

Comments from University of California, San Francisco Program on Reproductive Health and the Environment on Formaldehyde; Draft Risk Evaluation Peer Review of the Science Advisory Committee on Chemical *ad hoc* nominees

Submitted online via Regulations.gov to docket EPA-HQ-OPPT-2023-0613-0002

The following comments are being submitted by the University of California, San Francisco (UCSF) Program on Reproductive Health and the Environment (PRHE). We have no direct or indirect financial or fiduciary interest in the manufacture or sale of any chemical that would be the subject of the deliberations of this Committee.

We appreciate the opportunity to provide input on the candidates for selection as *ad hoc* peer reviewers assisting the United States Environmental Protection Agency (“EPA”) Science Advisory Committee on Chemicals (“SACC”) with the peer review of the EPA’s evaluation of the risks of formaldehyde being conducted to inform risk management decisions under the Toxic Substances Control Act (“TSCA”) and Federal Food, Insecticide, Fungicide, and Rodenticide (“FIFRA”) (hereafter referred to as the “*ad hoc* formaldehyde SACC”).

EPA is required to nominate candidates for the SACC that represent relevant backgrounds and expertise. Pursuant to section 2625(o) of TSCA, the SACC is required to “provide independent advice and expert consultation, at the request of the Administrator, with respect to the scientific and technical aspects of issues relating to the implementation of this title” and will include “representatives of such science, government, labor, public health, public interest, animal protection, industry, and other groups as the Administrator determines to be advisable, including representatives that have specific scientific expertise in the relationship of chemical exposures to women, children, and other potentially exposed or susceptible subpopulations.”¹

Furthermore, when composing federal advisory committees like the SACC, EPA must ensure that members represent balanced interests and industry bias is publicly disclosed and avoided. The Federal Advisory Committee Act (“FACA”) imposes requirements on federal agencies when they establish or utilize any advisory committee, like the SACC.² For example, when an agency seeks to obtain such advice or recommendations, it must ensure the advisory committee: is “in the public interest;”³ is “fairly balanced in terms of points of view represented and the function to be performed;”⁴ and will not be “inappropriately influenced by . . . any special interest, but will instead be the result of the advisory committee’s independent judgment.”⁵

EPA’s proposed list of *ad hoc* formaldehyde SACC nominees does not meet these criteria for the following reasons:

1. **EPA failed to include transparent or effective financial conflict of interest disclosure statements.** There are several candidates whose biographical profiles do not disclose publicly their financial relationships with industries, some of which have a particular

¹ 15 U.S.C. § 2625(o).

² 5 U.S.C. App. II, § 3(2).

³ Id. App. II, § 9(2).

⁴ Id. § 5(b)(2).

⁵ Id. § 5(b)(3).

interest in the topic of this committee. While this information can be found in some published papers, not all funding arrangements can be tracked. Disclosure and financial conflict of interest policies play an essential role in protecting EPA and committee work products from the possibility of biased scientific conclusions and must be strictly enforced and routinely addressed to ensure the quality of SACC reviews and other work products. Further, although disclosing conflicts of interest was previously seen as sufficient to manage committee members' interests, research has shown paradoxically that those members who disclose conflicts of interest provide more biased advice due the belief that they have adequately warned recipients of the information they have provided and/or to compensate for the fact that their advice will be disregarded.^{6,7} Systematic reviews have established that that disclosed financial conflicts are associated with research outcomes biased towards the sponsor, demonstrating that disclosure alone is not a solution to reducing bias.⁸ The most effective approach to avoiding bias is to not include those that have a financial conflict of interest.

- 2. EPA failed to nominate candidates representing balanced viewpoints.** The proposed *ad hoc* formaldehyde SACC nominees do not represent populations directly impacted, susceptible, vulnerable, and/or highly exposed to formaldehyde. To comply with FACA, EPA must nominate representatives that have *specific scientific expertise* in the relationship of chemical exposures to workers, women, children, and other potentially exposed or susceptible subpopulations, and also representatives with diverse knowledge sources and balanced view points that represent unique perspectives regarding these critical issues. EPA must consider nominating individuals from community groups, NGOs, environmental justice communities, or other groups that provide unbiased and relevant expertise that is not currently reflected in the *ad hoc* formaldehyde SACC nominees. There are many examples of successful implementation of such approaches, which have demonstrated that incorporating knowledge resources outside of traditional academic and science fields can greatly enrich the decision-making process.⁹

In addition, EPA failed to release the charge questions for the *ad hoc* formaldehyde SACC for public comment. Without this information, the public cannot adequately provide input and scrutiny on the peer review process for upcoming formaldehyde rulemakings. In the charge questions, we strongly urge EPA to not revisit issues addressed in the National Academies of Sciences, Engineering, and Medicine (NASEM) review of the draft IRIS formaldehyde assessment.¹⁰ These issues have been evaluated and validated by scientists from authoritative bodies and constitute the best available science and should accordingly be left out of the charge questions.

⁶ Loewenstein G, Sah S, Cain DM. The unintended consequences of conflict of interest disclosure. *JAMA*2012;307:669-70. doi:10.1001/jama.2012.154. pmid:22337676

⁷ Romain PL. Conflicts of interest in research: looking out for number one means keeping the primary interest front and center. *Curr Rev Musculoskelet Med*. 2015 Jun;8(2):122-7. doi: 10.1007/s12178-015-9270-2. PMID: 25851417; PMCID: PMC4596167.

⁸ Lundh A, Lexchin J, Mintzes B, Schroll JB, Bero L. Industry sponsorship and research outcome. *Cochrane Database Syst Rev*2017;2:MR000033.pmid:28207928

⁹ Anderson, B.E., Naujokas, M.F. and Suk, W.A., 2015. Interweaving knowledge resources to address complex environmental health challenges. *Environmental health perspectives*, 123(11):1095-1099.

¹⁰ National Academies of Sciences, Engineering, and Medicine. 2023. Review of EPA's 2022 Draft Formaldehyde Assessment. Washington, DC: The National Academies Press. <https://doi.org/10.17226/27153>.

Our comments address the following main points that EPA must consider when nominating *ad hoc* formaldehyde SACC members:

- 1. EPA must eliminate or address financial conflicts of interest among selected nominees;**
- 2. EPA must consider the nomination of individuals who provide balanced viewpoints, including from NGOs, community groups, and other sectors that are not currently represented; and**
- 3. We strongly oppose the nominations of 18 proposed candidates with financial ties to industry or the American Chemistry Council (ACC), and support the nominations of Patrick N. Breyse, Bernard Goldstein, and Luoping Zhang.**

We appreciate the opportunity to provide public input. Please do not hesitate to contact us with any questions regarding these comments.

Respectfully,

Jessica Trowbridge, PhD, MPH
Associate Research Scientist
Program on Reproductive Health and the Environment
Department of Obstetrics, Gynecology and Reproductive Sciences
University of California, San Francisco

Rashmi Joglekar, PhD
Associate Director of Science, Policy and Engagement
Program on Reproductive Health and the Environment
Department of Obstetrics, Gynecology and Reproductive Sciences
University of California, San Francisco

Tracey Woodruff, PhD, MPH
Professor and Director
Program on Reproductive Health and the Environment
Department of Obstetrics, Gynecology and Reproductive Sciences
University of California, San Francisco

Daniel Axelrad, MPP
Independent Consultant
Washington, DC

Nicholas Chartres, PhD
Senior Research Fellow
School of Pharmacy,
Faculty of Medicine & Health, The University of Sydney
Sydney, NSW

DETAILED COMMENTS:

1. EPA must eliminate or address financial conflicts of interest among selected nominees.

EPA committees must be composed to ensure that industry bias is publicly disclosed and avoided. The Federal Advisory Committee Act (“FACA”) requires EPA to ensure that the advisory committee acts “in the public interest”¹¹ and that EPA transparently vets financial conflicts of interest that bias panel members toward undervaluing scientific evidence of health harms or adverse environmental impacts.¹² FACA also requires EPA to ensure advisory committees are “fairly balanced in terms of points of view represented and the function to be performed”¹³ and that “independent judgment” among committee members is not “inappropriately influenced” by “any special interest.”¹⁴

These prohibitions call for special care with respect to the service on advisory committees of individuals whose employer or business would benefit financially from the committee’s recommendations. Here, the *ad hoc* formaldehyde SACC will likely be asked to review and evaluate the validity of methods that will be used to estimate the health risks of formaldehyde. The SACC comments could therefore lead to underestimation of formaldehyde risks, which would benefit industries who advocate to retain formaldehyde uses. As such, it is questionable whether any employee of or consultant to a company that financially benefits from the production, use, or disposal of formaldehyde could serve on the *ad hoc* formaldehyde SACC without skirting FACA’s safeguards.

