**ORAL ARGUMENT NOT YET SCHEDULED**

Nos. 16-1105, 16-1113, 16-1125, 16-1126, 16-1131, 16-1137, 16-1138, 16-1146

**IN THE UNITED STATES COURT OF APPEALS**
**FOR THE DISTRICT OF COLUMBIA CIRCUIT**

NORTH AMERICA'S BUILDING TRADES UNIONS,

Petitioner,

v.

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

Respondent.

On Petitions for Review of a Final Rule of the Occupational Safety & Health Administration, U.S. Department of Labor

# FINAL BRIEF FOR PETITIONERS-INTERVENORS CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, THE STATE CHAMBER OF OKLAHOMA, AND THE GREATER NORTH DAKOTA CHAMBER OF COMMERCE

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## CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rules 26.1 and 28(a)(1), and Federal Rule of Appellate Procedure 26.1, the undersigned counsel certifies as follows:

**(A) Parties and Amici**. All parties and intervenors appearing before the Court are listed in the Joint Opening Brief of Industry Petitioners.

**(B) Rulings Under Review**. These consolidated cases involve petitions for review of the final rule titled "Occupational Exposure to Respirable Crystalline Silica" (Docket No. OSHA-2010-0034, RIN 1218-AB70), promulgated by the Occupational Safety and Health Administration of the United States Department of Labor on March 25, 2016, and published in the Federal Register at 81 Fed. Reg. 16,286.

**(C) Related Cases**. There are no other cases related to the consolidated petitions.

March 23, 2017

/s/ William S. Consovoy
William S. Consovoy

## CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and D.C. Circuit Rule 2.1, Petitioners-Intervenors state as follows:

The Chamber of Commerce of the United States of America ("the U.S. Chamber") is a non-profit, tax-exempt organization incorporated in the District of Columbia. The U.S. Chamber is the world's largest business federation. The U.S. Chamber represents 300,000 direct members and indirectly represents the interests of more than 3 million companies and professional organizations of every size, in every industry, from every region of the country. An important function of the U.S. Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. The U.S. Chamber has no parent corporation, and no publicly held company has 10% or greater ownership in the U.S. Chamber.

The Oklahoma Chamber is a non-profit, tax-exempt organization incorporated in the State of Oklahoma. The Oklahoma Chamber represents more than 1,500 Oklahoma businesses and 350,000 employees. It has been the State's leading advocate for business since 1926. The Oklahoma Chamber has no parent corporation, and no publicly held company has 10% or greater ownership in the Oklahoma Chamber.

The North Dakota Chamber is a non-profit, tax-exempt organization incorporated in the State of North Dakota. Founded in 1924, the North Dakota

Chamber works to make North Dakota's business climate the best in the nation. The North Dakota Chamber has no parent corporation, and no publicly held company has 10% or greater ownership in the North Dakota Chamber.

March 23, 2017

/s/ William S. Consovoy
William S. Consovoy

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# GLOSSARY

| | |
|---|---|
| Industry Pet. Br. | Joint Opening Brief of Industry Petitioners |
| JA | Joint Appendix |
| $\mu g/m^3$ | Micrograms per cubic meter of air |
| NIOSH | National Institute for Occupational Safety and Health |
| OSHA | Occupational Safety and Health Administration |
| OSH Act | Occupational Safety and Health Act of 1970 |
| PEL | Permissible exposure limit |
| Silica Rule | *Occupational Exposure to Respirable Crystalline Silica; Final Rule*, 81 Fed. Reg. 16,286 (Mar. 25, 2016) |

## STATEMENT OF THE ISSUES

Did OSHA carry its burden of showing, through substantial evidence, that there is a significant risk of material harm under the agency's prior permissible exposure limits for respirable crystalline silica and that OSHA's final rule would eliminate or significantly reduce this harm?

## STATUTES AND REGULATIONS

Relevant statutes and regulations are reproduced in the addendum to the Joint Opening Brief of Industry Petitioners ("Industry Pet. Br.").

