

Louis Anthony Cox, Jr, PhD
Chair
Clean Air Scientific Advisory Committee
US Environmental Protection Agency

Re: Docket EPA-HQ-ORD-2014-0859

Dear Dr Cox

I write to provide comments on the current CASAC process related to the Integrated Science Assessment for Particulate Matter. My background includes serving as Chair of CASAC and then as President Reagan's appointee as EPA Asst. Administrator for Research and Development. I have published well over a hundred scientific papers about various air pollutants. I am a member of the National Academy of Medicine and have served as member of chair of over 20 academy committees dealing predominantly with environmental issues. I also served as chair of the Health Effects Institute Research Committee, and of the NIH Toxicology Study Section.

As you know, I have great respect for your scientific credentials. Further, to the extent I am knowledgeable, I do not disrespect the credentials of any single current member of CASAC. But as a group you do not have the credentials to perform the mandated CAA functions of CASAC now that the CASAC subcommittee on particulates has been disbanded.

It has long been recognized that the seven member CASAC committee is not able to provide sufficient depth and breadth of expertise to provide a cogent and useful review of the literature pertinent to the Administrator's decision to set NAAQS standards "requisite to protect public health" and with "an adequate margin of safety." Early on this led to the development of expert panels who would review the appropriate EPA document and provide advice to CASAC as to its scientific merits and shortfalls. Since that time the volume of information available has expanded greatly, including through the development of important air pollution research programs throughout the world. Two disciplines particularly pertinent to assessing the dose response relationship between NAAQS pollutants and adverse endpoints have dramatically developed during this time period. Just consider that when I chaired CASAC neither the current international organizations in environmental epidemiology or in exposure science had even been formed.

I am particularly concerned that the first subcommittee dropped was that for particulates – although the points I am making are also relevant to ozone for which the subcommittee has also been dissolved. I will consider them both together because I wish to compare ozone and particulates with two other NAAQS pollutants, carbon monoxide and lead. I believe this comparison is highly relevant to my assertion that CASAC cannot carry out the requirements of the Clean Air Act without expert subcommittees, even for pollutants such as carbon monoxide and lead which are on the other end of the scale of complexity.

These standards are the only outdoor standards which we now exceed in significant parts of our country. The science underlying ozone and particulate formation is far more complicated than that for other NAAQS pollutants such as carbon monoxide or lead. Rather than being directly released from readily identifiable sources, all of the ozone and much of the particulates we breathe form in the atmosphere through processes that depend heavily on complex chemical and physical interactions. For

both ozone and particulates there are multiple precursor sources, including in both cases fossil fuel emissions from power sources and transportation. The pollutants can also interact with each other. For example, photochemical oxidation leading to ozone may also increase the toxicity of hydrocarbon particulates. Disentangling this multiplicity of pollutants and interactions in relation to the health effects literature requires a breadth and depth of expertise that is not achievable with only a seven-member panel who are also responsible for providing advice on multiple other pollutants and on the diverse welfare endpoints involved in secondary standard determinations.

I strongly doubt that we could get the needed advice from the seven-member CASAC committee for simpler pollutants, such as carbon monoxide and lead for which the sources and endpoints are relatively clear cut and for which little new science needs to be considered. Further, unlike ozone and particulates, there are simple blood tests to define the extent of human exposure. It is manifestly impossible to ask CASAC to meet its congressionally mandated Clean Air Act requirements without scientific input from experts in the many fields pertinent to understanding the impacts of ozone and particulates.

Understanding what EPA leadership is doing with CASAC needs to be put in the context of their overall goal of divorcing scientific processes from policy judgments. This goes well beyond their head in the sand attitude to global climate change and other significant environmental threats. One approach has been to change any advisory committee membership so as to downplay expertise. The new selection criteria focuses on the usual politically motivated distributional issues. It also disqualifies any academic receiving funding from EPA, but not personnel from state or local agencies. The success in divorcing consideration of scientific expertise affects all agency advisory processes but is nowhere more evident than in the [new CASAC committee](#) appointed in October. This committee now contains four state or local agency personnel – perhaps by coincidence all from states with Republican governors to whom they ultimately report. Of the remaining three members, one is a consultant, one is from the US military and one is an academic scientist. Individually they appear to have expert but often overlapping qualifications. But none of them has particular expertise in epidemiology, a core discipline in providing evidence linking exposure levels to adverse health endpoints.

