ENVIRONMENTAL DEFENSE

January 27, 2006

Clean Air Scientific Advisory Committee
Particulate Matter Review Panel
U.S. Environmental Protection Agency
Science Advisory Board
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460
c/o Mr. Fred Butterfield
Designated Federal Officer
Butterfield.fred@epa.gov

Dear Dr. Henderson and Clean Air Scientific Advisory Committee members,

Thank you once again for the significant time and effort you have invested in reviewing the PM NAAQS. We greatly appreciate your consideration of the following comments on EPA's PM NAAQS proposal. Our comments focus on the proposed annual standard for PM2.5 and on the proposal to limit monitoring for PM10-2.5 to communities with populations greater than 100,000, and to exempt mining and agriculture from regulations aimed at complying with that standard. These comments are submitted on behalf of the more than 400,000 members of Environmental Defense.

Comments on the Annual PM2.5 Standard

The Clean Air Scientific Advisory Committee's (CASAC's) decision to endorse reduction in both the annual standard and the daily $PM_{2.5}$ standard demonstrates its scientific consensus that adverse health effects are caused by exposures below the current annual standard. Specifically, the CASAC recommended lowering the annual standard from 15 $\mu g/m^3$ to between 13-14 $\mu g/m^3$, in conjunction with a more protective daily standard between 30-35 $\mu g/m^3$, in order to protect public health.

The original Six Cities and ACS cohort studies provided clear evidence of a monotonic relationship between particle pollution and mortality down to the lowest levels studied, that is, 11 $\mu g/m^3$ in the Six Cities study, and 9 $\mu g/m^3$ in the ACS study. In addition, a newly-published extension of the Six Cities study (Laden et al., 2006) provides direct, specific evidence for an increased population risk of cardiopulmonary mortality at annual exposure levels well below the current standard.

Specifically, this study, published in January 2006, shows that decreases in $PM_{2.5}$ exposure from levels at or below 15 $\mu g/m^3$ in two of the six cities were associated with a decrease in mortality. Such "intervention" studies in environmental health documenting changes in health outcomes in response to decreases in exposure are rare and extremely valuable.

Beyond this new study, we consider the findings in existing publications sufficiently robust to support lowering the annual $PM_{2.5}$ standard. The HEI reanalysis of the ACS cohort study provides direct evidence for premature mortality associated with annual exposures below 15 $\mu g/m^3$. For example, the standardized residual plot for all-cause and cardiopulmonary mortality shown in figure 6 of Part II of the Krewski et al. 2000 reanalysis (see below in this document) shows the upper 95% confidence limit has a downward trend from 15 to 10 $\mu g/m^3$.

Similarly, the estimation of the impact of cumulative PM exposure during the observation period of the cohort study demonstrates greatest steepness of the concentration response curve at the low end of cumulative exposure. While not an empirical demonstration of the experience of individuals living in areas with annual averages below 15 $\mu g/m^3$, the individuals represented in this part of the curve certainly lived in areas experiencing the lower end of the observed range of exposures in this study. It is worth noting that the effect estimates for a 10 µg/m^3 increase in $PM_{2.5}$ in the ACS cohort follow-up increased as average exposure levels decreased from 21.1 µg/m^3 to 14.0 µg/m^3 (Pope et al., 2002, table 2), and subject-weighted relative risks of death and lung cancer at the mean exposure level of 14.0 µg/m^3 remained significantly increased (ibid., figure 5). Again, this supports the position that serious health effects occur with chronic exposures below this level.