Federal ethics regulations also require EPA to “[a]ssure that the interests and affiliations of advisory committee members are reviewed for conformance with applicable conflict of interest statutes.”¹⁵ Therefore, before finalizing the selection of individual *ad hoc* peer reviewers, EPA must employ a vetting process for conflicts of interest that includes: publicly identifying and disclosing any conflicts that include financial ties with industry; determining whether a conflict of interest exists with the committee member; and finally implementing the necessary procedures to manage any conflicts of interest to ensure the composition of the *ad hoc* formaldehyde SACC is free from financial conflicts of interest. This vetting process will also ensure that the burden of vetting financial conflicts of interest does not inappropriately fall on the public.

In its request for comments on the *ad hoc* formaldehyde SACC, EPA claims that it will evaluate for “financial conflicts of interest, appearance of a loss of impartiality, or any prior development of the documents under consideration.”¹⁶ However, in violation of FACA and this claim, there are several *ad hoc* formaldehyde SACC nominees for which EPA failed to provide biographical

¹¹ 5 U.S.C. App. II, § 9(2).

¹² 5 U.S.C. App. II, § 3(2).

¹³ *Id.* § 5(b)(2).

¹⁴ *Id.* § 5(b)(3).

¹⁵ 41 C.F.R. § 102-3.105(h)

¹⁶ US EPA. (2024). Science Advisory Committee on Chemicals (SACC); Request for Comments on nominations. Available: <https://www.regulations.gov/document/EPA-HQ-OPPT-2023-0613-0002>

profiles that have disclosed financial relationships with industries, some of which have a particular interest in the topic of this committee. While this information can be found in some published papers, not all funding arrangements can be tracked. Without disclosure of financial conflicts of interest, EPA cannot ensure that committee work products are free of biased scientific conclusions, as required by FACA. In addition, failing to prescreen candidates for ethics concerns places the burden of vetting candidates on the public, and it could inappropriately allow for candidates with potential conflicts of interest to be nominated to the SACC. EPA must evaluate potential conflicts of interest as the first step in determining whether an individual is eligible for nomination to the *ad hoc* formaldehyde SACC.

In addition, research has demonstrated that disclosure of financial conflicts of interest alone is not sufficient to avoid bias. Systematic reviews have confirmed that disclosed financial conflicts of interest in scientific studies are associated with research outcomes biased towards the financial sponsor and therefore demonstrates why disclosure is not a solution to reducing bias in guideline committees.¹⁷ Even when controlling for methodological biases, studies sponsored by industry or that have an author with a financial conflict of interest are more likely to have results that favor the sponsor's products than studies with no industry sponsorship or author conflict of interest.^{18,19,20,21} The influence of financial ties on research can be traced to a variety of types of biases, and this conflict of interest needs to be distinguished from non-financial interests in the research.²²

Committee members who disclose conflicts of interest actually provide more biased advice due to the belief that they have adequately warned recipients of the information they have provided and/or to compensate for the fact that their advice will be disregarded.^{23,24} Conflicts of interest among committee members are increasingly being recognized as significant contributors to bias in guideline recommendations.^{25,26,27} For example, an association has been established between

¹⁷ Lundh A, Lexchin J, Mintzes B, Schroll JB, Bero L. Industry sponsorship and research outcome. *Cochrane Database Syst Rev*2017;2:MR000033.pmid:28207928

¹⁸ Odierna DH, Forsyth SR, White J, et al. The cycle of bias in health research: a framework and toolbox for critical appraisal training. *Account Res.* 2013;20(2):127-41. 11

¹⁹ Fabbri A, Lai A, Grundy Q, et al. The Influence of Industry Sponsorship on the Research Agenda: A Scoping Review. *Am J Public Health.* 2018;108(11):e9-e16. 12

²⁰ Psaty BM, Prentice RL. Minimizing bias in randomized trials: the importance of blinding. *JAMA.* 2010;304(7):793-4. 13

²¹ Psaty BM, Kronmal RA. Reporting mortality findings in trials of rofecoxib for Alzheimer disease or cognitive impairment: a case study based on documents from rofecoxib litigation. *JAMA.* 2008;299(15):1813-7.

²² Bero LA, Grundy Q. Why Having a (Nonfinancial) Interest Is Not a Conflict of Interest. *PLoS Biol.* 2016 Dec 21;14(12):e2001221. doi: 10.1371/journal.pbio.2001221. PMID: 28002462; PMCID: PMC5176169.

²³ Loewenstein G, Sah S, Cain DM. The unintended consequences of conflict of interest disclosure. *JAMA*2012;307:669-70. doi:10.1001/jama.2012.154. pmid:22337676

²⁴ Romain PL. Conflicts of interest in research: looking out for number one means keeping the primary interest front and center. *Curr Rev Musculoskelet Med.* 2015 Jun;8(2):122-7. doi: 10.1007/s12178-015-9270-2. PMID: 25851417; PMCID: PMC4596167.

²⁵ Blake P, Durão S, Naude CE, Bero L. An analysis of methods used to synthesize evidence and grade recommendations in food-based dietary guidelines.

²⁶ Tabatabavakili S, Khan R, Scaffidi MA, Gimpaya N, Lightfoot D, Grover SC. Financial conflicts of interest in clinical practice guidelines: a systematic review. *Mayo Clin Proc Innov Qual Outcomes*2021;5:466-75. Doi:10.1016/j.mayocpiqo.2020.09.016 pmid:33997642

²⁷ Brems JH, Davis AE, Clayton EW. Analysis of conflict of interest policies among organizations producing clinical practice guidelines. *PLoS One*2021;16:e0249267. doi:10.1371/journal.pone.0249267 pmid:33930893

financial conflicts of interest among expert reviewers and clinical guideline recommendations that favor the interests of the industry providing support.^{28,29} Several factors influence the extent to which committee members are likely to influence guidelines and recommendations, including the relevance of the topic to the committee members interest and type and magnitude of the relationship comprising the conflict.³⁰ Therefore, allowing *ad hoc* formaldehyde SACC nominees with financial ties to any of the regulated chemical companies would risk biasing the recommendations they make towards industry interests. The “megaphone effect” that multiple *ad hoc* and SACC members with financial conflicts of interest could create by making aligned recommendations raises additional concerns and creates the potential for systemic bias.³¹

Therefore, individuals who have been nominated to the *ad hoc* formaldehyde SACC who also have financial relationships with companies that can benefit from the recommendations of the committee should be excluded from consideration.^{32,33,34,35,36} We further recommend that EPA use predetermined criteria to evaluate and respond to the risk of bias from the interests of prospective SACC members, as outlined in Table 1 below.³⁷

