August 25, 2022

Dr. Kathryn Guyton
Senior Program Officer
Board on Environmental Studies and Toxicology
500 Fifth St., N.W.
Washington, D.C. 20001

Dear Dr. Guyton:

The American Chemistry Council Formaldehyde Panel ("the Panel") provides the following substantive comments on the provisional committee of the National Academies of Sciences, Engineering, and Medicine (NASEM) that will conduct what the public expects to be a credible scientific peer review of EPA's 2022 draft IRIS formaldehyde assessment. NASEM has long been seen as a source of non-biased, credible scientific evaluations, in large part because it works to guard against bias, conflicts of interest and imbalance of scientific expertise.

The Provisional Panel is not Fairly Balanced

In establishing committees, Section 15(b)(1) of the Federal Advisory Committee Act ("FACA") requires NASEM to "make its best efforts to ensure that […] (B) the committee membership is fairly balanced as determined by the Academy to be appropriate for the functions to be performed …." NASEM's Policy on Composition and Balance, Conflicts of Interest, and Independence for Committees Used in the Development of Findings, Conclusions, and Recommendations ("the NASEM Policy") sets forth the policies and procedures for meeting these FACA requirements. In particular, the NASEM Policy notes that consideration should be given "to the appropriate balance among disciplines and fields of expertise, taking into account the subtleties and complexities of the issues to be addressed by the committee;" and "whether there is an appropriate range of perspectives."[1] However, based on review of the bios of the provisional committee members posted to the NASEM website, there appears to be a lack of balance in discipline and expertise in the provisional committee. As described later, we found no representation of scientific expertise in occupational epidemiology, biological modeling including mechanisms of carcinogenicity (including leukemia), physiological based pharmacokinetic modeling (PBPK) and reproductive and developmental toxicity.

NASEM is also required to ensure that committees it establishes are free from conflicts of interest and avoid the appearance of a lack of impartiality. As described below, the inclusion of several members of the provisional committee raises at least sufficient issues that NASEM must take a closer look and either address the potential issue in writing or remove the panel member to

avoid even the appearance of such issues. For the reasons described below we think the latter is likely needed for certain provisional committee members.

The Provisional Panel is not Fairly Balanced

Ensuring appropriate member balance and composition are fundamental to the work of the peer review committee. "Differing and new perspectives on an issue, shaped by individual knowledge and experience, can be vital to achieving an informed, comprehensive, and authoritative understanding and analysis of a problem and potential solutions."[2] Importantly, the D.C. Circuit underscored FACA's legislative history in deciphering the "fairly balanced" requirement:

> The legislative history makes clear, 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 presentation on the committee**. [3]

NASEM Policy requires that the committee be composed of experts who have "an appropriate range of perspectives on the issues to be addressed by the committee"[4] which raises the question as to whether NASEM has adequately addressed this need to have balanced scientific perspectives. As noted previously by NASEM, "The membership of the committee should reflect the diversity of the communities of scientists, engineers, health professionals and other experts from which the committee members are drawn, and of the communities that have a stake in the outcome of the committee's work."[5] As described in the 2003 policy[6]:

> The assessment of the necessary perspectives required for a particular study committee may also involve considerations that go beyond specific disciplinary scientific or technical concerns. For some studies, for example, it may be important to have an "industrial" perspective or an "environmental" perspective. This is not because such individuals are "representatives" of industrial or environmental interests, because no one is appointed by the institution to a study committee to represent a particular point of view or special interest. Rather it is because such individuals, through their particular knowledge and experience, are often vital to achieving an informed, comprehensive, and authoritative understanding and analysis of the specific problems and potential solutions to be considered by the committee."[7]

Additional support for this view comes from other scientific bodies. The Keystone Center's Research Integrity Roundtable argues that "A matter that affects a stakeholder sector as a whole either would not be considered to create a conflict or would require the same kind of waiver as any other conflict of interest"…."[8] The American Chemical Society's statement on Scientific Integrity in Public Policy emphasizes that: "Advisory committees should contain a diversity of technical expertise and opinions, selected from recognized, credible experts in the field from all sectors… Employer, professional or political affiliations… should not preclude anyone from serving on advisory committees."[9]

Unfortunately, the provisional committee lacks the requisite balance – it lacks scientists with backgrounds and expertise in private sector[10] industrial toxicology and industrial epidemiology.

Additionally, to the extent the NASEM continues to include those that have been supportive of, or involved with, EPA's approach to the draft IRIS assessment, it must balance those views with individuals that have raised concerns with the approach.

NASEM must address the concerns raised below and ask itself if the provisional committee as currently constituted fully comports with the requirements of both FACA and the NASEM Policy. If fairly addressed NASEM would conclude that committee as constituted does not meet these requirements. The Panel recommends committee membership changes discussed below to address these shortcomings, and requests that NASEM provide a written response to the issues raised in this letter. Such a written response is needed to provide transparency and document the scientific integrity of the process, and without such a response, questions will likely persist over the credibility and objectivity of the peer reviewers.

