IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN CHEMISTRY COUNCIL, INC.,
Plaintiff,

v.

NATIONAL ACADEMY OF SCIENCES;

U.S. ENVIRONMENTAL PROTECTION AGENCY;

MICHAEL S. REGAN, in his official capacity as Administrator of U.S. Environmental Protection Agency,

Defendants.

Case: No. 23-cv-2113

MEMORANDUM IN SUPPORT OF MOTION FOR PRELIMINARY OR PERMANENT INJUNCTIVE RELIEF

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I. INTRODUCTION

ACC asks this Court to preliminarily or permanently enjoin EPA from citing, relying on, disseminating, or otherwise using the NAS Report reviewing EPA's 2022 draft formaldehyde Assessment, issued in pre-publication form on August 9, 2023, unless and until EPA and NAS comply with all applicable FACA requirements. ACC and its members face imminent, irreparable harm from EPA's reliance on the NAS Report to, inter alia, finalize "IRIS" risk values for formaldehyde—a critical chemical building block essential to many products.

The Committee, which NAS constituted for the purpose of reviewing EPA's draft formaldehyde Assessment under a contract awarded it by EPA, violated the provisions of FACA applicable to NAS, 5 U.S.C. § 1014, in many ways. The Committee failed to disclose, let alone justify, Committee members' apparent conflicts of interest. The Committee is unbalanced and biased, lacking personnel with expertise in relevant scientific disciplines–as well as *any* members from industries that use formaldehyde. Certain Committee members demonstrated strong bias in favor of EPA's Assessment throughout the process—and they were not counterbalanced by others more skeptical of EPA's process or conclusions. The Committee also failed to publish information and materials it is required to provide to the public under FACA, including but not limited to member biographies, meeting minutes, and public submissions. And the Committee has been improperly controlled by EPA, which dictated its composition and limited the scope of its review so as to make resulting conclusions meaningless. In short, the Committee's review process has been superficial and toothless, rather than the robust, arms-length analysis required by FACA.

Because of these FACA violations, the Committee's Report on EPA's formaldehyde Assessment is the tainted fruit of a poisoned process. The public cannot be assured that it is scientifically sound—and indeed it is not. The Report (Ex. A) admits that EPA limited the scope of the Committee's review to, in essence, the form rather than the substance of the Assessment.

But despite admitting that the Committee did not attempt to substantively verify EPA's conclusions regarding toxicity and human health hazards from formaldehyde, the Report nonetheless seems to sanction those very conclusions. And EPA has already characterized the Report as sanctioning EPA's conclusions on toxicity, while failing to mention the Report's recognition of the deliberately limited scope of the Committee's inquiry.[1]

Because the Committee failed to comply with FACA's requirements for NAS reviews of agency activities, *see* 5 U.S.C. § 1014(b), and because EPA improperly controlled NAS's review, *id*. § 1014(a)(1), EPA "may not use" the Report. *Id.* § 1014(a). But there is substantial evidence that EPA is about to do just that.[2] Indeed the Report urges EPA to move expeditiously to finalize the formaldehyde Assessment. Ex. A, NAS Report at xii. To do so, EPA must rely on NAS's Report, because peer review is a necessary step before finalizing IRIS assessments.[3] This IRIS Assessment will then be used in many ways, ranging from direct regulation by EPA and other agencies to enforcement actions by the Department of Justice, and to support proposed state-level

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[1] EPA, *NASEM Releases Peer Review Report of Draft IRIS Formaldehyde Assessment*, https://www.epa.gov/newsreleases/national-academies-sciences-engineering-and-medicine-releases-peer-review-report-draft (Aug. 9, 2023), ("The consensus NASEM study report released today acknowledges the substantial improvements made by EPA. The NASEM committee notes that EPA's draft 'follows the advice of prior National Academies reports and that its findings on hazard and quantitative risk are supported by the evidence identified.'").

[2] *See id*. ("EPA is currently assessing the recommendations provided by the NASEM committee and plans to use the report to revise the draft IRIS formaldehyde assessment prior to finalization. EPA's [ ] offices intend to use the final assessment as part of the scientific input for developing risk assessments and . . . to support future risk management decisions.").

[3] *See, e.g.*, *NCEA Policy and Procedures for Conducting IRIS Peer Reviews*, at 5 (eff. July 30, 2009), https://www.epa.gov/sites/default/files/2014-05/documents/policy_iris_peer_reviews.pdf ("All draft human health assessments developed under the IRIS program are subjected to rigorous, independent external peer review."); EPA, *Basic Information about the Integrated Risk Information System*, https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system#process (last visited Oct. 4, 2023) (listing "External Peer Review" as step 4 in the IRIS process, before revisions and finalization).

bans of formaldehyde.[4] To allow EPA to disseminate and rely on the Report, characterizing it as sanctioning EPA's conclusions regarding toxicity, cancer, and other potential hazards related to formaldehyde, would irreparably harm ACC's members. It would also harm the public, which relies on products (including furniture, electric vehicles, wood products, and crop nutrition products, to name just a few) for which formaldehyde is a key building block. ACC therefore asks this Court to enjoin EPA from using the Report until NAS complies with FACA's requirements.

II. LEGAL BACKGROUND

When Congress amended FACA in 1997, it clarified that any committee "created by the National Academy of Sciences" is excluded from the definition of "advisory committee" under FACA, Federal Advisory Committee Act – 1997 Amendments, Pub. L. No. 105-153, § 2, 111 Stat. 2689 (1997), and is exempt from the requirements in the first 14 sections of FACA.

However, the 1997 amendments did not absolve NAS and its committees of all obligations under the Act. To the contrary, Congress added a new section 15 to FACA, containing special requirements relating to the committees of the Academy, including public disclosure requirements. 5 U.S.C. § 1014. Congress expected that, as a result of the 1997 amendments, "the processes used by NAS . . . w[ould] be more open to scrutiny by all interested parties[,]" and "[t]he American people [will] be assured that all NAS . . . studies will be conducted in a balanced and objective manner." H.R. Rep. No. 105-843, at 206 (1999).

III. FACTUAL BACKGROUND

Formaldehyde is a critical chemical building block for numerous sectors and essential items including housing, sustainable wood products, agriculture, medical devices, food safety and

[4] *E.g.*, MD SB916 "Environment - Ethylene Oxide – Prohibition" (2023), https://mgaleg.maryland.gov/2023RS/fnotes/bil_0006/sb0916.pdf (proposing to ban ethylene oxide); COMAR 26.11.16.03 (determining screening levels for air pollutants in Md. based on values "developed by the Cancer Assessment Group of [EPA]").

electric vehicles. Some of ACC's members use formaldehyde and/or produce formaldehyde products, and thus have been deeply involved in and anxiously following the Committee's review of EPA's latest formaldehyde Assessment. Unfortunately, this process has been flawed from the outset, and has violated core FACA requirements applicable to NAS.

A. The IRIS process and EPA's flawed 2011 formaldehyde assessment.

EPA's IRIS Program "identif[ies] and characteriz[es] the health hazards of chemicals found in the environment."[5] IRIS assessments develop various "toxicity values for health effects resulting from chronic exposure to chemicals" and provide both hazard identification (identifying types of health outcomes associated with the chemical) and dose-response assessments (quantifying the relationship between chemical exposure and the health hazard).[6] One of the steps to finalize an IRIS assessment is peer review by an external peer review body, such as NAS.[7] After EPA completes its IRIS assessment, other EPA offices combine exposure assessments with the IRIS toxicity values to characterize health risks and implement risk management strategies.[8]

When making decisions based on IRIS values, EPA does not "conduct an independent,

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[5] EPA, *Basic Information about the Integrated Risk Information System*, https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system#process (last visited Oct. 4, 2023).

[6] *Id.*; *see also* Order at 1-2, *United States v. Denka Performance Elastomer, LLC*, No. 23-cv-00735 (E.D. La. Aug. 30, 2023).

[7] *NCEA Policy and Procedures for Conducting IRIS Peer Reviews*, at 5 (eff. July 30, 2009), https://www.epa.gov/sites/default/files/2014-05/documents/policy_iris_peer_reviews.pdf ("All draft human health assessments developed under the IRIS program are subjected to rigorous, independent external peer review."); EPA, *Basic Information about the Integrated Risk Information System*, https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system#process (last visited Oct. 4, 2023) (listing "External Peer Review" as step 4 in the IRIS process, before revisions and finalization).

[8] EPA, *Basic Information about the Integrated Risk Information System*, https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system#process (last visited Oct. 4, 2023).

critical scientific review of" alternative assessments and values to "select the most scientifically supported approach"; rather, it just uses the IRIS value, reasoning that EPA's Office of Research and Development ("ORD"), which includes the IRIS program, considers the IRIS assessment "to be the 'best available scientific information.'"[9]

In June 2010, EPA released its IRIS toxicological assessment of formaldehyde titled "Toxicological Review of Formaldehyde – Inhalation Assessment" (the "2010 Assessment").[10] EPA then contracted with NAS to provide an independent review of EPA's 2010 Assessment. NAS's conclusions were highly critical of EPA's work. As The New York Times explained, NAS "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.'"[11] NAS's 2011 report concluded that "[t]he committee is concerned about the persistence of problems encountered with IRIS assessments over the years, especially given the multiple groups that have highlighted them."[12]

B. ACC's participation in EPA's post-2011 process and EPA's new Assessment.

After the NAS review of the 2010 Assessment, EPA reviewed its work and began preparing

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[9] EPA, *Response to Public Comments for the Ethylene Oxide (EtO) Draft Risk Assessment*, at 2 (DRA) (Mar. 27, 2023), https://www.epa.gov/system/files/documents/2023-04/eto-rtc.pdf.

[10] NAS, *Review of EPA's Draft IRIS Assessment of Formaldehyde* (2011), at ix ("2011 NAS Report"), https://nap.nationalacademies.org/catalog/13142/review-of-the-environmental-protection-agencys-draft-iris-assessment-of-formaldehyde.

[11] Jeremy P. Jacobs, *NAS Reviewers Slam EPA's Formaldehyde Assessment*, The 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.

