Comments on the U.S. EPA's Proposed Rule, "Strengthening Transparency in Regulatory Science" 83 Fed. Reg. 18,768 (Apr. 30, 2018)

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The following comments are submitted on behalf of individual members of the Utah Air Quality Board including: a representative from the public who is trained and experienced in public health, an engineering professor not associated with industry and who is an expert in air quality matters, a representative from the public who represents an environmental non-profit organization, and a government representative that does not represent the federal government. The Utah Air Quality Board is the primary air quality policy maker for the State of Utah and is responsible for enacting rules pertaining to air quality activities including the development of state implementation plans to attain and maintain National Ambient Air Quality Standards. Board members are appointed by the governor and confirmed by the senate. By statute, board members must be knowledgeable of air pollution matters and represent a variety of interests, industries, and professions. These comments are submitted by individual board members and not on behalf of the board itself nor on behalf of other board members not identified at the end of the comments.

Based on our experiences, and in light of the impacts of the proposed rule on the individuals and organizations we represent, we concur with the expert opinions of numerous medical societies, scientific organizations, and state air quality agencies in opposing the proposed "Strengthening Transparency in Regulatory Science" and recommend that EPA withdraw the proposed rule.

Regulatory decisions made by the EPA should be based on the best available science. For air quality regulations this includes scientific studies that seek to identify pollutants that are responsible for adverse health effects, the health impacts short-term and long-term exposure to air pollution, and the identification of subpopulations with increased susceptibility to ambient air pollution. In answering these and other critical questions, the results of any individual study

is relatively unimportant compared to the composite body of evidence synthesized across multiple independent studies.

We find the existing procedures and safeguards commonly used to conduct, disseminate, and synthesize scientific research more than adequate in ensuring the validity and integrity of the science used to inform EPA decision-making. The proposed rule does not identify any deficiencies in the long established approach of using scientific studies to inform agency decisions nor does it provide any rationale for how the proposed rule, if promulgated, would remedy these deficiencies.

While the background of the proposed rule does mention a general concern regarding the reproducibility of scientific studies, it fails to acknowledge the extensive efforts that have already been enacted by funding agencies, scientific journals, and scientific societies to ensure the transparency and reproducibility of biomedical research. The proposed rule also fails to provide any evidence of a replication crisis among the types of studies that have traditionally been used as the basis for air quality regulations. Given the procedures already in place to ensure scientific integrity it would be redundant and inefficient for the EPA in enact the proposed rule or to act as a clearinghouse for data that are already generally available.

We oppose asking scientific researchers to make publically available administrative claims datasets (e.g., hospital admission and emergency department records, Medicare records, etc.) or other population datasets (e.g., National Health and Nutritional Examination Survey, NIH-AARP Diet and Health Study, etc.) which would not only violate data use and institutional review board agreements but is wholly unnecessary given that these records are already openly available to any individual or group that adheres to data privacy requirements.

We also oppose any effort by EPA, under the guise of transparency, to disregard the findings of scientific studies assessing the health impacts of air pollution when making regulatory decisions. We find it disingenuous that the proposed rule suggests that health datasets can be sufficiently de-identified in the public domain in a way that would simultaneously allow for reanalysis while also preventing the illegal disclosure of protected information.[i] Since there is no way to provide de-identified data in the public domain that would allow for secondary reanalysis of both the exposure assessment and health analysis in studies assessing the

health impacts of air pollution, the EPA should instead continue to focus on assessing results across multiple studies to evaluate the veracity and general applicability of scientific findings.

In cases where a scientific study is the first of its kind, and as such has not yet been replicated using independent study populations, we suggest that the EPA follow the example of past EPA administrators in waiting for additional studies to be completed (except in the case of exceptional circumstances) before taking regulatory action based on its study findings.[ii] While this situation may appear to provide the best argument for reanalysis of individual studies it provides little value in informing policy decisions and is not a replacement for replication of study findings in multiple distinct health studies.

We specifically oppose any proposed or future action that would disregard the well established effects of particle air pollution on mortality risk in the United States, either as part of future regulatory decisions or in cost benefit analyses included in mandated regulatory impact assessments. These adverse risks have been confirmed and verified both through extensive reanalysis of individual studies[iii] and more importantly through additional studies that have been completed using numerous independent study populations in the US, Canada, and many other parts of the world.[iv] Regardless of whether these effects are reported by the EPA as ranges or as combined estimates of mortality risk, the continued inclusion of mortality impacts in regulatory analysis is critical for federal regulatory decisions that impact air quality in Utah. If the proposed transparency rule is promulgated, we ask that the associations of particle pollution and mortality risk are specifically and preemptively excluded from the judgment of the EPA Administrator in adhering to data availability requirements.

We strongly oppose the proposal to grant the EPA administrator with authority to consider "on a case-by-case basis" which studies will be used to inform significant regulatory decisions. Picking and choosing which studies to use as the basis of agency actions is antithetical to both sound scientific analysis and evidence-based rulemaking.

In summary we agree with the findings of the U.S. Court of Appeals for the D.C. Circuit in *American Trucking Associations v Environmental Protection Agency* that the Clean Air Act imposes no obligation to obtain and make public the data underlying certain "key studies" and similarly reject arguments that a general requirement be imposed for EPA to obtain and

publicize the data underlying published studies on which the agency relies. We also agree with the court's finding that "requiring agencies to obtain and publicize the data underlying all studies on which they rely 'would be impractical and unnecessary.'"[v]

Signed,

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Footnotes:

[i] Assessing the health impacts of air pollution at the individual level requires information about the location of patients, the time when health events occur, and personal information that is used to account for potential confounding effects (smoking status, income, insurance status, education level, etc.). At best, publically available de-identified patient datasets would need to have the assessment of air pollution exposures already assigned (which requires precise location information and is matched to the time of health events) which would effectively preclude the type of secondary verification sought for in the proposed rule.

[ii] Former Administrator Johnson provides an effective example in how he considered the results of the California Children's Health Study, which at the time was the first of its kind, as part of the 2006 review of the PM NAAQS.

[iii] See Health Effects Institute Special Report: Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality, July 2000. Available at: https://www.healtheffects.org/system/files/Reanalysis-ExecSumm.pdf.

[iv] Additional studies are too numerous too exhaustively list here but the recent paper by Di et. al., (2018) "Air Pollution and Mortality in the Medicare Population" lists at least 11 studies that have found positive associations between long-term pollution exposure and mortality, all of which have been published since the 2009 EPA ISA that determined long-term exposure to PM2.5 to be causal for premature mortality risk. See N Engl J Med. 2017 Jun 29; 376(26): 2513–2522.

[v] See *American Trucking Associations v EPA,* 283 F.3d 355, 372 (D.C. Circuit 2002). Subsequent legal challenges that EPA should be required to obtain and make public the underlying data from studies used as the basis of regulatory action have similarly been rejected even if it is requested for a single study as opposed to all studies on which the agencies relies. See 2010 U.S. Court of Appeals for the D.C. Circuit ruling in *Coalition of Battery Recyclers Association v Environmental Protection Agency*,604 F .3d 613, 623 (D.C. Circuit 2010).