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.

On Petition For Review of Final Action of the United States Environmental Protection Agency

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FINAL BRIEF FOR RESPONDENTS UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, et al.

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February 8, 2012

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UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

NATIONAL ENVIRONMENTAL DEVELOPMENT ASSOCIATION'S CLEAN AIR PROJECT Petitioner, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, Respondent.	)	Docket No. 10-1252 (and consolidated cases)

RESPONDENTS' CERTIFICATE OF COUNSEL

Pursuant to Circuit Rule 27(a)(4), counsel for Respondents United States Environmental Protection Agency and Lisa Jackson, Administrator (collectively "EPA") submit this certificate as to parties, rulings, and related cases.

(A) Parties and Amici

(i) Parties, Intervenors, and Amici Who Appeared in the District Court

This case is a petition for review of final agency action, not an appeal from the ruling of a district court.

(ii) Parties to These Cases

1. Petitioners:

National Environmental Development Association's Clean Air Project

Montana Sulphur & Chemical Company

SO_2 NAAQS Coalition

Utility Air Regulatory Group

ASARCO LLC

State of North Dakota

State of Nevada

State of Louisiana

Louisiana Department of Environmental Quality

State of Texas

Texas Commission on Environmental Quality

2. Respondents:

United States Environmental Protection Agency ("EPA")

Lisa P. Jackson, EPA Administrator.

3. Intervenors:

State of Louisiana

Louisiana Department of Environmental Quality

State of South Dakota

State of Nevada, Department of Conservation and Natural Resources, Division of Environmental Protection

American Lung Association

Environmental Defense Fund

4. Amici:

Oklahoma Department of Environmental Quality

State of New Jersey

(B) Rulings Under Review

The Agency actions under review are "Primary National Ambient Air Quality Standard for Sulfur Dioxide," 75 Fed. Reg. 35,520 (June 22, 2010), and "Denial of the Petitions to Reconsider the Final Rule Promulgating the Primary National Ambient Air Quality Standard for Sulfur Dioxide," 76 Fed. Reg. 4780 (Jan. 26, 2011).

(C) Related Cases

The cases on review has not been previously before this Court or any other Court.

Respectfully submitted,

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February 8, 2012

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GLOSSARY

CAA	Clean Air Act
CASAC	Clean Air Act Scientific Advisory Committee
EPA	United States Environmental Protection Agency
ISA	Integrated Science Assessment
NAAQS	National Ambient Air Quality Standard
NYDOH	New York Department of Health
NO_2	Nitrogen Oxides
$PM_{2.5}$	fine particulate matter
ppb	parts per billion
ppm	parts per million
REA	Risk and Exposure Assessment
RTC	Response to Comments
SO_2	oxides of sulfur
UARG	Utility Air Regulatory Group

JURISDICTION

The Court lacks jurisdiction over Petitioners' first claim seeking review of statements in the final rule preamble because those statements are not final agency action, are not ripe for review, and Petitioners lack standing. The Court has jurisdiction over Petitioners' second claim seeking review of the level of the National Ambient Air Quality Standard ("NAAQS") pursuant to 42 U.S.C. § 7607(b)(1).

STATEMENT OF ISSUES

1. Whether statements in the final rule preamble concerning EPA's anticipated approach for designating areas as attainment, nonattainment, or unclassifiable, and for subsequent implementation actions, are final agency action that is ripe for judicial review.

2. Whether EPA's adoption of a primary NAAQS for oxides of sulfur ("SO_2") with a level of 75 parts per billion ("ppb") to address identified health risks from short-term exposures to SO_2 was arbitrary or capricious.

3. Whether the fact that previous regulations are reducing SO_2 concentrations barred the Administrator from revising the SO_2 standard to address identified public health risks not addressed by the previous standards.

STATUTES AND REGULATIONS

Applicable statutes are contained in Petitioners' Brief.

STATEMENT OF THE CASE

Petitioners seek judicial review of EPA's revision of the primary NAAQS for SO_2, and of EPA's denial of requests to administratively reconsider the NAAQS. This action also responds to the Court's remand of the primary SO_2 NAAQS in American Lung Ass'n v. EPA, 134 F.3d 388 (D.C. Cir. 1998).

SO_2 is "[a] highly reactive colorless gas smelling like rotten eggs, sulfur dioxide derives primarily from fossil fuel combustion. Best known for causing 'acid rain,' at elevated concentrations in the ambient air, SO_2 also directly impairs human health." Id. at 389. In its review of the SO_2 NAAQS the Agency examined the substantial body of evidence concerning the effects of SO_2 on public health and engaged in an extensive process of soliciting public comment and consulting with the statutorily-created Clean Air Scientific Advisory Committee ("CASAC"). Based on this thorough review of the science, the Agency concluded that the SO_2 standard should be revised to provide additional protection from short-term exposures to SO_2. Accordingly, the Agency revoked the prior 24-hour and annual standards and promulgated a new 1-hour primary standard established at a 75 ppb level with a 99th percentile form. 75 Fed. Reg. 35,520 (June 22, 2010). Petitioners filed six petitions for judicial review, which this Court consolidated on September 8, 2010.

Following EPA's promulgation of the NAAQS, Petitioners asked EPA to administratively reconsider the NAAQS and to stay its effectiveness pending such reconsideration. At the same time, Petitioners sought from this Court a judicial stay of the effectiveness of the NAAQS pending judicial review, which the Court denied in an Order dated April 7, 2011. The revised NAAQS took effect on August 23, 2010, and remains in effect. On January 14, 2011, the EPA Administrator denied Petitioners' administrative requests. 76 Fed. Reg. 4780 (Jan. 26, 2011). Petitioners filed five petitions for judicial review of this denial, which this Court consolidated with each other and with the petitions for review of the NAAQS on May 27, 2011.

I. OVERVIEW OF THE NAAQS PROVISIONS

The NAAQS provisions of the Clean Air Act ("CAA") establish a comprehensive scheme to protect public health and welfare from ubiquitous air pollutants. This scheme is implemented through a sequential series of regulatory actions taken by EPA and the States. First, sections 108 and 109 of the Act require EPA to establish, review and revise air quality criteria and standards. 42 U.S.C. §§ 7408, 7409. In some cases, when EPA establishes a NAAQS, the Agency also promulgates regulatory requirements governing subsequent implementation, but neither section 109 nor any provision of the CAA requires this. CAA section 107 provides the States an opportunity to recommend whether areas within their

borders should be designated as "nonattainment," "attainment," or "unclassifiable" for the newly established NAAQS, and EPA is required to promulgate final designations. Id. § 7407. Section 110 and other provisions of CAA title I then call on the States to establish State Implementation Plans ("SIPs"), which, upon submission to and approval via notice and comment rulemaking by EPA, impose federally enforceable controls on sources of air pollution as necessary to attain and maintain the NAAQS. Id. §§ 7410, 7502, 7514-7514a; see Lead Indus. Ass'n, Inc. v. EPA, 647 F.2d 1130, 1137 (D.C. Cir. 1980).

The NAAQS process begins with the development of "air quality criteria," which must reflect the latest scientific knowledge on "all identifiable effects on public health or welfare" that may result from a pollutant's presence in the ambient air. 42 U.S.C. § 7408(a). Based on the air quality criteria, EPA promulgates "primary" and "secondary" NAAQS to protect against a pollutant's effects on public health and welfare. Id. § 7409(b). "Primary" standards must be set at levels that, "in the judgment of the Administrator," are requisite to protect public health with "an adequate margin of safety"; "secondary" standards must protect public welfare against known or anticipated adverse effects. Id. Congress "specifically directed the Administrator to allow an adequate margin of safety to protect against effects which have not yet been uncovered by research and effects whose medical significance is a matter of disagreement." Lead Indus., 647 F.2d at 1154.

Congress further defined public health broadly to include not just average healthy individuals but also sensitive people such as children who may be particularly vulnerable to air pollution. American Lung Ass'n, 134 F.3d at 389. In establishing the primary standards, EPA considers a number of factors, including the nature and severity of health effects, the types of health evidence, the kind and degree of uncertainty, and the size and nature of sensitive populations at risk. Lead Indus., 647 F.2d at 1161.

EPA must set NAAQS without considering the cost of achieving them. Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 471 (2001). Thus, issues such as the administrative burden of implementing the NAAQS or the economic effects on regulated polluting entities cannot be considered by EPA's decisions in setting a NAAQS. American Lung Ass'n, 134 F.3d at 389.

To ensure that NAAQS will keep pace with advances in scientific knowledge, Congress also required that EPA review the criteria and NAAQS at least once every five years, and revise them as "appropriate in accordance with [sections 108 and 109(b)]." 42 U.S.C. § 7409(d)(1). In this review, EPA must consider, and explain any significant departure from, the recommendations of CASAC, an independent committee established specifically to advise the Administrator on air quality criteria and NAAQS. Id. §§ 7409(d)(2)(B), 7607(d)(3).

II. DEVELOPMENT OF THE SO_2 NAAQS

EPA first promulgated a primary NAAQS for SO_2 in 1971. 36 Fed. Reg. 8187 (Apr. 30, 1971). That rule established standards of 0.14 parts per million ("ppm") averaged over a 24-hour period, not to be exceeded more than once per year, and a 0.030 ppm annual arithmetic mean. See 40 C.F.R. § 50.4(a), (b). EPA and the States have subsequently implemented the 1971 NAAQS, with most – but not all – areas successfully demonstrating attainment and maintenance of the NAAQS. See, e.g., 43 Fed. Reg. 40,412, 40,415-16 (Sept. 11, 1978); 43 Fed. Reg. 45,993, 46,000-02 (Oct. 5, 1978); 67 Fed. Reg. 22,168, 22,170-71 (May 2, 2002). In May 1996, after a lengthy review, EPA announced a final decision not to revise the NAAQS. 61 Fed. Reg. 25,566 (May 22, 1996); see 75 Fed. Reg. at 35,522. In reviewing that decision, this Court held that EPA had failed to adequately explain the basis for its conclusion that 5-minute peak SO_2 exposures to asthmatics do not constitute a public health problem. American Lung Ass'n, 134 F.3d at 391-93. In the rule under review here EPA has addressed that issue by establishing a new primary standard with a 1-hour averaging time that protects public health against short-term (5-minute to 24-hour) SO_2 exposures. 75 Fed. Reg. at 35,536 n.14; 35,537-39.

