ORAL ARGUMENT SCHEDULED FOR FEBRUARY 20, 2014

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

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

NATIONAL ASSOCIATION OF MANUFACTURERS, *et al.*,
Petitioners,

v.

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

Petition for Review of Final Rule of the
United States Environmental Protection Agency

FINAL BRIEF OF INTERVENORS SUPPORTING RESPONDENTS

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Dated: January 17, 2014

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NATIONAL ASSOCIATION OF MANUFACTURERS, *et al.*, Petitioners, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al.*, Respondents.	No. 13-1069 (consolidated with No. 13-1071)

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

American Lung Association, Environmental Defense Fund, Natural Resources Defense Council, and Sierra Club (collectively, "Public Health Intervenors") submit this certificate as to parties, rulings, and related cases.

(A) Parties, Intervenors, and *Amici*

The parties to this action are those set forth in the certificate filed with the Joint Opening Brief of Industry Petitioners.

(B) Rulings Under Review

Industry Petitioners seek review of the final action taken by the United States Environmental Protection Agency entitled "National Ambient Air Quality

Standards for Particulate Matter," published on January 15, 2013, at 78 Fed. Reg. 3086.

(C) Related Cases

These consolidated cases have not previously been before this Court or any other court. Public Health Intervenors are unaware of any related cases within the meaning of Circuit Rule 28(a)(1)(C).

DATED: January 17, 2014

Respectfully Submitted,

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PUBLIC HEALTH INTERVENORS' RULE 26.1 DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1 and Circuit Rule 26.1, American Lung Association, Environmental Defense Fund, Natural Resources Defense Council, and Sierra Club (collectively, "Public Health Intervenors") make the following disclosures:

American Lung Association

Non-Governmental Corporate Party to this Action: American Lung Association ("ALA").

Parent Corporations: None.

Publicly Held Company that Owns 10% or More of Party's Stock: None.

Party's General Nature and Purpose: ALA is a corporation organized and existing under the laws of Maine. ALA is a national nonprofit organization dedicated to a world free of lung disease and to saving lives by preventing lung disease and promoting lung health. ALA's Board of Directors includes pulmonologists and other health professionals.

Environmental Defense Fund

Non-Governmental Corporate Party to this Action: Environmental Defense Fund ("EDF").

Parent Corporations: None.

Publicly Held Company that Owns 10% or More of Party's Stock: None.

Party's General Nature and Purpose: EDF is a corporation organized and existing under the laws of New York. EDF is a nonprofit organization of over 360,000 members nationwide focused on protection of public health and the environment.

Natural Resources Defense Council

Non-Governmental Corporate Party to this Action: Natural Resources Defense Council ("NRDC").

Parent Corporations: None.

Publicly Held Company that Owns 10% or More of Party's Stock: None.

Party's General Nature and Purpose: NRDC is a corporation organized and existing under the laws of the State of New York. NRDC is a nonprofit

membership organization of approximately 350,000 members nationwide focused on protection of public health and the environment.

Sierra Club

Non-Governmental Corporate Party to this Action: Sierra Club ("The Club").

Parent Corporations: None.

Publicly Held Company that Owns 10% or More of Party's Stock: None.

Party's General Nature and Purpose: Sierra Club, a corporation organized and existing under the laws of the State of California, is a national nonprofit organization dedicated to the protection and enjoyment of the environment.

DATED: January 17, 2014

Respectfully Submitted,

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES **PAGE(S)**

* Authorities upon which we chiefly rely are marked with an asterisk

STATUTES

CODE OF FEDERAL REGULATIONS

FEDERAL REGISTER

LEGISLATIVE MATERIALS

GLOSSARY OF ACRONYMS AND ABBREVIATIONS

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

The Act	Clean Air Act
AHA	American Heart Association
AHA Comments	*Comments*, EPA-HQ-OAR-2007-0492-9512
ALA	American Lung Association
ALA Comments	*Comments*, EPA-HQ-OAR-2007-0492-9826
API	American Petroleum Institute
API Comments	EPA-HQ-OAR-2007-0492-9530
CASAC	Clean Air Scientific Advisory Committee
CASAC Review Letter	EPA-HQ-OAR-2007-0492-0113
EDF	Environmental Defense Fund
EPA	Environmental Protection Agency
FIPs	Federal Implementation Plans
NAAQS	National Ambient Air Quality Standard
NRDC	Natural Resources Defense Council
PM	Particulate Matter

$PM_{2.5}$	Fine Particulate Matter
Policy Assessment	EPA-HQ-OAR-2007-0492-0339
Response to Comments or RTC	EPA-HQ-OAR-2007-0492-10095
Science Assessment	EPA-HQ-OAR-2007-0492-0079
SD	Standard Deviation
Sick of Soot	*Sick of Soot*, EPA-HQ-OAR-2007-0492-9826
SIPs	State Implementation Plans
UARG	Utility Air Regulatory Group
UARG Comments	EPA-HQ-OAR-2007-0492-9483

STATUTES AND REGULATIONS

Pursuant to Circuit Rule 28(a)(5), pertinent statutes and regulations appear in a separately bound Statutory and Regulatory Addendum.

INTRODUCTION

The Environmental Protection Agency's ("EPA's") adoption of a more health protective annual standard for fine particulate matter ("$PM_{2.5}$") is overwhelmingly supported by the health effects evidence in the record and will result in significant national health benefits, including the prevention of thousands of premature deaths each year. To retain the less protective 1997 annual standard—which Industry Petitioners support—EPA would have had to ignore the numerous studies published since the 1997 standard showing that $PM_{2.5}$ causes cardiovascular, respiratory, and other harms at lower ambient levels, as well as the recommendations of EPA's independent scientific advisory committee and conclusions of its expert staff. Indeed, this body of evidence was sufficient to support a standard even more protective than the one EPA adopted, as Public Health Intervenors and leading medical societies advocated in public comments on the rulemaking.

As further detailed below, Industry Petitioners' attempts to circumvent the compelling body of scientific evidence that supports strengthening the $PM_{2.5}$ annual standard are meritless.

The Public Health Intervenors are American Lung Association ("ALA"), Environmental Defense Fund ("EDF"), Natural Resources Defense Council ("NRDC"), and Sierra Club. Public Health Intervenors are national nonprofit organizations dedicated to protecting the public health from air pollution. These organizations have consistently made the protection of air quality a high priority and have a long history of advocacy for stronger particulate matter standards. Public Health Intervenors submitted extensive comments on the EPA proposal that led to adoption of the $PM_{2.5}$ standard challenged here. *See Comments*, EPA-HQ-OAR-2007-0492-9826 ("ALA Comments"), JA1637. Each of these organizations has members who are being exposed to unsafe levels of $PM_{2.5}$ and whose health would be threatened if the $PM_{2.5}$ standard were weakened or if implementation of standards was delayed or inadequate.[1]

STATEMENT OF FACTS

We add the following considerations to the relevant background set forth in EPA's brief.

[1] The Industry Petitioners are National Association of Manufacturers, Utility Air Regulatory Group, PM NAAQS Coalition, and Chamber of Commerce of the United States of America.

