

**Testimony of the American Petroleum Institute on the Science Advisory
Board (SAB) Teleconference:**

**With Regard to the SAB draft report on Strengthening Transparency in
Regulatory Science Proposed Rule**

January 17, 2020

Thank you for the opportunity to provide public comment today. My name is Ted Steichen a Senior Policy Advisor at the American Petroleum Institute (API).

API is the only national trade association representing all facets of the oil and natural gas industry, which supports 10.8 million U.S. jobs and nearly 8 percent of the U.S. economy. Our more than 600 members - from large integrated oil and gas companies to small independent companies - comprise all segments of the industry. API member companies are producers, refiners, suppliers, retailers, pipeline operators and marine transporters as well as service and supply companies providing much of the nation's energy. Science used when developing policy and regulations impacts virtually all aspects of API member business.

These comments regard the draft SAB Consideration of the Scientific and Technical Basis of EPA's Proposed Rule titled Strengthening Transparency in Regulatory Science, hereafter "the report."

The SAB addressed EPA's approach to clearly identify and make available to the public all studies (or other regulatory science) relied upon in final agency actions; this discussion highlights that this proposed regulation can be implemented best on

studies going forward and not retroactively. Clear requirements for a study (or other regulatory science) established at the start of research development will provide for the possibility of the highest level of science transparency.

The report's second major comment deals with the Administrator's granting of exemptions when a study does not comply with the transparency standards. It appears the SAB is interpreting these proposed regulations to be about exempting certain studies from the requirement to make information available to the public. Section 30.9 of the Proposed Rule is not about exempting studies from the requirements, but instead about what can be done when an important study has been conducted in such a way as the supporting science is not in a state where it is feasible to ensure all underlying data can be made available for independent validation. The need for exemptions should diminish in time, as the regulations are finalized and implemented, future studies should be able to more fully meet transparency standards.

API supports the SAB suggestion that EPA further define "dose response data and models" and "pivotal regulatory science" and recommends that EPA include a specific request for comment on these definitions in the anticipated Re-Proposed Rule.

Clearly privacy and confidentiality are supported by all, and existing requirements must be met. API is concerned that this important issue, however, might be used to obstruct efforts to strengthen transparency. Progress can best be made when all

stakeholders look for solutions and do not use privacy and confidentiality as easy talking points to not fully participate in this rulemaking effort.

The SAB makes the point that data management is an important element of science transparency, with reference to “raw” data as well as personal data. Tapping the expertise across a wide range of disciplines can hopefully contribute to finding the best approach for all the potential data custodians.

The report includes a discussion of a potential model for reanalyzing datasets. The cited example was completed in 2000 and is characterized as a reanalysis of the Six Cities Study and the American Cancer Study. That effort yielded information of a potential confirmatory nature, but it cannot be characterized as a full reanalysis of the datasets associated with the original studies due to limitations in access to data.

API appreciates the efforts of the SAB in providing thoughtful input to EPA’s rulemaking efforts to strengthen science transparency.