



August 16, 2018

Andrew Wheeler, Acting EPA Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue
Washington, DC 20460

Re: Comments on Proposed Rule "Strengthening Transparency in Regulatory Science" Docket No. EPA-HQ-OA-2018-0259-0001

Dear Acting Administrator Wheeler,

The undersigned nursing organizations and nurses appreciate the opportunity to comment on the necessity of science-based policy to protect human health. Our organizations strongly oppose any efforts to limit the best available science used in the development of health-based standards.

While we support transparency in science-based decision making, this rule would not strengthen transparency, but rather severely restrict and limit the data available to determine the health impacts of environmental exposures and adequately protect Americans. In order for a study to be included for evaluation under the proposed rule, researchers would be required to make all data publicly available, which is ethically and legally unfeasible in certain instances due to patient confidentiality requirements. In many cases making health data publicly available could also breach the informed consent agreement signed by both the participant and the investigator.

In regard to scientific reviews for policy-making decisions, the raw data may not be available for previously completed and published studies. Historic, landmark studies, that are the basis for policies that have contributed to significant improvements in public and environmental health, would be inappropriately excluded from review. The studies that would be disregarded under this rule are credible studies that help inform EPA's decision-making. As it is written, the proposed rule would not contribute to transparency, but rather reduce the body of best available evidence upon which decisions by EPA are based.

As nurses involved in the development of scientific research findings and supportive of the utilization of these findings in health and environmental policy, our other major concerns include the threat to patient privacy and the potential for development of regulations and standards that are not reflective of the true burden of health impacts from environmental exposures.

Regarding patient confidentiality, when evaluating the health impacts of exposures researchers collect data that must remain private, such as name, medical history, geographic location, age, occupation, and any other information that could lead to identification of an individual. There are strict human subjects' protection guidelines that are used to protect the privacy of study participants and the federal government must continue to ensure that this sensitive information is not made public. Individuals participating in research sign a consent form, which is a contractual agreement, which includes assurances that their



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individual information will remain confidential. The inability of a scientist to guarantee confidentiality would be a major barrier to being able to recruit a diverse population of participants, thus potentially greatly biasing the research findings.

This rule would block the ability of investigators to evaluate the best available health research findings, excluding many studies that have indicated harm from environmental exposures on human health, ultimately resulting in weaker environmental and health protections. The exclusion of well-vetted research is a tactic argued by industry and is ultimately an effort to suppress research that shows harm to public health from operations and/or products. In addition, the rule could allow the elimination of historical data sets that are not stored in currently used electronic formats. The availability of historical public data to scientists is essential to understanding health impacts of environmentally mediated harm over time.

The review process currently utilized by EPA in evaluation of scientific research to inform policy is already transparent and involves rigorous peer-review and evaluation by independent experts. Additionally, once findings are published, EPA provides ample opportunity for the public to provide feedback before regulations and standards are finalized.

This rule as proposed undermines EPA's responsibility as a science-based agency that is charged with protecting human health and the environment. Therefore, in closing, we are strongly encouraging EPA to withdraw the proposal and ensure the continuation of the already transparent review process that is currently used.

Sincerely,

Alliance of Nurses for Healthy Environments
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Association of Public Health Nurses
Eastern Nursing Research Society
Public Health Nursing Section of the American Public Health Association
Quad Council Coalition of Public Health Nursing Organizations
Southern Nursing Research Society
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