**National Diabetes and Digestive and Kidney Diseases Advisory Council**
National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health
Department of Health and Human Services

## I. CALL TO ORDER
***Dr. Rodgers***

Dr. Griffin Rodgers, Director, NIDDK, called to order the 203rd meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council at 8:30 a.m. on February 1, 2017, in Building 31, Conference Room 10, the NIH Campus, Bethesda, Maryland.

### A. ATTENDANCE – COUNCIL MEMBERS PRESENT

Dr. Joseph Bonventre
Dr. David Brenner
Dr. Mark Donowitz
Dr. Joel Elmquist
Dr. Lisa Guay-Woodford*
Dr. Caren Heller
Dr. Lee Kaplan
Dr. David Klurfeld
Mr. Richard Knight
Dr. Paul H. Lange*
Ms. Ellen Leake
Mr. Thomas Nealon*
Dr. Jeffrey Pessin
Dr. Craig Peters
Dr. Alan Saltiel
Dr. Jean Schaffer
Dr. Ian Stewart
Ms. Pamela Taylor

*Served as an *ad hoc* member for this meeting.

**Also Present:**
Dr. Griffin Rodgers, Director, NIDDK
Dr. Gregory Germino, Deputy Director, NIDDK
Dr. Brent Stanfield, Executive Secretary, NIDDK Advisory Council

## B. NIDDK STAFF AND GUESTS

Abbott, Kevin – NIDDK
Abraham, Kristin – NIDDK
Agodoa, Lawrence – NIDDK
Akolkar, Beena – NIDDK
Andersen, Dana – NIDDK
Arreaza-Rubin, Guillermo – NIDDK
Baker, Jenna – NIDDK
Bavendam, Tamara – NIDDK
Begum, Najma – NIDDK
Berti-Mattera, Liliana – CSR
Best, Caroline – Am. Urol. Assoc.
Bishop, Terry – NIDDK
Blondel, Olivier – NIDDK
Boerboom, Lawrence – CSR
Bourque, Sharon – NIDDK
Bremer, Andrew – NIDDK
Burgess-Beusse, Bonnie – NIDDK
Camp, Dianne – NIDDK
Carrington, Jill – NIDDK
Castle, Arthur – NIDDK
Cerio, Rebecca – NIDDK
Chen, Hui – CSR
Chowdhury, Bratati – NIDDK
Connaughton, John – NIDDK
Copeland, Randy – NIDDK
Cowie, Catherine – NIDDK
Curtis, Leslie – NIDDK
Dale, Dirks – Health & Med. Coun.Wash.
Davila-Bloom, Maria – NIDDK
Dayal, Sandeep – NIDDK
Doherty, Dee – NIDDK
Donohue, Patrick – NIDDK
Doo, Edward – NIDDK
Drew, Devon – NIDDK
Evans, Mary – NIDDK
Farishian Richard – NIDDK
Fisher, Rachel – NIDDK
Fonville, Olaf – NIDDK
Fradkin, Judith – NIDDK
Gamliel, Dee – NIDDK
Gansheroff, Lisa – NIDDK
Goglas, Philip – Health & Med. Coun.Wash.
Gossett, Danny – NIDDK
Goter-Robinson, Carol – NIDDK
Greenwel, Patricia – NIDDK
Guo, Xiaodu – NIDDK
Haft, Carol – NIDDK
Hall, Sherry – NIDDK
Hamilton, Frank – NIDDK
Hoff, Eleanor – NIDDK
Hoffert, Jason – NIDDK
Hoofnagle, Jay – NIDDK
Hoshizaki, Deborah – NIDDK
Hyde, James – NIDDK
James, Stephen – NIDDK
Jones, Teresa – NIDDK
Karp, Robert – NIDDK
Ketchum, Christian – NIDDK
Kimmel, Paul – NIDDK
Kirkali, Ziya – NIDDK
Kranzfelder, Kathy – NIDDK
Kuczmarski, Robert – NIDDK
Kusek, John – NIDDK
Laakso, Joseph – Endocrine Society
Laughlin, Maren – NIDDK
Lee, Jessica – NIDDK
Leschek, Ellen – NIDDK
Li, Yan – NIDDK
Linder, Barbara – NIDDK
Lynch, Christopher – NIDDK
Malik, Karl – NIDDK
Malozowski, Saul – NIDDK
Martey, Louis – NIDDK
Maruvada, Padma – NIDDK
Martinez, Winnie – NIDDK
Moxey-Mims, Marva – NIDDK
Mullins, Christopher – NIDDK
Narva, Andrew – NIDDK
Newman, Eileen – NIDDK
Nguyen, Van – NIDDK
Norton, Jenna – NIDDK
Osganian, Voula – NIDDK
Pawlyk, Aaron – NIDDK
Payne, January – NIDDK
Perrin, Peter – NIDDK
Perry-Jones, Aretina – NIDDK
Pike, Robert – NIDDK
Pileggi, Antonello – CSR
Ramani, Rathna – NIDDK
Rankin, Tracy – NIDDK
Rasooly, Rebekah – NIDDK
Regan, Karen – NIDDK
Reiter, Amy – NIDDK
Rivers, Robert – NIDDK
Rojas, Raul – CSR
Rosenberg, Mary Kay – NIDDK
Roy, Cindy – NIDDK
Rushing, Paul – NIDDK
Rys-Sikora, Krystyna – NIDDK
Saslowsky, David – NIDDK
Sato, Sheryl – NIDDK
Sechi, Salvatore – NIDDK
Serrano, Jose – NIDDK
Shelness, Gregory – CSR

Shepherd, Aliecia – NIDDK
Sherker, Averell – NIDDK
Silva, Corinne – NIDDK
Singh, Megan – NIDDK
Smith, Jaime – NIDDK
Smith, Philip – NIDDK
Spain, Lisa – NIDDK
Star, Robert – NIDDK
Stoeckel, Luke – NIDDK
Tatham, Thomas– NIDDK
Teff, Karen – NIDDK
Thornton, Pamela – NIDDK
Tilghman, Robert – NIDDK
Tuncer, Diane – NIDDK
Unalp-Arida, Aynur – NIDDK
Utama, Herman– NIDDK
Van Raaphorst, Rebekah – NIDDK
Wallace, Julie – NIDDK
Wang, Xujing – NIDDK
Weiner, Jeff – NIDDK
Woynarowska, Barbara – NIDDK
Wright, Elizabeth – NIDDK
Xia, Ashley – NIDDK
Yang, Jian– NIDDK
Yanovski, Susan – NIDDK

## C. ANNOUNCEMENTS

***Dr. Rodgers***

**New and *Ad Hoc* Council Members**

Before introducing the new regular and *ad hoc* members joining the meeting, Dr. Rodgers reviewed the three subcouncils of the NIDDK Advisory Council: the Division of Digestive Diseases and Nutrition (DDN) Subcouncil; the Division of Diabetes, Endocrinology, and Metabolism (DEM) Subcouncil; and the Division of Kidney Urology and Hematologic Disease (KUH) Subcouncil. He then introduced each of the new and *ad hoc* members and the subcouncils on which they will serve.

