

22 March 2019

US Environmental Protection Agency  
1200 Pennsylvania Avenue NW  
Washington, DC 20460

Docket Numbers: EPA-HQ-OAR-2015-0072, EPA-HQ-ORD-2014-0859

EPA Administrator Andrew Wheeler and the Clean Air Scientific Advisory Committee (CASAC):

Thank you for the opportunity to comment. I am the research director at the Center for Science and Democracy at the Union of Concerned Scientists. On behalf of more than half a million citizens and scientists, we advocate for the use of science for a healthy planet and a safer world. The Center for Science and Democracy works to advance the roles of science and public participation in policy decision-making. We have never advocated for an ambient air quality standard different from the CASAC recommendation, only to ensure the proper process is followed and scientific advice is heeded.

### **Scientific Issues**

The Clean Air Act requires that the EPA set particulate matter (PM) standards at levels that protect public health and welfare with an adequate margin of safety. CASAC is charged with considering all available evidence and providing science advice on the standards. At this stage in the PM standard update, there are significant challenges to both the science and process that CASAC is following.

The PM Integrated Science Assessment (ISA) provides an important scientific update on the health and welfare effects of particulate matter. This document deserves to be scrutinized and improved by experts on all facets of the assessment. Such expertise is especially necessary for the review of particulate matter, because of its complexity and variability in size, concentrations, and chemical composition. And CASAC's review of the ISA should be helping EPA to identify new research questions and to refine its characterization of the state of the science. However, this has not been the case.

Given limitations in expert input discussed below, it is crucial that CASAC rely on the wealth of knowledge in the published literature, as reflected in the ISA draft. CASAC should consider all available science at its disposal and it should rely on the established approach for assessing the causal links between particulate pollution and health impacts, as detailed in the preamble to the ISAs.<sup>i</sup> The causal framework employed by the EPA has evolved over the past decade, has been endorsed by 11 prior CASACs and 138 experts, and has been deemed adequate in the courts.<sup>ii, iii</sup>

Yet, the March 7 draft letter by the CASAC chair proposes upending this scientifically backed and time-tested approach.<sup>iv,v,vi</sup> The chair's proposal would create an unattainable burden of proof on the scientific community to demonstrated causal links between PM reductions and changes in health outcomes, as it is not feasible or ethical to design and carry out population-level manipulative causation studies.<sup>vii</sup>

Importantly, following such a proposal is incompatible with CASAC's charge to recommend PM standards that protect public health with an adequate margin of safety including sensitive subpopulations. Protecting groups such as the elderly, children, and those with lung diseases, with an adequate margin of safety requires the EPA to consider all evidence and use expert judgement. Relying on a framework that discounts epidemiologic evidence and requires manipulative causation for all causal determinations made by the agency is unlikely to meet this Clean Air Act mandate.

I urge the members of CASAC and the EPA to listen to the recommendations of top experts in the scientific community and reject this proposal. It is the job of CASAC to make recommendations consistent with the current scientific understanding of the links between PM and health and welfare effects. Following the chair's proposal prevents the EPA from relying on the best available science.

### **Process Issues**

A flawed process produces a flawed result. Thus far, CASAC has not followed a process that is likely to lead to a science-based recommendation to the EPA Administrator. The initial science advice structure set up by EPA leadership has failed to provide the agency with an opportunity for the robust science advice it has always received on National Ambient Air Quality Standards (NAAQS), given the significantly reduced expertise the agency is now receiving (See Figure).

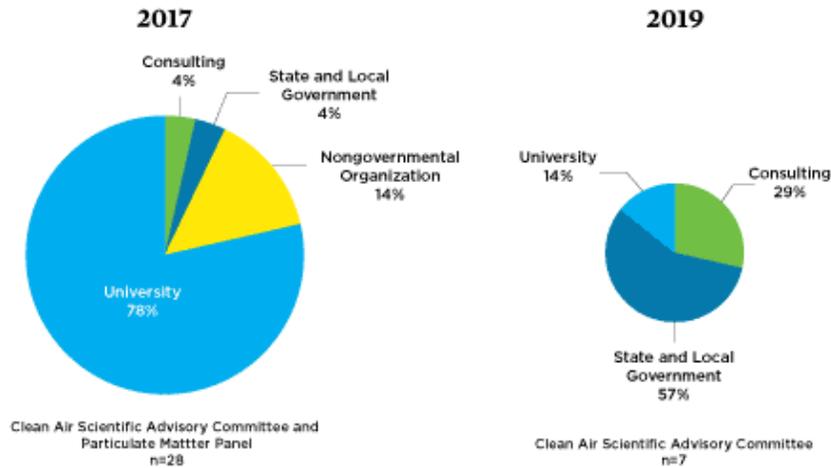
In addition to the significant gaps in expertise that have resulted from EPA leadership's choice of CASAC members, dismissal of the PM review panel has severely limited the degree of independent expertise the EPA and CASAC are receiving on the PM ISA and subsequent documents that inform the standard. Indeed, members of CASAC too have continued to recognize the need for additional expertise to inform their review of the PM standards, both in written comments and during meeting discussion.