In this review, the Agency reviewed the large body of evidence that has been developed to evaluate the effects of exposure to SO_2 concentrations on public

health, including clinical, toxicological, and epidemiologic studies. As part of its review, EPA prepared an Integrated Science Assessment ("ISA") that summarized and analyzed the results of the studies and drew scientific conclusions based on this evidence. Drafts of the ISA were made available for public comment and were twice reviewed by CASAC at public meetings. 75 Fed. Reg. at 35,523. There are two types of human health studies considered in the ISA. The first are epidemiological studies, in which ambient concentrations of SO_2 are compared with indications of mortality or morbidity, such as emergency room visits or hospital admissions. The second are controlled human exposure studies ("clinical studies"), in which subjects with moderate asthma are exposed to low concentrations (e.g., 200 to 600 ppb) of SO_2 for 5 to 10 minutes while engaging in moderate exercise and are then evaluated for changes in lung functions. Id. at 35,525-27. The ISA also considered animal toxicology studies.

Based on the totality of the evidence before it, the ISA concluded that there was sufficient evidence to infer a causal relationship between respiratory morbidity and short-term (5-minutes to 24-hours) exposure to SO_2. Id. at 35,525/1. This is the strongest finding the ISA can make. Id. The ISA based its conclusion on "the consistency, coherence, and plausibility of findings observed in human exposure studies of 5-10 minutes, epidemiologic studies mostly using 1-hour daily

maximum and 24-hour average SO_2 concentrations, and animal toxicological studies using exposures of minutes to hours." Id. at 35,525/2.

From the clinical studies, the ISA found that moderate or greater decrements in lung function occur in some exercising mild and moderate asthmatics exposed to SO_2 concentrations as low as 200-300 ppb for 5 to 10 minutes.[1] Id. Both the number of affected asthmatics in these studies and the severity of the effect increased with increasing SO_2 exposure. Id. at 35,525/2-3. Furthermore, at concentrations of 400 ppb and greater the effects were often statistically significant at the group mean level (i.e., at the level of the group in the particular clinical study) and frequently were accompanied by respiratory symptoms. Id.

With regard to the epidemiologic studies, the ISA found that numerous studies demonstrated that in locations meeting the prior 24-hour and annual SO_2 NAAQS, there were positive associations between ambient SO_2 concentrations and respiratory symptoms in children, as well as with emergency department visits and hospitalizations for all respiratory causes and with asthma across multiple age groups. Id. at 35,525/3. The ISA concluded that these epidemiologic studies were consistent and coherent because the associations were found in studies conducted in numerous locations with a variety of methodological approaches, were

[1] Specifically, a 15 percent or greater decline in Forced Expiratory Volume and/or a 100 percent or greater increase in specific airway resistance in one second.

consistent with the mode of action of SO_2 on the respiratory tract, and were consistent with the results of the clinical studies. Id. The ISA evaluated whether the health effects were the result of exposure to SO_2, rather than to a potential confounding pollutant or pollutants, and concluded that "the limited available evidence indicates that the effect of SO_2 on respiratory health appears to be generally robust and independent of the effects of gaseous co-pollutants, including NO_2 and O_3, as well as particulate co-pollutants, particularly $PM_{2.5}$." ISA at 5-9 (JA 01459).

To inform its examination of the impact of SO_2 exposures on public health, the Agency prepared a Risk and Exposure Assessment ("REA"). Two drafts of the REA were made available for public comment and for review by CASAC. 75 Fed. Reg. at 35,523/1-2. The REA evaluated the likelihood of 5-minute exposures to SO_2 concentrations of 100 to 400 ppb for sensitive populations, such as asthmatic children, under various air quality scenarios, and the resulting public health impacts. Id. at 35,527-29. The results of these analyses suggested that the then-existing SO_2 standards may not be adequately protective of public health. Id. at 35,528/3. The results of this analysis also demonstrated that a 1-hour daily maximum standard in the range of 50-100 ppb could substantially limit exposures of asthmatic children at moderate or greater exertion from 5-minute SO_2 concentrations greater than or equal to 400 ppb and appreciably limit their

exposure to concentrations of 200 ppb or greater. Id. The analysis also demonstrated that a 1-hour standard of 150 ppb could still substantially limit exposures of these children to 5-minute concentrations of 400 ppb or greater, but would provide considerably less protection from 5-minute concentrations of 200 ppb or greater. Id. at 35,528-29.

In the final rule, the Administrator determined that the current standards were not adequate to protect public health with an adequate margin of safety. The entire body of scientific evidence indicates that there is a causal relationship between exposure to SO_2 and the types of respiratory morbidity effects reported in the clinical, epidemiologic, and other studies. Specifically, in epidemiologic studies, adverse effects (including emergency department visits and hospital admissions) are associated with short-term levels of SO_2 occurring in areas that attain the current primary standards, and in some cases in areas with SO_2 concentrations considerably below the level allowed by the standard. In addition, the REA indicated that a substantial number of asthmatic children would be exposed to levels of SO_2 above the 400 ppb and 200 ppb 5-minute benchmarks in areas with air quality just achieving the current 24-hour and annual standards. Based on the health evidence and the exposure and risk analysis, EPA determined that the current standards needed to be revised to provide adequate protection

against the health risks from short-term exposures to SO_2, especially for asthmatics. Id. at 35,536/1-2.

EPA determined that a 1-hour standard (daily maximum) should be adopted to provide protection from short-term exposures ranging from 5 minutes to 24 hours. Id. at 35,538-9. The standard requires the 3-year average of the 99th percentile 1-hour daily maximum values to meet the specified level. Id. at 35,541/2-3. With respect to the evidence in the clinical studies, the Administrator considered evidence concerning both the 400 ppb and 200 ppb 5-minute exposure benchmarks, recognizing that the effects at 200 ppb were appreciably less severe than those at 400 ppb and higher. Taking into account the exposure and risk assessment, the Administrator determined that an hourly standard no higher than 100 ppb was needed to appropriately limit exposure to concentrations of 200 ppb and 400 ppb SO_2. Id. at 35,547/1.

The epidemiologic evidence, however, indicated that a standard with a level lower than 100 ppb was warranted. The Administrator noted that there have been more than 50 peer-reviewed epidemiologic studies published worldwide evaluating SO_2 (ISA Tables 5-4 and 5-5 (JA01464-72)). These studies have generally reported positive, although not always statistically significant, associations between adverse health outcomes (i.e., respiratory-related emergency department visits and hospitalizations) and ambient SO_2 concentrations. The epidemiologic studies

involve people exposed to ambient levels of SO_2 in real world conditions and generally include both populations potentially at increased risk for SO_2-related respiratory effects (such as children, older adults, and those with pre-existing respiratory disease) and the general population. The Administrator noted that the ten studies conducted in the United States (some of which studied multiple locations) reported mostly positive, and sometimes statistically significant, associations between ambient SO_2 concentrations and emergency department visits and hospital admissions in locations where 99th percentile 1-hour daily maximum SO_2 levels ranged from approximately 50 to 460 ppb.

Within this broader range of SO_2 concentrations, the Administrator focused on a cluster of three U.S. studies that had used multi-pollutant models with particulate matter as a means of evaluating whether the study results were confounded by other pollutants. In these three studies, the air quality was between 78 and 150 ppb (for the 99th percentile of the 1-hour SO_2 concentrations) and the SO_2 effect estimate remained positive and statistically significant in multipollutant models with particulate matter, i.e., NYDOH (2006) (JA 00546-803), Ito, et al., (2007) (JA 00804-19), and Schwartz, et al., (1995) (JA 01103-10). 75 Fed. Reg. at 35,547/2. The Administrator determined that the epidemiologic evidence overall provides strong support for setting the standard at 75 ppb. This level would be sufficiently below the lowest of the 1-hour concentrations in locations where this

cluster of three epidemiologic studies were conducted (i.e., below 78 ppb) and would substantially limit 5-minute exposures equal to or greater than 200 ppb, so that the standard provided an adequate margin of safety. Id. at 35,548/1-2. Based on all of these factors, the Administrator determined that a 1-hour standard at 75 ppb (99th percentile) would be sufficient but not more than necessary to protect public health with an adequate margin of safety. Id. at 35,548/2.

III. IMPLEMENTATION OF THE SO_2 NAAQS

Within one year after promulgation of a new or revised NAAQS (or sooner if reasonably required by EPA) States are directed to submit to EPA a list of all areas that the State recommends be designated by EPA as attainment, nonattainment, or unclassifiable for the new or revised NAAQS. 42 U.S.C. § 7407(d)(1)(A). In the case of the revised primary SO_2 standards, such recommendations were due by June 3, 2011. Within two years of promulgation (or in some cases three years), the Act requires EPA to promulgate designations. Id. § 7407(d)(1)(B)(i). EPA may modify any submitted list of designations provided by a State as the Agency deems necessary if it gives the State 120 days notice, and must promulgate designations as EPA deems appropriate for any area for which no designation recommendation is provided by a State. Id. § 7407(d)(1)(B)(ii). Thus, EPA's statutory obligation to promulgate designations is independent of whether a State submits recommendations.

The Clean Air Act requires States to submit to EPA for approval a revised SIP to implement, maintain and enforce the NAAQS in all areas within their borders within three years of promulgation of a new or revised NAAQS. Id. § 7410(a)(1). Revised SIPs for the 1-hour SO_2 NAAQS are due by June, 2013. These revised SIPs must contain, among other things, necessary programs to meet the applicable requirements of the Clean Air Act. Id. § 7410(a). In addition, for areas designated nonattainment by EPA, States must submit SIPs demonstrating how such areas will be brought into attainment for the NAAQS by specific deadlines. Id. §§ 7502, 7514-7514a. These latter SIPs will be due no later than 18 months following designation. Id. § 7514(a). In response to all SIP submissions from States, EPA undertakes notice-and-comment rulemaking to approve or disapprove the SIPs. Id. § 7410(k).