The NASEM committee tasked with peer reviewing the 2010 draft IRIS formaldehyde assessment consisted of 15 members with expertise in epidemiology, exposure assessment, leukemogenesis, mechanisms of carcinogenicity, inhalation toxicology, neurotoxicology, reproductive and developmental toxicology, statistics, physiologically based pharmacokinetic modeling and risk assessment. As the Chair of the 2011 review testified to Congress: "Our review of the draft assessment was written by a 15-member committee that had a wide range of scientific expertise, appropriate to the task."[11] According to EPA, "While the 2010 draft [IRIS formaldehyde assessment] is of similar length, the current assessment represents an entirely new draft developed de novo."[12] Thus, the NASEM committee tasked with peer reviewing the 2022 draft IRIS formaldehyde assessment, at a minimum, has to reflect similar expertise of the previous NASEM committee. As proposed, the committee representation is not sufficiently similar in terms of expertise. In addition, as the Panel has previously noted,[13] EPA's unnecessarily narrow and rigid approach to the committee task and charge questions, including limitations on the scope of the review, which do not allow for comments to determine if that the 2011 NASEM recommendations have been addressed, highlight flaws in the current Formaldehyde IRIS process. These limitations and the prohibition on an "independent assessment" by the Committee, eviscerates the scientific value of reappointing experts who have served on past NASEM reviews related to formaldehyde or IRIS.

Importantly, the contract (task order) between EPA and NASEM for the current peer review recommended committee appointments with areas of expertise including: occupational epidemiology, especially in areas of cancer, reproductive, asthma and other immunological effects, and respiratory effects; biological modeling; and exposure measures for observational epidemiology studies of environmental and occupational exposures.[14] Based on the Panel's review of the truncated bios posted to the NASEM website, the provisional committee appears to lack expertise in occupational epidemiology, biological modeling including mechanisms of carcinogenicity (including leukemia), PBPK modeling and reproductive and developmental toxicity. Although nearly half of the 13 provisional committee members are epidemiologists, to what extent do they have expertise and research experience in occupational epidemiology? This would be critical deficiency, especially since the NASEM committee tasked with peer reviewing the 2010 draft IRIS formaldehyde assessment contained two occupational epidemiologists, and EPA relies upon occupational cohorts in its draft 2022 IRIS formaldehyde assessment to draw carcinogenicity

conclusions. The NASEM committee that peer reviewed the 2010 draft IRIS formaldehyde assessment also contained two experts in leukemogenesis.

Additionally, the Panel strongly urges NASEM to include expertise in endogenous formaldehyde and its role in assessing potential toxicity from exogenous exposure to formaldehyde. The 2011 NASEM report on the 2010 draft IRIS formaldehyde assessment recommended that EPA evaluate when exogenous formaldehyde exposure appreciably alters normal endogenous formaldehyde concentrations. As stated by NASEM in 2011, "The endogenous production of formaldehyde complicates the assessment of the risk associated with formaldehyde inhalation and remains an important uncertainty in assessing additional dose received by inhalation, particularly at sites beyond the respiratory tract."[15]

To address the voids in committee expertise, and to comply with both FACA and the NASEM requirements, the Panel recommends that NASEM select additional committee members to supplement the provisional panel to ensure the panel consists of the right expertise and knowledgebase to conduct the required robust scientific peer review of the 2022 draft. If NASEM is interested in addressing these gaps in expertise, the Panel would be glad to help identify additional experts with the requisite backgrounds. Appendix A includes a list of individuals with relevant experience whom we believe may be willing to serve on this panel. In addition to the areas noted above, the Panel recommends experts in risk assessment and toxicology, areas that are foundational to the draft formaldehyde IRIS assessment.

If NASEM is reluctant to increase the overall size of the committee, the Panel recommends that NASEM reduce the current provisional membership to accommodate new provisional appointments by decreasing the current number of non-occupational epidemiologists.

NASEM Must Examine Potential Conflicts of Interest or the Appearance thereof

The NASEM Policy emphasizes that members must be "transparent about their relevant relationships and publications, and independent from the sponsors of the committee's work." It further directs members of a committee to disclose publications "relevant to the issues to be addressed" at the time of committee formation. Similar direction is provided, for example, in the Proceedings of the National Academy of Sciences guidelines, which identify a disqualifying "competing interest due to a personal association" for editors and reviewers as including a manuscript "whose authors include a person with whom you had an association, such as a thesis advisor (or advisee), postdoctoral mentor (or mentee), or coauthor of a paper…."[16] Keystone Center Research Integrity Roundtable: "Caution must be exercised to ensure that panel members are not engaged in evaluating their own work…. However, certain other situations could constitute conflicts such as reviewing the work of a relative or close colleague."[17] We request relevant relationships, publications, grants, testimony, and public statements be disclosed in the provisional committee member biographies.

Independent of the issues of expertise, the Panel believes that NASEM must take a closer look at several provisional members before approving them for service on the Panel– Dr. Lauren Zeise, Dr. Lianne Sheppard, and Dr. Ivan Rusyn. These provisional panel members have had previous significant involvement or interactions with EPA related to formaldehyde raising significant

questions as to if their service is appropriate. For at least some of these individuals we believe it clear that, their "[a]ppointment to the committee is not appropriate."[18]

We note that other proposed committee members may also have similar issues. Unfortunately, our ability to comment on the membership in the provisional committee, potential bias, and compliance with NASEM disclosures requirements has been significantly constrained due to the lack of availability of materials that would provide insight into these issues. We previously requested an extension of the comment period, as well as relevant materials. When this request was denied, we renewed both our extension request and request for these materials. As of today, NASEM has not responded to this additional request. As a result, we have not been able to evaluate if all of the provisional committee members made the required disclosures, such as relevant relationships, publications, and potential interests that give an appearance of a lack of impartiality. For example, we are not able to determine if disclosures were made related to coauthoring articles and serving as a co-principal investigator on an EPA grant with another author, whose studies will be evaluated in the NASEM review. Nor are we able to determine if grants awarded by EPA were disclosed, which may raise concerns about independence from the sponsoring agency.

