DEPARTMENT OF HEALTH AND HUMAN SERVICES NATIONAL INSTITUTES OF HEALTH NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

MEETING SUMMARY OF THE NATIONAL ADVISORY ENVIRONMENTAL HEALTH SCIENCES COUNCIL

June 5, 2025

The 175th meeting of the National Advisory Environmental Health Sciences Council convened on June 5, 2025. Open session convened at 9:00 a.m. and ended at 11:52 a.m. on June 5, 2025. A closed session took place from 12:30 pm to 1:00 pm on June 5, 2025. Dr. Richard Woychik, Director, NIEHS, presided as chair. The meeting was virtual only and all participants attended via MS Teams. The meeting was also webcasted to the public.

Participating Council Members:

Olivier Deschenes, PhD Darryl Hood, PhD Keri Hornbuckle, PhD Cathrine Hoyo, PhD Gokhan Mutlu, MD Maria Savasta-Kennedy, JD

NIEHS Staff:

Trevor Archer, PhD Irina Alva-Weinstein Jennifer Baker David Balshaw. PhD Valerie Bartlett Sharon Beard, MS Abee Boyles, PhD Michelle Campbell, MB Danielle Carlin, PhD Toccara Chamberlain, MA Yuxia Cui, PhD J'Zhane Dobson Christopher Duncan, PhD Anika Dzierlenga, PhD Nicole Garbarini, PhD Amanda Garton, MSPP Kimberly Gray, PhD Jenny Greer Michelle Heacock, PhD Heather Henry, PhD Jonathan Hollander, PhD

Michael Humble, PhD Bonnie Joubert, PhD Cindy Lawler, PhD Rebecca Mao, PhD John Maruca Jacqueline Marzec, MS Tracie McGraw Aubrey Miller, PhD Nathan Mitchiner Srikanth Nadadur, PhD Liam O'Fallon, MA Amelia Pearson, MHR Eric Persaud. PhD Clark Phillips Ashlinn Quinn, PhD Lingamanaidu Ravichandran, PhD Caleb Rogers Françoise Santos Christopher Schnur Thaddeus Schug, PhD Daniel Shaughnessy, PhD Carol Shreffler, PhD Varsha Shukla, PhD Claudia Thompson, PhD Brittany Trottier, PhD Frederick Tyson, PhD Ashley Vargas, PhD Leroy Worth, PhD Richard Woychik, PhD Darryl Zeldin, MD Alicia Zorn

Members of the Public Present – During Open Session Only:

Ernie Hood, Bridport Services, LLC

OPEN SESSION

The meeting was open to the public on June 5, 2025, from 9:00 am to 11:52 am. In accordance with the provisions set forth in Section 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), the meeting was closed to the public on June 5, 2025, from 12:30 pm to 1:00 pm for consideration of grant applications. Notice of the meeting was published in the Federal Register. Dr. Richard Woychik presided as Chair.

I. Call To Order and Opening Remarks

NIEHS and NTP Director Dr. Richard Woychik, welcomed attendees and called the meeting to order. He read the Government in the Sunshine Act guidance. DERT Director, Dr. David Balshaw, asked Council members present at the meeting to introduce themselves. Council members Dr. Stephania Cormier, Dr. Tim Greenamyre, Dr. Patricia Nez-Henderson, and Ex-Officio Dr. Suzanne Fitzpatrick were unable to attend. Members of the NIEHS senior leadership team introduced themselves. Dr. Balshaw then reviewed the logistics for the meeting and reminded attendees of virtual meeting etiquette.

II. Review of Confidentiality and Conflict of Interest

Dr. David Balshaw read the conflict-of-interest statement. "This certifies that in the review of applications or projects conducted by the National Advisory Environmental Health Sciences Council on today's date, I absented myself and I did not participate in the discussion of, nor vote on, any applications or projects in which I or, to my knowledge, my spouse, minor child, or close professional associates have a financial interest nor on any applications or projects from an organization or institution where I am an employee, consultant, officer, director, or trustee, am negotiating for employment, or otherwise have a financial interest. In Council actions in which we voted on a block of applications or projects without discussing any individual one—the 'en bloc' actions—my vote did not apply to any applications from any institution fulfilling the criteria in the preceding paragraph." Members should sign the certification and email them to Valerie Bartlett today. Dr. David Balshaw also went over the use of MS TEAMS breakout rooms for members and attendees in conflict during closed session.