***Mr. Thomas Nealon, III*** joined the meeting as an *ad hoc* member and served on the DDN Subcouncil. Mr. Nealon is the vice chair of LNR Asset Services and the director of legal affairs at LNR Property LLC. He earned his J.D. degree from Georgetown University Law Center and is adjunct professor at the University of Miami School of Law in the program in real property development. He is also a fellow of the American College of Real Estate Lawyers and a member of the Commercial Real Estate Finance Council. Mr. Nealon is also CEO and national board chair for the American Liver Foundation.

***Dr. Jeffrey E. Pessin*** joined the council as a new regular member who will serve on the DEM Subcouncil. Dr. Pessin earned his Ph.D. in biochemistry from the University of Illinois at Champaign-Urbana, and was professor of physiology and biophysics at the University of Iowa and William and Jane Knapp Professional Chair of Pharmacological Sciences at Stony Brook University. He is currently director of the Diabetes Research Center and Judy R. and Alfred A. Rosenberg Professional Chair in Diabetes Research at the Albert Einstein College of Medicine. Dr. Pessin is principal investigator (PI) on five NIH awards, including three NIDDK R01 awards exploring the role of inflammatory responses in adipocyte cell death, the regulation of liver lipogenesis in obesity and fatty liver disease, and an exploration of novel signaling pathways in skeletal muscle using rodent model systems. He is also PI at the Einstein-Mount Sinai Diabetes Research Center, which has five biomedical cores that support basic, pre-clinical, and translational research. Dr. Pessin has authored more than 230 peer-reviewed publications, and has served on and chaired peer-review panels for the NIH, the National Science Foundation, the American Diabetes Association, and several other organizations.

Joining the meeting and serving on the KUH Subcouncil were Mr. Richard Knight, Dr. Lisa Guay-Woodford, and Dr. Paul Lange. Mr. Knight joined the council as a new regular member, while Dr. Guay-Woodford and Dr. Lange joined the meeting as *ad hoc* members.

***Richard Knight***, who holds an M.B.A., is the vice president for finance and planning of WIMSCO, LLC and serves on the board of advisors for the Bowie (Md.) State University College of Business, where he is also an adjunct instructor in business and marketing. Mr. Knight combines business and financial expertise with a strong interest in kidney disease. Mr. Knight serves as vice president and chair of public policy for the American Association of Kidney Patients, and as a member of the board of directors for the Mid-Atlantic Renal Coalition. He is also a founding member of the End-Stage Renal Disease Health Information Technology Project, and a member of the Kidney Health Initiative.

***Dr. Lisa Guay-Woodford*** is a pediatric nephrologist whose research focuses on identifying clinical and genetic factors involved with the pathogenesis of inherited renal disorders, most notably autosomal recessive polycystic kidney disease. She is director of both the Center for Translational Sciences and the Center for Clinical and Translational Science Institute at Children's National Hospital. She is also the Richard L. Hudson professor of pediatrics and associate vice president for clinical and translational research at The George Washington University. In addition, she is adjunct professor in the faculty of health sciences at Virginia Tech Carilion Research Institute. Dr. Guay-Woodford received her medical degree from Harvard Medical School, and did her residency in pediatrics, followed by a fellowship in pediatric nephrology, at Boston Children's Hospital. She is a trustee of the Polycystic Kidney Research Foundation. She also serves on the board of directors of the Association for Clinical and Translational Sciences, and the strategic planning committee for the Pediatric Academic Societies.

***Dr. Paul Lange*** has served as the director of prostate cancer research and professor in the department of urology at the University of Washington School of Medicine. He is Chair Emeritus of the department of urology, and the Pritt Family Endowed Chair in prostate cancer research. Dr. Lange has expertise in genitourinary oncology and prostate cancer. He leads the Institute for Prostate Cancer Research, a collaboration between University of Washington Medicine and the Fred Hutchinson Cancer Research Center. He received his M.D. from Washington University in St. Louis and did his internship at the University of Rochester. He was a clinical associate in the intramural program at NIH, and he did a surgical residency at Duke, and a residency in urology at the University of Minnesota Medical Center in Minneapolis. Dr. Lange has received the Lifetime Achievement Award from the Prostate Research Foundation and the Huggins Medal from the Society for Urologic Oncology. He has been named a Distinguished Member of the Western Section of the American Urological Association, and has authored more than 290 peer-reviewed publications.

Dr. Rodgers welcomed the new and *ad hoc* members and thanked them for their service.

## In Memoriam

Dr. Rodgers noted that ***Mary Tyler Moore*** passed away the previous Wednesday at the age of 80. The actor had close ties to NIDDK as an advocate for patients with type 1 diabetes and for research focused on finding a cure. Ms. Moore was diagnosed with type 1 diabetes more than 45 years ago and was one of the first celebrities who was open about her diagnosis. She and her husband, Dr. Robert Levine, who served as an NIDDK council member, have worked with the Juvenile Diabetes Research Foundation (JDRF). Dr. Rodgers and Dr. Judith Fradkin wrote to Ms. Moore and Dr. Levine before her passing. Dr. Rodgers read from the letter: "Mary, you are an inspiration for every person with Type 1 Diabetes and proof that one person can make a positive difference for all. Your heartfelt testimony to Congress, your love for and dedication to children with type 1 diabetes, and tireless work behind the scenes have created momentum that will continue for years and years to come." The letter went on to commend both Ms. Moore and Dr. Levine, saying: "Thanks to you, we are seeing progress from major efforts to understand the causes of type 1 diabetes and to find ways to delay, prevent and eventually reverse the disease. And in years to come, when you see type 1 diabetes research advancing both resulting from NIH and JDRF funding, we hope that you will know that you certainly had a hand in all those advances."

Dr. Rodgers noted that the greater diabetes patient and research advocacy community certainly mourns Ms. Moore's passing. As the letter indicated, her legacy will continue. On behalf of NIDDK, Dr. Rodgers offered heartfelt condolences to Dr. Levine.

Dr. Rodgers also announced with sadness the passing on January 22 of ***Dr. Jared Grantham***, a long-time grantee, who was 80 years old. He was an internationally recognized researcher who focused on finding a cure for polycystic kidney disease during a career that spanned more than 50 years. He was recognized by the American Society of Nephrology with two of the Society's highest accolades—the Homer Smith and John P. Peters Awards—for his outstanding contribution to the science of nephrology. He was also the founding editor of the *Journal of the American Society of Nephrology*. Dr. Grantham was a co-founder of the PKD Foundation, which has operated for more than 30 years and has invested more than $40 million in basic and clinical research. Dr. Grantham's scientific and advocacy work have formed the cornerstone for progress in the development of a cure for PKD.

## NIDDK Staffing Update

***Dr. Jessica Lee*** joined NIDDK as deputy director of DDN as well as senior scientific advisor for clinical and translational research in digestive diseases. Dr. Lee received her undergraduate degree in brain and cognitive sciences from Massachusetts Institute of Technology, her MD degree from SUNY Upstate Medical University, and a master's degree from Harvard Medical School's Scholars in Clinical Science program. She completed her internship and residency in pediatrics at Children's Hospital Montefiore-Albert Einstein College of Medicine and subspecialty training in pediatric gastroenterology at Boston Children's Hospital. In 2011, she joined the FDA Center for Drug Evaluation and Research (CDER) as medical officer in the Division of Gastroenterology and Inborn Errors Products, where she was a key leader in evaluating new drug products in gastroenterology, a team leader responsible for training new

medical officers, and an organizer and participant in multiple workshop and meetings. She has received numerous honors and awards, particularly in inflammatory bowel disease. At DDN, Dr. Lee will have broad responsibility for leadership of clinical research programs in digestive diseases. As deputy director, she will assist with administrative activities in the division.

