

**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 4, 2024

The 172nd meeting of the National Advisory Environmental Health Sciences Council convened on June 4, 2024. Open session convened at 9:03 am and ended at 4:30 pm June 4. A closed session took place from 4:45 pm to 5:45 pm June 4, 2024. Dr. Rick Woychik, Director, NIEHS, presided as Chair. The meeting was hybrid; some participants attended in person, and some attended via Zoom.

Participating Council Members

Yulia Iossifova Carroll, MD, PhD (*ex officio*)
Stephania Cormier, PhD (pending new member) (attended via Zoom for open session only)
Olivier Deschenes, PhD (attended via Zoom)
Suzanne Fitzpatrick, PhD (*ex officio*) (attended via Zoom)
Annette Guiseppi-Elie, PhD, EPA (*ad hoc, ex officio*)
J. Timothy Greenamyre, MD, PhD
Andrij Holian, PhD
Darryl Hood, PhD
Keri Hornbuckle, PhD
Cathrine Hoyo, PhD (pending new member) (attended via Zoom for open session only)
Jani Ingram, PhD
Thomas LaVeist, PhD
Gary Miller, PhD
Gökhan Mutlu, MD (attended via Zoom)
Maria Savasta-Kennedy, JD (attended via Zoom)

NIEHS Staff

Alicia Abdelmasih
Kathy Ahlmark
Irina Alva
Trevor Archer, PhD
David Balshaw, PhD
Jennifer Baker
Valerie Bartlett
Sharon Beard
April Bennett

Abee Boyles, PhD
Michelle Campbell
Danielle Carlin, PhD
Warren Casey, PhD
Toccara Chamberlain
Jennifer Collins
Gwen Collman, PhD
Yuxia Cui, PhD
Beverly Duncan, PhD
Chris Duncan, PhD
Anika Dzierlenga, PhD
Benny Encarnacion
Maya Evanitsky
Murali Ganesan, PhD
Nicole Garbarini, PhD
Amanda Garton
Kimberly Gray, PhD
Jenny Greer
Arshya Gurbani
Michelle Heacock, PhD
Heather Henry, PhD
Jon Hollander, PhD
Mike Humble, PhD
Gary Johnson
Bonnie Joubert, PhD
Heather Knox
Cindy Lawler, PhD
Victoria Ledbetter
Gerald Lilly, MD, MPH
Mbeja Lomotey, Dr.P.H.
Rebecca Mao, PhD
Kimberly McAllister, PhD
Katherine McGinnis
Carolina Medina
Parris Milly
Nathan Mitchiner
Srikanth Nadadur, PhD
Liam O'Fallon
Suzanne Osborne
Heather Patisaul, PhD
Eric Persaud, DrPH
Kristi Pettibone, PhD
Ashlinn Quinn, PhD
Lingamanaidu Ravichandran, PhD
Thaddeus Schug
Dan Shaughnessy, PhD

Carol Shreffler, PhD
Varsha Shukla, PhD
Claudia Thompson, PhD
Brittany Trottier
Tierra Tucker
Fred Tyson, PhD
Ashley Vargas, PhD
Rick Woychik, PhD

Members of the Public Present

Mohammad Athar, PhD, University of Alabama, Birmingham
Karen Block, PhD, Veterans Administration
Sue Fenton, PhD, North Carolina State University
Ernie Hood, Bridport Services, LLC
Kirk Laflin, National Partnership for Technology Education (NPETE)
William Nash, National Partnership for Technology Education (NPETE)
Livia A. Veress, MD, University of Colorado

OPEN SESSION

The meeting was open to the public on June 4, 2024 from 9:03 a.m. to 4:30 p.m. 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 4, 2024 from 4:45 p.m. to 5:45 p.m. for consideration of grant applications. Notice of the meeting was published in the *Federal Register*. Dr. Rick Woychik presided as Chair.

I. Call To Order and Opening Remarks, Review of Confidentiality and Conflict of Interest

NIEHS and National Toxicology Program (NTP) Director Rick Woychik, Ph.D., welcomed attendees and called the meeting to order. He provided guidance from the Government in the Sunshine Act. DERT Director David Balshaw, Ph.D., asked Council members in the room and present on the Zoom call to introduce themselves. Members of the NIEHS senior leadership team introduced themselves. Dr. Balshaw went over some of the logistics for the meeting, and read the conflict of interest statement. Council members Philip Bourne, Ph.D., and Patricia Nez Henderson, Ph.D., were unable to attend.

II. Consideration of February 2024 Meeting Minutes

Approval of the February 2024 meeting minutes was moved by Dr. Hood and seconded by Dr. Greenamyre. Council voted to approve the minutes, with all in favor.

III. DTT work in U.S. Active Duty and Veteran Populations

Dr. Balshaw introduced a Council mini-symposium focused on a number of NIEHS activities on veterans' health and related topics.

Division of Translational Toxicology (DTT) Scientific Director, Dr. Heather Patisaul, introduced the first speaker, DTT Director of Strategic Partnerships Dr. Warren Casey.

Dr. Casey began his presentation with background information about DTT, its mission and strategic framework.

