U.S. Department of Health and Human Services National Institutes of Health Office of AIDS Research

Office of AIDS Research Advisory Council Fifty-Seventh Meeting June 24, 2021

Virtual

https://videocast.nih.gov/watch=41903

Meeting Minutes

Council Members Present: Dr. Blanton S. Tolbert (Acting Chair), CAPT Mary Glenshaw (Executive Secretary), Dr. Maureen M. Goodenow (Associate Director for AIDS Research and Director, Office of AIDS Research), Dr. Margaret L. Brandeau, Dr. Tricia H. Burdo, Dr. Kathleen L. Collins, Dr. Heidi M. Crane, Ms. Lynda M. Dee, Dr. Veronica Miller, Dr. Ricardo A. Rivero, Dr. Jonah B. Sacha, Dr. Kimberly K. Scarsi, Dr. Bruce R. Schackman, Dr. John W. Sleasman, Dr. Babafemi Taiwo

Ex Officio Members Present: COL Julie A. Ake, Dr. Victoria J. Davey, Dr. Carl W. Dieffenbach, Dr. Rohan Hazra, RADM Jonathan Mermin

Advisory Council Representatives Present: Dr. Francis Ali-Osman, Dr. Monica Gandhi, Dr. Carlos del Rio, Dr. Dianne Rausch

NIH Office of AIDS Research Leadership, Invited Speakers, and Guests: Dr. Marie Bernard, Dr. Ericka Boone, Dr. Namandjé N. Bumpus, Dr. Rohan Hazra, RADM Timothy Holtz, Dr. Henry Masur, Dr. Anna Ordóñez, Dr. Alice Pau, Mr. Harold J. Phillips

Welcome and Introductions

CAPT Mary Glenshaw, Ph.D., M.P.H., Office of AIDS Research, National Institutes of Health Blanton Tolbert, Ph.D., Acting OARAC Chairperson, Professor, Case Western Reserve University

CAPT Mary Glenshaw and Dr. Blanton Tolbert opened the fifty-seventh meeting of the National Institutes of Health (NIH) Office of AIDS Research Advisory Council (OARAC). Meeting materials provided to Council members included the agenda, a conflict-of-interest form, and minutes from the fiftysixth OARAC meeting, held on February 23, 2021.

A motion to accept the minutes of the fifty-sixth OARAC meeting was approved unanimously.

Dr. Tolbert reviewed the fifty-seventh meeting agenda, noting the inclusion of time for public comments.

Report from the NIH Office of AIDS Research (OAR) Director

Maureen M. Goodenow, Ph.D., OAR, NIH

Dr. Maureen M. Goodenow welcomed attendees and pointed out that OAR and much of the NIH had been teleworking for more than 1 year. About 34 million cases of COVID-19 and more than 600,000 related deaths have occurred in the United States; 180 million cases and 4 million deaths have occurred

from COVID-19 worldwide. The rapid, nimble, and creative responses to the pandemic have resulted in multiple effective vaccines and treatments in about a year. New infections in the United States have declined to between 12,000 and 15,000 per day, with several hundred daily deaths. More than 300 million vaccine doses have been administered in the United States, supported by significant investment in biomedical research and by multi-sector partnerships to develop vaccines and treatments. In March and April 2020, federal departments and agencies were directed to marshal all legally available federal resources to combat the crisis using short-term, time-limited flexibilities. NIH researchers, including HIV researchers, pivoted to COVID-19 research under these flexibilities. Researchers and the community rallied to apply infrastructure, technologies, clinical trials networks, and partnerships across the government, academia, and the private sector to massive rapid and innovative responses.

The flexibilities were scheduled to expire in June 2020 but were extended through September 30, 2020. After expiration of the flexibilities, the NIH and OAR once again are required by foundational 1993 legislation to ensure that HIV funds are used to support the highest priorities for HIV research to end the global HIV pandemic in accordance with the <u>NIH Strategic Plan for HIV and HIV-Related Research</u> and the research priorities outlined in <u>NIH HIV/AIDS Research Priorities and Guidelines for Determining</u> <u>AIDS Funding</u>. The NIH continues to limit non-mission critical travel through the end of the calendar year, so events will continue to be virtual until further notice.

Dr. Goodenow commented that the COVID-19 pandemic has illuminated structural racism and social inequities in the United States. In June 2020, Dr. Francis Collins affirmed NIH's commitment to addressing structural racism in the biomedical research enterprise; initial results of efforts implemented at that time were reported later in this meeting.

HIV researchers and community members contributed significantly to COVID-19 research efforts. The HIV research footprint is apparent in the mRNA vaccine platform, clinical trials networks for testing candidate vaccines, and rapid testing and molecular epidemiology for tracking. Many approaches used to address the COVID-19 pandemic have implications for focusing the next phases of the HIV research agenda. The accomplishments in HIV research have changed the trajectory of HIV pathogenesis, but developing vaccines for prevention and strategies for cures remains essential to end the HIV pandemic. Dr. Goodenow encouraged attendees to seize the moment and adopt lessons from the COVID-19 response to accelerate implementation of the mRNA platform for HIV vaccines, increase the use of technology for novel testing strategies to follow effectiveness of treatments, investigate neurological complications of HIV across the lifespan, capitalize on imaging and modeling to identify new therapeutic targets, and expand the pool of diverse early-stage HIV investigators to meet the challenges of 21st-century HIV research.

Dr. Goodenow memorialized HIV research pioneer Dr. Charles Boucher and provided updates on leadership. Mr. Xavier Becerra was confirmed as Secretary of the U.S. Department of Health and Human Services (HHS), Dr. Rachel Levine was confirmed as the Assistant Secretary for Health, and VADM Vivek Murthy was confirmed as the U.S. Surgeon General. Mr. Harold Phillips was appointed Director of the White House Office of National AIDS Policy (ONAP) and is the first director of this office in more than 4 years. Ms. Samantha Power has been sworn into office as the Administrator of the U.S. Agency for International Development, Dr. Demetre Daskalakis has been named the Centers for Disease Control and Prevention (CDC) Director of the Division of HIV/AIDS Prevention, and Dr. Leandro Mena has been appointed Director of the Division of Sexually Transmitted Disease Prevention at the CDC. Dr. Goodenow acknowledged Dr. Stacy Carrington-Lawrence, who is moving from OAR to the National Institute on Aging.

