VIEWPOINT

The Use and Misuse of Transparency in Research
Science and Rulemaking at the Environmental Protection Agency

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Transparency in science is a laudable goal. By describing with sufficient clarity, detail, and completeness the methods they use, and by making available the raw data that underlie their analyses, scientists can help ensure the reproducibility of their results and thus increase the trustworthiness of their findings and conclusions. At the same time, transparency is not in an of itself a definitive standard for the usefulness of science in policy making.

A proposed rule at the Environmental Protection Agency (EPA), "Strengthening Transparency in Regulatory Science,"[1] goes too far in barring from pivotal consideration in regulations any scientific study that does not have all data and analytic models made publicly available, unless special dispensations are granted. In particular, epidemiological and clinical studies that are designed to protect the confidentiality of personal health information may be highly germane to establishing environmental standards yet ethically barred from making all data publicly available. Other studies may rely on proprietary information, and their main findings may have been replicated in independent, proprietary studies, yet under the proposed rule, such studies similarly could not be relied on as a basis for regulation. The proposed rule provoked hundreds of thousands of comments and also was the subject of a recent congressional hearing.[2]

> Rather than jeopardize public health and environmental sustainability through ill-considered restrictions on evidence, the EPA should use scientifically sound ways of assessing the totality of evidence to gain confidence in the reliability of scientific results.

While sometimes falling short in its use of science,[3] the EPA has traditionally strived to base regulations on the best available scientific evidence. For example, in 1997 the EPA adopted new air pollution regulations based mainly on 2 large epidemiological studies. The Harvard Six Cities study had begun in the 1970s to monitor the health of more than 8000 adults and children in 6 cities over 15 years while simultaneously tracking levels of air pollution, mainly related to burning of fossil fuels to generate electricity. Published in December 1993, the study found a strong gradient of mortality associated with increasing levels of airborne small particulates (diameter <2.5 μm).[4] A second, independent study by the American Cancer Society followed 500 000 people in 154 cities for 8 years and reached similar conclusions in 1995.[5]

Acting in response to these strong findings, the EPA issued regulations in 1997 that extended pollution standards down to particles as small as 2.5 μm. Filtering such tiny particles required costly compliance measures by industries that burn fossil fuels to generate power. When the new regulations had been proposed in 1996, the American Petroleum Institute and other industry groups questioned the reliability of the epidemiological studies, noting differences in lifestyle, smoking, or other confounding factors that might have been responsible for the findings. Indeed, the investigators had to control for such potential confounders in their analyses, and because the studies involved confidential medical information, their data had not been made public. To quell criticism about this lack of transparency, the investigators of both studies turned to the nonprofit Health Effects Institute to reanalyze the original studies. Jointly sponsored by the automobile industry and the EPA to serve as an independent, expert resource, the Health Effects Institute was well positioned to serve as an independent analyst and also was able to provide adequate assurance of maintaining patient confidentiality. Reanalysis of the data, led by a team from the University of Ottawa, corroborated the published results of both studies in July 2000.[6]

After the 1997 EPA regulation appeared and the fossil fuel industry objected to the lack of access to the underlying data, Sen Richard Shelby (R, Alabama) inserted a provision in the 1999 Omnibus Appropriations Bill (Public Law 105-277) that directed the Office of Management and Budget to apply provisions of the Freedom of Information Act (FOIA) to any federally funded study that had been used to develop policy or rules. After the Office of Management and Budget received thousands of comments on its proposed implementation, mainly favorable from industry and critical from academic and scientific circles, it adopted rules that applied protections of confidential medical information for any FOIA request and limited in other ways the applicability of the Shelby amendment.

The current EPA proposed rule,[1] advanced in 2017 under the EPA's then-administrator Scott Pruitt, is seen by many public health leaders as the most recent maneuver to hamper rulemaking and give opponents greater latitude to raise questions about the scientific underpinnings of public health and environmental regulations.

Regardless of the intent behind the proposed EPA rule, greater transparency in methods and data will serve to enhance the reliability of science. Transparency and rigor in science were at the heart of a 2019 congressionally

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mandated National Academies of Sciences, Engineering, and Medicine report on reproducibility and replicability in science.[7] The report distinguishes between efforts to repeat a computational analysis based on the same data (reproducibility) from an effort to examine whether a new study reaches conclusions similar to another (replicability). In these terms, the American Cancer Society replicated the Harvard Six Cities Study (and vice versa), and the Health Effects Institute reproduced the results of both previous studies. The Academies report highlights the growing complexity of science, particularly with reliance on massive data sets and multistep computation, and stresses the importance of tools and repositories that would support computational reproducibility. This is especially relevant to epidemiological and other studies, in which investigators make judgments about adjusting for confounding variables, and in any science susceptible to poor analytical practices such as post hoc hypotheses that are not clearly identified as such.

Especially salient in relation to the proposed EPA rule, the Academies study emphasizes utilizing the full body of relevant scientific knowledge to reach a conclusion rather than focusing primarily on the reproducibility or replicability of any one study. In this spirit, in its guidance to industry providing evidence of effectiveness for human drugs and biological products, the US Food and Drug Administration advises, "Results that are obtained from studies that are of different design and independent in execution, perhaps evaluating different populations, endpoints, or dosage forms, may provide support for a conclusion of effectiveness that is as convincing as, or more convincing than, a repetition of the same study."[8] More generally, a framework for assessing and summarizing the totality of evidence called GRADE (Grading of Recommendations Assessment, Development, and Evaluation) has been endorsed by more than 100 organizations worldwide and is gaining acceptance in the academic community.

An EPA dedicated to the best use of science in regulation would not automatically exclude studies based on the absence of publicly available data. As demonstrated by the Health Effects Institute, other means are available to reanalyze data in pivotal studies and preserve the proprietary character or patient confidentiality in an original study. Complementarily, public availability of data is no guarantee that the data were correctly generated and free of transcription or other errors.

At this writing, a final EPA rule has yet to be released. On November 11, 2019, a concerning report in the *New York Times* asserted that EPA had amended its original proposed rule to make it apply retroactively and in ways that would allow the EPA administrator wide discretion in the choice of studies on which to rely.[9] The EPA immediately issued a blistering rebuttal that adamantly rejected as false many elements in the *Times* article. The current EPA administrator, Andrew Wheeler, has indicated his intention to release a final rule in 2020.

As the scientific, public health, and medical communities strive to prevent misuse of transparency in a way that would hinder scientifically sound rulemaking, scientists, epidemiologists, clinical investigators, research institutions, funders, and journal editors can and should take steps to enhance the reproducibility of research.[7,10] Rather than jeopardize public health and environmental sustainability through ill-considered restrictions on evidence, the EPA should use scientifically sound ways of assessing the totality of evidence to gain confidence in the reliability of scientific results.

ARTICLE INFORMATION

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