

ORAL ARGUMENT NOT YET SCHEDULED

United States Court of Appeals
for the
District of Columbia Circuit

No. 06-1410
(consolidated)

AMERICAN FARM BUREAU FEDERATION, et al.,
Petitioners,

v.

ENVIRONMENTAL PROTECTION AGENCY,
Respondent.

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

JOINT BRIEF OF HEALTH AMICI

American Thoracic Society, American Medical Association, American Association
of Cardiovascular and Pulmonary Rehabilitation, National Association for the
Medical Direction of Respiratory Care, and American College of Chest Physicians

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Dated: October 9, 2007

CERTIFICATE AS TO PARTIES, RULINGS AND RELATED CASES

A. Parties and *Amici*. All parties and *amici* appearing before the agency and this Court are listed in Environmental Petitioners' opening brief. Health Amici submitted their Corporate Disclosure statements pursuant to Rule 26.1 along with their motion for leave to participate as *amici*, which this Court granted.

B. Ruling Under Review. All references to the matters at issue appear in Environmental Petitioners' opening brief.

C. Related Cases. The case on review has not previously been before this Court. Health Amici are not aware of any related cases within the meaning of Cir. Rule 28(a)(1)(C).



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GLOSSARY

CAA	Clean Air Act
CASAC	Clean Air Scientific Advisory Committee
NAAQS	National Ambient Air Quality Standard
PM2.5	Fine particulate matter

STATEMENT OF INTEREST

American Thoracic Society, American Medical Association, American Association of Cardiovascular and Pulmonary Rehabilitation, National Association for the Medical Direction of Respiratory Care, and American College of Chest Physicians (“Health Amici”) play a significant role in the fight against lung and heart disease and in the promotion of human health. This Court granted Health Amici’s motion for leave to file this brief.

As associations of professional health care providers, Health Amici daily confront the adverse health effects that fine particulate matter (“PM_{2.5}”) causes. Health Amici have a substantial interest in the instant case because they believe that the Environmental Protection Agency’s (“EPA”) annual standard for PM_{2.5} is insufficiently protective, thereby impeding their efforts to promote human health.

ARGUMENT

In the Clean Air Act (“CAA”), Congress directs the Administrator of EPA to create national ambient air quality standards (“NAAQS”) that are “requisite to protect the public health” while “allowing an adequate margin of safety.” 42 U.S.C. § 7409(b). The Administrator must promulgate NAAQS that will prevent known dangers to public health and protect the public against unidentified or disputed risks. Am. Trucking Ass’ns, Inc. v. EPA, 283 F.3d 355, 370 (D.C. Cir. 2002).

The Administrator must base NAAQS on the scientific evidence, not on economic considerations. Whitman v. Am. Trucking Ass'ns, Inc., 531 U.S. 457, 474 (2001). The Administrator, pursuant to 42 U.S.C. § 7409(d), created the Clean Air Scientific Advisory Committee (“CASAC”) to review the scientific evidence regarding the impacts of criteria pollutants and to recommend air quality standards that science demonstrates are requisite to protect public health.

In this case, CASAC concluded that epidemiological studies provide “clear and convincing scientific evidence” that demonstrates a relationship between PM_{2.5} exposure below annual levels of 15µg/m³ and adverse health outcomes, including severe cardio-respiratory illnesses and death. CASAC Letter at 1 (Sept. 29, 2006) (JA ____). Based on this “clear and convincing” evidence, CASAC recommended lowering the annual PM_{2.5} NAAQS to between 13-14µg/m³. Id. at 2 (noting that every major medical and health group, including Health Amici, agree with CASAC’s recommendations). Despite CASAC’s recommendation, the Administrator refused to lower the annual PM_{2.5} NAAQS below the pre-existing standard of 15µg/m³.

