ORAL ARGUMENT SCHEDULED FOR MAY 3, 2012

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

No. 10-1252 (and consolidated cases)

NATIONAL ENVIRONMENTAL DEVELOPMENT ASSOCIATION'S CLEAN AIR PROJECT, *et al.*,
Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al.*,
Respondents.

Petition for Review of Final Administrative Action
of the United States Environmental Protection Agency

FINAL BRIEF OF RESPONDENT-INTERVENORS AMERICAN LUNG ASSOCIATION AND ENVIRONMENTAL DEFENSE FUND

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Dated: February 8, 2012

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UNITED STATES COURT OF APPEALS
DISTRICT OF COLUMBIA CIRCUIT

NATIONAL ENVIRONMENTAL DEVELOPMENT ASSOCIATION'S CLEAN AIR PROJECT, *et al.*, Petitioners, v. U.S. ENVIRONMENTAL PROTECTION AGENCY and LISA P. JACKSON, Administrator, Respondents.	Case No. 10-1252 (and consolidated cases)

ENVIRONMENTAL INTERVENORS' CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

In accordance with D.C. Circuit Rule 28(a)(1), American Lung Association and Environmental Defense Fund (collectively, "Environmental Intervenors") hereby direct the Court to the attached Circuit Rule 26.1 disclosure statement and otherwise adopt Respondents' Certificate of Counsel.

DATED: February 8, 2012

Respectfully submitted,

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ENVIRONMENTAL INTERVENORS' RULE 26.1 DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1, American Lung Association and Environmental Defense Fund (collectively, "Environmental Intervenors") make the following disclosures:

American Lung Association: American Lung Association has no parent companies, and there are no publicly held companies that have 10 percent or greater ownership interest in the American Lung Association.

American Lung Association, a corporation organized and existing under the laws of the State of Maine, is a national nonprofit organization dedicated to improving lung health and preventing lung disease.

Environmental Defense Fund: Environmental Defense Fund has no parent companies, and there are no publicly held companies that have a 10 percent or greater ownership interest in Environmental Defense Fund.

Environmental Defense Fund, a corporation organized and existing under the laws of the State of New York, is a national nonprofit organization that links science, economics, and law to create innovative, equitable, and cost-effective solutions to society's most urgent environmental problems.

DATED: February 8, 2012

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GLOSSARY OF ACRONYMS AND ABBREVIATIONS

Pursuant to Circuit Rule 28(a)(3), the following is a glossary of acronyms and abbreviations used in this brief:

the Act	Clean Air Act
ALA	American Lung Association
ATS	American Thoracic Society
CASAC	Clean Air Scientific Advisory Committee
EDF	Environmental Defense Fund
EPA, the agency	Environmental Protection Agency
EPA Br.	Brief for Respondents United States Environmental Protection Agency, *et al.*
EPA, RTC	EPA-HQ-OAR-2007-0352-1450
JA	Joint Appendix
ISA	*Integrated Science Assessment for Sulfur Oxides—Health Criteria*
NAAQS, standard	National Ambient Air Quality Standard
Pet. Br.	Opening Brief of State Petitioners, Non-State Petitioners, and Supporting Intervenors
ppb	Parts per billion
ppm	Parts per million
PSD	Prevention of Significant Deterioration

REA	*Risk and Exposure Assessment to Support the Review of the SO_2 Primary National Ambient Air Quality Standards: Final Report*
SO_2	Sulfur dioxide

STATUTES AND REGULATIONS

Pertinent statutes and regulations appear in an addendum to the Joint Opening Brief of State Petitioners, Non-State Petitioners, and Supporting Intervenors ("Pet. Br.").

STATEMENT OF FACTS

Founded in 1904, the American Lung Association ("ALA") is a national nonprofit organization with an expertise in the science of lung health. It is dedicated to the conquest of lung disease and the promotion of lung health. Environmental Defense Fund ("EDF") is a national nonprofit environmental organization dedicated, among other things, to protecting the public health from air pollution. These two organizations have long argued for adoption of a clean air standard to protect against dangerous short-term exposures to sulfur dioxide gas, and have intervened in this case to support the Environmental Protection Agency's ("EPA's" or "the agency's") adoption of such a standard.

I. BACKGROUND.

Sulfur dioxide ("SO_2") is a "highly reactive" gas that "directly impairs human health." *American Lung Ass'n v. EPA*, 134 F.3d 388, 389 (D.C. Cir. 1998). Short-term bursts of SO_2 pollution—as brief as five minutes—cause harmful health effects. *E.g.*, 75 Fed. Reg. 35,520, 35,535/3 (June 22, 2010), JA132. In particular, SO_2 "induces bronchoconstriction in asthmatics." *American Lung*, 134 F.3d at

390; *accord* 75 Fed. Reg. at 35,525/3-26/1, JA122-23. In bronchoconstriction, the airways in the lungs narrow, making it more difficult for a person to breathe. *E.g.*, EPA-HQ-OAR-2007-0352-1170 at 11 [hereinafter ALA Comments], JA1035. The person may experience "shortness of breath, coughing, wheezing, chest tightness, and sputum production," *American Lung*, 134 F.3d at 389, and end up gasping for breath, *see* 75 Fed. Reg. at 35,526/1, JA123. Even if the person does not feel symptoms during an episode of bronchoconstriction, he or she may face "a significant health risk" because of the SO_2-induced damage to the lungs. EPA, EPA/600/R-08/047F, *Integrated Science Assessment for Sulfur Oxides—Health Criteria* 3-4 (Sept. 2008) [hereinafter ISA], JA1369. *See generally id.* at 3-4 to -6, 5-2, JA1369-71, 1452.