The CDC recently published three new reports using 2015–2019 HIV surveillance data, identifying signs of progress and remaining challenges in HIV prevention. Increased survival has increased the number of

people living with HIV despite decreases in new infections. By the end of 2019, approximately 1.2 million people ages 13 and older were living with HIV infection in the United States, compared to nearly 1.1 million in 2015. Between 2015 and 2019, new HIV infections in the United States declined 8 percent after a period of stability. However, people of color continue to be severely and disproportionately affected, with rates of infection four to eight times higher than those for white individuals. More than half of new HIV infections in 2019 were diagnosed in Southern states. Dr. Goodenow emphasized that these data represent the state of the HIV epidemic in the United States before the COVID-19 pandemic and initiation of the *Ending the HIV Epidemic in the U.S.* (EHE) initiative but provide the baseline for future assessments of the effects of the COVID-19 pandemic and EHE on the HIV epidemic.

Dr. Goodenow noted recent engagement activities in which OAR participated. The NIH Intramural NeuroHIV Workshop in March discussed unique aspects of the intramural program that allow investigation of HIV neuropathogenesis and the ability to quickly translate more observations to clinical trials; state-of-the-art imaging resources; interdisciplinary collaborations; and new modes of detection and intervention, including the use of nanobodies and darunavir, an HIV protease inhibitor, as novel imaging agents. A recently published *Lancet* series on HIV in the United States, with implications for rural America, linked to many themes raised during the NIH OAR West Virginia listening session. Dr. Goodenow noted that COVID-19 has devastated communities also affected by HIV and increased health disparities and inequities—including those related to limited access to health care services, such as in rural areas—in the United States. The COVID-19 epidemic has expanded the use of telemedicine in HIV prevention and care and emphasized the importance of research and science in advancing public health and health equity. The NIH OAR is analyzing HIV research efforts in rural America and will have results for the OARAC in October.

The April National EHE meeting included more than 300 academic investigators, community partners, local health department officials, and federal counterparts. During the meeting, Dr. Goodenow outlined current and future plans for NIH's HIV/AIDS research program. On June 7, OAR represented the NIH in a congressional staff briefing led by Dr. Levine with the senior HHS EHE leadership team to outline progress on EHE and how HHS will use funds in the future. The next week, Dr. Goodenow and Dr. Anthony Fauci participated in a panel discussion on the impact of 40 years of HIV and AIDS on the United States and globally. The event was hosted by the Global AIDS Policy Partnership and the Federal AIDS Policy Partnership, in collaboration with the Congressional HIV/AIDS Caucus. In March, RADM Timothy Holtz addressed the virtual annual Research Centers in Minority Institutions (RCMIs) grantee meeting, which expands national capacity for health research by providing support to academic institutions with doctoral programs, commitment to educating students in underrepresented groups, and facilities with clinical services for medically underserved communities. Some Centers for AIDS Research (CFARs) and AIDS Research Centers (ARCs) are co-located with RCMIs, providing opportunities for collaboration. Some RCMIs are located in geographic areas highly affected by HIV, expanding opportunities to increase research capacity and the diversity of early-stage investigators in these areas. Additionally, the NIH OAR facilitated a new funding opportunity with the National Institute on Minority Health and Health Disparities (NIMHD) and the HHS Minority HIV/AIDS Fund to support and enhance RCMIs conducting EHE research.

The NIH OAR continues to hold listening sessions around the country. Since the last OARAC meeting, sessions have been held in Nebraska and San Diego. Emerging HIV trends and challenges noted in the Nebraska session include the difficulty of accessing HIV services, obstacles to service delivery, supply chain challenges for HIV research, suboptimal regional support networks, and the need for workplace diversity and inclusion. Key takeaway issues include the need to recognize the heterogeneity and challenges of rural health in low HIV-prevalence settings and opportunities to triangulate programming, services, and research networks. For example, methamphetamine use is prevalent in Nebraska, but opioid use is predominant in West Virginia. Rural drug use and HIV issues must include both opioid and non-

opioid approaches. The San Diego listening sessions included discussions regarding health care and research challenges among the HIV and aging community; in the context of drug use and addiction, specifically opioids and methamphetamines; U.S.–Mexico border challenges, including migrants and migrant worker mobility; and increased diagnoses of sexually transmitted infections (STIs). Community stakeholders highlighted the need for mental health support for persons with HIV dealing with racialized trauma; the need for training on de-stigmatizing language among service providers; and the importance of cultural humility, trauma, and health training.

In fiscal years (FYs) 2020 and 2021, NIH OAR supported increasing the number of early-career HIV grants by approximately 20 percent. The goal is to ensure that at least 5 percent of HIV grantees each year are early-career investigators, the same proportion as the overall NIH portfolio. NIH OAR hosted four listening sessions with early career investigators. Themes that emerged related to mentoring, peer review, funding mechanisms, networks and community, and the impact of COVID-19. The NIH OAR then convened a virtual expert panel, which discussed challenges faced by early-career HIV researchers and ideas to increase their diversity and support at both institutional and NIH levels. Suggestions included increasing flexibility in funding mechanisms, enhancing support for lower-resourced institutions, increasing support for mentoring activities, expanding access to existing NIH HIV networks and resources, improving fair peer review of early-career applications, and creatively incentivizing research in HIV.

Dr. Goodenow noted the 40th anniversary of the June 5, 1981 *Morbidity and Mortality Weekly Report* that first reported the disease later named AIDS. The NIH OAR developed a communications campaign, which will continue through World AIDS Day on December 1, to recognize milestones achieved through science; honor the more than 32 million people who have died from AIDS-related illnesses globally; and support the goals of EHE. Dr. Goodenow encouraged attendees to visit the NIH <u>OAR website</u> for more information.

Dr. Goodenow highlighted the \$3.09 billion FY 2021 NIH HIV research budget and noted that the FY 2022 President's Budget includes \$3.1 billion for NIH HIV research. Additional information is available in NIH <u>OAR's FY 2022 Congressional Budget Justification</u>, which was released in early June. The HIV/AIDS portfolio now is almost 100 percent aligned with overarching priorities, but NIH HIV research funding has increased only modestly over the past 20 years. Recent budget increases have lagged behind the increases in costs associated with conducting research. Dr. Goodenow explained that the overall cost of HIV management is projected to continue increasing as persons with HIV live longer and experience more comorbidities associated with HIV and antiretroviral therapy (ART). She emphasized the benefits of strengthening the HIV/AIDS research investment now to end the HIV pandemic.