He discussed the PROMETHEUS project: PROject for Military Exposures and Toxin History Evaluation in U.S. service members. The project was established to bring federal assets together with public-private partners to further study how exposure to toxic chemicals in the environment impact service members' health and future potential for development of conditions such as cancer. The program is focused on developing actionable tool for prevention of exposure-related cancer and understanding mechanisms of disease development that may enable early detection or enhanced precision treatments. It began as part of the 2022 Cancer Moonshot 2.0 initiative under the Department of Defense (DoD) Murtha Cancer Center Research Program. It is an umbrella of collaborative efforts with the Veterans Administration (VA), NIEHS, the National Cancer Institute (NCI) and public/private partners, conducting research that integrates retrospective and prospective exposure data, phenotypic data, and biospecimens unique to the DoD and VA, but relevant to civilian exposures as well. It includes:

- Department of Defense Serum Repository (DoDSR), which has collected over 70 million serum specimens from over 10 million service members since 1986.
- Veteran Military Occupational & Environmental Exposure Assessment Tool, a self-report questionnaire.
- Military Biomarkers Research Study
- The Framingham Study, a longitudinal research program to transform our understanding of the biological underpinnings of cancer.
- Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Network, which is analyzing the DNA, RNA, and protein expression of 8,000 annotated human tissue specimens.
- Use of DoDSR sera and toxin exposure data in APOLLO-enrolled patients to identify potential biomarkers of cancer risk, biology, and outcomes for Early Onset Colorectal Cancer and Early Onset Breast Cancer.
- Prospective Exposure Studies using OneDraw, a personally administered blood collection device.

Dr. Arun Pandiri from DTT has used PROMETHEUS resources to initiate collaborative research projects. He is looking at mutational signatures of cancers associated with exposure to carcinogens. One project involves linking exposures at Marine Corps Base Camp Lejeune to presumptive cancers, comparing tumors from Camp Lejeune Marines to tumors from Camp Pendleton personnel. Another examines mutational signatures of tumors from the Agent Orange tumor registry.

Dr. Hood noted that there is a significant cohort that does not meet the stringent inclusion criteria for many of the studies Dr. Casey had described, and suggested that it may be feasible to include another arm in the study design to include those being missed. Dr. Casey replied that there must be a balance in terms of sample collections and budgets. He said that the studies were designed to maximize efficiency and budgetary discretion.

Dr. Ingram asked about the breast cancer study Dr. Casey had mentioned, which parsed out different ethnic groups, and wondered if Native Americans would be included, since a significant number of them are in the military. Dr. Casey said that all minorities are a higher percentage of the military population compared to the general population, and will certainly be included.

Dr. Carroll asked about biomarkers of exposure, particularly with regard to biomarkers of wildfire exposure. Dr. Casey said that to his knowledge there are no existing studies directly measuring human samples in that area, but that there is exciting work going on measuring biomarkers of exposures among firefighters.

Dr. Miller commented on the serum repository work. He noted that some of it had been performed nine years ago, and the mass spectrometry technology has evolved substantially since then. He suggested that the resource represents great potential with the improved technology available. Dr. Casey said there are plans to utilize the new tools in military biomarker studies.

IV. Veterans Health Administration Military Exposure Research

Dr. Karen Block briefed the Council on the many initiatives in progress researching military exposures. She is Director of the Gulf War Research Program and Designated Federal Officer for the Research Advisory Committee on Gulf War Veterans' Illnesses within the VA Office of Research and Development. She is leading an interagency effort to address the PACT Act of 2022.

She noted that the military population is subject to many exposures, including Agent Orange, nerve agents, solvents, anti-malarial treatments, dust and sand, fuels, pesticides, radiation, depleted uranium, vaccines, oil well fires, and burn pits. Those are

mostly deployment-related exposures. Non-deployed military personnel are also subject to unique exposures.

She said there are two major offices within the VA that conduct research on military exposures. First is the Health Outcomes Military Exposures (HOME) Office, which among several responsibilities maintains the six Congressionally-mandated exposure registries: Agent Orange, Gulf War, Ionizing Radiation, Airborne Hazards and Open Burn Pit, Toxic Embedded Fragments, and Depleted Uranium. HOME also oversees the Individual Longitudinal Exposure Record (ILER) for Research. ILER is a joint DoD/VA trusted source, a web-based application that links individual exposures to locations.

The second major VA office is the Office of Research and Development (ORD), where Dr. Block works. ORD is comprised of:

- ~100 VA Medical Centers that conduct research
- Over 90% are connected with medical schools.
- VA Research is an intramural program. It is not a granting institution, but funds awards for research.
- ORD funds peer-reviewed research conducted by VA field investigators.
- ORD has a broad, extensive research portfolio that balances the needs of all veterans, including research in clinical trials, basic biomedical research, health services, and rehabilitation.

Dr. Block described the importance of collaborative research related to the VA, which allows access to subject matter expertise, technologies, and data and specimen repositories. By way of example, she described Project IN-DEPTH, a collaborative effort between the VA and the NIH's National Institute of Neurological Disorders and Strokes (NINDS), and the collaboration between the VA and Columbia University, Post-Exertion Malaise in Gulf War Illness (a.k.a. the GWI Exercise Study).

