THE ADMINISTRATOR OF THE ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

MAR 0 7 2014

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

Dear Mr. Chairman:

Thank you for your letter of February 14, 2014, regarding the United States Environmental Protection Agency's (EPA's) response to a subpoena *duces tecum* (subpoena) from the Committee on Science, Space, and Technology (Committee).

As you note in your letter, during and immediately after my November 14, 2013, appearance before your Committee, we agreed to additional dialogue regarding the EPA's response to the subpoena. I understand that our staffs have had several discussions since that date, and made significant progress toward a common understanding of this matter. I want to thank you and your staff for your willingness to engage in these discussions, as I believe they have been both productive and constructive.

Your subpoena sought data from the American Cancer Society and Harvard Six Cities cohorts, as well as analyses and re-analyses of that data. In particular, the subpoena sought data from studies that utilized data from the American Cancer Society and Harvard Six Cities cohorts. Once the EPA received the subpoena, we conducted a diligent search for data, as well as analyses and re-analyses of that data that were already in our possession, custody, or control that would be responsive to the subpoena. In addition, we considered what data, as well as analyses and re-analyses of that data, were not in our possession, custody, or control on the date we received the subpoena, but that may still be within the scope of the Committee's subpoena. For data, as well as analyses and re-analyses of that data, that were not in the EPA's possession, custody, or control but that could still be considered within the scope of the subpoena, the EPA sought to identify a legal authority for the agency to obtain that information so that it could be provided to the Committee. In this case, the Shelby Amendment (Public Law 105-277) provides the EPA with the authority to obtain certain research data that was not in the agency's possession, custody, or control on the date we received the subpoena, and the EPA utilized that authority to obtain that data.

The actions taken in response to the subpoena are detailed in an enclosure (Enclosure 1) to this letter, and included multiple interactions with the third party owners of the research data in an effort to obtain that data. Once the agency successfully obtained the research data, we undertook a review of this data to determine whether the release of the data would raise privacy concerns. The agency sought the

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assistance of the Centers for Disease Control in this inquiry as well, in an effort to ensure the privacy of the subjects of the data was not compromised.

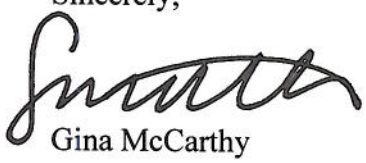
Through its efforts, the EPA located within its possession, custody, or control, or obtained through its authority, the data for five studies listed in the subpoena. Any other data, as well as analyses and re-analyses of that data, that may be within the scope of the subpoena, whether specifically listed in the subpoena or not, are not (and were not) in the possession, custody, or control of the EPA, nor are they within the authority to obtain data that the agency identified. However, the issuance of the subpoena does not provide the agency with any additional authority to obtain data, as well as analyses and re-analyses of that data, that we otherwise do not have the authority to obtain.

All responsive data, as well as analyses and re-analyses of that data, located or obtained during our efforts to respond to the subpoena have been provided to the Committee. The EPA provided that data to the Committee through letters sent prior to our receipt of the subpoena, and then our letters responding to the subpoena of August 19, 2013, September 16, 2013, and September 30, 2013. The EPA provided the Committee with the data for these five studies in exactly the same format the data were provided to us. Importantly, the agency was able to work through the various privacy concerns so that we would not need to de-identify any of the data. As of the EPA's letter of September 30, 2013, the agency has provided the Committee with all of the data covered by the subpoena that the agency has obtained or has the authority to obtain under the Shelby Amendment. Additionally, the EPA has not withheld any data in our possession that is responsive to the subpoena. Thus, the EPA has completed its response to the subpoena. The EPA acknowledges, however, that the data provided are not sufficient in themselves to replicate the analyses in the epidemiological studies, nor would they allow for the one to one mapping of each pollutant and ecological variable to each subject. For the reasons explained in our previous letters on this topic, these acknowledgements do not call into question the EPA's reliance on these studies for regulatory actions.

Your February 14, 2014, letter also requests the grant agreements related to the studies covered by the subpoena, and those documents are being provided with this letter. These EPA grant agreements span from 1998 to 2006 and contain a variety of data access provisions. Despite that variation, the EPA has reviewed each of the agreements and determined that each grant agreement contained data access provisions that are consistent with the EPA grant regulations at the time of the award. The EPA's current practice is to incorporate into our grant agreements a reference to the agency's regulations regarding access to research data funded by the grant.

Thank you again for the opportunity to explain the actions the EPA took in responding to your subpoena. If you have additional questions, please do not hesitate to contact me or your staff may contact Tom Dickerson at (202) 564-3638 or Dickerson.Tom@epa.gov.

Sincerely,



Gina McCarthy

Enclosures

Enclosure 1
Actions Taken in Response to Subpoena

The United States Environmental Protection Agency (EPA) was served with the House Committee on Science, Space, and Technology's (Committee's) subpoena *duces tecum* (subpoena) on August 1, 2013. Once the agency received the subpoena, we undertook diligent actions to respond.

While the agency did in fact have some data responsive to the subpoena in our possession on the date we received the subpoena, we did not possess certain other data. The agency quickly began to take actions to obtain additional data. In particular, the agency had multiple interactions with Health Effects Institute (HEI) as we worked to obtain research data from that organization. The EPA obtained the final set of research data that is both covered by the subpoena and subject to the Shelby Amendment in late August, after the original return date for the subpoena.

Once data was in our possession, the agency's efforts focused on preparing for the provision of the data to the Committee. Because of the types of studies involved in the subpoena, before the agency could provide the Committee with the data we had to review that data for privacy considerations. The EPA brought together an ad hoc data review committee on August 2, 2013, to begin the process of reviewing all data responsive to the subpoena that was currently in our possession. That committee included representatives from the Office of Air and Radiation, the Office of Research and Development, and the Office of General Counsel. The committee reviewed each set of research data as we obtained it, rather than waiting until all of the data were obtained to begin that phase of our response.

In instances where the agency had potential privacy concerns, consistent with our obligations under the Public Health Services Act (42 U.S.C. 241(d), the agency consulted with the Centers for Disease Control regarding the releasibility of that data. In particular, the agency had multiple interactions with the Centers for Disease Control related to the research data for 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. The agency's efforts ultimately resulted in the Centers for Disease Control reaching the conclusion that all of the research data could be provided without the need for de-identification. The EPA concluded its final consultation with the Centers for Disease Control on September 27, 2013, and made its final production of data to the Committee just days later on September 30, 2013.