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UNITED STATES COURT OF APPEALS
 FOR DISTRICT OF COLUMBIA CIRCUIT

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CLERK

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

AMERICAN FARM BUREAU FEDERATION, et al.,)
)
 Petitioners,)
 v.)
 ENVIRONMENTAL PROTECTION AGENCY,)
)
 Respondent.)

Docket No. 06-1410 (and consolidated cases)

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

FINAL OPENING BRIEF OF STATE PETITIONERS and STATE AMICI

Petitioners New York, California, Connecticut, Delaware, Illinois, Maine,
New Hampshire, New Jersey, New Mexico, Oregon, Pennsylvania
Department of Environmental Protection, Rhode Island, and Vermont,
the District of Columbia, and the South Coast Air Quality Management District, and
Amici Arizona, Maryland, and Massachusetts

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Dated: March 7, 2008

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to Circuit Rule 28(a)(1), the undersigned counsel of record certify as follows:

A. PARTIES AND AMICI

Petitioners

The following parties appear in these consolidated cases as petitioners:

In case no. 06-1410, filed December 14, 2006, the American Farm Bureau Federation and National Pork Producers Council.

In case no. 06-1411, filed December 15, 2006, American Lung Association, Environmental Defense, and National Parks Conservation Association (“Environmental Petitioners”).

In case no. 06-1413, filed December 18, 2006, the National Mining Association (NMA). On May 23, 2007, NMA filed a motion to voluntarily withdraw its petition for review. The Court granted the motion on May 31.

In case no. 06-1414, filed December 18, 2006, Newmont USA Limited. On June 12, Newmont filed a motion to dismiss its petition for review and to withdraw as an intervenor on the side of EPA, which the Court granted on July 5, 2007.

In case no. 06-1415, filed December 18, 2006, the National Cattlemen’s Beef Association.

In case no. 06-1416, filed December 18, 2006, the States of New York, California, Connecticut, Delaware, Illinois, Maine, New Hampshire, New Jersey, New Mexico, Oregon, Rhode Island, Vermont, the Pennsylvania Department of Environmental Protection, the District of Columbia, and the South Coast Air Quality Management District (“State Petitioners”).

In case no. 06-1417, filed December 18, 2006, the Agricultural Retailers Association.

In case no. 06-1418, filed December 18, 2006, the Utility Air Regulatory Group (UARG).

On May 8, 2007, UARG filed a motion to dismiss its petition for review, which the Court granted on July 5, 2007.

In case no. 06-1419, filed December 18, 2006, the Fine Particulate Matter Petitioners Group (FPMPG). On May 8, 2007, FPMPG filed a motion to dismiss its petition for review, which the Court granted on June 4, 2007.

Respondent

The Environmental Protection Agency (EPA) is respondent in these consolidated cases.

Intervenors

The following parties have intervened in these consolidated cases:

On the side of EPA's action on the standard for fine particulate matter: the American Chemistry Council, American Coke and Coal Chemicals Institute, American Forest and Paper Association, Inc., American Iron and Steel Institute, American Petroleum Institute, Chamber of Commerce of the United States of America, Corn Refiners Association, Inc., Council of Industrial Boiler Owners, National Association of Manufacturers, National Cotton Council of America, National Oilseed Processors Association, National Petrochemical & Refiners Association, Portland Cement Association, and Utility Air Regulatory Group. On the side of Respondent EPA's action on the standard for coarse particulate matter: the Alliance of Automobile Manufacturers, the Coarse Particulate Matter Intervenors Group, the National Cattlemen's Beef Association, the American Farm Bureau Federation, the National Pork Producers Council, and the National Mining Association.

Amici

The following parties appear as amici in these consolidated cases:

In support of State Petitioners: the Commonwealth of Massachusetts, the State of Arizona, and the State of Maryland. In support of Environmental Petitioners, the American Thoracic Society, American Academy of Pediatrics, American Association of Cardiovascular and Pulmonary Rehabilitation, National Association for the Medical Direction of Respiratory Care, American Medical Association, and American College of Chest Physicians.

In support of respondent EPA, the National Association of Home Builders.

B. RULINGS UNDER REVIEW

State Petitioners seek review of the following final action by EPA:

1. A rule entitled "National Ambient Air Quality Standards for Particulate Matter; Final Rule," published at 71 Fed. Reg. 61,145-61,233 (Oct. 17, 2006), that amends 40 C.F.R. §§ 50.3, 50.6, Appendix K, Appendix L, and Appendix N, and adds § 50.13 and Appendix O.

C. RELATED CASES

The rule at issue has not been previously reviewed in this or any other court.

Dated: March 6, 2008

Respectfully submitted,

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GLOSSARY OF ACRONYMS AND ABBREVIATIONS

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

ACS	American Cancer Society
CASAC	Clean Air Scientific Advisory Committee
EPA	United States Environmental Protection Agency
$\mu\text{g}/\text{m}^3$	Micrograms per cubic meter (a measurement of pollutant concentration in the air)
NAAQS	National Ambient Air Quality Standards
PM	Particulate Matter
PM _{2.5}	Fine PM, includes PM that is less than or equal to 2.5 micrometers in diameter
PM ₁₀	Coarse PM, includes PM that is less than or equal to 10 micrometers in diameter, but greater than 2.5 micrometers in diameter
SIP	State Implementation Plan

PRELIMINARY STATEMENT

The National Ambient Air Quality Standards (“NAAQS”) are the cornerstone of public health protection under the Clean Air Act. The Administrator of the Environmental Protection Agency must set the NAAQS at a level that protects public health with “an adequate margin of safety.” Here, the Administrator chose a NAAQS level that results in no margin of safety at all. In an unprecedented rejection of the advice of the independent science advisory board established under the statute, the Administrator refused to strengthen the annual NAAQS for fine particulate matter despite the board’s finding that harmful health effects occur at the level of the current standard and the agency’s own analysis that thousands of lives are likely to be saved if the annual standard is made more stringent. The Administrator’s decision was arbitrary and capricious, and should be vacated.

JURISDICTIONAL STATEMENT

The Court has exclusive jurisdiction under Section 307(b) of the Clean Air Act (the “Act”) to review any challenge to the Administrator’s promulgation of a NAAQS. 42 U.S.C. § 7607(b). New York, California, Connecticut, Delaware, Illinois, Maine, New Hampshire, New Jersey, New Mexico, Oregon, Rhode Island, Vermont, the Pennsylvania Department of Environmental Protection, the District of Columbia, and the South Coast Air Quality Management District (“State Petitioners”)¹ challenge EPA’s nationally applicable regulations published at 71 Fed. Reg. 61,145-61,233 (Oct. 17, 2006) (the “Rule”), in which EPA decided not to strengthen the annual NAAQS for fine particulate matter (“PM_{2.5}”). As set forth in the

¹ Arizona, Maryland, and Massachusetts are amici supporting State Petitioners. From this point forward, the term “State Petitioners” refers collectively to State Petitioners and Amici.

Certificate as to Parties, supra at i-iii, State Petitioners filed a petition for review of the Rule within the 60-day period provided in 42 U.S.C. § 7607(b).

STATEMENT OF ISSUES

1. Whether the EPA Administrator acted arbitrarily and capriciously when he decided not to strengthen the annual PM_{2.5} NAAQS on grounds that the scientific evidence was uncertain, where the statute requires the Administrator to set the NAAQS at a level that protects public health with an adequate margin of safety, and where EPA's independent science advisers concluded that there is clear and convincing evidence in the record that the current annual standard is inadequate to prevent premature deaths and serious illnesses caused from exposure to PM_{2.5} pollution.

STATUTES AND REGULATIONS

The relevant statutory provisions of the Act are 42 U.S.C. §§ 7407, 7408, 7409, 7410, and 7607 (Sections 107, 108, 109, 110, and 307 of the Act). The Rule has been codified at 40 C.F.R. §§ 50.3, 50.6, 50.13, and Appendix K, Appendix L, Appendix N, and Appendix O. The Rule language, relevant statutory and regulatory provisions, and legislative history excerpts are contained in the separate Addendum.

STATEMENT OF THE CASE

States, environmental organizations, several companies, and industry trade groups filed petitions challenging several aspects of the Rule. State and environmental petitioners are primarily challenging the Administrator's decisions concerning the fine PM standard, including his decision not to strengthen the annual PM_{2.5} NAAQS. Industry petitioners' challenges focus on the NAAQS for coarse particulate matter. By order dated December 27, 2006, the Court

consolidated these petitions and designated American Farm Bureau Federation v. EPA (No. 06-1410) as lead case.

STATEMENT OF FACTS

The NAAQS Process

Every five years EPA must complete a thorough review of the NAAQS and “make such revisions in such criteria and standards and promulgate such new standards as may be appropriate.” 42 U.S.C. § 7409(d)(1). The NAAQS must be based on air quality criteria reflecting “the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health and welfare which may be expected from the presence of such pollutant in the ambient air.” 42 U.S.C. § 7408(a)(2). EPA records the scientific evidence in a “Criteria Document” and develops a “Staff Paper” to bridge the gap between the scientific review and judgments the Administrator must make on the NAAQS.

The statute directs the Administrator to set the primary NAAQS at a level that is “requisite to protect the public health with an adequate margin of safety.” 42 U.S.C. § 7409(b)(1). The Administrator must identify the maximum airborne concentration of a pollutant that the public health can tolerate, decrease the concentration to provide an adequate margin of safety, and set the standard at that level. Whitman v. American Trucking Ass’ns, 531 U.S. 457, 465 (2001). Nowhere are the costs of achieving the standard made part of that calculation. Id. The NAAQS must be set at a level that protects not only average health individuals, but also those who are sensitive to the air pollutant at issue. American Lung Ass’n v. EPA, 134 F.3d 388, 389 (D.C. Cir. 1998).

Once EPA establishes NAAQS for a pollutant, the standard becomes the centerpiece of a

complex statutory approach aimed at reducing the pollutant's atmospheric concentration. American Trucking Ass'ns, Inc. v. Whitman, 283 F.3d 355, 358-59 (D.C. Cir. 2002). EPA and the States must first designate areas that fail to meet the NAAQS. Id. (citing 42 U.S.C. § 7407(d)(1)-(2)). Subsequently, each State must adopt a plan that provides for the implementation, maintenance, and enforcement of the NAAQS through, for example, the regulation of power plant and automobile emissions. Id. at 359 (citing 42 U.S.C. § 7410(a)(1)). States must submit their plans to EPA for approval, and may be required to make revisions if EPA finds the plans inadequate. Id.

The Role of EPA's Science Advisory Committee

As part of the NAAQS review process, Congress provided that an independent scientific review committee would analyze information concerning the effects of air pollutants and “recommend to the Administrator any new national ambient air quality standards and revisions of existing criteria and standards as may be appropriate.” 42 U.S.C. § 7409(d)(2)(B). These scientific experts are known as the Clean Air Scientific Advisory Committee (“CASAC”). By bringing independent scientific expertise to their evaluation of EPA's Criteria Document and Staff Paper, CASAC provides an objective justification for the pollution standards the Agency selects. American Trucking Ass'ns v. Browner, 175 F.3d 1027, 1059 (D.C. Cir. 1999) (Tatel, J., dissenting), reversed sub nom Whitman v. American Trucking Ass'ns, 531 U.S. 457 (2001); see also H.R. Rep. No. 95-924, 95th Cong., 1st Sess. at 183 (1977) (creation of CASAC prompted by the “need for greater research, the importance of the national ambient air quality standards, and . . . the desire for continued independent scientific review of the [EPA's] exercise of judgment”). The EPA Administrator appoints the seven full-time members of CASAC, which under the

statute includes “at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies.” 42 U.S.C. § 7409(d)(2)(A).

