

Congress of the United States

House of Representatives

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

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June 12, 2013

The Honorable Robert Perciasepe
Acting Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Dear Acting Administrator Perciasepe:

On March 4, 2013, a letter was sent from this Committee to Gina McCarthy, Assistant Administrator for the Office of Air and Radiation at the Environmental Protection Agency (EPA), requesting that EPA take immediate steps in accordance with current law and Administration policy to obtain and release the underlying research data from specific PM_{2.5} studies that EPA has relied on to support multiple rulemakings. In this same letter, we also requested that EPA obtain and immediately release the underlying data supporting a critical ozone study (Jerrett 2009) that relies on these same datasets and that EPA has referenced 18 times in its Integrated Scientific Assessment (ISA) in preparation for the upcoming ozone rulemaking.

The Agency's April 10, 2013, response to that letter acknowledges that the previously released information is "not sufficient" to allow replication of the study results. In the three months that have passed since our most recent request, we have yet to receive any commitment from the Agency that, in the case of Jerrett 2009, it will discontinue the use of this data or in the case of the most recent PM_{2.5} long term cohort studies, immediately obtain and release that data. In May, EPA proposed new Tier III Vehicle Emission and Fuel Standards that depend on these same datasets to provide a majority of the claimed benefits. EPA's response also shows a general lack of understanding of Administration policy and the nature of the requested data:

- While EPA is correct in noting that the responses to the personal interview questionnaires collected 30 years ago include confidential information, the electronic input and output files used in the actual analysis for these studies are unlikely to contain confidential data. This was confirmed by Health Effects Institute (HEI) in 2000 when it conducted a reanalysis of the studies.¹

¹ Krewski et al. 2000, *Part I: Replication and Validation*; (p 42). The HEI Report confirms that an electronic data file ("Mort6C.file") containing a copy of the Harvard Six cities database "did not contain any information that could be used to identify the individual study participants."

- EPA's proffered excuse for not obtaining the data because the studies "received funding from a number of different sources, including the EPA, other federal agencies, and non-federal sources" conflicts with OMB policy which clearly states that funding Agencies retain the right to obtain all data developed from mixed funding sources.²
- EPA's response also incorrectly states that NDI data cannot be released, ignoring the fact referenced in its own attachment on page 3 that Harvard University had released (and EPA transmitted) coded NDI data in 2011.

We also remain deeply concerned that EPA continues to rely on this data, even while the National Research Council has cautioned against using them in its 2004 report.³ In that report, the NRC concluded that updates of these two cohorts alone would be of "little use for decisionmaking" due to the outdated nature of the information and dwindling relevance to today's population and risk profile. The full NRC discussion on this point is attached for review. For example, since the time the data were initially collected, smoking rates have declined from 40 to 20 percent, while education levels (used as a surrogate for socioeconomic status in air pollution studies) have increased. A number of other factors affecting the surveyed population's health status have also changed, including improved treatments for hypertension and cholesterol that have contributed to reductions in the cardiovascular mortality rates in the U.S. Because the American Cancer Society and Harvard Six City cohorts have not been updated, there is a clear concern that the health benefits attributed to reduced PM_{2.5} and ozone levels over the past 30 years could in fact be incorrect due to other changes affecting the health status of the surveyed individuals that may have a much greater bearing.

EPA's recent clarification about which studies it relies upon fails to acknowledge this central point. Indeed, the fact that EPA has chosen not to rely on two studies using this outdated cohort information (Pope 2002 and Laden 2006) in the Regulatory Impact Assessment for the Tier III rulemaking but instead to use Krewski 2009 and Lepeule 2012 does not address this weakness but rather exacerbates the problem since both of these more recent studies use more recent and lower air pollution data but continue to rely on the same outdated cohort information.

Throughout this process, EPA has responded to our questions in a cavalier manner, hoping perhaps we were not reading the NRC reports carefully or were simply unaware of the law or guidance governing data access. The opposite is true. Our examination has underscored two central points:

- EPA must immediately refrain from relying on and citing studies that continue to use 30-year old cohort data. This includes all PM_{2.5} and ozone studies that rely on the American Cancer Society and the Harvard Six Cities cohorts. The NRC's main criticism in 2004 is even more relevant today, nine years later.

² *Federal Register*, Vol. 64, No. 195 (Friday, October 8, 1999). See section G: Projects Funded From Multiple Sources.