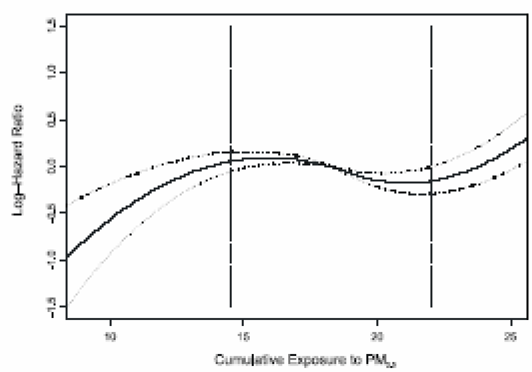

Figure 10. Impact of cumulative exposure to fine particles in the ACS Study. Flexible quadratic spline estimate (3 *df*) of the nonlinear effect of increasing the exposure to fine particles on the log–hazard ratio of mortality in a case-cohort subset of the ACS Study, adjusted for BMI, education level, and pack-years of smoking for current- and former-smokers. The log–hazard ratio was associated with a change in fine particles (24.5 µg/m^3) equal to the difference in mean concentrations between the most-polluted city and the least-polluted city. Along the horizontal axis, the solid curve represents the point estimate of the log–hazard ratio and the dashed curves the point-wise 95% confidence interval. The left and right dashed vertical lines indicate the first and third quartiles of fine particles in the sample of 2,500 individuals included in the ACS Study.

From Krewski et al., Part II, Sensitivity Analysis, (Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality, A Special Report of the Institute's Particle Epidemiology Reanalysis Project) HEI 2000 p. 175