She also provided details about The Sergeant First Class Heath Robinson Promise to Address Comprehensive Toxics (PACT) Act of 2022, the law that expands VA health care and benefits for veterans exposed to burn pits and other toxic substances. Since its enactment, the PACT Act has seen more than 1.3 million related claims completed by the VA. A long list of new conditions (23 "presumptive conditions") are now presumed to be service-connected and related claims and benefits are now being expedited. In terms of research, the PACT Act mandated the establishment of the Toxic Exposure Research Working Group (TERWG) consisting of employees of VA, DoD, EPA, HHS and other entities involved in research activities regarding the health consequences of toxic exposures experienced during military service. Dr. Block is a co-chair of the TERWG. Drs. David Balshaw, Ruth Lunn, Suril Mehta, and Sri Nadadur from NIEHS are members of the TERWG Strategy Team, which among other duties has

been charged with developing a five-year strategic plan for the group. The plan outlines three high-level categories of research priorities:

- Category A: Characterizing the military exposome
- Category B: Linking military exposures to toxicity and adverse health outcomes
- Category C: Preventing and mitigating adverse health outcomes from military toxic exposures

A TERWG infrastructure strategy was incorporated to frame interagency needs for leveraging resources and conducting of the 5-year mission-aligned strategic plan.

The TERWG key actions planned for FY25 include:

- Continue TERWG under the partnership with OSTP's National Science and Technology Council (NSTC)/Joint Subcommittee on Environment, Innovation, and Public Health (JEEP).
- Establish an organizational entity dedicated to coordinating operational/administrative, scientific, and regulatory activities for research on toxic military exposures (VHA/ORD).
- Develop and manage mechanisms for collaborative military toxic exposures research including governmental and non-governmental partnerships.

Dr. Holian asked Dr. Block whether, even with the PACT Act of 2022, all veterans are covered for all of the relevant challenges they experience. He said it seems that many veterans are still frustrated with getting into the system for health care. Dr. Block said that the PACT Act did not cover all veterans of all eras, but focused on deployment-related locations and time. She noted that anecdotal evidence suggests that even veterans who did not deploy suffer from adverse health outcomes, so the TERWG will be focusing on occupational and training efforts. Dr. Holian asked whom to contact. Dr. Block suggested the TERWG.

Dr. Hood asked how electronic health records (EHRs) will be used in Category A research. Dr. Block suggested that the ILERs would be used to build cohorts based on locations or exposures. Ultimately it will be important to connect the chemicals and substances being used with individuals. Occupational research may be the best way to do so, she said.

Dr. Guiseppe-Elie congratulated Dr. Block on how well the TERWG strategic plan effort is progressing. Dr. Block said it will be important to now start thinking about the implementation phase.

Dr. Woychik asked Dr. Block about the sustainability framework for the model, and whether the VA has indefinite funding to support the effort for a sustainable period of

time. He also asked whether funding is provided for all of the necessary elements to keep the cohort together. Dr. Block said that her group has a budget , and also has a special funding vehicle called the Toxic Exposure Fund, which Congress included with the PACT Act. It is presently funded at \$30 million per year, but may go up. She expressed optimism that much can be accomplished due to sustainability and databases, with a need to consider information sharing in more detail. Dr. Woychik asked for more information on that issue: collecting all of this data, where is it going, and are we collecting it in a way that it is seamlessly integratable across different data infrastructures? Dr. Block agreed that data integration capability will be important for understanding for leveraging the information. Dr. Woychik pointed out that the danger is that there would end up being data repositories that do not integrate well with each other. He asked how the TERWG is reaching out to people with complementary capabilities, and whether her group actually funds such projects, or if people who use their resource have to come in with their own funding. Dr. Block said that they are investigator-initiated awards, but there are plans to incorporate other state-of-the-art technologies.

Dr. Miller asked if this might be a place to get the many groups to adopt a single ontology, which would be a huge step forward. Dr. Woychik agreed, and said that now is the time to do so. He emphasized the importance of creating data repositories that seamlessly integrate with each other. The challenge is to achieve central coordination to generate the greatest value from these resources.

V. Workforce Credentialing Program for Veterans and Their Families

Mr. Kirk Laflin and Mr. William Nash from the National Partnership for Technology Education (NPETE) presented data on the organization's programs. NPETE is an NIEHS Worker Training Program grantee designed to provide training to outgoing service members and their families as they enter the civilian workforce.

Each year, over 200,000 service men and women leave the service and enter the workforce, with over 150,000 spouses accompanying the service member.

Unemployment tends to be higher for veterans than among the general public. Military Occupation Specialty Skills do not produce civilian credentials.

NPETE successfully operates in partnership with Barton Community College in Kansas.

The program focuses on complementing skills acquired during military service in career fields that complement skill sets attained during service, in areas such as occupational safety and health, environmental, and hazardous materials management.

NPETE received a 5-year grant from NIEHS and uses it to support more than 35 classes per year, including OSHA-certified courses. From 2015 through May 2024,

NPETE has offered 174 courses with 2,874 student enrollments; an average of over 10,000 contact hours per year. This year, there have been over 13,000 contact hours, with 5 classes still remaining. With the addition of virtual class capabilities, classes are now offered via Zoom in 4 time zones, with enrollment on a first-come, first-served basis. In the current year, there have been participants from 32 states, as well as students from Germany, Japan, South Korea, Poland, Guam, and Puerto Rico.

