Oral Testimony Before the CASAC Ozone Review Panel
on the First Draft Ozone REA

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November 5, 2012

Thank you for the opportunity to speak today on behalf of the American Petroleum Institute. These comments will focus on three main issues with the risk assessment based on the epidemiology evidence in the first draft REA (US EPA, 2012): the calculation of effects down to a zero ozone level, the use of alternative concentration-response functions (CRFs) in the core and sensitivity analyses, and whether results are informative for purposes of the policy assessment. Overall, EPA should not present risk estimates down to a zero level because these are not informative to establishing the NAAQS; EPA needs to consider CRFs based on alternative models; and preliminary risk estimates in the first draft REA should not be used to inform the policy assessment.

The first issue relates to the way EPA used BenMAP to estimate health effects. Rather than its current approach of generating model runs to calculate "total" ozone-related risks down to a zero or lowest measured ambient ozone level, EPA should use BenMAP to directly calculate the change in risk from the differences in recent air quality and levels that meet the current and alternative levels. In doing so, EPA will more easily be able to generate confidence bounds around these estimates, which are important for assessing the level of uncertainty. In addition, these are the only risk numbers that should be used to inform the adequacy of the current standard vs. alternative standards. Generating additional risk estimates, such as estimates for ozone levels down to zero or a lowest measure level, is not an informative approach for determining the adequate level of the standard as it relies on levels of ozone for which there are no epidemiology data, and ozone levels that are unrealistic or unattainable.

There is a substantial amount of uncertainty in the underlying epidemiology studies that form the basis of the core risk estimates. EPA must fully acknowledge the uncertainty and variability in these estimates, including a risk estimate of zero, based on the uncertainty in the epidemiology evidence. In doing so, EPA should use alternative CRFs, including CRFs based on epidemiological studies that account for confounding by co-pollutants such as PM, in the core estimates and sensitivity analyses. Evidence of confounding effects from PM indicate a reduction in risk when PM is included in the model. If confounding is not accounted for in the risk assessment, effect estimates will be overstated. CRFs based on alternative ozone metrics and alternative models should also be included in the risk analysis.

As noted by CASAC, the REA is an incomplete draft document. EPA is proposing substantial changes to the methods that will be used in the second draft, which could substantially change the risk results. In addition, EPA only evaluated a small fraction of the cities, and it did not conduct sensitivity analysis or evaluate alternative levels of the ozone standard. Due to the preliminary nature of the REA results, this draft REA should not be relied on in the policy assessment for determining the adequacy of the current standard.

In conclusion, CASAC should endorse an EPA approach that directly calculates the differences in risk estimates from recent air quality and attainment levels for the current or alternative levels, as these results
would be more informative for the NAAQS process, rather than risks down to zero or the lowest measured limit. In addition, EPA should use alternative CRFs in its risk analysis, including estimates that adjust for co-pollutants, alternative ozone metrics, and model structures. Lastly, results from this first draft REA are incomplete and likely to change in the second draft and thus should not be used to inform recommendation in the policy assessment.

References