Julie E. Goodman, Ph.D., DABT
Gradient, Cambridge, MA

on behalf of the
American Petroleum Institute

Comments on US EPA Draft
Risk Assessment to Support the Review of the PM Primary National Ambient Air Quality Standards (September 2009)

FR Doc. E9–21821

October 5, 2009

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First external draft REA (Sept. 2009) does not address uncertainties/variability acknowledged by US EPA in Dec 2005 risk assessment, resulting in erroneous risk estimates

- In the 2006 final rule, US EPA
  - Acknowledged significant uncertainties and variability in the quantitative risk assessment supporting the PM NAAQS review
    - Concentration-response function
    - Confounding and effect modification
    - Measurement error
    - Heterogeneity of $PM_{2.5}$
  - Determined the risk assessment did not provide a basis for determining the level of the $PM_{2.5}$ standard
- The 2009 Draft REA fails to address these uncertainties
  - Leads to inaccurate and imprecise risk estimates

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Health endpoints deemed "likely causal" or "suggestive" should not be considered

- Causality framework
  - Does not properly account for numerous uncertainties in epidemiological studies
  - Does not consider fully other lines of scientific evidence to support epidemiological evidence (*e.g.,* toxicological findings)
- Causal associations in 2009 ISA
  - CV effects associated with short- and long-term $PM_{2.5}$ exposures
- Only CV endpoints should be used in the REA

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Studies used in the REA as basis for C-R functions

- Short-term $PM_{2.5}$ mortality (all-cause, CV, and respiratory)
  - Zanobetti and Schwartz (2009) – 112 cities, average of 0- to 1-day lags
- Short-term $PM_{2.5}$ morbidity (hospital admission for CV and respiratory outcomes)
  - Bell *et al.* (2008) – 202 counties across the US, only people > 65 years of age, CV no lag and respiratory 2-day lag
  - For select cities, single-city estimates of CV and ED visits also used
- Long-term $PM_{2.5}$ mortality (all-cause, cardiopulmonary, IHD, lung cancer)
  - Krewski *et al.* (2009) – extension of the ACS study

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Zanobetti and Schwartz (2009) is inconsistent with similar study and shows no consistent statistically significant effects across regions

- Zanobetti and Schwartz (2009) mortality risk estimates are > 3 times higher than those presented by Dominici *et al.* (2007) in a similar multi-city study (*e.g.*, % increase in all-cause mortality of 0.29 vs. 0.98)
- Effect estimates presented by Zanobetti and Schwartz (2009) vary widely by climatic region for CV and respiratory mortality
- For the majority of regions, mortality effect estimates are not significant

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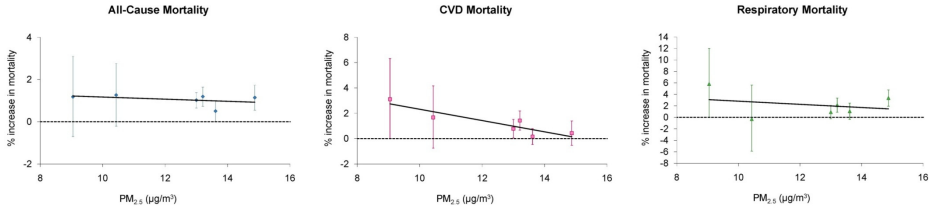
No concentration-response by region



Zanobetti and Schwartz, 2009

- Regional mortality estimates associated with short-term $PM_{2.5}$ generally not statistically significant
- Highest mortality effects observed in the region with the lowest average $PM_{2.5}$ concentrations
- Observed correlations between effects and concentrations are contrary to basic toxicology principles

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Multi-pollutant models should be used in the core analysis

- Co-pollutants confound the associations between $PM_{2.5}$ and various health outcomes (Krewski *et al.*, 2000) and likely yield overestimates of risk
- Single-pollutant models should be considered in the sensitivity analysis

