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Comments on Advance Notice of Proposed Rulemaking: Increasing Consistency and Transparency in Considering Costs and Benefits in the Rulemaking Process

Comments submitted online via Regulations.gov to EPA-HQ-OA-2018-0107

The following comments are being submitted by the University of California, San Francisco (UCSF) Program on Reproductive Health and the Environment (PRHE). We have no direct or indirect financial or fiduciary interest in the subject of these comments.

We appreciate the opportunity to provide comments on the U.S Environmental Protection Agency's (EPA's) advanced notice of proposed rulemaking for "Increasing Consistency and Transparency in Considering Costs and Benefits in the Rulemaking Process." EPA is considering proposing new regulations for changing the way the Agency considers costs and benefits in regulatory decisions, including specific analytic approaches to quantify benefits and costs. Overall, a new rule is not needed as EPA's current methods for calculating benefits and costs are transparent and tailored to meet statutory mandates. Evidence shows that EPA rules to limit pollution have large benefits for public health, and previous scientific advisory boards (SAB) have reviewed EPA's economic analyses and found them to be scientifically and technically robust.

1. Current EPA methods are transparent as demonstrated with public access to *Guidelines for Preparing Economic Analyses*.

EPA already has outlined sound scientific methodologies for performing economic analyses of environmental regulations and policies in its publicly available *Guidelines for Preparing Economic Analyses.*[1] These protocols are electronically available both as an entire workbook and as individual chapters divided by topic to make methods transparent and easily accessible.

2. EPA should not propose a new rule. Its current benefit-cost methods are adequate and specific to the mandates EPA must comply with.

The *Guidelines* are specifically designed to meet the needs of the Agency to comply with statute and executive orders. The economic analyses chapters[2] outline methods to determine if regulatory action is necessary based on a statute or executive order. If the given statute or

[1] US EPA (December 2010) Guidelines for Preparing Economic Analyses. Available: https://www.epa.gov/sites/production/files/2017-08/documents/ee-0568-50.pdf.

[2] US EPA (December 2010) Guidelines for Preparing Economic Analyses. Chapter 2: Statutory and Executive Order Requirements for Conducting Economic Analyses. Pg. 2-1 – 2-5.

executive order directed at EPA requires amended procedural steps or additional economic analyses, the *Guidelines* provides directions to more specific protocols for applicable Office of Management and Budget (OMB) or EPA guidelines[3] in additional EPA source documents. Terminology in all documents is defined in a glossary and used consistently throughout the protocol.

3. EPA rules have large benefits for public health and have been endorsed by scientific review committees. EPA can update existing guidance to reflect current science as needed.

The methodologies applied to EPA benefit-cost analyses are peer-reviewed by the SAB Environmental Economics Advisory Committee made up of academic and industry experts. This committee provides independent advice for assessing costs and benefits of EPA environmental programs from a science and research perspective. These peer-reviewed and scientifically validated protocols have resulted in EPA rules that have large benefits for public health. For example, the Clean Air Interstate Rule[4] annually costs the government $4 billion, while the annual net health benefits in 2001 were estimated to be up to $149 billion.[5] The health benefits outweigh the economic cost by approximately $145 billion, a drastic savings. As another example, the Control of Emissions from New Marine Compression-Ignition Engines at or Above 30 Liters per Cylinder Rule[6] costs $4 billion annually; however, the OMB calculates the annual net health benefits by 2030 to reach $266 billion,[7] up to 87 times the costs of the rule. These examples demonstrate the importance of EPA rules, developed with current peer-reviewed benefit-cost analysis protocols, to the health of every day families.

The *Guidelines* were originally published in 2010 and updated in 2014 and 2016 to incorporate new science for evaluating benefits and costs. Following the most recent update in 2016, EPA "has adopted (a loose-leaf format) to facilitate the incorporation of new information in the future. This new, more flexible format, in addition to the electronic release of the document, will allow future updates and additions without requiring a wholesale revision of the document."[8] The *Guidelines* were specifically designed and written to inform policy-making processes and meet the mandates set forth by OMB for regulatory review. Adherence to the EPA's own guidebook for benefit-cost analyses for rulemaking would implicitly create consistency without the development of a new rule.