While we again renew or request for this information, and time to comment based on it, we have been able to identify the following based on available information.

- Dr. Lauren Zeise, as director of the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA), oversees the development of risk assessments, hazard evaluations and toxicity reviews. OEHHA and U.S. EPA's National Center for Environmental Assessment (in which the IRIS Program was situated) worked to harmonize risk assessment methods, share data and evaluations, as well as expertise, and engage in other joint cooperative efforts under a Memorandum of Understanding. Given that Dr. Zeise will be asked to review a product of the IRIS program, namely the 2022 draft IRIS formaldehyde assessment, the close ongoing working relationship between OEHHA and U.S. EPA on matters that are directly relevant to the current draft assessment raises questions regarding potential conflicts of interest. Therefore, we request information on whether NASEM has verified the status of Dr. Ziese's MOU. Dr. Zeise also served as a member of the NASEM review of formaldehyde in the NTP 12th RoC, which endorsed the NTP's carcinogenic conclusions on formaldehyde. Zeise withdrew from the 2014 NASEM review of the IRIS process[19] following disclosure of a memorandum of understanding between her employer and U.S. directly related to IRIS.[20] Concerns about independence and impartiality highlighted in this letter continue to be highly relevant, even if the status of such an MOU has changed. Concerns regarding relationships, including close collaboration with EPA IRIS staff, including the NASEM study director, on issues directly relevant to this review as well as clear inaccuracies in Zeise's biography argue against her inclusion on this committee. In addition, Zeise adds to an already imbalanced committee in terms of appropriate expertise, geographic diversity, and background, with a disproportionate number of provisional committee members having spent the majority of their careers with governmental entities, including universities, in the state of California. Given these

questions, NASEM should ask "that particular scientific expertise does she bring to the science of formaldehyde that will bring clarity to the epidemiology issues or advance mode of action considerations when evaluating EPA's 2022 draft IRIS assessment, and can this expertise be found in someone that does not present similar concerns?"

- Dr. Sheppard has extraordinarily close ties to the U.S. EPA, the sponsor of NASEM's review of formaldehyde. She is a recipient of current EPA grants which may be directly relevant to issues central to this review.[21] She also currently serves as Chair of EPA's Clean Air Scientific Advisory Committee and a member of EPA's Science Advisory Board. EPA and OMB policies make clear that repeatedly turning to the same individuals raises legitimate questions about independence and impartiality. The multitude of directly relevant relationships with the study sponsor, at a minimum, create an appearance of conflict of interest. In addition, she recently co-authored a highly controversial meta-analysis on glyphosate which suggests a compelling link between glyphosate exposure and increased risk for Non-Hodgkin Lymphoma (NHL), in stark contrast to other global health and regulatory agencies that have also examined the potential carcinogenicity of glyphosate.[22] She may have failed to disclose relevant relationships, including previous close collaboration with the lead author of key studies, the evaluation of which will be a central purpose of the NASEM review.[23] Given these questions, NASEM should ask "that particular scientific expertise does she bring to the science of formaldehyde that will bring clarity to the epidemiology issues or advance mode of action considerations when evaluating EPA's 2022 draft IRIS assessment, and can this expertise be found in someone that does not present similar concerns?"

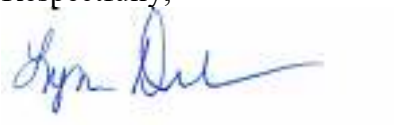
- Dr. Ivan Rusyn served on both the previous NASEM committee to review the 2010 draft IRIS formaldehyde assessment and the NASEM committee to review formaldehyde in the National Toxicology Program 12th Report on Carcinogens. He has also chaired a NASEM Committee hosting workshops "to support development of EPA's IRIS" reviews[24] , served as a faculty fellow in the National Center for Environmental Assessment (NCEA) and held a webinar with the EPA on the development of a "Roadmap to Revision" for the IRIS assessment in response to the 2011 NASEM recommendations[25].Dr Rusyn stated that, as a faculty fellow in NCEA from 2011- 2013,[26] "I interacted with IRIS staff on a variety of scientific and methodological issues directly relevant to implementation of the advice from the National Academies."[27] Accordingly, the NASEM should determine whether this direct engagement with EPA concerning the IRIS assessment qualifies as 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 of the [Committee's] activity"[28] and if so, would this constitute a disqualifying conflict of interest per NASEM policies on 1) reviewing one's own work and/or 2) lack of independence from the Sponsor due to participation in deliberative or decision-making process with EPA during the Sponsor's revision of the IRIS assessment.[29]

  Dr Rusyn is certainly an eminent scientist in the field of toxicology, and these comments are not meant in any way to cast aspersions on his scientific qualifications or his character. Rather, they are made solely to alert NASEM to concerns that could have impacts on the objectivity and credibility of the Committee's work in reviewing the IRIS assessment. Moreover, while any one of these relationships and their relationship to the

formaldehyde peer review standing alone might not be sufficient to be disqualifying the totality of them creates, at a minimum, an appearance that NASEM could easily address by appointment of an alternative reviewer.