For example, EPA should exclude the nominations of any *ad hoc* formaldehyde SACC nominee that is considered “high risk” for financial conflict of interest until 3-5 years have passed since eliminating conflict(s) of interest. “High risk” individuals have financial ties with a chemical company (a company employee, paid adviser or consultant, recipient of speaker fees, owner of financial holdings in the company (e.g., shares, patents, royalties), recipient of research grant

²⁸ Nejstgaard CH, Bero L, Hróbjartsson A, et al. Association between conflicts of interest and favourable recommendations in clinical guidelines, advisory committee reports, opinion pieces, and narrative reviews: systematic review. *BMJ*2020;371:m4234.pmid:33298430

²⁹ Coyne DW. Influence of industry on renal guideline development. *Clin J Am Soc Nephrol*2007;2:3-7, discussion 13-4. doi:10.2215/CJN.02170606 pmid:17699377

³⁰ Parker L, Bero L. Managing risk from conflicts of interest in guideline development committees *BMJ* 2022; 379 :e072252 doi:10.1136/bmj-2022-072252

³¹ Ralston R, Hil SE, da Silva Gomes F, Collin J. Towards preventing and managing conflict of interest in nutrition policy? an analysis of submissions to a consultation on a draft WHO tool. *Int J Health Policy Manag*2021;10:255-65.pmid:32610752

³² Bero L, Anglemyer A, Vesterinen H, Krauth D. The relationship between study sponsorship, risks of bias, and research outcomes in atrazine exposure studies conducted in non-human animals: Systematic review and meta-analysis. *Environment International*. 2016;92-93:597-604

³³ Yank V, Rennie D, Bero LA. Financial ties and concordance between results and conclusions in meta-analyses: Retrospective cohort study. *British Medical Journal*. 2007;335(7631):1202-5.

³⁴ Mandrioli D, Kearns CE, Bero LA. Relationship between Research Outcomes and Risk of Bias, Study Sponsorship, and Author Financial Conflicts of Interest in Reviews of the Effects of Artificially Sweetened Beverages on Weight Outcomes: A Systematic Review of Reviews. *PLoS One*. 2016;11(9):e0162198.

³⁵ Lundh A, Lexchin J, Mintzes B, Schroll JB, Bero L. Industry sponsorship and research outcome. *The Cochrane database of systematic reviews*. 2017;2:MR000033-MR.

³⁶ Woodruff TJ, Rayasam SDG, Axelrad DA, Koman PD, Chartres N, Bennett DH, Birnbaum LS, Brown P, Carignan CC, Cooper C, Cranor CF, Diamond ML, Franjevic S, Gartner EC, Hattis D, Hauser R, Heiger-Bernays W, Joglekar R, Lam J, Levy JI, MacRoy PM, Maffini MV, Marquez EC, Morello-Frosch R, Nachman KE, Nielsen GH, Oksas C, Abrahamsson DP, Patisaul HB, Patton S, Robinson JF, Rodgers KM, Rossi MS, Rudel RA, Sass JB, Sathyanarayana S, Schettler T, Shaffer RM, Shamasunder B, Shepard PM, Shrader-Frechette K, Solomon GM, Subra WA, Vandenberg LN, Varshavsky JR, White RF, Zarker K, Zeise L. A science-based agenda for health-protective chemical assessments and decisions: overview and consensus statement. *Environ Health*. 2023 Jan 12;21(Suppl 1):132. doi: 10.1186/s12940-022-00930-3. PMID: 36635734; PMCID: PMC9835243.

³⁷ Parker L, Bero L. Managing risk from conflicts of interest in guideline development committees *BMJ* 2022; 379 :e072252 doi:10.1136/bmj-2022-072252

money from company, recipient of monetary gift (e.g., to cover conference travel, accommodation, registration), managerial or advisory position, including unpaid) or position of control or decision making within such a chemical corporation.

Table 1. Risk management model for financial conflicts of interest among *ad hoc* formaldehyde SACC nominees. Adapted from: Parker L, Bero L. Managing risk from conflicts of interest in guideline development committees *BMJ* 2022; 379 doi: <https://doi.org/10.1136/bmj-2022-072252>

Risk Level	Type of interest	Example	Examples of entity generating secondary interest	Suggested management
High risk	Financial link* with large national or multinational chemical corporation or position of control or decision making within such a corporation	Applicant, partner, or child is one of the following: A company employee Paid adviser or consultant Recipient of speaker fees Owner of financial holdings in the company (e.g., shares, patents, royalties) Recipient of research grant money from company Recipient of monetary gift (e.g., to cover conference travel, accommodation, registration) Managerial or advisory position, including unpaid (e.g., director, trustee, member of advisory board)	Large international chemical product manufacturers (e.g., Unilever, Procter & Gamble, , 3M) Chemical companies providing raw material used in large scale manufacturing and processing (e.g., Monsanto, DuPont, BASF, Bayer, Dow Chemical, Syngenta) Trade organizations and other groups that represent chemical company interests (e.g., American Chemistry Council, Treated Wood Council, Fertilizer Institute, Arsenic Science Task Force)	Reject committee membership until 3-5 years have passed since eliminating conflict(s) of interest (e.g., by divesting financial links, resigning from position, or rejecting speaker fees)
	Position of control or decision making over small industry company	Applicant, partner, or child is owner of small company	Local manufacturers such as boutique personal care product maker, small business, Small scale manufacturing business	

Risk Level	Type of interest	Example	Examples of entity generating secondary interest	Suggested management
Medium risk	Financial link* with chemical industry, with no decision making or control over corporation	Applicant, partner, or child is a small chemical company employee	Local manufacturers such as boutique personal care product maker, small business, Small scale manufacturing business	Individual cannot chair and may have only restricted participation in guideline committee until 3-5 years have passed since eliminating conflict(s) of interest
	Financial link* with government-chemical industry partnership	Applicant, partner, or child receives grant funding for research from formal partnership between government department and multinational chemical company	Grant from government health department-multinational chemical company partnership to study health effects	
	Personal financial gain from chemical related work	Applicant, partner, or child is paid for self-employed work related to chemicals (e.g., book, consulting)	Not applicable	
Low risk	Professional interests of prospective member	<p>Author of empirical studies, systematic reviews (where the research and researchers are not funded by industry or other chemical sector business)</p> <p>Recipient of research grant from non-industry sources (e.g., government)</p> <p>Member of previous guidelines committee</p> <p>Key opinion leader— e.g., author of opinion based articles, advocacy (not funded by industry or other chemical sector business)</p> <p>Member of a professional society that</p>	Not applicable	Full participation

Risk Level	Type of interest	Example	Examples of entity generating secondary interest	Suggested management
		is not industry funded Working as a health professional in a public health/environmental health/medical related field (e.g., toxicologist, medical doctor)		
Minimal or no risk	Personal experiences, values, or lifestyle habits of prospective member	Political and economic views Spiritual or religious affiliation Cultural practices, upbringing, ethnicity Professional and personal experiences Lifestyle habits and preferences, including dietary patterns Health problems, including dietary allergies and intolerances and those with recommended dietary restrictions Social relationships, including professional interest group membership, friendly or hostile connections with others	Not applicable	Full participation

2. EPA must consider the nomination of individuals who provide balanced viewpoints, including from NGOs, community groups, and other sectors that are not currently represented.