III. Consideration of Previous Meeting Minutes

Approval of the September 2024 meeting minutes was first moved to a vote by Dr. Maria Savasta-Kennedy and seconded by Dr. Darryl Hood. Approval of the April 2025 meeting minutes was first moved by Dr. Maria Savasta-Kennedy and seconded by Dr. Kerri Hornbuckle. Council voted to approve the minutes, with all in favor. Dr. David Balshaw mentioned the future Council meeting dates. The September 2025 meeting will be in-person.

IV. Report of the NIEHS Director

Dr. Richard Woychik briefed Council on NIH and NIEHS developments since the September 2024 Council meeting. He reminded attendees that with every new administration, there are new administration priorities. NIH and NIEHS staff are implementing the current administration's new priorities. NIEHS has experienced a reduction in force for some of the key staff across several of the divisions. He also indicated that there have been plans to reorganize NIEHS and the NIH with extremely

challenging timelines, and that the details are still emerging. Most notably, with the new priorities and staffing, it has impacted NIEHS' ability to get grants funded in a timely manner. Dr. Woychik thanked the Council members for their service and their patience with the Council process. He also thanked everyone in the grantee and the stakeholder community for understanding. Dr. Woychik also thanked the Council members for their flexibility with the February Council meeting date being moved to an April date instead. At the April date the Council members held a closed session only and were able to provide the second-level review for applications originally assigned to the February council meeting date. He emphasized to the Council members and the public, that the NIH and NIEHS are making awards as expeditiously as possible.

Dr. Woychik stated that NIH staff will not be able to discuss the status of any specific applications with respect to grant compliance, supplication status, termination, or appeal status. Additionally, NIH staff will not be able to discuss any items related to pending or ongoing litigation.

Dr. Richard Woychik presented a slide showing the NIEHS FY 2023-2026 Funding Summary. He showed that the FY2025 NIEHS budget was flat from the FY2024. The FY2026 President's budget released last week shows around a 35 percent reduction in both NIEHS' HHS allocation and Superfund allocations. Dr. Woychik stated that also in the budget there was also language to move NIEHS out of the NIH into a new proposed agency called the Administration for a Healthy America (AHA). In this language, NIEHS would be part the of the Environment Health account with NIOSH and other parts of CDC. AHA would additionally subsume the work of Office of Assistant Secretary of Health (OASH), Health Resources and Services Administration (HRSA), Substance Abuse and Mental Health Services Administration (SAMHSA), and several centers and programs formerly in the Center of Disease Control and Prevention (CDC). Dr. Woychik reminded everyone that this is a proposal from the White House and is not final until Congress passes the budget and that there may be additional changes made. NIH and senior leadership team are actively engaged in meetings to provide type of input to the policymakers.

Dr. Richard Woychik talked about the new HHS Secretary Robert Kennedy Jr. Secretary Kennedy is specifically addressing items that NIEHS 'is all about' with tackling the chronic disease epidemic, eliminating toxic additives in food and consumer products, and promoting clean water and air initiatives.

Dr. Woychik talked about the new NIH Director Dr. Jay Bhattacharya. Dr. Bhattacharya's vision for NIH includes improving population health, ensuring reliable research results, and making big advances in innovation, new technologies, new ideas, and new approaches to old problems. Dr. Bhattacharya sees tremendous value of NIEHS in realizing his vision in improving health.

NIEHS hosted Mr. Eric Schnable, NIH Chief Operating Officer, in a campus tour with the priority focus on supporting the critical operations and daily functions that allow the NIEHS thrive. He was impressed with the visit and what the NIEHS does to help support the NIH mission.

NIEHS invited Dr. Stephanie Haridopolos, the Acting Chief of Staff Office of the Surgeon General HHS, to attend the Exposome Moonshot Forum in Washington DC. This happened after Dr. Haridopolos contacted Dr. Woychik about a manuscript from Dr. Alison Motsinger-Reif's (NIEHS staff) work on polyexposure scores. Dr. Motsinger-Reif's manuscript described how polyexposure scores could serve as a better predictor of disease outcomes than than traditional polygenic risk scores. While in DC at the Forum, Dr. Woychik and Dr. Motsinger-Reif visited with staff of Office of the Surgeon General (OSG). OSG staff were very interested in mitochondrial biology and in learning more about the mitochondrial transplantation technology. As a follow-up, Dr. Janine Santos (NIEHS staff) was invited and met with Dr. Stephanie Haridopolos to discuss the mitochondrial transplantation technology in greater detail.

