

**ORAL ARGUMENT SCHEDULED FOR DECEMBER 18, 2001**

UNITED STATES COURT OF APPEALS  
FOR THE DISTRICT OF COLUMBIA CIRCUIT

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**No. 97-1441**  
& Consolidated Cases  
(Ozone NAAQS)

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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

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**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 Ozone," 62 Fed. Reg. 38856 (July 18, 1997).

(C) Related Cases.

American Trucking Assns. v. USEPA, D.C. Cir. 97-1440 (and consolidated cases).

DATED: October 12, 2001.

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## **GLOSSARY**

APC	Appalachian Power Company
CAA	Clean Air Act
CASAC	Clean Air Scientific Advisory Committee
CD	Criteria Document
EPA	Environmental Protection Agency
FEV1	forced expiratory volume in 1 second
NAAQS	national ambient air quality standard
O3	ozone
OSHA	Occupational Safety and Health Administration
ppm	parts per million
RTC	Response to Comments
SIP	State Implementation Plan
SP	Staff Paper

## STATUTES AND REGULATIONS

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

## STATEMENT OF ISSUES

1. Whether the 1997 ozone national ambient air quality standard (NAAQS) is lower than necessary to protect public health with an adequate margin of safety, and is therefore arbitrary and capricious.
2. Whether the Court should vacate the 1997 ozone NAAQS.

## STATEMENT OF THE CASE

These petitions challenge the decision of the Environmental Protection Agency (EPA) -- consistent with the advice of its statutorily convened science advisory committee -- to promulgate a more health-protective national ambient air quality standard addressing ozone, an air pollutant that represents the primary component of smog. Compare 62 Fed. Reg. 38894-95 (July 18, 1997)[JA39-40] (new standard at 0.08 ppm ozone, averaged over eight hours) with 44 Fed. Reg. 8220/3 (February 8, 1979)[JA3498] (pre-existing standard at 0.12 ppm, averaged over one hour).

Most of the challenges raised by Petitioners have been resolved, either by this Court's 1999 rulings or the Supreme Court in Whitman v. American Trucking Assns., 121 S. Ct. 903 (2001). Citing the Supreme Court's remand for this Court to address "preserved" challenges, Petitioners and intervenor-petitioners (collectively, "Petitioners") argue that the 1997 NAAQS is arbitrary and capricious and unlawful, and should be vacated. Intervenor and amicus states Massachusetts, et al., and intervenor American Lung Association, oppose Petitioners' challenges.

## SUMMARY OF ARGUMENT

Given the scientific record documenting adverse health effects from ozone at levels allowed by the prior ozone NAAQS, including some effects at the level of the new NAAQS, there is no merit to Petitioners' argument that the new NAAQS is lower than necessary to protect public health with an adequate margin of safety. EPA's decision to promulgate a more protective standard is solidly supported by an extensive scientific database including both human clinical and epidemiological studies, as well as by prior ozone NAAQS decisions, and easily passes muster under a precautionary statute like CAA § 109(b)(1).

## ARGUMENT

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, no party has challenged the 1997 ozone NAAQS on the grounds that it is insufficiently stringent -- i.e., not low enough. Therefore, the issue before the Court is whether the standard is too protective, or too low.

### **I. THE 1997 OZONE NAAQS IS NOT LOWER THAN NECESSARY TO PROTECT PUBLIC HEALTH WITH AN ADEQUATE MARGIN OF SAFETY.**

Should EPA have set a less protective standard than the one chosen -- either by simply reaffirming the 1979 standard (0.12 ppm, 1-hour average) or by setting an eight-hour standard at

0.09 ppm, 8-hour average? The clear answer is no, based on the law, the record before EPA, and the agency's findings on that record.

**A. Because Adverse Effects Undisputedly Occur at the Level of the Prior NAAQS, and There Are Even Some Effects at the Level of the New NAAQS, There Is No Merit to Petitioners' Argument that the New NAAQS Is More Protective Than Necessary.**

As the Supreme Court made clear, NAAQS must be set at a level "requisite to protect public health from the adverse effects of the pollutant in the ambient air." Whitman, 121 S. Ct. at 912 (emphasis added). See 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).<sup>1</sup>

Under this undisputed standard, the 1997 NAAQS is clearly not lower (i.e., more protective) than necessary. The record before EPA included compelling scientific evidence showing adverse effects not only at ozone levels allowed by the previous standard (0.12 ppm, one-hour), but even some effects at the more stringent 1997 standard level (0.08 ppm, eight hour).

