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Andrew Wheeler, Administrator
Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
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May 7, 2020

Re: Comments on the EPA March 18, 2020 Supplementary notice regarding the EPA's "Strengthening transparency in regulatory science" proposal

Administrator Wheeler,

Instead of responsibly addressing the concerns expressed by our Society, and by the vast majority of other commenters to date, regarding the dangers of the EPA's "Transparency" rule proposed on April 30, 2018, the Agency's most recent March 18, 2020 supplemental notice has doubled down on the problematic features previously identified in the original proposal, and expanded the range of potential damage to public health that it will enable.

Before discussing the multiple ways that this supplemental notice has worsened the EPA's damaging proposed "Transparency" rule, **it is important to restate that we recommend that EPA entirely withdraw this supplement and the original proposed rulemaking.** These are needless regulations seeking to solve a purported problem that does not exist. Sufficient safeguards already exist in the present peer review system, and the approach put forward by this proposed regulation will not achieve the Agency's claimed goals of "transparency." As stated in an attached Editorial published in the journal *Science* (04 May 2018, Vol. 360, Issue 6388), and co-signed by Editors of major scientific and medical journals (including the *Science*, *Nature*, *Public Library of Science (PLOS) Journals*, and *Cell*) (Berg et al., 2018) (attached):

"Many peer-reviewed scientific journals have recently adopted policies that support data sharing, consistent with the Transparency and Openness Promotion (TOP) standards. These standards, however, recognize the array of workflows across scientific fields and make the case for data sharing at different levels of stringency; in not every case can all data be fully shared. Exceptional circumstances, where data cannot be shared openly with all, include data sets featuring personal identifiers....Excluding relevant studies simply because they do not meet rigid transparency standards will adversely affect decision-making processes."

Moreover, as stated by EPA in their own 2016 Plan to increase access to results of EPA-funded scientific research – the quality of the research is not dependent on data availability. It states: "The validity of scientific conclusions drawn from research publications or their associated research data, or EPA's ability to consider those conclusions and data in its actions, does not depend on compliance with this Plan." (See: <https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransparencyplan.pdf>)

Regarding the specific problems with this supplemental notice of proposed rulemaking, the proposed rule would onerously apply retroactively, not just to future research and publications. As discussed in the supplemental notice, EPA is proposing to review and consider all studies regardless of the date on which they were created when developing a significant regulatory action or "Influential Scientific Information" defined by the notice as scientific

information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions. For example, when EPA reassesses its standards every five years, it will downgrade consideration of studies from the past that do not conform to the new rules. Since many past studies cannot practically comply with this rule, as they cannot ethically release the personal health data collected in their studies, this will have the untoward effect of sidelining much of the best available science from consideration by the EPA during pollutant standard revisions. This will weaken the scientific foundations of the prevailing environmental standards, and almost certainly lead to diminished public health protections in the United States.

Second, this supplement now expands the range of scientific inputs that it will inappropriately and needlessly restrict from consideration. The proposed rule, if finalized, will apply to significant regulatory actions and influential scientific information (https://cfpub.epa.gov/si/si_public_pr_agenda_archive.cfm), and will expand the extent to which the full range of science can be inappropriately restricted by the proposed rule from being considered, and for a widened range of government decision-making.

Third, the new “tiered” approach does not prevent loss of privacy. As discussed in a recent editorial published in the Lancet (Thorp et al., 2019) (attached), and signed by Editors of Science, Nature, PLOS, PNAS, Cell, and Lancet: “As leaders of peer-reviewed journals, we support open sharing of research data, but we also recognise the validity of scientific studies that, for confidentiality reasons, cannot indiscriminately share absolutely all data. Datasets featuring personal identifiers—including studies evaluating genomes of thousands of people to characterise medically relevant genetic variants—are but one example. Such data may be critical to developing new drugs or diagnostic tools but cannot be shared openly; even anonymised personal data can be subject to re-identification (e.g., Sweeney, 2013; De Montjoye et al., 2015; Rocher et al., 2019) (attached), and it has been a long-standing practice for agencies and journals to acknowledge the value of data privacy adjustments. The principles of careful data management, as they inform medicine, are just as applicable to data regarding environmental influences on public health. Discounting evidence from the decision-making process on the basis that some data are confidential runs counter to the EPA stated mission ‘to reduce environmental risks...based on the best available scientific information’.” (USEPA, 2016). Indeed, the EPA 2016 document on transparency stated that “Classified or otherwise protected EPA-funded scientific research will not be made publicly available.” (USEPA, 2016).

Finally, the EPA proposed rule does not account for conflicts of interest (and in particular financial conflicts of interest) by those requesting access to data, opening the possibility for research data that are to be used for regulatory purposes to be accessed by anyone, regardless of their affiliation. Thus, it will not prevent agents of vested interests from obtaining the publicly available data demanded by this proposed rule, and then running their own studies with the intention of discrediting science. There is already empirically based evidence that results of studies conducted by the pharmaceutical and tobacco industry favor those industries; indicating that we can anticipate self-serving biased analyses of EPA provided data by vested interest funded analysts under this proposed EPA approach (White and Bero, 2010; Bero, 2017; Lundh et al., 2017) (attached). Indeed, it has been previously documented in an extensive review of a similar proposal (upon which this EPA proposal is based) made by a vested interest (a tobacco company): when such data have been accessed using a similar provision in the state of Georgia, the data were abused in an attempt to discredit the research they did not like, but the original research was later replicated by other researchers (Thurston, 1998) (attached). This new attempt to implement the tobacco company-inspired data release proposal will undoubtedly have similar inappropriate and untoward damage to scientific research if this so-called “Transparency” rule is implemented.

We call on the US EPA to rescind this rule in its entirety, and return to the tried and proven methods used by the EPA in the past that have been so successful in applying sound science to its decision-making processes.

Sincerely,

George D. Thurston, Chair of the ISEE NA Chapter Policy Committee

On behalf of the International Society for Environmental Epidemiology North American Chapter

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