U.S. Department of Health and Human Services
National Institutes of Health

Minutes of the First Joint Meeting of the National Advisory Council on Alcohol Abuse and Alcoholism, National Advisory Council on Drug Abuse, and National Cancer Advisory Board

December 13, 2012
Teleconference/Web Meeting Originating in
Bethesda, Maryland

The National Advisory Council on Alcohol Abuse and Alcoholism, National Advisory Council on Drug Abuse, and National Cancer Advisory Board convened for their first joint meeting at 11:30 a.m. on December 13, 2012. The meeting originated at National Institutes of Health (NIH), Bethesda, Maryland, chaired by Dr. Lawrence A. Tabak, Principal Deputy Director, NIH.

National Advisory Council on Alcohol Abuse and Alcoholism Members Present:

Andrea G. Barthwell, M.D.
Linda L. Chezem, J.D.
Fulton T. Crews, Ph.D.
Marianne L. Fleury
Andres G. Gil, Ph.D.
Kathleen Grant, Ph.D.
Andrew C. Heath, D.Phil.
John H. Krystal, M.D.
Craig McClain, M.D.
Edward P. Riley, Ph.D.
Linda P. Spear, Ph.D.
Gyongyi Szabo, M.D., Ph.D.
Daniel R. Kivlahan, Ph.D. (ex officio)

National Advisory Council on Drug Abuse Members Present:

Nabila El-Bassel, D.S.W.
Elizabeth F. Howell, M.D.
Terry L. Jernigan, Ph.D.
Thomas A. Kirk, Ph.D.
Robert H. Lenox, Ph.D.
Caryn E. Lerman, Ph.D.
Barbara J. Mason, Ph.D.
Michael A. Nader, Ph.D.
John P. Rotrosen, M.D.
Steven M. Wolinsky, M.D.

National Cancer Advisory Board Members Present:

Tyler E. Jacks, Ph.D.
Bruce A. Chabner, M.D.
Waun Ki Hong, M.D.
Beth Y. Karlan, M.D.
H. Kim Lyerly, M.D.
Michael A. Babich, Ph.D. (ex officio alternate)
Patricia Bray, M.D. (ex officio alternate)
Michael Kelley, M.D. (ex officio alternate)
Michael Stebbins, Ph.D. (ex officio alternate)

Chair: Lawrence A. Tabak, D.D.S., Ph.D.

National Institute on Alcohol Abuse and Alcoholism (NIAAA) Acting Director: Kenneth R. Warren, Ph.D.

National Institute on Drug Abuse (NIDA) Director: Nora D. Volkow, M.D.

National Cancer Institute (NCI) Division of Cancer Control and Population Sciences Director: Robert Croyle, Ph.D.

Special Assistant to the Principal Deputy Director, NIH: Justin D. Hentges, M.P.P.

NIDA Senior Staff:

Anto Bonci, M.D.; Wilson Compton, M.D., M.P.E. ; Gaya Dowling, Ph.D.; Joseph Frascella, Ph.D.; Steven Grant, Ph.D.; Steve Gust, Ph.D.; Susan Harrelson, Ph.D.; Teresa Levitin, Ph.D.; Jacques Normand, Ph.D.; Joni Rutter, Ph.D.; David Shurtleff, Ph.D.; Jack Stein, Ph.D.; Susan Weiss, Ph.D. ; Cora Lee Wetherington, Ph.D.

NIAAA Senior Staff:

Abraham P. Bautista, Ph.D.; Vivian B. Faden, Ph.D.; Lorraine Gunzerath, Ph.D.; Robert Huebner, Ph.D.; Howard Moss, M.D.; Gary Murray, Ph.D.; Ph.D.; Peggy Murray, Ph.D.; Antonio Noronha, Ph.D.

NCI Senior Staff:

Paulette S. Gray, Ph.D., Ms. Claire Harris, George Komatsoulis, Ph.D.

Additional Participants:

Approximately 155 observers joined the meeting, including federal staff, representatives of constituent groups, liaison organizations, and members of the general public

Call to Order and Introductions

Dr. Lawrence A. Tabak called to order the first joint meeting of the National Advisory Council on Alcohol Abuse and Alcoholism, National Advisory Council on Drug Abuse, and National Cancer Advisory Board in open session at 11:35 a.m. on Thursday, December 13, 2012, and welcomed participants.

Review of Policy and Procedures

Mr. Justin D. Hentges, Special Assistant to NIH's Principal Deputy Director, reviewed policy and procedures regarding rules of conduct and conflict of interest as set forth in the report "Standards of Ethical Conduct for Employees of the Executive Branch."