## STATEMENT OF THE CASE

Silica is a compound composed of the two most abundant elements in the earth's crust: silicon and oxygen. Silica exists naturally and is a basic component of soil, sand, gravel, rocks, quartz, and many other minerals. Silica is found commonly in both a crystalline state (at issue here) and, less often, a non-crystalline (*i.e.*, amorphous) state. *See* Comments of Robert Lieckfield, Jr. at 3 (Jan. 27, 2014) (JA2684).[1]

Silica has been used for industrial purposes for thousands of years, as it is an indispensable raw material for products containing metals and glass. Silica is essential for numerous products and industries, including construction (*e.g.*, cement, glass, bricks, tiles, and roofing materials), transportation (*e.g.*, roads,

[1] Unless indicated otherwise, Intervenors use the terms "respirable crystalline silica," "crystalline silica," and "silica" interchangeably. *See* Industry Pet. Br. at 5 n.2.

railroads, cars, ships, and airplanes), energy (*e.g.*, oil and gas production), and consumer products (*e.g.*, computers, cell phones, and hand tools). *See* Comments of the U.S. Chamber of Commerce at 4 (Feb. 11, 2014) (JA2737).

Like other workplace substances, respirable exposure to silica, at certain levels, can lead to health problems. In particular, silica exposure can cause silicosis, which is the permanent scarring of the lungs that occurs through the inhalation of silica dust. Chronic silicosis, the most common form of silicosis, generally develops only after many decades of exposure to high levels of silica. Acute silicosis, which is rarer, may develop after intense exposure to high concentrations of silica over several months or years. *See* Comments of Jonathan Borak at 4-8 (Jan. 27, 2014) (JA3978-3982).

Given these dangers, the federal government has long regulated workplace silica exposure. In the Occupational Safety and Health Act of 1970 ("OSH Act"), Congress instructed the Occupational Safety and Health Administration ("OSHA") to issue as an occupational safety or health standard any "national consensus standard" and any "established Federal standard" that would improve employee safety or health. 29 U.S.C. § 655(a). Accordingly, in 1971, OSHA adopted a permissible exposures limit ("PEL") for quartz (the most common form of silica) that reflected this "national consensus" and "established" standard. *See National Consensus Standards and Established Federal Standards*, 36 Fed. Reg. 10,466,

10,506 (May 29, 1971). OSHA's standard was approximately 100 micrograms of silica per cubic meter of air, averaged over an eight-hour day (100 μg/m$^3$) for "general industry" (all industries except agriculture, construction and maritime) and 250 μg/m$^3$ for the construction and shipyard industries. *Id.*

Despite the well-recognized success of these longstanding protections, discussed below, on March 25, 2016, OSHA issued a final rule that imposes onerous new duties on employers that use silica in the workplace. *Occupational Exposure to Respirable Crystalline Silica; Final Rule*, 81 Fed. Reg. 16,286 (Mar. 25, 2016) (JA0001) ("Silica Rule" or "Rule"). Under the Silica Rule, no employee (in all industries, except agriculture) may be exposed to 50 micrograms of silica per cubic meter of air, averaged over an eight-hour day (50 μg/m3). *See id*. Businesses thus must use control methods (such as "process enclosures that isolate the employee from the exposure" and "dust suppression") to achieve massive reductions in silica exposure: a 50% reduction in general industry (down from 100 μg/m$^3$) and an 80% reduction in construction and maritime industries (down from 250 μg/m$^3$). *Id.* at 16,453 (JA0169). The Rule also imposes demanding new requirements related to exposure assessment, respiratory protection, medical surveillance, hazard communication, recordkeeping, and housekeeping practices. *See id*. at 16,287-88 (JA0003-0004).

