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Congress of the United States
House of Representatives

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

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September 3, 2013

The Honorable Gina McCarthy
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Dear Administrator McCarthy:

For nearly two years, the Science Committee has asked EPA to release the taxpayer-funded data that underlies regulations that are among the most costly in U.S. history. Despite acknowledgement by senior Administration officials that the data should be made available to the public,[1] EPA repeatedly has refused to share that data with the Committee and the American people. On August 1, 2013, the Committee finally lost patience and authorized me to subpoena the data from you.

On August 19, 2013, several hours after the subpoenaed information was due, one of your staff members sent a file of already public information along with a letter outlining excuses for why EPA did not comply with the subpoena and produce all of the requested data in a timely manner. You did not provide the Committee with anything new.

Your staff member's letter does suggest that now, under subpoena, EPA has taken at least limited steps to gather some of the subpoenaed data. While I hope that those steps lead to EPA producing all of the subpoenaed data, neither your steps thus far nor the excuses offered in your staff member's letter fulfill your obligations under the subpoena. EPA currently stands in default. I urge you to correct this default by promptly producing all of the data to which the Committee is entitled.

EPA has failed to comply with its obligations under the subpoena

The subpoena requested only three categories of documents. Specifically, it requested all documents in your possession, custody, and control related to (1) the Harvard Six Cities Study, (2) the Cancer Prevention Study II, and (3) analyses and re-analyses of these studies, including particularly seven studies identified in the subpoena.

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[1] In a November 2011 letter, you committed to "take action… as soon as possible to provide you with any data and analysis produced with EPA funds." Similarly, in testimony last year, Dr. John Holdren, the President's Science Advisor, stated that "Absolutely, the data on which regulatory decisions and other decisions are based should be made available to the Committee and should be made public." This is consistent with multiple White House and EPA directives, memoranda, policies, and executive orders related to regulations, scientific integrity, and transparency.

In response, you produced no documents responsive to request number 1. Indeed, neither you nor your staff made any effort either to describe any steps that you have undertaken to produce the relevant data or to excuse your failure timely to produce that data.

You produced no documents responsive to request number 2. Again, neither you nor your staff made any effort either to describe any steps that you have undertaken to produce the relevant data or to excuse your failure to produce that data.

As to request number 3, your staff reported that you have taken certain preliminary steps toward producing the relevant data, but delivered only a combination of excuses, vague assurances, and already public information. More particularly, as to four of the seven analyses and re-analyses specifically identified by the Committee in request number 3, you did not provide a single piece of data. As to the remaining three analyses and re-analyses (associated with the Laden et al. (2006), Pope et al. (2002), and Pope et al. (2009) studies), the data you provided (i) was already public information, and (ii) was, by EPA's own admission, not provided "in a manner sufficient for independent replication and re-analysis" with "sufficient information to allow a one-to-one mapping of each pollutant and ecological variable to each subject," as required by the subpoena.[2] In other words, the only data actually produced was, on its face, worthless to the Committee and the American public.

EPA has no legal excuse for failing to comply with the subpoena

The excuses that your staff offered for your failure to produce the subpoenaed data are meritless.

Your staff asserts that "much of the data" subpoenaed by the Committee "are held solely by the outside research institutions that conducted these large-scale epidemiological studies." First, that is a remarkable assertion by an agency that purports to rely on such data –data that it apparently has not even obtained, much less reviewed – to impose extraordinary costs on the American people. Second and in any event, the subpoena is not limited to documents in your possession. It requires production of all documents in your possession, custody, or control. "Control" is the legal right, authority, or ability to obtain documents upon demand.[3] Thus, responsive documents that EPA has "the legal right, authority or ability to obtain" from outside research institutions are within the scope of the subpoena. Under OMB Circular A-110, EPA has the right to "obtain, reproduce, publish, or otherwise use the data" from these studies. Whether or not the data is presently in EPA's possession, EPA was and is obligated to obtain responsive data and produce it to the Committee.

Your staff does acknowledge that you have obtained the research data from one study (Lepeule et al. (2012)).[4] Harvard University's delivery of these data to EPA is welcome news, as

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[2] "The EPA recognizes that the data provided... are not sufficient in themselves to replicate the analyses int eh epidemiological studies...." Letter from Arvin Ganesan to Lamar Smith, April 10, 2013, *available at* http://science.house.gov/sites/republicans.science.house.gov/files/documents/20130410.pdf.

