

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

AMERICAN CHEMISTRY COUNCIL, INC.,
700 2nd Street, NE, Washington, DC 20002,

Plaintiff,

v.

NATIONAL ACADEMY OF SCIENCES;
2101 Constitution Ave., NW, Washington, DC 20418,

U.S. ENVIRONMENTAL PROTECTION AGENCY; and
1200 Pennsylvania Ave., NW, Washington, DC 20460,

MICHAEL S. REGAN, in his official capacity as
Administrator of U.S. Environmental Protection Agency,
1200 Pennsylvania Ave., NW, Washington, DC 20460,
Defendants.

Case: No. 23-cv-2113

**FIRST AMENDED COMPLAINT
FOR DECLARATORY, INJUNCTIVE, AND MANDAMUS RELIEF**

PRELIMINARY STATEMENT

1. This suit relates to an allegedly independent review by the National Academy of Sciences (“NAS”) within the National Academies of Sciences, Engineering, and Medicine (the “Academies”) (NAS and the Academies are referred to herein collectively as “NASEM”) of the U.S. Environmental Protection Agency’s (“EPA” or “the Agency”) toxicological assessment of formaldehyde. Formaldehyde is a critical chemical building block for hundreds of key sectors and essential items including housing, sustainable wood products, agriculture, medical devices, food safety and electric vehicles.

2. In its provision of “advice or recommendation[s]” to a federal agency, NASEM is subject to certain requirements of the Federal Advisory Committee Act (“FACA”), 5 U.S.C. § 1014. For example, FACA requires that members of the NASEM committee reviewing EPA’s

work product cannot have conflicts of interest, and it also requires that the committee be fairly balanced, that NASEM permit the public to comment on proposed committee members, and that NASEM make certain information public. FACA also prohibits a federal agency, such as EPA, from managing or otherwise exercising control over a NASEM review.

3. NASEM has not met these requirements. Contrary to FACA, NASEM has utilized an unbalanced Committee that lacks members with sufficient, essential, and critically needed epidemiological, biological, industrial, toxicologic, and other areas of expertise. There are also numerous conflicts of interest that include close connections between certain Committee members and the EPA Integrated Risks Information System (“IRIS”) program office and specific EPA personnel involved in the drafting of the formaldehyde IRIS assessment the Committee is tasked with reviewing. EPA went so far as to suggest Committee panel members to NASEM. NASEM has also limited the public’s access to key information and its ability to meaningfully comment on Committee members in violation of FACA. And EPA exercised undue control over the Committee by manipulating the nomination process, limiting the independent evaluation of the science, and sending the Committee specific scientific information it should use during the review process.

4. The American Chemistry Council, Inc. (“ACC”) has repeatedly informed NASEM and EPA of these concerns, and has requested that NASEM remedy the deficiencies in the composition of the Committee and publish the information that it is required to make available to the general public. NASEM has failed to acknowledge or correct any of the problems.

5. Plaintiff ACC brings this complaint for declaratory relief finding that NASEM violated FACA and mandamus relief compelling NASEM to comply with FACA; and injunctive relief prohibiting EPA from arbitrarily and capriciously relying on any report unlawfully issued by the Committee in violation of the Administrative Procedure Act (“APA”), 5 U.S.C. § 706.

INTRODUCTION

6. In June 2010, EPA released its toxicological assessment of formaldehyde titled “IRIS Toxicological Review of Formaldehyde (Inhalation)” (the “2010 Assessment”). EPA then contracted with NASEM to provide an independent review of EPA’s 2010 Assessment. NASEM’s conclusions were highly critical of EPA’s work. As the New York Times explained, NASEM “panned” the 2010 Assessment, “sharply disagree[ing] with the agency’s conclusions and declar[ing] the effort in need of ‘substantial revision,’ and even going so far as to conclude that “‘EPA’s draft assessment was not prepared in a logically consistent fashion, lacks clear links to an underlying conceptual framework and does not sufficiently document methods and criteria used to identify evidence for selecting and evaluating studies.’”¹

7. After the NASEM review of the 2010 Assessment, EPA reviewed its work and prepared a revised formaldehyde assessment. In September 2021, while EPA worked on this revised assessment, the Agency contracted with NASEM to form a new committee of scientists to evaluate the not-yet publicly available draft. In April 2022, EPA released its amended draft formaldehyde assessment (“the Assessment”) to the public.

8. Under this contract, NASEM formed the Committee. On August 9, 2023, the Committee released the Prepublication Copy of NASEM’s Review of EPA’s 2022 Draft Formaldehyde Assessment (“the Report”). However, NASEM assembled the Committee and developed the Report in violation of FACA, 5 U.S.C. § 1014, as detailed further below.

9. *First*, NASEM assembled a Committee whose members are not fairly balanced and have apparent conflicts of interest that NASEM has not addressed. The Committee lacks members

¹ Jeremy P. Jacobs, *NAS Reviewers Slam EPA’s Formaldehyde Assessment*, N.Y. Times (Apr. 8, 2011), <https://archive.nytimes.com/www.nytimes.com/gwire/2011/04/08/08greenwire-nas-reviewers-slam-epas-formaldehyde-assessmen-83879.html?pagewanted=all>.

with sufficient expertise in crucial disciplines, and lacks members with diverse backgrounds and experiences. Multiple members of the Committee and the NASEM Study Director have conflicts that limit their independence and impartiality, such as substantial, direct connections to the EPA IRIS program, including direct involvement in the IRIS Assessment under review and prior work addressing issues with the IRIS program that are directly relevant to the current review. Regardless, NASEM certified to EPA that it is not aware of any conflicts, which is not true. The lack of a balanced Committee violates FACA. Furthermore, FACA prohibits actual or apparent conflicts of interest unless they are publicly disclosed and justified as unavoidable.

10. *Second*, NASEM did not allow for a reasonable opportunity for meaningful public input regarding committee appointments, and it also failed to disclose required information about the Committee members, their communications, and the Committee's work. This lack of transparency and limitation on public input violates FACA, and it likely also contributed to the unbalanced makeup of the Committee.

11. *Third*, EPA impermissibly exercised control over the Committee. EPA has done so directly, including by telling NASEM which scientists should be on the Committee, limiting the Committee's public meetings, and prohibiting the Committee from reviewing any materials other than the Assessment and EPA's documentation. EPA has also controlled the Committee indirectly, including through Committee members with either personal connections to or financial reliance on EPA. Therefore, under Section 1014(a) of FACA and its implementing regulations, 5 U.S.C. § 1014(a) and 41 C.F.R. § 102-3.185, EPA cannot use any report created by the Committee.

12. *Fourth*, the Committee, without explanation, ignored relevant information from sources outside EPA in violation of NASEM's scientific integrity obligations under its contract.

13. Given the above violations of FACA and the lack of scientific integrity, any reliance on or use of the Report by EPA would be arbitrary, capricious, and unlawful, and thus would violate the APA, 5 U.S.C. § 706(2). This Court should therefore enjoin EPA from relying on the Report.

PARTIES

14. Plaintiff, the AMERICAN CHEMISTRY COUNCIL (“ACC”), is a trade association, headquartered in Washington, D.C. and founded in 1872, that represents its members – over 190 leading companies engaged in the business of chemistry. ACC serves as the collective voice of the chemical manufacturing sector and its value chain, and is committed to fostering progress in our economy, environment, and society. ACC has an interest in ensuring an accurate, scientific understanding of the risks of formaldehyde and has invested significant time, effort, and financial resources in studying formaldehyde and presenting peer reviewed scientific information to decisionmakers.

15. A number of ACC members are producers, suppliers and users of formaldehyde and formaldehyde products, as well as trade associations representing key formaldehyde applications.² Within ACC, a subset of these members have also established an informal Federal Advisory Committee Act work group to evaluate legal and scientific integrity issues related to the peer review of EPA and other scientific products that may be used as the foundation for regulation.

16. In advance of EPA’s 2022 release of its IRIS Assessment, ACC evaluated the potential research that could help address NASEM’s 2011 recommendations and launched and funded numerous scientific research projects to fill data needs. Largely as a result of these costly

² A subset of ACC members has formed and funded the ACC Formaldehyde Panel, a group within ACC that pursues formaldehyde-related scientific research, regulatory and legislative advocacy, and outreach.

efforts by ACC, since 2010, over 50 peer reviewed publications on various key formaldehyde-related topics have been added to the scientific literature to inform the formaldehyde hazard and dose-response assessment. ACC presented all of this information to EPA IRIS staff when the information was generated. EPA's IRIS Assessment, however, disregards a significant amount of that information. More recently, ACC attempted to present key scientific information to NASEM Committee members in public meetings as well as through written submissions, but NASEM has made clear (for example, in its March 6, 2023 response letter declining to provide an opportunity for meaningful public engagement with the Committee) that its focus is solely on the materials cited by EPA.

17. ACC also attempted to engage with NASEM regarding both the science and the review process as NASEM selected Committee members and the Committee began its evaluation.³ ACC repeatedly requested additional information from NASEM, informing NASEM of its obligation to provide documents, and also informed NASEM about aspects of its process that are not in accordance with the law or that will reduce the accuracy and scientific integrity of any report. NASEM has not responded to most of these communications, and in its limited responses, it has merely provided a blanket assertion of compliance with the law without responding to ACC's substantive concerns.

³ ACC, *Did EPA Dismiss Recommendations from the National Academy of Sciences and Its Own Best Practices in its Draft Formaldehyde Assessment?* (Apr. 21, 2023), <https://www.americanchemistry.com/chemistry-in-america/news-trends/blog-post/2023/did-epa-dismiss-recommendations-from-the-national-academy-of-sciences-and-its-own-best-practices-in-its-draft-formaldehyde-assessment>.

18. For example, in response to an April 20, 2023 letter sent by outside counsel for ACC describing in detail the myriad issues with the Committee's formation and actions,⁴ NASEM's only response was that concerns about "the Committee's analysis of the information provided to it is premature" and that "the study is being conducted in accordance with the policies and procedures of the National Academy of Sciences that implement the requirements of Section 15 of the Federal Advisory Committee Act."⁵

19. Previously, on March 6, 2023, NASEM responded to one of ACC's letters noting the lack of public information and the fact that NASEM was only meaningfully considering information from EPA and not other scientists. NASEM's response admitted that the "public" meetings were "organized to provide an opportunity for the committee to engage in a question-and-answer session with EPA" because it is "the committee's view that the sponsor, EPA, is best positioned to provide clarifications and answer questions on the assessment of formaldehyde."⁶ It took this view because "[t]he committee's charge is to review the assessment prepared by EPA, and not to conduct their own assessment of formaldehyde," "comment on other interpretations of

⁴ Letter from Amanda Berman, Crowell & Moring LLP, to Drs. Marcia McNutt and Clifford Duke, NASEM (Apr. 20, 2023), [https://urldefense.com/v3/https://www.americanchemistry.com/media/files/acc/industry-groups/formaldehyde/files/2023-apr-20-letter-from-crowell-to-nas_!!LB4zUoiJ9F1unGg!soCmm1aQH0tmMqIkWa5yJ2uQPD90JQj9_WzLBPLNzWgcGemWQd0F0pcPj9Tp73cyu1CwyIOaHT94IEcQu6E3P889WrMZgI2WhY1k\\$.](https://urldefense.com/v3/https://www.americanchemistry.com/media/files/acc/industry-groups/formaldehyde/files/2023-apr-20-letter-from-crowell-to-nas_!!LB4zUoiJ9F1unGg!soCmm1aQH0tmMqIkWa5yJ2uQPD90JQj9_WzLBPLNzWgcGemWQd0F0pcPj9Tp73cyu1CwyIOaHT94IEcQu6E3P889WrMZgI2WhY1k$.)

