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"Is there a toxicological rationale for US EPA's tightening the National Ambient Air Quality Standards for fine particulate matter (PM-2.5) in our ambient (outdoor) air?"

Good morning, Mr. Chairman and members of the Subcommittee on Energy and Power. Thank you for inviting me to testify this morning. I'm Peter Valberg, Principal at Gradient, an environmental consulting firm near Boston. I've worked for many years in public health and human health risk assessment and inhalation toxicology. For more than a decade, I was a faculty member at the Harvard School of Public Health, and I was a member of a National Academy of Sciences panel that worked on evaluating public health benefits of air-pollution regulations. I've also testified before the Clean Air Science Advisory Committee (CASAC). In my testimony regarding airborne particulate matter, or "PM," I point to the importance of experimental science in evaluating PM health effects, because EPA's health-effects analyses of $PM_{2.5}$ rely too heavily on statistical associations and undervalue the role of laboratory science in helping understand the toxicology of breathing PM in outdoor air.

There are major questions about EPA's forecast of serious health effects caused by small increments in PM levels at concentrations close to the NAAQS. Most importantly, neither data from lab animals inhaling PM nor the human clinical data validate a causal basis for the statistical associations between PM levels and, say, mortality, that are reported by observational epidemiology studies. Our scientific knowledge regarding the health risk of any exposure is supported by three legs of evidence: one leg is observational studies, or, epidemiology, another leg comes from clinical data and experimental studies with lab animals, and the third leg is understanding of biological mechanism. If any legs are weak or missing, as in the case of ambient PM, the reliability of our knowledge is compromised.

Researchers have carefully monitored both human volunteers and animals breathing all types of PM, often at levels hundreds of times greater than in outdoor air. They don't find evidence of sudden death or life-threatening effects. Moreover, toxicologists have studied the chemicals that constitute particles in outdoor air, and no one has found any ambient $PM_{2.5}$ constituents that are life threatening when breathed at levels we encounter outdoors (Valberg, 2004). Remember that, in human responses to

chemical intake, "the dose makes the poison." With regard to mechanistic support, EPA does not provide a sequence of recognized biological events whereby breathing low levels (12 to 13 μg/m^3) of outdoor $PM_{2.5}$ can cause death or disease requiring hospitalization.

On a more practical side, EPA's health harm projections for PM, which are based on the statistical associations alone, are contradicted by the health of people in dusty occupations, and by everyday experience of all of us when we breathe elevated levels of PM in our own homes, cars, and other personal environments, such as lawn mowing, raking leaves, barbecuing, vacuuming, and sitting by the fireplace or campfire. These PM concentrations are vastly higher than PM in typical outdoor air. Even though many of these activities are short term, their elevated levels contribute significantly to our annual and lifetime $PM_{2.5}$ dose, and EPA does not make clear that, according to their health harm projections for PM, these indoor levels should be vastly more harmful than outdoor $PM_{2.5}$.

Worker studies show that occupational environments with levels of dust and smoke in compliance with occupational standards do not exhibit excess mortality. (Abraham *et al*., 2011; Dell *et al*., 2008; Fryzek *et al*., 2003; Harber *et al*., 2003; Wild *et al*., 2008) For example, for workers exposed to airborne copy-machine toner, Alison Abraham, Jon Samet, and collaborators determined that the workers' PM exposures over many years averaged in the range of 340 μg/m^3, yet mortality rates were <u>not</u> increased, but <u>below</u> expected rates. *i.e.*, the standardized mortality ratio (SMR) was 0.88, and this was statistically significantly below 1.00 (Abraham *et al*., 2011).

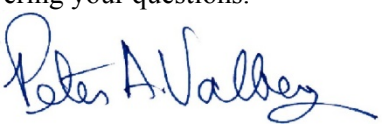
EPA relies on statistical associations between central-monitor PM levels and population mortality rates, but correlations cannot establish causal links. The computer models needed to uncover the PM-mortality correlations require many assumptions and adjustments, and the results you get depend on the model you use, how you set it up, and how many different tests you run. It's not possible to correct for the many non-PM air pollutants, as well as non-pollution factors that may confound the PM-mortality associations. This model dependency is a known problem, and it has been pointed out in several publications. *e.g.*, Koop and Tole (2004); Cox (2012) and Greven *et al*. (2011) Many unknown factors can affect population mortality rates. For example, studies have shown that population mortality rates

are correlated with calendar date, day of the week, stock prices, weather, or outcome of sports competitions (Phillips *et al*.; Ma *et al*.; Keatinge and Donaldson; Kloner *et al*.; Valberg). Yet, we would not think of outlawing certain calendar dates, or the Super Bowl, even though the associations with increased mortality are quite consistent.

Even if we restrict our attention to the statistical studies *per se*, there is considerable unexplained heterogeneity in reported PM effect factors across urban areas, with no risks reported for many cities, leaving uncertainty as to whether lowering the $PM_{2.5}$ NAAQS will truly yield health benefits. Numerous reports can be found where analyses of short-term or long-term ambient PM concentrations leads to inconsistent, or null, health impacts. (Short term: Chock *et al*. 2000; Clyde *et al*. 2000; Klemm and Mason 2003; Moolgavkar 2003; Ito 2003. Long-term: Krewski *et al*. 2000 [for models that include SO_2]; Beelen *et al*. 2008; Enstrom 2005; Lipfert *et al*. 2006 [for models that included traffic density]; Chen *et al*. 2005 [for males in the cohort]; Brunekreef *et al*. 2009; Zeger *et al*. 2008) In a recent study of the association of $PM_{2.5}$ levels with risk of stroke, an increase in $PM_{2.5}$ levels <u>decreased</u> the risk of stroke. "Overall, $PM_{2.5}$ was associated with a − 0.7% change in ischemic stroke risk per 10 $\mu g/m^3$" (O'Donnell *et al*., 2011). Likewise, a recent study in Japan evaluated the effects of PM on stroke and found no effect (Turin *et al*., 2012). Such results pointing in opposite directions highlight significant remaining uncertainties in the PM associations, and EPA does not explain why these "no effect," or inconsistent findings, should be disregarded in favor of those studies that show small, but statistically significant, effects.

In summary, EPA's statistical approach is fraught with numerous assumptions and uncertainties, and EPA does not provide adequate experimental evidence and laboratory science to support a causal role for $PM_{2.5}$, at levels below the current $PM_{2.5}$ NAAQS, causing serious health effects, like mortality. Moreover, since EPA admits they have no understanding of which $PM_{2.5}$ constituents they believe cause their predicted deaths – does it make sense to lower the standard without such information?

Thank you for the opportunity to testify today, and I look forward to answering your questions.



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