When EPA proposes to issue a new NAAQS or revise an existing NAAQS, EPA must “set forth or summarize and provide a reference to any pertinent findings, recommendations, and comments by [CASAC].” 42 U.S.C. § 7607(d)(3). If the proposed rule “differs in any important respect from any of [CASAC’s] recommendations,” EPA must explain the reasons for the difference. Id.

The legislative history makes clear that Congress intended courts ruling upon a challenge of EPA’s decision on the NAAQS to consider CASAC’s findings on the matter. See H.R. Rep. No. 95-924 at 183 (Congress intended that CASAC’s recommendations “will not only aid the Administrator and the Congress, but also the courts in judicial review of any national ambient air quality standard or of the Administrator’s failure or refusal to set or revise such a standard with respect to any pollutant.”). Thus, although the Administrator is not bound by CASAC’s recommendation on the NAAQS level, his rejection of CASAC’s advice should raise a red flag as to whether EPA engaged in reasoned decision making. Significantly, until this Rule, no Administrator had ignored CASAC’s recommendations on the level of the NAAQS. Letter from Dr. Henderson, CASAC to Administrator Johnson (Sept. 29, 2006) at 3 (J.A.3285).

PM_{2.5} Pollution

Particulate matter – commonly known as soot – includes a broad class of chemically and physically diverse substances that exist as discrete particles (liquid droplets or solids) over a wide range of sizes. 71 Fed. Reg. 61,146. Coarse particulate matter (PM₁₀) includes particles with a diameter less than or equal to 10 micrometers, but greater than 2.5 micrometers. Fine particulate

matter (PM_{2.5}) – or fine soot – refers to particulate matter with a diameter of less than or equal to 2.5 micrometers. Id. Sources of PM_{2.5} include motor vehicles, power generation, combustion sources at industrial facilities, and residential fuel burning. Id.

Because fine soot can lodge in the lungs, short-term and long-term exposure to PM_{2.5} pollution can cause numerous harmful health effects, including premature death, chronic respiratory illness, decreased lung function, cardiovascular disease, and asthma. See 71 Fed. Reg. 2,625, 2,627-33 (Jan. 17, 2006) (summarizing harmful effects). Several subgroups in the population, including children, senior citizens, and people with existing lung and heart diseases (including diabetes), are more susceptible to harm from PM_{2.5} than the rest of the population. Id. at 2,636. These subgroups of sensitive populations total more than 100 million people (more than a third of the U.S. population): 22 million Americans have been diagnosed with heart disease, 39 million with hypertension, almost 12 million with diabetes, 9 million with chronic bronchitis, 3 million with emphysema, while almost 19 million adults and 9 million children have chronic asthma. Criteria Document, Table 9.4 (J.A.975). In addition, about 38 percent of the U.S. population are either under 18 years of age or are 65 or older. Id. at 9-89 (J.A.974).

In 1997, EPA established revised NAAQS for PM_{2.5} that included both a 24-hour standard of 65 micrograms per cubic meter (“ $\mu\text{g}/\text{m}^3$ ”) and an annual standard of 15 $\mu\text{g}/\text{m}^3$. 62 Fed. Reg. 38,652 (July 18, 1997). The Administrator selected the annual standard as the controlling standard to protect against the range of effects associated with both short- and long-term exposures. The purpose of the 24-hour standard was to provide supplemental protection against spikes in PM_{2.5} pollution that might cause short-term harm to the public health. Id. at 38,675-76. After a challenge by industry groups and others, the Supreme Court affirmed the

NAAQS in 2001. Whitman, 531 U.S. 457.

The Rulemaking Process and the Proposed Rule

Shortly after completing the last PM NAAQS rulemaking in 1997, EPA staff began the process of preparing for the next review. As part of this process, EPA staff reviewed extensive new evidence that had accrued on effects from exposure to PM_{2.5}. EPA staff concluded that with respect to harm caused by PM_{2.5} exposure, the science was even more compelling than in the previous review:

[T]here is now “strong epidemiological evidence” for PM_{2.5} linking short-term exposures with cardiovascular and respiratory mortality and respiratory morbidity, and long-term exposures with cardiovascular and lung cancer mortality and respiratory morbidity (CD, p. 9-46). This latter conclusion reflects greater strength in the epidemiological evidence specifically linking PM_{2.5} and various health endpoints than was observed in the last review.

EPA Staff Paper at 5-4 (quoting in part EPA Criteria Document) (J.A.1860). EPA staff concluded that the scientific evidence justified lowering the annual PM_{2.5} standard to as low as 12 µg/m³. See Staff Paper at 5-23 (J.A.1880) (“A standard of 12 µg/m³ would be consistent with a judgment that a more precautionary standard was warranted, potentially reflecting consideration of the seriousness of the mortality effects, for which there is strong evidence of likely causal relationships, and of the limited but suggestive evidence of possible links to effects on fetal and infant development and mortality.”).

CASAC also participated actively in the scientific review leading up the proposed rule; CASAC recommended that the Administrator strengthen both the 24-hour and the annual standards for fine particulate pollution. Regarding the latter, CASAC advised that the annual standard be revised to a level in the 13-14 µg/m³ range. 71 Fed. Reg. at 2,652. CASAC

explained that because some metropolitan areas with relatively high annual PM_{2.5} concentrations experience little variation in daily concentrations, lowering the level of the 24-hour standard without lowering the level of the annual standard would result in minimal health benefits in those areas. Id. at 2,651. This is because “much of the risk related to daily exposures results from the large number of days during which the 24-hour average concentrations are in the low- to mid-range.” Staff Paper at 5-31 (J.A.1888). As for the range of 13-14 µg/m³, CASAC recommended 13 µg/m³ as the lower end of the range because the studies revealed that uncertainties regarding health effects from exposure to PM_{2.5} “increase rapidly below the level 13 µg/m³.” See 71 Fed. Reg. 61,174.

In the proposed rule, the Administrator proposed to lower the level of the 24-hour standard from 65 µg/m³ to 35 µg/m³. 71 Fed. Reg. 2,625, 2,649-50 (Jan. 17, 2006). Despite EPA staff’s findings and the recommendations of the CASAC, however, the Administrator proposed to leave the annual standard at 15 µg/m³. Id. at 2,651-53. The Administrator stated that the studies considered as part of this NAAQS review “provide a basis for considering a standard no higher than 15 µg/m³” but that “in the Administrator’s view these studies do not provide a clear basis for selecting a level lower than the current standard of 15 µg/m³.” Id. at 2,651. In his view, keeping the standard at the current level “would be requisite to protect public health with an adequate margin of safety from serious health effects.” Id. Because EPA staff had concluded that the scientific evidence could justify an annual standard as low as 12 µg/m³, the Administrator solicited public comments on a standard in the 12-15 µg/m³ range.

The Administrator provided the following reasons for departing from CASAC’s advice to strengthen the annual standard: (1) whether to revise the annual standard requires a “policy

judgment” by the Administrator on what level is required to protect the public health with an adequate margin of safety, and (2) “evidence from the long-term studies, in conjunction with judgments concerning whether and over what range of concentrations reported associations are likely causal . . . reasonably supports retaining the current level of the annual standard.” 71 Fed. Reg. 2,652. The Administrator cited two studies of the effects of PM_{2.5} on premature mortality – the American Cancer Society study (the “ACS Study”) and the Six Cities Study – and the subsequent reanalyses of these studies done in 2000. Although agreeing “conceptually” with CASAC that revising the 24-hour standard alone would not result in reductions in PM_{2.5} pollution in areas with relatively high annual PM_{2.5} concentrations and that experience little variation in daily concentrations, the Administrator stated that he would rely on the long-term studies and his judgments regarding causation in making his decision. Id.

During the comment period, several of State Petitioners, as well as many prominent medical and public health organizations, urged EPA to make the annual and the 24-hour PM_{2.5} NAAQS more protective. California advocated for a standard of 12 µg/m³, noting that the state had recently adopted a 12 µg/m³ standard under state law after a lengthy and peer-reviewed rulemaking process. Letter from Gov. Schwarzenegger to Administrator Johnson (Apr. 17, 2006) (J.A.3812).

CASAC asked the Administrator to reconsider his proposed decision on the annual PM_{2.5} standard and urged him to set the standard within the range CASAC had recommended, *i.e.*, 13-14 µg/m³. Letter from Dr. Henderson, CASAC to Administrator Johnson (March 21, 2006) at 3-4 (J.A.3271-72). CASAC cited several reasons in support: First, EPA’s own risk assessment showed that lowering the level of the annual standard would likely reduce health risks,

potentially saving thousands of lives. 71 Fed. Reg. 61,174. Second, lowering the level of the 24-hour standard without lowering the level of the annual standard would be insufficient to provide protection against adverse effects in areas with higher annual average concentrations. Id. Third, the scientific evidence established that short-term adverse effects of PM_{2.5} persist in cities with annual PM_{2.5} concentrations below the current standard, down to approximately 13 µg/m³. Id. Fourth, the evidence demonstrated that harmful effects occur from exposure to long-term PM_{2.5} concentrations at or below the level of the current standard. Id.

The Final Rule

In the Rule, the Administrator again refused to strengthen the annual PM_{2.5} standard of 15 µg/m³. 71 Fed. Reg. 61,144 (Oct. 17, 2006). His rejection of CASAC's finding on the level of the standard necessary to protect public health with an adequate margin of safety was unprecedented in final NAAQS decisions dating back to the creation of CASAC in the late 1970s. CASAC 9/29/06 letter at 3 (J.A.3285).

The Administrator rejected CASAC's conclusion that the results of EPA's risk assessment justified strengthening the standard, stating that there were too many uncertainties in the risk assessment to use it as a basis to lower the annual standard. Id. at 61,174. Next, he rejected CASAC's reliance on the results of short-term exposure studies to demonstrate harmful health effects at levels at and below 15 µg/m³ because in his view, it was "more appropriate to consider the short-term exposure studies as a basis for the level of the 24-hour standard and to consider the long-term exposure studies as a basis for setting the level of the annual standard." Id. at 61,174. The Administrator did not contest CASAC's scientific findings about the short-term exposure studies and further acknowledged that similar short-term studies formed the basis

for setting the level of the annual standard at $15 \mu\text{g}/\text{m}^3$ in the last NAAQS review. Id. However, the Administrator concluded that evidence from short-term exposure studies was not an “appropriate basis” for selecting a more protective annual standard. Id.

Finally, in response to CASAC’s conclusion that harmful effects occur as a result of exposure to long-term $\text{PM}_{2.5}$ concentrations at or below the level of the current standard, the Administrator took the position that CASAC failed to identify the evidence in the long-term exposure studies on which CASAC relied. Id. at 61,175. Therefore, the Administrator could not “determine in what ways his judgments about the evidence may differ from CASAC’s views.” Id. The Administrator concluded that “remaining uncertainties weigh against reaching the conclusion that the level of the annual $\text{PM}_{2.5}$ standard should be lowered on the basis of these studies.” Id. at 61,175. He gave the greatest weight “in particular to the results of the extended ACS study,” see id. at 61,172, citing to the fact that “even though the long-term average $\text{PM}_{2.5}$ concentration across the cities in the extended ACS study ($17.7 \mu\text{g}/\text{m}^3$) is lower than in the original study ($21 \mu\text{g}/\text{m}^3$), the level of the current standard is still appreciably below the long term average of the extended ACS study and that of the Six Cities study ($18 \mu\text{g}/\text{m}^3$).” Id. at 61,175. The Administrator expressed his belief “that it is reasonable to base the decision on the standard level on long-term average $\text{PM}_{2.5}$ concentrations in the key long-term exposure studies, because the evidence of an association in any such study is strongest at and around the long-term average where the data in the study are most concentrated.” Id.

