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United States Senate

March 2, 2022

COMMITTEES

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Dr. Clifford Duke
Director
Board on Environmental Studies and Toxicology (BEST)
National Academies of Sciences, Engineering, and Medicine (NASEM)
500 Fifth St., N.W.
Washington, D.C. 20001

Dear Dr. Duke:

In late 2021, the U.S. Environmental Protection Agency (U.S. EPA) contracted with NASEM to establish an ad hoc committee to peer review EPA's 2021 draft Integrated Risk Information System (IRIS) formaldehyde assessment and to issue a report. This peer review will receive a great deal of attention, especially given formaldehyde's role as an essential building block chemical for a myriad of industrial, housing, consumer, agricultural, transportation, and public health uses. ¹ I write with concerns about recent NASEM decisions which could undermine the integrity and public confidence in this review.

This is not the first time the NASEM has been asked to review a draft IRIS formaldehyde assessment. In 2011, prompted by requests from the U.S. Senate, another NASEM ad hoc committee issued a highly critical and hugely impactful report that not only took U.S. EPA to task on the draft assessment itself but on the entire IRIS program and its chronic pattern of issuing deficient, inconsistent, and nontransparent chemical assessments.²

I further understand that Dr. Kathryn Guyton will serve as the responsible NASEM staff officer for the current review. In this role, she will be intimately involved in all aspects of the 18-month review, from soliciting nominations and public comments, panel coordination, and assisting with the drafting of the report, among other vital tasks. NASEM's recently updated Policy on Composition and Balance, Conflicts of Interest, and Independence³ addresses the ability to include panelists "with contrasting views to maintain balance" if a peer reviewer suffers from bias, lack of independence, or strongly held views. However, such balancing is not possible with the responsible NASEM staff officer. NASEM's commitment to independence and avoiding the appearance of lack of impartiality is even more critical given the recent controversy involving a senior White House official over a retracted paper which violated NASEM's guidelines on competing interests due to personal associations.⁴

Considering the 2011 report, NASEM's institutional "reputation for providing independent, objective, and nonpartisan advice," and the potential economic and public health impacts of the ad hoc committee's imminent peer review, I was concerned to learn that Dr. Guyton had extensive involvement

¹ For example, formaldehyde is the only chemical approved by the Food and Drug Administration for the control of Salmonella in animal feed.

² http://books.nap.edu/catalog.php?record_id=13142#toc.

³ https://www.nationalacademies.org/about/institutional-policies-and-procedures/conflict-of-interest-policies-and-procedures.

⁴ Roger Pielke Jr., "Fishy Science: Implications of the retraction of a recent paper for scientific integrity in the White House," The Honest Broker Newsletter, December 22, 2021, https://rogerpielkejr.substack.com/p/fishy-science.

⁵ https://www.nationalacademies.org/about/our-study-process.

with the revisions to the IRIS formaldehyde assessment during her career as a senior official in U.S. EPA's Office of Research and Development (which houses IRIS). Based on public information and records released by U.S. EPA in late December 2021, 6 these personal connections include: coordinating closely with, as well as with supervisory responsibilities for and coauthor relationships with, EPA employees who are actively involved in the 2010 and 2021 IRIS assessments for formaldehyde, including the assessment managers and individuals whose work products are under review; being a member of the Agency's "Formaldehyde Team," exchanging frequent emails on the 2011 NASEM review and U.S. EPA's response; frequent coordination on formaldehyde and IRIS matters with participants in the 2011 NASEM review and current BEST members; and serving as a reviewer for U.S. EPA's 2020 *ORD Staff Handbook for Developing IRIS Assessments*.⁷

Perhaps most troubling is an email from Dr. Guyton to her EPA colleague Dr. Barbara Glenn, who manages the IRIS formaldehyde team as assessment manager, regarding a presentation the team was preparing in response to the 2011 NASEM criticism, where Dr. Guyton argued aggressively against changing major conclusions of the assessment or additional peer review (the exact process she will be overseeing as responsible staff officer):

I realize I am coming in after the movie has started...but I suggest deleting reference to potential additional peer review on the last slide. I would endorse a strong team opinion that additional peer review will not be needed given that the major conclusions will not change...whether this is politically viable however, I don't know. But if you go back for another peer review, that will add years to your pain.

And yet Dr. Guyton is now managing the NASEM peer review she determined is not needed. I understand that Dr. Guyton is a respected scientist, but her direct and personal involvement matters under review risks undermining NASEM's reputation and a fair and objective review of the draft IRIS formaldehyde assessment. Ensuring the credibility and integrity of the peer review of the highly anticipated draft IRIS formaldehyde assessment demands nothing less. I respectfully request that a NASEM officer be assigned who does not have a conflict of interest with the assessment under review and evaluate whether this new officer should revisit steps taken in late 2021, including solicitation of nominees, to transparently establish a process beyond reproach.

Sincerely,

John Kennedy

United States Senator

Michael Regan, Administrator, U.S. EPA
Elizabeth Eide, Executive Director, Division on Earth and Life Studies, NASEM
Christopher King, Executive Director, Office of Congressional & Government Affairs

cc:

⁶ Available at: https://foiaonline.gov/foiaonline/action/public/home.

⁷ https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=350086.