DEPARTMENT OF HEALTH AND HUMAN SERVICES NATIONAL INSTITUTES OF HEALTH NATIONAL CENTER FOR COMPLEMENTARY AND INTEGRATIVE HEALTH NATIONAL ADVISORY COUNCIL FOR COMPLEMENTARY AND INTEGRATIVE HEALTH Minutes of the Seventy-Eighth Meeting September 10, 2021

NACCIH Members Present Virtually

Dr. Belinda Anderson, New York, NY Dr. Todd Braver, St. Louis, MO Dr. Robert Coghill, Cincinnati, OH Dr. Anthony Delitto, Pittsburgh, PA Dr. Roni Evans, Minneapolis, MN Dr. Diana H. Fishbein, University Park, PA Dr. Margaret (Meg) Haney, New York, NY Dr. Richard E. Harris, Ann Arbor, MI Dr. Kendi Hensel, Fort Worth, TX Dr. Tammy Born Huizenga, Grand Rapids, MI Dr. Girardin Jean-Louis, New York, NY Dr. Benjamin Kligler, Washington, DC* Dr. John MacMillan, Santa Cruz, CA Dr. Wolf Mehling, San Francisco, CA Dr. Karen Sherman, Seattle, WA Dr. Lynne Shinto, Portland, OR Dr. Justin L. Sonnenburg, Stanford, CA Dr. Barbara Timmermann, Lawrence, KS Dr. Gloria Yeh, Boston, MA

NACCIH Members Not Present

Dr. Chester "Trip" Buckenmaier, III, Rockville, MD*

*Ex Officio Member

I. Closed Session

The first portion of the seventy-eighth meeting of the National Advisory Council for Complementary and Integrative Health (NACCIH) was closed to the public, in accordance with the provisions set forth in Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C., and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2). A total of 157 applications were assigned to the National Center for Complementary and Integrative Health (NCCIH). Applications that were noncompetitive, not discussed, or not recommended for further consideration by the scientific review groups were not considered by Council. Council agreed with staff recommendations on 84 scored applications, which requested \$34,170,759 in total costs.

II. Open Session Call to Order; Review of Council Operating Procedures

Dr. Partap Khalsa, NACCIH Executive Secretary, convened the open session at 11:40 a.m. ET. The minutes of the May 2021 Council meeting were approved unanimously. Dr. Khalsa noted that oral public comments cannot be given during this virtual meeting, but written comments can be submitted to him by email (Partap.Khalsa@nih.gov) or postal mail within 15 days after the meeting. Comments must be under 700 words. The comments will be added to the Council minutes.

III. NCCIH Director's Welcome and Report

Dr. Langevin welcomed a new ex-officio Council member, Dr. Chester "Trip" Buckenmaier, III, program director and principal investigator for the Uniformed Services University Defense and Veterans Center for Integrative Pain Management. Dr. Buckenmaier has a longstanding interest in pain management and integrative approaches in the military setting.

A potential new NIH entity called the Advanced Research Projects Agency for Health (ARPA-H) is under consideration by Congress and was included in the President's Fiscal Year (FY) 2022 budget at a requested funding level of \$6.5 billion. ARPA-H would accelerate biomedical innovation and adoption of technologies and approaches to revolutionize health care and medicine. The ARPA-H model is similar to that of the Department of Defense's Defense Advanced Research Projects Agency (DARPA), which makes investments in research and development programs to accelerate breakthrough technologies for national security.

Dr. Catherine Bushnell, scientific director of the Division of Intramural Research (DIR), retired in July 2021, but will continue to collaborate with NCCIH as a scientist emeritus at the National Institutes of Health (NIH). Dr. Miroslav (Misha) Bačkonja, who specializes in the clinical assessment of pain symptoms and signs, is joining the DIR as supervisory physician. Other new staff appointments include Dr. Diane Joss, health program specialist, Division of Extramural Research (DER); two new scientific review officers in the Division of Extramural Activities, Drs. Sushmita Purkayastha and Sonia Nanescu; and many new scientists in DIR labs.

