Comments re to Supplementary Proposal re 2018 Strengthening Transparency in Regulatory Science

Submitted via regulations.gov
Acting Administrator Andrew Wheeler
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Attn: Docket No. EPA-HQ-OA-2018-0259-9322

Re: *Comment on Supplemental Notice of Proposed Rulemaking—Strengthening Transparency in Regulatory Science*, 85 Fed. Reg. 15396 (Mar. 18, 2020) The Proposed Strengthening Transparency in Regulatory Science Rule published in April 2018 caused a great deal of concern in the public health community as rather than strengthening science, this rule would have led to a censoring of quality science by requiring total public availability of dose response data and models underlying significant regulatory decision making. Subsequently, EPA published a Supplemental Notice of Proposed Rulemaking in March 2020 that expanded the scope of the original proposal to apply to *all* data and models, not just dose-response data and models, used to support significant regulations *and* influential scientific information.

EPA realized that basic terms lacked clear definitions in their original proposal on "Transparency" of Science. This point was raised by many of the nearly 600,000 public comments received. In its supplemental proposal, EPA has attempted to define certain key terms, but these definitions are either ambiguous or inappropriate. For example, proposed definitions for *influential scientific information* or of *pivotal science* are entirely vague such that the scope and scale of the proposal are unknowable. What is the point of distinguishing between pivotal science and pivotal regulatory science? Who defines what are *significant* policy decisions? It is unclear why EPA has deleted the definition of "*research data*" which is abundantly clear and generally well understood. EPA's proposal to use the term reanalyze rather than replicate introduces additional confusion: they do NOT mean the same thing. Replicate means to repeat; reanalyze means to go back over the original data and look at it again. It is clear the objective of reanalysis in this context is to find a problem in the original conclusions. Using EPA's definition of reanalyze means that *independent validation* is reanalysis by other experts. The strength of scientific data is not reanalysis *ad nauseum* of a single data set but repetition of a similar study under different conditions by different investigators which comes to a similar conclusion.

The public health consequences of focusing on data availability as opposed to study quality are enormous. Much data which involves people, whether with regard to the characterization of exposure or effects, requires privacy protections and public accessibility to such data is not required to evaluate their quality. The supplemental proposal suggests that all studies can be examined, but determinations of whether, or to what extent, a study can actually be relied upon by the agency to support the development of significant regulations or influential scientific information continues to hinge on public availability of underlying data, with the final decision resting with the Administrator, who is rarely a scientist. This entire premise of EPA's "Transparency" proposal is a thinly veiled attempt to censor science. As Harvey Fineberg, the former head of the National Academy of Medicine has said, this is a proposal in search of a non-existent problem.

I am now a private citizen, although I spent 40 years serving the American people as a federal scientist, 19 of them at EPA. I directed the National Institute of Environmental health Sciences of the NIH and the National Toxicology Program of the Department of Health and Human Services from January of 2009 to October of 2019. The NIEHS is the largest funder of environmental health research in the world, and much of the human health studies which play a key role in shaping policy have been funded by NIEHS. The National Toxicology Program is a problem-solving program which involves testing of chemicals of concern and evaluating hazards. NIEHS also has a Superfund Research Program which addresses health concerns related to hazardous waste sites. EPA has played a key role in many of the NIEHS programs. Ignoring the best quality science for only the most available will undermine the decisions of the Agency and fail to protect human health from environmental stressors.

I am putting myself on record as opposed to EPA's proposed Strengthening Transparency in Regulatory Science rule which if finalized would ultimately put public health at significant risk.