

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

**MINUTES OF THE ONE HUNDRED SIXTY-SECOND MEETING OF THE
NATIONAL ADVISORY ENVIRONMENTAL HEALTH SCIENCES COUNCIL**

February 16-17, 2021

The National Advisory Environmental Health Sciences Council convened the open session of its one hundred sixty-first regular meeting on February 16 and 17, 2021 as a Zoom virtual meeting. The closed session of the meeting was held earlier in the day February 16.

The meeting was open to the public on February 16, 2021 from 10:45 a.m. to 2:30 p.m., and on February 17, 2021 from 10:00 a.m. to 2:00 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 February 16, 2021 from 10:00 a.m. to 10:45 a.m. for consideration of grant applications. Notice of the meeting was published in the *Federal Register*. Dr. Rick Woychik presided as Chair.

Participating Council Members

William Cibulas, Jr., PhD (*ex officio*)
José Cordero, MD, MPH
Suzanne Fitzpatrick, PhD (*ex officio*)
Andrew Geller, PhD, EPA (*ex officio*)
Lynn Goldman, MD, MPH
Irva Hertz-Picciotto, PhD
Shuk-Mei Ho, PhD
Terrance Kavanagh, PhD
Katrina Korfmacher, PhD
Edith Parker, DrPH
Trevor Penning, PhD
Marla Pérez-Lugo, PhD
Brad Racette, MD
Susan Schantz, PhD
Andy Shih, PhD
Patrick Sung, DPhil
Robyn Tanguay, PhD
Jalonne White-Newsome, PhD
Robert Wright, MD, MPH

NIEHS Staff

Kathy Ahlmark
Sara Amolegbe
Camilo Asuncion
David Balshaw, PhD
Martha Barnes
Linda Bass, PhD
Sharon Beard
Brian Berridge, DVM, PhD
Abee Boyles, PhD
Danielle Carlin, PhD
Toccaro Chamberlain
Jennifer Collins
Gwen Collman, PhD
Yuxia Cui, PhD
Christie Drew, PhD
Chris Duncan, PhD
Anika Dzierlenga
Lisa Edwards
Gary Ellison, PhD, MPH
Benny Encarnacion
Amanda Garton
Nidhi Gera, PhD
Kimberly Gray, PhD
Jenny Greer
Janet Hall, MD, MS
Astrid Haugen
Michelle Heacock, PhD
Heather Henry, PhD
Jon Hollander, PhD
Mike Humble, PhD
Bonnie Joubert, PhD
Helena Kennedy
Nicole Kleinstreuer, PhD
Heather Knox
Alfonso Latoni, PhD
Cindy Lawler, PhD
Chris Long
Robbie Majors
Lindsey Martin, PhD
John Maruca
Jacqui Marzec
J. Patrick Mastin, PhD
Kim McAllister
Liz McNair

LaTavia Miller
Parris Milly
Nathan Mitchiner
Rosemary Moody
Srikanth Nadadur, PhD
Liam O'Fallon
Kristi Pettibone, PhD
Clark Phillips
Nicole Popovich
Alicia Ramsaran
Lingamanaidu Ravichandran, PhD
Scott Redman
Les Reinlib, PhD
Jim Remington
Carol Shreffler, PhD
Thad Schug, PhD
Dan Shaughnessy, PhD
Varsha Shukla, PhD
Melissa Smarr, PhD
Spencer Smith
Bill Suk, PhD, MPH
Laura Thomas, PhD
Claudia Thompson, PhD
Brittany Trottier
Steven Tuyishime, PhD
Fred Tyson, PhD
Michelle Victalino
James Williams
Leroy Worth, PhD
Rick Woychik, PhD
Demia Wright, MPH
Darryl Zeldin, MD

Members of the Public Present

Houmam Araj, PhD, NEI
Andrea Baccarelli, PhD, Columbia University
L. Michelle Bennett, PhD, NCI
Dana Dolinoy, PhD, University of Michigan
William (Bill) Elwood, PhD, NIH
Ernie Hood, Bridport Services, LLC
Tara Schwetz, PhD, NIH
Cheryl Walker, PhD, Baylor University College of Medicine
Dave Yeung, PhD, NIAID

I. Call To Order and Opening Remarks

NIEHS and NTP Director Rick Woychik, Ph.D., welcomed attendees and called the meeting to order. He asked Council members in the Zoom call to introduce themselves. He recognized retiring Council members Drs. Cordero, Ho, Schantz, Shih, and Sung, and thanked them for their service. Deputy DERT Division Director J. Patrick Mastin, Ph.D., went over some of the logistics for the meeting.

II. Consideration of September 2020 Meeting Minutes

Approval of the September 2020 meeting minutes was moved and seconded, and Council voted to approve the minutes, with all in favor.