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<sup>1</sup> 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." H. Rep. 728, 90th Cong., 1st Sess. 4-5 (1967) ("1967 H. Rep."). Accord, S. Rep. 403, 90th Cong., 1st Sess. 9 (1967) ("1967 S. Rep."). Here the record amply supports EPA's findings linking adverse health effects to ambient ozone levels.

**Human clinical data.** For example, EPA noted important new data from laboratory studies on humans:

Based on a significant body of information available since the last review, there is now clear evidence from human clinical studies that O<sub>3</sub> effects of concern are associated with the 6- to 8-hour exposures tested. ... This includes evidence of the following statistically significant responses at 6- to 8-hour exposures to the lowest concentration evaluated, 0.08 ppm O<sub>3</sub>, at moderate exertion: lung function decrements, respiratory symptoms (e.g., cough, pain on deep inspiration), nonspecific bronchial responsiveness, and biochemical indicators of pulmonary inflammation.

62 Fed. Reg. 38863-64[JA8-9] (emphasis added). After considering the results of the clinical studies, and EPA staff's criteria for defining which health effects should be considered adverse (which in turn were based on criteria of the American Thoracic Society), EPA concluded that "responses of some sensitive individuals [to 0.08 ppm] are sufficiently severe and extended in duration to be considered adverse." 62 Fed. Reg. 38864/1[JA9] (emphasis added).

Indeed, Petitioners themselves do not dispute that the data show some adverse effects at 0.08 ppm. Pet. Br. 13 (of those participating in the human clinical studies, "about 10% had FEV decrements of 20% or more at 0.08 ppm"), 14 n.52 (under EPA staff's criteria, temporary lung function changes exceeding 20% are adverse), 21-22 (at 0.08 ppm, some sensitive individuals could experience adverse effects).

The new data also show more extensive adverse effects at a 0.09 standard than at 0.08.

EPA concluded:

Based on EPA's updated analyses of estimated moderate or large decreases in lung function and moderate to severe pain on deep inspiration in outdoor children in nine urban areas (Richmond 1997), a standard set at 0.09 ppm would allow approximately 40 percent to 65 percent more outdoor children to experience such effects than would a 0.08 ppm standard, and approximately 70 to 120 percent more occurrences of such effects in outdoor children per year. ... [T]he differences in these percentages between the two standard levels represent tens of thousands more children, and hundreds of thousands more occurrences of adverse effects in these children, in these nine urban areas alone, for a 0.09 ppm standard as compared to a 0.08 ppm standard.

62 Fed. Reg. 38867-68[JA12-13].

Similarly, EPA found significant differences between 0.08 and 0.09 for overall exposures of concern, which EPA judged “to be an important indicator of the public health impacts of those O<sub>3</sub>-related effects for which information is too limited to develop quantitative estimates of risk:”

Based on EPA’s exposure analysis in the nine urban areas, a standard set at 0.09 ppm would allow more than three times as many children to experience 8-hour average exposures of concern as would a 0.08 ppm standard, with the number of outdoor children likely to experience such exposures increasing from approximately 100,000 to more than 300,000 in the nine urban areas alone, representing an increase from approximately 3 percent to approximately 11 percent of the outdoor children likely to experience such exposures.

Id.

**Epidemiological data.** In addition to the human clinical data, EPA also noted that “[n]umerous epidemiological studies have reported excess hospital admissions and emergency department visits for respiratory causes (for asthmatic individuals and the general population) attributed primarily to ambient O<sub>3</sub> exposures, including O<sub>3</sub> concentrations below the level of the current standard.” 62 Fed. Reg. 38864/1[JA9] (emphasis added). As the Criteria Document noted, these studies “provide strong evidence that ambient exposures to O<sub>3</sub> can cause significant exacerbations of preexisting respiratory disease in the general public at concentrations below 0.12 ppm O<sub>3</sub>.” CD 7-171[JA1624] (emphasis added). EPA concluded that “increased hospital admissions and emergency room visits ... are clearly adverse to individuals.” 62 Fed. Reg. 38864/2[JA9] (emphasis added).