In refusing to lower the annual PM_{2.5} NAAQS below 15µg/m³, the Administrator rejected “clear and convincing” epidemiological studies demonstrating that the general public and susceptible populations will face substantially lower risks of death and adverse health effects if the annual standard

is reduced to 13-14 $\mu\text{g}/\text{m}^3$. The “clear and convincing” evidence establishes that an annual $\text{PM}_{2.5}$ NAAQS of 15 $\mu\text{g}/\text{m}^3$ does not protect the public from the “first adverse health effect” of $\text{PM}_{2.5}$ pollution, Lead Indus. v. EPA, 647 F.2d 1130, 1141 (D.C. Cir. 1980), and is not, therefore, requisite to protect public health with an adequate margin of safety, 42 U.S.C. § 7409(b); Am. Trucking Ass’ns, 283 F.3d at 360.

I. Epidemiological Studies Demonstrate the Relationship between $\text{PM}_{2.5}$ Exposure and Adverse Health Effects.

The Administrator, in retaining the annual $\text{PM}_{2.5}$ NAAQS at 15 $\mu\text{g}/\text{m}^3$, ignored “clear and convincing” epidemiological evidence demonstrating that adverse health effects from exposure to $\text{PM}_{2.5}$ concentrations below 15 $\mu\text{g}/\text{m}^3$. Congress recognizes the importance of using epidemiological studies to identify how exposure to air pollutants affects human health. 42 U.S.C. § 7403(d)(1)(A); see also Ethyl Corp. v. EPA, 541 F.2d 1, 26 (D.C. Cir. 1976) (en banc).

Epidemiological studies provide statistical evidence demonstrating the association between different air pollutants and specific health problems. S. REP. No. 403, 90th CONG., 1st Sess. 9 (1967); accord H. REP. No. 728, 90th CONG., 1st Sess. 3 (1967). Since the first NAAQS in 1971, EPA Administrators have relied on epidemiological studies to promulgate NAAQS. 62 FED. REG. 38,658/3 (July 18, 1997).

Epidemiological studies are useful in setting standards because they measure the effects of real world concentrations of air pollutants, such as PM_{2.5}, on public health. EPA Staff Paper at 2652-53 (JA ____). These studies identify adverse health outcomes across a variety of PM_{2.5} concentrations and evaluate the health outcomes observed at different concentrations. Taken together with the studies demonstrating a specific adverse biological response to PM_{2.5} pollution, (R.D. Brook et al., 2002) (JA ____); (A.J. Ghio et al., 2000) (JA ____); (H. Gong et al., 2000) (JA ____), epidemiological studies provide important information about the impact of PM_{2.5} on public health.

II. Epidemiological Studies Demonstrate Adverse Health Effects Below the Mean Concentration.

An epidemiological study observes health outcomes at various PM_{2.5} concentrations and identifies a mean PM_{2.5} concentration where known adverse health effects are expected. While epidemiological studies provide important evidence on the health impacts of various PM_{2.5} concentrations, those studies are not 100% certain of the mean concentration at which adverse health effects are known.

Recognizing that measurement error may exist, epidemiological studies identify ranges (“standard deviations”) of PM_{2.5} concentrations above and *below* the observed mean concentration that are more or less likely to contain the true mean concentration. The range established by the first standard deviation is

typically 68% likely to contain the true mean concentration. The second standard deviation is 95% likely to contain the true mean concentration. Because adverse health effects are known to occur within the standard deviations, the mean concentration of an epidemiological study does not describe the “first adverse effect level” of PM_{2.5} pollution.

The Administrator should be at least 95% confident that the NAAQS will protect the public health. See Am. Trucking Ass’ns, Inc. v. EPA, 195 F.3d 4, 6-7 & n.1 (D.C. Cir. 1999), rev’d in part on other grounds, Whitman, 531 U.S. 457. Given the mandate of the CAA, the Administrator must promulgate a NAAQS at a level that ensures, with 95% confidence, the protection of public health. This level, inevitably, is lower than the mean concentration identified in epidemiological studies.

Based on some epidemiological studies with mean concentrations slightly above 15µg/m³, the Administrator retained the existing annual standard at 15µg/m³. 71 FED. REG. 61,144, 61,146 (Oct. 17, 2006). Given the Administrator’s duty to set the PM_{2.5} NAAQS at a level sufficient to protect the public from the “first adverse health effect,” Lead Indus., 647 F.2d at 1141, this conclusion was improper.