In enacting these new requirements, OSHA acknowledged that it bore the burden of proving "that there is a significant risk of material impairment of health at the existing PEL and that issuance of a new standard will significantly reduce or eliminate that risk." *Id*. at 16,299 (JA0015). To meet its burden, OSHA expressly declined to rely on the real-world surveillance data collected by the States and federal government that "illustrat[ed] … a significant general trend in the reduction of deaths associated with silicosis over the past four to five decades." *Id*. at 16,330 (JA0046). Remarkably, OSHA deemed this data "inappropriate for estimating risks or benefits associated with various exposure levels" and refused to regard it as consequential. *Id*. Instead, OSHA relied solely on estimated harms that a hypothetical worker might suffer from continual exposure to silica over 45 years. *Id*. at 16,291, 16,330 (JA0007, JA0046).

OSHA ultimately concluded that exposure to silica "increases the risk" of certain respiratory and non-respiratory diseases and that the Silica Rule would substantially reduce this risk. *Id.* at 16,300 (JA0016). Specifically, OSHA estimated that "lifetime silicosis mortality risk is 11 deaths per 1,000 workers at the previous general industry PEL, and 7 deaths per 1,000 workers at the revised PEL," and "lifetime lung cancer mortality excess risk associated with 45 years of exposure to [silica] ranges from 11 to 54 deaths per 1,000 workers at the previous general industry PEL of 100 $\mu g/m^3$ … and 5 to 23 deaths per 1,000 workers at the

revised PEL of 50 μg/m$^3$." *Id.* at 16,303 (JA0019). OSHA predicted that the Silica Rule would cost all regulated industries more than $1 billion per year. *Id*. at 16,527 (JA0243); *see id.* at 16,580 (JA0296) (rejecting cost estimates of $6.1 billion annually for general industries and $4.9 billion annually for construction industries).

Various business and labor groups filed petitions for review of the Silica Rule, which were later consolidated in this Court. Intervenors were granted leave to intervene in support of the petitioners.

## SUMMARY OF THE ARGUMENT

The OSH Act does not license OSHA "to establish a utopia free from any hazards." *Am. Textiles Mfrs. Inst., Inc. v. Donovan*, 452 U.S. 490, 517 (1981) (quoting 116 Cong. Rec. 37,614 (1970)). OSHA's authority to regulate is limited to enacting regulations "reasonably necessary" to a safe and healthy workplace. 29 U.S.C. §§ 652(8), 655(b). Before enacting any new health and safety regulations, therefore, OSHA must bring forth "substantial evidence" that employees face a "significant risk of material health impairment" and that the proposed rule will significantly reduce or eliminate that risk. *Indus. Union Dep't, AFL-CIO v. Am. Petroleum Inst. (Benzene)*, 448 U.S. 607, 653 (1980) (plurality opinion).

OSHA has not met this burden for at least two reasons. First, OSHA ignored countervailing empirical evidence showing that employees did not face significant

risks under the existing silica limits. For more than 40 years, OSHA has limited workplace exposure to silica, and during that time silica-related deaths in the United States have plummeted. Moreover, to the extent silica-related deaths continue to occur, they are *not* because of inadequate silica limits. Most (if not all) of these deaths occur because the employee was exposed to silica at a higher level than allowed by OSHA's then-existing silica limits—either because the employee was exposed before 1971, when no regulations existed, or because he was exposed at a workplace that was violating OSHA regulations. These reputable federal and state data directly undermine OSHA's justification for the Silica Rule.

Second, OSHA never identified the threshold point at which individuals will suffer material harms from silica exposure and, accordingly, the agency cannot justify its predictions about the health harms that will be prevented through lower silica exposure limits. Courts, agencies, and scientists have long recognized that individuals can be exposed to low doses of chemicals, often for long periods of time, and suffer no harms, because the body can detoxify low doses before they do any damage. This "threshold" concept—that there is a level at which individuals can be exposed and face no material risk of harm—forms the basis of modern toxicology. Yet OSHA disregarded these principles, proceeding on the theory that there is no safe level of exposure to silica. That is untenable. Before imposing billions of dollars of costs on industry, OSHA needed to identify *why* a new silica

limit of 50 μg/m$^3$ was materially better than the existing limits—especially because empirical evidence and epidemiological studies showed that the existing silica limits were fully protective. OSHA's failure to do so dooms the Rule.