The President's budget for NIH for FY 2022 includes a substantial proposed increase in funding for NCCIH, from approximately \$154 million in FY 2021 to \$185.3 million. The budget has been approved by the House of Representatives and is going through the Senate.

The NIH Blueprint for Neuroscience Research, in collaboration with many NIH Institutes and Centers (ICs), has launched an initiative on interoception to improve understanding of brain-body connections. NCCIH has funded seven basic science projects addressing connections between the brain and other organs. These connections may underlie many effects of mind and body therapies. NIH's <u>UNITE initiative</u> aims to study and address fundamental aspects of equity through multiple components. Two requests for applications (RFAs) have been issued. NCCIH is participating in the Trans-NIH Resilience Working Group initiative.

Updates related to COVID-19 include:

- NIH is a partner in the "Say Yes! Covid Test" program (free at-home rapid antigen testing).
- Under its Rapid Acceleration of Diagnostics–Underserved Populations (RADx-UP) program, NIH is funding projects at selected institutions in eight states to build the evidence on how to return students and staff to schools safely and sustainably.
- The Researching COVID to Enhance Recovery (RECOVER) initiative brings together various stakeholder groups to address problems of understanding, treating, and preventing long-term effects of COVID-19; NCCIH is an active participant.

A commentary by Dr. Langevin, "Moving the Complementary and Integrative Health Research Field Toward Whole Person Health," was recently published in *The Journal of Alternative and Complementary Medicine*.

Recent NCCIH-funded research includes:

- A study comparing a single session of a pain management skills intervention with eight sessions of cognitive behavioral therapy in adults with chronic low-back pain
- A study of the effects of medical providers' facial appearance on patient expectations about pain and analgesic treatment
- A study on reservoirs of myeloid cells in the bones of the skull and how they communicate with the brain and the meninges; this has implications for the nervous, immune, and musculoskeletal systems
- A study in the field of gut-brain-microbiota axis research in which the effects of a combination of probiotics and prebiotics (i.e., a "synbiotic") on chronic stress behaviors in rodents were examined

Funding opportunity announcements (FOAs) with NCCIH leadership or other participation include:

- The Common Fund's Faculty Institutional Recruitment for Sustainable Transformation (FIRST) program to empower and enable institutions to recruit and support cohorts of faculty from diverse backgrounds: RFA-RM-21-025
- Program announcements on music and health: PAR-21-100, PAR-21-099, and PAR-20-266
- Reissues (following some modifications) of mind and body clinical research program announcements (PAR-21-240, -241, -242, and -243) to offer more entry points into clinical research and accelerate movement in the field
- Notices of Special Interest (NOSIs): NOT-AT-21-002 for interoception research and NOT-AT-21-006 for fundamental science research on complementary and integrative health approaches
- Notices of Intent to Publish: NOT-AT-21-015 and -016, for the NIH Health Care Systems Research Collaboratory

In collaboration with other ICs, NCCIH held a well-attended 2-day workshop, "Approaches to Effective Therapeutic Management of Pain for People With Sickle Cell Disease (SCD)," in July 2021. An initiative on SCD pain was approved for FY 2022. Two SCD-related Notices of Intent to Publish were released recently, NOT-AT-21-017 and -018.

Following up on the NIH HEAL (Helping to End Addiction Long-termSM) Initiative workshop in 2020 on myofascial pain, NCCIH released NOT-AT-21-012 on developing imaging and other relevant biomarkers of myofascial tissues for clinical pain management.

The Common Fund's Bridge to Artificial Intelligence (Bridge2AI) program has launched. NCCIH is participating, with one potential theme—salutogenesis, the process by which individuals return to health.

The NIH music and health initiative, co-led by NCCIH and the National Institute on Aging, held three workshops from March to August 2021, toward advancing the science on music-based interventions for brain disorders of aging. One planned outcome is a toolkit for research on music and health, including a consolidated set of common data elements for music-based intervention protocols. Archived events can be searched under "Music and Health" on the <u>NIH VideoCast webpage</u>.

A <u>virtual workshop on methodological approaches for whole person research</u> will take place on September 29 and 30. A virtual workshop, "<u>Precision Probiotic Therapies</u>—<u>Challenges and Opportunities</u>," will be held on November 5 and 8.