The Panel urges NASEM to add the appropriate expertise on the provisional committee and ensure that the scientific views of the committee members are appropriately balanced, as required by both FACA and the NASEM Policy. We request committee representation in the fields of occupational epidemiology, biological modeling including mechanisms of carcinogenicity (including leukemia), PBPK modeling and reproductive and developmental toxicity. Additionally, we request that NASEM respond in writing and disclose the provisional committee members' relevant relationships, publications, grants, testimony, and public statements.

Respectfully,



Lynn Dekleva Ph.D.
Senior Director
Chemical Products & Technology Division
American Chemistry Council
On Behalf of the ACC Formaldehyde Panel

cc: Dr. Marcia McNutt
Ms. Audrey Mosley
Dr. Clifford Duke
Dr. Elizabeth Eide

Enclosure: Appendix A

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[1] The NASEM Policy at 1.
[2] The NASEM Policy at 1-2.
[3] *Nat'l Anti-Hunger Coal. v. Exec. Comm. of President's Private Sector Survey on Cost Control*, 711 F.2d 1071, 1074, n.2 (D.C. Cir. 1983). (emphasis added; internal citations omitted).
[4] National Academies of Science, Engineering and Medicine, Policy on Composition and Balance, Conflicts of Interest, and Independence for Committees Used in the Development of Findings, Conclusions, and Recommendations, at 1 (2021)
[5] *Id.* at 2.

[6] While NASEM updated the NASEM Policy in September 2021 without public input, EPA's Peer Review Handbook and the White House Office of Management and Budget's Final Information Quality Bulletin for Peer Review continue to rely on the 2003 POLICY ON COMMITTEE COMPOSITION AND BALANCE AND CONFLICTS OF INTEREST FOR COMMITTEES USED IN THE DEVELOPMENT OF REPORTS for its interpretation of its peer review requirements. See https://www.epa.gov/osa/office-management-and-budgets-final-information-quality-bulletin-peer-review, https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/memoranda/2005/m05-03.pdf
https://www.epa.gov/sites/default/files/2020-08/documents/epa_peer_review_handbook_4th_edition.pdf
[7] 2003 Policy at 3.
[8] https://www.keystone.org/wp-content/uploads/2015/08/ResearchIntegrityRountableReport.pdf (pg. 13)
[9] https://www.acs.org/content/dam/acsorg/policy/publicpolicies/science-policy/scientific-integrity.pdf.
[10] The National Academies, Policy on Committee Composition and Balance and Conflicts of Interest, for Committees Used in the Development of Reports, May, 2003. While NASEM has indicated that the 2021 policy governs this review, it has provided no clear indication as to why a private sector perspective is no longer needed.
[11] https://www.govinfo.gov/content/pkg/CHRG-112hhrg67255/pdf/CHRG-112hhrg67255.pdf.
[12] New Task Order under NAS Contract #68HERC19D0011, between the U.S. EPA and the National Academy of Sciences, Sept. 7, 2021.
[13] https://www.americanchemistry.com/industry-groups/formaldehyde/resources/acc-comments-on-the-charge-questions-and-committee-task-for-peer-review-of-draft-formaldehyde-assessment.
[14] *Id.*
[15] National Research Council. 2011. Review of the Environmental Protection Agency's Draft IRIS assessment of Formaldehyde. Washington, D.C.: The National Academies Press.
[16] https://www.pnas.org/pb-assets/authors/ifora-1658169511760.pdf.
[17] https://www.keystone.org/wp-content/uploads/2015/08/ResearchIntegrityRountableReport.pdf (pg. 13).
[18] The NASEM Policy at 2.
[19] https://www.nationalacademies.org/our-work/review-of-the-iris-process?bname=nrsb.
[20] https://downloads.regulations.gov/EPA-HQ-ORD-2010-0396-0069/attachment_2.pdf.
[21] https://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/display.abstractDetail/abstract_id/10841/report/0.
[22] L. Zhang et al., *Exposure to glyphosate- based herbicides and risk for non-Hodgkin lymphoma: A meta-analysis and supporting evidence*, Mutation Research/Revies in Mutation Research, Vol. 781, pp. 186-206, July-Sept. 2019, available at, https://www.sciencedirect.com/science/article/abs/pii/S1383574218300887.
[23] https://ehp.niehs.nih.gov/doi/abs/10.1289/isee.2020.virtual.O-SY-1623

[24] https://www.nationalacademies.org/our-work/workshops-to-support-development-of-epas-iris-toxicological-reviews.
[25] https://foiaonline.gov/foiaonline/api/request/downloadFile/Kate%20Guyton%20-%20All%20Documents%20Archive%20Notes%20Mail.pdf/f21cdc9b-b1e9-41ed-9b6a-659da21e6c90?x-csrf-token=41682b34-4e77-4789-8c7c-b32b31284e95
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[26] https://republicans-science.house.gov/_cache/files/a/2/a2e745af-d8e1-4ec8-8ad2-b911a9ab43e3/BA4E9317509D052F516127CA4CF5F256.2019-03-27-testimony-rusyn.pdf
[27] https://republicans-science.house.gov/_cache/files/a/2/a2e745af-d8e1-4ec8-8ad2-b911a9ab43e3/BA4E9317509D052F516127CA4CF5F256.2019-03-27-testimony-rusyn.pdf