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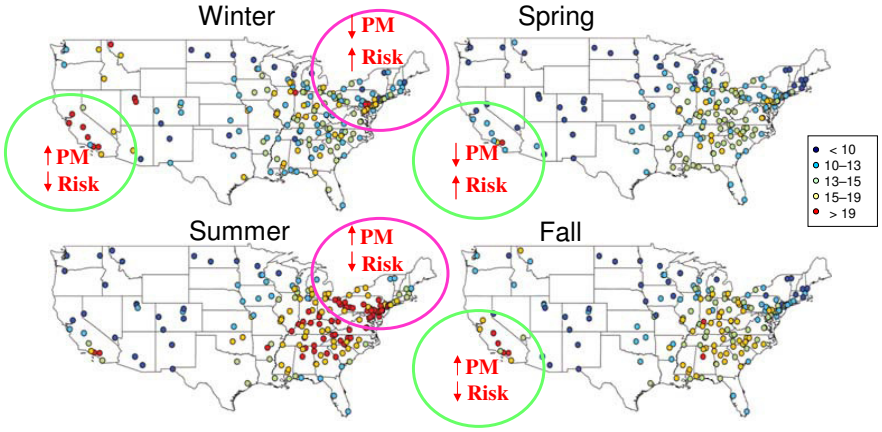
Patterns of effect estimates for CV hospital admissions are inconsistent with patterns of $PM_{2.5}$ concentrations



Bell et al., 2007

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The 2009 REA should not be used to inform a new health-based standard for $PM_{2.5}$

- Many uncertainties remain
- Confounding is still a major issue
- Includes classifications that are not "causal"
- Studies that are the basis for short-term $PM_{2.5}$ effects do not show consistent and statistically significant effects across regions (*i.e.,* patterns are often the opposite of what would be expected)

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Supporting Slides

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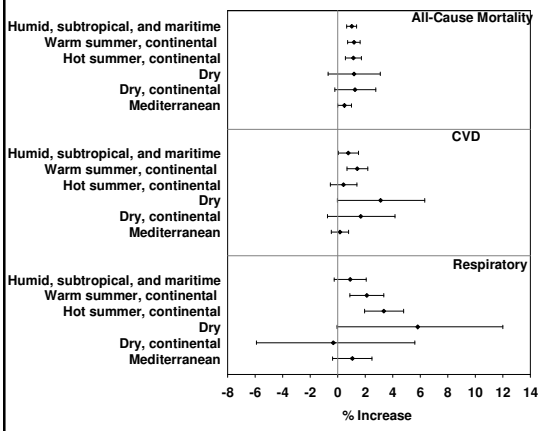
Studies used as the basis for C-R do not show consistent and significant effects across regions



- Figure shows that effect estimates for CVD and respiratory mortality vary widely by region
- In addition, for the majority of regions, effects are not significant

Zanobetti and Schwartz, 2009

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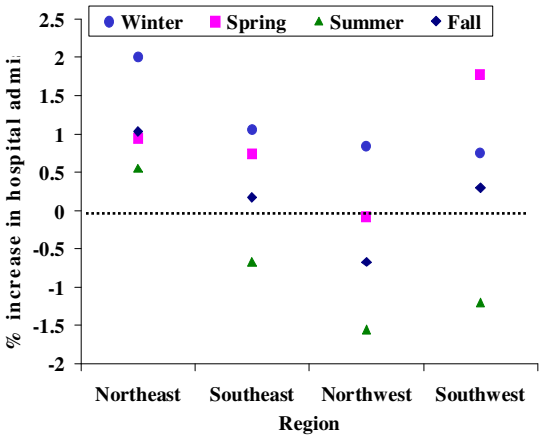
Similar inconsistencies observed for morbidity effects



- Estimated hospital admissions for CV effects vary by region and season
- Only effect estimates for the northeast were statistically significant

Bell et al., 2008

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