ORAL ARGUMENT NOT YET SCHEDULED

No. 13-1069 (consolidated with No. 13-1071)

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

NATIONAL ASSOCIATION OF MANUFACTURERS, *et al.*,

Petitioners,

v.

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

Respondents.

On Petitions for Review of Final Agency Action of the United States Environmental Protection Agency

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GLOSSARY OF TERMS

Act	Clean Air Act
Agency	U.S. Environmental Protection Agency
API Comments	Comments of the American Petroleum Institute (Aug. 31, 2012), EPA-HQ-OAR-2007-0492-9530
CAA	Clean Air Act
CASAC	Clean Air Scientific Advisory Committee
Census Report	U.S. Census Bureau, Current Housing Reports, Series H150/09, *American Housing Survey for the United States: 2009* (2011), *available at* http://www.census.gov/prod/2011pubs/h150-09.pdf
EPA	U.S. Environmental Protection Agency
Final Rule	EPA, National Ambient Air Quality Standards for Particulate Matter; Final Rule, 78 Fed. Reg. 3086 (Jan. 15, 2013)
FIP	Federal Implementation Plan
Greven *et al.* (2011)	Greven, Sonja, *et al.*, *An Approach to the Estimation of Chronic Air Pollution Effects Using Spatio-Temporal Information*, 106:494 J. of the Am. Statistical Ass'n 396 (2011), EPA-HQ-OAR-2007-0492-10054
ISA	EPA, EPA/600/R-08-139F, Integrated Science Assessment for Particulate Matter (Dec. 2009), EPA-HQ-OAR-2007-0492-0079

JA	Joint Appendix
NAAQS	National Ambient Air Quality Standard
NAM Comments	Comments of the National Association of Manufacturers, *et al.* (Aug. 31, 2012), EPA-HQ-OAR-2007-0492-9425
OAQPS	U.S. Environmental Protection Agency Office of Air Quality Planning and Standards
Page Memorandum	Memorandum from Stephen D. Page, Director, EPA OAQPS, to Air Division Directors & Deputies, Regions I-X (Apr. 1, 2010), EPA-HQ-OAR-2007-0492-0410
PM	Particulate Matter
$PM_{2.5}$	Fine Particulate Matter
Proposal	EPA, National Ambient Air Quality Standards for Particulate Matter; Proposed Rule, 77 Fed. Reg. 38890 (June 29, 2012)
PSD	Prevention of Significant Deterioration
RTC	EPA, Responses to Significant Comments on the 2012 Proposed Rule on the National Ambient Air Quality Standards for Particulate Matter (June 29, 2012; 77 FR 38890) (Dec. 2012), EPA-HQ-OAR-2007-0492-10095

Russell Letter	Letter from Armistead (Ted) Russell, Chair, CASAC, Ambient Air Monitoring & Methods Committee, & Jonathan M. Samet, Chair, CASAC, to the Hon. Lisa P. Jackson, Administrator, EPA, EPA-CASAC-11-001 (Nov. 24, 2010), EPA-HQ-OAR-2007-0492-0391
SIP	State Implementation Plan
Subpart 4	Clean Air Act Title I, Part D, Subpart 4, CAA §§ 188-190, 42 U.S.C. §§ 7513-7513b
UARG	Utility Air Regulatory Group
UARG Comments	Comments of the Utility Air Regulatory Group (Aug. 31, 2012), EPA-HQ-OAR-2007-0492-9483
$\mu g/m^3$	micrograms per cubic meter

SUMMARY OF ARGUMENT

First, by soliciting public comments on only an arbitrary and narrow range of levels from 11 to 13 $\mu g/m^3$ to set as the new primary annual $PM_{2.5}$ NAAQS—as well as only those "approaches," "evidence," and "information" that support "the choice of levels within [that] range"—EPA effectively prejudged the threshold question of whether that NAAQS need be revised *at all*. 77 Fed. Reg. 38,890, 38,943 (June 29, 2012), JA__. EPA cannot immunize itself from judicial review of an outcome-driven rulemaking by pointing to boilerplate invitations in the Proposal for comments on "all issues." EPA compounded the error with other procedural errors: its subsequent failure to engage significant comments and new data that pointed to regulatory options outside of the prejudged, narrow range of levels in the Proposal; its arbitrary refusal to consider some studies at all; and its capricious weighting of other studies based on whether the study's outcome supported EPA's prejudged regulatory range.

Second, EPA's near-road monitoring provision ignores the requirement that monitors be sited in areas that represent area-wide air quality and general population exposures, not where pollutant concentrations are greatest. EPA also failed to seek comment on its decision to use near-road monitoring data to assess NAAQS compliance. Furthermore, EPA failed to provide any basis for reversing its prior policy determination that, when subjected to reasonable constraints, spatial

averaging is requisite to protect public health. EPA's assertion that it need not address the adequacy of its prior determination is inconsistent with this Court's precedent and EPA's position in the Final Rule.

Third, EPA's promulgation of the Final Rule immediately triggered certain legal obligations and started the clock for others. The Final Rule is unlawful because, as EPA admits, it failed to have available the rules needed to address those legal obligations.

ARGUMENT

I. EPA UNLAWFULLY REVISED THE PRIMARY ANNUAL $PM_{2.5}$ NAAQS.

A. EPA's Boilerplate Request for Comment on "All Issues" Cannot Cure Its Prejudgment of the Need To Revise the NAAQS.

EPA prejudged the threshold question of whether to revise the primary annual $PM_{2.5}$ NAAQS and solicited comment on only a narrow range of standards well below the existing level. *Id.* ("[T]he Administrator solicits public comment on this range of levels [from 12 to 13 $\mu g/m^3$] and … alternative annual standard levels down to 11$\mu g/m^3$…."). EPA now seeks to insulate itself from judicial review by pointing to boilerplate language it included in the Proposal's background section that invited "general, specific, and technical comments on all issues involved with this proposal." *Id.* at 38,899, JA__. But such a boilerplate request for comments on "all issues" cannot serve as notice to the regulated community of

the issues about which EPA is truly receptive to modification. Such requests for comment are "too general to be adequate." *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 549 (D.C. Cir. 1983).

