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

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

Written Comments of John Bachmann on behalf of the Environmental Protection Network.

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

Thanks to CASAC and EPA for the opportunity to provide these written comments relevant to the upcoming teleconference during the current review of National Ambient Air Quality Standards (NAAQS) for particulate matter (PM). I am representing the [Environmental Protection Network](http://environmentalprotectionnetwork.org) (EPN), a volunteer organization of former EPA employees and others concerned about continuing protection of public health and the environment. I worked for EPA's Air Office for 33 years, many of them as Associate Director for Science/Policy and New Programs. I was heavily involved in all reviews of the PM NAAQS through 2006.

EPN is commenting principally because EPA has wholly ignored the comments and recommendations that we¹ -- and many former CASAC members and others -- made both prior and at the December CASAC public meeting regarding the need to return the NAAQS review process to a sound, unbiased science and policy footing. As evidenced by the recent CASAC draft letter, this continued inaction has resulted in an understaffed and divided committee that lacks the expertise, experience, and balance needed to ensure the quality and credibility of the NAAQS review process. In short, EPA management has broken the process and refused to fix it, which presents numerous logistical, technical and legal impediments for moving forward towards completion of the review by the end of 2020.

EPN's main points include:

1. The process the EPA Administrator has adopted for this review of the particulate matter standards is fatally flawed. We see no way this seven member CASAC can produce a coherent and credible scientific review of the relevant science or the adequacy of the standards themselves.

¹ J.Bachmann. December 9, 2018. Written comments on behalf of the Environmental Protection Network submitted to Docket Numbers: EPA-HQ-OAR-2015-0072; EPA-HQ-ORD-2014-0859.
[https://yosemite.epa.gov/sab/sabproduct.nsf/F1ED8235CFFA09458525835B00795CFC/\\$File/John+Bachmann+Comments+to+CASAC+Meeting+on+PM+ISADec9.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/F1ED8235CFFA09458525835B00795CFC/$File/John+Bachmann+Comments+to+CASAC+Meeting+on+PM+ISADec9.pdf)

- The Administrator dissolved the panel of some twenty scientific experts knowing similar panels have long been seen as necessary to assist the CASAC in the review. As the CASAC draft letter itself states: *“The breadth and diversity of evidence to be considered exceeds the expertise of the statutory CASAC members, or indeed of any seven individuals.”*
 - The best and fastest way to restore credibility would be to reinstate that panel, as these experts have already been vetted for this work, and are among the nation’s foremost experts in all of the relevant scientific disciplines. They are also more familiar with the review process than most of the current CASAC members. They would provide a broader array of perspectives from the scientific community than the current group, which includes only one academic scientist, four representatives from state programs (the Clean Air Act calls for one member from a state) and a consultant. Most notably, the panel excludes experts in air pollution epidemiology and related disciplines that have been central in past CASAC deliberations. EPA and CASAC should reject suggestions in the draft letter for half measures to add expertise, variously involving cherry picking a few individuals new to the process or worse, relying on a crowd sourcing contractor.
2. This small committee is deeply divided in their interpretation of the scientific information. While the chair developed -- and some members support -- the criticisms of EPA’s approach to determination of the likelihood of causal relationships between fine particle pollution (PM_{2.5}) and health effects, others support EPA’s findings and approach, which are in fact consistent with CASAC reviews over the last decade. As stated by the latter group:
- *“Other members of the CASAC are of the opinion that, although uncertainties remain, the evidence supporting the causal relationship between PM_{2.5} exposure is robust, diverse, and convincing. The epidemiological observations have been reproduced around the world in communities with widely varying exposures. The findings of many of the largest studies have been repeatedly reanalyzed, with confirmation of the original findings. The EPA’s causality determination, rather than considering the epidemiological evidence “in isolation,” includes a wide range of evidence from a variety of sources, including human clinical exposure and animal toxicology studies that have provided rational biological plausibility and potential mechanisms. This causality determination was first clearly promulgated in the 2009 ISA, with full CASAC support. It is widely accepted by the scientific community and many public health organizations, including the World Health Organization. There is no credible or convincing new evidence since 2009 to question or refute this determination. Indeed, there is new evidence from epidemiological studies supporting the relationship between PM_{2.5} and mortality, and new toxicology studies informing the mechanisms involved and supporting their plausibility. The evidence supporting a causal relationship between PM and mortality is even more robust than it was in 2009.”*
 - Yet the conclusions of the Chair and two toxicologists call into question the case and the approach for concluding a causal relationship between fine particles and mortality. This is in stark contrast to the position taken not only by some on the present committee, but also the consistent consensus of the two previous CASAC

reviews of the PM standards. While it is appropriate to point out where the draft ISA should be improved in updating the basis for retaining or modifying conclusions on causality of PM fractions, this small cadre is not representative of the prevailing scientific opinion on the mortality risk presented by particulate matter.