I. NAAQS Must Be Set to Protect Public Health with an Adequate Margin of Safety.

EPA must set a primary national ambient air quality standard ("NAAQS") for a pollutant that is "requisite to protect the public health" with "an adequate margin of safety." 42 U.S.C. §7409(b)(1). Both EPA and the courts recognize that NAAQS are "preventative in nature." *Ethyl Corp. v. EPA*, 541 F.2d 1, 15 (D.C. Cir. 1976); *accord* H.R. Rep. 95-294, at 49-51 (1977) (Clean Air Act amendments designed "[t]o emphasize the preventive or precautionary nature of the act, i.e., to assure that regulatory action can effectively prevent harm before it occurs"); EPA-HQ-OAR-2007-0492-0079, at 1-3, JA0592 ("Science Assessment"). In considering uncertainty, EPA must err on the side of caution in terms of protecting human health and welfare. *See Am. Trucking Ass'ns v. EPA*, 283 F.3d 355, 369 (D.C. Cir. 2002) ("The Act requires EPA to promulgate protective primary NAAQS even where . . . the pollutant's risks cannot be quantified or 'precisely identified as to nature or degree.'"); *ALA v. EPA*, 134 F.3d 388, 389 (D.C. Cir. 1998) (EPA must "decide what margin of safety will protect the public health from . . . not just known adverse effects, but those of scientific uncertainty").

II. $PM_{2.5}$ Is a Dangerous Air Pollutant.

$PM_{2.5}$ is a lethal airborne pollutant that causes premature death and a host of other significant health harms. 78 Fed. Reg. 3086, 3103/2-3 (Jan. 15, 2013). Sources of $PM_{2.5}$ include emissions from motor vehicles and diesel engines, coal-

fired power plants, and other industrial sources. Science Assessment at 2-4 to 5, JA0619-20; *Am. Farm Bureau Fed'n v. EPA*, 559 F.3d 512, 515 (D.C. Cir. 2009). Not surprisingly, elevated levels of $PM_{2.5}$ pollution are found in and near metropolitan areas with high traffic. ALA Comments at 107-08, JA1743-44. The particles that make up $PM_{2.5}$ are microscopic, enabling them to lodge deep within the lungs where they cause cardiovascular problems like heart attacks and strokes, respiratory disease and asthma exacerbation, and death. 78 Fed. Reg. at 3103/2-3; Science Assessment at 2-9 to 11, JA0624-26; *Sick of Soot*, EPA-HQ-OAR-2007-0492-9826, at 6, JA1779 ("Sick of Soot"). Those with preexisting lung or heart disease, elderly persons, children, and individuals with low socioeconomic status are most susceptible to the threats posed by $PM_{2.5}$ pollution. 78 Fed. Reg. at 3104/1.

EPA has long regulated particulate matter as a criteria air pollutant under the Clean Air Act ("the Act"). 78 Fed. Reg. at 3090/3. In 1997, EPA established an annual $PM_{2.5}$ standard of 15 $\mu g/m^3$ and a 24-hour standard of 65 $\mu g/m^3$. *Id.* at 3091/2-3. In 2006, EPA made the 24-hour standard more protective by lowering it to 35 $\mu g/m^3$, but retained the 15 $\mu g/m^3$ annual standard. *Id.* at 3092/3. At that time, the Clean Air Scientific Advisory Committee ("CASAC"), a statutorily-created independent scientific review committee, expressed serious concerns that "the decision to retain without change the annual $PM_{2.5}$ standard does not provide an

'adequate margin of safety . . . requisite to protect the public health.'" *Id.* at 3093/1.

Upon judicial challenge by public health and environmental groups, the D.C. Circuit invalidated EPA's decision to retain the unprotective 15 $\mu g/m^3$ annual standard. *Am. Farm Bureau*, 559 F.3d at 515. The Court held that "EPA failed to explain adequately why an annual level of 15 $\mu g/m^3$ is 'requisite to protect the public health,' including the health of vulnerable subpopulations, while providing 'an adequate margin of safety.'" *Id.* at 519. The Court admonished EPA for ignoring the advice of CASAC and for failing to consider evidence of adverse health effects on children and other sensitive subpopulations at lower levels of exposure. *Id.* at 521-22, 525-26.

III. EPA Followed a Comprehensive and Thorough Process in Development of the 2012 $PM_{2.5}$ Annual Standard.

Following remand, EPA undertook a more extensive review of the latest scientific evidence to develop the 2012 $PM_{2.5}$ annual standard. EPA prepared multiple drafts of the Science Assessment based on the most meaningful new science and submitted those to CASAC and the public for comment and review. 78 Fed. Reg. at 3094/1. In its final Science Assessment, EPA concluded that both short-term and long-term $PM_{2.5}$ exposure causes mortality and cardiovascular harm, and that short-term and long-term $PM_{2.5}$ exposure is "likely" to cause

adverse respiratory effects. *Id.* at 3103/2-3; Science Assessment at 2-10 to 11, JA0625-26.

Based on the scientific studies and conclusions presented in the Science Assessment and an accompanying risk assessment, EPA staff prepared a Policy Assessment that concluded that EPA should consider strengthening the annual standard to a level between 13 and 11 $\mu g/m^3$. EPA-HQ-OAR-2007-0492-0339, at ES-1, JA1067 ("Policy Assessment"). EPA staff found that "the evidence most strongly supports consideration of an alternative annual standard level in the range of 12 to 11 $\mu g/m^3$. *Id.* EPA staff also recognized that "no discernible thresholds have been identified for any health effects." *Id.* at ES-1 to 2, JA1067-68. EPA considered two rounds of comments from CASAC and the public before finalizing the Policy Assessment. 78 Fed. Reg. at 3094/2-3.

CASAC's input was gathered and considered throughout this process. CASAC advised that the 15 $\mu g/m^3$ standard was "not protective," and concluded that an annual standard within the range of 13 to 11 $\mu g/m^3$ was supported by the evidence. *Id.* at 3109/1, 3138/3. CASAC found no evidence of a threshold level of exposure below which no adverse effects were experienced. *Id.* at 3183/3. CASAC also recommended the elimination of "spatial averaging"—a method whereby states were allowed to treat an entire community as complying with the annual

standard even if individual monitors showed unsafe levels. EPA-HQ-OAR-2007-0492-0113, at 13, JA0874 ("CASAC Review Letter").

In 2012, EPA proposed a revised annual standard and received more than 230,000 comments on the proposal. *See* 77 Fed. Reg. 38,890 (June 29, 2012); 78 Fed. Reg. at 3095/1. Public Health Intervenors submitted comments outlining additional and substantial evidence of harm caused by $PM_{2.5}$ at levels of exposure well below the 2006 standards, and urged EPA to strengthen the annual standard to 11 $\mu g/m^3$ and the 24-hour standard to 25 $\mu g/m^3$. ALA Comments at 6, 15, 18-20, 38-61, JA1642, 1651, 1654-56, 1674-97. The American Thoracic Society, American Public Health Association, American Heart Association ("AHA"), American Academy of Pediatrics, Physicians for Social Responsibility, Trust for America's Health, and other public health organizations likewise called for the same outcome. *Comments*, EPA-HQ-OAR-2007-0492-9512, at 12-13, JA1493-94 ("AHA Comments").

Public Health Intervenors submitted analysis indicating that an annual standard of 11 $\mu g/m^3$ coupled with a 24-hour standard of 25 $\mu g/m^3$ would avoid more than 35,000 premature deaths annually, as compared to 15,000 deaths avoided with a 12 $\mu g/m^3$ annual standard and a 35 $\mu g/m^3$ 24-hour standard. ALA Comments at 77-78, JA1713-14; Sick of Soot at 2, JA1778. Public Health Intervenors also showed that the stronger standards they sought would spare

Americans 2,350 heart attacks, 23,290 hospital and emergency room visits, and 1.4 million cases of aggravated asthma each year. Sick of Soot at 2, JA1778.