EPA's reliance on its "all issues" invitation to comment ignores the purpose of notice-and-comment rulemaking, which is to allow an "opportunity for interested parties to offer comments that could persuade the agency to modify its rule." *Am. Water Works Ass'n v. EPA*, 40 F.3d 1266, 1274 (D.C. Cir. 1994). If general notice were sufficient, EPA could effectively override the purpose of notice-and-comment rulemaking by including a protective general notice in every rulemaking. But it cannot: "Agency notice must describe the range of alternatives being considered with reasonable specificity. Otherwise, interested parties will not know what to comment on…." *Small Refiner*, 705 F.2d at 549.

Here, EPA specified the "range of alternatives being considered" as primarily 12 to 13 $\mu g/m^3$, with 11 $\mu g/m^3$ as a possibility. 77 Fed. Reg. at 38,943, JA__. Regardless of EPA's general notice, this specific request unequivocally establishes EPA was willing to entertain only NAAQS within that narrow range. Thus, before the comment period began, EPA had already answered the threshold question of the sufficiency of the existing standard.

B. EPA Unlawfully Failed To Consider or Respond Fully to Comments and Studies That Support the Existing Standard.

Contrary to EPA's arguments, EPA systematically gave preferential treatment to evidence supporting its preferred outcome, while ignoring or de-emphasizing contrary evidence. This practice is unlawful. *Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 237 (D.C. Cir. 2008). EPA misstates Petitioners' arguments and, in some cases, directly contradicts the Final Rule. The Agency's contorted arguments only underscore the procedural deficiencies in EPA's rulemaking.

1. EPA's Failure To Respond to Comments Supporting the Existing NAAQS Was Unlawful.

EPA does not dispute it failed to respond to comments addressing studies that support the existing standard, but were not cited in any of EPA's assessments.[1] Rather than responding, EPA claims it can simply refer commenters to analyses conducted during its prior NAAQS reviews that did not address the new information. EPA cannot dispense with significant comments and new data so cavalierly.

The Act requires EPA to respond to "each of the significant comments, criticisms, and new data submitted … during the comment period." CAA

[1] Intervenors' review of these studies, Int. Br. 18-20, 22-23, cannot cure EPA's failure to respond to comments during the rulemaking.

§ 307(d)(6)(B). "Significant comments are those which if true, raise points relevant to the agency's decision *and which, if adopted, would require a change in an agency's proposed rule*." *City of Portland v. EPA*, 507 F.3d 706, 715 (D.C. Cir. 2007) (internal quotation omitted) (emphasis in original). Commenters submitted a series of new studies supporting exposure thresholds for $PM_{2.5}$-related health effects and contradicting EPA's conclusions regarding an association between $PM_{2.5}$ exposure and mortality. *See* API Comments at 18-20, JA__-__. These studies demanded a response from EPA because they would lead EPA to maintain the existing standard.

EPA's dismissal of these comments is groundless. First, EPA argues, without support, that it need not respond to new data unless commenters provide "discussion or analyses of those studies." EPA Br. 38. This argument contradicts the plain language of section 307(d)(6)(B), which expressly contemplates EPA's consideration of "new data." Regardless, commenters did explain the relevance of these studies and provided full citations to EPA. API Comments at 18-20, JA__-__. Nothing more was required.

Second, EPA asserts it adequately responded to commenters by referring to prior NAAQS assessments. EPA Br. 37-38, 40-41; *see also* Int. Br. 16-17. But these prior assessments did not address the new studies cited by commenters or the new data they contain. EPA cannot ignore new data by simply pointing to its prior

analyses, particularly when their conclusions are substantively different and fundamentally equivocal. For example, EPA candidly admitted the potential for exposure thresholds was "a source of uncertainty that … requires further investigation." RTC at II-41, JA__. Having acknowledged that further investigation is required, EPA cannot ignore relevant new studies and data received during the comment period.

2. EPA Arbitrarily Applied Its Rule Against Considering Studies Published After the Integrated Science Assessment.

EPA agrees it must apply consistent standards when evaluating studies that support and contradict its Proposal. EPA Br. 31. EPA mischaracterizes, however, the studies cited by commenters and its own review processes. Not only does EPA arbitrarily exclude relevant studies, it fails to apply its own review criteria appropriately.

EPA explained that its review considered only studies that, among other things, "had undergone scientific peer review," EPA Br. 31 (citing ISA 1-9, JA__), and that studies published after the ISA need not be given "equal weight" and would instead be addressed in "the next NAAQS review," *id.* at 32-33. Regardless of the propriety of this criterion, EPA applied it in an inconsistent and arbitrary manner to obtain its desired outcome.

For example, EPA relied heavily on its own "analysis of distributions of underlying population-level data" to support the revised standard. *See* 78 Fed.

Reg. at 3086, 3149 (Jan. 15, 2013), JA__. But contrary to EPA's assertions, EPA Br. 34 n.13, EPA's post-ISA study was never subjected to peer review, much less CASAC review. Although EPA transmitted the analysis to CASAC, Memorandum from L. Wegman, OAQPS, to H. Stallworth, CASAC (Apr. 20, 2011), EPA-HQ-OAR-2007-0492-0338, JA__, EPA did not request CASAC's review, and there is no record of such review. CASAC's silence cannot qualify as sufficient peer review under EPA's criteria. EPA Br. 34 & n.13.

