NATIONAL
ASSOCIATION
of SCHOLARS

March 16, 2020

The Honorable Andrew Wheeler
Administrator
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

[Re: proposed rulemaking – Strengthening Transparency in Regulatory Science - Supplemental notice of proposed rulemaking - Docket ID No. EPA-HQ-OA-2018-0259; FRL-10004-72-ORD]

Dear Administrator Wheeler,

I have already written to express my support the Environmental Protection Agency's (EPA) proposed rulemaking "Strengthening Transparency in Regulatory Science."[1] Both the current state of science about dose-response and larger concerns about reproducibility in scientific research support this measure. I write now to comment further on the "Supplemental notice of proposed rulemaking" EPA has published to modify "Strengthening Transparency in Regulatory Science."

I write as President of the National Association of Scholars (NAS). NAS is a network of scholars and citizens united by our commitment to academic freedom, disinterested scholarship, and excellence in higher education. As part of our mission, we support the highest standards of truth-seeking in the sciences, and seek to have government policy support and rely upon science that eschews political advocacy and subjects its own procedures to the strictest scrutiny.

In response to the EPA's solicitation for comment on the "Supplemental notice of proposed rulemaking" EPA has proposed as a modification to "Strengthening Transparency in Regulatory Science," we respectfully provide the following comments and suggestions.

1) **EPA will modify the regulatory text initially proposed in the 2018 proposed rulemaking at 40 CFR 30.3, 30.5, 30.6 and 30.9 so that these provisions would apply to <u>all</u> data and models. Transparency should not be limited to dose-response data and dose-response models, because other types of data and models will also drive the**

[1] Peter Wood, "UPDATED: NAS Public Comment on Strengthening Transparency in Regulatory Science," June 19, 2018, https://www.nas.org/blogs/article/updated_nas_public_comment_on_strengthening_transparency_in_regulatory_scie.

requirements and/or quantitative analysis of EPA final significant regulatory decisions and influential scientific information.

NAS endorses this widening of the rulemaking's scope. Dose-response science deserves particular scrutiny,[2] but all aspects of EPA policymaking should use transparent science.

This widened scope, however, will require detailed follow-up rulemaking, to apply the rule appropriately to every subcategory of data and models used by EPA. NAS suggests that this rulemaking include provision for committees deputed to provide detailed guidance for how it should be implemented in every relevant subcategory.

NAS also notes that this widened scope may have limited practical effect, given EPA's proposed modification below to give claims of privacy and/or confidentiality priority over transparency requirements. NAS will suggest below modifications to how EPA treats claims of privacy and/or confidentiality, so as (among other goals) to maximize the efficacy of EPA's widening of the scope of its transparency requirements.

2) **EPA will clarify the definition and use of terms including *capable of being substantially reproduced*, *data*, *independent validation*, *influential scientific information*, *model*, *models*, *model assumptions*, *pivotal regulatory science*, *pivotal science, publicly available*, and *reanalyze*.**

NAS endorses these clarifications of definitions and use of terms.

NAS also notes that EPA would be well-served by a systematic reform to provide clear definitions of all terms relevant to policymaking. NAS suggests that EPA, following government best practices in the Department of Defense,[3] institute a *formal ontology* to establish terminological exactitude in all policymaking.[4]

3) **EPA will, other things equal, give greater consideration to studies where the underlying data and models are publicly available for independent validation. The**

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[2] Peter Wood, "Concerns about the National Academy of Sciences and Scientific Dissent," December 15, 2015, https://www.nas.org/articles/nas_letter; Edward J. Calabrese, "Societal Threats from Ideologically Driven Science," December 13, 2017, https://www.nas.org/articles/societal_threats_from_ideologically_driven_science.

[3] DM2, DoDAF Formal Ontology, DoD Architecture Framework Version 2.02, DoD Deputy Chief Information Officer, Department of Defense, https://dodcio.defense.gov/Library/DoD-Architecture-Framework/dodaf20_ontology1/.

