases." *See* Doc.ID.2307, p.47 (JA __), *quoting* Cox Comments, p.55. Now, on review, OSHA retreats to a

minimalist position, arguing that, "even if the Vacek study does not support a direct link between silica and lung cancer, it supports OSHA's *overall finding* of significant risk of material harm for workers who are exposed to silica." Resp.Br. p.59 (emphasis added). Even accounting for the leeway to which OSHA may be entitled where its "findings must be made on the frontiers of scientific knowledge," *Benzene*, 448 U.S. at 656, the Agency forfeits that privilege when it has so obviously considered only those studies that support its stated policy goals while ignoring the body of research that does not.

OSHA's treatment of renal disease exemplifies the flaws in the Agency's repeated insistence that whatever cherry-picked data it puts on display necessarily constitutes "substantial evidence." During the rulemaking, OSHA argued that silica exposure at the prior 100 $\mu g/m^3$ PEL created significant risk for renal disease, thus supposedly supporting the change to the PEL at issue. OSHA rejected the ACC Silica Panel's evidence that the renal disease risk estimates were "rank speculation," arguing that its risk findings were grounded in the "best available evidence." 81 Fed Reg. at 16,343 (JA __). After Industry Petitioners pointed out in their brief that, despite picking and choosing among the available studies and scientific data, OSHA failed entirely to make out a case that there was a significant risk of renal disease mortality at the prior PEL, the Agency conceded that the "evidence underlying its estimates for renal disease is less robust" than for the other disease endpoints.

Resp.Br. p.30 n.12. The Agency now asserts that it is relying "more heavily on its risk estimates for the other health endpoints as the bases for the Silica Rule." *Id.* A telling concession: what was once the "best available evidence" and, in OSHA's assessment "substantial," is now, at best, "less robust."

B. OSHA's Rejection of a Threshold for Silica-Related Respiratory Disease Is Not Supported by the Evidence.

OSHA conceded both in the final Rule and its brief that considerable scientific uncertainty exists about whether there is a threshold for silica exposure – that is, a level of exposure below which no one suffers ill effects. OSHA nevertheless holds fast to its conclusion that if a threshold exists it is "likely" well below the new PEL. Resp.Br. p.36. Accordingly, OSHA used only non-threshold exposure-response models in its risks assessments for silicosis and lung cancer. 81 Fed. Reg. at 16,351 (JA__). The Agency argues both that no threshold exists and that the threshold is below the PEL. Neither conclusion is supported by the best evidence.

OSHA's conclusion that no threshold exists is not based on any studies that specifically evaluate exposures at the prior or current PELs. Not one study in the record reliably separates out exposure above the prior PEL from exposure at or under the current PEL. OSHA argues that it reviewed multiple studies involving workers exposed below the former PEL, which found "substantial evidence of illness and deaths" at that level. Resp.Br. p.38. However, closer examination of those studies show they cannot support OSHA's conclusion.

For instance, the 3,300 South Dakota gold miners studied by Steenland and Brown (1995), Doc.ID.0451, (*see* Resp.Br. p.39), had worked at least a year underground between 1940 and 1965, a time period during which exposures were inevitably quite high, and not ameliorated by the protective measures that have only recently become available. *See*, *e.g.*, Doc.ID.2307, pp.124-132 (JA__-__). Chest x-rays were obtained in cross-sectional surveys in 1960 and 1976 and used along with death certificates to ascertain cases of silicosis; 128 cases were found *via* death certificate, 29 were found by chest x-ray, and 13 were found by both. 81 Fed. Reg. at 16,316 (JA__). OSHA concedes that the inclusion of death certificate diagnoses complicates interpretation of the risk estimate from this study. *Id.* Moreover, the exposures in this study were averaged, with some exposures being quite high, but a dose-rate effect was not considered. *Id.* Adding to the lack of clarity, OSHA did not discuss any information from this study about confounders such as smoking. All of these factors weight decisively against this study constituting substantial evidence of there being a low-level threshold for silicosis or any other disease.

OSHA points to "multiple studies involving workers exposed below the alleged 'safe dose level'" of the prior 100 $\mu g/m^3$, and suggests that these "found substantial evidence of illnesses and death." Resp.Br. p.38. These same studies, however, all suffer from significant exposure uncertainty. According to Dr. Cox, such errors tend to "smooth out," and therefore conceal, threshold exposure-response

relationships, making "any apparent thresholds that survive this smoothing tendency appear to occur at lower concentrations than the true thresholds." Doc.ID.2307, p.63 (JA__), *quoting* Cox Comments, p.46; *see also id*., pp.75-78 (JA__-__). It was on this basis that Dr. Cox criticized the Kuempel *et al*. (2001) study, as well as the study by Steenland and Deddens (2002), both cited by OSHA as evidence of the absence of a silica threshold. OSHA offers no adequate rebuttal.

Indeed, OSHA's own peer reviewers raised this same concern. Bruce Allen observed:

> If anything, the weaknesses of all the studies with respect to exposure histories (both with respect to the atmospheric concentrations and the job-specific features that lead to worker exposures to those concentrations) may not have been presented with enough emphasis to convey just how limiting and problematic that process can be … The values presented [in the pooled cohorts of Steenland et al.] do not give me a very strong sense that exposure misclassification was negligible ….

Doc.ID.1716, pp.151-152 (JA__-__). Dr. Crump concurred:

> A major source of error that apparently was not accounted for is in assuming that the average measure of exposure assigned to a job is the true average. But it is not always clear how representative the underlying measurements were … There is possibly considerable error in such estimates. Another source of uncertainty in the averages stems from the need to convert from one measurement method to another (e.g., from particle counts to gravimetric measures).

Doc.ID.1716, p.162 (JA__). In general, underlying exposure assessments "may only be rough estimates of the true exposures." Doc.ID.2307, p.64 (JA__), *quoting* British Health and Safety Executive Phase 2 Report, p.15.

OSHA contends it has tested and accounted for potential exposure uncertainty through the ToxaChemica (2004) quantitative analysis, previously discussed, and concludes that any such errors "did not substantially affect the results in the majority of studies examined." Resp.Br. pp.54-55. Apart from the design flaws in the ToxaChemica analysis, noted above, it is noteworthy that the analysis itself was undertaken by Drs. Steenland and Bartell. As Dr. Cox noted, hiring Dr. Steenland to "opine on the technical robustness and soundness of his own studies and conclusions, rather than choosing independent experts in the relevant area of statistics to scrutinize the statistical approach," created the possibility of investigator bias and confirmation bias, even if inadvertent. Doc.ID.2307, p.78 (JA__), *quoting* Cox Comments, p.59. In light of this, probably the most charitable characterization of the ToxaChemica analysis is that it does not put to rest the many significant questions that remain about exposure uncertainty. OSHA cites authority for the proposition that the Agency can adopt a no-threshold assumption. Resp.Br. p.41. This is true, but only if such an assumption is based on substantial evidence. Substantial evidence is lacking here.

Finally, as noted in Industry Petitioners' opening brief, OSHA improperly rejects consideration of the "dose-rate effect." The Agency acknowledged that not accounting for a dose-rate effect, if one exists, could overestimate risk at lower concentrations. 81 Fed. Reg. at 16,375 (JA__). Nonetheless, OSHA concludes that

a cumulative exposure model was appropriate, Resp.Br. pp.61-63, and gives short shrift to the important consideration of the intensity of silica exposure, as opposed to the duration.

OSHA reviewed two studies that examined dose-rate effects on silicosis exposure-response relationships: Buchanan *et al.* (2003) and Hughes *et al.* (1998). Resp.Br. p.62. It concluded that "neither found a dose-rate effect relative to cumulative exposure at silica concentrations anywhere near 100 µg/m³." However, those studies *did* find a dose-rate effect. Buchanan found that cumulative quartz exposure accumulated at higher concentrations resulted in proportionally greater risks of radiologic abnormalities than the same cumulative exposure accumulated at lower concentrations, with dramatic differences at higher intensities. *See* Doc.ID.2307, p.92 (JA__).

In addition, OSHA chose not to rely on several studies which found a dose-rate effect, such as a study of diatomaceous earth workers by Park *et al*. There, investigators found that, when workers having the same cumulative exposures are compared, the silicosis incidence rate in the 1942-1954 period (when silica exposure levels were high) was ***13.3 times higher*** than in later years (when silica levels were estimated to be considerably lower). *See* Doc.ID.2307, pp.92-93 (JA__-__).

Thus, the dose-rate effect is a significant factor in silica-related disease. This only makes sense: the cumulative exposure models average exposures and/or

assume that exposure remains constant over a long period of time. This cannot be so – no one is exposed to a single, constant level of silica over a period of 45 years.

C. OSHA Fails to Support Its Finding That Silica Exposure Is Related to Lung Cancer.

OSHA acknowledges the scientific debate on the connection between silica exposure and lung cancer, but invokes the *Benzene* standard to argue that it should be given the benefit of the doubt in this matter so it is not "paralyzed" by disagreement within the scientific community. *See* Resp.Br. p.43. But systematically casting aside contrary evidence to achieve a predetermined outcome is no way to avoid paralysis. Nor can any rule derived from such a process be said to be supported by substantial evidence.