***Dr. Peter Savage*** retires in February from DEM after 46 years of federal service and a distinguished research career that he started and completed at NIDDK. As a postdoctoral fellow, he studied insulin resistance in the Pima Indians at NIDDK's Phoenix Epidemiology and Clinical Research Branch. He went on to work at the Veterans Administration and then the NIDDK-funded Diabetes Research and Training Center at the University of Michigan. From there, he was recruited to the National Heart Lung and Blood Institute (NHLBI) to lead the extramural division responsible for clinical and epidemiologic cardiovascular disease research. Under his leadership, NHLBI undertook the ACCORD study, the largest randomized trail addressing the effects of glucose, blood pressure, and lipid control on cardiovascular disease in people with type 2 diabetes. He also oversaw a follow-on study, called ACCORDion, which continued to shed light on longer-term benefits of glucose control on microvascular outcomes. After those studies, Dr. Savage moved to NIDDK, where he implemented the Restore Insulin Secretion (RISE) study, which is addressing whether early intervention for type 2 diabetes leads to sustained improvement in beta cell function, reducing the need for diabetes medication to control glycemia. Two of the three studies are nearly complete and should have results soon. The third and largest component of RISE is a four-arm randomized trial that is still enrolling patients. Dr. Savage's contributions include mentoring staff and adding to our insights and understanding of the pathogenesis of type 2 diabetes.

***Dr. Pamela Thornton*** joined DEM to lead NIDDK's Center for Diabetes Translation Research and DEM's R18 program. She will manage research on translation of diabetes research into clinical practice and public health, with an emphasis on addressing underserved populations and health disparities. Dr. Thornton comes to NIDDK from the National Institute of General Medical Sciences (NIGMS), where she oversaw the Building Infrastructure Leading to Diversity (BUILD) Initiative. BUILD is a novel training and scientific workforce development program funded by the Office of the NIH Director/Common Fund. Before joining NIH, Dr. Thornton had a decade of experience in the nonprofit sector working on modernization of public health infrastructure, including interoperability of electronic health records. Dr. Thornton received a B.S. in psychology from Howard University and a Ph.D. in social work from the University of Maryland in Baltimore. Her postdoctoral work at the University of Michigan Institute for Social Research focused on peer support to improve African-American and Latina maternal and child health.

***Dr. Xujing Wang*** joined DEM to work on data-intensive projects requiring major biocomputational efforts, including The Environmental Determinants of Diabetes in Youth (TEDDY) study, the Human Islet Research Network (HIRN), and the type 2 diabetes component of Accelerating Medicines Partnership (AMP). Dr. Wang served previously as the director of the system biology core for the Division of Intramural Research at NHLBI. She received her B.S. in physics from Nan Kai University in China, and a Ph.D. in theoretical physics from Texas A&M University. She completed her postdoctoral training in biophysics and medical engineering at MD Anderson Cancer Center. She then joined the Medical College of Wisconsin's Department of

Pediatrics, where she applied her biocomputational skills to the study of type 1 diabetes genetics with support from an NIDDK R01 award. Before joining NIH, she had a joint appointment as associate professor in the department of physics at the University of Alabama at Birmingham (UAB) and principal investigator in the UAB Diabetes Center, where she pursued an array of interdisciplinary projects.

***Dr. Jenna Baker*** has also joined DEM as a program manager for the Common Fund Illuminating the Druggable Genome program that NIDDK is leading in conjunction with the National Center for Advancing Translational Sciences. She joins us from the intramural program at National Human Genome Research Institute (NHGRI) where she was a post-doctoral fellow. She received her B.A. in physical anthropology from Syracuse University, her M.A. in biology from the University of Colorado, and a Ph.D. in paleobiology from George Washington University. She has held appointments as an instructor and assistant professor at the University of Maryland extension campus in Germany, and most recently she conducted research in functional and computational genomics, focusing on nuclear receptors and pharmacogenomics.

***Dr. Michael Flessner*** has retired from KUH. During nearly seven years at NIDDK, Dr. Flessner served as program director in kidney inflammation and inflammatory diseases program. He was a also project scientist for the NIH Common Fund program on microphysiologic systems known as Tissue on a Chip. With 18 years of prior experience as an NIH-funded extramural principal investigator, Dr. Flessner contributed to the success of several consortia, including the Consortium for Imaging Studies of Autosomal Dominant Polycystic Kidney Disease (PKD); HALT Progression of PKD; Cure Glomerulonephropathy (CureGN); Time to Reduce Mortality in End-Stage Renal Disease; and the Fibrosis Consortium. Dr. Flessner will continue to work with NIDDK as a contractor.

NIDDK welcomes ***Dr. Salina Waddy*** as medical director of NIDDK's Office of Minority Health Research Coordination (OMHRC), where she will focus on both diversity and health disparities. Dr. Waddy is an expert in health disparities, chronic disease, and genetics. She earned her M.D. from Columbia University and completed her residency in neurology and fellowships in stroke and neurogenetics at Emory University. She served on the faculty of Emory before joining NIH as medical officer for health disparities for the National Institute of Neurological Disorders and Stroke (NINDS). At NINDS she developed the Stroke Prevention Intervention's Research Program, a U54 cooperative agreement program that supports trials aimed at reducing disparities in stroke incidence, recurrence, and poor outcomes. Dr. Waddy also worked across NINDS to develop a broader research agenda for neurological disparities research that included dementia, pain, and other neurologic diseases. She also worked on areas of overlap between health disparities and global health research, including the genetics, epidemiology, and treatment of stroke in Sub-Saharan Africa. She has been part of numerous phase II and III clinical trials in stroke, Parkinson's Disease, and Huntington's Disease.

NIDDK also welcomes ***Dr. Jennie Larkin*** to the Division of Extramural Activity as a director of the Office of Research Evaluation and Operations (OREO) where she will oversee a wide range of data development and reporting activities, including funding opportunity announcements, processes, and other important operations support activities. She joins NIDDK after serving for

several years as a senior advisor for the extramural program and strategic planning in the Office of the Associate Director for Data Science, where she was responsible for setting up the Big Data to Knowledge (BD2K) initiative. Prior to that, Dr. Larkin served as a program officer in the Division of Cardiovascular Sciences at NHLBI, where she had a portfolio in systems biology, informatics, and computational biology. She earned her Ph.D. from Stanford University and did postdoctoral research at both Stanford and the University of California at Berkeley. She has also worked as a staff scientist at The Institute for Genetics Research.

***Dr. Carol Goter-Robinson*** and ***Dr. Robert Wellner***, scientific review officers (SROs), retired on January 3, 2017. Dr. Goter-Robinson retired after 23 years of federal service, 13 of those with NIDDK. As a SRO at NIDDK, she organized reviews of NIDDK centers, program projects, and clinical trial applications. She was also responsible for reviews of fellowship applications assigned to DEM. Dr. Wellner joined the NIDDK scientific review branch in 2005 and retired with 35 years of federal service, including 12 with NIDDK. He was responsible for one of NIDDK's standing review committees, the Digestive Diseases and Nutrition C Subcommittee (DDK-C), which reviews mentored career development and institutional training grants assigned to DDN. On behalf of NIDDK, Dr. Rodgers offered congratulations to both Dr. Goter-Robinson and Dr. Wellner for their federal service and wished them all the best on their retirement.