[28] Section on *Reviewing One's Own Work* https://omb.report/icr/202007-0648-006/doc/102524900
[29] Independence from Sponsors section in https://www.nationalacademies.org/docs/D4D336B1CB9047B19928EA8785ED2E43C913B841539A

Appendix A: Recommended Scientific Experts Bios

Occupational Epidemiology

Harvey Checkoway, PhD

Dr. Checkoway is a professor at the University of California San Diego in the department of Family Medicine and Public Health. His main areas of research and teaching are occupational and environmental risk factors for chronic diseases. Recent examples of research projects for which he is principal investigator are studies of environmental and genetic risk factors for Parkinson's disease; occupational exposures and risks for cancer and parkinsonism among Shanghai women textile workers; parkinsonism among welders. Dr. Checkoway was added to the NASEM-committee tasked with peer reviewing the 2010 draft IRIS formaldehyde assessment to address the lack of occupational exposure expertise in the provisional committee.

Endogenous and Exogenous Exposures

Kun Lu, PhD

Dr. Lu is an Associate Professor at the University of North Carolina at Chapel Hill Department of Environmental Sciences and Engineering. The overarching goal of Dr. Lu's lab is to better understand health effects of environmental exposure and individual response by integrating the microbiome, exposome, omics profiling, and biomarker development. Dr. Lu's lab is working on a number of important environmental chemicals ranging from heavy metals to pesticides, as well as others with significant public health concerns. Dr. Lu has published 13 articles related to formaldehyde, many of which include state of the art techniques for labeling and analyzing formaldehyde, demonstrating that exogenous formaldehyde does not move past the portal of entry.

Genotoxicity

Les Recio, PhD DABT

Dr. Recio is a director at ScitoVation with over 30 years of experience in toxicology research in the areas of mutagenesis, toxicogenomics, and regulatory genotoxicity assessments. His research program has included studies using primary and immortalized rodent and human cell lines, transgenic rodent models, and molecular genetic approaches to examine mechanisms and identify biomarkers of cytotoxicity, genotoxicity, and mutagenicity at the molecular, cellular, and animal level. His research program focused on mode-of-action and the development of data useful for benchmark dose analysis to derive point of departure estimates used in risk assessments. More recently Dr. Recio has been committed to developing New Approach Methods to replace or reduce the reliance on animal testing by developing genotoxicity assessments in human hepatocyte models. In collaboration with MIT (Dr. Bevin Engelward) and U of Ottawa (Dr. Carole Yauk), he developed a human-relevant genotoxicity testing platform using metabolically competent human hepatocytes integrated with rapid detection of genotoxicity and mode-of-action based genomic profiling.

Leukemia

Lucy A. Godley, MD, PhD

Dr. Lucy A. Godley is the Hospira Foundation Professor of Medicine, Comprehensive Cancer Research, and Human Genetics at University of Chicago Medicine. Dr. Godley is an expert in the care and treatment of patients with diseases of the bone marrow, including leukemias, lymphomas and multiple myeloma. She also cares for patients undergoing stem cell transplantation and patients with benign hematologic conditions. Dr. Godley has a special interest in the molecular basis of bone marrow malignancies and is an active researcher in the field. In her laboratory, Dr. Godley studies the basis for cancer cells' abnormal patterns of DNA methylation, as well as inherited forms of bone marrow cancers. She has received numerous awards for her research, including the Howard Hughes Medical Institute Physician Postdoctoral Award, the Cancer and Leukemia Group B (CALGB) Foundation Clinical Research Award, the American Society of Clinical Oncology Young Investigator Award, the Cancer Research Foundation Young Investigator Award, the Schweppe Foundation Career Development Award and the Kimmel Scholar Award. She was inducted into the American Society of Clinical Investigation in 2012.

Michael J. Thirman, MD

Dr. Michael J. Thirman is an associate Professor of Medicine and Comprehensive Cancer Research at the University of Chicago Medicine. Dr. Thirman specializes in the medical management of adults with hematologic disorders, leukemia, lymphoma, myelodysplastic syndromes, and myeloproliferative disorders. His laboratory focuses on the role of MLL fusion proteins in the development of leukemia. The overall goals of his research are to understand the mechanisms that mediate transformation of normal hematopoietic stem cells and to develop targeted therapies based on these insights. Dr. Thirman also directs clinical trials in acute myeloid leukemia and chronic lymphocytic leukemia. He serves on the editorial board of Blood Advances, the Medical Advisory Board of the Leukemia Research Foundation, and the Board of Trustees of the Illinois chapter of the Leukemia and Lymphoma Society. He is a recipient of the Stohlman Scholar Award by the Leukemia and Lymphoma Society and was selected as a Chicago Magazine Top Cancer Doctor.