The SO_2 Rule, like its predecessors, includes regulatory provisions that establish the NAAQS itself, as well as regulations governing revocation of the prior NAAQS and the installation and use of monitors utilized to measure ambient concentrations of SO_2. See, e.g., 40 C.F.R. §§ 50.4(e); 50.14(c)(2)(vi); 50.17; part 50 Appendices A-1 and T; part 53, and part 58. Historically, to determine if an area is in attainment with the SO_2 NAAQS, either for purposes of making designations or determining whether States have demonstrated in their SIPs that they will timely attain the NAAQS, EPA has used a combination of results from

monitors and air quality modeling, even though EPA has not promulgated requirements that States or sources conduct modeling to support designations or SIP approvals. See, e.g., 43 Fed. Reg. at 40,415-16; 43 Fed. Reg. at 46,000-02; 57 Fed. Reg. 13,498, 13,545, 13,547-48 (Apr. 16, 1992); 59 Fed. Reg. 12,886, 12,887 (Mar. 18, 1994); 75 Fed. Reg. at 35,571 n.35, citing "SO_2 Guideline Document," EPA-452/R-94-008 (February 1994); and 67 Fed. Reg. at 22,170-71, 22,183-87. Instead, EPA has regulations requiring the use of modeling in permitting new or modified sources. 40 C.F.R. § 51.160(f). At 40 C.F.R. pt. 51, Appendix W, EPA has promulgated guidelines on air quality models, to be used for implementation purposes, such as in SIP development and new source review ("NSR") and prevention-of-significant-deterioration ("PSD") permitting actions. See, e.g., 40 C.F.R. pt. 51, Appendix W, § 1.0.

In the current rule EPA revised the regulatory requirements for the minimum number and placement of monitors and adopted a new reference method for detecting ambient SO_2, but did not promulgate any regulations regarding modeling. Neither did EPA promulgate requirements governing other subsequent implementation actions such as designations or SIP submissions, apart from narrow provisions addressing the timing of revocation of the prior NAAQS. See 40 C.F.R. § 50.4(e).

In the preamble to the proposed SO_2 Rule, EPA discussed the revisions to the monitoring network proposed to address the proposed change from the 24-hour and annual standards to a single 1-hour standard. 74 Fed. Reg. 64,810, 64,846-55 (Dec. 8, 2009). EPA did not discuss its historic and current uses of modeling in implementing the still-effective annual and 24-hour SO_2 standards. Instead, EPA provided a general summary of the statutory implementation provisions that would apply following final revision of the NAAQS, without addressing the practice of implementing the SO_2 NAAQS dating back three decades. In public comments on the proposal, numerous parties suggested that the proposed monitoring network was both inadequate in scope and overly burdensome to administer, and some commenters suggested that modeling should be used to relieve the administrative burden that a more extensive monitoring regime would otherwise impose. 75 Fed. Reg. at 35,551/1.

In the preamble to the final rule, EPA provided a more detailed discussion of its anticipated implementation of the revised SO_2 NAAQS, and included a more complete accounting of its prior history of SO_2 implementation. EPA explained in response to comments that the Agency anticipated that it would, in subsequent actions, continue its historic practice of relying on both modeling and monitoring for determining whether an area is attaining the SO_2 NAAQS. The Agency also adopted rules for a smaller monitoring network than initially proposed. 75 Fed.

Reg. at 35,550-51. However, the preamble makes clear that, except for the promulgated requirements relating to the scope of the monitoring network and revisions to the detection method for SO_2, the Agency is still developing its policy for such future actions as designations and SIP approvals/disapprovals and intended to issue further guidance, some of it through a notice-and-comment process. Id. In fact, EPA has issued additional guidance, and announced an intention to also, for the first time, conduct further rulemaking to establish final and binding regulatory requirements governing implementation of the SO_2 NAAQS. See., e.g., 76 Fed. Reg. 61,098, 61,099 (Oct. 3, 2011), citing its draft "Guidance for 1-Hour SO_2 NAAQS SIP Submissions," available at http://www.epa.gov/airquality/sulfurdioxide/implement.html. The preamble also states EPA's expectation that any decisions about whether to base an attainment designation or determination on monitoring alone, without reliance on modeling, would be made on a case-by-case basis. 75 Fed. Reg. at 35,552 n.22.

Petitioners submitted petitions for reconsideration to EPA requesting that EPA administratively reconsider and stay the effectiveness of the revised NAAQS. Petitioners' requests were largely based on objections to the implementation guidance discussion in the final NAAQS preamble. EPA denied these requests on January 14, 2011. 76 Fed. Reg. 4780.

SUMMARY OF ARGUMENT

The Court lacks jurisdiction over Petitioners' challenge to a non-binding discussion in the final rule preamble describing in general terms how EPA intends to implement the revised NAAQS in subsequent regulatory actions. That preamble discussion is not final agency action and is not ripe for judicial review. EPA's future actions will provide the appropriate opportunities for any objections to EPA's implementation policies. Similarly, Petitioners lack standing because the preamble discussion does not cause the injuries they allege. The preamble discussion did not establish any binding or enforceable requirements regarding implementation policies and makes clear that the Agency is still developing its approach and that the Agency intends to issue further guidance and take public comment on several implementation issues, a process that is now ongoing. Furthermore, the preamble discussion on the use of modeling in future regulatory actions concerning the new 1-hour SO_2 NAAQS is consistent with the Agency's long-standing position under the prior 24-hour and annual SO_2 NAAQS, and thus does not represent any change in the Agency's views. To the extent the proposal suggested a change in those views to reflect a greater reliance on monitoring, Petitioners were on notice that the Agency might choose not to make such a change.

The level of the 1-hour SO_2 NAAQS is consistent with the formidable body of epidemiologic, clinical, and other information evaluated by the Agency and is consistent with CASAC's consensus recommendation. In particular, EPA reasonably relied on epidemiologic studies demonstrating positive associations between ambient SO_2 concentrations and health effects such as emergency department visits and hospital admissions to establish the standard level of 75 ppb, and reasonably determined that the results of those studies were not confounded by co-pollutants. EPA also reasonably determined, again consistent with consensus CASAC advice, that 5-minute exposures to SO_2 concentrations of 200 ppb result in adverse effects to susceptible subpopulations, although EPA's determination of the level of the standard was driven primarily by results of the epidemiologic studies, rather than the clinical evidence.

The Clean Air Act requires EPA to establish primary NAAQS that are requisite to protect public health with an adequate margin of safety. Nothing in the statute requires EPA to refrain from setting such a standard because ambient SO_2 concentrations are being reduced by other regulatory measures. Moreover, the record demonstrates that ambient levels of SO_2 result in adverse effects on public health.

STANDARD OF REVIEW

The standard of review is set forth in CAA section 307(d), which provides that challenged portions of the final rule may not be set aside unless they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or in excess of EPA's "statutory jurisdiction, authority, or limitations." 42 U.S.C. § 7607(d)(9).

The "arbitrary or capricious" standard presumes the validity of agency actions, and a reviewing court is to uphold an agency action if it satisfies minimum standards of rationality. Small Refiner Lead Phase-Down Task Force v. EPA, 705 F.2d 506, 520-21 (D.C. Cir. 1983); Ethyl Corp. v. EPA, 541 F.2d 1, 34 (D.C. Cir. 1976) (en banc). Where EPA has considered the relevant factors and articulated a rational connection between the facts found and the choices made, its regulatory choices must be upheld. Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). Where the agency's decision rests on an evaluation of complex scientific data within the agency's technical expertise, courts are extremely deferential. Ethyl Corp., 541 F.2d at 36 ("[The court] must look at the [agency's] decision not as the chemist, biologist, or statistician that [it is] qualified neither by training nor experience to be, but as a reviewing court exercising our narrowly defined duty of holding agencies to certain minimal standards of

rationality."); American Trucking Ass'ns, Inc. v. EPA, 283 F.3d 355, 374 (D.C. Cir. 2002) ("ATA III").

With regard to questions of statutory interpretation, the Court must first consider whether Congress has directly addressed the particular question at issue. Chevron, U.S.A., Inc. v. NRDC, 467 U.S. 837, 842-43 (1984). If the statute is silent or ambiguous on a particular issue, the Court must accept the agency's interpretation if it is reasonable; the agency's interpretation need not represent the only permissible reading of the statute nor the reading that the Court might originally have given the statute. Id. 843 & n.11.

ARGUMENT

I. EPA HAS NOT TAKEN FINAL ACTION ON ITS APPROACH TO IMPLEMENTATION OF THE SO_2 NAAQS.

Petitioners' first claim (Pet'rs Br. at 24-41) does not challenge any portion of the promulgated SO_2 NAAQS, but rather several statements in the preamble that Petitioners assert bind EPA to a changed approach to assessing the attainment status of air quality control regions and evaluating States' SIP submissions. Specifically, Petitioners assert that the preamble statements impose a new requirement that EPA base these determinations on air quality modeling, despite the fact that such determinations will be made in separate proceedings based on case-specific facts. Petitioners' claim lacks merit because: (1) EPA has generally utilized air quality modeling in making these determinations for the SO_2 NAAQS,

and thus the preamble does not represent any change to the Agency's long-standing position; (2) EPA was not taking final action on how it will implement the SO_2 NAAQS but rather presented only preliminary, non-binding guidance regarding how it intends to develop its position through guidance and public comment, a process that is currently ongoing, and will continue to develop through future case-specific regulatory actions; (3) Petitioners' claim is not ripe and Petitioners lack standing because EPA has not yet made any attainment designations or approval/disapproval decisions on submitted SIPs which actions will necessarily depend upon case-specific factual records and can be individually judicially reviewed; and (4) to the extent the proposal was suggesting a change in EPA's long-standing practice of using modeling for implementation of the SO_2 NAAQS toward a greater reliance on monitoring, Petitioners should have known that the Agency might choose not to alter its position and thus Petitioners had adequate notice and opportunity to comment.