Although the studies relied on by the Administrator observed mean PM_{2.5} concentrations above 15µg/m³, the first and second standard deviations in those

studies included concentrations below $15\mu\text{g}/\text{m}^3$, establishing that adverse health effects occur at $\text{PM}_{2.5}$ concentrations below $15\mu\text{g}/\text{m}^3$. (C. Pope et al., 1995) (JA ____). Because the “clear and convincing” evidence establishes that adverse health effects occur between $13\text{-}14\mu\text{g}/\text{m}^3$, CASAC Letter at 1 (Sept. 29, 2006) (JA ____), the Administrator failed to “protect the public health” when he relied on the mean concentrations of a few studies without considering the adverse health impacts resulting from $\text{PM}_{2.5}$ levels below the mean concentrations.

III. Epidemiological Studies Demonstrate Statistically Significant Adverse Health Effects Below the Proposed $\text{PM}_{2.5}$ NAAQS.

“Clear and convincing” epidemiological studies establish that adverse health impacts occur below $15\mu\text{g}/\text{m}^3$. Both CASAC and EPA staff scientists recognized that adverse health impacts would occur if the annual $\text{PM}_{2.5}$ NAAQS were retained at $15\mu\text{g}/\text{m}^3$. CASAC Letter at 3-4 (Mar. 21, 2006) (JA ____); EPA Staff Paper at 4-63 to 4-64 (JA ____).

One study evaluated $\text{PM}_{2.5}$ concentrations in six cities and found a correlation between $\text{PM}_{2.5}$ pollution and all-cause, cardiovascular, and lung cancer mortality. Based on the health data gathered, the study authors determined, with 95% confidence, that for every $10\mu\text{g}/\text{m}^3$ increase in the average $\text{PM}_{2.5}$ level, the risk of mortality increases by 16%. (F. Laden et al., 2006) (JA ____). While this study demonstrates that scientific evidence has not yet defined the $\text{PM}_{2.5}$ concentration at which no adverse health effects occur, the evidence

does establish that adverse health effects occur at $13\mu\text{g}/\text{m}^3$, which is the lowest concentration at which CASAC found a sufficiently reliable relationship between adverse health effects and $\text{PM}_{2.5}$ pollution to warrant revision of the NAAQS.

Similarly, a study of nearly 1.2 million adults across fifty cities concluded that the most significant adverse effects from $\text{PM}_{2.5}$ exposure occur at the lower end of the range between $9\mu\text{g}/\text{m}^3$ and $16\mu\text{g}/\text{m}^3$. The mean $\text{PM}_{2.5}$ level of the study was $18.2\mu\text{g}/\text{m}^3$, and the standard deviation of the study was 4.4. Considering the standard deviations, the study observed increased mortality risk from $\text{PM}_{2.5}$ concentrations as low as $9.4\mu\text{g}/\text{m}^3$. (M. Abrahamowicz et al., 2003) (JA ____).

Even slight changes in the annual $\text{PM}_{2.5}$ standard would provide substantially more protection of human health. Lowering the annual $\text{PM}_{2.5}$ standard to $14\mu\text{g}/\text{m}^3$ would avoid up to 11,000 more premature deaths than the current $15\mu\text{g}/\text{m}^3$ standard. Regulatory Impact Analysis at 5-85 (JA ____). Lowering the annual standard to $13\mu\text{g}/\text{m}^3$ would prevent up to 168 deaths annually in Detroit, Michigan, alone. EPA Staff Paper at 4-63 to 4-64 (JA ____). These findings establish that the Administrator, by retaining the annual standard at $15\mu\text{g}/\text{m}^3$, failed to adopt an annual $\text{PM}_{2.5}$ NAAQS “requisite to protect public health.”

IV. Morbidity Effects and Effects on Susceptible Populations Occur at Lower $\text{PM}_{2.5}$ Concentrations Than Mortality Effects Suffered By the General Population.

The adverse health impacts from $\text{PM}_{2.5}$ exposure do not merely include

increased risk of death, but also include morbidity effects—health effects that do not result in death—that begin to occur at lower PM_{2.5} levels than mortality effects. (C. Pope et al., 2002) (JA ____). PM_{2.5} standards that only protect the public from the mortality effects are insufficient to protect the public from the morbidity effects.

