Oral Statement to CASAC on the *Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter, External Review Draft*

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My name is Dr. Anne Smith. My comments here (and that I have provided in more detail in writing to CASAC) are on the quantitative risk analysis in Section 3.3 and Appendix C of the draft PA.

I have a long track record of research on methods of incorporating uncertainty into quantitative risk analyses, and I have authored 7 articles published in the past 5 years specifically focused on how EPA conducts its risk analyses for criteria pollutants like PM2.5. These papers have not been cited in the draft PA.

Based on these, I conclude that the draft PA's risk analysis fails to provide useful or reliable information to support the science-policy judgment that the Administrator must make for the PM NAAQS.

This is because it fails to incorporate the most important types of uncertainty that affect its calculations.

EPA's risk analysis *does* provide what appear to be uncertainty ranges around its risk estimates, but each range actually reflects only one minor form of uncertainty: noise in the data used by epidemiologists to statistically estimate evidence of a PM-health association. This is called "statistical error."

There are a host of other far larger sources of uncertainty that are not at all reflected in those risk ranges. These missing sources of uncertainty are variously called "model uncertainty," "epistemic uncertainty," or "scientific" uncertainty. They arise because *the essence of risk analysis is extrapolation*.

What do I mean by "extrapolation"? An epidemiological study attempts to infer statistically what *did* happen under one set of circumstances, and a risk analysis then attempts to predict what *would* happen under different circumstances. Even statistically-significant epidemiological associations may not be reliable for the kinds of extrapolations that a risk analyst must make. At best, they can serve as a starting point for the risk analyst's deliberations.

This distinction is recognized in the risk analysis profession's paradigm, which identifies four separate structural elements of a sound risk analysis: (1) hazard identification, (2) exposure assessment, (3) dose-response assessment and (4) risk characterization. Risk characterization, which combines information from the exposure and dose-response assessment steps, is the subject of Section 3.3 and Appendix C.

Note, however, the clear distinction in this paradigm between hazard identification and dose-response assessment.

Within this paradigm, epidemiological studies are, first and foremost, for assessing whether a hazard *exists* from exposure to ambient $PM_{2.5}$. Unfortunately, the Agency does not clearly recognize the additional evaluations that are required when shifting from that hazard identification step to the dose-response assessment step. The Agency's analysts simplistically use coefficients from the epidemiological studies *at face value* as a deterministic dose-response formula. This is not sufficient for an informative characterization of risks.

In my own analyses, I have shown that epistemic uncertainties affecting PM2.5 risk calculations do NOT just widen the range about the risk estimate. Rather, they asymmetrically add more probability on the lower rather than higher side of the risk estimate. This is the sort of insight that is of relevance to a decision maker.

Is there a better method to address epistemic uncertainties in the risk analysis than used in the PA? Yes. It is called "integrated uncertainty analysis". One of my papers recounts how the Agency realized over 40 years ago that integrated uncertainty analysis was needed to support a well-informed NAAQS decision. *And that it would entail using subjective judgments about the epistemic uncertainties*.

It's also important for CASAC to recognize that integrated uncertainty analysis was used in the first PM2.5 HREA back in 1997. It can be done!

One of my papers shows how EPA's elimination of such uncertainty from its next 2 PM HREAs rendered them irrelevant to the next 2 PM NAAQS decision makers. The same fate awaits the risk analysis in the draft PA.

Is the BenMAP tool part of the problem? BenMAP cannot perform integrated uncertainty analysis. Instead, BenMAP focuses all of its energy on doing deterministic risk calculations at a level of geographic and demographic disaggregation that is far out of line with our present degree of knowledge about the true risk relationships.

I have submitted written comments that expand on these points. They also summarize each of my 7 recent articles and explain how they stand as a group in support of my conclusions.