On November 2, NCCIH will sponsor a virtual lecture in the Integrative Medicine Research Lecture Series, "Reading Between the Tweets: Social Technologies for Predicting and Changing Health Behavior," by Dr. Sean Young of the University of California, Irvine. The 2021 Stephen E. Straus Distinguished Lecture in the Science of Complementary Therapies will be given by Professor Rhonda Magee, University of San Francisco School of Law, on December 15, 2021. Her topic will be how mindfulness may help people deal with the challenges of racism and social identity-based bias.

Discussion: Dr. Mehling praised the presented work of the Center. Dr. Anderson commented that the potential budget increase is exciting, including funds for research on the opioid crisis. In response to a question from Dr. MacMillan on ARPA-H, Dr. Langevin said NCCIH hopes it comes to pass, and NIH has already had some listening sessions. ARPA-H could be an exciting opportunity to develop translational technologies to be used in the real world; the focus is not only basic science but also serving patients. Dr. Kligler commented that this kind of high-powered approach to address complex systems is needed at the Department of Veterans Affairs (VA), including as it pushes its Whole Health care approach. Dr. Haney asked whether preliminary feedback would be provided by ARPA-H (as DARPA does) on whether an applicant's initial idea should go forward. Dr. Langevin explained the "Innovation Funnel" model, which has been used successfully for the NIH RADx program and is similar to that in venture capital funding. Dr. Yeh applauded NCCIH and its leadership and commented she has seen the Center grow and become more of a voice and force across NIH. Dr. Langevin thanked Dr. Yeh and noted that the Center builds on prior successes and a solid foundation. Dr. Evans offered congratulations on the work in progress. Dr. Sherman said it is outstanding that NCCIH is demonstrating whole person health (WPH) to NIH in its various initiatives. Dr. Kligler said Dr. Langevin's and NCCIH's leadership is important not only to NCCIH and NIH but to the field of integrative health and to the American health care system. Dr. Langevin expressed excitement about the upcoming WPH research workshop. Dr. Mehling commented that he is seeing orthopedists noticing NCCIH initiatives more. Dr. Langevin responded that one NCCIH goal is to reach more into medical specialties that were not previously aware of the relevance of its work.

IV. Update on the NCCIH Division of Intramural Research (DIR)

Dr. David Shurtleff, acting director of the DIR, thanked Dr. Bushnell and highlighted her accomplishments at NIH since 2012, including building the DIR, hiring staff, and establishing its mission and direction.

The DIR's mission is to conduct basic, clinical, and translational research focusing on the role of the nervous system, other physiological systems, and psychosocial factors in perceiving, modifying, and managing pain. It also strives to provide a rich environment to train and develop the next generation of researchers. Over the next several years, the DIR plans to expand on past accomplishments to encompass a multidisciplinary, collaborative research program with strong epidemiological, clinical, translational, and basic research. This includes cutting-edge pain research; a robust and diverse environment that trains and supports the next generation of pain researchers; expanded presence of pain research at NIH; a strong commitment to equity, diversity, and inclusion in the pain research field; and service to patients with pain and to the NIH Clinical Center (CC).

Dr. Maryland Pao of the National Institute of Mental Health has been NCCIH DIR acting clinical director for 2 years. Dr. Bačkonja will start soon as supervisory physician. DIR has three principal investigators/lab chiefs: Dr. Lauren Atlas of the Section on Affective Neuroscience and Pain, Dr. Alexander Chesler of the Section on Sensory Cells and Circuits, and Dr. Yarimar Carrasquillo of the Section on Behavioral Neurocircuitry and Cellular Plasticity. Additionally, Dr. Yuanyuan (Kevin) Liu is a Stadtman Tenure-Track Investigator with a joint appointment at NCCIH and the National Institute of Dental and Craniofacial Research.