OSHA's summary of the history of this regulation leaves no doubt that reducing the silica PEL has been a longstanding goal for this agency. Resp.Br. pp.6-12. That approach informs OSHA's review of the epidemiological studies, and is nowhere more apparent than in its Supplemental Review of Epidemiological Studies on Lung Cancer. Doc.ID.1711, Att.A, "Suppl. Review" (JA__).

As Industry Petitioners discussed in their opening brief, OSHA took issue with a review conducted by Gamble (2011) of studies used by the International Agency for Research on Cancer to explore the relationship between lung cancer and silica exposure. OSHA says that it disagrees with Gamble's "weight of the evidence" approach to these studies, Resp.Br. p.57, n.30, but it is remarkable that,

according to the chart OSHA prepared (Doc.ID.1711, Att.A, pp.14-23 (JA__-__)), it found itself in agreement with Gamble on the conclusions reached in only three out of twenty studies. OSHA methodically searched for reasons to disagree with Gamble's conclusions, unless Gamble happened to take OSHA's point of view. Consider also OSHA's discussion of a 2007 study by Chen *et al.* Doc.ID.1711, Att.A, pp.30-32 (JA__-__). OSHA's summary of one portion of that study (a nested case-control study of Chinese pottery workers)[3] has all of OSHA's indicia of reliability: it estimated average values of respirable dust – and the silica content of total dust – for each facility studied, as well as each job title and each calendar year; and it controlled for the effect of PAHs and smoking, both of which are occupational "confounders" when studying the relationship between silica and disease, through a regression analysis. Indeed, according to Gamble, and as discussed at length in Doc.ID.2307, pp.48-51 (JA__-__), the Chen study did a better job adjusting for PAHs exposure than studies on which OSHA relied: McLaughlin *et al.* (1992) and Liu *et al*. (2013).

[3] The Chen study included data on cohorts other than pottery workers. OSHA limited its review of the Chen *et al.* study to pottery workers because, allegedly, "that was the only result that differed from that reported by McLaughlin *et al.* (1992)." In fact, the Chen study did not find an increased lung cancer risk in tungsten miners, who had the *highest* silica exposures and no significant confounding exposures to arsenic or polycyclic aromatic hydrocarbons (PAHs). *See* Doc.ID.2307, p.33 (JA__).

While the McLaughlin study had reported a weak association between exposure to respirable crystalline silica and lung cancer, the Chen study had reported no such association at all. The latter concluded that the risk of lung cancer was related to PAHs exposure, but not to respirable crystalline silica. Yet, OSHA rejected the well-designed Chen study:

> The fact that the association between respirable crystalline silica and lung cancer becomes nonsignificant after adjustments for PAHs does not mean that respirable crystalline silica is not a risk factor. It means that the effects of the two exposures cannot be separated and that PAHs are adjusting out the real effect of respirable crystalline silica.

Doc.ID.1711, Att.A, p.31 (JA__). In fact, OSHA's reason for rejecting the Chen study is not at all consistent with the very findings in that study. But this is of no concern to OSHA, which at this point revealed that, as it turns out, "the Chinese pottery cohort was not one of the key ones that influenced OSHA's decision." *Id.* Why? OSHA now finds it relevant that the Chinese pottery worker cohort itself was smaller than the other worker cohorts examined in other studies. *Id*. at 32 (JA__).[4] In other words, OSHA disregarded a well-designed study that did not support its confirmation bias because of this one factor, while making allowances for defects or flaws in the studies it preferred (such as Attfield and Costello's decision to exclude

[4] In fact, the pottery worker cohort examined in the Chen study (120 cases and 459 controls) was notably larger than that in McLaughlin (62 cases and 238 controls). Doc.ID.1711, Att.A, p.30 (JA__). OSHA never indicated that the results of the even smaller McLaughlin study had no "influence" on its decision making process until the results from the Chen study were highlighted.

the highest exposure group from its analysis, because that group showed no exposure-response relationship).

OSHA did the same with the animal studies referenced on which the Agency relies (*see* Resp.Br. pp.44-45) to support its view that silicosis is not a necessary precursor to lung cancer. As the ACC Silica Panel noted, the positive associations between silica exposure and tumor formation in animals are largely confined to the rat, which is not a good model for evaluating potential human lung carcinogenicity. Doc.ID.2307, pp.29-31 (JA__-__).

OSHA's outcome-determinative approach does not warrant deference. Certainly, epidemiological studies face problems associated with the difficulty of adjusting for occupational confounders, or accurately calculating exposures. That is all the more reason why, in order to meet its burden of showing that the final Rule is supported by substantial evidence, OSHA needed to take seriously scholarly and scientific criticism of the studies on which the Agency relies.

D. OSHA Has Not Justified Its Refusal to Exclude the Brick Industry From the Scope of This Rule.

1. OSHA's Risk Assessments Are Inapplicable To The Brick Industry.

Before promulgating any permanent health or safety standard, OSHA is required to make a threshold finding that a place of employment is unsafe, in the sense that "significant risks are present and can be eliminated or lessened by a

change in practices." *Benzene*, 448 U.S. at 642. OSHA's arguments about risks to brick industry employees do not withstand scrutiny.

OSHA's finding of significant risk to brick industry employees rests on the study by Love, *et al.* (1999), introduced into the record by Dr. Robert Glenn on behalf of the brick industry. According to OSHA, the Love study suggests that there are considerable risks of radiological abnormalities for brick workers at the prior general industry PEL of 100 µg/m³. Resp.Br. p.64. OSHA is unable to quantify those risks, but, importantly, they are *lower* than those OSHA deems acceptable at the *new* general industry PEL of 50 µg/m³. The Love study found 25 cases of silicosis out of 1831 workers (1.4%); the studies on which OSHA's risk assessments rely (Resp.Br. p.28, Table A) conclude that risks of silicosis morbidity at the *new* general industry PEL ranges from 20 workers per 1000 to 170 workers per 1000 (2% to 17%).

The same is true for OSHA's risk estimates for all other disease endpoints, which, with only three exceptions, all exceed 1.4%. Even if one assumes (as OSHA does, without supporting evidence) that the silicosis cases identified in the Love study are underreported, or that the study suffers from a dearth of older or retired workers, there is no evidence to support the notion that risks to brick workers would exceed the risks OSHA has deemed acceptable for purposes of this rule. Thus, OSHA has not shown by substantial evidence that there is a need to impose the new

standards on the brick industry. Its workers already are at lower risk than most other workers will be at the revised general industry PEL.

This conclusion is borne out by the many other studies submitted by the brick industry. OSHA chose to disregard these studies because they did not include exposure-response information, as the Love study did. Thus, while OSHA seeks refuge in the proposition that the studies on which it relies need not "achieve a level of perfection or certainty that does not exist in the real world," Resp.Br. p.54, the Agency is comfortable disregarding studies that do not measure up to its self-serving standard.

In any event, the results of these other studies are striking: they uniformly show extremely low rates of silicosis in the brick plants studied. The highest rate of silicosis was reported in a 1939 study of 325 workers in twenty West Virginia brick plants, a point in time when exposure levels were far higher than those faced by brick workers today. Doc.ID.2343, Table 21 (JA__-___). The two National Institute for Occupational Safety and Health ("NIOSH") studies of North Carolina brick workers are notable for use of non-dust exposed control populations, and the finding that there was no significant difference in the number of abnormal radiographic films between the brick workers and the controls. The Love study reported the same phenomenon using a control group of postal and telecommunication researchers not

exposed to dust; indeed, that group showed more lung changes than the brick workers did. Doc.ID.2343, pp.50-51 (JA__-__).

In an adroit, if illogical, maneuver, OSHA relies on the Love study to support its finding that the brick industry should be covered by the new PEL, while at the same time rejects the argument that the Agency should have developed a "quantitative risk assessment based on the Love *et al.* study" in order to justify subjecting the brick industry to the new standard because "that study excluded retired workers and had inadequate worker follow-up." 81 Fed. Reg. at 16,378 (JA__). In any event, OSHA has failed to identify a significant risk to brick workers that will be materially reduced by imposition of the new general industry PEL.

2. OSHA Has Not Adequately Distinguished Its Treatment of the Sorptive Minerals Industry.

OSHA's Opposition offers no rational explanation for its disparate treatment of the sorptive minerals industry and the brick industry. The fact that OSHA decided not to subject one industry to the new standard is not, as OSHA suggests, evidence of the Agency's due diligence with regard to its evaluation of the risks to which workers in the other industry were exposed at the prior PEL. Both industries submitted evidence that silica in the clays they use does not pose the same health risks as silica in other types of work, and OSHA conceded that the silica used in both those industries is of lower toxicity than in other industries. OSHA then criticized

the studies submitted by both industries in substantially the same terms, but came to radically different conclusions as to each.

The only distinction OSHA makes in its analysis of these two situations is that there is "insufficient evidence" of lifetime risk in the sorptive minerals industry, but (based on the Love study) there is evidence of a significant lifetime risk to brick workers. As explained above, that analysis does not hold water. Further, to the extent OSHA disputes that the Love study is adequate to support a quantitative risk assessment, the logical conclusion to draw about the brick industry would have been the one it drew with respect to sorptive minerals: there is insufficient evidence to justify reducing the PEL. The brick industry respectfully asks the Court to look beyond OSHA's facile attempts to distinguish these two industries.

