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Dr. Louis Anthony (Tony) Cox, Jr., Chair
Clean Air Science Advisory Committee (CASAC)
U.S. Environmental Protection Agency Washington, DC

Re: Comments for the October 22, 2019 CASAC Teleconference

Dear Dr. Cox and members of the Clean Air Science Advisory Committee,

On behalf of the North American Chapter of the International Society for Environmental Epidemiology (ISEE), I wish to make several major points today with regard to the peer review of the EPA's Policy Assessment for Particulate Matter:

1) CASAC should follow the advice of the Independent Particulate Matter Review Panel that was inappropriately dismissed without notice by a press release on October 10, 2018;
2) The latest scientific evidence indicates that the present particulate matter air quality standards are not sufficient to protect public health, and need to be made stricter;
3) CASAC should add composition-based particulate matter standards to more effectively protect the public against the most toxic components of particulate matter.

First, by its own admission in an April 11, 2019 letter, the CASAC committee needs scientific help in addressing a complex issue like the evaluation and regulation of particulate matter air pollution, stating "The breadth and diversity of evidence to be considered exceeds the expertise of the statutory CASAC members." We agree with that assessment, and recommend that the original CASAC particulate matter subcommittee, now operating as an independent committee led by Dr. Chris Frey, be consulted, and their advice followed.

Second, a review of the available scientific literature and the draft Particulate Matter Integrated Science Assessment (ISA) document makes it clear that there are significant and severe adverse health effects occurring below the present short- and long-term air quality standards. For example, the recent study by Hayes et al (2019) of the large and well-controlled NIH-AARP cohort has found that there is a statistically significant increase in cardiovascular deaths in the 8 to 12 $\mu g/m^3$ fine particulate matter ($PM_{2.5}$) annual average concentration range vs. below 8 $\mu g/m^3$ (HR = 1.04 per

10 μg/m^3). Thus, a long-term standard closer to 8 μg/m^3 is needed to more properly protect public health from the severe adverse effects of fine particulate matter.

Furthermore, multiple studies using causal inference methods, which are robust to model misspecification and confounding bias, have been published (e.g. Wang et al 2016, Schwartz et al 2016, Makar et al 2017). These studies have reported statistically significantly harmful effects of particulate matter exposures, even below the current air quality standards. In addition, Kioumourtzoglou and coworkers studied 19 million Medicare participants in 81 cities in the U.S. and looked at long term mortality rates and $PM_{2.5}$ exposure. They used a difference in differences analysis, a standard method in causal analysis. More recent difference in differences analyses include the study by Wang et al. (2016) in New Jersey, by Renzi et al (2019) in Lazio, Italy, and Yitshak-Sade et al. (2019) using all Medicare participants in the Northeast and mid-Atlantic states. Earlier difference in differences studies include Janke and Henderson (2009) and Zanobetti et al. (2007). Moreover, Wang et al (2017) applied a doubly robust propensity score-based approach to analyzing deaths among Medicare participants in the US Southeast. Schwartz et al. (2018) also applied a propensity score methods to examine the effect of $PM_{2.5}$ on life expectancy. Another paper by Abu et al. (2019) combined a propensity score approach with randomization by moving to look at all Medicare participants in the United States who changed address at least once. Regarding acute effects of $PM_{2.5}$, Schwartz et al. (2019) examined 135 cities using three causal methods; instrumental variables, negative controls, and propensity score methods. In fact, the effects estimated in these studies are similar to those in studies using more traditional regression methods. This consistency and robustness of results is of utmost importance. A single study will never prove or disprove a causal effect. Evidence of causation, rather, comes from collective weight of evidence, consistent across many studies that use different populations, different study designs, and which are susceptible to different sources of bias (NASEM, 2017). There is, thus, strong evidence in the literature show that causal methods have found $PM_{2.5}$ associations with adverse health effects, and that significantly harmful health effects occur even at concentrations below the current national standards.

Third, the evidence provided by this ISA and previous ISA documents indicates that certain constituents of $PM_{2.5}$ are more strongly associated with adverse effects than others. In order to most efficiently protect public health, the most toxic particles must be the focus of regulation. Based on available information, pollution from fossil fuel combustion, including coal, oil, and diesel combustion, are among the very most toxic, as indicated by particulate sulfur (S, sulfates) and elemental carbon (EC) indices of exposure. For example, in the recent Thurston et al (2016) study of the large and also well-characterized ACS cohort, particulate sulfur was found to be associated

with a statistically significant increased risk of death from ischemic causes (HR = 1.06 per 0.53 $\mu g/m^3$ S, or 1.6 $\mu g/m^3$ SO_4), as was particulate elemental carbon (HR = 1.03 per 0.26 $\mu g/m^3$). By also regulating these fine particulate matter constituents, in a manner similar to the way particulate lead (Pb) already is regulated, the most health damaging $PM_{2.5}$ particles will properly be of primary focus of future $PM_{2.5}$ mitigation strategies.

Overall, the process followed by CASAC has been inadequate, due to the lack of proper advice. Fine particulate matter air pollution represents a real and significant public health risk that must be properly addressed if the US EPA is to achieve its mandate under the Clean Air Act of 1970 "to establish National Ambient Air Quality Standards (NAAQS) to protect public health and public welfare" (42 U.S.C. §7401 et seq.,1970).

Sincerely,

Professor George D. Thurston, Sc.D.
NYU School of Medicine
On behalf of the ISEE North American Chapter

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