In short, the record documents, and EPA found, adverse health effects at the level of the more lenient 1979 standard (0.12, one-hour average), and even some effects at the level of the 1997 standard itself. The 1997 NAAQS, set in the range where actual scientific studies document adverse effects, is to be sharply distinguished from standards set below the scientifically

documented range based on extrapolation from studies at higher levels.<sup>2</sup> Especially since NAAQS must protect public health against adverse effects, see p. 3, supra (citing caselaw), Petitioners' argument that the 1979 standard was sufficient to protect public health -- and that the 1997 standard is more protective than necessary -- must be rejected.

Similarly, Petitioners' suggestion (at 48) that EPA should have set an eight-hour standard at 0.09 must be rejected. EPA found that an eight-hour standard at 0.09 is roughly equivalent to the 1979 one-hour standard, 61 Fed. Reg. 65725/2[JA51], and Petitioners do not dispute that finding. See Pet. Br. at 48. For the same reason that EPA declined to simply reaffirm the 1979 standard, it properly rejected a 0.09 eight-hour standard as insufficient to protect public health.<sup>3</sup>

**B. Petitioners' Attacks on EPA's Decision to Set a More Protective Ozone NAAQS Are Meritless.**

**(1) The 1997 Ozone NAAQS Was Based on Compelling Scientific Evidence.**

Petitioners take issue with the scientific evidence underlying EPA's decision, characterizing it as "inconclusive" and "highly ambiguous." Pet. Br. 11, 12. To the contrary, the

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<sup>2</sup> 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).

<sup>3</sup> While Petitioners challenge the level of the eight-hour standard, they do not take issue with EPA's decision to change from a one-hour to an eight-hour averaging time. That decision, which reflected CASAC's unanimous recommendation, 62 Fed. Reg. 38,861-62[JA6-7], was based on EPA's finding that an eight-hour averaging time would produce a significantly more uniformly protective national standard, which EPA found to be an important public health policy consideration. Id. 38,862[JA7].

science that led EPA to promulgate a more protective NAAQS is unusually "clear" and "strong," pp. 4-5, supra (quoting EPA), consisting not merely of the animal experimental data on which many agency decisions are based,<sup>4</sup> but also on human experimental data and human epidemiological data documenting effects at ozone levels allowed by the 1979 standard — and even some effects at the level of the 1997 standard itself. 62 Fed. Reg. 38872/1[JA17] ("the bulk of the human health effects evidence supporting a decision on an appropriate O3 standard is based on controlled human exposure studies that relate known O3 exposures directly to responses in individuals"),38865/1[JA10] ("field ... and epidemiological studies" confirmed the results of the clinical studies). These effects were expressly determined by EPA — based on staff recommendations informed by the criteria of the American Thoracic Society — to be adverse for sensitive individuals. Pp. 4-5, supra.<sup>5</sup> Both the decision to adopt an eight-hour standard, and the range from which the standard was chosen, were supported by the Clean Air Scientific Advisory Committee. EPA Br. 38.

Petitioners attack EPA's reliance on human clinical studies, arguing that "the record did not establish whether the kinds of respiratory responses that sometimes occurred in the laboratory occurred in people breathing ambient -- i.e., outside -- air as a result of ozone inhalation." Pet. Br. 13-14. To the contrary, as indicated above, EPA also relied on epidemiological studies that

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<sup>4</sup> See, e.g., Environmental Defense Fund v. EPA, 510 F.2d 1292, 1298-99, 1300 (D.C. Cir. 1975)(upholding EPA decision based on animal data); Troy Corp. v. Browner, 120 F.3d 277, 292 ¶ 4 (D.C. Cir. 1997)(same).