[12] 2011 NAS Report, at 14, https://nap.nationalacademies.org/catalog/13142/review-of-the-environmental-protection-agencys-draft-iris-assessment-of-formaldehyde.

a revised formaldehyde assessment under IRIS.[13] ACC participated in this process and attempted to help the agency utilize the best possible scientific evidence in a logical manner. ACC evaluated the potential research that could help address NAS's 2011 recommendations and launched and funded numerous scientific research projects to fill data needs identified during NAS's review of EPA's 2010 Assessment.[14] Largely as a result of these costly 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.[15] ACC provided this information to EPA IRIS staff when the information was generated.[16] As far as ACC can tell, EPA did not consider most of the studies and materials submitted by ACC.[17]

In April 2022, EPA released its amended draft formaldehyde Assessment to the public.[18] EPA's IRIS Assessment disregards—indeed, it appears to have completely ignored the submission of—most of the studies and information provided by ACC.[19]

C. EPA limits the scope of NAS's review of the Assessment and interferes with the Committee selection process.

In April 2022, EPA contracted with NAS through a task order that prescribed the terms under which NAS must operate in conducting its review of the Assessment. Task Order #68HERC21F0401 under NAS Contract #68HERC19D0011 (Sept. 7, 2021) ("Task Order," Ex. C). EPA mandated that the Committee "shall not conduct an independent assessment separately

[13] Ex. A, NAS Report at 1.
[14] Ex. B, ACC Decl. ¶ 8.
[15] *Id*.
[16] *Id*.
[17] *Id*.
[18] Ex. A, NAS Report at 2.
[19] Ex. B, ACC Decl. ¶ 8.

from the IRIS document nor shall the NAS comment on the broader aspects of the IRIS program" and address only "the charge questions set forth by EPA." *Id.* at 2. The peer review charge questions solicited NAS's proposed revisions and additional considerations on EPA's assessment methods and organization, and EPA's conclusions on the health effects from inhaled formaldehyde, including toxicokinetics, respiratory system health effects, noncancer systemic health effects, and carcinogenic potential.[20] Notably, by limiting NAS to addressing only narrow issues described in the charge questions, EPA precluded the review or consideration of other information relevant to the human health risks posed by inhalation of formaldehyde, including alternative interpretations of the science. *See* Ex. C, Task Order at 2. EPA even limited the length of the Committee's public peer review meetings to eight total hours in the task order. *Id.* at 3.

In addition to limiting the scope of the NAS's review, EPA also influenced the selection of Committee members. On October 1, 2021, NAS issued a call for nominations for the Committee. *See* Ex. D, E-mails between Dr. Kathryn Guyton and Stan Barone (Oct. 4-14, 2021). The nomination period closed on October 29, 2021. *Id.* Through a Freedom of Information Act ("FOIA") request, ACC obtained correspondence between the Committee's Study Director, Dr. Kathryn Guyton, and staff from EPA's Office of Chemical Safety and Pollution Prevention and ORD regarding Committee appointments. *See id.*; Ex. E, E-mails between Dr. Kathryn Guyton and EPA Staff (Sept. 23-Oct. 14, 2021). That correspondence shows that, in October 2021, Dr. Guyton solicited nominations for Committee members from EPA staff member Stan Barone, with whom she had previously worked. *See* Ex. D, E-mails between Dr. Kathryn Guyton and Stan Barone (Oct. 4-14, 2021). In response to Dr. Guyton's solicitation, Dr. Barone apparently

[20] Final External Peer Review Charge Questions for the IRIS Toxicological Review of Formaldehyde—Inhalation (June 2022), https://www.regulations.gov/document/EPA-HQ-ORD-2010-0396-0104.

suggested nominations, and Dr. Guyton thanked him for "these great suggestions." *Id.* at 1. Dr. Guyton also informed EPA that "[t]here will be 'recycling' from the prior committee" and provided a name was redacted in EPA's FOIA response. Moreover, Dr. Guyton also asked EPA who the Agency would like to select "for a neurotox person." *Id.* Mr. Barone responded that he "[l]ove[s] recycling" and presumably provided further membership recommendations in the part of the letter that has been redacted. EPA redacted the information on the basis that it was exempt under FOIA as revealing the Agency's deliberative process. *Id.*

D. NAS selects an unbalanced, biased Committee and fails to disclose conflicts, including Committee members' links to EPA and the Assessment.

On August 5, 2022, NAS announced a provisional committee of 13 members[21] and solicited public comment on NAS's appointments. The comment period was set to close on August 25, 2022. On August 15, 2022, ACC requested that NAS extend the comment period for at least 20 additional calendar days to provide for a reasonable opportunity for the public to comment on the proposed appointments. On August 19, 2022, NAS responded to ACC's request and declined to extend the comment period. Ex. S, E-mails between Dr. Clifford Duke, NASEM, and Julianne Ogden, ACC (Aug. 15-19, 2022). ACC proceeded to submit comments on August 25, 2022, asserting that the provisional committee was not fairly balanced in terms of scientific expertise needed to conduct a comprehensive review of the Assessment, and comprised of members with

[21] The Committee members include Dr. Jonathan M. Samet, Dr. Aisha S. Dickerson, Dr. Dana C. Dolinoy, Dr. David C. Dorman, Dr. Rakesh Ghosh, Dr. Sabine S. Lange, Dr. Andrew F. Olshan, Dr. Ivan Rusyn, Dr. Lianne Sheppard, Dr. Katya Tsaioun, Dr. Joseph Wiemels, Dr. Lauren Zeise, and Dr. Yiliang Zhu. NAS, Review of EPA's 2022 Draft Formaldehyde Assessment https://www.nationalacademies.org/our-work/review-of-epas-2022-draft-formaldehyde-assessment#sectionCommittee (last visited Oct. 4, 2023).

real and apparent conflicts of interests.[22] Following the close of the comment period, and without response to ACC's comments, NAS finalized the committee as proposed.[23]

As described in ACC's August 25, 2022 Comments, the Committee's composition is not fairly balanced because it lacks scientific expertise in occupational epidemiology, pharmacokinetic modeling, hematology, and reproductive effects, which were all expressly recommended for appointment in the EPA task order. Ex. C, Task Order at 2-3. NAS's Report alleges that the Committee includes expertise on reproductive effects; however, the Committee members' biographical information contained in the Report does not demonstrate expertise in this field. *See* Ex. A, NAS Report at 16. The Committee also does not include any scientists with expertise in private sector industrial toxicology and industrial epidemiology. Indeed, the Committee lacks *any* private sector perspective or expertise. Of the 13 Committee members, 11 carry academic positions, and two serve in state environmental protection agencies.

ACC attached as Appendix A to its August 25, 2022 Comments (Ex. F) a list of potential committee members with relevant expertise. That list included scientists with backgrounds in occupational epidemiology, endogenous and exogenous exposures, genotoxicity, leukemia, mode of action assessment, pharmacokinetics, biologically-based dose response modeling, risk assessment, and toxicology. *Id.* at 9-13. If NAS was reluctant to increase the size of the Committee, ACC suggested that NAS make room for additional experts by decreasing the number of non-occupational (*i.e.*, academic) epidemiologists, which field is over-represented on the Committee.

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[22] *See* Ex. F, Letter from ACC to Dr. Kathryn Guyton, Senior Program Officer of the Board on Environmental Studies and Toxicology, NASEM (Aug. 25, 2022).

[23] *See* NAS, Committee for the Review of EPA's 2022 Draft Formaldehyde Assessment, https://www.nationalacademies.org/our-work/review-of-epas-2022-draft-formaldehyde-assessment#sectionCommittee (last visited Oct. 4, 2023).

Id. at 4. Indeed, seven of the thirteen Committee members appearing to be epidemiologists, but none with any background in *occupational* epidemiology.[24] *See* Ex. A, NAS Report at 126-30.

In addition to selecting an unbalanced Committee, NAS selected a Committee with real and apparent conflicts of interests, and failed to disclose or even attempt to justify those conflicts. In comments to NAS, dated August 25, 2022, ACC explained that at least three Committee members, including Dr. Lauren Zeise, Dr. Lianne Sheppard, and Dr. Ivan Rusyn, in addition to the Committee Study Director, have had significant connection to the IRIS Program. Ex. F at 5-7.

Dr. Lauren Zeise serves as the director of the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA), in which she oversees the development of risk assessments, hazard evaluations, and toxicity reviews in the state of California. Ex. A, NAS Report at 129. EPA's National Center for Environmental Assessment (NCEA), which was reorganized into the Center for Public Health and Environmental Assessment (CPHEA), previously worked with OEHHA pursuant to a 2009 Memorandum of Understanding (MOU).[25] This relationship raises potential conflicts of interests concerns because the IRIS Program is located in and managed by CPHEA.[26] Pursuant to the MOU, OEHHA and NCEA committed to harmonizing risk assessment methods between the two agencies, sharing data and evaluations, jointly evaluating data, sharing statistical and epidemiological expertise, and providing mutual peer review of similar work products. *Id.* To date, NAS has failed to respond to

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[24] These members are Drs. Jonathan Samet, Aisha Dickerson, Rakesh Ghosh, Andrew Olshan, Lianne Sheppard, Joseph Wiemels, and Yiliang Zhu. All appear to be academics or regulators.

[25] 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.

[26] *See* EPA, *Basic Information about the Integrated Risk Information System*, https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system (last visited Oct. 4, 2023).

any of ACC's inquiries regarding the status of any existing MOU between EPA and OEHHA.

ACC also raised potential conflicts with regard to Dr. Ivan Rusyn, who has served on numerous committees relevant to the Assessment, including the 2011 NAS committee that reviewed the 2010 draft formaldehyde assessment and the NAS committee that reviewed formaldehyde in the National Toxicology Program 12th Report on Carcinogens. Ex. A, NAS Report at 128. During Congressional testimony, Dr. Rusyn stated that, he "interacted with IRIS staff on a variety of scientific and methodological issues directly relevant to implementation of the advice from the National Academies."[27] Dr. Rusyn also made comments that demonstrate his lack of impartiality, including by characterizing the formaldehyde IRIS assessment as a "high-quality comprehensive assessment[s] that [is] ready for" finalization.[28]

Further, ACC has identified potential conflicts from Dr. Lianne Sheppard's numerous relationships with EPA, including financial funding. Dr. Sheppard serves as the Chair of EPA's Clean Air Scientific Advisory Committee and a member of EPA's Science Advisory Board. Ex. A, NAS Report at 128. She is also a recipient of an EPA grant for a study of long-term exposure to air pollution, which extends through August 2023.[29] Moreover, Dr. Sheppard has collaborated closely with the lead author of a key study in the Assessment, the evaluation of which was a central

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[27] *EPA's IRIS Program: Reviewing Its Progress And Roadblocks Ahead*, Hearing Before the Subcomm. on Investigations and Oversight, 116th Cong. 2, Statement of Dr. Ivan Rusyn ("Statement of Dr. Ivan Rusyn"), at 2 (Mar. 27, 2019), https://republicans-science.house.gov/_cache/files/a/2/a2e745af-d8e1-4ec8-8ad2-b911a9ab43e3/BA4E9317509D052F516127CA4CF5F256.2019-03-27-testimony-rusyn.pdf.