When asthma attacks occur, those affected may need to visit the emergency room or be admitted to the hospital because of their difficulty breathing. *See, e.g.*, EPA, EPA-452/R-09-007, *Risk and Exposure Assessment to Support the Review of the SO_2 Primary National Ambient Air Quality Standards: Final Report* 33 (July 2009) [hereinafter REA], JA244. Almost half of children with asthma miss days of school due to asthma exacerbation, and a quarter of adults with asthma report missing days of work. ALA Comments at 26, JA1050. Children, senior citizens, and asthmatics are especially at risk from SO_2 pollution. 75 Fed. Reg. at 35,527/1-2, JA124. Over 23 million people in the United States, including 7 million

children, have asthma. ALA Comments at 11, JA1035; *accord* 75 Fed. Reg. at 35,527/2 (about nine percent of adults and seven percent of children in United States suffer from asthma), JA124.

The SO_2 primary National Ambient Air Quality Standard ("NAAQS" or "standard") challenged here takes direct aim at the short-term bursts of SO_2 pollution that cause these harms. In this, the NAAQS marks EPA's long-delayed response to this Court's 1998 ruling in *American Lung Association v. EPA*, 134 F.3d 388.[1] There, ALA and EDF challenged EPA's 1996 decision not to establish a short-term SO_2 standard despite the agency's finding that bursts of SO_2 pollution caused physical effects hundreds of thousands of times per year and that these physical effects caused disruptions to the victims' lives. *American Lung*, 134 F.3d at 390-91. Instead, EPA claimed that these effects did not amount to a public health problem requiring a NAAQS, a conclusion this Court found to be arbitrary. *Id.* at 391-93.

The *American Lung* Court reiterated that the Clean Air Act (also, "the Act") takes a "'preventative' and 'precautionary'" approach to setting NAAQS. *American Lung*, 134 F.3d at 389 (quoting *Lead Indus. Ass'n v. EPA*, 647 F.2d 1130, 1155 (D.C. Cir. 1980)). EPA may not consider costs in setting a NAAQS.

[1] In fact, the new NAAQS is the first revision of the primary, health-protective SO_2 NAAQS since its establishment in 1971. 75 Fed. Reg. at 35,522/2-23/1, JA119-20.

E.g., *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 464-71 (2001). The agency must "'err on the side of caution by setting primary NAAQS that allow an adequate margin of safety.'" *Coal. of Battery Recyclers Ass'n v. EPA*, 604 F.3d 613, 621 (D.C. Cir. 2010) (quoting *Am. Trucking Ass'ns v. EPA*, 283 F.3d 355, 369 (D.C. Cir. 2002)) (internal quotation marks and alteration omitted); *see also Am. Farm Bureau Fed'n v. EPA*, 559 F.3d 512, 533 (D.C. Cir. 2009) (EPA has authority "to 'err on the side of caution' in setting NAAQS" (quoting *Lead Indus. Ass'n*, 647 F.2d at 1145)). This means that the NAAQS assuredly must protect against "known adverse effects," *American Lung*, 134 F.3d at 389, but Congress also "specifically directed [EPA] to allow an adequate margin of safety to protect against . . . effects whose medical significance is a matter of disagreement," *Lead Indus. Ass'n*, 647 F.2d at 1154.

The *American Lung* Court also held that

> Congress defined public health broadly. NAAQS must protect not only average healthy individuals, but also "sensitive citizens"—children, for example, or people with asthma, emphysema, or other conditions rendering them particularly vulnerable to air pollution. If a pollutant adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard.

American Lung, 134 F.3d at 389 (citations omitted); *see also, e.g.*, *Coal. of Battery Recyclers Ass'n*, 604 F.3d at 618. Thus, Congress mandated that EPA set NAAQS with a precautionary tilt, without any consideration of costs or implementation concerns whatsoever, and with attention to protecting vulnerable subpopulations.

II. EVIDENCE BEFORE THE AGENCY ON THE STANDARD.

Since this Court's decision in *American Lung*, the evidence of serious health impacts from high short-term SO_2 levels has grown even stronger. The agency considered over 50 peer-reviewed epidemiological studies from around the world, many of which were not available to it in 1996. 75 Fed. Reg. at 35,547/1, JA144; ALA Comments at 19, JA1043. These studies "consistent[ly] and coherent[ly]" showed that higher short-term SO_2 levels correlated with hospitalizations and emergency room visits for respiratory symptoms and with children experiencing respiratory symptoms, including at hourly levels around or below 75 parts per billion ("ppb"). *E.g.*, 75 Fed. Reg. at 35,525/3, JA122. Some of these studies reported adverse effects for short-term, one-hour exposures to levels of SO_2 at about 50 ppb. 75 Fed. Reg. at 35,543/2, JA140; ALA Comments at 19-20, JA1043-44. Some studies used "multi-pollutant models" that account for the confounding effects of other air pollutants in ascertaining the effects of SO_2 pollution. 75 Fed. Reg. at 35,547/2-3, JA144; EPA-HQ-OAR-2007-0352-1450 at 25 [hereinafter EPA, RTC], JA1194.

