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Members of the Clean Air Scientific Advisory Committee:

I am writing to express my profound concern over the CASAC Draft Report (herein referred to as “Draft Report”) on the EPA’s Draft ISA (herein referred to as “Draft ISA”) to be considered at the meeting of March 28, 2019.

I am a Professor in the Department of Civil and Environmental Engineering and the Department of Engineering and Public Policy at Carnegie Mellon University, where I am also Director of the Center for Atmospheric Particle Studies. My expertise lies in the development of chemical transport models and their application to policy and decision-making. I was one of the original experts appointed to the CASAC PM Review Panel that had been part of this NAAQS review process. In March 2018, I was obliged to remove myself from the Review Panel due to the new EPA rule that prevents recipients of EPA research funding from sitting on review panels. Since the entire Review Panel was disbanded in October 2018, I have continued to follow the NAAQS process as part of the Independent Particulate Matter Review Panel. Nevertheless, the opinions expressed below represent my own professional judgment and not necessarily those of the institutions mentioned above.

The Draft Report asserts that the Draft ISA does not “follow widely accepted scientific methods for deriving sound, independently verifiable, scientific conclusions from available data.” I disagree strongly with the reasoning put forth in the Draft Report to denigrate the scientific rigor of the Draft ISA document. I find the following flaws in the Draft Report.

The Draft Report misunderstands the role of expert judgment in scientific reasoning. In several places, the Draft Report complains about “subjective” expert judgments and “opinions”. It goes without saying that any scientific enterprise is built upon a foundation of objectivity and empiricism, and this is indeed the case with the Draft ISA, which cites an extensive literature to support its findings. However, in the final analysis, the advancement of science has always depended on expert judgment to synthesize, interpret, and generalize from narrower, and sometimes conflicting, bits of empirical evidence.

This was true when the Royal Society was founded in the 1660s to allow eminent scientists to hear and debate each other's findings. This was true in 1863 when Abraham Lincoln signed into law the act that founded the National Academy of Sciences "to provide scientific advice to the government." It is true today every time a research paper undergoes peer review, and it should be noted that the evaluation criteria outlined in the Draft ISA are far more rigorous and specific than those of leading scientific journals. It continues to be true as different scientific communities weigh the complex and often conflicting evidence published in the peer-reviewed literature to move towards scientific consensus on a question. And, it is true in more formal settings such as the drafting of scientific assessment documents essential to informed decision-making by EPA and other federal agencies. It is especially true for systems of great complexity, such as those found in the realm of public health.

If scientific reasoning were simple enough that every important synthesis statement could "transparently verifiable" as simply "true or false", it could be done by robots and not humans. Instead, the Clean Air Act recognizes that expert judgment is essential when it calls for an "independent scientific review committee" as part of the NAAQS review process. Expert judgment is clearly implied in the text of the Clean Air Act when it says that NAAQS should be established for air pollutants "which may reasonably be *anticipated* to endanger public health or welfare", based on "identifiable effects on public health or welfare which may be *expected* from the presence of the pollutant in the ambient air" and "known or *anticipated* adverse effects on welfare." (italics mine) Ultimately, the Draft Report's emphasis on eliminating "opinion" is a chimera, a rhetorical trick to remove the essential element of expert judgement from the scientific process by cloaking it in the guise of "objectivity".

The Draft Report burdens public health by setting standards of evidence inappropriately and in contradiction to the requirements of the Clean Air Act. In any complex public health assessment, a team of experts will have to use their judgment, including partly subjective interpretation of objective evidence, to reach policy-relevant conclusions. In this process, one needs to think clearly about weighing the benefits of false negatives and false positives. False positives, if an air pollutant is incorrectly deemed to cause health effects, lead to unnecessary and costly regulation. False negatives, if an air pollutant is incorrectly deemed not to cause health effects, lead to unnecessary loss of life (and other outcomes), which is also costly in both human and narrow economic terms. Appropriate standards of evidence attempt to strike a balance between these errors.

The text of the Clean Air Act makes clear Congress's intent that the scientific evidence need not be iron-clad for EPA to act. Text cited above ("anticipated to endanger public health", "effects ... which may be expected", "known or anticipated adverse effects") strongly suggest Congress's intent that EPA act cautiously with regard to setting the NAAQS, erring on the side of protecting public health. Moreover, the NAAQS itself is supposed to be set "allowing an adequate margin of safety" with regard to public health.

