

Charlestown Navy Yard
120 Second Avenue
Boston MA 02129-4533 USA
+1-617-886-9330
FAX +1-617-886-9335
www.healtheffects.org

Testimony of

Daniel S. Greenbaum, President
Health Effects Institute

On:

The Science on the Health Effects of Particulate Matter Air Pollution

Before the:

Committee on Environment and Public Works
United States Senate

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Mr. Chairman and members of the Committee, thank you for the opportunity to testify before you today on the health effects of particulate matter (PM). I come before you as the President of the Health Effects Institute, a non-profit, independent research institute funded jointly and equally by the US EPA and industry to provide high-quality, impartial science on the health effects of air pollution. For over 25 years we have conducted targeted research on a variety of pollutants and health effects, and I am pleased to summarize our understanding concerning PM and health for you today.

I also had the privilege to serve, from 1998 until 2004, as a member of the National Research Council *Committee on Research Priorities for Airborne Particulate Matter*, a congressionally chartered panel that both set priorities for national PM research, and monitored the progress in implementing those priorities by US EPA and other public and private agencies.

I would like today to briefly highlight three topics of direct relevance to the current discussion of US EPA's proposal for revisions to the National Ambient Air Quality Standards for PM (the "PM NAAQS"):

- Science progress we have made since 1997,
- The most recent findings on the relationships between different levels of ambient PM and health effects (so-called "concentration-response"), and
- Key science needs going forward.

Progress since 1997

Since Congress identified the need for substantial enhanced research on PM in the wake of the 1997 PM_{2.5} NAAQS decision, established the NRC Committee, and appropriated substantial new funds for PM research, much progress has been made in answering key questions for the current NAAQS review process, and for future ones.

Specifically:

- We know much more about the sources and transport of fine particles, and about personal exposure to those particles, especially for sensitive groups like the elderly and children.
- We have conducted the first multi-city epidemiology studies of effects, and analyzed and reanalyzed many of the major studies of human effects, finding that in general the earlier studies were well done and could be confirmed. At the same time there has been some evidence that the population health effects we had seen in those earlier studies may in some cases be smaller than previously thought.
- Unlike in 1997, we now have numerous laboratory, animal, and human toxicology studies that have begun to indicate potential biological mechanisms by which PM may cause health effects, especially new findings of effects on the heart and circulatory system. Although we have made progress, most science observers would agree that there is still much to learn about the mechanisms by which PM may cause these effects.

Although there continue to be, as there always are, important questions about PM that need further research, I think Congress, the Federal Government, and the scientific community can take tremendous pride in the substantial progress that has been made.

The “Concentration-Response” Relationship: Ambient PM Levels and Health Effects

Among the most important questions addressed over the past few years is the question of whether exposure to PM has been shown to have health effects at all levels of pollution – i.e. down to zero – or whether there is a “threshold” below which no effects are expected. This question is, of course, central to deciding at what level to set a NAAQS. There are two major types of epidemiologic studies that have been done – of *short term effects* and *long term effects* - and I would like to briefly review what these studies have shown us.

Short Term Effects

In 1997, there were studies of daily changes in air pollution and health effects in a number of individual cities (so-called “daily time series studies”). Since then, scientists have conducted much more rigorous multi-city studies of daily air pollution and health, most notably the National Morbidity Mortality and Air Pollution Study (NMMAPS) funded by HEI and led by investigators at the Johns Hopkins Bloomberg School of Public

Health. That study examined daily changes in air pollution and health in the 90 largest US cities. To answer the question of whether there is a threshold for effects, the investigators analyzed mortality and pollution levels across the 20 largest cities and the 90 largest.

In brief, as shown in Figure 1, they found that there appeared to be a linear relationship between mortality and air pollution down to the lowest measured levels for all causes of mortality, and for deaths from heart and lung disease, without an apparent threshold. There *did* appear, however, to be a threshold for the effect of PM on “other” causes of mortality (e.g. non-respiratory cancer, liver disease). The HEI Review Committee, which intensively peer reviews all HEI research, advised “caution in drawing conclusions from the apparent absence of a threshold” for all-cause and cardiopulmonary mortality, for a number of statistical and analytic reasons. They noted however that “the reported associations are at ambient concentrations well below the current US daily standard... thus the ambient concentration level at which any threshold might exist is likely to be correspondingly low.”