FACA requires EPA to compose the *ad hoc* formaldehyde SACC to be "fairly balanced in terms of points of view represented and the function to be performed."³⁸ The current proposed list of *ad hoc* formaldehyde SACC nominees does not represent a balance in viewpoints, in violation of FACA. For example, there is no representation from directly impacted, susceptible, vulnerable,

³⁸ Id. § 5(b)(2).

producers.⁴⁵ He has advocated on behalf of ACC on the formaldehyde risk assessment methodology,⁴⁶ and has advocated directly to EPA on the formaldehyde risk assessment as highlighted on ACC's website.⁴⁷ His research on the carcinogenicity of formaldehyde was funded by ACC's 501(c)(3) arm, Foundation for Chemistry Research and Initiatives, formerly the Research Foundation for Health and Environmental Effects on formaldehyde.^{48, 49}

Pamela H Dalton, PhD, MPH, Principal investigator at Monell Chemical Senses Center who has received funding from Formacare for her work on formaldehyde.⁵⁰ Has close ties to ACC as listed on the ACC website⁵¹ and has advocated directly to EPA on the formaldehyde risk assessment.⁵²

Linda D. Dell, MS, Principal at Ramboll and has received funding from Hexion for her research on the carcinogenicity of formaldehyde.⁵³ Hexion is a major manufacturer and distributor of

⁴⁵ <https://www.americanchemistry.com/about-acc#:~:text=This%20opens%20in%20a%20new%20window.&text=The%20American%20Chemistry%20Council%20ACC,our%20country%20and%20the%20world>.

⁴⁶ See, e.g., Comments submitted by ACC Formaldehyde TSCA Risk Evaluation Consortium on Formaldehyde; TSCA Review Docket EPA-HQ-OPPT-2018-0438 (Jun. 2, 2023), <https://www.regulations.gov/comment/EPA-HQ-OPPT-2018-0438-0115>; see also https://downloads.regulations.gov/EPA-HQ-OPPT-2018-0438-0115/attachment_1.pdf; https://downloads.regulations.gov/EPA-HQ-OPPT-2018-0438-0115/attachment_3.pdf; https://downloads.regulations.gov/EPA-HQ-OPPT-2018-0438-0115/attachment_4.pdf.

⁴⁷ See ACC, *NASEM Meetings Highlight Broad Scientific Criticism for EPA's Draft Formaldehyde Assessment*, <https://www.americanchemistry.com/chemistry-in-america/news-trends/blog-post/2023/nasem-meetings-highlight-broad-scientific-criticism-for-epa-s-draft-formaldehyde-assessment>, (last accessed Mar. 12, 2024).

⁴⁸ Conolly, R.B., Schroeter, J., Kimbell, J.S., Clewell, H., Andersen, E., & Gentry, P.R. (2023). Updating the Biologically Based Dose-Response Model for the Nasal Carcinogenicity of Inhaled Formaldehyde in the F344 Rat. *Toxicological Sciences* 193(1). <https://academic.oup.com/toxsci/article/193/1/1/7076626> (Funding: "Foundation for Chemistry Research & Initiatives (FCRI), a 501(c)(3) tax-exempt organization established by the American Chemistry Council (ACC).").

⁴⁹ Conolly, R.B., Campbell, J.L., Clewell, H.J., Schroeter, J., Kimbell, J.S., & Gentry, P.R. (2023). Relative Contributions of Endogenous and Exogenous Formaldehyde to Formation of Deoxyguanosine Monoadducts and DNA-Protein Crosslink Adducts of DNA in Rat Nasal Mucosa. *Toxicological Sciences* 191(1). <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9887723/> ("This work was funded by the Foundation for Chemistry Research & Initiatives (FCRI), a 501(c)(3) tax-exempt organization established by the American Chemistry Council (ACC).").

⁵⁰ See, e.g., Comments submitted by Pamela Dalton on Formaldehyde (Inhalation) IRIS Assessment; Toxicological Review of Formaldehyde Inhalation Toxicity Docket ID EPA-HQ-ORD-2010-0396 (Jun. 15, 2022) <https://www.regulations.gov/comment/EPA-HQ-ORD-2010-0396-0086>; see also Formacare, *About Formacare*, <https://www.formacare.eu/about-formacare/> (last visited Mar. 6, 2024), ("Formacare is the formaldehyde sector group of the [European Chemical Industry Council \(Cefic\)](#) representing key European producers of formaldehyde and derivatives ... Members of formacare represent approximately 95% of the formaldehyde produced in the EU 27, and Norway.")

⁵¹ See, e.g., Comment submitted by Pamela Dalton on Integrated Risk Information System Toxicological Review of Formaldehyde (Inhalation); Draft Docket EPA-HQ-ORD-2010-0396 (Jun. 15, 2022), https://downloads.regulations.gov/EPA-HQ-ORD-2010-0396-0086/attachment_1.pdf

⁵² See, e.g., Comment submitted by Pamela Dalton on Integrated Risk Information System Toxicological Review of Formaldehyde (Inhalation); Draft Docket EPA-HQ-ORD-2010-0396 (Jun. 15, 2022), https://downloads.regulations.gov/EPA-HQ-ORD-2010-0396-0086/attachment_1.pdf

⁵³ Mundt, K.A., Gentry, P.R., Dell, L.D., Rodricks, J.V., & Boffeta, P. (2017). Six Years After the NRC Review of EPA's *Draft IRIS Toxicological Review of Formaldehyde*: Regulatory Implications of New Science in Evaluating Formaldehyde Leukemogenicity. *Regulatory Toxicology and Pharmacology* 92.

formaldehyde.⁵⁴ Her research has also been funded by the ACC's 501(c)(3) arm, Foundation for Chemistry Research and Initiatives, formerly the Research Foundation for Health and Environmental Effects, including on formaldehyde.^{55, 56, 57}

Pamela Robinan Gentry, PhD DABT. Served as consultant and advisory board member for ACC and Hexion Inc.⁵⁸ Hexion is a major producer and distributor of formaldehyde, and Gentry's research is funded by Hexion⁵⁹ and the ACC's 501(c)(3) arm, Foundation for Chemistry Research and Initiatives, formerly the Research Foundation for Health and

<https://www.sciencedirect.com/science/article/pii/S027323001730363X?via%3Dihub> (“This work was supported in part by Hexion, Inc., a leading manufacturer of thermoset resins, based in Columbus, Ohio [USA](#).”)

⁵⁴ <https://www.hexion.com/en-us/chemistry/formaldehyde-and-derivatives>

⁵⁵ See, e.g., Checkoway, C., Lees, P.S.J., Dell, L.D., Gentry, P.R., & Mundt, K.A. (2019). Peak Exposures in Epidemiologic Studies and Cancer Risks: Considerations for Regulatory Risk Assessment. *Risk Anal.* 39(7).

<https://onlinelibrary.wiley.com/doi/10.1111/risa.13294> (“This research was sponsored in part by the Foundation for Chemistry Research and Initiatives, a tax-exempt public foundation described in Section 501(c)(3) of the Internal Revenue Code, and the Electric Power Research Institute (EPRI)”).

⁵⁶ See, e.g., Mundt, K.A., Gallagher, A.E., Dell, L.D., Natelson, E.A., Boffetta, P., & Gentry, P.R. (2017). Does occupational exposure to formaldehyde cause hematotoxicity and leukemia-specific chromosome changes in cultured myeloid progenitor cells? *Critical Reviews in Toxicology* 47(7).

<https://www.tandfonline.com/doi/full/10.1080/10408444.2017.1301878> (“This project was supported by funding provided by the Foundation for Chemistry Research and Initiatives (FCRI), formerly the Research Foundation for Health and Environmental Effects (RFHEE), a 501(c)(3) tax-exempt organization established by the American Chemistry Council (ACC).”).

⁵⁷ See, e.g., Checkoway, H., Dell, L.D., Boffetta, P., Gallagher, A.E., Crawford, L., Lees, P.S.J., & Mundt, K.A. (2016). Formaldehyde Exposure and Mortality Risks From Acute Myeloid Leukemia and Other Lymphohematopoietic Malignancies in the US National Cancer Institute Cohort Study of Workers in Formaldehyde Industries. *J. Occupational Env't Medicine* 57(7). <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4479664/> (“This project was sponsored by the Research Foundation for Health and Environmental Effects (RFHEE), a tax exempt public foundation described in Section 501(c)(3) of the Internal Revenue Code”).