The new NIH Pain Research Center, of which Dr. Shurtleff is acting director, was established in 2020 within the CC and is led by NCCIH. It has 11 participating ICs and will serve as a magnet to pull together and support NIH

collaborative intramural research on pain. Its mission is to identify and better understand mechanisms of diverse pain states, develop and test personalized therapies to better manage pain or prevent the development of chronic pain and opioid abuse, and predict individual patient response to therapies and pain outcomes. Studies are underway on sickle cell disease, pain perception, influences on pain expression and assessment, rare somatosensory processing disorders, mechanoreceptors and tactile allodynia, technology development based on induced pluripotent stem cells, and vagus nerve stimulation in relation to pain and affect. Dr. Shurtleff expressed excitement about the center and the future of the NIH intramural research program.

Discussion: Dr. Fishbein asked whether there are opportunities for short-term internships in the DIR. Dr. Shurtleff said that the division is open to these kinds of collaborations and sees bidirectional benefit in them.

V. Presentation by Dr. Alexander Chesler on "Molecules, Cells, and Circuits for Touch and Pain"

Dr. Chesler, a molecular neuroscientist by training, leads the DIR section focused on increasing understanding of the distinct subtypes of mechanosensory neurons (mechanosensation is the ability to detect mechanical stimuli such as pressure and stretch), the molecular architecture underlying force transduction, and the physiological roles these molecules and cells play in touch and pain.

PIEZO2 is a stretch-gated ion channel shown to be critically important for detection of mechanical stimuli. Ongoing studies at the CC are focused on patients who have profound but selective deficits in mechanosensation caused by damaging mutations in the *PIEZO2* gene. In this work, Dr. Chesler collaborates with Dr. Carsten Bönnemann, a senior investigator at the National Institute of Neurological Disorders and Stroke (NINDS) who discovered *PIEZO2* mutations in 2014. This rare disorder's symptoms include skeletal abnormalities such as progressive scoliosis and contracted joints in the hands and feet, problems with proprioception (a "sixth sense" describing awareness of one's body in space), and difficulties with other tactile senses. If patients are blindfolded, they have difficulty with tasks that most people take for granted such as walking, reaching, and grabbing objects. Changes in just two bases out of the 3 billion in the human genome are sufficient to cause this dramatic phenotype. The CC patients had previously consulted other providers and clinics about their neuromuscular problems but diagnoses and explanations were elusive.

Studies in patients and mice have helped define the role the *PIEZO2* gene plays in mechanosensation and how select sensory inputs affect perception and touch. Related publications from Dr. Chesler's group include major reports in the *New England Journal of Medicine* (2016), *Science Translational Medicine* (2018), *Nature* (2020), and *Neuron* (2021).

Dr. Chesler and his team plan to continue dissecting the molecules, cells, and neural circuits for mechanosensation, a line of research that shows promise for better understanding of pain and interoception (two NCCIH research priorities). Furthermore, it is hoped future work on the cellular and molecular underpinnings of PIEZO2 will eventually inform clinical care for patients with this rare inherited disease. Members of his section have been innovative in discovering or modifying many techniques and technologies to answer questions and facilitate discovery. What Dr. Chesler finds most fascinating about the PIEZO2-deficient patients is not what they cannot do but what they can do. He stated how gratifying it has been to be part of the NIH Intramural Program because of the ability to work across NIH.

Discussion: Dr. Haney praised this work and asked what earlier diagnoses these patients have typically received. Dr. Chesler said that patients had generally visited multiple specialty clinics, particularly for evaluation of scoliosis. Dr. Harris asked whether a human or a rodent model with a knockout of, or deficiency in, PIEZO2 would respond to something like acupuncture that involves internal sensation. Dr. Chesler said he did not know, but his group would like to find out more, for example, about what systems are engaged when acupuncture needles are inserted and twisted during treatment. Dr. Shurtleff said Dr. Chesler's work in translating basic

science to clinical studies demonstrates that having an NCCIH presence in the NIH CC is beneficial to collaboration and answering questions.