[4] Ontology for Government, National Center for Ontological Research, University at Buffalo, https://ubwp.buffalo.edu/ncor/quick-start/ontology-for-government/.

Agency will also give greater consideration to studies based on data and models that include confidential business information, proprietary information or personally identifiable information if these data and models were available through restricted access in a manner sufficient for independent validation. Where there is no access to data and models, or access is limited, the Agency may still consider these studies, depending on the other attributes of the studies. EPA will allow use for pivotal regulatory science and/or pivotal science of studies with restricted data and models (i.e., those that include confidential business information (CBI), proprietary data, or Personally Identifiable Information (PII) that cannot be sufficiently de-identified to protect the data subjects) if there is tiered access to these data and models for independent validation. The Agency will identify those studies that are given greater consideration and provide a short description of why greater consideration was given. Where the Agency is making data or models publicly available, it shall do so in a manner that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security. Information is considered ''available in a manner sufficient for independent validation'' when it includes the information necessary to understand, assess, and reanalyze findings.

EPA's proposed modification gives claims of privacy and/or confidentiality priority over transparency requirements. This modification practically will impose substantial limits on the effect of *Strengthening Transparency in Regulatory Science*, since *privacy*, *confidentiality*, and *tiered access* are all concepts and practices that inhibit full transparency. NAS endorsed the previous, unmodified transparency requirements, and we still believe that transparency should take priority over *privacy* and *confidentiality* in EPA policymaking. However, if EPA wishes to proceed with these modified rules, we make the following recommendations for how to implement them.

A) EPA should provide a time limit for its willingness to accept *privacy*, *confidentiality*, and *tiered access*. Scientific research can meet full transparency standards in time, even if it cannot meet it immediately. A time limit will provide EPA researchers and independent scientists an incentive to change their practices. We suggest a time limit of no more than 20 years—say, 31 December 2040. This time limit might be subdivided, so that fields that require substantial longitudinal studies have longer time limits than fields that do not.

B) EPA should define precisely how much *greater consideration* it will give to studies where the underlying data and models are available for independent validation. EPA should also distinguish between publicly available research and research available only via tiered access, and give *greater consideration* to studies whose underlying data and models are publicly available than to studies whose underlying data and models are only available via tiered access. EPA

should also define precisely *greater consideration*, if necessary by definitions for all relevant policymaking subcategories.

C) EPA should catalog all scientific research informing policymaking that fails to meet full transparency requirements. EPA should detail, for each rulemaking that uses *pivotal regulatory science* and/or *pivotal science*, which research fails to meet full transparency requirements, why, and what is needed (altered legal agreements, new research) for that rulemaking to be fully supported by transparent science. EPA should also estimate the time and cost needed to make sure that each such rulemaking is fully supported by transparent science.

D) EPA should define *tiered access* precisely, so as to maximize transparency. EPA should scrutinize its regulatory models (Research Data Center, National Center for Health Statistics, Centers for Disease Control) carefully, and make sure that its own definition of *tiered access* defines all terms with absolute clarity, provides equally clear procedures designed to maximize transparency and facilitate reproduction studies, and requires EPA administrators to provide clear and explicit reasons why a proposed replication study should not be permitted.

E) EPA should dedicate funding to improving all *pivotal regulatory science* and/or *pivotal science*, so that it meets full transparency requirements. EPA should use the catalog, budget, and schedule recommended in B) above to create a priority-order list of all research that must be funded to meet full transparency requirements. EPA should permanently dedicate a portion of its budget to sponsoring research that will substitute fully transparent research for research that fails to meet transparency standards.

NAS believes that these reforms will strengthen the Environmental Protection Agency's longstanding commitment to using only the most reliable science to inform its decision-making. We also believe these reforms will strengthen American science, by prompting researchers to incorporate and make routine in their practices the highest standards of reproducibility.

Sincerely yours,

Peter Wood
President
National Association of Scholars