

ORAL ARGUMENT SCHEDULED FOR DECEMBER 18, 2001

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 97-1440
& Consolidated Cases
(Particulate Matter NAAQS)

AMERICAN TRUCKING ASSOCIATIONS, INC., *et al.*,
Petitioners

v.

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

On Petition For Review Of A Final Rule Of The
United States Environmental Protection Agency

**BRIEF FOR INTERVENOR-RESPONDENTS MASSACHUSETTS AND NEW JERSEY;
FOR NEW YORK, *et al.*, AMICI IN SUPPORT OF RESPONDENT; AND FOR
INTERVENOR-RESPONDENT AMERICAN LUNG ASSOCIATION**

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Intervenor American Lung Association hereby makes the disclosures required by D.C. Circuit Rule 26.1:

American Lung Association has no parent companies, and no publicly held company has a 10% or greater ownership interest in American Lung Association.

American Lung Association, a nonprofit corporation organized and existing under the laws of the State of Maine, is a national organization dedicated to the conquest of lung disease and the promotion of lung health.

(B) Rulings under Review.

"National Ambient Air Quality Standards for Particulate Matter," 62 Fed. Reg. 38652 (July 18, 1997).

(C) Related Cases.

American Trucking Assns. v. USEPA, D.C. Cir. 97-1441 (and consolidated cases).

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GLOSSARY

APC	Appalachian Power Company
BS	British Smoke
CAA	Clean Air Act
CASAC	Clean Air Scientific Advisory Committee
CO	carbon monoxide
CBT	Citizens for Balanced Transportation
CD	Criteria Document
EPA	Environmental Protection Agency
NAAQS	national ambient air quality standard
NO ₂	nitrogen dioxide
OSHA	Occupational Safety and Health Administration
O ₃	ozone
PM	particulate matter
PM _{2.5}	particles less than or equal to 2.5 microns in diameter
PM ₁₀	particles less than or equal to 10 microns in diameter
RIA	Regulatory Impact Analysis
RR	relative risk
RTC	Response to Comments
SO ₂	sulfur dioxide
SP	Staff Paper
TSP	total suspended particulate
µg/m ³	micrograms per cubic meter

STATUTES AND REGULATIONS

Pertinent statutes and regulations are in an addendum at the end of this brief.

STATEMENT OF ISSUES

1. Whether the arguments raised by State/Industry Petitioners in this remand (a) were rejected by this Court's 1999 decision, or (b) are "preserved" challenges within the proper scope of this remand.
2. Whether the Environmental Protection Agency's (EPA's) decision to set fine particle national ambient air quality standards (NAAQS) was arbitrary, capricious, or not in accordance with law.
3. Whether the 1997 fine particle NAAQS are lower than necessary to protect public health with an adequate margin of safety, and therefore arbitrary and capricious.
4. Whether the Court should vacate the 1997 fine particle NAAQS.

STATEMENT OF THE CASE

This case presents a public health issue of the utmost importance. See Ethyl Corp. v. EPA, 541 F.2d 1, 24 (D.C. Cir. 1976) (recognizing "the special judicial interest in favor of protection of the health and welfare of people"). EPA has concluded that particulate matter concentrations permitted by its pre-existing air quality standards promulgated in 1987 are associated with large numbers of deaths, hospitalizations, and other serious health effects. The agency's conclusion was reached after detailed and thorough consideration of a body of peer-reviewed scientific literature that is far more extensive than that available to the agency in promulgating the 1987 standards, which were upheld by this Court.

Relying on that conclusion, EPA has promulgated air quality standards for fine particles, the particle fraction that is most clearly associated with the observed health effects. 62 Fed. Reg.

38711-12 (July 18, 1997)[JA61-62]. EPA estimates that 3,000-15,000 deaths, 6,000-10,000 hospital admissions for respiratory and cardiopulmonary causes, tens of thousands of cases of respiratory illness, and millions of days of missed work and restricted activity will be prevented just by partial attainment of the new standards. RIA 12-43[JA3486]. Various state and industry petitioners and intervenor-petitioners (collectively, "Petitioners") seek to set aside those standards. Intervenor and amicus states Massachusetts, et al., and intervenor American Lung Association, oppose Petitioners' challenges.¹

SUMMARY OF ARGUMENT

Petitioners' remand briefs assert challenges to EPA's decision to set fine particle NAAQS, and to the level of those NAAQS. The first challenge was rejected in this Court's 1999 decision, and the second is not a "preserved" issue within the scope of the Supreme Court's remand. Alternatively, assuming Petitioners' arguments are properly before the Court, those arguments must be rejected. The record amply supports EPA's decision to set fine particle NAAQS, and refutes any contention that those NAAQS are too stringent.

ARGUMENT

I. PETITIONERS' CHALLENGES HAVE EITHER BEEN REJECTED, OR ARE NOT "PRESERVED."

A. This Court Has Already Upheld EPA's Decision to Set Fine Particle NAAQS.

Petitioners assert various flaws that they claim undermine EPA's decision to set fine particle NAAQS -- including allegations about lack of biological mechanism, confounders, and uncertainties. See, e.g., Pet. Br. 46-49. However, such assertions were made in the 1998

¹ In addition, petitioners Citizens for Balanced Transportation, et al., challenge the fine particle standards as insufficiently stringent. This brief takes no position on that challenge, and "Petitioners" as used herein refers to State/Industry Petitioners.

briefing,² and the Court nonetheless resoundingly upheld EPA's decision to set fine particle NAAQS. American Trucking Assns. v. USEPA, 175 F.3d 1027, 1055-56 (D.C. Cir. 1999).

While most expressly addressed to Petitioners' arguments concerning biological mechanism, the Court's clear decision upholding establishment of fine particle NAAQS necessarily rejected Petitioners' other challenges as well. For example, Petitioners' assertion that "confounding" factors undermine EPA's attribution of health effects to PM_{2.5} was necessarily rejected by the Court's conclusion that "the growing empirical evidence demonstrating a relationship between fine particle pollution and adverse health effects amply justifies establishment of new fine particle standards." 175 F.3d at 1056 (emphasis added). Indeed, the Court expressly noted that this evidence includes "numerous epidemiological studies ... [c]overing diverse geographic locations with widely varying mixes of air pollution," id. (emphasis added) -- a clear reference to one of EPA's primary grounds for rejecting the confounders argument. See pp. 14-15, infra.