NIEHS and NTP staff updates since September Council meeting were then announced. Dr. Janet Hall retired from federal service in March 2025 after ten years at NIEHS. Dr. Mike Fessler began serving as Clinical Director on December 29, 2024, after serving as Acting Clinical Director since July 2024. Christine Flowers, after almost twenty years of service, retired on February 28, 2025, from her position as Director of Office of Communications and Public Liaison (OCPL). Jesse Saffron has taken on the role as Acting Director of OCPL. After forty-one years of service, Dr. Gwen Coleman retired as Director of Strategic Coordination, Planning, and Evaluation (SCOPE). Dr. Nicole Garbarini assumed the role of Director of SCOPE. Dr. Nicole Kleinstreuer was selected as the Acting NIH Deputy Director for Program Coordination, Planning, and Strategic Initiatives (DPCPSI).

V. Report of the DERT Director

Dr. David Balshaw began his presentation to Council about DERT developments since the September 2024 Council meeting with a staffing update. At the September 2024 Council meeting DERT had 93 FTEs available with 85 current employees. Since then, DERT has been impacted by retirements, consolidations, and reduction in force, leaving DERT with 57 employees as of this meeting. Dr. Balshaw welcomed one new DERT employee since the September Council meeting, Dr. Aubrey Miller within the Office of Division Director as the Senior Medical Advisor.

Dr. David Balshaw went over the requirement to document the Advisory Council's usual procedures in a Standard Operation Procedures (SOP) document. There have been no changes made to the existing NAEHS Council standard operating procedures, but they

are now documented in an SOP for Council members. Dr. Balshaw also went over there the Council Delegated Authorities (CDAs), for which there are no changes from last year. The CDAs documents which Council authorities that the Advisory council delegates to NIEHS staff without bringing it to Council first for approval. The CDAs currently allows staff to make change of institution, change of PI, continuation of grant with an interim PI, extension without funds, and extension with funds. Approval of the NAEHS Council SOP and CDAs was first moved to a vote by Dr. Darryl Hood and seconded by Dr. Catherine Hoyo. Council voted to approve the SOP and CDAs with all in favor.

Dr. David Balshaw went over the NIEHS 2022-2024 Triennial Inclusion Advisory Council Report certifying compliance with NIH policy on inclusion. Approval of the 2025 NIEHS Triennial Inclusion Report was first moved by Dr. Maria Savasta-Kennedy and seconded by Dr. Kerri Hornbuckle. Council voted to accept the Inclusion Report, with all in favor.

Dr. Balshaw went over DERT accomplishments, reviewing FY2024 extramural funding and grant distribution.

- Stating there were 1,414 applications reviewed and the payline was 7 percent for R01, R03, and R21 grants.
- Comparing the NIEHS and NIH RPG success rate. NIEHS rate is still below NIH at 16.3 percent compared to 18.6 percent.
- FY2024 distribution of extramural grants total \$445.8 million.
- FY2024 research project grants distribution by mechanism total \$284.2 million.
- Superfund in FY2024 grant distribution total \$74.8 million, of that \$26 million was with the Worker Training Program and \$48.8 million was with the Superfund Research Program.

Managing FY2025 has been challenging related to loss of staff, delayed January Council meeting until April, and changes in the HHS and NIH policies and priorities. To improve our ability to efficiently make awards in FY2025 within DERT:

- We will be emphasizing non-competing awards.
- Increasing the payline to 11 percent and minimizing Raise-to-Pay nominations from staff.
- In the fourth quarter, using strategies such as multiyear funding appropriate competing and non-competing awards.

The best way to stay informed with NIH Policies is to go to Grants.NIH.gov, then under Notices of NIH Policy Changes, click on NIH Guide for Grants and Contracts.

Dr. Balshaw announced there were two NIEHS grantees that received the 2025 President's Early Career Award for Science and Engineering, Dr. Paloma Beamer a

professor at University of Arizona and Dr. Kymberly Gowdy an associate professor at The Ohio State University.