The program will continue with ongoing funding and will seek to establish new partnerships, such as the recent partnership with the Home Builders Association. NPETE will continue to market the program, with plans to expand to other installations and include Reserve and National Guard units as well as veterans service organizations.

Dr. Savasta-Kennedy asked to hear more about the practical application of the classes being provided for the veterans. Mr. Nash replied that the 40-hour HAZWOPER training course he had mentioned is conducted totally in person and is 70% hands-on. The other classes are OSHA Education Center classes and follow OSHA's guidelines. He said that in some of the classes, such as respiratory protection, they will actually mail out respirators to attendees. He said that the 40-hour HAZWOPER is the foundation for everything within the program, as well as working with local community colleges that are near military installations that have the necessary equipment. Ms. Savasta-Kennedy asked about partnerships in the community to foster post-certification employment. Mr. Nash mentioned a partnership in Colorado Springs, Colorado as a prime example of an active partnership.

Dr. Ingram asked whether Mr. Laflin or Mr. Nash had ever been in contact with the Institute for Tribal Environmental Professionals, which trains tribal environmental workers all over the country. Mr. Laflin said that his group has been working with tribal colleges for a number of years, and several participate in NPETE, as well as working with several of the tribal governments.

VI. Molecular Underpinning of Vesicant Chemical Injury and MCM Development

The next section of the mini-symposium highlighted two of the projects supported by the CounterACT Program, the trans-NIH initiative that supports basic and translational research aimed at the identification of better therapeutic medical countermeasures (MCMs) against chemical threat agents.

Dr. Mohammad Athar from the UAB Center of Excellence in Arsenicals briefed the Council on his research on arsenicals, which are one group of chemicals in the category called vesicants. These chemicals were developed and weaponized during World Wars

I and II. Of these lewisite (2-chlorovinyl-dichloroarsine) is the best-known rapid action chemical given the nickname “Dew of Death.”

Arsenicals cause severe, painful inflammation in the skin, eye, and lungs. Cutaneous exposure also causes severe systemic injury often leading to lethality in humans if not decontaminated immediately. Dr. Athar’s group focuses on unraveling the molecular pathogenesis of arsenicals in the skin following cutaneous exposure in addition to developing murine models of systemic injury, in order to develop effective MCMs.

Dr. Athar described his experiments using 4-phenyl butyric acid (4-PBA), and existing FDA-approved treatment for urea cycle disorders, 4-PBA+taurusodiol, FDA-approved to treat ALS, and N-acetyl cysteine (NAC), FDA-approved to treat acetaminophen overdose toxicity. The work has shown that the combination of 4-PBA and NAC may be highly effective in treating lewisite exposures, and appears to be equally effective against other arsenicals-induced vesicant injury.

Dr. Athar also presented data on investigation of the epigenetic reader bromodomain 4 (BRD4) as a novel, potent therapeutic target for mitigating arsenicals-induced tissue injury.

These two distinct MCMs have advanced with remarkable efficacy in two animal models against lewisite and other vesicants with defined molecular targets and mechanisms of action. Dr. Athar’s laboratory has developed an impressive pipeline of MCMs, which are at different stages of preclinical development and include novel (with IP rights) and repurposed drugs.

Dr. Hood asked Dr. Athar to elaborate on his mention of nociception. He said that in his experiments, he found activation of pain receptors and there had been a reduction in pain when applying the MCMs.

Dr. Greenamyre asked about Dr. Athar’s depiction of ROS production as one of the initial steps in the pathogenic cascade. Dr. Athar said they had found two proteins that take part in the oxidative signaling.

Dr. Holian congratulated Dr. Athar on this “beautiful, large body of work.” He asked whether some of the oxidative stress might also be coming from mitochondrial damage. Dr. Athar said that the damage caused by these chemicals is huge and mitochondrial damage also occurs. He explained some of the genetic and epigenetic effects.

Dr. Holian asked when the treatments had to be given. Dr. Athar said they are topical agents that can be used multiple times after exposure to vesicants.

Dr. Archer noted that BRD4 is a member of a large family of epigenetic regulators, and asked Dr. Athar if he had looked at other members of the family, as well as interactions

with other epigenetic modulators. Dr. Athar said that when they had started, most of the knowledge was limited to BRD4. He added that there is much interest in the bromodomains group, including BRD4 inhibitors as potential treatments for Covid-19. In addition, Dr. Athar explained that his interest expands beyond BRD4 as he is also studying BRD7 and BRD9 in collaboration with his earlier mentor Dr. Bickers of Columbia University, New York.

Dr. Carroll discussed the destruction of the U.S. chemical warfare agents stockpile, and that the CDC was in charge of the protection of the public health and the workers' health at the facility in charge of the weapons destruction. She asked about the fisherman being exposed to the agents after so many years having been dumped in the ocean. Dr. Athar said that the degradation of the chemical weapons leads to enhanced concentration of arsenics in the geographical areas where these chemical weapons are loitering in oceans or are buried. However, we recently showed in a review paper that arsenic levels in those areas were initially low and therefore the observed high levels of arsenic are due to destruction of chemical weapons.