[3] *United States ITC v. ASAT, Inc.*, 411 F.3d 245, 254 (D.C. Cir. 2005); *see also* WRIGHT, MILLER & COOPER, 8A FEDERAL PRACTICE & PROCEDURE § 2210.

[4] The Committee is aware that the data associated with the Lepeule et al. (2012) study may be coterminous with the data from the Harvard Six Cities study. If this were the case, then EPA's production of the data underlying that study (in response to document request number 3 from the subpoena schedule) could potentially provide the data

EPA apparently no longer disputes that at least that data is in its possession, custody, and control. But your excuses for nonetheless not producing the data, as required by the subpoena, are troubling.

Certainly your inability to de-identify the data in a timely fashion does not excuse non-compliance with the subpoena. The Committee recognized the privacy issues potentially implicated by the documents, and accordingly granted you the option to reply with de-identified data.[5] But that was permissive, not mandatory. Even if you were unable to de-identify the documents, you still were required to produce them. When you do so, the Committee will take appropriate steps to de-identify the data, or otherwise assure appropriate confidentiality, as discussed in the next section of this letter, below.

Your staff further suggests that either a provision of the Public Health Services Act (PHSA) or a confidentiality agreement that Harvard University purportedly signed with the CDC excuse your failure to comply with the subpoena. Neither provides any such excuse.

First, Congress's power to issue and enforce congressional subpoenas is broad and other than in certain limited circumstances of proper assertion of executive privilege (obviously not implicated here), Congress is entitled to information in the Executive Branch's possession, custody, or control, period.[6]

Second, even if a statute could restrict the Committee's access to information (which it cannot), nothing in the Public Health Services Act (PHSA) so restricts the Committee's right to this data; indeed, the data that the Committee seeks is not even implicated by the terms of that statute. You cite 42 U.S.C. § 242m(d), but that provision on its face only applies, at most, to information "obtained in the course of activities undertaken or supported under section 242b, 242k, or 242*l* of this title." EPA did not obtain the relevant data in the course of activities covered by those sections. Rather, it obtained the data only in the course of gathering information pursuant to the Committee's subpoena. Additionally, § 242m(d) only purports to

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with regard to the Harvard Six Cities study (document request number 1 from the subpoena schedule). Please indicate in response to this letter whether in fact the Lepeule dataset that you received from Harvard includes all of the data from the Harvard Six Cities study within the scope of the Committee's subpoena.

[5] *See* Subpoena Instruction No. 3 ("Documents responsive to the subpoena may be produced in a de-identified form . . . .").

[6] *See, e.g.*, *Eastland v. United States Serviceman's Fund*, 421 U.S. 491, 504 n.15 (1975) ("'[T]he scope of [Congress's] power of inquiry . . . is as penetrating and far-reaching as the potential power to enact and appropriate under the Constitution.'" (quoting *Barnblatt v. United States*, 360 U.S. 109, 111 (1959))); *Watkins v. United States*, 354 U.S. 178, 187 (1957) ("The power of the Congress to conduct investigations is inherent in the legislative process. That power is broad. It encompasses inquiries concerning the administration of existing laws as well as proposed or possibly needed statutes. . . . It comprehends probes inyo department so fthe Federal Government to expose corruptions, inefficiency or waste."); *id.* ("It is unquestionably the duty of all citizens to cooperate with the Congress in its efforts to obtain the facts needed for intelligent legislative action. It is their unremitting obligation to respond to subpoenas, to respect the dignity of the Congress and its committees and to testify fully with respect to matters within the province of proper investigation."); *McGrain v. Daugherty*, 273 U.S. 135, 175 (1927) ("A legislative body cannot legislate wisely or effectively in the absence of information respecting the conditions which the legislation is intended to affect or change; and where the legislative body does not itself possess the requisite information – which not infrequently is true – recourse must be had to others who do possess it. Experience has taught that mere requests for such information often are unavailing, and also that information which is volunteered is not always accurate or complete; so some means of compulsion are essential to obtain what is needed. All this was true before and when the Constitution was framed and adopted. In that period the power of inquiry – with enforcing process – was regarded and employed as a necessary and appropriate attribute of the power to legislate--indeed, was treated as inhering in it.").

prohibit information from being used for any purpose "other than the purpose for which it was supplied." Here, the Committee intends to use the data exactly for the purpose for which it was supplied—to analyze the health effects of exposure to certain air pollutants.