Shortly before the Rule was published, CASAC again wrote the Administrator to express concerns about, *inter alia*, his decision not to strengthen the annual $\text{PM}_{2.5}$ standard despite clear and convincing scientific evidence that the current standard is insufficient to protect public health

with an adequate margin of safety:

The CASAC recommended changes in the annual fine-particle standard because *there is clear and convincing scientific evidence that significant adverse human-health effects occur in response to short-term and chronic particulate matter exposures at and below 15 $\mu\text{g}/\text{m}^3$, the level of the current annual $\text{PM}_{2.5}$ standard.* The CASAC affirmed this recommended reduction in the annual fine-particle standard in our letter dated March 21, 2006 concerning the proposed rule for the PM NAAQS, in which 20 of the 22 members of the CASAC's Particulate Matter Review Panel – including all seven members of the chartered (statutory) Committee – were in complete agreement. While there is uncertainty associated with the risk assessment for the $\text{PM}_{2.5}$ standard, this very uncertainty suggests a need for a prudent approach to providing an adequate margin of safety. *It is CASAC's consensus scientific opinion that the decision to retain without change the annual $\text{PM}_{2.5}$ standard does not provide an "adequate margin of safety . . . requisite to protect public health" (as required by the Clean Air Act), leaving parts of the population of this country at significant risk of adverse health effects from exposure to fine PM.*

CASAC 9/29/06 letter at 1-2 (J.A.3283-84) (emphasis original). Despite CASAC's concerns, the Administrator issued the Rule without any change to the annual standard of 15 $\mu\text{g}/\text{m}^3$. 71 Fed. Reg. 61,124 (40 C.F.R. § 50.13(a)).

The difference of 1-2 micrograms of $\text{PM}_{2.5}$ pollution between the annual standard in the Rule and the annual standard recommended by CASAC may seem small. However, the resulting harmful effects are significant. For example, EPA's regulatory impact analysis estimated that up to 11,000 premature deaths across the country could be avoided if the Administrator revised the annual standard to 14 $\mu\text{g}/\text{m}^3$. See Regulatory Impact Analysis at 5-85 (J.A.4483). Similarly, the risk assessment prepared by EPA staff showed that lowering the annual standard to 13 $\mu\text{g}/\text{m}^3$ (combined with the 35 $\mu\text{g}/\text{m}^3$ 24-hour standard) would likely result in approximately 168 fewer deaths per year from $\text{PM}_{2.5}$ pollution in the city of Detroit alone. See Staff Paper at 4-63-64 (J.A.1839-40). Because more than 100 million Americans are especially vulnerable to harm

caused by exposure to PM_{2.5} pollution, even small changes in PM_{2.5} concentration can result in large public health impacts. See Criteria Document at 9-93 (J.A.978).

STANDARD OF REVIEW

Under Section 307(d)(9) of the Act, an EPA action may be reversed if it is:

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; or (D) without observance of procedure required by law, if (i) such failure to observe such procedure is arbitrary and capricious, (ii) the requirement of . . . [a timely objection] has been met, and (iii) the errors were so serious and related to the 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.

42 U.S.C. § 7607(d)(9). The Court's role is to determine whether "the agency has exercised a reasoned discretion, with reasons that do not deviate from or ignore the ascertainable legislative intent." Lead Industries Ass'n v. EPA, 647 F.2d 1130, 1145 (D.C. Cir. 1980) (internal quotations and citation omitted). In evaluating the Administrator's decision in setting or revising the NAAQS, the Court has an "obligation to 'undertake a substantial inquiry into the facts' underlying challenged agency actions." ATA v. Whitman, 283 F.3d at 364 (quoting Lead Industries, 647 F.2d at 1146) (internal quotations and additional citation omitted). The Administrator must have "take[n] into account all the relevant studies revealed in the record" and "make an informed judgment based on available evidence." Natural Resources Defense Council v. EPA, 902 F.2d 962, 971 (D.C. Cir. 1990) (citation omitted).

SUMMARY OF ARGUMENT

The statute mandates that the Administrator set the NAAQS to protect public health with an adequate margin of safety. In refusing to strengthen the annual PM_{2.5} standard, the

Administrator erroneously disregarded relevant and important scientific evidence that his science advisors at CASAC and his own staff found supported lowering the annual PM_{2.5} standard. By rejecting this evidence, the Administrator violated the congressional mandate that he set the standard at a level that protects the health of the general public and sensitive groups with an adequate margin of safety.

STANDING

State Petitioners' standing to sue is self-evident.² The Administrator's decision not to strengthen the annual PM_{2.5} standard of 15 µg/m³ will likely result in harm to the health of many citizens in our States. See, e.g., Letter from Northeast States for Coordinated Air Use Management ("NESCAUM") to Administrator Johnson (April 11, 2006), Attachment A at 2-6 (J.A.4500-04) (discussing the health impacts of failing to strengthen the annual standard on public health in eight Northeast states). State Petitioners will have to bear increased health care costs to treat illnesses caused by exposure to PM_{2.5} pollution at this level. A decision from the Court vacating the Administrator's decision on the annual standard would likely compel EPA to strengthen the standard, benefitting public health in our States, and in turn lessening the financial burden on State Petitioners. This injury is sufficient to establish standing. See, e.g., Massachusetts v. EPA, 127 S.Ct. 1438, 1452-58 (2007) (States had standing under Section 307(b) of the Act to challenge EPA denial of rulemaking petition to regulate greenhouse gases from automobiles based on threatened injury to public health and property).

² Although State Petitioners believe that their standing is apparent based on the record and further evidence need not be introduced, State Petitioners submit with this brief the attached Declaration of Robert Chinery, PE in the event that the Court wishes to review additional evidence of standing outside the record.

ARGUMENT

THE ADMINISTRATOR'S DECISION THAT THE CURRENT ANNUAL PM_{2.5} STANDARD PROTECTS PUBLIC HEALTH WITH AN ADEQUATE MARGIN OF SAFETY WAS ARBITRARY AND CAPRICIOUS

The Administrator must set the primary NAAQS at a level necessary to protect the public health with “an adequate margin of safety.” 42 U.S.C. § 7409(b)(1). As EPA itself acknowledged in this rulemaking, this statutory language “was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of the standard setting” and “to provide a reasonable degree of protection against hazards that research has not yet identified.” 71 Fed. Reg. 2,622. The Administrator must “err on the side of caution in making the necessary decisions” in setting the standard to reflect an emphasis on the “predominant value of protection of public health.” Lead Industries Ass’n, 647 F.2d at 1152, 1154-55 (citation omitted); see ATA v. Browner, 175 F.3d at 1059 (Tatel, J., dissenting) (the adequate margin of safety requirement mandates that EPA “ensure a high degree of protection”); Natural Resources Defense Council v. EPA, 824 F.2d 1146, 1152 (D.C. Cir. 1987) (describing how a “margin of safety” is used in engineering “as a safety factor . . . meant to compensate for uncertainties and variabilities”) (citation and internal quotations omitted). The seriousness of the health effects and size of the population at risk are important considerations in the degree of caution the Administrator should apply in interpreting the results of scientific evidence to determine what margin of safety is adequate. See Lead Industries, 647 F.2d at 1161-62. In rejecting evidence relied upon by CASAC and his own staff that demonstrated the inadequacy of the current annual standard, the Administrator violated the statutory mandate that he set the annual standard at a level that protects public health with an adequate margin of safety. By

ignoring well-founded evidence that harmful effects, including premature death, occur as a result of exposure to PM_{2.5} pollution *at and below* the level of the current annual standard, the Administrator's decision to retain that standard translates into no margin of safety at all, an action plainly prohibited by the statute.

A. The Administrator Erred by Rejecting the Findings of CASAC that the Epidemiological Evidence Requires Strengthening the Annual Standard to Protect Public Health with an Adequate Margin of Safety.

The Administrator erred in concluding that the current annual standard of 15 µg/m³ is adequate to protect public health with an adequate margin of safety from exposure to PM_{2.5} pollution. First, the Administrator erroneously disregarded epidemiological studies that both CASAC and EPA staff concluded were relevant. Second, the Administrator overlooked the fact that the principal study on which he relied underestimated the effects of PM_{2.5} pollution on the general population. Finally, even the studies that the Administrator found reliable demonstrated that the current annual standard is inadequate.

1. The Administrator erroneously disregarded studies that CASAC and EPA staff found relevant and important to determining the appropriate annual PM_{2.5} standard. Congress expressly created CASAC to cull the relevant scientific studies and make recommendations as to the appropriate NAAQS. 42 U.S.C. § 7409(d)(2). CASAC concluded that "clear and convincing scientific evidence" shows that harmful effects, including premature death, are caused by short-term and long-term exposures to PM_{2.5}, including at concentrations at and below 15 µg/m³, the level of the current standard. CASAC 9/29/06 letter at 1 (J.A.3283). Regarding short-term exposure, CASAC cited three studies: (1) Mar, et al. (1999, 2003), which examined the effects of PM_{2.5} pollution on premature mortality in Phoenix, Arizona; (2) Fairley (1999, 2003), which

evaluated the effects of PM_{2.5} pollution on premature mortality in Santa Clara County, California; and (3) Burnett, et al. (2000, 2003), which examined the effects of PM_{2.5} pollution on premature mortality in eight Canadian cities. Staff Paper at 5-7 (J.A.1863). The authors of the Phoenix and Santa Clara studies found statistically significant associations for premature mortality at annual average PM_{2.5} concentrations of approximately 13 µg/m³. Staff Paper at 5-32 (J.A.1889). Similarly, in the Canadian multi-city study, Burnett, et al. found significant associations with total and cardiovascular mortality at a mean PM_{2.5} concentration of 13.3 µg/m³. Id.

Although the Administrator did not take issue with CASAC's findings that these exposure studies demonstrated harmful effects at concentrations of PM_{2.5} at or below the standard of 15 µg/m³, he rejected CASAC's advice that these studies be used as part of the determination of the level of the annual PM_{2.5} NAAQS needed to provide an adequate margin of safety. See 71 Fed. Reg. 61,174. He concluded that it was "more appropriate" to rely instead only on long-term exposure studies as a basis for determining the appropriate level of the annual PM_{2.5} standard. Id.

The Administrator's decision to exclude the short-term exposure studies conflicts with the general principle that in determining the NAAQS, the Administrator must take into account *all* of the relevant studies in the record. See ATA v. Browner, 175 F.3d at 1052-53 (EPA's decision to disregard several studies in setting ozone NAAQS was unreasonable where Agency imposed a higher information threshold for those studies), reversed on other grounds, 531 U.S. 457. Regardless of whether long-term exposure studies are "more appropriate" than short-term exposure studies to determine the level of the annual NAAQS, that conclusion does not provide a reasoned basis for wholly disregarding relevant short-term studies in making the adequate margin of safety determination. CASAC found them to be relevant to determining the annual standard

because these three studies documented harmful effects at average PM_{2.5} concentrations at or below 15 µg/m³. EPA staff agreed with CASAC that these short-term exposure studies were relevant in determining the appropriate level of the annual standard. See Staff Paper at 5-32 (J.A.1889) (concluding that these short-term exposure studies provide a basis for considering an annual PM_{2.5} standard within the range of 12-13 µg/m³ and that a standard of 13 µg/m³ would be consistent with a judgment that “appreciable weight should be accorded these studies as a basis for an annual standard that would protect against PM_{2.5}-related mortality associated with short-term exposure.”). Indeed, the Administrator conceded that the annual standard was established in 1997 at 15 µg/m³ *based on short-term exposure studies*. 71 Fed. Reg. 61,174; see 62 Fed. Reg. 38,676 (approach taken by Administrator in selecting the level of the annual PM_{2.5} standard “consisted of determining a provisional level based on the short-term exposure studies, and then determining whether the long-term exposure studies are consistent with that level”).