⁵ Letter from Dr. Clifford Duke, NASEM, to Amanda Berman, Crowell & Moring (May 4, 2023), [https://urldefense.com/v3/https://americanchemistry.com/media/files/acc/industry-groups/formaldehyde/files/nasem-letter-to-acc-5-4-2023_!!LB4zUoiJ9F1unGg!soCmm1aQH0tmMqIkWa5yJ2uQPD90JQj9_WzLBPLNzWgcGemWQd0F0pcPj9Tp73cyu1CwyIOaHT94IEcQu6E3P889WrMZgPMYAb0Z\\$.](https://urldefense.com/v3/https://americanchemistry.com/media/files/acc/industry-groups/formaldehyde/files/nasem-letter-to-acc-5-4-2023_!!LB4zUoiJ9F1unGg!soCmm1aQH0tmMqIkWa5yJ2uQPD90JQj9_WzLBPLNzWgcGemWQd0F0pcPj9Tp73cyu1CwyIOaHT94IEcQu6E3P889WrMZgPMYAb0Z$.)

⁶ Letter from Dr. Kathryn Guyton, NASEM, to Sahar Osman-Sypher, ACC (Mar. 6, 2023), <https://americanchemistry.com/media/files/acc/industry-groups/formaldehyde/files/nasem-review-of-epa-s-2022-formaldehyde-iris-assessment>; see also ACC, *supra* note 3.

scientific information relevant to the hazards and risks of formaldehyde[, or] . . . to review alternative opinions of EPA’s formaldehyde assessment.”⁷

20. ACC and its members have suffered and will suffer injuries as a result of NASEM’s unlawful failure to provide ACC required information and to respond to ACC’s concerns, as well as due to NASEM’s release of the Report, which appears to sanction EPA’s draft Assessment, even while admitting that the Committee’s review was limited in scope.

21. ACC has expended a great deal of effort to inform EPA of the problems with the NASEM review. ACC drafted, and on March 10, 2022, submitted, a letter to the Administrator of the EPA that delineated the Panel’s concerns with NASEM’s review of the Assessment.⁸ In it, ACC noted its concern that EPA regularly failed to allow NASEM to exercise independent judgment in evaluating the Assessment, which would likely result in the Agency being unable to use NASEM’s advice pursuant to FACA.⁹ Further, ACC copied EPA on its April 20, 2023, letter to NASEM leadership identifying NASEM’s FACA violations and explaining that use of a resulting report by EPA would violate the APA.¹⁰

22. ACC’s work described above—the generation of data to address the data needs identified by NASEM, the presentations to EPA and NASEM, and repeated correspondence attempting to ensure EPA’s and NASEM’s compliance with the law—have all cost ACC substantial time and money without providing ACC with the opportunity to be heard and have that information impartially considered. ACC retained experts, drafted and submitted hundreds of

⁷ Letter from Dr. Kathryn Guyton to Sahar Osman-Sypher, *supra* note 6.

⁸ Letter from Dr. Lynn Dekleva, ACC Formaldehyde Panel, to Hon. Michael Regan, U.S. EPA (Mar. 10, 2022), <https://www.americanchemistry.com/industry-groups/formaldehyde/resources/formaldehyde-panel-follow-up-letter-to-epa>.

⁹ ACC, *supra* note 3.

¹⁰ Letter from Amanda Berman to Drs. Marcia McNutt and Clifford Duke, *supra* note 4, at 15.

pages of comments, and was forced to incur additional expenses to retain legal counsel to advocate for its rights and compliance with the law. All of these efforts were designed to represent its members' interests in a proper scientific evaluation to support correct legal and policy conclusions. These efforts have diverted ACC's resources and member-contributed resources away from its other activities (including non-lobbying activities) on behalf of its members. ACC therefore has organizational standing to pursue these claims against NAS and EPA.

23. ACC also has associational standing to bring these claims. ACC brings this suit on behalf of member companies, such as Hexion and Bakelite Synthetics, which produce and/or use formaldehyde as an integral part of their businesses. ACC's members have been and will be directly harmed by EPA's incorrect assessment of the hazards of formaldehyde because of the many ramifications of such an assessment, and now by NASEM's apparent ratification of that assessment in its Report. For example, EPA indicated it intends to use the final IRIS assessment as the foundation for standards and regulatory actions such as those under the Toxic Substances Control Act, with which industry must comply.¹¹ The U.S. Department of Justice has also asserted

¹¹ EPA, Final Scope of the Risk Evaluation for Formaldehyde CASRN 50-00-0, at 74 (Aug. 2020), https://www.epa.gov/sites/default/files/2020-09/documents/casrn_50-00-0-formaldehyde_finalscope_cor.pdf ("EPA plans to include information developed from the draft IRIS hazard and dose response assessment."); InsideEPA, *EPA Revives IRIS Formaldehyde Assessment To Inform TSCA Evaluation* (Mar. 12, 2021), <https://insideepa.com/daily-news/epa-revives-iris-formaldehyde-assessment-inform-tsca-evaluation> ("EPA is resuming the formaldehyde IRIS assessment . . . with plans to use its findings in a TSCA evaluation of the ubiquitous chemical"); March 7, 2023 M. Freedhoff remarks at Chemical Watch Conference ("EPA's Office of Research and Development does a lot of the scientific work to support many of these risk assessments. For example, IRIS assessments identify and characterize the subchronic and chronic human health hazards of chemicals found in the environment, and are developed through a multi-year process that includes external peer review." "If another EPA office has recently evaluated and peer reviewed a hazard for a given chemical, it may not make sense for us to re-do all of that work. Instead, we should just consider the science that post-dates that review and its likelihood that it would alter the outcome.").

that hazard values developed by the IRIS Program, like those in the IRIS Assessment, are of sufficient quality that courts can take judicial notice of such conclusions and EPA can use the conclusions as the basis for enforcement actions. EPA has made clear that it “plans to use the [NASEM] report to revise the draft IRIS formaldehyde assessment prior to finalization.”¹² In a May 2023 communication with another EPA peer review body, the Human Studies Review Board (“HSRB”), EPA indicated that “[o]nce the National Academy of Sciences, Engineering, and Medicine completes its review of the draft IRIS assessment for formaldehyde, [EPA’s Office of Chemical Safety and Pollution Prevention] plans to rely on the chronic non-cancer inhalation reference concentration (RfC) and cancer inhalation unit risks (IUR) from IRIS” for their forthcoming human health risk evaluations of formaldehyde under the Toxic Substances Control Act (“TSCA”) and the Federal Insecticide Fungicide and Rodenticide Act (“FIFRA”).¹³ Such plans for use of the Report are consistent with past EPA practice because the Agency has a “normal process to finalize the assessment by considering the peer . . . review comments received, making final revisions to the assessment in response to those comments, and then issuing the . . . IRIS assessment.”¹⁴

¹² EPA, National Academies of Sciences, Engineering, and Medicine Releases Peer Review Report of Draft IRIS Formaldehyde Assessment (Aug. 9, 2023), <https://www.epa.gov/newsreleases/national-academies-sciences-engineering-and-medicine-releases-peer-review-report-draft>.

¹³ EPA, Memorandum of Materials for Review by Human Studies Review Board for the May 16-18, 2023 Meeting (Apr. 21, 2023), https://www.epa.gov/system/files/documents/2023-05/HSRB_transmittal_and_charge_2023_May_16-18%20FINAL.pdf.

¹⁴ Reconsideration of the 2020 National Emission Standards for Hazardous Air Pollutants, 87 Fed. Reg. 77985, 77990 (Dec. 21, 2022).

24. Despite the narrow scope of the Committee’s review, the Assessment’s deficiencies as identified in the Report, and the problems with the Committee’s review, EPA has characterized the Report as confirming that EPA’s Assessment “follows the advice of prior National Academies reports and that its findings on hazard and quantitative risk are supported by the evidence identified.”¹⁵

25. Only a thorough, transparent, and unbiased review by a fairly balanced and properly composed NASEM Committee can ensure that the government does not rely on its flawed IRIS Assessment. ACC has also documented how a draft IRIS assessment or the results of a NASEM review process can have meaningful impacts to regulatory, enforcement, and legal actions.

26. The interests ACC seeks to protect are fundamental to its members, and neither the claim asserted nor the relief requested requires an individual member to participate in the suit. ACC therefore has associational standing to bring these claims on behalf of its members whose businesses rely on formaldehyde.

27. ACC and its members suffered an injury in fact that is traceable to the actions of the Defendants’ violations of FACA and APA, and that harm is redressable by a favorable decision from this court. Unreliable reports on formaldehyde promoted by the federal government create concrete and particularized injuries to members of ACC that regularly use the chemical to create products that modern society is dependent upon. The promotion or imposition of regulations based on a faulty process would impose unjustifiable hurdles and restrictions on all companies that use formaldehyde, so NASEM’s flawed review poses actual and imminent injury to ACC.

28. Defendant the UNITED STATES ENVIRONMENTAL PROTECTION AGENCY (“EPA”) is an agency within the executive branch of the federal government, headquartered in

¹⁵ EPA, *supra* note 12.

Washington, D.C, that is tasked with protecting human health and the environment. It sponsors and conducts research, and develops and enforces environmental regulations. The IRIS Program is located within EPA’s Center for Public Health and Environmental Assessment (“CPHEA”) in the Office of Research and Development (“ORD”). EPA’s IRIS Program identifies and characterizes the health hazards of chemicals found in the environment. As EPA acknowledges “IRIS assessments are an important source of toxicity information used by EPA, state and local health agencies, other federal agencies, and international health organizations.”¹⁶

29. Defendant MICHAEL REGAN is the Administrator of U.S. Environmental Protection Agency, and is responsible for enforcing the nation’s environmental statutes. He is sued in his official capacity.

30. Defendant NATIONAL ACADEMY OF SCIENCES (“NAS”), an academy of the National Academies of Sciences, Engineering, and Medicine, was established in 1863 by an Act of Congress, signed by President Lincoln, as a private, nongovernmental institution to advise the nation on issues related to science and technology. According to the Academies’ website, NAS is a “separate operating unit” within the Academies.¹⁷ Its primary purpose is to provide independent, objective advice to inform policy with evidence. NAS agreed to a task order with EPA under which NASEM formed the Committee and is performing the tasks described by this complaint.

¹⁶ EPA, Basic Information about the Integrated Risk Information System, <https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system> (last visited June 30, 2023).

¹⁷ National Academies, About Us, <https://www.nationalacademies.org/about> (last visited June 30, 2023).

JURISDICTION AND VENUE

31. Plaintiff brings this action under FACA, 5 U.S.C. §§ 1001-1014; the APA, 5 U.S.C. § 500 *et seq.*; and the Mandamus Act, 28 U.S.C. § 1361. This Court therefore has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1361, and 5 U.S.C. § 704.

32. Venue is proper in this district pursuant to 28 U.S.C. § 1391(b) & (e) because all Defendants reside in this district, where a substantial part of the acts and omissions giving rise to this action took place.

LEGAL BACKGROUND

A. The Federal Advisory Committee Act (“FACA”)

33. Congress created FACA, in part, to ensure that committees advising the federal government are subject to uniform standards and procedures and that the public remain apprised of their existence, activities, and cost. *Pub. Citizen v. U.S. Dep’t of Just.*, 491 U.S. 440, 446 (1989) (citing 5 U.S.C. § 1002(b)). “FACA’s principal purpose was to establish procedures aimed at enhancing public accountability of federal advisory committees.” *Ctr. for Law & Educ. v. U.S. Dep’t of Educ.*, 209 F. Supp. 2d 102, 113 (D.D.C. 2002). FACA demands transparency and public participation when the executive branch seeks advice from non-federal entities. To achieve these goals, FACA imposes requirements on “advisory committees.”