Adverse Pulmonary Effects of Highly Toxic Chemicals – A Comparative Analysis of Chemical Inhalation Burns

Dr. Livia Veress from the Center for Advanced Drug Development at the University of Colorado Anschutz School of Medicine presented her research on adverse pulmonary effects of highly toxic chemicals. She concentrated on inhalation injury effects from exposures to sulfur mustard (SM), methyl-isocyanate (MIC), and chlorine gas. Sulfur mustard and chlorine gas are long-standing chemical weapons, MIC is a widely used chemical in industrial manufacturing, and is best-known as the agent involved in the 1984 pesticide plant leak in Bhopal, India, which killed thousands.

SM was the first vesicant agent used as a chemical weapon. It is best known for its use in World War I, but has been used continually, as recently as 2015 in Syria.

Dr. Veress presented a clinical case—a soldier in WWI who died 4 days after the initial exposure. She provided details about the clinical findings, including the presence of pseudo-membranes called casts, which often block airways (thrombosis) and cause death.

Her studies in a rat and pig models showed that acute SM inhalation exposure causes dose-dependent survival and oxygen desaturation. Morbidity and mortality occur due to the development of airway casts.

She has conducted several studies of potential pharmacological treatments. She has shown that treatment with Alteplase, the clot-busting drug tPA used to treat strokes, is effective in treating acute airway injury after SM inhalation in rats and swine.

Turning to MIC, Dr. Veress presented a clinical case involving a 26-year-old female who was exposed to a cloud of the gas from a nearby chemical plant and died from asphyxia due to respiratory failure. She described her studies on MIC treatment using Altepase and the chemoprotective agent MESNA, both of which have shown efficacy in MIC and SM.

Chlorine exposures stem from both industrial uses and chemical weapons. Death from exposure is caused by asphyxiation or acute respiratory failure, but most individuals who suffer single gassings recover normal pulmonary function. Dr. Veress reported her group's experiments using scopolamine and atropine as potential treatment modalities.

Dr. Greenamyre asked Dr. Veress how many times she would administer tPA in correlation with the ongoing toxicity of the exposure, and whether there were any hemorrhagic complications. She said they expected to have to give the tPA for 7 days, and they have seen no hemorrhagic issues. She added that based on those findings, the group had developed a guideline for treatment in the clinical world.

VII. Report of the NIEHS Director

Dr. Woychik briefed Council on Institute developments since the February 2024 Council meeting.

He began by addressing budgetary matters. He reported that as of March 4, 2024, the President signed into law 6 of the 12 appropriation bills, including funding for NIEHS Superfund-related programs at \$79.7 million, 4% below FY23 levels. As of the week of March 18, he signed the second FY24 Minibus, including the remaining 6 appropriations bills, which included the Labor-HHS portion of the NIEHS budget, at a mark of \$913.9 million, which is flat from (the same as) FY23 funding. President Biden released his FY25 budget on March 11. For the Labor-HHS portion of the NIEHS budget, it proposes \$916.7 million, a 0.3% increase over FY23 and FY24 levels. For the Interior and Environment portion of the NIEHS budget, it proposes \$83.0 million, a roughly 4% increase over FY24 levels. The FY25 budget proposal is flat from FY23 levels.

Dr. Woychik described an April 30, 2024 Congressional event hosted by ACT for NIH at the Library of Congress. "It was an incredible event—many of the speakers, Republicans and Democrats ... were speaking in very positive and enthusiastic terms about supporting the work of the NIH," he said. Attendees included several senators and representatives. He had an opportunity to meet one-on-one with several of them to talk about NIEHS.

He went over cross-NIH environmental justice (EJ) strategic actions, as requested recently by HHS Secretary Becerra, who asked all HHS operating divisions to identify a senior point of contact for all EJ activities and identify three strategic and transformative

EJ actions. NIEHS Deputy Director Trevor Archer is the point of contact for NIH. The three EJ actions for NIH will be:

1. Environmental Health Disparities Centers
 - a. Building on the existing Centers of Excellence in Environmental Health Disparities involving NIEHS, National Institute of Minority Health and Health Disparities (NIMHD), and National Institute of Child Health and Human Development (NICHD)
 - b. Multidisciplinary research capacity building and community engagement
2. Environmental Justice Scholars
 - a. Following the Climate and Health Scholars program model
 - b. Bring scholars with diverse expertise in EJ to NIH
3. Environmental Justice Training
 - a. For communities, workers, researchers, health care and public health professionals, and policy makers, to build community capacity

Dr. Woychik provided status updates on EJ Workgroup activities for each of the EJ actions.

He reported to the Council on his recent community tours and forums. He described his visit to the San Joaquin Valley, California:

- A highly diverse region with vast stretches of farmland and a rich multicultural history.
- Played a pivotal role in the birth of the EJ and farmworker rights movements.
- One of the poorest and most polluted regions in the nation.
- Scientists and community groups associated with the UC Davis Environmental Health Sciences Center are playing key roles in producing actionable research to confront these inequities.