***Dr. Ryan Morris*** has joined the Scientific Review Branch. Dr. Morris has a background in renal transport physiology. He received his Ph.D. from the UAB where he studied the regulation of the epithelial sodium channel by arginine vasopressin. He came to the NIH as a postdoctoral fellow in the Laboratory of Kidney and Electrolyte Metabolism at NHLBI. He then served for nearly 10 years as a scientific review officer at the CSR in the Digestive, Kidney, and Urologic Systems Initial Review Group. At CSR, he was responsible for both urological and renal study sections.

***Dr. Barbara Woynarowska,*** a scientific review officer with NIDDK since 2004, has been selected as the chief of the Training and Mentored Research Section of NIDDK's Scientific Review Branch. Prior to joining NIDDK, Dr. Woynarowska was an associate professor at the University of Texas Health Sciences Center at San Antonio in the Department of Radiation Oncology. During her tenure as an SRO, she has organized review of many different types of grant mechanisms and is currently responsible for NIDDK's DDK-D Subcommittee, which reviews both mentored career development and institutional training applications assigned to the Division of Kidney, Urologic, and Hematologic Diseases. In her new role, she will also be responsible for overseeing the six committees that evaluate all training applications assigned to NIDDK.

***Dr. Jaime Smith*** joins NIDDK's Office of Scientific Program and Policy Analysis. Dr. Smith first came to NIH as a post-doctoral fellow in NINDS Intramural Research Program, studying the structure and function of voltage-gated ion channels. After completing her fellowship, she joined the Legislative Policy Office in the Office of the NIH Director.

After reviewing the arriving and departing staff members, Dr. Rodgers introduced the 2017 edition of ***NIDDK Recent Advances & Emerging Opportunities***, an annual publication that highlights examples of NIDDK-supported research advances during fiscal year 2016. He pointed

out that the colorful cover of this year's edition is a network of points representing aggregated clinical data obtained from electronic health records. The three separate clusters correspond to three subtypes of type 2 diabetes, distinguished by their clinical features and different risks for diabetes complications. The publication contains accounts of discoveries and research progress, as well as stories of patients who are living with diseases that are part of NIDDK's research mission. The publication also highlights the scientific presentations made at Advisory Council meetings during 2016, including those given by Dr. Bonventre, Dr. Saltiel, and Dr. Kaplan. Also included are data on funding trends, and updates on NIDDK's core values that were first presented at our May 2012 Council meeting.

Dr. Rodgers pointed out that production of this book was an institute-wide effort, and he acknowledged the Office of Scientific Program and Policy Analysis for developing the content and managing the project, and the extramural and intramural research divisions for providing input and guidance. Dr. Rodgers welcomes comments on the report, copies of which were available to Council Members and attendees. The publication is also available in electronic form on the NIDDK website.

## II. CONSIDERATION OF SUMMARY MINUTES OF THE 202nd COUNCIL MEETING

***Dr. Rodgers***

The Council approved, by voice vote, the Summary Minutes of the 202nd Council meeting, which had been sent to them in advance for review.

## III. FUTURE COUNCIL DATES

**2017**

May 10-11 (Wednesday and Thursday)
***Building 31, Conference Rooms 10, 6 and 7***
September 6-7 (Wednesday and Thursday)
***Natcher Conference Center (Building 45)***
***Conference Rooms E1/E2, D and F1/F2***

**2018**

January 24-25 (Wednesday and Thursday)
***Natcher Conference Center (Building 45)***
***Conference Rooms E1/E2, D and F1/F2***
May 16-17 (Wednesday and Thursday)
***Natcher Conference Center (Building 45)***
***Conference Rooms E1/E2, D and F1/F2***
September 12-13 (Wednesday and Thursday)
***Building 31, Conference Rooms 10, 6 and 7***

Most meetings are expected to be a single day. However, the NIDDK asks Council members to reserve two days for each meeting should a situation arise where a longer meeting is required.

## IV. ANNOUNCEMENTS

***Dr. Brent Stanfield***

**Confidentiality**

Dr. Brent Stanfield reminded the Council Members that material furnished for review purposes and discussion during the closed portion of the meeting is considered confidential. The content of discussions taking place during the closed session may be disclosed only by the staff and only under appropriate circumstances. Any communication from investigators to Council Members regarding actions on an application must be referred to the Institute. Any attempts by Council Members to handle questions from applicants could create difficult or embarrassing situations for the Members, the Institute, and/or the investigators.

**Conflict of Interest**

Dr. Stanfield reminded the Council Members that advisors and consultants serving as Members of public advisory committees, such as the NIDDK Advisory Council, may not participate in situations in which any violation of conflict of interest laws and regulations may occur. Responsible NIDDK staff shall assist Council Members to help ensure that a Member does not participate in, and is not present during, the review of applications or projects in which, to the Member's knowledge, any of the following has a financial interest: the Member, or his or her spouse, minor child, or partner (including close professional associates), or an organization with which the Member is connected.

To ensure that a Member does not participate in the discussion of, nor vote on, an application in which he/she is in conflict, a written certification is required. A statement is provided for the signature of the Member, and this statement becomes a part of the meeting file. Dr. Stanfield directed each Council Member to a statement in his or her meeting folder regarding the conflict of interest in review of applications. He asked each Council Member to read it carefully, sign it, and return it to NIDDK before leaving the meeting.

Dr. Stanfield pointed out that at Council meetings when applications are reviewed in groups without discussion, also called "*en bloc*" action, all Council Members may be present and may participate. The vote of an individual Member in such instances does not apply to applications for which the Member might be in conflict.

Regarding multi-campus institutions of higher education, Dr. Stanfield said that an employee at one campus may participate in any particular matter affecting another campus, if the employee's financial interest is solely at one campus and the employee has no multi-campus responsibilities.

**Annual Approval of the Council Operating Procedures**

The Council approved by voice vote its 2017 Operating Procedures, which had been sent in advance for review and are essentially identical to those for 2016.

## V. REPORT FROM THE NIDDK DIRECTOR
***Dr. Rodgers***

### Budget Update

Dr. Rodgers reported that the budget for the current fiscal year has not been approved by Congress and the government continues to operate on a continuing resolution. Both the Senate and the House-proposed budgets would include welcome increases for both NIDDK and the NIH. The Senate version represents a 6.2 percent increase over 2016, bringing the total to $34 billion for NIH, and NIDDK's budget would increase by 4.1 percent, or more than $75 million, to $1.89 billion. The House would place the budget for NIH at $33.3 billion (a 3.9 percent increase), of which NIDDK would receive $1.86 billion, a 2.5 percent increase (or $43.75 million) over 2016. In both budgets, most of the increases in the NIH budget (close to $600 million) are targeted towards specific initiatives, including the Precision Medicine Initiative (PMI), Anti-microbial Resistance, the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative, and Alzheimer's Disease. The government will continue operating with last year's budget until at least April 28, which is about seven months into the current fiscal year. Dr. Rodgers pointed out that while NIDDK is operating under the same budget as last year, NIDDK has incurred increased administrative obligations to support NIH operations, diminishing the funds available for research activities in fiscal year 2017.

