ORAL ARGUMENT SCHEDULED FOR SEPTEMBER 15, 2008

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

CORRECTED FINAL REPLY 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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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
$\mu g/m^3$	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

SUMMARY OF ARGUMENT

EPA's brief makes two important concessions supporting the position of State Petitioners and Amici (collectively, "State Petitioners") that the Administrator violated the statute by not setting the National Ambient Air Quality Standard ("NAAQS") for fine particulate matter ("$PM_{2.5}$") at a level that protects public health with an adequate margin of safety. First, EPA admits that the Administrator did not consider short-term exposure studies at all in setting the annual $PM_{2.5}$ standard, studies that EPA's Clean Air Scientific Advisory Committee ("CASAC") and EPA staff found relevant to setting an annual standard that adequately protects public health. Second, EPA admits that the Administrator chose not to consider – again contrary to CASAC's and EPA staff's advice – EPA's health risk assessment, which showed that thousands of lives could be saved if a more protective standard was chosen. Given that more than 100 million people are vulnerable to $PM_{2.5}$ pollution, and the well-established link between $PM_{2.5}$ pollution and premature death and serious illnesses, the Administrator was required by the statute to err on the side of caution in setting the annual standard.

EPA also offers no reasoned basis for disregarding the Gauderman study showing damage to children's lungs from exposure to $PM_{2.5}$ at and below the level of the current annual standard, demonstrating that the current standard does not adequately protect sensitive populations. Nor does EPA demonstrate that the Administrator explained in the record how the current annual standard, based solely on mortality studies, adequately protects sensitive populations against morbidity effects, which the record shows occur from exposures to lower concentrations of $PM_{2.5}$.

EPA has not shown that it reasonably set the NAAQS at a level that protects public health

with an adequate margin of safety, as the Clean Air Act requires.

ARGUMENT

THE ADMINISTRATOR'S DECISION NOT TO STRENGTHEN THE ANNUAL STANDARD FOR $PM_{2.5}$ WAS ARBITRARY AND CAPRICIOUS

The Administrator must set the NAAQS at a level that protects public health with an adequate margin of safety. 42 U.S.C. § 7409(b)(1). EPA has failed to rebut State Petitioners' argument that the Administrator's decision not to revise the annual $PM_{2.5}$ standard was arbitrary on several grounds in light of the Act's requirement that the agency must "err on the side of caution" in setting the NAAQS. American Trucking Ass'ns v. Whitman, 283 F.3d 355, 369 (D.C. Cir. 2002) ("ATA III").

A. The Administrator Unreasonably Disregarded Epidemiological Evidence that Requires Strengthening the Annual Standard.

1. The Administrator failed to consider relevant short-term exposure studies demonstrating that the current annual standard fails adequately to protect public health.

In our opening brief, State Petitioners cited three studies demonstrating a link between premature mortality and short-term exposure to $PM_{2.5}$ at levels that are below the annual standard of 15 $\mu g/m^3$. See State Br. 16-17 (discussing studies showing premature death where average levels were 13-13.3 $\mu g/m^3$). EPA admits (Br. 37-39) that the Administrator did not consider these studies in determining the annual standard, and that short-term exposure studies were used to establish the annual standard at 15 $\mu g/m^3$ in the last NAAQS review. Further, EPA does not dispute that CASAC and EPA staff concluded that these studies were relevant in this rulemaking to determine the level of the annual standard necessary to protect public health. This failure to consider relevant studies in setting the NAAQS was erroneous. See American Trucking Ass'ns

v. Browner, 175 F.3d 1027, 1052-53 (D.C. Cir. 1999) (rejecting EPA's decision to ignore relevant studies in determining ozone NAAQS where EPA imposed higher standard of proof on the excluded studies), reversed on other grounds, Whitman v. American Trucking Ass'ns, 531 U.S. 457 (2001).

EPA's attempts to justify the Administrator's decision to ignore this relevant evidence are unpersuasive. First, EPA points out (Br. 36) that the Administrator did consider these studies in determining the 24-hour $PM_{2.5}$ NAAQS. But, the fact that the Administrator found these studies reliable in determining the level of the 24-hour standard does not discharge his obligation to consider them in determining the annual standard when, as CASAC and EPA staff concluded, those studies are also relevant to the latter standard.[1] EPA does not contend that the short-term exposure studies are irrelevant, but asserts (Br. 33) that the Administrator considered studies that were "most directly relevant" to harmful effects of long-term exposure. But, in setting the NAAQS, "the Administrator must 'take into account *all* the relevant studies revealed in the record,'" not just those that are most directly relevant. Natural Resources Defense Council v. EPA, 902 F.2d 962, 971 (D.C. Cir. 1990) (quoting American Petroleum Inst. v. Costle, 665 F.2d 1176, 1187 (D.C. Cir. 1981)) (emphasis added).

