ENDOCRINE SOCIETY
Hormone Science to Health

January 16, 2020

United States Environmental Protection Agency
Science Advisory Board
1200 Pennsylvania Avenue
NW, Washington, DC 20460

Re: Draft SAB Report on "Strengthening Transparency in Regulatory Science"

Dear Members of the Board,

On behalf of the Endocrine Society, I appreciate the opportunity to provide written public comment to the United States Environmental Protection Agency (EPA) Science Advisory Board (SAB) regarding the draft report "Consideration of the Scientific and Technical Basis of EPA's Proposed Rule Titled *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 over 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 provide guidance and are engaged on multiple global efforts to minimize public harms from exposure to EDCs through science-based policies and effective testing and regulatory strategies.

As stated in our May 21, 2018 comments on the proposed rule, the Endocrine Society supports appropriate public access to data and methodology for independent validation. However, we are seriously concerned that the proposed regulation will restrict EPA's ability to develop and implement effective restrictions on hazardous chemicals. As such, this proposed rule would increase the potential for human and ecological harms due to chemical exposures. Furthermore, the proposed rule is difficult to operationalize and lacks important details that would shed light on how the rule might be implemented and to what effect.

The Endocrine Society commends the authors of the draft report for highlighting significant weaknesses in the proposed rule. We also share the authors' concern about the potential for politicization of the scientific evaluation process, and the potential for inappropriate exclusion of scientifically important studies. Following our review of the draft report we highlight two overarching issues that are well addressed in the report and deserve careful consideration by EPA as they weigh the potential implications of the rule.

The Proposed Rule Remains Unclear and Lacks Important Details

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The draft report correctly identifies many requirements and terms that are vaguely defined and subject to various interpretations. While we share many of the same questions, we are particularly concerned about the lack of clarity surrounding the use of the terms "dose response data and models." As we mentioned in our 2018 comment letter, endocrine systems commonly display non-monotonic dose responses, with effects at extremely low dose ranges; chemical interference with endocrine systems would be expected to share these features. The draft report accurately notes that EPA has not clarified how non-monotonic dose-response data or other "alternative" models might be considered "in scope" under the proposed rule and what information would be required to be compliant with the rule.

The authors also identify important technical questions related to the feasibility of making "data and models available in a manner sufficient for independent validation." We echo the importance of clearly articulating how non-GLP/investigational studies will be evaluated against the requirements of the proposed rule. Many Endocrine Society members investigating the effects of chemicals on hormone systems and endocrine disease conduct cutting-edge research in academic labs, often exploring more sensitive endpoints that are not typically captured in guideline or GLP-compliant studies. EPA must clearly define the expectations for these studies so that information from academic labs can be included in chemical assessments.

Existing Policies Provide for Independent Validation

We are encouraged that the draft report accurately notes that existing scientific validation systems, including replication studies and peer-review in scientific journals such as those published by the Endocrine Society, are already capable of providing strong independent validation of scientific conclusions without access to "raw" data. The National Institutes of Health has established effective policies governing the sharing of data among researchers and with appropriate access by the public at large. The National Academies have also covered issues related to transparency, along with other recommendations on how information should be collected, evaluated, and assimilated in risk assessments as contained in the National Academies' report Science and Decisions: Advancing Risk Assessment[1].

We therefore strongly support the authors' conclusion that "existing methodologies and technologies already in widespread use … can be used to provide protected access to data." We also support the authors' assertion that the "standards applied by the EPA should be the same as the standards applied by editors of reputable scientific journals." Many journals, including those published by the Endocrine Society, are establishing guidelines and standards for the submission of datasets to repositories that are consistent with NIH policies and the FAIR (findable, accessible, interoperable,

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

re-usable) principles for scientific data management and stewardship. We believe that research that abides by these policies and has been published in high-quality peer-reviewed journals should be considered independently validated and sufficiently available to the public.

Summary of Recommendations

In conclusion, the Endocrine Society remains extremely concerned that the proposed rule *Strengthening Transparency in Regulatory Science* lacks transparency, is unclear about data utilization and modeling of low-dose effects, and fundamentally lacks justification. We anticipate that the rule in its current construction will result in harmful effects on public health. We commend the authors of the draft SAB report for carefully evaluating the proposed rule and calling into question not only the potential impact of the rule but also recognizing that the EPA "has not fully identified the problem to be addressed" by the rule.

We encourage EPA to thoughtfully and carefully consider these and other important issues highlighted in the report. Thank you for considering the Endocrine Society's comments. If we can be of any further assistance, please contact Endocrine Society Director of Science Policy Joseph Laakso, PhD via e-mail (jlaakso@endocrine.org).

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President, Endocrine Society.