

Children's Health Protection Advisory Committee

February 7, 2020

VIA ELECTRONIC SUBMISSION

EPA Science Advisory Board
c/o Thomas Armitage Ph.D.
Designated Federal Officer
EPA Science Advisory Board Office
USEPA Science Advisory Board (1400R)
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

RE: Comments on the Science Advisory Board (SAB) Draft Report on EPA's Proposed Rule titled Strengthening Transparency in Regulatory Science from your liaison member from the EPA Children's Health Protection Advisory Committee (CHPAC).

Dear Members of the Science Advisory Board:

We continue to appreciate the opportunity to provide a CHPAC liaison member to the SAB. We developed the following brief comments for your consideration after reviewing your October 2019 draft report "SAB Consideration of the Scientific and Technical Basis of EPA's Proposed Rule Titled Strengthening Transparency in Regulatory Science" and after Dr. Scher participated in the January 21, 2020 teleconference to discuss the report. In keeping with our liaison role, we have focused our comments on the anticipated impacts of the proposed rule on children's environmental health research and on EPA's ability to protect children's health in regulatory decision-making.

We agree with many of the critiques and recommendations in the draft SAB report. We are primarily concerned that the proposed rule as written contains an unresolvable conflict between the transparency provisions and the legal and ethical obligations of the EPA and health researchers to protect privacy and medical data of research subjects. Furthermore, EPA should not exclude high quality research studies that can't fully meet the transparency provisions as written due to legitimate ethical or legal constraints. Instead, the rule should consider less extreme solutions identified in the draft SAB report.

We urge EPA to recognize and preserve the critical and essential role that children's environmental health research plays in understanding the unique risks to children and properly protecting children in Agency risk assessments. Children have unique windows of developmental susceptibility, physiology and behaviors that combine to create health risks that differ from adults sharing the same environment. Much of our current understanding of these risks would have been impossible to achieve without careful epidemiological studies that investigated exposure pathways unique to children, children's exposure to environmental agents, and associations between pre and postnatal exposures and adverse neurological, endocrine and behavioral development.

Children's environmental health research inherently involves vulnerable categories of subjects (children, pregnant women). Common Rule (45 CFR 46) and HIPPA requirements are intended to protect the privacy of patients and research participants including disclosure of medical and personal information. These requirements are particularly critical for children, who have not attained legal age for consent. Unfortunately, privacy and confidentiality issues cannot be addressed through anonymization or de-identification of study records alone, as study datasets frequently contain variables that may compromise participant privacy even without direct personal identifiers. For example, recruitment may be tied to births at hospitals during a set time period (identified in the

study methods section) which could be combined with demographic data (e.g., age of mother), as well as other data such as occupation or spatial variables (e.g., air pollution levels in the participants' zip code, contaminant levels in their water system, or proximity of the home to traffic corridors, agricultural fields or a contaminated site). Several studies cited in the SAB report have demonstrated the ability of third parties to identify study participants by cross-referencing environmental and demographic attributes. While EPA acknowledged the necessity of protecting personally identifiable information in the August 2019 SAB meeting, no mechanism was identified by the SAB that fully resolves the inherent conflict between the scope of transparency required by this proposed rule and the legal and ethical requirements to protect research participants' privacy.

It is unreasonable to adopt a rule that removes health research studies from consideration if the underlying data cannot be released because study authors are bound to comply with privacy, ethical, or legal requirements. Instead, the benefit of fully releasing study data for public inspection and reanalysis needs to be balanced against the critical public benefit provided by large, high quality human health research studies when setting key regulations to protect public health. Key regulations are often based on risks to the most highly exposed and/or vulnerable population, which is often the fetus or child. Therefore, "scientific studies that are pivotal to the (regulatory) action being taken" (proposed rule, 83 FR 18768) frequently includes environmental health research studies on children. As such, children's environmental health research studies could be disproportionately disqualified from consideration by the proposed rule. If this occurs, children may be insufficiently protected.

The SAB identified better ways for the Agency to improve transparency without violating privacy rights of study participants under federal and state law. These included use of data sharing agreements, use of trusted third parties (Federal Statistical Research Data Centers, Health Effects Institute), and working in concert with the National Academies of Science and other federal partners to adopt evolving but achievable transparency standards in health research going forward. All these are preferable to the current proposal.

The SAB recognizes that "strengthening transparency in regulatory science is a worthy goal." The SAB should consider expanding upon that general statement by noting that broader access to information about exposures to toxic chemicals, particularly chemicals in products, would also improve the ability of scientists to better target their research in ways that support EPA's regulatory work to ensure healthy environments for children.

The proposed rule as currently written does not merely need better definitions, clarity, a guidance document and impact analyses. It must also identify a mechanism that can achieve the stated transparency goal (public access to individual-level data) while also complying with legal requirements of the Agency to base its decisions on the best available science and systematic reviews, protect confidential business information, and prevent the release of personally identifiable health information and medical records. Without a mechanism, the rule as written appears unworkable.

Sincerely,

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cc: Nica Louie, Designated Federal Officer, EPA CHPAC
Jeanne Briskin, Director, EPA Office of Children's Health Protection
CHPAC members