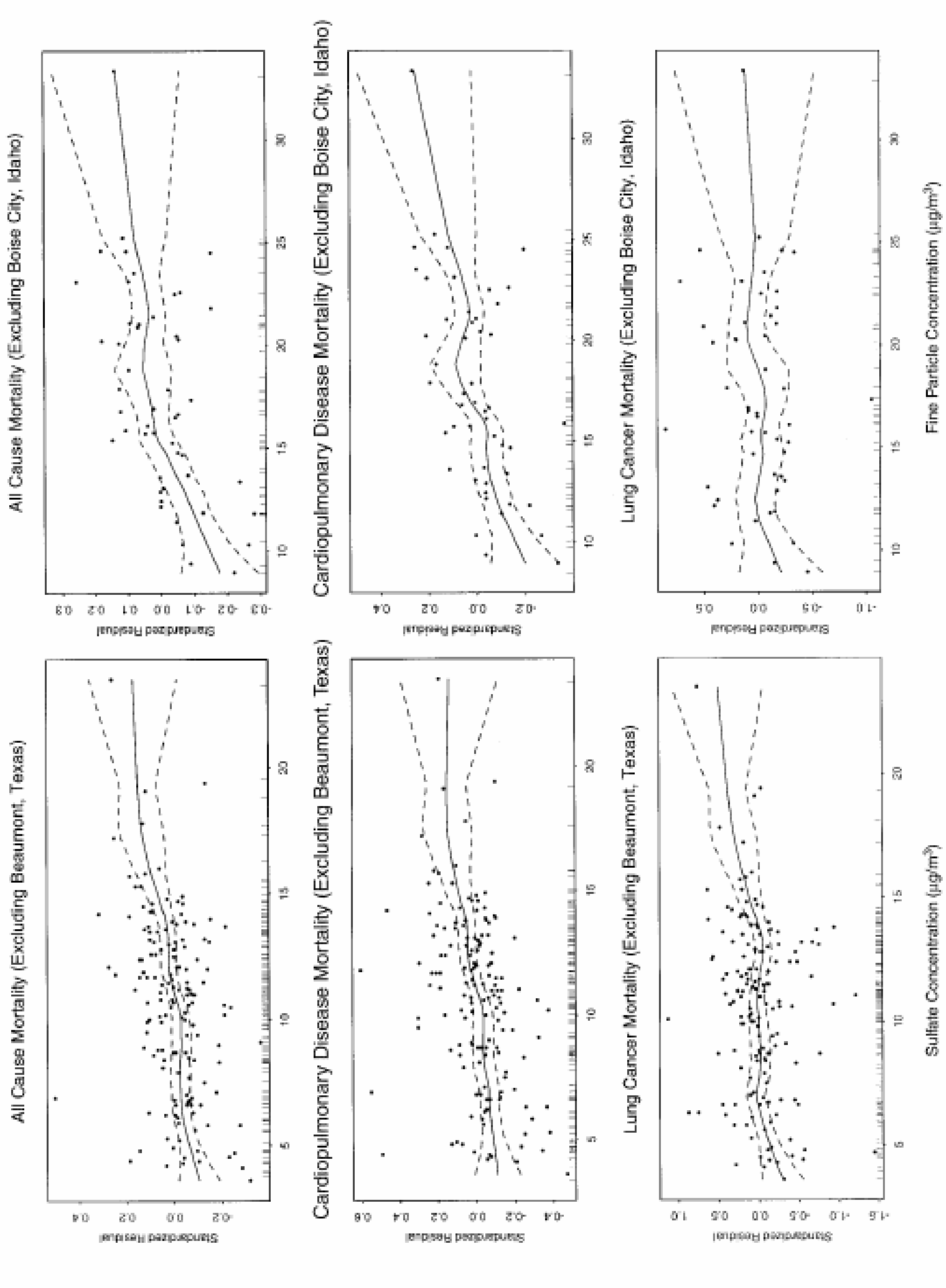

Figure 6. *Shape of concentration-response function (standardized residuals) in the ACS Study.* Standardized residuals of mortality from all causes, cardiopulmonary disease, and lung cancer by ambient concentrations of sulfate (linear-quadratic model) or fine particles (linear-quadratic-cubic model) for the reanalysis of the ACS Study. Based on the Extended Model and calendar year as the time axis. Standardized residual scaled to unity at minimum concentration. Baseline hazard function stratified by 1-year age groups, gender, and race.

From Krewski et al., Part II, Sensitivity Analysis, (Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality, *A Special Report of the Institute's Particle Epidemiology Reanalysis Project) HEI 2000 p. 162*

In addition to these studies of the effects of chronic exposures to $PM_{2.5}$, there is evidence from the literature of acute effects of fine particulates to corroborate that health effects occur from chronic exposures below 15 μg/m^3. Schwartz et al. (2002) used a variety of curve smoothing techniques to demonstrate concentration response relationships well below 15 μg/m^3. Given the plausible shared mechanism of inflammatory cascades being triggered by $PM_{2.5}$ for both acute myocardial infarction and chronic atherosclerosis, the demonstration of increased short-term myocardial infarction risks at daily levels below 15 μg/m^3 may in fact be one of the strongest arguments for promulgating an annual standard below that level.

These rigorous, objective cohort studies performed in the last decade provide evidence to support the occurrence of severe health effects at annual exposure levels below 15 μg/m^3. In the case of the Six Cities and ACS studies, they have been subjected to extremely rigorous auditing and reanalysis, and their results have remained robust. We believe the weight of evidence, as demonstrated above, is without question on the side of increased mortality risk from long-term exposures to $PM_{2.5}$ below 15 μg/m^3. Lowering the annual standard to 12 μg/m^3, or below, in conjunction with a daily standard of at most 25 μg/m^3 is consistent with the best scientific evidence and fulfills the mandate of the Clean Air Act to protect public health, including the health of sensitive populations, with an adequate margin of safety.

<u>Comments on the Coarse PM Standard</u>

Environmental Defense appreciates the consideration CASAC gave to the coarse PM standard after the Staff Paper was released this past summer. We support a standard set at a level of 30 $\mu g/m^3$, which is lower than the range you recommended. We also continue to believe that this standard must be set to protect all Americans, as required by the Clean Air Act. Because EPA has not demonstrated that "urban-type" coarse PM is not present in many communities with population less than 100,000, and because in fact the same sources and processes (e.g., traffic, road dust, industrial sources) can affect communities of all sizes, a protective standard must be established and applied across the country.

While we continue to disagree with your recommendation that EPA specify an "urban" coarse particle indicator, we appreciated the Committee's emphasis on the need for further research on the composition and health impacts of coarse-mode particles found in rural as well as urban areas. In your September 15, 2005 letter to Administrator Johnson, you said "CASAC recommends that monitoring of both rural and urban areas be done for total particulate levels, size distribution and composition. It is essential to have data collected on a wide range of both urban and rural areas in order to determine whether or not the proposed $UPM_{10-2.5}$ standard should be modified at the time of future reviews."