VI. Introduction to the NIH Office of Nutrition Research (ONR)

Dr. Christopher J. Lynch, acting director of the NIH ONR, explained that over the past several years, NIH has been bolstering nutrition research in light of the broad impact that nutrition has on health and disease. This interest is cross-cutting across many NIH ICs. In May 2020, NIH announced its first-ever agency-wide strategic plan for nutrition research, the goal of which is to further advance the science and address diet-related diseases across the lifespan. In January 2021, after a period of study and comment from the research community and the public, NIH transferred the ONR from the National Institute of Diabetes and Digestive and Kidney Diseases to the NIH Office of the Director's Division of Program Coordination, Planning, and Strategic Initiatives. This reorganization positions the ONR to enhance engagement of the ICs in implementing the strategic plan, develop new collaborations and relationships within and outside NIH, and ensure coordination and leadership for nutrition research across NIH.

ONR's mission is to advance nutrition science to promote health and reduce the burden of diet-related diseases. Its four strategic objectives are to (1) spur discovery and innovation through foundational research; (2) investigate the role of dietary patterns and behaviors for optimal health; (3) define the role of nutrition across the lifespan; and (4) reduce the burden of disease in clinical settings.

The implementation strategy for the plan includes NIH-wide activities and initiatives, including implementation working groups (IWGs) on topics such as nutrition and health disparities. A virtual workshop, "Food Insecurity, Neighborhood Food Environment, and Nutrition Health Disparities: State of the Science," is scheduled for September 2021, and a request for information on research to end hunger, food insecurity, and nutrition insecurity has been released (NOT-OD-21-183).

Dr. Lynch discussed the <u>Nutrition for Precision Health program</u> (NPH), a Common Fund program powered by NIH's <u>All of Us Research Program</u>. Each participant undergoes complete genome sequencing, which informs their medical-genetic report. NPH will add more tools to help researchers use these data and will build on other recent advances in biomedical science such as artificial intelligence, machine learning, and microbiome research.

NPH's primary goal is to develop algorithms to predict individual responses to foods and dietary patterns, using a comprehensive set of microbiome, genomic, physiological, metabolic, behavioral, cognitive, contextual, electronic health record, survey, and environmental data, in large, diverse cohorts of participants. Secondary goals are to improve dietary assessment methods and to serve as a nutrition science discovery engine. Innovative aspects of the program include (1) an option to house study participants in special "domiciles" that will greatly facilitate dietary/nutritional assessment and reporting and (2) study data not being owned by investigators, but free to everyone.

The first awards under RFA-RM-21-005 will be made in early 2022, and after a planning year, the first participant is expected to be enrolled in early 2023.

Dr. Lynch also described ONR's NIH Research on Nutrition Listening Sessions (NutRitioNaLS) program. Because in-person meetings are often not possible at present, virtual sessions between nutrition research stakeholders (e.g., trainees, scientists, and groups) and relevant ONR staff are being offered.

Discussion: Dr. Sonnenburg asked whether biobank samples will be archived, and investigators will be able to apply for access for independent research. Dr. Lynch said yes; he hopes the ICs will be interested in sponsoring RFAs for ancillary studies. Dr. Sonnenburg recommended population-level, public-health implementation of some of the findings, which could be done before pursuing precision approaches. Dr. Lynch commented that this

appears more efficient, but he then gave an example in which it was done in a hospital setting and many patients did not show improved outcomes. For cost versus benefit, it is better to identify who could benefit from specific approaches. Dr. Sonnenburg hoped to see participants followed beyond the timeframe of the strategic plan, and Dr. Lynch noted a 5-year time limitation.

Dr. Langevin asked whether there would be value in NPH obtaining information about people's physical activity and sleep. Dr. Lynch said he expects so and mentioned the utility of technologies such as sensors, wearables, and cellphones. Dr. Craig Hopp of the NCCIH Division of Extramural Research (DER) asked whether NPH could also be designed to investigate the benefits of dietary supplements. Dr. Lynch said that the team will have to assess in the first group whether the participants take supplements. A micronutrient-deficient diet such as a highcarbohydrate diet has been suggested to ONR by outside groups; this could clarify which genes or pathways are associated with, for example, resilience. Two of the questions that interest NCCIH are (1) whether supplementation is as effective in deficiency as other routes and (2) what happens with supraphysiological doses of supplements.