Two major new initiatives were announced recently and included in the President's Budget. The <u>Advanced Research Projects Agency for Health</u> (ARPA-H) is intended to accelerate the pace of breakthroughs to transform medicine and health and will be created within the NIH. ARPA-H was inspired by the Defense Advanced Research Projects Agency (DARPA), which has driven advances for the Department of Defense for more than 60 years. DARPA-like approaches already have been used in response to COVID-19. The other new initiative is an investment of \$3.2 billion from the American Rescue Plan as part of a new <u>Antiviral Program for Pandemics</u> (APP), which will bring together leading scientists from academia and industry to accelerate the development of new antiretrovirals, with a specific focus on direct-acting antiretrovirals, and will target both COVID-19 and other viruses with pandemic potential.

Dr. Goodenow reviewed the meeting agenda and thanked members for prioritizing OARAC meetings.

Discussion Highlights

OARAC members asked Dr. Goodenow and the administration to prioritize appointing a director of the President's Emergency Plan for AIDS Relief (PEPFAR) and emphasized the importance of this role.

In response to a question about drivers of the HIV epidemic in the South, Dr. Goodenow noted challenges related to demographics, structural access to health care, and rurality. RADM Jonathan Mermin added population size is a factor to consider, as the population is high in the South, which increases the absolute number of persons with HIV relative to other regions. Obstacles to accessing support services, social determinants of health, and homophobia and racism affect access to HIV treatment. Distributed need may limit the reach of community-based organizations, which are more successful in urban settings. RADM Mermin noted that strategies implemented in response to COVID-19, such as telemedicine and self-testing, could be useful for addressing these challenges in the long run. Dr. Goodenow noted that previous listening sessions in the South have highlighted the significant physician deserts in some states. RADM Mermin confirmed that because some of these challenges are not HIV-specific, rates of some other conditions are higher in the South as well.

NIH UNITE Initiative

Marie Bernard, M.D., Co-Chair, NIH UNITE Initiative, Chief Officer for Scientific Workforce Diversity, NIH

Dr. Marie Bernard provided an overview of the <u>UNITE Initiative</u>, which was created after the events of 2020 clarified the ongoing reality of racial injustice and emphasized a collective responsibility to address the issue. The initiative began with a series of Institute and Center (IC) director meetings to discuss and identify issues; two self-assembled affinity groups at the NIH and the Anti-Harassment Steering Committee then met with NIH leadership. These efforts led to a shared commitment to address structural racism.

A number of initial issues were identified. Biomedical research and the administrative system that supports it must be devoid of hostility grounded in race, sex, and other federally protected characteristics. Those involved in the new initiative are committed to delineating elements that may perpetuate structural racism in biomedical research within both the NIH and the extramural community, leading to a lack of personal inclusiveness, equity, and diversity. All ideas must be given an equal and fair review without regard to current dogma, precedents, or who presents the ideas. Health disparities and inequities contribute to morbidity and mortality, so redressing their fundamental causes and identifying effective interventions is critical.

The UNITE Initiative represents five interactive workstreams: (1) *understanding* stakeholder experiences through listening and learning; (2) *new* research on health disparities, minority health, and health equity; (3) *improving* the NIH culture and structure for equity, inclusion, and excellence; (4) *transparency*, communication, and accountability with internal and external stakeholders; and (5) changing policy, culture, and structure to promote workforce diversity in the *extramural* research ecosystem. Initial recommendations were presented in late February.

The UNITE Initiative recommended that the NIH publicly commit to identifying and correcting any NIH policies or practices that may have helped to perpetuate structural racism. In response to this recommendation, Dr. Collins published a <u>statement</u> on March 1 apologizing to those who have experienced structural racism within the biomedical enterprise and committing the NIH to instituting new ways to support diversity, equity, and inclusion and identifying and dismantling any policies and practices at the NIH that may harm the workforce and the science. The initiative recommended that the NIH

continue to aggressively implement approaches to address the "Ginther Gap"—the lower success rates of minority researchers—and enhance portfolio diversity, which is ongoing.

Additionally, the initiative recommended that the NIH launch a multi-phased, multi-tiered, and multiintegrated Common Fund initiative focused on transformative health disparities research initiatives to reduce health disparities and inequities. Two funding opportunity announcements (FOAs) were released on March 26: Transformative Research to Address Health Disparities and Advance Health Equity and Transformative Research to Address Health Disparities and Advance Health Equity at Minority-Serving Institutions.

The initiative recommended that the NIH ensure a robust enterprise-wide commitment to support the NIMHD FOA focused on the effects of structural racism and discrimination on health disparities and inequities and encourage funding levels that are commensurate with overall IC resources. A request for applications (RFA) titled Understanding and Addressing the Impact of Structural Racism and Discrimination on Minority Health and Health Disparities was released, with a commitment of up to \$30.8 million by 25 NIH Institutes, Centers, and Offices (ICOs). Another initial recommendation to develop a sustainable process to systematically gather and make public the demographics of NIH's internal and external workforce was fulfilled by amending the data book of the Office of Extramural Research to add new demographic factors; additionally, data on the racial and ethnic demographics of NIH's scientific, administrative, and health staff were published.

The initiative recommended that the NIH implement policy changes that promote anti-racism and remove barriers to professional growth for staff from diverse backgrounds, including underrepresented groups. An Anti-Racism Steering Committee was established and is open to all members of the NIH workforce, with a current membership of more than 470 individuals. This committee is designed to address issues regarding policies and procedures that lead to wrongs, but it will not address individual cases, which will continue to be addressed by the NIH Office of Equity, Diversity, and Inclusion.

The NIH has initiated the recommendation to develop a performance expectation for IC directors to be accountable for equity, diversity, and inclusion efforts and actively participate in NIH-wide diversity efforts through a diversity, equity, and inclusion officer or other means appropriate for the IC. Another initiated recommendation is to expand the Distinguished Scholars Program to senior investigators hired with tenure and enhance recruitment of researchers from underrepresented groups as candidates for open intramural investigator positions.

UNITE's recommendations for the future include:

- Support the President's Budget recommendations to increase funding for several ICs to facilitate health disparities, minority health, and health equity research;
- Continue to listen to and learn from a wide variety of stakeholders, including those not frequently engaged;
- Develop actionable data dashboards that track and provide visualizations of intramural workforce and NIH health disparities, minority health, and health equity research investments with key performance indicators and metrics;
- Release additional FOAs that focus on IC-specific disease and topic areas related to health disparities, minority health, and health equity;
- Develop programs to spur institutional culture change in support of inclusivity and equity;
- Increase career opportunities for underrepresented groups, starting with K-12 STEM education;
- Examine NIH staff interactions with applicants to address bias or inequities that may affect funding opportunities;

- Develop programs to expand NIH interactions with and support of historically Black colleges and universities (HBCUs), Tribal colleges and universities (TCUs), and other minority-serving institutions (MSIs);
- Change physical and virtual representations at the NIH to more accurately reflect the diversity of society; and
- Publish revised NIH internal guidance for reporting racial discrimination.