34. In 1997, Congress amended FACA to exempt NASEM from some requirements, but explicitly required NASEM to comply with certain other requirements, enacting a section of the U.S. Code devoted to “Requirements relating to the National Academy of Sciences and the National Academy of Public Administration.” 5 U.S.C. § 1014. Congress therein provided that “[a]n agency may not use any advice or recommendation provided by the National Academy of

Sciences . . . that was developed by use of a committee created by that academy under an agreement with an agency, unless” certain requirements are met. *Id.*

35. *First*, the committee must not have been “subject to any actual management or control by an agency or an officer of the Federal Government.” 5 U.S.C. § 1014(a)(1).

36. *Second*, the membership of the committee must be “appointed in accordance with” specified requirements, including that NASEM must:

- “provide public notice of the names and brief biographies of individuals that the Academy appoints or intends to appoint to serve on the committee,”
- “provide a reasonable opportunity for the public to comment on appointments before they are made,”
- “make its best efforts to ensure that . . . no individual appointed to serve on the committee has a conflict of interest that is relevant to the functions to be performed, unless such conflict is promptly and publicly disclosed and the Academy determines that the conflict is unavoidable,”
- “make its best efforts to ensure that . . . the committee membership is fairly balanced as determined by the Academy to be appropriate for the functions to be performed,” and
- ensure that the final report is “the result of the Academy’s independent judgment.”

5 U.S.C. § 1014(b)(1)

37. Defendant NASEM’s Policy on Composition and Balance, Conflicts of Interest, and Independence for Committees Used in the Development of Findings, Conclusions, and Recommendations (the “Policy”)¹⁸ sets forth NASEM’s policies and procedures for meeting

¹⁸ NASEM, Policy on Composition and Balance, Conflicts of Interest, and Independence for Committees Used in the Development of Findings, Conclusions, and Recommendations (Sept. 7, 2021) [hereinafter “NASEM Policy”], <https://www.nationalacademies.org/documents/embed/link/LF2255DA3DD1C41C0A42D3BEF0989ACAECE3053A6A9B/file/D4D336B1CB9047B19928EA8785ED2E43C913B841539A?noSaveAs=1>.

FACA’s “fairly balanced” requirement. In particular, the Policy notes that consideration should be given “to the appropriate balance among disciplines and fields of expertise, considering the subtleties and complexities of the issues to be addressed by the committee” and “whether there is an appropriate range of perspectives.”¹⁹

38. The Policy is also designed to address conflicts of interest and ensure public notice about potentially-problematic relationships. The Policy defines disqualifying conflicts of interest to include a financial interest, or a current relationship with an entity that has a financial interest, that “could be directly and predictably affected by the outcome of the committee’s work.” The Policy requires disclosure of any unavoidable conflicts at the “time of committee formation, posted on the National Academies’ website, and documented in any report of the committee.” In addition, the Policy requires disclosure of “relationship[s] within the last five years” between the committee member and any “entity that has a financial interest that could be affected directly and predictably by the outcome of the committee’s work” or any “entity that has taken a public position on an issue that is central to the work of the committee.” Types of relationships that must be disclosed include employment, compensated or “uncompensated advisory or consulting services, including uncompensated advisory service on a scientific or technical advisory board,” as well as certain research support. The Policy also requires disclosure of any “relevant publication of a study committee member,” which means “any published or otherwise public statement authored by the committee member alone or with others during the last five years that takes a position on an issue that is central to the work of the committee.” It also requires disclosure of “[a]ny other information regarding a committee member, of which the committee member is aware, that in the judgment of

¹⁹ *Id.* at 1.

the National Academies could have a significant impact on public perception of the objectivity and value of the committee's work.”

39. *Third*, NASEM must comply with other procedural requirements when developing its report. As applicable to this matter, NASEM must:

- “provide public notice of committee meetings that will be open to the public,”
- “ensure that meetings of the committee to gather data from individuals who are not officials, agents, or employees of the Academy are open to the public,”
- “make available to the public . . . written materials presented to the committee by individuals who are not officials, agents, or employees of the Academy”, and
- “make available to the public . . . a brief summary of any committee meeting that is not a data-gathering meeting” and such summary must “identify the committee members present, the topics discussed, materials made available to the committee, and other matters the Academy determines should be included.”

5 U.S.C. § 1014(b)(2), (3), (4).

B. The Administrative Procedure Act (“APA”)

40. The APA allows a person “suffering legal wrong because of agency action, or adversely aggrieved by agency action” to seek judicial review of that action. 5 U.S.C. §§ 702-704. Under the APA, a reviewing court may “compel agency action unlawfully withheld or unreasonably delayed,” *id.* § 706(1), and “hold unlawful and set aside agency action, findings, and conclusions” that are “arbitrary, capricious, an abuse of discretion, or not otherwise in accordance with law,” *id.* § 706(2).

FACTUAL BACKGROUND

A. Formaldehyde – A Critical Chemical Building Block

41. Formaldehyde is a critical chemical building block for hundreds of key sectors and essential items including housing, sustainable wood products, agriculture, medical devices, food

safety and electric vehicles. This key substance in the economy is one of the most studied chemicals in use today, and more than 40 years of advanced science and practical experience indicate clearly defined safe thresholds for formaldehyde exposure. These thresholds have been utilized by international scientific and regulatory bodies to develop risk-based exposure levels.

42. The economic or health impacts would be significant if policymakers incorrectly identify the toxicological effects of formaldehyde, such as through an inaccurate IRIS value that is not based on the best available science. Thus, the toxicology of formaldehyde warrants a robust, fair, and comprehensive review. Despite this need, as detailed below, EPA has failed on several occasions to utilize established methodologies and meet key scientific standards when reviewing formaldehyde.

B. EPA's Flawed 2010 Assessment and NASEM's Scathing 2011 Review

43. Beginning in the 2000s, the EPA embarked on a process of re-evaluating the health impacts of formaldehyde. In 2010, EPA's IRIS program released its draft health assessment of formaldehyde, and EPA asked NASEM to convene a committee to conduct an independent scientific review of the draft.

44. In response, NASEM convened a committee in 2011 to review EPA's 2010 Assessment. The committee found significant deficiencies in how EPA's assessment organized and considered the existing science. NASEM asserted that EPA "overstated" its conclusions that formaldehyde damages the nervous system and human reproductive systems. It also condemned EPA's methodology by stating: "Overall, the committee found that EPA's draft assessment was not prepared in a logically consistent fashion, lacks clear links to an underlying conceptual

framework and does not sufficiently document methods and criteria used to identify evidence for selecting and evaluating studies.”²⁰

45. NASEM also acknowledged that this EPA IRIS assessment was not an outlier—EPA’s IRIS assessments had consistently displayed these problems. As a result, the 2011 NASEM committee determined that key sections of the IRIS assessment did not align with the available scientific information. The 2011 committee also identified areas where additional scientific information would be informative to the revised formaldehyde assessment.

C. EPA Revises Its Formaldehyde Assessment, and ACC Submits Relevant Data.

46. After the critique of EPA’s 2010 Assessment and in preparation for a revised assessment, ACC evaluated the potential research that could help address NASEM’s 2011 recommendations and launched numerous scientific research projects to fill data needs. Largely as a result of these efforts, since 2010 over 50 peer reviewed publications on various key formaldehyde-related topics have been added to the literature to inform the formaldehyde hazard and dose-response assessment. ACC presented EPA’s IRIS staff with this information as it was generated. More recently, ACC provided the information to the Committee to permit a consideration of data during the Committee’s review.

47. On January 11, 2021, ACC requested that EPA take additional steps to address the deficiencies identified in the 2011 NAS review and use the best available science.²¹ Then, on March 10, 2022, ACC submitted a letter to the Administrator of the EPA that expressed concerns with the degree to which EPA addressed the deficiencies identified in NASEM’s 2011 review and

²⁰ See Jacobs, *supra* note 1.

²¹ Letter from ACC Stakeholders to Hon. Michael Regan, U.S. EPA (Jan. 11, 2021), <https://www.americanchemistry.com/industry-groups/formaldehyde/resources/acc-stakeholder-letter-to-epa-on-nasem-review-of-draft-iris-assessment>.

EPA's limitations placed on NASEM's independent review of the Assessment.²² ACC noted its concerns that EPA appeared to be limiting NASEM's ability to exercise independent judgment in evaluating the Assessment and, as ACC explained, such control over NASEM could limit EPA's ability to use NASEM's advice, pursuant to FACA.²³ ACC concluded its letter to EPA by noting that it hoped EPA's 2022 Assessment would reflect the significant scientific improvements and revisions recommended by the 2011 NASEM review.

48. In April 2022, EPA released its revised draft IRIS Assessment. EPA then charged NASEM with reviewing the draft Assessment, contracting with NASEM through a task order that required NASEM to form a committee and answer specific, limited charge questions—but to do so in accordance with all applicable laws and government contracting standards.

D. The Committee Issues the Report, Admitting Constraints Imposed By EPA But Appearing To Nonetheless Sanction The Assessment.

49. On August 9, 2023, the Committee released its prepublication copy of the Report. The Report concludes that “[o]verall, the committee found that the methods used for the assessment were appropriate and reflect EPA's current practices in some components of the IRIS process” and the Assessment's “findings on hazard and quantitative risk are supported by the scientific evidence identified.” Report at xi-xii.

50. The Report and NASEM's related press release conclude “that the 2022 Draft Assessment follows the advice of prior National Academies reports and that its findings on hazard and quantitative risk are supported by the evidence identified” and that “[b]ecause formaldehyde is a widely used, high-volume production chemical, EPA should undertake these recommendations

²² Letter from Dr. Lynn Dekleva to Hon. Michael Regan, *supra* note 8.

²³ ACC, *supra* note 3.

expeditiously to complete a revised assessment document that can be implemented without delay.”²⁴

51. Based on such statements by the Committee, members of Congress have “applaud[ed] the IRIS program on receiving this stamp of approval from the Academies” and “urge[d] EPA to finalize the assessment expeditiously.”²⁵

52. Multiple statements in the Report reveal that the review was under the control and management of U.S. EPA and the subsequent report was not the result of the Academy’s independent judgment as required by Section 15(b)(1) of FACA.

53. Despite the Report’s broad language implying support for the Assessment, the Report notes that the Committee did not “conduct an independent hazard evaluation or dose-response assessment,” “comment[] on other interpretations of scientific information,” or “review [] alternative opinions.” Report at 1, 16. The Report further notes that the Committee “did not review specific changes in the 2022 Draft Assessment against the recommendations in the 2011 NRC report...,” “did not conduct an independent assessment of formaldehyde’s hazards or risks,” and that the Committee’s case study of one particular scientific study, which found EPA’s methods to not be replicable, “was not carried out to provide an independent assessment of formaldehyde by the committee.” Report at 24, 5, 135.

²⁴ NASEM, Review of EPA’s 2022 Draft Formaldehyde Assessment: Consensus Study Report Highlights (Aug. 2023), https://nap.nationalacademies.org/resource/27153/BEST_Fomaldehyde_Highlights.pdf

²⁵ U.S. House Representatives Comm. on Sci., Space, & Tech., Science Committee Leaders Applaud National Academies Decision on IRIS Assessment of Formaldehyde (Aug. 13, 2023), <https://democrats-science.house.gov/news/press-releases/science-committee-leaders-applaud-national-academies-decision-on-iris-assessment-of-formaldehyde>.