[28] *Id*. at 9.

[29] EPA, *Grantee Research Project Results: The Multi-Ethnic Study of Atherosclerosis and Air Pollution: Next Stage*, Grant No.: RD838300, https://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/display.abstractDetail/abstract_id/10841/report/0.

purpose of the Committee's review.[30] Specifically, Dr. Sheppard was a co-author with Dr. Luoping Zhang, who authored studies that EPA relied on to evaluate the human health risks from formaldehyde exposure. *E.g.*, Assessment at 1-140, 1-525 to 1-526.[31] Neither NASEM nor Dr. Sheppard disclosed this relationship to the public.

Finally, the NAS Study Director, Dr. Kathryn Guyton, has served in various supervisory roles within the IRIS Program and with regard to the 2010 draft IRIS Assessment. Dr. Guyton was an EPA career scientist in the IRIS Program. While serving as Deputy National Program Director for the Human Health Risk Assessment Research Program, she developed, "review[ed] and comment[ed] on" drafts of EPA's formaldehyde assessment in response to the 2011 NAS peer review; *i.e.*, she worked on the very Assessment that the Committee was then tasked with reviewing.[32] And in 2011, while working at EPA, Dr. Guyton argued against changing major conclusions of EPA's 2010 Assessment or conducting additional peer review.[33] Dr. Guyton stated in an email to her EPA colleague Dr. Barbara Glenn, who is now a manager of the Assessment, that she would "endorse a strong team opinion that additional peer review will not be needed, given that the major conclusions will not change . . . ."[34] Dr. Guyton asserted that another peer review

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[30] *See* 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. 186-206 (July-Sept. 2019), https://www.sciencedirect.com/science/article/abs/pii/S1383574218300887.

[31] EPA, *Toxicological Review of Formaldehyde—Inhalation, CASRN 50-00-0* (Apr. 2022), https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=544587.

[32] Ex. G, E-mails between Dr. Guyton and Dr. Bob Sonawane, NCEA (May 15, 2013).

[33] Ex. H, E-mails between Dr. Kathryn Guyton and Dr. Barbara Glenn (June 9, 2011). Notations on these emails, produced by EPA in response to a FOIA request, indicate that EPA may have intended to redact the text, but EPA did not do so successfully.

[34] *Id.*

"will add years to [Dr. Glenn's] pain."[35] Now, in her role as the Study Director, Dr. Guyton exercises great influence over the Committee and their review of the Assessment. She is responsible for developing meeting agendas, preparing background materials, and writing and editing the report.[36] And the study director "has primary responsibility" for ensuring compliance with statutory and contractual obligations, including FACA and the committee's charge.[37]

In a letter dated April 20, 2023, ACC reiterated its recommendation to address these conflicts of interest, as well as the lack of balance on the Committee, by selecting new Committee members and restarting the review process.[38] NAS denied this request without explanation.[39]

E. NAS fails to publicly disclose information about the Committee's process and limits public participation.

NAS has withheld and continues to withhold key information about Committee members. As an initial matter, the biographical information that NAS provided on its website and in the Report regarding the Committee members includes high-level summaries of the members' education and work experience. Ex. A, NAS Report at 126-30. However, these "biographies" do not discuss the members' relevant relationships, publications, grants, testimony, or public statements. ACC has submitted multiple requests to NAS to disclose key biographical details of

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[35] *Id.*

[36] *The Study Process of the National Academies of Sciences, Engineering, and Medicine, A Guide for Committee Members*, at 6 (Feb. 2016), https://sites.nationalacademies.org/cs/groups/ssbsite/documents/webpage/ssb_173594.pdf.

[37] *The Study Process of the National Academies of Sciences, Engineering, and Medicine, A Guide for Committee Chairs*, at 5 (Feb. 2016), https://sites.nationalacademies.org/cs/groups/ssbsite/documents/webpage/ssb_173593.pdf.

[38] Ex. I, Letter from Counsel for ACC to Dr. Marcia McNutt and Dr. Clifford Duke, The National Academies of Sciences, Engineering, and Medicine ("NASEM") at 14 (Apr. 20, 2023).

[39] Ex. J, Letter from Dr. Clifford Duke, Director, NASEM to Counsel for ACC (May 4, 2023).

the then-proposed Committee members, to which it has not responded.[40]

NAS also has denied public access to materials presented to the Committee, including nominations of Committee members from EPA and other stakeholders, communications with EPA and comments received regarding the Committee's membership, and materials from Members of Congress. ACC only learned of EPA's influence on the Committee selection through a FOIA request. Through its own efforts, ACC also became aware that Members of Congress have sent correspondence to NAS regarding the Committee's composition and independence. *See* Ex. P, Letter from Members of Congress to Dr. Elizabeth Eide, Executive Director, NASEM (July 28, 2022); Ex. Q, Letter from Sen. John Kennedy to Dr. Clifford Duke, NASEM (Mar. 2, 2022). NAS has not published these letters in the public access file.

NAS also has withheld information about and limited public participation in its September 1 and September 22, 2022 meetings. The Committee met to discuss its composition, balance, and conflicts of interest, but NAS failed to summarize its discussions or conclusions. Instead, it posted an entry on the NAS website that merely identified the Committee members present and topic discussed, which it listed as "Composition, balance, and conflict of interest discussion."[41] No substantive information about that "discussion" was provided to the public.

IV. STANDING

ACC has organizational and associational standing to bring its FACA claims against NAS

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[40] *See* Ex. F, Letter from ACC to Dr. Guyton, Senior Program Officer of the Board on Environmental Studies and Toxicology, NASEM (Aug. 25, 2022); Ex. K, Letter from ACC to Dr. Clifford Duke, Director of the Board on Environmental Studies and Toxicology, NASEM (Aug. 19, 2022); Ex. L, Letter from ACC to Dr. McNutt, President, NASEM (Aug. 15, 2022).

[41] NASEM, Committee Meeting (Sept. 1, 2022), https://www.nationalacademies.org/event/09-02-2022/review-of-epas-2022-draft-formaldehyde-assessment-bcoi-discussion; NASEM, Committee Meeting (Sept. 22, 2022), https://www.nationalacademies.org/event/09-22-2022/review-of-epas-2022-draft-formaldehyde-assessment.

and EPA. "The now familiar requirements for constitutional standing are an injury in fact, fairly traceable to the challenged conduct, and redressable by a favorable judicial decision." *NAACP Legal Def. & Educ. Fund, Inc. v. Barr*, 496 F. Supp. 3d 116, 128 (D.D.C. 2020). Where a party claims a procedural injury, courts relax the immediacy and redressability requirements. *Summers v. Earth Island Inst.*, 555 U.S. 488, 496–97 (2009); *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 572 n.7 (1992). Standing exists where "there is some possibility that the requested relief will prompt the injury-causing party to reconsider the decision that allegedly harmed the litigant." *Massachusetts v. EPA*, 549 U.S. 497, 518 (2007).

Associations have organizational standing where "the defendant's allegedly wrongful action prompts an organization to 'increase[ ] the resources [it] must devote to programs independent of its suit' against the defendant[.]" *Equal Rts. Ctr. v. Post Props., Inc.*, 633 F.3d 1136, 1138 (D.C. Cir. 2011) (citation omitted). A plaintiff organization must show (1) "a direct conflict between the defendant's conduct and the organization's mission[,]" and (2) that the organization has "used its resources to counteract the asserted harm." *Nw. Immigrant Rts. Project v. USCIS*, 496 F. Supp. 3d 31, 46 (D.D.C. 2020) (quotation omitted). ACC satisfies both elements.

First, NAS's unlawful review of the Assessment and EPA's pending use of the resulting Report conflict with ACC's mission to advocate for sound policymaking and scientific integrity in the innovation and manufacture of chemistry products.[42] By failing to comply with FACA, NAS threatens the scientific integrity of the Assessment. NAS's review and EPA's planned use of that review are inconsistent with ACC's objective to promote public policy that is supported by sound science, and ACC's efforts to enhance innovation and create jobs in the chemical industry. These

[42] About ACC, https://www.americanchemistry.com/about-acc (last visited Oct. 4, 2023) ("The ACC's mission is to advocate for the people, policy, and products of chemistry" to improve innovation and manufacturing in the United States.).

actions have inhibited ACC's operations by requiring it to devote substantial time and effort, which would otherwise be spent on other work for members, to tracking and participating in the Committee's process, including by submitting studies on formaldehyde and comments.

Second, ACC has diverted its resources to press NAS and EPA to comply with FACA. As detailed in the attached declaration (Ex. B), well before ACC began this litigation, ACC expended significant resources in trying to participate in the Committee review process, including by funding and providing studies and other relevant information to NAS. ACC's Formaldehyde Panel took actions to try to address EPA and NAS's failures during the assessment and review process. Ex. B, ACC Decl. ¶ 4. For example, ACC and the Panel drafted letters to EPA and NAS raising concerns about the review process and NAS's apparent FACA violations. *Id.* ¶¶ 9, 11–12. ACC and the Panel also requested additional opportunities to comment and provide information. *Id.* ¶¶ 13–14. And ACC expended resources to obtain documents withheld by EPA and the Committee through FOIA. *Id.* ¶ 10. This diversion of resources to try to participate in the review process gives ACC organizational standing to pursue this suit. *See Scenic Am., Inc. v. U.S. Dep't of Transp.*, 983 F. Supp. 2d 170, 178-79 (D.D.C. 2013) (plaintiff had organizational standing where it participated in agency meetings and challenged agency action).

Associations also have standing to sue on behalf of their members if "(1) at least one of its members would have standing to sue in [its] own right" by demonstrating injury, causation, and redressability, "(2) the interests the association seeks to protect are germane to its purpose, and (3) neither the claim asserted nor the relief requested requires that an individual member of the association participate in the lawsuit." *Sierra Club v. EPA*, 292 F.3d 895, 898 (D.C. Cir. 2002) (citation omitted). That associational standing test is also easily met here.

First, ACC has identified specific members who have standing to pursue this action. *See*

Summers, 555 U.S. at 498–99. As detailed in the declarations attached as Exhibits M and N, ACC members Hexion and Bakelite produce and use formaldehyde. *See* Ex. M, Hexion Decl. ¶¶ 2, 5–6; Ex. N, Bakelite Decl. ¶¶ 2, 5, 8. They have been injured by NAS and EPA's unlawful conduct of the Assessment review process, and they face imminent further injury from EPA' reliance on the Report to, *inter alia*, set an IRIS value for formaldehyde that is not based on sound science—and that will essentially suggest to the public and regulators that products that release even a little formaldehyde (less than that found in human breath) are dangerous or harmful.