In contrast, the studies that commenters cited were published in peer-reviewed journals and meet EPA's criteria. *See* NAM Comments at 24, JA__ (citing Greven *et al.* (2011)); API Comments at 13-14, 20, JA__-__, __ (citing Greven *et al.* (2011), Cox (2012), Fraas (2011), and Fraas and Lutter (2011)). EPA's attempt to discredit these studies by characterizing them as "assessing the *monetary* costs and benefits from revised NAAQS," EPA Br. 33 (emphasis in original), lacks merit.[2] To the contrary, these studies specifically addressed exposure thresholds—an issue central to EPA's decision to revise the NAAQS—as a key source of uncertainty in measuring health benefits of reduced $PM_{2.5}$ exposure. EPA cannot exclude contrary studies that meet its criteria for

[2] EPA ignores entirely Greven *et al.* (2011), JA__, which directly addressed the health impacts of $PM_{2.5}$ exposure.

consideration, while simultaneously relying on supportive studies that fall short of these criteria. This is the epitome of arbitrary rulemaking.

3. EPA Arbitrarily Weighted Similar Studies Differently Based Solely on the Studies' Outcome.

EPA exacerbates its errors by emphasizing studies reporting statistically significant results favoring its preferred outcome, while dismissing contrary data from other high-quality studies. The lack of a statistically significant association does not denote a failed or substandard study; rather, it denotes an outcome where $PM_{2.5}$ exposure *does not correlate* with human health effects. EPA must take such studies into account in determining the concentration at which $PM_{2.5}$ causes adverse human health effects.

EPA downplays its primary reliance on statistically significant results by asserting it "considered the *collective* evidence before it." *Id.* at 35 (emphasis in original). But highlighting the breadth of evidence does not alter the fact that EPA "placed greater emphasis on studies reporting statistically significant results." 78 Fed. Reg. at 3112, JA__. It is appropriate for EPA to consider all available evidence when asking whether an association exists between $PM_{2.5}$ exposure and adverse health effects, but it must do so objectively, giving equal weight to equally credible, peer-reviewed studies, including those that do *not* demonstrate a

statistically significant association.[3] EPA offers no rational explanation for assigning extra weight to studies answering the question affirmatively.

Petitioners do not dispute statistical significance can play a role in selecting an appropriate NAAQS level. Thus, EPA need not increase the stringency of a NAAQS based "on studies that do not report statistically significant associations." EPA Br. 36-37; *see also Mississippi*, slip op. at 27. But the *lack* of statistically significant results can also be highly probative of the inappropriateness of reducing the NAAQS, as EPA did here. Studies such as Greven *et al.* (2011) are particularly relevant because they provide a rational explanation, such as the existence of confounding factors, for the lack of statistically significant associations.

EPA cannot give greater weight to statistically significant associations simply because it has done so in the past. *See* EPA Br. 36. Regardless of prior practice, it was arbitrary for EPA to assign less or no weight to equally valid studies that failed to find statistically significant associations below 15 $\mu g/m^3$.

[3] In *Mississippi v. EPA*, No. 08-1200, slip op. at 27 (D.C. Cir. July 23, 2013, amended Dec. 11, 2013), the Court recognized statistical *quality* can provide a basis for assigning studies different weights and affirmed EPA's lack of reliance on studies with small sample sizes. But statistical *significance* is not a proxy for statistical *quality*.

C. EPA's Errors Materially Impacted the Rule's Outcome.

EPA's systematic reliance on review procedures to promote studies that support a revised NAAQS while excluding or marginalizing contrary data was not harmless error. Commenters presented a substantial body of evidence demonstrating the existing standard's sufficiency and calling into question key evidence on which EPA relied. Had EPA considered this information on an equal footing with its preferred studies, it would have significantly changed the Final Rule by maintaining the preexisting NAAQS.[4]

EPA fails to address the compounding effect of these procedural errors by asserting each violation is harmless in isolation. For example, EPA asserts its failure to consider comments on the lack of association between $PM_{2.5}$ exposure and mortality was "harmless, in view of the overwhelming evidence across hundreds of peer-reviewed studies supporting the Agency's causality determinations for mortality." *Id.* at 41; *see also id.* at 39-40. But EPA's procedural errors extend beyond its exclusion of certain studies and pervade its assessment of the studies in the ISA. EPA cannot rely on a procedurally deficient

[4] Petitioners have not waived this argument. Int. Br. 24. Although Petitioners did not quote section 307(d)(8) verbatim, they provided objective cause to significantly change the Proposal by maintaining the existing NAAQS. Pet. Br. 32-34. In fact, Petitioners' argument was entitled, "EPA's Errors Materially Impacted the Rule's Outcome." *Id.* at 32. Parroting the statutory language is not required.

analysis to demonstrate another procedural error was harmless. Each of EPA's procedural errors is material standing alone; their aggregate effect is substantial.

II. EPA'S MONITORING REQUIREMENT REVISIONS ARE UNLAWFUL.

A. EPA's Near-Road Monitoring Requirement Unlawfully Abandons Any Link Between NAAQS Compliance and Relevant Population Exposures.