Previously available clinical studies (where people with mild or moderate asthma were exposed to short-term SO_2 bursts while exercising) showed that people suffered moderate or greater reductions in their lung function when exposed to 200 ppb of SO_2 for five to 10 minutes. ISA at 3-5 to -6, JA1370-71. In

addition, several new clinical studies also showed that exposure to SO_2 can harm lung function and cause exercising asthmatics to experience respiratory symptoms. *Id.* at 3-4 to -6, JA1369-71.

EPA also considered clinical studies in which subjects breathed in SO_2 directly from a mouthpiece, bypassing the nose. *See* 75 Fed. Reg. at 35,542/3-43/1, JA139-40; *see also* ALA Comments at 15-16, JA1039-40. Many people breathe at least partially through their mouths at various times, especially during periods of exercise, of nasal congestion, or of asthma attack. ALA Comments at 16, JA1040. These studies showed that a five-minute exposure to SO_2 at 100 ppb—half the 200 ppb level at which other clinical studies found bronchoconstriction, *see* 75 Fed. Reg. at 35,546/2-3, JA143—induced bronchoconstriction in people with mild asthma. ISA at 3-4, JA1369; ALA Comments at 15, JA1039. A five-minute exposure to 100 ppb equates to a one-hour exposure ranging from about 22 to 50 ppb, according to one estimation method; for a five-minute exposure to 200 ppb, the comparable one-hour range would be 43 to 100 ppb.[2]

[2] A daily five-minute peak reported by an air quality monitor is, on average, about twice as high as the same day's monitor-reported one-hour maximum. *See* REA at 374 tbl.10-1, JA400; ALA Comments at 17-18, JA1041-42. The maximum ratio reported is 4.6 to 1. *See* REA at 374 tbl.10-1, JA400; ALA Comments at 17-18, JA1041-42. The low-end one-hour approximations in the text reflect the maximum ratio, while the high-end numbers reflect the average ratio.

The statutorily established Clean Air Scientific Advisory Committee ("CASAC"), 42 U.S.C. § 7409(d)(2), provided unambiguous support for EPA's ultimate interpretation of the sizable body of scientific evidence before the agency. When a draft of the REA proposed to use 400 ppb (five-minute exposure) as the benchmark for adverse SO_2 effects, CASAC adamantly disagreed: "The CASAC believes strongly that the weight of clinical and epidemiology evidence indicates there are detectable clinically relevant health effects in sensitive subpopulations *down to a level at least as low as* 0.2 [parts per million ("ppm")] SO_2."[3] CASAC Letter of Aug. 22, 2008, at i (emphasis added), JA424; *accord id.* at vi ("Collectively, this evidence should lead to a conclusion that 0.2 ppm *or even a lower level* of short-term exposure is an appropriate lower bound value for EPA's benchmark analysis." (emphasis added)), JA429. CASAC also agreed with the need for a short-term, one-hour SO_2 standard and agreed with the second-draft REA's proposed range of 50-150 ppb. CASAC Letter of May 18, 2009, at 1, JA432.

The American Lung Association and American Thoracic Society ("ATS") also supported the manner in which EPA interpreted and applied the ATS's guidelines for finding adverse effects. *See* ALA Comments at 15, 27, JA1039,

[3] A value of 0.2 ppm equates to 200 ppb.

1051; EPA-HQ-OAR-2007-0352-1151 at 1-2 [hereinafter ATS Comments], JA1020-21. ALA strongly supported establishing the one-hour SO_2 standard at a level no higher than 50 ppb. ALA Comments at 14, JA1038. ATS also recommended that EPA set the one-hour SO_2 standard at 50 ppb. ATS Comments at 2, JA1021.

The health benefits of the new standard are sizable. EPA projects that the final 75 ppb standard will prevent 2,300-5,900 premature deaths per year as of 2020. EPA, *Final Regulatory Impact Analysis (RIA) for the SO_2 National Ambient Air Quality Standards (NAAQS)* 5-35 tbl.5.14 (June 2010) [hereinafter EPA, *Regulatory Impact Analysis*], JA1531. It will also prevent some 54,000 asthma attacks and thousands of hospital admissions and emergency room visits. *Id.*, JA1531.[4]

SUMMARY OF ARGUMENT

Implementation Approach. Petitioners' attacks on EPA's specification of AERMOD as the preferred air quality model for SO_2 are time-barred because EPA first so specified on November 9, 2005, and the Act required any challenge to that

[4] In carrying out the analysis, EPA only estimated benefits that "are incremental to an air quality baseline that reflects attainment with the 2008 ozone and 2006 [fine particulate matter] National Ambient Air Quality Standards." EPA, *Regulatory Impact Analysis*, at 5-1, JA1528. Because these are the most current NAAQS for those pollutants, the predicted health benefits of the new SO_2 standard are in addition to those provided by existing standards for fine particle pollution.

action to be brought within sixty days of that date. Petitioners' specific claims that EPA will make incorrect designations and usurp the states' role in the designation process are premature, as EPA has yet even to identify its proposed designations, and Petitioners will have ample opportunity to comment on and challenge any designations they believe to be improper. Even if Petitioners' arguments were timely, EPA's anticipated approach of relying on both monitoring and modeling to inform designations is fully consistent with the Act, and Petitioners' claims about modeling's purported deficiencies lack merit.