Dr. Bernard quoted Dr. Martin Luther King, Jr., emphasizing that "injustice anywhere is a threat to justice everywhere," and commented that the changes made as a result of the UNITE initiative are expected to benefit the entire biomedical world.

NIH UNITE Initiative: Extramural Committee

Ericka Boone, Ph.D., Co-Chair, NIH UNITE Initiative Extramural Committee, Acting Director, Biomedical Research Workforce, Director, Division of Loan Repayment, NIH; Anna E. Ordóñez, M.D., M.A.S., Co-Chair, NIH UNITE Initiative Extramural Committee, Acting Director, Office of Clinical Research, National Institute of Mental Health, NIH

Dr. Ericka Boone pointed out that many researchers from underrepresented backgrounds have not benefited satisfactorily from recent efforts. The UNITE E (extramural) committee is committed to decreasing the gaps in representation; Dr. Boone emphasized that heterogeneity in science benefits science as a whole. The charge of the E committee is to perform a broad systematic evaluation of NIH extramural policies and processes to identify and change practices and structures that perpetuate a lack of inclusivity and diversity within the extramural research ecosystem. By engaging in these efforts, the E committee will be able to make recommendations that aid the NIH in its diversity goals as a continuous practice. The E committee developed a framework based on foundational work in previous programs and identified four main areas of focus: (1) career pathways for underrepresented groups; (2) limited resources and capacity at HBCUs, TCUs, and MSIs; (3) inequities at extramural institutions, particularly in the environment and culture; and (4) inequities at the NIH, particularly regarding processes and procedures.

One of the committee's priorities is to build and sustain research capacity to enable more robust participation in the modern research enterprise. The committee is engaging actively with internal and external stakeholders to understand the issues affecting MSIs; in summer 2021 and early 2022, the committee will focus on engagement, especially given the importance of communication in building relationships with institutions that do not have a long history with the NIH. More accessible and targeted outreach and programming is planned. The committee is strategizing proposals for specific areas of concern for MSIs. The committee prioritizes identifying NIH processes and policies that contribute to inequities in extramural funding and is meeting with subject-matter experts in NIH peer review, extramural funding opportunity and concept development, and extramural staff development. More targeted listening sessions are planned for the summer; healthy proposals for interventions, new programs, and policy recommendations should be ready by the fall.

Regarding extramural institutional culture, the E committee aims to develop and launch programs to spur institutional culture change in support of inclusivity and equity, first by supporting institutional climate surveys, then testing innovative interventions. The committee approaches this area using an ecosystem-level approach by identifying roles for those within institutions who can partner with researchers in underrepresented groups. Dr. Boone emphasized the importance of ensuring that people feel safe coming to work and showing them that their talent and effort is recognized. Finally, to increase career opportunities to researchers from underrepresented groups, the committee has been reviewing existing programs to identify gaps and successful programs that can be scaled up. The next steps in the process are to identify investigators at various stages of the career path, evaluate programs offering enhanced career

development programs and addressing career transition points, and review NIH's engagement with stakeholders from underrepresented groups.

Discussion Highlights

When asked about support for researchers from underrepresented groups working in areas of science other than health disparities, Dr. Bernard commented that a significant proportion of researchers from underrepresented groups work in health disparities research. The intent of the Common Fund initiatives is to address morbidity and mortality trends across the nation, particularly related to COVID-19.

In response to a question about workforce diversity metrics and goals, Dr. Bernard explained that specific targets for racial and ethnic group proportions cannot be defined, but patterns within the workforce can be compared to those in the general population and broader scientific world. She noted the need to better understand barriers and ensure ample opportunities are provided.. Dr. Boone pointed out that the UNITE I (improving culture) committee will address the collection of sexual orientation and gender identity (SOGI) data and emphasized the importance of gathering data to identify gaps and develop solutions that improve equity.

When asked about the vision for IC director accountability, Dr. Bernard acknowledged that the current administration may have some HHS-wide diversity, equity, and inclusion performance standards but every IC has an opportunity to evaluate its current initiatives and what could be improved. Some internal experts have been recruited and an external expert likely will be recruited to help develop plans individualized for the needs of each IC. The management of ethics and anti-harassment across the NIH has set a precedent for impactful initiatives. OARAC members suggested involving community-based organizations.

Dr. Bernard reiterated progress to date, beginning with the study by Donna Ginther that established the "Ginther Gap" or the disadvantages of underrepresented groups in grant success. This led to the establishment of Dr. Bernard's position, the Chief Officer for Scientific Workforce Diversity. Although the success rates for underrepresented groups have improved, Dr. Bernard emphasized that the real problem is that the numbers of grants awarded to institutions on behalf of minority researchers are very small. Dr. Boone commented that prior to the beginning of the UNITE initiative, engagement levels for individuals of color at the NIH were very low, but the interest shown by leadership in addressing diversity, equity, and inclusion has improved morale significantly.

When asked whether any funding mechanisms incorporate mentoring or outreach elements for underrepresented groups, Dr. Bernard pointed to a FOA for the Brain Research Through Advancing Innovative Neurotechnologies[®] (BRAIN) Initiative that requires a plan to enhance diverse perspectives and added that the Center for Scientific Review is piloting innovative initiatives to reduce implicit bias in reviews.

OARAC members discussed the portion of minority researchers who choose to work in the private sector after training in academic research. Dr. Bernard explained that although the ideal may be for trainees to become leading established, funded researchers, becoming industry and education leaders are also successful outcomes that continue to spread science. Researchers from underrepresented groups face barriers at every step in their career path; career counseling at earlier stages may help. Dr. Anna Ordóñez pointed out that data show a significant drop between the number of minority researchers at the postdoctoral level and those at the faculty level. More targeted funding initiatives are in development that could add support to such career transition points. She emphasized the need to expand the understanding of success without negating existing problems.

OARAC members suggested developing regional collaborations, including both institutions and community-based organizations, to address representation. Dr. Boone confirmed that such programs are in development, adding that larger institutions can learn from partner institutions.

When asked about performance standards, Dr. Bernard commented that such standards are the "stick" approach, whereas the Common Fund's Faculty Institutional Recruitment for Sustainable Transformation (FIRST) program is a "carrot" approach that gives institutions the opportunity to compete for funding to enhance faculty diversity. Additional incentives could include a prize for institutions successfully developing policies that can be modeled in other institutions. Dr. Ordóñez added that other agencies may have successful culture-changing programs that could be shared.