Because the 12 $\mu g/m^3$ NAAQS is an annual standard and because the highest monitored concentration in an area determines the area's attainment status, 78 Fed. Reg. at 3279-80, JA__-__ (to be codified at 40 C.F.R. pt. 50, App. N, §§ 4.1(a), 4.2(a)), monitors must be cited to reflect concentrations to which a population could reasonably be exposed over one year, *see* 40 C.F.R. pt. 58, App. D, § 4.7.1(c)(3).[5] Consistent with this principle, EPA's prior rules required monitors "be sited in a *population-oriented* area of expected maximum concentration." *Id.* § 4.7.1(b)(1) (2012) (emphasis added). "Population-oriented" means "residential areas, commercial areas, recreational areas, industrial areas where workers from more than one company are located, and other areas where a substantial number of people may spend a significant fraction of their day," 40 C.F.R. § 58.1. As EPA previously explained, it relied on data from "population-oriented" monitors

[5] EPA argues the annual standard serves to protect against short-term $PM_{2.5}$ exposure. EPA Br. 52. But that is the purpose of the 24-hour standard. *See* 40 C.F.R. § 50.13(a).

because PM NAAQS—including the revised NAAQS at issue here—are based on epidemiological studies using "fixed-site, population-oriented, ambient monitors as a surrogate for actual PM exposures," and these monitors provide the only "plausible linkage" observed between monitored concentrations and actual human exposures. 61 Fed. Reg. 65,638, 65,645-49 (Dec. 13, 1996).

In the Final Rule, however, EPA abandoned its reliance on population-oriented monitors by basing compliance determinations on data from a single *un*representative roadside monitor, intentionally sited to capture unusually high $PM_{2.5}$ levels. 78 Fed. Reg. at 3235-36, JA__-__. This approach can trigger a nonattainment designation for an entire metropolitan area, regardless of overall air quality and population exposures.

EPA's decision to mandate near-road monitoring to capture measurements "where $PM_{2.5}$ concentrations may be elevated," EPA Br. 53, rather than in areas where concentrations are representative of "area-wide air quality," 40 C.F.R. pt. 58, App. D, § 4.7.1(b) (2013), is unlawful. The reasons EPA provides for doing so are meritless.

First, the record is devoid of any support for EPA's claims that a "significant fraction of the population … live or otherwise spend time in proximity to major roads." EPA Br. 47; *see also* Int. Br. 25. EPA's only support for this assertion is a Census Report that was never subject to public comment, *see infra* Section II.B.2,

and thus cannot support EPA's decision. CAA § 307(d)(6)(C); *Sierra Club v. Costle*, 657 F.2d 298, 398 (D.C. Cir. 1981).

Second, EPA argues the near-road monitoring requirement is lawful because EPA says it will make compliance determinations using only those monitors it deems "representative of area-wide air quality," and EPA asserts that to represent area-wide air quality, near-road monitors only need be "representative of many *near-road locations* within the same urban area" instead of the urban area itself. EPA Br. 49 (emphasis altered). This argument is also without merit. It is not enough merely to claim that near-road compliance monitors will represent air quality in the broader area where people are exposed. That is because roadsides make up only a small part of metropolitan areas and are prone to higher-than-normal $PM_{2.5}$ levels. The criteria EPA applies to roadside monitors under its current interpretation bear no necessary relationship to factors that objectively would help determine representativeness. *Any* site with high localized $PM_{2.5}$ concentrations could be considered "representative of area-wide air quality" and eligible for comparison to the annual $PM_{2.5}$ standard if similar aberrations occur at "many" other locations in the area, regardless of actual population exposures at those locations or how air quality at those locations compares with air quality in the rest of the area. This is an unreasonable interpretation of "representative" and "area-wide" because it strips those terms of all meaning.

Third, EPA's reliance on data from outlier monitors contradicts the Agency's own regulations, which state that the "most important" monitors for characterizing $PM_{2.5}$ emissions should "represent conditions in areas where people commonly live and work *for periods comparable to those specified in the NAAQS*." 40 C.F.R. pt. 58, App. D, § 4.7.1(c)(3) (emphasis added). This flatly contradicts EPA's assertion that it can base attainment of an annual standard on monitoring at "any of the locations in which people spend time" and removes any link between the exposures against which a standard protects and the data on which EPA judges compliance. EPA Br. 52.

Finally, EPA misrepresents CASAC's recommendations regarding near-road monitoring. *Id.* at 53. CASAC recommended such monitors for the limited purpose of "better *characterizing* near-road pollutant concentrations," not for determining compliance. Russell Letter at i, JA__ (emphasis added).

B. EPA Provided No Opportunity for Comment on Its Decision To Use Near-Road Monitoring for Determining Compliance.

1. EPA Failed To Give Notice of the Role To Be Played by Near-Road Monitors.

EPA mentioned in passing in the Proposal that "collection of NAAQS comparable data" is one objective for near-road monitors. 77 Fed. Reg. at 39,009, JA__. That brief reference, however, did not give notice that EPA intended to use

near-road monitoring data for attainment designations. EPA Br. 54. Rather, it suggested only that such data would be used for research purposes.[6]

EPA's record statements confirm this intention. For example, EPA said the goal of near-road monitoring was "[t]o better understand the potential health impacts of these exposures," and the objectives included "support for long-term health studies investigating adverse effects on people, … [and] validat[ing] performance of models." 77 Fed. Reg. at 39,009, JA__. The Proposal distinguished near-road monitoring sites from representative sites used for determining compliance. *Id.* at 39,010, JA__ ("[N]ear-road sites would be located … within reasonable proximity to an area-wide $PM_{2.5}$ compliance monitoring site at which a similar PM monitor is used (i.e., for comparison purposes)."). Such EPA statements misled the public on the role EPA intended near-road monitoring to play and prevented meaningful comment on the issue.

2. EPA May Not Rely on the Census Report.

The Census Report is the *only* evidence EPA has ever cited to support its conclusions regarding population exposures near roads. Thus, the public must

[6] UARG's general comments on the Proposal's near-road monitoring provisions are irrelevant because they reflected the Proposal's limited scope. *See* UARG Comments at 54, JA__ (EPA's objectives all "involve support for research").

have an opportunity to comment on that report. EPA, however, never gave that opportunity.