Likewise, Petitioners' other challenges to EPA's decision to set fine particle NAAQS -- including arguments concerning the size of relative risk in the epidemiological studies, and uncertainties in the science (see, e.g., Pet. Br. 42 n.161, 46-49) -- were necessarily rejected by the Court's conclusion that epidemiological evidence was sufficient, and that the specific epidemiological studies relied on by EPA "easily" meet the statutory standard. 175 F.3d at 1056 ("[t]he numerous epidemiological studies appearing in this record ... easily satisfy the standard articulated in the statute," and indeed constitute "growing empirical evidence demonstrating a relationship between fine particle pollution and adverse health effects") (emphasis added).

² See, e.g., Non-State Pet. Br. (May 7, 1998) at 26-33.

The Court's 1999 ruling also undermines Petitioners' procedural argument (Pet. Br. 55-60) that EPA allegedly refused to make available data needed for analysis of the confounder issue. Given the Court's solid endorsement of the science demonstrating a causal relationship between fine particles and adverse health effects, and the Court's conclusion that that science amply justifies establishment of new fine particle standards, Petitioners cannot satisfy a key prerequisite for success on a procedural claim: they cannot show "a substantial likelihood that the rule would have been significantly changed" had the alleged procedural errors not been made. See Clean Air Act § 307(d)(8), 42 U.S.C. § 7607(d)(8). See also EPA Br. 42.

B. Petitioners' Challenges to the Level of the Fine Particle NAAQS Have Already Been Rejected, Or Are Not "Preserved."

Petitioners' remand briefs take issue with EPA's choice of levels for the fine particle NAAQS. See, e.g., Pet. Br. 37, 40-41, 49-54. As explained in Part III, below, the record refutes any argument that the chosen levels are too stringent. However, as a threshold matter, these arguments are not even properly before the Court. First, the broad arguments concerning level that Petitioners assert in their remand briefs go well beyond their "preserved" arguments. Second, to the extent Petitioners preserved any arguments concerning the level of the fine particle NAAQS in their 1998 briefs, those arguments were necessarily rejected by this Court in its 1999 decision.

(1) The Challenges to the Level of the NAAQS Now Being Asserted By Petitioners Were Not Preserved.

The Supreme Court's remand to this Court encompasses only "preserved" challenges. Whitman, 121 S. Ct. 903, 914 (2001). To be considered "preserved" under this Court's precedent, an argument must be made in a petitioner's opening brief -- not in its reply brief, at oral

argument, or later.³ Moreover, the argument must have been made in sufficient detail, not in a cursory fashion.⁴

This case illustrates the importance of these principles. As the Supreme Court recognized in Whitman itself, "§ 109(b)(1) and the NAAQS for which it provides are the engine that drives nearly all of Title I of the CAA." 121 S. Ct. at 909 (emphasis added). Accord, Train v. Natural Resources Defense Council, 421 U.S. 60, 66-67 (1975); Union Electric Co. v. EPA, 427 U.S. 246, 258 (1976). Here, EPA long ago determined -- based on evidence upheld by this Court -- that a fine particle standard is needed to protect against serious adverse health effects including many thousands of premature deaths each year, and larger numbers of serious illnesses and missed workdays and schooldays. Four years after they were issued, these much-needed standards are still mired in litigation seeking to undo them. Indeed, the five-year statutory deadline for EPA to review and (as appropriate) revise the 1997 fine particle NAAQS will expire next July -- only seven months after the scheduled argument date in this remand.

³ See, e.g., Benkelman Telephone Co. v. FCC, 220 F.3d 601, 607 n.10 (D.C. Cir. 2000) (argument held "waived because the argument was raised for the first time in the petitioners' reply brief"); Natl. Lime Assn. v. EPA, 233 F.3d 625, 632-33 (D.C. Cir. 2000) (declining to reach argument raised for first time at oral argument, even though it had been raised in petitioner's rulemaking comments).

⁴ See, e.g., Washington Legal Clinic v. Barry, 107 F.3d 32, 39 (D.C. Cir. 1997) (declining to reach argument raised in "bare-bones" and "cursory" fashion); Sierra Club v. USEPA, 167 F.3d 658, 666 (D.C. Cir. 1999) (declining to reach argument presented in "conclusory" manner); Giday v. INS, 113 F.3d 230, 234 (D.C. Cir. 1997) ("although Giday's brief contains a passing reference to an alleged violation of his constitutional due process rights, he provides no support for this argument, and we generally decline to address issues so sketchily briefed"); District No. 1 v. Maritime Administration, 215 F.3d 37, 43 (D.C. Cir. 2000) (declining to reach argument that was "conclusorily asserted" in opening brief); Washington Water Power Co. v. FERC, 201 F.3d 497, 503 (D.C. Cir. 2000) (declining to reach argument "[a]bsent a more direct mention").

Petitioners had a fair opportunity in their 1998 opening briefs to frame and properly brief any issues they wished to present for the Court's consideration. In sharp contrast to their 1998 briefs, which were focused on EPA's authority to set a fine PM standard at all, Petitioners now launch a broad-ranging attack on EPA's line-drawing pursuant to the § 109(b)(1) "requisite" standard -- i.e., on the agency's conclusion that fine particle standards at 15 $\mu\text{g}/\text{m}^3$ annual and 65 $\mu\text{g}/\text{m}^3$ 24-hour, rather than other levels, are "requisite" to protect public health with an adequate margin of safety. See, e.g., Pet. Br. 37, 40-41, 49-54. To shift ground and put forward non-preserved issues at this late date does a deep disservice to public health and the congressional mandate to protect it, as well as to the numerous attorneys, agency staff, and Court personnel who would be burdened by such an unfair and inefficient second bite at the apple.

As EPA itself has previously noted, Petitioners' opening 1998 briefs failed to preserve any arguments regarding the level of the fine particle NAAQS. EPA's 1998 merits brief, referring to the Non-State/Ohio petitioners, stated (at 48 n.39): "These parties do not challenge any specific aspect of the PM_{2.5} standards -- e.g., indicator, averaging time, level or form. Instead, they allege that EPA erred in establishing any fine-particle standards." (First emphasis added.).

In response, Non-State Petitioners' 1998 reply brief (at 1) pointed to pages of their opening brief that they claim had preserved arguments as to level. The cited pages fall far short. Two of them (pp. 9 and 25 -- one of which is not even in the argument section, but rather is in the statement of the case) simply contend that EPA's standards are set at levels stricter than CASAC recommended. The other pages (pp. 29-31) relate to petitioners' arguments regarding the role of confounding factors, arguments that were rejected by the Court in its 1999 holding. Nowhere did State or Industry Petitioners present any discussion or analysis explaining why

EPA's decision where to draw the line was unlawful or arbitrary and capricious. Nor -- of crucial importance given the focus of Petitioners' remand brief -- did any State or Industry Petitioner argue that the chosen fine particle levels fail to meet the § 109(b)(1) "requisite" standard, or present any discussion or analysis supporting such an argument.

