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Regarding Air Quality and Children's Health

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Good morning and thank you for the opportunity to testify regarding air quality and children's health. I am Julie E. Goodman, Ph.D., Diplomate of the American Board of Toxicology (DABT). I am a Principal at Gradient, a firm specializing in human health risk assessment in Cambridge, Massachusetts. I also teach a graduate-level epidemiology course at the Harvard School of Public Health. I am presenting testimony this morning on my own behalf as an independent scientist. I am not representing myself under any federal contract or grant.

Clean air and children's health are very important to me, both as a scientist and as a mother. We all want clean air and appropriate standards if they result in health benefits. But unless there is evidence that standards would improve health or reduce the disease burden associated with air pollution, resources should be used towards other measures that would more clearly benefit society.

Several issues with EPA's risk assessment methodologies were noted this year by a committee assembled by the National Research Council (NRC) of the National Academy of Sciences (NRC, 2011). This committee reviewed EPA's draft assessment of formaldehyde (US EPA, 2010b) and noted a number of things that had also been identified in previous EPA assessments conducted over the last decade. Some of the concerns raised include a lack of information regarding study selection criteria, inconsistent methods for evaluating the strengths and weaknesses of studies, and the lack of a clear framework for evaluating the weight of evidence for establishing what causes adverse health effects. These are also major limitations with EPA's evaluations of the National Ambient Air Quality Standards (NAAQS), including the ongoing reconsideration of the ozone standard, which is scheduled to be finalized in July (*e.g.*, US EPA, 2008a and b, 2009, 2010a, 2011).

A key point of my testimony today is that, because of these limitations identified by the NRC committee, the methods used by EPA to assess the risks of air pollution are likely to overestimate the benefits of more stringent air quality standards. This potentially diverts limited national resources to implementing air quality standards that do not improve public health.

In the evaluation of air pollution studies, including the ongoing ozone science assessment, EPA does not evaluate the strengths and weaknesses of individual studies consistently. In several instances, EPA criticized one study for using a certain methodology, while another study – using the same methodology – did not receive the same critique. This resulted in the latter study receiving more weight in the overall analysis, when both studies should have been considered equally. This was consistent with what the NRC committee said about the formaldehyde assessment, in that "[s]ome studies receive a fuller

treatment, including a more extensive assessment of bias and its consequences for estimating effect measures, and others receive less attention."

This is a particularly salient issue when studies come to different conclusions. EPA has a tendency to overemphasize study results that suggest a pollutant may be associated with a health effect and de-emphasize, or fail to consider at all, study results indicating no association. This leads to a biased assessment of the data. If similar studies show that a certain level of pollution is harmful in some cases but not harmful in others, one must question *both* results – not just the latter.

Study outcomes depend on many factors besides pollution, so the results of a single study or part of a study are not sufficient to determine what is occurring in the general population. Rather, real effects should be seen in patterns within and across all relevant epidemiology studies, and consistent with the results of other types of studies, such as toxicity, mechanistic, and exposure studies. This does not necessarily mean that all studies should be in complete agreement; rather, if a pollutant is truly causing a health effect, it will be evident when all of the data are considered as a whole. EPA does not take this approach in assessing studies.

Overall, and consistent with the NRC formaldehyde committee findings, a presentation of the study selection criteria and a clearly articulated framework for weighing the evidence are critical for any determination of whether an air pollutant is causing a health effect. The NRC formaldehyde committee recommended that all key studies "need to be thoroughly evaluated with standardized approaches that are clearly formulated based on the type of research." The committee also stated, "Strengthened, more integrative, and more transparent discussions of weight of evidence are needed. The discussions would benefit from more rigorous and systematic coverage of the various determinants of weight of evidence, such as consistency." These scientific guidelines should be followed by EPA when evaluating air pollution studies as well. Today, they are not.

Finally, I would like to emphasize that I am not suggesting that air pollutants do not cause harm at high concentrations. Studies have shown consistently that they do. The issue is whether effects occur at air pollution levels observed today. Correcting the weaknesses cited by the NRC committee by using a transparent, weight-of-evidence methodology could significantly improve our understanding of the risks posed by air pollution. This would ensure that we do not use limited national resources to implement air quality standards that do not benefit the health of children or the population at large.

References

National Research Council (NRC). 2011. "Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde (Prepublication Copy)." National Academies Press, Washington, DC, 155p. Accessed on April 8, 2011 at http://www.nap.edu/catalog/13142.html, April.

US EPA. 2008a. "Integrated Science Assessment for Oxides of Nitrogen." National Center for Environmental Assessment (NCEA), EPA/600/R-09/071, July.

US EPA. 2008b. "Integrated Science Assessment for Sulfur Oxides - Health Criteria." Office of Research and Development, EPA/600/R-08/047F, September.

US EPA. 2009. "Integrated Science Assessment for Particulate Matter (Final)." National Center for Environmental Assessment (NCEA), EPA/600/R-08/139F, December.

US EPA. 2010a. "National Ambient Air Quality Standards for Ozone (Proposed Rule)." Docket Number EPA-HQ-OAR-2005-0172; 40 CFR parts 50, 58, 115p., January.

US EPA. 2010b. "Toxicological Review of Formaldehyde - Inhalation Assessment (CAS No. 50-00-0) in Support of Summary Information on the Integrated Risk Information System (IRIS). Volumes I-IV (Draft)." EPA/635/R-10/002A, June.

US EPA. 2011. "Integrated Science Assessment for Ozone and Related Photochemical Oxidants (First External Review Draft)." National Center for Environmental Assessment (NCEA), EPA/600/R 10/076A, March.