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Before

Clean Air Scientific Advisory Committee on the
Policy Assessment for Fine Particulate Matter ($PM_{2.5}$)
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Chairman Cox, and Members of the Committee, Good Morning, my name is Stewart Holm and I am Chief Scientist at the American Forest & Paper Association (AF&PA) and the American Wood Council (AWC). I appreciate the opportunity to provide comments to the Clean Air Scientific Advisory Committee (CASAC) on the Policy Assessment (PA) for fine particulate matter ($PM_{2.5}$). We support basing the decision on whether a National Ambient Air Quality Standard (NAAQS) revision is appropriate on an unbiased review of the latest scientific information.

The American Forest & Paper Association (AF&PA) serves to advance a sustainable U.S. pulp, paper, packaging, tissue and wood products manufacturing industry through fact-based public policy and marketplace advocacy. AF&PA member companies make products essential for everyday life from renewable and recyclable resources and are committed to continuous improvement through the industry's sustainability initiative — *Better Practices, Better Planet 2020*. The forest products industry accounts for approximately four percent of the total U.S. manufacturing GDP, manufactures over $200 billion in products annually and employs approximately 950,000 men and women. The industry meets a payroll of approximately $50 billion annually and is among the top 10 manufacturing sector employers in 45 states.

The American Wood Council is the voice of North American wood products manufacturing, an industry that provides almost 450,000 men and women in the United States with family-wage jobs. AWC represents 86% of the structural wood products industry, and members make products that are essential to everyday life from a renewable resource that absorbs and sequesters carbon. Staff experts develop state-of-the-art engineering data, technology, and standards for wood products to assure their safe and efficient design, as well as provide information on wood design, green building, and environmental regulations. AWC also advocates for balanced government policies that affect wood products.

Understanding the relationship between chronic exposure to $PM_{2.5}$and mortality is a fundamental challenge in supporting an appropriate NAAQS for $PM_{2.5}$. EPA states that a causal relationship is one where the pollutant has been shown to result in health and welfare effects at relevant exposures based on studies encompassing multiple lines of evidence -- and chance, confounding, and other biases can be ruled out with reasonable confidence. This is the correct framing of the causality question, but we find that the EPA process for evaluating and interpreting studies is insufficient for establishing causality. Moreover, the process fails to provide adequate information to assist the Administrator's public health policy judgements and decisions. The Policy Assessment needs to present the potential implications of placing more or less weight on various evidence, such as air quality and risk information, as well as the associated uncertainties and limitations of the cited studies. The selection of studies, distillation of their data and how they are presented to the Administrator is critically important. Omitting key studies from consideration can greatly diminish the quality and validity of the evaluation.

There are many studies that have reported a statistical association between $PM_{2.5}$ and mortality. Some of the key studies are based on cross-sectional comparisons of people in different cities. These cross-sectional studies can be vulnerable to confounding due to differences across the city populations that may be correlated with $PM_{2.5}$ exposure. Socioeconomic or behavioral factors could explain some or all of the correlations with health effects. Further, cross-sectional studies often do not address the influence of long-term time trends in both ambient $PM_{2.5}$ levels and mortality. Based on the national trend, $PM_{2.5}$ levels in cities are decreasing, while life expectancy is increasing. If the relationship between $PM_{2.5}$ exposure and mortality is not causal, but rather $PM_{2.5}$ concentrations and life expectancy coincidentally follow similar trends, then this can produce a spurious relationship between exposure and mortality. A statistical correlation does not mean causation at these lower exposure levels.

The CASAC noted that the draft ISA omitted several relevant studies and mischaracterized others. More specifically, your letter (p. 14) concerning the ISA pointed to several studies that should be included in the review. These included studies by Janes et al. (2007), Greven et al. (2011) and Pun et al. (2017) that incorporated "a difference-in-difference analysis." I cited these studies in my testimony to you last December on the ISA and gave a copy to EPA staff. These papers have not been included in the PA. To briefly discuss their importance, I'd like to summarize Pun et al.

Pun examined the relationship between monthly 1-year-averaged $PM_{2.5}$ exposures and monthly mortality for a cohort from the Medicare data base. Importantly, Pun et al. shows that the long-term relationship between $PM_{2.5}$ and mortality is confounded by some other, unmeasured long-term trend(s). This lack of a clear and consistent long-term relationship between $PM_{2.5}$ exposure and mortality raises the potential for spatial confounding in the cross-sectional studies mentioned earlier.

Another important component of the Pun study was the conduct of multivariable regression analyses to assess the association between mortality and $PM_{2.5}$ without and with adjusting for potential confounding by behavioral covariates from the Selected Metropolitan/Micropolitan Area Risk Trends of the Behavioral Risk Factor Surveillance System (BRFSS).

In summary, for both All-cause and Cause-specific outcomes, temporal data for the non-adjusted model is positive and statistically significant. On the other hand, spatio-temporal outcomes for all cause and cause-specific information for the US are often lower and statistically insignificant. Additionally, comparing temporal data for non-adjusted versus BRFSS-adjusted outcomes shows that the adjusted outcomes show much lower values that are statistically insignificant, and some cause-specific outcomes have point estimates below 1.

In contrast to the papers reviewed in the PA, the Pun paper provides an approach that breaks down information from an observational epidemiologic study into distinct temporal and spatio-temporal components which might experience different degrees of confounding bias. Most previous studies of long-term air pollution exposure have focused on the cross–sectional comparisons. In Pun, comparisons are made over time, using each city as its own control. The result is a substantial difference in the estimated $PM_{2.5}$ All-cause mortality as well as Cause-specific mortality. Although both $PM_{2.5}$ and mortality are trending downward nationally, cities with steeper reductions in $PM_{2.5}$ do not tend to have steeper reductions in mortality. The study illustrates the associated uncertainties and limitations that should be brought forward to the Administrator to assist in his evaluation of PM health data. Without the Agency providing an adequate review, we think that CASAC should recommend that the EPA staff revise its advice to the Administrator to include a recommendation of retaining the existing NAAQS.

References:

1. Janes H, Dominici F, Zeger SL. Trends in air pollution and mortality: an approach to the assessment of unmeasured confounding. Epidemiology. 2007 Jul;18(4):416-23
2. Greven S, Dominici F, Zeger S. An Approach to the Estimation of Chronic Air Pollution Effects Using Spatio-Temporal Information. J Am Stat Assoc. 2011;106(494):396-406.
3. Pun VC, Kazemiparkouhi F, Manjourides J, Suh HH. Long-Term PM2.5 Exposure and Respiratory, Cancer, and Cardiovascular Mortality in Older US Adults. Am J Epidemiol. 2017 Oct 15;186(8):961-969.