Level of the Standard. The wealth of scientific evidence before the agency overwhelmingly supported adoption of a one-hour NAAQS at least as protective as the one EPA chose to protect people with asthma from the harmful effects of short-term bursts of SO_2 pollution. The record shows that SO_2 levels at—and even below—the 75 ppb standard adopted by EPA send people to emergency rooms and hospitals, and clinical studies link SO_2 pollution at such levels with impairment of people's ability to breath. The standard is well within the range recommended by CASAC—EPA's official scientific advisory body under the Clean Air Act—and the American Thoracic Society and American Lung Association supported setting the standard at an even more protective level.

Irrelevance of Other Pollution Control Programs. The Act requires EPA to set the NAAQS at a level requisite to protect public health, regardless of

whether other pollution control programs might provide some protection against the pollutant of concern. In any event, other programs cited by Industry are not adequate substitutes for the public health protections the NAAQS provides because they do not require limits on dangerous short-term peaks of SO_2 pollution.

ARGUMENT

I. PETITIONERS' ATTACKS ON THE PROPOSED HYBRID APPROACH TO IMPLEMENTING THE STANDARD ARE TIME-BARRED AND BASELESS.

A. Challenges to Modeling Are Untimely.

Petitioners' complaints (at 26-28) about the overall accuracy of EPA's recommended air model, AERMOD, come nearly five years beyond the statute of limitations period. EPA's rules have specified AERMOD as the preferred model for general use, including for one-hour averaging and for SO_2 dispersion, since 2005. *See* 70 Fed. Reg. 68,218, 68,218/1, 68,253/3, 68,254/2 (Nov. 9, 2005), JA1, 36, 37. Any attempt to challenge those rules now is time barred. 42 U.S.C. § 7607(b)(1) (requiring that any challenge to final EPA action under the Act be filed within 60 days).

Petitioners' more specific complaint, that the use of AERMOD in making designations "will lead to areas being incorrectly designated 'nonattainment,'" Pet. Br. at 26, is plainly premature. *See* Brief for Respondents United States Environmental Protection Agency, *et al.* ("EPA Br.") at 32. EPA's designations

are not due until June 2012. *See* 42 U.S.C. § 7407(d)(1)(B)(i). Before then, the states will have an opportunity to dispute EPA's proposed designations if the states believe the designations are wrong. *See id.* § 7407(d)(1)(B)(ii) (giving states 120 days before EPA promulgation of designations to dispute modifications of states' recommendations). And after EPA promulgates its designations, any aggrieved party (with standing) can seek judicial relief. *See, e.g.*, *Catawba County v. EPA*, 571 F.3d 20 (D.C. Cir. 2009) (resolving challenges by states, counties, and industry to EPA's designation of certain areas for fine particulate matter pollution). Until EPA makes designations, however, Petitioners cannot challenge in this Court the (unmade, hypothetically erroneous) designations.

Finally, contrary to Petitioners' claim (at 38), EPA's anticipated implementation approach to designations did not (and will not) somehow usurp the states' role in the designations process. States must submit "initial designations" to EPA, after which EPA must promulgate the final, legally effective designations. 42 U.S.C. § 7407(d)(1)(A)-(B); *Catawba County*, 571 F.3d at 40. As this Court has held, the agency "owes the states a measure of *procedural* deference" in that "EPA must wait its turn before it makes any individual county designations," but EPA owes no "*substantive* deference" to state designation recommendations. *Catawba County*, 571 F.3d at 40 (emphasis in original) ("Though EPA may, of course, go along with states' initial designations, it has no obligation to give any

quantum of deference to a designation that it deems necessary to change." (internal quotation marks omitted)).

B. Petitioners' Challenges to the Use of Modeling Are Unfounded.

Even if properly before the Court, Petitioners' complaints about EPA's anticipated approach of using both modeling and monitoring results in implementing the SO_2 standard are groundless. The Clean Air Act is silent as to whether EPA should privilege or avoid either monitoring or modeling in making designations. *See* 42 U.S.C. § 7407(d). EPA thus may exercise its reasoned discretion and consider both air monitoring and modeling data when making designations. *See, e.g.*, *Chevron U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 842-43 (1984). EPA's historical use of modeling in implementing the SO_2 NAAQS, 75 Fed. Reg. at 35,551/2-3, JA148; EPA Br. at 22-25, and the localized, site-specific impacts of SO_2 pollution, *see, e.g.*, 75 Fed. Reg. at 35,551/1-3, JA148, underscore the reasonableness of such an approach here.

As a factual matter, too, Petitioners' aspersions against modeling lack merit. AERMOD has been shown to be accurate for one-hour SO_2 predictions. The Agency relied on a systematic study of the model's performance in predicting SO_2 levels and found that "[t]he AERMOD 1-hour concentration predictions showed good agreement with measured concentrations, particularly for those at the upper end of the concentration distribution." EPA, RTC at 42, JA1211; *see also id.* at

147 (noting that application of AERMOD to one-hour SO_2 levels for source permitting "has been extensively evaluated based on 17 field study databases, several of which included hourly SO_2 monitored concentrations from operating facilities"), JA1247. Contrary to Petitioners' false claim that "AERMOD *will* predict SO_2 concentrations 35 percent higher than" reality, Pet. Br. at 27 (emphasis added), AERMOD averages a mere 3 percent overprediction, with predictions at different sites ranging from 24 percent *lower* than reality to 35 percent higher than reality. EPA, RTC at 42, JA1211.

