

DRAFT FOR IMMEDIATE RELEASE: May 16, 2003
For More Information: Dan Greenbaum or Bob O’Keefe 617 886 9330

**HEALTH EFFECTS INSTITUTE ISSUES REVISED ANALYSES OF OVER 40 STUDIES OF
AIR POLLUTION AND HEALTH:**
Brings to a Close Year-Long Effort to Correct Statistical Issues

BOSTON, MA. -- The Health Effects Institute (HEI) today published at its website (www.healtheffects.org) the results of revised analyses of nearly 40 publications of studies of air pollution and health in the US, Europe, and Canada. With this publication, HEI caps a year-long effort by many investigators, the US Environmental Protection Agency (EPA), and Health Effects Institute Review Panels and Scientific Staff to address statistical issues raised about these studies in Spring 2002 by investigators at Johns Hopkins University and Health Canada. The differences between these revised analyses and the original analyses varied substantially across studies: in general, the results showed a smaller but continuing association between air pollution and health. In their statement on the results (attached), the HEI Review Panels convened to peer review the revised analyses said:

“As with findings of the original analyses, all of the revised findings will continue to inform the regulatory process regarding PM. At the same time, these revised analyses have renewed the interest in important questions and uncertainties that should inform future time-series analyses of air pollution and health.”

The studies involved – which analyzed time series of daily levels of air pollution, health indicators, and weather, and generally found an association between particulate matter air pollution (PM) and health – have been one part of the scientific basis used by EPA, California, the European Commission, and other agencies to set ambient standards for PM. They include systematic multicity

studies (such as the HEI-funded National Morbidity, Mortality, and Air Pollution Study [NMMAPS] in the US, and similar studies in Europe and Canada) as well as a number of city-specific studies.

Because many factors can vary along with pollution and health, air pollution studies must use statistical models to control for these other factors. Although many methods can be used for this purpose, generalized additive models (GAMs) have been favored in recent years. In May 2002, NMMAPS investigators at Johns Hopkins University discovered that part of the GAM programming in the S-Plus statistical software, which they and many others had used to fit GAMs to time-series data, was not entirely appropriate for this purpose. Specifically, the default convergence criteria and number of iterations were unlikely to allow convergence when calculating effect estimates. At about the same time, investigators at Health Canada found that, under certain conditions, programming to calculate standard errors of the regression coefficients in GAM software resulted in underestimates of the standard errors.

In response, the NMMAPS investigators moved quickly, with support from HEI, to revise all of their previous analyses using statistical techniques to address the issues raised. At the same time, EPA identified an additional 37 publications by 19 primary investigators that had used GAMs and were important to the current review of PM standards underway at EPA. They asked those investigators to conduct similar revised analyses and asked HEI to provide peer review for these revised analyses. HEI's Health Review Committee had already organized a Special Review Panel for the NMMAPS analyses and expanded that Panel to also review the additional reports. The HEI Special Report published today details the results. The first section addresses the impact of the issues on the NMMAPS. The second section addresses the impact on additional studies selected by the US Environmental Protection Agency (EPA). The Special Review Panels of the Health Effects Institute contributed Commentaries on the findings.

In their Commentaries, and in an accompanying HEI Statement summarizing the findings of all of the revised analyses, the HEI Review Panels noted a number of key findings.

Their study-specific conclusions were:

- In general, the estimates of effect in NMMAPS decreased substantially, but the qualitative conclusions did not change.

- Formal tests in NMMAPS for heterogeneity of PM effect across cities did not indicate heterogeneity. The Panel recognized, however, that the power to assess the presence of heterogeneity was low because of the generally larger city-specific standard errors. The possibility of heterogeneity therefore remains.
- The overall impact of the other revised analyses included:
 - While the number of studies showing an association of PM with mortality was slightly smaller, the PM association persisted in the majority of studies.
 - In some of the large number of studies in which the PM association persisted, the estimates of PM effect were substantially smaller.
 - In the few studies in which investigators performed further sensitivity analyses, some showed marked sensitivity of the PM effect estimate to the way time and weather were included in statistical models

Among their general conclusions were:

- These revised analyses have renewed the awareness of the uncertainties present in estimates of short-term air pollution effects based on time-series data. Neither the appropriate degree of control for time, nor the appropriate specification of the effects of weather, has been determined for time-series analyses. In the absence of adequate biological understanding of the time course of PM and weather effects, and their interactions, the Panel recommends exploration of the sensitivity of future time-series studies to a wider range of alternative degrees of smoothing and to alternative specifications of weather variables.

The Panels also comment on the likely impact of the new findings on future time-series studies, the use of statistical software, the calculation of public health impact estimates, and the likely increased reliance on studies of the effects of long term exposure.

The full study is available to download from the HEI web site. Questions on the report and the results should be directed to: Dan Greenbaum (dgreenbaum@healtheffects.org) or Bob O'Keefe (rokeefe@healtheffects.org) or by calling 617 886 9330.

- END -