These examples stand in stark contrast to the approach advocated in the Draft Report, which complains that the Draft ISA "presents no validation results comparing

hypothetical predictions or calculations for new situations to observations” and calls for “comparing these predictions to observations when new situations are encountered in reality (e.g., in designed experiments, controlled trials, or natural experiments).” The Draft Report does not make a case for the widespread feasibility of well-controlled experiments, natural or otherwise, in the realm of air pollution science that would lead to such easy and clear-cut comparisons. Indeed, how could the EPA make “empirically validated” predictions for a future with different air quality due to a change in the NAAQS? The Draft Report’s insistence on “accountability studies” and narrow definitions of causality are out-of-step with the established practice of the scientific community. The Draft Report goes on to consider potential effects of confounding variables without considering the extensive efforts made in existing literature to consider and rule out potential problems they might cause.

By declaring a “lack of scientific support” and “no empirically validated predictions”, the Draft Report establishes severe standards of evidence on the one hand and on the other hand overlooks the strength of the evidence presented in the Draft ISA. One might read the Draft Report and conclude that CASAC has entirely dismissed the well-established discipline of epidemiology as a science. It incorrectly suggests that air pollution epidemiologists have been careless about how exposure misclassification or confounding factors might affect their results. On the contrary, the repeated findings of epidemiological studies with different study designs, supplemented by the evidence from toxicology, is very strong. Dismissing it because it is neither simple to interpret nor to “empirically validate” unnecessarily throws out valuable evidence to the detriment of public health.

The Draft Report’s unrealistic standards with respect to empirical validation of conclusions is another rhetorical trick that attempts to disguise a cavalier attitude towards public health as concern for scientific integrity.

The Draft Report fundamentally misunderstands the role of a scientific assessment document. The Draft Report asserts that the Draft ISA does “not follow standard scientific method by formulating, testing, modifying, and applying predictive hypotheses based on data.” This is typical of scientific assessment documents, which summarize the existing literature. It is in the primary, peer-reviewed scientific literature where hypotheses are formulated and tested, and the Draft ISA indeed bases its conclusions on these types of studies.

The Draft Report makes misleading or unsupported statements. Two examples will have to suffice:

- The Draft Report states that the Draft ISA does not distinguish “between effects of PM and effects of confounders such as poverty” and repeatedly suggests that poverty is a confounding factor. For that to be true, poverty would have to be correlated to PM exposure. In the data I have seen, it is not, and the Draft Report does not present any evidence that it is. The Draft Report generally ignores the

- extent to which potential confounding factors have been considered and addressed in the scientific literature around air pollution epidemiology.
- The Draft Report asserts that “The CASAC finds that, in the absence of clear, operational definitions for key terms and concepts, including the causal determination categories, Chapters 4-12 can lead to varying opinions about the extent to which key conclusions have been established as valid.” This ignores the definitions provided in Table P-2 of the Draft ISA, which numerous prior CASAC panels have previously reviewed and approved and which have been used productively in numerous NAAQS reviews.

Recent changes to the NAAQS review process have left it in disarray. Following the recommendations of the Draft Report would lead to additional delay and disarray. Changes to CASAC membership have left it with less collective research experience and lacking expertise in the critical area of epidemiology. Two of its members were appointed in 2017 and five were appointed in 2018. The dismissal of the PM Review Panel exacerbated this problem. The Draft Report tacitly admits this problem when it “recommends that [CASAC] be provided with access to additional technical expertise, as needed, to thoroughly review the Second Draft ISA.” If additional technical expertise is needed to review a revised ISA, it is clear that the current Draft ISA did not receive a thorough review. The Draft Report recommends further upending the process by making changes to the long-standing and successful causal framework (Table P-2 of the Draft ISA). Many of the recommendations of the Draft Report attempt to change methods and definitions that had already been reviewed by the PM Review Panel as part of this NAAQS review cycle.

It is time to stop experimenting with the NAAQS review process in mid-cycle. Doubtless, there are numerous incremental improvements that can be made to the NAAQS review process, but the wholesale changes proposed mid-cycle in the Draft Report are throwing the baby out with the bath water. The most productive approach at this point would be to reinstate the previously disbanded PM Review Panel and proceed according to widely accepted definitions and procedures that have served the nation well in past review cycles.

Sincerely,
Peter Adams
Professor
Director, Center for Atmospheric Particle Studies