Rather than argue it made the Census Report available for comment, EPA claims it is "publicly-available," EPA Br. 54-55, and that Intervenors submitted the report in their comments, Int. Br. 30 n.9, 31. That a document is publicly available or that a commenter knew of it is irrelevant. It is incumbent upon *EPA* to identify the bases for its proposal and present them for public comment, not upon the *public* to search out information on which EPA might subsequently rely. *Solite Corp. v. EPA*, 952 F.2d 473, 484 (D.C. Cir. 1991) (per curiam) (agency must make available studies and data used in reaching decisions and commits "serious procedural error" if "meaningful commentary" cannot occur). Likewise, that one party comments on something "does not imply that the *public* had notice of, or an opportunity to comment on, EPA's changes to the regulation." *Daimler Trucks N. Am. LLC v. EPA*, No. 12-1433, slip op. at 13 (D.C. Cir. Dec. 11, 2013) (emphasis in original); *Fertilizer Inst. v. EPA*, 935 F.2d 1303, 1312 (D.C. Cir. 1991) ("Commenting parties cannot be expected to monitor all other comments submitted to an agency.").

Although EPA attempts to downplay the Census Report's role,[7] that report provides the only support for EPA's conclusions regarding population exposures near roads.[8] Because EPA did not make the report available for public comment, the Agency may not rely on it to support its use of near-road monitoring data for attainment determination purposes.

3. EPA Cannot Avoid Judicial Scrutiny by Failing To Act on a Petition for Reconsideration.

Also meritless is EPA's claim that this Court may not review EPA's failure to allow public comment until EPA denies a long-pending petition for reconsideration. EPA Br. 55. The CAA plainly contradicts EPA's argument by stating "[t]he filing of a petition for reconsideration … of any otherwise final rule or action shall not affect the finality of such rule or action for purposes of judicial review…." CAA § 307(b)(1). Congress amended section 307(b)(1) in part to clarify that petitions for reconsideration do not affect finality for judicial review purposes. *See* S. Rep. No. 101-228, at 372 (1989), *reprinted in* 1990 U.S.C.C.A.N. 3385, 3755. EPA cannot avoid judicial scrutiny by failing to act upon Petitioners'

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[7] EPA claims the Census Report "merely corroborated EPA's conclusion at proposal that … 'large[] numbers of impacted populations' in the largest urban areas in the country" may experience near-road exposures. EPA Br. 56 (citing 77 Fed. Reg. at 39,009, JA__) (second alteration in original).

[8] The RTC is replete with references to this report. *See* RTC at V-8, V-19, V-20, V-34 n.43, V-42 n.44, JA__, __, __, __, __.

long-ago-filed petition for reconsideration. The petition should be viewed as constructively denied.

C. EPA Failed To Provide a Rational Basis for Eliminating Spatial Averaging.

EPA's elimination of spatial averaging, which would permit averaging of monitoring results within narrow constraints, was arbitrary and capricious because EPA failed to evaluate whether the existing form remained requisite to protect public health with an adequate margin of safety. Pet. Br. 41-48. In response, EPA offered several misguided and post-hoc arguments that cannot negate the utter lack of support for EPA's central argument in the Final Rule that the constraints on spatial averaging adopted in 2006 are no longer requisite to protect the public health.

When EPA established an annual $PM_{2.5}$ NAAQS, it determined that a form incorporating spatial averaging was consistent with the underlying health evidence and was requisite to protect public health. 62 Fed. Reg. 38,652, 38,671 (July 18, 1997). Implicit in this determination was the recognition that NAAQS apply to large areas, and people will be exposed to a range of $PM_{2.5}$ concentrations. Even after EPA concluded in 2006 that persons near monitoring locations reporting the highest $PM_{2.5}$ concentrations were more likely to be members of at-risk populations, EPA did not waver from its original determination and instead

strengthened constraints that limited—but did not eliminate—the allowable variation between monitors. 71 Fed. Reg. 61,144, 61,167 (Oct. 17, 2006).

After adopting and consistently applying this policy, EPA does not have unfettered discretion to eliminate it. Instead, "'an agency changing its course … is obligated to supply a reasoned analysis for the change.'" *Jicarilla Apache Nation v. Dep't of the Interior*, 613 F.3d 1112, 1119 (D.C. Cir. 2010) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983)); *see also* Pet. Br. 42-43.

EPA argues it provided a reasoned basis for eliminating spatial averaging because "it had determined after further review and analysis that continuing to allow such potential inequities *to any degree* would be insufficiently protective of public health with an adequate margin of safety." EPA Br. 43 (emphasis added).[9] This argument is not in the rulemaking record. Instead, in the Final Rule, EPA asserted "public health would not be protected with an adequate margin of safety in all locations, as required by law,[10] if *disproportionately higher* exposure concentrations in at-risk populations … were averaged together with lower

[9] Additional exposure data on at-risk populations that EPA gathered after 2006 merely confirm what EPA already knew in 2006 and do not provide a rational basis for further changes.

[10] The reference to "in all locations" is not, as EPA alleges, "required by law" and is found nowhere in section 109(b).

concentrations measured at other sites in a large urban area." 78 Fed. Reg. at 3127, JA__ (emphasis added).[11] EPA's focus in the Final Rule on *disproportionate* variations in exposure indicates that a form permitting *some* variation in $PM_{2.5}$ exposure could still be requisite to protect public health with an adequate margin of safety—the very position EPA took in 1997 and 2006. *See, e.g.*, 71 Fed. Reg. at 61,167 (disproportionate impacts would be avoided as long as "[t]he annual mean concentration at each site [is] within 10 percent of the spatially averaged annual mean"). EPA cannot justify eliminating spatial averaging through post-hoc arguments that contradict the reasoning it offered in the record. *See Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 50 ("[A]n agency's action must be upheld, if at all, on the basis articulated by the agency itself."). Intervenors' argument that eliminating spatial averaging is consistent with EPA's prior policy is baseless. Int. Br. 34. EPA explicitly rejected elimination of spatial averaging in the 2006 rulemaking. 71 Fed. Reg. at 61,167.

