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RANKING MEMBER

Congress of the United States
House of Representatives

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

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August 6, 2013

The Honorable Lamar Smith
Chairman
Committee on Science, Space, and Technology
2321 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Smith,

On August 1, 2013, the Committee on Science, Space, and Technology met and authorized the issuance of subpoenas on a party-line vote. On August 2, the EPA Administrator was served with a subpoena issued by you pursuant to this authorization (attached). As you know, I strongly opposed the authorization and issuance of this subpoena. However, as you have determined to proceed despite my strong objections, I have several questions about how this process will be conducted by the Committee.

As the Democratic Members of the Committee pointed out during the business meeting to authorize the subpoenas, you had previously indicated that you planned to transmit any research data obtained pursuant to the subpoena to unidentified third parties. Upon repeated questioning by Democratic Members of the Committee, you refused to identify to whom you intended to pass this data. Representative Edwards pointed out that legitimate scientific researchers already had the ability to access the Harvard University and American Cancer Society data sets. When she asked the Majority to identify legitimate scientists who didn't already have access to this data, you responded:

> "For example, Dr. Stan Young, assistant director of the National Institute of Statistical Sciences, has been denied access to the Harvard Six Study data. Similarly, Dr. Jim Enstrom, epidemiologist and research professor at the UCLA School of Public Health, has been denied access to the Cancer Prevention Study 2 data, that's an example of one for each."

Mr. Chairman, since these are the only two researchers you identified during the markup, I think it would be instructive to highlight some issues we've discovered pertaining to each of these individuals.

As you noted at the business meeting, Dr. Stanley Young is employed by the National Institute of Statistical Sciences (NISS). However, upon contacting the Director

of NISS, Dr. Alan Karr, he noted that Dr. Young was acting on his own behalf, not on the behalf of NISS, and had no authority to commit NISS. Further, he noted that NISS does not have the resources available to undertake such a data analysis. I would note that when the Health Effects Institute conducted a thorough re-analysis of the Harvard Six Cities Study and the American Cancer Society related study, it took a team of 30 researchers three years to complete their work. It certainly seems unlikely that one statistical researcher, acting on his own, could replicate this task in a useful timeframe.

Moreover, In Dr. Young's letter addressed to you on July 29, 2013 (attached), he makes some disturbing claims. Regarding privacy concerns of participants involved in the studies, he states:

> "In general, individual privacy concerns should disappear with death."

This is a bizarre claim. It is well recognized that restrictions on the release of personal medical records apply after death. The Health Insurance Portability and Accountability Act of 1996 (HIPAA), which regulates the use and disclosure of Protected Health Information, explicitly applies to deceased individuals. This is a basic misunderstanding of the legal requirements regarding the protection personal health information.

However, these issues pale in comparison to the issues raised by the other researcher you mentioned at the business meeting. You mentioned Dr. Jim Enstrom as an example of a legitimate researcher who has been denied access to the American Cancer Society's CPS 2 data. You noted that Dr. Enstrom is affiliated with UCLA; however, Dr. Enstrom was terminated by that institution in 2012. What you did not mention is that Dr. Enstrom was a long-time consultant to the tobacco industry, and he conducted tobacco industry funded studies on the health effects of tobacco. For instance, in 2003 Dr. Enstrom published a study questioning the negative health effects of second-hand smoke[1]. This study was partially financed by the tobacco industry. My staff has subsequently determined that over a long period of time, Dr. Enstrom's relationship with the tobacco industry has resulted in payment to him of hundreds of thousands of dollars. I've attached to this letter certain documents establishing this relationship, including scanned copies of payments from tobacco companies to Dr. Enstrom.

To say that I am disappointed that you would identify a paid tobacco industry consultant as a legitimate researcher would be a gross understatement. I am appalled. I am appalled that you would even consider subpoenaing the personal health records contained in the Harvard Six Cities and American Cancer Society data sets to supply to tobacco industry consultants. However, based on your own statements at the business meeting, this apparently is exactly the type of thing you are contemplating.