Mode of Action

Susan Borghoff, MSPH, PhD, DABT

Dr. Susan Borghoff is a Principal Scientist at ToxStrategies, Inc. Dr. Borghoff is a recognized expert in evaluating modes of action by which agents cause toxicity, modulate endocrine pathways, and cause cancer in rodents, and the relevance of these responses for assessing human risk. She has been involved with critical reviews of toxicity and carcinogenicity studies, advising on specific study designs to fill data gaps for understanding modes of action, and as an Expert Panel member for scientific oversight of industry-sponsored toxicity and carcinogenicity testing programs. Dr. Borghoff's experience also includes implementing a program to conduct GLP regulatory studies associated with the US Environmental Protection Agency (USEPA)-mandated Endocrine Disruption Screening Program (EDSP) and co-chairing a workshop titled, "Lessons Learned, Challenges, and Opportunities: The US Endocrine Disruptor Screening Program," held in Research Triangle Park in 2013 to assess this program.

Pharmacokinetics

Lorenz R. Rhomberg, PhD, ATS[1]

Dr. Rhomberg is an Advising Principal at Gradient with an expertise in quantitative risk assessment, including dose-response analysis, pharmacokinetic modeling, and probabilistic methods, with special experience in chlorinated solvents and endocrine-active agents. His practice includes work in support of environmental litigation as well as work relating to a variety of regulatory programs including CERCLA, FIFRA, TSCA, and REACH, among others. Before joining Gradient, Dr. Rhomberg was on the faculty of the Harvard School of Public Health and was employed by US EPA. Dr. Rhomberg is active in professional groups and environmental policy development, focusing on current issues in the interpretation of toxicological data in human health risk assessment through service on panels sponsored by government, industry, and such organizations as the National Academy of Sciences and the UN Environmental Program. Dr. Rhomberg was recognized as the Outstanding Practitioner of the Year by the Society for Risk Analysis in 2009 and was named a Fellow of that Society in 2016. In 2017 he was given the Society of Toxicology's Arnold Lehman Award for contributions to the development of risk analysis.

Pharmacokinetics and Biologically-Based Dose-Response Modeling

Rory Conolly, ScD

Rory Conolly is a senior consultant at Ramboll with over 30 years of experience in computational modeling of toxicological mechanisms linking environmental and occupational exposures to the development of adverse health effects. This work includes physiologically based pharmacokinetic (PBPK) modeling and development of quantitative adverse outcome pathways (qAOPs). Dr. Conolly emphasizes iterative model development: when new, relevant information becomes available, models are updated, increasing confidence in their use to inform risk assessment decision-making. This approach requires sophistication not only in model development but also in effectively communicating their capabilities. Dr. Conolly received the Society of Toxicology's (SOT) Lehman Award for lifetime achievement in risk assessment in 2005 and has served as president of the organization's Risk Assessment and Biological Modeling specialty sections. He served on the National Academy of Sciences Board on Environmental Studies and Toxicology, is an adjunct professor of Toxicology at Michigan State University and has over 140 peer-reviewed publications.

Richard (Rick) A. Corley, PhD

Richard A. Corley is a consultant at Greek Creek Toxicokinetics Consulting, LLC. Prior to Greek Creek, he was a Laboratory Fellow from the Pacific Northwest National Laboratory operated by Battelle for the US Department of Energy. He specializes in the development and application of physiologically based pharmacokinetic models and multi-scale computational fluid-dynamic models of the respiratory system. Dr. Corley is a widely recognized expert in oral, dermal, and inhalation toxicology, as well as on three-dimensional computational fluid-dynamic models of the respiratory system. He served on the NASEM committee tasked with peer reviewing the 2010 draft IRIS formaldehyde assessment.

Risk Assessment

William (Bill) H. Farland, PhD, ATS

Dr. Bill Farland is a Professor Emeritus at the Colorado State University. Prior to joining the faculty at Colorado State University he served as the Deputy Assistant Administrator, Science at the U.S. Environmental Protection Agency. Dr. Farland has served on numerous committees, boards, and professional societies including the Society of Risk Analysis, the American Occupational Therapy Foundation, and the Scientific Advisory Council of the Risk Sciences and Public Policy Institute of Johns Hopkins University School of Hygiene and Public Health.

Julie E. Goodman, Ph.D., DABT, FACE, ATS
Dr. Goodman is a Principal at Gradient. Her expertise is in the areas of toxicology and epidemiology, and their application to human health risk assessments. She focuses on substances in consumer products, pharmaceuticals, and medical devices, as well as chemicals in the workplace and the environment. Dr. Goodman is board certified in toxicology, and a fellow of both the American College of Epidemiology and the Academy of Toxicological Sciences. She was also an adjunct faculty member in the Department of Epidemiology at the Harvard T. H. Chan School of Public Health, where she taught a class on meta-analysis for several years. Before joining Gradient, she was a Cancer Prevention Fellow at the National Cancer Institute. Dr. Goodman has authored numerous original peer-reviewed research articles, review articles (including systematic reviews, meta-analyses, and weight-of-evidence evaluations), and book chapters on a wide variety of chemicals and health outcomes. She has presented scientific findings and analyses at scientific and professional conferences, to community groups and regulatory and legislative bodies, and in litigation settings.