III. Chemical Threat Agent(s)-induced Pulmonary and Ocular Pathophysiological Mechanisms

Dr. Srikanth Nadadur from the DERT Exposure, Response and Technology Branch briefed the council on a new funding opportunity related to research on chemical threat agents with pulmonary and ocular adverse effects. The FOA is a joint effort in collaboration with the National Eye Institute and the National Institute of Allergy and Infectious Diseases. It will solicit research to understand the fundamental mechanisms of pulmonary and ocular toxicity of diverse understudied chemicals in the list compiled by the Department of Homeland Security (DHS) Chemical Terrorism Risk Assessment (CTRA) program, which has identified almost 200 chemicals as public health threats to date.

The NIEHS-led CounterACT grant and cooperative agreement research program supports research through four different PARs that fund Centers of Research Excellence, identification and optimization of lead medical countermeasures (MCMs), and exploratory/developmental projects in translational research. Ultimately, lead MCM compounds are referred to the HHS Biomedical Advanced Research and Development Authority (BARDA) for further development leading to FDA approval. Thus far three compounds have transitioned to BARDA.

Dr. Nadadur described the chemicals included in the pulmonary/ocular portfolio, which comprise almost one-third of the 200 CTRA chemicals. Many are known chemical warfare agents.

The major goal of the concept is to support development of a discovery pipeline of understudied chemical threat agents, with characterization of fundamental molecular, cellular and physiological pathways involved in acute toxicity by a combination of *in vitro* and *in vivo* approaches that develop reliable and translatable animal models.

Dr. Penning was the first Council discussant. He said that Dr. Nadadur had identified some gaps that need attention. He felt that the proposed program presents an opportunity to accomplish more than the single-agent focused centers. He said he would like to know more about how the CTRA risk assessment came up with the 200 chemicals. He noted that very little is known about many of the 50 chemicals Dr. Nadadur had identified as pulmonary/ocular threats, particularly the margin of exposure or safety. He felt that it would be important to prioritize those chemicals for investment. The RFA to emerge could be one of two types – it could be an RFA that would take the best applications, or some prioritization within the RFA of the chemicals of most concern. A broader opportunity of the program would be to expand it into occupational exposures and hazmat workers. Knowing that there are at least 50 chemicals to focus on, he wondered whether \$12 million would do the job. He said it could be a tiered program, starting small and then with an increasing funding stream based on metrics of success, which will need to be identified. He liked the concept that many of the agents may have a common mechanism of action, allowing the possibility of a countermeasure that would address more than one toxicant. Overall, he said he supports the program.

Dr. Nadadur noted that the chemicals he mentioned were examples of possible research topics. He agreed that it would be important to encourage identification of a common mechanism or mode of action, or target for further development.

Dr. Kavanagh said that it would be important to highlight chemical in silico modeling in the RFA. If a common mechanism is seen, it would help to accelerate discovery. He recommended engaging pharmaceutical firms as partners in some of the research, potentially as subcontractors for some of the more expensive aspects of the research, potentially repurposing some pharmaceuticals, even failed drugs. He agreed about the importance of prioritization. He wondered about the possibility that the need for a security clearance could be a hurdle for the research, and how that would be handled in the RFA. He said it would be important that the RFA include information on safety plans for laboratories working with the agents.

Dr. Nadadur said that if the amounts of chemical are small, it may not be necessary for a laboratory to go through the process of acquiring a security clearance. It depends of the amount and type of compound.

Dr. Penning agreed with Dr. Kavanagh that the RFA should include specific language about biohazards. Dr. Nadadur said that it would. Dr. Penning added a concern about acute, delayed lung injury leading to fibrosis.

Dr. Goldman endorsed the program. She noted that some of the countermeasures could also be applicable in occupational or pulmonary medicine and urged that that information be out in the open where physicians can access it. She added that it may be

possible to get financial support for the research from the chemical industry, who want to be responsible and responsive stewards. She hoped that the outreach plans for the program would include the occupational and pulmonary communities. Dr. Nadadur described some of the outreach activities that have taken place.

Dr. White-Newsom asked about the criteria of prioritization of the agents, and whether the population living near stockpiles of bad chemicals is being taken into account. She wondered whether questions of environmental justice and equity were being asked with regard to prioritization and pointed out that there is an opportunity to make that part of the criteria. Dr. Nadadur replied that the current focus of the program is to promote the development of countermeasures. Priority is assessed annually in consultation with DHS and BARDA. He said that as the program develops, there will be opportunities to interact with communities as part of its outreach efforts.

Dr. Wright said that diagnostics is a research gap. For example, “very few physicians would recognize mustard gas poisoning.” He felt there should be more research in that area, for example, developing ambient sensors. Dr. Nadadur cited development of biomarkers of exposure as a promising area.