54. These severe limitations are the result of EPA's control of and limitations on the Committee's work and Report.

55. These significant constraints reflect the September 2021 contract between EPA and NASEM which mandated that the Committee "shall not conduct an independent assessment separately from the IRIS document nor shall the NAS comment on the broader aspects of the IRIS program" and that the committee "shall be limited to responding to the materials provided by the EPA" with a directive that other background information provided to the Committee, including by public commenters or other authoritative bodies, "shall not be reviewed by the NAS."²⁶

E. NASEM Ignored Its Procedural Obligations, Creating A Committee That Lacks Balance, Has Real and Apparent Conflicts Of Interest, And Is Controlled By EPA.

56. NASEM failed to follow the procedural requirements of FACA when forming and operating the Committee. NASEM failed to adhere to basic standards of the peer-review process such as use of a balanced committee and avoidance of conflicts of interest. NASEM also limited transparency and meaningful public input regarding committee appointments, which may have exacerbated the Committee's formation problems. Moreover, EPA exercised impermissible influence over the Committee. Each of these key procedural deficiencies is described below.

57. *First*, NASEM failed to develop a fairly balanced Committee, which is required for the peer-review process. NASEM has not taken reasonably available steps to improve the Committee's balance, and has, instead, excluded entire categories of needed expertise and experience.

²⁶ ACC, Comments on the Charge Questions and Committee Task for Peer Review of Draft Formaldehyde Assessment (Apr. 13, 2022), <https://www.americanchemistry.com/industry-groups/formaldehyde/resources/acc-comments-on-the-charge-questions-and-committee-task-for-peer-review-of-draft-formaldehyde-assessment>.

58. *Second*, NASEM failed to address multiple Committee members' real and apparent conflicts of interest. The degree of conflicts is unclear because of NASEM's lack of transparency, discussed below, but ACC has determined that certain Committee members have close ties to EPA's IRIS Program, and the specific EPA IRIS Assessment that NASEM reviewed. These conflicts actually and/or potentially prevent objectivity in the Committee's review.

59. *Third*, the Committee has not allowed for meaningful public input regarding committee appointments and has not been sufficiently transparent with the public. NASEM withheld (and continues to withhold) key information about Committee members, and it unreasonably limited stakeholders' opportunity to comment on the proposed Committee composition. NASEM also limited public discourse regarding Committee appointments by failing to disclose comments about the Committee, including those provided by EPA, and failing to provide the public with an adequate summary of committee meetings. Indeed, NASEM's "summary" for the Committee's September 1, 2022 meeting to address its composition, balance, and conflicts of interest consisted of only the statement: "The following topics were discussed in the closed sessions. Topics: Composition, balance, and conflict of interest discussion."²⁷

60. *Fourth*, EPA exercised impermissible control over NASEM's review process. For example, the Committee's Study Director asked EPA staff which scientists should serve on the Committee, and EPA identified at least one scientist that it wanted on the Committee and encouraged the Study Director to select members drawn from the prior NASEM committee. EPA also has the ability to control (and, in at least one instance has controlled) the Committee through communications with Committee members and staff, who are so bound to EPA that they likely

²⁷ NASEM, Review of EPA's 2022 Draft Formaldehyde Assessment BCOI Discussion (Sept. 1, 2022), <https://www.nationalacademies.org/event/09-02-2022/review-of-epas-2022-draft-formaldehyde-assessment-bcoi-discussion>.

feel obligated by EPA “suggestions” based on their close ties to the Agency, including based on work with EPA on the IRIS Program and formaldehyde assessments.

1. NASEM Developed A Committee That Is Not Fairly Balanced.

61. The Committee’s composition is neither consistent with Section 1014(b)(1)(B) of FACA nor the Policy implementing that provision because it lacks a range of scientific perspectives necessary for a comprehensive and reliable peer review of EPA’s draft formaldehyde assessment. Despite being made aware of deficiencies, NASEM has not made efforts to achieve the required balance.

62. The Committee lacks expertise in occupational epidemiology; biological modeling including mechanisms of carcinogenicity; physiologically-based pharmacokinetic (“PBPK”) modeling; hematology; and reproductive and developmental toxicity, which are critical scientific disciplines that were specifically recommended for appointment in the EPA task order.²⁸ Expertise in these fields is crucial for a robust and reliable scientific peer review of EPA’s draft assessment. For example, an occupational epidemiology perspective is needed because EPA relies on occupational cohorts to draw carcinogenicity conclusions in its Assessment.

63. The Committee also fails to include expertise in endogenous formaldehyde and its role in assessing potential toxicity from exogenous exposure to formaldehyde. This gap is particularly concerning given that NASEM stated in its 2011 review of the 2010 assessment that, “[t]he endogenous production of formaldehyde complicates the assessment of the risk associated

²⁸ Performance Work Statement for Task Order #68HERC21F0401 under NAS Contract #68HERC19D0011, at 4 (Sept. 7, 2021).

with formaldehyde inhalation and remains an important uncertainty in assessing the additional dose received by inhalation.”²⁹

64. The Committee lacks any scientists with sufficient backgrounds and expertise in private sector industrial toxicology and industrial epidemiology. Indeed, the Committee lacks *any* private sector perspective or expertise. According to EPA’s Peer Review Handbook, including member(s) with industry perspective helps to ensure the appropriate balancing of peer-reviewers with “diverse work history and affiliation.”³⁰ Scientists with expertise in private sector industrial toxicology and industrial epidemiology are uniquely poised to consider real-world usage of and exposure to formaldehyde and similarities or differences from scenarios in various studies. And industry experts should be included on the panel because industry will be directly affected by the final assessment.

65. In its letter to NASEM, dated August 25, 2022, ACC recommended, in order to address the lack of expertise and balance, that NASEM appoint additional committee members. ACC provided a list of potential committee members with relevant expertise for consideration.³¹ If NASEM was reluctant to increase the overall size of the Committee, ACC suggested in the alternative that NASEM make room on the Committee for new experts by decreasing the current

²⁹ National Research Council, *Review of the Environmental Protection Agency’s Draft IRIS Assessment of Formaldehyde* (The National Academies Press 2011), <https://doi.org/10.17226/13142>.

³⁰ EPA Science and Technology Policy Council, Peer Review Handbook, at 72 (4th Ed.), https://www.epa.gov/sites/default/files/2020-08/documents/epa_peer_review_handbook_4th_edition.pdf.

³¹ Letter from Dr. Lynn Dekleva, ACC Formaldehyde Panel, to Dr. Kathryn Guyton, NASEM (Aug. 25, 2022), <https://www.americanchemistry.com/industry-groups/formaldehyde/resources/nasem-committee-composition-comment>.

number of non-occupational epidemiologists, who are over-represented (of the thirteen-member Committee, seven members appear to be non-occupational epidemiologists).

66. NASEM did not address these concerns, and it has not developed a balanced committee or made best efforts to do so, as required by FACA. NASEM held at least two closed meetings to discuss issues related to the balance of the committee (as well as conflicts), but NASEM has not provided any public information indicating it followed its policies or made any efforts to address the concerns regarding balance.

67. In a letter dated April 20, 2023, ACC reiterated its recommendation that NASEM select new committee members to address the balance deficiencies discussed above and restart the review process with the involvement of the new Committee members.³² NASEM denied this request without explanation.³³

68. NASEM's Report does not address the balance of the Committee.

69. Several sections of (as well as omissions from) the Committee's August 9 Report demonstrates that the Committee was not fairly balanced for the functions to be performed, as required by FACA Section 15(b)(1) and previously highlighted in comments from ACC³⁴ and other stakeholders.

³² Letter from Amanda Berman to Drs. Marcia McNutt and Clifford Duke, *supra* note 4, at 15.

³³ See Letter from Dr. Clifford Duke to Amanda Berman, *supra* note 5.

³⁴ Letter from Dr. Lynn Dekleva to Dr. Kathryn Guyton, *supra* note 31; Letter from Dr. Lynn Dekleva, ACC Formaldehyde Panel, to Dr. Marcia McNutt, NASEM (Aug. 25, 2022), Letter from Dr. Lynn Dekleva, ACC Formaldehyde Panel, to Dr. Marcia McNutt, NASEM (Aug. 15, 2022) <https://www.americanchemistry.com/industry-groups/formaldehyde/resources/formaldehyde-panel-extension-request-to-nasem>; Letter from Dr. Lynn Dekleva, ACC, to Dr. Clifford Duke, NASEM (Aug. 19, 2022) <https://www.americanchemistry.com/industry-groups/formaldehyde/resources/response-to-nasem-on-extension-denial>.

2. NASEM Failed To Address Committee Members' And Staff's Real and Apparent Conflicts Of Interest.

70. NASEM appointed committee members and utilized key staff with apparent conflicts of interest, principally with EPA and its IRIS Program which the Committee is tasked with critiquing.

71. The extent of the conflicts is unclear because NASEM has not disclosed relevant relationships, publications, grants, testimony, and public statements made by the Committee members—despite repeated requests from ACC.³⁵ Notwithstanding NASEM's failure to provide that information, ACC determined that at least three Committee members have had prior significant involvement with EPA regarding the IRIS Program, raising serious concerns about the Committee's independence and impartiality.

72. Dr. Lauren Zeise, in her role as director of the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment ("OEHHA"), oversees the development of risk assessments, hazard evaluations and toxicity reviews in the state of California. EPA's National Center for Environmental Assessment (NCEA), which was reorganized into the Center for Public Health and Environmental Assessment (CPHEA), has previously worked with OEHHA pursuant to a 2009 Memorandum of Understanding (MOU) to coordinate risk assessment methodology, share data and evaluations, and engage in other joint cooperative efforts.³⁶ Given that the IRIS Program is located in and managed by CPHEA, this history raises concerns regarding potential conflicts between Dr. Zeise's interests and those of NASEM. Dr. Zeise recognized this

³⁵ Letter from Dr. Lynn Dekleva to Dr. Kathryn Guyton, *supra* note 31; Letter from Dr. Lynn Dekleva to Dr. Marcia McNutt, *supra* note 34; Letter from Dr. Lynn Dekleva to Dr. Clifford Duke, *supra* note 34.

³⁶ Attachment to ACC Comments on the Provisional Appointments to the National Research Council's Committee to Review the IRIS Process (2010), https://downloads.regulations.gov/EPA-HQ-ORD-2010-0396-0069/attachment_2.pdf.

conflict when she withdrew from a prior NASEM committee reviewing the IRIS Program following the disclosure of the same 2009 MOU between OEHHA and NCEA directly related to the IRIS Program.

73. To date, NASEM has not responded to ACC's August 25, 2022 inquiry regarding the status of any existing MOU between EPA and OEHHA. Even if no MOU exists, considerable concerns remain regarding the propriety of Dr. Zeise's Committee membership given the historical relationship regarding the IRIS Program between her organization (OEHHA) and EPA's group that houses the IRIS Program (NCEA).

74. Dr. Ivan Rusyn served on the 2010 NASEM committee that reviewed EPA's 2010 Assessment and on the NASEM committee to review formaldehyde in the National Toxicology Program 12th Report on Carcinogens. In addition, he chaired a NASEM Committee hosting a workshop to "support development of EPA's IRIS Toxicological Reviews," which addressed scientific issues "related to systematic review, hazard identification, and dose-response analysis."³⁷ Dr. Rusyn stated that while serving as a faculty fellow to the IRIS Program from 2011 to 2013, he "interacted with IRIS staff on a variety of scientific and methodological issues directly relevant to implementation of the advice from the National Academies."³⁸ Dr. Rusyn's direct engagement with EPA concerning formaldehyde and issues directly relevant to this IRIS Assessment conflicts with the EPA Peer Review Handbook, which states that an independent peer

³⁷ NASEM, Workshops to Support Development of EPA's IRIS Toxicological Reviews, <https://www.nationalacademies.org/our-work/workshops-to-support-development-of-epas-iris-toxicological-reviews> (last visited Mar. 13, 2023).