<sup>5</sup> See also Troy, 120 F.3d at 289 (seriousness of pulmonary irritation is "self-evident").

assess correlations between ambient ozone and health effects. But Petitioners are not satisfied with those, either (Pet. Br. 12, 17-18).<sup>6</sup>

Petitioners would place EPA in a Catch-22 situation, in which the agency is unable to rely on either controlled human exposure studies or epidemiological studies. Petitioners' attempt to wall EPA off from consideration of compelling scientific evidence must be rejected. Over three decades ago, Congress recognized that human clinical studies and epidemiological studies are among "four types of evidence which link air pollution to specific health detriment." 1967 S. Rep. 9. Accord, 1967 H. Rep. 3. Indeed, Congress 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." CAA § 103(d)(1)(A), 42 U.S.C. § 7403(d)(1)(A) (emphasis added). Petitioners' attempt to discredit EPA's reliance on such evidence must be rejected.

**(2) Under a Precautionary Statute Mandating Protection Against Incompletely Understood Dangers, Petitioners' Attempt to Deny Protection Against Known Adverse Effects Must A Fortiori Be Rejected.**

Petitioners argue that NAAQS must be based on a finding of "unacceptable public health risk." See, e.g., Pet. Br. 42-44. 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. 42 n.150 (emphasis added). The "significant risk" standard is --

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<sup>6</sup> Petitioners complain that the epidemiological studies linking hospital admissions to ozone concentrations were not based on eight-hour ozone data. Pet. Br. 12, 17-18. Those studies did, however, provide "strong evidence" that the 1979 NAAQS -- which after all, is a one-hour standard -- fails to protect against serious adverse health effects. See p. 5, supra. They also furnish strong evidence for rejecting Petitioners' preferred eight-hour standard at 0.09 ppm: as indicated above, such a standard would be roughly equivalent in protection to the 1979 one-hour standard. See also EPA Br. 27 (explaining that, contrary to Petitioners' assertion, the epidemiological studies are indicative of a significant public health problem).

as confirmed by this Court in a case ratified by Congress in the 1977 Amendments -- a precautionary one. In Ethyl Corp. v. EPA, 541 F.2d 1, 14-15 (D.C. Cir. 1976), this Court interpreted § 109(b)'s mandate for protection of public health with an "adequate margin of safety," § 109(b)(1), finding in that language a congressional directive that NAAQS "be preventive in nature." (Emphasis added.) Accord, Hercules Inc. v. EPA, 598 F.2d 91, 104 (D.C. Cir. 1978) (construing similar phrase in Federal Water Pollution Control Act, Court held that EPA must "protect against incompletely understood dangers to public health ..., in addition to well-known risks"), quoted in Natural Resources Defense Council v. USEPA, 824 F.2d 1146, 1165 (D.C. Cir. 1987) (construing similar phrase in § 112 of Clean Air Act).

In an interpretation addressed inter alia to the "margin of safety" requirement of § 109(b)(1), 541 F.2d at 15, Ethyl rejected industry's argument that EPA was required to document "proof of actual harm" as a prerequisite to regulation, instead upholding EPA's conclusion that the Act contemplates regulation where there is "a significant risk of harm." Id. at 12-13 (emphasis added). Noting the newness of many human alterations of the environment, the Court found:

Sometimes, of course, relatively certain proof of danger or harm from such modifications can be readily found. But, more commonly, 'reasonable medical concerns' and theory long precede certainty. Yet the statutes — and common sense — demand regulatory action to prevent harm, even if the regulator is less than certain that harm is otherwise inevitable.

Id. at 25. Accord, Industrial Union Dept. v. American Petroleum Institute, 448 U.S. 607, 655-56 (1980) (plurality) (agency need not support finding of significant risk "with anything approaching scientific certainty," but rather must have "some leeway where its findings must be made on the frontiers of scientific knowledge," and "is free to use conservative assumptions in interpreting the data," "risking error on the side of overprotection rather than underprotection").