Second, EPA argues (Br. 38-39) that the Administrator reasonably changed the approach used in the last NAAQS review, when EPA based the level of the annual standard on short-term

[1] Contrary to Fine PM Industry Intervenors' assertion (Br. 3-5), State Petitioners did not argue that the statute mandates that the Administrator follow CASAC's recommendations, simply that the Administrator's failure to do so "should raise a red flag whether EPA engaged in reasoned decision making." State Br. 5. In addition, although Industry Intervenors cite (Br. 6-7) to a few instances in which the Administrator rejected CASAC's advice, none of these involved a situation such as this where the Administrator rejected CASAC's conclusion that the scientific evidence required that a more protective standard be set to provide an adequate margin of safety.

exposure studies, because long-term exposure studies in the current NAAQS review are more robust than in the previous round. State Petitioners are not questioning the Administrator's discretion to give greater weight to long-term exposure studies. It was, however, unreasonable for the Administrator to refuse to consider short-term exposure studies *at all* when CASAC and EPA staff had concluded that they were relevant. Moreover, EPA does not contend that the decision in the last NAAQS review to set the level of the annual standard at 15 $\mu g/m^3$ based on short-term exposure studies was unreasonable, further undercutting the legitimacy of the Administrator's decision not to consider such studies this time around.

Third, EPA asserts (Br. 39-43) that the revised 24-hour standard will address adverse health effects from short-term exposure to $PM_{2.5}$ in the areas in which the three studies were conducted (Phoenix, Santa Clara County, California, and eight Canadian cities), and that adopting an annual standard of 13 $\mu g/m^3$ would not provide additional protection to those areas. Even if such an argument could justify excluding relevant evidence, it lacks merit. As EPA itself notes, the average 24-hour concentration of $PM_{2.5}$ in Phoenix was 32 $\mu g/m^3$, below the revised 24-hour standard of 35 $\mu g/m^3$. Therefore, setting the 24-hour standard *above* current levels is unlikely to provide further protection to Phoenix residents. Indeed, EPA's risk assessment shows that lowering the 24-hour standard does not decrease the number of premature deaths in Phoenix. See EPA Risk Assessment at E-23 (JA-2412). Even if EPA were correct that lowering the annual standard to 13 $\mu g/m^3$ would not provide further protection against short-term exposure to $PM_{2.5}$ in these areas, where the average concentration levels were 13 $\mu g/m^3$, there can be no dispute that it would provide health protection in cities such as New York, where average yearly concentrations are above 14 $\mu g/m^3$. Indeed, as pointed out in our opening brief (p. 23), EPA's

own Regulatory Impact Analysis estimates that as many as *11,000 premature deaths* would be avoided across the country if the annual standard were lowered by just 1 $\mu g/m^3$, to 14 $\mu g/m^3$.

Furthermore, the Administrator does not dispute CASAC's conclusion that the revised 24-hour standard will result in minimal health protection in areas that experience little variation in daily $PM_{2.5}$ concentrations.. 71 Fed. Reg. at 2,651; see also Staff Paper at 5-31 (JA-1888) (explaining that "much of the risk related to daily exposures [to $PM_{2.5}$] results from the large number of days during which the 24-hour average concentrations are in the low- to mid-range.") and CASAC 3/21/06 letter at 3 (JA-3271) (identifying Detroit and St. Louis as cities that exemplify this problem). Instead, EPA argues (Br. 43-44, n.19) that the Administrator was free to ignore this consideration because "CASAC did not . . . cite any studies indicating an association between long-term $PM_{2.5}$ exposure and health effects in such cities." But the Administrator was well aware of the Gauderman study of fourth grade children in Southern California, which showed likely irreversible lung damage in children where long-term average concentrations of $PM_{2.5}$ were 15 $\mu g/m^3$, the level of the current standard. See 71 Fed. Reg. 61,172; see also State Br. 25-28.