Dr. Ordóñez commented on the rigid nature of the traditional academic research career pathway, noting that although the NIH is not sufficiently supporting minority researchers in acquiring R01s, many other aspects of the culture need to change to make the pathway appealing.

HIV Clinical Guidelines Working Groups of OARAC Working Group Updates

Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV Henry Masur, M.D., Chief, Critical Care Medicine Department, Clinical Center, NIH

Dr. Henry Masur outlined updates in the Adult and Adolescent Opportunistic Infection (OI) Guidelines, emphasizing that the Guidelines are used widely and highly valued by the NIH and OAR. The Adult and Adolescent OI Guidelines are divided into 28 chapters. Updates to the sections on bartonella, immunizations, and coccidioidomycosis have been published, with updates to chapters on cytomegalovirus, hepatitis B, human papillomavirus, tuberculosis, and cryptococcus in process. Updates are not planned for the remaining sections. Dr. Masur explained that the subject group leads meet every quarter to review whether chapters should be updated. Usage statistics indicate that the topics of interest are correlated closely with the frequency of OIs.

Antiretroviral Agents in Adults and Adolescents Living with HIV

Alice K. Pau, Pharm.D., Staff Scientist and Clinical Pharmacist, National Institute of Allergy and Infectious Diseases (NIAID), NIH

Dr. Alice Pau reported that the Adult and Adolescent Antiretroviral (ARV) Guidelines were updated on June 3, 2021. The most important updates are usually posted in the "What to Start" section. Although no new ARVs were added in the previous year, the Panel reviewed the recommended ARVs and decided to move raltegravir (RAL) regimens from the category "Recommended for Most Persons with HIV" to "Recommended Under Certain Clinical Situations." Updated data on the use of dolutegravir (DTG) during conception suggest the incidence of neural tube defects is much lower than earlier data suggested, supporting the change in recommendation. RAL has a lower barrier to resistance than DTG and bictegravir, RAL-based regimens have a higher pill burden than other INSTI-based regimens, and no single-tablet regimen is available for RAL. Additionally, the "What to Start" section was separated into individual sections by drug class to make it easier to navigate.

In the Virologic Failure section, the recommendation that a new regimen should include at least two and preferably three fully active agents was changed. The revised recommendation is that a new regimen can include two fully active agents if at least one with a high resistant barrier is included, such as DTG or boosted darunavir. Clinical trial data on the use of fostemsavir in patients with multiple drug–resistant HIV were added. Several key updates were made to the main Guidelines text. In the section on Optimizing ART in the Setting of Viral Suppression, users are instructed to focus on long-acting cabotegravir plus rilpivirine. In the section on substance use and HIV, the Guidelines now discuss the knowledge gap regarding the safety and efficacy of long-acting injectable ARV regiments in this

population. Updates to the section on Tuberculosis and HIV focus on ARV drugs to use with once-weekly isoniazid and rifapentine (3HP) for latent mycobacterium tuberculosis infection treatment and note that DTG once daily can be used in patients who do not require twice-daily therapy.

The section on Adolescents and Young Adults (AYAs) with HIV has been rewritten, with more focus on challenges in management of AYAs who acquire HIV past the first decade of life, which acknowledges that most HIV infections in AYAs now are not acquired perinatally and have different psychosocial and adherence challenges. The section discusses critical steps to take when transitioning patients from pediatric to adult care. The section on Women with HIV was revised with a focus on updated data on weight gain and ART in women, updated information on DTG and neural tube defects, and a new subsection on issues related to HIV, menopause, and ART. In the section on Cost Considerations and HIV, a subsection was added on cost related to comprehensive HIV care; the table on ARV drug cost was updated, as well. In the Drug-Drug Interactions section, information was added regarding drug-drug interactions related to cabotegravir, rilpivirine, and fostemsavir. Other updates include those to the sections on poor CD4 recovery and persistent inflammation, adverse effects, and appendix tables.

ARV Agents in Pediatric HIV Infection Prevention and Treatment of Opportunistic Infections in HIV-Exposed and HIV-Infected Children Antiretroviral Drugs in Pregnant Women with HIV Infection and Interventions to Reduce Perinatal HIV Transmission

Rohan Hazra, M.D., Acting Associate Director of Extramural Research, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH

Dr. Rohan Hazra outlined updates to the Pediatric ARV Guidelines. The full guidelines were published on April 14, 2021 and were reviewed at the previous OARAC meeting; the annual reviews now are in progress. The Panel is reviewing new data and implications for recommendations regarding use and dosing of abacavir in neonates and infants and use of the adult doravirine dose in adolescents.

Dr. Hazra recounted updates to the Perinatal Guidelines. He detailed ongoing efforts regarding more inclusive language and content to address the care of transgender and nonbinary individuals who are pregnant or trying to conceive. A presentation in April 2021 addressed gender diversity and visibility, accuracy, and inclusion in the Perinatal Guidelines. Updates have been a standardized effort of a small group with Panel leadership, a Guidelines technical assistance consultant, and a community member.

Several proposed revisions are pending full Panel consideration and approval. Minor revisions in the Panel name and Guidelines title to address inclusiveness are pending full Panel vote. Overview content is being developed as a subsection of the Introduction; this content will address language and extrapolation/application of data from studies in cisgender women to gender minorities, limit the scope, and focus on HIV-related content. The Panel is working to identify language options to be used in addition to gender-neutral language to promote visibility and awareness of the needs of cisgender women, transgender men, and other gender-diverse individuals who can become pregnant and breastfeed or chest feed through induced lactation. For clarity and accuracy, summaries of study results involving cisgender women will be presented as they are in the publications, rather than changing the results to gender-neutral language.

The Pediatric OI Guidelines are engaging in a rescoping process involving the more than 35 pediatric infectious disease and pharmacology experts on the Panel. The Pediatric OI Guidelines are developed in collaboration with the CDC, the HIV Medicine Association of the Infectious Disease Society of America, and the Pediatric Infectious Disease Society, with additional input from the American Academy of Pediatrics. Each topic is reviewed, updated, and published individually. The rescoping retreat includes 50 participants from Panel membership plus external pediatric infectious disease and HIV and pharmacology

experts. A pre-retreat webinar was held in May, followed by release of a survey. The rescoping retreat was held on June 17 to critically evaluate the scope, content, and process of updating the current Pediatric OI Guidelines; improve the focus of the Guidelines on HIV-associated OIs; and assist the Panel in revising the Guidelines to better align with the contemporary needs of clinical providers caring for children affected by HIV.