⁵⁸ See, e.g., Mundt, K.A., Gallagher, A.E., Dell, L.D., Natelson, E., Boffetta, P., & Gentry, P.R. (2018). Formaldehyde, Hematotoxicity, and Chromosomal Changes—Letter. *Cancer Epidemiol. Biomarkers Prev.* 27(1). <https://aacrjournals.org/cebp/article/27/1/119/71380/Formaldehyde-Hematotoxicity-and-Chromosomal> (“K.A. Mundt reports receiving a commercial research grant from Foundation for Chemistry Research and Initiative (FCRI); reports receiving other commercial research support from American Chemistry Council, FCRI, and Hexion, Inc.; and is a consultant/advisory board member for American Chemistry Council and Hexion, ... L.D. Dell reports receiving a commercial research grant from FCRI ... Gentry reports receiving a commercial research grant from FCRI; reports receiving other commercial research support from American Chemistry Council, FCRI, and Hexion, Inc.; and is a consultant/advisory board member for American Chemistry Council and Hexion, Inc.”).

⁵⁹ Mundt, K.A., Gentry, P.R., Dell, L.D., Rodricks, J.V., & Boffeta, P. (2017). Six Years After the NRC Review of EPA's *Draft IRIS Toxicological Review of Formaldehyde*: Regulatory Implications of New Science in Evaluating Formaldehyde Leukemogenicity. *Regulatory Toxicology and Pharmacology* 92.

<https://www.sciencedirect.com/science/article/pii/S027323001730363X?via%3Dihub> (“This work was supported in part by Hexion, Inc., a leading manufacturer of thermoset resins, based in Columbus, Ohio [USA](#).”)

Environmental Effects, on formaldehyde,^{60, 61, 62, 63, 64} including research used by ACC Formaldehyde TSCA Risk Evaluation Consortium in direct advocacy to EPA TSCA staff.⁶⁵

John K Howell Jr. PhD, MA, President at GHS Resources, Inc, which supports chemical companies in submitting pre-manufacture notices to EPA, training and consulting services for specialty chemical companies including those in the lubricant industry. President of the Northern Illinois & Wisconsin Railway Corporation (NIWX), a locomotive leasing company that, among other services, refurbishes locomotives at their contract shop;⁶⁶ refurbishing locomotives involves the use of metalworking fluids and lubricants for which formaldehyde is a critical component.

⁶⁰ Conolly, R.B., Campbell, J.L., Clewell, H.J., Schroeter, J., Kimbell, J.S., & Gentry, P.R. (2023). Relative Contributions of Endogenous and Exogenous Formaldehyde to Formation of Deoxyguanosine Monoadducts and DNA-Protein Crosslink Adducts of DNA in Rat Nasal Mucosa. *Toxicological Sciences* 191(1). <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9887723/> (“This work was funded by the Foundation for Chemistry Research & Initiatives (FCRI), a 501(c)(3) tax-exempt organization established by the American Chemistry Council (ACC).”).

⁶¹ Conolly, R.B., Campbell, J.L., Clewell, H.J., Schroeter, J., Kimbell, J.S., & Gentry, P.R. (2023). Relative Contributions of Endogenous and Exogenous Formaldehyde to Formation of Deoxyguanosine Monoadducts and DNA-Protein Crosslink Adducts of DNA in Rat Nasal Mucosa. *Toxicological Sciences* 191(1). <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9887723/> (“This work was funded by the Foundation for Chemistry Research & Initiatives (FCRI), a 501(c)(3) tax-exempt organization established by the American Chemistry Council (ACC).”).

⁶² Lu, K., Hsiao, Y., Liu, C., Schoeny, R., Gentry, R., & Starr, T.B. (2021). A Review of Stable Isotope Labeling and Mass Spectrometry Methods to Distinguish Exogenous from Endogenous DNA Adducts and Improve Dose-Response Assessments. *Chemical Research in Toxicology* 35(1). <https://pubs.acs.org/doi/10.1021/acs.chemrestox.1c00212> (“financial support from the Foundation for Chemistry Research Initiatives (FCRI), which is a 501(c)(3) tax-exempt organization established by the American Chemistry Council (ACC).”).

⁶³ Campbell, J.L. Jr., Gentry, P.R., Clewell, H.J. III, & Andersen, M.E. (2020). A Kinetic Analysis of DNA-Deoxy Guanine Adducts in the Nasal Epithelium Produced by Inhaled Formaldehyde in Rats—Assessing Contributions to Adduct Production From Both Endogenous and Exogenous Sources of Formaldehyde. *Toxicological Sciences* 177(2). <https://academic.oup.com/toxsci/article/177/2/325/5879298> (“Foundation for Chemistry Research & Initiatives (FCRI), a 501(c)(3) tax-exempt organization established by the American Chemistry Council (ACC).”).

⁶⁴ Gentry R., Thompson C.M., Franzen, A., Salley, J., Albertini, R., Lu, K., & Greene, T. (2021). Using Mechanistic Information to Support Evidence Integration and Synthesis: a Case Study with Inhaled Formaldehyde and Leukemia. *Crit. Rev. Toxicol.* 50(10). (“This project was a concept presented jointly by Ramboll and ToxStrategies to the Formaldehyde Science Panel of the American Chemistry Council (ACC) (<https://www.americanchemistry.com>; <https://formaldehyde.americanchemistry.com>) in 2018, as it represented a data gap in the science for formaldehyde ... this work was supported by the Foundation for Chemistry Research & Initiatives (FCRI), a 501(c)(3) tax-exempt organization established by the ACC with funding from industry...”).

⁶⁵ Conolly, R.B., Schroeter, J., Kimbell, J.S., Clewell, H., Andersen, E., & Gentry, P.R. (2023). Updating the Biologically Based Dose-Response Model for the Nasal Carcinogenicity of Inhaled Formaldehyde in the F344 Rat. *Toxicological Sciences* 193(1). <https://academic.oup.com/toxsci/article/193/1/1/7076626> (Funding: “Foundation for Chemistry Research & Initiatives (FCRI), a 501(c)(3) tax-exempt organization established by the American Chemistry Council (ACC).”).

⁶⁶ [Northern Illinois & Wisconsin Railway Corporation \(niwx.com\)](https://www.niwx.com) ; (23) [John Howell | LinkedIn](https://www.linkedin.com/in/john-howell-jr/)

Debra A. Kaden, PhD, ATS; Senior Practitioner at Ramboll. Has received funding from Hexion and Formacare for her research on formaldehyde.^{67,68} Formacare represents chemical and manufacturing companies that produce 95% of the formaldehyde in the European Union.⁶⁹

Sang-Tae Kim, PhD, DABT, ATS, ERT, Senior Principal toxicologist at Ashland, a company that purchases and uses formaldehyde.⁷⁰ He is a member of committees at various Ashland supported industry associations, including the Society of Chemical Manufacturers and Affiliates (SOCMA),⁷¹ which represents the interests of specialty batch chemical industries⁷²; International Pharmaceutical Excipients Council-Americas (IPEC-Americas),⁷³ and for the ACC.⁷⁴ His research conducted while employed at Ashland found that the cancer risk from personal care and cosmetics products containing formaldehyde “is negligible”.⁷⁵

Andrew Maier, PhD, CIH, DABT, Senior Principal Health Scientist at Stantec Consulting Services, for which ACC is a client. He has received research support from ACC including via

⁶⁷ Albertini, R. J., & Kaden, D. A. (2017). Do chromosome changes in blood cells implicate formaldehyde as a leukemogen?. *Critical reviews in toxicology*, 47(2). <https://pubmed.ncbi.nlm.nih.gov/27685449/> (“This project was undertaken with funds provided to Ramboll Environ by Hexion Inc., a global manufacturer operating approximately 60 industrial facilities around the world with interest in FA and FA derivatives. Hexion participates in the American Chemistry Council Formaldehyde Panel”)

⁶⁸ Lang, I., Bruckner, T., & Triebig, G. (2008). Formaldehyde and chemosensory irritation in humans: a controlled human exposure study. *Regulatory toxicology and pharmacology* 50(1), <https://pubmed.ncbi.nlm.nih.gov/17942205/> (“The authors... thank the FormaCare sector group of CEFIC, Brussels, Belgium for the financial contribution to perform this study.”).

