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appearing on behalf of the
American Petroleum Institute

regarding the epidemiology evaluation in the
Integrated Science Assessment for Particulate Matter
Second External Review Draft (July 2009)

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Public Comments on the First Draft PM ISA are not Addressed in the Second Draft

- The framework for causality is not consistently applied and does not place enough weight on uncertainties and variability
- The ISA provides a biased portrayal of the data on short- and long-term exposures to PM
 - Majority of studies reported null or weakly positive findings
 - Information on co-pollutants or other exposure-related factors was not included in many studies
 - Exposure misclassification could have biased results in either direction
- Studies relied on to assess the C-R relationship between PM and morbidity or mortality were not sufficient for concluding a linear model
 - Key studies that do not support a linear C-R relationship are not included in ISA
- Available data do not indicate that PM causes additional health effects not identified in the 2004 AQCD for ambient PM

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Short-term Exposure Studies of PM_{10-2.5} and CV Effects

- No new data to support change
- 2nd draft considers both mortality and morbidity

Causal Determination	1st Draft ISA	2nd Draft ISA
CV effects	Inadequate	Suggestive

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Long-term Exposure Studies of PM_{2.5} and CV Effects

- No new data to support change
- US EPA notes inconsistencies in epidemiological data in 1st draft ISA, which only considered morbidity
- 2nd draft considers “both mortality and morbidity as part of a suite of effects”
- CV mortality studies do not support such a change

Causal Determination	1st Draft ISA	2nd Draft ISA
CV effects	Likely	Causal

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Long-term Exposure Studies of PM_{2.5} and Cancer

- No new data to support change
- 2nd draft classification based on
 - Lung cancer mortality studies – vast majority of results are null
 - Toxicological studies using inappropriate exposure routes–intratracheal instillation (results in massive particles in the lung) or dermal
- Associations with DNA damage cannot be linked specifically to PM_{2.5}
- Animal carcinogenicity studies of diesel exhaust, which includes PM, have only shown increased tumor formation at concentrations several orders of magnitude above ambient levels

Causal Determination	1 st Draft ISA	2 nd Draft ISA
Cancer	Inadequate	Suggestive

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Concentration-Response Relationship

- Studies relied on to assess the C-R relationship between PM and morbidity or mortality were not sufficient for concluding a linear model
- Several studies, not in the ISA, support a nonlinear model, including study with ACS dataset
 - Abrahamowitz *et al.*, 2003
 - Nicolich and Gamble, 1999
 - Smith *et al.*, 2000
 - Brauer *et al.*, 2002

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Conclusions

- The framework for causality is not consistently applied and does not place enough weight on uncertainties and variability
- The ISA provides a biased portrayal of the data by emphasizing null or weakly positive findings and studies with no information on co-pollutants
- The data do not support the changes to more conservative classifications in the second draft ISA
- The data are not sufficient for concluding a linear C-R relationship
- The second draft ISA does not provide evidence that supports a causal, likely to be causal, or suggestive of a causal relationship for the association between PM and key health effects at exposure levels below the current annual or 24-hour NAAQS

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Supporting Slides

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2nd Draft PM ISA

- Does not indicate that PM_{2.5} or PM_{10-2.5} cause additional health effects not identified in the 2004 AQCD for ambient PM
- Does not provide reduced uncertainties or stronger evidence for the previously identified effects
- Does not provide evidence that risk estimates for previously identified effects have increased since the last review
- Does not provide further information on the possibility that effects occur at lower levels than previously identified

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Framework for Causality

- Has not significantly changed from the first draft ISA
- Is not consistently applied
- Places too much weight on ecological epidemiology studies
- Does not place enough weight on uncertainties
 - Confounders
 - Measurement error
 - Exposure misclassification
 - Model uncertainty
- Does not adequately consider
 - Weak associations
 - Lack of consistency of observed associations
 - Lack of specificity of exposures and health effects
 - The preponderance of non-statistically significant findings

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Biased Portrayal of the Data on Short- and Long-Term PM_{2.5} and PM_{10-2.5} Exposures

- Majority of studies reported null or weakly positive findings
- Weakly positive findings often became non-significant when adjusted for confounders
- Information on co-pollutants or other exposure-related factors was not included in many studies
- Exposure misclassification could have biased results in either direction
 - Most studies used measurements from central monitors as surrogates for personal exposures
 - Some studies did not measure PM exposures at all
- New data since the first draft ISA do not change the overall weight of the evidence for causality even though several classifications were changed to be more conservative in the second draft ISA

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