Discussion Highlights

Dr. Masur clarified that although the Guidelines often are used internationally or in treatment of conditions other than HIV, the Panels update them with a tight focus on the mission to provide U.S.-based information on HIV treatment. He added that the recommendations in the Guidelines are not validated for any other populations and emphasized the complexity of immunosuppression.

Updates from the NIH Advisory Council Representatives

National Advisory Council on Drug Abuse (NACDA)

Carlos del Rio, M.D., Department of Global Health, Rollins School of Public Health, Emory University School of Medicine

Dr. Carlos del Rio presented highlights from the May 11, 2021 NACDA meeting, noting that an exciting HIV Prevention and Treatment Network (HPTN) clinical trial, HPTN 094, launched in five U.S. cities to determine whether delivering integrated health services through mobile health clinics can improve HIV and substance use disorder outcomes among people with opioid use disorder or those who inject drugs. If effective, mobile clinics could serve as an innovative strategy for expanding access to care and providing uninterrupted treatment for this underserved population. Dr. del Rio commented on the importance of developing ways for ICs to fund studies that address such crosscutting themes. The National Institute on Drug Abuse (NIDA) HIV Newsletter was launched in May 2021 and will highlight research gaps and findings at the intersection of HIV and substance abuse, which may stimulate more research in this area. Dr. del Rio listed HIV-related concepts approved at the most recent NIDA Council meeting and commended the breadth of science covered by these requests for proposals.

National Advisory Mental Health Council (NAMHC)

Dianne Rausch, Ph.D., Director, Division of AIDS Research, National Institute of Mental Health, NIH

Dr. Dianne Rausch outlined several concepts presented at the May 18, 2021 NAMHC meeting. The concept titled Improving Use of Novel HIV Prevention and Treatment Options Through Behavioral and Communication Science aims to encourage research to improve the use of novel HIV prevention and treatment options through behavioral and communication science. Although ART and pre-exposure prophylaxis (PrEP) are effective, adherence is a challenge. Additionally, any new HIV treatment and prevention options will require clear communication to optimize the uptake. One major issue related to adherence and uptake is the distrust of vaccines, which has evolved particularly quickly on social media. In one study, although the number of participants in antivaccination communication patterns on social media is relatively small, they often are positioned at the centers of social media networks and heavily entangled with clusters of undecided people. Pro-vaccination users tended to communicate among themselves; antivaccination users tended to infiltrate neutral clusters. The scope of this concept includes basic behavioral science and health communications research to understand barriers and facilitators, development and testing of novel behavioral interventions and communication strategies, and implementation science research to optimize messaging and delivery.

The second concept is a renewal of the National NeuroAIDS Tissue Consortium (NNTC), a research resource that supports studies of the pathogenesis of HIV-associated neurological dysfunction in the

context of long-term HIV disease. The NNTC is a critical resource that initially enrolled people with endstage HIV close to death; as treatment has improved, the program has expanded to include following a subset of patients longitudinally and collecting postmortem samples. Objectives of the four clinical sites include maintaining the active cohort through recruitment, community outreach, clinical assessments, and collection of clinical samples; collecting postmortem tissue; assessing pathology; and performing data quality control. The data coordinating center's objectives include managing requests; maintaining research data sets; coordinating data, including specimens and laboratory, clinical, and pathological data; and performing data audits and analyses. The NNTC has acquired data from more than 3,000 participants and is actively following 500 individuals. Considerations for the NAMHC included the scientific, technical, or program significance of the goals; the availability of the technology and resources; the extent to which practical uses for the anticipated results exist; and the adequate inclusion of women, minorities, and children as applicable.

AIDS Research Advisory Committee (ARAC)

Monica Gandhi, M.D., M.P.H., Professor of Medicine and Associate Chief, Division of HIV, Infectious Diseases; Global Medicine Director, UCSF-Gladstone Center for AIDS Research; Medical Director, "Ward 86" HIV Clinic, San Francisco General Hospital

Dr. Monica Gandhi provided updates from the June 7, 2021, ARAC meeting. She noted that the NIAID R01 payline is at the 14th percentile for established principal investigators (PIs) and 18th percentile for new PIs. K applications are at the 20th percentile. Dr. Gandhi acknowledge the importance of the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) Network in developing both therapeutics and vaccines for COVID-19. Dr. Gandhi noted that three R01 FOAs were published in March 2021 for funding in FY 2022 that apply to the treatment, prevention, or epidemiology pillars of the EHE initiative. Each encourages applicants to develop creative, locally defined, and culturally sensitive strategies with local implementing and community partners to address local EHE priorities.

Dr. Gandhi outlined an initiative announced at the recent ARAC meeting on the development of assays for testing susceptibility to broadly neutralizing antibodies (bNAbs) to screen those who carry resistant virus prior to treatment or entry into trials. Current clinical trials of bNAbs enroll participants without knowledge of the susceptibility of the participant's virus to the bNAb, which adversely affects trial outcomes because participants with pre-existing resistance are included in the trials. ARAC participants also discussed the recompete of several coordinating centers in the Regional Prospective Observational Research in Tuberculosis (RePORT) project, a consortium of collaborative, prospective observational research networks in six high tuberculosis- and HIV-burden countries. Another initiative is a new R01 to advance research to discover and validate novel biomarkers of tuberculosis infection and subsequent risk of progression to tuberculosis disease in young children living with and without HIV. The final funding opportunity discussed at the meeting was the Resources to Advance Pediatrics and HIV Prevention Science (RAPPS) program, an N01 reissue RFP to provide drug development resources to support advancement of the next generation of HIV biomedical prevention products and HIV treatment and prevention strategies in maternal and pediatric populations.

Discussion Highlights

In response to a question about leveraging successful collaborations between academia and private pharmaceutical companies, Dr. Gandhi commented that the increased focus on such partnerships at the ARAC meeting may be related to the successes of COVID-19 collaborations. COL Julie Ake commented on an industry collaboration to create an HIV vaccine that is in advanced development stages.

Attendees discussed the importance of communication science around vaccines and the critical nature of uptake and acceptance considerations.

OARAC members commented on the importance of existing research networks in the rapid development of COVID-19 treatments and vaccines, which emphasizes the value of long-term investment in clinical research infrastructure and encouraged the NIH to use this message to justify funding decisions.

Dr. del Rio elaborated on one of the RFAs approved by NACDA—Investigating Transposable Elements and Mobile DNA as Targets of Integration for Establishing HIV Reservoirs in the Brain—which examines sites of latency in the brain. Integration of HIV in microglia likely contributes to HIVassociated neurological effects; addiction, which influences the epigenome, probably can influence these transposable elements and affect how HIV integration occurs at that level. Proposals should assess molecular, genetic, and epigenetic factors and the role of substance abuse in HIV integration. Dr. del Rio noted that this RFA is particularly exciting because of how it combines both basic and very translational research.