Moreover, the serious nature of harm caused by exposure to PM_{2.5} pollution (premature death, chronic respiratory illness) and the large size of the population susceptible to harm from exposure to PM_{2.5} pollution (more than 100 million people) made it especially important here that the Administrator “err on the side of caution” in “taking into account the available evidence.” ATA v. Whitman, 283 F.3d at 378; see Lead Industries at 1161-62 (the more serious the health effects and larger the size of the sensitive population, the more conservative the Administrator should be in interpreting the evidence). As EPA has acknowledged, combining fairly small risks and small changes in PM_{2.5} concentration with large groups of the U.S. population results in widespread public health impacts. Criteria Document at 9-93 (J.A.978); see Brief of Petitioner EPA in Browner v. American Trucking Ass’ns (U.S. Sup. Ct. No. 99-1257), 1999 U.S. Briefs

1257, *10 (“The Administrator concluded, based on the nature of the health effects and the huge size of the affected populations . . . that revision to the [PM] standards is not only appropriate, but necessary.”) (citations omitted). The Administrator’s decision to exclude these studies reflects his total disregard of these principles. Had he considered them, he would have been compelled to set the annual standard below 15 $\mu\text{g}/\text{m}^3$ in order to comply with the statutory mandate to protect public health with an adequate margin of safety. 42 U.S.C. § 7409(b)(1); see American Lung Ass’n, 134 F.3d at 393 (expressing doubt “that the Administrator may decline to establish a margin of safety in the face of documented adverse health effects”).

2. The unreasonableness of the Administrator’s decision to disregard these studies is highlighted by the fact that the main long-term exposure study on which he relied had an important limitation. That study – the ACS Study – likely underestimated the effects of $\text{PM}_{2.5}$ pollution on the general population. EPA staff observed that the evidence demonstrated that “estimated effects of fine particles did vary with educational level: the association between an increase in fine particles and mortality tended to be higher for individuals without a high school education than for those with more education.” Criteria Document at 8-92-93 (J.A.636-37). In the ACS Study, the subjects were by-and-large well-educated adult males. EPA staff warned that “because this [study] has a much higher percentage of well-educated persons than the general public . . . the overall PM effect estimates are likely underestimated by this study cohort than are likely to be found for the general public.” Criteria Document at 8-104 (J.A.648).³ In contrast,

³ EPA’s provisional findings on new studies that were not formally included as part of this NAAQS review further bolsters this conclusion. See Provisional Assessment of Recent Studies on Health Effects of Particulate Matter Exposure (July 2006) at E-1 (follow-up studies to the ACS Study and Six Cities Study “suggest that previous studies may have underestimated the magnitude of mortality risks” in long-term exposure to $\text{PM}_{2.5}$) (J.A.2512).

the three short-term exposure studies that CASAC and EPA staff found relevant reflected the effects of fine particulate matter on a wider range of the general population: well-educated and not.

3. As CASAC and EPA staff concluded, there was ample evidence in the epidemiological studies on which the Administrator did rely to demonstrate that the current annual standard inadequately protects public health from PM_{2.5} pollution. The Administrator focused on the fact that the two long-term exposure studies of the effect of PM_{2.5} on premature death – the ACS Study and Six Cities Study – were conducted in areas having mean concentrations of PM_{2.5} that were above the 15 µg/m³ standard (17.7 µg/m³ in the ACS Study, and 18 µg/m³ in the Six Cities Study). See 71 Fed. Reg. 61,175. Notwithstanding this fact, EPA staff concluded that in light of “the seriousness of the mortality effects, for which there is strong evidence of likely causal relationships, and of the limited but suggestive evidence of possible links to effects on fetal and infant development and mortality,” these two studies (among others) would justify an annual standard of 12 µg/m³. See Staff Paper at 5-23 (J.A.1880). Specifically, EPA staff noted that the most recent data from the extended ACS Study showed adverse effects where the mean PM_{2.5} concentration was 14 µg/m³, below the level of the current standard. Staff Paper at 5-22 (J.A.1879). The authors of the ACS study themselves found that, for the 1999-2000 period when the mean concentration was below the current annual standard, there were statistically significant associations between long-term PM_{2.5} exposure and all-cause, cardipulmonary, and lung cancer mortality. Id.⁴

⁴ In addition, although the Administrator focused only on the mean concentration, the mean plus or minus one standard deviation is more important in terms of analyzing exposure effects. See Staff Paper at 5-22 (J.A.1879) (such an approach may reasonably be used to (cont.)

4. Finally, the Administrator's stated reasons for disregarding CASAC's findings and recommendations are invalid. In defending his decision rejecting CASAC's advice to strengthen the annual standard, the Administrator asserted that choosing the level of the NAAQS necessary to protect public health with an adequate margin of safety is a "policy judgment." 71 Fed. Reg. 61,173. This Court has acknowledged such a principle, but only when the Administrator decides on a level within a range that is supported by the scientific evidence. See ATA v. Whitman, 283 F.3d at 363-64 (If "there is uncertainty about the health effects of concentrations of a particular pollutant within a particular range, EPA may use its discretion to make the 'policy judgment' to set the standards at one point within the relevant range rather than another.") (citation omitted). In this case, the Administrator set the standard at a level that was above the range that EPA's scientific experts recommended, *i.e.*, 13-14 $\mu\text{g}/\text{m}^3$. See 71 Fed. Reg. 61,173. Moreover, given that CASAC has concluded that there is "clear and convincing evidence" that maintaining the annual standard at 15 $\mu\text{g}/\text{m}^3$ will not protect public health with an adequate margin of safety, CASAC 9/29/06 letter at 1 (J.A.3282), this case does not present a situation in which the court is being asked to "interfere with reasonable interpretations of equivocal evidence." Contrast e.g., NRDC v. EPA, 902 F.2d at 968-69 (affirming Administrator's decision on PM NAAQS "in light of the divergent results in the studies and the agency's mandate to provide an adequate margin of safety").

(cont.) characterize "the range over which the evidence of association is the strongest"). In many of the long-term exposure studies, including Six Cities and ACS studies, the mean minus one standard deviation is approximately 15 $\mu\text{g}/\text{m}^3$ or below.

B. The Administrator Erred by Disregarding the Risk Assessment Analysis, which CASAC and EPA Staff Determined Should be Considered in Determining the Standard Necessary to Protect Public Health with an Adequate Margin of Safety.

Both CASAC and EPA staff concluded that the Agency's risk assessment analysis conducted in this rulemaking was of sufficient quality to deserve consideration in determining the level of the annual standard necessary to provide an adequate margin of safety. Based on data from the ACS Study and the Six Cities Study, the risk assessment examined mortality associated with PM_{2.5} exposure in nine cities using different levels for the annual and 24-hour PM_{2.5} NAAQS. See Staff Paper at 4-25 (J.A.1801). EPA staff characterized it as "a more comprehensive risk assessment for PM_{2.5}" than in the last PM NAAQS review because of the "more extensive and stronger body of evidence now available on health effects related to both short- and long-term exposure" and the availability of more extensive air quality data. Staff Paper at 5-2 (J.A.1858). Also, while the previous risk assessment examined the anticipated effects of PM_{2.5} exposure in two cities (Los Angeles and Philadelphia), the new assessment extended the analysis to nine cities (Boston, Detroit, Los Angeles, Philadelphia, Phoenix, Pittsburgh, San Jose, Seattle, and St. Louis). EPA, "Particulate Matter Health Risk Assessment for Selected Urban Areas (Dec. 2005)," at 5 (J.A.2151).

The results of the risk assessment demonstrated that leaving the annual standard of 15 µg/m³ in place (combined with the new 24-hour standard of 35 µg/m³) would result in approximately 3,700 premature deaths from PM_{2.5} exposure in just the nine cities. Risk Assessment at 117 and E-17 - E-31 (J.A.2263, 2406-20); Comments of American Lung Ass'n, et al. ("ALA") (April 17, 2006) at 40, Figure 4 (J.A.3576). It also showed that lowering the 24-hour standard alone would not reduce risk of long-term mortality at all in two cities (Detroit and

Phoenix) and only marginally reduce mortality risk in a third (St. Louis). ALA Comments at 23, Figure 1 (J.A.3559). On the other hand, lowering the annual standard to $13 \mu\text{g}/\text{m}^3$, as recommended by CASAC, would avert approximately 500 fewer deaths annually from $\text{PM}_{2.5}$ pollution in Detroit, Pittsburgh, and St. Louis combined. See Risk Assessment at 117-18, E-71-72, and E-77-78 (J.A.2263-64, 2461-62, 2467-68). EPA's regulatory impact analysis, which used a similar methodology as the risk assessment, estimated that across the country, up to *11,000 premature deaths* could be avoided if EPA lowered the level of the annual standard to $14 \mu\text{g}/\text{m}^3$. See Regulatory Impact Analysis at 5-85 (J.A.4483).

The Administrator rejected his staff's risk assessment analysis due to what he considered "important limitations as a basis for setting a standard level" stemming from "important uncertainties" in the assessment process. See 71 Fed. Reg. 61,174. But while CASAC and EPA staff acknowledged these uncertainties, both concluded that the risk assessment should be considered as part of the NAAQS determination. CASAC 3/21/06 letter at 3 (J.A.3271) ("While the risk assessment is subject to uncertainties, most of the PM Panel found EPA's risk assessment to be of sufficient quality to inform its recommendations."); Staff Paper at 5-46 (J.A.1903) (recommending the Administrator "tak[e] into account both evidence-based and risk-based considerations"). EPA staff took steps to minimize the uncertainties inherent in conducting the risk assessment, such as including "only health endpoints for which the [Criteria Document] evaluation or staff assessment find that the overall weight of the evidence supports the conclusion that $\text{PM}_{2.5}$ is likely causally related." Staff Paper at 4-34 (J.A.1810). EPA staff also took CASAC's advice to conduct extensive sensitivity analyses and to revise the threshold assumptions to make the risk assessment more reliable. See CASAC 3/21/06 letter at 3

(J.A.3271). Finally, EPA staff used data from the same two studies relied upon by the Administrator in his decision on the annual standard. See Staff Paper at 4-25 (J.A.1801). Thus, the Administrator's position that the risk assessment was not sufficiently reliable to be considered in setting the annual PM_{2.5} standard was refuted by CASAC and his own staff.

The Administrator's approach here also stands in stark contrast to that taken in the last PM NAAQS review, where the results from the risk assessment were considered in setting the annual and 24-hour PM_{2.5} NAAQS. See 62 Fed. Reg. 38,656. While acknowledging the significant uncertainty associated with that risk analysis, the Administrator then concluded that the quantitative risk estimates "represent reasonable estimates as to the possible extent of risk for these effects given the available information." Id. The fact that the risk assessment analysis for the instant rulemaking was even "more comprehensive" due to stronger evidence and more extensive air quality data, see Staff Paper at 5-2 (J.A.1858), demonstrates that the Administrator acted unreasonably when he disregarded the risk assessment analysis in this case.

If the Administrator had considered the results of the risk assessment in determining the standard, he would have concluded that lowering the level of the annual standard (even by just 1-2 $\mu\text{g}/\text{m}^3$) would measurably decrease the risk of harm from PM_{2.5} exposure in one-third of the cities analyzed by EPA staff. His failure to do so violated the statutory command that he set the standard to protect public health with an adequate margin of safety. 42 U.S.C. § 7409(b)(1); see Cass R. Sunstein, Is the Clean Air Act Unconstitutional? 98 Mich. Law Rev. 303, 360 (1999) (If "10,000 people or 1,000 are likely to die each year as a result of exposure to a certain level of [a pollutant], EPA must act; it is not authorized to allow that level of risk.").

C. The Administrator Erred in Refusing to Consider an Important Study on Lung Damage in Children and also Failed to Explain How the Current Annual Standard Protects Sensitive Populations with an Adequate Margin of Safety.