“One of the important things I can be doing, and senior leadership here at NIEHS can be doing, is getting out in front of the community. We have to get out and listen to what their concerns are. Being in front of these groups and visiting in these communities gives me a level of appreciation for the dire straits and the dire conditions that these people are living under,” he said.

“The soil is contaminated, the water is contaminated, and the children playing in their front yards are being exposed to clouds of pesticides being sprayed on the fields. So it is really just an incredible environmental justice issue.”

He also covered in some detail his visit to the Imperial Valley in southern California, in collaboration with the USC Environmental Health Sciences Center. In that area, much of the Salton Sea has evaporated, thanks in large part to geothermal and lithium mining

operations in the region, which has created contaminated playa dust. Residents experience staggering rates of asthma morbidity, with 1 in 5 children diagnosed with asthma. “There’s not adequate access to a health care system. Many of the hospitals are closing ... There aren’t physicians to write the prescriptions for the children who need the drugs to treat their asthma. It’s really a desperate situation,” he said.

Dr Woychik strongly advocated an all-of-government approach—including community-based organizations, public agencies, and academic researchers—to dealing with such EJ issues.

Turning to the exposome, he discussed the International Human Exposome Network (IHEN) Project kick-off meeting he had attended in Brussels February 27-28, 2024. The project has been funded for 3 years at 3 million Euros in order to establish the IHEN, with the overall purpose of improving global research and cooperation on the exposome. The project’s objectives are:

- Design a Global Exposome Network
- Identify and make available exposome tools and resources at a global scale
- Evaluate the proposed network and its toolbox via a series of case studies
- Develop a roadmap for future exposome research
- Engage stakeholders in IHEN

Dr. Woychik also attended a symposium in Sapporo, Japan, May 27-29, 2024, on Aging and the Exposome.

Regarding mechanistic and translational biology and toxicology, he discussed a new NIH Common Fund project called Complement-ARIE (Complement Animal Research in Experimentation), which is designed to speed the development, standardization, validation, and use of human-based New Approach Methodologies (NAMs). The programs goals are to:

- Better model and understand human health and disease outcomes across diverse populations
- Develop NAMs that provide insight into specific biological processes or disease states
- Validate mature NAMs to support regulatory use and standardization
- Complement traditional models and make biomedical research more efficient and effective

In support of those objectives, the NIH Common Fund issued the Complement-ARIE Challenge Prize Competition to solicit entries for new methods and approaches in NAMS. Twenty prize winners will share a total prize purse of \$1 million.

Looking at developments in computational biology and data science, Dr. Woychik described the NIH Cloud Lab. It is a no-cost, 90-day program for NIH intra- and extramural researchers to try commercial cloud services in an NIH-approved environment. The Cloud Lab offers a suite of interactive tutorials designed to help participants perform viable research in the cloud.

He provided details about a new NIH Common Fund program developed in response to a priority identified by the new NIH Director, Dr. Bertagnolli. CARE for Health (Communities Advancing Research Equity for Health) will support clinical research in primary care settings. The initiative (which was officially announced June 6, 2024, just after the June 4 Council meeting) will have an initial investment of \$30 million over fiscal years 2024 and 2025. CARE for Health will be:

- A primary care-focused clinical research infrastructure that is disease-agnostic, facilitating clinical research in mission areas across all ICs
- Focused on integrating innovative research with routine clinical care in real-world settings
- A foundation for sustained engagement with communities underrepresented in clinical research

In conclusion, Dr. Woychik welcomed new staff member Nicole Garbarini, Ph.D. to the SCOPE Policy, Planning, and Evaluation team. He noted the recent passing of for NIEHS and NTP executive Dr. George Lucier. He thanked retiring Council members Drs. Trevor Penning, Irva Hertz-Picciotto, and Karen Vasquez. He also presented certificates of appreciation to Council members who will be retiring as of the September, 2024 Council meeting, which will be virtual: Drs. Jani Ingram, Andrij Holian, Thomas LaVeist, and Gary Miller. He also recognized the impending retirement of Council member Dr. Philip Bourne, who was unable to attend this meeting.

Dr. Ingram commented on Dr. Woychik's Imperial Valley visit. She noted that it is the lettuce capital of the world. It is a difficult area, and "it's a mess," she said. Dr. Woychik agreed. "Every element of it is just desperate, and it's horrendous," he said. "How can we let this happen in a country like the United States?"

Dr. Carroll congratulated Dr. Woychik on the "all-of-government" approach. She asked what involvement and reaction he had seen from industry and employers in the areas, and how the approach could be kept sustainable. Dr. Woychik replied that the employers were not to be found in his experience, although some were present at the community forum. They hold much power and influence in their local communities. He did not have a solution other than trying to convince the communities that there is a future and there are things they could be doing to help make change happen to improve the quality of their health. Part of it will be the all-of-government approach he is

advocating, partnering with other agencies of the federal government with mutual interests and complementary capabilities. The hope is that it will be a standard going forward, rather than individual agencies thinking they must act solely on their own.