⁶⁹ See Formacare, *About Formacare*, <https://www.formacare.eu/about-formacare/> (last visited Mar. 6, 2024), (“Formacare is the formaldehyde sector group of the [European Chemical Industry Council \(Cefic\)](#) representing key European producers of formaldehyde and derivatives ... Members of formacare represent approximately 95% of the formaldehyde produced in the EU 27, and Norway.”)

⁷⁰ See Ashland, *Uses and Applications of Formaldehyde*, https://www.ashland.com/file_source/Ashland/Documents/Sustainability/rc%20formaldehyde.pdf, (last visited Mar. 6, 2024), (“Formaldehyde is used to produce chemical intermediates, formaldehyde containing resins and in the production of fertilizer, paper, and plywood. It is also used in the production of cosmetics and sugar, in well drilling fluids, as a preservative for grains and seed dressings, in the production of latex, in leather tanning, in embalming fluids, tissue preservation, in wood preservation, and in photographic film production. Ashland uses formaldehyde to produce phenol formaldehyde and urea formaldehyde resins and manufactures certain resins by reacting formaldehyde with polyacrylamide and guanidine-cyano blends”).

⁷¹ Nominee Bios at 15.

⁷² See SOCMA, *About SOCMA*, <https://www.socma.org/socma-unveils-key-findings-from-contract-manufacturing-outlook-survey-in-the-specialty-chemicals-industry/>, (last visited Mar. 6, 2024), (“Solely dedicated to the specialty and fine chemical industry, SOCMA builds commercial connections, supports safe manufacturing and operations, and advocates for regulatory and legislative policies for the batch and specialty chemical sector.”); *See also* current list of SOCMA members, which includes Ashland; <https://www.socma.org/socma-membership/membership-list/>, (last visited Mar. 6, 2024).

⁷³ Nominee Bios at 15; *See also* current list of IPEC-Americas Member Companies, which includes Ashland; <https://ipeamericas.org/join-us/member-companies>, (last visited Mar. 6, 2024).

⁷⁴ Nominee Bios at 15; *See also*; ACC’s 2020 Board of Directors, which includes Bill Wulfsohn, Chairman and CEO of Ashland; <https://www.americanchemistry.com/chemistry-in-america/news-trends/press-release/2019/american-chemistry-council-elects-new-class-to-board-of-directors>, (last visited Mar. 6, 2024).

⁷⁵ See Kim, S. T., Shao, K., Oleschkewitz, C., & Hamilton, R. (2023). Margin of exposure to free formaldehyde in personal care products containing formaldehyde-donor preservatives: Evidence for consumer safety. *Regulatory toxicology and pharmacology*, 145., <https://www.sciencedirect.com/science/article/abs/pii/S0273230023001873>.

Stantec.⁷⁶ Additionally, he is director of the Occupational Alliance for Risk Science, managed by Toxicology Excellence for Risk Assessment (TERA). TERA is led by Dr Michael Dourson, a highly conflicted and failed Trump nominee⁷⁷ with close ties to the chemical industry.⁷⁸

Rogert O. McClellan, DVM, MMS, DSc, President Emeritus of the Chemical Industry Institute of Toxicology (CIIT)⁷⁹ and funded by the ACC.⁸⁰ Advocated for a study a cancer risk model developed by CIIT,⁸¹ a study that was later used by industry allowing plywood plants to continue

⁷⁶ See <https://journals.sagepub.com/doi/10.1177/07482337221140946> and See <https://www.sciencedirect.com/science/article/abs/pii/S0009279723000492>.

⁷⁷ [Trump's E.P.A. Chemical Safety Nominee Withdraws - The New York Times \(nytimes.com\)](https://www.nytimes.com/2021/01/27/us/politics/trump-chemical-safety-nominee-withdraws.html)

⁷⁸ <https://publicintegrity.org/environment/one-stop-science-shop-has-become-a-favorite-of-industry-and-texas/> and <https://tera.org/about/FundingSources.html>

⁷⁹ Based on Roger O. McClellan's Curriculum Vitae, he served as the President Emeritus for the Chemical Industry Institute of Toxicology from 1999-2020, Accessed March 8, 2024, https://drive.google.com/file/d/1szZGEBDZ_W4B5EbU8PooJ5JRTmpM8vuE/view?usp=share_link, ("The institute which operated post-McClellan's tenure as the Hamner Institutes for Health Sciences closed in 2020 ... The research was funded for many years primarily by 30 major chemical companies. This support base was expanded near the end of Dr. McClellan's term through a partnership with the American Chemical Council which represents 190 leading chemical companies.").

⁸⁰ *Hamner Inst. Closes its Doors*, C&EN 94, 2, 16-17 (Jan. 11, 2016) (explaining that "the Chemical Industry Institute of Toxicology," subsequently known as the Hamner Institutes for Health Sciences, "was founded by 11 chemical companies in 1974 to gauge the potential impact of chemicals on human health. In 2001, 90% of its \$18 million budget came from the Long-Range Research Initiative of the American Chemistry Council."), <https://pubs.acs.org/doi/full/10.1021/cen-09402-buscon008>.

⁸¹ https://downloads.regulations.gov/EPA-HQ-ORD-2010-0396-0097/attachment_1.pdf ("In the interest of full disclosure as the President (1988-1999) of the Chemical Industry Institute of Toxicology I advocated for the study of formaldehyde as a prototypical chemical to advance the use of mechanistic toxicological evidence in understanding human health risks of chemicals. The Institute's expenditures on Formaldehyde research exceeded those on any other chemical. The Institute's research findings are at the core of the IRIS document."); also see Draft IRIS Toxicological Review of Formaldehyde (Inhalation); Formaldehyde Overview External Draft April 2022, Docket EPA-HQ-ORD-2010-0396 (April 26, 2022), <https://downloads.regulations.gov/EPA-HQ-ORD-2010-0396-0040/content.pdf>, ("A biologically based dose-response (BBDR) time-to-tumor model for the formaldehyde-induced rat nasal tumors was available (Conolly et al., 2003; CIIT, 1999). This model consisted of interfacing dosimetry models for formaldehyde and formaldehyde-induced DPX in the rat nasal passages (Kimbell et al., 2001a; Kimbell et al., 2001b; Conolly et al., 2000) with two-stage clonal expansion (TSCE) models for predicting the probability of occurrence of nasal SCC (Conolly et al., 2003)."); see also research funded by ACC to update this model: Conolly, R.B., Schroeter, J., Kimbell, J.S., Clewell, H., Andersen, E., & Gentry, P.R. (2023). Updating the Biologically Based Dose-Response Model for the Nasal Carcinogenicity of Inhaled Formaldehyde in the F344 Rat. *Toxicological Sciences* 193(1). <https://academic.oup.com/toxsci/article/193/1/1/7076626> (Funding: "Foundation for Chemistry Research & Initiatives (FCRI), a 501(c)(3) tax-exempt organization established by the American Chemistry Council (ACC).").