3. Based on the above, EPN wholly agrees with the suggestion by CASAC member Mark Frampton regarding how the committee should proceed with respect to the draft letter: *“In order to provide the needed expertise in the review process, EPA should immediately re-appoint the PM review panel, and convene an additional CASAC public meeting to review and discuss the panel’s comments, before CASAC finalizes its advice on the current draft ISA.”*
4. By changing the NAAQS process, eliminating the full panel and appointing new members without experience in CASAC NAAQS reviews, EPA management ignored the advice provided by CASAC and commitments made by EPA in the review of 2016 the Integrated Review Plan for PM. EPA staff working on the ISA have been blindsided by the new chair, who has strongly held views on the issue of causality and epidemiology, who suggests EPA abandon the weight-of-evidence approach for examining causality, which has been supported by the recommendations and reviews of past committees. In its place, he suggests eliminating most of the epidemiology studies used in past reviews and using an impractical hypothesis generation approach that would resemble more development of a new meta-study than an assessment of the available literature. While Dr. Cox’s views on causality and accountability should be heard, they should be discussed by a broader group that includes multiple peers experienced in air pollution epidemiology and statistics.
 - In 2016, the PM CASAC panel reviewed the agency’s draft plan for developing the ISA as well as other documents. The April 16th letter stated, *“This section is generally well written, and the hierarchy of causality determinations is a strength. However, perhaps more needs to be said about how the causality ratings are assigned during the development of the ISA. These are in fact judgements based on the weight of the evidence, and this should be acknowledged here.”*
 - EPA staff might reasonably have expected comments with respect the clarity of how the causality ratings were assigned, but not a rejection of the entire weight-of-evidence approach. The Chair’s preemptive rejection of earlier CASAC guidance on the approach for the ISA and his suggestion of an unworkable hypothesis testing approach is unreasonable. Nor is such a change supported by the science. Many former members of CASAC panels, as well as EPN and others, have indicated their continued support of the weight-of-evidence approach at the December 2018 CASAC meeting.
 - At the December meeting, EPN, Dr. Corwin Zigler, Dr. Lianne Sheppard and others warned that the application of causal inference methods to air pollution work has not been fully vetted nor advanced to the point where it should be considered as a replacement for all other approaches to epidemiology, much less other fields considered in the weight-of-evidence approach used in the Framework.

The paper by Dominici and Goldman that appeared this week in *Science*² makes a compelling case that Dr. Cox's overarching suggestions should not be adopted in revising the ISA.

- It is important to note that, while critical of Dr. Cox's preemptive suggestions, Drs. Zigler and Dominici have long been advocates for the development and use of causal inference methods in air pollution research, as I learned when I assisted in some of their efforts beginning in 2013.
5. EPN agrees that, while waiting to see if the agency takes the steps needed for a valid peer review of the ISA by a qualified CASAC panel, EPA should sift through such individual comments as it has and begin to address them as warranted to improve the current draft. This should include examining not only the individual comments from current CASAC members, but paying particular attention to the detailed comments on particular topics provided as public comments by the group of former CASAC panel members organized by Dr. Frey.³
- Some individual CASAC comments take note of the absence of some recent studies. These include the HEI accountability studies, negative studies, and more. These omissions are due in part because, following standard procedures, EPA stopped sorting studies for inclusion in the draft ISA at some point in mid-2017. The inclusion of more recent studies has been limited. This means that other important studies not noted by CASAC members will also be missed. Some of these include a meta-analysis of 53 cohort studies of fine particles and mortality,⁴ a U.S. PM cohort study based on publicly available data⁵ as well as some newer studies using causal methods that were not highlighted in CASAC's draft comments.⁶