Dr. Hood noted the involvement of the EPA, which under the Justice 40 Executive Order, should be devoting substantial financial resources to EJ communities. Dr. Woychik added that community engagement will be critical to success. He said he had had the opportunity to meet with some of the community groups, and that they are knowledgeable, highly capable, and passionate about fixing things and making change happen. So the all-of-government approach can exist as a catalyst to bring together the resources of the local, state, and federal governments to work with community leaders. He said that bringing awareness is vital to improving the desperate situations in EJ communities.

Focusing on the awareness issue, Ms. Savasta-Kennedy discussed the tractor driver Dr. Woychik had mentioned who had no training for protecting himself when spraying pesticides. She felt that having someone from the federal level shine a light on the issue brings more pressure politically to what is happening on the local level. So in addition to the all-of-government approach, there is an important function for the federal government to bring attention to the local level. Dr. Woychik said that NIEHS is hiring a new Community Engagement Coordinator to work on such things.

Sharon Beard said that NIEHS can go out and provide training to farmworkers like those Dr. Woychik had mentioned. She said connections need to be made to find out if there are tools in the toolbox of training programs to address those types of needs. She mentioned some of the existing training programs for migrant workers. Dr. Woychik said, “All workers should be given an opportunity to learn how to protect themselves.” He praised Ms. Beard for the great success of the Worker Training Program.

VIII. Report of the DERT Director

DERT Director Dr. David Balshaw briefed Council on DERT activities and accomplishments since the February 2024 Council meeting.

He related DERT staff developments, including the departures of Linda Bass, Ph.D., Barbara Gittleman, Lindsey Martin, Ph.D., Jim Remington, and Alfonso Latoni, Ph.D. He welcomed new staffers Jennifer Baker, Valerie Bartlett, Amelia “Mia” Pearson, and Irina Alva-Weinstein.

Dr. Balshaw summarized DERT meetings since the last Council meeting, and looked ahead to upcoming DERT meetings.

He briefly alluded to the NIH Cloud Lab computing program, a 90-day program for NIH intramural and extramural researchers with a \$500 credit to access Amazon Web Services, Google Cloud, or Microsoft Azure.

He provided updates on OER policies on unilateral closeouts, foreign subawards, NRSA stipends and other costs, as well as a simplified review framework.

He went into considerable detail on unobligated balances—what they are and what DERT is doing to manage them. He provided definitions of:

- Unobligated Balance (UOB): funds awarded in a previous year that are not formally obligated to a specific expenditure
- Unliquidated Obligation: funds (from the current or previous year) that have been formally obligated to an expenditure that has not been liquidated (had the funds removed from the account)
- Carryover: a request to access funds from an UOB to enable an obligation in the current year beyond what can be funded from the current award
- “Draw Down”: when the recipient withdraws funds from the Payment Management System
- Bona Fide Needs rule: The U.S. Government may not award more funds in a year than can be reasonably be expected to be utilized for a current-year need (including UOB, carryover, supplements, and the current year funding).

He also described the Streamlined Noncompeting Award Process (SNAP). He discussed how DERT is managing UOBs, with details on mid-project no-cost extensions, restructuring, and offset processes. He provided examples of each.

Dr. Miller observed that Dr. Balshaw had sounded apologetic when he discussed the strategies for mitigating Unobligated Balances, although that is just enforcing the rules. Dr. Balshaw said he was not apologetic, but acknowledges that it is “a pain point.” Dr. Miller said that institutions must follow their budgets, and observed that perhaps NIH grantees have gotten very sloppy by thinking they have a slush fund, and that it is totally reasonable to have to follow the requirements.

Dr. Cormier said that the P grants are a bit more difficult, the P42s in particular. She noted that she has about a half million dollars in an unobligated balance that her institution is not allowing her to touch because they do not have carry forward approved. She asked Dr. Balshaw to comment on how to cross that hurdle. He replied that there is pressure to process carry forward requests in a timely manner. There needs to be a partnership between DERT staff and her staff and budget office to address the situation. There is a need to be working in coordination to address such points. Dr. Cormier said

DERT has been very responsive, but the institutions have their own policies, and it creates a loop that is difficult to overcome.

Dr. Greenamyre noted that Dr. Balshaw was speaking to a relatively small audience of fundees, and asked what the next steps are to get everyone on the same page. Dr. Balshaw suggested that anyone interested should watch the publicly available recording of this presentation.

Dr. Ingram asked Dr. Balshaw to elaborate on the new, simplified review process. He replied that rather than focusing on, what is the significance of this project, what is the level of innovation in five different criteria, the conversation is to be reframed to ask, is this important work to be done? Also, is this important work that *can* be done? Dr. Ingram suggested that even if it can't be done, then even if it is important, it should not be funded. Dr. Balshaw noted that funding is NIEHS's decision, but the evaluation of the scientific merit will be based on an overall score that balances *should it be done* with *can it be done*.

Regarding grant proposals and the review process, Dr. Carroll asked whether the reviewers would use set questions that they will score. Dr. Balshaw said it is a two-criteria score now, so under the new framework there will be the two criteria, with an overarching priority score on top of that. There will also be an objective "acceptable/not acceptable" for the investigator and environment criteria.