As in *NAACP*, ACC and its members have suffered informational injuries from the unlawful actions of the Committee. *See NAACP*, 496 F. Supp. 3d at 128 (Legal Defense Fund had "informational standing" to bring FACA claims that committee had not "provided timely notice of or public access to its meetings and has not made its records available for public inspection."); *Pub. Citizen v. DOJ*, 491 U.S. 440, 449 (1989) ("refusal to permit appellants to scrutinize [a] Committee's activities to the extent FACA allows constitutes a sufficiently distinct injury to provide standing"). ACC and its members have been denied access to information FACA requires the Committee to publish (*e.g.*, summaries of the meetings; biographies of Committee members; and third party submissions). ACC and its members also have been denied the opportunity to present information to the Committee and have that information considered. *See* Ex. B, ACC Decl. ¶ 14. Such violations of statutory procedural requirements give rise to standing. *NAACP*, 496 F. Supp. 3d at 128; *Iowa League of Cities v. EPA*, 711 F.3d 844, 871 (8th Cir. 2013).[43]

ACC's members have also suffered representational injuries as a result of the Committee's lack of balance and EPA's unlawful control of the Committee. In *NAACP*, this Court explained

[43] *See also Sierra Club v. EPA*, 699 F.3d 530, 533 (D.C. Cir. 2012) ("Having shown its members' redressable concrete interest, [an association] can [show standing by] assert[ing] violation of the APA's . . . requirements[.]").

that the NAACP Legal Defense Fund had alleged injury sufficient to show standing to bring a FACA "fair balance" claim where it was not given the opportunity to identify personnel to sit on the committee at issue. 496 F. Supp. 3d at 128 (noting "the government has denied LDF access to a representative voice on the Commission" even though "LDF has an interest in and is directly impacted by the Commission's function"). Similarly, ACC—the organization representing American chemical manufacturers that are "directly impacted by" (*id*.) the Report and Assessment —requested, but was denied, a representative voice on the Committee (*e.g.*, a Committee member with experience in occupational epidemiology or industrial toxicology). Instead, NAS encouraged EPA to propose members. "[D]enial of access to representation on an advisory committee is a sufficiently concrete harm to constitute an injury in fact." *Id.* at 129.[44]

Finally, in addition to these existing injuries, as producers and users of formaldehyde, ACC's members also face imminent harm sufficient to give them standing to pursue FACA claims and seek declaratory and injunctive relief. As described in section V.B, below, EPA will use NAS's Report to regulate formaldehyde, including by setting an "IRIS" value that will be the basis for regulation by EPA and states. For example, EPA's Office of Air and Radiation "generally uses" IRIS values to assess and regulate hazardous air pollutants.[45] Further, the Report's apparent sanctioning of EPA's conclusions regarding the potential hazards associated with formaldehyde could immediately be used to suggest that the formaldehyde in ACC's members' products is

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[44] *See also Nat'l Anti-Hunger Coal. v. Exec. Comm. of President's Priv. Sector Surv. on Cost Control*, 711 F.2d 1071, 1074 n.2 (D.C. Cir. 1983) (FACA's "'fairly balanced' requirement was designed to ensure that persons or groups directly affected by the work of a particular advisory committee would have some representation on the committee. When the requirement is ignored, [ ] persons having a direct interest in the committee's purpose suffer injury-in-fact sufficient to confer standing[.]"); *Physician's Educ. Network v. Dep't of Health, Educ. & Welfare*, 653 F.2d 621, 623 n.3 (D.C. Cir. 1981) (per curiam) (collecting cases).

[45] Revisions to Air Emissions Reporting Req's, 88 Fed. Reg. 54118, 54135 n.26 (Aug. 9, 2023).

associated with health hazards and impacts—to the detriment of members' businesses.

As in *NAACP*, ACC and its members' injuries are redressable through an order providing declaratory and injunctive relief. That may include declaring that the Report was produced by a process that did not comply with FACA's requirements and enjoining EPA from relying on, or otherwise using NAS's Report—at least until NAS has complied with FACA.[46] At the very least, the Court could require NAS and EPA to include in the Report a statement that it was not produced in compliance with FACA, and should not be relied on in regulatory or judicial proceedings.

Second, ACC satisfies the associational standing requirements because seeking judicial review of NAS and EPA's FACA violations and preventing EPA from using the product of an unlawful and scientifically unsound review process is germane to ACC's purposes. ACC's mission is to "advocate for the people, policy, and products of chemistry" to improve innovation and manufacturing in the United States, and ACC achieves its mission by promoting "science-based policy solutions across all levels of government."[47] It is thus germane to ACC's purpose to advocate that, when EPA assesses an important chemistry like formaldehyde, and when NAS reviews EPA's work, those processes are fully informed and scientifically sound—and challenge those processes when they do not comply with FACA's requirements.

Last, direct participation by ACC's members in this suit is not required for ACC to pursue its FACA and APA claims on their behalf. The FACA claims raised, and the declaratory and injunctive relief sought, can be pursued and enjoyed by ACC's members without their individual participation as plaintiffs in this suit. ACC therefore has both organizational and associational

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[46] *NAACP*, 496 F. Supp. 3d at 130 ("The Court can … order the Commission to [provide information]; order defendant Barr to . . . ensure the Commission has a fairly balanced membership; and order defendants to refrain from publishing any report . . . until the requirements of FACA are satisfied. This relief will … redress[ ] the asserted injuries[.]").

[47] *About ACC*, https://www.americanchemistry.com/about-acc (last visited Oct. 13, 2023).

standing to pursue the FACA and APA claims raised in this suit against EPA and NAS.

V. ARGUMENT

Section 15 of FACA imposes numerous requirements on NAS, and prohibits EPA from relying on advice or recommendations from NAS unless all such requirements are satisfied. 5 U.S.C. § 1014. These requirements include that NAS provide public notice of appointments to committees and reasonable opportunity for public comment on such appointments. *Id.* § 1014(b)(1). In selecting a committee, NAS must "make its best efforts to ensure" that the committee is "fairly balanced" for the functions to be performed, and no individual appointed to the committee has a conflict of interest relevant to the function to be performed, unless NAS publicly discloses the conflict and determines that it is unavoidable. *Id.* § 1014(b)(1)(A)-(B). Additionally, data gathering meetings must be opened to the public, unless the Academy determines that doing so would disclose matters exempt under FOIA, and the Academy must provide public notice of all meetings open to the public. *Id.* § 1014(b)(3). If the meetings are not open to the public, the Academy must provide summaries. *Id.* § 1014(b)(4). Finally, written materials and reports must also be made available to the public, unless the Academy determines that doing so would disclose matters exempt under FOIA. *Id.* § 1014(b)(3).

NAS violated these FACA requirements in multiple ways, as described below. This Court need only agree that one of these many failings violates FACA in order for preliminary or permanent relief enjoining EPA from using the Report to be justified. This is because the provision governing the review of agency work by a NAS committee plainly prohibits the agency from using NAS's work product if it does not comply with any one of the applicable requirements. 5 U.S.C. § 1014(a) (agency "may not use any advice or recommendation" produced by a NAS committee in violation of the applicable requirements). Any use of the Committee's Report by EPA would therefore be arbitrary, capricious, and unlawful, in violation of the APA, 5 U.S.C. § 706(2), and

this Court should enjoin EPA taking such unlawful action—as it otherwise soon will.

A. NAS has violated FACA in numerous ways.

NAS has violated FACA by selecting a committee that is not fairly balanced, and whose members have apparent conflicts of interest that NAS has not addressed; failing to allow for a reasonable opportunity for public input regarding committee appointments; and failing to disclose required information to the public, thereby limiting the public's participation in the review process.

1. *NAS appointed a committee that is not fairly balanced.*

Section 15 of FACA requires NAS to "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). NAS's Policy for implementing section 15 of FACA notes that, in selecting a committee, NAS should consider the range of relevant expertise and perspectives on the issues to be addressed by the committee while "taking into account the subtleties and complexities of the issues to be addressed by the committee."[48] NAS violated FACA and its implementing policy by selecting a committee that lacks a range of scientific perspectives necessary to conduct a reliable peer review of the Assessment.

The Committee lacks expertise in several scientific fields crucial to its task of reviewing EPA's hazard identification and dose-response analysis of formaldehyde. While the thirteen-member Committee includes seven *non-occupational* epidemiologists (*i.e.*, academics and regulators), it does not include a single scientist with practical experience in *occupational* (*i.e.*, working or applied) epidemiology, pharmacokinetic modeling, or hematology. Further, although

[48] NASEM, *Policy on Composition and Balance, Conflicts of Interest, and Independence for Committees* ("Policy") (Sept. 7, 2021) at 1, https://www.nationalacademies.org/documents/embed/link/LF2255DA3DD1C41C0A42D3BEF0989ACAECE3053A6A9B/file/D4D336B1CB9047B19928EA8785ED2E43C913B841539A?noSaveAs=1

the NAS Report alleges the Committee includes expertise on reproductive effects, the Committee members' biographical sketches do not show that any members have experience in this field. Ex. A, NAS Report at 16. These disciplines were not only recommended by EPA for appointment in the task order, Ex. C, Task Order at 3, but they are crucial to a comprehensive and authoritative evaluation of human health hazards and carcinogenicity potential from formaldehyde inhalation.

For example, expertise on occupational epidemiology is necessary where the Assessment relies on occupational cohorts to draw carcinogenicity conclusions, Ex. A, NAS Report at 8, and otherwise relies on a number of occupational studies to evaluate the effect of formaldehyde exposure on numerous noncancer health effects, including pulmonary function, allergy and asthma, and developmental toxicity. *E.g.*, *id*. at 61 (relying on occupational studies to evaluate pulmonary function); *id.* at 67 (relying on occupational studies to evaluate respiratory pathology); *id.* at 75 (relying on occupational studies to evaluate reproductive and developmental toxicity). The absence of a committee member with expertise in occupational epidemiology is also particularly concerning where the prior NAS committee tasked with peer reviewing the 2010 IRIS formaldehyde assessment contained three occupational epidemiologists.[49] Other advisory committees that include occupational epidemiologists identified faults in the epidemiologic studies and concluded that they could not overcome data developed in controlled environments,[50] whereas the Committee failed to identify the issues in those same studies.