Moreover, even Petitioners' statements of issues referenced no claim concerning EPA's line-drawing. The only issue that even referred to the level of the standard was Issue #1 in the Non-State Petitioners' brief (at 1):

Whether the Administrator's determination that adoption of NAAQS for PM_{2.5} at the specified levels is "appropriate" and "requisite to protect the public health" under CAA §109 (the "Administrator's PM_{2.5} determination") is arbitrary, capricious, or an abuse of discretion because it is based on a record that (a) consists of flawed epidemiological studies that did not analyze the possibility that other "confounding" factors had caused the health effects the Administrator attributes to PM_{2.5}, (b) contains no clinical or toxicological studies supporting the existence of adverse health effects, and (c) does not establish a biological mechanism by which PM_{2.5} could cause adverse health effects?

That issue states three specific challenges to the standard adopted by EPA: confounding factors, lack of clinical or toxicological studies, and lack of biological mechanism. It does not even state, let alone preserve, the broad challenge now being advocated by Petitioners. As explained in Part I.B(2) below, to the extent these three issues were preserved by Petitioners' 1998 briefs, they were rejected by this Court.⁵

Petitioners' position appears to be that because the Court's 1999 decision discussed line-drawing, their current line-drawing challenge must be considered preserved. The Court discussed line-drawing, however, solely in the context of the constitutional non-delegation issue.

⁵ In any event, even if the 1998 statement of issues had included a reference to EPA's line-drawing, such a reference would not have "preserved" the issue. As indicated above, under this Court's precedent a mere reference to an issue that is not developed in sufficient detail in the opening brief does not suffice to preserve the issue.

175 F.3d at 1034-40. Here Petitioners are advancing non-constitutional challenges alleging that the fine particle NAAQS are arbitrary, capricious, and not in accordance with law due to allegedly improper line-drawing. That challenge was not preserved by their 1998 opening briefs.⁶

Petitioners also apparently assume that, because Whitman enunciated a holding concerning the standard for setting NAAQS, Petitioners are entitled in this remand to brief the impact of that standard on EPA's line-drawing for the fine particle NAAQS. The Supreme Court, however, did not remand for this Court to entertain any argument that might be suggested to a petitioner by Whitman's holding -- instead, it remanded only for consideration of "preserved" challenges. 121 S. Ct. at 914. Indeed, this Court's briefing order provided: "The briefs shall address only 'preserved challenges' not hitherto resolved by the Supreme Court or by this Court, but may argue the effect of Whitman on those challenges." D.C. Cir. Order of May 29, 2001 (citation omitted; emphasis added). Petitioners' attempt to argue Whitman's effect on non-preserved challenges must be rejected.

(2) If Petitioners Raised Any Arguments Regarding the Level of the Standards, Those Arguments Were Narrow Ones That Were Necessarily Rejected By This Court's 1999 Decision.

Petitioners' 1998 statement of issues, quoted above, states three specific challenges to the standards adopted by EPA: confounding factors, lack of clinical or toxicological studies, and lack of biological mechanism. Each of these challenges was rejected by this Court in its 1999 ruling.

⁶ The Court's 1999 opinion noted (175 F.3d at 1034) that the non-delegation challenge had been raised by Small Business Petitioners. Those petitioners' opening fine particle brief (at 16 & n.17) cross-referenced their ozone brief. That brief (at 20-21) raised a non-delegation challenge (albeit in short, highly general language), but neither it nor any other industry or state 1998 opening brief raised a non-constitutional argument that the fine particle NAAQS were set at levels inconsistent with the § 109(b)(1) "requisite" standard.

Petitioners' 1998 arguments on the role of confounding factors (see Non-State Pet. Br. 27-31) raised no line-drawing challenge to the specific fine particle NAAQS levels chosen, instead arguing that confounders undermined EPA's ability to set any level: "The Core Studies and RA provide the central justification for EPA's standards. If the Core Studies and RA had been corrected through confounder re-analysis, this would have produced a fundamentally different record for the selection of the numerical standards." Id. 31 (emphasis added). In holding that the epidemiological studies sufficed for the setting of a fine particle standard, 175 F.3d at 1055-56, this Court necessarily rejected the argument that the studies' conclusions are undermined by confounding factors -- a holding that applies equally to Non-State Petitioners' argument as to level.

The same can be said for the other two subissues presented in Non-State Petitioners' 1998 opening brief. Since a standard is not a standard without a level, the assertion that a biological mechanism is a prerequisite to the setting of a fine particle standard level necessarily amounts to the assertion that such a mechanism is a prerequisite to the setting of a fine particle standard -- precisely the argument this Court rejected in its 1999 decision. Id. Likewise, to assert that clinical or toxicological evidence is a prerequisite to setting a standard level is to ignore the Court's 1999 holding that such evidence is not a prerequisite to the setting of a standard. Id.

In short, Petitioners' challenges to the level of the standard are not properly before this Court because they have previously been resolved by this Court's 1999 decision, or are not preserved. If the Court nonetheless decides to reach those challenges, they should be rejected for reasons set forth below.

II. EPA PROPERLY DECIDED TO ESTABLISH FINE PARTICLE NAAQS.

A. The Extensive Epidemiological Database Linking Serious Adverse Effects to Fine Particles Amply Justifies Establishment of Fine Particle NAAQS.

Petitioners continue to take issue with EPA's decision to establish fine particle NAAQS. They have not disputed the adverse nature of the public health effects at issue (e.g., death, hospitalization, respiratory illness, and missed work and school days), see 62 Fed. Reg. 38657/1 (1997)[JA7],⁷ but instead challenge EPA's reliance on epidemiological studies, which they claim do not demonstrate causation. See, e.g., Pet. Br. 11-12, 45-48. This Court's 1999 decision resoundingly rejected this argument, see p. 3, supra, and with good reason. Congress recognized that epidemiological studies are one of "four types of evidence which link air pollution to specific health detriment," S. Rep. 403, 90th Cong., 1st Sess. 9 (1967) ("1967 S. Rep."), accord, H. Rep. 728, 90th Cong., 1st Sess. 3 (1967) ("1967 H. Rep."), and indeed has directed EPA to "conduct studies, including epidemiological, clinical, and laboratory and field studies, as necessary to identify and evaluate exposure to and effects of air pollutants on human health." 42 U.S.C. § 7403(d)(1)(A) (emphasis added).