Next, EPA argues NAAQS rulemakings are unique because "[i]n reviewing NAAQS the Court ask[s] only whether EPA's proposed NAAQS is requisite; the Court does not ask why the prior NAAQS once was requisite but is no longer up to

[11] Avoiding disproportionately higher exposures does not provide a reasoned basis for eliminating spatial averaging because EPA acknowledged that potentially disproportionate exposures and risks could be mitigated by imposing constraints on spatial averaging. 78 Fed. Reg. at 3126, JA__.

the task." EPA Br. 46 (internal quotation omitted) (first alteration added). But nothing in section 109(b)(1) limits the scope of the applicable standard of review. EPA is not immune from reversal for failure to "reasonably explain[] it actions," and to justify its changed position on spatial averaging. *Mississippi*, slip op. at 12.

Despite EPA's assertion that it can ignore the 2006 form's adequacy and focus solely on whether the new form is requisite to protect public health, the record states otherwise. As EPA explained repeatedly in the Final Rule, the basis for eliminating spatial averaging was the 2006 form's alleged inadequacy: "As discussed above and in the proposal (77 FR 38924), these analyses showed that the current constraints on spatial averaging may be inadequate in some areas to avoid substantially greater exposures for people living near monitors recording the highest $PM_{2.5}$ concentrations…." 78 Fed. Reg. at 3126-27, JA__-__; *see also id.* at 3125, JA__. Regardless of *Mississippi* and EPA's post hoc arguments here, EPA made the adequacy of the 2006 form a central issue in eliminating spatial averaging. It cannot hide from that now.

EPA fails to demonstrate the 2006 form's inadequacy because its analyses do not apply that form's constraints. Pet. Br. 47-48. EPA makes no attempt whatsoever to defend its analyses. Instead, it argues its decision was reasonable because it was unanimously endorsed by CASAC. EPA Br. 44. But EPA cannot blindly adopt CASAC's recommendations, particularly when CASAC relied on the

same faulty analyses as EPA's staff. Letter from J. Samet, CASAC, to L. Jackson, EPA at 13 (May 17, 2010), EPA-HQ-OAR-2007-0492-0113, JA__.[12] The generic reasonableness of EPA's concern for sensitive populations is not at issue. *See* EPA Br. 44. EPA cannot justify eliminating spatial averaging when it lacked any data suggesting the existing form is inadequate.

Finally, contrary to EPA's assertion, *id.* at 46-47, Petitioners did not waive their argument that EPA lacked a basis for asserting the 2006 form is inadequate. The CAA requires an objection be "raised with 'reasonable specificity' during the comment period," but "does not require that precisely the same argument that was made before the agency be rehearsed again, word for word, on judicial review." *Appalachian Power Co. v. EPA*, 135 F.3d 791, 817-18 (D.C. Cir. 1998) (per curiam). NAM asserted "nothing in the data cited by the EPA suggests that the prior form was no longer sufficient to protect the public health." NAM Comments at 20, JA__. NAM further explained "EPA has failed to identify any change in the latest scientific knowledge between 2006 and 2012 which would justify any change at all in the $PM_{2.5}$ form as it pertains to spatial averaging." *Id.* These comments challenged, with reasonable specificity, EPA's conclusions regarding the adequacy of the 2006 form.

[12] CASAC's role is advisory; selecting an appropriate standard is left exclusively to the Administrator. CAA § 109(b)(1).

III. THE FINAL RULE IS INVALID BECAUSE EPA FAILED TO PROVIDE THE NECESSARY RULES TO ADDRESS THE LEGAL CONSEQUENCES RESULTING FROM THE FINAL RULE'S PROMULGATION.

The Final Rule immediately triggered certain legal obligations and started the clock for others: (1) applicants seeking PSD permits must immediately demonstrate compliance with the revised standard; and (2) the clock began running for states to make designations and submit Infrastructure and Attainment SIPs. EPA does not dispute that, nor does it dispute that the rules[13] available for dealing with these immediate legal obligations either are insufficient, were issued after the Final Rule's promulgation, or have yet to be developed. EPA has thus failed to provide states and the regulated community with the rules needed to fulfill the legal requirements resulting from the revised NAAQS.

As is clear from *EME Homer City Generation, L.P. v. EPA*, 696 F.3d 7, 32-33 (D.C. Cir. 2012), *cert. granted*, 133 S. Ct. 2857 (2013), EPA must inform states of their implementation responsibilities and give them the tools and time to fulfill them. Because EPA failed to "make[] the target clear,"[14] *id.* at 32, the Final Rule is unlawful.

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[13] *See* Pet. Br. 50 n.14 (use of terms "guidance" or "tools" herein is not an admission that notice-and-comment rulemaking is not required).

[14] EPA's attempts to distinguish *Homer* fail. EPA Br. 66-67; *see also* Int. Br. 36-37. First, *Homer*, although on appeal, is the law of this Court. *See* Pet. Br. 49. Second, that *Homer* involves interstate pollution is irrelevant to the principle

A. The PSD Permitting Problems Arising From the Final Rule Render It Unlawful.

EPA interprets the CAA to require PSD applicants to demonstrate compliance with a revised NAAQS immediately. Page Memorandum at 2, JA__; 78 Fed. Reg. at 3252, 3259, JA__, __. Petitioners explained the inadequacy of the available models and test methods for PSD permitting. Pet. Br. 51-54. EPA agrees improved regulatory models are needed. EPA Br. 60; *see also id.* at 61 (EPA "improve[d]"—but did not fix—test methods), 62 n.26 (admitting "limitations in the methods"). Instead, EPA argues it "has provided an array of tools and resources" and that Appendix W "occupies over 50 pages in the Code of Federal Regulations." *Id.* at 59. The length of the regulations or number of tools and resources is irrelevant when they cannot accomplish the needed task.