VI. Break

VII. Concept: Impact of Environmental Exposures on Gut-Brain Signaling in Neurological Conditions

Dr. David Balshaw introduced Dr. Jonathan Hollander and Dr. Anika Dzierlenga from the DERT Genes, Environment, and Health Branch, and introduced Dr. Darryl Hood and Dr. Cathrine Hoyo as the assigned Council Reviewers on the concept.

Dr. Hollander and Dr. Dzierlenga briefed Council on the scientific concept, Impact of Environmental Exposures of Gut-Brain Signaling in Neurological Conditions. New program to assess exposures on gut-brain signaling.

Dr. Anika Dzierlenga presented an outline of the talk:

- Gut microbiome as a mediator of human health and disease
- What is the gut-brain axis?
- An ongoing discussion: retreat and workshops
- Case studies
- NOFO objectives

Gut microbiome is the richest and has great influence on health. Various physiological states impact gut microbiome including changes in environment. Trends in microbiome research have evolved over time, with increased complexity of research question enabled by sophistication in approach. For example, DNA-based approaches which describe microbiome composition have evolved to RNA/metabolomics approaches which describe microbial products that interface with host pathways. When these products interact with host pathways, they can contribute to disease progression. The gut microbiome is very relevant to environmental exposure pathways, as it serves as both a target and as a mediator of toxicity. It plays a role in determining interindividual variability in response to exposures, which makes it a potentially useful molecular signature for precision environmental health. It is modifiable and could serve as an intervention target, or as a biomarker of exposure, disease state, and/or therapeutic efficacy.

Gut microbiome plays an important role in mediating communication along the gut-brain axis. There are many well-defined pathways, such as communication along the vagus nerve, mediation of the immune system, GI production of neuroactive metabolites, and intersection with other organ systems. NIEHS has hosted a series of workshops, including "The impact of Environmental Exposures on the Microbiome and Human Health", and "At the Crossroads of Exposure, Microbiome, and the Nervous System

Workshop." These workshops were designed to bring together toxicologists with microbiome scientists, and the focus included mechanisms, models and methods, consideration of lifespan, importance of collaboration, and translational approaches. NIEHS also co-hosted a trans-NIH workshop on the gut-brain axis in Parkinson's Disease, which delved more into clinical topics, such as coordinating clinical care and leveraging gut interventions for treatment. All together, these workshops highlighted enticing opportunities in this field.

Dr. Anika Dzierlenga turned the presentation over to Dr. Jonathan Hollander, who introduced Parkinson's disease (PD) as an example highlighting the importance of the gut-brain connection in disease risk and progression. Key pathological markers of the disease include reduction of dopamine in neurons in the substantia nigra and the increased presence of protein deposits (i.e., Lewy bodies) in the brain. Environmental and genetic factors contribute to the development of PD, for which there is currently no known cure. Dr. Hollander presented two theoretical approaches for how environmental exposures can have direct effects on PD pathology by entering the brain when a toxicant is inhaled (i.e., "brain-first" model) or ingested (i.e., "body-first" model). With the body-first approach, study of the gut may reveal a critical window in which the disease develops for years before diagnosis.

Dr. Hollander discussed a few studies, the first of which investigators injected paraquat (PQ) for 4, 6, and 8 weeks in mice. Results showed damage in the digestive tract along with increase in inflammatory markers with longer PQ exposures. These findings suggest pesticide exposure can be linked with gut-brain changes. He then discussed a second study that revealed the importance of the gut-brain axis extends beyond risk of neurodegenerative diseases such as PD, but also in areas such as healthy neurodevelopment and potential psychiatric outcomes. Dr. Hollander presented a final study showing the gut microbiome was found to be protective against exposure-induced behaviors and brain changes associated with neurodevelopmental deficits.

Dr. Hollander subsequently discussed how the gut is amenable to therapeutic treatment that can have a direct effect on disease and health. Common therapeutic intervention strategies used by investigators include probiotics and prebiotic supplementation, fecal microbiota transplantation and dietary modification. Collectively, these interventions have potential promise to treat or delay neurological disorders by modulating gut microbiota.

Dr. Hollander induced the new NIEHS-led program by stating its main goal is to expand and leverage the role of gut microbiome-brain axis for improved detection, prevention, and intervention strategies for environmental exposure-induced neurological disease. He provided several examples of applications they may receive from this solicitation, including studies that use applicable model system to elucidate mechanisms,

characterize neuroactive microbial metabolites and target receptors, assess gut microbiota signatures or pilot potential intervention targets and strategies.