EPA's attempt to use this Court's decision in ATA III to support its margin of safety argument backfires. EPA argues that the margin of safety for the $PM_{2.5}$ annual standard upheld in ATA III was actually less than the margin provided in this rulemaking. EPA Br. 69-72 (asserting that the difference between the level of the annual standard of 15 $\mu g/m^3$ and the average concentration of the studies on which EPA relied was less than 1 $\mu g/m^3$ in ATA III, compared to 2.7-3 $\mu g/m^3$ below studies relied on here). However, in ATA III, the Administrator established the standard at 15 $\mu g/m^3$ based on the average concentration of *short-term* exposure studies. See

62 Fed. Reg. 38,676. Had the Administrator considered short-term exposure studies here, he necessarily would have concluded that an annual standard of 15 $\mu g/m^3$ provides no margin of safety at all. EPA cannot have it both ways, arguing that the short-term exposure studies are irrelevant to setting the annual standard in this rulemaking but at the same time using short-term studies from the last NAAQS review to advance the agency's margin of safety argument here.

EPA's reliance on ATA III is further undercut by its acknowledgment (Br. 72) that in that case, the possibility of adverse health effects at lower annual concentrations was "highly uncertain." By contrast, here CASAC concluded that "clear and convincing evidence" established that a more protective annual standard was necessary given that adverse health effects were well-established at or below the level of the current standard. See CASAC 9/29/06 letter at 1 (JA-3282); see also Staff Paper at 5-8 ("fairly strong evidence" of morbidity effects at the level of the current standard) (JA-1864). NRDC v. EPA, 902 F.2d at 971-72, where EPA concluded that evidence supporting a lower level was "quite limited and uncertain," is inapposite for the same reason.

Finally, EPA has no response to our argument (Br. 18) that, consistent with ATA III and Lead Industries Ass'n v. EPA, 647 F.2d 1130 (D.C. Cir. 1980), the statute's precautionary approach is particularly warranted here because, as EPA found, more than 100 million people are especially vulnerable to $PM_{2.5}$ pollution, so even small changes in $PM_{2.5}$ levels can result in widespread health impacts. Criteria Document, Table 9.4 (JA-975). Indeed, EPA makes this very point (Br. 103-04) in defending the Administrator's decision not to exclude rural coarse particles from PM_{10} regulation in light of the "the large population groups potentially exposed to non-urban coarse particles, and the nature of health effects at issue, which included serious

morbidity and mortality."

2. Consideration of short-term exposure studies is particularly imperative given the serious limitation in the principal study the Administrator did rely on.

EPA fails to rebut State Petitioners' argument that it was particularly unreasonable for the Administrator to ignore relevant short-term exposure studies when the principal long-term exposure study that the Administrator relied upon suffered from a serious limitation.[2] That study – the American Cancer Society ("ACS") study – likely underestimated the number of deaths in the general population caused by long-term exposure to $PM_{2.5}$. States Br. 19-20; see Regulatory Impact Analysis at 5-28, n.13 (JA-4477) (ACS study "is not representative of the demographic mix in the general population. The ACS [study] is almost entirely white and has higher income and education levels relative to the general population"). EPA argues (Br. 52, n.22) that the under-representation of individuals without a high school education had no bearing on using the study to set the annual standard because the "relevant information obtained from the ACS study concerned the existence of an association between long-term $PM_{2.5}$ concentration levels and health effects, not the specific magnitude of those effects." However, State Petitioners' point (Br. 19), is that EPA staff concluded that the ACS study underestimates precisely that "association" between long-term $PM_{2.5}$ exposure and harm in the general population.

3. The ACS study itself demonstrates that the current annual standard does not adequately protect public health.

EPA does not successfully rebut our point that the ACS study alone – as interpreted by

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[2] EPA erroneously asserts (Br. 52, n.22) that "State Petitioners claim that it was unreasonable to rely on the ACS study . . . ." Instead, State Petitioners contend that given the important limitation in the study, which was acknowledged by EPA staff, it was unreasonable for the Administrator to rely principally on this study and to exclude the short-term studies that did not have this limitation. State Br. 19-20.

both EPA staff and CASAC – justifies lowering the annual standard below 15 $\mu g/m^3$. EPA argues (Br. 56) that staff's recommendation of a 13 $\mu g/m^3$ standard was driven by an assumption that the Administrator would give appreciable weight to long-term morbidity studies. State Petitioners agree with EPA staff that the Administrator *should* have given appreciable weight to these long-term morbidity studies, see Point C, *infra*, but staff also cited "the most recent extended ACS mortality study" as grounds for setting the annual standard at 13 $\mu g/m^3$. Staff Paper at 5-23 (JA-1880).