Pharmacogenomics of Antiretrovirals and the Importance of Inclusivity in Science

Namandjé N. Bumpus, Ph.D., Director, Department of Pharmacology and Molecular Sciences, Professor of Pharmacology and Molecular Science, Johns Hopkins University School of Medicine

Dr. Namandjé Bumpus explained that her laboratory is interested in understanding the difference in response to drugs—including efficacy and toxicity—at a mechanistic level. She pointed out that science needs to include all people to fully understand how drugs work. The majority of currently marketed drugs are cleared through metabolism; when the body recognizes the drugs as foreign, enzymes act on them to turn them into metabolites, which can be excreted or remain in the body. Drug metabolism controls how much of the drug a patient swallows ends up in the bloodstream, so genetic differences in metabolism can affect the overall level of exposure to the drug. Many classes of drug-metabolizing enzymes exist, but their expression varies among people of different regions of origin. Drug studies have been conducted mostly on younger males of European descent, but whether enzymes are expressed in the study population determines whether the drugs are metabolized. When safety and dose are chosen based on less-diverse studies, these values will not apply to people with different genetic backgrounds. Additionally, many drugs must be phosphorylated to be activated, such as tenofovir (TFV). Some people may experience TFV failure because they genetically are unable to phosphorylate the drug for activation.

Dr. Bumpus and her team investigated which kinases activate TFV in clinically relevant tissues. Several candidate kinases were identified that could perform the first and second steps of activation. When adenylate kinase 2 (AK2) was knocked down in samples from healthy individuals, there was a marked decrease in the first phosphorylation step. Similar experiments with, pyruvate kinases showed a decrease in addition of the second phosphate to TFV. When these experiments were repeated in other tissues, AK2 continued to perform the first activation step, but the kinases involved in the second step differed, showing that TFV activation pathways are cell- and tissue-specific. When these kinases were examined in different individuals from various parts of the world, a significant amount of genetic variance was observed, including more than one variant in some people, suggesting that TFV activation has an individual phenotype. When tested *in vitro*, some AK2 variants exhibited decreased TFV. Dr. Bumpus commented that although adherence is the most common reason for ART failure, some people may be unable to activate the drugs despite adherence.

Dr. Bumpus explained that although clinical tests are planned, these genetic variants are rare. Preliminary analyses are promising. In one test, people taking TFV as part of PrEP were stratified into those with no variants and those that were heterozygous for a variant that Dr. Bumpus's team theorized led to loss of function. In those with variants, TFV levels were undetectable. Dr. Bumpus commented that much translational work remains but this result was encouraging. In another test, variants of creatine kinase— which plays an important role in forming the active compound of TFV—showed decreased TFV

activation *in vitro*. Dr. Bumpus also pointed out that the ARV community often does not consider dephosphorylation of drugs, but genetic variance may affect how quickly phosphorylation is removed, which reiterates the need to look at genetic variants in many people. Genetic differences may link to adverse outcomes. For example toxicity maybe influenced by genetic differences in metabolic ability and stress.

Dr. Bumpus stressed that inclusivity in science is imperative—to create drugs that work for all people, study participants must be diverse. She reiterated that unexpected outcomes may not always be related to adherence but may have biological causes, which can only be understood if trials include everyone. Diversity in the scientific workforce is equally important to advance science. Dr. Bumpus pointed out the need to normalize biological differences that may be small but nevertheless exist and affect patients. She emphasized that science needs to be made a more hospitable place for more people and that the scientific climate must be changed to improve drug effectiveness and fully understand biological mechanisms that affect outcomes.

Discussion Highlights

Council members recognized the importance of this research in both capturing the diversity of the human population in a scientific way and providing a scientific justification for inclusion.

When asked about differences between other ARV drugs, Dr. Bumpus explained that although the studies are in early stages, genetic differences in esterases are clear. The complexity of the drug metabolism process requires providers to think about patients as individuals because, when enough data are gathered, some people will have combinations of genetic variants.

In response to a question about toxicity in pregnancy, Dr. Bumpus replied that the majority of toxicities are related to drug metabolism; fetal metabolizing enzymes are not yet well understood. Changes in blood flow or volume during pregnancy could have effects as well.

When asked what OARAC members can do to advance inclusivity, Dr. Bumpus commented that the NIH is engaged in many initiatives but must fund more researchers and from broader backgrounds. She commented that diverse junior investigators have fewer opportunities to advance to leadership and noted that the disproportionate impact of HIV on people of African descent needs a voice in research.

Dr. Bumpus clarified that although multiple enzymes act on TFV, most enzymes show tissue specificity in expression. The mechanisms of this specificity remain unknown.

Discussion: New Directions for Federal HIV Coordination

Harold J. Phillips, MRP, Director, ONAP, Domestic Policy Council, Executive Office of the President

Mr. Phillips recognized the 40th anniversary of the first description of AIDS, commenting that the U.S. government is taking this time to reflect and honor the 32 million people who have died from AIDS in the United States and recognize the resilience of the HIV community. This occasion provides the opportunity for the U.S. government to recommit fully to working with partners to end the epidemic at home and abroad, as well as to reenergize efforts in the wake of COVID-19. He commented that the U.S. government needs to reengage with many sectors across society and around the world to continue contributions and innovations to end the HIV epidemic. Mr. Phillips noted that the many commemorations in June are an opportunity to return HIV to the forefront of the conversation.

Mr. Phillips reviewed key EHE accomplishments in 2020, including the distribution of \$6 million by the CDC and IHS and the launch of HHS's <u>Ready</u>, <u>Set</u>, <u>PrEP program</u>. Nine new Prevention through Active

Community Engagement (PACE) officers began supporting EHE in three key geographic areas. All 57 geographic areas developed and submitted EHE plans. Programs involved in EHE continued to serve those with and at risk for HIV throughout the pandemic, with an emphasis on equity. The FY 2020 Health Resources and Services Administration (HRSA) Bureau of Primary Health Care (BPHC) Primary Care HIV Prevention (PCHP) Progress Report shows that within 11 months of award, 93 percent of health centers were able to hire new staff between March and August, with nearly 865,000 patients tested for HIV. More than 3,000 patients were diagnosed with HIV and received follow-up within 30 days. Almost 85 percent of PCHP-funded health centers reported more than one newly diagnosed patient linked to care within 30 days. Additionally, nearly 63,000 patients were prescribed PrEP. Data from Ryan White HIV/AIDS Program (RWHAP) EHE-funded providers from March through August show that nearly 6,300 clients who received services during that time were new to RWHAP and an additional 3,600 were re-engaged in RWHAP services.