Dr. Rodgers reviewed three possible scenarios for a budget this year. In the first scenario, the government would operate on continuing resolution for the remainder of fiscal year 2017 (at fiscal year 2016 levels). There is still some hope that Congress might approve a budget (that might include some increase for NIH), as a second scenario. If there is no agreement on a continuing resolution or a budget, there could be a government shut-down—the third scenario. Despite these uncertainties, NIDDK and NIH are moving forward with planning for 2018. The Office of the Director has prepared its portion of the President's budget request, which is usually sent to Congress in early February. Changes in administration sometimes delay budget requests.

### Government Transition

Dr. Rodgers reported that the Trump administration has asked Dr. Francis Collins to stay on for now as director of the NIH. The Senate Health committee on Health, Education and Labor is considering the nomination of Dr. Thomas Price as new HHS Secretary. Dr. Price is an orthopedic surgeon and has served six terms in the House representing Georgia's 6$^{th}$ district.

President Trump issued an executive order on January 23 that freezes federal hiring. At the present time, NIH is unable to bring on any new staff.

### 21$^{st}$ Century Cures Act

On December 13, 2016, the 21$^{st}$ Century Cures Act was signed by President Obama. The Act provides $4.8 billion over 10 years for three initiatives: The Precision Medicine Initiative, the Brain Initiative, and the Cancer Moonshot. The Act also provides some funding for regenerative medicine. Dr. Rodgers pointed to a recent article in the *New England Journal of Medicine* highlighting how and in which fiscal years the money would be allocated. Brain Research

through Advancing Innovative Neurotechnologies (BRAIN) and Precision Medicine Initiative (PMI) would each receive about $1.5 billion over the 10-year period from 2017 to 2026. The Cancer Moonshot, which has been renamed the Beau Biden Cancer Moonshot, will receive about $1.8 billion.

## VI. NIDDK TRAINING AND CAREER PROGRAMS

***Dr. Tracy Rankin***

*Dr. Rodgers introduced the presentation by providing some background regarding NIDDK Training and Career Programs. The mission of NIDDK is to conduct and support medical research and research training and to disseminate science-based information on endocrine and metabolic diseases, such as diabetes, obesity, and digestive, kidney, urologic, and hematologic diseases. Fostering exceptional research training and mentoring opportunities and maintaining an NIDDK-focused pipeline of outstanding investigators is critically important to the Institute's research progress. NIDDK will continue to support significant opportunities for graduate and post-doctoral level students as well as research career development awards, undergraduate research and other educational opportunities.*

*Dr. Rodgers introduced Dr. Tracy Rankin, career development and training program director for KUH, who gave the presentation on behalf of NIDDK's career and training program directors.*

Dr. Rankin started her presentation expressing the hope that it will be the start of an ongoing dialogue with the Advisory Council about the content, efficacy, and strategic development of NIDDK's training programs. The focus of the training programs is to support young, aspiring scientists as they start and increase their commitment to a research career, eventually becoming productive members of the investigative workforce. She explained that two of the five pillars of Dr. Rodger's vision for NIDDK relate directly to the training program:

- Preserve a stable pool of talented new investigators
- Foster exceptional research training and mentoring opportunities

The goal of the training program is to ensure that a diverse, highly trained pool of investigators is ready to contribute to the knowledge base about NIDDK-relevant diseases.

NIDDK offers myriad grant programs that help individuals acquire skills, develop intellectual independence, generate fundamental new knowledge through research projects, and participate in the research workforce.

NIDDK has training programs for all levels, from high school and undergraduate all the way through mid-career faculty. They include:

- **Research education grant** (R25): NIDDK uses this award primarily to support summer research experiences for high school students and undergraduates.
- **Medical student support** (T35): This is a National Research Service Award (NRSA) mechanism that is targeted towards supporting medical students—usually between the first and second year—in summer research experiences.
- **Institutional training grants** (T32s): These awards are made to institutions that recruits, vet and appoint individuals to training programs for a period of two to three years. While most of these grants support post-doctoral work, this category can also support "pre-doctoral" individuals, usually Ph.D. candidates. This is one of NIDDK's larger training programs.
- **Institutional programs** (K12): Similar to those offered within the Clinical and Translational Science Awards (CTSAs), these programs provide mentored training to help individuals become independent researchers. NIDDK limits these awards to two areas: type 1 diabetes research and benign urology research.
- **Post-doctoral fellowships** (F32s): These are National Research Service Awards that provide stipend support for a limited period. Applicants must have an identified sponsor so that the researcher has faculty supervision. Total NRSA support is limited to three years.
- **Career development awards** (K series): These awards go to more senior fellows and post-docs with at least two years of experience. These applicants—who can have either a clinical degree (such as an M.D.) or a Ph.D.—must also have an identified mentor. The grants provide up to five years of a mentored research experience, generally with a minimum protected effort time of 75 percent, and an aim of preparing the researcher for their first R01 grant. This is a NIDDK's largest training program in terms of budgetary commitment.
- **Supplemental grants** (R03): NIDDK has a small R03 program designed to supplement current K awardees as they reach the end of their career development training. The aim is to provide pilot funds to help K awardees become more competitive for their first R01 application.
- **Fast-track career development awards** (K99/R00): These grants go to post-docs who may need an additional "incubation period" before competing for an R01 award.
- **Mid-career mentoring awards** (K24): These grants provide support for mid-career scientists so they can devote a portion of their time to mentoring activities.

Together, these programs add up to approximately 8 percent of NIDDK's total FY16 budget. Compared with other NIH institutes, NIDDK is in the upper quartile in terms of proportion of budget focused on training support. NIDDK's absolute dollar spending levels on training programs is comparable to that of the NCI and higher than the NIAID, two ICs whose budgets are substantially larger than that of NIDDK. During the past decade, NIDDK has increased participation in training and development programs, and the budget for this has increased in absolute dollars. However, when adjusted for inflation, the buying power of those dollars has decreased slightly.

## Descriptive and Outcome Measures

*Application and Award Dynamics*

Looking at data from the last five years, the numbers of T32s applications varied from fewer than 60 to approximately 70 per year. Success rates for T32s were above 40 percent (and often approaching or above 60 percent) for all but one year (2013—the year of the sequestration). The number of F32 applications has fluctuated from just below, to just above, 200, and F32 success rates have been in the 25 to 33 percent range, which Dr. Rankin characterized as reasonably robust. The numbers of career development awards (K01, K08, K23 and K99) as a class (K) have been stable at approximately 100 per year. There has been some deceleration in K application numbers over the past five years. Overall success rates for K awards have shown some uptick and have generally been in the 30 percent range.

*Degree Profiles of Trainees*

Just under half of the T32 trainees between 2011 and 2015 had M.D.'s; 38 percent had a Ph.D. and a small proportion have both an M.D. and a Ph.D. About 6 percent of trainees had other degrees, such as Doctor of Pharmacy, Doctor of Osteopathy, or Doctor of Veterinary Medicine.