The 1977 Amendments confirmed and adopted the precautionary interpretation enunciated in Ethyl, enacting special provisions (Pub. L. No. 95-95, § 401, 91 Stat. 790-91 (August 7, 1977)) designed to "apply this interpretation to all other sections of the act relating to public health protection." H.R. Rep. No. 294, 95th Cong., 1st Sess. 49 (1977) (emphasis added) ("1977 House Report"). Accord, id. at 50 n.3. See also id. at 51 (amendments are designed inter alia to "emphasize the precautionary or preventive purpose of the act (and, therefore, the Administrator's duty to assess risks rather than wait for proof of actual harm)").<sup>7</sup>

Elsewhere in the 1977 legislative history, the drafters rejected the argument "that unless conclusive proof of actual harm can be found based on the past occurrence of adverse effects, then the [national ambient air quality] standards should remain unchanged," finding that this approach "ignores the commonsense reality that 'an ounce of prevention is worth a pound of cure.'" 1977 House Report at 127.

Under the precautionary approach mandated by the margin of safety requirement, as confirmed by Ethyl and the 1977 Amendments, EPA's decision to set a more protective standard than the prior one easily passes muster. That decision was based, not on mere "reasonable medical concerns' and theory," Ethyl, 541 F.2d at 25, but on "clear" scientific evidence documenting adverse health effects at levels allowed by the 1979 standard, and some effects at the 0.08 ppm level of the new standard. Pp. 4-5, supra. See Ethyl, 541 F.2d at 28 (EPA "must take account of available facts"); id. at 25 ("[s]ometimes, of course, relatively certain proof of

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<sup>7</sup> Section 109 itself was not among the provisions amended, because it had already been found to be precautionary. Ethyl, 541 F.2d at 15. By adopting the precautionary Ethyl interpretation as the uniform basis for standard-setting under the Act — including under § 108, which governs the listing of pollutants for regulation under § 109 — Congress confirmed its approval of that interpretation.

danger or harm from ... [environmental] modifications can be readily found"). Under the Act's precautionary mandate, the Court cannot reject such a standard as overly protective.

**(3) The "Context" of Ozone's Health Effects Supports EPA's Decision to Establish More Protective NAAQS.**

Petitioners incorrectly argue that EPA's decision to establish more protective ozone NAAQS is undermined by the agency's alleged failure to place the health effects evidence "in context." Pet. Br. 40. Accord, id. 44. To the contrary, the record documents the importance of those effects. EPA expressly found that the human clinical studies documented adverse effects for sensitive individuals at 0.08 ppm. 62 Fed. Reg. 38864/1[JA9]. EPA's conclusion that adverse effects were experienced by "some" of the clinical study participants at 0.08 ppm, id., even if interpreted extremely cautiously as encompassing only relatively few of the sixty individuals participating in the two key prolonged exposure studies at that level,<sup>8</sup> would still mean that a significant percentage of exposed individuals can be expected to experience adverse effects at 0.08 ppm. Moreover, because the individuals tested in these studies were all healthy young adults,<sup>9</sup> these results understate the likely impact on sensitive populations such as asthmatics. CD 9-26[JA1767] ("The magnitude of individual changes can become more important in persons with impaired respiratory systems (e.g., asthmatics) who already have reduced baseline lung function.").

Importantly, the clinical study responses were not distributed evenly among all subjects. Rather, as EPA noted, "[t]here is a large range of physiological responses among humans, with at least a 10-fold difference between the most and least responsive individuals." CD 9-4[JA1744].

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<sup>8</sup> See CD 7-58 Fig. 7-4[JA1515] (60 individuals tested at 0.08 ppm, 6.6-hour duration).

<sup>9</sup> See CD 7-54[JA1511] (Horstman and McDonnell).

Indeed, "[i]t is well known that considerable interindividual differences in the magnitude of response to O<sub>3</sub> exposure exist. The individual lung function and, to a lesser extent, respiratory symptom responses to O<sub>3</sub> have been demonstrated to be reproducible over a period of time, indicating that some individuals are consistently more responsive than others to O<sub>3</sub>." Id. 9-19[JA1759].

Thus, in the 6.6-hour experiments at 0.08 ppm, the sixty subjects tested varied greatly in their response, with ten percent exhibiting lung function drops (measured as FEV<sub>1</sub>, the amount of air expelled from the lung in one second) of 20% or more — ranging as high as 25%-37.9%. Id. 7-58 (Fig. 7-4)[JA1515] (bar chart showing FEV<sub>1</sub> decrements); RTC 81 ¶ 5[JA161] (10% of responders had FEV<sub>1</sub> decrement of 20% or more); McDonnell (1991), II-I-316, at 149[JA2775] (highest measured FEV<sub>1</sub> decrement was 37.9%). These decrements were produced under moderate exertion, in contrast to the heavy exertion used in the study that was the key basis for the 1979 standard. 62 Fed. Reg. 38859/3[JA4]. This is of concern because "[m]oderate exertion levels are more frequently experienced by individuals than heavy exertion levels." Id.