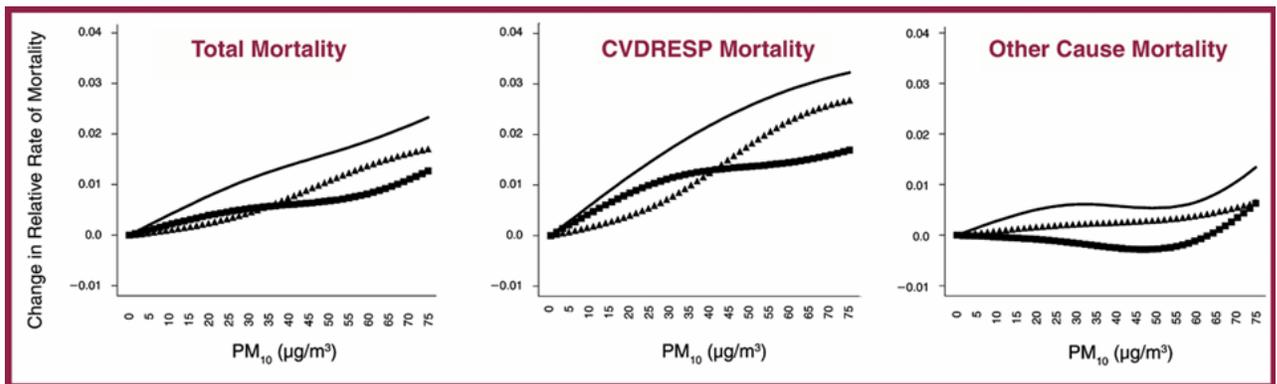


Figure 1. Short Term (Daily) Effects
National Morbidity, Mortality and Air Pollution Study (NMMAPS)
20 largest US cities (Daniels et al HEI 2004)

Long-Term Effects

In 1997, there were two principle studies of the effects of longer term exposure on mortality, the Harvard Six Cities Study and the American Cancer Society Study (ACS), which examined death rates among thousands of individuals living in cities with varying levels of pollution. Since that time, although there have been other long-term studies published there are still very few, and much attention has focused on HEI’s Reanalysis of these two studies and on extended analyses in the American Cancer Society Study population (which still covers the broadest national population). In both of these efforts, initial analyses have examined the “concentration-response” relationship between levels of pollution in each community and levels of health effects.

HEI Reanalysis - At the request of Congress (in the FY 1998 Appropriations Bill), US EPA, and others, HEI gained access to all underlying data in the two studies and

selected an independent investigator - Dr. Daniel Krewski - and his team to conduct a detailed audit and reanalysis. Their work, which was also intensively peer reviewed by the HEI Review Committee, tested the original studies against a wide variety of alternative explanations about why people in the most polluted cities would have higher rates of premature mortality. In the end, the investigators and HEI's Review Committee agreed that these alternative analyses did not change the original findings of associations between PM and premature mortality, although there were new findings as well about an association of mortality with sulfur dioxide.

Dr. Krewski and his team also conducted an initial analysis of the "concentration-response" relationship between PM levels in each of the cities and relative risks of mortality. Figure 2 presents the results, summarizing for each community (signified by a point on the graph) the annual air pollution level and the risk of death due to heart and lung disease. They then attempted to estimate the "average" relationship across all of the communities (the solid line) and the range of uncertainty around that average (the "95% confidence intervals" indicated by the dashed lines). As you can see there is some "scatter" in the data, especially at the highest and lowest PM levels studied, but also an overall trend of increasing mortality risk with increases in pollution levels starting at relatively low levels. In reviewing this initial analysis, the HEI Review Committee found that "for all-cause and cardiopulmonary mortality, the results show an increasing effect across the entire range of fine particles or sulfate but no clear evidence either for or against overall linearity."