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[49] NAS, Committee Roster for 2011 Review of EPA's Draft IRIS Assessment of Formaldehyde, https://www.nationalacademies.org/our-work/review-of-epas-draft-iris-assessment-of-formaldehyde#sectionCommittee.

[50] Draft Report of the EPA Human Subjects Review Board at 9-10 ("the controlled chamber studies . . . have preferred study design and greater scientific rigor than the observational studies . . . HSRB recommends that EPA use exposure levels from chamber studies rather than observational studies"), https://www.epa.gov/system/files/documents/2023-10/july-2023-hsrb-report-woe-formaldehyde.pdf.

The Committee also is not fairly balanced because it lacks scientists with backgrounds and expertise in industrial toxicology and epidemiology. Consistent with EPA's Peer Review Handbook, selecting members with an industry perspective helps to ensure the appropriate balancing of peer reviewers with diverse work history and affiliation.[51] Scientists with expertise in 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 Committee because industry will be directly affected by the final assessment. *See Nat'l Anti-Hunger Coal.*, 711 F.2d at 1074, n.2 (The fairly balanced requirement was "designed to ensure that persons or groups directly affected by the work of a particular advisory committee would have some representation on the committee.").

Moreover, the Committee's lack of balance with regard to scientific expertise and occupational and industrial background is further exacerbated by its lack of viewpoint balance. A number of committee members made public comments that raise serious concerns regarding the Committee's objectivity. For example, the Committee Chair, Dr. Samet, published a blog post the week after the Committee began deliberations in October 2022, in which he stated that EPA's methods and causal judgments on IRIS since 2011 "have proved to be effective and have supported many measures that have advanced public health."[52] Additionally, Dr. Rusyn testified before Congress in 2019, advocating for EPA to complete the IRIS formaldehyde assessment.[53]

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[51] EPA, Science and Technology Policy Council, *Peer Review Handbook* 72 (4th ed., Oct. 2015) ("EPA Peer Review Handbook"), https://www.epa.gov/sites/default/files/2020-08/documents/epa_peer_review_handbook_4th_edition.pdf.

[52] Jonathan Samet, *The COVID-19 Pandemic & More: Colorado's plateau continues …*, Colo. Sch. of Pub. 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.

[53] *See* Statement of Dr. Ivan Rusyn at 10.

These same opinions were reiterated in the Report. Dr. Samet notes in the Preface 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[.]" Ex. A, NAS Report at xi. Dr. Samet therefore concluded that "[o]verall, the committee found that the methods used for the assessment were appropriate[.]" *Id.* The Preface also asserts that the Assessment "needs to be completed to support EPA in accomplishing this mission" and "urges closure on the Draft Assessment." *Id.* at xii. The degree to which the Report repeats comments made by Committee members, before the review, in support of EPA's methodology raises serious doubts about the Committee's impartiality. Notably, EPA never charged NAS to opine on whether the IRIS Assessment should be completed, so the Committee's willingness to go beyond its charge when making such a recommendation contrasts with its unwillingness to extend beyond the charge questions in actual review of the Assessment, indicating clear imbalance and partiality.

The D.C. Circuit and this Court have previously acknowledged the importance of FACA's "fairly balanced" requirement and ordered committees subject to FACA to revisit their composition to ensure they satisfy that requirement. *See, e.g.*, *Cummock v. Gore*, 180 F.3d 282, 291-92 (D.C. Cir. 1999) (finding committee member excluded from committee deliberations due to dissenting opinion had enforceable rights under FACA's fairly balanced requirement); *Nat'l Anti-Hunger Coal. v. Exec. Comm. of President's Priv. Sector Surv. on Cost Control*, 566 F. Supp. 1515, 1517 (D.D.C. 1983) (finding executive committee was not fairly balanced as to substantive legislative policy issues regarding hunger benefits and granting declaratory relief).

For example, in *NAACP Legal Defense & Educational Fund*, this Court found that an executive committee charged with examining and making recommendations to the Attorney General on improving policing in the United States was not fairly balanced where it comprised

only of past and current law enforcement representatives, but lacked representatives from policed communities and other perspectives. 496 F. Supp. 3d at 144. This Court therefore granted declaratory, mandamus, and injunctive relief requiring that the committee composition be re-evaluated to consider adding representatives of excluded stakeholders. *Id.* at 145–46. This Court should do essentially the same to address NAS's FACA violation: it should enjoin EPA from relying on or using the Report, and also require NAS to include a statement that the Committee did not comply with FACA requirements in any publication of the Report.

2. *NAS appointed Committee members with real and apparent conflicts of interests, and has failed to address such conflicts*.

Section 15(b)(1)(A) of FACA requires NAS to "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." 5 U.S.C. § 1014(b)(1)(A). NAS's Policy implementing this statutory mandate requires that committee members be "transparent about their relevant relationships and publications, and independent from the sponsors of the committee's work."[54] Specifically, the Policy directs committee members to disclose relevant relationships, publications, and other relevant information "at the time of committee formation and in any report of the committee." *Id.* at 3. The Committee members have failed to comply with these clear directives, and NAS has in turn failed to disclose the Committee's conflicts of interests and

[54] Policy, *supra* n.49, at 1. Notably, NASEM amended the Policy (without taking comment) the same day EPA and NAS contracted for this review. Before, NAS's position was that one should not work on "an activity in which a critical review and evaluation of the individual's own work, or that of his or her immediate employer, is the central purpose" and there may be a conflict where the individual works with an organization "that espouses the same fixed position on the issue[.]" *Policy On Committee Composition And Balance And Conflicts Of Interest* at 5 (May 12, 2003), https://www.documentcloud.org/documents/21078147-national-academies-may-2003-conflict-of-interest-policy.

determine whether such conflicts are unavoidable.

Despite NAS's failure to respond to ACC's repeated requests to provide information needed to evaluate the extent of the Committee's conflicts, including the committee members' relevant relationships, publications, grants, testimony, and public statements made by the members, ACC has identified at least three Committee members with significant prior involvement with EPA regarding the IRIS Assessment Program. This raises serious concerns about the Committee's independence and impartiality in reviewing EPA's Assessment. At the very least, Section 15(b)(1)(A) of FACA required NAS disclose these connections and justify these Committee members participation despite the resulting apparent conflicts.

Dr. Lauren Zeise has a conflict of interest arising from her role as the director of the California Environmental Protection Agency's OEHHA, in which she oversees the development of risk assessments, hazard evaluations and toxicity reviews in the state of California. EPA's Center for Public Health and Environmental Assessment (CPHEA) includes a group that collaborated 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.[55] CPHEA houses and manages the IRIS Program, raising concerns regarding potential conflicts between Dr. Zeise's interests and NAS's interest in reviewing EPA's Assessment fairly and without bias. Indeed, Dr. Zeise was provisionally appointed to the 2014 NAS review committee but did not serve following the disclosure of the MOU between OEHHA

[55] *See* 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. Note that the National Center for Environmental Assess (NCEA) was reorganized into CPHEA.

and EPA.[56] NAS has not responded to ACC's inquiries regarding any MOU between EPA and OEHHA, which would again indicate a conflict of interest that should bar Dr. Ziese from reviewing EPA's work on the Assessment. Even if no MOU exists, there remains considerable concern regarding the propriety of Dr. Zeise's membership on the Committee given the historical relationship between the organization that Dr. Zeise leads, OEHHA, and the IRIS program.

Dr. Ivan Rusyn has also had significant involvement with EPA regarding the IRIS Assessment Program that raises concerns about his impartiality. Dr. Rusyn served on the 2011 NAS committee that reviewed the 2010 draft IRIS formaldehyde risk assessment and the NAS committee that reviewed formaldehyde in the National Toxicology Program 12th Report on Carcinogens. Notably, he chaired a NAS Committee that hosted workshops to "support development of EPA's IRIS Toxicological Reviews," which addressed scientific issues "related to systematic review, hazard identification, and dose-response analysis."[57] EPA and OMB policies call for avoiding repeatedly turning to the same peer reviewers, because "they may lose their impartiality (or the appearance of impartiality) relative to the work product(s)."[58] Separately, in 2019, Dr. Rusyn testified before Congress regarding EPA's IRIS Program and characterized the formaldehyde assessment as one of the "high-quality comprehensive assessments that are ready

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[56] NAS, *Committee Review of the IRIS Process*, https://www.nationalacademies.org/our-work/review-of-the-iris-process?bname=nrsb ("Committee Membership Roster Comments, Note: 7/31/2012: Lauren Zeise was provisionally appointed to the committee but will not be serving.").

[57] NAS, 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 Oct. 4, 2023).

[58] *EPA Peer Review Handbook* at 73, https://www.epa.gov/sites/default/files/2020-08/documents/epa_peer_review_handbook_4th_edition.pdf; Office of Management and Budget, *Final Information Quality Bulletin for Peer Review* at 18 (Dec. 16, 2004), https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/omb/memoranda/fy2005/m05-03.pdf.

for completion under the IRIS process" and noted that "delays in completing the evaluation of [formaldehyde] are unacceptable."[59] Notably, the Preface to the Report echoed this opinion. Ex. A, NAS Report at xi-xii.

Dr. Rusyn's direct engagement with EPA concerning the IRIS Assessment raises potential conflicts because, as a Committee member, he is tasked with conducting a peer review of work on which he previously consulted. *See EPA Peer Review Handbook* at 70. Indeed, while serving as a faculty fellow to the IRIS Program from 2011 to 2013, Dr. Rusyn worked on "scientific and methodological issues directly relevant to implementation of the advice from the National Academies," implementation of which was evaluated in the Report.[60] His work was directly relevant to EPA's charge that NAS assess "whether EPA's draft document adequately and transparently evaluated the scientific literature [and] used appropriate methods to synthesize the current state-of-the science[.]" Ex. A at 4. Combined with this prior work on the Assessment and IRIS methodology, Dr. Rusyn's comments regarding the need to finalize the Assessment indicate that he has a predetermined view, and cannot objectively evaluate the Assessment.

Next, ACC has identified multiple relationships between Dr. Lianne Sheppard and EPA that, when taken together, create an apparent conflict of interest. Dr. Sheppard serves as the Chair of EPA's Clean Air Scientific Advisory Committee and is a member of EPA's Science Advisory Board. Ex. A, NAS Report at 128. 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.[61] Given that EPA is

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[59] Statement of Dr. Ivan Rusyn at 10.

[60] *Id.* at 2.

[61] *See* EPA, Grantee Research Project Results: *The Multi-Ethnic Study of Atherosclerosis and Air Pollution (MESA Air): Next Stage*, EPA Grant Number: RD838300, https://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/display.abstractDetail/abstract_id/10841/report/0.

the sponsor of NAS's review of the draft risk assessment on formaldehyde, Dr. Sheppard's numerous direct, financial relationships with the agency raises conflict of interest concerns that NAS must address—but did not attempt to do so at any point in the course of the review process.