³⁸ EPA's IRIS Program: Reviewing its Progress and Roadblocks Ahead: Hearing Before the Subcomm. on Investigations and Oversight, and Subcomm. on Env't of the H. Comm. on Sci., Space, and Tech., 116th Cong. 2 (2019) (statement of Dr. Ivan Rusyn, Texas A&M University), <https://republicans-science.house.gov/cache/files/a/2/a2e745af-d8e1-4ec8-8ad2-b911a9ab43e3/BA4E9317509D052F516127CA4CF5F256.2019-03-27-testimony-rusyn.pdf>.

reviewer should not be associated with the generation of a work product “either directly by substantial contribution to its development or indirectly by significant consultation during the development of the work product.”³⁹ The EPA Peer Review Handbook advises *against* the use of the same peer reviewer on sequential assessments of the same work product to avoid the appearance of partiality.⁴⁰

75. Separately, Dr. Rusyn has provided Congressional testimony related to EPA’s IRIS Program, in which he described the formaldehyde assessment as one of the “high-quality comprehensive assessments that are ready for completion under the IRIS process” and noted that “delays in completing the evaluation of [formaldehyde] are unacceptable and detrimental to the protection of public health.”⁴¹ Dr. Rusyn’s work and statements raise an inference of a connection to the IRIS Program that could hinder his independent analysis, and indicate that he has a predetermined view of the IRIS Assessment that would interfere with his ability to objectively assess EPA’s work.

76. Dr. Lianne Sheppard has multiple relationships with EPA that, when taken together, create an apparent conflict of interest. Dr. Sheppard is the Chair of EPA’s Clean Air Scientific Advisory Committee and a member of EPA’s Science Advisory Board. She is also a recipient of an EPA grant for the study of long-term exposure to air pollution and the development of cardiovascular disease.⁴² Given that EPA is the sponsor of NASEM’s review of the draft

³⁹ EPA Science and Technology Policy Council, Peer Review Handbook, *supra* note 30, at 70.

⁴⁰ *Id.* at 73.

⁴¹ EPA’s IRIS Program: Reviewing its Progress and Roadblocks Ahead: Hearing Before the Subcomm. on Investigations and Oversight, and Subcomm. on Env’t of the H. Comm. on Sci., Space, and Tech. (statement of Dr. Ivan Rusyn, Texas A&M University), *supra* note 38, at 9-10.

⁴² See EPA, Grantee Research Project Results: The Multi-Ethnic Study of Atherosclerosis and Air Pollution (MESA Air): Next Stage, EPA Grant Number: RD838300,

formaldehyde Assessment, Dr. Sheppard's numerous direct relationships with the agency raise the appearance of a conflict of interest. She has also closely collaborated with the lead author of key studies, the evaluation of which will be a central purpose of this review, though neither she nor NASEM disclosed this relationship to the public.⁴³

77. Moreover, the NASEM study director, Dr. Kathryn Guyton, also has conflicts of interest. Dr. Guyton was previously an EPA career scientist within the IRIS Program. While holding the position of Deputy National Program Director for Human Health Risk Assessment, which includes IRIS, she was actively engaged in developing and reviewing drafts of EPA's formaldehyde assessment in response to the 2011 NASEM peer review of the 2010 Assessment. Dr. Guyton was even listed as a point of contact for EPA's IRIS reforms in response to the 2011 NASEM review.⁴⁴ Indeed, Dr. Guyton served as a "disciplinary workgroup co-chair" during an intra-agency review of EPA's draft assessment. She was a supervisor and coauthor with the EPA formaldehyde chemical managers and authors of the Assessment that is now under review.⁴⁵ This substantive, years-long involvement with the Assessment is omitted from Dr. Guyton's biography

https://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/display.abstractDetail/abstract_id/10841/report/0.

⁴³ Luoping Zhang *et al.*, *Exposure to Glyphosate-based Herbicides and Risk for non-Hodgkin Lymphoma: A meta-analysis and supporting evidence*, 781 *Mutation Rsch./Revs.* in *Mutation Rsch.* 186 (July-Sept. 2019), <https://www.sciencedirect.com/science/article/abs/pii/S1383574218300887>.

⁴⁴ EPA, Human Health Risk Assessment Fact Sheet, https://content.govdelivery.com/attachments/USA-EPA/2012/07/23/file_attachments/143376/HHRA%2BFact%2BSheet%2BJul2012.pdf (last visited Sept. 8, 2023).

⁴⁵ See Kathryn Z. Guyton *et al.*, Human Health Effects of Tetrachloroethylene: Key Findings and Scientific Issues, 122(4) *Env't Health Persps.* 325 (Apr. 1, 2014), <https://ehp.niehs.nih.gov/doi/full/10.1289/ehp.1307359>; see also EPA, Toxicological Review of Formaldehyde—Inhalation CASRN 50-00-0 (Interagency Review Draft), at xxvii (Dec. 2021), https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=544460.

on NASEM’s website, but it appears to create a conflict of interest. Her own work will necessarily be the subject of the Committee’s review.

78. Finally, the Committee’s reliance on and praise for work from the International Agency for Research on Cancer (“IARC”) to support EPA’s conclusions regarding carcinogenicity, *see, e.g.* Report at 39, implicates an additional conflict of interest for Drs. Guyton and Samet. The report lauds and cites as support IARC’s statements on formaldehyde carcinogenicity, but the Report does not disclose that Dr. Guyton, NASEM’s Study Director, and the Committee Chair, Dr. Samet, both have significant financial and institutional ties to IARC, including work on developing, updating, and promoting the IARC procedures related to cancer hazard identification, which the Committee has accepted, endorsed, and used as evidence. Notably, Dr. Samet has close, ongoing ties to IARC; he has “participated in and chaired multiple International Agency for Research on Cancer Working Groups.” Indeed, a 2019 publication by Dr. Samet identifies his “more than three decades” of chairing and participating in IARC groups as a conflict of interest, also noting in the text that his work with IARC creates “potential biases and COIs” – conflicts of interest, particularly related to “serving on expert panels.”⁴⁶

79. Dr. Samet’s Committee biography omits this information, and NASEM has not disclosed any information on financial ties or relationships between Dr. Samet, Dr. Guyton, any other panel member and IARC. Such a failure to disclose key relationships is a violation of the Policy.

80. NASEM’s Report does not address these conflicts of interest.

3. The Committee Has Not Provided Required Transparency Or Allowed For Meaningful Public Input, Particularly About Committee Appointments.

⁴⁶ Jonathan M. Samet, *Expert Review Under Attack: Glyphosate, Talc, and Cancer*, Am. Pub. Health Ass’n, (June 5, 2019), <https://ajph.aphapublications.org/doi/10.2105/AJPH.2019.305131>.

81. NASEM impermissibly failed to provide the public with meaningful information that must be disclosed under FACA. NASEM did not make available to the public information regarding individuals it intended to appoint, comments it received, or the discussions at meetings.

82. NASEM withheld and continues to withhold key information about Committee members. NASEM was required to provide “brief biographies” of proposed members, yet the public information regarding then-proposed (now current) Committee members was sparse and lacking key details such as relevant relationships, publications, grants, testimony, and public statements. NASEM failed to provide adequate biographies of the members to allow the public to understand a panelist’s qualifications, and to comment on any potential bias.

83. ACC submitted multiple requests to NASEM to obtain information that would allow the public to review key biographical details, but NASEM has not provided this information. That failure precluded the public from meaningfully evaluating the scientific integrity, balance, independence, control and management, and conflicts of interest associated with the Committee.

84. Appendix A to NASEM’s Report includes “Committee Member Biographical Sketches,” which still omit the relevant information.

85. NASEM also failed to provide transparency by denying public access to materials presented to the committee by individuals who are not officials, agents, or employees of NASEM. The withheld information includes, but is likely not limited to, nominations from and communications with EPA regarding the membership, other public comments regarding the provisional membership, materials from Members of Congress, and letters from ACC.

86. For example, through a Freedom of Information Act (FOIA) request, ACC learned that EPA employees provided NASEM with committee nominations and encouraged “recycling”

of committee members from prior NASEM committees.⁴⁷ NASEM did not make these communications and recommendations “available to the public”; ACC had to file a FOIA request to access such key information. In fact, ACC had previously requested such documents from NASEM, which failed to respond.⁴⁸ When the requested materials were finally provided through FOIA, they were heavily redacted by EPA, and thus ACC—and the public at large—still does not have all of the relevant information regarding EPA’s role in selecting Committee members.

87. NASEM also did not publish the comments and letters from ACC to NASEM addressing, *inter alia*, Committee membership and NASEM’s access to and use of data and scientific perspectives.

88. ACC does not know the full extent of materials the Committee has received from those outside NASEM, precisely because such information has been withheld. NASEM cannot withhold from the public such relevant materials about its nomination process or other written materials presented to the Committee by individuals who are not officials, agents, or employees of NASEM. NASEM has failed to provide public access to other key materials, as well. Although ACC does not know the full extent of materials the Committee has received from those outside NASEM, NASEM has not published materials it has received from Members of Congress or from ACC.

89. The Report claims that “[w]ritten input provided by members of the public is available upon request via the study’s public access file.” Report at 17. However, NAS has ignored

⁴⁷ E-mails between Dr. Kathryn Guyton, NASEM, and Dr. Stan Barone, EPA (Oct. 4-14, 2021).

⁴⁸ *See, e.g.*, Letter from Sahar Osman-Sypher, ACC Formaldehyde Panel, to Dr. Kathryn Guyton, NASEM (Sept. 9, 2022), <https://urldefense.com/v3/https://www.americanchemistry.com/content/download/11862/file/Letter-to-NASEM-on-Info-Request.pdf> ;!!LB4zUoiJ9F1unGg!q22lrHt4n710BCyalGdsa8X_djeK6RJnzTCZQnah21y1rFEIXNZOVU5TZ5mLGhHuAaH1Qc9E3YTZhRvQwiT7dB2cuWYpBRm_7uw\$.

ACC's numerous requests to provide information it received from those outside NASEM, and the written input discussed above is not in the public access file. Such a denial of transparency violates FACA.

90. Moreover, NASEM unlawfully withheld information about its meetings. On September 1, 2022 the Committee met to discuss its balance and conflicts of interest.⁴⁹ This was not a data gathering meeting; so, under Section 1014(b)(4) of FACA, 5 U.S.C. § 1014(b)(4), NASEM was required to provide "a brief summary of [the] committee meeting."

91. Contrary to FACA, the "summary" of this meeting that NASEM placed on its website is not a summary at all; it does not summarize any discussion or conclusion. NASEM merely identified the topics (e.g. "conflict of interest discussion"). Absent any information about the discussion or conclusions, including whether the meeting resulted in any changes to the provisional committee or disclosure of conflicts, such a conclusory list of topics cannot fairly be deemed a "summary." NASEM's closed meeting and denial of information regarding this meeting violate FACA, Section 1014(b)(4).

92. NASEM's Report does not provide any additional information about this meeting.

93. Through these actions and others, NASEM failed to provide a reasonable opportunity for the public to comment on proposed Committee appointments before they were made. On Friday, August 5, 2022, NASEM announced the provisional committee with an August 25, 2022, deadline to comment, allowing 20 calendar days (14 work days).