Furthermore, EPA's post-rulemaking release of "a new 60-page plus Draft Guidance for $PM_{2.5}$ Permit Modeling" simply underscores how prevalent the problems are and how complicated this issue is. *Id.* at 60. If permit applicants could easily fix the problems themselves using alternative methods, 60-pages plus

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for which Petitioners cite *Homer*. Third, EPA's assertion that *Homer*'s language regarding NAAQS providing "'a clear numerical target'" somehow means the principle does not apply here is nonsensical. EPA Br. 67 (quoting *Homer*, 696 F.3d at 32). Petitioners are not arguing the NAAQS fails to provide "a clear numerical target," but instead that EPA failed to provide the rules needed to comply with the legal obligations arising from the Final Rule.

of guidance would be unnecessary. Notably, EPA does not claim this draft guidance solves the problems.

Instead of addressing the modeling tools' limitations and the problems they cause, EPA shifts the burden to permit applicants, noting applicants can propose "an alternative model … on a case-by-case basis." *Id.* & n.25. This is backwards. EPA cannot respond to the models' and test methods' inadequacy by telling permit applicants to fix the problems.

EPA also incorrectly asserts this issue is unripe and that permit applicants should challenge any permit denials in individual permit proceedings. *Id.* at 60-61. This issue is ripe because EPA asserts PSD applies immediately when a revised NAAQS becomes effective. Page Memorandum at 2, JA__; 78 Fed. Reg. at 3252, 3259, JA__, __. This is a legal and concrete determination. *NRDC v. EPA*, 22 F.3d 1125, 1133 (D.C. Cir. 1994) (per curiam). The flaws are programmatic and do not differ on a case-by-case basis where individual permit challenges would be more appropriate. Furthermore, Petitioners' injury does not "turn[] on speculation" of permit application denials. EPA Br. 60, 62. Petitioners' members are injured because they *cannot complete* PSD permit applications that meet CAA requirements without tools that do not yet exist. *See* Pet. Br. 51-54.

B. The Delay in Rules Regarding Designations and SIPs Render the Final Rule Unlawful.

NAAQS promulgation sets in motion a timetable for mandatory state action. Pet. Br. 49. Failure to meet these deadlines results in EPA issuing designations and FIPs for the state. CAA §§ 107(d)(1)(B)(ii), 110(c)(1). This denies the state's right to be the first implementer of a NAAQS and to make critical decisions regarding which sources to control and by how much. *Union Electric Co. v. EPA*, 427 U.S. 246, 269 (1976).

EPA argues nothing requires it to issue guidance regarding designations or SIPs and further argues that nothing makes states' obligations contingent on the issuance of guidance. EPA Br. 63, 65, 66. This misses the point. EPA made clear in the Final Rule that it would be issuing such guidance and rules. 78 Fed. Reg. at 3251, JA__. Once EPA decided such rules were necessary, it needed to make them available to avoid truncating the time periods Congress gave states.[15] EPA claims

[15] EPA argues Petitioner NAM took an opposite position in its comments, stating EPA guidance on designations and SIPs was inappropriate and unnecessary. EPA Br. 63 n.27, 64 n.28. There is no conflict here. NAM argued states should be given latitude to make designations and prepare SIPs without undue interference from EPA. NAM Comments at 32, JA__. Once EPA committed in the Final Rule to issue directions to the states, however, it had an obligation to do so when it promulgated the NAAQS to avoid truncating the states' time periods. Whether EPA *should* issue such guidance to the states is a separate issue.

states need not wait on EPA to begin their work, EPA Br. 63-64, but states must follow EPA's direction or risk EPA disapproval.

EPA argues it has not shortened the one-year time period given to states to make designations. *Id.* at 63. EPA's actions demonstrate otherwise. Promulgation of the Final Rule started the clock for states to make designations. CAA § 107(d)(1)(A). EPA stated in the Final Rule it would "provide technical information and guidance to states" to assist in designations because "EPA understands that developing recommendations on appropriate nonattainment area boundaries is a significant effort for states…." 78 Fed. Reg. at 3251, JA__.

EPA did not provide any guidance until April 2013, when it directed states to "base their boundary recommendations on … five factors…." Memorandum from G. McCarthy, Assistant Adm'r, to Reg'l Adm'rs, Regions 1-10, Initial Area Designations for the 2012 Revised Primary Annual Fine Particle National Ambient Air Quality Standard at 5 (Apr. 16, 2013), *available at* http://www.epa.gov/pmdesignations/2012standards/docs/april2013guidance.pdf, JA__. EPA made clear states that did not perform the five-factor analyses would risk their designation analysis being deemed insufficient, in which case "EPA will propose those boundaries that it determines to be appropriate based upon the five factor analyses…." *Id.* at 6, JA__. States did not learn of the five-factor analyses until four months after the clock started. But the states' time was cut by much more

than that. To conduct the five-factor analyses, EPA provided states with eleven datasets, seven of which were not available until September 18, 2013. *See* EPA, Area Designations for the 2012 Annual Fine Particle ($PM_{2.5}$) Standard; Designations Guidance and Data, http://www.epa.gov/pmdesignations/2012 standards/techinfo.htm. This gave states *less than three months* to complete their designations. By failing to provide tools at promulgation, EPA cut short the states' time by more than nine months. This renders the Final Rule unlawful.[16]

Likewise, EPA committed to prepare a new set of rules that would apply to the development of Infrastructure and Attainment SIPs. 78 Fed. Reg. at 3251, JA__. Once EPA decided "business as usual" would not apply, it had an obligation to have the rules available to states before the timetable for state action began.[17] It failed to do so here, issuing the promised guidance for Infrastructure SIPs nine months after the clock started for states to prepare those SIPs. EPA Br. 65. Although EPA plans to propose implementation rules governing Attainment SIPs[18] in May 2014, it has not provided a date by when it expects to issue a final

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[16] EPA must provide states at least 120 days. CAA § 107(d)(1)(A).