The epidemiological database available to EPA amply justified establishment of fine particle NAAQS to protect against adverse public health effects occurring at particulate concentrations allowed by the prior NAAQS. In contrast to, for example, the 1971 photochemical oxidant NAAQS, which was based on a single epidemiological study,⁸ the 1997

⁷ Petitioners cite EPA's ozone NAAQS preamble for the general proposition that not all respiratory symptoms are adverse, Pet. Br. 42 n.160, but do not dispute EPA's express finding in the particulate matter preamble that the "increased respiratory symptoms" linked to particulate matter constitute "significant adverse health effects." 62 Fed. Reg. 38657/1[JA7].

⁸ 36 Fed. Reg. 8186/2 (1971)[JA(ozone)3539]; 43 Fed. Reg. 26962/2-3, 26965 (table) (1978)[JA(ozone)3516, 3519].

PM NAAQS was based on "[o]ver 60" such studies that "found consistent, positive, significant associations between short-term PM levels and mortality and morbidity endpoints." SP V-54[JA2011]. Of special concern, "[m]any of the studies showing PM effects were conducted in areas where the current PM10 standards are largely met." 62 Fed. Reg. 38665/2[JA15] (emphasis added). Accord, SP, front cover caption[JA1900], CD 13-1[JA1779].

Far from merely expressing "concern[]" about these results, Pet. Br. 19, 40, 48, EPA expressly found that "PM air pollution is likely causing or contributing to significant adverse effects at levels below those permitted by the current standards." 62 Fed. Reg. 38656/2[JA6] (emphasis added).

In sharp contrast to the six sentences that represented EPA's entire explanation of the 1971 PM NAAQS, 36 Fed. Reg. 1502/2 (1971)[JA260], EPA provided thorough and detailed analysis that convinced all four of CASAC's epidemiologists of the need for new NAAQS addressing fine particles, the particle fraction most clearly identified with the effects. Wolff 6/13/96 Ltr., Table 1[JA3165]. Three of those epidemiologists concluded:

EPA has appropriately synthesized this evidence and drawn a responsible public health conclusion, namely, that particulate concentrations at current levels are causally associated with excess mortality and morbidity. Furthermore, we agree that fine particulates, as currently indexed by PM2.5, are the most appropriate indicator for the component of the particulate air mass to which these adverse effects are attributed.

Lippmann 3/20/96 Ltr 7[JA3159] (emphasis added).

B. Petitioners' Attacks on EPA's Decision to Set Fine Particle NAAQS Are Meritless.

(1) Especially Given the Precautionary Nature of the Clean Air Act NAAQS Provisions, the Evidence Available to EPA More Than Suffices to Warrant Establishment of Fine Particle NAAQS.

Petitioners repeatedly claim that EPA's decision to set fine particle NAAQS is undermined by "uncertainties" and "gaps" in the record. See, e.g., Pet. Br. 12, 45-49, 50-54.

Petitioners fundamentally misconstrue the nature of the Clean Air Act NAAQS provisions. As prescribed by the statutory language and legislative history and repeatedly held by this Court (including in an en banc decision that was ratified by the 1977 Amendments), those provisions are precautionary ones that do not require definitive proof as a prerequisite to standard-setting. See Brief of Massachusetts, et al., in No. 97-1441 (10/12/01) at 8-10. Indeed, this Court's prior decision on the 1987 particulate matter NAAQS emphasized this very point. See pp. 20-22, infra.

Moreover, most of the alleged uncertainty cited by Petitioners relates to (1) EPA's quantitative risk assessment, or (2) the agency's discussion of air pollution levels below the level of the 1997 NAAQS. Petitioners' arguments are meritless.

First, EPA clearly stated that it placed little weight on the quantitative risk assessment, and instead relied on the epidemiological studies themselves. See EPA Br. 36 n.27. Petitioners' apparent position that numerical risk assessment is a necessary part of NAAQS-setting (Pet. Br. 41, 47-48) finds no support in the Act or judicial precedent. Indeed, EPA long ago rejected the notion that the agency is statutorily required not only to assess the harmfulness of various pollution levels, but also to quantify how many individuals will come into contact with those levels. See, e.g., 44 Fed. Reg. 8210/1 (1979)[JA(ozone)3488] ("Standards must be based on a judgment of a safe air quality level and not on an estimate of how many persons will intersect given concentration levels. EPA interprets the Clean Air Act as providing citizens the opportunity to pursue their normal activities in a healthy environment."). See also S. Rep. 1196, 91st Cong., 2d Sess. 10 (1970) (NAAQS must protect sensitive citizens "who in the normal course of daily activity are exposed to the ambient environment"), 36 ("Recommendations that children not run to and from school and that events be suspended are not a substitute for reducing pollution.").

Second, EPA statements concerning uncertainties about the effects of pollution below the levels of the 1997 NAAQS in no way undermines the agency's conclusions about the effects of pollution at higher levels. See EPA Br. 30 & n.21.

(2) EPA Considered in Detail, and Properly Rejected, Arguments that "Confounders" Undermine the Agency's Conclusions Concerning the Serious Health Effects of Particulate Matter.

Petitioners continue to argue that the health effects that EPA attributes to particulate matter instead result from "confounders" such as other pollutants. See, e.g., Pet. Br. 46-47. To the contrary, EPA considered this issue in great detail and properly concluded that the alleged confounders cannot explain the health effects observed in the epidemiological studies, and that particulate matter is causally linked to those effects.

Among the epidemiological evidence considered by EPA were numerous studies that expressly incorporate analysis of confounders, yet still showed a statistically significant PM effect. "Since a number of mortality and morbidity studies have shown that the PM effect on health is not sensitive to other pollutants, we may conclude that findings regarding the PM effects are valid." CD 13-57[JA1835].

EPA did not stop there, however. Rather, the agency recognized that concentrations of certain pollutants often rise and fall together, because for example the pollutants are associated with the same pollution sources or weather conditions. CD 12-329-30[JA1703-04]. Where such co-associated pollutants occur in a geographic area, reanalysis of the epidemiological data from that area will not necessarily succeed in sorting out the responsibility of each pollutant for the observed health effects. For example, the reanalysis of Philadelphia data cited by petitioners found that the effects of ozone, CO, and NO₂ "can be substantially separated" from those of TSP and SO₂, but that the effects of TSP "cannot be completely separated from SO₂ ... based solely

on the epidemiological analyses in this single city." 62 Fed. Reg. 38660/3[JA10] (emphasis added).