Next, EPA continues to downplay the fact that the most recent data from the ACS study (from 1999-2000) showed a positive association between long-term exposure and mortality with an average $PM_{2.5}$ concentration of 14 $\mu g/m^3$, below the current standard. Staff Paper at 5-22 (JA-1879). EPA's argument (Br. 62-65), that the association between exposure to $PM_{2.5}$ at an average concentration of 14 $\mu g/m^3$ and mortality is not as reliable as if data from an earlier period of the study (1979-83) is averaged, lacks merit. The 1999-2000 period in the ACS study included much more recent data, 150,000 more participants, and significantly more extensive monitors than the 1979-1983 study period. See ACS Study at 1133 (JA-4319). Thus, even the study the Administrator principally relied upon demonstrates that an annual standard of 15 $\mu g/m^3$ does not protect public health with an adequate margin of safety.

B. The Administrator Unreasonably Rejected EPA's Risk Assessment in Determining the Level of the Annual Standard.

EPA's provides no reasonable defense of the Administrator's decision to disregard his staff's risk assessment, which estimated that thousands of premature deaths would likely occur if the annual standard was kept the same. In the rulemaking, the Administrator acknowledged that

CASAC and EPA staff both found the risk assessment of sufficient quality to use in selecting the level of the annual standard. 71 Fed. Reg. 61,173-74; Staff Paper at 5-46 (JA-1903).[3] Moreover, EPA provides no answer to State Petitioners' argument (Br. 18-19) that because EPA's own analysis showed that lowering the level of the annual standard would likely reduce significant health risks, potentially saving thousands of lives, the Administrator had to lower the annual standard to meet his statutory obligation to establish an adequate margin of safety.

EPA unsuccessfully tries to downplay the number of deaths that EPA staff predicted are likely to occur if the annual standard remains unchanged. The number of deaths estimated using different levels for the annual and 24-hour standards vary depending on which concentration is assumed to be the threshold (*i.e.*, "cutpoint") for harm from $PM_{2.5}$ exposure.[4] In State Petitioners' opening brief, we noted that the risk assessment showed that leaving the annual standard at 15 $\mu g/m^3$ (combined with the 24-hour standard of 35 $\mu g/m^3$) would result in approximately 3,700 premature deaths from $PM_{2.5}$ exposure in the nine cities examined (based on a cutpoint of 7.5 $\mu g/m^3$). State Br. 22. EPA suggests (Br. 25) that State Petitioners should have used the 10 $\mu g/m^3$ cutpoint recommended by CASAC instead. However, even if a cutpoint of 10 $\mu g/m^3$ were used, there would be 1,357 premature deaths in just these nine cities, EPA Risk

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[3] EPA incorrectly frames the issue (Br. 29-30) as whether the Administrator provided a reasonable explanation "for his judgment that he should use an evidence-based approach rather than a quantitative risk-based approach" to set the NAAQS. State Petitioners did not take such an "either or" position, but instead argued (Br. 22-24) that the Administrator arbitrarily rejected his staff's and CASAC's advice that both types of evidence should be considered in arriving at an adequate margin of safety.

[4] It is unknown whether there is a threshold below which exposure to $PM_{2.5}$ is safe. For the risk assessment, EPA staff chose three different cutpoint levels, ranging from the most conservative of 7.5 $\mu g/m^3$ to the least conservative of 12 $\mu g/m^3$, with a middle value of 10 $\mu g/m^3$. See Staff Paper at 5-24 (JA-1881).

Assessment at 117, E-17-31 (JA-2263, 2406-20), a number that EPA cannot argue is insignificant. Given the severity of the harm and large number of individuals likely to be affected, and the fact that the Agency's own analysis showed that lowering the level of the annual standard would likely reduce significant health risks, the Administrator acted contrary to the statute in keeping the current standard. See State Br. 18-19.

EPA also contends (Br. 19-23) that the Administrator properly disregarded the risk assessment because of uncertainties in the analysis. But the risk assessment was based on data from the very epidemiological studies that the Administrator relied upon. State Br. 24. Therefore, many of the points EPA makes (Br. 20-21) about uncertainties in the risk assessment (concerning PM coefficients/health effects, threshold level, transferability of concentration response functions, etc.) apply equally to the underlying ACS study, which the Administrator concluded was "remarkably robust." EPA Br. 50. Moreover, if the Administrator did operate from the premise that "the usefulness of the results [from the risk assessment] is directly related to the extent the underlying studies support this assumption," (EPA Br. 28), the ACS study showed, as discussed above, adverse effects where the mean $PM_{2.5}$ concentration was below 15 $\mu g/m^3$.