Moreover, where a party can show that another model will perform better than AERMOD or is more appropriate in a particular situation, use of that other model can be authorized. 40 C.F.R. Pt. 51, app.W, § 3.2.2; 75 Fed. Reg. at 35,575/3, JA172. Thus, there is no basis for Petitioners' belief (at 26) that EPA's anticipated approach "will lead to" incorrect designations.

II. THE SO_2 NAAQS LEVEL IS NO MORE STRINGENT THAN REQUISITE.[5]

Only Industry Petitioners challenge the one-hour SO_2 standard itself; no state joins Industry's challenge. *See* Pet. Br. at 41 n.39. As further detailed below, Industry's objections to the standard are groundless.

[5] ALA and EDF concur with the major points made in EPA's response to Industry Petitioners' second argument.

A. EPA Properly Found the Science Supported an SO_2 NAAQS at Least As Protective As the One It Chose.

1. The Health Effects Evidence Is Overwhelmingly Supportive.

In setting the SO_2 standard at 75 ppb, EPA had the benefit of epidemiological studies, clinical studies, and animal toxicology studies that, taken together, firmly supported its decision. *See* EPA Br. at 38-47. All this evidence supported the finding of a causal relationship—the strongest finding EPA can make in an ISA—between short-term exposure to SO_2 and respiratory harms. 75 Fed. Reg. at 35,525/1-2, JA122; *see also* ISA at 1-11 tbl.1-2, 5-2, JA1363, 1452. EPA analyzed a range of epidemiological studies that examined the hospitalizations and emergency room visits associated with short-term exposures to SO_2 pollution, *see* EPA, RTC at 25 (citing ISA at 3-29 fig.3-8, JA1394), JA1194, paying particular attention to those that addressed the potential for confounding by other pollutants, 75 Fed. Reg. at 35,547/2-3, JA144. These studies showed—at a statistically significant level, even after accounting for potential confounding by other pollutants—that the higher the SO_2 level, the more people had such severe asthma attacks that they went to the emergency room, and the more people suffered such extreme problems breathing, including asthma attacks, that they were

admitted to the hospital.[6] *Id.*, JA144; *see also* ISA at 5-16 to -17 tbl.5-5, JA1466-67.

The clinical studies and animal toxicology studies support the plausibility of the epidemiological studies and bolster the conclusion that short-term exposure to elevated levels of SO_2 harms human health. 75 Fed. Reg. at 35,544/1, JA141. The clinical studies plainly show that short-term (five-minute) exposure to 200 ppb of SO_2—roughly equivalent to one-hour SO_2 levels of 43-100 ppb, *see supra* p. 6—has adverse effects on exercising asthmatics. *See* EPA Br. at 48-53. Notably, these studies do not include severe asthmatics or very young children, two populations likely to be particularly sensitive to damaged lung function. 75 Fed. Reg. at 35,526/2 & n.5, 35,532/3-33/2, JA123, 129-30; *see also* ISA at 3-9, JA1374. The ISA explained that clinical studies demonstrate that exercising asthmatics exposed to 200 ppb of SO_2 for five to ten minutes "experience moderate or greater bronchoconstriction"—"decrements in lung function." ISA at 3-5, JA1370; *id.* at 5-3 & tbl.5-1, JA1453. Diminished lung function (even if the person reports no symptoms)[7] increases risk to that person's health both because

[6] Other epidemiological studies found connections between short-term SO_2 exposure and people experiencing other respiratory symptoms that did not require hospitalization or emergency room visits. ISA at 5-5, 5-6 fig.5-1, JA1455, 1456.

[7] Children may be loathe to stop playing, for example, and acknowledge symptoms.

the person is less likely to try to treat it, *id.* at 3-4, JA1369, and because the person faces an increased risk of suffering a more severe effect if the diminution occurs simultaneously with another respiratory risk factor, like an infection or another pollutant, 75 Fed. Reg. at 35,526/2, 35,532/1, JA123, 129.

As the ISA explained, the clinical, epidemiological, and animal studies cohere to support the conclusion that short-term exposures to 200 ppb of SO_2 cause adverse health effects. ISA at 5-2, JA1452; *see also* 75 Fed. Reg. at 35,526/2-3, JA123. The effects the clinical and epidemiological studies linked to SO_2 exposure—breathing impairment, emergency room visits, and hospital admissions—are plainly "adverse" under ATS's guidelines. *See* 75 Fed. Reg. at 35,546/2-3, JA143. Thus, EPA's finding that exposure to five-minute bursts of SO_2 pollution "at least as low as 200 ppb" amounts to an adverse effect on exercising asthmatics, *id.* at 35,532/3, JA129, was well grounded.