Slightly more than three quarters of F32 awardees over the past five years had a Ph.D.; only 16 percent have an M.D. degree and an even smaller proportion have a dual Ph.D./M.D. degree. Most F32 awards are focused on fundamental research in animal models or using de-identified human data and samples, referred to as "human subject minus," or HS-, research. Less than 20 percent of F32-supported awards include research that involves human subjects (HS+).

Thirty-five percent of K awardees are M.D.s and just under half are Ph.D.s. Thirteen percent of this group holds dual M.D./Ph.D. degrees. Approximately 55 percent of K awardees are involved in HS- research and approximately 45 percent involved in HS+ research.

*Outcome Measures*

Dr. Rankin discussed the goals and objectives of the different training programs and made the point that the focus of each is somewhat different and perhaps progressively narrow. An objective of the T32 program is to enhance research training for careers that will impact health-related research needs, which is a fairly broad goal. The F32 program is designed to enhance the research training for those with potential to become productive, independent investigators. Dr. Rankin noted that it is clearer in the F32 FOA that we expect individuals supported by the F32 to have high potential for an independent research career. She then noted that the expectations rise for K program, which is designed to prepare individuals for an independent research career.

Given this background, one way to evaluate the success of the programs is to track whether awardees go on to apply for and receive grant support—especially R01 grant support—after their NIDDK-funded training.

Dr. Rankin reviewed data on the cohort of trainees who completed their training between 2005 and 2010.

- There was a total of 1671 T32-supported trainees between 2005 and 2010. Forty-one percent went on to submit any follow-up application and 21 percent went on to receive any type of award that can be tracked in the NIH data systems (include not only NIH awards but also awards from other HHS components and some other agencies). Twelve percent of T32-supported trainees went on to submit an R01 application and five percent received an award.
- The majority (56%) of the 344 F32 awardees submitted an independent research grant application and more than forty percent received an award (hence most of those who applied, received an award). Thirty-six percent applied for an R01 and 23 percent received an R01 award.
- There was a total of 573 K awardees between 2005 and 2010. Eighty-seven percent of these K awardees submitted any type of follow-up application and 66 percent received an award. Seventy-nine percent of the K awardees submitted an R01 application and 49 percent received an R01 award.

To summarize, Dr. Rankin made the point that NIDDK makes substantial investments in the training pipeline. She then noted several other observations that she highlighted:

- There is a high percentage of M.D.s in the overall training pipeline, especially in the T32 and K programs; while Ph.D. researchers receive most F32 awards.
- Dual degree holders (i.e., M.D./Ph.D.) are most likely to go on to secure funding after the completion of their training.
- Career development awardees are committed to research and are likely to acquire an R01 award.

Dr. Rankin then presented questions that the training directors and other NIDDK staff have considered for Council discussion, including:

- Can we more clearly define objectives that are specific, measurable, achievable, relevant and time-bound (SMART) that will help determine program effectiveness?
- Do we have the right mix of M.D., Ph.D., and dual degree researchers to accomplish the NIDDK research mission?
- Do we have the right allocation of resources among the different training programs for different career stages, as well as individual versus institutional awards?
- How can we determine when is the best time to recruit people into the research pipeline? Are there roles for recruiting earlier or later in a career?

In closing, Dr. Rankin thanked Teresa Lindquist in the Division of Extramural Activities, who pulled the data together, and the other training directors for their help developing the presentation.

**Council Questions and Discussion**

*How many T32-funded individuals apply for and get K awards? This is an important number to know since applying to and getting K awards can be a requirement for faculty appointments in medicine.*

Dr. Rankin estimated that about 30 percent those who receive T32 support go on for individual fellowships. The data to derive percentages of T32 trainees who go on to apply for and receive K awards are available. However, those data were not included in the presentation. Dr. Rankin indicated that NIDDK could provide those data.

*How many K-99 awards are funded each year*?

Within NIDDK, it's limited to about 10-12 a year, Dr. Rankin estimated.

*Is there any plan for changing the green card citizenship requirement for K and F32 awards?*

Dr. Rankin reminded the audience that the authorizing language for NIH's training programs—except for the K99—restricts eligibility to U.S. citizens or those who have permanent residency in the United States. As such, it would take an act of Congress to change that requirement.

*Do you have data on re-submission success rates on F32, K, or other applications?*

Dr. Rankin said that her team had not looked specifically at re-submission rates; the data presented lumped original submissions with re-submissions. That information could be broken out, if requested.

*For the T32 awards, what are the review criteria? How are individuals going into pharma, biotech, non-profits, and even private practice viewed by the review panels?*

The biomedical research workforce working group commissioned by Dr. Collins several years ago shifted the review criteria to define success as any contribution to the research enterprise, not just as an academic investigator with an R01 but also working in industry or a biomedically oriented foundation. It would not include going into private practice necessarily. These outcomes are considered when the award comes up for renewal.

*For T32-trainees, have subsequent application and award rates changed? Has it gone down in recent years?*

Dr. Rankin said she has not analyzed that data, but she feels that the success rate has been consistent not only across NIDDK, but also other institutes. She said this question relates to one of her questions: what is the goal of the institutional program? Is it to give individuals experience in research so that they bring that knowledge to their private practice or other next endeavor? Or is it that they stay directly involved in research? The program has been around since the early 1970s

and has not changed much structurally since then.

*What other measures of success are you tracking?*

Dr. Rankin reported that NIDDK tracks a wide range of awards, including awards from other agencies, including loan repayments or subprojects on a larger grant. Pulling additional data for other measures of success is a continuing challenge because it involves going through each competitive application and looking at the tables where applicants show their progression during the past 10 years. Future applicants may be required to fill those tables out electronically so that we can pull that data more easily.

*Is there a way of getting more granular than the type of degree when identifying who goes on to a successful research career? Does it make a difference when the individual is first exposed to science, whether it is in high school, college, or other post-graduate education? Is there a large variation by institution or mentorship experience?*

Dr. Rankin admitted that data would be useful but capturing it is labor-intensive. She said she looks forward to working with Dr. Larkin, who has recently joined NIDDK, and who has experience that will help design more careful evaluations which may be able to identify some of these factors. She also speculated that perhaps more important than quantitative data was qualitative data about who goes on to be a successful part of the R01 workforce.

*Is the number of K08s—basic science awards—dropping? It used to be that one could enter a T32 program without much experience and within two years have published a basic science paper. Now people spend four or five years just doing research—basically a Ph.D. equivalent—to publish a basic science paper. I wonder if there is a drop-off because there is less support for basic research, and it's more difficult to get the publication requirement for the F32. Those doing clinical research seem to have an easier time getting published.*

Dr. Rankin answered that the T32 program may need to be re-examined, particularly for M.D.-trained individuals who may come into the program naïve to research. The program is currently capped at three years. Do we need a longer time of support? Even a modest level of support may give individuals the time to gain the Ph.D.-level research experience needed to compete at the next level.

She noted that the National Institute of Neurological Disorders and Stroke (NINDS) has taken a different tack particularly with F32s; reviewers are focusing less on the publications and preliminary data, and more on the individual candidate. She suggested NIDDK could tweak the review criteria to reduce the number of papers required to be competitive for fellowships after T32 support.

She concurred with the observation that the number of clinical trained investigators doing basic science has declined during the last five years, and the number of clinically trained investigators doing patient-oriented research has increased. This is true for NIH overall, as well as for NIDDK

specifically, although there are some differences among the different subcouncils of NIDDK. This will be discussed in the subcouncil meetings.

