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Will House Science Panel Need an Ethical Review?

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U.S. House of Representatives Committee on Science, Space and Technology **Pen pals.** Representatives Eddie Bernice Johnson (D-TX), left, and Lamar Smith (R-TX), right, have been exchanging letters over Smith's effort to subpoena data from the U.S. Environmental Protection Agency.

Since U.S. House of Representatives science committee Chair Lamar Smith (R-TX) <u>subpoenaed</u> the Environmental Protection Agency (EPA) on 1 August for data from decades-old air pollution studies, the agency has remained silent on how it will respond. But a vehement back-and-forth has filled that silence, as the panel's top Democrat, Eddie Bernice Johnson (TX), continues to spar with Smith over the move's wisdom. Last week, the exchange included Johnson's suggestion that the panel might need an independent oversight board to approve its use of sensitive data—and a letter from a researcher who claims Johnson defamed him during the fierce debate over the subpoena.

Smith argues that raw data from two seminal studies linking airborne soot to higher death rates—the so-called Harvard Six Cities Study and American Cancer Society research known as Cancer Prevention Study II—should be made public for reanalysis, because they underpin costly pollution regulations. But because this data contains personal health information about participants who were promised confidentiality, Johnson and fellow Democrats argue that the subpoena violates the participants' trust.

Smith has repeatedly promised that committee staff members would handle any personal health information with care. But the wording of the subpoena, which gives EPA Administrator Gina McCarthy a 19 August deadline to present the data, has Democrats uneasy. It states that the information "may be produced in a de-identified form that removes personally identifiable information," but also demands that these data be sufficient for independent replication of the original findings. Critics of the subpoena argue that it will be impossible for independent researchers to replicate the studies with de-identified data, meaning the committee will need to get the complete raw data, including sensitive personal information.

In <u>a letter</u> to Chairman Smith on 6 August, Johnson said the subpoena's wording was evidence that the Republicans intend to go after data that is not fully de-identified. And that raises a new question, she wrote: Will the committee follow the same rules as federally funded research institutions entrusted with sensitive health information about human subjects? Will it, for example, establish an institutional review board (IRB) to oversee the process and ensure it meets ethical standards?

In his <u>8 August response</u>, Smith reiterated that any personal health information in the subpoenaed documents would be removed before third parties saw the data, but did not respond to Johnson's IRB question. Smith also asserts that de-identification is a simple process that should cause no delay in the EPA's response.

Not everyone is so confident. Darrell West, director of the Brookings Center for Technology Innovation, notes that data collected from smaller communities, as in the Six Cities study, can be problematic, because it might be possible to reconstruct a participant's identity even after names and addresses are removed. Others told *Science*Insider that the question of whether the science panel would need IRB approval for holding and handling any original data isn't easy to answer, because Congress can—and often does—exempt itself from federal regulations.

There's a chance that such issues could end up being hashed out in court, if EPA resists the subpoena. West, for one, believes that if the raw Six Cities data can't be adequately deidentified, the committee has no legal right to request them.

Meanwhile, one of the researchers who says he was denied access to the American Cancer Society data has also become involved in the fray. At the 1 August committee meeting to approve the subpoena, Smith named James Enstrom, formerly an epidemiologist at the University of California, Los Angeles (UCLA), as an example of a legitimate scientist whose request for raw data had been unfairly turned down by the society.

Johnson, however, challenged Enstrom's credentials in her 6 August letter. Enstrom, she wrote, was a longtime tobacco industry consultant who conducted industry-funded research questioning the negative health effects of secondhand smoke and was fired by UCLA in 2012.

Enstrom fired back with his own letter on 8 August, writing that he wanted "to fully refute the defamatory statements about me" and asking Johnson to "immediately withdraw" her comments. He is a past user of American Cancer Society data, he wrote, and has never been a consultant to the tobacco industry, although the industry has funded his research. He also noted that he is now involved in a wrongful termination suit against UCLA, which he claims fired him in retaliation for studies that found that fine soot particles did not cause "premature deaths" in California.