

03-22-19 Preliminary Draft Comments on the 03-07-19 Draft CASAC PM ISA Report.

These preliminary pre-meeting comments are from individual members of the CASAC to assist in meeting deliberations and do not represent CASAC consensus comments nor EPA policy.

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Dr. Steven Packham

The Draft Report with the proposed edits in Dr. Lange's 03-20-19 preliminary comments is acceptable to me as written with the exception that I am not in favor of removing the paragraph on page 2 (lines 9 - 12). I accept Dr. Lange's observation that it essentially restates elements of the second and third *fundamental limitations* previously listed in the Draft Report; but I think this paragraph provides important added value in terms of clarity and emphasis.

I also think the four *fundamental limitations* listed in the Draft Report must be addressed in a second draft of the PM ISA. It appears that this will require significant adjustments in drafters' scope and philosophy of science and the reintroduction and use of biological data essentially as presented in the 1996 Air Quality Criteria Document (U.S. EPA, 1996).

Presenting supplementary documentation during next week's teleconference might be considered helpful and supportive of the Draft Report. I would specifically recommend presenting 1) the 1996 AQCD Chapter 10 to address the "*standard scientific method for formatting, testing, modifying and applying predictive hypotheses based on data*" limitation, and the 2013 HEI Perspective 3 Understanding the Health Effects of Ambient Ultrafine Particles showing how hypothetical biological pathways should be presented in scientific reviews; and 2) Pacher et al. (2007) review of Nitric Oxide and Peroxynitrite in Health and Disease as an example of the "*Lack of comprehensive review...*" limitation; and 3) Shah et al. (2008) Effect of Inhaled Carbon Ultrafine Particles on Reactive Hyperemia in Healthy Human Subjects as an example of clinical human studies needing more thorough and transparent integration in a second draft of the ISA to address the "*Lack of scientific support for policy deliberations and decision-making*" limitation.

References

U.S. EPA (U.S. Environmental Protection Agency). (1996). Air Quality Criteria Document for Particulate Matter, Washington, DC.

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