VII. NCCIH Clinical Trials Oversight and Clinical Research Toolbox

Dr. Robin Boineau, acting director and medical officer of the NCCIH Office of Clinical and Regulatory Affairs (OCRA), presented this follow-up to two earlier presentations to Council.

After an applicant receives a Notice of Award for an NCCIH grant, the applicant has many things to think through and do. OCRA has had ongoing conversations with Council members on the knowledge and tools that would better assist investigators in being successful in these processes and NCCIH interactions. Conversations took place with investigators as well. Much of this effort originates from a movement of harmonization taking place across NIH to increase the rigor and reproducibility of its funded research. The major themes that NCCIH heard in these conversations were that the Center should provide:

- A rationale for the process
- More timely information to allow for planning
- Additional training on the clinical trials process and NCCIH's role in oversight
- Print resources (to be developed)
- A "buddy system" to guide investigators

Oversight and oversight levels are necessary to help investigators meet NIH requirements for clinical studies; minimize risks to participants; maximize the chances for success, scientific potential, and impact in funded work; enhance the likelihood of publication in high-impact journals; and ensure good stewardship of government funds. NCCIH recently established six oversight levels, as explained on the NCCIH <u>Clinical Research Toolbox</u> <u>webpage</u>. As NCCIH rolls out this new information, it plans to provide training information to the extramural community through the NCCIH blog, a webinar, sessions at training meetings and at conferences, and an FAQ page.

Discussion: Dr. Sherman said that a logical and concise process like this makes much sense. Dr. Evans requested more clarity on the indications for site monitoring, and Dr. Boineau responded that NCCIH looks very carefully at each grant, including factors that drive the level of oversight—for example, some populations are very hard to recruit. The process is not a "cookbook" but rather one of NCCIH staff looking at the different elements and talking them through.

Dr. Coghill asked what is being done to ensure grants can start in a timely fashion. Dr. Boineau thinks that letting everyone know about the entire process will be helpful. Also, it is very important for investigators to answer all the comments from the first review. Sometimes, in trying to turn things around quickly, grantees miss some

elements. Any back-and-forth adds more time to the protocol review process. Dr. Boineau also thinks breaking down a timeline is helpful. Dr. Emmeline Edwards, director of the DER, said that good communication and partnership between NCCIH and investigators and transparency in the process are likely to support a project starting on time and continuing to progress.

Dr. Fishbein commented that she and others have experienced long delays, and these changes should systematize the process and open channels of communication so delays will not occur. Dr. Boineau confirmed this and mentioned that Dr. Fishbein's experience as an NCCIH-funded investigator is helpful. Dr. Edwards added that NCCIH is very much paying attention to the time element in this process. Dr. Shurtleff commented that this endeavor has been a 20-year one, and in recent years NCCIH has "taken a scalpel to the process" and found the pressure points. Continued feedback will be important.

VIII. Two Reports on the NCCIH/VA Workshop on Well-Being Measurement

Dr. Edwards gave a high-level overview of the NCCIH perspective on "Enhancing Well-Being Measurement in Health Research, Clinical Care, and Population Health Promotion," a workshop on June 14, 2021 co-organized by NCCIH and the VA. (A <u>summary of the workshop</u> is available on NCCIH's website.)

The concepts of most importance and interest to NCCIH for this meeting were inclusion of well-being measures in health research, clinical care, and population health promotion; moving more toward a consensus on approaches to well-being measurement; the relationship between well-being and health; and issues of health equity and measurement of well-being in diverse populations. Dr. Edwards saw much synergy between the meeting and NCCIH research priorities such as the Emotional Well-Being (EWB) Research Program—a trans-NIH program—and WPH in the NCCIH strategic plan.

High-priority research topics for the six EWB research networks are ontology and measurement of EWB, mechanisms of EWB in health, biomarkers of EWB, the relationship between EWB and prevention, technology and outcome measures for mechanistic studies of EWB, and development and validation of EWB measures. All projects include an emphasis on EWB measurement. Another area to explore is the relationship between well-being and WPH. An individual's sense of well-being could contribute to WPH by promoting health-enhancing behaviors and vice versa; if so, that relationship would be bidirectional and positively reinforcing. Upcoming activities include a workshop in September 2021 at the Harvard T.H. Chan School of Public Health on the impact of prosocial behavior on individual and societal health and well-being, a meeting in spring 2022 for principal investigators in NIH's EWB networks, two lectures in spring 2022 on EWB topics as part of NCCIH's Integrative Medicine Research Lecture Series; and future collaborations with the VA.