## ARGUMENT

### I. OSHA Bears the Rigorous Burden of Proving That Employees Face Significant Risks From Silica Exposure Under Existing OSHA Regulations That This New Silica Rule Will Eliminate or Significantly Reduce.

Under the OSH Act, OSHA can promulgate occupational safety and health standards only if they are "reasonably necessary or appropriate to provide safe or healthful employment and places of employment." 29 U.S.C. §§ 652(8), 655(b). Thus, before promulgating any standard, OSHA must 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 (emphasis added).

Importantly, "'safe' is not the equivalent of 'risk-free.'" *Id*. The OSH Act is "concerned, not with absolute safety, but with the elimination of significant harm." *Id*. at 646. For example, "significant risk" exists when "a disabling lung disease caused by breathing cotton dust affect[s] as many as 30% of the workers in carding or spinning rooms in some American cotton mills and … as many as 100,000 active or retired workers [are] suffering from the disease." *Id.* By contrast, "few people would consider" activities "such as driving a car or even breathing city air,"

which "entail some risk of accident or material health impairment," to be "unsafe" or a "significant risk of harm." *Id*. at 642.

The OSH Act's threshold requirement of significant risk "imposes an important limitation on [OSHA's] regulatory authority." *Nat'l Maritime Safety Ass'n v. OSHA*, 649 F.3d 743, 750 (D.C. Cir. 2011). Because "there are literally thousands of substances used in the workplace that have been identified as carcinogens or suspect carcinogens," OSHA cannot impose regulations merely by showing *some* risk of harm. *Benzene*, 448 U.S. at 646. Otherwise, OSHA could seize "unprecedented power over American industry" and "impose enormous costs that might produce little, if any, discernible benefit." *Id.* at 645. Congress never would have given OSHA such power. Absent this constraint, the law "would make such a 'sweeping delegation of legislative power' that it might be unconstitutional." *Id*. (citation omitted); *cf. Michigan v. EPA*, 135 S. Ct. 2699, 2707 (2015) ("One would not say that it is even rational, never mind 'appropriate,' to impose billions of dollars in economic costs in return for a few dollars in health or environmental benefits.").

As a consequence, for an OSHA standard to survive judicial review, "the burden [is] on the Agency to show, on the basis of substantial evidence, that it is at least more likely than not that" the workplace environment or the hazard in question "presents a significant risk of material health impairment." *Benzene*, 448

U.S. at 653. Importantly, by requiring OSHA to show that its conclusions are "supported by substantial evidence in the record considered as a whole," 29 U.S.C. § 655(f), the OSH Act imposes a more "stringent" and demanding standard than the APA's "arbitrary and capricious" standard, *Nat'l Oilseed Processors Ass'n v. OSHA*, 769 F.3d 1173, 1178 (D.C. Cir. 2014). In conducting this "harder look," the Court must "take into account not just evidence that supports the agency's decision, but also countervailing evidence." *AFL-CIO v. OSHA*, 965 F.2d 962, 970 (11th Cir. 1992) (citation omitted). The Court also must review the quality of OSHA's evidence, focusing, in particular, on whether the agency has brought forth "empirical evidence" of an actual risk. *Am. Petroleum Inst. v. OSHA*, 581 F.2d 493, 503 (5th Cir. 1978).

Anticipating criticism, OSHA improperly tried to minimize its obligations. Recognizing that silica-related illnesses have markedly declined, OSHA claimed that "it is of no import that the incidence of the illness may be declining." *Silica Rule*, 81 Fed. Reg. at 16,290 (JA0006) (citing *Nat'l Min. Ass'n v. Sec'y, U.S. Dep't of Labor*, 812 F.3d 843, 883 (11th Cir. 2016)). That of course is wrong. If work-related health problems have declined dramatically and are beginning to approach *de minimis* levels under existing OSHA regulations, the agency necessarily must take these factors into account when determining whether new regulatory burdens are "reasonably necessary."