Future of Substance Use, Abuse, and Addiction-Related Research at the National Institutes of Health

Dr. Lawrence A. Tabak began his overview of the new Trans-NIH Substance Use, Abuse, and Addiction Integration Plan with a brief organizational history of NIH's research in these areas. In the mid-1960s the precursors of NIAAA and NIDA were established as Centers within the National Institute of Mental Health (NIMH), and in 1971 NIAAA became an Institute within NIMH. In 1973 Congress created the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), with NIMH, NIAAA, and the newly created NIDA as equal entities in the new Agency. The U.S. Senate requested a position statement from the Department of Health and Human Services in 1987 on the organization of basic research and health services programs, and in 1992 ADAMHA was dissolved, with NIMH, NIDA, and NIAAA transferred to NIH as independent Institutes. ADAMHA's services component became the Substance Abuse and Mental Health Services Administration (SAMHSA). Responding to a 2003 congressional request, the National Academies of Science recommended that NIH study whether NIAAA and NIDA should be merged.

Dr. Tabak explained that in April 2009 the Scientific Management Review Board (SMRB) was charged to study whether organizational change within NIH could further optimize research into substance use, abuse, and addiction (SUAA), and maximize human health and/or patient well-being. Feedback was elicited through intensive discussion with many stakeholders, two public forums held by the SUAA Working Group, input from Council members, and public deliberations by the SMRB.

The SMRB's Working Group analyzed the issues and presented two options to the SMRB: (1) form a Trans-NIH Initiative on Substance Use, Abuse and Addiction that would preserve existing Institutes and Centers (ICs) intact and integrate relevant addiction-related research portfolios; or (2) create a new Substance Use, Abuse and Addiction Institute that would focus on addiction research and related public health initiatives, integrate the relevant research portfolios from NIAAA, NIDA, and other ICs (notably NCI), dissolve NIAAA and NIDA, and transfer unrelated research to other relevant ICs across NIH.

SMRB members concurred on the need for some form of reorganization of SUAA-related research that would encompass all NIH addiction-related research. By a vote of 12-3-1 the SMRB recommended that the "NIH director ... move to implement ... the establishment of a new institute focusing on addiction-related research and public health initiatives." NIH agreed with the SMRB's findings that the current organization of SUAA-related research does not optimally capitalize on existing and potential synergies, and that the optimal organization must encompass all SUAA-related research at NIH. The optimal organization would better enable recognition and development of scientific opportunities in SUAA research, assist in meeting public health needs, and improve training opportunities for the next generation of investigators.

To address these matters, the NIH Director established a Substance Use, Abuse, and Addiction Task Force in December 2010, chaired by Drs. Tabak and Steven Katz (Director, National Institute on Arthritis and Musculoskeletal and Skin Diseases), to analyze the portfolio across the Agency and recommend the optimal organization to enhance this area of research. Science was the primary driving factor in the analysis. Through fall 2012 the SUAA Task Force gathered input from potentially affected IC scientific staff on IC programs and scientific rationale for inclusion (or potential exclusion) in the optimal organization. The SUAA Task Force also conducted an extensive analysis of the NIH portfolio.

Concomitant with SUAA Task Force efforts, a Scientific Strategic Planning Committee began in July 2011 to develop a draft Scientific Strategic Plan to identify new opportunities and synergies for SUAA research to complement existing priorities. Through fall 2012 the committee gathered input from NIH scientific staff and external stakeholders. Based on extensive input, the planning committee developed a draft strategic plan that focused on new scientific opportunities, including 40 recommendations in four areas: basic sciences, prevention sciences, treatment sciences, and medical consequences. Potential opportunities include poly-substance use and abuse, comorbidities of addiction and other diseases (e.g., schizophrenia and smoking), and design of clinical trials to represent the populations that are treated. (The draft plan is accessible at http://feedback.nih.gov/index.php/suaa/nih_suaa_integration.)

During this time, NIH leadership observed an increased level of joint efforts between NIAAA and NIDA staff. In the Intramural Program, for example, a single clinical director was named to oversee both NIAAA and NIDA intramural programs; a joint intramural effort, Collaboration on Addition Genetics, was established; and discussions have been underway to establish a joint Optogenetics Laboratory. Among extramural programs, a joint funding opportunity announcement for prevention will be issued to benefit U.S. military personnel, veterans, and their families; NIDA's Seek, Test, Treat, and Retain (STTR) program is expected to be expanded to include primary alcohol dependence; other joint HIV initiatives are in the development pipeline; NIDA provided support for the NIAAA Longitudinal Adolescent Initiative; and NIDA provided support for the NIAAA epidemiologic survey on alcohol, drug, and mental health comorbidities. Plans are underway to support research to develop and test a combined tool for screening and brief intervention for alcohol, tobacco, and other drugs that is compatible with electronic health records.

