The CASAC - PM Committee - Setting Air Quality Standards by Robert F. Phalen, Ph.D., Professor of Medicine and Co-director, Air Pollution Health Effects Laboratory, University of California, Irvine CA, U.S.A.

My participation in the CASAC subcommittee on Particulate Matter(CASAC-PM) was stimulating and enlightening. Everyone involved, committee members, EPA staff, and public presenters, were well-qualified, efficient, and dedicated. But we are here, in part, to explore possible improvements in the process, so I will summarize some of my personal observations to that end. Many of the problems arose from the outdated mandate that the U.S. EPA had to follow.

- The mandate is too restrictive, and does not allow the full competence of the EPA to be used in protecting public health. Evaluating air pollutants one-by-one can lead to air standards that do not make sense given the complexities of air chemistry (e.g. suppression of one pollutant can cause the mixture to have increased toxicity). The mandate to err on the side of increased safety can also be a disservice to public health. And, the policy to set nationwide standards can place unreasonable burdens on some industries and some regions of the U.S.
- 2. Linear incrementalism, in which CASAC only comments on each step in a long process can lead to conclusions that to not pass a "common-sense criterion". The questions posed to CASAC-PM appeared to be restrictive, carefully-crafted, and led to inevitable conclusions.
- 3. Defining particulate matter by aerodynamic mass fractions, with composition not taken into account, is poor science in my opionon, and it punishes some regions and industries. Furthermore, it does not apply to ultrafine particles (the count can be quite large without having any appreciable mass).
- 4. The current risk assessment process is seriously flawed. It is based on individual mass fractions, and can lead to regulations that do not serve public health. The 2009 National Academy of Sciences Report (National Research Council, "Science and Decisions: Advancing Risk Assessment", The National Academy Press, Washington, DC, 2009) advises that the "decision" to set a standard, not the "pollutant" is what must undergo risk assessment. The public must live with all of the relevant consequences of an air standard, not just selected effects of the substance under consideration (The general economy, jobs, and costs of goods and services have dominant impacts on public health, but they are not even considered by CASAC).
- 5. The public comments were not weighed and discussed by CASAC-PM in spite of the fact that most were well-reasoned and relevant. If the agenda included time for discussion of public comments and formal acceptance or rejection of their recommendations, the process might be improved.
- 6. The CASAC-PM subcommittee did not adequately inform the EPA Administrator on the pitfalls, scientific limitations, and even the range of adverse health consequences associated with the recommended PM standards. Not understanding the feasibility, economic hardships, and unintended adverse health consequences can place the

Administrator in the embarassing position of issuing a standard that may harm public health.

7. The public will not be adequately informed about the adverse effects associated with new standards. "Informed consent" is a fundamental ethical principle that should be applied to mandates, including air standards. Informed consent must include, and elucidate, the adverse consequences that flow from a decision. CASAC-PM was not allowed to adequately discuss the adverse consequences associated with air standards.

In sum, the current process, although elegant and efficient, in my opinion is flawed, narrow, and possibly ethically questionable.

It is important to reiterate that all of the people involved performed their tasks enthusiastically and competently. Thank you for this opportunity to provide what I hope are constructive comments.