

# Testimony Before the CASAC Ozone Review Panel on the Second Draft Ozone Integrated Science Assessment

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Thank you for the opportunity to speak today on behalf of the American Petroleum Institute. I will be discussing two points over the next few minutes. The first is that the causal determination for cardiovascular effects should not be upgraded to "likely," and the second is that EPA should not consider risks down to a zero ozone level.

In its draft letter to the EPA Administrator (US EPA, 2012), CASAC stated that evidence from toxicology, human clinical, and epidemiology studies support a change of the causal determination for cardiovascular effects from "suggestive" to "likely." This is simply not the case. As discussed in the ISA (US EPA, 2011), the epidemiology evidence is limited and lacks coherence among specific endpoints. The animal evidence is only for very elevated ozone concentrations and the outcomes are not consistent with any reported in the human studies. There is no clear mode of action by which ambient ozone could cause cardiovascular outcomes.

It appears that the main bases for EPA's proposed "suggestive" association are the high-exposure animal data and EPA's (and CASAC's) conclusion that there is a likely association between ozone and cardiovascular mortality. In fact, as discussed in more detail in the written comments Gradient submitted in December (Goodman, 2011), there is inadequate evidence to support a "likely causal" determination for cardiovascular mortality, in part because the issue of confounding by PM has yet to be resolved. Thus, the cardiovascular morbidity association should remain, at most,

"suggestive, " and the cardiovascular mortality association should be downgraded to "suggestive," as well.

As for my second point, at the CASAC meeting in January, EPA said it would be considering risks to a zero ozone level in the upcoming risk assessment. While EPA continues to assert that there is no threshold for ozone effects, I point to both the toxicology evidence and the evidence from controlled human exposure studies that suggest otherwise. In addition, several researchers have reported thresholds for ozone, including Stylianou and Nicolich (2009), Xia and Tong (2006), and Smith *et al.* (2009). As discussed by Rhomberg *et al.* (2011), the challenge in identifying a threshold for ozone effects in epidemiological studies stems from the fact that exposure measurement error can linearize concentration-response functions, masking the true threshold. In addition, as noted by EPA, heterogeneity in effect estimates across cities that are combined into one national function can make it difficult to identify a threshold. Finally, assessing risks down to zero does not reflect the reality that a zero ozone level is unattainable. Some level of background ozone should be considered in risk calculations.

In conclusion, the evidence presented in the Second Draft ISA for ozone does not support upgrading the causal determination for short-term cardiovascular disease. Instead, EPA should consider changing the determination for cardiovascular mortality to "suggestive" as well. Also, EPA should not calculate risks to a zero ozone level, as this is not supported by the science.

## References

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