*Comparing success rates for F32s and T32s, could the average number of years an individual receives support account for some of the differences? A shorter support time may not be enough time to transition to the next level.*

Dr. Rankin replied that most awardees receive T32 support for 2 years, while F32 awardees may get 1 or 2 years, depending on how much T32 support they had previously. Ph.D.s often get a full three years; many T32-supported clinicians who apply for F awards are only eligible for 1 or 2 more years.

*What do we want to achieve with the T32 program? If the goal of research training is to improve the R01-funded workforce, then expanding the length of support may help achieve that goal. But that may not be the case if the goal is broader, i.e. to reach those working in the pharmaceutical industry or the area of policy.*

Dr. Rankin said that her team has had extensive discussions about this question, and one of the reasons for this presentation was to tap the knowledge of the NIDDK Council to help think through the goals of the program, especially considering the large investment NIDDK makes in it. The two goals are not exclusive, but they are different and dictate which outcomes to capture. As we move to electronic capture of data regarding outcomes, it's a good time to consider which data will help us evaluate the efficacy of the programs.

*Has there been analysis of the critical factors within institutions—rather than individual trainees—that contribute to trainee success?*

Dr. Rankin said this is under consideration but when the data are stratified by institution, the numbers start to get small, and their statistical significance comes into question. This type of analysis may be more feasible for the T32 program than other institutional programs, because there are usually many T32 programs in the same institution, even though they may be in different fields, such as nephrology, cardiovascular science, and general medical science. It may be possible to identify a cohort effect, particularly if there is cross-talk between the trainees that promotes their ability to acquire research skills.

*Is it possible to add to the new electronic table the information needed to capture alternative outcomes, such as policy, biotech, pharma., so that we can analyze that information in the future?*

Dr. Rankin said this concept is under discussion. The form now is open text, but perhaps introducing a drop-down list of the most common outcomes would make the information easier to track.

*Would you be able to capture information about those who were not PIs or co-PIs but were significant personnel on an R01?*

Dr. Rankin said that they capture multiple PIs on a project, but she did not believe project directors and other roles were captured in the data. The new table will allow T32 applicants to indicate roles on any application they are part of.

## VII. UPDATE FROM THE ACTING DIRECTOR, NATIONAL CANCER INSTITUTE: CANCER MOONSHOT

**Dr. Lowy**

*Dr. Rodgers introduced Dr. Douglas R. Lowy, who was named acting director of NCI in April 2015. Prior to his appointment, Dr. Lowy served as Deputy Director of NCI for five years, helping lead the Institute's key scientific initiatives. Dr. Lowy received his M.D. from New York University School of Medicine and trained in internal medicine at Stanford University and in dermatology at Yale. His research interests include the biology of papillomaviruses and regulation of normal and neoplastic cell growth. He has carried out his papillomavirus research in collaboration with Dr. John Schiller, with whom he has authored more than 125 papers during the past 30 years.*

*Dr. Rodgers explained that President Barack Obama announced the establishment of the Cancer Moonshot initiative during the State of the Union address on January 12, 2016. The aim of the initiative is to increase the availability of cancer therapies to patients and to improve cancer prevention and early detection.*

Dr. Lowy reviewed the background of the Cancer Moonshot, focusing on the scientific aspect of the initiative, the recommendations of the Blue-Ribbon Panel associated with the initiative, and the plan to fund and support cancer research. NCI plans to collaborate with other Institutes and Centers within the NIH to develop and carry out the research agenda set for by the Cancer Moonshot.

The Cancer Moonshot came about from a series of meetings in 2015 with Vice President Joe Biden at the White House, attended by Dr. Francis Collins, Dr. Lowy, and other colleagues. The overall goals of the Cancer Moonshot are to:

- Accelerate progress in cancer prevention, screening, and treatment and encourage wider and faster uptake of cutting edge research into standards of care;
- Encourage greater cooperation and collaboration in academia, government, and private sector research;
- Enhance data sharing.

Dr. Lowy admitted that the need for increased cancer research is not new, but it is now matched by the opportunity to benefit from a major infusion of additional resources. Mortality rates for many types of cancer have been dropping over the past 15 years, and there are greater opportunities for increasing our understanding of cancer and for benefiting patients through improved cancer prevention, screening, treatment, and survival rates. Immunotherapy has come of

age, and advances particularly in immune checkpoint inhibitors present new opportunities for treating people with cancer.

Some core features of the Cancer Moonshot have grown directly from the Precision Medicine Initiative. They include the **Genomic Data Commons** (GDC), opened in June at the University of Chicago. The GDC started with roughly 14,000 cancers from The Cancer Genome Atlas (TCGA) and its pediatric equivalent (TARGET) and will house data from all NCI-supported clinical trials. Other research entities have been invited to add their annotated cancers to the library; for example, Foundation Medicine, Cambridge, Mass., a commercial company that develops genomic analysis diagnostic products, has added 18,000 cancers with an analysis of about 350 genes. Another 20,000 cancers will be added in the next year. The database includes mostly molecular analysis but there are plans to increase clinical annotation as well.

Another component is the **NCI Virtual Drug Formulary**, which aims to shorten the time needed to start multi-drug cancer treatment trials when the drugs come from more than one pharmaceutical company. The formulary will remove a major roadblock to precision medicine clinical trials, particularly those conducted through academic centers. Agents will be provided for both clinical and pre-clinical studies. Pharmaceutical companies will have eight weeks to review proposals. The Virtual Drug Formulary opened in January 2017 and currently contains 15 drugs from six companies. The goal is to have 40 drugs from 10 companies.

In addition to the Cancer Moonshot Federal Task Force, of which Dr. Collins and Dr. Lowy are members, the Initiative formed a **Blue-Ribbon Panel**, a working group of the National Cancer Advisory Board. The goal of the panel is to identify major scientific opportunities that are poised to be accelerated, as well as major scientific and regulatory hurdles that might be overcome through additional emphasis and funding. The committee developed 10 recommendations for the Cancer Moonshot. The full report from the Blue-Ribbon Panel is available at cancer.gov/brp.

The 28 Panel members come from different sectors and include:

- investigators doing basic and applied research
- patient advocates
- representatives of pharmaceutical companies and biotech firms
- experts in bioinformatics, mathematical biology

In addition, the Panel set up seven working groups to bring another 100 individuals into the process.

The full list of the Panel's recommendations is available online, but Dr. Lowy highlighted a few, including:

- Establishment of a **cancer immunotherapy translational science network** to discover and evaluate novel immune-based approaches for adult and pediatric cancers and develop preventive vaccines against cancers not attributable to infectious agents. Two relatively

recent trials showed substantial clinical benefits from the use of a PD1 immune checkpoint inhibitor in patients with metastatic melanoma and advanced Merkel-cell carcinoma. Merkel-cell carcinoma has showed almost no sustained responses with standard therapy, yet half the patients who received the PD1 inhibitor showed a long-term response. Patients who had virus-positive cancers were more likely to respond to the treatment, but a subset of patients with virus-negative cancers also responded. Part of the Panel's aim is to increase understanding of the molecular basis for different responses to treatment by sharing data among researchers both in the United States and internationally.