Under the criteria set forth in the Staff Paper, which were informed by guidelines of the American Thoracic Society, Staff Paper (SP) 59-60[JA1869-70], FEV<sub>1</sub> decrements >10% that persist >4 hours are adverse if repeated, both for individuals with impaired respiratory systems and sensitive healthy individuals. SP 67, 71-72[JA1876, 1881-82]. Moreover, the Criteria Document indicated that "[t]he magnitude of individual changes can become more important in persons with impaired respiratory systems (e.g., asthmatics) who already have reduced baseline lung function. Any change in function that causes these individuals to drop below 40 to 50% of predicted would be considered clinically adverse." CD 9-26[JA1767]. Given that asthmatics' baseline lung function "can be within the normal range (100 ± 20% predicted) or may be less

than 50% predicted," CD 9-7[JA1747], single ozone exposures causing FEV1 decrements of 30-37.9% will produce adverse effects in many ozone-responsive asthmatic individuals, including many whose baseline function is well above the lower end of the range. In any event, repeated exposures to such decrements would certainly be adverse under the criteria enunciated in the Staff Paper.

In addition to the lung function decrements and symptoms that were quantified in the clinical studies, the scientific record documents potentially more serious effects which -- for ethical and practical reasons -- could not be as readily quantified. See EPA Br. 15-16, 17-18 (discussing significance of evidence showing that ozone increases airway responsiveness, causes inflammation, and increases susceptibility to infection).

Likewise, as EPA has explained, the epidemiological studies document a serious public health problem affecting large numbers of people -- far more than the number actually hospitalized. EPA Br. 27.

The record before EPA also contains statements by those who breathe ozone, attesting to the impact this pollutant has upon their lives:

When I was four years old, I was playing outside on a really hot day and I started wheezing and my lungs started tightening up. So I came in and told my mom.

We went to the doctor the next day and the doctor said I had asthma. The worst thing about having an asthma attack is that it almost feels like you are going to die because your lungs close up and it is really hard to breathe.

The last two summers have been really bad for me. On days when the ozone is bad, I can't even go outside to play.

IV-F-84a at 168-69[JA3394-95] (ten-year-old Bethany Myles of Chicago).

When there are ozone warnings, I can't be out of the air-conditioning. If I do go outside, I have an asthma attack. An asthma attack feels like I am suffocating. No one should have to feel this way.

IV-F-84a at 39[JA3389] (ten-year-old Jeff Damitz of Chicago).

We had at least 26 days this summer of "unhealthful" ground level ozone under the ME [Maine] standard of .08 ppm. That's a big part of our summer, a very big part. This ground level ozone is a real problem, a serious problem.

It's not just a statistical problem, either, because some standard was exceeded. I can feel it personally. I have exercised vigorously outside on "unhealthful" days and become physically sick — a funny nauseous feeling with a headache.

IV-F-102 at 1[JA3380] (Charles M. Sexton of South Portland, ME).

In short, the clinical and epidemiological studies -- when extrapolated to the national population -- belie any suggestion that ozone's adverse effects strike only a few scattered individuals. Especially since NAAQS must protect public health against adverse effects, see p. 3, supra (citing caselaw), there is no basis for Petitioners' argument that the 0.08 ppm 1997 standard is too stringent.<sup>10</sup>

**(4) EPA's Prior Ozone Decisions Support the Agency's Decision to Establish a More Protective NAAQS Here.**

Petitioners attempt to draw support from EPA's prior decisions concerning ozone NAAQS. Pet. Br. 8-10. As EPA explains, however, those earlier decisions did not consider recent scientific evidence documenting adverse health effects at lower ozone concentrations and more moderate exercise levels. EPA Br. 7-9, 15. A more detailed discussion of those decisions follows.

