Congress of the United States
Washington, DC 20515

November 13, 2019

Dr. Marcia McNutt
President
National Academy of Sciences
500 5th Street NW
Washington, DC 20001

Dear Dr. McNutt,

As Members of the House Committee on Science, Space, and Technology, we write to respectfully request that the National Academy of Sciences review the Environmental Protection Agency's proposed rule titled Strengthening Transparency in Regulatory Science (Docket No. EPA-HQ-OA-2018-0259). We are deeply concerned that the proposed rule would impede, if not eradicate, the Environmental Protection Agency's (EPA) ability to protect Americans from significant risks to human health and the environment by limiting the scope of research that the EPA could consider in making decisions.

As a cornerstone of its regulatory process, the EPA relies on peer-reviewed science. Much of the science that is used to inform regulatory actions is developed outside of the EPA. Scientific studies often include personal information and other data that is confidential if, for example, it includes the personal health information of individuals who participated in a study. The EPA publicly discloses studies that support regulatory action; none of the information used by the EPA is secret.

Transparency is a laudable goal, and it can be accomplished through collaboration with and input from the scientific community. As you know, the National Academies have issued numerous reports to advise the EPA on opportunities to improve transparency on the collection and analysis of data. Most recently, these reports include: *Reproducibility and Replicability in Science, Open Science by Design,* and *Fostering Integrity in Research.* Unfortunately, instead of responding to the recommendations from the National Academies, the EPA has instead proposed a rule that will limit the research that EPA can rely upon in regulatory decision-making.

It is of the utmost importance that the EPA be able to comprehensively consider the best available scientific evidence when determining what actions may be necessary to address risks and protect public health. The proposed rule includes provisions that would deviate from the standard approaches to dose-response modeling—a fundamental part of understanding potential effects from chemical exposures, particularly for vulnerable populations. In 2009, the National Research Council recommended that the EPA "should develop formal guidance for dose-response analysis under the unified framework."[1] Yet, in the proposed rule, the EPA dismissed

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

non-threshold dose-response relationships without providing any evidence to justify the assertion outlined at length in *Science and Decisions*.

Furthermore, it is deeply troubling that the proposed rule is inconsistent with the EPA's statutory obligation to use the best available science as required in the Toxic Substances Control Act, Safe Drinking Water Act, and Clean Water Act. The proposed rule would preclude the use of a range of scientific research that has long been used to safeguard the public.

Additionally, there is tremendous uncertainty about whether the proposed rule would apply retroactively to existing standards and regulations. Retroactive application would severely undermine existing public health and environmental protections that keep the public safe and healthy.

As you noted in a July 16, 2018 letter to Administrator Wheeler, the effects of the proposed rule will "depend on many aspects of the rule's implementation that are not described in detail in the Federal Register notice."[2] We learned from Administrator Wheeler's testimony before the House Committee on Science, Space, and Technology on September 19, 2019, that the EPA plans to issue a supplemental proposed rule in 2020.[3]

The proposed rule and its implications on the EPA's statutory obligations warrant further consideration and scrutiny by an authoritative, independent, non-partisan scientific organization. The National Academy of Sciences (NAS) embodies this mission and work. We agree with your statement that "The proposed rule's scope, complexities, and potential serious implications for regulatory science and action clearly warrant additional, thorough, independent, objective, and context-specific evaluation and analysis."[4] To make sure that the EPA is not precluded from using the best science in its regulatory processes, we request that the NAS review the issues central to the proposed rule: scientific integrity, appropriate measures to vet scientific research, and approaches to dose-response modeling.

Specifically, we ask that the NAS review the following:

- What approaches does the EPA currently use to collect, vet, and evaluate scientific research used in regulatory decision-making? What recommendations does the NAS have for the EPA to improve transparency in the collection, evaluation, and analysis of data?
- What are the effects of making underlying data used by the EPA in decision-making publicly accessible? How does confidentiality of data collected and analyzed by federal statistical agencies compare to studies that are within the scope of the proposed rule? What safeguards currently exist to protect Personally Identifiable Information and Confidential Business Information in the EPA's scientific research and how would the proposed rule affect those safeguards?

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[2] McNutt, Marcia, et al. to Andrew Wheeler, July 16, 2018. http://www.nationalacademies.org/includes/EPA Proposed Rule Docket EPA-HQ-OA-2018-0259 NASEM Comment.pdf?_ga=2.154132664.1228221923.1572880613-835747178.1572880613.

[3] Science and Technology at the Environmental Protection Agency. 116th Congress. 3. (2019) (Testimony of Andrew R. Wheeler).https://science.house.gov/imo/media/doc/9.19.19%20Wheeler%20Testimony.pdf

[4] McNutt, Marcia, et al. to Andrew Wheeler, July 16, 2018. http://www.nationalacademies.org/includes/EPA Proposed Rule Docket EPA-HQ-OA-2018-0259 NASEM Comment.pdf?_ga=2.154132664.1228221923.1572880613-835747178.1572880613.

- How would the criteria and processes in the proposed rule affect the EPA's ability and current statutory obligations to use all available scientific evidence in regulatory decisions? If finalized in its current form, how would retroactive application of the proposed rule affect the scientific foundation of the EPA's regulatory decision making?
- How does the proposed rule respond to impediments to reproducibility as outlined in the Academies' *Reproducibility and Replicability in Science* report?
- How would the proposed rule affect the EPA's use of epidemiological studies? What are best practices in dose-response modeling? To what extent should dose-response include the use of default models and explicit consideration of variability?

The EPA's ability to meet its mandate to protect public health and the environment depends on the foundation of science that is independently verifiable; free from political interference, bias, or ideology; and without any conflicts of interest. According to reports, the EPA's Office of Science Advisor was excluded in the development of the proposed rule and the Science Advisory Board has been limited in the scope of its review.[5] It is our hope that the NAS can work with the EPA to comprehensively review the proposed rule.

It is our intent to make sure that the EPA is using robust science – especially at a time when the world is facing the consequences of the climate crisis and toxic substances continue to jeopardize access to clean air and water.

Thank you for your consideration of this request.

Sincerely,

Suzanne Bonamici
Member of Congress

Mikie Sherrill
Member of Congress

CC: EPA Administrator Andrew Wheeler

[5] Steven Mufson and Chris Mooney, "EPA excluded its own top science officials when it rewrote rules on using scientific studies," *Washington Post*, October 3, 2018. https://www.washingtonpost.com/energy-environment/2018/10/03/epa-excluded-its-own-top-science-officials-when-it-rewrote-rules-using-scientific-studies/?utm_term=.407824f59d93