In setting the appropriate level of NAAQS, the Administrator must ensure “that especially sensitive persons such as asthmatics and emphysematics are included within the group that must be protected.” Lead Industries, 647 F.2d at 1152. Congress intended that “[i]f a pollutant adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard.” American Lung Ass’n, 134 F.3d at 389 (citation omitted); see S. Rep. No. 91-1196, 91st Cong., 2d Sess. 410 (1970) (“Ambient air quality is sufficient to protect the health of such persons whenever there is absence of adverse effect on the health of a statistically related sample of persons in sensitive groups from exposure to the ambient air.”).

1. The Administrator erroneously rejected an important new study demonstrating harm to children exposed to PM_{2.5} pollution.

The Administrator improperly refused to consider an important study showing that PM_{2.5} exposure – including at levels below the current annual standard – damages children’s lungs. This study, by Gauderman, et al. (2000, 2002) of fourth grade children in Southern California, found likely irreversible lung damage in children that had long-term exposure to PM_{2.5} pollution, including at concentrations below 15 µg/m³. 71 Fed. Reg. 61,172. As a general matter, children are more susceptible to air pollutants because their lungs are still developing and because their airways are narrower than those of adults. American Academy of Pediatrics 10/5/05 letter at 2 (J.A.4494). Other factors may render children more vulnerable to PM_{2.5} exposures, including more time spent outdoors, greater activity levels and ventilation, and higher doses per body weight and lung surface area. Criteria Document at 9-84 (J.A.969). The Southern California

study reported a decline in lung function growth in children with long-term exposure to PM_{2.5} concentrations ranging from 7 to 32 µg/m³, with an overall mean of 15 µg/m³. Staff Paper at 5-23 (J.A.1880). In the study, exposure to PM_{2.5} was significantly associated with clinically-reduced lung function at age eighteen, which is likely to be irreversible and is a strong risk factor for future health consequences as an adult. See American Academy of Pediatrics 10/5/05 letter at 1-2 (J.A.4493-94). The study's authors found no threshold level of PM_{2.5} associated with the lung damage. Staff Paper at 5-8 (J.A.1864). While acknowledging this study's "important new findings," see 71 Fed. Reg. 61,172, the Administrator rejected use of the Southern California study as a basis for lowering the annual standard. Id. at 61,176. The Administrator discounted the findings of the study on the grounds that it was "the only study reporting decreased lung function growth, [and was] conducted in just one area of the country." Id. at 61,172. His refusal to factor the findings of the Southern California study into the margin of safety determination for children on the ground that those effects have yet been conclusively proven is flatly inconsistent with the Court's precedent that the Administrator must set the NAAQS at a level that offers adequate protection against harmful effects that are unknown or uncertain as to degree.

For example, in Lead Industries, the Court rejected industry petitioners' argument that the Administrator was required to set the NAAQS only at a level designed to protect against health effects that are clearly known. The Court held that requiring the agency "to wait until it can conclusively demonstrate that a particular effect is adverse to health before it acts is inconsistent with both the Act's precautionary and preventive orientation and the nature of the Administrator's statutory responsibilities." 647 F.2d at 1155; see Ethyl Corp. v. EPA, 541 F.2d 1, 25 (D.C. Cir. 1976) (noting that the Act and common sense "demand regulatory action to

prevent harm, even if the regulator is less than certain that harm is otherwise inevitable.”); cf. Public Citizen v. Federal Motor Carrier Safety Admin., 374 F.3d 1209, 1219 (D.C. Cir. 2004) (merely because the magnitude of an effect is uncertain is not a justification for disregarding the effect entirely).

The Administrator’s attempt to discount the study of the Southern California children on the grounds that it is the only one to document “decreased lung function growth” in children at or around the level of the annual standard is also at odds with his own staff’s views. EPA staff cited the study as a principal justification for an annual standard of 13 $\mu\text{g}/\text{m}^3$. Staff Paper at 5-23 (J.A.1880). Also, EPA staff noted that a prior study from the last NAAQS review likewise suggested harm to children’s lung function at exposures at or below 15 $\mu\text{g}/\text{m}^3$. The staff observed that the findings of the Southern California study were “approximately equal to the long term mean $\text{PM}_{2.1}$ concentration in the earlier 24 City study, showing effects on children’s lung function, in which the long-term mean concentration was 14.5 $\mu\text{g}/\text{m}^3$, ranging from 9 to 17 $\mu\text{g}/\text{m}^3$ across the cities.” See id.

In addition, the Administrator’s argument that the study should be discounted because it was “conducted in just one area of the country,” id. at 61,172, is meritless. There is certainly no basis to believe that the lungs of fourth grade children in Southern California are any different than the lungs of fourth graders in Boston, Des Moines, or Washington, D.C. In fact, EPA relied on other studies in this NAAQS review that were conducted in only one area of the country, see 71 Fed. Reg. 61,180 (citing studies conducted in Tuscon, AZ, Reno, NV, and Anchorage, AK, among others).

The Administrator’s decision to ignore the Southern California study’s findings that

likely *irreversible* lung damage results in children who have long-term exposure to average PM_{2.5} concentrations that are *below* the level of the current annual standard cannot be sustained. Even if the study itself does not justify lowering the annual standard to protect children, his insistence that the findings can be ignored at this time because they have not been conclusively proven is fundamentally at odds with this Court's precedent and Congress' directive that the Administrator "allow an adequate margin of safety to protect against effects which have not yet been uncovered by research and effects whose medical significance is a matter of disagreement." Lead Industries, 647 F.2d at 1154.

2. The Administrator failed to explain how the current annual standard will protect the health of sensitive populations with an adequate margin of safety.

The Administrator also erred by failing to explain how the current annual standard adequately protects the more than 100 million sensitive individuals (including infants, children, the elderly, and individuals with pre-existing illnesses such as heart disease and chronic asthma) from harm caused by exposure to PM_{2.5} pollution. The Administrator relied solely on two mortality studies (the ACS and Six Cities studies) in determining the level of the annual NAAQS needed to protect public health with an adequate margin of safety. These studies focused on the relationship between PM_{2.5} concentration and premature mortality, not on morbidity effects such as chronic respiratory illness. These morbidity effects are of particular concern to those who are more susceptible to harm from PM_{2.5} exposure, and who suffer adverse effects (*e.g.*, asthma attacks) at lower PM_{2.5} concentrations than levels that cause premature death. Yet, nowhere in the preamble to the proposed rule or final rule did the Administrator explain how an annual standard of 15 µg/m³ provides an adequate margin of safety for sensitive groups. This failure to

provide a reasoned explanation or how the current standard protects sensitive groups with an adequate margin of safety requires, at a minimum, remand to the Agency. See American Lung Ass'n, 134 F.3d at 391-92 (remanding to EPA for reasoned explanation on decision not to establish NAAQS limiting short-term bursts of sulfur dioxide because Administrator failed to explain why the thousands of documented cases of adverse effects from these bursts did not amount to a public health problem within the meaning of the Act). As the court held in American Lung Ass'n, where "Congress has delegated to an administrative agency the critical task of assessing the public health and the power to make decisions of national import in which individual lives and welfare hang in the balance, that agency has the heaviest of obligations to explain and expose every step of its reasoning." Id. at 392.

CONCLUSION

For the reasons set forth above, the Court should vacate the Administrator's refusal to revise the annual PM_{2.5} standard to reflect recent scientific evidence that the current standard does not adequately protect public health with an adequate margin of safety.

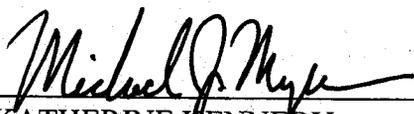
Dated: March 6, 2008

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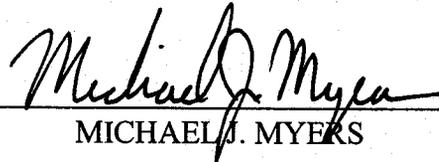
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CERTIFICATE OF COMPLIANCE WITH WORD-VOLUME LIMITATIONS

I hereby certify that the foregoing brief of State Petitioners and Amici complies with Fed. R. App. P. 32(a)(7), as modified by the Court's July 31, 2007 Order (which permitted State Petitioners and Amici to file an opening brief of up to 8,750 words). The word count function of the word processing system used to prepare this brief indicates that it contains 8,732 words (inclusive of footnotes and citations but exclusive of certificate as to parties, rulings and related cases, tables of contents and authorities, glossary, attorney's certificates, and addendum).


MICHAEL J. MYERS

**DECLARATION OF ROBERT CHINERY MS, PE
CONCERNING PETITIONER STATE OF
NEW YORK'S STANDING**

ORAL ARGUMENT NOT YET SCHEDULED

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

AMERICAN FARM BUREAU FEDERATION, et al.,)	
)	
Petitioners,)	
v.)	Docket No. 06-1410 (and
)	consolidated cases)
ENVIRONMENTAL PROTECTION AGENCY,)	
)	
Respondent.)	
)	

**DECLARATION OF ROBERT CHINERY MS, PE
CONCERNING PLAINTIFF STATE OF NEW YORK'S STANDING**

Pursuant to 28 U.S.C. § 1746, Robert Chinery declares as follows:

Overview

1. I am an environmental scientist and engineer employed by the New York State Office of the Attorney General.
2. I submit this declaration in support of the petitions for review filed in these consolidated actions by the States of New York, California, Connecticut, Delaware, Illinois, Maine, New Hampshire, New Jersey, New Mexico, Oregon, Pennsylvania Department of Environmental Protection, Rhode Island, Vermont, the District of Columbia, and the South Coast Air Quality Management District (collectively, "State Petitioners") challenging EPA's decision not to lower the level of the annual national ambient air quality standard ("NAAQS") for PM_{2.5}.

Personal Background

3. I am currently employed as an Environmental Scientist 3 and I have worked in the Attorney General's Environmental Protection Bureau as an environmental scientist and engineer

since 2005. My responsibilities have included, among others, researching and evaluating federal and state laws and regulations that may affect New York State's environment and the health and welfare of New York's citizens. Prior to joining the Attorney General's office in 2005, I worked for 15 years for the New York State Department of Health ("DOH") as a research scientist. My duties at DOH included human health risk assessment and environmental fate and transport modeling and management of environmental health risks. I have authored or contributed to many environmental health risk and management studies. For example, I have contributed to several epidemiological studies that linked concentration of criteria pollutants, including fine particulate matter, to human health effects. I have also contributed to epidemiological studies that link climatic conditions to human health effects.

4. I received a B.S. in 1978 from the New Jersey Institute of Technology in Chemical Engineering and a Masters Degree from Rensselaer Polytechnic Institute in 1992 in Environmental Engineering. I have a professional engineering licence in the state of New York. A copy of my resume is attached hereto as *Exhibit A*.

PM_{2.5} Pollution in New York State

5. Short-term and long-term exposure to PM_{2.5} pollution can cause a variety of harmful health effects, including premature death, chronic respiratory illness, decreased lung function, cardiovascular disease, and asthma. See 71 Fed. Reg. 2,627-33 (summarizing harmful health effects). Certain subgroups in the population, including infants, children, senior citizens, and people with existing lung and heart diseases (including diabetes) are more susceptible to harm from PM_{2.5} than the rest of the population. The Northeast States for Coordinated Air Use Management (NESCAUM) has estimated that within the New England, New Jersey, and New

York area, 38% of the total population are less than 18 or greater than 65 years of age, 4–18% of adults have cardiopulmonary or diabetes health conditions, 12–15% of children have respiratory allergies or lifetime asthma, and 72% of all persons (across child, adult, and elderly age groups) live in densely populated urban areas with elevated PM_{2.5} concentrations, likely creating heightened exposure scenarios.¹

6. PM_{2.5} pollution is a significant public health problem in New York State, especially in the New York City metropolitan area. The DOH just completed a study in New York City to investigate the relationship between emergency room admissions for elevated asthma and the levels of criteria pollutants, including PM_{2.5}.² The study indicated a statistically significant association between PM_{2.5} and asthma emergency room visits in the Bronx. This study has raised concern about asthma attacks in communities, such as the Bronx, with higher asthma burdens.