The <u>America's HIV Epidemic Analysis Dashboard</u> (AHEAD) was launched in August 2020 and upgraded in February 2021 with interactive features, but when data use was examined with an equity lens, Mr. Phillips and his team realized that much remained to be done to make the dashboard accessible, understandable, and relatable. It contains ongoing uploads of new data from all 50 states, a Housing Opportunities for Persons With AIDS (HOPWA) EHE resource locator tool, webinars, and presentations to state and local EHE workgroups. Planned additions include stratified demographic data, data on social determinants of health, strategies to help jurisdictions share best practices, weekly office hours for technical assistance, and a user guide.

Minority HIV/AIDS Fund (MHAF) topics are a way for the Office of the Assistant Secretary for Health to signal what the office prioritizes. FY 2021 topics include NIH EHE team-initiated implementation research, with partnerships with HBCUs; NIH strategies to address social and structural determinants of health using an intersectional approach and examine how communities impacted by HIV face multiple insecurities; and MHAF-funded needs assessments in Title X clinics. PACE officers, who are federal staff working to engage local stakeholders and communities, have been involved in a number of partnerships with pharmacists, faith-based organizations, community-based organizations, and business leaders.

Mr. Phillips commented that EHE remains a priority for the Biden Administration. President Biden has requested \$670 million from Congress for this initiative and committed to helping accelerate and strengthen efforts to end the HIV/AIDS epidemic in the United States. Mr. Phillips emphasized that the administration is continuing core public health issues, including HIV—as well as returning to those issues where focus has shifted during the COVID-19 pandemic—but assessing what the COVID-19 pandemic has revealed about public health needs. He pointed out that many Americans now have a greater understanding of the effects of public health and added that applications to public health schools have increased.

Mr. Phillips outlined ONAP's priorities, beginning with revising the <u>HIV National Strategic Plan</u>. The office plans to build on the existing plan but ensure it reflects the current administration's priorities, including equity, elimination of stigma and discrimination, and access to health coverage. The new plan will include strategies that address social determinants of health, will engage other departments and programs, and will include progress measures. The goal is to release the plan on December 1, World AIDS Day. ONAP's priorities related to social justice, equity, and health care access are designed to ensure that geographic regions and populations are not left behind. Mr. Phillips noted the similarities between HIV and COVID-19 in this area, commenting that studies have suggested that the HIV epidemic can be ended by 2030 in some geographic areas, in line with EHE goals, but in others the goal likely will not be met. ONAP hopes to develop policies, procedures, and programs that can support a more equitable approach. Additionally, the office plans to ensure that the needs of the HIV community are understood and addressed as access to health care coverage continues to expand.

ONAP is developing new partnerships across public and private sectors, such as with federal agencies and programs outside of HHS, agencies inside HHS, faith- and community-based agencies, academic institutions, and such health care providers as pharmacists, oral health providers, nurses, and STI specialty clinics. Behavioral health is an administration priority; screening, linkage, and access to services all must be improved. Mr. Phillips commented that significant work is required to address the stigma of mental health care, but harm reduction and syringe services programs are part of ONAP's plan.

Mr. Phillips commented on the need to accelerate the release and dissemination of information and implementation science results. He added that those in the NIH community are the problem solvers of the U.S. research enterprise and should be looked to when a problem arises. Mr. Phillips suggested that developing a research agenda to address the specific needs of the African American community should be considered. Additionally, the CDC did not include 2-1-1 in its latest guidelines, so NIH partners may need to increase the amount of science available to study 2-1-1 to increase consumer choice about PrEP. Mr. Phillips commented that although the NIH has conducted a significant amount of research on stigma, the implementation of that research must be promoted and supported. He emphasized that addressing the HIV epidemic is a whole-of-society initiative—ONAP sets the pace and tone, but partners are needed to ensure the work is successful, particularly during a global pandemic.

Discussion Highlights

In response to a question about geographic areas not currently part of EHE's priority jurisdictions that may be falling behind, Mr. Phillips explained that ONAP is beginning to review estimates of EHE targets, geographic areas, and time frames in light of COVID-19 and the opioid epidemic. Guidance for areas with lower numbers of HIV cases, based on lessons learned from high-impact areas, is intended for inclusion in the revised National HIV Plan.

OARAC members encouraged Mr. Phillips to reorganize the President's Advisory Council for HIV/AIDS (PACHA), appoint a PEPFAR director, and leverage the efforts related to COVID-19 to improve the HIV field. Mr. Phillips confirmed that as many as 11 vacancies on PACHA can be filled and ONAP intends to add community members and a broad diversity of voices.

When asked about the many overlapping issues in the HIV field—including a potential decrease in testing during 2020 and the need for all future plans to directly address racism—Mr. Phillips planned to raise those concerns, noting the need to secure support for more braided funding streams and creative thinking.

Public Comment

CAPT Mary Glenshaw, Ph.D., M.P.H., OAR, NIH

CAPT Glenshaw summarized three comments received.

The first commenter suggested that individuals infected with HIV should be identified as dangerous, supported criminalization of HIV transmission, and expressed skepticism about the prevalence of racism in America.

Leisha McKinley-Beach, a national HIV consultant, commented that addressing structural racism requires dismantling the current public health system and rebuilding on a foundation of equity, as well as increasing Black leadership and implementing all public initiatives through a human rights and social justice framework.

Jules Levin, executive director of the National AIDS Treatment Advocacy Project, commented on the need for more research and infrastructure improvements to meet the needs of the aging population of persons with HIV.

Closing Remarks and Adjournment

Maureen M. Goodenow, Ph.D., OAR, NIH Blanton Tolbert, Ph.D., Acting OARAC Chairperson, Professor, Case Western Reserve University

Dr. Goodenow thanked the Council members and speakers, and reminded attendees that the October meeting will be virtual.

Dr. Tolbert added his thanks and adjourned the meeting at 4:46 p.m. EDT.

Certification

I hereby certify that, to the best of my knowledge, the foregoing summary minutes of the 57th Office of AIDS Research Advisory Council meeting are accurate and complete.

Blanton S. Tolbert Digitally signed by Blanton S. Tolbert Date: 2021.11.04 16:02:47 -04'00'

Blanton Tolbert, Ph.D. Acting Chair, OARAC Date

Mary Glenshaw -S Date: 2021.12.23 14:56:04 -05'00'

CAPT Mary Glenshaw, Ph.D., M.P.H. Executive Secretary, OARAC

Date