[17] That states have been submitting SIPs to address PM since 1971 is irrelevant. Int. Br. 36. EPA made clear in the Final Rule that a new set of rules would apply to SIPs for the new NAAQS.

[18] Petitioners imprecisely stated "no state has previously been required to develop a SIP under Subpart 4." Pet. Br. 57. Petitioners should have stated no state has previously been required to develop a SIP under Subpart 4 for $PM_{2.5}$.

rule. EPA, Regulatory Agenda (Fall 2013), http://resources.regulations.gov/public/custom/jsp/navigation/main.jsp (select EPA and search for 2060-AQ48).

Cutting these statutorily-prescribed periods short violates the CAA. *NRDC v. EPA*, 22 F.3d 1125 (D.C. Cir. 1994); *NRDC v. Thomas*, 805 F.2d 410 (D.C. Cir. 1986); *see also* Pet. Br. 60-62. EPA is incorrect that *NRDC v. EPA* and *NRDC v. Thomas* do not apply here. EPA Br. 65 n.29. Those cases stand for the principle that EPA's failures, either to issue guidance or provide lead time, cannot truncate statutorily-prescribed time periods for states and regulated entities to act. It is irrelevant that the guidance in *NRDC v. EPA* was statutorily required or that implementation plans were not at issue in *NRDC v. Thomas*. Here, as in those cases, EPA's error unlawfully cut short statutorily-prescribed time periods.

Finally, EPA wrongly asserts Petitioners have identified no injury resulting from EPA's failure to provide timely tools to states to enable them to make their designations and to prepare their SIPs. *Id.* at 64-66. Petitioners explained their injury in their opening brief. Pet. Br. 55-57.

C. EPA Has the Authority To Address Implementation Issues in NAAQS Rulemakings.

EPA has the authority to address Petitioners' implementation concerns. Section 109(d)(1) requires EPA to review NAAQS at least every five years in accordance with sections 108 and 109(b) and to revise them "as may be appropriate." As part of that process, EPA must ensure that any new NAAQS can

be implemented. Where tools for implementation are unavailable, EPA has options, such as deferral of the NAAQS, a stay of its effectiveness, or a transition policy. Pet. Br. 50, 58-59. In this case, implementation tools were unavailable. Instead of relying on legitimate options for addressing this problem, EPA claims it lacks the authority to do so. This claim is meritless.

First, the plain text of the CAA does not prevent EPA from addressing implementation issues when it promulgates a new NAAQS. Instead of impeding EPA, section 109(d)(1) gives EPA discretion to determine whether NAAQS revision is "appropriate." EPA could have deferred revising the NAAQS on the grounds that it would not be appropriate to do so until the needed implementation rules were in place. Section 109(b) also provides the Administrator discretion by allowing the "judgment of the Administrator" to factor into the determination. CAA § 109(b)(1), (2).

Second, *Whitman v. American Trucking Associations*, 531 U.S. 457 (2001), does not prohibit any such EPA action. Contrary to EPA's assertion that it may not consider anything besides public health and welfare in NAAQS revisions, EPA Br. 57-58, the Supreme Court in *Whitman* declined to rule on the argument that NAAQS "need not be based *solely* on [the] criteria [developed under CAA § 108(a)(2)]; and that those criteria themselves, while they must include 'effects on public health or welfare …,' are not necessarily *limited* to those effects." *Id.* at 469

(emphases in original). Instead, the *Whitman* Court held only that cost considerations were prohibited. *Id.* Petitioners are not arguing EPA failed to consider costs in the Final Rule.[19]

Third, EPA argues it "unequivocally" stated in the Proposal that implementation matters "'are not relevant to the establishment of the NAAQS.'" EPA Br. 58 (quoting 77 Fed. Reg. at 39,017, JA__). Of course, saying so does not make it true. EPA's argument that "Petitioners cite to no provision of the Act that compels EPA to provide implementation" rules is similarly unavailing. *Id.* It goes without saying that EPA must provide the tools necessary for entities to satisfy obligations that were triggered by EPA's promulgation of the NAAQS.

CONCLUSION

The Final Rule is arbitrary, capricious, and otherwise unlawful, and the Court should grant the petitions for review and order the relief requested in Petitioners' opening brief.

[19] EPA's reliance on *American Trucking Associations v. EPA*, 175 F.3d 1027 (D.C. Cir. 1999) (per curiam), EPA Br. 58, fails for the same reason. That decision addressed only whether EPA may consider costs and was silent on other factors. *Id.* at 1040-41.

Respectfully submitted,

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Dated: December 19, 2013

CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(a)(7)(C) of the Federal Rules of Appellate Procedure and Circuit Rules 32(a)(1) and 32(a)(2)(C), I hereby certify that the foregoing Joint Reply Brief of Petitioners contains 6,990 words, as counted by a word processing system that includes headings, footnotes, quotations, and citations in the count, and therefore is within the word limit set by the Court.

/s/ Allison D. Wood

Dated: December 19, 2013

CERTIFICATE OF SERVICE

Pursuant to Rule 25 of the Federal Rules of Appellate Procedure and Circuit Rule 25(c), I hereby certify that I have this 19th day of December, 2013, served a copy of the foregoing Joint Reply Brief of Petitioners electronically through the Court's CM/ECF system.

/s/ Allison D. Wood