⁸¹ See, EPA "1999

emitting formaldehyde.^{82,83,84} Conducted research in collaboration with authors from Dow on linear low dose methodology funded by ACC.⁸⁵

Kenneth A. Mundt, PhD, FACE, Independent consultant with undisclosed industry clients⁸⁶ worked for ChemRisk until 2023. Dr. Mundt has published several industry-funded articles on formaldehyde and his publications have been promoted on the website of the ACC.^{87,88,89} In addition, he submitted comments and other materials to EPA and the SACC on behalf of the Halogenated Solvents Industry Alliance,⁹⁰ Vantage Specialty Chemicals,⁹¹ Hexion Specialty Chemicals,⁹² and the Formaldehyde Council.⁹³

⁸² See, EPA “1999 National-Scale Air Toxics Assessment; Formaldehyde” <https://archive.epa.gov/airtoxics/nata1999/web/html/formald.html>, (last updated Feb. 21, 2016), (“For the 1999 national-scale assessment, EPA is estimating risks from formaldehyde using a cancer unit risk (potency) estimate developed by the CIIT Centers for Health Research (formerly the Chemical Industry Institute of Technology), published in 1999. EPA has also used the CIIT cancer potency estimate for certain air toxics rules, such as the technology-based standard for the plywood industry.”)

⁸³ <https://www.latimes.com/archives/la-xpm-2004-may-21-na-plywood21-story.html>

⁸⁴ Union of Concerned Scientists, “Plywood Rule Used Industry Funded Research, Ignored Independent Scientific Studies”, Accessed March 8, 2024, <https://www.ucsusa.org/resources/attacks-on-science/plywood-rule-used-industry-funded-research-ignored-independent>, (“In 2004, the Environmental Protection Agency (EPA) adopted a new air pollution rule that would exempt many plywood manufacturers from restrictions on the emission of formaldehyde and other pollutants into the air”).

⁸⁵ See: e.g., Rhomberg, L.R., Goodman, J.E., Haber, L.T., Dourson, M., Andersen, M.E., Klaunig, J.E., Meek, B., Price, P.S., McClellan, R.O., & Cohen, S.M. (2011). Linear Low-Dose Extrapolation for Noncancer Health Effects is the Exception, Not the Rule. *Crit. Rev. Toxicol.* 41(1). <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3038594/> (“This paper was prepared with financial support provided by the American Chemistry Council to Gradco LLC d/b/a Gradient ... This paper was prepared with financial support to Gradient, a private environmental consulting firm, and several other organizations from the American Chemistry Council.”)

⁸⁶ See: <https://www.linkedin.com/in/kenneth-mundt-9944681a>

⁸⁷ Mundt, K. A., Gallagher, A. E., Dell, L. D., Natelson, E. A., Boffetta, P., & Gentry, P. R. (2017). Does occupational exposure to formaldehyde cause hematotoxicity and leukemia-specific chromosome changes in cultured myeloid progenitor cells? *Critical Reviews in Toxicology*, 47(7), 598–608. <https://doi.org/10.1080/10408444.2017.1301878>

⁸⁸ Mundt, K. A., Gallagher, A. E., Dell, L. D., Natelson, E. A., Boffetta, P., & Gentry, P. R. (2017). Does occupational exposure to formaldehyde cause hematotoxicity and leukemia-specific chromosome changes in cultured myeloid progenitor cells? *Critical Reviews in Toxicology*, 47(7), 598–608. <https://doi.org/10.1080/10408444.2017.1301878>

⁸⁹ <https://www.americanchemistry.com/chemistry-in-america/news-trends/press-release/2018/new-formaldehyde-science-addresses-scientific-uncertainties-raised-by-nas>

⁹⁰ Comments of Kenneth A. Mundt on Draft Toxic Substances Control Act (TSCA) Risk Evaluation for Methylene Chloride to the TSCA Science Advisory Committee on Chemicals (SACC), Docket EPA-HQ-OPPT-2019-0437 (Nov. 26, 2019), <https://www.regulations.gov/comment/EPA-HQ-OPPT-2019-0437-0046>.

⁹¹ Comments of Kenneth A. Mundt, Fellow, American College of Epidemiology, Senior Principal Health Scientist, and Andrew Maier, Senior Managing Health Scientist, Cardno ChemRisk, on Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review, Docket EPA-HQ-OAR-2018-0746 (Jan. 15, 2020), <https://www.regulations.gov/comment/EPA-HQ-OAR-2018-0746-0032>.

⁹² Comments of Kenneth A. Mundt on the National Toxicology Program Draft Background Document for Formaldehyde (Oct. 16, 2019), https://downloads.regulations.gov/EPA-HQ-ORD-2010-0396-0068/attachment_4.pdf.

⁹³ *Id.*

Nikaeta P. Sadekar, PhD, DABT, Senior Scientist with the Research Institute for France Materials (RIFM). RIFM is supported by the Fragrance Creators Association, the main trade association representing the U.S. fragrance industry,⁹⁴ which can contain formaldehyde as an added ingredient^{95,96} or a secondary contaminant,⁹⁷ RIFM is also the “principal scientific partner” to the International Fragrance Association.⁹⁸

Robert S. Skoglund PhD, DABT, CIH, CPPS, Employed at Covestro a leading supplier of polymers, such as precursors for polyurethane foams, coatings, and adhesives, among others. Skoglund co-authored a 2020 workshop report with authors from ExxonMobil Biomedical Sciences, ACC, Dow, Afton Chemical Corporation, and others focused on new approach methodologies and risk assessment of complex substances and mixtures. The workshop was supported by the International Council of Chemical Associations (ICCA) Long Range Research Initiative (LRI), with funding jointly provided by the LRI programs of ACC, the European Chemical Industry Council, and the Japan Chemical Industry Association.⁹⁹

⁹⁴ See Comment submitted by Fragrance Creators Association & American Cleaning Institute (ACI) p. 1 n.1 of comment letter, Docket EPA-HQ-TRI-2017-0434 (Dec. 21, 2021), <https://www.regulations.gov/comment/EPA-HQ-TRI-2017-0434-0543>. (“Fragrance Creators is the trade association representing the U.S. fragrance industry at-large. The organization’s member companies create and manufacture fragrances and scents for home care, personal care, fine fragrance, and industrial and institutional products. Fragrance Creators also represents companies that market finished products containing fragrance, as well as those that supply fragrance ingredients, including natural extracts and other raw materials, that are used in perfumery and fragrance mixtures. Fragrance Creators members also support the Research Institute of Fragrance Materials...”); see also RIFM board of directors which includes nonvoting liaisons from Industry Associations International Fragrance Association, Fragrance Creators Association, and International Federation of Essential Oils and Aroma Trades, <https://rifm.org/board-of-directors/> (last accessed Mar. 12, 2024).

⁹⁵ See Persistence Market Research, *Global Perfume Ingredients Chemicals Market: Introduction*, <https://www.persistencemarketresearch.com/market-research/perfume-ingredients-chemicals-market.asp> (last accessed Mar. 12, 2024).

⁹⁶ See, e.g., Kim, S. T., Shao, K., Oleschkewitz, C., & Hamilton, R. (2023). Margin of exposure to free formaldehyde in personal care products containing formaldehyde-donor preservatives: Evidence for consumer safety. *Regulatory toxicology and pharmacology*, 145., <https://www.sciencedirect.com/science/article/abs/pii/S0273230023001873> (“Preservatives play an important role in keeping personal care products in good condition by prohibiting or controlling the growth of harmful microorganisms such as bacteria, yeasts, and molds... For several decades, formaldehyde-donor (FD) preservatives have been widely used for the control of microbial growth in personal care products ... These FD preservatives are designed to release small amounts of formaldehyde over time rather than all at once...”); see also Malinauskiene, L., Blaziene, A., Chomiciene, A., & Isaksson, M. (2015). Formaldehyde may be found in cosmetic products even when unlabelled. *Open medicine (Warsaw, Poland)*, 10(1), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5152996/>, (“Formaldehyde as such is very seldomly used in cosmetic products anymore, but preservatives releasing formaldehyde in the presence of water are widely used in many cosmetic products (e.g., shampoos, creams, etc.), topical medications and household products (e.g., dishwashing liquids).”)