EPA used two approaches to address this issue. First, rather than considering the epidemiological data from each city in isolation, EPA took an integrative view of that data: "The large number of studies in a number of different geographic areas, provides an opportunity to evaluate the consistency and sensitivity of the PM estimates to different levels of potential influence by weather and copollutants." SP V-55[JA2012]. See 62 Fed. Reg. 38660-61[JA10-11] (quoting report by the Health Effects Institute, which was funded jointly by EPA and industry: "Consistent and repeated observations in locales with different air pollution profiles can provide the most convincing epidemiological evidence to support generalizing the findings from these models.").

Upon examining a range of studies analyzing mortality in different areas, EPA concluded that "the association [of mortality] with PM10 remains reasonably consistent through a wide range of concentrations of these potentially influential pollutants." SP V-56[JA2014]. Accord, CD 12-331-332[JA1705-06]. A letter submitted by three of the four epidemiologists on CASAC agreed:

The most persuasive evidence that the causal agent is some component of the airborne particulate mass is in studies of cities or seasons where other pollutants are present at very low concentrations. Across the range of the 20 studies mentioned above, particulate air pollution is the only pollutant that is consistently associated with excess daily mortality, and the estimate of its effect is relatively stable when adjusted for the presence of co-pollutants.

Lippmann 3/20/96 Ltr 3[JA3155].

Understandably, EPA found "unlikely" the proposition that, in each case where a health effect was observed, the non-PM pollutant was responsible. SP V-56[JA2014].

EPA finds much less plausibility in the argument advanced by some commenters that hypothetical, but as of yet unidentified and unsubstantiated, confounders account for PM associations in each and every study: if SO₂ is absent, then attribute the health effects to O₃; if SO₂ is absent and O₃ levels are low, then attribute the effect to CO or NO₂; if the PM effect is significant even when high levels of SO₂ and O₃ occur, then attribute the effect to humidity; and so on.

RTC A-22[JA344].

In addition to examining epidemiological studies in different areas, EPA also considered non-epidemiologic evidence. For example, concerning the PM-SO₂ interaction in Philadelphia, EPA found that small particles "can more effectively penetrate to the portions of the lung where irritation or other interactions with lung tissues might produce effects," while SO₂ -- absent very high peak levels -- produces only "minimal" deep lung effects. SP V-48-49[JA2005-06]. "This lack of penetration in the lung greatly reduces the likelihood that SO₂ alone could produce significant cardio-pulmonary effects, particularly for sensitive individuals spending more of their time indoors where SO₂ concentrations are low due to rapid removal by indoor surfaces." Id. V-49[JA2006]. In short, "consideration of the observed relationships and relevant information on air quality, indoor exposures, dosimetry, and mechanisms suggest that it is unlikely that an independent effect of SO₂ is occurring that does not involve PM." Id.

Finally, EPA questioned whether SO₂, which is actually a precursor of PM, should be considered a confounder at all, CD 12-335[JA1709] ("[t]here is some question about whether the confounding of certain co-pollutants such as PM and SO₂ should be regarded as true confounding when one pollutant is part of a causal pathway from pollution source to pollution monitor"), and noted that, even in the unlikely event PM-associated health effects in Philadelphia are caused solely by SO₂, "reductions in local and transported SO₂ precursor control prompted by a fine particle standard would reduce health risk." SP VII-12[JA2124].

Just as it sufficed to persuade all four of CASAC's epidemiologists of the need for fine particle NAAQS, see p. 11, supra, EPA's treatment of alleged confounders more than suffices to satisfy the requirements of reasoned decisionmaking under a precautionary statute like § 109(b)(1).

(3) The Strength of the Association Between Particulate Matter and Health Effects Was More Than Sufficient to Document a Serious Public Health Problem at Levels Allowed By the Prior NAAQS.

Petitioners continue to argue that the association between particulate matter and health effects was "weak" -- that is, the "relative risk" in the epidemiological studies was allegedly too small to justify setting fine particle NAAQS. Pet. Br. 42 n.161, 46 n.173, 53 n.198. However, Petitioners themselves state that relative risk in "critical studies" relied upon by EPA was 1.084. Id. 46 n.173. Their assertion that such an increased risk is "little different from '1.0'" -- i.e., little different from a zero increase in risk -- is absurd. A relative risk of 1.084 equals an 8.4% increase in incidence. When viewed in the context of large baseline figures such as total mortality, see, e.g., CD 12-33[JA1407] (annual U.S. mortality exceeds 850,000), risk increases of 8%, 5% or even 1% translate into large absolute numbers of Americans suffering death or serious illness:

Small RR does not imply a negligible health effect. For example, RR = 1.05 per 50 µg/m³ PM₁₀ found in some studies is equivalent to an increase of 10% in mortality rate between days with 50 µg/m³ and the same days with 150 µg/m³ PM₁₀. ... Indeed, it is fortunate that the magnitude of the association is not "large"; RR above 1.5 - 2.0 for these studies noted as being needed to be "strong" enough to be considered strong evidence for causality would imply massive numbers of deaths in urban populations due to current ambient PM exposures.

RTC A22-23[JA344-45]. Moreover, the database available to EPA included many studies -- not just at very high concentrations as in the London 1952 episode, but also at ambient concentrations typical of the United States -- with relative risk above the 1.5-2 level [i.e., 150%

to 200% increase in incidence] advocated by some commenters. RTC 68[JA295] (listing studies with relative risks from 1.53 to 7.03).

Thus, the relative risks in the studies translate into a serious public health problem implicating thousands of deaths, tens of thousands of hospitalizations and illnesses, and millions of missed school days and restricted activity days. The notion that EPA can act only if the incidence of these serious health effects is 40 or 50 times higher (for example, 300% to 400% instead of 8%, as was advocated in Non-State Petitioners' 1998 brief at 13 & n.41) flatly contravenes the Act's mandate to prevent adverse health effects.

EPA considered the relative risk issue in detail, and properly concluded that the relative risks in the epidemiological studies were sufficient to support a finding of causation. 62 Fed. Reg. 38658-59[JA8-9]; RTC 66-68, A-22 to 23, A42 to 44[JA293-95, 344-45, 364-66]; SP V-13 to V-13a, V-55[JA1964-65, 2012]. Moreover, contrary to Petitioners' assertion that EPA failed to consider whether these extensive health effects are "a public health problem," Pet. Br. 42, the agency properly noted that, "[a]lthough the increase in relative risk is small for the most serious outcomes, EPA believes it is significant from an overall public health perspective, because of the large number of individuals in sensitive populations that are exposed to ambient PM, as well as the significance of the health effects involved." 62 Fed. Reg. 38657/1[JA7] (emphasis added).

(4) Prior PM NAAQS Decisions Support Rather Than Undermine EPA's Decision to Establish Fine Particle NAAQS.