The NAS study director, Dr. Kathryn Guyton, also has conflicts of interest that undermine the Committee's impartiality. The Study Director plays an active and substantive role throughout the peer review process, "prepar[ing] background materials" and "writ[ing] or "edit[ing] portions of the [consensus study] report."[62] And as the study director, Dr. Guyton is responsible for ensuring that the Committee complies with FACA, and follows the Committee's charge as prescribed by EPA.[63] NAS Study Directors also draft a large part of the study report for review by the Committee members, thus shaping the framework and conclusions of the study. Accordingly, Dr. Guyton's close and longtime connection to the IRIS Program, detailed below, undermines a core principle of independent scientific peer review, in addition to violating FACA.

Dr. Guyton was previously an EPA senior manager within the IRIS Program, serving from 2005 to 2014, including as a senior official in the group that produces IRIS assessments. Dr. Guyton was the disciplinary workgroup "co-chair" during an intra-agency review of EPA's 2010 draft assessment for formaldehyde. Ex. O, E-mail from Dr. Guyton to EPA Staff (July 2, 2013). Dr. Guyton was engaged in the development and review of the EPA formaldehyde assessment drafts that were developed in response to the 2011 NAS peer review of the 2010 Assessment. *See* Ex. G, E-mails between Dr. Guyton and Dr. Bob Sonawane, NCEA (May 15, 2013). Finally, Dr.

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[62] *The Study Process of the National Academies of Sciences, Engineering, and Medicine, A Guide for Committee Members*, at 6 (Feb. 2016), https://sites.nationalacademies.org/cs/groups/ssbsite/documents/webpage/ssb_173594.pdf.

[63] *The Study Process of the National Academies of Sciences, Engineering, and Medicine, A Guide for Committee Chairs*, at 5 (Feb. 2016), https://sites.nationalacademies.org/cs/groups/ssbsite/documents/webpage/ssb_173593.pdf.

Guyton coauthored a study with the EPA authors and managers of the Assessment that is now under review.[64] Dr. Guyton's own work is thus now the subject of the Committee's review.

Dr. Jonathan Samet also has a conflict of interest due to his ties to the International Agency for Research on Cancer ("IARC"). Dr. Samet's connection to IARC is relevant to the functions of the Committee due to its reliance on and praise for IARC as a means to support EPA's conclusions regarding carcinogenicity. *See, e.g.*, Ex. A, NAS Report at 39. The report lauds and cites IARC's statements on formaldehyde carcinogenicity, *id.*, but NAS never disclosed that Dr. Samet, the Committee Chair, has significant, ongoing, financial and institutional ties to IARC. He "participated in and chaired multiple [IARC] Working Groups."[65] 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 that his work with IARC creates "potential biases and COIs" – conflicts of interest, particularly related to "serving on expert panels."[66]

In addition to the apparent and actual conflicts discussed above, the Committee as a whole has had significant, extensive relationships with EPA, including as reviewers on advisory committees, that undercut the Committee's independence and impartiality.[67] The 13 NAS

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[64] *See* Kathryn Z. Guyton *et al.*, *Human Health Effects of Tetrachloroethylene: Key Findings and Scientific Issues*, 122(4) Env't Health Persps. 325-334 (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, at xxvii (Interagency Review Draft) (Dec. 2021), https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=544460.

[65] Jonathan M. Samet, *Expert Review Under Attack: Glyphosate, Talc, and Cancer*, Am. J. Pub. Health (June 5, 2019), https://ajph.aphapublications.org/doi/10.2105/AJPH.2019.305131.

[66] *Id.*

[67] *See* Office of Management and Budget, *Final Information Quality Bulletin for Peer Review* at 18 (Dec. 16, 2004), https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/omb/memoranda/fy2005/m05-03.pdf ("[I]f a scientist has repeatedly served as a reviewer for the same agency, some may question whether that scientist is sufficiently independent[.]").

Committee members have served on over 220 federal advisory committees at EPA and the Department of Health and Human Services (HHS).[68] Overall, 12 of the 13 members have served on EPA or HHS advisory committee, 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 in reviewing the IRIS Assessment and its uses, including the Science Advisory Board and the Clean Air Scientific Advisory Committee. Moreover, at least one panel member serves as the principal investigator on a project relevant to the current formaldehyde Assessment, which runs through 2025 and relies on a grant from U.S. EPA.[69]

Although FACA permits persons with a conflict of interest to serve on a committee, NAS must first disclose the conflicts to the public and determine that the conflict is unavoidable (*i.e.*, explain why). 5 U.S.C. § 1014(b)(1)(A). But NAS failed to even acknowledge the existence of any conflicts of interests, let alone justify them as unavoidable—despite ACC's repeated efforts to inform and request additional information from NAS concerning these conflicts and potential others. Accordingly, it failed to comply with section 15(b)(1)(B) of FACA.

3. *NAS failed to disclose required information and limited public input.*

NAS also violated FACA by failing to provide information regarding its Committee appointments, including biographical information, and comments received.

When Congress enacted the 1997 FACA amendments, it recognized the importance of transparency in NAS's processes and therefore imposed several public disclosure requirements on

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[68] GSA, FACA Database, https://www.facadatabase.gov/FACA/s/FACADatasets.

[69] *See, e.g.*, EPA, *Grantee Research Project Results: A tiered hybrid experimental – computational strategy for rapid risk assessment of complex environmental mixtures using novel analytical and toxicological methods*, EPA Grant Number: R840450, https://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/display.abstractDetail/abstract_id/11291/report/0 (last visited Oct. 4, 2023).

NAS committees. *See* Pub. L. No. 105-153, 111 Stat. 2689 ("An Act to amend the Federal Advisory Committee Act to clarify public disclosure requirements that are applicable to the National Academy of Sciences[.]"). The public disclosure requirements under FACA, in part, direct NAS to provide (1) public notice and the names and biographies of individuals that the Academy intends to appoint; (2) a reasonable opportunity for the public to comment on such appointments before they are made; (3) written materials presented to the committee by individuals who are not officials, agents, or employees of NAS, unless it determines that making such material available would disclose matters exempt under FOIA; and (4) for meetings that are not data gathering meetings, a brief summary of the meeting, including the topics discussed, materials made available to the committee, and other materials NAS determines should be included. 5 U.S.C. § 1014(b)(1)-(4). NAS has violated each of these mandates.

NAS failed to adhere to FACA's mandate to provide the names and brief biographies of individuals that it intends to appoint to a committee. *See id.* § 1014(b)(1). The information NAS provided regarding proposed committee members was sparse and lacking key details such as relevant relationships, publications, grants, testimony, and public statements. NAS's Policy requires the disclosure of such information in order to comply with FACA requirements.[70] Despite ACC's numerous requests to NAS to provide information that would allow the public to review

[70] 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[.]" Policy, *supra* n.49, at 3–5. The Policy also requires disclosure of "any published or [ ] public statement authored by the [ ] member … during the last five years that takes a position on an issue that is central to the work of the committee." *Id.* at 5. And it requires disclosure of "[a]ny other information regarding a committee member . . . that . . . could have a significant impact on public perception of the objectivity and value of the committee's work[.]" *Id.*

key biographical details, NAS has failed to provide this information. This failure has precluded the public from meaningfully evaluating each panelist's qualifications, and the Committee's overall scientific integrity, balance, and independence. As an example of why this information is so critical, this Court found that the Committee's chair, Dr. Samet, was conflicted out of serving on another Panel based on the type of information that NAS has failed to make public in this case.[71]

NAS also violated section 15(b)(1) of FACA by failing to "provide a reasonable opportunity for the public on such appointments before they are made." NAS announced the provisional committee on Friday, August 5, 2022, and the comment period remained open for 20 days (14 working days), with an August 25 deadline. Ex. S, E-mails between Clifford Duke, NASEM, and Julianne Ogden, ACC (Aug. 15-19, 2022). ACC requested that NAS provide additional biographical information for the provisional committee and extend the comment period for an additional 20 days to provide a reasonable opportunity for the public to comment. Ex. L, Letter from ACC to Dr. Marcia McNutt, President, NASEM (Aug. 15, 2022). Contrary to past practice, however, NAS declined to extend the time to provide comments, and also refused to provide the requested information. Ex. S, E-mails between Clifford Duke, NASEM, and Julianne Ogden, ACC (Aug. 15-19, 2022).

Next, NAS failed to disclose materials presented to the committee by individuals who are not officials, agents, or employees of NAS, thereby violating section 15(b)(3) of FACA. The withheld information includes, but is not limited to, nominations from and communications with EPA regarding the Committee's membership, other public comments regarding the provisional committee, submissions from Members of Congress, *see* Exs. P-Q, and letters from ACC. For

[71] Mem. Op., *Lorillard, Inc. v. U.S. FDA*, No. 11-440 (D.D.C. July 21, 2014), https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2011cv0440-82.

example, through a FOIA request, ACC learned that EPA employees provided NAS with committee nominations and encouraged "recycling" of committee members from prior NAS committees. Ex. D, E-mails between Dr. Kathryn Guyton and Stan Barone (October 4-14, 2021). NAS did not make these communications "available to the public"; ACC learned of them only through a FOIA request, and they were still heavily redacted by EPA. Thus ACC—and the public—still do not have all of the relevant information regarding EPA's role in selecting Committee members, or access to all submission made to the Committee.

Finally, NAS unlawfully withheld information about its meetings held on September 1 and 22, 2022, during which the Committee discussed its composition, balance, and conflicts of interests. Because these meetings were not data gathering meetings, NAS was required to provide "a brief summary of [the] committee meeting[s]." 5 U.S.C. § 1014(b)(4). Contrary to FACA, however, the "summary" NAS provided on its website did not summarize either the content or outcome of the meetings. NAS only identified, in very broad terms, the topic discussed (*e.g.*, "conflict of interest discussion").[72] NAS failed to provide any information about the substance of the discussions, or whether the meeting resulted in any changes to the provisional committee or disclosure of conflicts. These non-informative postings cannot be fairly deemed even brief "summaries" of NAS's meetings. NAS thereby again violated FACA.