Public Health Intervenors' comments further showed that EPA's proposal to eliminate the use of spatial averaging to assess compliance with the annual standard was needed to protect communities and neighborhoods from exposure to unsafe levels of $PM_{2.5}$. ALA Comments at 23-25, JA1659-61. In addition, Public Health Intervenors and groups of medical professionals and health advocates submitted comments showing that millions of Americans live within 300 feet of major roadways and that their risk of dangerous exposures in those locations are particularly high. *Id.* at 101, JA1737; AHA Comments at 10, 13, JA1491, 1494.

SUMMARY OF ARGUMENT

EPA reasonably determined that the substantial and consistent scientific evidence of the harmful effects of ambient $PM_{2.5}$ exposure necessitated strengthening the $PM_{2.5}$ annual standard to protect the public health. The scientific evidence overwhelmingly supported an annual standard at least as protective as the one EPA adopted, and indeed was sufficient to justify even stronger standards. Contrary to Industry Petitioners' claims, EPA fully and adequately responded to comments that cited studies concerning $PM_{2.5}$ exposure thresholds and the association between $PM_{2.5}$ and mortality.

EPA's decision to require the placement of air monitors near heavily trafficked roadways in major urban areas to capture the elevated levels of $PM_{2.5}$ to which people are being exposed is well supported by the record, comports with the Clean Air Act, and is justified to adequately protect people living and spending time near roads. Moreover, the elimination of the use of spatial averaging of multiple monitoring sites to measure compliance with the annual standard will protect vulnerable populations from disproportionately high (and unsafe) concentrations of $PM_{2.5}$, and is both consistent with the Act and eminently reasonable. Finally, Industry Petitioners' claims concerning the need for implementation rules lack any basis in the Act or this Court's precedent.

ARGUMENT

I. The Health Effects Evidence Was More Than Sufficient to Support a Standard at Least as Protective as the One EPA Adopted.

A. EPA Reasonably Determined that the 2006 $PM_{2.5}$ Annual Standard Was Inadequate to Protect Public Health.

EPA evaluated an extensive body of scientific evidence in concluding that the 15 $\mu g/m^3$ annual standard was insufficient to protect public health. This thorough, careful review included examination of EPA's Science Assessment, risk assessment, and Policy Assessment, along with consideration of CASAC recommendations and public comments, all of which strongly pointed to the need for a more protective standard. 78 Fed. Reg. at 3106/2, 3120/2-3. Since EPA

finalized the $PM_{2.5}$ annual standard in 1997, more than 10,000 peer-reviewed scientific studies had been published that validated and extended earlier research linking fine particle pollution with serious morbidity effects and premature mortality. *See* ALA Comments at 4, 14, JA1640, 1650 (noting that more than a dozen long-term cohort studies were available for the 2012 rulemaking compared to just two studies available in 1997); *see also Mississippi v. EPA*, 723 F.3d 246, 256-57 (D.C. Cir. 2013) ("[T]hough a new study does little besides confirm or quantify a previous finding, such incremental (and arguably duplicative) studies are valuable precisely because they confirm or quantify previous findings or otherwise decrease uncertainty.").

EPA's Policy Assessment identified two questions bearing on the need for more protective standards: first, whether there are statistically significant health effects associated with $PM_{2.5}$ exposure in areas meeting the 2006 standards; and second, whether associations with $PM_{2.5}$ exposure extend to lower air quality concentrations than previously observed. 78 Fed. Reg. at 3106/3 (citing *Am. Trucking*, 283 F.3d at 369 (determining revision to make NAAQS more stringent is justified where health effects occur in areas meeting existing standard)).

EPA's answers to both inquiries supported strengthening the annual standard. *See* 78 Fed. Reg. at 3108/1-2 (Policy Assessment determined that collective weight of evidence shows health effects at concentrations lower than

previously observed and lower than allowed by 2006 annual standard); *id.* at 3119 (indicating evidence of health impacts in areas meeting 2006 annual standard); *see also* ALA Comments at 39, JA1675 ("Multiple, multi-city studies over long periods of time have shown clear evidence of premature death, cardiovascular and respiratory harm as well as reproductive and developmental harm at contemporary concentrations far below the level of the current standard.").[2] The Policy Assessment concluded that "currently available evidence clearly calls into question whether the current suite of primary $PM_{2.5}$ standards protects public health with an adequate margin of safety . . . [and] provides strong support for considering fine particle standards that would afford increased protection beyond that afforded by the current standards." 78 Fed. Reg. at 3108/2. In addition to these evidence-based conclusions, EPA determined that risks associated with just meeting the 2006 standards are "important from a public health standpoint in terms of both the severity and magnitude of the effects." *Id.* at 3109/2; *accord id.* at 3108/3.

CASAC agreed, describing the 15 $\mu g/m^3$ standard as "not protective" and concluding "currently available information clearly calls into question the adequacy of the current standards." *Id.* at 3109/1. Moreover, in comments on the first draft Policy Assessment, CASAC noted that "there are significant public

[2] Among other data, EPA analyzed extended follow-up of the American Cancer Society and Harvard Six Cities studies, finding "stronger evidence of an association with mortality at lower air quality distributions than had previously been observed." 78 Fed. Reg. at 3106/3.

health consequences at the current levels of the standard that justify consideration of lowering the $PM_{2.5}$ NAAQS further," such as premature death and cardiovascular and respiratory harm. *Id.*; EPA-HQ-OAR-2007-0492-0082, at 2-54, JA0850.

Major medical, public health, and environmental groups (including Public Health Intervenors), as well as the National Association of Clean Air Agencies and many state and local air departments and five state attorneys general provided additional support for a more stringent annual standard. 78 Fed. Reg. at 3110/1. In its comments, the American Heart Association called on EPA to "significantly strengthen" fine particulate standards "to help us protect the health of . . . our nation." AHA Comments at 1, 13, JA1482, 1494. Moreover, 350 physicians, environmental health researchers, and public health and medical professionals stated that new evidence since EPA's 2006 review "reinforces already strong existing studies and supports the conclusion that $PM_{2.5}$ is causally associated with numerous adverse health effects in humans at exposure levels far below the current standard." *Id.* at 1-2, JA1482-83; ALA Comments at 4-5, JA1640-41. These professionals concluded that the evidence "demands prompt action to protect

human health."[3] AHA Comments at 1-2, JA1482-83; ALA Comments at 4-5, JA1640-41.

In light of the extensive body of scientific evidence, EPA rationally concluded that the primary $PM_{2.5}$ annual standard was inadequate to protect human health with an adequate margin of safety and needed to be strengthened. 78 Fed. Reg. at 3110/1-3111/1. EPA's decision clearly comports with both the "minimal standards of rationality" that EPA action must satisfy, *Nat'l Envtl. Dev. Ass'n's Clean Air Project v. EPA*, 686 F.3d 803, 810 (D.C. Cir. 2012), and the precautionary nature of the Clean Air Act. *See supra*, Statement of Facts, Part I; *see also Am. Trucking*, 283 F.3d at 369.