Petitioners seek support in EPA's prior PM NAAQS decisions. Pet. Br. 9. However, consideration of those decisions simply underscores the far greater scientific database available to EPA in 1997, and the far more thorough analysis and explanation offered by the agency.

The 1971 PM NAAQS. In 1971, EPA promulgated NAAQS for PM and several other pollutants. 36 Fed. Reg. 8187/2 (April 30, 1971)[JA245]. Recognizing that "[c]urrent scientific

knowledge of the health and welfare hazards of these air pollutants is imperfect," EPA stressed that "the need for increased knowledge of the health and welfare effects of air pollution cannot justify failure to take action based on knowledge presently available." Id. 8186/1[JA244]. In particular, the agency emphasized that scientific certainty was not a prerequisite to setting of NAAQS:

Where the validity of available research data has been questioned, but not wholly refuted, the Administrator has in each case promulgated a national primary standard which includes a margin of safety adequate to protect the public health from adverse effects suggested by the available data.

Id. 8186/2 (emphasis added). The health effects of PM were addressed in three sentences. 36 Fed. Reg. 1502/2 (January 30, 1971)[JA260].

The 1987 PM NAAQS. In 1987, EPA promulgated revised PM NAAQS. 52 Fed. Reg. 24634 (July 1, 1987)[JA208]. While the reference method for the 1971 NAAQS had measured particles up to 25 to 45 microns in diameter ("total suspended particulate", or "TSP"), id. 24635/3[JA209], the 1987 standards addressed particles up to 10 microns in diameter ("PM10"). Id. 24663-64[JA237-38].

EPA emphasized that § 109's margin of safety requirement obligated the agency to act in the face of uncertainty. Id. 24635/1-2[JA209]. Consistent with this approach, EPA proceeded to set revised NAAQS despite significant uncertainties concerning PM and its effects:

- The Administrator did not identify a biological mechanism by which PM causes health effects at ambient levels, but rather relied on epidemiological studies that document correlations between PM concentrations and health effects. Id. 24641/1[JA215].

- The number of available studies was "small." Id. The 24-hour standard was based on several studies of mortality and morbidity in a single city (London), supplemented by two other

studies. Id. 24641-42 Table 1[JA215-16]. The annual standard was based on four studies. Id. 24644 Table 2[JA218]. See 61 Fed. Reg. 65649 n.12 (December 13, 1996)[JA130].

- "None of the published studies used the proposed PM10 indicator. Thus, assumptions must be used to convert the various results to common (PM10) units" 52 Fed. Reg. 24641/1-2[JA 215]. For example, with respect to the London studies -- the only studies cited by EPA as documenting mortality, id. 24641-42 Table 1[JA215-16] -- EPA observed: "given the uncertainties in converting from BS [British Smoke] to PM10 measurements, particularly at lower concentrations, and the possible differences in particulate composition between London at the time the data were gathered and the contemporary U.S., it is difficult to use these studies to set a precise level for a PM10 standard." Id. 24643/1-2[JA 217].

- The studies relied upon to set the 24-hour standard measured health effects following exposure to elevated levels of both PM and sulfur dioxide. Review of the NAAQS for Particulate Matter: Updated Assessment of Scientific and Technical Information (EPA December 1986) ("1986 SP Addendum"), at 43[JA3678] (referring to the London studies, EPA states that "it is still difficult to separate the effects of SO2 and BS on mortality," though the "preliminary" findings of an unpublished study "support the suggestion" that at lower SO2 values mortality effects "may" be associated with PM alone); Lawther, et al., Air Pollution and Exacerbations of Bronchitis, 25 Thorax 525, 535 (1970)[JA2743] (London morbidity study relied on in setting 24-hour NAAQS concluded that "there is no evidence that either of these pollutants [SO2 and smoke] would, by itself, produce the same response"); 1986 SP Addendum 44, 47[JA3679, 3682] (remaining two studies upon which 24-hour standard was based addressed "pollution episodes with elevated 24-hour TSP and SO2 levels," and "it is difficult to separate the effects of particles from SO2"). EPA explained:

The relative importance of SO₂ in these studies cannot be specified, but collectively the data suggest a greater role for particles. Thus the conservative assumption (for particles) is made that the response might have occurred without substantial amounts of SO₂ present.

Id. 51[JA3686] (emphasis added).

EPA proceeded to set NAAQS for PM₁₀ despite these uncertainties. Moreover, the agency made no finding that the 1971 NAAQS were inadequate to protect public health, instead basing revision on its finding that PM₁₀ would be a better indicator of PM health effects than TSP. 52 Fed. Reg. 24638-39[JA212-13].

To specify a level for the revised standards, the agency presented estimates of levels where effects are "likely" (i.e., levels "at or above which a consensus judgment suggests greatest certainty that the effects studied would occur, at least under the conditions that occurred in the original studies") and lower levels where effects are "possible" (i.e., levels at which "the staff found credible scientific evidence suggesting the existence of adverse health effects in sensitive populations, but substantial uncertainty exists regarding the conclusions to be drawn from such evidence"). Id. 24641/3[JA215] (emphasis added). Noting that the margin of safety requirement contemplates NAAQS "at pollution levels below those at which adverse health effects have been found or might be expected to occur in sensitive groups," id. 24641/2 (emphasis added), EPA set the NAAQS within -- and, in the case of the 24-hour standard, near the lower end of -- the "effects possible" range. Id. 24641-42 Table 1, 24643/3, 24644 Table 2, 24645/1[JA215-16, 217, 218, 219].

Industry groups challenged the standards, and this Court upheld them. Natural Resources Defense Council v. Administrator, 902 F.2d 962, 967-74 (D.C. Cir. 1990). The Court noted that it "must defer to the agency's interpretation of equivocal evidence, so long as it is reasonable." Id. 968. Moreover, in light of the Act's "'precautionary'" mandate to protect public health and the

"uncertain or conflicting" evidence, "the court 'will not demand rigorous step-by-step proof of cause and effect.'" Id. (citation omitted). Rather, EPA may "... draw conclusions from suspected, but not completely substantiated, relationships between facts, from trends among facts, from theoretical projections from imperfect data, from probative preliminary data not yet certifiable as "fact," and the like." Id. (citation omitted).

With respect to the 24-hour standard, the Court noted EPA's finding that "[t]he standard is in the lower portion of the range where sensitive, reversible physiological responses of uncertain health significance are possibly, but not definitely, observed in children." Id. 971 (citation omitted). Likewise, EPA had "concluded that a 'substantial margin of safety below the levels at which there is a scientific consensus that particulate matter causes premature mortality and aggravation of bronchitis' is warranted 'because of the seriousness of these effects and because of the recent analyses of daily mortality that suggest adverse effects may occur at particulate matter levels well below the consensus levels.'" Id. (citation omitted). The Court concluded that "[t]he Administrator articulated a satisfactory explanation, which is supported by the record evidence, that levels at the top end of the range might not adequately protect against adverse health effects." Id. (emphasis added).

