Comments on the Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter, External Review Draft

Julie E. Goodman, Ph.D., DABT, FACE, ATS
Gradient

Thank you for the opportunity to speak today regarding the "Policy Assessment [PA] for the Review of the National Ambient Air Quality Standards for Particulate Matter [PM], External Review Draft." I am an epidemiologist and board-certified toxicologist at Gradient, a risk sciences consulting firm. I am speaking on behalf of Gradient, but my time spent preparing these comments and attending this meeting has been funded by the American Petroleum Institute.

The draft PA notes that a conclusion that the current standards provide adequate health protection "would place little weight on the broad body of epidemiologic evidence reporting generally positive and statistically significant health effect associations, particularly for $PM_{2.5}$ air quality distributions likely to have been allowed by current primary standards, or on the $PM_{2.5}$ risk assessment."

Rather, it would place greater weight on uncertainties and limitations in the evidence and analyses. The draft PA indicates this conclusion includes the fact that studies that examine biological pathways do so at exposures well above those likely to occur in areas meeting the current standards, that accountability studies only evaluated exposures starting above the current standard, and that uncertainty in the risk assessment results from uncertainties in the underlying epidemiology studies, in the air quality adjustments, and in the application of study and air quality information to develop quantitative estimates of $PM_{2.5}$-associated mortality risk.

In fact, this conclusion does not place little weight on epidemiology evidence. On the contrary, it is primarily based on epidemiology evidence, and the risk assessment based on this evidence, that this conclusion is reached.

For example, the draft PA indicates that new studies support health effects at exposure concentrations below the current primary standards based on the mean $PM_{2.5}$ concentrations in key epidemiology studies and pseudo-design values calculated by the US Environmental Protection Agency (EPA). The mean $PM_{2.5}$ concentrations are impacted by potential exposure measurement error and the lack of near-road monitors. Exposure measurement error can be large as a result of irrelevant exposure measurement windows, unaccounted residential mobility or temporal variation, and poor prediction model performance. Near-road monitors tend to capture higher $PM_{2.5}$ concentrations than those in surrounding areas, so study-reported mean $PM_{2.5}$ concentrations would have been higher had near-road monitors been in place. Also, the draft PA focuses on the center of the $PM_{2.5}$ distributions, but associations observed at the center of the data are likely driven by the upper portion of the air quality distribution, assuming risk increases with exposure. Importantly, these issues make it such that these studies cannot rule out a threshold concentration-response relationship.

In addition, while pseudo-design values are more similar to design values than mean $PM_{2.5}$ concentrations, the pseudo-design values in the draft PA likely overestimated the extent to which study areas met the current standards because they were averaged over the entire study period (instead of three years) and because of the lack of near-road monitors. The observed distributions of pseudo-design values indicate that a large

proportion of the study populations in the key epidemiology studies were likely in areas that did not meet the current standard. Even so, these results indicate that the key studies do not provide sufficient evidence against the adequacy of protection provided by the current $PM_{2.5}$ standard.

The draft PA claims that the risk assessment supports substantial decreases in risk at standards of 8, 9, 10, and 11 μg/m^3. The draft PA directly evaluates "current" (2015) air quality conditions, a hypothetical air quality scenario in which air quality just meets the current annual standard of 12 μg/m^3 by scaling up current emissions, and a hypothetical air quality scenario in which air quality just meets an alternative annual standard of 10 μg/m^3. EPA then uses unvalidated linear extrapolation to evaluate an air quality scenario just meeting an alternative standard of 9 μg/m^3 and linear interpolation to evaluate 11 μg/m^3. However, there is no evidence presented that indicates that $PM_{2.5}$ concentrations would scale linearly between modeled alternative standards. The 8 μg/m^3 alternative standard was not evaluated at all.

In addition, the risk assessment was performed for a small fraction of the US that does not necessarily correlate with the areas in the epidemiology studies on which the risk assessment was based. Considering this and uncertainty in modeled $PM_{2.5}$ concentrations, as well as unconventional rounding choices and compounding levels of conservativism in the modeling, fine-scale distinctions between proposed alternative standards cannot be made. That is, the issues make the risk assessment inadequate to evaluate any differences between proposed standards that only differ by 1 μg/m^3. It is also notable that the draft PA acknowledges that it does not conduct a robust uncertainty analysis. That is, it does not quantify the impacts of many sources of uncertainty, including sources that have the potential to affect the conclusions of the risk assessment. This effectively renders meaningless the comparisons between the risk assessment results for different alternative standards.

Taken together, currently available scientific evidence and risk-based information does not provide sufficient evidence to call into question the adequacy of the public health protection afforded by the current annual and 24-hour $PM_{2.5}$ standards.