

Sheppard Oral Comments December 12, 2018

Members of CASAC, EPA staff, colleagues, ladies and gentlemen:

I am Lianne Sheppard, professor of Biostatistics and Environmental and Occupational Health Sciences at the University of Washington School of Public Health. I have served on 5 CASAC Panels, and just completed one term as a member of the chartered CASAC. As a public health professional, it has been my honor to serve EPA on CASAC. I believe this service is one of the most effective ways I am able to promote public health and serve the public good. Because I believe in this so strongly, I traveled from Washington State at my own expense to speak to you in person today.

EPA staff know that I provide tough reviews. I can be a harsh critic and I don't hold back when I communicate my concerns about their work. Today the integrated scientific assessment EPA has done for PM is less important than the threats to the scientific review process. While there are many scientific points in the current ISA that could be addressed, where thorough and informed CASAC deliberation will greatly improve the document, it is the process that most risks the integrity of EPA's work under the Clean Air Act.

Before I move to the process, I wish to make some comments on causality, given the apparent efforts by CASAC's Chair to introduce many new causal evidence considerations.

I was invited to be a discussant at the Causal Inference workshop at the HEI annual meeting. This was a daunting

invitation for me because I was and still am far from an expert in causal inference. However, thanks to my colleague Marco Carone, I gained an enormous understanding of the principles of causal inference and was able to provide a high-level perspective on the use of causal inference in air pollution epidemiology. Here are a few key messages:

- We should strive to incorporate causal inference thinking into epidemiologic studies. Even when the causal assumptions fail, the inferences using causal tools can more closely approximate the causal conclusions we wish to draw.
- There is a distinction between causal inference tools used in a single study and the weight of evidence causal determinations that are made by EPA and other regulatory bodies.
- Causal inference methods for application to air pollution studies are in their infancy and we are not ready to require that they be used for regulatory policy. Substantial research in causal inference methods in this context is needed before we will be close to imposing new causal inference requirements on research that informs regulatory policy.
- New methods need to be peer-reviewed and published in reputable statistical journals.

Most important, the CASAC and NAAQS review process is now broken

- As a member of CASAC from 2015 to October of this year, I am shocked that so many profound changes have been made to the CASAC review process and specifically to the PM review without any consultation of the chartered CASAC. I don't understand why neither EPA nor the CASAC Chair felt the need to consult the chartered CASAC about these changes. What is the point of CASAC?

- How is it appropriate for EPA to change the PM Integrated Review Plan (IRP) after CASAC approved it in August 2016? This document reflects an agreement between EPA and CASAC on an appropriate and orderly approach to the PM review. Yet EPA changed the dates, modified conditions, added requirements, and removed the PM Panel. Who decided this? Why wasn't CASAC consulted? Is it legal to have acted in the way the events have unfolded? It is certainly unethical and jeopardizes the credibility of the entire PM NAAQS process.
- The Administrative Procedure Act defines federal agency actions as “arbitrary and capricious” if it ignores its own advisory committee reports, ignores the scientific literature, or does not put qualified experts on its advisory panels. The changes to the CASAC process are arbitrary and capricious.

In conclusion,

- The chartered CASAC should have been consulted before any process changes were implemented.
- EPA should reinstate the PM review panel and revert to following CASAC-approved PM IRP.

I close with a quote from Kenneth Fisher's the public comment: “decisions made in ignorance won't protect [anyone] from the adverse health and financial consequences of bad choices”.