With respect to the annual standard, the Court noted EPA's reliance on studies that suggested the "possibility" of effects in the range from which the 50 $\mu\text{g}/\text{m}^3$ level was chosen. Id. At the same time, the Court recognized that "[o]ther studies provided evidence of no observed effects at or below 60 to 65 $\mu\text{g}/\text{m}^3$." Id. 971-72. While EPA "admit[ted] that the 50 $\mu\text{g}/\text{m}^3$ did not spring from a bounty of definitive research," the Court found that "such is not required." Id. 972. Rather, "[i]n setting margins of safety the Administrator need not regulate only the known

dangers to health, but may "err" on the side of overprotection by setting a fully adequate margin of safety." Id. (citation omitted; emphasis added).

In short, these earlier PM NAAQS decisions confirm the solid underpinnings of EPA's 1997 decision to establish more protective particle matter NAAQS. In the 1997 rulemaking, EPA had access to a far greater scientific database, including studies using a fine particle indicator; considered a wider range of issues (such as alleged confounders) in far greater detail than ever before; and reached a well-grounded conclusion that adverse health effects were occurring at levels allowed by the previous NAAQS.

III. UNDER WHITMAN, PETITIONERS' CHALLENGE TO THE FINE PARTICLE NAAQS LEVELS MUST BE REJECTED.

The Supreme Court in Whitman interpreted CAA § 109(b)(1) as requiring EPA to establish NAAQS for each listed pollutant "at a level that is requisite to protect public health from the adverse effects of the pollutant in the ambient air." 121 S. Ct. at 912 (internal quotations omitted). "Requisite, in turn, means sufficient, but not more than necessary." Id. (internal quotations and brackets omitted; emphasis added). Accord, id. at 914 (§ 109(b)(1) "requir[es] the EPA to set air quality standards at the level that is 'requisite' -- that is, not lower or higher than is necessary -- to protect the public health with an adequate margin of safety") (emphasis added).

In this case, Petitioners have not challenged the fine particle NAAQS on the grounds that they are insufficiently stringent or, in other words, that they are not low enough. Therefore, if Petitioners have properly raised any issue concerning whether the levels of those NAAQS are requisite, that issue is limited to whether the standards are too low -- i.e., lower than necessary to protect public health with an adequate margin of safety.

A. The 1997 Fine Particle NAAQS Are Not Lower Than Necessary to Protect Public Health with an Adequate Margin of Safety.

There is no merit to Petitioners' contention that the fine particle NAAQS are more stringent than necessary to protect public health with an adequate margin of safety. Initially, Petitioners err by arguing that a new NAAQS is by definition too stringent unless EPA makes an affirmative finding that the preexisting NAAQS was too weak: "Under Whitman, a revised standard is by definition 'more than necessary' if the existing NAAQS is 'sufficient' to address unacceptable health risks." Pet. Br. 40. Whitman imposed no requirement that such a finding be made concerning prior NAAQS, but rather focuses the reviewing court's inquiry on whether the new or revised NAAQS themselves are "requisite."⁹ In any event, EPA did find that adverse health effects were occurring at levels allowed by the prior particulate matter NAAQS. See p. 11, supra. See also EPA Br. 27. Thus, Petitioners' proposed test would not carry the day for them even if accepted.

Petitioners also contend that EPA must determine that the level of revised NAAQS is requisite to address "unacceptable public health risk." Pet. Br. 40-41. Aside from the lack of support for their position in the statute or judicial precedent, the proposed test would not assist Petitioners, because they concede that a "significant" risk suffices. Pet. Br. 48 (emphasis added). As shown in detail in our brief in the ozone case, the "significant risk" standard is a precautionary one that contemplates agency action to protect public health in the face of uncertainty. See Brief of Massachusetts, et al., in No. 97-1441 (10/12/01) at 8-10.

⁹ Indeed, under Petitioners' proposed test EPA would never be able to relax a NAAQS, as the agency did in 1979 for ozone in a decision upheld by this Court. See American Petroleum Institute v. Costle, 665 F.2d 1176 (D.C. Cir. 1981). A relaxation by definition presupposes an existing NAAQS that is sufficient -- indeed, more than sufficient -- to protect public health with an adequate margin of safety.

Under the precautionary approach applicable to NAAQS, Petitioners' contention that the fine particle NAAQS are too stringent is easily refuted. This Court has already accepted the validity of the epidemiological evidence "demonstrating a relationship between fine particle pollution and adverse health effects." 175 F.3d at 1056 (emphasis added). This finding is significant, in light of Whitman's holding that NAAQS must be "requisite to protect public health from the adverse effects of the pollutant in the ambient air." 121 S. Ct. at 912 (emphasis added). See also Lead Industries Assn. v. EPA, 647 F.2d 1130, 1153 (D.C. Cir. 1980); American Lung Association v. EPA, 134 F.3d 388, 389 (D.C. Cir. 1998). Indeed, Petitioners themselves concede that NAAQS must be set "below the level" at which "demonstrated adverse public health effects occur." Brief for Respondents Appalachian Public Power Co., et al., in American Trucking Assns. v. Browner, S. Ct. 99-1426 (Lexis 1999 U.S. Briefs 1426), at 25 (emphasis added).¹⁰

EPA based the fine particle NAAQS on numerous scientific studies showing a statistically significant relationship between fine particle concentrations and death and illness (including hospital admissions) at PM_{2.5} long-term mean daily concentrations of 16 to 21 µg/m³. 62 Fed. Reg. 38676/1[JA26]; SP E-8 to E-10[JA2224-28]. EPA set the annual standard at 15 µg/m³, i.e., just below the lower end of this range. 62 Fed. Reg. 38676/2[JA26]. Indeed, the 15 µg/m³ annual standard is well above the lower limit of long-term mean daily concentrations (11 µg/m³) found to be positively associated with mortality at "nearly" statistically significant

¹⁰ As an example of adverse public health effects, APC's Supreme Court brief cites the London Killer fog. However, over three decades ago Congress criticized "the false impression that air pollution is a health hazard only when unusual weather conditions conspire to produce localized disasters. ... The subtler, less dramatic long-range effects of air pollution are of much more serious consequence to the population as a whole." 1967 H. Rep. 4-5. Accord, 1967 S. Rep. 9. Petitioners do not and cannot contest the adverse nature of death, hospitalization and other important health impacts EPA found are linked to ambient levels of particulate matter.

levels. 62 Fed. Reg. 38676/1[JA 26]. See Ethyl, 541 F.2d at 28 n.58 ("Agencies are not limited to scientific fact, to 95% certainties.").