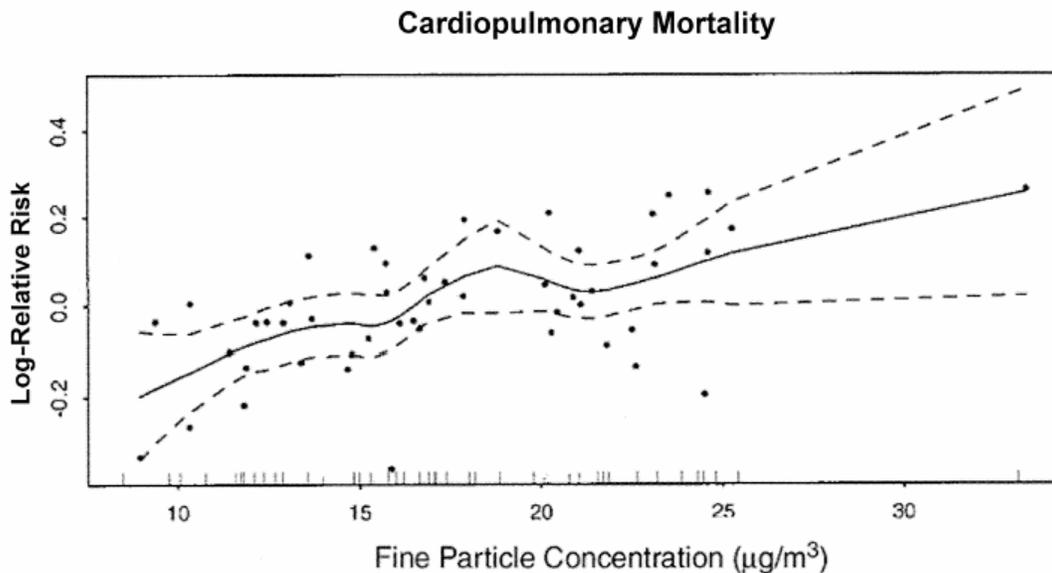


Figure 2 Long Term Effects
American Cancer Society Cohort
150,000 Individuals, 50 cities
HEI Reanalysis Results (Krewski, et al 2000)

Extended Analyses in the American Cancer Society Cohort Following the reanalysis, the original investigators for the ACS study led a broad team of experts in an

extended analysis of the data, including additional follow-up of more recent deaths among the study population, and using new PM2.5 data from monitors installed since 1997. That study found results similar to those found in the Reanalysis and also conducted analyses of the “concentration-response” relationship (shown in Figure 3). This also shows a general, though less steep, upward trend in mortality with increasing pollution levels, with the largest uncertainty being found at the very lowest and very highest levels where there are fewer cities. The Investigators concluded that: “Within the range of pollution observed in this analysis, the concentration response function appears to be monotonic and nearly linear. This does not preclude a leveling off (or even steepening) at much higher levels of air pollution.”