Further, OSHA wrongly asserts that it has an obligation to "set the standard that eliminates or reduces risk to the lowest feasible level." *Id.* at 16,291 (JA0007) (citing *UAW v. Pendergrass*, 878 F.2d 389 (D.C. Cir. 1989)). On the contrary, OSHA can impose stricter limits only if doing so "would result in greater than *de minimis* benefits." *Pendergrass*, 878 F.2d at 398; *see id*. at 399 ("[W]e again note the absence of a showing … that any feasible reduction would generate more than *de minimis* benefits."). OSHA cannot drive down exposure limits irrespective of the health gains it achieves. *See Am. Petroleum Inst.*, 581 F.2d at 503 ("[T]hat exposure to carcinogens at low levels is safer than exposure at higher levels" so that "reducing the permissible exposure limit from 10 ppm to 1 ppm will result in *some* benefit … does not yield the conclusion that *measurable* benefits will result." (emphasis added)).

Nor does OSHA have free rein to "incorporate a margin of safety" below the level at which employees face significant risks. *Silica Rule*, 81 Fed. Reg. at 16,291 (JA0007) (citing *Nat'l Min. Ass'n v. Mine Safety & Health Admin*., 116 F.3d 520 (D.C. Cir. 1997)). Although OSHA maintains "some leeway" when its findings "must be made on the frontiers of scientific knowledge," *Benzene*, 448 U.S. at 656, it has latitude to implement only a "marginally lower" standard than needed, *Nat'l Min. Ass'n*, 116 F.3d at 528. Any safety buffer thus must be reasonably tied to the exposure limit at which significant harms begin to occur. *AFL-CIO*, 965 F.2d at

979. If OSHA cannot justify these regulatory burdens as "reasonably necessary," the Court must vacate the rule. *See, e.g., id.* at 986-87 (vacating OSHA's Air Contaminants Standard).

## II. OSHA Cannot Carry Its Rigorous Burden of Showing Significant Health Risks That the Silica Rule Would Eliminate or Substantially Reduce.

For two reasons, OSHA's significant-risk findings are not supported by substantial evidence.

### A. OSHA Improperly Discounted Government Surveillance Data of Silica-Related Deaths That Refute OSHA's Significant-Risk Conclusions.

OSHA ignored countervailing empirical evidence showing that employees did not face significant risks under the *existing* silica limits. In the United States, state laws require death certificates to be completed for all deaths, and federal law mandates national collection and publication of deaths and other vital statistics. *See Silica Rule*, 81 Fed Reg. at 16,306 (JA0022); *Morbidity and Mortality Weekly Report: Indicators for Chronic Disease Surveillance*, Centers for Disease Control & Prevention (Sept. 10, 2004), https://goo.gl/Rq2wav. This data is collected by the National Institute for Occupational Safety and Health ("NIOSH"),[2] which then

[2] NIOSH obtains this data from the National Vital Statistics System, which is an inter-governmental system of sharing data between the States and the National Center for Health Statistics, a division of the Centers for Disease Control and Prevention. *About the National Vital Statistics System*, Centers for Disease Control & Prevention, https://goo.gl/NivJLV.

produces occupational mortality statistics for numerous respiratory conditions, including silicosis. *See Occupational Respiratory Disease Surveillance*, National Occupational Respiratory Mortality System (NORMS), https://goo.gl/RElcSf. These respiratory mortality data "are a fundamental source of demographic, geographic, and cause-of-death information" and "one of the few sources of health-related data that are comparable for small geographic areas and available for a long time period in the United States." *Mortality Data*, National Vital Statistics System, https://goo.gl/rX71p0. They also are "[t]he most comprehensive and current source of surveillance data in the [United States] related to occupational lung diseases, including silicosis." *Silica Rule*, 81 Fed. Reg. at 16,306 (JA0022).