Finally, EPA's suggestion (Br. 26, n.11) that State Petitioners "tellingly" did not argue in public comments for a 12 $\mu g/m^3$ annual standard combined with a 25 $\mu g/m^3$ 24-hour standard is baseless. Aside from being legally irrelevant to whether an annual standard of 15 $\mu g/m^3$ provides an adequate margin of safety, Environmental Petitioners (and Health Amici) *did* advocate for such a standard. See Comments of American Lung Ass'n (Apr. 17, 2006) at 40 (JA-3576). Moreover, California has adopted a 12 $\mu g/m^3$ annual standard. Letter from Gov. Schwarzenegger

to Administrator Johnson (Apr. 17, 2006) (JA-3812).

C. The Administrator Failed to Set the Annual Standard at a Level that Protects Sensitive Populations with an Adequate Margin of Safety and Failed to Provide a Reasoned Explanation.

EPA also fails to successfully refute State Petitioners' arguments that the Administrator did not set the annual standard at a level that adequately protects children and other sensitive populations and that he failed to explain his conclusion that the current standard provides the mandated margin of safety for these populations.

1. The Administrator erred in dismissing a long-term study on the damage to children's lungs caused by $PM_{2.5}$ pollution.

The Administrator erred by giving little or no weight to what he acknowledged to be an "important" long-term exposure study concerning lung damage to young children from $PM_{2.5}$. As discussed in State Petitioners' opening brief (pp. 25-26), Gauderman found lung damage in fourth-grade children in Southern California exposed to concentrations of $PM_{2.5}$ with a long-term average of 15 $\mu g/m^3$, the level of the current standard. As with the short-term exposure studies, the Administrator's treatment of this study is critical because, had he concluded that the study deserved measurable weight, he could not reasonably have kept the annual standard at 15 $\mu g/m^3$. The Administrator's reasons for disregarding the Gauderman study were arbitrary and contrary to the statute.

First, the Administrator's decision was contrary to the findings of his own staff. State Br. 27 (EPA staff cited the study as a basis for an annual standard of 13 $\mu g/m^3$). Even the passages from the Staff Paper and Criteria Document cited by EPA's attorneys support the position that the study should have been given at least some weight. See EPA Br. 55 (Gauderman study was

"fairly strong evidence" of association between $PM_{2.5}$ exposure and morbidity).[5] Indeed, the Administrator referred to the study's "important new findings." 71 Fed. Reg. 61,172. Yet EPA has advanced no principled reason for the Administrator's eventual decision to disregard the Gauderman study. Nor has EPA offered a reasoned explanation for the Administrator's use of the precautionary approach to continue regulating rural coarse particles as PM_{10} where the evidence of harm is "inconclusive," see EPA Br. 103-04, yet refusing to strengthen the annual standard despite "fairly strong evidence" that morbidity effects occur at the level of the current standard. This action was plainly arbitrary. See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins., 463 U.S. 29, 43 (1983).

Next, the Administrator erroneously discounted the Gauderman 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," 71 Fed. Reg. 61,172; see EPA Br. 53-54, 57-58. As explained in our opening brief (p. 27), EPA staff concluded that Gauderman's findings were consistent with the 24-City study, which suggested harm to children's lungs at exposures at or below 15 $\mu g/m^3$. The 24-City study was conducted in communities spread throughout the U.S. and Canada, undercutting EPA's attempt to cast Gauderman's findings as relevant to just one area. Even if the Administrator were correct that the Gauderman study only demonstrates harm to children in Southern California from exposure to $PM_{2.5}$ concentrations at or below 15 $\mu g/m^3$, the statute commands that the Administrator take a precautionary approach and not wait until harmful

[5] To the extent that EPA suggests (Br. 56) that the revised 24-hour standard will address morbidity effects, that suggestion can be quickly dismissed given that the Administrator did *not* adopt his staff's recommendation that if he were to keep the 15 $\mu g/m^3$ annual standard, he should adopt a 24-hour standard "within the middle or lower part of the range of 35 to 25 $\mu g/m^3$." Instead, he chose the high end of that range (35 $\mu g/m^3$).

