

Proposed Rule “Strengthening Transparency in Regulatory Science”

Docket No. EPA-HQ-2018-0259

Comments from
Janice Nolen, MA
National Assistant Vice President, Policy
American Lung Association

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Thank you for the opportunity to provide comments. My name is Janice Nolen and I am the National Assistant Vice President for Policy for the American Lung Association. The American Lung Association turns 114 years old this year. For more than a century, we have fought to save lives by protecting lung health and preventing lung disease. We oppose the proposed rule.

Many years ago in the early 1980s, my mother-in-law asked me to help her recruit participants in a major new study that they were doing. She worked for the American Cancer Society and they were looking to create a huge database of ordinary Americans who would be willing to provide them with confidential information about their health and medical experiences and would allow them to track for years to come. I was so pleased that two men from my church choir in Nashville agreed to participate. They completed the forms and other paperwork, and became two of the more than half a million participants in the Cancer Prevention Study II.

Fast forward a few decades and I learned that their data were now part of a landmark study—the American Cancer Society study—that revealed the risks to human health from breathing air pollution that I and my colleagues at the Lung Association were working hard to clean up. Their data and private health and medical data from hundreds of thousands of others were pointing the way to the need to clean up emissions from power plants, from diesel engines and fuels and many other sources. I never dreamed when my mother-in-law first made her request that EPA scientists and other researchers would mark that study as one of two seminal studies that helped reshape our understanding of the health risks from particulate matter air pollution. None of us then would have ever dreamed that the information these two men provided would have helped to identify and underline the threat to human life posed by the microscopic particles in the air we breathe.

Furthermore, that study and the Harvard 6 Cities study became examples of not only groundbreaking research, but of how questions about that research can be reviewed and resolved without having to lose the entire study. Unfortunately, that is an example that this proposal clearly fails to acknowledge.

These two studies with decades-old patient data, and others in the long list of studies that found evidence of harm from industrial emissions or unique events that no one hopes to replicate—like the Gulf oil spills—clearly appear to be targets of this proposed rule. Studies that have long been targets of industry polluters and their allies remain so in this proposal.

Once published, these studies raised alarms in the public health community about the increased likelihood of premature death from particulate matter in widespread parts of the nation. The studies raised alarms within industries about the increased likelihood that their polluting sources would have to clean up their emissions. Industry kicked in the messaging developed by the tobacco industry to

challenge the science using the same arguments we have in this proposal. I have in my office a page from a 1999 U.S. News and World Report article on the challenges to these studies that could have been written this year.

Scientists are working to become more transparent in their research. More researchers use publicly available information. But some studies cover populations that are so limited in size or specialized in their characteristics that those data should not be posted on the web for all the world to see. Anyone who has an account on Facebook should have a visceral knowledge of how important keeping confidential data confidential can be.

Meanwhile, EPA could readily review historical data and studies in ways that respect patient confidentiality and the gifts of data from people like my two choir member friends.

So far, EPA has failed to show any reason that changes are needed in the current system. Failed in its own transparency on this issue in fact, since EPA has not sought SAB review of this and not provided sufficient rationale for why EPA needs this change, much less how they would use this rule going forward.

We request EPA to withdraw this proposal. Thank you.