Collectively, this evidence supports a one-hour SO_2 standard at least as protective as 75 ppb. In particular, the three epidemiological studies that most directly addressed confounding—and found none—found a statistically significant relationship between one-hour SO_2 levels at 78-150 ppb and hospital admissions and emergency room visits. *Id.* at 35,547/2-48/1, JA144-45. Indeed, some of the epidemiological studies EPA considered found that even lower levels—50 ppb (one-hour)—of SO_2 were associated with increased emergency room visits. *Id.* at

35,543/2-3, 35,547/3, JA140, 144. "NAAQS 'must be set at a level at which there is an absence of adverse effect on sensitive individuals'"—those who are "particularly vulnerable to air pollution." *American Lung*, 134 F.3d at 389 (quoting *Lead Indus. Ass'n*, 647 F.2d at 1153) (internal quotation marks and alteration omitted). Thus, EPA's finding that one-hour SO_2 levels above 75 ppb present a public health threat was reasonable and well-supported by the record. *See* EPA Br. at 41 (citing *Am. Trucking Ass'ns*, 283 F.3d at 372).

2. Recommendations from CASAC and Lung Health Experts Strongly Support a Standard at Least As Protective as 75 ppb.

The recommendations of CASAC and public health organizations strongly support the conclusion that EPA did not set the standard at a level more stringent than necessary. Under the Act, CASAC's recommendations merit particular weight. Congress established CASAC to give independent, scientifically grounded recommendations to EPA on revisions to existing criteria documents and NAAQS. 42 U.S.C. § 7409(d)(2)(A)-(B). The Act "require[s] that EPA must either follow CASAC's advice or explain why the proposed rule 'differs . . . from . . . [CASAC's] recommendations.'" *Am. Trucking Ass'ns*, 283 F.3d at 378-79 (quoting 42 U.S.C. § 7607(d)(3)) (alterations in original). This Court has held that a cogent explanation of the science combined with reliance on the expert judgment

of CASAC and public health organizations demonstrates the rationality of EPA's decisions. *See, e.g.*, *Coal. of Battery Recyclers Ass'n*, 604 F.3d at 619.

Here, EPA's finding that short-term bursts of SO_2 cause adverse health effects and its decision to set the NAAQS no higher than 75 ppb to protect against these effects are in broad agreement with CASAC's recommendations and the comments of public health organizations. *E.g.*, 75 Fed. Reg. at 35,532/2-3, 35,548/2, JA129, 145 (both); CASAC Letter of May 18, 2009, at 1, 16 (level), JA432, 447; ALA Comments at 1, 15, 27 (adverse health effects), JA1025, 1039, 1051; ATS Comments at 1-2 (adverse health effects), JA1020-21.

CASAC supported setting the standard within the range of 50-150 ppb. CASAC Letter of May 18, 2009, at 1, JA432. It specifically noted that the evidence supported setting the standard as low as 50 ppb. *Id.* at 16 ("[EPA review document] clearly provides sufficient rationale for the range of levels beginning at a lower limit of 50 ppb."), JA447.

The American Lung Association and American Thoracic Society supported a standard even more protective than what EPA ultimately chose, both in averaging time and level. *E.g.*, ALA Comments at 3, 11-12, 14, 18, 20, 23 (both), JA1027, 1035-36, 1038, 1042, 1044, 1047; ATS Comments at 2 (level), JA1021. The American Lung Association described how a 50 ppb standard would be the most effective safe level based on the clinical studies' results and how the

epidemiological studies also supported setting the standard there. ALA Comments at 14, 18, JA1038, 1042. Although it supported a one-hour standard, ALA found that a five-minute standard in conjunction with a strengthened 24-hour standard would work better than a one-hour standard to protect vulnerable populations from SO_2 levels that clinical and epidemiological studies identified as harmful. *See id.* at 9-12, 20, JA1033-36, 1044. The American Thoracic Society explained that a 50 ppb one-hour standard "w[ould] more effectively protect the public, including vulnerable populations, from the effects of short-term exposure to SO_2." ATS Comments at 2, JA1021. Indeed, EPA's analysis showed that a 50 ppb standard would have about twice the health benefits as a 75 ppb standard. ALA Comments at 24-25 (tables based on draft EPA Regulatory Impact Analysis), JA1048-49.

Further supporting EPA's conclusion that the SO_2 NAAQS was not overly stringent, CASAC and lung health experts indicated that EPA could reasonably have found adverse health effects resulted from five-minute SO_2 exposures at levels at or below the 200 ppb level (which roughly corresponds to a one-hour level of 43-100 ppb, *see supra* p. 6) EPA used as a benchmark in its analysis. CASAC highlighted that the clinical studies likely did not fully characterize the adverse effects of SO_2 pollution on severe asthmatics and that "it is not unreasonable to presume that [severe asthmatics] would have responded to even a greater degree." CASAC Letter of Aug. 22, 2008, at vi, JA429. In light of this,

and the epidemiological evidence, CASAC "believe[d] strongly" that the clinical studies could support finding a benchmark for analysis even below the 200 ppb figure EPA used. *Id.* at i, JA424; *accord id.* at vi ("Collectively, this evidence should lead to a conclusion that 0.2 ppm *or even a lower level* of short-term exposure is an appropriate lower bound value for EPA's benchmark analysis." (emphasis added)), JA429. Further, both ALA and ATS explained that mouthpiece studies[8] showed that exposure to 100 ppb of SO_2 for even less than five minutes resulted in adverse effects on exercising asthmatics.[9] ALA Comments at 15, 17, JA1039, 1041; ATS Comments at 1, JA1020. (EPA in fact placed some weight on the mouthpiece studies in determining the level of the SO_2 standard. *See* 75 Fed. Reg. at 35,543/1, JA140.) Thus, the considered recommendations of expert public health bodies demonstrate that, at the very least, EPA did not set the SO_2 NAAQS to be overprotective of public health. *See, e.g.*, *Coal. of Battery Recyclers Ass'n*, 604 F.3d at 619.