If EPA seeks to update current benefit-cost analyses based on recent, best available science, these changes could be incorporated through a peer-review process into a revised version of the *Guidelines*. One area of improvement for future guidelines is to advance methods to incorporate noncancer health effects and health effects that have less certain evidence. Many health effects that could be quantified and monetized are not included because of outdated risk assessment practices. In particular, the current approach of threshold doses for noncancer health endpoints, which is not scientifically supported, does not allow for the incorporation of noncancer health endpoints in risk reduction estimates and subsequent related health

[3] US EPA (December 2010) Guidelines for Preparing Economic Analyses. Chapter 2: Statutory and Executive Order Requirements for Conducting Economic Analyses. Pg. 2-1 – 2-5.

[4] 70 Fed. Reg. 25161 (May 12, 2005)

[5] OMB (2016) *2016 Draft Report.* p 81, Table B-1. https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/legislative_reports/draft_2016_cost_benefit_report_12_14_2016_2.pdf.

[6] 75 Fed. Reg. 22895 (April 30, 2010)

[7] US EPA (2009) Regulatory Impact Analysis: Control of Emissions of Air Pollution from Category 3 Marine Diesel Engines. Docket No: EPA-HQ-OAR-2007-0121. pg. ES-7.

[8] US EPA (December 2010) Guidelines for Preparing Economic Analyses. Pg. 1-1.

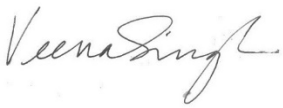
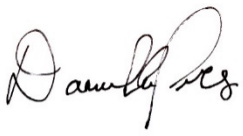
benefits in a benefit-cost analysis.[9] The U.S. National Academy of Sciences (NAS) recommends not assuming a threshold for a population dose-response assessment unless there is sound science indicating a population threshold for a given contaminant.[10] Probabilistic and regression models can approximate a dose-response function when adequate data is available.[11] Quantification of otherwise omitted noncancer health effects would allow for monetization of beneficial health risk reductions, making benefit-cost analyses consistent with current science and improving accuracy.

In addition, effects with less-certain evidence are often excluded from EPA benefit-cost analyses due to ambiguity of the strength of evidence in the risk assessment.[12] This practice can lead to exclusion of "suggestive" evidence, a common descriptor in noncancer health effects and key determination in risk estimates, in primary quantitative benefits analysis. Adoption of new models or methodology to translate complex uncertainty terms to a value-based estimated probability of causality would better characterize risk in benefit-cost analyses.

In summary, we do not think that EPA should propose a new rule for benefit-cost analyses. Instead, when the best available science and scientific consensus support adjusting EPA's practices on cost-benefit analysis, as it does with not assuming thresholds, the appropriate response is to consider revising existing guidelines using a peer-review process. Current EPA guidelines and the practices based on them already meet statutory and regulatory requirements; a careful process of updating guidelines when needed through a consensus-driven, peer-review process based on the best available science can improve accuracy while maintaining the transparency already established.

Thank you for the opportunity to provide comments. Please let us know if we can provide any additional information or be of further help.

Respectfully,

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[9] McGartland, A., Revesz, R., Axelrad, DA., Dockins, C., Sutton, P., and Woodruff, TJ. (2017) Estimating the health benefits of environmental regulations. *Science*, *357*(6350), 457-458.

[10] National Research Council (2009) *Science and Decisions: Advancing Risk Assessment*. Washington, DC: The National Academies Press. https://doi.org/10.17226/12209.

[11] Chiu, W., Axelrad, D., Dalaijamts, C., Dockins, C., Shao, K., Shapiro, A., & Paoli, G. (2018) Beyond the RfD: Broad Application of a Probabilistic Approach to Improve Chemical Dose–Response Assessments for Noncancer Effects. *Environmental Health Perspectives*, *126*(06).

[12] McGartland, A., Revesz, R., Axelrad, DA., Dockins, C., Sutton, P., and Woodruff, TJ. (2017) Estimating the health benefits of environmental regulations. *Science*, *357*(6350), 457-458.