Dr. Andrew Geller from EPA offered the possibility of working with the agency.

Dr. Mastin passed along a question about burn pit exposures. Dr. Nadadur said that this program is more focused on the chemicals identified through CTRA.

Dr. Mastin called for a motion and second to approve the concept, which he received. The council voted in favor, approving the concept.

IV. Report of the Director, NIEHS

Dr. Woychik briefed Council on Institute developments since the September 2020 Council meeting.

He described the NIEHS shared values that will help the Institute achieve its vision and mission, under the Strategic Plan:

- Workforce
- Communication
- Innovation
- Distributive Leadership
- Collaboration

He announced the establishment of a new senior leadership position, the Chief Innovation Officer. Dr. L. Michelle Bennett, on detail to NIEHS from NCI, will fulfill that role in an acting capacity for the near future.

He provided a summary of budget and appropriations affecting NIEHS. After five continuing resolutions since the start of the fiscal year in October, Congress passed and the president signed into law the Consolidated Appropriations Act, 2021, which is also referred to as the FY21 Omnibus Appropriations and COVID-19 supplemental bill, in December. NIH is currently funded at \$42.9 billion for FY21, an increase of \$1.4 billion or 3.5%. NIEHS is funded at more than \$814 million, a 1.5% increase over FY20. NIEHS Superfund activities are funded at \$81,500,000, an increase of .62% over FY20. Additionally, NIH secured COVID-19 Supplemental funding of \$1.15 billion to provide research and clinical trials related to long-term studies of COVID-19, and another \$100 million for the Rapid Acceleration of Diagnostics initiative.

Dr. Woychik described the recent visits to NIH by the new president and vice-president. He said, "It was encouraging to get such a strong showing of support from the highest levels of government.

He discussed recent scientific advances under the theme of Advancing Environmental Health Sciences, including studies from DIR, One NIEHS, DNTP, and DERT. The second theme of the NIEHS Strategic Plan, Promoting Translation – Data to Knowledge to Action, provided a context for description of the NIH Public Health Emergency and Disaster Research Response (DR2) Program, including One NIEHS efforts related to COVID response, exemplified by the NIEHS DR2 Centers and Grantees Group/Network. He also mentioned the NIEHS Director's Corner, a new regular column in the Environmental Factor newsletter.

The third Strategic Plan theme is Enhancing EHS Through Stewardship and Support. Under that banner, Dr. Woychik noted that Dr. Gary Ellison is on detail from NCI to work as Acting Director of DERT. He described the NIEHS Scholars Connect Program, and recognized the departure of Joseph "Chip" Hughes from the leadership of the Worker Training Program. Sharon Beard is now acting chief of the Worker Education and Training Branch.

Dr. Woychik concluded his presentation by presenting several instances of awards and recognitions received by NIEHS personnel and grantees.

Dr. Goldman asked Dr. Woychik about the National Academy of Medicine's (NAM) selection of health and climate as one of its Grand Challenges. She discussed the importance of funding for health research related to climate and health. She said she was concerned that NIEHS has not been very engaged in the issue as part of its core programs. She described proposals for a new NIH institute devoted to study of climate and health, and wondered why a separate institute would be needed, since there is already an institute devoted to environmental health. She said she was amazed by how many NAM people were interested in the issue.

Dr. Woychik said that the issue is very much on the NIEHS radar screen, particularly under the new administration. He noted that NIEHS has been very interested in the issue for a number of years, and that all of the NIH ICs should be involved in studying the health consequences of climate change, with development of a comprehensive plan around all aspects of climate change. He said the Biden administration is very interested in promoting climate change research, and he anticipates there will be significant progress to report in the near future.

Dr. Cordero said that he had served on the transition team for HHS, and that there had been a major effort on climate change and environmental justice. He noted that multiple agencies will be involved, presenting a great opportunity to move forward. Dr. Woychik noted that it will be important to increase awareness of the health implications of climate change. He said that the effort must come from more than just NIEHS, although the institute will play a major role. He cited NTP as a model, and felt that there should be a working group across NIH to take on the issue, as well as other federal agencies such as EPA. There must be a comprehensive plan to be able to make an impact, both in the near term and the longer term, he said. Dr. Goldman lauded the NIEHS track record of working with communities. Dr. Woychik noted that NIEHS has been leading the way across the NIH on community engagement. Dr. Collman described the RadX-UP program, and the Community Engagement Alliance for COVID-19 program.