[8] These mouthpiece studies "mimic oral breathing." ALA Comments at 15, JA1039; *accord, e.g.*, REA at 55 & n.9, JA266. Many people are oral or oronasal breathers at various times (like when exercising, suffering from nasal congestion, or gasping for breath during an asthma attack). ALA Comments at 16, JA1040.

[9] This level roughly corresponds to a 22-50 ppb one-hour standard. ALA Comments at 18, JA1042; *see also* REA at 394 ("a standard set at 50 ppb would provide increased protection against 5-minute SO_2 concentrations $\geq$ 100 ppb."), JA420.

B. Industry's Attempts to Second-Guess the Expert Judgment of EPA and CASAC Are Meritless.

EPA is entitled to great deference on matters of scientific judgment within the areas of its expertise. *See, e.g.*, *Am. Farm Bureau Fed'n*, 559 F.3d at 519. Industry provides no basis for departing from that deference here.

Industry incorrectly claims that EPA improperly honed in on three epidemiological studies. *See* Pet. Br. at 51-52. To the contrary, EPA rationally exercised its scientific judgment in focusing on three specific epidemiological studies to inform its decision on the level of the standard.[10] The agency reviewed more than 50 epidemiological studies and correctly found that, as a whole, they showed that emergency room visits and hospitalizations for respiratory ailments were positively correlated with SO_2 levels. 75 Fed. Reg. at 35,547/1, JA144. EPA then rationally decided to focus on the ten studies in the United States because of their clear relevance to air quality in the United States. *See* EPA, RTC at 23, JA1192. Similarly, given concerns about confounding, it was entirely reasonable for EPA to further focus on the three such studies that used a multi-pollutant model (which is specifically designed to account for confounding by other pollutants) and

[10] Industry's analogy between the analysis of scientific studies and the consideration of legislative history, *see* Pet. Br. at 42, 51, does not bear up under examination. EPA Br. at 44 n.13.

yielded statistically significant results that were consistent with the overall scientific data available to EPA. *See* 75 Fed. Reg. at 35,547/2-3, JA144.

Contrary to Industry's assertions (at 41-49), EPA reasonably relied on the clinical studies in finding that five-minute exposure to 200 ppb of SO_2 causes adverse impacts on exercising asthmatics. Those studies showed that a significant proportion—up to 30 percent—of subjects suffered "moderate to large decrements in lung function" when exposed to five-minute levels of SO_2 at 200 ppb. ISA at 3-33, JA1398. Such studies are designed such that "only a causal relationship between exposure and health outcome should produce observed associations." *Id.* at 1-4, JA1356. In gauging the strength of their evidence, EPA weighs multiple factors, including the concentration-response relationship in responders and the significance of the response, as well as evidence of statistical significance. *See id.* at 1-9 to -10 & tbl.1-1, JA1361-62. Here, EPA reasonably concluded that other factors (besides statistical significance, on which Industry focuses to the exclusion of all else) were sufficient to support a finding of causation, particularly the strong linear concentration-response relationship between SO_2 exposure and respiratory deficits among the group of responders, *see* ISA at 4-3 fig.4-2, 4-4 fig.4-3, 5-3, JA1438, 1439, 1453; *see also* 75 Fed. Reg. at 35,532/3-33/1 (discussing ISA), JA129-30, and the entire body of evidence from the clinical, epidemiological, and animal toxicology studies, all of which told the same story—that short-term

exposures to SO_2 cause harms to lung function, *e.g.*, ISA at 5-2 to -5, JA1452-55. This conclusion was vetted by a committee of 24 distinguished scientists who concluded that it was an appropriate interpretation of the science and agreed with the conclusion. CASAC Letter of May 18, 2009, at 4-5, 12-13 (listing CASAC members and consultants and stating "EPA . . . has appropriately identified causality between SO_2 exposure and respiratory morbidity"), JA435-36, 443-44.

Contrary to Industry's assertion (at 47-48), the alleged improvement seen in some clinical study subjects at short-term exposure to 200 ppb of SO_2 does not somehow undermine EPA's finding that SO_2 causes adverse effects in others. It was reasonable to conclude based on the clinical studies (bearing in mind their omission of especially sensitive individuals) that a certain population of asthmatics is more sensitive to SO_2 exposure than other asthmatics. *See* EPA, RTC at 13-14 (citing ISA at 4-3 to -4 & figs.4-2 to -3, JA1438-39), JA1182-83. The experience of another population of asthmatics, not as sensitive to SO_2 exposure, says nothing about the decrements suffered by the more sensitive population, and EPA's conclusion that there is a population of asthmatics vulnerable to SO_2 levels of 200 ppb was reasonable and supported by the record. *See* EPA Br. at 49-50.