94. In light of NASEM's failure to provide complete biographical information with its announcement and the fact that NASEM announced the names and the limited comment opportunity on a Friday afternoon in August, ACC requested that NASEM provide the additional

⁴⁹ NASEM, *supra* note 27.

biographical information and extend the comment period for an additional 20 calendar days to provide a reasonable opportunity for the public to comment.⁵⁰ That extension would have been consistent with common past NASEM practice. Yet, NASEM denied the extension and, together with its failure to provide key information, denied ACC and others a reasonable opportunity to comment on the appointments.

4. EPA Exercised Control Over The NASEM Process.

95. From the outset, EPA improperly influenced NASEM's peer review process. Its first step to control the Committee was to limit the contract task order under which the Committee must operate. EPA mandated that the Committee "shall not conduct an independent assessment separately from the IRIS document nor shall the NASEM comment on the broader aspects of the IRIS program," and shall only use "the charge questions set forth by EPA," also limiting the Committee to responding to the materials provided by EPA and not reviewing additional information. Dr. Guyton confirmed EPA's limitations on the Committee's independence, stating: "The committee's charge is to review the assessment prepared by EPA, and not to conduct their own assessment of formaldehyde. The Committee is also not charged to comment on other interpretations of scientific information relevant to the hazards and risks of formaldehyde" or "to review alternative opinions of EPA's formaldehyde assessment."⁵¹ EPA even dictated the length of "public peer review meeting(s)."⁵²

96. The Report makes clear that the Committee felt bound by EPA's mandate, so "[a]ny other topics not falling within the committee's charge were excluded from the committee's

⁵⁰ Letter from Dr. Lynn Dekleva to Dr. Marcia McNutt, *supra* note 34.

⁵¹ Letter from Dr. Kathryn Guyton to Sahar Osman-Sypher, *supra* note 6.

⁵² Performance Work Statement for Task Order #68HERC21F0401 under NAS Contract #68HERC19D0011, at 3 (Sept. 7, 2021).

purview.” Report at 16. Thus, the Committee did not “comment[] on other interpretations of scientific information,” and did not review “alternative opinions.” Report at 1, 16. The Report notes that it was “the documents provided by EPA that were reviewed by the committee” Report at 16.

97. ACC has consistently objected to these limitations on the scope of the Committee’s review, as it did in an April 2022 letter noting the “troubling signs that EPA may be seeking to unduly narrow the scope of this review, threatening the independence of the peer review process,” and proposing specific steps to avoid repeating the Agency’s past mistakes in this regard.⁵³

98. Next, EPA exercised control over the Committee through the selection of Committee members. In October 2021, Dr. Kathryn Guyton, the Committee’s Study Director, who previously worked at EPA on the IRIS formaldehyde assessment, solicited nominations for Committee members from EPA staff with whom she had previously worked. The EPA staff apparently suggested nominations, and Dr. Guyton thanked EPA “for these great suggestions.”⁵⁴ Dr. Guyton then informed EPA that “there will be ‘recycling’ from the prior committee, including” a name that was redacted in EPA’s FOIA response, and she asked EPA who the Agency would like “for a neurotox person.”⁵⁵ The EPA staff member said that they “Love recycling” and presumably provided further membership recommendations in the portion of the letter that has been redacted.⁵⁶

⁵³ ACC, Comments on the Charge Questions and Committee Task for Peer Review of Draft Formaldehyde Assessment, *supra* note 26.

⁵⁴ E-mails between Dr. Kathryn Guyton and Dr. Stan Barone, *supra* note 47.

⁵⁵ *Id.*

⁵⁶ *Id.*

99. Thus, the current NASEM Study Director sought EPA's recommended preferences for Committee members and revealed to EPA details of committee membership and the members' work on the prior committee. This was all done *before* proposed members were publicly identified and allegedly *before* any decisions had been made.

100. EPA not only presented specific scientists the Agency thought should be on the Committee, it encouraged the Study Director to select members drawn from the prior committee.

101. Through these actions, the Study Director ceded to EPA meaningful control over the selection of committee members. NASEM was subject to management or control by EPA because the Agency significantly influenced the Committee's membership in a way that members of the public cannot. EPA recognized as much by withholding information regarding its role in selecting committee members as pre-decisional and "deliberative" in nature (i.e., internal communications leading to *an EPA* decision) in response to ACC's FOIA requests.

102. Although EPA, like any member of the public, may offer suggestions of potential committee members during the public nomination process or comment on the proposed members during the public comment period, NASEM cannot actively solicit individual nominees from the sponsoring agency or provide the Agency advance notice of nominees or their past work to gauge Agency feedback before publicly identifying nominees.

103. Moreover, EPA is also indirectly controlling the activities and reports of the Committee through NASEM personnel with close ties to EPA and the IRIS Program. The NASEM Study Director, Dr. Guyton, was previously an EPA senior manager within the IRIS Program. She served at EPA from 2005 to 2014, including as a senior official in EPA's Office of Research and Development's ("ORD's") National Center for Environmental Assessment, which produces IRIS assessments. She served as a supervisor and co-author of EPA's 2010 draft assessment for

formaldehyde. Dr. Guyton was then listed as a point of contact for EPA's IRIS reforms in response to the NASEM's heavily critical 2011 review of that assessment.⁵⁷ And Dr. Guyton was a reviewer for, and oft cited within, EPA's 2020 ORD Staff Handbook for Developing IRIS Assessments.⁵⁸

104. NASEM's client for this review (EPA) thus consists of Dr. Guyton's former colleagues, with whom she worked closely on the prior IRIS formaldehyde assessment and to revise the IRIS assessment process after that assessment was panned by NASEM in 2011. Details of Dr. Guyton's connections to these EPA colleagues whose work NASEM will review is described in subsection E(2) (§ 77) above. These former colleagues have used their connection to Dr. Guyton to shape the review, such as by identifying "key references" or studies NASEM should consider when "reviewing formaldehyde."⁵⁹

105. Although the Study Director is not a member of the NASEM peer review committee *per se*, the Study Director plays an active and substantive role throughout the peer review process. Their role includes "prepar[ing] background materials" and "writ[ing] or edit[ing] portions of the consensus study report."⁶⁰ These duties are not mere ministerial tasks without influence on the nature or outcome of the peer review. For example, how background materials are developed has the potential to influence how peer reviewers view the scientific issues. In practice, NASEM Study Directors also draft a large part of the study report for review by the Committee members, thus

⁵⁷ EPA, *supra* note 44.

⁵⁸ EPA, Center for Public Health and Environmental Assessment, ORD Staff Handbook for Developing IRIS Assessments (Nov. 2020), https://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=541571.

⁵⁹ E-mails between Dr. Kathryn Guyton and Dr. Stan Barone, *supra* note 47.

⁶⁰ NASEM, The Consensus Study Process of the National Academies of Sciences, Engineering, and Medicine, A Guide for Committee Members, at 7 (Feb. 2016), https://sites.nationalacademies.org/cs/groups/ssbsite/documents/webpage/ssb_173594.pdf.

shaping the framework and conclusions of the study. Dr. Guyton's connection to EPA undermines a core principle of independent scientific peer review, in addition to violating FACA.

106. Dr. Guyton is not the only person involved with the Committee who may feel bound by EPA "suggestions." Based on a review of EPA's federal advisory committee lists, as well as the General Services Administration Federal Advisory Committee Act database, the 13 NASEM Committee members have served on over 220 federal advisory committees at EPA and the Department of Health and Human Services, including by serving as a special government employee and consultant members. Overall, 12 of the 13 members have served on EPA or HHS advisory committees, with 9 members having served on more than 10 panels. This work includes ongoing service on major chartered EPA advisory committees with a potential role reviewing the IRIS Assessment and its uses, including the Science Advisory Board and the Clean Air Scientific Advisory Committee. OMB Peer Review Guidance notes that "if a scientist has repeatedly served as a reviewer for the same agency, some may question whether that scientist is sufficiently independent from the agency to be employed as a peer reviewer on agency-sponsored projects."⁶¹

107. Moreover, recent and *ongoing* EPA grants to Committee members on topics relevant to the current formaldehyde Assessment bind many to EPA, allowing EPA to exercise real and apparent control over the review process. Based on a review of one EPA Office of Research and Development grantee database, some Committee members serve as principal investigators on projects running through 2023 that are relevant to the current formaldehyde Assessment but rely on grants from EPA.

⁶¹ Executive Office of the President, Office of Management and Budget, Final Information Quality Bulletin for Peer Review, at 18 (Dec. 16, 2004), <https://georgewbush-whitehouse.archives.gov/omb/memoranda/fy2005/m05-03.pdf>.

108. Thus, there is ample evidence that EPA is exercising control over the Committee through its connections to the Study Director, and such controlling influence may extend to other Committee members. NASEM therefore cannot certify that the Committee is not subject to EPA management or control and, under Section 1014(a) of FACA, EPA cannot use any resulting report.

F. The NASEM Committee Ignored Relevant Scientific Information and Perspectives In Violation Of NASEM's Scientific Integrity Obligations.

109. The Committee has willfully limited its receipt of, and not meaningfully considered, relevant information from sources outside EPA or perspectives from sources outside EPA, violating the scientific integrity requirements in NASEM's contract with EPA and making unreasonable any future reliance by EPA on any resulting report.

110. Under EPA's Acquisition Regulations, NASEM is required to maintain "scientific integrity" and to notify EPA if there is "an actual or suspected loss of scientific integrity." EPAAR 1552.203-72(d). "Scientific Integrity" "provides insulation from bias, . . . improper outside interference, and censorship." EPAAR § 1552.203-72(b). As such, NASEM was obligated to "Prohibit suppressing . . . scientific findings or conclusions." EPAAR § 1552.203-72(c)(1)(ii). To that end, NASEM is required to ensure that "the presentation of results and conclusions is impartial." EPAAR § 1552.203-72(c)(1)(v). Such requirements apply in order to allow EPA to reasonably rely on NASEM's conclusions, because, if NASEM's process lacked scientific integrity, it would be unreasonable and unsupportable for EPA to use the resulting conclusions.

111. NASEM failed to meet these scientific obligations by only considering EPA's view of the evidence, and has not developed its work with scientific integrity, in violation of its contract. During the "open sessions," which are ostensibly designed to solicit public comment on scientific issues, NASEM made clear that its true goal is "to engage in a question-and-answer session with

EPA,” not the public, and that “the committee’s view [is] that the sponsor, EPA, is best positioned to . . . answer questions on the assessment of formaldehyde.”⁶²

112. To that end, at its January 30, 2023 meeting, the Committee gave EPA an hour for its in-person audio-visual presentation and its direct communications with the Committee. In direct contrast, the Committee limited individual public comments to three minutes over Zoom with no visual aids—and limited which members of the public were permitted to speak so that the Committee could cap the total comment time for all non-EPA scientists to the same amount of time given to the Agency.⁶³

113. In response to ACC’s concerns regarding this procedure, NASEM admitted that the purpose of the meeting was “to provide an opportunity for the committee to engage in a question-and-answer session with EPA” because “[t]he committee’s charge is to review the assessment prepared by EPA, and not to conduct their own assessment of formaldehyde.”⁶⁴

114. NASEM admitted that it does not view its role as including “review [of] alternative opinions of EPA’s formaldehyde assessment.”⁶⁵ NASEM made clear that it weighs EPA’s information more heavily than information from other sources and has willfully limited its receipt and consideration of information from scientists outside the agency.

115. The Report echoes these limitations. It notes that “[t]he committee did not conduct an independent hazard evaluation or dose-response assessment,” did not “comment[] on other

⁶² Letter from Dr. Kathryn Guyton to Sahar Osman-Sypher, *supra* note 6.