A. EPA Has Not Changed Its Position On The Use Of Modeling In Implementation Of The SO_2 NAAQS.

Because of unique features of SO_2 pollution, EPA has historically placed a greater emphasis on air quality modeling for implementation of the SO_2 NAAQS than for other pollutants, a fact that this Court has previously noted. PPG Indus., Inc. v. Costle, 659 F.2d 1239, 1248 n.18 (D.C. Cir. 1981) ("EPA expressly prefers modeling over monitoring in many cases to make non-attainment designations. . . .

This practice is permitted by the statute, and has been upheld by the courts." (citations omitted)).

As EPA stated in a 1994 guidance document:

> For SO_2 attainment demonstrations, monitoring data alone will generally not be adequate. A small number of ambient SO_2 monitors usually is not representative of the air quality for an entire area. Typically, modeling estimates of maximum ambient concentration are based on a fairly infrequent combination of meteorological and source operating conditions. To capture such results on a monitor would normally require a prohibitively large and expensive network. Therefore, dispersion modeling will generally be necessary to evaluate comprehensively a source's impacts and to determine the areas of expected high concentrations. Air quality modeling results would be especially important if sources were not emitting at their maximum level during the monitoring period or if the monitoring period did not coincide with potentially worst-case meteorological conditions. Further, monitoring data is not adequate if sources are using stacks with heights greater than good engineering practice or other prohibited dispersion techniques.

SO_2 Guideline Document (available at www.epa.gov/ttn/oarpg/t1/memoranda/so2_guide_092109.pdf) at 2-5 to 2-6. See also id. at 2-1 ("Attainment determinations for SO_2 will generally not rely on ambient monitoring data alone, but instead will be supported by an acceptable modeling analysis which quantifies that the SIP strategy is sound and that enforceable emission limits are responsible for attainment.").

EPA has consistently applied that approach in implementing the prior SO_2 NAAQS. For example, in 2002 EPA disapproved in part Montana's SO_2 SIP revision request because its air quality modeling did not adequately demonstrate

attainment. 67 Fed. Reg. at 22,170-71. In making this determination, the Agency specifically responded to comments that modeling was not required, id. at 22,184, and that the Agency should have relied on monitoring data rather than modeling, id. at 22,184-86. See also 58 Fed. Reg. 41,430 (Aug. 4, 1993) (finding SO_2 SIP submission to be inadequate based on modeling); 57 Fed. Reg. at 13,545 (SO_2 SIP submissions require modeling); see generally 75 Fed. Reg. at 35,551/2-3.

Petitioners do not address this history of implementation of the SO_2 NAAQS, but rather assert that EPA has relied on monitoring citing EPA's practice with regard to NAAQS other than SO_2. Thus, the notices cited in footnote 4 of Petitioners' Brief (at page 5) relate to the NO_2, fine particulate matter, and ozone NAAQS. Similarly, Sierra Club v. EPA, 356 F.3d 296 (D.C. Cir. 2004), cited by Petitioners at page 29, concerned the ozone NAAQS rather than SO_2, and was not concerned with area designations. Thus, Petitioners provide no support for their claim that EPA has historically relied on monitoring alone for implementation of the prior SO_2 NAAQS and they ignore the clear history to the contrary.

Indeed, one of the Petitioners in this case, Montana Sulphur & Chemical Company, is presently challenging EPA's use of modeling to evaluate the Billings/Laurel SO_2 SIP and to promulgate a Federal Implementation Plan under the prior SO_2 NAAQS. See Montana Sulphur & Chem. Co. v. EPA, Case Nos. 02-71657, 08-72642 (9th Cir.). Participating as amici curiae in that challenge are

Petitioners National Environmental Development Association's Clean Air Project and the American Petroleum Institute. The regulatory actions at issue there spanned 15 years, beginning in the early 1990s. See, e.g., 58 Fed. Reg. 41,430 (Aug. 4, 1993); 64 Fed. Reg. 40,791 (July 28, 1999); 67 Fed. Reg. 22,168 (May 2, 2002); 71 Fed. Reg. 39,259 (July 12, 2006); and 73 Fed. Reg. 21,418 (Apr. 21, 2008).[2/] Given this long history involving the use of modeling in SIP approval decisions under the prior SO_2 NAAQS, Petitioners were well aware that the statements in the final preamble did not mark a departure from that practice.

EPA did propose to require a larger monitoring network of SO_2 monitors than what was promulgated, which would have permitted a greater reliance on monitoring (although in the proposal EPA noted that the Agency would still determine on a case-by-case basis whether the monitoring was adequate, 74 Fed. Reg. at 64,859/1-2). However, a proposal is just that. It does not represent the Agency's final position. Nor does it become the Agency's past practice or obliterate from history the Agency's actual past practice. In response to comments that the proposed monitoring network was unduly burdensome, in the final rule

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[2] Moreover, as Petitioners who have undergone a New Source Review or Prevention of Significant Deterioration permitting exercise well know, EPA's long-promulgated permitting requirements (which were not modified by the rule under review) require modeling to be used to show that newly constructed or modified major sources of SO_2 will not violate or interfere with attainment or maintenance of the NAAQS. See, e.g., 40 C.F.R. § 51.160(f).

EPA required a less extensive monitoring network than proposed and restated its long-standing view that modeling is the preferred analytical tool to determine whether areas are in attainment for the SO_2 NAAQS, subject to the specific facts presented by individual implementation actions such as designations and SIP approvals.

B. EPA Has Not Taken Final Agency Action On Implementation Of The SO_2 NAAQS.

Petitioners are not challenging any provision of the promulgated regulations in objecting to EPA's implementation guidance in the preamble, but rather are challenging EPA's preamble discussion of its planned approach to future regulatory actions that would make fact-specific decisions.[3] The preamble makes clear, however, that EPA's approach is still under development and that EPA intends to issue further guidance and to seek further comment on implementation of the SO_2 NAAQS. Specifically, the preamble states:

> In many respects, both the overview discussion below and the subsequent more detailed discussions explain our expected and intended future action in implementing the 1-hour NAAQS – in other words, they constitute guidance, rather than final agency action – and it is possible that our approaches may continue to evolve as we, States, and other stakeholders proceed with actual implementation. In other respects, such as in the final regulatory provisions regarding the promulgated

[3] Moreover, contrary to Petitioners' assertions (Pet'rs Br. at 22-28), how EPA implements the NAAQS under various provisions of the Act, such as section 7407 (designations) and 7410 (SIPs), is not an element of the standard itself, which is adopted pursuant to section 7409.

> monitoring network, we are explaining EPA's final conclusions regarding what is required by this rule. We expect to issue further guidance regarding implementation . . . . EPA intends to solicit public comment prior to finalizing this guidance.

75 Fed. Reg. at 35,550/3 (emphasis added).

Nowhere in the preamble (or in regulatory text) does EPA state that modeling must in all cases be used for designating areas as attainment, nonattainment or unclassifiable. Rather, the preamble states: "We expect that EPA's final area designation decisions in 2012 would be based principally on data reported from SO_2 monitors currently in place today, and any refined modeling the State chooses to conduct specifically for initial designations." Id. at 35,552/1 (emphasis added). The preamble then continues, "EPA anticipates making the determination of when monitoring alone is 'appropriate' for a specific area on a case-by-case basis, informed by the area's factual record, as part of the designations process." Id. at 35,552 n.22. Thus, the preamble does not dictate that monitoring alone is not sufficient for determining an area's attainment status, but makes clear that such determinations would be made on a case-by-case basis.

In its denial of the administrative petitions for reconsideration, EPA confirmed that nothing in the preamble discussion is final or binding on the Agency. In response to a reconsideration petition by Petitioner Utility Air Regulatory Group ("UARG"), EPA stated:

> [T]he claims that EPA's discussion has an impact on the promulgated standard ignore the fact that the guidance is not final binding action that has any immediate and direct effect on anything. As UARG appears to recognize, future implementation actions using EPA's "recommended" approaches which EPA "does not require" "could" have an impact by "possibly" or "likely" resulting in States using modeling in a way to "likely" overestimate SO_2 emissions only if, in fact, all of that actually occurs, which it may not. Thus, UARG's claim as presented necessarily concedes that any arguable impact on NAAQS compliance of the guidance discussion is speculative at this point. There is no reason to accept this result as inevitable, and if, in a given case (such as PSD permitting), UARG believes that a particular modeling method is over-predicting SO_2 emissions in a manner that is not representative of a source's potential to cause or contribute to a NAAQS exceedance, it will in that future action be able to object based on the facts then presented. But here there are no such facts to dispute, and it is therefore not possible for the guidance itself, as expressed in EPA's preamble, to have any impact on the NAAQS.

76 Fed. Reg. at 4799/2-3.

EPA responded similarly to claims that the final rule mandated the use of modeling in making designations or attainment demonstrations:

> [T]he final rule does not in fact provide that modeling "must" be used to demonstrate attainment, but instead leaves for future actions the decision whether in specific cases monitoring or modeling or some combination of the two will best measure ambient SO_2 concentrations. If EPA were to determine in a given action that the monitoring data were not sufficient to determine the area's attainment status, and thus that the area would have to be categorized as unclassifiable until sufficient monitoring data or modeling results were available, that designation would be the result of the insufficiencies in the data, not of anything that EPA has done in the final rule or discussed in the preamble guidance.

Id. at 4799/3.