Dr. Jonathan Hollander turned the presentation over to assigned Council reviewers, Dr. Darryl Hood and Dr. Catherine Hoyo, for comment:

Dr. Darryl Hood talked about the emerging recognition of gut-brain axis in health and will bridge various scientific disciplines in elucidating interventions. Collaborative interdisciplinary approaches will be prioritized. Dr. Catherine Hoyo talked about how it is aligned with NIEHS mission/Precision EH/mechanistic biology. NIEHS reinforces mechanistic insights and intervention strategies to enhance public health outcomes and may be a transformative impact across science disciplines. Dr. Darryl Hood then discussed how concept intersects AHA goals, promotes cross-disciplinary science and precision EH, mental health/aging, and supports several AHA agenda priorities. Dr. Catherine Hoyo offered some suggestions to strengthen to extend exposures to social and other non-chemical stressors (relate to exposome). Dr. Darryl Hood talked about the strengths – this is next step for microbiome science and suggestion: interest in other non-chemical stressors how impacts gut/brain axis.

Question and Answer portion of the presentation:

- Question: Dr. Maria Savasta-Kennedy: cumulative exposures and how will that aspect be captured or not in this program (practical application)
 - Answer: Dr. Anika Dzierlenga: investigators will pursue specific research questions, and when applicable would certainly be welcome to take that approach
- Question: Dr. Mutlu Gokhan: asked about lung exposure to air toxicants/pollution and gut microbiome.
 - Dr. Jonathan Hollander: It is recognized that systems outside the gut-brain axis are important in the development of neurological conditions, and this concept does not exclude this line of inquiry. However, there is a primary focus on the gut with this concept because it is very amenable to therapeutic intervention.
 - Dr. Anika Dzierlenga: This concept is not excluding any specific avenues of inquiry, as long as microbiome, neurological outcomes, and chemical exposures are included.

Dr. David Balshaw called for a motion to approve the concept. Dr. Maria Savasta-Kennedy first moved the concept to a vote, and Dr. Gokhan Mutlu seconded the motion. The Council members voted to approve the motion, with all in favor.

VIII. Adjournment

Dr. Richard Woychik thanked the Council members for their work on the meeting, and all attendees for their participation. Dr. David Balshaw added thanked the Council for its engagement and important advice. Dr. Richard Woychik adjourned the open session of the meeting at 11:52 am, June 5, 2025.

IX. **CLOSED SESSION**

This portion of the meeting was closed to the public in accordance with the determination that it concerned matters exempt from mandatory disclosures under Sections Section 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code and Section 10(d) of the Federal Advisory Committee Act, as amended. The closed session adjourned at 1:00 pm, June 5, 2025.

REVIEW OF APPLICATIONS

The NAEHS Council is advisory across the entire Institute. This Council has traditionally focused more on the NIEHS Extramural Division but has routinely received written updates and scientific presentations from the two NIEHS Intramural Divisions, the Division of Intermural Research (DIR) and the Division of Translational Toxicology (DTT). To ensure we are more deliberate in allowing Council to be advisory to the NIEHS Intramural Divisions' Board of Scientific Counselors (BSC), we intend to provide the BSC reports at all future councils when the reports are available.

This portion of the closed session is concerning the Extramural Division, including a discussion of procedures and policies regarding voting and confidentiality of application materials, committee discussions and recommendations. Members absented themselves from the meeting during the discussion of, and voting on, applications from their own institutions or other applications in which there was a potential conflict of interest, real or apparent. Members were asked to sign a statement to this effect. The Council considered and recommended 622 applications requesting \$215,147,814 in total costs. For the record, it is noted that secondary applications were also considered en bloc.

CERTIFICATION:

Richard P. Woychik -S

Digitally signed by Richard P. Woychik -S Date: 2025.06.27 10:13:40 -04'00'

Richard Woychik, PhD Chairperson National Advisory Environmental Health Sciences Council

DAVID M. BALSHAW -S Date: 2025.06.27 08:39:44 -04'00'

Digitally signed by DAVID M. BALSHAW -S

David Balshaw, PhD **Executive Secretary** National Advisory Environmental Health Sciences Council

Attachment: Council Roster