3. OSHA Has Not Responded to the Brick Industry's Well-Founded Arguments About Economic Infeasibility.

Because OSHA's conclusions about significant risk to brick workers are unsupported, its decision not to respond to the brick industry's economic feasibility arguments is improper. It has conceded the industry's position on economic infeasibility.

II. OSHA HAS FAILED TO PROVE THE RULE IS FEASIBLE IN THE FOUNDRY, HYDRAULIC FRACTURING, AND CONSTRUCTION INDUSTRIES.

In a concurring opinion in *Benzene*, Justice William Rehnquist concluded that the first sentence of Section 6(b)(5) of the Occupational Safety and Health Act of

1970 ("OSH Act"), 29 U.S.C. § 655(b)(5), was an unconstitutional delegation of congressional authority because it impermissibly shifted a legislative policy choice (*i.e.*, "whether the statistical possibility of future deaths should ever be disregarded in light of the economic costs of preventing those deaths") from Congress to the Secretary of Labor. *Benzene*, 448 U.S. at 671-88. In particular, Justice Rehnquist observed that confining the Secretary's authority to promulgate health standards to the extent such standards are "feasible" was a "legislative mirage":

> Read literally, the relevant portion of § 6(b)(5) is completely precatory, admonishing the Secretary to adopt the most protective standard if he can, but excusing him from that duty if he cannot. . . . [T]he language of § 6(b)(5) gives the Secretary absolutely no indication where on the continuum of relative safety he should draw his line.

Benzene, 448 U.S. at 675.

The Rule embodies these concerns. OSHA has set a PEL of 50 µg/m^3 based on a feasibility analysis that is woefully incomplete and does not remotely resemble reality. Respondent asks this Court simply to rubber stamp technological and economic feasibility analyses that are internally inconsistent, lack record support, and ignore significant pieces of contrary evidence. This request should be rejected.

A. Substantial Evidence Does Not Support OSHA's Finding That The Rule Is Technologically Feasible In The Foundry And Hydraulic Fracturing Industries.

1. OSHA Misunderstands the Impact of Exposure Variability on Feasibility for the Foundry Industry.

Industry Petitioners identify a major shortcoming in OSHA's technological feasibility analysis – its complete failure to consider significant evidence of exposure variability specific to foundry operations. Ind.Br. pp.55-60. Petitioner American Foundry Society ("AFS") introduced as evidence in the rulemaking proceeding a study applying a NIOSH strategy for assessing the statistical confidence of reaching a PEL of 50 µg/m^3 in the foundry industry (the "AFS/NIOSH Study"). *Id.* at 56-57. The AFS/NIOSH Study showed convincingly that, in order for a foundry employer to meet a PEL of 50 µg/m^3 with even 85% confidence, that employer would actually need to attain an average level of exposure of 20 µg/m^3. *Id.* at 57.

In Response, the Secretary does not dispute that OSHA failed to consider this specific piece of evidence.[5] Instead, Respondent asserts that Industry Petitioners are changing the legal test for technological feasibility and that OSHA addressed

[5] Petitioner Intervenor-Respondents North America's Building Trades Unions, *et al.* ("Union Intervenors") allege that OSHA did in fact consider the AFS/NIOSH Study. Union Intervenors Brief ("Un.Inv.Br."), p.15, n.5. The citations provided by the Union Intervenors, however, do not support such a statement. The citations only point to the same discussions that Industry Petitioners identified in their Opening Brief regarding exposure variability generally and a reference to the cost implications of same. *Id.*

exposure variability generally in the Rule. Resp.Br. pp.76-79. Respondent also reverts to his argument that any problems with compliance can be addressed through "flexible" enforcement or by shifting the burden on employers to prove to OSHA that the standard, as applied, is infeasible. *Id.* at 76-78. The Secretary's Response is unavailing.

First, OSHA completely ignored the AFS/NIOSH Study in promulgating the final Rule. On this basis alone, this Court should grant the Petition with respect to the foundry industry and remand to the Agency to fully consider this evidence. *See United Steelworkers of America v. Marshall*¸647 F.2d 1189, 1207 (D.C. Cir. 1981) ("*Lead I*") (OSHA must "present its reasons for rejecting significant contrary evidence and argument.").

Furthermore, the Secretary's argument that Industry Petitioners are changing the legal test for technological feasibility is incorrect. Resp.Br. p.76. Respondent seems to suggest that the ability of an employer consistently to meet a PEL is somehow not relevant to whether a standard can be met "in most operations most of the time." *Id.* The Secretary misses the point. Industry Petitioners are not arguing that the presence of exposure variability changes the legal test for feasibility. Rather, Industry Petitioners argue that to meet the PEL of 50 µg/m^3 in most operations *most of the time* with the significant exposure variability for silica, a foundry employer must control exposures to a much lower level on average. The burden falls upon

OSHA to prove that achieving this lower level is technologically feasible. *AFL-CIO v. OSHA*, 965 F.2d 962, 980 (11th Cir. 1992) (citing *Lead I*¸ 647 F.2d at 1266).

While this Court has identified broadly the parameters of the meaning of technological feasibility, *see, e.g.*, *Lead I*¸ 647 F.2d at 1263 (attempting to define and refine the concept of "feasibility" "given the very general statutory language" of Section 6(b)(5)), this Court has not stated definitively what constitutes meeting a PEL in most operations *most of the time*. The AFS/NIOSH Study presents this issue squarely for the Court's consideration.

Respondent suggests that exposure variability is nothing new and claims it has been an issue in past OSHA health standard rulemakings. Resp.Br. p.77. However, for the foundry industry, silica is omnipresent in the work environment. The record shows convincingly the ubiquitous nature of silica in the foundry industry. *See* Ind.Br. pp.55-56. Respondent's attempt to analogize exposure variability for silica in the foundry environment with exposure variability for other toxic substances in that environment is unpersuasive.[6]

[6] Respondent claims that OSHA's findings in the asbestos standard demonstrate that exposure variability is not unique to silica and was considered by the Agency in past rulemakings as not determinative of feasibility. Resp.Br. p.79. But that simply proves Industry Petitioners' point regarding the differences between silica and asbestos with respect to the impact of exposure variability. The foundry industry does not use millions of tons of asbestos each year to produce metal castings, as the record shows it does with silica. Ind.Br. p.55. It is the omnipresence of silica in the

Respondent also states that it considered exposure variability generally through four studies purportedly addressing the subject. Resp.Br. pp.77-79. As stated in Industry Petitioners Opening Brief, unlike the AFS/NIOSH Study, none of these studies dealt with the foundry industry specifically and, even so, none of them supports OSHA's assertion that this significant exposure variability can feasibly be controlled. *See infra* pp.51-52; Ind.Br. pp.59-60.

Respondent also points to OSHA's "flexible enforcement policy" and an employer's ability to challenge feasibility in enforcement proceedings. Resp.Br. pp.79-80. According to Respondent, OSHA is "committed" to this flexible enforcement, *id.* at 78, and has "clearly articulated its enforcement position in the preamble" to the Rule. *Id.* at 79, n.50. By using the crutch of "flexible" enforcement, OSHA necessarily concedes the standard's infeasibility. An employer must deal with the standard as written, rather than relying on the chimera that it might not be enforced.

Moreover, by no means has OSHA "clearly articulated" its flexible enforcement policy. Does "flexible" mean that citations will issue only if a particular sample is 52 µg/m^3? 60 µg/m^3? 80 µg/m^3? Or, more likely, is the purported flexibility nothing more than a restatement that OSHA – in the

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foundry environment that makes exposure variability so important and different from past standards.

unpredictable discretion of an individual compliance officer – may choose to re-sample an operation if the employer presents data showing that the inspection samples are not representative of typical exposures. 81 Fed. Reg. at 16,757-16,758 (JA__-__). Despite OSHA's claims to the contrary, when a compliance officer does on-site sampling, that sample is the result against which compliance is judged – on that day and at that time. *See* Doc.ID.1992, p.9 (JA__) (noting variability during OSHA inspections, citations relating to same); Doc.ID.2379, App.2 (JA__-__) (describing citation process and specific foundry enforcement).

Finally, OSHA's argument regarding an employer's infeasibility defense misunderstands the issue of exposure variability entirely. While OSHA is correct that courts recognize an employer's ability to prove that meeting a particular standard is infeasible in an enforcement action, this resource-consuming employer-by-employer burden is imposed only after OSHA has met its initial burden of demonstrating that compliance is technologically feasible on an industry-wide basis. OSHA has not done so here. *Lead I*, 647 F.2d at 1272 ("Agency must establish a presumption that industry can meet the PEL without relying on respirators.").

2. OSHA Misinterprets the AFS Questionnaire and Other Data.

While OSHA's failure to consider exposure variability and the *de facto* 20 $\mu g/m^3$ baseline is reversible error in its own right, Industry Petitioners identify numerous examples of foundry operations where substantial evidence does not

support OSHA's finding that it is technologically feasible to achieve compliance at the 50 µg/m^3 level. Ind.Br. pp.61-65.