Moreover, since promulgation of the final rule, EPA has published guidance documents on permitting and the designations of areas under the 1-hour SO_2 NAAQS, and has published draft guidance on the preparation of SO_2 SIPs and sought public comment on that draft guidance. On August 23, 2010, the Agency published guidance on implementing the Prevention of Significant Deterioration permit program with regard to the 1-hour SO_2 NAAQS. Available at www.epa.gov/nsr/guidance.html. On March 24, 2011, as Petitioners note in their brief, Pet'rs Br. at 21, EPA published guidance regarding designations of areas as attainment, nonattainment, or unclassifiable. Available at www.epa.gov/airquality/sulfurdioxide/guidance.html. On September 22, 2011, EPA published draft guidance on submission of SIPs for the 1-hour SO_2 NAAQS. Available at www.epa.gov/sulfurdioxide/implement.html. ("Draft Guidance"). EPA has requested public comment on the draft. 76 Fed. Reg. 61,098 (Oct. 3, 2011). Moreover, in the Draft Guidance EPA announced its intention to propose regulatory provisions to address some SO_2 NAAQS implementation elements, including, among other things, demonstrating NAAQS compliance by the use of monitoring and modeling and establishing the specific modeling requirements. See Draft Guidance at iii-iv.[4]

[4] There is no basis to the assertion in Petitioners' Rule 28(j) letter (Oct. 25, 2011) that EPA's taking public notice on this guidance and stated intention to propose (continued...)

Thus, the challenged preamble discussion is not final agency action. The standard for determining whether an agency action is final was established by the Supreme Court in Bennett v. Spear, 520 U.S. 154, 177-78 (1997). See, e.g., Nat'l Ass'n of Homebuilders v. Norton, 415 F.3d 8, 13 (D.C. Cir. 2005). To be reviewable, an agency action (1) must mark the consummation of the agency's decision making process and (2) must be an action by which rights or obligations have been determined or from which legal obligations flow. Id.

The preamble discussion satisfies neither prong. First, it is not the consummation of the Agency's decision-making process. As the preamble discussion makes clear, it reflects only the Agency's "expected and intended future action in implementing the new 1-hour NAAQS." 75 Fed. Reg. at 35,550/3. The preamble also made clear that the Agency intended to further develop its position through additional guidance and public comment. As just discussed, the Agency is currently in the process of developing that guidance, has expressed its intention to conduct national rulemaking to address several implementation issues, and will

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[4](...continued)
rulemaking supports their position that the preamble discussion is final agency action. To the contrary, EPA stated in the preamble that it intended to further develop its position and that it would seek public comment. It has now done so, and in any future proposed rulemaking will do so again, demonstrating that the preamble discussion was not in fact the Agency's final position.

necessarily have to conduct notice and comment rulemaking in responding to future SIP revisions.

Nor does the preamble discussion impose legal obligations on EPA, or legal consequences on the States or industry, that are not already independently imposed by the statute or by other regulations that are not before this Court. The preamble discussion makes clear that it is only preliminary guidance, and that it does not dictate any specific future regulatory decisions with regard to area attainment designations or SIP approvals. In fact, the preamble is quite explicit that the need for modeling, as opposed solely to reliance on monitoring data, is to be determined in the future on a case-by-case basis. Id. at 35,552 n.22.

The duty for States to submit area designation recommendations[5] and implementation plans showing enforcement and maintenance of the NAAQS[6] is created by sections 107 and 110 of the Clean Air Act, respectively. 42 U.S.C. §§ 7407, 7410. States were free to submit proposed designations based on any combination of monitoring data and modeling they chose. EPA will consider the submissions on a case-by-case basis in the process of making its final designations.

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[5] Because the deadline for making such submissions has passed, any claims that Petitioners may have had concerning those submissions are in any event moot.

[6] Petitioners' claim that the preamble creates legal consequences with regard to the States' 2013 SIP submissions is further belied by the fact that EPA is currently taking comment on its draft guidance regarding those submissions.

EPA will similarly review and make a decision on SIP submissions on a case-by-case basis in the future. But only EPA's future designation of an area as "nonattainment" will trigger a State's duty to then submit a full nonattainment area SIP under sections 172 and 191-192. 42 U.S.C. §§ 7502, 7514-7514a.

Finally, neither PPG Industries, 659 F.2d 1239, nor Portland Cement Ass'n v. Ruckelshaus, 486 F.2d 376 (D.C. Cir. 1973), is apposite because in neither case was there any question that EPA had made the challenged revision to the rule. In PPG Industries, EPA had changed the method of compliance with the 24-hour SO_2 NAAQS from a midnight-to-midnight period to a rolling 24-hour period. There was no question that EPA had changed the methodology, the only issue was whether EPA had provided adequate notice. In Portland Cement, petitioners challenged portions of the promulgated regulations, and the Court held that they had insufficient opportunity to comment because they did not have access to some of the data on which the rule was based. Thus, neither of these cases addressed the issue presented here, which is whether EPA has taken final action at all.

C. Petitioners' Challenge To Future EPA Actions Is Not Ripe; In The Alternative, Petitioners Lack Standing.

Petitioners' Brief makes clear that what Petitioners are actually seeking to challenge is not any action that EPA took in promulgating the revised NAAQS, but rather actions the Agency may take in the future designating areas as attainment, nonattainment or unclassifiable and approving or disapproving submitted SIPs.

Pet'rs Br. at 35-41. Specifically, Petitioners claim they will be harmed if EPA bases these future actions on modeling rather than monitoring. However, as this Court has previously recognized, when a party's claimed injury depends on discretionary action that the Agency will take in the future, that claim is not ripe, or alternatively, the party lacks standing because its injuries are caused not by the action being challenged, but rather by presumed future actions. Louisiana Envtl. Action Network v. Browner, 87 F.3d 1379 (D.C. Cir. 1996) ("LEAN").

The rationale of LEAN is clearly applicable here. Nothing in the final rule preamble directly impacts Petitioners. Rather, Petitioners' claim of injury is based on their assumption of how EPA will act in the future. However, those future decisions will have to be made on the basis of facts presented by each case, and EPA has stated in the preamble that the question of whether designations can be based solely on monitoring will be decided on a case-by-case basis. 75 Fed. Reg. at 35,552 n.22. Moreover, affected parties will have notice and a full opportunity to comment on EPA's use of modeling in making those decisions[7], and those decisions will be independently subject to judicial review. Simply stated, there is no way for Petitioners or the Court to know what action EPA will take until the

[7] Although the Clean Air Act does not require notice and comment rulemaking for area designations, it does require EPA to provide notice to States of any intended modification to a State's designation recommendations and to provide the State an opportunity to demonstrate why EPA's proposed modification is inappropriate. 42 U.S.C. § 7407(d)(1)(B)(ii), (2)(B).

Agency takes it. As the Court held in LEAN, this claim "presents the classic institutional reason to postpone review: we need to wait for 'a rule to be applied [to see] what its effect will be.'" 87 F.3d at 1385, quoting Diamond Shamrock v. Costle, 580 F.2d 670, 674 (D.C. Cir.1978).

Alternatively, again as the Court found in LEAN, because Petitioners' claim of injury depends on speculative future actions by EPA, any such injury is neither imminent nor concrete, and thus Petitioners lack standing. In LEAN petitioners challenged EPA regulations governing EPA's evaluation of state plans for enforcement of the Clean Air Act's limitations on the emission of hazardous pollutants. Petitioners claimed that the regulations could lead to the approval of state regulations that were either overly stringent or overly lax. The Court rejected both claims because Petitioners had not established that either situation would occur. 87 F.3d at 1382-84. Petitioners' claim in this case is even more speculative than that in LEAN because here Petitioners are not challenging a regulation but a preamble discussion that talks in general terms about EPA's possible future approach to implementation. Accordingly, Petitioners' challenges to these future EPA actions are not properly before the Court.

D. Petitioners Had Adequate Opportunity for Comment.

Even if the Court were to determine that the preamble discussion constituted reviewable final agency action and that Petitioners have demonstrated ripeness for review and standing to challenge it, Petitioners' claims fail because Petitioners had adequate opportunity for comment. As discussed above, EPA has historically used modeling for designations of specific areas for attainment for the prior SO_2 NAAQS and has in individual SIP actions required modeling to demonstrate that SIPs will result in attainment. As discussed above, Petitioners have no reason not to have been aware of the Agency's historical approach, and indeed have long disputed EPA's use of this approach in other actions.

Thus, to the extent the approach to designations and/or attainment demonstrations described in the proposal preamble was limited to monitoring, in de-emphasizing the role modeling has long played in SO_2 implementation it represented a departure from the Agency's prior practice. In such circumstances, affected parties are surely aware that not adopting the proposed change is a possibility. American Iron & Steel Inst. v. EPA, 886 F.2d 390, 400 (D.C. Cir. 1989) ("One logical outgrowth of a proposal is surely, as EPA says, to refrain from taking the proposed step.") In fact, the Agency did receive comments urging the Agency to retain its historic approach. 75 Fed. Reg. at 35,551/1. Petitioners' reliance on Small Refiner Lead, 705 F.2d at 549 (Pet'rs Br. at 34) is misplaced

because EPA is not "bootstrapping" notice from the comments. Rather, Petitioners were well aware of EPA's existing practice of using modeling, and thus had adequate notice that the proposal preamble represented a change from the Agency's past practice, a change that the Agency might choose not to make. The comments reflect that fact.

Petitioners' reliance on Am. Water Works Ass'n v. EPA, 40 F.3d 1266, 1275 (D.C. Cir. 1994), (Pet'rs Br. at 35) is misplaced for the same reason. Petitioners here had ample reason to know that EPA was proposing a change to its existing practice, and if Petitioners had relevant comments to offer (and they have not explained what those might have been) and chose not to make them, they were "asleep at the switch." Accordingly, there is no basis for Petitioners' claim that they lacked notice that the Agency might choose not to adopt a more monitoring-focused approach as discussed in the proposal preamble, but instead to retain its historic approach in which modeling is generally, though not always, utilized.

Furthermore, as discussed above, the decision as to whether to utilize modeling or monitoring or some combination of the two will be made in individual designation and SIP approval actions. Affected parties will have notice of the approach EPA intends to take based on the specific facts in each case and will have a full opportunity to comment on that approach. Thus, Petitioners' right to notice

and comment, and to challenge subsequent actions that cause them injury, is fully protected.