⁶³ NASEM, Committee to Review EPA’s 2022 Draft Formaldehyde Assessment: Meeting 3 Agenda (Jan. 30 2023), <https://www.nationalacademies.org/documents/embed/link/LF2255DA3DD1C41C0A42D3BEF0989ACAECE3053A6A9B/file/D75DD3A436BE4DF83F9232960665095194A3001588F0?noSaveAs=1>.

⁶⁴ Letter from Dr. Kathryn Guyton to Sahar Osman-Sypher, *supra* note 6.

⁶⁵ *Id.*

interpretations of scientific information,” and did not review “alternative opinions.” Report at 1, 16. The Report notes that it was “the documents provided by EPA that were reviewed by the committee.” (Report at 16.) Thus, the Committee’s review was effectively a review of the procedures by which EPA developed the Assessment, and not the underlying substance or the Agency’s conclusions.

116. Despite these limitations on the scope of review and analysis, the Report presents a broad conclusion that the Assessment’s “findings on hazard and quantitative risk are supported by the scientific evidence identified.” Report at xi-xii. Such a conclusion is not supported by the limited scope of review.

117. To the extent the Committee accepted public comments, NASEM published the relevant information in such a way as to limit outside scientists’ ability to prepare comments. On January 6, 2023, the Committee sent EPA a list of questions,⁶⁶ but NASEM did not publish these questions until the same day as the January 30 public meeting. EPA sent a 40-page response to those questions on January 27, but again, NASEM did not make this document available until the January 30 public meeting. By failing to give the public, including ACC and its members, reasonable time to review these detailed, technical documents in advance of the meeting, NASEM precluded meaningful public comments that could address strengths, weaknesses, mischaracterizations, or inaccuracies in EPA’s response.

118. For example, the Committee asked EPA how it determined study quality and assured consistency across working groups. Had they had time, members of the public could have presented meaningful input regarding the sufficiency of EPA’s answers or identified issues that

⁶⁶ NASEM, Committee to Review EPA’s 2022 Draft Formaldehyde Assessment: Meeting 3 Agenda, *supra* note at 63.

EPA failed to address. But NASEM denied ACC's request that it hold a public information gathering session, and precluded submission of such relevant comments so that only EPA could prepare and provide substantive responses. NASEM thus willfully exposed the Committee only to EPA's views and suppressed "alternative opinions of EPA's formaldehyde assessment."

119. Furthermore, the Committee Chair, Jonathan Samet, has made public comments that call into question his objectivity. The week after the Committee began deliberations in October 2022, Dr. Samet published a blog post, commenting on key issues in the review. For example, Dr. Samet stated that, since 2011, EPA "has fully revised its procedures for IRIS," and EPA's methods and causal judgments in IRIS "have proved to be effective and supported many measures that have advanced public health."⁶⁷ These comments by the chair, in advance of review of the formaldehyde IRIS Assessment, indicate a lack of objectivity regarding the subject of the ongoing review.

120. Dr. Samet has now repeated his views in the Preface to the Report, wherein he noted that, since 2011, "and in response to additional recommendations of the National Academies, the methods used by the IRIS Program have evolved" and "increasingly reflect the state of practice." Report at xi. Dr. Samet thus concludes that "[overall], the committee found that the methods used for the assessment were appropriate." *Id.*

121. The preface to the Report goes on to say that "EPA's mission is to protect human health," and the Assessment "addresses a widely used, high-volume production chemical," so the Assessment "needs to be completed to support EPA in accomplishing this mission." Report at xi-xii. It states that "the committee urges closure on the Draft Assessment" and "[t]he committee's

⁶⁷ Jonathan Samet, *The COVID-19 Pandemic & More: Colorado's Plateau Continues, and Causation and its Consequences*, Colorado School of Public Health Dean's Notes (Oct. 18, 2022), <https://coloradosph.cuanschutz.edu/news-and-events/newsroom/deans-notes/public-health-main-site-news/the-covid-19-pandemic-more-colorado-s-plateau-continues-and-causation-and-its-consequences>.

recommendations should be undertaken expeditiously to complete a revised assessment document that can be implemented without delay.” Report at xii.

122. The views expressed in the Report’s preface also mirror those in Dr. Rusyn’s 2019 Congressional testimony, years before beginning the Committee’s review, where he advocated for EPA to complete the IRIS formaldehyde assessment.⁶⁸ The degree to which the Report repeats Committee members’ comments from before their review of the Assessment indicate a lack of objectivity.

123. Moreover, the Report’s statement that the Assessment “needs to be completed to support EPA in accomplishing this mission” and that “the committee urges closure on the Draft Assessment,” Report at xi-xii, which contradict the numerous, specific recommendations and issues identified in the Report, do not indicate objective scientific integrity. Instead, these statements reflect the non-scientific policy viewpoints of the Chair, Study Director, and members of the Committee.

124. Juleen Lam, one of the “individuals chosen” by NASEM to conduct the “independent review” of the Report, Report at vii, has demonstrated bias and preconceived notions of the issues under review through her prior comments and publications. Therefore, the “independent review” does not, as NASEM suggests, “assist the National Academies of Sciences, Engineering, and Medicine in making each published report as sound as possible and to ensure that it meets the institutional standards for quality, objectivity, evidence, and responsiveness to the study charge.” Report at vii. On March 31, 2021, Dr. Lam published a blog post illustrating a

⁶⁸ See EPA’s IRIS Program: Reviewing its Progress and Roadblocks Ahead: Hearing Before the Subcomm. on Investigations and Oversight, and Subcomm. on Env’t of the H. Comm. on Sci., Space, and Tech. (statement of Dr. Ivan Rusyn, Texas A&M University), *supra* note 38, at 9.

closed mind on key scientific questions as well as bias against industry participation in the regulatory process and in favor of a particular outcome towards stringent regulation of formaldehyde.⁶⁹ Dr. Lam has also previously co-authored and submitted comments expressing her views regarding the draft IRIS Assessment under review,⁷⁰ EPA's TSCA prioritization,⁷¹ and the IRIS handbook,⁷² which are either directly or indirectly implicated by the IRIS Assessment and the Committee's review thereof. Dr. Lam also recently co-authored the article "A Science-Based Agenda for Health-Protective Chemical Assessments And Decisions: Overview And Consensus Statement," which, together with her comments, demonstrates her preconceived notion regarding industry, chemical hazards, and the IRIS program.⁷³ Dr. Lam's repeated comments provide additional evidence of a lack of objectivity, independence, and balance.

125. In addition, nearly all of the new reviewers of the Committee's report have previously served as NASEM committee members on reviews of IRIS or formaldehyde or have

⁶⁹ Dr. Juleen Lam, Formaldehyde and EPA – Time for a Change, Program on Reproductive Health and the Environment (Mar. 31, 2021), <https://prheucsf.blog/2021/03/31/formaldehyde-and-epa-time-for-a-change/>.

⁷⁰ University of California, San Francisco Program on Reproductive Health and the Environment, Comments on the Draft Toxicological Review of Formaldehyde – Inhalation Toxicity, at 5 (June 13, 2022), <https://www.regulations.gov/comment/EPA-HQ-ORD-2010-0396-0099>.

⁷¹ U.S. Academic Scientists, Comments on Risk-Based Prioritization Procedural Rule Under TSCA section 6(b)(1) (Aug. 24, 2016), <https://prhe.ucsf.edu/sites/g/files/tkssra341/f/wysiwyg/10%20TSCA%20Risk-Based%20Prioritization.pdf>.

⁷² Comments on the ORD Staff Handbook for Developing IRIS Assessments (Mar. 1, 2021), https://prhe.ucsf.edu/sites/g/files/tkssra341/f/wysiwyg/IRIS%20Handbook_UCSF%20PRHE_%20EPA%20IRIS_Final_0.pdf.

⁷³ T. Woodruff *et al.*, A Science-Based Agenda for Health-Protective Chemical Assessments and Decisions: Overview and Consensus Statement, 21 *Env't Health*, article no. 132 (Jan. 2023), <https://ehjournal.biomedcentral.com/articles/10.1186/s12940-022-00930-3>.

other ties EPA and the IRIS program. Report at vii. EPA's *Peer Review Handbook* calls for avoiding repeatedly turning to the same peer reviewers as "they may lose their impartiality (or the appearance of impartiality) relative to the work product(s)." ⁷⁴ The prior work of the "individuals chosen" by NASEM to conduct the "independent review" of the Report, Report at vii, indicate potential ties to NASEM, such as through their repeated work with NASEM committees. Such ties create conflicts and reduce scientific integrity.

G. NASEM Continues to Violate FACA Even After Plaintiff Raised Concerns

126. Since October 28, 2021, ACC repeatedly attempted to engage with NASEM regarding both the science and the process as NASEM selected Committee Members and the Committee began its evaluation. Most recently, on April 20, 2023, ACC sent a 15-page letter to NASEM detailing all of the concerns and violations described in this Complaint. ⁷⁵

127. These efforts to ensure an appropriate review were rebuffed by NASEM, which has failed to respond to most of ACC's concerns and communications and has not made any adjustments. For example, in response to ACC's April 20, 2023, NASEM responded to ACC with a two-paragraph letter stating that "speculation about the Committee's analysis of the information provided to it is premature" and "the study is being conducted in accordance with the policies and procedures of the National Academy of Sciences that implement the requirements of" FACA. ⁷⁶ NASEM did not explain how the deficiencies identified above and in ACC's letter did not constitute violations of FACA. NASEM has continued to convene meetings of its flawed Committee and has failed to make public the required information. Even in the Report, the

⁷⁴ EPA Science and Technology Policy Council, *Peer Review Handbook*, *supra* note 30, at 70.

⁷⁵ Letter from Amanda Berman to Drs. Marcia McNutt and Clifford Duke, *supra* note 4.

⁷⁶ *See* Letter from Dr. Clifford Duke to Amanda Berman, *supra* note 5.

Committee failed to make the required information public and has not addressed conflicts or balance of the Committee.

CLAIMS FOR RELIEF

COUNT I

Mandamus, 28 U.S.C. § 1361

**Violation of FACA, 5 U.S.C. § 1014(b)(1)(B):
Failure to Fairly Balance Committee's Membership**

128. Plaintiff repeats and incorporates by reference all of the allegations set forth above.

129. Section 1014(b)(1)(B) of FACA requires that NASEM “shall make its best efforts to ensure that . . . the committee membership is fairly balanced as determined by the Academy to be appropriate for the functions to be performed.” 5 U.S.C. § 1014(b)(1)(B).

130. The Committee is a committee created by NASEM under an agreement with EPA and is subject to FACA.

131. The Committee is not fairly balanced in terms of expertise or experience. The thirteen-member Committee includes seven non-occupational epidemiologists, but does not include a single scientist with a background or expertise in occupational epidemiology; biological modeling including mechanisms of carcinogenicity; PBPK modeling; hematology; reproductive and developmental toxicity, endogenous formaldehyde, or private sector industrial toxicology and industrial epidemiology. EPA specifically noted in its task order to NASEM that most of these disciplines were key to a robust review, and ACC has explained the need for the other expertise. A committee where over half of the members focus on the same discipline is not balanced.

132. NASEM thus failed to take best efforts to ensure that the Committee is fairly balanced, in violation of Section 1014(b)(1)(B) of FACA and NASEM's implementing Policy. The Court should so declare, and exercise its mandamus authority to direct NASEM to comply.