Nor is the 24-hour standard, set at 65 µg/m³, below the range of levels indicated by the epidemiological studies. To the contrary, the chosen level is above most of the 24-hour concentrations observed in the key studies documenting associations between PM_{2.5} and adverse health effects. See Memorandum of 9/30/96 from Patricia Koman[JA3508] (presenting 98th percentile values from short-term exposure studies).

These NAAQS set in the range where actual scientific studies document adverse effects are to be sharply distinguished from standards set below the scientifically documented range based on extrapolation from studies at higher levels.¹¹ Under precedent such as Whitman and Lead Industries, the 1997 fine particle NAAQS levels cannot be considered too stringent.

B. The Question Whether the Fine Particle NAAQS Are Stringent Enough to Protect Public Health With an Adequate Margin of Safety Is Not Raised By Petitioners.

Petitioners seek particulate matter NAAQS that are less -- not more -- stringent than EPA's 1997 fine particle NAAQS. Pet. Br. 64-66. Accordingly, the second part of the Whitman inquiry -- i.e., whether those NAAQS are sufficiently stringent to protect public health with an

¹¹ See, e.g., Industrial Union Dept. v. American Petroleum Inst., 448 U.S. 607, 652 n.60 (1980) (noting that OSHA had set occupational safety standard for benzene at one ppm, even though "there was no empirical evidence to support the conclusion that there was any risk whatsoever of deaths due to exposures at 10 ppm") (emphasis added); Natural Resources Defense Council v. USEPA, 824 F.2d 1146, 1165 (D.C. Cir. 1987) (discussing nonthreshold carcinogens, court notes that "when a straight line extrapolation from known risks is used to estimate risks to health at levels of exposure for which no data is available," that "[t]his method, which is based upon the results of exposure at fairly high levels of the hazardous pollutants, will show some risk at every level because of the rules of arithmetic rather than because of any knowledge") (emphasis added).

adequate margin of safety -- is not raised by Petitioners, and need not be addressed by the Court in their petitions.¹²

IV. THE COURT SHOULD DECLINE TO VACATE THE 1997 FINE PARTICLE NAAQS.

Petitioners' request to vacate the 1997 fine particle NAAQS (Pet. Br. 60-66) should be rejected. This Court previously declined to vacate those NAAQS in its June 1999 order, and Petitioners have pointed to no grounds for revisiting that decision. See EPA Br. 61-63. Indeed, given that fine particle NAAQS at least as stringent as those promulgated in 1997 are necessary to protect against adverse health effects, see pp. 24-25, supra, any remand could not result in less stringent NAAQS. Accordingly, leaving the 1997 NAAQS in place during any remand could not prejudice Petitioners.

Petitioners assert that EPA on remand will need to consider post-decisional evidence. Pet. Br. 63. Assuming arguendo that EPA must do so, Petitioners utterly fail to establish that such consideration is likely to lead to weaker NAAQS, and there would be no basis for such an assertion. See, e.g., EPA Br. 43 (citing recent scientific data confirming the linkage between fine particles and adverse health effects).

Nor is vacatur justified by Petitioners' allegation that EPA will need to weigh "health disbenefits." Pet. Br. 63 (emphasis added). No petitioner's 1998 opening brief raised a health disbenefit argument concerning the fine particle NAAQS, so such an argument is not a preserved challenge within the scope of this remand. Moreover, even in the ozone case, where such an

¹² That question is raised by the environmental petitioners (CBT, et al.). As indicated above, this brief takes no position on CBT's petition.

argument was raised and resulted in a remand, the Court nonetheless declined to vacate the ozone NAAQS during that remand. 175 F.3d at 1057; 195 F.3d at 10.

Petitioners also argue that, because the Court has vacated the 1997 coarse particle NAAQS, it should vacate the 1997 fine particle NAAQS as well. Pet. Br. 64. To the contrary, one month after the Court vacated the 1997 coarse particle NAAQS, it entered its June 1999 order declining to vacate the fine particle NAAQS. Petitioners offer no grounds for revisiting that order.

Finally, Petitioners argue not only that vacatur would cause no disruption, but that "vacatur is needed to avoid disruption." Pet. Br. 65-66 (emphasis added). Intervenor and Amicus States, each having extensive, real-world experience in developing and implementing programs to address air pollution under multiple NAAQS, disagree and offer the following observations.

The road from EPA promulgation of the fine particle NAAQS to attainment and maintenance thereof involves a number of steps. These include designation of attainment status (CAA §107(d)(1)), state adoption and submittal to EPA of SIP revisions (CAA §110(a)(1)), EPA approval of submitted SIP revisions (CAA §110(k)), and, finally, state and industry implementation of the various control measures contained in the EPA-approved SIP revisions (CAA §179(a)(4)).

The states are currently involved in fine particle monitoring, the planning stage in advance of EPA Federal Register publication of proposed attainment designation. Any burden faced by the states for the next few years would be, at most, de minimis. Further, Petitioners' claims as to confusion in compliance with these CAA requirements are overstated. As noted above, the states already have extensive experience in air quality planning under multiple NAAQS. In addition, EPA provides continuing, significant support, both in the form of grants

(CAA §105) and technical/scientific expertise (CAA §§102-104), to state air pollution planning and control programs, to help deal with any possible confusion.

Industry obligations to implement control measures would be required only in the last stage of the process outlined above. During the current, early planning stages, industry investment is typically limited to advocating its position.

Should Petitioners be successful in obtaining vacatur, it is state planning that would be disrupted and it is Intervenor and Amicus States' citizens, indeed all citizens, living in areas exhibiting unhealthful levels of particulate matter that would continue to experience a significant threat to their health and welfare. During the ensuing delay, EPA would be forced unnecessarily to repeat the process for determining that the pre-existing standard is inadequate and that the fine particle standards now before the Court are requisite to protect the public health with an adequate margin of safety.

CONCLUSION

The Court should deny State/Industry Petitioners' petitions.

DATED: October 12, 2001.

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing BRIEF FOR INTERVENOR-RESPONDENTS MASSACHUSETTS AND NEW JERSEY; FOR NEW YORK, *et al.*, AMICI IN SUPPORT OF RESPONDENT; AND FOR INTERVENOR-RESPONDENT AMERICAN LUNG ASSOCIATION does not exceed 8,750 words, and that two copies each of said brief have been served by United States first-class mail this 12th day of October, 2001, upon the following:

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