In response, Respondent relies principally on what it refers to as AFS's "own data" that Respondent ambitiously contends is supportive of OSHA's conclusion that the Rule is technologically feasible in the foundry industry. Resp.Br. pp.80-81. Respondent states that "AFS's own data show that 87% of exposure samples in the foundry industry were at or below the *prior* PEL, even before accounting for the possibility of additional controls to further lower exposure levels." *Id.* at 80 (emphasis added).

The "data" that Respondent cites is information from a questionnaire that Petitioners AFS presented to some of its members ("Questionnaire"). Doc.ID.4035, Ex.2 (JA__-__). The Questionnaire surveyed a range of topics, such as the types of castings produced and the costs for controls. *Id.* Respondent suggests that the results show that most foundries are in compliance with the previous PEL and can therefore reach the new PEL. Resp.Br. p.80.

Even if Respondent's interpretation of the data were correct (which it is not), a questionnaire that shows that 87% of exposure samples in the foundry industry were at or below the previous PEL proves nothing in terms of whether a foundry employer can reach OSHA's new PEL. In addition, the Questionnaire did not include detailed information on controls implemented throughout the wide variety

of foundries covered. *See* Doc.ID.4035, Ex.2 (JA__-__). To the extent Respondent is suggesting the Questionnaire proves that the new 50 µg/m^3 PEL can be met in most operations most of the time, it stretches this Court's definition of technological feasibility beyond credulity.

Respondent also attempts to poke holes in Industry Petitioners' arguments about the extent to which individual pieces of evidence support – or do not support – OSHA's technological feasibility findings. *Id.* at 80-82. In particular, in their Opening Brief, Industry Petitioners explain how actual enforcement actions undertaken by the Agency prove that the foundry industry cannot meet the previous PEL, let alone the new PEL. Ind.Br. pp.61-62.

Respondent does not dispute the importance of this evidence. Instead, Respondent puts its own spin on the information in the record and suggests that the studies showing the difficulty of compliance with the previous PEL actually showed instances of compliance.[7] Despite this spin, the record is clear that, in many

[7] The Secretary states summarily that "none" of the three Special Emphasis Programs identified in Industry Petitioners' Opening Brief show the inability of foundries to meet the previous PEL. Resp.Br. p.80. But, in his discussion, the Secretary is simply cherry-picking the data that it views as supportive of its position and, again, ignoring (or in one case burying in a footnote, Resp.Br. p.81, n.52) the data that shows non-compliance. *See also* Doc.ID.2379, App.2, p.10 (JA___) (non-compliance of cleaning and finishing). And, of course, this evidence relates to information showing non-compliance with the *previous* PEL, and not the much lower revised PEL.

inspections, foundry employers could not get below the previous PEL of 100 µg/m^3 – in many cases after trying several different control measures. *See id*. and references therein.

Finally, Respondent mistakenly clings to the view that controls and automation which may effectively control silica in one foundry can be easily replicated in any other foundry. Respondent also chastises Industry Petitioners for failing to "provide any evidence showing that automation could not be replicated." Resp.Br. p.84. OSHA's view with respect to the broad interchangeability of controls across foundries is critical to its technological feasibility analysis. Ind.Br. p.63-65.

However, Respondent is simply wrong that there is no evidence in the rulemaking record regarding the unique nature of each individual foundry and foundry operation. The record includes substantial testimony[8] that no two foundries are alike and control measures cannot be simply duplicated in foundries across the country. *See* Ind.Br. p.63; Doc.ID.2379, pp.43-44 (JA___-___) (describing the differences in foundries and the casting process); Doc.ID.2379, App.3, p.1 (JA___); Doc.ID.4229, p.13 (JA___) (describing differences in production rate from less than

[8] To the extent Respondent is suggesting that industry testimony does not constitute "evidence," then OSHA is not fairly and objectively considering information presented in the rulemaking record, as on countless occasions OSHA relies on testimony in the record (either in conjunction with other evidence or on its own) to justify positions taken. *See, e.g.*, 81 Fed. Reg. at 16,301-16,302, 16,326-16,328 (JA__-__, __-__).

one casting per week to tens of thousands per day). In fact, OSHA itself recognized the wide variety of manufacturing configurations that belie application of one set of specifications in one manufacturing environment to another: "In manufacturing industries such as foundries . . . local exhaust specifications must be custom designed for each establishment considering its manufacturing processes, equipment, and layout." 81 Fed. Reg. at 16,704 (JA__).

3. OSHA has not Demonstrated by Substantial Evidence that the Rule is Technologically Feasible in Hydraulic Fracturing.

Industry Petitioners establish that substantial evidence did not support OSHA's finding that the Rule is technologically feasible in the hydraulic fracturing industry. Ind.Br. pp.65-69. OSHA examined information on a wide variety of controls (*e.g.*, local exhaust ventilation at release points, a baghouse passive dust collection system that fits over individual thief hatches, a containment system that replaces a pneumatic loading process, caps on fill ports, particular enclosures on conveyors, etc.), but the record does not show that any of these controls can reliably reduce exposures below the new PEL of 50 µg/m^3. *Id.*

Lacking any true response to this, as expected the Secretary reverts to OSHA's ability to be "technology-forcing." Resp.Br. p.89. Industry Petitioners agree that prior courts have recognized that OSHA may be technology forcing in promulgating standards in certain situations. However, "technology-forcing" is not unlimited.

In this case, there is virtually no evidence demonstrating that the hydraulic fracturing industry can meet the new PEL. *In fact, there are no individual personal breathing zone samples in the record showing the effectiveness of controls*. Ind.Br. p.68. The *only* piece of evidence the Agency can point to where some sampling found exposures under the PEL of 50 µg/m^3 was one test conducted by one dust control company. 81 Fed. Reg. at 16,455-16,456 (JA__-__). However, sampling conducted of that same system by customers on actual worksites found that exposures were above the new PEL. *Id.* Furthermore, OSHA does not find in the rulemaking record that the system tested includes control measures for all dust emission points in the hydraulic fracturing process. *Id.* Nor does OSHA's allowance of five years to come into compliance get the Agency off the hook. There is no evidentiary basis for the five year period; the time period is just a "guess," and nothing more.

B. OSHA Has Failed To Prove The Rule Is Economically Feasible In The Foundry And Hydraulic Fracturing Industries.

1. OSHA's Underlying Assumptions in Estimating Costs for the Foundry Industry are not Supported by Substantial Evidence.

In its Opening Brief, Industry Petitioners demonstrate the substantial impact that the Rule will have on the foundry industry. Even with OSHA's flawed assumptions and underestimation of costs, OSHA finds significant impacts of the

cost of the Rule on the foundry industry. Ind.Br. p.70-71. And the impacts are more severe on small and very small foundries. *Id.* at 71.

When the flawed assumptions and underestimation of costs are corrected, however, the very real and threatening impacts of the Rule on the foundry industry emerge even more clearly. *See Lead I*, 647 F.2d at 1265 (a standard is economically infeasible if it threatens the existence of or causes massive economic dislocations within a particular industry or alters the competitive structure of that industry).

Industry Petitioners show that OSHA used faulty assumptions and incomplete analyses to "prove" that the Rule is economically feasible for the foundry industry. In particular, OSHA used a "per worker" approach to costing the Rule that did not reflect the real world of compliance for a typical foundry. OSHA also did not include in its economic analysis the costs for several controls for foundry operations that were specifically identified and considered in the technological feasibility analysis. Ind.Br. pp.78-79.

As with other areas, the Secretary's response to Industry Petitioners' arguments is to cower behind what he perceives as an impenetrable shield of judicial deference. Citing almost limitless authority to craft an analysis as he sees fit, the Secretary states that (1) OSHA's models for calculating costs were supported by the record and reflected "common sense," and (2) OSHA's failure to actually cost all

required controls was "rational," namely because the Rule gives employers options as to which controls to implement. Resp.Br. pp.122-23. The Secretary is wrong.

First, OSHA's per worker model for estimating control costs bears no resemblance to real life. In effect, OSHA tied the costs of controls to an estimate of the number of workers overexposed relative to the PEL. Resp.Br. p.115. The per worker model is not in fact how employers make decisions about installing controls, as the rulemaking record makes clear. *See, e.g.*, Doc.ID.4209, pp.103-105 and Att.5 (JA__-___, ___-___) (describing analytical flaws in per-worker model). OSHA's attempt to tie costs to the number of overexposed workers does not accurately predict costs – it just has the effect of underestimating the true costs to employers to implement controls. Ind.Br. p.74.

Industry Petitioners point to the model adopted by URS Corporation ("URS Model"), and rejected by OSHA, as the model that is reflective of the best available evidence of the cost of compliance. Ind.Br. p.75. The reason: the URS Model (using a binomial distribution) estimates costs based on the number of overexposed workers in a job category in typical very small, small, and large establishments. This approach better estimates costs by *establishment*, than the per worker model. *Id.* *See also* Doc.ID.4209, Att.5 (JA__-__) ("As compared to OSHA's cost model … [this model takes] a more realistic approach of distributing the overexposed workers more broadly over a larger number of facilities where engineering controls cover a

mix of both overexposed workers and workers who are not exposed above the PEL.")

