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OF THE  
UNITED STATES OF AMERICA

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May 18, 2020

**VIA ELECTRONIC FILING**

**RE: Environmental Protection Agency supplemental notice of proposed rulemaking on Strengthening Transparency in Regulatory Science [Docket ID No. EPA-HQ-OA-2018-0259]**

Cheryl A. Hawkins  
Office of Science Advisor  
Environmental Protection Agency  
1200 Pennsylvania Ave NW

Dear Ms. Hawkins:

The U.S. Chamber of Commerce appreciates the opportunity to submit these comments to the U.S. Environmental Protection Agency (EPA) regarding its supplemental notice of proposed rulemaking (SNPRM) on Strengthening Transparency in Regulatory Science.

As detailed in comments on the original proposed rulemaking in 2018, the Chamber strongly supports EPA's effort to build greater transparency into the regulatory decision-making process. The underlying intent of these reforms is grounded in the broadly agreed upon principle that citizens should have a right to the data and information that are used in the development of public policy.

This spirit of openness with respect to the regulatory process is found throughout government. It is enshrined in statute (known as "the Shelby Amendment") and countless federal directives and EPA memos reinforce the principle and detail guidance for implementing it. It is also supported by experts of all political stripes. In 2012 congressional testimony, White House science advisor Dr. John Holdren unequivocally endorsed this idea, stating that "absolutely, the data on which regulatory decisions and other decision are based should be made available to the Committee and should be made public."

Moreover, as the agency's Science Advisory Board recently stated, "strengthening transparency by improving access to data can lead to an increase in the quantity and the quality of evidence that informs important regulatory science and policy decisions. The scientific community is moving toward adopting the precept of sharing accurate data and information to increase

credibility, high-quality outcomes and public confidence in science. The SAB supports the adoption of this precept.”<sup>1</sup>

Unfortunately, while these basic principles are almost universally supported, EPA has not followed them consistently in practice. The proposed rule aims to institute a process to address those shortcomings, and we support its advancement. As the agency continues to refine and improve upon this effort through the SNPRM, we call particular attention to the following key issue areas:

Expanded scope. The SNPRM proposes that the scope of the rulemaking be expanded to apply to influential scientific information as well as regulatory decisions, and clarifies that it also applies to all data and models underlying both “pivotal science” and “pivotal regulatory science.” We support this expanded scope and application of transparency efforts given the importance of such information to regulatory decision-making as well as independent scientific validation.

Alternative approach. The Chamber supports the alternative approach contemplated in the SNPRM to use *all* high-quality studies in its decision-making, but give greater consideration and/or assign greater weight to research and studies that have made data available in a manner sufficient for independent validation. Indeed, this approach mirrors what we called for in our original comments (“the agency may want to consider flexible and non-binary approaches to transparency requirements...[including] assigning greater decision-making weight to publicly available data while still allowing for the consideration of non-available data.”)<sup>2</sup> This flexibility is particularly important in instances where EPA does not own the relevant data and models relied upon in regulatory decisions or otherwise lacks ability to access them.

Relatedly, we welcome EPA’s suggestion to employ a “tiered access” model in situations where complete data transparency is not feasible due to concerns over the release of confidential business information, proprietary data, or personally identifiable information. While the supplemental proposal presents these tiered access and weighted consideration approaches as separate options, we believe they can both be used in combination.

Federal Housekeeping Authority. The proposal seeks comment on whether it is appropriate to rely on EPA’s authority found in a variety of environmental statutes to promulgate this rulemaking, or to also cite the Federal Housekeeping Statute independently or in conjunction with these statutes. We recommend that EPA rely on the housekeeping statute in conjunction with overarching environmental authorities. The proposal is clearly intended to institute internal agency practices for the use of data and models, and is thus appropriate for and consistent with the housekeeping statute’s authorization of agencies to “prescribe regulations for the government of his department, the distribution and performance of its business, and the...use...of its records, papers, and property.”<sup>3</sup> This is particularly fitting if the agency chooses the modified approach

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<sup>1</sup> EPA Science Advisory Board comments on NPRM, April 24, 2020. Available at [https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthBOARD/2DB3986BB8390B308525855800630FCB/\\$File/EPA-SAB-20-005.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthBOARD/2DB3986BB8390B308525855800630FCB/$File/EPA-SAB-20-005.pdf)

<sup>2</sup> Public hearing testimony, July 17, 2018. Available at <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-5185>

<sup>3</sup> 5 U.S.C. 301

that does not exclude use of non-public data and models but rather allows use of all information while providing greater consideration to publicly available materials.