The CAA requirement to set NAAQS at the “first adverse health effect” caused by a pollutant, Lead Indus., 647 F.2d at 1141, obligates the Administrator to protect the public from the morbidity effects of criteria pollutants. See (C. Pope et al., 2002) (JA ____). In retaining the annual PM_{2.5} NAAQS, 71 FED. REG. at 61,167-68, the Administrator failed to comply with the CAA by dismissing the well-accepted notion and “clear and convincing” evidence that morbidity impacts, including chronic respiratory disease, cardiopulmonary disease, and lung cancer, occur at lower PM_{2.5} concentrations than mortality. (F. Laden et al., 2006) (JA ____); CASAC Letter at 1 (Sept. 29, 2006) (JA ____); (C. Pope et al., 2002) (JA ____).

Segments of the population, such as children, the elderly, and the infirm are highly susceptible to PM_{2.5} pollution. These sensitive populations suffer adverse health impacts at PM_{2.5} levels below the “first adverse effect level” for the general population. 71 FED. REG. 2620, 2636 (Jan. 17, 2006); (F. Laden et al., 2006) (JA

___). These susceptible individuals amount to approximately one-third of the U.S population. Criteria Document, 9-89 to 9-93 (JA ___).

A NAAQS that is “requisite to protect the public health” must protect these highly susceptible groups from adverse health effects. Lead Indus., 647 F.2d at 1141. In retaining the annual PM_{2.5} NAAQS at 15µg/m³, the Administrator ignored his duty to protect the individuals most susceptible to suffering adverse health effects from PM_{2.5} pollution. See S. REP. No. 91-1196, 91st CONG., 2d Sess. 410 (1970).

Children exposed to PM_{2.5} pollution suffer a significant reduction in lung function, which can lead to severe health problems later in life. (B. Binková et al., 2004) (JA ___). One study conducted with 1,759 fourth-grade students in twelve Southern California communities found that exposure to ambient PM_{2.5} pollution is correlated with significant deficits in respiratory growth. (W. Gauderman et al., 2004) (JA ___).

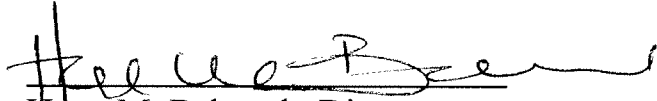
The Administrator failed to consider whether the annual PM_{2.5} NAAQS of 15µg/m³ would protect the health of susceptible populations or the general public from the morbidity effects of PM_{2.5} pollution. The “clear and convincing scientific evidence” demonstrates that the annual standard is not requisite to protect public health with an adequate margin of safety.

CONCLUSION

For the foregoing reasons, this Court should vacate the Administrator's decision not to strengthen the annual PM_{2.5} standard.

Dated: October 9, 2007

Respectfully submitted,

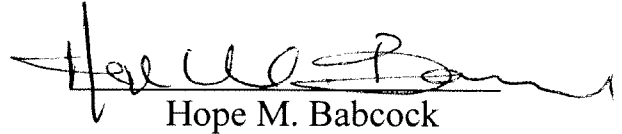


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CERTIFICATE OF COMPLIANCE WITH WORD LIMIT

I hereby certify that the foregoing brief of Health Amici complies with Fed. R. App. P. 32(a)(7), as modified by the Court's July 31, 2007 Order (which permitted Health Amici to file a brief of up to 2,000 words). The word count function of the word processing system used to prepare this brief indicates that it contains 1,969 words (inclusive of footnotes and citations, but exclusive of attorney's certificate).



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I certify that on October 9, 2007, I caused an electronic copy of the foregoing brief and addendum, along with two paper copies mailed by First Class Mail, to be served on the following:

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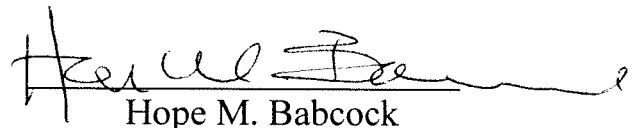
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