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Andrew Wheeler, Administrator
Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

August 3, 2020

Re: Comments on the EPA June 11, 2020 proposed rulemaking "Increasing Consistency and Transparency in Considering Costs and Benefits in the Rulemaking Process"

Administrator Wheeler,

We are submitting this letter because of our grave concerns about the possible implementation of the USEPA's June 11, 2000 needless and damaging codification of the agency's benefit-cost analyses (BCA) rulemaking process (Federal Register, Vol. 85, No. 113, Thursday, June 11, 2020, pg. 35612-35627). Before discussing the multiple flaws of this proposed rule, our Society has such great concerns about the rule that **we recommend that EPA entirely withdraws this proposed rulemaking.** As there are already established and sufficient guidelines for conducting BCA, there is no need to make a formal rule about them. Furthermore, it is inappropriate to codify science, as is proposed in this rulemaking. Science is an evolving process, and fixing EPA's Cost-Benefit methods to present-day approaches, at this one point in time, will inappropriately restrict the use of new and improved decision-making methods and approaches that can reasonably be expected to emerge in the future.

The proposed rulemaking seeks to solve a purported benefit-cost analysis problem that does not exist, as the present BCA guidelines are performing well. Since its inception in 1970, the EPA pursued, developed, and followed guidelines to conduct BCA. This is reflected by explicit requirements found in Executive Orders 12044, 12291, 12866, and 13563. Furthermore, the "best available science" that the agency relies on has sufficient quality safeguards through stringent peer review and data sharing standards. As stated in an 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 public 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/epascientificresearchtransperancyplan.pdf)

Our major practical concern is that this proposed rule codification, by restricting the science that can be considered, will be used to force the EPA to ignore many of the health benefits that would result from the

regulation of environmental contaminants, such as air pollution emissions, water pollution, and the implementation of our air and water quality standards, thereby undercutting the health and financial justification for those actions to protect public health.

The rule, if codified, would have several major untoward effects on the EPA's BCA process:

1) This unneeded regulation would force EPA to ignore key science relevant to the health effects considered as part of the EPA benefits-costs estimation process, eliminating adverse health effects from the benefits side of the analysis, and inappropriately reducing the financial justification of an environmental protection required under Executive Order 12866. It would therefore inappropriately prevent EPA from valuing the full range of potential health benefits, including those where the evidentiary base is suggestive, which effectively assumes that there is zero benefit to reducing these health effects, in violation of widely accepted economic principles (McGartland, et al., 2017); and,
2) This unneeded regulation would cause EPA to ignore many of the health benefits that are a direct result of regulatory action: those that arise from other co-pollutants that would also be reduced at the same time by the implementation of the EPA action, but would otherwise not be reduced. Of special concern is that the June 11, 2020 rule stipulates (on page 35620) that, in a BCA, "the pollutant analyzed in the study matches the pollutant of interest in the regulation." This would apparently prevent the EPA from including the many health co-benefits from other pollutants that would also be reduced at the same time the regulation is implemented. For example, using mercury, which is raised in the 2018 Federal Register posting for this rule, most emissions control options that would remove mercury from the exhaust of a coal-fired power plant would also remove health damaging particulate matter air pollution that would not otherwise be controlled. *Thus, the health benefits of the control of one pollutant are far larger than just the pollutant that is the direct aim of the regulation alone.* **All of the health benefits and their valuations should be fully included in the estimated benefits of a regulations**. Forcing EPA to ignore the particulate matter air quality benefits, in this example, ignores the science and inappropriately "cooks the books" of the benefits-costs estimation to underestimate the full benefits and to undermine public health protections. Importantly, the proposed regulation opens an avenue to avoid "[maximizing] net benefits (including potential economic, environmental, public health and safety, and other advantages, […])" pursuant of Executive Order 12866.

It is important to realize that this proposed rule is implicitly also aimed at achieving the same ends that the separate EPA "transparency rule" aims to achieve, to which a multitude of scientists have already strongly voiced their opposition on the legislative record of that proposed rule (USEPA, 2020) (Federal Register, Vol. 85, No. 53, Wednesday, March 18, 2020. pp. 15396-15406). For one, the "Transparency" component of this new BCA regulation will also apply retroactively to the science being considered, not just to future research and publications that EPA might rely on. 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. As such, this regulation imposes an onerous unfunded mandate upon researchers to make their data available in a form to meet EPA requirements. For example, when EPA reassesses its air quality 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 that they promised participants not to release, this will have the damaging 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 prevailing environmental standards, and lead to diminished public health protections in the United States.

In addition, the range of scientific inputs that can be expected to inappropriately and needlessly be restricted from consideration by this rule is overly broad, as the rule will apply to all "influential scientific information" (https://cfpub.epa.gov/si/si_public_pr_agenda_archive.cfm).

Another onerous aspect of the EPA's proposed data-handling approach is that it will jeopardize study participant and patient data privacy, since even anonymized personal data can be subject to re-identification,

especially if they include temporally- and geographically-specific data, such as environmental exposures that EPA health studies usually use. The rule states: "If the data and models are proprietary, the EPA proposes to make the underlying inputs and assumptions used, primary equations, and methodologies available to the extent permitted by law, while continuing to protect information claimed as confidential business information (CBI), personally identifiable information (PII), and other privileged, non-exempt information." However, 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 the research data collected by the EPA as a result of this rule. This would mean that research data that are to be used for regulatory purposes can 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 empirical evidence that studies supported or conducted by the pharmaceutical and tobacco industries favor their financial interests, indicating that we can anticipate self-serving 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 the current EPA rulemaking proposal is based) made by a vested interest (i.e. 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 Big Tobacco-inspired data release proposal will undoubtedly have similar inappropriate and untoward damage to scientific research. Thus, if this so-called "Transparency" aspect of the BCA rule were implemented, allowing vested interests to abuse the data in their "reanalyses" aimed at undermining confidence in the original study, the health of Americans would be put at risk; the EPA would fail its mission to "ensure that federal laws [protect] human health." (U.S. EPA, 2018).

We call on the US EPA to rescind this rule in its entirety, and return to the guideline approach that they themselves have used in the past that has been so successful in applying the latest sound science to its Benefit-Cost Analyses.

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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