Dr. Benjamin Kligler, National Director, Integrative Health Coordinating Center, Office of Patient Centered Care and Cultural Transformation, Veterans Health Administration, U.S. Department of Veterans Affairs, explained that "Whole Health" is an approach to care used by the VA that is closely related to NCCIH's WPH. As this approach has been implemented, it has generated increased interest within the VA in well-being promotion, not just disease prevention. Assessments within VA health care continue to be limited primarily to measurement of health symptoms and conditions, and there is a need to effectively measure well-being.

Dr. Kligler spoke highly of the VA's collaboration experience with NCCIH on this workshop. Very high levels of interest, attendance, and uptake were evident among attendees. The event's main goal was to "think and link," or encourage conversations among people who work on this topic in various sectors and organizations. Dr. Kligler gave as his takeaways:

• Different perspectives exist on the relationship between health and well-being, but there was consensus that poor health can coexist with some aspects of well-being.

- There was diversity in how well-being is defined and measured but a common focus on whether people are doing well rather than experiencing disease/dysfunction.
- Concern was evident that some indicators of well-being may not be achievable for all individuals (e.g., racial/ethnic disparities may exist in some aspects of EWB).
- Many approaches focus on internal indicators of well-being (e.g., happiness, satisfaction, sense of purpose).
- Well-being measurements could target social determinants of health (e.g., social isolation, financial instability).
- Some approaches also consider external indicators of well-being (e.g., objective life circumstances/functioning in key life roles).

Dr. Kligler hopes that in 2022 the VA will be able to support a larger meeting on well-being measurement, and if so, he would again like to collaborate with NCCIH.

The field needs a clinical tool that is compact, short, and easy enough to readily use in clinical practice to measure everyday life functioning. Dr. Dawne Vogt of the VA's National Center for PTSD (PTSD is post-traumatic stress disorder) has developed a tool with three questions in plain language that assess satisfaction, status/role involvement, and role functioning. The tool will be piloted in various clinical settings in six facilities over the coming year. VA will assess effective strategies for its implementation prior to large-scale rollout in 2023. As part of routine clinical care, it would help change patient/provider conversations so that well-being and health creation are routinely discussed with veterans.

Discussion: In response to a question from Dr. Edwards, Dr. Kligler said that this measurement tool has been validated so far in veterans only, but there is definite potential and interest, including from a practice-based research network, in wider testing. Dr. Anderson asked how translatable this work in the VA system will be to mainstream care. Dr. Kligler responded that this is a big question that raises other questions, such as whether the United States will ever move to value-based care. If U.S. health care systems are still stuck in a volume-based, fee-for-service model, that will pose the biggest barrier. VA is having a conversation with the Centers for Medicare & Medicaid Services and has seen some interest in potentially working the tool into some demonstration projects.

Dr. Sherman commented that the conversations are changing in her organization, if more slowly than in the VA, on integrated health and a more holistic view. If consumers want complementary and integrative modalities and providing them would make a health care system stand out more in the market, this will likely move forward. Dr. Kligler commented that the VA is cosponsoring a consensus panel at the National Academies of Medicine to examine models of whole person care, which should be informative about the landscape.

IX. Concept Clearance: Fostering Mental, Emotional, and Behavioral Health Among Children in School Settings: Opportunities for Complementary and Integrative Health

Dr. Della White, a program director in the DER, opened her presentation by noting that a series of reports since 2019 have sounded alarms regarding the importance of mental, emotional, and behavioral (MEB) health development among children and youth. Other themes include the importance of achieving behavioral health equity and the need to develop a life-course model to help young people transition to adulthood with better health in these areas. NCCIH cosponsored a workshop at the National Academies on "The State of Mental, Emotional, and Behavioral Health of Children and Youth in the United States," with the report released in 2019.