7. The New York State Department of Environmental Conservation reported PM_{2.5} concentrations in New York City (all 5 Boroughs) in a 2006 monitoring report.³ There were 25 monitors in operation during the 3-year period between 2003-2005 and the annual 3-year average PM_{2.5} concentration was reported for each monitor. This data indicates that levels of PM_{2.5}

¹ Philip R.S. Johnson and John J. Graham. Northeast States for Coordinated Air Use Management (NESCAUM), Boston, Massachusetts, USA. "Fine Particulate Matter National Ambient Air Quality Standards: Public Health Impact on Populations in the Northeastern United States." *Environ. Health Perspect.* 113:1140–1147 (2005).

² New York State Department of Health, Center for Environmental Health. "A Study of Ambient Air Contaminants and Asthma in New York City: Final Report," July 2006, NYSERDA Report 06-02.

³ New York State Department of Environmental Conservation, 2006 Region 2 Air Quality Data. "Inhalable Particulates" (<http://www.dec.ny.gov/chemical/29310.html>).

pollution in New York City in all monitors over the three-year period of 2003-05 averaged 14.6 $\mu\text{g}/\text{m}^3$. The range of the annual 3-year average concentration measured during this time period was 11.7-17.1 $\mu\text{g}/\text{m}^3$, with a median value of 14.8 $\mu\text{g}/\text{m}^3$. Nine of the monitors recorded concentrations of $\text{PM}_{2.5}$ that exceeded 15 $\mu\text{g}/\text{m}^3$ and 16 monitors recorded concentrations of $\text{PM}_{2.5}$ that exceeded 14 $\mu\text{g}/\text{m}^3$.

Adverse Effects from EPA's Decision Not to Strengthen the Annual $\text{PM}_{2.5}$ NAAQS

8. As explained in more detail below, I based my analysis of the adverse effects of EPA's decision on my review of the proposed and final $\text{PM}_{2.5}$ NAAQS rule and on the scientific evidence in the record relevant to the Administrator's decision. I conclude that not lowering the annual $\text{PM}_{2.5}$ NAAQS within the range of 13-14 $\mu\text{g}/\text{m}^3$ is projected to result in New Yorkers suffering more premature deaths. Increased illness to New Yorkers from exposure to $\text{PM}_{2.5}$ pollution is also likely. New York is also projected to incur increased health care costs to treat $\text{PM}_{2.5}$ -related illnesses. These projections are based on risk assessment methods in EPA reports included in the record.

A. Increased Deaths and Illnesses

9. Long-term annual $\text{PM}_{2.5}$ exposure is associated with premature deaths and an increase of harm from chronic respiratory illness, cardiovascular disease, and asthma. EPA's science advisors, the Clean Air Science Advisory Committee ("CASAC") concluded after reviewing the scientific evidence that the annual $\text{PM}_{2.5}$ NAAQS had to be lowered to 13-14 $\mu\text{g}/\text{m}^3$ to protect public health with an adequate margin of safety. The EPA Staff Paper indicated that epidemiological studies show a significant association between mortality and morbidity for

long-term exposures to PM_{2.5}.⁴ These studies indicate increased mortality and morbidity (morbidity such as bronchitis and coughing in children, airway obstruction in adults, decreased lung function in children, and lung function changes in adults) with increasing PM_{2.5} concentrations. An example of a morbidity concern mentioned above is the lung function study cited in the rulemaking record. Gauderman, et al. and Peters, et al. reported a decline in lung function growth in fourth-grade children in Southern California with long-term exposure to PM_{2.5} concentrations ranging from 7 to 32 µg/m³.⁵ The overall mean PM_{2.5} level in the study (over the 12 cities studied) was 15.1 µg/m³. The EPA Staff paper notes that in the Gauderman et al. studies there was no evidence of a threshold between lung function growth and average PM concentration.⁶

⁴ U.S. Environmental Protection Agency. Office of Air Quality Planning and Standards, Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information, OAQPS Staff Paper EPA-452/R-05-005a, December 2005. Appendix 3B: Mortality and Morbidity Effect Estimates and PM Concentrations from U.S. and Canadian Studies for Long-Term Exposures to PM₁₀, PM_{2.5} and PM_{10-2.5}.

⁵ Gauderman, W. J.; McConnell, R.; Gilliland, F.; London, S.; Thomas, D.; Avol, E.; Vora, H.; Berhane, K.; Rappaport, E. B.; Lurmann, F.; Margolis, H. G.; Peters, J. (2000) Association between air pollution and lung function growth in southern California children. *Am. J. Respir. Crit. Care Med.* 162: 1383-1390; Gauderman, W. J.; Gilliland, G. F.; Vora, H.; Avol, E.; Stram, D.; McConnell, R.; Thomas, D.; Lurmann, F.; Margolis, H. G.; Rappaport, E. B.; Berhane, K.; Peters, J. M. (2002) Association between air pollution and lung function growth in southern California children: results from a second cohort. *Am. J. Respir. Crit. Care Med.* 166: 76-84; Peters, J. M.; Avol, E.; Navidi, W.; London, S. J.; Gauderman, W. J.; Lurmann, F.; Linn, W. S.; Margolis, H.; Rappaport, E.; Gong, H., Jr.; Thomas, D. C. (1999) A study of twelve southern California communities with differing levels and types of air pollution. I. Prevalence of respiratory morbidity. *Am. J. Respir. Crit. Care Med.* 159: 760-767.

⁶ U.S. Environmental Protection Agency. Office of Air Quality Planning and Standards, Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information, OAQPS Staff Paper EPA-452/R-05-005a, December 2005. Page 5-8.

10. Several new studies that were published too late to be formally considered in this NAAQS review further bolster CASAC's conclusion that the annual standard must be strengthened to protect public health with an adequate margin of safety. In July 2006, EPA staff published "Provisional Assessment of Recent Studies on Health Effects of Particulate Matter Exposure," in which they concluded that:

Recent epidemiologic studies, most of which are follow-ups or extensions of earlier work, continue to find that long-term exposure to fine particles is associated with both mortality and morbidity, as was stated in the 2004 PM [Air Quality Criteria Document]. Notably, a follow-up to the Six Cities study shows that an overall reduction in PM_{2.5} levels results in reduced long-term mortality risk. Both this study and the analysis of the ACS cohort data in Los Angeles suggest that previous studies may have underestimated the magnitude of mortality risks. Some studies provide more mixed results, including the suggestion that higher traffic density may be an important factor. In addition, the California Children's Health Study reported that measures of PM_{2.5} exposure and PM components and gases were associated with reduction in lung function growth in children, increasing the evidence for increased susceptibility early in life, as was suggested in the 2004 PM [Air Quality Criteria Document]. The results of recent epidemiologic and toxicology studies have also reported new evidence linking long-term exposure to fine particles with a measure of atherosclerosis development and, in a cohort of individuals with cystic fibrosis, respiratory exacerbations."⁷

Also, a study of women's long-term exposure to PM_{2.5} was recently published in the New England Journal of Medicine by Miller, et.al. (February 2007) entitled "Long-term Exposure to Air Pollution and Incidence of Cardiovascular Events in Women."⁸ This study followed 65,893

⁷ U.S. Environmental Protection Agency, National Center for Environmental Assessment, Office of Research and Development, Provisional Assessment of Recent Studies on Health Effects of Particulate Matter Exposure, EPA/600/R-06/063, July 2006. Page E-1.

⁸ Kristin A. Miller, M.S., David S. Siscovick, M.D., M.P.H., Lianne Sheppard, Ph.D., Kristen Shepherd, M.S., Jeffrey H. Sullivan, M.D., M.H.S., Garnet L. Anderson, Ph.D., and Joel D. Kaufman, M.D., M.P.H. "Long-term Exposure to Air Pollution and Incidence of Cardiovascular Events in Women", New England Journal of Medicine, February 1, 2007,

postmenopausal women without previous cardiovascular disease in 36 U.S. metropolitan areas from 1994-1998. The yearly average PM_{2.5} exposure over the air monitoring period was 13.5 µg/m³. The investigators found that each increase in 10 µg/m³ of PM_{2.5} was associated with a 24% increase in the risk of a cardiovascular event and a 76% increase in the risk from death from cardiovascular disease. This recent study provides additional evidence of associated health effects from long-term exposure to PM_{2.5} below 15 µg/m³.

11. In evaluating the adverse effects of the Administrator's decision to leave the annual standard at 15 µg/m³, the additional health risk burden and costs to New York for mortality can be estimated using risk assessment techniques used by EPA in their Staff Paper and Regulatory Impact Analysis.⁹ EPA documented that health effects can be expected in populations exposed to levels of PM_{2.5} below 15 µg/m³. EPA used existing epidemiological studies to predict the effect on mortality below 15 µg/m³. I used a modeling methodology similar to the EPA modeling approach to predict the number of mortality cases that would be expected to be avoided in New York City if the PM_{2.5} NAAQS was set at a lower level, such as 13 or 14 µg/m³. I modified EPA's approach to assume that there was no health effects threshold and this would give similar results as the EPA model with a 7.5 µg/m³ cutpoint.¹⁰ I used long-term, 3-year average ambient air quality monitoring data from all 25 monitors in New York City mentioned above (average of 14.6 µg/m³ PM_{2.5} for all monitors). Mortality rates for diseases

Vol.356, No.5, 447-458.

⁹ U.S. Environmental Protection Agency: Regulatory Impact Analyses. Page 5-50 (Accessed April 13, 2007). <http://www.epa.gov/ttn/ecas/ria.html>

¹⁰ Ibid, page 5-82, table 5-29.

potentially related to PM_{2.5} exposure and population data for New York City were obtained from the Center for Disease Control. I relied on the two mortality studies also relied on by the EPA Administrator in his decision on the annual PM_{2.5} NAAQS (the ACS Study and Six Cities Study) to make the mortality estimates. I then made a series of assumptions in making future projections from the information in these sources (these assumptions are set forth in *Exhibit B*, with citations).

12. Based on my analysis, if the annual PM_{2.5} NAAQS was lowered to 14 µg/m³ from 15 µg/m³, 129-289 premature deaths would be projected to be avoided annually in New York City in 2016, the first year in which benefits associated with compliance with a revised annual standard can be measured (under the Rule, States are required to come into compliance with the annual standard by the end of 2015). Using the same analysis, if the annual PM_{2.5} NAAQS was lowered to 13 µg/m³ from 15 µg/m³, 347-744 premature deaths would be projected to be avoided annually in New York City in 2016.

13. With respect to morbidity effects, given that the mean value of the 3-year concentrations of PM_{2.5} of 25 monitors in New York City was 14.6 µg/m³ and the range was 11.7-17.1 µg/m³, the Gauderman study suggests that some New York City children face a risk of decline in lung function growth due to exposure to PM_{2.5}. This study was cited by EPA staff as a basis for strengthening the annual standard and suggests that increased morbidity is likely to occur in New York City if the annual standard is not strengthened from its current level of 15 µg/m³.

B. Increased Health Care Costs

14. New York State pays a portion of Medicaid health care costs (as a general matter,

state and county governments pay 50% of the total Medicaid costs and the federal government pays the rest). As a general principle, the more illnesses that Medicaid recipients in New York suffer, the higher the costs to the State/county related to their treatment. New York incurs a financial price as a result of the additional adverse effects that are likely to occur due to an NAAQS that does not protect public health with an adequate margin of safety.