The NIOSH data show that silica-related deaths have fallen dramatically over the past four decades and continue to decline. In 1968, there were 1,065 silica-related deaths in the United States. *See* Post-Hearing Brief of the U.S. Chamber of Commerce at 4-5 (Aug. 18, 2014); Centers for Disease Control & Prevention, NORMS National Database of Silicosis Deaths, https://goo.gl/BRfmzF. That number has fallen steadily ever since, dropping to 449 deaths by 1980, 308 deaths by 1990, 152 deaths by 2000, and 123 deaths by 2007. *Id.* As measured against the overall population, the age-adjusted death rate for silicosis has declined *by more than 96%*, falling from 8.21 deaths per million in 1968 to just 0.50 deaths per million in 2007. *Id.* By 2014, these numbers had

dropped to the lowest level ever recorded: 84 silica-related deaths for the year at a rate of 0.30 deaths per million. *Id*.

Even if every one of the deaths in recent years were attributable to deficient silica limits—a big "if," as discussed below—OSHA could not satisfy its burden that there is a "significant risk," given that more than 2.3 million employees are regularly exposed to silica in the workplace. *See Silica Rule*, 81 Fed. Reg. at 16,418 (JA0134). For example, in 2007, fewer than 0.006% of those exposed (1 in 18,700) died of silica-related causes. Comments of the U.S. Chamber of Commerce at 7-8 (Feb. 11, 2014) (JA2740-2741). These low silica-related mortality rates (relative to those exposed) could never rise to the level of "significant." *See AFL-CIO*, 965 F.2d at 973 n.15.

But OSHA's reasoning is even more flawed: the reality is that OSHA has failed to demonstrate that any of these deaths can be attributed to the inadequacy of existing OSHA silica limits. OSHA's failure to make such a finding is unsurprising, because these deaths simply cannot be attributed to inadequate regulations.

First, because the latency period for chronic silicosis (*i.e.*, the time between a person's first silica exposure and death) is "often significantly longer than 30 years, … it can be expected that many, if not most of the silicosis-related deaths in the CDC reports were first exposed to silica years before the creation of OSHA and

the adoption of its [existing] PEL." Comments of Jonathan Borak at 6 (Jan. 27, 2014) (JA3980). Even OSHA admits that "many silicosis deaths reported today are likely the result of higher exposures (both magnitude and duration), some of which may have occurred before OSHA adopted the previous PELs." *Silica Rule*, 81 Fed. Reg. at 16,327 (JA0043).

Second, as OSHA concedes, *id.* (JA0043), some of these deaths likely occurred because individuals were exposed to high levels of silica in violation of existing silica limits. OSHA and others have documented the history of inadequate compliance with OSHA's current silica exposure limits. *Id.* at 16,296 (JA0012); Comments of Jonathan Borak at 8 (Jan. 27, 2014) (JA3982). That is why many, including Intervenors, have urged OSHA and the business community to jointly focus on improved compliance with the current standards that have proved exceedingly effective at dramatically eliminating the risk of silica-related diseases. Intervenors have also urged OSHA and employers to jointly promote practical, effective protections such as personal protective equipment. *See Silica Rule*, 81 Fed. Reg. at 16,328 (JA0044).

OSHA responds that the NIOSH data is unreliable because it does not "capture the entirety of silicosis mortality that actually exists, due to underreporting of silicosis as a cause of death." *Id.* at 16,326 (JA0042). This is misdirection. Although it is possible that some silica-related deaths go unreported,

no amount of underreporting could bridge the gap between the significant harms OSHA believes are occurring and the actual surveillance data. OSHA estimates that the "lifetime silicosis mortality risk" at the existing industry PEL of 100 μg/m$^3$ is "11 deaths per 1,000 workers" exposed for a 45-year working lifetime. *Id.* at 16,303 (JA0019). But OSHA also estimates that more than 2.3 million workers are regularly exposed to silica in the workplace. *See id*. at 16,418 (JA0134). If OSHA's conclusions about the dangers of silica were accurate, tens of thousands of silica-related deaths would be occurring each year. But there is no evidence of such deaths. Indeed, OSHA concedes, "[T]here is little empirical evidence describing the extent to which silicosis is underreported as a cause of death." *Id*. at 16,329 (JA0045). OSHA cannot premise such an expensive and disruptive regulation on the mere supposition that the available data do not fully capture the extent of the problem.