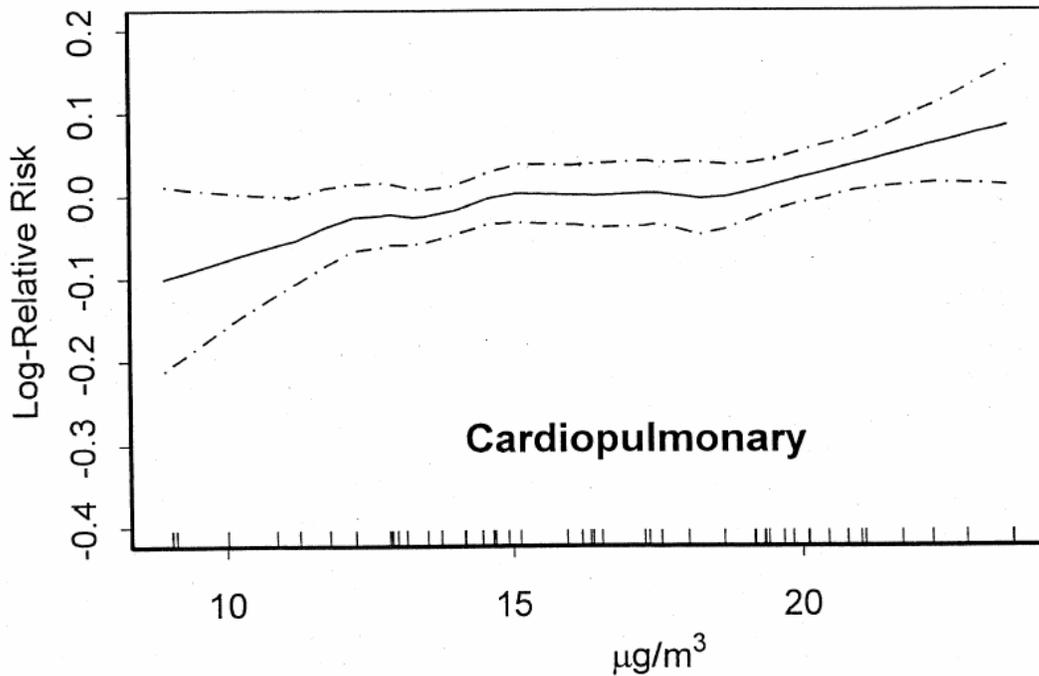


Figure 3. Long Term Effects
 American Cancer Society Cohort
 350,000 Individuals, 61 cities
 Extended ACS Results (Pope, et al 2002)

Summary: PM-Mortality Concentration-Response

In sum, recent analyses of the relationship between ambient levels of pollution and mortality have found a generally increasing trend of mortality with increases in pollution across a wide range of locations. The strongest evidence that there is not a threshold for these effects comes from studies of short-term effects, where any threshold is likely to be well below the current ambient standards. The initial analyses of these relationships in long term studies also shows this general pattern, albeit with somewhat greater uncertainty at the lowest and highest levels.

Key Research Needs Looking Forward

While we have made much progress in understanding PM exposure and health effects over the past decade, there continue to be, as there always are in science, important questions to be answered to help inform future decisions about ambient air quality standards and protecting public health. Two key areas needing continued attention are:

Continuous Improvement in the Statistics Used in Epidemiology

The analysis and reanalysis of studies on population health, air pollution and weather over the last decade have enhanced our ability to determine whether health effects can be tied to certain air pollutants. However, those same analyses have shown that the results can be significantly affected by the choices of statistical techniques and the assumptions made in each analysis. Looking forward, we need to pay continued attention to understanding the sensitivity of the results to different assumptions, quantifying the uncertainty of the results, and communicating clearly for each analysis both the results and the continuing uncertainties around those results.

Systematic Analyses of Which PM Components and Sources May Contribute the Most to Toxicity

Perhaps no other question will need as much attention, and will have as much implication for future regulations, than determining whether some components of the complex mixture of PM are more toxic than other components. Ultimately, this data will be essential to ensuring that regulations and control strategies are targeted at reducing those emissions which will have the most public health benefit at the least cost. This has also become important in light of the current proposal for a PM NAAQS for “coarse particles” which has proposed to exclude certain particles from consideration even before the needed studies are complete.

To date, there have been some individual city analyses of toxicity of different components supported by US EPA and others, *but no systematic national effort to compare results from across the country and from epidemiology and toxicology studies.* To fill that gap in time to inform a next round of PM NAAQS review, HEI has launched, with support from EPA and multiple industries, a systematic, multi-disciplinary effort which will:

- Conduct comprehensive, multi-city analyses of PM components and health
- Combine and compare epidemiology *and* toxicology across the country, and
- Provide the first-ever analyses of long-term effects of different PM components (all studies to date have looked only at daily changes in air pollution and health)

As indicated in both the NRC review of priorities for future PM and health research (NRC 2004), and in today’s report of the Government Accountability Office

concerning data needed for future PM benefits analysis, these studies will be central to ensuring that future PM actions are the most effective possible.

Summary: Progress Made and More to Be Done

In sum, we have made much progress since 1997 in answering key questions about whether and how PM can affect public health. Initial analyses have also helped us better understand the “concentration-response” relationship between levels of ambient air pollution and health effects and the generally increasing effects with increasing levels of pollution. At the same, looking forward there continue to be important issues to be addressed to inform future NAAQS and regulatory decisions, especially around the toxicity of different component and sources of PM.

Thank you for this opportunity to testify; I would be pleased to answer any questions you might have.

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