B. The Record Amply Supported an Annual Standard at Least as Protective as 12 µg/m^3.

The Clean Air Act requires air quality standards to "be set at a level at which there is 'an absence of adverse effect' on [] sensitive individuals" such as children, the elderly, and people with respiratory illnesses. *Lead Indus. Ass'n v. EPA*, 647 F.2d 1130, 1153 (D.C. Cir. 1980). Under this test, an annual standard at least as protective as the one EPA adopted was more than justified. The 12 µg/m^3 standard

[3] In their comments, Public Health Intervenors evaluated many of the same epidemiological studies as EPA, similarly concluding that the studies demanded strengthening the standard. *See* ALA Comments at 39-50, JA1675-86 (analyzing extended American Cancer Society Cohort; Medicare Cohort; Women's Health Initiative Cohort; Canadian Cohort; Harvard Six Cities Study; 112 City Study; and Medicare Air Pollution Study).

reflects a value below the long-term mean $PM_{2.5}$ concentrations reported in a set of epidemiological studies showing cardiovascular disease, respiratory ailments, and premature death. *See* 78 Fed. Reg. at 3135 fig.4; *see also* EPA Br. 25 (noting two long-term mean concentrations below 13 $\mu g/m^3$). EPA had the greatest confidence in health impacts at these long-term mean concentrations and reasonably set a standard below that level. *See Am. Trucking*, 283 F.3d at 372 (reasonable to establish 1997 $PM_{2.5}$ annual standard at level below long-term mean concentration); *see also* 42 U.S.C. §7409(b)(1) (standards must be established with an adequate margin of safety).

The Administrator's decision is likewise supported by EPA staff conclusions in the Policy Assessment and by CASAC recommendations. The Policy Assessment concluded "currently available evidence most strongly supported consideration of an alternative annual standard level in the range of 12 to 11 $\mu g/m^3$," and that a standard in this range "would more fully take into consideration the available information from all long- and short-term $PM_{2.5}$ exposure studies, including studies of at-risk populations, than would a higher level." 78 Fed. Reg. at 3137/1. CASAC recommended that the 13 to 11 $\mu g/m^3$ levels "are supported by the epidemiological and toxicological evidence, as well as by the risk and air quality information compiled," and observed no evidence of a threshold. *Id.* at 3138/3.

Indeed, as Public Health Intervenors argued in comments, the available evidence supports a level of 11 $\mu g/m^3$—even more stringent than the 12 $\mu g/m^3$ EPA ultimately adopted. *See* ALA Comments at 38-70, JA1674-1706. They urged EPA to consider setting the standard well below the long-term mean concentrations in the studies because adverse health effects do not just occur due to exposures at mean $PM_{2.5}$ concentrations, but also at levels well below the mean. *Id.* at 50, JA1686. Public Health Intervenors commented that in its 2006 review, EPA looked at concentrations 1 standard deviation ("SD") below the mean to focus on where the preponderance of evidence lay. *Id.* Here, the mean minus 1 SD in pertinent multi-city long-term exposure studies of the general population and older adults ranged from 9.8 to 11.3 $\mu g/m^3$, indicating that a standard of 12 $\mu g/m^3$ is not sufficient to protect against the majority of health effects reported. *Id.* EPA also identified a number of multi-city short-term studies of particular relevance to review of the $PM_{2.5}$ annual standard. The mean minus 1 SD levels in these studies ranged from 3.9 to 10.3 $\mu g/m^3$. And multi-city, long-term $PM_{2.5}$ studies showing adverse effects in children reported concentrations 1 SD below the mean ranging from 6.1 to 10.3 $\mu g/m^3$. *Id.* at 53-54, JA1689-90.

Given the extensive evidence of adverse health effects at $PM_{2.5}$ levels close to—and even below—12 $\mu g/m^3$, an annual standard at least as protective as that level was more than justified. *See Lead Indus. Ass'n*, 647 F.2d at 1153.

II. EPA Adequately Responded to Industry's Comments on the Scientific Evidence of $PM_{2.5}$ Harm.

Industry Petitioners disagree with EPA's conclusions on certain scientific and technical questions such as the existence of threshold levels of $PM_{2.5}$ exposure below which no harm occurs, and the causal connection between exposure to ambient $PM_{2.5}$ and mortality. Unwilling to challenge EPA's substantive conclusions directly, Industry Petitioners attack the procedure EPA followed in an attempt to undermine EPA's expert judgments. But EPA fully considered and adequately responded to Industry Petitioners' concerns.

A. EPA Fully Addressed Comments Concerning a $PM_{2.5}$ Threshold Below Which Harm Does Not Occur.

Contrary to Industry Petitioners' argument, Pet. Br. 23, EPA responded directly to the comments of the American Petroleum Institute ("API"), which argued that certain "review papers" call into question EPA's finding that there is no discernible threshold below which harm does not occur from exposure to $PM_{2.5}$.[4] EPA-HQ-OAR-2007-0492-9530, at 19-20, JA1524-25 ("API Comments"). Citing API's comment, EPA responded that it disagreed with the comment "due to the number of studies evaluated in the [Science Assessment] that continue to demonstrate a no-threshold [] model most adequately represents" the relationship between $PM_{2.5}$ exposure and health harms. EPA-HQ-OAR-2007-0492-10095, at II-

[4] API is not a petitioner in this action.

40, JA1916 ("Response to Comments" or "RTC"). EPA explained that although some studies raised uncertainties that have not been resolved and require further investigation, many scientific studies support the conclusion that a no-threshold model "is most appropriate." *Id.* at II-40 to 41, JA1916-17. In the response to comments section of the Final Rule, EPA stated that "the overall evidence from existing epidemiological studies does not support the existence of thresholds at the population level." 78 Fed. Reg. at 3119/1.

This direct response to API's comment addressed the commenter's concerns and satisfied EPA's obligation to respond to all "significant comments." 42 U.S.C. §7607(d)(6)(B). The plain language of the Act does not include a requirement—as Industry Petitioners imagine—to individually respond to every footnote or citation, especially where, as here, commenters failed to show any special and unique significance of the individual review papers they cited.

Moreover, EPA's evaluation of whether a threshold below which $PM_{2.5}$ ceases to cause harm could be identified was exhaustive and well supported by numerous health effects studies. 78 Fed. Reg. at 3098/1-2, 3101/1, 3107/1; Science Assessment at 2-25 to 26, 6-75, 6-197 to 200, JA0640-41, 0663, 0702-05; Policy Assessment at 2-1 to 2, 2-8 to 16, JA1090-91, 1097-1105. As EPA explained, updated analyses of the major epidemiological studies showed that "the concentration-response relationship was linear and 'clearly continuing below the

level'" of the 1997 standard—i.e., exposure to $PM_{2.5}$ continued to cause health harms at lower levels of exposure. 78 Fed. Reg. at 3107/1. Studies examining the relationship between $PM_{2.5}$ and mortality "have consistently found no evidence for . . . a safe threshold." Science Assessment at 6-75, JA0663. The papers briefly cited in API's comments do not contradict this extensive evidence and would not themselves support finding a safe exposure threshold. *See* Pet. Br. 23.[5]

EPA squarely addressed the issue of model uncertainty—which is raised in the Koop & Tole (2004) paper cited by API—in EPA's Response to Comments, stating that EPA "thoroughly considered" each of the areas of potential model uncertainties and "the overall effect of different model specifications" on the association between $PM_{2.5}$ exposure and mortality, and concluded that "[r]egardless of the model used, these studies collectively found evidence of consistent positive associations." RTC at II-39 to 40, JA1915-16; *accord* 78 Fed. Reg. at 3118/2-3; *see also* RTC at II-12, JA1888 ("EPA thoroughly considered the uncertainties and limitations of all studies during its evaluation.").