In response, the Secretary reiterates his criticisms of the URS Model by focusing on his contention that it inappropriately assigns overexposures randomly throughout facilities. Resp.Br. pp.116-118. As set forth in Industry Petitioner's Opening Brief, however, the URS approach better reflects the true costs of controls for establishments and, in particular, for small and very small employers, which dominate the foundry industry. Ind.Br. pp.73-75.

For example, in its economic analysis, OSHA calculates bundles of controls for numbers of overexposed workers. For small establishments (20 to 500 employees) OSHA calculated a control bundle for four overexposed workers and for very small establishments (less than 20 employees) OSHA calculated a control bundle for two overexposed workers. 81 Fed. Reg. at 16,475 (JA__). Under OSHA's per worker model, the fewer overexposed workers per establishment, the greater the cost of the controls per establishment.

In nearly all job categories in general industry in which there are overexposed workers, however, the record shows that there are actually so few overexposed workers in small and very small establishments that the per worker model does not come close to accurately reflecting the costs of controls per establishment. *See, e.g.*, Doc.ID.2379, App.3, p.19 (JA__). The net effect of this – as Industry Petitioners

have repeatedly stated – is that OSHA's cost estimates are way out of line with the true costs of compliance.[9] The URS Model corrects this mistake.

Industry Petitioners also identify numerous instances where OSHA included control measures in its analysis of technological feasibility, but did not include those same controls in its analysis of costs. Ind.Br. pp.77-80. In response, the Secretary does not deny that there is a fundamental incongruity between the technological feasibility analysis and the economic feasibility analysis. *See* Resp.Br. pp.122-124. In addition, Respondent does not address the numerous instances of control measures identified in the technological feasibility analysis and not costed at all. *Id.*; *see also* Ind.Br. pp.78-79. Instead, Respondent simply states that it would not be "rational" to account for the costs of "all" potential controls and that OSHA

[9] In its Opening Brief, Industry Petitioners also fault the Agency's assumption that 50% of the costs of implementing controls will be borne by employers to reach the previous PEL of 100 µg/m^3 and the remaining 50% will be borne by employers to reach the new PEL of 50 µg/m^3. The Secretary responds by citing an analysis of eight ferrous foundry facilities for the proposition that the majority of the costs of controls are expended to reach the previous PEL, as opposed to reaching the new PEL, and thus, OSHA's 50% estimate is a conservative one. Resp.Br. pp.120-121. Based on a review of the preamble and the citation included therein, it is almost impossible to determine the source material for the analysis. 81 Fed. Reg. at 16,473 (JA____). Industry Petitioners assume that it is Doc.ID.4249, Attachment 7, which is also referenced in Respondent's Brief. That analysis, however, shows nothing more than that a variety of different foundries have implemented various controls with varying degrees of success. Such a limited sample with generalized results cannot be applied across the entire foundry industry, particularly given the extensive evidence of the difficulty of reaching the new PEL of 50 µg/m^3.

developed cost estimates based on the "lowest cost combination of controls" that allows foundry employers to meet the new PEL. Resp.Br. pp.122-123 (internal citation omitted).

In this instance, however, OSHA has not done what it says it has done. Respondent suggests that it has costed the least combination of controls that allows foundry employers to meet the new PEL. And yet, the technological feasibility analysis is replete with studies that demonstrate the need for numerous other controls that are not included in OSHA's cost analysis. *See* Ind.Br. pp.78-79 and references cited therein. This is indefensible in any economic feasibility analysis, and all the more so here where it is OSHA which bears the burden of proving economic feasibility.

The Secretary also responds to Industry Petitioners criticism of OSHA's failure to cost substitution at all. Respondent justifies this in part by saying that "none" of OSHA's technological feasibility findings is based on substitution. Resp.Br. p.124. Respondent cites the entire Final Economic Analysis ("FEA") discussion of foundries for support for this statement, as though it is crystal clear from that 125 page discussion that substitution will never be required to achieve compliance. *Id.* But even a cursory review of that discussion shows that of the twelve job categories analyzed by OSHA, ten specifically reference substitution or the use of alternative materials. *See* Doc.ID.4247, pp.IV-263, 270, 274, 278, 281,

290, 291, and 302. (JA__, __, __, __, __, __, __, __). OSHA's decision not to include *any* cost for substitution is not based on substantial evidence in the rulemaking record.

Finally, Industry Petitioners argue that OSHA failed directly to address evidence provided by AFS regarding substantial unit costs (e.g., for ventilation and housekeeping) which necessarily would be incurred in an effort to achieve the new PEL. Ind.Br. pp.80-83. Instead, OSHA principally relied on information provided by its contractor, Eastern Research Group ("ERG").

The data and information submitted by AFS was the best available evidence of these unit costs; it is based on information and data gathered by actual foundry owners and operators – and by experts who worked for the owners and operators. *See* Doc.ID.2379, App.3, p.9 (JA__) (detailed costs from foundry owners on ventilation), p.10 (JA__) (detailed costs on substitution), p.11 (JA__) (detailed costs on pneumatic systems), p.13 (JA__) (detailed costs on housekeeping); Doc.ID.4035 p.11 (JA___) (detailed costs on ventilation from the Environmental Protection Agency).

Respondent attempts to justify its rejection of this information and evidence by suggesting that the AFS data did not provide sufficient detail or that the evidence was simply "implausible on its face." Resp.Br. p.130 n.82. OSHA's response in the Rule and Respondents argument in the brief, however, do nothing more than

demonstrate how the Agency "cherry-picks" information and evidence to suit its conclusions.

2. The Rule is not Economically Feasible in the Hydraulic Fracturing Industry.

OSHA also did not demonstrate the Rule was economically feasible in the hydraulic fracturing industry. The principle issue with OSHA's economic feasibility analysis is that "none of the potential controls that the Agency considered in its cost analysis for hydraulic fracturing have been demonstrated to meet the final PEL" or, frankly, even come close to meeting the final PEL. Ind.Br. p.83. In effect, OSHA predicted the cost of hydraulic fracturing employers implementing control measures that do not work.

Respondent attempts to dismiss this issue by reiterating its position that "[m]any controls are redundant, and OSHA adequately accounted for the control costs that will be incurred by the typical fracking employer." Resp.Br. pp.131-32. In fact, from a technological feasibility perspective, the controls costed in hydraulic fracturing (controlling dust from traffic, implementing water misting, and the creation of "dust booths") were never analyzed from the perspective of whether they would have any significant impact on employee exposures. OSHA's estimates of economic impacts must have some relationship to the controls that will need to be implemented by affected employers, and OSHA has established no such relationship here. *Lead I*, 647 F.2d at 1266 ("agency must of course provide a reasonable

assessment of the likely range of costs of its standard and the likely effects of those costs on the industry").

C. OSHA Failed To Demonstrate The Rule Is Feasible In The Construction Industry.

As with OSHA's feasibility analysis of the foundry and hydraulic fracturing industries, substantial evidence does not support the Agency's finding that the Rule is feasible in the wide range of job tasks and operations in the construction industry. The rulemaking record is replete with information showing how ubiquitous silica is on construction worksites and the dynamic, ever-changing conditions (many outside the control of construction employers) that influence the extent of silica exposure and the effectiveness of controls. The Agency pays lip service to the difficulties of compliance in construction, but then plows ahead with strained interpretations of evidence and deviations from past practice, all to finalize a rule with a PEL of 50 $\mu g/m^3$ that cannot be met in most construction operations most of the time.

1. OSHA Cannot Ignore Exposure Variability in Construction.

Industry Petitioners identify substantial evidence in the rulemaking record of significant exposure variability in the construction environment that impacts the average level to which construction employers would need to hold exposures in order to be confident that the PEL could be met. Ind.Br. pp.86-87. Even NIOSH stated in hearing testimony that due to exposure variability a construction employer

would need to control silica to average levels far below the PEL to ensure compliance on any given day at any given worksite. *Id.*

Respondent tries to dismiss this significant issue by arguing (1) that due to the Table 1 compliance option, any exposure variability concerns are "resolved," (2) OSHA has committed to a "flexible enforcement policy" that would take exposure variability into account (as Respondent also argued with respect to the foundry industry), and (3) even so, the four studies relied on for assessing exposure variability demonstrate that such variability is not as significant as Industry Petitioners allege in well-controlled construction environments. Resp.Br. pp.93-97. Respondent's arguments on exposure variability are misguided and demonstrate that OSHA is fundamentally unaware of how the Rule that it promulgated would actually work on a construction worksite.

First, OSHA cannot avoid the issue of exposure variability in construction because of Table 1. The Secretary continues to cling to the idea that virtually all construction employers will use Table 1 all of the time. As Industry Petitioners state, this is not true as a factual matter and – what is more troubling – this belief does not take into consideration the significant evidence in the rulemaking record where *even OSHA* stated that employers will need to deviate from Table 1. *See* Ind.Br. p.99.

Second, OSHA's "flexible enforcement policy," which is not a "get-out-of-jail free card" for the foundry industry as described above, makes no sense in

construction. Industry Petitioners state in their Opening Brief how in construction it would be impossible for OSHA to re-sample a particular job or task after an initial sample is taken that finds the PEL to be exceeded. Ind.Br. pp.89-90. In the vast majority of instances, the job or task that was initially sampled will no longer be occurring after the sample results have been returned from the laboratory. And, even if the job were continuing to occur at the time when a new sampling visit could be arranged, the actual task would most assuredly be different. Industry Petitioners specifically raise this in their Opening Brief and the Secretary ignores it in his Response Brief. *Compare* Ind.Br. pp.89-90 *with* Resp.Br. pp.94-95. Respondent cannot justify its failure to consider exposure variability in construction through reference to an enforcement policy *that cannot and will not work in construction*.