Mr. Chairman, this is no longer a dispute between the EPA and the Majority. By your actions, this has become an attack on the personal privacy of hundreds of thousands of Americans, an attack on the scientific process, and an attack on public health. I spent 16 years as a nurse at the Dallas Veterans Administration Hospital. During my time as a nurse, I saw first-hand the terrible toll in suffering and death caused by cancer and heart disease. We now know that much of that suffering was caused by smoking and exposure to polluted air. We know that because of the dedicated efforts of scientists at places like

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[1] Engstrom JE, Kabat GC. Environmental tobacco smoke and tobacco related mortality in a prospective study of Californians, 1960-1998. *BMJ USA* 2003; 3:369-373.

the American Cancer Society. These scientists fought for years to find and report the truth in the face of well financed attacks by consultants of the tobacco and polluting industries. I cannot begin to describe how much it saddens me that the Majority is apparently using the Committee on Science to further those industry financed attacks. I sincerely hope you will reconsider your misguided efforts before they result in real harm to our country's citizens and our institution.

However, if you choose to continue, I would ask that you respond to the following specific questions regarding how you will conduct this process as we move forward.

1. Who else will you subpoena?

The authorization the Committee approved on August 1 permits you to issue subpoenas to "the Environmental Protection Agency (EPA) and other custodians of research data." As Representative Grayson noted at the business meeting, this authorization lacks specificity as to who may subpoenaed.

As Democratic Members pointed out at the business meeting, the CPS 2 data set was compiled by the American Cancer Society, not the EPA. The EPA is not a custodian of this data. To our knowledge, the only custodian of this data is the American Cancer Society. This same situation exists for the full data sets related to the Harvard Six Cities Study, which Harvard possesses. Moreover, since the American Cancer Society funded the collection of the CPS 2 cohort data, EPA has no legal authority to lay claim to it. The Shelby Amendment (contained in PL 105-277) would not apply to CPS 2, as the data was compiled using non-Federal resources.

With regard to the Harvard data set, it is our understanding that Harvard researchers obtained health data from the National Death Index, which is part of the National Center for Health Statistics at the Centers for Disease Control and Prevention (CDC). As the EPA has already explained to the Majority in their June 7, 2012 letter to Chairman Harris, in order to obtain the data from the CDC the Harvard researchers signed a confidentiality agreement in accordance with section 308(d) of the Public Health Service Act (42 U.S.C. 242m(d)) promising not to publish or release data in any form to any party if a particular individual was identifiable. To release this data in an identifiable form would be a violation of the aforementioned law. Thus, when the EPA contacted Harvard to seek the study data (at the Majority's request), Harvard was required by law to provide only de-identified data. EPA transmitted this de-identified data to the Majority on June 7, 2012. EPA cannot legally obtain any further (presumably identifiable) data from Harvard without Harvard being in violation of the confidentiality agreement signed pursuant to the Public Health Service Act.

Thus, EPA is not a custodian of the study data you seek, and for the above highlighted reasons, EPA has no legal right to obtain the data in question beyond what they have already provided to the Committee. In order to obtain the data you claim to seek, you will have to subpoena other entities. The Members of the Committee have a right to know, do you intend to subpoena Harvard University or researchers affiliated with that institution and do you intend to subpoena the American Cancer Society or researchers affiliated with that institution?

2. Is your demand limited to de-identifiable data?

At the August 1 business meeting, Democratic Members of the Committee noted that the authorization allows you to subpoena data "which **may** be de-identified." (emphasis added). Representative Grayson attempted to amend the resolution to replace "may" with "shall," thus only authorizing the Committee to seek de-identifiable data. That amendment was opposed and defeated by the Majority. Subsequently, the subpoena you issued on August 1 states:

> "Documents responsive to the subpoena **may** be produced in a de-identified form that removes personally identifiable information from the documents, **but the documents shall be produced in a manner sufficient for independent replication and re-analysis and shall contain sufficient information to allow a one-to-one mapping of each pollutant and ecological variable to each subject.**" (emphasis added)

The plain language of the subpoena indicates that you are not limiting your data search to de-identified data, but rather, data sufficient for study replication.

This concerns me greatly. An August 2, 2013, article on the website for *Science* magazine quotes C. Arden Pope of Brigham Young University, who is one of the original authors of the studies in question. He states:

> "It's extremely hard to give a data set that will allow you to replicate the results in these studies that doesn't include information that then allows you—with an Internet search of obituaries—to quickly figure out who the people were."