MEB disorders often manifest first in childhood or adolescence. They contribute to high rates of disability, school dropout, cardiovascular and metabolic diseases, lost years of productivity, incarceration, and homelessness, and

they impact academic performance. MEB health is intrinsically linked to physical health. Children have limited access to MEB health services, especially in low-resource communities and among racial/minority and underserved youth. Promotion of MEB health and early prevention of MEB disorders are important for overall child development and the transition to adulthood. Schools have become key points for accessing MEB health and preventing MEB disorders.

This concept's goal is to contribute to the evidence base on complementary and integrative health approaches for promoting MEB health and preventing MEB disorders. Objectives are to support studies to rigorously test these approaches to promote healthy MEB development and/or prevent MEB disorders in school settings; examine MEB health as well as the impact on the whole child, including academic and physical health outcomes; focus on reducing health disparities and advancing MEB health equity among children in underserved and low-resource school settings; and assess multiple levels of influence on MEB health outcomes (e.g., individual, interpersonal, community, and societal). NCCIH will continue to work with other ICs to identify ways to support research on implementation strategies. Council unanimously approved this concept.

X. Concept Clearance: Expansion of NIH-DoD-VA Pain Management Collaboratory Research Activities

Dr. Peter Murray, a program director in the DER, presented this concept. The NIH-Department of Defense (DoD)-VA Pain Management Collaboratory (PMC), which began in 2017, has as its overall goal to test implementation and evaluation of nonpharmacologic approaches for pain management and common co-occurring conditions in the military and veterans' health care systems. The program will end in 2023–2024, and NCCIH sees an opportunity to build resources and expand the research to areas not currently addressed.

Previously, the PMC funded 11 large-scale, multisite, pragmatic clinical trials (called Demonstration Projects) and a Pain Management Collaboratory Coordinating Center (PMC3). A few ad hoc working groups have also been formed. This concept would use phased cooperative agreement research applications to conduct efficient, large-scale, pragmatic clinical trials as the next phase of Demonstration Projects. The focus on nonpharmacologic interventions will remain, but there will be more emphasis on dissemination and implementation research for interventions with demonstrated effectiveness. The coordinating center will learn and disseminate best strategies for implementing effective nonpharmacologic pain management interventions into the VA and DoD health care systems. It will also create a data sharing plan that would allow long-term storage and platforms to facilitate cross-project analyses. Council unanimously approved this concept.

XI. Reminder of How To Submit Public Comments

Dr. Khalsa reminded the audience that public comments could be sent to him by email or postal mail. Comments are limited to 700 words. If submitted within 15 days after this meeting, the comments will be included in the meeting minutes.

"From: jean public <jeanpublic1@gmail.com>
Sent: Monday, July 12, 2021 10:26 AM
To: Khalsa, Partap (NIH/NCCIH) [E] <<u>khalsap@mail.nih.gov</u>>
Subject: Re: CALL OUT THE CDC FOR POLITICS NOT HEALTH AT ALL

908-4550750 FLEMNIGTON NJ JEAN PUBLIEE

i do not know how we can have our health agencies taken over by politics so that science does not exist at these federal agencies anymore. they have been captured by big pharma and profiteers so that health is not an issue for them anymore, nor is open science where different findings are mediated instead of the dictatorial approach of a fauci who decides he is "science". i very much find that kind of approach appalling and want open science. science needs to be open and debate needs to happebn, not political dictatorship a la fauci. this comment is for the public record. i have lost faith in our health agencies because of the total corruption gonig on. please receipt. jean publee jean <u>public1@gmail.com</u>"

XII. Final Comments and Adjournment

Dr. Khalsa reviewed the process to submit public comments. Dr. Langevin thanked the members for their engaged attention, support, comments, and feedback, adding that NCCIH truly relies on them and she wants the process to be ongoing. The meeting was adjourned at 4:20 p.m. ET.

Partap S. Khalsa, D.C., Ph.D., D.A.B.C.O. Executive Secretary National Advisory Council for Complementary and Integrative Health Helene Langevin, M.D. Chairperson National Advisory Council for Complementary and Integrative Health