15. Related to health care costs, New York tracks the number of hospital admissions and discharges through its Statewide Planning and Research Cooperative System (SPARCS), which is maintained by the DOH.¹¹ Using the premature mortality assessment above and SPARCS hospital discharge and cost information for the most recent year publicly available (2002), I estimated the costs per discharge associated with treating illnesses associated with exposure to PM_{2.5} pollution. *Exhibit B* sets forth in detail the assumptions that I used in my analysis. Although it is not possible to exactly quantify the number of discharges associated solely with exposure to PM_{2.5} pollution, even a small fraction of the overall number would translate into significant costs incurred by New York for Medicaid recipients. For example, estimates of these costs can be made using the known total discharge costs for treatment of diseases related to PM_{2.5} from the SPARCS data. SPARCS records the billed costs for discharges in 2002 for all diseases. The data indicates the discharge costs for diseases, such as heart attacks, that are the same as those expected to be caused by PM_{2.5}. The total discharge costs for these diseases can be determined. A fraction of this cost can be assumed to be due to

¹¹ Statewide Planning and Research Cooperative System (Accessed April 24, 2007) <http://www.health.state.ny.us/statistics/sparcs/annual.htm>; Statewide Planning and Research Cooperative System (SPARCS) 2002 Annual Report, New York State Department of Health, Albany New York.

exposure to PM_{2.5} and PM_{2.5} related diseases that lead to mortality. The ratio of the estimates of mortality from PM_{2.5} exposure to the total mortality (from cardiovascular/respiratory diseases similar to those caused by PM_{2.5} exposure found in SPARCS) can be made for the year 2002 (then extrapolated to 2016). This ratio represents an estimate of the relative costs due to exposure to PM_{2.5} and resulting diseases that lead to mortality. The estimated Medicaid costs related to PM_{2.5} exposure-related diseases that could be saved by the state/county would be about \$13,000,000-\$26,000,000 (at 14 µg/m³) and \$32,000,000-\$68,000,000 (at 13 µg/m³) in 2016. This is based on my analysis for 2016, the first year that the potential benefits of any new, revised standard would be realized. The details of these estimates are given in the *Exhibit B*.

Conclusion

16. Based on my review of the proposed and final PM_{2.5} NAAQS rule and the scientific evidence in the record relevant to the Administrator's decision, I conclude that EPA's decision in the final rule not to lower the annual PM_{2.5} NAAQS within the range of 13-14 µg/m³ is projected to result in New Yorkers suffering more premature deaths. Increased illnesses from exposure to PM_{2.5} pollution are also likely. Correspondingly, New York State is also projected to incur increased health care costs to treat PM_{2.5}-related illnesses. These projections are based on risk assessment methods explicated in EPA reports included in the record.

I declare under penalty of perjury that I believe the foregoing to be true and correct.

Executed on March 6, 2008

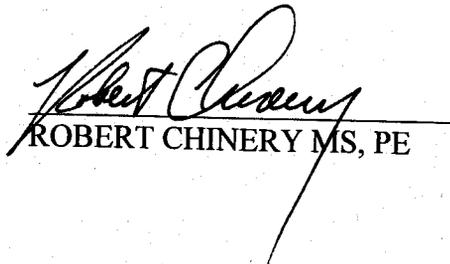

ROBERT CHINERY MS, PE

EXHIBIT A

ROBERT L. CHINERY, M.S., P.E.

EDUCATION

Graduate: Master of Science degree in environmental engineering from Rensselaer Polytechnic Institute, Troy, New York in May, 1992 (G.P.A. = 4.0).

Undergraduate: Bachelor of Science, Magna cum Laude, 1978 in Chemical Engineering from New Jersey Institute of Technology. Graduated fourth in a class of 80 (G.P.A. = 3.8).

LICENSURE: Licensed as a Professional Engineer in the State of New York.

MANAGERIAL and TECHNICAL EXPERIENCE

**ENVIRONMENTAL PROTECTION BUREAU, OFFICE OF THE ATTORNEY GENERAL,
NEW YORK STATE DEPARTMENT OF LAW, Justice Building, Albany, New York 12223
(November 2005 to present)**

Environmental Scientist (under Attorney General Eliot Spitzer). Perform litigation support/scientific research/interagency project coordination in the following areas:

- Design and implement a 1-2 million dollar study of gasoline oxygenates in private wells in NY in support of potential cost recovery lawsuit. Designed this first study of its kind in the United States. Implemented the study by directing a large interagency effort.
- Evaluated the environmental fate and toxicity testing requirements of pesticides. Scientific support for several OAG efforts to limit the use of pesticides that have effects in children by petitioning EPA to take action.
- Geospatial analysis of environmental data using Geographic Information Systems. Used GIS to support data analysis for lawsuits and design of environmental field studies.
- Environmental policy analysis/litigation support in the area of Global Climate Change. Evaluated carbon dioxide removal technologies and global climate modeling to support litigation. Contributed to the design and implementation the first of its kind epidemiological study evaluating the association between increasing temperature and hospital admissions for various diseases in New York State.
- Engineering analysis of many environmental problems such as: noise controls at cogeneration plants, septic system design, well construction, particulate matter controls at combustion sources and population exposure and environmental modeling assessments for dry-cleaning facilities and other pollution sources.
- Selection and supervision of contractors/experts

CENTER FOR ENVIRONMENTAL HEALTH, NEW YORK STATE DEPARTMENT OF HEALTH, Flanigan Square, 547 River St. Troy, New York 12180-2216 (November 1987 to July 1997 and August 2000 to November 2005).

This Center specializes in the protection of public health from environmental exposure.

DIVISION OF ENVIRONMENTAL HEALTH, Division-Level Special Projects Manager:

- Supervise (or personally implement) interdisciplinary, special research projects, new legislation, multi-party negotiations, and large interdepartmental projects such as bioterrorism preparedness.
- Key department investigator of health risks at the World Trade Center Collapse.
- Helped draft the multi-governmental risk assessment document that set air guidelines for the WTC clean-up.
- Developed the research basis, testing methodology, state standards and regulations for the first ignition propensity fire standard for cigarettes in the United States.
- Performed basic research in exposure assessment methodologies that supported department programs such as environmental fate analyses of chemicals, environmental permitting, physiologically based pharmacokinetic modeling and pesticide environmental fate.
- Substitute member of the NYS Electric Power Plant Siting Board.
- Involved in water supply modeling, quality issues and policy.

BUREAU OF TOXIC SUBSTANCE ASSESSMENT Section Chief, Exposure Assessment Section:

- Skilled in supervision, public presentation, negotiation, and resolution of environmental issues
- Supervisor of a staff of professionals
- Assisted in hazardous waste site investigation and remediation
- Performed exposure and risk assessments for environmental releases
- Performed air pollution modeling and source risk evaluation, and assisted DEC in permitting
- Evaluated toxicity, fate and transport of toxic substances
- Performed mathematical modeling of contaminant fate in all media
- Significant abilities in research, chemistry and analytical techniques
- Skilled in many types of environmental field studies

ENVIRONMENTAL PROTECTION BUREAU, NEW YORK STATE DEPARTMENT OF LAW, Justice Building, Albany, New York 12223 (April 1984 to November 1987)

Environmental Scientist and Engineer (under Attorney General Robert Abrams). Technical support for litigation for civil and criminal legal actions used to enforce New York State environmental laws. Worked on some of the largest hazardous waste sites in New York such as Love Canal, Hyde Park Landfill and 102nd St. Landfill in Niagara Falls.

- Responsible for technical negotiations with responsible parties
- Legal support as an expert witness and writing technical depositions
- Negotiated hazardous waste site investigations and remediations
- Negotiated engineering plans for remediation for all types of environmental releases.
- Worked closely with NYSDEC, USEPA, Department of Justice and, NYSDOH

U.S. ARMY TOXIC AND HAZARDOUS MATERIALS AGENCY, Aberdeen Proving Grounds, Maryland 21010 (April 1983 to April 1984)

Engineering Program Manager. Managed a research and development program to investigate the feasibility of chemical conversion of highly toxic warfare agents into less toxic marketable feedstocks.

- Supervision of engineering and scientific consultants.
- Responsibilities included managing schedule, cost and technical efforts
- Presented results to the National Academy of Sciences.

BUREAU OF HAZARDOUS WASTE ENGINEERING, New Jersey Department of Environmental Protection, 32 East Hanover Street, Trenton, New Jersey 08625 (September 1980 to April 1983)

Principal Environmental Engineer. Supervised five environmental engineering professionals.

- Responsibility for permitting hazardous waste RCRA TSD facilities.
- Experienced in formal hearings and public presentation hazardous waste issues.
-

ORGANICS DIVISION, HERCULES INCORPORATED, Neck Road, Burlington, New Jersey 08016 (January 1979 to May 1980)

Process Engineer. Member of a chemical production technical group responsible for technical support in a resin production plant.

- Responsible for R&D and start-up of HPLC Laboratory instrumentation
- Performed pilot plant design, construction and start-up for new resins
- Researched the use of UV, GC and IR techniques for chemical analysis
- Responsible for the design and start-up of a hazardous waste processing apparatus
- Supervised laboratory technicians, maintenance and plant personnel.

CHEMICAL ENGINEERING DEPARTMENT, Clarkson College of Technology, Potsdam, New York 13676 (Summer of 1977)

Performed research in Thermodynamics, funded by the National Science Foundation. Duties included literature research, theoretical thermodynamic mathematical modeling of chemical processes, extensive computer programming, report writing and oral presentations at faculty meetings.

COMPUTER SKILLS: Programming skills in Advanced Continuous Simulation Language, FORTRAN, and BASIC. Skilled in SYSTAT, Microsoft Word, LOTUS, MATHCAD, and various graphics and modeling packages. Adept at ArcView GIS.

TEACHING EXPERIENCE

BURNT HILLS/BALLSTON LAKE HIGH SCHOOL, Lakeview Road, Burnt Hills New York
(1999 School year).

Physics and Chemistry teacher. Responsible for design of curriculum, curriculum materials, and presentation of educational materials. Physics curriculum was implemented using a new, innovative program of guided discovery. This program provided a hands-on, theoretically based approach to individual discovery of physics concepts. This required designing laboratory investigations that allowed guided discovery of the laws of physics, very little lecturing was provided in this course.

ACADEMY OF THE HOLY NAMES, 1075 New Scotland Road, Albany, New York, 12208
(1998 School year).

Physics, Chemistry, Environmental Science and Marine Biology teacher for seniors and juniors. Students are college bound and represent diverse abilities. All students are required to take sciences through the 12th grade, which includes potential non-science majors and students with special needs. Responsibility includes labs, advisement, research mentoring, and course and curriculum development.

MAJOR SCIENTIFIC PUBLICATIONS AND REPORTS

J. Schreiber and R.L. Chinery, "Smoke Gets in Your Lungs: Outdoor Wood Boilers in New York State." Published by New York Attorney Generals office October 2005.

R. L. Chinery and R. Walker. "Development of Exposure Characterization Regions for Priority Ambient Air Pollutants." Internal review as of July 2005.

R. L. Chinery. "Derivation of a Cigarette Fire Safety Performance Standard." November 2002. Published in the State Register.

World Trade Center Indoor Air Taskforce Workgroup. "World Trade Center Indoor Air Assessment: Selecting Contaminants of Potential Concern and Setting Health-based Benchmarks." September 2002.

R.L. Chinery. "Inhalation Exposures from Household use of Methyl-t-Butyl Ether (MTBE) Contaminated Water Supplies." In internal peer review.

R.L. Chinery and A.K. Gleason. "A Compartmental Model for the Prediction of Breath Concentration and Absorbed Dose of Chloroform After Exposure While Showering." Risk Analysis:, Vol. 13, No. 1, 1993.

R.L. Chinery and A.K. Gleason. "Compartmental Model for the Prediction of Absorbed Dose of Chloroform: An Unsteady-State Skin Absorption Model," submitted to Risk Analysis.

R.L. Chinery. "Model of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin in the Lake Trout Food Chain." Masters Thesis. Rensselaer Polytechnic Institute, Troy, New York. March 1992.

New York State Department of Health. "Analysis of the Chemical and Physical Properties of Pesticides with Groundwater Leaching Potential." In internal review in March 1996.