Third, Respondent's attempts to rehabilitate the record regarding the "studies" cited on exposure variability are unavailing. As Industry Petitioners state in their Opening Brief, OSHA's claim in the preamble that the four studies examined used "multivariate statistical models to identify factors associated with increased exposure to silica during various *construction* activities," is simply untrue, when considering that three of the four studies described examined (1) rubber tire manufacturing and pig farmers' exposure to endotoxins, (2) countertop fabrication, and (3) stone restoration work. Ind.Br. pp.87-88.

Only one of the studies that OSHA examined even attempted to gather information from a broad range of construction activities. Respondent claims this study undermines Industry Petitioners assertion "that exposure is unpredictable and uncontrollable in the construction industry." Resp.Br. p.95. The study itself does not support this position, as Industry Petitioner's point out in their Opening Brief. Ind.Br. p.88. In addition, Respondent ignores the fact that OSHA *itself* states that exposures to silica on construction worksites are highly variable and "hard-to-predict." 81 Fed. Reg. at 16,495 (JA __). OSHA cannot have it both ways: it cannot claim exposures are hard-to-predict when it is convenient for its argument and then claim that exposures are predictable when it is inconvenient.

Finally, Respondent claims that Industry Petitioners take NIOSH's testimony "completely out of context." Resp.Br. pp.96-97. That is untrue. The testimony that was cited was in response to a question regarding whether an employer would need to hold average exposures to a level far below the PEL in order to ensure compliance with the PEL on any given day that a compliance officer came to a worksite and sampled. *See* Doc.ID.3579, pp.188-89 (JA___-___) ("Q: Is there a level that I'm going to shoot for, let's say the action level to ensure that in any particular case, I am safe if a compliance officer comes on site?"). NIOSH's response was directed to that issue – the issue raised here – and NIOSH's response was correct.

2. OSHA's Assumption of Construction Exposure is Unsupported.

Industry Petitioners argue that OSHA's assumption made for its technological feasibility analysis that a worker was exposed to no silica for the unsampled portion of a shift was flawed and not supported by substantial evidence in the rulemaking record. Ind.Br. pp.90-92. The assumption had the effect of systematically understating the extent of current levels of exposure and overestimating the effectiveness of controls.

Respondent does not dispute the effect of the assumption on its analysis. *See* Resp.Br. pp.97-101. However, Respondent contends that the assumption "makes sense" for the construction industry and is supported by substantial evidence. Resp.Br. p.98. Whether something "makes sense" in OSHA's view is not determinative of whether OSHA has met its regulatory responsibilities. *See Benzene*, 448 U.S. at 659 (OSHA must base decisions on specific evidence). And the substantial evidence supporting OSHA's findings is comprised of just three studies that, to the extent they can be read to mean anything, show that numerous tasks in construction are performed for a long period of time or a full-shift. Ind.Br. pp.92-94. The studies cannot be used as support for the generalized assumption that for *all* construction tasks OSHA should assume no exposure for the unsampled portion of the shift. Furthermore, Respondent does not address the findings of Flanagan *et al*. 2006, which refused to make conclusions about compliance with an

exposure limit unless the samples were "long term or 'full shift.'" *See* Resp.Br. pp.99-101.

Seemingly unconvinced that the evidence in the record supports such a broad assumption, Respondent adopts a common refrain of blaming rulemaking participants and others for not providing additional evidence. Resp.Br. pp.100-101. OSHA cannot simply rely on a smattering of information to support a critical assumption underlying one of the two key components of Section 6(b)(5) of the OSH Act and then when questioned on it, simply throw up its hands and state that there was no other information provided it by rulemaking participants.

3. Table 1 Demonstrates the Standard is Infeasible.

Industry Petitioners also demonstrate the infeasibility of the standard through OSHA's very own Table 1 and its extensive reliance on respirators. Ind.Br. pp.95-99. Of the 31 tasks – and locations for those tasks – analyzed on Table 1, one-third of them require some form of respiratory protection when the task is performed for just over four hours. *Id.* at 95. And OSHA estimates that approximately 300,000 construction employees will need to wear respirators for at least 30 days per year, a significant number of employees under any fair metric. *Id.* at 96.

In response to this overwhelming use of respirators that will occur as a result of the Rule, Respondent accuses Industry Petitioners of over-counting tasks in Table 1 requiring respirator use and downplays OSHA's own estimate of almost 300,000

respirator users. Resp.Br. pp.102-03. Respondent then concludes by saying that even if OSHA's own numbers were correct – which one would hope would be the case – the number of respirator users in construction under the Rule would be roughly 13%, an amount that would "hardly" undercut technological feasibility. Resp.Br. p.103.

What Respondent fails to address was OSHA's recent decision to reject a PEL of 1 µg/m^3 in its Hexavalent Chromium rule in favor of a PEL of 5 µg/m^3 because it concluded that too many employees would be required to wear a respirator if the lower PEL were adopted. Ind.Br. pp.96-97. In the Hexavalent Chromium rule, the percentage of employees that would have been required to wear a respirator at a PEL of 1 µg/m^3 – a PEL that OSHA concluded was technologically infeasible – was just 9.5%, a significantly lower percentage than the 13%. Put simply, only a few years ago OSHA concluded that if as many as 9.5% of employees were required to wear a respirator then that was too many and the PEL requiring that extent of respirator use was technologically infeasible. Now, OSHA has changed its position – apparently – and believes that if 13% of employees are required to wear a respirator then that is *not* too many and the standard is technologically feasible.

In the preamble to the Rule, OSHA does not explain this change in position. Nor does the Secretary address his past practice in his Response Brief. *See* Res.Br. pp.101-103. It is unlawful for the Agency to deviate from its past practice in such a

significant way without a reasoned explanation. *See Ramaprakash v. FAA*, 346 F.3d 1121, 1124 (D.C. Cir. 2003) ("an agency cannot ignore a substantial diversion from its prior policies").

More broadly, it shows that the Agency has established no guiding principle for what actually constitutes an acceptable level of respirator use. In Hexavalent Chromium, the acceptable level was 3.5%, with 9.5% being unacceptable as described above. In this Rule, it is 13%. In the next rule, maybe it will be 20% or 30%. The reality, however, is that there is no standard at all that guides the Agency in this regard.

4. The Record Lacks Substantial Evidence of Technological Feasibility.

In addition, Industry Petitioners identify "evidence" used by the Agency to support its technological feasibility analysis for the 12 application groups in construction that (1) does not in fact demonstrate that a PEL of 50 µg/m^3 can be met, or (2) is so sparse that it is virtually impossible to draw any conclusions about the feasibility of the new PEL. Ind.Br. pp.99-105. *See, e.g.*, *Nat'l Mar. Safety Ass'n v. OSHA*, 649 F.3d 743, 753 (D.C. Cir. 2011) ("In light of the lack of record evidence regarding feasibility *vel non*, we cannot conclude that substantial evidence supports OSHA's feasibility determination."). Of the 12 application groups that OSHA examined, OSHA on its own concluded that a PEL of 50 µg/m^3 was infeasible for three groups (abrasive blasting, concrete dowel drilling, and tuckpointing). Industry

Petitioners identify another four groups where the evidence does not come close to supporting a finding of feasibility.[10]

In response, the Secretary attempts to rehabilitate the evidence supporting OSHA's position. For each application group examined, however, the Secretary's responses are lacking.

- For **Hole Drillers Using Handheld or Stand-Mounted Drills**, Industry Petitioners note that only 21 samples were gathered supporting feasibility and only two constituted full-shift exposure. Indeed, the only evidence showing that the PEL could be reached was two studies examining the effectiveness of controls in controlled, laboratory conditions. Ind.Br. p.100. The Secretary responds largely by blaming stakeholders for not providing additional evidence and arguing that in fact laboratory testing conducted in small enclosed areas "resemble drilling in real-world conditions." Resp.Br. p.106. To the extent the Secretary actually believes that conducting a well-controlled laboratory study "resembles" real-world conditions, that is completely at odds with the rulemaking record (*see* Doc.ID.2319, p.27 (JA___); Doc.ID.2322, App.G, p.19 (JA___); Doc.ID.4217, p.13 (JA___); and Doc.ID.4220, p.8. (JA__)) and shows the Secretary does not actually understand the

[10] Industry Petitioners do not concede that OSHA has demonstrated that the Rule is technologically feasible in the other five application groups. Industry Petitioners highlighted the flaws in the four groups discussed in the Opening Brief as they are the most glaring.

challenges of controlling silica in a dynamic, ever-changing construction work environment.