³ National Research Council, *Research Priorities for Airborne Particulate Matter: IV. Continuing Research Progress* (2004), Board on Environmental Studies and Toxicology (BEST), p 135.

- EPA must immediately obtain all of the underlying research data supporting the previously requested PM_{2.5} and ozone studies, and release all non-confidential data in accordance with current law and Administration guidance. EPA must also take steps to determine whether confidential data sets can be de-identified to help ensure transparency in its decision making.

Current law and OMB guidance are clear in requiring EPA to obtain and release the data. To confirm there are no confidential data in the electronic input and output files and whether de-identification procedures can be applied, EPA must first obtain the data – which it openly admits to not having. The EPA's continued refusal to comply with this Committee's oversight request undermines the credibility of its regulations.

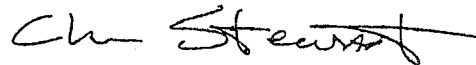
EPA officials should justify their agenda through an open and transparent process that is based on good science, if they can. EPA has projected that its upcoming ozone standard will be the most costly environmental regulation in U.S. history. Working families will bear these costs. They have a right to know what scientific data supports EPA's claims.

EPA must respect the law and the public's right to this information. In order to avoid formal action by this Committee to obtain the requested information, we urge you to comply with our request by July 8, 2013.

Sincerely,



Lamar Smith
Chairman
House Science, Space and Technology



Chris Stewart
Chairman
Environment Subcommittee

cc: Rep. Eddie Bernice Johnson, Ranking Member, Committee on Science, Space, and Technology
Ms. Gina McCarthy, Assistant EPA Administrator
Dr. Glenn Paulson, Science Advisor to the EPA Administrator
Dr. Ken Olden, NCEA Director
Dr. John Holdren, Director, OSTP
Ms. Sylvia Mathews Burwell, Director, Office of Management and Budget

References

Jerrett et al. "Spatial analysis of air pollution and mortality in Los Angeles." *Epidemiology* 16(2005): 727-736.

Jerrett et al. "Long-term ozone exposure and mortality." *N Engl Med* 360 (2009): 1085-1095

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Krewski et al. "Extended follow-up and spatial analysis of the American Cancer Society study linking particulate air pollution and mortality." *HEI Research Report, 140*, Health Effects Institute, (2009) Boston, MA

Laden et al. "Reduction in Fine Particulate Air Pollution and Mortality." *American Journal of Respiratory and Critical Care Medicine*. 173 (2006): 667-672

Lipfert et al. "PM_{2.5} constituents and related air quality variables as predictors of survival in a cohort of U.S. military veterans." *Inhal. Toxicol.* 18 (2006): 41-72.

Lepeule et al. "Chronic Exposure to Fine Particles and Mortality; An Extended Follow-Up of the Harvard Six Cities Study from 1974 to 2009." *Environ Health Perspect.* Jul; 120(7) (2012): 965-70

Pope et al. "Lung Cancer, Cardiopulmonary Mortality, and Long-term Exposure to Fine Particulate Air Pollution." *Journal of the American Medical Association* 287 (2002): 1132-1141.

Pope et al. "Particulate air pollution as a predictor of mortality in a prospective study of U.S. adults." *Am. J. Respir. Crit. Care Med* 151 (1995): 669-674.

Attachment A:

Excerpt from the National Research Council's 2004 report, *Research Priorities for Airborne Particulate Matter: IV. Continuing Research Progress*

INVESTIGATING THE HEALTH EFFECTS OF LONG-TERM EXPOSURE TO AIR POLLUTION

Epidemiological Approaches

The striking findings of the Harvard Six Cities Study (Dockery et al. 1993), which linked chronic exposure to increased mortality, provided a strong impetus for reevaluating the PM NAAQS, particularly after their confirmation in the 1995 publication based in the American Cancer Society's Cancer Prevention Study 2 (CPS 2) (Pope et al. 1995). The findings on increased mortality associated with longer-term exposures to higher concentrations of particles suggested that the associations observed in the time-series studies did not reflect only a slight advancement of the timing of death for frail individuals. The findings of the two studies were confirmed with an extensive reanalysis (Krewski et al. 2000) and on further follow-up of the CPS 2 cohort (Pope et al. 2002). Findings from several other cohort studies have also been reported (Abbey et al. 1999; Lipfert et al. 2000; Hoek et al. 2002). Although these cohorts have provided critical evidence for long-term effects, evidence from further follow-up of these two U.S. cohorts alone will have little use for decisionmaking. The cohorts were established decades ago, and some critical data items, including residence history and potential confounding and modifying factors, have not been comprehensively updated. Consequently, an increasing degree of exposure misclassification can be anticipated as the participants move from their original residences. And, most important, characterization of current air quality cannot recreate the complex air environments in which the individuals and populations lived and worked in the many years for which data are not available. Long-term studies are likely to remain central, however, in assessing the public health burden caused by air pollution. For quantitative risk assessment and cost-benefit analysis, estimates of the disease burden associated with exposure to particles are needed. These estimates could come from a new generation of studies with more complete information on short- and long-term exposures to PM, its components, and exposures to other pollutants.