With respect to Roberts & Martin (2006), another paper cited in API's comments, API failed to explain how this paper's discussion of study criteria relates to EPA's evaluation of $PM_{2.5}$. To the extent it is even relevant, this paper

[5] Even petitioner Utility Air Regulatory Group ("UARG") acknowledged in its comments that "with a pollutant such as PM . . . no exposure threshold for effects can be identified." EPA-HQ-OAR-2007-0492-9483, at 8, JA1346 ("UARG Comments").

would not alter EPA's conclusion that "the overall evidence" does not support the existence of thresholds below which no harm occurs. 78 Fed. Reg. at 3119/1.

Gamble & Lewis (1996), a review paper partially funded by the Institute of Petroleum that predates the 1997 standards, concludes that there is no causal relationship between short-term particulate matter ("PM") exposure and mortality at levels below 150 $\mu g/m^3$ for a 24-hour standard. This position was long ago discredited: in 1997, EPA adopted a 24-hour standard of 65 $\mu g/m^3$, and subsequently lowered it in 2006 to 35 $\mu g/m^3$ on the basis of substantial evidence of harm at that level of exposure. *Am. Farm Bureau*, 559 F.3d at 517-18. Commenters made no attempt to explain what relevance the author's critique of a 150 $\mu g/m^3$ 24-hour standard has to whether thresholds exist below a 15 $\mu g/m^3$ annual standard.

Moolgavkar (2005) is a review paper critiquing EPA's 1997 particulate matter rulemaking. Commenters did not explain how, if at all, the author's critique of the 1997 rulemaking is relevant to the rulemaking adopting the 2012 standards. The paper does not include health thresholds among its significant critiques; however, the author does state in passing that evidence has been found of both linear and non-linear relationships between $PM_{2.5}$ and mortality. API's comment does not present an issue necessitating a response, but even if it did, EPA fully explained in the Final Rule and Response to Comments that despite some uncertainties in the data, the overall body of evidence showed that $PM_{2.5}$ continues

to cause harm at low levels without evidence of thresholds. 78 Fed. Reg. at 3119/1; RTC at II-40 to 41, JA1916-17.

Cox (2012), Fraas (2011), and Fraas & Lutter (2012) were published after the cut-off date for inclusion in the Science Assessment, a cut-off that EPA applied equally to all commenters, including to recent studies submitted by Public Health Intervenors. 78 Fed. Reg. at 3111/3. And these papers are cost analyses legally irrelevant to the NAAQS standard-setting process and therefore incapable of altering any of EPA's health-based conclusions. In any case, more recent evidence does not support Industry Petitioners' position. EPA reviewed significant studies published after the Science Assessment cut-off date and found these studies were consistent with its conclusion that $PM_{2.5}$ is associated with harm at lower levels of exposure. *Id.* at 3095/2. In addition, Public Health Intervenors' comments describe recent evidence of strong associations between $PM_{2.5}$ and cardiovascular disease and/or mortality at levels of exposure below the 2006 annual standard. ALA Comments at 35, 43-44, JA1671, 1679-80; *see also* AHA Comments at 10-11, JA1491-92.

B. EPA Fully Addressed Comments Concerning the Relationship Between $PM_{2.5}$ and Mortality.

EPA also adequately responded to comments about the association between $PM_{2.5}$ and mortality. As EPA explained in its Final Rule and Response to Comments, EPA undertook an extensive review of the scientific evidence

concerning causation—including numerous epidemiological, toxicological, and controlled human exposure studies—and concluded, based on accepted criteria for determining causality, that there was strong evidence that $PM_{2.5}$ causes premature mortality, consistent with CASAC's views. 78 Fed. Reg. at 3103/2-3, 3112-14, 3120; RTC at II-9 to 12, JA1885-88. EPA stated that "the associations are consistent across hundreds of studies as demonstrated throughout the [Science Assessment]," while recognizing the remaining limitations with current evidence. RTC at II-12 to 13, JA1888-89; *accord* 78 Fed. Reg. at 3103/2-3, 3113/2. This response adequately addressed the commenters' concerns that the association between $PM_{2.5}$ and mortality was not established and fully satisfied EPA's duty to respond to significant comments.

EPA arrived at this determination through a rigorous and thorough assessment of the association between $PM_{2.5}$ and mortality. Hundreds of new epidemiological studies on the effects of particulate pollution—many of which examine the association between $PM_{2.5}$ and mortality—have been published since 1997. 78 Fed. Reg. at 3097/2; AHA Comments at 1, JA1482. EPA set forth and followed criteria to focus its consideration of this large body of evidence on the most relevant studies for its analysis of the link between $PM_{2.5}$ and mortality. Science Assessment at 1-8 to 12, JA0597-0601 (explaining criteria for study

inclusion); *id.* at 2-14 to 15, JA0629-30 (summarizing findings in more than fifty-five pertinent epidemiological studies); *see also id.* at 7-83 to 86, JA0757-60.

EPA's determination that $PM_{2.5}$ causes premature mortality is overwhelmingly supported by the scientific evidence and is not contradicted by the studies cited by industry commenters, Pet. Br. 23-24. Extended follow-up analyses of large, multi-city epidemiological studies "provided consistent and stronger evidence of an association with mortality at lower air quality distributions than had previously been observed." 78 Fed. Reg. at 3106/3. For example, a large cohort study of American Cancer Society data found positive associations between $PM_{2.5}$ and mortality, and a 2009 reanalysis that incorporated additional data found associations at a mean annual exposure level of 14 $\mu g/m^3$, below the level of the 2006 annual standard. 78 Fed. Reg. at 3106/3; Science Assessment at 2-15, 7-17, JA0630, 0722; AHA Comments at 10, JA1491. Furthermore, public health groups and medical professionals submitted comments analyzing evidence that the annual standard should be more protective than the level EPA finalized. *See supra*, Argument, Part I.B, p. 15.

The papers briefly cited in API's comments do not provide contrary evidence. In fact, both Clyde et al. (2000) and Moolgavkar (2003)[6] found

[6] Moolgavkar (2003) was incorrectly cited by commenters as Moolgavkar (2000). *Compare* API Comments at 19, JA1524 *with* Science Assessment at 6-233, JA0716.

associations between $PM_{2.5}$ and mortality under some scenarios. And EPA fully considered Moolgavkar (2003) in its Science Assessment and its provisional review of recent studies. Science Assessment at 6-147 to 148, 233, JA0685-86, 0716; EPA-HQ-OAR-2007-0492-10067, at 20, JA1822. Gamble (1998) is a review paper that discusses whether the weight of the evidence as of 1998 (when few toxicological or controlled human studies were available) supported a causal association between $PM_{2.5}$ and mortality. At the time of the 2012 rulemaking, more than a dozen long-term cohort studies addressed these health effects, along with numerous studies of short-term effects and substantial new toxicological and controlled study evidence. ALA Comments at 14, JA1650; 78 Fed. Reg. at 3114. Industry commenters made no attempt to explain which, if any, of the paper's critiques remain applicable.[7]

[7] In any case, EPA addressed the substance of the Gamble (1998) paper's primary critiques about the use of epidemiological studies. *See* 78 Fed. Reg. at 3112/2-3 (addressing critique that "epidemiological studies are observational in nature and cannot provide evidence of a causal association"); *id.* at 3113/2-3 (causality determinations based on multiple types of evidence, not just epidemiological studies); *id.* at 3113/3, 3115/2 to 3117/3 ("EPA has carefully evaluated the potential for confounding"); *id.* at 3114/2-15/1 (animal toxicological studies and controlled human exposure studies provide biological plausibility for epidemiological results); RTC at II-23 to 25, JA1899-1901 (rejecting argument that associations between $PM_{2.5}$ and mortality defied biological plausibility when evaluated against effects of cigarette smoking).

