

Producing Credible Science for Decisions

Testimony of
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Summary

The production of high quality, credible science is of critical importance to informing often-controversial policy decisions on environment and health. For over 30 years the Health Effects Institute, an independent not-for-profit research institute with joint and balanced funding from US EPA and industry, has produced trusted science in a variety of forms to inform air quality decisions. This testimony draws from that experience – and from the results of the recent report of the Bipartisan Policy Center (*Improving the Use of Science in Regulatory Policy*) – to highlight *key principles* of producing credible science, including:

- Engaging scientists who are *independent and objective*;
- Funding science through vigorous *open competition*;
- Applying the *full range of multi-disciplinary skills*;
- Subjecting all results to *intense peer review*, and *re-analysis* if needed; and
- Conducting and reporting science with *full transparency*.

This testimony describes how each of these key principles contributes to producing credible science; the critical elements necessary for applying them successfully, and the degree to which practice at US EPA and elsewhere in government includes these approaches currently and/or could be enhanced.

TESTIMONY

Mr. Chairman, and members of the Committee, it is my pleasure to appear before you at this important hearing, *Fostering Quality Science at EPA: Perspectives on Common Sense reform – Day II*. I am Daniel S. Greenbaum, President of the Health Effects Institute (HEI), an independent not-for-profit research institute with joint and balanced funding from US EPA and industry that, for over 30 years, has produced trusted science in a variety of forms to inform air quality decisions. I also was pleased to serve recently on the Committee of the Bipartisan Policy Center on *Science and Policy*, a multi-party expert panel that made recommendationsⁱ on improving the development and use of science in policy. I draw on the rich experience of HEI, and the recommendations of the Science and Policy Committee to highlight several important principles for producing credible science to inform environment and health decisions.

The Health Effects Institute

HEI was born out of controversy. During implementation of the Clean Air Act rules for air quality and vehicle emissions in the 1970s, there was substantial disagreement between manufacturers and the US EPA about the underlying health science driving decisions. HEI was established with the support of US EPA and industry as an independent, non-partisan entity to produce health science that could be agreed to by all parties – and could serve as the basis for better decisions. HEI is designed with several key elements to ensure its impartiality:

- *Joint and balanced core funding from US EPA and industry;*
- *An independent, high level Board of Directors* of distinguished science and policy leaders to guarantee the integrity of the science, with members agreed to by the EPA Administrator and industry but not containing any current sponsor employees.
- Standing Committees of subject matter experts in exposure, toxicology, epidemiology, statistics and other disciplines who are not employees of sponsors and who may not have demonstrated “a lack of objectivity” in their field:
 - *A Research Committee* to design, conduct competitions for, and oversee all research
 - *A Review Committee* to conduct intensive peer review of all HEI-funded research, and prepare a Commentary on the scientific findings and their implications for decisions.
- Special Expert Committees appointed according to the same principles to conduct targeted *reanalyses* of key studies and *systematic reviews of the literature* in important areas.
- Full *transparency*, with all results published and available for free electronically, and active provision of access to underlying data
- Importantly, HEI produces policy-relevant science, *but does not take policy positions.*

With these elements in place, HEI has funded over 250 studies of a wide range of air pollutants; reanalyses of a number of epidemiologic studies central to decisions; and special reviews of the literature on diesel exhaust, air toxics, traffic effects, and more. HEI's work has been widely accepted as credible and comprehensive, and is regularly cited in decision making in the US and worldwide.

Principles of Credible Science

HEI was not established to replace all science produced for air quality policy decisions. Much science was then and is today produced directly with funding from US EPA, the National Institutes of Health, and others. But HEI's design was developed to produce science of the highest quality and credibility at the most critical and often controversial junctures of science and decisions, and the key principles that HEI has applied can inform the enhancing of credibility of all science produced for informing decisions. These *key principles* are:

- Engaging scientists who are independent and objective: quality science for decisions requires the active involvement of a wide range of talented individuals, from diverse perspectives. Many scientists are fully engaged in their research and teaching, and hesitant to become overly involved in often controversial science/policy settings. One result of this is that at times one can find a range of scientists actively engaged in the work of organizations like the National Academy of Sciences, but, despite the best recruitment efforts of entities such as the Science Advisory Board, unwilling to engage in the scientific work of agencies like EPA. To further enhance skills, HEI has sought to engage scientists from a wide variety of arenas, not just environment and health; it is essential that public and private science organizations actively reach out to the widest possible range of scientists, seeking consciously to engage scientists with diverse perspectives and skills.

For maximum credibility, scientist recruitment must also ensure that scientists do not carry with them real or readily perceived conflicts of interest, e.g. a direct financial interest in the outcome of the scientific deliberation. The BPC Science and Policy Report systematically reviews the many detailed approaches that have been adopted by US EPA, other Federal agencies, the NAS, and others for identifying both biases and conflicts of interest, and recommends enhanced approaches to this important task.

It is important, however, that such reviews of bias and conflicts not act to unnecessarily place scientist selection in a "strait jacket" that, for example, disqualifies well qualified scientists simply because they have been funded by industry or US EPA, or have done work, or work currently, for industry or an environmental organization. Some of the best experts

have received funds from a range of sponsors, are capable of providing a balanced perspective on the science, and should be included unless there is a real and current conflict of interest.