Dr. Korfmacher discussed how the five leadership values guide toward the overall goal of addressing environmental public health problems and contribute to health equity. She said that prioritization is key, and asked how vulnerable communities could help prioritize which chemicals are studied. She said the focus is on how innovation is defined, and how it leads to impact on health equity. Dr. Woychik said that her comments showed that the five values, packaged together, made sense and provides a way to implement. He agreed that innovation is not just about new technologies. He said he is absolutely committed to the value of shared leadership, with input from all members of the EHS community. He said that the values can be implemented through the themes and goals of the strategic plan.

Dr. Ho said she appreciated the inclusion of global collaboration. She noted that post-COVID, innovation will be accelerated. Dr. Woychik noted that there has been little attention to the role of environmental exposures in individuals' immune responses to COVID. He said he would work on the issue as part of his "environmental statesmanship."

Dr. Kavanagh noted that as part of climate change, food insecurity and water insecurity could have huge impacts on people's health. Dr. Woychik mentioned the role of NTP in looking at exposures related to climate change.

Dr. Hertz-Picciotto said that her group is working with ten community organizations to expedite the use of mobile testing vans in her area of central California. Dr. Woychik commented that he and Dr. Hertz-Picciotto recently briefed Congress on some of the environmental challenges associated with wildfires and climate change.

V. Computationally Augmented Intelligence for Predictive Toxicology

NTP Associate Director Dr. Brian Berridge introduced Dr. Nicole Kleinstreuer, Acting NICEATM Director.

She described the NICEATM and ICCVAM programs, and provided background information about augmented intelligence, which is the concept of using information technology, data science, and machine learning to support and enhance human intellect. Augmented intelligence underpins the cycle of modern toxicology and environmental health sciences in a computational toxicology continuum, incorporating big data, predictive models, experimentation, and mechanistic models. Those elements combine toward the goal of generating insights into human disease processes and their susceptibility to environmental perturbations.

Fundamental to the success of the process is the concept of FAIR resources: findable, accessible, interoperable, and reusable. Dr. Kleinstreuer provided several examples of processes designed to support the FAIR concept for data, such as manual efforts to identify and curate historical reference data, and the use of computational tools to evolve those efforts via automated study identification, automated information extraction, and automated endpoint mapping. She cited examples of interoperability across systems, with the ultimate goal being to have a fully automated pipeline. She discussed the Integrated Chemical Environment (ICE: <https://ice.ntp.niehs.nih.gov/>), which is NICEATM's dashboard for interacting with FAIR data resources, providing intuitive access to high-quality, curated data and tools to support:

- Chemical evaluations
- Data integration
- Informatics analyses
- Model development

ICE tools include curation to assist meaningful assay selection and model building.

Dr. Kleinstreuer described OPERA (OPEn (q)saR App), a free and open-source quantitative structure-activity relationship (QSAR) tool with a suite of AI/ML models. OPERA predictions include:

- Physchem properties
- ADMA properties

- Tissue partition coefficient inputs
- Models for toxicity endpoints
- QSAR predictions for 800k chemicals

She discussed global collaborative projects to apply machine learning to predict endpoints of regulatory importance, including work on multi-task learning that began during the CATMos project.

Dr. Kleinstreuer also went over tool development projects from her intramural appointment, such as InterPred, Tox21 BodyMap, and ChemMaps. As an example of the contribution of computational methods within the NTP translational toxicology pipeline, she described CardioToxPi, which uses Tox21HTS data to prioritize environmental chemicals with significant activity against cardiovascular failure modes.

She called the Council's attention to a recent special issue of the journal *Chemical Research in Toxicology*, which was devoted to developments in computational toxicology.

Dr. Wright said that the one piece he was curious about was human populations, in terms of exposomics and gene-environment interactions. Dr. Kleinstreuer said that there is work going on in those areas, and her group is focused on partnering with the researchers working on them.

Dr. Cordero asked two questions. First, he inquired to what extent her group's learning could contribute to developing standards for publications. Second, how could the systems help in the future with chemicals of unknown toxicity? Dr. Kleinstreuer described some of the existing standardized reporting formats, such as the one from OECD. She said there are a number of ongoing efforts to create internationally harmonized datasets that are annotated with common standards. Responding to the second question, she said that chemicals of unknown toxicity, especially those lacking testing data, are an excellent example of the utility of computational toxicological tools.

Dr. Ho asked how the new tools would influence the ongoing NIH projects, such as All of Us. Dr. Kleinstreuer said there need to be mutually informative lines of communication between her group's work and the projects that are collecting human data related to the exposome and disease burden. Dr. Ho said that in her experience, some of the large NIH projects tend to leave NIEHS out, increasing the importance of work such as described by Dr. Kleinstreuer, to be able to change the NIH mindset. Dr. Woychik said that he would press the issue with other IC directors.