C. Industry Failed to Show Significance of Cited Studies.

To the extent Industry Petitioners are claiming EPA committed procedural error in not separately addressing every study cited in API's comments, they have not met the statutory test for invalidating the rule on procedural grounds. 42 U.S.C. §7607(d)(8) ("[C]ourt may invalidate the rule only if the errors were so serious and related to matters of such central relevance to the rule that there is a substantial likelihood that the rule would have been significantly changed if such errors had not been made."). As a threshold matter, Industry Petitioners fail to assert even—let alone demonstrate—a "substantial likelihood" that EPA's $PM_{2.5}$ annual standard would be significantly changed. *See* Pet. Br. 32 (arguing Final Rule "*could have changed*" (emphasis added)); *id.* at 34 (noting "Final Rule *may well* have been different" (emphasis added)). Accordingly, Industry Petitioners waive any "substantial likelihood" claim. *Am. Wildlands v. Kempthorne*, 530 F.3d 991, 1001 (D.C. Cir. 2008) (refusing to consider an argument not raised in party's opening brief).

Even assuming some procedural violation, which Industry Petitioners have failed to establish, *see supra*, Argument, Part II.A & Part II.B, the information in these few studies does not alter the overwhelming weight of record evidence supporting revision of the annual standard to 12 $\mu g/m^3$. *See Coal. for Responsible Regulation v. EPA*, 684 F.3d 102, 122 (D.C. Cir. 2013); *Mississippi*, 723 F.3d at

260 ("[I]t is hard to imagine how eliminating both studies from EPA's NAAQS calculation would have altered EPA's ultimate decision.").

III. EPA Reasonably Required Monitoring of Air Quality Near Roads.

Contrary to Industry Petitioners' assertions, near-road monitoring complies with the Clean Air Act and is well-supported by the record. In the Final Rule, EPA concluded that "requiring a modest network of near-road compliance $PM_{2.5}$ monitors is necessary to provide characterization of concentrations in near-road environments including for comparison to the NAAQS." 78 Fed. Reg. at 3238/2. Near-road monitors will fill a longstanding gap in the network for monitoring $PM_{2.5}$ pollution. *Id.* at 3241/1.The record is replete with evidence that people living and spending time near major roads are suffering serious health impacts from $PM_{2.5}$ pollution. *See, e.g.*, *id.* at 3239/3-40/1. Without appropriately sited monitors to detect unsafe pollution levels, the Clean Air Act's key requirements to remedy such pollution will be seriously undermined in near-road neighborhoods.

Monitoring in areas of known or potentially high pollution concentrations does not render health standards more stringent, as Industry Petitioners argue. Pet. Br. 34. Instead, such monitoring provides more accurate information about ambient air quality and pollution concentrations that may pose risks to exposed populations Congress intended to protect. EPA's near-road monitoring protections are justified

by both the science and the Act, and will more accurately reflect the $PM_{2.5}$ concentrations that millions of Americans are exposed to every day.

Industry Petitioners contend that for $PM_{2.5}$ standards with averaging times of 24 hours and one year, EPA may place monitors only where people spend time outdoors for "24-hours at a time" or a "full year." Pet. Br. 36, 39. This argument is nonsensical and finds no support in the Act. Monitoring locations are not linked in this way to a standard's averaging times. Moreover, their argument ignores that few people live outdoors for 24 hours at a time or a full year, no matter where monitors are placed.

A. The Clean Air Act Requires that the NAAQS Protect All Populations, Including Those Spending Time Near Roads.

Industry Petitioners do not and cannot demonstrate that it is arbitrary or unlawful for EPA to require monitoring to ensure NAAQS attainment near roadways. The Clean Air Act mandates that the NAAQS be attained in *all* parts of the country in order to safeguard "ambient air quality."[8] *See* 42 U.S.C. §7409(a)-(b); *see also id.* §7401(b)(1). Congress requires the following in section 107(a) of the Act:

> Each state shall have the primary responsibility for assuring air quality *within the entire geographic area* comprising such State by submitting an implementation plan for such State which will specify the manner in which

[8] EPA regulations define "ambient air" to mean the "portion of the atmosphere, external to buildings, to which the general public has access." 40 C.F.R. §50.1(e).

> national primary and secondary ambient air quality standards will be achieved and maintained.

Id. §7407(a) (emphasis added).

Section 110 of the Act affirms this broad geographic scope, requiring state plans implementing the NAAQS to "provide[] for implementation, maintenance, and enforcement of such primary standard in each air quality region (or portion thereof) within such State." *Id.* §7410(a)(1).

EPA recognizes its statutory obligation in implementing the $PM_{2.5}$ NAAQS is "not to achieve an average ambient air quality, with some areas above or below the standard, but to establish a level of air quality that all areas achieve." RTC at V-21, JA2004. Pursuant to its statutory duty, and with ample support in the record that people are exposed to polluted air near roads, EPA found that near-road exposures "occur in locations that represent ambient air for which the agency has a responsibility to ensure the public is protected with an adequate margin of safety. Ignoring monitoring results from such areas . . . would abdicate this responsibility." 78 Fed. Reg. at 3240/3.

Industry Petitioners claim that near-road monitors will not be "representative of area-wide" ambient air quality. Pet. Br. 35-40. This argument ignores that the Final Rule only classifies monitors as representative of area-wide air quality after a case-specific inquiry of the particular near-road environment. 78 Fed. Reg. at 3240/3. As EPA found, *id.*, the near-road environment is part of the ambient air.

Moreover, the Clean Air Act gives EPA broad authority to require appropriate monitoring. *See, e.g.*, 42 U.S.C. §7619(a)(2) ("The Administrator shall promulgate regulations establishing an air quality monitoring system . . . which provides for air quality monitoring stations in major urban areas and other appropriate areas"). Nowhere, however, does the Act require each monitor to be representative of an *entire* nonattainment area. *Id.* §7410(a)(2)(B) (requiring each state to provide for monitoring in its state implementation plan ("SIP")).

Nor do EPA's regulations on the placement of monitors preclude monitoring near roads. To the contrary, EPA's regulations further underscore EPA's legal authority to site monitors in the near-road environment. The regulations state that for $PM_{2.5}$, "[a]t least one monitoring station is to be sited [in a population-oriented] area of *expected maximum concentration*." 40 C.F.R. §58, app. D, subpart 4.7.1(b)(1) (emphasis added). Similarly, in areas with multiple state and local air monitoring stations, "a monitoring station is to be sited in an area of poor air quality." *Id.* subpart 4.7.1(b)(3). Thus, $PM_{2.5}$ monitors must be sited to reflect maximum concentrations in polluted areas of the country. EPA's regulations explicitly forbid EPA from ignoring heavily polluted areas, as Industry Petitioners argue EPA should have done. Pet. Br. 37-38.

Likewise, requiring monitoring of air quality near major urban roadways does not somehow make the $PM_{2.5}$ NAAQS more (and unlawfully) stringent, as

Industry Petitioners claim. Pet. Br. 35. The placement of monitors does not affect the stringency of the standards or the obligation that areas attain the levels established in the Final Rule. Monitoring ambient air near roads does not have "the effect" of making the $PM_{2.5}$ standards more stringent, but merely implements the NAAQS in the manner directed by the Act, by helping to assure attainment of the NAAQS in all ambient air, for all exposed populations.