Industry's claims (at 45-49 & n.41) that EPA erred in its application of the ATS criteria are meritless for the reasons EPA gives. *See* EPA Br. at 48-49. Indeed, ATS itself raised no objections to how EPA applied its criteria for finding

an adverse health effect. *See* ATS Comments at 1, JA1020. In fact, ATS supported EPA's setting the standard even lower than 75 ppb. *Id.* at 2, JA1021.

Thus, EPA properly looked at the whole body of evidence. *See* ALA Comments at 9 ("Each discipline [clinical studies, animal toxicology, and epidemiology] has its strengths and limitations, but taken together they tell a strong story about the adverse effects of sulfur dioxide pollution on human health."), JA1033. In doing so, the agency reasonably took into account CASAC's advice and the Act's preventative tilt. *See* CASAC Letter of August 22, 2008, at vii ("In characterizing risks, the Agency should give consideration to the possibility that SO_2 not only has effects of clinical significance for individuals but also has population-level effects that may be relevant to public health."), JA430; *supra* pp. 3-4. Petitioners' disagreement with EPA's well-reasoned exercise of its judgment is no ground for reversing the agency decision. *See*, *e.g.*, *Am. Trucking Ass'ns*, 283 F.3d at 372.

III. INDUSTRY'S CLAIMS ABOUT THE BENEFITS OF OTHER CLEAN AIR ACT PROGRAMS ARE LEGALLY IRRELEVANT AND FACTUALLY INCORRECT.[11]

As EPA correctly explains (at 53-56), the Act requires that NAAQS must be set at the level requisite to protect public health, regardless of whether that level will be achieved through implementation of other programs.

Even if other programs were relevant, they are not sufficient to prevent harmful short-term bursts of SO_2 pollution. Only the NAAQS takes direct aim at short-term exposures that EPA has reasonably found to be dangerous, *e.g.*, 75 Fed. Reg. at 35,550/1-2, JA147; *see also American Lung*, 134 F.3d at 390-91 (describing harms resulting from exposures to SO_2 bursts). Without the new SO_2 NAAQS, the Prevention of Significant Deterioration ("PSD") program Industry touts (at 56) would not have to assure safe short-term SO_2 concentrations. *See, e.g.*, *Alaska Dep't of Envtl. Conserv. v. EPA*, 540 U.S. 461, 473 (2004) ("[The Act] also provides that a PSD permit may issue only if a source will not cause, or contribute to, air pollution in excess of . . . any NAAQS." (internal quotation marks omitted)). Other programs, like the acid rain program, rely on trading emissions credits, allowing some plants to forego controls in favor of buying credits. ALA

[11] ALA and EDF also adopt EPA's responses to Industry Petitioners' third argument. No state joins Industry's challenge on this issue. *See* Pet. Br. at 54 n.44.

Comments at 12, JA1036. As a result, such programs do not protect local populations against emissions increases or SO_2 spikes that have been shown to be harmful. *Id.*, JA1036. Thus, even if these other programs could as a matter of law substitute for the NAAQS (which they cannot), they do not in fact provide adequate protections compared to the NAAQS.

CONCLUSION

For the reasons given above, ALA and EDF respectfully request that the petitions for review be denied. Should the Court nonetheless find that part of EPA's action was procedurally flawed or arbitrary, the appropriate remedy would be to remand the flawed portion without vacating the NAAQS. *Fertilizer Institute v. EPA*, 935 F.2d 1303, 1312 (D.C. Cir. 1991); *see also*, *e.g.*, *Ne. Md. Waste Disposal Auth. v. EPA*, 358 F.3d 936, 950 (D.C. Cir. 2004) (remanding under Clean Air Act without vacatur for procedural violation when "consequences of vacating would be quite disruptive" (internal quotation marks omitted)). The standard is distinct from and thus may stand regardless of EPA's anticipated implementation approach. *See PPG Indus., Inc. v. Costle*, 659 F.2d 1239, 1247-48 (D.C. Cir. 1981) (noting that Congress placed different limits on EPA when setting NAAQS as opposed to when discussing measurement methods for NAAQS). Vacatur would further delay the long overdue standard, putting thousands at risk of premature death, asthma attacks, hospitalization, and other serious harms, *see*

supra pp. 1-4, 8, thereby undermining the Act's central element, *see Whitman*, 531 U.S. at 465, 468 (pursuant to § 109(b)(1) of the Act, EPA must establish NAAQS to protect public health, and "[section] 109(b)(1) and the NAAQS for which it provides are the engine that drives nearly all of Title I of the [Act]").

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Respectfully submitted,

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CERTIFICATE REGARDING WORD LIMITATION

Counsel hereby certifies that, in accordance with Federal Rule of Appellate Procedure 32(a)(7)(C), the foregoing Final Brief of Respondent-Intervenors American Lung Association and Environmental Defense Fund contains 5,992 words, as counted by counsel's word processing system.

DATED: February 8, 2012

/s/Seth L. Johnson
Seth L. Johnson

CERTIFICATE OF SERVICE

I hereby certify that on this 8th day of February, 2012, I have served the foregoing **Final Brief of Respondent-Intervenors American Lung Association and Environmental Defense Fund** on all registered counsel through the court's electronic filing system (ECF).

/s/Seth L. Johnson
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