

**Comments on EPA's Second External Review Draft
"Policy Assessment for the Review of the Particulate Matter
National Ambient Air Quality Standards"**

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I am Jon Heuss with AIR, Inc. George Wolff and I provided written comments on the first draft PA.¹ In addition, Charles River Associates, Gradient Corporation, and the American Chemical Council provided important comments.² These submissions raised substantive issues relevant to the policy choices in the PA yet the second draft either does not acknowledge or insufficiently acknowledges the concerns.

The most important points are:

1. The assumption of equal toxicity by PM mass that undergirds the risk analysis is flawed

All the discussions of causality in the IPA must be qualified as they were in the 2004 CD to refer to "PM (or one or more PM component) acting alone and/or in combination with gaseous pollutants" rather than to PM mass alone. In the last review, the Administrator placed little weight on the quantitative risk assessment because it was not clear that controls that would reduce fine PM would also reduce the toxic components. That concern is still relevant.

2. The epidemiological evidence is not as strong or consistent as portrayed in the PA

New large U. S. multi-city studies show that the magnitude of PM associations with acute morbidity and mortality endpoints is smaller than thought in 2004. The pattern in the multi-city studies shows that single-city studies bias the apparent associations upward due to publication bias, provides strong evidence that stochastic variability is greater than heretofore thought, and clear spatial and temporal patterns³ that are not consistent with an

¹ J. M. Heuss and G. T. Wolff, AIR, Inc. Comments on the U. S. EPA's First External Review Draft of the Policy Assessment for Particulate Matter, Air Improvement Resource, Inc. report prepared for the Alliance of Automobile Manufacturers, April 23, 2010; Docket No. EPA-HQ-OAR-2007-0492-0095.1.

² See Docket No. EPA-HQ-OAR-2007-0492-0092.1, Docket No. EPA-HQ-OAR-2007-0492-0096.1, Docket No. EPA-HQ-OAR-2007-0492-0094.1.

³ AIR comments on the draft ISA noted that all of the studies that have examined geographic variability have concluded that the associations are greater in the East compared to the West. These include Peng et al. 2005 and Dominici et al. 2007b for acute PM₁₀ mortality, Zeger et al. 2008 for chronic PM_{2.5} mortality, Franklin et al. 2007 for acute PM_{2.5} mortality, and Dominici et al. 2006 for cardiovascular hospital admissions. In most of these cases there is no significant association in the West. This was also shown in the HEI re-analysis of the ACS study but not

effect of generic PM_{2.5} mass. The PA should acknowledge these patterns and conclude that relying on specific single-city studies in light of the stochastic variation is unsound. All of these findings provide support for the conclusion that the current standards adequately protect the public health.

3. Model selection uncertainty is more important than acknowledged in the PA

The pattern of combined associations in HEI's a recently-released APHENA study is not consistent with what one would expect if PM₁₀ health effect associations have a real physiological basis. The APHENA study is important because PM₁₀ includes both fine and coarse PM and because a more stringent 24-hour PM₁₀ standard is one of the options under consideration to protect against coarse PM effects.

4. If EPA claims that PM mass regardless of composition causes health effects, a comparison with PM risks in other exposure situations is warranted

The cardiovascular health signal relied upon by EPA is not consistent or coherent with fine PM risks from indoor pollution in developed countries, indoor pollution in underdeveloped countries, smoking, and occupational exposures.

5. The arguments the PA uses to defend making the annual PM_{2.5} standard more stringent lack rigor

The cardiovascular signal observed in the Eastern U. S. in the large ACS and Medicare cohorts is not present in the Western U. S. It is also not present in the large cohort study from the Netherlands, Beelen et al., 2008. The spatial differences and inconsistencies in the chronic mortality studies lend additional credence to the conclusion that, to the extent there are positive PM_{2.5} associations, they are caused either by unidentified covariates, by components of PM not PM mass, or by historic high exposures and sources unique to the Eastern U. S. These possibilities are not discussed in the draft PA. Even if these possibilities are dismissed, the Charles River and Gradient comments concerning the lack of knowledge of the appropriate exposure period for attributing effects in the cohort studies that may cause recent associations need to be fully vetted in the PA. Thus, there is substantial evidence in support of retaining the current annual PM_{2.5} standard that is not being considered in the current draft PA. In addition, the draft PA already indicates that consideration should be given to retaining the current 24-hour PM_{2.5} standard.

6. With regard to coarse PM, we agree with EPA that urban and rural coarse thoracic PM should be treated equally.

highlighted. See Grant, L.; EPA Staff Presentation to CASAC, July 23, 2001; Key Revisions and Scientific Issues for Second External Review Draft of Air Quality Criteria for Particulate Matter; Slide 46 indicates an excess risk from 10 µg/m³ PM_{2.5} in the ACS cohort of +29 % in the Industrial Midwest, +25 % in the Southeast, +14 % in the Northeast, and -9 % in the West (West is a combination of cities in the Northwest, Southwest, Upper Midwest, and Southern California. NMMAPS geographic regions).

EPA should focus on identifying the toxic components of ambient PM. Tightening the generic fine or coarse PM standards without knowing what causes the wide variations from positive to negative in acute PM individual-city associations, or region-wide chronic PM associations, at the same PM exposure, is scientifically unsound.

7. Since there is a similar pattern of acute epidemiological associations for each of the criteria pollutants, the extent to which gaseous air pollutants can cause the biological responses attributed to PM in the PA should be rigorously evaluated.

As each criteria pollutant is being reviewed, EPA is using selected single-city single-pollutant associations for that pollutant to set the NAAQS, for example, in the recently completed NO₂⁴ and SO₂⁵ reviews. In the recent ozone proposal, EPA cites epidemiological evidence as a main reason to support the low end of the proposed range for a revised primary standard.⁶ Now in the PM case, selected single-pollutant individual city associations are being used in Chapter 3 to evaluate a range for a potential 98th percentile PM₁₀ standard. Aside from the issues of stochastic variation and publication bias which inflate the apparent strength of single-pollutant associations, reliance on single-pollutant results in potential double- or triple-counting of health effects since single-pollutant models are known to produce results that are biased high. Goodman⁷ notes that depending on published single-estimate, single-site analyses is an invitation to bias.

⁴ 75 Federal Register 6501, February 9, 2010.

⁵ 75 Federal Register 35548, June 22, 2010.

⁶ 75 Federal Register 2997, January 19, 2010.

⁷ Goodman, S. N.; The Methodologic Ozone Effect, *Epidemiology*, **2005**, 16, 430-435.