Laurie C. Haws, MS, PhD, DABT, ATS
Dr. Laurie Haws is a cofounder and Managing Principal Scientist with ToxStrategies. She is a board-certified toxicologist and a Fellow of the Academy of Toxicological Sciences (ATS), and has more than 30 years of experience in the areas of toxicology, human health risk assessment, risk communication, and scientific and regulatory policy. She has substantial experience evaluating potential human health risks associated with exposures to a wide variety of chemicals and metals. Dr. Haws also has extensive experience assessing potential human health risks associated with personal, occupational, and community-wide exposures to air contaminants, particularly related to chemical, petrochemical, and shale gas exploration and production activities. She is a recognized expert at evaluating data concerning modes and mechanisms of action and in using this type of data to assess the relevance of findings to humans. A substantial portion of her career has been spent in the government sector, both as a researcher and most recently as a manager in the Toxicology and Risk Assessment Section at the Texas Commission on Environmental Quality (TCEQ).

<u>Toxicology</u>
Norbert E. Kaminski, PhD
Dr. Norbert E. Kaminski is a Professor of Pharmacology and Toxicology and is the Director for the Center for Research on Ingredient Safety and Director of the Institute for Integrative Toxicology, at Michigan State University. He has served on a number of advisory panels, peer review panels and State of Michigan Committees. Dr. Kaminski has over 28 years of experience in conducting hypothesis driven investigative research directed at elucidation of the cellular and molecular mechanisms by which drugs and chemicals alter immune competence. Dr. Kaminski's

laboratory has been investigating the molecular mechanisms by which cannabinoids alter immune competence for over 25 years, which began with his laboratory's discovery of cannabinoid receptor expression within cells of the immune system. His laboratory has also had a longstanding focus on elucidation of the molecular mechanisms that are responsible for impairment of B cell function by dioxins.

James E Klaunig, PhD, ATS, IATP

Dr. Klaunig is founding Professor and Chair of the Department of Environmental Health at the School of Public Health at Indiana University Bloomington. His research has focused on understanding the toxicological and pathological effects of chemical agents including pharmaceuticals, and involves the application of systems biology, pathology and toxicology. Dr. Klaunig's work has concentrated primarily in the area of chemically induced carcinogenesis with particular interest in the mechanisms by which agents induce liver and lung cancer. A foundation of his mechanistic studies has been the application of these results to further understanding and producing scientifically based human risk assessment. Dr. Klaunig has served both his academic community, the state, national, and scientific societies.

From: Kate Guyton
To: Rusyn, Ivan I
Subject: RE: Upcoming webinar by Prof Ivan Rusyn; incoming requests
Date: 01/26/2012 05:07 PM

LOL we may need that depending what you say about HCHO assessment... do I need to provide a bullet-proof vest?

"Rusyn, Ivan I" ---01/26/2012 05:04:45 PM---Can we sell tickets in support of ... aynger management? Ivan Rusyn

From: "Rusyn, Ivan I" <iir@unc.edu>
To: Kate Guyton/DC/USEPA/US@EPA
Date: 01/26/2012 05:04 PM
Subject: RE: Upcoming webinar by Prof Ivan Rusyn; incoming requests

---

Can we sell tickets in support of ... aynger management?

Ivan Rusyn
Sent from Samsung Galaxy SII

-------- Original message --------
Subject: Upcoming webinar by Prof Ivan Rusyn; incoming requests
From: Kate Guyton <Guyton.Kate@epamail.epa.gov>
To:
CC: Amanda Persad <Persad.Amanda@epamail.epa.gov>,Ambuja Bale <Bale.Ambuja@epamail.epa.gov>,Andrew Kraft <Kraft.Andrew@epamail.epa.gov>,Barbara Glenn <Glenn.Barbara@epamail.epa.gov>,Brian Pachkowski <Pachkowski.Brian@epamail.epa.gov>,Channa Keshava <Keshava.Channa@epamail.epa.gov>,Connie Kang <Kang.Connie@epamail.epa.gov>,Danielle DeVoney <DeVoney.Danielle@epamail.epa.gov>,David Miller <Miller.David@epamail.epa.gov>,David Szabo <Szabo.David@epamail.epa.gov>,Deborah Segal <Segal.Deborah@epamail.epa.gov>,"Gary.Ginsberg@po.state.ct.us" <Gary.Ginsberg@po.state.ct.us>,George Woodall <Woodall.George@epamail.epa.gov>,Ghazi Dannan <Dannan.Ghazi@epamail.epa.gov>,Glinda Cooper <Cooper.Glinda@epamail.epa.gov>,"Rusyn, Ivan I" <iir@unc.edu>,Jennifer Mall <Mall.Jennifer@epamail.epa.gov>,Kathleen Newhouse <Newhouse.Kathleen@epamail.epa.gov>,Lynn Adams <Adams.Lynn@epamail.epa.gov>,Maureen Gwinn <Gwinn.Maureen@epamail.epa.gov>,Nina Wang <Wang.Nina@epamail.epa.gov>,Raghu Nath <Nath.Raghu@epamail.epa.gov>,Rob Dewoskin

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Hi everyone,

A couple of follow-up items:

1. Thanks to Ivan for agreeing to address us on Monday at 10 am regarding Review of EPA's Draft IRIS Assessment of Formaldehyde [Chapter 7: A Roadmap for Revision]. Please read this report in advance and be prepared for discussion [read: I may call on you!]. At Stan's suggestion, I have opened the webinar to NCEA-All with >80 acceptances. Because adobe connect is limited to 50 participants, please share audio/webinar access with your on-site colleagues if possible [otherwise-- log in early!]. As an incentive, we will have snacks in PYN 7100 (BYO coffee). I am sure this webinar will be beneficial to our planning process so please take advantage of this opportunity. I have notified the other HHRA theme/project/task leads and spoken with several of our Theme 1 project/leads (Sue R, Marty, Samantha) and they are looking forward to it as well. :-)

2. Team resources. Since we are working across locations, I will set up a Lotus Notes Team room to facilitate document sharing. Meantime I'll use the O: drive (thanks for that suggestion, Rob). If there are other ideas for doing so, do let me know.