Improved transparency of existing data. The Chamber's comments on the original 2018 NPRM called on EPA to undertake efforts to protect and de-identify sensitive information to allow for its continued use in regulatory decision-making. While the SNPRM's alternative approach that allows consideration of all data and models reduces the need for such efforts, de-identification and other measures that allow for greater transparency and release of data and models pivotal to regulatory development would continue to advance the objectives of this rulemaking, and thus remain worthy of pursuit. Moreover, under the modified approach, making this data publicly available would allow it to receive greater consideration in the regulatory process, thus providing a longer-term incentive to external researchers to increase data sharing and transparency. Relatedly, we support the SAB's recommendation encouraging EPA to provide funds for reanalysis of datasets that are critically important for regulation. Efforts such as these will continue to increase public confidence in the regulatory process and, ultimately, in EPA itself.

Exemption authority. The Chamber's 2018 comments on the original NPRM called on EPA to develop further guidance and processes for employing the administrator's exemption authority under the proposal. The SNPRM clarifies that the exemption may be given "if compliance is impracticable because technological barriers render sharing of the data or models infeasible." While the alternative approach contemplated in the SNPRM allowing consideration of all relevant data and models would presumably reduce the need for such exemptions, in the absence of this approach, additional specificity clarifying how and when the Administrator might apply such authority should be provided to ensure clear and consistent use of this authority while also improving public understanding of these internal processes.

Communication of uncertainties and sensitivity analysis. Finally, the proposed rule requires EPA to document uncertainties associated with assumptions and methods related to data and models underlying pivotal regulatory science. We strongly support this requirement. As the SAB notes in its comments, "Epidemiologists, statisticians, and risk analysts have written at length over several decades about how to test, validate, and document assumptions and methods for dose-response modeling and uncertainty and variability characterization, and these modern methods should be applied to make the factual and assumption-based foundations of pivotal studies as clear as possible."

In short, high quality scientific studies identify assumptions, their variability, and any other confounders that add to uncertainties in datasets. High quality regulations should do the same. Unfortunately, in the past, EPA has not always adequately communicated uncertainties and sensitivity analyses in which modest changes to input values or assumptions lead to large changes in outputs and their corresponding projected policy impacts. We therefore reiterate our recommendation that EPA provide guidance on how to report these parameters in official regulatory analyses, as well as incorporate them into public communications and marketing materials associated with such regulations. Such guidance would not only support the goals of this rulemaking, it would also advance implementation of the Office of Management and Budget's Information Quality Act Guidelines, which aim to increase the credibility of federal decisions by requiring that influential analyses "be disseminated with sufficient descriptions of

data and methods to allow them to be reproduced by qualified third parties who may want to test the sensitivity of agency analyses.”<sup>4</sup>

Conclusion. This SNPRM furthers EPA’s objective in the proposed rule to establish an internal framework through which it can systematically assess and determine how best to use data and models in agency decision-making. In 1983, then-EPA Administrator William Ruckelshaus famously declared that, in order to secure and maintain the public’s trust, the agency should operate as if it were “in a fishbowl.” This effort is a critical step toward implementing Ruckelshaus’ vision. We commend EPA for undertaking this difficult challenge, and we support continued refinement and advancement of the proposal.

Thank you for the opportunity to comment on this important matter.

Sincerely,

A handwritten signature in blue ink, appearing to read "Neil Bradley". The signature is fluid and cursive, with a large loop at the end of the last name.

Neil Bradley

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<sup>4</sup> Memorandum to Executive Departments and Agencies on Improving Implementation of the Information Quality Act, April 24, 2019. Available at <https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-15.pdf>