



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

AUG 19 2013

OFFICE OF CONGRESSIONAL AND  
INTERGOVERNMENTAL RELATIONS

The Honorable Lamar Smith  
Chairman  
Committee on Science, Space and Technology  
U.S. House of Representatives  
Washington, D.C. 20515-6301

Dear Chairman Smith:

The U.S. Environmental Protection Agency (the EPA or agency) is in receipt of a subpoena *duces tecum* from the United States House of Representatives Committee on Science, Space, and Technology. The subpoena seeks data from the American Cancer Society and Harvard Six Cities cohorts, as well as attendant documents necessary to understand that data.<sup>1</sup> I write to respond on behalf of the agency.

As you know, the agency has consistently provided the Committee with data that is in its possession. Specifically, on June 7, 2012, and June 14, 2012, the EPA provided the Committee with the data associated with the following studies:

Laden, F., J. Schwartz, F.E. Speizer, and D.W. Dockery. 2006. "Reduction in Fine Particulate Air Pollution and Mortality." *American Journal of Respiratory and Critical Care Medicine*. 173: 667-672.

Pope, C.A., III, R.T. Burnett, M.J. Thun, E.E. Calle, D. Krewski, K. Ito, and G.D. Thurston. 2002. "Lung Cancer, Cardiopulmonary Mortality, and Long-term Exposure to Fine Particulate Air Pollution." *Journal of the American Medical Association* 287:1132-1141.

As we have explained previously, however, much of the data you seek are held solely by the outside research institutions that conducted these large-scale epidemiological studies, not the EPA. The agency has consistently sought to obtain the data requested by the Committee and other members of Congress. For example, in response to requests from Senator Vitter, the EPA has requested from the relevant researchers the research data associated with several additional studies that are required to be provided under the Shelby Amendment, consistent with applicable protections for private medical and similar information. Specifically, the EPA requested research data associated with the following studies:

Krewski D, Jerrett M, Burnett RT, Ma R, Hughes E, Shi, Y, et al. 2009. "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, Boston, MA.

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<sup>1</sup> The EPA confirmed the scope of the subpoena in a telephone conference with Todd Johnson, Staff Director for the Subcommittee on Environment, and others, on August 15, 2013.

Lepeule J, Laden F, Dockery D, Schwartz J 2012. "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):965-70.

Pope, CA III, E Majid, D Dockery. 2009. "Fine Particle Air Pollution and Life Expectancy in the United States." *New England Journal of Medicine* 360: 376-386.

The EPA's efforts to obtain the data are producing results. On August 2, 2013, the EPA received the research data from the Pope et al. (2009) and Lepeule et al. (2012) studies. Consistent with our demonstrated practice of producing research data that are within our control, enclosed with this letter the EPA is providing the Committee with the research data the EPA received from Harvard University on the Pope et al. (2009) study. This research data came entirely from public sources and is an analytic file (in Excel format) that contains life expectancy data and socio-demographic data.

As your subpoena acknowledges, some of the data you requested may need to be provided in a de-identified form so as to protect the personal privacy of the participants in the studies. The research data from the Lepeule et al. (2012) study contains two categories of research data: (1) "Air Pollution" data that relates to fine particulate air pollution levels and (2) "Vital Statistics" data from the National Death Index (NDI). Because the research data contains information from the NDI, which is part of the National Center for Health Statistics at the Centers of Disease Control and Prevention (CDC), Harvard University signed a confidentiality agreement to obtain this information in accordance with section 308 of the Public Health Services Act (42 U.S.C. § 242m(d)), promising not to publish or release data in any form to any party if a particular individual is identifiable.

Therefore, after reviewing research data related to the Lepeule et al. (2012) study, the EPA is concerned that the data may reveal sensitive personally identifiable information about the study participants. Consistent with our obligations under the Public Health Services Act, on August 16, 2013, the EPA sought advice and assistance from the CDC to determine whether there may be restrictions on disclosure of this data to your Committee, and if so, how to address the possibility of de-identifying the data in a way that would allow the agency to provide the Committee with the data from this study as well. We will keep the Committee apprised of the CDC's review, and produce the data expeditiously should the CDC identify an effective way to protect the personally identifiable information of the study participants.

The agency continues to work with the Health Effects Institute to try and obtain the data we have requested from them. On August 16, 2013, HEI informed the EPA that they expect to provide the EPA with their research data soon. Once the EPA receives that research data from HEI, we will expeditiously review it for the privacy considerations discussed above, and provide the Committee with any data that does not raise privacy concerns. Should we identify privacy concerns with the release of the research data, we will inform the Committee of that concern.

Finally, on July 8, 2013, the agency sent forward to Dr. Michael Jerrett Senator Vitter's request for the full set of data files relating to his 2009 study entitled "Long-term Ozone Exposure and Mortality" published in the *New England Journal of Medicine*, which is not presently subject to the Shelby Amendment.

As is demonstrated above, the EPA has consistently sought to obtain the data requested by the Committee. There are, however, limitations on the agency's legal ability to compel a third party to

provide us with data, especially when that data was funded with private, not federal, funding. Unfortunately, our receipt of the subpoena from the Committee does not, and cannot, provide us with legal authority to compel a third party to comply with our requests where that legal authority did not already exist. While the agency will continue to work with the Committee and the relevant researchers to obtain and then produce the data demanded under the subpoena, some data may remain outside of the EPA's control and, therefore, outside of our ability to provide to the Committee.

In closing, the EPA's efforts to obtain the requested research data and to provide the Committee with any data we obtain demonstrate the agency's good faith efforts to comply with the Committee's requests and subpoena. The EPA looks forward to continuing to work with the Committee on this issue.

Sincerely,

A handwritten signature in black ink, appearing to read "Laura Vaught".

Laura Vaught  
Associate Administrator

Enclosure

cc: The Honorable Eddie Bernice Johnson  
Ranking Member