- For **Jackhammers and Other Powered Handheld Chipping Tools**, Industry Petitioners state that OSHA's finding of feasibility is driven solely by the proposition that jackhammering is performed for less than four hours a shift and that substantial evidence in the record does not support this position. Ind.Br. p.101. The Secretary does not dispute that OSHA's feasibility analysis hinges on the length of time that jackhammering is performed, *see* Resp.Br. p.106, but states that Industry Petitioners did not identify any evidence in the record showing that jackhammering is performed for more than four hours. The Secretary is wrong, however. Substantial evidence shows numerous instances where jackhammering is performed for much longer than four hours and Industry Petitioners identify in their Opening Brief instances *where OSHA has specifically recognized this*. Ind.Br. p.101.

- For **Masonry Cutters Using Stationary Saws**, Industry Petitioners highlight how OSHA's feasibility analysis hinges on the use of wet methods and notes that wet methods cannot always be used. Ind.Br. p.102. In response, the Secretary simply states that he believes that wet methods can be used in most instances and that Industry Petitioners point to no contrary evidence. Resp.Br. p.107. Again, the Secretary is wrong, as the record shows the many instances where wet methods cannot be used on construction job sites. *See* Doc.ID.4247, pp.IV-15-

15 (JA__-__); Doc.ID.2291, p.13 (JA__); Doc.ID.2298, p.3 (JA__); Doc.ID.2214, p.3 (JA__).

- Finally, for **Mobile Crushing Machine Operators and Tenders**, Industry Petitioners show the paltry data underlying the analysis and note that the Agency's finding of feasibility is essentially dependent upon one study, conducted with extensive controls and under ideal conditions that did not even find that exposures were below the new PEL. Ind.Br. p.103-04. The Secretary in response notes essentially that controls could have been improved at the one job site examined and that if the controls had been improved, the results may have been under the PEL, based on "guidance from the Health and Safety Executive of Great Britain, NIOSH's Dust Control Handbook, and a progress report from an ongoing study of demolition dust and silica dust control." Resp.Br. p.108. None of the guidance cited by the Secretary, of course, is specific to the study conducted by OSHA's own contractor, nor does it address the ideal environmental conditions for producing low levels of silica that existed during the time of the study. At bottom, OSHA is speculating that the use of additional controls will get exposures below 50 $\mu g/m^3$ and inappropriately concluding based on essentially one study that the PEL can be reached in this job category in most operations most of the time.

5. Substantial Evidence Does Not Demonstrate the Rule is Economically Feasible in Construction.

Industry Petitioners establish how several unsupported assumptions made by OSHA led to an economic analysis that made little sense on its face and could not come close to accurately characterizing the impact of the Rule on construction employers. Ind.Br. p.106. The costs estimated for employers in several construction industries are so low as to be laughable. For example, OSHA estimates the standard will cost a residential home builder just $364 dollars a year to implement. *Id*. With costs this low, it is no wonder that the Agency concluded that the Rule would not threaten the competitive structure of the construction industry. OSHA estimates these absurd numbers by systematically making flawed assumptions and not considering all costs to employers who are unable to comply with the requirements of Table 1.

Respondent dismisses the low costs through a sort of economic sleight-of-hand, emphasizing that many affected employers are very small, the costs are "annualized," and they represent an average. Resp.Br. p.137. Respondent further attempts to justify OSHA's assumption that construction employers perform silica generating tasks for only 150 days per year by citing to different evidence in the rulemaking record than it cited to initially and suggesting that engaging in silica generating tasks for an additional 100 days actually *decreases* the estimated costs of compliance for employers. And finally, the Agency continues to cling to its belief

– belied by language in its own supporting documentation – that virtually all employers will use Table 1, thereby avoiding the need to estimate compliance costs for those employers who choose not to follow Table 1 or cannot do so due to the nature of a particular project.

First, Respondent's explanation for the very low projected costs to construction employers are wholly unavailing. The fact that the costs represent an "average" does not make them more reasonable. While it is true that some employers might pay more than the "average," some employers will pay less, which makes OSHA's estimates even more unrealistic. And even so, to come up with an average cost that is in the low hundreds of dollars clearly means that the full range of costs is similarly unrealistically low.

Respondent's additional argument that the costs make sense because they are annualized does not explain such low estimates. As Industry Petitioners point out in their Opening Brief, the costs of compliance involve implementing controls, adopting various work practices, conducting monitoring (for those employers who are not following Table 1), adopting respiratory protection programs for newly covered employees, implementing written exposure control plans, providing ongoing medical surveillance (including referrals to specialists), providing information and training to employees, and maintaining records. All of these

requirements remain in force indefinitely, and the cost analysis must reflect these continuing obligations.

The Secretary also responds to Industry Petitioners' objection to a flawed assumption about the number of days per year on which construction activities occur. Resp.Br. p.139. Respondent first states that OSHA mis-cited the support for OSHA's view that construction work only occurs for 150 days during the year, rather than for 250 days. The preamble indicated that the support for the assumption was based on a comment received by the "Reform OSHA Coalition." Respondent now contends that this cite was wrong, but the support for the proposition can be found at Exhibit 0004. Resp.Br. pp.139-142.

To the contrary, Exhibit 0004 neither suggests a 150-day work year nor provides any information justifying such an assumption. In fact, there is no mention of 150 days anywhere in the 583 pages of Exhibit 0004. It appears that the evidence of the 150 days comes only from the following comment received: "The application of the FTE analysis to the additional equipment costs is based on the wholly unfounded assumption, contrary to actual experience, that this additional equipment could be used with perfect efficiency (i.e., never idle) so that it is only at a particular site during the time the at-risk tasks are being performed." Doc.ID.0004, p.578 (JA__). It is impossible to see how this statement constitutes the best available evidence that construction work is performed for just 150 days a year.

Respondent then goes on to argue that, if OSHA were to have assumed construction work occurred for 250 rather than 150 days a year, such an assumption would decrease the costs of the Rule. This makes no sense. To the extent that some compliance costs accrue each time a construction task involving potential exposure to silica occurs and must be controlled, these costs will increase the more often the task needing control is performed. OSHA, though, apparently thinks differently and contends that the Agency would estimate lower rather than higher costs if construction work were performed more often each year. OSHA's counterintuitive position on this issue stems from how OSHA converted known capital costs for equipment used in construction to daily costs for this equipment. It is this conversion step in OSHA's modeling – not real life – that the Agency points to when it states that increasing the number of assumed days of construction results in decreased costs.

Finally, Respondent argues that it was entirely proper for OSHA to ignore any costs for employers to comply with the alternative exposure control option (including meeting the PEL and conducting exposure monitoring) based upon its belief that employers will universally comply with Table 1. OSHA is simply wrong with that assumption: OSHA completely ignores the numerous instances where even it admits that Table 1 cannot or will not be used. *See* 81 Fed. Reg. at 16,718, 16,720, 16,730, 16,732, 16,735, and 16,749 (JA___, ___, ___, ___, ___, ___).

III. SEVERAL ANCILLARY PROVISIONS IN THE RULE ARE NOT REASONABLY NECESSARY AND APPROPRIATE.

A. OSHA's Information Restrictions In The Medical Surveillance Provisions Deviate From Past Practice And Violate The OSH Act.

Industry Petitioners argue that medical surveillance under the Rule deviates from past OSHA practice and fails to effectuate the purposes of the OSH Act. Ind.Br. p.110-12. Employers are required to provide medical surveillance to certain employees but are only informed of (1) the date of the examination, (2) if the examination met the requirements of the Rule, and (3) any recommended limitations on the employee's use of respirators. 81 Fed. Reg. at 16,864, 16,881 (JA___, ___). The Rule specifically prohibits the physician or other licensed healthcare professional ("PLHCP") from disclosing "any recommended limitations on the employee's exposure to respirable crystalline silica" absent written consent of the employee. *Id*. This deficiency is important for two reasons. First, it could result in an employer continuing to expose an employee to silica after he is showing signs of silica-related health effects. Second, it deprives the employer of information that could be used to adjust the work environment or implement new controls to protect other employees. Both are plainly contrary to OSHA's mission.

In response, the Secretary essentially argues that information about employee's health effects would provide no value to employers because of the long latency period of silica-related disease and information about respiratory protection

alone provides a sufficient nexus between medical surveillance and the workplace. Resp.Br. pp.150-151.

OSHA's contention that there is no value to employers knowing that the employees on their worksite are showing signs of silica-related disease because of the disease's long latency period is a stunning position taken by an Agency whose mission is to assure the safe and healthful working conditions of employees. Moreover, OSHA has a long history of requiring medical surveillance for disease outcomes with long latency periods. *See, e.g.*, 52 Fed. Reg. 34,460, 34,472 (Sept. 11, 1987) (JA___, ___); 56 Fed. Reg. 64,003, 64,010, 64,086 (Dec. 6, 1991) (JA__, __, __).

Respondent further claims that providing information on an employee's fitness to wear a respirator provides a sufficient nexus between medical surveillance and the workplace. Respondent's contention that the Rule "strikes the proper balance between encouraging employee participation and providing the employer with needed information to protect its employees" is unavailing. Resp.Br. pp.153-54. Again, it is stunning for the Agency to contend that simply providing the employer with information about an employee's respirator use is sufficient to protect employees – all the while withholding information and recommended limitations on the employee's continued exposure to silica at the worksite even though such exposure may damage their health.