Moreover, OSHA concedes that "the available surveillance data do show a decline in the silicosis mortality since 1968," and such significant improvement cannot be explained by "differing rates of reporting [or] underreporting of silicosis on death certificates." *Id*. at 16,326 (JA0042). In other words, OSHA recognizes that these "reductions in death attributable to silicosis are real, and not a statistical artifact." *Id*. Underreporting also would not change the fact that silica-related deaths are occurring for reasons other than the existing exposure level, such as

high exposures that occurred decades ago and non-compliance with current regulations.

OSHA therefore cannot escape the fact that decades of surveillance evidence *refute* OSHA's conclusions that employees face significant risks under the existing PEL of 100 μg/m$^3$. OSHA cannot ignore these data merely because it prefers its own estimates of harm, which were derived solely from epidemiological studies based on a hypothetical worker's continual exposure to silica over 45 years. *See id.* at 16,303 (JA0019); *see also Am. Petroleum Inst.,* 581 F.2d at 503 ("The lack of substantial evidence of discernable benefits is highlighted when one considers that OSHA is unable to point to any empirical evidence documenting a leukemia risk at 10 ppm even though that has been the permissible exposure limit since 1971."). OSHA had the burden to "take into account not just evidence that supports the agency's decision, but also countervailing evidence." *AFL-CIO*, 965 F.2d at 970. OSHA plainly failed to do so here. The Silica Rule should be vacated for that reason alone.

### B. OSHA's Significant-Risk Findings Are Unsupportable Because OSHA Failed to Identify a Threshold Below Which Employees Face No Material Risk.

OSHA's significant-risk findings also are not supportable because OSHA never identified the threshold point at which individuals will suffer material harms

from silica exposure. As a result, OSHA cannot justify its predictions about the health harms that will be prevented by a lower silica limit.

As far back as the 16th century, it was known that "[a]ll things are poison and nothing is without poison. It is the dose only that makes a thing not a poison." Comments of the U.S. Chamber of Commerce at 4 (June 3, 2014) (JA5248). This "threshold" concept—that there is a "safe level of exposure" for all chemical compounds—is "fundamental to the science of toxicology" and "widely addressed in the scientific research literature." *Id.* at 4-5 (JA5248-5249). As the Eleventh Circuit has explained:

> "[T]he relationship between dose and effect (dose-response relationship) is the hallmark of basic toxicology." "Dose is the single most important factor to consider in evaluating whether an alleged exposure caused a specific adverse effect." Often "low dose exposures—even for many years—will have no consequence at all, since the body is often able to completely detoxify low doses before they do any damage." Furthermore, "for most types of dose-response relationships following chronic (repeated) exposure, thresholds exist, such that there is some dose below which even repeated, long-term exposure would not cause an effect in any individual."

*McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1242 (11th Cir. 2005) (quoting *Science for Judges I: Papers on Toxicology and Epidemiology*, 12 J.L. & Pol'y 1 (2003)).

Courts thus have consistently rejected expert reports that disregard the "threshold" concept. As one court observed in a similar context, "it is not a valid assertion that because high dose exposure to asbestos is bad for you, then low dose

exposure to asbestos is, *in fact*, bad for you, or that a specific plaintiff's exposure at an unknown low dose exposure level, in fact, contributed to that plaintiff's asbestos-related disease." *In re Toxic Substance Cases*, No. 03-319, 2006 WL 2404008, at *7 (Pa. Ct. Com. Pl. Aug. 17, 2006). The argument that a compound is harmful at any level because it is harmful at a high dosage is easily disprovable. "Large amounts of alcohol can intoxicate, larger amounts can kill; a very small amount, however, can do neither. Large amounts of nitroglycerine or arsenic can injure, larger amounts can kill; small amounts, however, are medicinal …. In short, the poison is in the dose." *Id*.; *see also* Victor E. Schwartz & Mark A. Behrens, *Asbestos Litigation: The "Endless Search for A Solvent Bystander"*, 23 Widener L.J. 59, 70-79 (2013) (identifying dozens of courts rejecting the "any exposure" theory of causation).

