

Public Comments on CASAC Review of EPA's Particulate Matter Policy Assessment
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I am a Professor of Preventive Medicine at the University of Southern California, where I have conducted epidemiological studies of air pollution for over 20 years. I direct both the Southern California Children's Environmental Health Center and the Southern California Environmental Health Sciences Center. I am a member of the Independent PM CASAC, comprised of former members of the EPA Committee disbanded a year ago, which provided an independent evaluation of the Policy Assessment to the Administrator. However, today I speak on my own behalf.

The CASAC Chair has criticized the epidemiological studies which form part of the basis for the EPA staff assessment that the current standard is not adequate to protect public health. However, there is no epidemiologist on the Committee, which has acknowledged that it lacks relevant expertise to evaluate the Policy Assessment. The key conclusion of the Assessment that the current PM_{2.5} standard is too high is based partly on well-designed prospective studies published largely since the previous EPA review of the standard. They have shown robust associations of mortality with chronic exposure at levels below the current annual standard of 12 $\mu\text{g}/\text{m}^3$. The EPA staff limited the assessment to studies conducted in the U.S. and Canada to reflect the effects of exposures to people in North America. The analyses in these studies were conducted using well established methods and showed that effects were robust to potential confounding, i.e. that PM_{2.5} mortality was not explained by social deprivation, racial or other demographic characteristics, nor by many other relevant factors; it is unlikely that weather would explain these effects. Moreover, the causal inference that PM kills was based on results of decades of epidemiological studies of different designs yielding consistent results. As important, a vast scientific literature demonstrates that chronic PM_{2.5} exposure causes disease and death in experimental animals, that it causes effects in biological pathways in experiments on cells and on animals that are also affected in exposed human populations in the real world and in studies in which volunteers receive brief, low level exposures experimentally. This approach to determining causality based on the consistent evidence from many scientific disciplines has been endorsed in a consensus of the scientific community developed and refined over decades.

The CASAC Chair suggests that only population studies analyzed using so-called "manipulative causality" and other "causal inference" approaches yield valid inference and can be used for risk assessment. In fact, recent studies using these approaches have also found increased mortality in populations exposed to PM_{2.5},⁽¹⁾ including at levels below the current standard.^(2, 3) However, these approaches have not been widely used in air pollution epidemiology, and the recent assessment of a lead investigator in perhaps the foremost group applying these methods to the study of air pollution health effects was that it is premature to conclude that a "manipulative causality" framework is better than other epidemiological approaches that have been endorsed historically by almost a

dozen PM CASACs over several decades, as maturing science has demonstrated effects at ever-lower levels of exposure to PM.⁽⁴⁾ Rather, these alternative methods may provide complementary information for the Integrated Science Assessment and Policy Assessment, as this field of air pollution epidemiology matures. In contrast to this conclusion, the clear implication of the Chair's perspective is that effects at or above the current standard of 12 ug/me also cannot be considered causal.

The Chair's approach is part of a program including a proposed - so-called "transparency" - rule that would exclude large and influential studies from consideration in standard setting, because commitments made to protect the privacy of participants' confidential information preclude sharing the raw data with anyone who would like to reanalyze the studies, either to use alternative causal inference analytical strategies or for other purposes. This program was strongly condemned recently in an unusual joint statement by the editors of *Science* and *Nature*, the world's two leading scientific journals, and other prestigious journals, reflecting the overwhelming consensus of the scientific community.⁽⁵⁾ This - some would say reckless - program would upend standard setting, to the detriment of public health. In the absence of appropriate expertise on the committee, members should dissent from an immature approach. Lives are at stake.

References

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