3. Identification of problems/issues and projects. To facilitate our planning for this task, I will be circulating a form tomorrow that we may use to identify problems/issues and also develop a compendium of ongoing projects. For those also involved in Project 2, this will bear remarkable resemblance to the form that Weihsueh developed (he is helping me modify it for our purposes). The form is in Word but also reports out to Excel. I hope to have a draft of this ready to share tomorrow.

Thanks,
Kate

Kate Z. Guyton, PhD DABT
Toxicologist, NCEA, ORD, US EPA
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Mailing Address: US EPA (8623-P), 1200 Pennsylvania Ave. NW, Washington
DC 20460
FedEx and Ground Deliveries: Two Potomac Yard (North Building), 2733 S. Crystal Drive, Arlington VA 22202

From: Kate Guyton/DC/USEPA/US
To: Amanda Persad/DC/USEPA/US@EPA, Ambuja Bale/DC/USEPA/US@EPA,
Andrew Kraft/DC/USEPA/US@EPA, Barbara Glenn/DC/USEPA/US@EPA,
Brian Pachkowski/DC/USEPA/US@EPA, Channa Keshava/RTP/USEPA/US@EPA, Connie Kang/DC/USEPA/US@EPA,
Danielle DeVoney/DC/USEPA/US@EPA, David Miller/DC/USEPA/US@EPA, David Szabo/DC/USEPA/US@EPA, Deborah
Segal/DC/USEPA/US@EPA, Gary.Ginsberg@po.state.ct.us, George Woodall/RTP/USEPA/US@EPA, Ghazi Dannan/DC/USEPA/US@EPA,
Glinda Cooper/DC/USEPA/US@EPA, iir@unc.edu, Jennifer Mall/DC/USEPA/US@EPA, Kathleen Newhouse/DC/USEPA/US@EPA,
Lynn Adams/DC/USEPA/US@EPA, Maureen Gwinn/DC/USEPA/US@EPA,
Nina Wang/CI/USEPA/US@EPA, Raghu Nath/DC/USEPA/US@EPA, Rob
Dewoskin/RTP/USEPA/US@EPA, Sury Vulimiri/DC/USEPA/US@EPA,
Susan Makris/DC/USEPA/US@EPA, Ted Berner/DC/USEPA/US@EPA,
Thomas Bateson/DC/USEPA/US@EPA, Yu-Sheng Lin/DC/USEPA/US@EPA
Cc: Debra Walsh/RTP/USEPA/US@EPA, Lyle Burgoon/RTP/USEPA/US@EPA,
Stan Barone/DC/USEPA/US@EPA, David Bussard/DC/USEPA/US@EPA
Date: 01/23/2012 02:56 PM
Subject: Orientation for HHRA Theme 4 Project 1 Task 3

Hi everyone,

Thank you for joining our orientation meeting today. Below please find the HHRA organization chart discussed.
[attachment "Attachment B - HHRA_Program_Structure_w_20% contingency.docx" deleted by Kate Guyton/DC/USEPA/US]

Action items:
1. Winter reading list [All]; Kate will be organizing webinars on these topics:

1) Science and Decisions: Advancing Risk Assessment [please focus on hazard identification issues]
2) Review of EPA's Draft IRIS Assessment of Formaldehyde [Chapter 7: A Roadmap for Revision]
3) Toxicity Testing in the 21st Century: A Vision and a Strategy

I have posted PDFs at L:\Lab\NCEA\National Academies Press Docs; you may also download a free PDF copy or order a book at: http://www.nap.edu/.

2. Compendium of ongoing projects-- Kate will circulate a form for you to complete

3. NCCT communities of practice website: http://www.epa.gov/ncct/communities_of_practice.html

We will have our next meeting in approximately 2 weeks. Feel free to email me with any questions you may have about this task in the interim.

Thanks,
Kate

Kate Z. Guyton, PhD DABT
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{In Archive} Fwd: Chapter 7

Rusyn, Ivan I to: Kate Guyton 01/24/2012 11:45 AM

History: This message has been replied to.

Archive: This message is being viewed in an archive.

Would this work for you?

Ivan Rusyn
Sent from Samsung Galaxy SII

-------- Original message --------
Subject: RE: Chapter 7
From: "Mantus, Ellen" <EMantus@nas.edu>
To: "Rusyn, Ivan I" <iir@unc.edu>
CC:

Hi Ivan,

I spoke with Jim Reisa, and I think that the primary advice is that since they have asked you to talk about the report (that is, represent the report and the Academies) is that you stay within the boundaries of the report and its message. Basically, stick to the report and be consistent with the report in what you say. I have attached the briefing slides that we used for Congress, which had a few more slides on Chapter 7 than the EPA presentation that we used (also attached).

Ellen

Ellen K. Mantus, Ph.D.

Formaldehyde_Congress.ppt

Formaldehyde_EPA_v4.ppt