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Executive Director*

May 15, 2020

Comments submitted online

RE: Strengthening Transparency in Regulatory Science Supplemental Notice of Proposed Rulemaking

Dear EPA Administrator Andrew Wheeler:

Public Responsibility in Medicine and Research (PRIM&R) appreciates the opportunity to comment on the Strengthening Transparency in Regulatory Science Supplemental Notice of Proposed Rulemaking, published March 18, 2020.

PRIM&R is a nonprofit organization dedicated to advancing the highest ethical standards in the conduct of research. Since 1974, PRIM&R has served as a professional home and trusted thought leader for the research protections community, including members and staff of human research protection programs and institutional review boards (IRBs), investigators, and their institutions. Through educational programming, professional development opportunities, and public policy initiatives, PRIM&R seeks to ensure that all stakeholders in the research enterprise understand the central importance of ethics to the advancement of science.

Upon initial release of the proposed rule, “Strengthening Transparency in Regulatory Science,” PRIM&R offered the position that “the proposed rule arbitrarily and unnecessarily restricts access to and use of rigorous science in environmental policymaking, to the detriment of the public’s health and trust in the regulatory process.”

The supplement to the rule released in March does not assuage these concerns. First, the expansion of the scope of the rule to include “influential scientific information” exacerbates our worry that the rule will “make it more difficult for the agency to make decisions that adequately protect the public’s health, as its mission requires.” Though transparency is a laudable, shared goal for much of today’s scientific enterprise, it is not the case that only fully public research data is useful for understanding and promoting public health. Indeed, transparency can be achieved in different ways that satisfy the demands of different kinds of science, while still maintaining respect

for persons and intellectual property. Systematically and arbitrarily favoring fully-public data for even more of the Agency's work only further imperils citizens whose health depends on the EPA's using the best science, not just the most public.

The expansion of scope represented by the supplement also increases the already substantial burden that this rule would place on researchers to ensure the privacy and confidentiality of research subjects. As we articulated in our original comments, "the rule fails to acknowledge the enormously burdensome and costly complexities involved in redacting [individuals'] information in a way that both protects individuals' privacy and ensures that the data is still useful for future analysis." The supplement would make this problem worse, as burdensome redaction would be required for influential information, rather than only regulatory decisionmaking information.

Effectively mandating fully-public (or, from their perspective, insufficiently-redacted) data also leaves potential human subjects of research with an uncomfortable choice: take part in studies that may compromise their privacy and confidentiality, or lose the opportunity to participate in science for the betterment of human health altogether. Undermining potential subjects' confidence that their information will be protected skews the already unfavorable ratio of risk to benefit of participation in research. This will likely reduce the population of people willing to participate in research, which will severely hamper the conduct of science.

The proposed rule subverts the aims of transparency in a manner that may harm public health, increases time and resource burdens on scientists, and threatens to reduce the ability of researchers to recruit study subjects. PRIM&R stands ready to provide any further assistance or input that might be useful during this process. Please feel free to contact me at 617.303.1872 or [ehurley@primr.org](mailto:ehurley@primr.org).

Sincerely,

Elisa A. Hurley, PhD  
Executive Director, PRIM&R