II. EPA REASONABLY ESTABLISHED THE LEVEL OF THE STANDARD AS 75 PARTS PER BILLION

Petitioners' only challenge to substance of the promulgated regulation is to the level of the standard set by EPA. They do not challenge the finding of a causal relationship between respiratory morbidity and short-term exposure to SO_2, the need for a short-term standard, the choice of a 1-hour averaging time, or the 99th percentile form of the standard. Rather, they challenge only EPA's finding that the clinical studies and other evidence demonstrate that adverse health effects occur following 5-minute exposures to ambient SO_2 concentrations as low as 200 ppb (Pet'rs Br. at 41-49) and EPA's reliance on the epidemiologic studies (Pet'rs Br. at 49-54).

Both of these arguments are without merit. As shown in section II.B below, EPA's judgment as to the adversity of health effects from short-term exposure to 200 ppb of SO_2 is supported by the breadth of evidence before the Agency and consistent with advice EPA received from CASAC. In any case, although the adverse health effects demonstrated in the clinical studies with short-term exposures to concentrations of 200 ppb were one of the factors EPA considered in revising the standard, the standard level of 75 ppb was not established primarily on the basis of the clinical studies at 200 ppb. Rather, the primary basis for the level

is the broad body of epidemiologic evidence, including a cluster of three epidemiologic studies demonstrating positive associations between ambient SO_2 and respiratory-related emergency department visits and hospital admissions in locations where the 99th percentile 1-hour SO_2 concentrations were as low as 78 ppb.

Petitioners' challenges to EPA's epidemiologic studies are similarly misplaced. As demonstrated in section II.A, the three studies on which EPA primarily relied in setting the level of the standard do show a number of statistically significant positive correlations between health effects and SO_2 levels including when other pollutants are considered. Furthermore, statistical significance is just one of the means of evaluating the validity of the relationships determined with epidemiologic studies. As this Court has previously held, EPA can look to other indicia of reliability such as the consistency and coherence of a body of studies as well as other confirming data to justify reliance on the results of a body of epidemiologic studies, even if individual studies may lack statistical significance when considering potential confounding pollutants. ATA III, 283 F.3d at 371. Furthermore, the objections raised by Petitioners to the individual studies were considered and reasonably rejected by EPA.

A. EPA Properly Relied On The Epidemiologic Studies In Establishing The Level Of The Standard.

EPA carefully evaluated the epidemiologic studies in the light of all the evidence, including clinical and toxicologic studies, and, evaluated as a whole, the evidence strongly demonstrates a causal association between exposure to SO_2 and the types of respiratory health effects reported in the epidemiologic studies. 75 Fed. Reg. at 35,525-26, 35,548/1. EPA found that the results of the epidemiologic studies were coherent and consistent for a body of studies conducted in a variety of locations with a variety of methodological approaches. 75 Fed. Reg. at 35,525/3, 35,535/3; see also 74 Fed. Reg. at 64,835-39 (showing results of domestic studies) and ISA at 5-6 and 5-7 (domestic plus international studies) (JA 01456, 01457).[8] This conclusion is further supported by the consistency of the respiratory effects observed in the epidemiologic studies with the mode of action of SO_2 on the

[8] The ISA evaluates the "consistency and coherence" of the epidemiologic evidence as follows: "Associations between short-term ambient SO_2 concentrations and respiratory symptoms, [emergency department] visits, and hospitalizations are largely positive, with several of the more precise effect estimates (suggestive of greater study power) indicating statistical significance. The epidemiologic findings of asthma symptoms with 24-h avg SO_2 exposures are generally coherent with increases in symptoms reported in asthmatics in human clinical studies . . . ." ISA at 5-5 (JA 01455).

human respiratory system. 75 Fed. Reg. at 35,535/3; ISA at 5-2 (JA 01452).[9] As explained in the ISA:

> The immediate effect of SO_2 on the respiratory system is bronchoconstriction. This response is mediated by chemosensitive receptors in the tracheobronchial tree. These receptors trigger reflexes at the central nervous system level resulting in bronchoconstriction, mucus secretion, mucosal vasodilation, cough, and apnea followed by rapid shallow breathing. . . . Asthmatics are more sensitive to the effects of SO_2 likely resulting from preexisting inflammation associated with this disease. . . . These biological processes are likely to underlie decreased lung function and increased hyperresponsiveness observed in response to SO_2 exposure.

ISA at 5-2 (JA 01452); see also Response to Comments ("RTC") at 28-29 (JA 01197-98) (noting that "the evidence from controlled human exposure, toxicological and epidemiologic studies for the respiratory health effects of SO_2 are consistent with the mode of action of SO_2, as it is currently understood").

The human clinical studies further reinforce EPA's conclusions concerning the consistency, plausibility and coherence of the epidemiologic evidence. As the Administrator stated:

> the ISA emphasized that controlled human exposure studies provide support for the plausibility of the associations reported in epidemiologic studies. The ISA noted that the results of controlled human exposure and epidemiologic studies form a plausible and coherent data set that supports a causal relationship between short-term (5-minutes to 24-

[9] EPA need not establish a mode of action to act in issuing or revising a NAAQS, ATA III, 283 F.3d at 371, but the identification of a mode of action for SO_2 consistent with observed health effects further strengthens the reasonableness of the Agency's conclusions.

> hours) SO_2 exposures and adverse respiratory effects, and that the epidemiologic evidence (buttressed by the clinical evidence) indicates that the effects seen in the epidemiologic studies are attributable to exposure to SO_2.

75 Fed. Reg. at 35,544/1.[10] These results were also coherent in that the respiratory effects observed in controlled human exposure studies of 5–10 minutes further provided a basis for a progression of respiratory morbidity that could lead to the increased emergency department visits and hospital admissions observed in epidemiologic studies. 75 Fed. Reg. at 35,525/3; ISA at 5-5 (JA 01455).

Based on this body of evidence, the Administrator relied primarily upon the epidemiologic studies in setting the level of the standard, and in particular on the cluster of three U.S. studies (i.e., NYDOH (2006) (JA 00546-803), Ito, et al., (2007) (JA 00804-19), and Schwartz et al, (1995) (JA 01103-10) that reported positive associations between ambient SO_2 values and health effects (respiratory related emergency department visits and hospital admissions) in cities where the 99th percentile 1-hour SO_2 concentration ranged from 78 to 150 ppb. In those studies the SO_2 effect estimate remained positive and statistically significant in

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[10] See also 75 Fed. Reg. at 35,535/3 ("the epidemiologic evidence supported by the controlled human exposure evidence, generally indicates that the effects seen in these studies are attributable to exposure to SO_2, rather than co-pollutants, most notably PM2.5"); id. at 35,525/3 (evidence of effects is "coherent in that respiratory symptom results from epidemiologic studies of short-term (predominantly 1-hour daily maximum or 24-hour average) SO_2 concentrations were generally in agreement with respiratory symptom results from controlled human exposure studies of 5-10 minutes").

multi-pollutant models that included particulate matter.[11/] 75 Fed. Reg. at 35,547-48. In considering the need for an adequate margin of safety, the Administrator set the standard at 75 (rather than 78). Id. at 35,548/1. The Administrator's analysis here is similar to the one upheld by this Court in ATA III, 283 F. 3d at 372, where EPA relied on a body of studies demonstrating a relationship between fine particulate matter concentration and health impacts and the Agency set the level of the standard just below the lowest level found that showed a statistically significant correlation. With regard to the level of the standard, the Court held:

> While we cannot say those studies necessitated a standard level of 15 $\mu g/m^3$, neither have we any basis for concluding that EPA's decision was unreasonable or unsupported by the record. We repeat: "That the evidence in the record may also support other conclusions, even those that are inconsistent with the Administrator's, does not prevent us from concluding that [her] decisions were rational and supported by the record."

283 F.3d at 372 (quoting Lead Indus., 647 F.2d at 1160).

Seeking to challenge this powerful body of evidence, Petitioners here, like the Petitioners in ATA III, argue that the results of the three epidemiologic studies are confounded by other pollutants. Petitioners also argue that the Agency's evaluation of whether the health effects reported in the epidemiologic evidence are

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[11] Particulate matter is of significance because SO_2 gas can convert into sulfate particulate after its emission as a gas, and it is important to determine whether the health effects seen are the result of SO_2 by itself or its subsequent conversion into fine particulate matter.

likely the result of exposure to SO_2 depends on the effects observed in the clinical studies, which they (incorrectly) dispute. Pet'rs Br. at 50. With regard to this second point, Petitioners are mistaken that EPA's finding that the epidemiologic study results are likely the result of exposure to SO_2 is based solely on the 200 ppb level used in some of the clinical tests. As demonstrated above, EPA's finding that there is a causal association between exposure to SO_2 and the types of health effects reported in the epidemiologic studies rests on the entire body of the evidence, not just the clinical evidence, and not on one particular level in those clinical studies. 75 Fed. Reg. at 35,548/1.[12/]

Petitioners incorrectly assert (Pet'rs Br. at 50) that EPA relied on the 200 ppb clinical studies to establish biological plausibility because the ISA states that SO_2 exposures at levels "as low as" 200 to 300 ppb are capable of eliciting respiratory effects in asthmatics. This statement means that the body of clinical evidence adds plausibility to the epidemiologic evidence and that this clinical evidence includes effects at levels as low as 200 ppb-300 ppb, not that only the 200 ppb studies establish biological plausibility. See ISA at 5-5 (JA 01455) ("Collectively, these findings provide biological plausibility for the observed

[12] Similar findings linking the biological plausibility of the epidemiologic evidence to the clinical evidence, without regard to the levels observed in the clinical studies, are RTC at 24, 34 (JA 01193, 01203) and ISA at 3-28 (JA 01393).

associations between ambient SO_2 levels and ED visits and hospitalizations") (emphasis added).

Moreover, EPA's statements that the epidemiologic studies "should not be considered in a vacuum" and that EPA was not "relying solely on the epidemiologic studies to evaluate whether associations reported in these studies (e.g., associations with emergency department visits) are likely the result of ambient SO_2 exposure," 75 Fed. Reg. at 35,531/2, emphasize the strength of the overall evidence for a causal relationship between SO_2 exposures and the health effects seen in the epidemiologic studies, rather than weakness in the epidemiologic evidence as Petitioners mistakenly assert. See Pet'rs Br. at 50.