Dr. Penning asked how predictive toxicology takes metabolism into account. Dr. Kleinstreuer said that metabolism is always a large issue, especially with in vitro systems that do not include metabolic capability. Thus, computational methods to

predict the effects of metabolism must be developed. More and more microphysiological systems do employ metabolic capabilities for a biologically realistic, informed approach to assessing chemical toxicity. There are computational tools to predict metabolic activities, she noted. Dr. Penning asked if there were any examples of systems where there were no adverse outcome pathways initially but AOPs were identified through computational methods. Dr. Kleinstreuer said that AOPs are presented linearly, but biology is not that simple, with networks of AOPs interacting. She said an entire subfield of computational toxicology is dedicated to hypothesizing AOP networks and quantifying key event relationships.

Dr. Kavanagh asked to what extent some of the large databases contain things like engineered nanomaterials, flavorants from vaping, or potentially toxic natural products. Dr. Kleinstreuer agreed that those are challenging areas since computational models are easier to build on monoconstituent substances with well-defined structures. She described some of the work groups at NTP active in those areas.

VI. DERT Director's Report

Dr. Mastin briefed the Council on DERT developments since the September 2020 meeting.

He provided staffing updates, and detailed the Council Delegated Staff Actions, which are actions delegated to DERT staff that require no follow-up action with Council. The purpose is to help ensure the smooth operations of the extramural division in conducting business with its grantees. The actions are:

1. Change of Institution
2. Change of PI
3. Continuation of Grant with Interim PI
4. Extension Without Funds
5. Extension With Funds

Council voted to approve the motion.

Dr. Mastin summarized FY2020 extramural funding and grant distribution.

- 1,533 applications were reviewed.
- Total funding for extramural grants was \$378.4 million, 73% of which (\$274 million) was for RPGs.
- Average RPG cost was: competing \$414,000, non-competing \$457,000
- The payline was at 10%.
- The NIEHS success rate for R01s was 14.1%, for RPGs was 14.2%.
- 170 competing RPGs totaled \$70.3 million (45 solicited, 125 unsolicited)

- 446 non-competing RPGs totaled \$204 million
 - 74% were R01s (\$157 million)
- The total Worker Training Program (WTP) funding was \$26.5 million.
- The total Superfund Research Program funding was \$50.4 million.
- WTP received \$10 million from the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020

The total set-aside for FY21 RFAs is \$28.7 million. The total co-fund set-aside is \$4.8 million.

Dr. Mastin reported on several DERT meetings that took place since the last Council meeting, and previewed several upcoming DERT meetings.

Addressing racism, diversity, equity and inclusion in EHS research, he described the Research Supplements to Promote Diversity in Health-Related Research:

- Receive and fund more diversity supplement applications
 - \$2.0 million set-aside
- Review and award diversity supplement applications faster
 - Monthly review
- Advertise to receive more applications
 - Website updates...more to come
- Evaluation Plan: Data Collection and Metrics
 - Review and update process to lower grants management burden
 - Review other procedures to streamline and increase consistency

Dr. Mastin introduced Dr. Gary Ellison, who will be on detail from NCI to be Acting Director of DERT.

Dr. Ellison described his background, which he characterized as “My Circuitous Route to a Federal Career in Health Science Administration.” He summarized his interest in the Acting DERT Director detail as follows:

- Appreciation of the environment’s role across a greater number of disease states
- Greater exposure to and oversight of a range of disciplines within DERT
- Opportunity to lead beyond program to include review and grants management
- Great strength of DERT is its highly qualified, motivated and engaged staff
- Impressive efforts to address racial injustice through a focus on diversity, equity and inclusion

He noted his educational and professional experience, spanning industry, academia, and government. He became an NCI Program Director in 2008, and currently is chief of the Environmental Epidemiology Branch, which he described in detail.

He talked about his vision for bringing leadership as DERT Acting Director, which would include leadership in addressing diversity, equity and inclusion (DEI).

- Develop a framework for addressing racism and DEI
 - DERT workforce culture
 - Extramural research
- Align DERT/NIEHS efforts with NIH's anti-racism efforts
- Define metrics for progress and ensure that DERT tracks and evaluates its diversity, equity and inclusion activities

Dr. Perez-Lugo said that it appears DERT is funding research in areas that seem to have little impact on policy. EHS knowledge does not seem to permeate decision-making processes, and result in needed actions, she observed. She asked what other kinds of research may better illuminate structural issues. Dr. Ellison noted that NIEHS has been a leader in focusing on having community involvement in all of its research, with no exception for DEI research. He cited a research effort being led by NIMHD, which NIEHS has signed on to, to address structural racism and potential interventions. "There's still a lot of work to do, and that's going to be part of our ongoing discussion," he said.