effects are demonstrated nationwide before making the standard adequately protective for all. The Administrator must set the NAAQS at a level that protects "against effects which have not yet been uncovered by research and effects whose medical significance is a matter of disagreement." 647 F.2d at 1154.[6]

Also, EPA erroneously argues (Br. 58-59) that the Court's seminal Lead Industries decision is inapposite here because that case purportedly dealt just with the uncertainty of the effect from a pollutant, not uncertainty concerning the level at which the pollutant causes an adverse effect. To the contrary, the Court in Lead Industries upheld the Administrator's precautionary approach to setting the "level" of the NAAQS for lead with an adequate margin of safety as the statute requires. 647 F.2d at 1161-62. Thus, EPA's constrained reading of the statute's margin of safety requirement finds no support in the decision.

2. The Administrator failed to explain how the annual standard protects sensitive populations with an adequate margin of safety.

In response to State Petitioners' argument (Br. 28-29) that the Administrator failed to explain how the current annual standard protects sensitive populations (such as children) with an adequate margin of safety, EPA cites (Br. 60) to the preamble section where it identified the large number of groups susceptible to harm from exposure to $PM_{2.5}$. However, acknowledging these sensitive groups is not tantamount to explaining how leaving the standard at 15 $\mu g/m^3$ will protect them.

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[6] Even if EPA's approach had support in the statute, it erred by not explaining why the NAAQS for $PM_{2.5}$ may legally be set at a level that does not protect the health of the tens of millions of people living in Southern California who are exposed to $PM_{2.5}$. See American Lung Ass'n v. EPA, 134 F.3d 388, 391-92 (D.C. Cir. 1998) (Administrator erred by failing to adequately explain decision not to establish standard to protect asthmatics despite acknowledged evidence of harm).

EPA also has no answer for State Petitioners' point (State Br. 28) that in setting the annual standard using *mortality* studies, the Administrator failed to explain how this standard would protect sensitive populations from *morbidity* effects – such as chronic respiratory illness – that occur at exposure levels lower than those that cause death. Indeed, as discussed above, the Administrator had before him the Gauderman studies, "fairly strong evidence," Staff Paper at 5-8 (JA-1864), that one sensitive population (children) suffers lung damage at $PM_{2.5}$ concentrations at or below the current standard. Also, the Administrator had staff's findings that the ACS study likely underestimated the effect of $PM_{2.5}$ exposure on less-educated individuals, many of whom likely suffer from pre-existing illness (e.g., hypertension, diabetes, or asthma), another sensitive population identified by EPA in the rulemaking. Rather than citing an explanation in the record of how a standard of 15 $\mu g/m^3$ will protect children and the other sensitive populations that collectively represent 100 million Americans from morbidity effects of exposure to $PM_{2.5}$ at that level, EPA merely repeats (Br. 60) the refrain that the Administrator "found that the most reliable data was from long-term mortality studies, and that the morbidity studies provide an uncertain basis for setting the level of the standard." Regardless, the Administrator has the "heaviest of obligations to explain" how these mortality studies protect sensitive populations with an adequate margin of safety. See American Lung Ass'n, 134 F.3d at 391-92. At a minimum, the case must be remanded to the Agency to provide that explanation.

CONCLUSION

Based on the foregoing, the Court should vacate the Administrator's refusal to revise the annual $PM_{2.5}$ standard to reflect scientific evidence that the current standard does not adequately protect public health with an adequate margin of safety.

Dated: August 22, 2008

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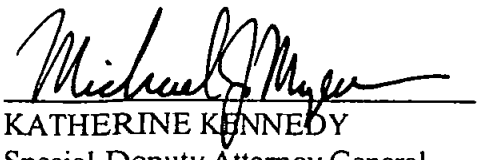
By: 

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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 reply brief of up to 4,375 words). The word count function of the word processing system used to prepare this brief indicates that it contains 4,371 words (inclusive of footnotes and citations but exclusive of tables of contents and authorities, glossary, and attorney's certificates).

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CERTIFICATE OF SERVICE

I hereby certify that on the 22nd day of August, 2008, two copies of the Correct Final Reply Brief of State Petitioners and State Amici 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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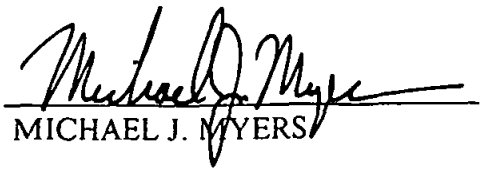

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