Furthermore, as Petitioners acknowledge, EPA directly spoke to the issue of potential confounding of the epidemiologic studies by other pollutants, and especially particulate matter. Pet'rs Br. at 50. First, the Agency found that the consistency, coherence, and plausibility of all of the evidence makes clear that the observed effects are reasonably attributable to SO_2 exposure. Second, a means of evaluating whether epidemiologic results are confounded by other pollutants is to use multi-pollutant statistical models. 75 Fed. Reg. at 35,531/1. Looking to the studies using such models, EPA noted the "cluster of three epidemiologic studies [the Ito, Schwartz, and NYDOH studies] between 78-150 ppb (for the 99^{th} percentile of 1-hour SO_2 concentrations) where the SO_2 effect estimate remained

positive and statistically significant in multi-pollutant models with PM." 74 Fed. Reg. at 64,844/1.[13/]

Petitioners' challenges to these three studies are without merit. With regard to the Ito study, Petitioners argue that it should not be relied on because it no longer shows statistical significance (although the SO_2 effect estimate remains positive) in multi-pollutant models with NO_2. Pet'rs Br. at 52-53. However, EPA reasonably considered and rejected this argument. First, the study not only remained positive but also remained statistically significant in regression models including particulate matter. ISA Table 5-5 (JA 01466). Second, with regard to NO_2, EPA noted (as had the study authors) that the attenuation of the SO_2 effect in regression models that include NO_2 may be due to less exposure error in NO_2 measurements than in SO_2 measurements and reasoned that this attenuation likely

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[13] EPA's focus on these studies, and EPA's interpretation of the epidemiologic evidence generally, is not a case of "[l]ooking over the crowd to pick its friends." Pet'rs Br. at 51. First, EPA reasonably gave special attention to the three studies that used recognized statistical methodologies for evaluating the influence of potential confounding pollutants. Second, EPA took "into account all the relevant studies revealed in the record" and made "an informed judgment based on the available evidence," American Petroleum Inst. v. EPA, 665 F. 2d 1176, 1187 (D.C. Cir. 1981), reasonably explaining why the epidemiologic evidence indicates that the observed effects are attributable to exposure to SO_2. Moreover, consistent with its reliance on the three studies, EPA did not place significant reliance on epidemiologic studies reporting an association between SO_2 concentrations and adverse health effects in cities with SO_2 concentrations as low as 50 ppb because those studies did not use multi-pollutant statistical models to evaluate the potential for confounders and not all results reported were positive. 75 Fed. Reg. at 35,547/3.

reflected this difference, not that the effects in the study are attributable to NO_2. 75 Fed. Reg. 35,545/1.

With respect to the Schwartz study, Petitioners argue that results in New Haven were confounded by ozone, and in Tacoma by ozone and particulate matter. Pet'rs Br. pp 52-53. The Schwartz study involved two cities (New Haven, Connecticut and Tacoma, Washington) deliberately chosen for contrast. The study results for New Haven remained positive and statistically significant in co-pollutant models with particulate matter. ISA Table 5-5 (JA 01467). The central effect estimate in the New Haven portion of the study remained positive and barely altered in regression models with ozone, but lost statistical significance because ozone is only measured in warm weather and inclusion of ozone reduced the number of study days by 40 percent, so that the study overall lost statistical power. 75 Fed. Reg. at 35,545/1-2; see also RTC at 24 (JA 01193) noting that differing results in multi-pollutant models can reflect loss of model stability rather than effects of a confounding pollutant.[14] EPA consequently found the effect of SO_2 to be robust to inclusion of co-pollutants in this study as well.

Finally, Petitioners claim that EPA should not have accepted the results of the NYDOH study because, while the results for SO_2 were positive and statistically significant for the Bronx (including in co-pollutant models including particulate

[14] Dr. Ito made the same observation. Ito at S58 (JA 00817).

matter), they were not in Manhattan. Pet'rs Br. at 53. EPA reasonably explained the differences between the two study areas: the statistical power of the Bronx portion of the study was vastly greater than the Manhattan portion because it had nearly six times the number of emergency visits, i.e., nearly 30,000 asthma visits in the Bronx during the study period compared to approximately 5,000 in Manhattan during the same period. 75 Fed. Reg. at 35,544/2-3; RTC at 68 (JA 01229). The lack of statistical power in the Manhattan portion of the study does not make the Bronx portion unreliable.

More fundamentally, Petitioners' challenges to these three studies fail to account for the overwhelming support provided by the entire body of scientific evidence for the existence of a causal relationship between ambient SO_2 levels at the levels in these studies and serious adverse health effects. As discussed above, EPA's analysis of the issue of potential confounders here is strongly supported by this Court's analysis of a similar issue in ATA III. Though the Agency in that case acknowledged the lack of an established causal mechanism for the relationship between fine particle concentrations and health effects and recognized the possibility of confounding by co-pollutants, the Agency found that the consistency and coherence of a body of studies performed in a variety of different locations gave the Agency sufficient confidence in the results of the studies to use them as

the basis for establishing the standard. This Court upheld the Agency's decision holding that it would defer to:

> EPA's entirely plausible reasoning regarding the confounder issue: According to the Agency, the "consistency of PM effects across areas with widely varying concentrations of potentially confounding copollutants," together with Agency staff's "extended analyses of the Philadelphia studies," amply justify the conclusion that "PM, alone or in combination with other pollutants, is associated with adverse effects at levels below those allowed by current standards."

283 F.3d at 371 (quoting 62 Fed. Reg. 38,652, 38,661 (July 18, 1997)).

The present case is even stronger than that considered in ATA III. Here there is a consistent and coherent body of epidemiologic evidence, with evidence that the SO_2 association in the epidemiologic studies remains robust and independent of the effects of co-pollutants, including particulate matter, an enormous body of clinical evidence supporting the conclusion that SO_2 is the causative agent, plus an established causal mechanism between SO_2 exposure and health effects that is consistent with the evidence from the epidemiologic and clinical studies. Petitioners' argument that the epidemiologic evidence is inherently flawed and fails to support the level of the standard is consequently without merit.

B. EPA Properly Determined That The Effects From Short-Term Exposure To Ambient SO_2 Levels As Low As 200 ppb Were Adverse And EPA Reasonably Considered This Information in Setting the Level of the Standard.

Petitioners also challenge EPA's establishment of the 75 ppb level on the ground that EPA based the level on clinical studies at the 200 ppb concentration level and that this reliance was inappropriate because these studies allegedly do not demonstrate an adverse health effect. Pet'rs Br. at 41-49. Both of these claims are incorrect. First, as described in section II.A above, EPA based the level of the standard primarily on the epidemiologic studies that reported positive associations in cities with 1-hour daily maximum ambient SO_2 concentrations as low as 78 ppb and the undisputed adverse public health effects of increased emergency department visits and hospital admissions. EPA set the level of the standard to provide protection against the public health risks identified in these epidemiologic studies. This in itself is decisive.

Second, EPA's conclusion that adverse health effects can be caused by 5-10 minute exposures to ambient levels of SO_2 down to 200 ppb is supported by the evidence and is consistent with CASAC's advice. See 75 Fed. Reg. at 35,531-33. The clinical studies demonstrate that 5-10 minute exposure to SO_2 concentrations as low as 200-300 ppb result in approximately 5 to 30 percent of exercising asthmatics in those studies experiencing moderate or greater decrements in lung function . Id. at 35,532/1. EPA reasonably explained why this effect can be

considered adverse under the American Thoracic Society guidelines: the effects seen in this population of asthmatics diminished their reserve lung function placing them at greater risk if affected by another respiratory agent such as a virus or ozone. Id. Furthermore, subjects participating in the clinical studies did not include severe asthmatics, who could be anticipated to have more severe responses. Finally, CASAC made clear that it considered that adverse effects extended to ambient 5-10 minute exposures of 200 ppb. As CASAC said in its letter on the first draft REA, "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 ppm SO_2" August 22, 2008 Letter at 1 (JA 00424); see also 75 Fed. Reg. at 35,532/1-2 (quoting similar emphatic advice from CASAC that the 5-minute exposures at 200 ppb in the clinical studies show adverse effects); see also American Farm Bureau Fed'n v. EPA, 559 F. 3d 512, 521 (D.C. Cir. 2009) (importance of CASAC advice); Coalition of Battery Recyclers Ass'n v. EPA, 604 F.3d 613, 619-20 (D.C. Cir. 2010) (same). Based on the evidence and CASAC's advice, EPA reasonably concluded that short-term exposures in the ambient air to levels as low as 200 ppb can result in adverse health effects to exercising asthmatics. 75 Fed. Reg. at 35,532/3.

EPA also reasonably addressed Petitioners' assertion that the studies do not show adverse health effects at 200 ppb because equal numbers of asthmatics showed increases as decreases in lung function at that level. Pet'rs Br. at 48. As EPA pointed out, the studies demonstrate clear differences in the manner in which asthmatics responded – those who experienced moderate or greater decrements in lung function at higher SO_2 concentrations tended, on average, to experience greater decrements in lung function at lower concentrations, including 200 ppb, when compared with all subjects combined. 75 Fed. Reg. at 35,532-33. Figures 4-2 and 4-3 of the ISA illustrate this effect, demonstrating the extra susceptibility in these study subjects. (JA 01438, 01439). EPA thus reasonably concluded that the effects seen at the 200 ppb level in the clinical studies are not random, but point to a segment of the asthmatic subjects being more sensitive to SO_2 exposure.[15] RTC at 14 (JA 01183) ("[g]iven this clear relationship of exposure and effect at all levels in the sensitive asthmatics (i.e., those who experienced significant decrements in lung function at the highest exposure concentration used (600 ppb)), EPA does not accept the commenters' premise that the results of the study do not demonstrate adverse effects").