EPA has long correctly recognized that it may not deny protections against adverse health effects of air pollutants by claiming that the people experiencing those effects are insufficiently numerous or that levels that are likely to cause adverse health effects occur only in areas that are infrequently visited. 78 Fed. Reg. at 3240; 44 Fed. Reg. 8202, 8210 (Feb. 8, 1979) ("[NAAQS] must be based on a judgment of a safe air quality level and not on an estimate of how many persons will intersect given concentration levels. EPA interprets the Clean Air Act as providing citizens the opportunity to pursue their normal activities in a healthy environment."). The NAAQS mandate "carries the promise that ambient air in all parts of the country shall have no adverse effects upon any American's health." 116 Cong. Rec. 42,381 (Dec. 18, 1970) (remarks of Senator Muskie, floor manager of the conference agreement on the 1970 Clean Air Act). EPA's decision to require near-road monitoring is thus fully consistent with Congress's intent to protect all Americans from air pollution. Moreover, because those individuals who are

particularly sensitive to $PM_{2.5}$ pollution live or spend time near roads, near-road monitoring additionally helps fulfill EPA's statutory duty to guard against health impacts in vulnerable subpopulations. *See ALA*, 134 F.3d at 389; 78 Fed. Reg. at 3240/3.

B. EPA's Decision to Require Monitoring Near Major Urban Roads Is Well-Supported by the Record.

EPA reasonably concluded from the record that near-road monitoring was needed to better protect the "significant fraction of the population [that] lives near major roads." 78 Fed. Reg. at 3240/3. EPA and commenters recognized that "more than 45 million Americans [are] living less than 300 feet from a highway," and that $PM_{2.5}$ emissions from traffic have serious health consequences.[9] *Id.* at 3239 n.228. EPA has observed that "exposure to near-roadway pollution may increase a person's chances of developing a wide range of health problems, including asthma, hypertension, leukemia, lung cancer, and perhaps even premature mortality." *See* ALA Comments at 113, JA1749 (quoting EPA, *Along the Road*,

[9] EPA has employed these demographic figures for at least the last four years, in numerous instances. *See, e.g.*, EPA, *Health Effects of Roadway Pollution* 1 (2010), *available at* http://www.epa.gov/ord/priorities/docs/NearRoadway_fact_sheet.pdf. *See also, e.g.*, 74 Fed. Reg. 34,404, 34,419 (July 15, 2009) ("The most current American Housing Survey [] is from 2007 and lists a higher fraction of housing units within the 300 foot boundary than do prior surveys . . . 47.8 million people meet[]the 300 foot criteria"); ALA Comments at 107, JA1743; AHA Comments at 13, JA1494.

http://www.epa.gov/research/gems/scinews_near-road.htm (last updated Feb. 10, 2011)).

Near-road $PM_{2.5}$ from traffic significantly impacts ambient levels of the pollutant. Recent monitoring and modeling data suggest that incremental exposure to $PM_{2.5}$ from traffic ranges from 1.5 to as much as 5 $\mu g/m^3$ above urban scale background concentrations. ALA Comments at 108, 112, JA1744, 1748 (citing Pechan (2009) and Gould (2012)). Specifically, recent studies indicate that "emissions from on-road vehicles cause a significant increment in ambient air concentrations near highways that are not accounted for in areas where $PM_{2.5}$ monitors have not been sited in the impact zone near highways." *Id.*[10] Thus, contrary to Industry Petitioners' claim, Pet. Br. 37, the evidence shows that the near-road environment is not sufficiently monitored by existing $PM_{2.5}$ monitors. 77 Fed. Reg. at 39,009/2-11/1.

Similarly, the record reveals that significant public exposure to $PM_{2.5}$ can occur near roads. The Science Assessment contains extensive documentation of the health impacts from exposure to near-road $PM_{2.5}$, including studies showing positive correlations between $PM_{2.5}$ from traffic and rates of depression, respiratory

[10] *See also* EPA-HQ-OAR-2007-0492-0391, at xix, JA1255 ("The majority of panelists acknowledged that there is an increment to $PM_{2.5}$ in the near road environment"), 5, JA1266 ("$PM_{2.5}$ . . . is a NAAQS that may often be highest at [near-road] sites."); 78 Fed. Reg. at 3241/1 (finalizing, for first time, $PM_{2.5}$ near-road monitoring network).

symptoms, and cardiovascular mortality. Science Assessment at 6-205 to 207, JA0710-12. Table 6-18 of the Science Assessment lists studies that document health effects associated with traffic-related $PM_{2.5}$ emissions. *Id.* at 6-207 tbl.6-18, JA0712. EPA's Response to Comments reiterates that "given the ubiquitous nature of roadway emissions in major urban areas," near-road monitors are appropriately representative of "typical portions of major urban areas as they provide information about $PM_{2.5}$ concentrations in areas where millions of people work, live and go to school." RTC at II-106 to 107, JA1982-83.

If, as industry concedes, traffic is an indicator of $PM_{2.5}$, Pet. Br. 37, and, as established in the record, many people live near roads, then EPA acted rationally by deciding to require monitoring of heavily trafficked urban areas. Industry Petitioners offer no alternative analysis of the number of people living near roads, and their comments and brief fail to overcome the extensive documentation of health harms from elevated $PM_{2.5}$ concentrations near roads.

IV. EPA's Elimination of Spatial Averaging Was Lawful and Rational.

EPA's elimination of spatial averaging, like its addition of near-road monitors, will better reflect actual concentrations of $PM_{2.5}$ in the ambient air to which people are exposed. This change will provide a more accurate picture of NAAQS attainment and nonattainment and, consequently, will better protect sensitive populations.

The elimination of spatial averaging will also bring $PM_{2.5}$ NAAQS in adherence with the Clean Air Act. Public health groups have long opposed spatial averaging on the basis that it directly conflicts with the Act and fails to protect vulnerable groups. *See, e.g.*, EPA-HQ-OAR-2001-0017-0333 at 24-25, JA0410-11. Spatial averaging allows an area to claim compliance with the NAAQS even if particular portions of the area exceed the NAAQS (so-called pollution "hotspots"), so long as those exceedances are "averaged out" by lower levels recorded in other portions of the area. In this way, spatial averaging allows people to be exposed to unsafe pollution concentrations in their neighborhoods and workplaces. As public health groups have long argued, the Clean Air Act does not countenance geographic zones in which national health standards may be exceeded.

Industry Petitioners do not, and cannot, reconcile spatial averaging with the plain language of the Clean Air Act. As noted above, the Act requires all areas of the country to meet the NAAQS, not just some of them. 42 U.S.C. §7409(a)-(b). The Act's requirement that the "entire geographic area comprising" each state meet the NAAQS does not permit spatial averaging, where some monitors are allowed to violate the $PM_{2.5}$ annual NAAQS. *Id.* EPA's elimination of spatial averaging, like its addition of near-road monitoring, aligns the $PM_{2.5}$ NAAQS with the congressional mandate that "ambient air in all parts of the country," not just some parts, meets the NAAQS. 116 Cong. Rec. 42,381.

Moreover, spatial averaging is "unique to this standard and is not used with other PM standards nor with other NAAQS." 78 Fed. Reg. at 3124/3 n.66. Industry Petitioners do not show why or how allowing spatial averaging serves any rational or practical purposes. Only two areas of the country used spatial averaging to meet the 1997 standards, and since then, "no area has used spatial averaging to demonstrate attainment." *Id.* at 3125/3. In arguing to retain spatial averaging, Industry Petitioners aim to preserve an illegal and harmful option that no state has used in at least seven years.