Based on significant strides by NIAAA and NIDA over the previous two years, NIH Director Francis Collins announced in November 2012 that NIH would pursue functional integration to support SUAA research in the future and to achieve the SMRB's goal to change the status quo. Success stories to date for functional integration include the NIH Neuroscience Blueprint, which involves 15 ICs that voluntarily organize synergistic, complementary activities otherwise impossible for a single IC. Budgetary challenges represented a strong impetus to focus the agency's energies on the spectrum of NIH's biomedical research enterprise, rather than on a narrow set of issues.

Dr. Tabak explained that Trans-NIH Substance Use, Abuse, and Addiction Functional Integration will involve membership across NIH led by a steering committee of the directors of NIAAA, NIDA, and NCI. NIH envisions Councils' participation in the process, with designated staff from NIAAA, NIDA, and NCI, along with other ICs, to support the functional integration. The Strategic Plan will serve as a blueprint for the Functional Integration Steering Committee. Clear metrics will assist ongoing evaluation to ensure that the process meets the relevant mission, and future refinements are anticipated. Next steps will include a regular series of planning and monitoring discussions by the Steering Committee, which will develop further initiatives for FY 2014 and beyond with outreach and consultation with stakeholders.

The Steering Committee will assess and determine an appropriate joint funding target for FY 2014 and for subsequent years, informed by portfolio turnover and the amount of research the ICs conduct. Opportunities will be developed for discussion of additional areas of integration, and an appropriate schedule for Joint Council meetings will be determined. The Steering Committee will report on progress of activities to all three Councils at their January/February meetings.

Dr. Nora Volkow, Director, NIDA, asserted that functional integration offers opportunities to attend to substance use disorders across NIH and establishes a forum to integrate research on aspects of comorbidity that have not fared well in the past. Dr. Kenneth Warren, Acting Director, NIAAA, expressed NIAAA's enthusiasm for this opportunity, noting leadership's awareness for many years that a number of initiatives are best addressed together. Dr. Warren concurred with Dr. Volkow's view of the need to address comorbidities, noting in particular the need to investigate comorbidity of drugs, alcohol, and tobacco with psychiatric and other diseases. Dr. Robert Croyle, Director, Division of Cancer Control and Population Sciences, NCI, stated that tobacco control remains the most relevant topic for NCI, which currently participates in a trans-NIH interest group, an FDA/NIH group that coordinates tobacco regulatory science, and an HHS-wide tobacco control steering committee. He expressed interest in expanding work in comorbidities and in stimulating discussion across ICs to leverage research infrastructure, including epidemiological cohorts and research networks.

Dr. Tabak expressed gratitude to Drs. Volkow, Warren, and Croyle for their professionalism, leadership, and commitment to doing what is best for the science .

Council Discussion

Dr. Linda Spear endorsed the decision to proceed with functional integration, which will promote new research collaborations to strengthen addiction research across multiple entities, while also respecting and protecting the unique and essential diversity of the research portfolio at each Institute. She commended NIH for moving quickly in a search for a new NIAAA director but urged attention to avoiding appointing a search committee chair with the appearance of a conflict of interest. Dr. Tabak responded that all members of search committees recuse themselves in situations where conflict or the appearance of conflict exists, and that NIH monitors all searches closely.

In response to Dr. Craig McClain's inquiry on how historically poor reviews of research on comorbidities at study sections will be addressed, Dr. Tabak stated that Dr. Collins recently appointed Dr. Richard Nakamura as the new director of the Center for Scientific Review. Discussions among Drs. Nakamura, Volkow, Warren, and Croyle will help better guide review processes within the Institutes themselves. NIH also is assembling and sharing with leadership some data points based on feedback received throughout the process.

Dr. Fulton Crews congratulated NIH on the plan for functional integration and for including NCI in the model. Observing throat, liver, and pancreatic cancers' generally high association with alcohol use, he urged consideration of the integrative pathology of cancer related to alcohol use and how integrations other than nicotine might cross these Institutes. Dr. Croyle stated that NCI funds work in diet and health behavior change, genomics, health care delivery, and drug development; staff already has discussed improved leverage of the enterprise, for example, in clinical trials, epidemiology, and disease etiology. He acknowledged the potential benefits of cross-Institute work on comorbidity risk factors, etiology, mechanisms, and genomics.

Dr. Kathleen Grant inquired about NIMH's role in research on comorbidities with drugs of abuse and particularly alcohol, and schizophrenia, depression, obsessive compulsive disorders, and anxiety disorders. Dr. Tabak stated that NIMH will engage in the functional integration and that NIMH's relative contribution will hinge on the respective size of its current portfolio in SUAA research.

Ms. Mimi Fleury, president and cofounder of Community of Concern, thanked NIAAA and NIDA leaders for their support in updating her organization's booklet "Parents' Guide for Prevention of Alcohol, Tobacco, and Other Drug Use." Fellow NIAAA Council members and NIDA scientists had translated their research into lay terms to present to parents.