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[15] In light of this strong evidence, Petitioners' claim (Pet'rs Br. at 47) that the clinical evidence could be interpreted as showing that SO_2 exposure caused lung function improvements is without merit. Likewise, their assertion that EPA "cherry-picked" the results of the clinical evidence, id. at 44, is incorrect.

EPA properly concluded that this group of asthmatics with increased susceptibility warrants protection under the NAAQS. Contrary to Petitioners' arguments that the Clean Air Act does not extend protection to those individuals who are most susceptible, Pet'rs Br. at 49, not only does the Act extend protection to susceptible subpopulations, but this group also includes even more susceptible subpopulations such as severe asthmatics who are not tested in clinical studies for ethical reasons. CASAC Letter of August 8, 2008 at v (JA 01115) ("For ethical reasons severe asthmatics were not part of these clinical studies, but it is not unreasonable to presume that they would have responded to even a greater degree"); 75 Fed. Reg. at 35,533/1-2.[16] See also Coalition of Battery Recyclers, 604 F.3d at 618 (basing level of NAAQS on susceptibility of highly exposed children reasonable).

Petitioners further assert that EPA improperly projected clinical study results to the entire population of asthmatics because the clinical results at the 200 ppb level were not statistically significant at the group mean level in the clinical studies. Pet'rs Br. at 46-47. This reliance on statistical significance as a single

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[16] See also CASAC Letter of August 8, 2008 at iv (JA 01114) ("The Panel is concerned about the potential underestimation of the proportion of asthmatic persons affected by short-term exposure to SO_2 because only mild and moderate asthmatic adults were recruited to participate in the clinical studies. People with more severe asthma or poor control of their symptoms may be more susceptible and may respond more adversely to SO_2").

dispositive criterion is misplaced. These are controlled human exposure studies, where the only etiologic agent to which the subjects are exposed is SO_2, and every other potentially causal element is controlled, readily supporting the inference that SO_2 is causing the observed effects. RTC at 14 (JA 01183); ISA at 1-4 (JA 01356).[17] Again, lack of statistical significance at the group mean level reflects only that the studies have limited statistical power due to the small number of subjects tested, rather than doubt as to a causal nexus.

This conclusion is borne out by the consistency and coherence of all of the evidence in the record. EPA recognized that the respiratory effects seen at 200 ppb are less severe than those seen at 400 ppb. 75 Fed. Reg. at 35,547. However, the effects observed in the clinical studies for sensitive moderate asthmatics at 200 ppb exposure levels are consistent and coherent with the clinical evidence at higher levels (where there is no dispute that the effects are adverse) as well as with the epidemiologic evidence and with the mode of action for SO_2 and respiratory effects. ISA at 5-9 (JA 01459). Consequently, EPA was being entirely reasonable, as well as consistent with CASAC's emphatic advice, in using the observed effects at 200 ppb 5-minute exposure levels, along with other information including that severe asthmatics would likely experience greater effect, to conclude that the

[17] See also the description of the study design in Linn 1987 (one of the chief clinical studies) at 1127-28 (JA 1086-87).

effects of short-term exposures to ambient levels as low as 200 ppb SO_2 were adverse. EPA reasonably considered these adverse effects in its decision as to the level of the 1-hour standard, while primarily relying on the epidemiologic studies

III. THE CLEAN AIR ACT REQUIRES THAT EPA ESTABLISH THE NAAQS AT A LEVEL THAT IS REQUISITE TO PROTECT THE PUBLIC HEALTH WITH AN ADEQUATE MARGIN OF SAFETY

There is no basis to Petitioners' claim that in determining whether to revise the SO_2 NAAQS EPA should have considered that various regulatory programs are already reducing ambient concentrations of SO_2. Pet'rs Br. at 54-57. This claim is inconsistent with both the law and the facts.

Clean Air Act section 109(b)(1), 42 U.S.C. § 7409(b)(1), states that: "National primary ambient air quality standards, prescribed under subsection (a) of this section shall be ambient air quality standards the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health." The Act requires EPA to review the standards every five years. Id. § 7409(d)(1).

In the current review of the SO_2 standard, the Administrator determined that the existing standard is not requisite to protect public health with an adequate margin of safety because the standard does not provide adequate protection from the public health effects caused by short-term exposures to SO_2 and that adverse health effects (such as emergency department visits and hospital admissions) are

associated with SO_2 exposures in areas meeting the previous standards. 75 Fed. Reg. at 35,535-36. Accordingly, the Administrator revised the standard to make it protective of human health. See id. at 35,533/3 ("EPA is required to review whether the present standards – not present air quality – are requisite to protect public health with an adequate margin of safety…. In making this determination it is relevant to consider exposures and risks which could be permissible under the current standards").

Petitioners assert that the Administrator's action is unlawful despite the clear language of the statute that the NAAQS must be requisite to protect public health. Specifically, Petitioners assert that the Administrator was required to refrain from promulgating the revised NAAQS because existing regulatory programs are reducing SO_2 concentrations and a revised NAAQS would have "few, if any, health benefits" compared to the prior NAAQS. Pet'rs Br. at 54-57.

Petitioners argue that their claim is supported by 42 U.S.C. § 7409(d)(1), which provides that at five-year intervals the Administrator is required to review the NAAQS and "shall make such revisions in such criteria and standards and promulgate such new standards as may be appropriate in accordance with section 7408 of this title and subsection (b) of this section." Id. Petitioners assert that the use of the word "appropriate" in this provision gives the Administrator leeway to consider factors such as existing regulatory programs and resulting air quality in

determining whether to revise a NAAQS or promulgate a new NAAQS. Petitioners' argument, however, ignores the fact that such revisions must be appropriate "in accordance with . . . subsection (b)." 42 U.S.C. § 7409(d)(1). Subsection (b) requires that the NAAQS be requisite to protect public health with an adequate margin of safety. Thus, subsection (d)(1) specifically incorporates the standard of subsection (b) and provides no authority for the Administrator to allow a NAAQS to remain unchanged if it does not meet that standard.

Both this Court and the Supreme Court have held that section 7409(b) does not allow EPA to consider the cost of compliance in promulgating a NAAQS. Whitman, 531 U.S. at 471; American Lung Ass'n, 134 F.3d at 389. In its analysis of claims to the contrary, the Supreme Court said:

> Accordingly, to prevail in their present challenge, respondents must show a textual commitment of authority to the EPA to consider costs in setting NAAQS under § 109(b)(1). And because § 109(b)(1) and the NAAQS for which it provides are the engine that drives nearly all of Title I of the CAA, 42 U.S.C. §§ 7401-7515, that textual commitment must be a clear one.

531 U.S. at 468. That same test applies to Petitioners' claim to have found a requirement for EPA to consider existing regulatory programs in setting the NAAQS. They fail that test because there is no such textual commitment in section 7409.

Finally, Petitioners' claim that this Court's decision in ATA III supports their claim (Pet'rs Br. at 57) is completely at odds with the holding in that case. In ATA III, the Court rejected an argument that EPA had failed to determine whether attainment of the existing standard would be adequate to protect public health before promulgating a revised standard. The Court held that EPA properly considered the adequacy of the old standard and reasonably determined that it was inadequate because, among other things, adverse health effects were observed in areas attaining the old standard. 283 F.3d at 370-71. See also American Farm Bureau, 559 F.3d at 521 (EPA failed to adequately explain why 24-hour standard for PM2.5 was adequately protective for short-term exposures when health effects from such exposures were associated with levels allowed by the annual standard). Thus, in ATA III the Court held that EPA may promulgate a more stringent standard where adverse health effects persist after attainment of the existing standard, which shows that the existing standard is inadequate. Thus, nothing in ATA III supports Petitioners' claim that EPA may not consider the health effects at air quality levels attaining the existing standard ("attainment-level emissions," Pet'rs Br. at 57) and must consider only current air quality levels and regulatory measures in determining whether the existing NAAQS is adequately protective of public health.

In any case, the record demonstrates emphatically that adverse health effects occur not just at SO_2 levels allowed by the previous SO_2 NAAQS, but also that "in locations meeting the current SO_2 NAAQS, numerous epidemiologic studies reported positive associations between ambient SO_2 concentrations and respiratory symptoms in children, as well as emergency department visits and hospitalizations for all respiratory causes and asthma across multiple age groups." 75 Fed. Reg. 35,525/3.[18] Moreover, both monitored and modeled 5-10 minute SO_2 ambient air quality levels exceed both the 200 ppb and 400 ppb benchmarks shown to be adverse in clinical studies while attaining the level of the pre-existing NAAQS. See REA at 120-21, 127-129 (JA 00278-79, 00285-87); see also RTC at 30 (JA 01199) (noting that monitored 1-hour concentrations of SO_2 have been in the range of 50 to between 600 and 700 ppb). Thus, Petitioners are not only incorrect as a matter of law but as a matter of fact: ambient SO_2 air quality is not at levels requisite to protect public health with an adequate margin of safety. EPA was therefore required to revise the standard.

[18] These studies include the Schildcrout 7 City study, the Schwartz 6 City study, the Neas study, the Lin Bronx NY study, the Jaffe study, and Wilson Portland Maine study, as well as the Schwartz, NYDOH, and Ito studies on which EPA primarily relied to set the level of the standard, all of which showed statistically significant results for a variety of respiratory symptoms. ISA at 5-6 and 5-7 Figures 5-1 and 5-2 (JA 01456, 01457); 74 Fed. Reg. at 64,835-39.

CONCLUSION

The petitions for review should be denied.

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February 8, 2012

CERTIFICATE OF COMPLIANCE WITH WORD LIMITATION

Pursuant to Federal Rule of Appellate Procedure 32(a)(7)(C), I hereby certify that the foregoing Brief of Respondent EPA contains 13,993 words as counted by the Word Perfect 12 word processing system, and thus complies with the applicable word limitation.

/S/ Norman L. Rave, Jr.
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CERTIFICATE OF SERVICE

I hereby certify that on February 8, 2012, the foregoing Brief of Respondent was served electronically through the Court's CM/ECF system on all registered counsel.

/S/ Norman L. Rave, Jr.
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