IX. Council Discussion

Dr. Balshaw introduced an open session Council discussion by noting that Dr. Bertagnolli had asked for feedback about her Common Fund initiative on research in primary care settings. He asked the Council members to weigh in on how such a program may impact environmental health, and how NIEHS may be able to contribute to the larger NIH-wide effort. Dr. Woychik noted that Dr. Bertagnolli is looking to enhance existing programs, and asked Council members to consider whether there are existing clinical programs where an environmental health perspective can be added to get them into primary care settings. He said that one of her interests is how to get the program into less urban areas and underserved parts of urban communities, involving environmental justice communities whether they are rural or urban.

Dr. Ingram said that as part of an American Cancer Society grant, her group working with a Navajo population is conducting grand rounds, to disseminate both what is being learned about environmental exposures to health care workers, who tend to cycle through the clinics.

Dr. Carroll mentioned that public health often deals with rural populations that are underserved by health care, with clinics closing and access to physicians or health care

facilities dwindling. She noted that there is funding coming for digital equity, with health services and accessibility being part of that. She asked whether telehealth services would be incorporated in the Common Fund initiative. Dr. Woychik said he did not know the answer to that, but that it was a good question. He described his experience when he lived in Maine, and telehealth was an effective vehicle for getting health care to rural areas.

Dr. Miller stated that it seems that a clinical research team would likely start with a clinic visit, a primary care connection, but there is low likelihood of in-person follow-up. So it would help to have an app developed, so that when the researcher leaves, the participant could enter the follow-up background information from their home in a telemedicine type of setting. He suggested that the Common Fund develop an app that could include a questionnaire addressing environmental issues. Dr. Woychik agreed that that was a relevant point and could be a specific recommendation to be made. He added that there should be an electronic health record that includes information about environmental exposures. There is a desperate need for physicians to ask their patients about their occupations, for example, whether they are an agricultural worker in the fields and likely to be exposed to pesticides, at which time the physician could suggest protective methods. Currently, there is little attention paid to environmental exposures within the primary care setting.

Dr. Balshaw asked Dr. Block to comment on her success with integrating ILER into VA clinical care. He asked how that experience has worked, and how she has worked with physicians to integrate that information into their management of patients. Dr. Block said that when the PACT Act was passed, there was a requirement that physicians ask those questions, so a Toxic Exposure Screening (TES) was created. It was simple, five-question form, asking about exposure to Agent Orange, or Gulf War burn pits, for example. The TES would put a flag into the system that if there was a concern—40% of veterans had expressed such a concern—it would lead to a medical exam. She said the ILER had not been linked directly, so she was very interested to hear ideas about that aspect for her own agency's use.

Dr. Hornbuckle asked about the concept of integrating environmental health into existing clinical care. She said the VA is an excellent example, with robust, county-wide networks with community-based outpatient clinics, so it can be seen how there could be success there, but with rural clinics far from urban city centers, there are understaffed, overworked physicians who will be asked to do yet another thing. So she wondered if there was a need to be a little more thoughtful about how to approach those communities—what researches are brought, ensuring follow-up and long-term commitments to those places where such commitments are possible. Dr. Ingram agreed, and noted that researchers should take on that role, and not settle for just training the trainers. She cited an example from the University of New Mexico, where

community members have also been recruited to disseminate information. She added that one of her students had come up with a survey questionnaire about a person's knowledge of environmental exposures, and that it would be important for such efforts to be tailored to specific locations.

Regarding the NIH Director's initiative, Dr. Hood said that it would be important as a starting point to acknowledge the historic underrepresentation and algorithmic bias in EHRs. It would contribute to improving research equity. With large language learning models emerging, initial underrepresentation would be amplified by those models. Dr. Woychik said that Dr. Bertagnolli is likely to be aware of the issue, and her reference to health equity is a way of embracing it.

Dr. Guiseppe-Elie noted that the PACT Act is part of efforts to promote complementary, non-duplicative, amplified work, which should be encouraged. She also brought up data sharing, with the need to develop interoperative databases. Dr. Woychik agreed that seamless interoperability is critical. Without it, there will continue to be "a bit of a mess" where everyone collects it the way they want to collect it. He mentioned an analogy Dr. Bertagnolli had expressed, comparing data sharing to toothbrushes: "Everyone recognizes that you need a toothbrush, but no one else wants to use anyone else's toothbrush." He said that the need to do something differently must be recognized, because there is much duplication of effort. Better synchrony is needed. It will also be important to get away from the model that something cannot be done unless there is funding to do it. Working in collaborative efforts such as climate change and health, which started before there was any funding, will be important, recognizing that the challenge is much bigger than what any one person can do.

XIV. Adjournment

Dr. Balshaw thanked Dr. Vargas, Valerie Bartlett, and Jennifer Baker for their efforts in organizing the meeting, as well as the audiovisual team. He thanked the Council members for their engagement and input. Dr. Woychik thanked Dr. Balshaw for his efforts. He adjourned the open session of the meeting at 4:30 pm, June 4, 2024.

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 5:45 pm, June 4, 2024.

REVIEW OF APPLICATIONS

The session included 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 467 applications requesting \$215,472,019 in total costs. For the record, it is noted that secondary and not discussed applications were also considered en bloc.

CERTIFICATION:

Rick Woychik, PhD
Chairperson
National Advisory Environmental
Health Sciences Council

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

Attachment:
Council Roster