Further, EPA's elimination of spatial averaging was contemplated in EPA's last $PM_{2.5}$ NAAQS review. Industry Petitioners inaccurately frame EPA's decision as a complete reversal of past agency policy. This is not the case. Spatial averaging was first introduced in the 1997 $PM_{2.5}$ standard. In 2006, the next round of review, EPA considerably tightened constraints on spatial averaging "in part on an analysis of the potential for disproportionate impacts on potentially at-risk populations." 78 Fed. Reg. at 3125/1 (citing 71 Fed. Reg. 61,144, 61,166 (Oct. 17, 2006)). EPA's decision in 2006 anticipated that additional evidence of disproportionate impacts could justify the elimination of spatial averaging. The 2012 decision simply built on the 2006 findings.

Discontinuing spatial averaging also helps achieve the objectives of Executive Order 12,898, titled "Federal Actions to Address Environmental Justice

in Minority Populations and Low-Income Populations." 78 Fed. Reg. 3267/2-3. As part of its evaluation of compliance with Executive Order 12,898, "the EPA is eliminating the spatial averaging provisions as part of the form of the primary annual $PM_{2.5}$ standard to avoid potential disproportionate impacts on at-risk populations." *Id.* EPA stated that it "expects this final rule will lead to the establishment of uniform NAAQS for PM," as required by the Clean Air Act. *Id.*; *see also id.* at 3088/2-3. Not only is the elimination of spatial averaging consistent with EPA's obligations under Executive Order 12,898, it is required to satisfy EPA's duty to devise NAAQS that protect not only average healthy individuals, but also those persons most at risk of harm from $PM_{2.5}$. *See ALA*, 134 F.3d at 389; 78 Fed. Reg. at 3267/3 ("EPA has identified persons from lower socioeconomic strata as an at-risk population for PM-related health effects.").

The elimination of spatial averaging, coupled with the creation of a near-road monitoring network, will allow EPA to more accurately assess $PM_{2.5}$ concentrations to which people are actually exposed. Such an outcome is both rational and fully consistent with the Act and its purposes.

V. EPA Was Not Required to Issue Guidance Documents Along with the Final $PM_{2.5}$ NAAQS.

Finally, Industry Petitioners argue that the $PM_{2.5}$ NAAQS are arbitrary and capricious because, when EPA finalized the NAAQS, it did not simultaneously adopt discretionary guidance related to NAAQS implementation. Pet. Br. 48-62

(identifying certain prevention of significant deterioration guidance and guidance related to the designation process, infrastructure SIPs, and non-attainment SIPs). States, however, have been submitting SIPs since 1970, and SIPs to address PM since such standards were first finalized in 1971 (regulating total suspended particulates). The Final Rule merely tightens the stringency of the NAAQS and adjusts the process for assessing air quality—precisely the type of changes that states have been responding to for decades. Industry Petitioners' suggestion that states must now have guidance from EPA either at the same time as EPA finalizes a NAAQS or before states submit SIPs is baseless. These arguments fly in the face of this history, the plain text of the Act, and this case law, all of which underscore the imperative of timely compliance with the NAAQS. *Gen. Motors Corp. v. EPA*, 496 U.S. 530, 533 (1990).

Absent any statutory requirement to issue the guidance documents Industry Petitioners request, Industry Petitioners point to this Court's decision in *EME Homer City Generation, L.P. v. EPA*, 696 F.3d 7 (D.C. Cir. 2012), *cert. granted in part* 133 S. Ct. 2857 (2013) as support for their position. *Homer City*, however, dealt with a different substantive provision of the Act—section 110(a)(2)(D) or the Good Neighbor provision, which involves multiple clean air obligations of

different states. The rationale of *Homer City*, which is currently on appeal,[11] derived from the majority's view that EPA had issued a rule quantifying previously unforeseeable state good neighbor obligations at the same time that EPA had issued federal implementation plans ("FIPs") to implement emissions reductions to meet those obligations. 696 F.3d at 37 n.34. In doing so, however, the Court sharply distinguished instances where, as here, EPA has established a NAAQS, concluding no additional quantification was needed because "[a] NAAQS is a clear numerical target" and "[i]f a state misses that clear numerical target, it has only itself to blame." *Id.* at 32. Here, EPA has provided quantification in the form of the NAAQS and states now have the responsibility to develop and submit SIPs. Guidance may help in that process, but is not required by the Act or *Homer City*. *See Vt. Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 548 (1978) (reviewing court not empowered to impose procedures not required by statute).

Nor can Industry Petitioners find any support in the portion of the *Homer City* opinion setting aside EPA-issued FIPs. There, in the majority's view, EPA's issuance of FIPs "denied the States that first opportunity to implement the reductions required under their good neighbor obligations," *Homer City*, 696 F.3d

[11] Having granted certiorari to review, the Supreme Court is currently considering arguments by EPA and by present intervenors ALA, EDF, NRDC, and Sierra Club that the *Homer City* majority erred in finding that the states do not have initial statutory responsibilities to submit Good Neighbor plans within three years of a NAAQS revision, independent of EPA guidance, as plainly provided under section 110(a)(1). 42 U.S.C. §7410(a)(1).

at 28, but here, EPA has issued no FIPs, and indeed, Industry Petitioners raise their claims before states have had the full benefit of the statutorily-prescribed period for developing and submitting SIPs. Industry Petitioners instead seek to invalidate the NAAQS themselves. However, the plain text of the Act clearly establishes EPA as the sole authority responsible for setting and revising the NAAQS. *E.g.*, 42 U.S.C. §7409(b) (primary NAAQS shall be standards "which in the judgment of the Administrator . . . are requisite to protect the public health"); *id.* §7409(d) (requiring that at five year intervals, "the Administrator shall complete a thorough review of the [NAAQS] . . . and shall make such revisions . . . and promulgate such new standards as may be appropriate"). *Homer City's* reasoning is utterly inapplicable here.

Finally, Industry Petitioners argue that EPA could have determined it was not "appropriate" to revise the NAAQS until it was prepared to issue implementation guidance, though Industry Petitioners wrongly suggest that EPA can "avoid" the plain language of the statute. Section 109 requires that EPA establish NAAQS "requisite to protect public health" that "provide an adequate margin of safety," 42 U.S.C. §7409(b), and that EPA do so solely on the basis of public health without considering costs. *See Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 465 (2001) (the Act "does not permit the EPA to consider costs in setting the [NAAQS]"). Industry Petitioners' suggestion that EPA could have declined to

revise the NAAQS based on anything other than public health considerations is expressly prohibited by the Act and contrary to controlling precedent. *See id.*; *Lead Indus.*, 647 F.2d at 1148-49.

CONCLUSION

For the foregoing reasons, the petitions for review should be denied.

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CERTIFICATE REGARDING WORD LIMITATION

Counsel hereby certifies on this 17th day of January, 2014, in accordance with Federal Rule of Appellate Procedure 32(a)(7)(C), that the foregoing **Final Brief of Intervenors Supporting Respondents** contains **8707** words, as counted by counsel's word processing system, and thus complies with the applicable word limit established by the Court.

/s/Nicholas Morales
Nicholas Morales

CERTIFICATE OF SERVICE

I hereby certify that on this 17th day of January, 2014, I have served the foregoing **Final Brief of Intervenors Supporting Respondents** on all registered counsel through the Court's electronic filing system (ECF).

/s/Nicholas Morales
Nicholas Morales