B. EPA's improper control of the Committee also violates FACA.

Section 15 of FACA prohibits a federal agency from relying on any advice or recommendation provided by a NAS committee if that committee was subject to the agency's

[72] NASEM, Committee Meeting (Sept. 1, 2022), https://www.nationalacademies.org/event/09-02-2022/review-of-epas-2022-draft-formaldehyde-assessment-bcoi-discussion; NASEM, Committee Meeting (Sept. 22, 2022), https://www.nationalacademies.org/event/09-22-2022/review-of-epas-2022-draft-formaldehyde-assessment.

management or control. 5 U.S.C. § 1014(a). The regulations implementing FACA clarify that an agency can "enter into a funding agreement" to prepare a report "containing advice or recommendations to the agency . . . without subjecting" NAS 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 (emphasis added). Here, however, EPA exercised control over the Committee by limiting its independent evaluation, providing the Committee specific scientific information it should use during the review process, and manipulating the nomination process.

EPA improperly threatened the independence of the peer review process from the outset when it limited the contract task order, thereby controlling the Committee's deliberations. EPA 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." Ex. C, Task Order at 2. EPA limited the Committee to responding to narrow "charge questions set forth by EPA" and the materials provided by the Agency, and not considering other relevant materials. *Id*. EPA even dictated the length of the Committee's "public peer review meeting(s)[.]" *Id.* at 3.

Dr. Guyton confirmed EPA's limitations on the Committee's independence and reiterated that "[t]he committee's charge is to review the assessment prepared by EPA, and not to conduct their own assessment of formaldehyde." Ex. R, Letter from Dr. Kathryn Guyton to S. Osman-Sypher at 2 (Mar. 6, 2023). She noted that "[t]he committee is also not charged to comment on other interpretations of scientific information relevant to the hazards and risks of formaldehyde[.]" *Id.* The Report itself reiterates these limitations on the scope of the Committee's review. For example:

> The committee's charge was to review the 2022 Draft Assessment prepared by EPA, and not to conduct its own formaldehyde assessment. The committee also

> was not charged with commenting on other interpretations of scientific information relevant to the hazards and risks of formaldehyde, or with reviewing alternative opinions of EPA's assessment. Any other topics not falling within the committee's charge were excluded from the committee's purview.

Ex. A, NAS Report at 16. Thus, EPA's limitations in the contract task order effectively controlled the scope and content of the Committee's discussion.

Next, EPA exercised control over the Committee by telling NAS who it should appoint. In October 2021, nearly a year before NAS publicly announced the provisional committee, Dr. Guyton solicited nominations for Committee members from EPA staff with whom she had worked. *See* Ex. D, E-mails between Dr. Kathryn Guyton and Stan Barone (October 4-14, 2021). EPA staff suggested nominations, and Dr. Guyton thanked EPA "for these great suggestions." *Id.* Dr. Guyton then informed EPA that "[t]here will be 'recycling' from the prior committee[,] including [a name that has been redacted]", and asked EPA who the Agency would like "for a neurotox person." *Id.* The EPA staff member responded that they "[l]ove recycling", and presumably provided further membership recommendations in the part of the email that has been redacted. *Id.* This shows that the current NAS Study Director solicited, and EPA selected, the Committee members.

EPA's Peer Review Handbook states that EPA "should avoid commenting on the contractor's selection of peer reviewers" and, if EPA suggests any peer reviewers, it should provide "a pool of qualified peer reviewers … in alphabetical order," the proposal "should include more individuals than the number required for the review," and EPA should specifically note "that it is a suggested list and other qualified candidates may exist who are not on the list."[73] EPA's proposal of a few specific names and comments favoring "recycling" directly conflict with those

[73] *EPA Peer Review Handbook* at 59, https://www.epa.gov/sites/default/files/2020-08/documents/epa_peer_review_handbook_4th_edition.pdf.

rules, and show improper EPA control of the Committee selection process. EPA recognized as much by withholding this information (in response to FOIA requests) as pre-decisional and "[d]eliberative."[74] In other words, EPA characterized its proposal of Committee members to NAS as *internal* communications leading to *an EPA decision*. Although EPA, like any member of the public, may offer suggestions for committee members during the nomination process or comment on proposed members, NAS's direct solicitation of nominees and EPA's proposal of specific members violate FACA's requirement that the referring agency not control the review.

C. EPA's planned reliance on the Committee's flawed and unlawful report violates FACA, and would violate the APA. It should therefore be enjoined.

For all the reasons described above, NAS failed to comply with section 15(b) of FACA, and the Committee's process was improperly controlled by EPA in violation of 5 U.S.C. § 1014(a)(1). Where there has been a violation of even one of these requirements, FACA plainly prohibits EPA from "any" use of or reliance on the Committee's Report, including even in proposed rulemaking or agency action. *Id.* § 1014(a) (agency "may not use any advice or recommendation provided by [NAS] that was developed by use of a committee created by that academy under an agreement with an agency, unless" it meets the subsequent listed requirements, including that there be no improper control by the agency).

Furthermore, under the APA, courts may set aside agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," *id.* § 706(2)(A), or "in excess of statutory jurisdiction, authority, or limitations[.]" *Id.* § 706(2)(C). It would be plainly unlawful, arbitrary, and capricious for EPA to take any action in reliance on the Report. Yet, the Agency has already indicated that it will do just that, absent court intervention.

[74] Ex. D, E-mails between Dr. Kathryn Guyton and Stan Barone (Oct. 4-14, 2021).

This Court therefore should enjoin EPA from making any finding or conclusion based on the Report, or otherwise using or relying on the Report, in violation of the APA. This Court alternatively has the power to enjoin EPA from relying on the Report under the Mandamus Act, 28 U.S.C. § 1361. *NAACP*, 496 F. Supp. 3d at 145 (granting mandamus relief and compelling advisory committee to comply with obligations under FACA); *Elec. Priv. Info. Ctr. v. Nat'l Sec. Comm'n on A.I.*, 466 F. Supp. 3d 100, 123 (D.D.C. 2020) (same).

D. ACC and its members face imminent irreparable harm.

ACC's members face imminent irreparable harm should EPA be permitted to use or rely on the Report. "To show irreparable injury, a party seeking a preliminary injunction must ordinarily show . . . that the harm is 'certain and great,' 'actual and not theoretical,' and so 'imminen[t] that there is a clear and present need for equitable relief to prevent irreparable harm[.]'" *Capitol Hill Baptist Church v. Bowser*, 496 F. Supp. 3d 284, 301 (D.D.C. 2020) (quoting *League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 7–8 (D.C. Cir. 2016)).

Courts have found irreparable injury sufficient to justify a preliminary injunction to prevent government agencies from using a report generated in violation of FACA in rulemaking and for other purposes. *Alabama-Tombigbee Rivers Coal. v. Fish & Wildlife Serv. of U.S. Dep't of Interior*, Civ. A. No. 93-AR-2322-S, 1993 WL 646409, at *2–*4 (N.D. Ala. Nov. 9, 1993) (finding "that plaintiffs will suffer severe and irreparable harm" from use of the report, even though the government argued that plaintiffs "can seek and obtain any necessary corrective action within the rule-making process" and explaining that to find otherwise would create "the potential for mischief"). Here, ACC's members similarly face great harm should EPA be permitted to disseminate, cite, rely on, or otherwise use NAS's Report rubber-stamping EPA's Assessment.

First, absent an injunction, EPA will immediately use the Report—the fruit of an unlawful

process—to modify and then finalize the IRIS Assessment. It is doing so "on an expedited time frame."[75] EPA has stated that it "plans to use the [NAS] report to revise the draft IRIS formaldehyde assessment prior to finalization."[76] Such plans are consistent with past EPA practice. 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."[77] After receiving peer review, EPA considers the comments and revises IRIS assessments to address any concerns raised, before issuing the final IRIS assessment and values.[78] EPA has implemented a policy under which all draft human health assessments developed under the IRIS Program are subjected to peer review, so EPA cannot finalize the Assessment without using the Report or without commissioning and using an alternate peer review, which it has not done.[79] Here, despite the narrow scope of the Committee's review and the deficiencies identified in the Report (Ex. A, at 5-10), 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."[80] EPA

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[75] Hearing on Science and Technology Activities at EPA Before H.R. Comm. on Science, Space, and Technology, 118th Cong., Statement of Michael Regan at 1:48:35-1:50:04 (Sept. 27, 2023), https://www.youtube.com/watch?app=desktop&v=s9x1sxi5eO0.

[76] EPA, *[NASEM] 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.

[77] Reconsideration of 2020 National Emission Standards for Hazardous Air Pollutants; Misc. Organic Chemical Manuf. Residual Risk Review, 87 Fed. Reg. 77985, 77990 (Dec. 21, 2022).

[78] *NCEA Policy and Procedures for Conducting IRIS Peer Reviews*, at 3, 5 (eff. July 30, 2009), https://www.epa.gov/sites/default/files/2014-05/documents/policy_iris_peer_reviews.pdf.

[79] *Id.* at 5. *See also* EPA, *Basic Information about the [IRIS]*, https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system#process (last visited Oct. 4, 2023).

[80] EPA, *[NASEM] 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.

thus has made clear that it will treat the Report as supporting EPA's draft Assessment, finalize the Assessment in a form that is essentially the same as EPA's draft, and set IRIS values accordingly.

EPA will then use the IRIS Assessment in ways that directly impact ACC and its members, including as a basis for regulations. In an April 2023 communication with the Human Studies Review Board ("HSRB"), EPA indicated that "[o]nce [NAS] 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").[81] EPA has admitted that it will use the IRIS Assessment for purposes of regulation under TSCA and FIFRA, but it is also likely to use the final Assessment for other purposes as well. For example, EPA has used other IRIS assessments as the basis for regulation under the Emergency Planning and Community Right-to-Know Act[82] and the Clean Air Act.[83] In fact, EPA recently proposed air emissions reporting requirements that are to be based on IRIS values.[84] The proposed rule regulates formaldehyde based on the previous IRIS values[85]—but EPA will no doubt replace those old values with the Assessment's values once finalized. Only an order

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[81] EPA, *Memorandum of Materials for Review by HSRB for the May 16-18, 2023 Meeting* at 3 (Apr. 21, 2023), https://www.epa.gov/system/files/documents/2023-05/HSRB_transmittal_and_charge_2023_May_16-18%20FINAL.pdf.

[82] *Nat'l Oilseed Processors Ass'n v. Browner*, 924 F. Supp. 1193, 1199 (D.D.C. 1996).

[83] *See* National Emission Standards for Hazardous Air Pollutants: Misc. Organic Chemical Manufacturing Residual Risk and Technology Review, 85 Fed. Reg. 49084 (Aug. 12, 2020).

[84] 88 Fed. Reg. at 54135 n.26.