² 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>

³ Frey, H.C., A.V. Diez Roux, J. Balmes, J.C. Chow, D.W. Dockery, J.R. Harkema, J. Kaufman, D.M. Kenski, M. Kleinman, R.L. Poirot, J.A. Sarnat, E.A. Sheppard, B. Turpin, and S. Vedal, "CASAC Review of EPA's Integrated Science Assessment (ISA) for Particulate Matter (External Review Draft – October 2018)," 34 page letter and 100 pages of attachments submitted to Chair, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency and to Docket EPA–HQ–ORD–2014–0859, December 10, 2018. [https://yosemite.epa.gov/sab/sabproduct.nsf/086D8B853E0B63AE8525835F004DC679/\\$File/PMRP+Letter+to+CASAC+181210+Final+181210.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/086D8B853E0B63AE8525835F004DC679/$File/PMRP+Letter+to+CASAC+181210+Final+181210.pdf)

⁴ Vodonos A, Awad YA, Schwartz J. The concentration-response between long-term PM 2.5 exposure and mortality; A meta-regression approach. *Environ Res*. 2018;166:677–89.

⁵ Pope CA III, Ezzati M, Cannon JB, Allen RT, Jerrett M, Burnett RT. Mortality risk and PM2.5 air pollution in the USA: an analysis of a national prospective cohort. *Air Quality, Atmosphere & Health* 2017 Published on-line December 8, 2017; doi.org/10.1007/s11869-017-0535-3).

⁶ M. Makar, J. Antonelli, Q. Di, D. Cutler, J. Schwartz, F. Dominici, Estimating the Causal Effect of Low Levels of Fine Particulate Matter on Hospitalization. *Epidemiology* **28**, 627–634 (2017); J. Schwartz, K. Fong, A. Zanobetti, A National Multicity Analysis of the Causal Effect of Local Pollution, NO₂, and PM_{2.5} on Mortality. *Environ. Health Perspect.* **126**, 87004 (2018); Schwartz, J., Wang, Y., Kloog, I., Yitshak-Sade, M., Dominici, F. and A. Zanobetti. Estimating the Effects of PM_{2.5} on Life Expectancy Using Causal Modeling Methods. *EHP*. 126(12) December 2018. <https://doi.org/10.1289/EHP3130>; Hsiao-ChiChuang, Kin-FaiHo, Lian-YuLin, Ta-YuanChang, Gui-BingHong, Chi-MingMa, I-JungLiu, Kai-JenChuang, Long-term indoor air conditioner filtration and cardiovascular health: A randomized crossover intervention study *Environment International*. 106, 91-96. September 2017. <https://www.sciencedirect.com/science/article/pii/S0160412017306827?via%3Dihub>

- Assuming EPA will be making some revisions to the ISA based on individual comments, it is important that staff conduct a conditional search for particularly relevant papers published since mid-2017. The Clean Air Act mandates that “*Air quality criteria for an air pollutant shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities.*” Suggestions from CASAC and the public may be helpful, but they cannot be considered adequate to meet this requirement. EPA has mechanisms for addressing studies that appear after an ISA is completed.
- EPA should conduct this search of the recent literature, even if management decides to follow a suggestion in the May 2018 Pruitt approach and choose not to submit a revised ISA for a full CASAC review. As noted above, a full CASAC review would include reinstating the CASAC expert panel.
- In considering comments on clarifying how studies are selected and evaluated, EPA should be wary of suggested “systematic” criteria for excluding epidemiology studies, as the current CASAC panel lacks such expertise. An example of such problematic criteria is found on page A-76 of the draft letter comments. One suggests “*simply excluding studies that fail to control for temperature as an important confounder would eliminate many of the studies in Table 11-5 (North American epidemiologic studies of long-term exposure to PM2.5 and mortality) and other tables and figures summarizing evidence the Draft ISA.*” The author provides no evidence showing long-term temperature metrics is a serious confounder in long-term cohort studies of air pollution, and apparently is unaware that the HEI reanalysis of the two cohort studies in 2000 did include an adjustment for temperature, finding little if any change in the results.⁷ Using this criterion to remove cohort studies from consideration without contrary evidence is unfounded. These criteria would also eliminate studies that simply make claims about how changing PM levels would change mortality, if it did not actually measure reductions. At least the author made the goal of these criteria clear, stating that “*they would eliminate most (possibly all) of these numerous studies.*” These suggestions are in stark contrast with the position of all previous PM CASAC review panels.

⁷ Health Effects Institute. Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality (2000). <https://www.healtheffects.org/publication/reanalysis-harvard-six-cities-study-and-american-cancer-society-study-particulate-air>