ENDOCRINE SOCIETY
Hormone Science to Health

The Honorable Andrew Wheeler
Administrator
United States Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, DC 20460

April 6, 2020
Re: EPA-HQ-OA-2018-0259

Dear Administrator Wheeler,

The Endocrine Society appreciates the opportunity to comment on the supplemental notice of proposed rulemaking for "Strengthening Transparency in Regulatory Science." Founded in 1916, the Endocrine Society is the world's oldest, largest, and most active organization dedicated to the understanding of hormone systems and the clinical care of patients with endocrine diseases and disorders. Our membership of nearly 18,000 includes researchers who are advancing our understanding of the effects of exposures to chemicals that interfere with hormone systems, also known as endocrine-disrupting chemicals (EDCs). We maintain that even with the supplement the rule remains deeply flawed and urge EPA to withdraw the rule entirely.

We have been following the development of the rule since the original 2018 notice of proposed rulemaking to ensure that changes proposed by EPA do not needlessly restrict the use of valuable scientific information for regulatory decisions that improve public and environmental health. We note that the supplement attempts to provide definitions that were requested in our earlier comments on this rule. However, we are disappointed that most of our original concerns with the draft rule are not addressed in the supplement; many issues are instead amplified by the proposed changes.

The supplement to the notice expands the scope of the original rule such that the provisions will apply not only to the dose-response data and models, but to all data and models "underlying pivotal regulatory science and pivotal science which support significant regulatory decisions and influential scientific information." Furthermore, the rule would also apply to historical data and analyses, which would potentially remove from consideration well-supported studies that were conducted under specific confidentiality agreements to protect participant privacy. This expansion of scope to encompass essentially all scientific information considered by the agency, in the context of nearly any potential rulemaking or revisions, is highly problematic given that many fundamental questions remain concerning how the agency will apply the rule to important sources of data. The rule and supplement still fail to explain:

- How publicly funded, peer-reviewed studies that comply with NIH data deposition and access policies will be considered. These studies not only use sophisticated technologies to inform us about the effects of chemicals on hormone systems and endocrine diseases, but also inform us about the basic science of hormones, development and health.
- Whether the agency will ensure that confidential business information will also be held to the same standards of transparency, disclosure, and access.
- How historical data, which may have been collected under different policies and procedures to ensure confidentiality, will be treated.

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Other practical details about the implementation of the rule remain unresolved, including many issues raised by the EPA's Science Advisory Board draft report on the scientific and technical basis for the rule. First, it is not clear precisely if/how EPA will pursue tiered access to data or make a final determination on whether the level of access is sufficient to be compliant with the rule. Second, it is unclear who will perform any "re-analyses" of peer reviewed data nor how these will be conducted, and the reason for this need is not well rationalized. Other changes described in the supplement further contribute to an overall lack of clarity. The proposal to create two pathways for data based on the level of accessibility fails to define which studies would be considered "high-quality" and is similarly vague about what "greater consideration" would entail. We maintain that publicly funded, peer-reviewed studies should not be disadvantaged during agency scientific reviews.

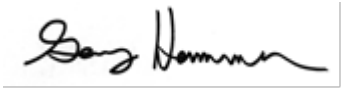
We also note with concern that the supplement provides the Administrator with significant leeway to provide exemptions to the rule without defining the criteria and considerations that the Administrator would use. This creates a *de facto* loophole that could further decrease transparency by permitting studies submitted by regulated entities to be prioritized above academic studies that must adhere to strict participant confidentiality agreements.

In conclusion, the supplement to "Strengthening Transparency in Regulatory Science" further increases our concern that the rule will be used to restrict highly regarded peer-reviewed scientific studies that provide evidence in support of regulatory action on harmful chemicals. We maintain that the Agency's stated reason for this rule is not justified by any available evidence. Specifically, the Agency states that, "EPA should ensure that the data underlying [its actions] are publicly available in a manner sufficient for independent validation." However, the Agency provides no evidence that EPA decisions have been misled by the use of data published in the peer-review literature. In short, the stated reason for this rule lacks scientific justification and credibility.

Given the concerns described above, and those shared by many other public health and scientific groups, we urge EPA to withdraw the proposed rule and instead adopt policies governing data sharing and access that are consistent with those of other research agencies such as the National Institutes of Health. Furthermore, journals published by scientific societies that have established guidelines and standards for the submission of datasets to repositories should be considered trusted sources for EPA scientific reviews.

Thank you for considering our comments, if we can be of further assistance, please contact Joseph Laakso, PhD, Director of Science Policy at jlaakso@endocrine.org.

Sincerely,



Gary Hammer MD, PhD
President
Endocrine Society