Finally, EPA is not even a party to the purported CDC-Harvard agreement, leaving any such agreement particularly irrelevant to the Committee's subpoena.

For all of the above reasons your staff's excuses for your failure to produce the data underlying the Lepeule et al. (2012) study fall short, and, for the same reasons, your continued non-compliance with respect to the Health Effects Institute (HEI) data and the Jerrett (2009) study are similarly unexcused.

Your staff does not deny that the HEI data is within your control. EPA could have obtained this data when the Committee first asked for it years ago. Your staff claims that you are in the process of obtaining it "soon."[7] The deadline was August 19. Please detail the specific steps you have taken and are taking to obtain this data.

As to the Jerrett (2009) data, your staff asserts that this study is "not presently subject to the Shelby Amendment," but offers no support for this assertion. Please explain the assertion, and detail the specific steps you have taken and are taking to obtain that data pursuant to the subpoena and EPA's right to "obtain, reproduce, publish or otherwise use the data" associated with this taxpayer-funded study.

De-identification is practicable

The Committee shares EPA's interest in ensuring that no personally identifiable information is made public in the course of EPA's production of the required data. But I reiterate that the option the Committee afforded you to de-identify the data before complying with the subpoena was just that—an option. Compliance is mandatory. Even if you cannot de-identify the information in a timely manner, you still must deliver the data to the Committee so that we can analyze it and, if necessary, de-identify it ourselves.

The Committee stands ready to de-identify the documents before making them available outside the Committee for analysis. If you produce the information in a non-de-identified format, the Committee will not make the information public in a form that makes any particular individual identifiable. We are confident that the data can be de-identified with relative ease. The National Academy of Sciences has stated that "Statistical agencies, working closely with scholars, have for more than 40 years simultaneously improved the technologies that protect confidentiality and the modalities that provide appropriate access to microdata" and that "Nothing in the past suggest that increasing access to research data without damage to privacy and confidentiality rights is beyond scientific reach." Indeed, Harvard has provided relevant information to multiple EPA-funded researchers and the Health Effects Institute, and has taken steps to de-identify past information provided to the Agency and Congress.[8]

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[7] On August 20, 2013, HEI officials confirmed to Committee staff that the information to be provided "soon" would not be sufficient for independent replication and re-analysis.

[8] Letter from Gina McCarthy to Andy Harris, June 7, 2012, *available at* http://science.house.gov/sites/republicans.science.house.gov/files/documents/20120607.pdf.

We therefore are concerned with your failure to de-identify the data on time and your decision to consult with the CDC about de-identification. We have been down this road before. Last year, you told the Committee that you were consulting with CDC about how to de-identify virtually the same dataset.[9] This consultation failed to lead to delivery of data suitable for reproduction and reanalysis. Given this history, we are skeptical that these steps you have taken will lead to a production of the information required by the subpoena.

If you are genuinely frustrated by an inability to de-identify the data promptly, the Committee can recommend several experts who we are confident could de-identify the data in a matter of days.

Conclusion

It is time to bring EPA's two years of non-responsiveness to a close. EPA is using the subpoenaed data to support regulations that could cost the American people trillions of dollars. Yet EPA has refused to make the data available to Congress or the American people. Regulations based on secret data have no place in a democracy.

Please respond to this letter by September 16, 2013, detailing the specific steps you are taking to produce by September 30, 2013, at the latest, all documents demanded by the subpoena. My staff is available to assist in any way necessary to help you overcome any practical obstacles to compliance. I remain hopeful that the subpoena will be complied with in the spirit of cooperation appropriate to relations between Congress and the Executive. If you continue to default on your subpoena obligations, I will not hesitate to pursue all other means available to compel production of the relevant data.

Sincerely,

Lamar Smith
Chairman
Committee on Science, Space, and Technology

cc: The Hon. Eddie Bernice Johnson, Ranking Member, Committee on Science, Space, and Technology

[9] *Id.*