In other words, you cannot replicate these studies with de-identified datasets.

I suspect this revelation is not a complete surprise to you. After all, the EPA supplied the Majority with a de-identified data set for the Harvard Six Cities Study last year, yet the Majority still included data from that study in your subpoena to the EPA. Clearly, you have judged the de-identified data from the Harvard Six Cities Study which you already possess to be insufficient for your stated purposes of study replication.

I think the information I've highlighted above clearly indicates that you are not limiting your demand for data to de-identifiable information. Nonetheless, can you please confirm that you are not limiting your demands to de-identifiable data?

3. How will you ensure the proper handling of human subject research data?

As previously noted, the Majority appears to be seeking identifiable human subject research data. At the very least, the subpoena permits this type of data to be included in a response to the Committee. As you should know, various Federal and state laws govern the handling of such data. Furthermore, the scientific research community follows certain other standards regarding the conduct of human subject research. Typically, institutions handling this type of sensitive information have a set of institutional controls and reviews to ensure compliance. Moreover, they employ Institutional Review Boards (IRB) which act as independent ethical monitors.

In my history of service on the Committee, I've never known the Committee to employ any of these institutional practices, since the Committee has not engaged in

the practice of human subject research nor acted as a custodian of human subject research data. Since you appear committed to obtaining identifiable human research data, the Committee will presumably become a custodian of this sensitive data. You then have an obligation to conduct this Committee in keeping with applicable U.S. laws and practices regard the handling of this sensitive information. This is a serious obligation.

The Members of this Committee and the American people whose records you are seeking deserve to know what controls you have put in place to ensure proper handling of their sensitive health records. Please detail what measures you have taken in this regard, and if you will employ the use of an IRB, please indicate who will act in this capacity. Also please specifically identify which Majority staff will have access to this data and what specific qualifications and training they have in the handling of human subject research data. Please also indicate if you or your staff are prepared to sign confidentiality agreements which are typically required to access this data (including data subject to the Public Health Service Act), and how you plan to accomplish your stated objective of distributing this data to third parties without violating these confidentiality agreements and applicable U.S. and state laws.

4. **How do you intend to address liability concerns related to this request?**

During the August 2 business meeting, Representatives Edwards and Grayson brought up valid concerns about the legal liability of the custodians of this research data should they disclose the data in the form you apparently require. The researchers who collected the data for the Harvard Six Cities Study and CPS 2 made assurances of confidentiality of the research data. In the case of the Harvard Six Cities Study, a confidentiality agreement was signed pursuant to the Public Health Service Act, and violating that agreement would constitute a violation of the law. In the case of the data the American Cancer Society collected for their CPS 2 cohort, they guaranteed confidentiality to the CPS 2 participants. As has been noted numerous times before, the CPS 2 cohort consists of 1.2 million people. Violating these confidentiality guarantees could subject the American Cancer Society to massive civil liability.

These research institutions are world renowned. They contribute immensely to American prosperity and public health. To subject these institutions to criminal or civil liability as a result of the Majority's misguided fishing expedition would be a terrible injustice. Please detail how you intend to mitigate the liability issues surrounding the disclosure of the confidential data you have demanded from these institutions (by way of the EPA).

Mr. Chairman, I have many concerns about this entire process. Unfortunately the Minority's concerns seem to be falling on deaf ears. I hope you will provide thoughtful answers to the questions I've asked. The American people deserve no less. After all, it is their health records you are asking for, not the EPA's.

I implore you again to stop what you are doing. The actions you are taking are wrong. You are abusing Congressional power to harass the EPA Administrator. You are undermining our legitimate scientific research enterprise. You are violating the trust that hundreds of thousands of research volunteers placed in our country's premier research institutions. And for what purpose? To provide human health data to tobacco industry

consultants? If you continue on this path, you will cause irreparable harm to our Committee and our country. Please reconsider the path you have chosen.

Thank you for your attention to this matter.

Sincerely,

Eddie Bernice Johnson

EDDIE BERNICE JOHNSON
Ranking Member
Committee on Science, Space, and Technology

3 Attachments

Cc: Members, Committee on Science, Space, and Technology