- Increased focus on **fusion oncoproteins in pediatric cancer** to improve understanding of the drivers—and inhibitors—of pediatric cancers. While there has been progress in the treatment of pediatric cancer leading to a 20 percent decrease in mortality rates, the incidence of cancer in children has not changed substantially over the past few years. One of the recommendations focuses on increasing understanding of the molecular pathogenesis of pediatric cancers.

- Increased attention to **precision prevention and early detection of cancer** by implementing evidence-based approaches. Three areas were called out for focus, including HPV vaccination, colorectal cancer screening and tobacco cessation. Obesity, of special interest to NIDDK, is also an important factor in the development of many cancers, but it was not included because the Panel wanted to limit their areas of focus. Dr. Lowy explained the rationale behind the three areas of focus:
    - **Colorectal cancer screening**: dramatically decreases the mortality of colorectal cancer but is currently under-utilized, especially among minority populations and in rural area.
    - **Tobacco cessation:** Newly diagnosed cancer patients who stop smoking have better outcomes.
    - **HPV vaccination:** New data from Australia, where the vaccine has been available to women at no charge since 2007, shows that the incidence of covered types of HPV *in men* dropped from 10 percent to 1 percent prevalence, indicating that widespread vaccination led to "herd immunity." He noted that male vaccination did not start until 2013. Uptake of the vaccine in the United States has been slower, but there is still evidence for herd immunity, as the prevalence of HPV 16 and 18 have dropped by 60 percent since introduction of the vaccine. He predicted that higher uptake of the vaccine could lead to a dramatic decrease in HPV-associated cancers.

The Panel also recommended:

- Support for the **development of retrospective analysis of biospecimens** from patients treated according to the standard of care.
- **Creation of a human tumor atlas**, an amplification of the work started 10 years ago with the Cancer Genome Atlas. Technological advances now allow analysis on smaller samples,

both malignant and premalignant lesions, and even single cells, as well as the support cells in their micro-environment. Studying these cells over time will allow a better understanding of the evolution of cancer.

- **Development of new enabling technologies** to help understand cancer, diagnose it, and monitor treatments and responses.

The last part of Dr. Lowy's talk focused on developments in the Beau Biden Cancer Moonshot initiative, funded by the 21st Century Cures Act. The initiative is funded at $1.8 billion over seven years, with about $300 million for fiscal year 2017 and 2018, increasing to $400 million in 2019, and dropping to $200 million for the remaining years.

The uneven funding presents challenges in providing consistent support for the research, which Dr. Lowy said could be addressed in a number of ways, including:

- "No-year funding." This approach would use the $300 million allocated in 2017 to fully fund $60 million worth of five-year projects, rather than making first-year awards totaling $300 million. The advantage of this approach is flexibility to fund new research in later years. The disadvantage is that there would be relatively few awards in 2017, detracting from the initiative's intention to "hit the ground running."
- Maximize first-year awards in 2017. This approach would maximize the number of projects that receive initial funding, but would limit the initiative's ability to make first-year awards to new projects in later years. It would also limit the time available for input regarding the new initiatives.
- A hybrid approach, which is what Dr. Lowy indicated is planned, will compromise by spending at least $150 million on new first-year awards in fiscal year 2017, and use the remainder to fund at least $100 million in first-year awards in fiscal year 2018 and at least $50 million in fiscal year 2019. Dr. Lowy noted that NCI will plan to take advantage of its regular appropriation to supplement some of the Moonshot funds, to enable NCI to be more efficient in supporting new research. The Moonshot funding will be supplemented with less than one percent of the NCI's regular appropriation.

Dr. Lowy indicated that other institutes can participate in the Moonshot this fiscal year by discussing potential projects either him or NCI Deputy Director Dinah Singer. The NCI will actively seek ways to help other Institutes participate in Moonshot-related research and invites other institute staff members to join one of the 12 implementation teams aligned with the working group recommendations. The teams will develop and propose initiatives, seek input from the cancer research community, organize workshops, and provide oversight and coordination of funded initiatives. As examples of potential collaborative projects, NCI and the National Institute of Biomedical Imaging and Bioengineering (NIBIB), are developing a joint request for applications (RFA) for technology to identify circulating tumor DNA. NCI is also issuing a joint RFA with the NIAID to evaluate autoimmune consequences of immune checkpoint blockade.

NCI is also pursuing public-private partnerships with philanthropies in the U.S. and internationally, in countries that are interested in participating in the Moonshot.

**Council Question and Discussion**

*This year more people will die from liver cancer than from breast cancer, even though there are many more cases of breast cancer. Is there any plan to study liver cancer mortality, which has been rising for the last 30 years?*

Dr. Lowy said the NCI is planning a workshop on liver cancer, where treatments and cures have seen the least success compared with other cancers. He said Hepatitis C and rising obesity have both been important contributing factors, and that liver cancer tends to be diagnosed late, after tumors have advanced to the point where treatment options are limited.

## VIII. SCIENTIFIC PRESENTATION

*Dr. Rodgers announced that NIDDK Advisory Council member Dr. Joel Elmquist would give the Scientific Presentation entitled "**Using Mouse Genetics to Unravel the CNS Pathways Regulating Energy Balance and Glucose Homeostasis**."*

*Joel K. Elmquist, D.V.M., Ph.D., is a professor of internal medicine, pharmacology, and psychiatry. He is the Maclin Family Distinguished Professor in Medical Sciences in Honor of Dr. Roy A. Brinkley, the Carl H. Westcott Distinguished Chair in Medical Science, and the Director of the Division of Hypothalamic Research within the Department of Internal Medicine at University of Texas, Southwestern.*

*His research focuses on the functional neuroanatomy of the mammalian hypothalamus. His laboratory works mainly on the regulation of body weight homeostasis, food intake, and controls of the autonomic nervous system. Dr. Elmquist earned his D.V.M. and Ph.D. degrees at Iowa State University. He then did postdoctoral work at Harvard Medical School, the Beth Israel Deaconess Medical Center. He has written more than 150 peer-reviewed papers. He received the American Diabetes Association Outstanding Scientific Achievement Award in 2014.*

## IX. CONSIDERATION OF REVIEW OF GRANT APPLICATIONS

A total of 1088 grant applications (230 primary and 858 dual), requesting support of $377,689,218 were reviewed for consideration at the February 1, 2017, meeting. An additional 121 Common Fund applications requesting $40,208,415 were presented to Council. Funding for these applications was recommended at the Scientific Review Group recommended level. Prior to the Advisory Council meeting, 1343 applications requesting $381,277,240 received second-level review through expedited concurrence. All the expedited concurrence applications were recommended for funding at the Scientific Review Group recommended level. The expedited concurrence actions were reported to the full Advisory Council at the February 1, 2017, meeting.

## X. ADJOURNMENT

***Dr. Rodgers***

Dr. Rodgers expressed appreciation on behalf of the NIDDK to the Council members, presenters, and other participants. He thanked the Council members for their valuable input. There being no other business, the 203rd meeting of the NIDDK Advisory Council was adjourned at 4:30 p.m.

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

Griffin P. Rodgers, M.D., M.A.C.P.
Director, National Institute of Diabetes and Digestive and Kidney Diseases, and
Chairman, National Diabetes and Digestive and Kidney Diseases Advisory Council