EPA's proposed monitoring rule for PM10-2.5 directly contradicts your recommendation about the need for monitoring in both rural and urban areas, by establishing the requirement that PM10-2.5 monitoring sites must be "within a U.S. Census Bureau defined urbanized area that has a population of at least 100,000 persons," and that the population density of the block group containing the site must be greater than

500 persons per square mile. Figure 1 of the monitoring proposal illustrates the fact that PM10-2.5 monitors would not be required or eligible for comparison with the NAAQS in many rural counties and small and mid-size communities that are currently non-attainment areas for PM10. These communities, for example, include Sheridan, Wyoming and Missoula, Montana. Although there are currently 11 PM10 nonattainment areas within these two states, under EPA's monitoring guidelines, there would be no PM10-2.5 monitors in any of these areas. EPA's monitoring rule thus severely impairs the objective of increasing understanding of the level, size distribution and composition of coarse PM in rural areas and small to mid-size communities.

Environmental Defense also appreciated the emphasis that CASAC placed in its September 15, 2005 letter to Administrator Johnson on viewing the "urban" coarse particle indicator as a "surrogate for the components of the urban coarse PM that differ in composition from coarse-mode particles of natural origin." With regard to this point, we are deeply concerned that EPA's proposal offers a blanket exemption to the agriculture and mining industries from regulation under the proposed PM10-2.5 standard. The docket for the proposed NAAQS contains a draft of EPA's proposal that states that the PM10-2.5 indicator would "exclude any ambient mix of PM10-2.5 dominated by rural windblown dust and soils and agricultural and mining sources <u>that is not enriched with contaminants typical of urban sources</u>." In the final proposal, this sentence was revised to read "exclude any ambient mix of PM10-2.5 that is dominated by rural windblown dust and soils and PM generated by agricultural and mining sources." While the exemptions for agriculture and mining sources are unjustified in any case, a blanket exemption that does not even consider whether coarse PM from these sources is enriched with contaminants that are toxic or typical of urban sources clearly contradicts CASAC's view that the "urban" label was a surrogate for the more toxic components of PM10-2.5, wherever they might be found.

Thank you for considering our views.

Sincerely,

John Balbus, M.D.

Jana Milford, Ph.D., J.D.

Literature Cited

EPA Science Advisory Board/Clean Air Standards Advisory Committee. EPA's Review of the National Ambient Air Quality Standards for Particulate Matter (Second Draft PM Staff Paper, January 2005) *A Review by the Particulate Matter Review Panel of the EPA Clean Air Scientific Advisory Committee.* EPA-SAB-CASAC-05-007. June 2005. Accessed at http://www.epa.gov/sab/pdf/casac-05-007.pdf on11-30-05

Daniel Krewski, Richard T Burnett, Mark S Goldberg, Kristin Hoover, Jack Siemiatycki, Michael Jerrett, Michal Abrahamowicz, Warren H White, and Others (2000) Part II, Sensitivity Analysis, (Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality A Special Report of the Institute's Particle Epidemiology Reanalysis Project) Health Effects Institute, Cambridge, MA.

Laden F, Schwartz J, Speizer FE, Dockery DW. Reduction in Fine Particulate Air Pollution and Mortality: Extended follow-up of the Harvard Six Cities Study. Am J Respir Crit Care Med. 2006 Jan 19; [Epub ahead of print]

Pope CA 3rd, Burnett RT, Thun MJ, Calle EE, Krewski D, Ito K, Thurston GD. Lung cancer, cardiopulmonary mortality, and long-term exposure to fine particulate air pollution. JAMA. 2002 Mar 6;287(9):1132-41.

Schwartz J, Laden F, Zanobetti A. The concentration-response relation between PM(2.5) and daily deaths. Environ Health Perspect. 2002 Oct;110(10):1025-9.