New York State Department of Health. "An Assessment of Environmental Samples from Dairy Farms Near Municipal Incinerators. Report on Phase II Study." In internal review in December 1995.

New York State Department of Health. "Groundwater/Indoor Air Investigation in a Neighborhood South of Kodak Park." August 1990.

New York State Department of Health. "Indoor Air Investigation of Public School 41, Rochester, New York." April 1989.

New York State Department of Law. "A simple Diffusion Model to Predict Basement Concentrations of Toxic Chemicals Volatilizing from Groundwater." March 1986.

EXHIBIT B

EXHIBIT B

Detailed Estimates of Mortality and Costs Associated with

Alternative PM_{2.5} NAAQS in New York City

The purpose of this exhibit is to estimate the projected mortality rates in New York City associated with annual PM_{2.5} NAAQS set at values lower than 15 $\mu\text{g}/\text{m}^3$. Two alternative values are analyzed, 14 and 13 $\mu\text{g}/\text{m}^3$. EPA requires that the states demonstrate compliance by 2015 with the new annual standard. It is not until 2016 that potential benefits of a new, revised standard would be realized.

1. Premature Mortality

The estimate of the benefits from changes in the NAAQS are dependant on the current, baseline mortality rates (for example, those associated with cardiopulmonary diseases and lung cancer) and the number of people subject to these diseases in the population. Neither of these two numbers are known for the year 2016 so it is assumed that the rates for the latest year in which we have data are the same rates that would exist in 2016. The relationship between the concentration (PM_{2.5}) and response (premature mortality) come from relatively recent epidemiological studies. The two studies used are ACS (Pope, 2002)¹ and Harvard 6 Cities (Dockery, 1993).² Mortality rates and population data are obtained from Center for Disease

¹ Pope, CA III, Burnett, RT, Thun, MJ, Calle, EE, Krewski, D, Ito, K, Thurston, GD, 2002, Lung Cancer, Cardiopulmonary Mortality, and Long-Term Exposure to Fine Particulate Air Pollution, JAMA, 287, 9, 1132-1141.

² Dockery, DW, Pope, CA, Xu, X, Spengler, JD, Ware, JH, Fay, ME, Ferris, BG, and Speizer, FE, 1993, An Association between Air Pollution and Mortality in Six U.S. Cities, NEJM, 329, 1753-1759.

Control-Wonder Website and are for the year 1998 and 2000, respectively.³

The 3-year average from every PM_{2.5} monitor in New York City was reviewed. This data was taken from the New York State Department of Environmental Conservation website and covers the years 2003-2005.⁴ All 25 monitors with complete data in New York City were averaged.

Assumptions used in Mortality calculations:

1. Baseline Mortality Rates per 100,000 population in 1998 in NYC are the same in 2016.
2. Population (greater than 35 years old) in 2000 is the same in 2016.
3. Pope et. al. (2002) concentration-response function for PM_{2.5} is 0.6 % mortality decrease per 1 µg/m³ decrease in PM_{2.5} as cited in the EPA Staff Paper, Appendix 3B.⁵
4. Dockery et. al. (1993) concentration-response function for PM_{2.5} is 1.3% mortality decrease per 1 µg/m³ decrease in PM_{2.5} as cited in the EPA Staff Paper, Appendix 3B.⁶
5. Mortality rates for NYC (5 Boroughs) are for ICD-9 codes: 401-440, 460-519, and 162 from CDC-Wonder.
6. No health effect threshold in the concentration-response function used in (3) and (4)

³ Centers for Disease Control and Prevention: CDC-Wonder. (Accessed April 13, 2007). <<http://wonder.cdc.gov/>>.

⁴ New York State Department of Environmental Conservation, 2006 Region 2 Air Quality Data. "Inhalable Particulates" (<http://www.dec.ny.gov/chemical/29310.html>).

⁵ U.S. Environmental Protection Agency, 2005. Office of Air Quality Planning and Standards, Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information, OAQPS Staff Paper EPA-452/R-05-005a December 2005.

⁶ Ibid.

above.

7. Population in 5 boroughs (ages greater than 35 years) in 2000 was 3,780,504 from CDC-Wonder.
8. The mortality rates in NYC were averaged for the 5 boroughs. For the ICD-9 Codes above, the average in 1998 was 956.340 deaths/100,000 at age 35 years and greater.⁷
9. The current 3-year average PM_{2.5} level (for years 2003, 2004 and, 2005) for all the 25 monitors in NYC is 14.6 µg/m³ (Range: 11.7-17.1 µg/m³; Median: 14.8 µg/m³). This level is assumed to be the same in 2016.

1. A. Benefits associated with a reduction from 14.6 µg/m³ to 14 µg/m³.

$$\text{Benefit (based on Pope et al. 2002) = (956.34 Cases/100,000) X} \\ 3,780,504 \text{ Population X (0.0036}^8\text{)}$$

129 deaths potentially avoided per year in 2016 in NYC

⁷ Bronx =1,011deaths /100,000 population over 35 years
King's=981.8 deaths /100,000 population over 35 years
Queen's= 945.3 deaths/100,000 population over 35 years
Richmond=1030.9 deaths/100,000 population over 35 years
New York= 812.7 deaths/100,000 population over 35 years

⁸ Based on the equation: $-(\exp - (C-R \times (14.6 \mu\text{g}/\text{m}^3 - \text{Assumed NAAQS})) - 1)$.

$$\text{Benefit (based on Dockery et.al. 1993)} = (956.34 \text{ Cases}/100,000) \times 3,780,504 \text{ Population} \times (0.008)$$

289 deaths potentially avoided per year in 2016 in NYC

1. B. Benefits associated with a reduction from 14.6 $\mu\text{g}/\text{m}^3$ to 13 $\mu\text{g}/\text{m}^3$.

$$\text{Benefit (Pope 2002)} = (956.34 \text{ Cases}/100,000) \times 3,780,504 \text{ Population} \times (0.0096)$$

347 deaths potentially avoided year in 2016 in NYC

$$\text{Benefit (Dockery 1993)} = (956.34 \text{ Cases}/100,000) \times 3,780,504 \text{ Population} \times (0.0206)$$

744 deaths potentially avoided per year in 2016 in NYC

2. Hospital Discharge Costs

The Statewide Planning and Research Cooperative System (SPARCS) was used to gather information on the number of hospital admissions and discharges for 2002 in the state of New York and New York City. Both the online database and the SPARCS 2002 annual report was

used to gather data for the costs/charges for discharges from PM_{2.5} related diseases.^{9,10} The Premature Mortality assessment above describes the diagnosis codes associated with PM_{2.5} exposure mortality (ICD-9: 401-440, 460-519, and 162). For the year 2002, SPARCS classified their data for admissions and discharges based on Diagnosis Related Group (DRG) codes. DRGs classify hospital cases into approximately 500 groups based on ICD diagnoses, procedures, age, and sex. A comparison between the ICD-9 codes and DRG codes was performed to match the diagnoses. The DRG codes used in this analysis were the following respiratory and cardiovascular codes: 75-102, 104-118, 120-127, 129-131-, 135-145, 475, 478, 479, 515-518, 525-527, 535, 536, 547-558, 565, and 566.¹¹ Using the SPARCS database for ages from 20-85+ (35 years and up was not available, the smallest age division was 20-44 years), total charge for discharges for these DRG codes was computed as \$11,174,420,000 in 2002.¹² Charges include both the covered and non-covered portions of patient stay for ancillary services and accommodations. Reimbursement rates can be lower depending on the payer/insurance provider that a patient utilizes at the time of discharge; however the total charge represents the sum of all the procedures that have taken place prior to discharge. Using the time value of money (at a 5%

⁹ Statewide Planning and Research Cooperative System (Accessed April 24, 2007) <<http://www.health.state.ny.us/statistics/sparcs/annual.htm>>.

¹⁰ Statewide Planning and Research Cooperative System (SPARCS) 2002 Annual Report, New York State Department of Health, Albany New York.

¹¹ Solucient, LLC: "Diagnosis Related Groups Handbook by Solucient Publications" (Accessed May 3, 2007) <http://solucient.ecnext.com/coms2/page_drg_item_list>.

¹² The SPARCS database gives information for the total number of diagnoses made per DRG and the total average amount spent per diagnosis and treatment. The DRG codes and costs for the respiratory and cardiovascular diseases related to PM exposure were tabulated and the total charges were determined.

discount rate) these costs would be approximately \$22,125,000,000 in 2016. This is a future estimate of the total discharge costs for all diseases that are the same as PM_{2.5} mortality-related diseases discussed by EPA in the rulemaking record. See, e.g., 71 Fed. Reg. 2,627-33.

The portion of the total cost that could be attributed to PM_{2.5} related exposure can be estimated. The following assumptions are made:

1. All the assumptions used to calculate premature mortality are used.
2. The Medicaid portion of total discharge costs in NYC in 2002 is the same in 2016.
3. The Medicaid portion of total costs paid by the federal government (50%) in 2007 is the same in 2016.
4. The total cost in 2016 for all the discharges for the DRG codes selected is \$22,125,000,000.
5. The relationship between mortality and the number of hospital discharges for PM_{2.5} related diseases is linear and constant from 2002 to 2016.

The total mortality in the 5 boroughs of NYC in 1998 was 956.34/100,000 population and the total population was 3,780,504 in 2000 for the population older than 35 years. These are assumed to remain the same in 2016. Therefore the total mortality from the selected DRG's in NYC is assumed to be 36,154 in 2016. The estimate of the mortality that is projected to be PM_{2.5} exposure-related in 2016 is given above (see "1. Premature Mortality") and is 129-289 (for assumed NAAQS of 14 $\mu\text{g}/\text{m}^3$) and 347-744 (for assumed NAAQS of 13 $\mu\text{g}/\text{m}^3$). This represents about 0.4-0.8 % (at 14 $\mu\text{g}/\text{m}^3$) and 0.95%-2.05% (at 13 $\mu\text{g}/\text{m}^3$) of the total mortality expected from these diseases. Assuming that the ratio of mortality to the number of hospital

discharges remains constant, the estimated portion of the total hospital cost potentially saved due to reduced PM_{2.5} related mortality would be \$88,000,000-\$177,000,000 (at 14 µg/m³) and \$210,000,000-\$454,000,000 (at 13 µg/m³). According to SPARCS, the expected primary Medicaid payment per discharge compared to the total expected payment per discharge for all hospital procedures in the 5 boroughs of NYC in 2002 was about 30%.¹³ According to the Office of Health Insurance Programs, Division of Health Care Finance at the NYS Department of Health, the federal government pays 50% of Medicaid costs and the state and local governments pay the rest.¹⁴ These Medicaid cost contributions and sources of reimbursement related to the PM_{2.5} DRG codes are assumed to remain the same until 2016. The portion of the PM_{2.5} mortality related Medicaid costs that could be expected to be saved by the state/county is estimated to be 15% (30% times 50%) of the total costs or \$13,000,000-26,000,000 (at 14 µg/m³) and \$32,000,000-68,000,000 (at 13 µg/m³) in 2016.

¹³ SPARCS Annual Report, Tables 9(I) "Discharges/average length of stay by County of Hospitalization and Hospital by Expected Primary Source of Reimbursement" page 58.

¹⁴ Personal communication Evan LaVoie, 9/19/2007.

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

AMERICAN FARM BUREAU FEDERATION, et al.,)	
)	
Petitioners,)	
v.)	Docket No. 06-1410 (and
)	consolidated cases)
ENVIRONMENTAL PROTECTION AGENCY,)	
)	
Respondent.)	
)	

CERTIFICATE OF SERVICE

I hereby certify that on the 7th day of March, 2008, two copies of State Petitioners' final opening brief were served, either by first class mail (where an e-mail address has been provided) or by overnight mail delivery and further that a courtesy copy was sent to counsel electronically where an e-mail address had been provided:

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