Despite this widespread agreement validating the "threshold" concept in toxicology, OSHA found "considerable uncertainty about whether there is any threshold below which silica exposure causes no adverse health effects." *Silica Rule*, 81 Fed. Reg. at 16,351 (JA0067). OSHA therefore used "non-threshold exposure-response models" to estimate the risks from silica exposure at various levels. *Id*. at 16,359 (JA0075). These models presume that because silica is harmful at high levels of exposure, then silica must be harmful at *any* level, with the severity of the harm rising or falling linearly depending on the level of

exposure. *See id.* at 16,351 (JA0067) (finding "significant, albeit reduced, risk at the 50 μg/m$^3$ exposure limit").

But using non-threshold models to predict significant risk not only contradicts the basic principles of toxicology discussed above, it belies common sense. If a person could become sick through any exposure to silica, then *everyone* would be at risk of silica-related diseases because silica is ubiquitous in the ambient air. Silica is one of the most abundant minerals on the planet. According to the Environmental Protection Agency, the average ambient levels of silica "have ranged between 1 and 3 μg/m$^3$ and, in most circumstances, are not likely to exceed an 8 μg/m$^3$ annual average." Post-Hearing Brief of the U.S. Chamber of Commerce at 8 (Aug. 18, 2014) (JA5792). This exposure can increase through everyday activities, such as walking down a beach, playing in a child's sandbox, or hitting a golf ball out of a sandtrap. *Id.* at 7 (JA5791). If cumulative exposure to silica is harmful regardless of the exposure levels, this lifetime exposure to ambient air levels of silica would cause countless individuals to develop silica-related diseases. *Id.* Yet there is no evidence that anyone has contracted silica-related diseases outside of the workplace.[3]

[3] Indeed, there is ample evidence that the threshold level for developing silica-related diseases is significantly *higher* than the prior general-industry standard of 100 μg/m3. *See* Industry Pet. Br. at 22-48.

OSHA ultimately threw up its hands, lamenting that "common issues with epidemiological studies limit the Agency's ability to determine whether and where a threshold effect exists for silicosis and lung cancer." *Silica Rule*, 18 Fed. Reg. at 16,359 (JA0075). Even if true, *but see supra* at 19 n.3, such difficulties do not absolve OSHA of its statutory obligations. OSHA has the burden of providing "substantial evidence" that its regulations are "reasonably necessary." OSHA's failure to identify an exposure threshold at which harms occur fundamentally discredits the agency's predictions. OSHA's simple assumption—that lowering silica exposure limits will decrease the risk of significant harms regardless of the level of exposure—is antithetical to basic tenets of toxicology and incompatible with principles of sound rulemaking.

## CONCLUSION

For the foregoing reasons, the Court should grant the petitions and vacate the Silica Rule.

Respectfully submitted,

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## CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(a)(7)(C) and D.C. Circuit Rule 32, as modified by the Court's October 13, 2016, briefing order granting Petitioners-Intervenors 5,000 words, this brief complies with the applicable type-volume limitations because it contains 4,574 words, excluding the parts of the brief exempted by Rule 32(a)(7)(B)(iii).

This brief complies with typeface requirements of Rule 32(a)(5) and the type-style requirements of Rule 32(a)(6), because it has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman 14-point font.

March 23, 2017

/s/ William S. Consovoy
William S. Consovoy

**CERTIFICATE OF SERVICE**

I hereby certify that all counsel of record who have consented to electronic service are being served today with a copy of this document via the Court's CM/ECF. All parties in this case are represented by counsel consenting to electronic service.

March 23, 2017

/s/ William S. Consovoy
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