COUNT II

Mandamus, 28 U.S.C. § 1361

**Violation of FACA, 5 U.S.C. § 1014(b)(1)(A):
Failure to Avoid Conflicts of Interest**

133. Plaintiff repeats and incorporates by reference all of the allegations set forth above.

134. Section 1014(b)(1)(A) of FACA requires NASEM to ensure that “no individual appointed to serve on the committee has a conflict of interest that is relevant to the functions to be performed, unless such conflict is promptly and publicly disclosed and the Academy determines that the conflict is unavoidable.” 5 U.S.C. § 1014(b)(1)(A).

135. In implementing this statutory requirement, NASEM’s Policy states (at 1) that committee members must be “transparent about their relevant relationships and publications, and independent from the sponsors of the committee’s work.” The Committee and its members have not followed this directive.

136. The Committee is a committee created by NASEM under an agreement with EPA and is subject to FACA.

137. As set forth above, numerous persons serving on the Committee have actual and/or potential conflicts of interest that are relevant to the functions of the Committee; i.e., review of EPA’s IRIS Assessment. Dr. Guyton, Dr. Zeise, Dr. Rusyn, and Dr. Sheppard all have personal connections to EPA, its IRIS program, and the Assessment that preclude objectivity and an unbiased review of the Assessment.

138. Although FACA Section 1014(b)(1)(A) permits persons with a conflict of interest to serve on a committee if the conflict is unavoidable and publicly disclosed, NASEM has failed to assert that these numerous conflicts are unavoidable, let alone explain why such an exception

may apply. NASEM likely cannot do so given the many qualified alternative panel members, including those identified by ACC. NASEM has not even disclosed the pertinent conflicts.

139. NASEM failed to disclose and address Committee members' conflicts of interest in violation of FACA Section 1014(b)(1)(A). This Court should so declare, and exercise its mandamus authority to direct NASEM to comply.

COUNT III

Mandamus, 28 U.S.C. § 1361

Violation of FACA, 5 U.S.C. § 1014(b)(1): Failure to Provide Biographies of Committee Members

140. Plaintiff repeats and incorporates by reference all of the allegations set forth above.

141. Section 1014(b)(1) of FACA requires NASEM to ensure that it provides the public with “the names and brief biographies of individuals that the Academy appoints or intends to appoint to serve on the committee.”

142. The Policy expands on the meaning of this FACA requirement, stating that committee members must be “transparent about their relevant relationships and publications.” Policy at 1. The Policy further directs members of a committee to disclose publications “relevant to the issues to be addressed” at the time of committee formation. *Id.* at 3.

143. The Committee is a committee created by NASEM under an agreement with EPA and is subject to FACA.

144. NASEM failed to provide adequate biographies of the members to allow the public to understand a panelist's qualifications, and to comment on any potential bias. The public information regarding Committee members was sparse and lacking key details such as relevant relationships, publications, grants, testimony, and public statements. NASEM should have, but did

not, provide the public with information pertaining to relevant relationships, publications, and potential interests that give an appearance of a lack of impartiality.

145. Such inadequate information does not satisfy the FACA Section 1014(b)(1) requirement to provide biographies of Committee members. This Court should so declare, and exercise its mandamus authority to direct NASEM to comply.

COUNT IV

Mandamus, 28 U.S.C. § 1361

Violation of FACA, 5 U.S.C. § 1014(b)(3) and (4): Failure to Publicly Disclose Committee Materials and Meeting Summaries

146. Plaintiff repeats and incorporates by reference all of the allegations set forth above.

147. Under FACA Section 1014(b)(3), NASEM must “make available to the public . . . written materials presented to the committee by individuals who are not officials, agents, or employees of the Academy, unless the Academy determines that making material available would disclose matters” subject to a FOIA exemption.

148. The Committee is a committee created by NASEM under an agreement with EPA and is subject to FACA.

149. NASEM denied public access to materials presented to the Committee. For example, ACC submitted letters to the Committee, yet NASEM has not made those submissions publicly available. EPA employees also sent written materials, such as emails, to the Committee, but NASEM has withheld these materials.

150. Under FACA Section 1014(b)(4) NASEM must “make available to the public as soon as practicable . . . a brief summary of any committee meeting that is not a data gathering meeting, unless the Academy determines that the summary would disclose matters” subject to a FOIA exemption. FACA specifies that, at minimum, the summary “shall identify the committee

members present, the topics discussed, [and] materials made available to the committee”, though it should also include any “other matters that the Academy determines should be included.” NASEM has not complied with these requirements.

151. NASEM has thereby violated FACA Section 1014(b)(4). This Court should so declare, and exercise its mandamus authority to direct NASEM to comply.

COUNT V

Mandamus, 28 U.S.C. § 1361

Violation of FACA, 5 U.S.C. § 1014(b)(1): Failure to Provide Opportunity for Public Comment

Plaintiff repeats and incorporates by reference all of the allegations set forth above.

152. Section 1014(b)(1) of FACA requires that NASEM “provide a reasonable opportunity for the public to comment on appointments before they are made or, if the Academy determines prior comment is not practicable, in the period immediately following the appointments.”

153. The Committee is a committee created by NASEM under an agreement with EPA and is subject to FACA.

154. NASEM did not provide a reasonable opportunity for the public to comment on Committee appointments. From the time NASEM announced the provisional committee, it allowed only 20 calendar days (14 work days) for public comment, in the middle of summer when many are traveling. Contrary to past practice, NASEM declined to extend the time to provide comments when asked by ACC, and refused to provide requested information regarding proposed Committee members.

155. NASEM thus denied ACC and others a reasonable opportunity to comment on the appointments in violation of Section 1014(b)(1) of FACA. This Court should so declare, and exercise its mandamus authority to direct NASEM to comply.

COUNT VI

Mandamus, 28 U.S.C. § 1361

Violation of FACA, 5 U.S.C. § 1014(b)(1)(C): Failure to Exercise Independent Judgment

156. Plaintiff repeats and incorporates by reference all of the allegations set forth above.

157. To comply with FACA, committees have a nondiscretionary duty to ensure that “the final report of the Academy will be the result of the Academy’s independent judgment.” 5 U.S.C. § 1014(b)(1)(C).

158. The Committee is a committee created by NASEM under an agreement with EPA and is subject to FACA.

159. EPA has controlled the NASEM Committee, including by effectively selecting the Committee members, specifying information the Committee should review, limiting the Committee’s ability to review alternative analyses, and otherwise controlling the activities and reports of the Committee. The resulting Report cannot be said to be NASEM’s independent judgement.

160. NASEM has failed to ensure the independence of its final Report, in violation of FACA Section 1014(b)(1)(C). This Court should so declare, and exercise its mandamus authority to direct NASEM to comply.

COUNT VII (against EPA)

APA, 5 U.S.C. § 706

Unlawful Reliance on Report in Violation of FACA, 5 U.S.C. § 1014(a), and the APA

161. Plaintiff repeats and incorporates by reference all of the allegations set forth

162. Pursuant to Section 1014(a) of FACA, 5 U.S.C. § 1014(a), an agency may not use the advice or recommendation of a NASEM committee if the committee was “subject to any actual management or control by an agency or an officer of the Federal Government.”

163. The Committee is a committee created by NASEM under an agreement with EPA and is subject to FACA.

164. Appendix A to the regulations implementing Section 1014 of FACA (41 C.F.R. Pt. 102–3, Subpart E) clarifies that an agency can “enter into a funding agreement with” NASEM to prepare a report “containing advice or recommendation to the agency . . . without subjecting” NASEM to “actual management or control” “*if the members of the committee are selected by the academy and if the committee’s meetings, deliberations, and the preparation of reports are all controlled by the academy.*” 41 C.F.R. Pt. 102–3, Subpt. E, App. A. Here, as described above, EPA effectively selected Committee members and controlled the activities and reports of the Committee.

165. Section 1014(a) of FACA also prohibits an agency from using advice provided by NASEM if the Committee failed to satisfy FACA Section 1014(b)(1); i.e., if the Committee failed to provide “brief biographies of individuals that the Academy appoints or intends to appoint to serve on the committee,” “provide a reasonable opportunity for the public to comment on appointments before they are made,” or “make its best efforts to ensure that . . . no individual appointed to serve on the committee has a conflict of interest.” 5 U.S.C. § 1014(b)(1). The Committee failed to satisfy these requirements, and therefore EPA may not lawfully rely on its Report.

166. Moreover, Section 1014(a) of FACA prohibits an agency from using advice of NASEM if the Committee failed to satisfy FACA Sections 1014(b)(2) through (b)(4). Thus, EPA

cannot rely on a report from NASEM unless NASEM “ensure[d] that meetings of the committee to gather data from individuals who are not officials, agents, or employees of the Academy [were] open to the public”; “ma[de] available to the public . . . written materials presented to the committee by individuals who are not officials, agents, or employees of the Academy”; and “ma[de] available to the public . . . a brief summary of any committee meeting that is not a data-gathering meeting.” 5 U.S.C. § 1014(b)(3), (4). As described above, the Committee failed to satisfy each of these requirements.

167. Finally, an agency may not make findings or conclusions that are arbitrary or capricious. 5 U.S.C. § 706. NASEM’s willful blindness to information and perspectives outside of EPA results in a lack of scientific integrity. Any EPA finding or conclusion based on a report from NASEM that was developed without scientific integrity would be arbitrary and capricious.

168. It would be unlawful, arbitrary, and capricious for EPA to rely on the Committee’s Report, in violation of 5 U.S.C. § 706. This Court should enjoin EPA from doing so.

COUNT VIII (against all Defendants)

Declaratory Judgment Act, 28 U.S.C. § 2201

169. Plaintiff repeats and incorporates all of the allegations set forth above.

170. Where statutory duties are violated, courts may also act pursuant to the Declaratory Judgment Act, including as an alternative or in addition to granting mandamus relief.

171. As described in Counts I - VII, Defendants have violated Section 1014 of FACA.

172. Plaintiff is entitled to a declaration under 28 U.S.C. § 2201 that the conduct described in each of the aforementioned counts violates FACA.

PRAYER FOR RELIEF

Wherefore, Plaintiff respectfully request that this Court enter judgment in its favor and against Defendants as follows:

- a) Declare that Defendant NASEM violated FACA by, *inter alia*:
 - 1) violating the requirement that the Committee be “fairly balanced” in that the Committee lacks any members with backgrounds and expertise in private sector toxicology or the other disciplines described above;
 - 2) failing to address committee members’ actual and apparent conflicts of interest;
 - 3) withholding key information about committee members’ biographies;
 - 4) failing to publish written materials presented to the Committee or a summary of Committee meetings;
 - 5) inappropriately limiting the public’s ability to comment on nominations; and
 - 6) failing to ensure independent judgment;
- b) Declare that EPA impermissibly controlled the Committee in violation of FACA;
- c) Direct and enjoin NASEM to include on all copies of the Report, whether in hard copy or electronic and whether prepublication copies or publication copies, a disclaimer that the Committee was convened in violation of FACA and the Report was not generated in accordance with FACA so the Report should not be used by any agency;
- d) Declare that EPA’s use of the Report issued by the Committee would be arbitrary, capricious, or otherwise contrary to law in violation of the APA;
- e) Permanently enjoin EPA from accepting, publishing, using, or relying upon the Report or any conclusions or recommendations produced by the existing Committee;
- f) Direct NASEM to comply with FACA in any future review of EPA’s formaldehyde Assessment;
- g) Award Plaintiff its reasonable costs, including attorneys’ fees, incurred in bringing this action; and
- h) Grant any other relief as the Court deems just and equitable.

Dated: September 15, 2023

Respectfully submitted,

/s/ Amanda Shafer Berman

Amanda Shafer Berman

(D.C. Bar No. 4978600)

Amy Symonds

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