Despite these consistent calls for additional expertise by CASAC members, echoed by public comments, the CASAC chair has continued to press forward without addressing these concerns. As a result, the PM NAAQS review is proceeding without the science advice needed to ensure a health-protective standard.

This lack of expertise has been abundantly clear in CASAC meeting discussion and written comments from CASAC members. Rather than discussing key areas of uncertainty and the implications of new important research on particulate matter and health, as would be most helpful for the EPA to hear in deliberations from its top science advisors, CASAC instead has spent its valuable time within an expedited review process questioning and renegotiating well-established concepts, such as the value of the field of epidemiology, the importance of studying effects on at risk populations, and the connection between particulate exposure and premature mortality.

Figure.

### Changes to EPA Science Advice on Ambient Particulate Pollution Standards



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Further, the greatly expedited proposed schedule to complete the PM review by 2020 is likely to limit the ability of the EPA and CASAC to follow a science-informed process.<sup>viii</sup> Typically, the process of EPA staff, CASAC, and the PM review panel compiling, reviewing, and revising the ISA, Risk and Exposure Assessment (REA), and Policy Assessment (PA) requires far more time than this schedule allows. CASAC and EPA leadership should follow a careful, robust process to assess the current state of the science on particulates and health, regardless of whether it meets the arbitrarily aggressive timeline laid out.

Additionally, the expedited timeline with fewer drafts and fewer public meetings will mean fewer opportunities for public input. More than 23 million Americans live in areas with particulate pollution levels that exceed the current standard,<sup>ix</sup> with serious public health consequences, including premature death, cardiovascular effects, and respiratory effects.<sup>x</sup> The public deserves sufficient opportunity to weigh in on a regulation with such far-reaching impacts.

The expedited time frame and planned merging of documents, combined with gaps in expertise on CASAC and the lack of PM review panel and public input opportunities— together—are likely to undermine the ability of the EPA to set a science-based standard for particulate matter, protective of public health with an adequate margin of safety, as required by the Clean Air Act. And indeed, we are already seeing significant limitations and ill-advised changes to the committee's approach to the science.

I urge the committee to seek input from the necessary experts and to follow the timeline necessary in order to make a science-based recommendation that protects the public.

Sincerely

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<sup>i</sup> [https://ofmpub.epa.gov/eims/eimscomm.getfile?p\\_download\\_id=526136](https://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=526136)

<sup>ii</sup>

[https://yosemite.epa.gov/sab/sabproduct.nsf/44E735B0EB05DACD852583B500714CA2/\\$File/JVandenberg+response+to+TCox+ltr+of+121718.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/44E735B0EB05DACD852583B500714CA2/$File/JVandenberg+response+to+TCox+ltr+of+121718.pdf)

<sup>iii</sup> US EPA. Particulate Matter (PM) Standards - Documents from Review Completed in 2012 – Litigation. (2012)

[https://www3.epa.gov/ttn/naaqs/standards/pm/s\\_pm\\_2007\\_lit.html](https://www3.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_lit.html)

<sup>iv</sup>

[https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebProjectsCurrentCASAC/FE50D8FD06EA9B17852583B6006B7499/\\$File/03-07-19+Draft+CASAC+PM+ISA+Report.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebProjectsCurrentCASAC/FE50D8FD06EA9B17852583B6006B7499/$File/03-07-19+Draft+CASAC+PM+ISA+Report.pdf)

<sup>v</sup> The National Academies of Sciences, Engineering, and Medicine, Using 21st Century Science to Improve Risk-Related Evaluations (National Academies Press, 2017). <http://www.toxicologia.org.ar/wp-content/uploads/2017/02/Risk-Book-2017.pdf>

<sup>vi</sup> The National Academies of Sciences, Engineering, and Medicine, Scientific Evidence for Causation in the Population 7, 150 (2008) <https://www.nap.edu/read/11908/chapter/10>

<sup>vii</sup> Goldman, G.T. and F. Dominici. (2019) Don't abandon evidence and process on air pollution policy. *Science*. 21 March. DOI: 10.1126/science.aaw9460. Online at

<http://science.sciencemag.org/content/early/2019/03/20/science.aaw9460>

<sup>viii</sup> <https://www3.epa.gov/ttn/naaqs/standards/pm/data/201612-final-integrated-review-plan.pdf>

<sup>ix</sup> <https://www3.epa.gov/airquality/greenbook/popexp.html>

<sup>x</sup> <https://www.epa.gov/pm-pollution/health-and-environmental-effects-particulate-matter-pm>