Testimony on the Proposed Rule: National Ambient Air Quality Standards for Particulate Matter (June 2012)

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Thank you for the opportunity to speak today. I am Dr. Julie Goodman, an epidemiologist and board-certified toxicologist at Gradient, an environmental consulting firm in Cambridge, Massachusetts. I also teach a graduate-level epidemiology course at the Harvard School of Public Health. I received funding from the American Petroleum Institute to travel here today, but I am speaking on my own behalf.

Based on my expertise in air pollution science, I conclude that EPA's rationale for lowering the $PM_{2.5}$ annual standard to a level between 12 and 13 $\mu g/m^3$ was not based on a scientifically sound approach.

EPA stated that the body of scientific evidence – which includes epidemiology, toxicology, and mechanistic data – is consistent and together supports lowering the standard to protect against potential PM-related health effects. Over the next few minutes, I will discuss three reasons why this is not the case. First, even though EPA asserted that these data all factor into the overall conclusions in the proposed rule, it is evident that EPA based its conclusions almost solely on the epidemiology data. Aside from being an unbalanced approach, these studies are not informative for PM levels below the current standard. Second, despite evidence to the contrary, EPA assumed that PM has no threshold, or level below which it is not likely to affect human health. This assumption biases the way epidemiology data are analyzed, making risks appear higher. Third, EPA arbitrarily selected a proposed annual $PM_{2.5}$ standard that is "just below" average concentrations reported in a select few epidemiology studies. This is a non-scientific method, and these particular studies are no more definitive than other studies not showing effects at these levels.

As for my first point, EPA incorrectly concluded that new epidemiology studies provide stronger evidence of associations between both long- and short-term $PM_{2.5}$ exposure and mortality. Like the studies evaluated in the prior review of the NAAQS, issues with these studies include confounding by co-pollutants and other factors; heterogeneity in PM concentration and composition; exposure measurement error; and the statistical models. Even disregarding these limitations, the epidemiology data as a whole are inconsistent both within and among studies, with some analyses suggesting increased risks for some health effects and others reporting no effects at average annual levels below and above the current PM standard. Taken together, this indicates that the epidemiology data are not sufficient to support lowering the standard.

With regard to my second point, EPA incorrectly concluded that "[t]oxicological studies provide supportive evidence that the cardiovascular morbidity effects observed in long-term exposure epidemiological studies are biologically plausible and coherent with studies of cardiovascular-related mortality." This is not the case. Animal studies do not consistently find effects on potential markers of cardiovascular disease, even at exposures that far exceed ambient levels. Overall, experimental exposure studies in both animals and humans demonstrate that inhaling $PM_{2.5}$ only affects human health at very high doses that overwhelm natural defense mechanisms. That is, the body's natural defenses can

effectively deal with a certain level of $PM_{2.5}$, indicating there is an exposure level below which $PM_{2.5}$ is not likely to cause effects. Also, the effects observed at high exposure levels are mild and reversible, which is not consistent with the more severe effects reported in the epidemiology studies on which EPA relied. This is true not only for cardiovascular effects, but respiratory effects as well.

My third point is in regard to the way in which EPA selected the proposed level of the standard. In the Policy Assessment, EPA assessed whether there is a PM concentration at which there is an "unacceptable degree of uncertainty" and "the possibility that an effects threshold may exist becomes more likely." EPA provided three studies that indicated a high degree of uncertainty at PM levels below the current annual standard. EPA concluded, however, that the results did not suggest the existence of a potential threshold but, rather, "the comparative lack of air quality data at lower $PM_{2.5}$ concentrations." Choosing a standard "just below" average concentrations reported in a select few epidemiology studies is not justified when the science suggests an unacceptable degree of uncertainty.

In conclusion, EPA did not fully consider the whole body of evidence and relied almost solely on epidemiology studies. EPA also did not fully consider the evidence that PM health effects have a threshold. Finally, EPA did not use a scientifically appropriate method to select the level of the standard. EPA should consider the issues with the epidemiology studies and that the epidemiology, toxicity, and mechanistic data are not coherent for PM exposures below the current standard. Also, the rationale for the proposed standard is arbitrary and not based on sound science. Overall, the available scientific data do not support lowering the annual PM standard.