VII. Perspectives on Precision Environmental Health

Dr. Cheryl Walker, Director of the Center for Precision Environmental Health at the Baylor College of Medicine, briefed the Council on the latest research in precision environmental health (PEH), which describes the next generation of environmental health research occurring at the intersection of G (epigenome/genome) perturbations X E (environmental exposures) X D (data-omics, i.e., exposome, proteome, metabolome).

PEH is analogous to precision medicine, but differs in that it has the goal of disease prevention, as opposed to disease treatment.

Dr. Walker discussed the previous NIEHS investments in PEH, dating back to 1997 with the Environmental Genome Project.

She described the relationship of PEH to primary, secondary, and tertiary disease prevention, ultimately moving toward personalized prevention via:

- New targets, mechanisms and biomarkers for environmental exposures linked to human disease
- Conserved pathways and mechanisms of disease
- New opportunities for forward and reverse translation

She provided several examples of reverse translation and opportunities to deploy PEH. She noted that 70-90% of human diseases are attributable to environmental causes. Thus, there is an enormous opportunity for personal prevention in terms of population health, taking advantage of environment-enriched predictive tools such as personal risk factors, environmental data, and genomics—all feeding into tools based on machine learning and artificial intelligence. The All of Us research program is an example of such an approach.

Dr. Walker noted that PEH depends on:

- Attracting a critical mass of the world's best scientists around groundbreaking PEH research.
- Uniting basic science, technology, and innovation to bring the power of environmental health directly to individuals.

Dr. Walker's colleagues, Dr. Dana Dolinoy from the University of Michigan and Dr. Andrea Baccarelli from Columbia University, presented data from their research projects associated with PEH.

Dr. Wright related the discussion back to systemic racism. He noted that exposure to toxic chemicals is not random, but tracks with socioeconomic status. Likewise, access to treatment is not random. He said there are interesting social justice and environmental justice issues that could be addressed by employing exposomics or environmental chemical analysis in patients. He said there are few examples of studies addressing those questions, and asked what the barriers might be. Dr. Walker replied that it would be interesting to stratify human data by the parameters mentioned by Dr. Wright, as a good example of reverse translation. Dr. Baccarelli said he agreed with Dr. Wright's analysis, and that it presents a unique opportunity. Dr. Dolinoy noted that the cost of exposome analysis can be a barrier. Dr. Wright wondered if a targeted analysis of chemicals that are already understood may be practical, such as obesogenic chemicals.

Dr. Kavanagh asked about single-cell molecular phenotyping, and about the role of diet and dietary factors in metabolomic analyses, which may give insights on how to prevent disease by modifying diets. Dr. Baccarelli said that many variations and exogenous exposures measured by metabolomics. Dr. Walker said that single-cell analysis is much more common today than five years ago. Dr. Woychik pointed to the BRAIN initiative as an example of research looking at epigenetic modifications in single cells.

Dr. Penning noted that several years ago the Gates Foundation had written about "precision public health." Their point was to identify those most vulnerable and then take limited resources and focus on those individuals who were most vulnerable. He said the

epigenomic component of PEH may be where the field will be several years from now. However, there are things that can be done within PEH right now, that are actionable.

Dr. Hertz-Picciotto noted that many genetics and pathways related to neuroinflammation and autism have been well-characterized. It has been seen that some of the environmental factors involved operate on those pathways, which makes some of the epidemiologic data plausible. Thus, it is possible to target compounds known to work on those pathways, rather than necessarily looking at the entire exposome. Dr. Dolinoy said that Dr. Hertz-Picciotto's point fit with the concept of reverse translation. However, if you identified an epigenetic predictor of future disease risk, there are potential interventions, such as epigenetic therapies for certain types of diseases. Dr. Hertz-Picciotto reiterated the point about the importance of research that can lead to policy and action and mitigation.

Dr. Woychik concluded the session by mentioning that it will be important to deploy the types of tools and approaches presented by Drs. Walker, Dolinoy, and Baccarelli, and with more intersections with genetics and genomics researchers. For precision medicine to work, environmental exposures must be factored into the equation, he said. He pledged to continue his practice of scientific statesmanship to spread the word and develop better collaborations with other ICs.

VIII. Promoting Equity, Diversity, and Inclusion in Biomedical Research

Dr. Tara Schwetz, Associate Deputy Director, NIH briefed the Council on DEI activities at NIH.

She presented a compelling case for diversity in the biomedical enterprise, sharing evidence that diverse teams outperform homogenous teams. She shared data on underrepresentation in the U.S. scientific and engineering workforce. In terms of the NIH-supported PhD recipients' workforce, the number of racial and ethnic minorities has increased slowly over time, but the proportion has not changed much.

She presented several other sets of data depicting the representation of racial and ethnic minorities in the scientific workforce, which continues to be low.