When the CASAC membership was adjusted to avoid independent academic experts, it was hoped that the scientific integrity of the process would be maintained through the public input of the expert subcommittees. Cunningly, Mr. Wheeler's action has removed that 40-year-old prop from the science advice edifice. Also with the goal of divorcing science from policy, but not yet successful, EPA leadership is currently [using transparency as a sham pretext](#) to discard much of the scientific literature supporting the protection of public health from environmental pollutant.

I do not know for certain what I would do if I were in your position. I would like to believe that I would have had the courage to resign as chair of CASAC if Administrator Anne Gorsuch, President Reagan's initial appointee as head of EPA, would have done what Acting Administrator Wheeler has done to you and to the members of your committee. In these circumstances how can you carry out your important congressionally mandated responsibility to protect the American public by making recommendations based on thorough evaluation of the scientific literature.

Over the decades, CASAC members have been appointed based on their scientific expertise. In contrast, an October 31, 2017, memo from Administrator Scott Pruitt requires that members of EPA federal advisory committees should “reflect prominent participation from state, tribal, and local governments,” and that priority should be given to “geographic diversity.” There is no mention of the importance of having experts of high stature that represent the wide range of scientific disciplines, and the depth of knowledge and experience, necessary to the work of committees such as CASAC or the EPA Scientific Advisory Board (SAB). On October 10, 2018, EPA announced that Acting Administrator Wheeler appointed five new members to the 7-member chartered CASAC. The current CASAC is comprised of representatives from four state agencies, one federal agency, a consulting firm, and one academic researcher. For the most part, these members were selected for their geographic location or affiliation, rather than primarily based on depth of expertise.

In the context of the ozone review, the CASAC does not include nationally or internationally recognized experts in epidemiology, which is a key scientific discipline. The CASAC lacks nationally or internationally recognized experts in exposure assessment. The CASAC lacks the diversity of multiple expert perspectives on toxicology, including from experts who are at the forefront of toxicological research and recognized as national or international experts. The CASAC lacks adequate breadth and depth of expertise in air quality science, including measurements of background concentrations. The CASAC also lacks proper coverage of expertise pertaining to issues related to the scope of public welfare, such as effect of tropospheric ozone on climate and vegetation. CASAC has typically been comprised of leading nationally and internationally recognized scientific experts, who are active in research in their respective fields and at the forefront of the latest scientific knowledge, not stakeholders selected for their geographic location or governmental affiliation.

The memorandum states that “no member of an EPA federal advisory committee currently receive EPA grants,” but that this “principle should not apply to state, tribal, or local government agency recipients of EPA grants.” This is illogical for four reasons. One is the obvious inconsistency of implying that receiving a grant creates a conflict of interest for one but not another class of persons. The second is the longstanding recognition that receipt of a peer-reviewed scientific research grant, for which the Agency does not manage the work nor control the output, is not a conflict of interest. Per the Office of Management and Budget (OMB): “When an agency awards grants through a competitive process that includes peer review, the agency’s potential to influence the scientist’s research is limited. As such, when a scientist is awarded a government research grant through an investigator-initiated, peer-reviewed competition, there generally should be no question as to that scientist’s ability to offer independent scientific advice to the agency on other projects.” A 2013 report by the EPA Office of Inspector General reaffirmed that receipt of an EPA research grant is not a conflict of interest. However, there can be situations in which a member of an advisory committee should recuse themselves from discussions that might pertain to their own work. Thus, third, the CASAC has had recusal policies in place for dealing with this issue and situations in which a member’s work may come up for deliberation. Fourth, the memorandum does not acknowledge that persons with financial or professional ties to regulated industries have at the very least, the same appearance of conflict of interest.