- Funding science through vigorous *open competition*: a hallmark of the highest quality science is to ensure that it is selected and funded through the highest levels of peer-reviewed competition. HEI and a number of other research programs, including US EPA's STAR grants program (which has received exemplary reviews from the National Research Council) have used well-established techniques for soliciting, reviewing, scoring, and selecting such projects. At the same time, this is an area where the broad-based recruitment of scientists to participate in these selection processes, and the recusal of scientists from reviewing applications from their own institutions, is essential to ensuring a "level playing field" for competitors from the widest possible set of institutions and scientific perspectives.
- Applying the *full range of multi-disciplinary skills*: Since its inception, HEI has seen fully multi-disciplinary science as the only way to answer complex questions facing decision makers in environmental health. Thus, for example, a team studying the health effects of certain emissions, or peer reviewing the results of such a study, must include engineering and exposure measurement expertise. And the best health studies will draw on a combination of toxicological and epidemiological techniques to determine whether a certain exposure is having an effect. Perhaps most important, HEI has placed the field of biostatistics at the center of its work, insisting on pre-designed statistical analysis plans for each major project, and subjecting each study's results to intense statistical review to ensure that (a) the best and most appropriate statistical techniques were applied and (b) any positive results (i.e. those showing an "effect") are placed in the context of the full range of positive and negative results before interpreting the study's conclusions.
- Subjecting all results to *intense peer review*, and *re-analysis* if needed: Peer review has been a cornerstone of science for generations and has served well, in general, to identify the strongest contributions to the scientific literature on a wide variety of topics. However, with the profusion of scientific journals in recent years, and the diversification of peer review processes, the degree to which any particular journal article is subjected to the highest level of peer review can vary substantially. This is further complicated by the tendency of journals to be more interested in publishing studies that have found a positive "effect," a "publication bias" which has now been documented in a number of settings.ⁱⁱ

The HEI peer review process was designed to address these shortcomings, especially for science at critical intersections between science and decisions. That process includes several key elements: (a) a comprehensive report of all findings, not necessarily only the "positive" results; (b) a broad based standing panel of experts (the HEI Review Committee) which has had nothing to do with the study and meets in person to review each report and to prepare a

detailed Commentary on the study findings and their implications; (c) the active engagement of at least two biostatisticians in each review; and (d) the contractual ability to request and gain access to *all* underlying data generated in the study and used in the analysis. These and other steps result in a level of peer review that is widely regarded as being as intense as, and in some cases more intense than, the peer review at the best scientific journals.

HEI has, at times, also been asked by Congress, US EPA, industry, and others to go beyond its intensive peer review of its own studies to play two other intense review roles: the *reanalysis of key studies* that are particularly central to decisions (e.g. the HEI reanalysis of the Harvard Six Cities and American Cancer Society studiesⁱⁱⁱ); and the *systematic review of the complete scientific literature on emissions, exposure, and health* (e.g. recent reviews of the science on the potential effects of exposure to air toxics and to traffic-generated air pollution^{iv}). In each of these cases HEI's Board of Directors appoints multi-disciplinary expert panels according to the same principles of independence to oversee reanalysis and systematic literature reviews. *And* those efforts are then in turn subjected to high levels of peer review by experts who have not previously been involved.

- Conducting and reporting science with *full transparency*: From its inception HEI has sought to produce its work with the widest degree of disclosure of results and underlying data. This is critical to ensuring that all results – both positive and negative – are reported, and that the broader science community can fully access, and further analyze, the results and data. HEI's comprehensive reports present, for free web distribution, all methods and results, along with the Commentary of the HEI Review Committee. And since the mid-1990s HEI's Board of Directors has had in place a *Data Access Policy* that has both encouraged HEI investigators to make their data and analysis freely available on the Web (for example the data underlying HEI's National Morbidity, Mortality and Air Pollution Study (NMMAPS)^v), and to facilitate - wherever HEI investigators have full ownership of underlying data - access for other investigators to the data.

Conclusions - Toward Credible Science for Environment and Health Decisions

In conclusion, it is clear that science can and should play an important role in providing the foundation for decisions on environment and health, and that to do so the science needs to be of the highest quality *and* credibility. US EPA and other agencies have established procedures to produce and review science for decisions, and in many cases those procedures work to enhance the quality and credibility of the science. The HEI experience, founded out of a desire by both industry and US EPA for more readily trusted science, has illustrated a number of key principles that can lead to even better science for decisions in the years to come. Thank you for this opportunity to testify. I would be pleased to answer any questions the Committee may have.

ⁱ Bipartisan Policy Center. 2009. Improving the Use of Science in Regulatory Policy. Washington, DC: Bipartisan Policy Center

ⁱⁱ Cf. Samet JM, Zeger SL, Dominici F, Curriero F, Coursac I, Dockery DW, Schwartz J, Zanobetti A. 2000. The National Morbidity, Mortality, and Air Pollution Study, Part II: Morbidity and Mortality from Air Pollution in the United States. Research Report 94. Health Effects Institute, Cambridge MA.

ⁱⁱⁱ Krewski D, Burnett RT, Goldberg MS, Hoover K, Siemiatycki J, Jerrett M, Abrahamowicz M, White WH. 2000. Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality. A Special Report of the Institute's Particle Epidemiology Reanalysis Project. Health Effects Institute, Cambridge, MA.

^{iv} Cf. HEI Panel on the Health Effects of Traffic-Related Air Pollution. 2010. Traffic-Related Air Pollution: A Critical Review of the Literature on Emissions, Exposure, and Health Effects. HEI Special Report 17. Health Effects Institute, Boston, MA.

^v www.ihapss.jhsph.edu