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August 20, 2019

By Electronic Submission to Dr. Thomas Armitage, armitage.thomas@epa.gov

Dr. Thomas Armitage
Designated Federal Officer (DFO)
EPA Science Advisory Board (1400R)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

RE: Written Statement for SAB Public Teleconference on EPA’s Proposed Rule,
“Strengthening Transparency in Regulatory Science”

Dear Dr. Armitage,

We write on behalf of 32 concerned medical and public health experts, scientists, researchers, and clinicians to urge the Science Advisory Board (“SAB”) to conduct a full review of the Environmental Protection Agency’s (“EPA”) proposal “Strengthening Transparency in Regulatory Science,” 83 Fed. Reg. 18,768 (Apr. 30, 2018) (“the Proposal”). The narrow review that Administrator Wheeler has requested is not adequate to address the many troubling implications of the Proposal for the scientific integrity of EPA’s decision-making. As explained in a comment letter we submitted to EPA on August 7, 2018 (which we have attached to this letter), the Proposal will result in the exclusion of crucially important public health data from the agency’s consideration when setting regulatory standards and will therefore undermine—not strengthen—EPA’s decision-making. Given that EPA has stated that it intends to finalize the Proposal by the end of this year, it is critically important that the SAB weigh in on all aspects of the Proposal as soon as possible.

The Proposal, if finalized, would prohibit EPA from basing important regulatory actions on reliable, significant, responsibly-conducted, and best available scientific studies merely because the raw data are not “publicly available in a manner sufficient for independent validation.” 83 Fed. Reg. at 18,773. EPA qualifies this requirement, however, by providing that “[w]here the Agency is making data or models publicly available, it shall do so in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security.” *Id.* This qualification does not address our concerns.

In the comment letter we submitted to EPA last year, we explained that:

The proposed rule will undermine EPA's ability to fulfill its mission to protect human health, safety, and the environment by using the best available information and science. First, the proposed rule would exclude from EPA's consideration any reports, studies, analyses, and models that rely on confidential, inaccessible, or unavailable data but that historically have been considered the best available science and therefore used to support regulations and standards designed to protect public health and safety. Second, in so doing, the rule also eliminates EPA's access to fundamental information necessary for identifying and calculating the "health benefits" of rules and standards needed to protect public health. Finally, it threatens to impose significant costs on both the federal government and independent scientists. Worst of all, the proposed rule creates these multiple problems without providing any significant countervailing benefits.

Other major figures in the scientific community reiterated these criticisms of the Proposal. For example, the editors-in-chief of *Science*, *Nature*, *PLOS*, *PNAS*, and *Cell* published a joint statement explaining that:

It does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them; rather, it is paramount that the full suite of relevant science vetted through peer review, which includes ever more rigorous features, inform the landscape of decision making. Excluding relevant studies simply because they do not meet rigid transparency standards will adversely affect decision-making processes.¹

Similarly, a coalition of sixty-nine public health, medical, academic, and scientific groups commented that:

If EPA excludes studies because the data cannot be made public, people may be exposed to real harm. The result would be decisions affecting millions based on inadequate information that fails to include well-supported studies by expert scientists. These efforts are misguided and will not improve the quality of science used by EPA nor allow the agency to fulfill its mandate of protecting human health and the environment.²

Since our original submittal, EPA has taken every opportunity to diminish the role of science and scientists in its decision-making. For example, the agency has disbanded the particulate matter review panel, which in the past advised the Clean Air Scientific Advisory Committee on the establishment of National Ambient Air Quality Standards for particulate matter and fine particulates. EPA also terminated the Integrated Risk Information System ("IRIS") assessment for formaldehyde. Of immediate relevance to the Proposal, EPA recently decided not to revoke the existing food tolerances for chlorpyrifos under the Federal Food, Drug, and Cosmetic Act. In

¹ Jeremy Berg, et al., *Joint Statement on EPA Proposed Rule and Public Availability of Data*, *Science*, Vol. 360, Issue 6388, eaau0116 (2018), <https://science.sciencemag.org/content/360/6388/eaau0116>.

² Public Health, Medical, Academic, and Scientific Groups Oppose EPA Transparency Rule (July 16, 2018), <https://mcmprodaas.s3.amazonaws.com/s3fs-public/EPA%20Transparency%20Rule%20FINAL.pdf?oNbdIjRo8Ick2LxdMeWaqWuYu4NM3unc>.

reaching this decision, EPA identified “the lack of any meaningful raw data from the epidemiologic data that are the centerpiece of this area of inquiry” as the “most significant[.]” reason for refusing to act.³ As demonstrated by this decision, even without finalizing the Proposal, EPA is already implementing its principles in its regulatory decisions.

In sum, over the past year, the role of science and reason at EPA have not been strengthened; they have been dismissed. Scientists, public health experts, and the medical community have all been marginalized in EPA’s ongoing effort to roll back rules, undermine regulatory standards, and promote business interests over public health and environmental protection.

We urge you to use the August 27, 2019 meeting to push back and remind EPA of its statutory obligations to base its decisions on science—not on business interests or the interest of the President in promoting coal and other fossil fuels. In your capacity as expert advisors, you should urge EPA to withdraw the Proposal and engage in meaningful discussions with you and other experienced members of the scientific and public health communities who have nearly unanimously opposed the proposed rule.

EPA has unlawfully and inappropriately curtailed the role of the SAB. EPA did not consult with the SAB before publishing the Proposal. Only now, more than a year later, after much protest, is EPA allowing limited SAB input. But EPA has wrongfully restricted the SAB’s input to one narrow aspect of the Proposal: “mechanisms for secure access to personally identifying information (PII) and confidential business information (CBI) as discussed in the proposed rule consistent with existing laws and policies that protect PII and CBI.”⁴ The SAB’s statutory role is significantly broader. Given the central importance of the Proposal to SAB’s mission and EPA’s ability to fulfill its statutory duties, and because the Proposal departs from scientific norms, the SAB should weigh in on all aspects of the Proposal.

Thank you for considering these comments and raising these issues with EPA.

Sincerely yours,

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³ Chlorpyrifos; Final Order Denying Objections to March 2017 Petition Denial Order, 84 Fed. Reg. 35,555, 35,563 (July 24, 2019).

⁴ Strengthening Transparency in Regulatory Science: Notification of a Public Teleconference of the Chartered Science Advisory Board, 84 Fed. Reg. 38,894, 38,895 (Aug. 8, 2019).

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