[85] EPA, TSD Supporting Data for AERR Proposal at "URE and RfC" worksheet, cell C77, https://www.regulations.gov/document/EPA-HQ-OAR-2004-0489-0097 (noting use of the last-finalized IRIS URE for formaldehyde, 0.000013 ug/m3).

from this Court can prevent EPA from using the Assessment (which EPA now views as blessed by the Report) to regulate in myriad ways.

The finalized IRIS Assessment, relying on the unlawful and flawed Report, will cause direct, irreparable harm to ACC and its members. EPA has made clear that, where it must make a decision based on dose-response values, it will use the IRIS values once finalized, giving them regulatory preference over other values.[86] For example, EPA has indicated it will use them to evaluate the risks of then set standards for formaldehyde under TSCA.[87] If it does so, it will determine that formaldehyde constitutes an "unreasonable risk" across many "conditions of use" critical to ACC's members, resulting in onerous regulations.[88] EPA's use of IRIS values consistent with the Assessment thus will cause substantial and irreparable harm to the businesses of ACC's members who produce and use formaldehyde.[89]

EPA is not the only part of the federal government that uses IRIS values in a way that will harm ACC's members. DOJ has also asserted that hazard values developed by the IRIS Program, like those in the 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. For example,

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[86] *See* 85 Fed. Reg. at 49128, n.7 ("we generally use UREs from the EPA's Integrated Risk Information System (IRIS)," and "we look to other reputable sources" only for "pollutants without IRIS values"); 87 Fed. Reg. at 77989 (EPA has "an established approach" that "generally results in an EPA IRIS value being given preference[.]").

[87] EPA, *Memorandum of Materials for Review by HSRB for the May 16-18, 2023 Meeting* at 3 (Apr. 21, 2023), https://www.epa.gov/system/files/documents/2023-05/HSRB_transmittal_and_charge_2023_May_16-18%20FINAL.pdf (EPA "plans to rely on the" values "from IRIS" for evaluations of formaldehyde under the Toxic Substances Control Act); 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[.]").

[88] Ex. B, ACC Decl. ¶ 22.

[89] *See generally* Hexion and Bakelite Declarations, Exs. M, N.

earlier this year the DOJ filed a complaint seeking injunctive relief under the CAA based on a company's emissions of a chemical based on the IRIS value.[90] EPA sought a preliminary injunction, relying on the fact that "[a]lthough IRIS assessments and their conclusions are not law, courts recognize that IRIS assessments, because of the rigorous vetting process, are 'generally accepted as a reliable source of information on the potential hazardous effects of those chemicals that are included in IRIS.'"[91] DOJ recently doubled down, suggesting that as long as EPA follows the IRIS development process the resulting values should be viewed as high quality and representing the Agency's established scientific position.[92] EPA has admitted that "EPA and other agencies rely on IRIS assessments"[93], and they rely on the assessments in ways that will regulate ACC members' use of formaldehyde or create liability for such use.[94] States also regulate chemicals based directly on IRIS values, thus compounding the harm ACC's members face from EPA's impending finalization of the Assessment based on the unlawful Report.[95]

EPA's proposed IRIS values, which EPA is now poised to finalize based on the Report, will suggest to the public and regulators that products containing even minute amounts of formaldehyde (below natural background levels and often less than that found in human breath)

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[90] Compl. ¶¶ 41-43, *Denka Performance Elastomer, LLC* (E.D. La. Feb. 28, 2023).

[91] Mem. in Supp. of U.S. PI Mot. at 7, *Denka Performance Elastomer, LLC* (E.D. La. Mar. 20, 2023) (citation omitted).

[92] *Id.* at 7; Reply re U.S. PI Mot. at 12, *Denka Performance Elastomer, LLC* (Sept. 6, 2023).

[93] Mem. in Supp. of U.S. PI Mot. at 7, *Denka Performance Elastomer, LLC* (Mar. 20, 2023).

[94] For example, the National Institute for Occupational Safety and Health also relies on IRIS values to set worker safety standards, with which ACC members must comply. *NIOSH Chemical Carcinogen Policy* (July 2017), https://www.cdc.gov/niosh/docs/2017-100/pdf/2017-100.pdf?id=10.26616/NIOSHPUB2017100revised.

[95] *See* Cal. Code Regs. Tit. 22, § 69021 (values from "IRIS shall be used where either" California has not already specified "toxicity criteria for a" chemical "or the IRIS toxicity criteria value is more stringent than the" value previously set by California).

are dangerous or harmful to human health.[96] This would subject ACC's members to enforcement actions, regulation, and de-selection from the market. EPA and others typically justify such use based on assertions that IRIS assessments have undergone "an extensive peer and public review process that adhered to the guidelines in EPA's Peer Review Handbook[.]"[97] Only a thorough, transparent, and unbiased peer review by a balanced peer-review body, undertaken in compliance with all applicable FACA requirements, can ensure that EPA, DOJ, and others do not rely on a flawed IRIS Assessment to set flawed IRIS values—to the detriment of ACC's members.

The harm ACC's members face is "likely irreparable," *Standing Rock Sioux Tribe v. U.S. Army Corps of Engineers*, 540 F. Supp. 3d 45, 62 (D.D.C. 2021), and beyond remediation. First, IRIS values carry "the stigma of a hazard determination, [which] once imposed, is very difficult to erase, even if the technology or substance is completely exonerated through additional scientific research."[98] Moreover, EPA has taken positions that would effectively preclude ACC from challenging the IRIS values, the IRIS Assessment, or EPA's use of the NAS Report once it finalizes the IRIS values. According to EPA, ACC and its members cannot challenge the IRIS values when EPA finalizes them because "IRIS assessments … are not 'final' within the meaning

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[96] ACC, *Our Breath Does Not Cause Cancer*, https://www.americanchemistry.com/content/download/5622/file/Formaldehyde-Our-Breath-Does-Not-Cause-Cancer.pdf (last visited Oct. 13, 2023).

[97] 87 Fed. Reg. at 77989. *See also* Compl. ¶ 41, *Denka Performance Elastomer, LLC* (E.D. La. Feb. 28, 2023) ("The conclusions of the 2010 IRIS Assessment were subsequently confirmed by an independent external peer review panel"); Mem. in Supp. of U.S. PI Mot. at 7, *Denka Performance Elastomer, LLC* (E.D. La. Mar. 20, 2023) ("The conclusions of the 2010 IRIS Assessment were then vetted and confirmed by an independent external peer review panel."); Reply in Supp. of U.S. PI Mot. at 11, *Denka Performance Elastomer, LLC* (E.D. La. Sept. 6, 2023) ("qualified experts comprised the EPA's peer review panels").

[98] John D. Graham, Testimony for the Joint Economic Committee of the U.S. Congress at 8-9 (Apr. 30, 2014), https://www.jec.senate.gov/public/_cache/files/def8558f-e82d-4b94-aaec-b4d40f9b0455/graham-testimony.pdf.

of APA[.]"[99] EPA's position has also been that, when developing regulations, it can conclusively rely on the IRIS values and need not consider alternative evidence unless the Agency believes the new data is sufficient to disprove the IRIS value.[100] EPA thus has made clear that, once it finalizes the IRIS value, it does not believe the public can comment on or challenge the IRIS assessments. Thus, if EPA is permitted to use the NAS Report to finalize the IRIS Assessment, EPA will deny ACC and its members any opportunity to meaningfully challenge or change the final IRIS values. And ACC and its members will not have any other opportunity to prevent EPA from regulating formaldehyde based on a faulty assessment and illegal peer review. Thus, should EPA be permitted to finalize the IRIS values based on NAS's Report, ACC and its members will suffer harm without any ability to challenge or remediate it, making that harm irreparable.

E. The equities and the public interest favor entry of a preliminary injunction.

Where relief is sought against the government, the balance of equities and public interest factors of the preliminary injunction analysis merge. *Capitol Hill Baptist Church*, 496 F. Supp. 3d at 302. "There is generally no public interest in the perpetuation of unlawful agency action. To the contrary, there is a substantial public interest in having governmental agencies abide by the federal laws that govern their existence and operations." *League of Women Voters*, 838 F.3d at 12 (internal quotation marks and citations omitted). Here, the public interest is not served by allowing EPA to rely on, publish, refer to, and incorporate into its actions an IRIS value for formaldehyde that is the result of a process that violated FACA—including because the public was not kept fully apprised of that process or allowed to fully participate in it as required under FACA. Indeed, the

[99] Mem. in Supp. of Mot. to Dismiss 16, *Denka Performance Elastomer, LLC* (May 9, 2023).

[100] *E.g.*, 85 Fed. Reg. at 49098 ("consideration of these individual analyses did not prompt the Agency to pursue reassessment of the EPA's IRIS ethylene oxide Assessment for purposes of this rulemaking"). ACC disagrees with EPA's position and is challenging it in litigation. *See* Br. of Petitioners, *Huntsman Petrochemical LLC v. EPA*, No. 23-1047 (D.C. Cir. July 24, 2023).

very purpose of FACA is to promote transparency and ensure the public is informed of, and can participate in, government-sponsored review and decision-making processes. *NAACP*, 496 F. Supp. 3d at 122–23 (FACA was designed to ensure that "'Congress and the public remain apprised of [advisory committee's] existence [and] activities'" and to prevent the wasteful creation of "'biased proposals.'") (quoting *Pub. Citizen*, 491 U.S. at 446, 453).

Congress had good reasons for requiring that NAS comply with certain parts of FACA. The imprimatur of the National Academy of Sciences on an agency work product carries great weight. A NAS-approved risk assessment will be looked to by the public to determine whether it should be concerned about the presence of formaldehyde in everyday products. A NAS-approved IRIS value that is irrationally low—below the level of formaldehyde often found in human breath—could cause unnecessary and unwarranted public concern.[101] It is thus not in the public interest to allow EPA to set an IRIS value based on a NAS Report that does not comply with FACA's requirements. Conversely, there is little harm to EPA from instructing it not to rely on the Committee's Report pending a final decision on the merits of ACC's claims. That would simply preserve the status quo. The equities and public interest therefore support a preliminary injunction.

VI. CONCLUSION

For the foregoing reasons, Plaintiff respectfully requests that the Court grant its motion for preliminary or permanent injunctive relief.

Dated: October 13, 2023

Respectfully submitted,

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[101] *E.g.*, Joce Sterman *et al.*, *Invisible gas may pose a cancer risk in towns, but experts say the EPA is failing to warn* (Sept. 14, 2020), https://wchstv.com/news/spotlight-on-america/invisible-gas-may-pose-a-cancer-risk-in-towns-but-experts-say-the-epa-is-failing-to-warn.

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