

Sheppard Oral Comments on the PM ISA Draft Report **March 28, 2019**

My name is Lianne Sheppard. I am Professor in the School of Public Health at the University of Washington, a previous member of the chartered CASAC, and past Chair of the CASAC NO_x Review Panel.

This Draft Report is a product unmatched in CASAC's history for its inappropriate content and lack of adherence to CASAC's mandate. As stated in the CASAC-approved PM Integrated Review Plan (IRP), CASAC's mandate for the ISA review is to provide "independent review of draft documents for scientific quality and sound implementation of causal frameworks". In the context of this ISA review, CASAC's mandate is not to restructure the scientific review process, impose new conditions for the validity of EPA's scientific review, or to recommend new approaches to developing causal determinations. The Draft Report reveals that *this CASAC* has strayed from its mandate in multiple counterproductive ways. Without corrective action, I believe *this CASAC* will lose all credibility and further undermine the NAAQS process.

This CASAC must explain why it is providing advice that is inconsistent with the structure and purpose of the ISA as described in the IRP. As one small example, *this CASAC*, in strongly recommending that EPA add "empirical tests" to its review, must elaborate on how such tests would be accomplished within the framework of the ISA process and how they will enhance EPA's review of the published literature.
... Otherwise *this CASAC* has no credibility

This CASAC must explain how the studies it claims that EPA omitted from the ISA meet EPA's criteria for inclusion in the ISA, as documented in the IRP.
... Otherwise *this CASAC* has no credibility

This CASAC must back up its claims that "substantial discordant and conflicting evidence remains ignored or unresolved" in the ISA with a complete list of occurrences containing specific details that will empower EPA to follow up.
... Otherwise *this CASAC* has no credibility

This CASAC is recommending that EPA's scientific review rely on papers published by the CASAC Chair. These references must be removed because it is not appropriate for CASAC to promote preferentially its own members' research.
... Otherwise *this CASAC* has no credibility

This CASAC must explain how it thinks its recommendation for an updated Executive Summary that adds multiple complex topics (such as distinguishing types of PM exposure, individual vs. population risks, modeled vs. observed changes in risks, and association vs. causation) will remain an Executive Summary.

.... Otherwise *this CASAC* has no credibility

This CASAC is calling into question the causal determination for the effect of PM_{2.5} on mortality, a judgment that has been settled for years and affirmed by multiple previous CASACs. In doing so, the onus is on *this CASAC* to support its perspective with evidence and explain why its view should supersede all previous determinations. As summarized in the IRP, this ISA builds on previous versions, most notably for determinations CASAC has already accepted as causal. In questioning this causal determination, the Draft Report shows complete lack of appreciation for the ISA plan as outlined in the IRP. If even a few members of *this CASAC* wish to continue to call into question the causality determination for PM_{2.5} effects on mortality, then the onus is on *these CASAC members* to also consider the evidence summarized in previous ISAs, and provide complete and specific rationale for why all those previous CASACs reached an incorrect conclusion.

.... Otherwise *this CASAC* has no credibility

This CASAC is deviating from all previous CASACs in proposing a Draft Report that does not reach consensus. The onus is on the CASAC Chair to work with the entire CASAC to achieve consensus in the Final Report.

.... Otherwise *this CASAC* has no credibility

I see a few glimmers of hope in the Draft Report. The members of CASAC who support the judgment of a causal relationship between PM_{2.5} exposure and mortality have proposed text that is straightforward, crisp and clear, in stark contrast to the rest of the Draft Report. My hope is that you, the current CASAC, will build on this strength and continue the tradition of your predecessors of providing EPA with excellent independent, scientifically appropriate, and useful advice.

Thank you

For the record, I am also submitting my oral clarifying comments delivered at the December 12-13 CASAC meeting for the review of the PM ISA.

Sheppard clarifying comments
December 12, 2018

I had a chance to do a more thorough review of Chapter 3 during today's deliberations. I have multiple suggestions to improve that chapter, suggestions that weren't brought up in CASAC's deliberations. If any EPA staff are interested, please ask me for more input.

I reiterate my comments from this morning. The CASAC process is broken and the sweeping changes that have been made are arbitrary and capricious. Today's deliberations have made it abundantly clear that seven individuals are not sufficiently qualified to conduct the PM review that occurred today. The process changes deserved deliberation well in advance of today's meeting. That deliberation is still needed. As Chris Frey just said, the credibility of this review is contingent on the process. The process is broken.

The job of the CASAC Chair is to not dominate the review, but rather to support and enable a full perspective from the entire Committee. If the Chair speaks more than 20% of the deliberation time, then CASAC is veering dangerously towards being a committee of one. The Chair's effort to set his own CASAC agenda is another profound concern because it veers far from the appropriate Chair role.

I highlight for CASAC the unusually high volume of public commenters today, and the significant fraction of individuals representing themselves. Public comments at CASAC meetings are an essential part of the process, and typically most commenters represent a funded agenda, whether it be an industry, a trade group, a non-government organization, or an advocacy group. Today was different. Many independent scientists have felt compelled to speak up because of their commitment to quality, integrity, and public health, not to mention their perception of profound threats to the process. CASAC should put considerable weight on the concerns of these independent commenters.

I appreciate that you, the chartered CASAC, have been put in an impossible position and that each and every one of you has gamely stepped up to do your best under the circumstances. I urge each of you to find ways you can act to ensure CASAC returns to a scientifically and ethically sound process. This is your public duty. It is profoundly serious and of critical importance to your fellow Americans.

Thank you