UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

June 28, 2018

EPA-SAB-18-003

The Honorable E. Scott Pruitt
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Subject: Science Advisory Board (SAB) Consideration of EPA Proposed Rule: Strengthening Transparency in Regulatory Science

Dear Administrator Pruitt:

As part of its statutory duties, the Environmental Protection Agency's (EPA) Science Advisory Board (SAB) met on May 31, 2018, to discuss whether to review the adequacy of the scientific and technical basis of the planned regulatory actions in the 2017 Unified Regulatory Agendas, as authorized by section (c) of the Environmental Research, Development and Demonstration Authorization Act of 1978 (ERDDAA). During this meeting, the SAB also discussed possible review of the science supporting the proposed rule *Strengthening Transparency in Regulatory Science (RIN 2080-AA14)*. The SAB found that the proposed rule deals with issues of scientific practice and proposes constraints to the use of scientific studies in particular contexts. The proposed rule solicits comment on a number of scientific issues that would benefit from expert advice and comment from the SAB.

Initiating the Screening Review

The ERDDAA requires the EPA to make available to the SAB proposed criteria documents, standards, limitations, or regulations provided to any other Federal agency for formal review and comment, together with the relevant scientific and technical information upon which the proposed action is based. The SAB may then make available to the Administrator, within the time specified by the Administrator, its advice and comments on the adequacy of the scientific and technical basis of the proposed action.

EPA's usual process is to provide the SAB with information about the publication of the semi-annual regulatory agenda and to provide descriptions of major planned actions that are not yet proposed but appear in the semi-annual regulatory agenda, augmented to include proposed regulations, criteria documents, standards, or limitations that are expected to undergo interagency review[1]. The EPA's descriptions provide available information regarding the science that is informing these agency actions.

SAB members and the SAB Staff Office were made aware of a proposed rule entitled *Strengthening Transparency in Regulatory Science* (RIN 2080-AA14) through an April 25, 2018, press event and an April 30, 2018, *Federal Register* notice, as well as news articles. The EPA announced the proposed rulemaking with a 30-day public comment period. SAB members had no information regarding the timeline for finalizing the rule and the proposed rule was not identified as a major action in either of the Spring 2017 or Fall 2017 semi-annual Regulatory Agendas.

An SAB Work Group met by teleconference on May 3, 2018, to discuss its recommendations on major planned actions in the Fall 2017 semi-annual regulatory agenda and included the proposed rule *Strengthening Transparency in Regulatory Science (RIN 2080-AA14)* as part of the discussion. That Work Group provided the SAB with a memorandum[2] documenting the discussions and recommending that the proposed rule merits review by the SAB. Subsequently the SAB became aware that the proposed rule was included in the Spring 2018 semi-annual Regulatory Agenda published on May 9, 2018. A second *Federal Register* notice was published May 25, 2018 extending the public comment period to August 16, 2018 and announcing a public hearing to be held in Washington, DC on July 17, 2018.

The SAB Should Consider the Proposed Rule's Scientific and Technical Basis

During the meeting on the May 31, 2018, the full SAB agreed with the Work Group that the proposed rule merits review by the Board and discussed the scientific issues that should be considered. For example, there are important scientific considerations needed for transparency. The Board recognizes that the long-term trend in most scientific fields is for authors to supply public access to data and analytic methods after scientific findings are published. Such transparency may help to ensure scientific integrity and facilitate robust analysis, as well as allowing supplementary lines of knowledge to be developed from the same data. Some fields of science are moving faster than others in the direction of transparency. For studies published many years ago, it may not be feasible to deliver public access to data and analytic methods.

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[1] EPA Memorandum: Coordination with the Science Advisory Board Regarding Proposed Criteria Documents, Standards, Limitations and Regulations. (See page 9 of Attachment A in the Fall 2017 memorandum available at: https://yosemite.epa.gov/sab/sabproduct.nsf//9263940BB05B89A885258291006AC017/$File/WG_Memo_Fall17_RegRevAttsABC.pdf)

[2] Preparations for Chartered Science Advisory Board (SAB) Discussions of Proposed Rule: Strengthening Transparency in Regulatory Science RIN (2080-AA14) Available at: https://yosemite.epa.gov/sab/sabproduct.nsf//E21FFAE956B548258525828C00808BB7/$File/WkGrp_memo_2080-AA14_final_05132018.pdf

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There are also sensitive situations where public access may infringe on legitimate confidentiality and privacy interests, and where exceptions from complete public access may be appropriate. In addition, there are considerations associated with the cost and effort that would be required in making large and complex existing datasets available within Institutional Review Board requirements, including the issue of who would be responsible for implementing the rule and any additional obligations. Thus, the development of guidelines and rules in this arena requires careful collaboration with the scientific community.

Although the proposed rule cites several valuable publications that support enhanced transparency, the precise design of the proposed rule appears to have been developed without a public process for soliciting input specifically from the scientific community. Nor does the preamble to the rule describe precisely how the proposal builds on previous efforts to promote transparency such as the Information Quality Act and EPA's Information Quality Guidelines.

Other key science issues associated with the proposed rule to increase transparency that may benefit from SAB advice are:

- Considerations related to the use of epidemiologic studies and methods that are based on confidential human subject data while also providing transparency in the underlying data;
- Consideration of the multiple existing methods to assess the validity of prior epidemiologic studies, that do not provide public access to data and analytic methods;
- Consideration of the selection of dose-response models and factors such as biological plausibility, mode of action, or mechanism of action to identify the most scientifically-appropriate model(s);
- The need to clearly define crucial sound science concepts such as "replication" and "validation"; and
- The identification and evaluation of mechanisms used by expert panels in vetting science that do not engage in reanalysis of original data with original methods, yet entail a rigorous review process that goes beyond typical journal peer review procedures.

The SAB recognizes that the EPA has already received thousands of public comments in addition to the large number of comments from grassroots write-in campaigns. The SAB urges the Agency to fully consider those comments and request, receive, and review scientific advice from the SAB before revising the proposed rule.

The EPA has long been a leader in the use of science in decision-making. The proposed rule, *Strengthening Transparency in Regulatory Science*, would focus on the EPA's foundational policies related to the use of science in rulemaking and policy development. Further, the rule has the potential to influence policy development and guidance across the government. The SAB looks forward to defining the set of scientific and technical issues upon which the proposed rule rests and developing a charge for an SAB work group to provide advice and comments on those issues.

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On behalf of the SAB, I thank you for the opportunity to support EPA through consideration of the science supporting actions in the Agency's regulatory agenda.

Sincerely,

/s/

Dr. Michael Honeycutt, Chair
Science Advisory Board

Enclosure
(1) Roster of SAB Members

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NOTICE

This report has been written as part of the activities of the EPA Science Advisory Board (SAB), a public advisory group providing extramural scientific information and advice to the Administrator and other officials of the Environmental Protection Agency. The SAB is structured to provide balanced, expert assessment of scientific matters related to problems facing the Agency. This report has not been reviewed for approval by the Agency and, hence, the contents of this report do not necessarily represent the views and policies of the Environmental Protection Agency, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names of commercial products constitute a recommendation for use. Reports of the SAB are posted on the EPA Web site at http://www.epa.gov/sab

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Science Advisory Board

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[3] Dr. Ramos did not attend the May 31-June 1 meeting.

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