Dr. Gyongyi Szabo commended the decision to proceed with functional integration and inquired about the percentage of the portfolio to be devoted to functional integration, and whether it will be driven by science and potential initiatives. Dr. Tabak stated that both scientific opportunities and practical considerations will drive finances. Natural turnover of the ICs' portfolios will represent the total resources for new investment, and funding for functional integration would represent a subset of that amount.

Dr. Terry Jernigan inquired about how functional integration will address the basic science problem of developing risk phenotypes and the intersection with other adverse outcomes of general interest to the Institutes. Dr. Tabak stated that considerable interest was expressed at a recent congressional hearing about how to prevent young adolescents from engaging in use of substances harmful to their health. Dr. Volkow observed the opportunity to partner with the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development and NIMH. Ongoing activities include studies to determine genes that make one vulnerable, how genes affect brain development and function, and how genes modulate their reactivity to the environment in ways that can make one more or less resilient to the effects of drugs. Many factors relate not just to higher risk of substance use disorders, but also to higher risk for a variety of behaviors that can lead to adverse medical outcomes, such as trauma and mental illness. She explained that the problem relates to basic genetics, imaging, characterization of brain development, and animal models used to assess the effect of environmental exposures on vulnerability for substance use disorder if another mental illness is present. Dr. Warren asserted that much is to be gained by tackling issues jointly that previously were addressed in a single-Institute fashion. NIAAA has paid major attention to both the environment and the genetic basis of underage drinking, for example, and looks forward to opportunities to engage across NIH and to engage more partners to tackle a broader range of important problems. Dr. Croyle noted that many scientific investigators and prevention communities do not self-identify as solely alcohol or drug or cancer prevention or tobacco control. Much of the work in communities in research and practice is accomplished by working collectively, particularly in adolescent health. He wants to ensure that NIH's research enterprise responds by working sufficiently synergistically. He noted the need also to work in concert with the Centers for Disease Control and Prevention, SAMHSA, Office of National Drug Control Policy, and the education and urban health communities.

Public Comment

In response to a question by Mr. Andrew Kessler, representing the California Association of Alcoholism and Drug Abuse Counselors (CAADAC), Dr. Tabak clarified that no new resources will be made available for collaborative efforts. Dr. Volkow noted that, in addition to examples cited earlier, NIDA will provide supplemental funding to add alcohol as part of its screening and interventions research in the criminal justice system. NIDA also will supplement its Clinical Trials Network infrastructure to enable every

clinical trial to evaluate alcohol in addition to illicit substances and nicotine, and thus gain much more knowledge without doubling funding. Dr. Volkow added that funds will be dedicated for comorbidity studies. Dr. Warren stated that all existing partnerships between NIAAA and NIDA will continue. He looks forward to implementing a new joint NCI-NIDA-NIAAA enterprise that integrates alcohol, drugs, and tobacco prevention, building on an effective model. Dr. Warren pointed out that integration is responsible for the establishment of an intramural collaboration on addiction genetics, as well as the imminent hiring within NIAAA of a scientist to collaborate with the NIDA's ontogenetics intramural program, currently located in Baltimore. Dr. Croyle explained that upcoming collaborations will resemble earlier trans-NIH efforts that emphasize such nondisease issues as efficient research with multiple disease endpoints, infrastructure, and tools and methods. He stated that he looks forward to discussing how to leverage current NCI resources to address drug addiction and dependence issues.

Dr. Kenneth Leonard, Research Institute on Addictions, University at Buffalo, inquired about a parallel integrative process for training and career development opportunities. Drs. Tabak and Warren confirmed that NIH will include cross-training and career development programs. Dr. Volkow added that whereas some grantees have funding from both NIDA and NIAAA, it will be necessary to integrate efforts in areas where training is minimal or nonexistent. She described the success of the Neuroscience Blueprint, which trains neuroscientists across all brain diseases, the cross-cutting training programs for neuroscientists to use imaging technologies, and the program to train computational neuroscientists.

Concluding Remarks and Adjournment

Dr. Tabak invited participants to submit comments through December 28, 2012, to be shared with members of the three advisory bodies. Dr. Tabak thanked leaders and staff of the participating agencies, as well as Council members, for their advice and continuing engagement.

The meeting adjourned at 12:38 p.m.

CERTIFICATION

I hereby certify that, to the best of my knowledge, the foregoing minutes are accurate and complete.

For NIAAA:

Kenneth R. Warren, Ph.D.
Acting Director
National Institute on Alcohol Abuse and Alcoholism
and
Chair
National Advisory Council on Alcohol Abuse and
Alcoholism

For NIDA:

Nora Volkow, M.D.
Director
National Institute on Drug Abuse
and
Chair
National Advisory Council on Drug Abuse

For NCI:

Tyler E. Jacks, Ph.D.
Chair
National Cancer Advisory Board