Dr. Schwetz described several NIH biomedical research training programs, highlighting the need for diversity efforts through the entire pathway.

She focused on the NIH Common Fund's Faculty Institutional Recruitment for Sustainable Transformation (FIRST) program, which aims to enhance and maintain cultures of inclusive excellence in the biomedical research community. FIRST is funded at \$241 million for 9 years.

Dr. Schwetz recounted ongoing efforts at NIH to address racial inequities in biomedical research and in the biomedical workforce, and the role of NIH as a leader in the space. She described a series of intense IC Directors meeting discussions on DEI in 2020, relating the main topics of discussion. Candid feedback was also received from NIH staff and leaders:

- NIH Black/African American Senior Investigators
- 8 Changes for Racial Equity (8CRE)
- Anti-Harassment Steering Committee

The potential approach to address the DEI challenges includes creation of trans-NIH committees that report to the NIH Steering Committee and to the NIH Advisory Committee to the Director (ACD). They would identify 5 interrelated, but distinct, workstreams:

- Understanding stakeholder experiences through listening and learning
- New research on health disparities/inequities
- Internal workforce
- Extramural research workforce
- Talking and communicating with our internal external stakeholders

Planned activities include:

- Collect feedback and relevant data from the NIH community, partners, and other external stakeholders
- Analyze data and feedback from the NIH community and external groups
- Review and modify culture, policies, and practices to create a more diverse and equitable NIH community
- Increase diversity of staff through mentorship and career opportunities
- Fund research that improves understanding of underserved communities and health disparities/health inequities
- Develop communications plans that target a variety of audiences

Dr. Woychik noted that Dr. Schwetz's presentation provided a sense that the situation is not static and that there are many activities taking place.

Dr. Perez-Lugo said that although the lack of representation of minorities in biomedical research is a structural issue, the solutions being implemented are individual in nature. She asked if different sets of literature from other areas have been looked at, such as organizational sociology or industrial psychology. She also asked if NSF and NAS have been contacted to consolidate and collaborate in efforts to increase diversity in the workforce. She noted that tenure processes do not incentivize team research. She

asked whether work is going on with institutions to change incentives for meeting the needs of a diverse workforce. Dr. Schwetz said that many of the efforts underway are trying to shift from the individual approach to a more systemic approach addressing structural, systemic issues. She said that there have been conversations with colleagues in other sectors, as suggested by Dr. Perez-Lugo.

Dr. Hertz-Picciotto noted that review panels need to be looked at in terms of DEI considerations. She wondered if the culture of review panels needs to change, although it would be a big challenge. Dr. Schwetz said that part of the issue hearkens to the priorities that each institute set.

Dr. Wright said that his institution had hired an outside consultant to evaluate DEI issues. Also, he said that he and his colleagues are required to put metrics and a timeline in their applications. Dr. Schwetz agreed that that is a component NIH values and thinks is an essential part of what will be done. She pointed out that the elements she had presented were still in development and that more information would emerge over the coming weeks.

Dr. White-Newsome agreed with Dr. Hertz-Picciotto that changing the mindset of people making decisions is critical. She asked about budget issues related to minority health and health disparities. She also concurred with the discussion about accountability and metrics. Dr. Schwetz said that in terms of budget, Congress sets the budget for each of the institutes across NIH. There is a “fair amount of wiggle room” for the individual IC directors and leadership to impart their scientific priorities. Dr. White-Newsome asked whether the priorities are being set with the people who are hoped will benefit from the process. Dr. Schwetz said that listening to and engaging with communities, in the broadest sense, is critical—beyond just the traditional stakeholders. “While we have done a variety of different things over the years to enhance diversity across the different NIH programs, we are trying to take a step back. There has been a lot done and there has been some progress, but this is a long-standing challenge that we need to reflect on what we as an institution can do and take this more systemic approach,” she said.

Dr. Cordero asked about the lack of diversity at the leadership level of NIH, and what NIH is planning to do to enhance it. He also asked about enhancing budget efforts to eliminate health disparities. Dr. Schwetz replied that the approach to the diversity of the internal workforce is a huge challenge for NIH, but in terms of leadership, as you climb the ladder it gets more and more white and more and more male, so there is a case to be made for enhancing diversity at each level. In terms of the budget for NIMHD, she noted that each of the other ICs fund their own research on minority health and health disparities.

Dr. Ho talked about the pipeline and competing for talent. She said the talent pool needs to be expanded. For example, the Dreamers and people returning to work could be possibilities for recruitment. She also suggested that the time for grant applications could be extended, and discussed parallel enhancement programs.