**1971 NAAQS.** In 1971, EPA promulgated an ozone primary NAAQS at 0.08 ppm, averaged over one hour. 36 Fed. Reg. 8187/3 (April 30, 1971)[JA3540]. See American Petroleum Institute v. Costle, 665 F.2d 1176, 1182 (D.C. Cir. 1981) (though the 1971 standard

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<sup>10</sup> Petitioners' argument that some respiratory effects are caused by agents other than ozone, Pet. Br. 14, 44, is no basis for ignoring the Act's clear mandate by denying protection against those effects that are caused by ozone. Indeed, the existence of other burdens on people's lungs makes it more -- not less -- urgent to reduce the burden caused by ozone.

was nominally addressed to photochemical oxidants, compliance was gauged by measuring only ozone). This standard, substantially more stringent than the eight-hour 0.08 ppm NAAQS challenged here, was primarily based on a single epidemiological study, which EPA interpreted as indicating increased incidence of asthma attacks at 0.10 ppm. 36 Fed. Reg. 8186/2[JA3539]; 43 Fed. Reg. 26962/2-3, 26965 (table) (June 22, 1978)[JA3516, 3519]. Thus, the 1971 NAAQS was 0.02 ppm – 20% -- below the EPA-determined lowest effects level. 36 Fed. Reg. 8186/2[JA3539] ("The revised primary standard includes a margin of safety which is substantially below the most likely threshold level suggested by this data.") (emphasis added).

**1979 NAAQS.** In 1979 EPA revised the NAAQS to 0.12 ppm, averaged over one hour. The "key study" underlying this standard (57 Fed. Reg. 35546/3 (August 10, 1992)[JA3465]) was a human clinical study that found "most of the subjects experienced subjective symptoms of discomfort (e.g., congestion, chest pain, and cough) when exposed to 0.15 ppm for one hour under the most stressful exercise protocol (equivalent to running about 6 miles in an hour)." 44 Fed. Reg. 8208/1[JA3486] (emphasis added). EPA rejected the argument that these effects were not of concern because they were reversible:

The criteria document states that physical discomfort, as manifested by symptoms such as difficulty in breathing, chest tightness, and pain on deep inspiration, has usually been observed in clinical studies in conjunction with pulmonary function changes. Even when reversible, respiratory symptoms may restrict normal activity or limit the performance of tasks.

Id. 8207/2-3[JA3485].

Relying on the above study and others, EPA concluded that "the most probable level for adverse health effects in sensitive persons, as well as in healthier (less sensitive) persons who are exercising vigorously, falls in the range of 0.15-0.25 ppm." Id. 8216/1-2[JA3494] (emphasis added). Thus, the selected NAAQS of 0.12 ppm was 0.03 ppm – again, 20% -- below the EPA-

determined probable effects level. In explaining its decision to set the standard at that lower level, EPA noted that the agency was required not only to assess the "[p]robable adverse health effect level in sensitive persons," but also to make a "[j]udgment of a standard level below the probable effect level that provides an adequate margin of safety." Id. 8213/3[JA3491] (emphasis added).

EPA also explained its rejection of an argument that NAAQS should be based, not only on the effects of ozone on exposed individuals, but also on the likelihood that exposure will occur. Id. 8210/1[JA3488] (commenter states: "The standard could be much less stringent without endangering the health of such persons if EPA accounted for the portion of time that persons are indoors and, thus, not exposed to higher ambient concentrations.").

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.

Id. (emphasis added). See also 1970 S. Rep. 10 (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.").

Thus, instead of basing the NAAQS on a quantitative assessment of exposure, EPA simply concluded that

at levels in the range of 0.15-0.25 ppm, adverse health effects will almost certainly be experienced by significant numbers of sensitive persons. Unless the standard is set somewhat below that level, the Agency would not be exercising that degree of prudence called for by the "adequate margin of safety" requirement of the Clean Air Act.

Id. 8217/1[JA3495] (emphasis added). In short, EPA set its standard, not at the level where "significant numbers" of sensitive individuals would "almost" certainly experience adverse effects, but below that level.