Furthermore, Respondent ignores a key part of OSHA's contrary finding made recently in the Hexavalent Chromium rule that employer receipt of employee health information provides the employer "with a medical basis to aid in the determination of placement of employees *and* to assess the employee's ability to use protective clothing and equipment." Ind.Br. pp.112-13 (emphasis added). Here, OSHA ignores the first stated purpose in order to focus on the second. OSHA has not, and cannot, justify this deviation from past practice.[11]

B. OSHA's Limitation On Dry Sweeping And The Use Of Compressed Air Is Not Narrowly Tailored Or Supported By Substantial Evidence.

Industry Petitioners argue that OSHA's limitation on dry sweeping, dry brushing,[12] and the use of compressed air is overly broad and not supported by substantial evidence in the record. In response, the Secretary claims that the Rule is reasonable "because exposure at the PEL still poses a significant risk to workers."

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[11] Furthermore, Respondent essentially ignores Petitioners' arguments regarding Section 4(b)(4) of the OSH Act, 29 U.S.C. § 653(b)(4), which prohibits OSHA from infringing on state workers' compensation systems.

[12] In footnote 106 of its brief, Respondent claims that "dry brushing" was not mentioned in Petitioner's brief "and, thus, remains unchallenged." Resp.Br. p.163 n.106. Industry Petitioners are flummoxed by the Secretary's assertion. According to the preamble, "OSHA's intent in the proposed rule was to restrict dry brushing activity *that was comparable to dry sweeping*, such as using a brush as a tool to clean clothing or surfaces." 81 Fed. Reg. at 16,797 (JA __) (emphasis added). Thus, Industry Petitioners maintain that they have challenged dry sweeping, dry brushing, the use of compressed air, and any comparable activity contemplated by the Rule.

Resp.Br. p.164. Further, Respondent claims that the Rule is narrowly tailored, seemingly due to the "feasibility exception" added to the final standard from the proposal. Resp.Br. pp.163-64.

Contrary to Respondent's assertions, OSHA has not shown that dry sweeping, dry brushing, or the use of compressed air presents any significant health hazard that the Rule claims to address. In the preamble, OSHA cites one study of Finnish construction workers which compared silica exposure levels during dry sweeping with silica exposures during alternative cleaning methods and concluded that "estimated worker exposures were about three times lower when workers used wet sweeping and five times lower when they used vacuums." 81 Fed. Reg. at 16,794 (JA____) (citing Doc.ID.1163). This evidence is insufficient to support OSHA's prohibition on *all* dry sweeping, dry brushing, or use of compressed air[13] that contributes to employee exposure to silica at *any* level, not just at a level above the PEL. 29 C.F.R. §§ 1910.1053(h)(1)-(2), 1926.1153(f)(1)-(2), 81 Fed. Reg. at 16,864, 16,880 (JA____, _____).

[13] As Respondent's note in their brief, the Rule's prohibition on compressed air provides that compressed air may be used "in conjunction with a ventilation system that effectively captures the dust cloud created by the compressed air; or [where] no alternative method is feasible." 29 C.F.R. §§ 1910.1053(h)(2)(i)-(ii), 1926.1153(f)(2)(i)-(ii), 81 Fed. Reg. at 16,864, 16,880 (JA____, _____).

Potentially recognizing that the restrictions are overbroad, Respondent attempts to deny the obvious by stating that the provisions at issue are in fact narrowly tailored. Respondent appears to base this contention on what it terms the "feasibility exception" in the Rule: "The employer shall not allow dry sweeping or dry brushing where such activity could contribute to employee exposure to respirable crystalline silica *unless* wet sweeping, HEPA-filtered vacuuming or other methods that minimize the likelihood of exposure *are not feasible*." 29 C.F.R. §§ 1910.1053(h)(1), 1926.1153(f)(1), 81 Fed. Reg. at 16,864, 16,880 (JA____, _____) (emphasis added). The feasibility exception, however, does not narrowly tailor the requirement, because, as Respondent points out, employers always have the ability to claim infeasibility. Resp.Br. p.162-63. Adding an exception for "feasibility" in the language of the standard does nothing to "tailor" what is a broad, unnecessary, requirement, which OSHA actually expanded from the proposed to the final Rule.

IV. OSHA'S RULEMAKING PROCEDURES VIOLATED SECTION 6 OF THE OSH ACT AND SECTION 553 OF THE ADMINISTRATIVE PROCEDURE ACT.

A. OSHA Deprived The Public Of Notice And An Opportunity To Comment On Significant Exposure Data.

Industry Petitioners demonstrate that OSHA committed a serious procedural error by failing to disclose data from the OSHA Information System ("OIS") until the last day of the data-submission period. *See* Ind.Br. pp.116-118. Respondent contends that this Court should reject Industry Petitioners' argument for three

reasons: (1) OSHA provided a sufficient length of time for post-hearing briefs, (2) the OIS data was only offered to supplement the record, and (3) Industry Petitioners were not harmed by OSHA's decision *not* to extend the post-hearing briefing period. Respondent's arguments miss the mark.

First, Industry Petitioners have not alleged that the post-hearing *briefing period* was too short. Instead, Industry Petitioners point out that OSHA submitted the OIS data on the last day of the *data-submission period*, which did not allow an opportunity for interested parties to submit their own data in response.

Second, Respondent's contention that the OIS data merely served to supplement the record is disingenuous. As discussed in Industry Petitioner's Opening Brief, while OIS data may serve as a supplement in some respects, OIS is the *sole* data source in the FEA for 10 general industry jobs/tasks and 2 construction jobs/tasks, and comprises more than 50% of the data samples for an additional 15 general industry jobs/tasks and 4 construction jobs/tasks.[14] Ind.Br. p.118. The affected industries were deprived of the opportunity to submit additional evidence specifically addressing these particular jobs/tasks. Because this data served as a critical piece of OSHA's decision-making, it should have been disclosed with

[14] Notably, **of the nine jobs/tasks included for "Foundries – Captive," OIS was the sole data source for seven of those jobs/tasks** and the source of more than 50% of the remaining two jobs/tasks. Doc.ID.4248, Exhibit 19, pp.7-8 (JA __-__).

sufficient time for the affected industries to submit contrary data. *See, e.g.*, *Chamber of Commerce of U.S. v. SEC*, 443 F.3d 890, 900 (D.C. Cir. 2006) ("[T]he most critical factual material that is used to support the agency's position on review must have been made public in the proceeding and exposed to refutation.") (internal citations omitted).

Third, Respondent argues that Industry Petitioners "failed to demonstrate how they were harmed by OSHA's choice not to further extend the post-hearing briefing period." Resp.Br. p.168. Once again, OSHA misses the mark because Industry Petitioners have not argued that OSHA should have extended the post-hearing briefing period. Industry Petitioners were harmed because they were not given an opportunity to meaningfully submit evidence in response to OSHA's last-minute data dump.

B. OSHA Improperly Relied On Its Contractor ERG.

As described above, this Rule brings to the surface Justice Rehnquist's warnings regarding the broad unconstitutional delegation of authority from Congress to the Secretary of Labor. While troubling in its own right, OSHA actually compounded that problem further by unlawfully delegating its responsibilities to a private contractor, ERG, to compile information for the Agency's use in performing the technological and economic feasibility analysis of the Rule *and* independently serving as "experts" that OSHA relies on as the best available evidence to support

its conclusions. Industry Petitioners also show that OSHA's failure to make ERG available at the informal public hearing constitutes procedural error by the Agency.

The Secretary, in response, notes (1) OSHA's historic use of contractors supports the role of ERG in this rulemaking, (2) that OSHA disclosed all of the information in the record that it relied upon, and (3) that the OSH Act requires the Agency to rely upon the best available evidence and that, in certain instances, such evidence might be (presumably) evidence from ERG. Resp.Br. p.168-71. Respondent also asserts that it is under no obligation to make any particular witness available in the informal public hearing. *Id.* at 171.

Respondent's arguments are unavailing and "miss the forest for the trees." As Industry Petitioners state, OSHA created a byzantine maze of "information" and "evidence" citing unnamed sources, unsupported data, and conversations between ERG staff and OSHA that masquerade as evidence. *See, e.g.*, Doc.ID.4247, p.III-23 (JA___); p.IV-362 (JA__); p.V-41 (JA___); p.V-284 (JA___); p.V-296 (JA__). And, as set forth above, OSHA relied on this information, often while dismissing other strong evidence submitted to the rulemaking record by industry participants

that did not fit with OSHA's feasibility narrative. OSHA compounded this error by not making ERG available to testify.[15]

CONCLUSION

For the foregoing reasons, the petitions should be granted and the Rule vacated.

[15] The Secretary contends that Industry Petitioners did not request that ERG be made available to testify. Industry Petitioners disagree that the onus is on participating stakeholders to request key sources of information be made available for cross-examination by the public but, even so, the record shows requests were made for the Agency to disclose in greater detail the work of ERG, the qualifications of the contractors, their methods used, etc. *See* e.g., Doc.ID.3579, pp.32-33 (JA___-____).

Respectfully submitted,

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UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT
North America's Building Trades v. OSHA, et al, No. 16-1105(L)

CERTIFICATE OF SERVICE

I, Robyn Cocho, being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

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Any required paper copies will be filed with the Court within the time allowed by rule. All counsel for Amicus Curiae appearing at the time of this filing will also be serve via CM/ECF notice.

March 3, 2017

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