Dr. Goldman said that many of the important structural issues are also the structural barriers to team science and some of the other problems the field is trying to address. There is too much authority and power in the hands of just a few PIs, she said. She said that some of the work being done by Dr. Schwetz could help in issues such as structural racism and gender bias, and also to make some profound changes in how science is reported. Dr. Schwetz said those points need to be considered moving forward.

IX. DEI Discussion and Working Group Roll-out

Dr. Woychik briefed the Council on the establishment of the NAEHSC Council Working Group on Anti-racism, Diversity, Inclusion, and Equity. The group will be chaired by Council member Karen Vasquez, Ph.D., from the University of Texas, who was unable to attend the Council meeting due to the Texas weather emergency. The group's charge is to be:

- Advisory to the National Advisory Environmental Health Sciences Committee (NAEHSC) on matters related to racism, diversity, equity, and inclusion, primarily as they apply uniquely to research in the area of environmental health science.
- Examples:
 - Ideas for increasing diversity in the EHS workforce
 - Best approaches for recruitment and retention of talented individuals from underrepresented minorities
 - Examples of activities at universities or other institutions
 - Identification of gaps in research related to how race and ethnicity affect responses to environmental exposures
 - Identification of factors that cause inequity in funding across racial and ethnic groups

Input from the working group to Council will help Council provide advice to senior leadership of NIEHS in those areas. Dr. Woychik went over the plans for membership in the group:

- Chaired by a member of Council—Karen Vasquez
- Other current or former members of Council—2-3, 2-year terms
 - Jose Cordero
 - Edith Parker
 - Andy Shih

- Members from academia, industry, government, etc.
 - George Daston, Procter & Gamble, SOT
- Two representatives from NIEHS
 - One from extramural (DERT)
 - One from intramural (DIR or DNTP)
- Total membership 12-15
- Still have slots to fill. Suggestions should be sent to Dr. Vasquez

Dr. Mastin reiterated that the group is designed to advise Council, not senior leadership. He pointed out that the charter is not final.

Drs. Cordero, Shih, and Parker expressed their appreciation for being included in the working group.

Dr. Perez-Lugo discussed the NIH Council of Councils Working Group on Integrating Social Research, suggesting that there may be a connection between that group and the NIEHS Council working group. Dr. Woychik said that IC directors want to make sure that all efforts are coordinated. He added that it would be important to also coordinate with the working group for the Advisory Committee to the Director (ACD), which will address gender equity, racism, and DEI.

Dr. White-Newsome asked who would be the point person for coordination. Dr. Woychik said it would be premature to comment on that, but that soon there would be developments emerging from NIH.

Dr. Woychik recognized the contribution of Dr. Korfmacher, who had asked to ensure that community and tribal input would be included in the working group charter.

Dr. Penning noted that in every recruitment at his institution, it is mandatory to have a diversity officer present on the committee, and he suggested that it might be a good idea to have a diversity member mandatory for study sections. Dr. Woychik said it was an interesting point, and said he would bring the idea to the discussion with the IC directors. Dr. Mastin said he would like to see the working group tackle the funding gap, potentially including ideas on how to tweak the review process.

Dr. Perez-Lugo asked how to make more explicit a commitment to follow-up from NIEHS on the recommendations that Council makes. Dr. Woychik said that part of the commitment would be to develop very specific metrics, deadlines, and deliverables.

Dr. Cordero endorsed Dr. Penning's suggestion about a diversity officer being included in study sections, and suggested attention to broad diversity in study sections.

Dr. Korfmacher said there were two sides to the issue, who is doing the work and the nature and prioritization of the work itself. She asked that more Council time be devoted

to the second side. Dr. Mastin said he would be sure to include it on the agenda for the next meeting. Dr. Parker said it would be useful to have a dedicated time to reach out to each Council member for their ideas before the next meeting, which could be done offline.

Dr. Collman described the NIH ACD working group, with an upcoming meeting devoted to some of the issues discussed by Dr. Schwetz. Dr. Woychik urged all to attend that special session of the ACD. The URL to attend was listed in the meeting chat box.

X. Adjournment

Dr. Mastin thanked everyone involved with the meeting, particularly Liz McNair, Rosemary Moody, Nathan Mitchiner, and John Maruca. Dr. Woychik thanked Dr. Mastin and his team for their efforts, along with the members of Council. He adjourned the meeting at 1:50 pm, February 17, 2021.

CERTIFICATION:

Richard P. Woychik -S
Digitally signed by
Richard P. Woychik -S
Date: 2021.03.23
12:08:27 -04'00'

Rick Woychik, PhD
Chairperson
National Advisory Environmental
Health Sciences Council

James P. Mastin -S
Digitally signed by
James P. Mastin -S
Date: 2021.03.23
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J. Patrick Mastin, PhD
Executive Secretary
National Advisory Environmental
Health Sciences Council

Attachment:
Council Roster