EPA's standard was challenged, both by industry and environmental groups, and upheld. American Petroleum Institute v. Costle, 665 F.2d 1176 (D.C. Cir. 1981). The Court noted that "[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. at 1186. The Court also recognized the substantial gaps in EPA's information base:

[T]he Administrator considered the evidence in the record that related to less predictable risks of ozone exposure, a relevant consideration in setting margins of safety. The Administrator considered the lack of medical evidence concerning especially sensitive persons, the possibility that ozone and other pollutants might combine to create cumulative effects, the significance of long-term exposure to otherwise safe ozone levels, inconclusive studies indicating very low ozone damage thresholds, and uncertainties arising from meterological [sic] and calibration errors in measurements.

Id. at 1187 (emphasis added).

**1993 Decision.** When EPA initiated a review of the 1979 ozone NAAQS pursuant to § 109(d), CASAC advised the agency that many of CASAC's members believed the standard provided "little or no margin of safety," and some of them favored lowering the standard to 0.10 ppm or lower. 58 Fed. Reg. 13018/1[JA3459]. Moreover, CASAC's 1989 closure letter noted:

Of particular concern to CASAC is the potential for effects arising from exposures to ozone with daily peak concentrations at or near 0.12 ppm for periods of 6-8 hours and with co-exposure to other pollutants. This concern is due to air quality analyses which have shown that even in areas which do not repeatedly exceed the ozone standard, ozone concentrations can remain close to 0.12 ppm for several hours per day for extended periods of time in summer. There was concern based on recent controlled human exposure, epidemiology and toxicology studies, that such prolonged exposures could result in increased respiratory impairment.

Id. 13018/2[JA3459]. CASAC stated, however, that "it would be some time before enough of this developing information would be published in scientific journals to receive full peer review and, thus, be suitable for inclusion in a criteria document. CASAC concluded such information can better be considered in the next review of the ozone standards." Id. 13018/1[JA3459]. Although the body of peer-reviewed scientific literature on 6-8 hour exposures increased substantially in the four years between CASAC's May 1989 letter and EPA's March 1993 final decision, EPA nonetheless postponed consideration of that literature until the next round of review. Id. 13013[JA3454]. In litigation resulting from that postponement, American Lung Association v. Browner, D.C. Cir. 93-1305, EPA was granted a voluntary remand to consider the new information. Order of June 27, 1994. The decision challenged herein represents EPA's response to that remand, as well as the first ozone NAAQS decision to consider the clinical evidence of adverse health effects at 0.08 ppm. Cf. Pet. Br. 8-10 (erroneously suggesting the contrary).

In short, prior EPA ozone NAAQS decisions -- including two NAAQS promulgations that set standards 20% below the level where adverse effects were documented -- undermine rather than support Petitioners' challenge to NAAQS set in the range where adverse health effects are documented.

## **II. THE COURT SHOULD DECLINE TO VACATE THE 1997 OZONE NAAQS.**

Petitioners' request to vacate the 1997 ozone NAAQS (Pet. Br. 57-62) should be rejected. This Court previously declined to vacate the NAAQS in its 1999 opinions, and Petitioners have pointed to no grounds for revisiting that decision. See EPA Br. 45-48. Indeed, given that an ozone NAAQS at least as stringent as that promulgated in 1997 is necessary to protect against adverse health effects, see pp. 3-6, 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 argue not only that vacatur would cause no disruption but that "disruption will result if the NAAQS is not vacated." Pet. Br. 60 (emphasis in original). 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. These observations also explain why Petitioners are premature in arguing (at 61) that "failure to vacate the revised ozone NAAQS may well 'engender costly compliance activities' by the states that must implement any NAAQS and by the owners and operators of facilities that emit ozone-forming NO<sub>x</sub> and VOC emissions." (Footnote omitted.)

The road from EPA promulgation of the 1997 ozone 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)).

EPA has yet to publish in the Federal Register any proposed attainment designations. Any burden faced by the states for the next few years would be, at most, de minimis. Confusion is not likely to be a significant problem, given that 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 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 ozone, 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 revised ozone standards now before the Court are requisite to protect the public health with an adequate margin of safety.

### CONCLUSION

The Court should deny the petitions for review.

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 12<sup>th</sup> day of October, 2001, upon the following:

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