Recognizing both the limitations of these studies and the need for ongoing information on long-term exposure to air pollution and health, the committee recommends that research approaches continue to be developed on the basis of existing and new cohorts. Mechanisms are needed for enrollment and tracking of cohorts over time to provide an ongoing characterization of any impact on health of long-term exposure to air pollution. Without substantial commitment of personnel and funds, studies, such as the Six Cities Study and the CPS 2 cohorts, cannot be readily and feasibly undertaken. Rather, such studies might be based on cohorts routinely enrolled for other purposes, for example, investigating cardiovascular diseases (Atherosclerosis Risk in Communities [ARIC 2004] and the Cardiovascular Health Study [CHS 2003]), Medicare participants, and cohorts assembled by the National Center for Health Statistics. However, even such studies will require substantial funding, and their value must be compared with data collection specifically designed as long-term studies of health effects of air pollution. Medicare has a large cohort under follow-up that is maintained with replacement sampling. The Veterans'

Administration also has a large cohort under follow-up. In addition, there might be other opportunities for adding a component related to air pollution and health; the anticipated National Children's Study (2004) is one example. That study might provide insights into air pollution and childhood asthma or lung development, for example. New cohort studies of persons having informative patterns of exposure or heightened susceptibility may also be warranted.

Studies of effects of long-term exposure to PM, based on residence location and other information, need to include large numbers of participants and to incorporate exposure estimates. With information on residence location, the EPA's monitoring data, captured in the Air Quality System (AQS) database (EPA 2004), could be used to estimate exposures. However, these data might not be optimal for health studies, and additional data collection or model data would be needed to better capture population exposure (see Chapter 6). For example, the spatial detail within communities might be better captured with focused monitoring and use of population exposure models. As the AQS data are increased from the new speciation sites and other data-collection efforts, it should become possible to develop estimates for exposures beyond particle mass alone. It is critically important that future monitoring strategies go beyond currently regulated pollutants to allow the testing of a broader range of epidemiological hypotheses.

An additional concern in any cohort study is the availability of information on potential confounding and modifying factors. Life styles and the associated frequency of chronic diseases, particularly heart and lung diseases, are variable across the country. There is a potential for a varying profile of susceptibility to PM across the country and for confounding as well. Some approaches based on population-level data can be identified that might be used to characterize potential confounding and modifying factors. Population-level data are available on tobacco sales, although they are a poor surrogate for actual smoking rates within the cohorts; available data on prevalence of tobacco use and mortality provide an index of the underlying rates of chronic heart and lung disease, particularly coronary heart disease and chronic obstructive pulmonary disease. Population sampling might be done to augment those data resources. However, such population-level data are inherently imperfect measures of individual-level exposures. Some health-system-based cohorts, such as Medicare, include information on diagnoses leading to outpatient visits and hospitalizations. Those data could be used to identify susceptible groups.

The development of new approaches to carrying out these cohort studies will be challenging and time-consuming and should be supported by EPA or other agencies. In 2001 and again in 2003, EPA sought new cohorts for studies of long-term effects through its Science to Achieve Results (STAR) grant mechanism, but it should also support an ongoing planning effort. Although a request has been initiated by EPA to establish a long term cohort to follow up cardiovascular events, it is important for EPA to recognize the need for continued and substantial financial support necessary for these types of studies. At the same time, it will be important for EPA to continue to support additional alternative approaches. The spectrum of human health effects has expanded over the past several years (see Table 5-1). Because each of these effects has the potential to result in substantial economic and social consequences, as well as significant health impairment, it is important that continued work be undertaken to quantify as much as possible the degree to which PM contributes to these conditions.