⁹⁷ See Kazemi, Z., Aboutaleb, E., Shahsavani, A., Kermani, M., & Kazemi, Z. (2022). Evaluation of pollutants in perfumes, colognes and health effects on the consumer: a systematic review. *Journal of environmental health science & engineering*, 20(1), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9163252/>.

⁹⁸ See International Fragrance Association, *Membership of IFRA; Partner organizations*, <https://ifrafragrance.org/about-ifra/membership> (last accessed Mar. 12, 2024), (“Our principal scientific partner is the Research Institute for Fragrance Materials (RIFM)”).

⁹⁹ Sauer, U. G., Barter, R. A. Becker, R. A., Benfenati, E., Berggren, E., Hubesch, B., Hollnagel, H. M., Inawaka, K., Keene, A. M., Mayer, P., Plotzke, K., Skoglund, R., & Albert, O. (2020). 21st Century Approaches for Evaluating Exposures, Biological Activity, and Risks of Complex Substances: Workshop highlights. *Regulatory Toxicology and Pharmacology*, 111., <https://doi.org/10.1016/j.yrtph.2020.104583>.

Judy A. Strickland, PhD, DABT, Retired principle Predictive Toxicologist with Inotiv, with undisclosed clients in the bio-pharmaceutical field. Member of the American Society for Cellular and Computational Toxicology whose sponsors include Corteva.¹⁰⁰

Lisa M. Sweeney, PHD, DABT, CHMM, toxicologist with UES, Inc. with various customers in the aerospace and automobile industry.¹⁰¹ Submitted commented on behalf of ACC on the use of Physiology Based Pharmacokinetic Models in Risk Assessment.¹⁰²

Chadwick M. Thompson, PhD, Employed by ToxStrategies, a consulting firm contracted by the ACC Formaldehyde Panel¹⁰³ and who has participated in research funded by the ACC on the carcinogenicity of formaldehyde.^{104,105}

Clinton J Woods, MA, Global director of Product Stewardship and Regulatory Affairs at Hexion.

This is not an exhaustive list of potential conflicts of interest among the nominees. EPA must review nominees for potential conflicts of interest prior to requesting public comment. Additionally, the burden of discovering and reporting potential conflict of interest should not fall on the public. We recognize that industry experts have information that may be valuable to the deliberations of the federal advisory committees and the policies of EPA, including for example, technical, scientific, and market data. We therefore suggest that they avail themselves of the

¹⁰⁰ American Society for Cellular and Computational Toxicology, *Current Organizational Sponsors*, <https://www.ascctox.org/supporting-organizations> (last accessed Mar. 12, 2024).

¹⁰¹ UES, *Solving Scientific Challenges for 50 Years*, [About | UES, Inc.](#) (last accessed Mar. 12, 2024).

¹⁰² See, e.g., Comments of Michael L. Gargas, Lisa M. Sweeney, Christopher R. Kirman, and Robert G. Tardiff, Ph.D., ATS, all four of The Sapphire Group, Inc, on Approaches for the Application of Physiologically Based Pharmacokinetic (PBPK) Models and Supporting Data in Risk Assessment, Docket EPA-HQ-ORD-2005-0022 (Oct. 12, 2005), https://downloads.regulations.gov/EPA-HQ-ORD-2005-0022-0011/attachment_1.pdf, (“Acknowledgement: This work was sponsored by The Halogenated Solvents Industry Alliance, CropLife America and the American Chemistry Council.”)

¹⁰³ See ToxStrategies profile, <https://toxstrategies.com/company/people/chad-m-thompson-ph-d-mba/> (last visited Mar. 8, 2024);

¹⁰⁴ See, e.g., Thompson, C. M., Gentry, R., Fitch, S., Lu, K., & Clewell, H. J. (2020). An updated mode of action and human relevance framework evaluation for Formaldehyde-Related nasal tumors. *Critical reviews in toxicology*, 50(10), <https://www.tandfonline.com/doi/full/10.1080/10408444.2020.1854679>, (“This project was a concept presented jointly by ToxStrategies and Ramboll to the Formaldehyde Science Panel of the American Chemistry Council (ACC) in 2018, as it represented a data gap in the science for formaldehyde... This work was supported by the Foundation for Chemistry Research & Initiatives (FCRI), a 501(c)(3) tax-exempt organization established by the ACC with funding from industry... It is anticipated that regulatory authorities will consider the contents of this review in making regulatory decisions regarding the potential health effects of formaldehyde.”)

¹⁰⁵ See, e.g., Gentry, R., Thompson, C. M., Franzen, A., Salley, J., Albertini, R., Lu, K., & Greene, T. (2020). Using mechanistic information to support evidence integration and synthesis: a case study with inhaled formaldehyde and leukemia. *Critical reviews in toxicology*, 50(10) <https://www.tandfonline.com/doi/full/10.1080/10408444.2020.1854678>, (“This project was a concept presented jointly by ToxStrategies and Ramboll to the Formaldehyde Science Panel of the American Chemistry Council (ACC) in 2018, as it represented a data gap in the science for formaldehyde... This work was supported by the Foundation for Chemistry Research & Initiatives (FCRI), a 501(c)(3) tax-exempt organization established by the ACC with funding from industry... It is anticipated that regulatory authorities will consider the contents of this review in making regulatory decisions regarding the potential health effects of formaldehyde.”)

opportunity to present information to the SACC during the public comment period, which includes both a short oral and written comment opportunities.

Finally, we strongly support the nominations of:

Patrick N. Breyse, PhD, CIH, Professor Emeritus at Johns Hopkins Bloomberg School of Public Health and former Director of the Agency of Toxic Substances and Disease Registry (ATSDR). Dr Breyse's research focuses on risk and exposure assessment, including characterizing pollutant sources, exposure measurement and interpretations, use of biomarkers to measure exposure dose and effect. His expertise includes the impact of indoor and outdoor air pollution on respiratory health including childhood asthma, chronic obstructive pulmonary disease and respiratory tract infections.

Bernard Goldstein, MD, Dean Emeritus of the University of Pittsburg Graduate School of Public Health. He is an environmental toxicologist whose research has focused on the use of biological markers in the field of risk assessment. He has published extensively in the areas of blood toxicity, and exposure to carcinogens and carcinogenesis. He served on various governmental committees included for the U.S. EPA, ATSDR and the National Academy of Sciences. He served on the Working Group for the International Agency for Research on Cancer (IARC) Monographs on the Evaluation of Carcinogenic Risks to Humans for Formaldehyde, 2-Butoxyethanol and Propylene 2 glycol mono-t-butyl ether, and was the chair for the IARC Working Group on the Evaluation of Carcinogenic Risks to Humans: Wood dust and Formaldehyde.

Luoping Zhang, PhD, Professor Emeritus at the University of California, Berkeley School of Public Health, Division of Environmental Health Sciences. Her research has focused on the fields of toxicology, genome toxicity, and molecular epidemiology, with a particular emphasis on the molecular mechanisms of bone marrow and blood toxicity, including publishing multiple peer review publications on formaldehyde exposures and toxicity. She has served on the Carcinogen Identification Committee for California EPA's Office of Environmental Health Hazard Assessment, on the National Academy of Science's Committee for the Review of EPA's Toxicological Assessment of Tetrachloroethylene and other peer review panels and advisory boards.