

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 209th meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council at 8:30 a.m. on January 16, 2019, in Conference Rooms E1/E2, Natcher Conference Center, Building 45, the NIH Campus, Bethesda, Maryland.

A. ATTENDANCE – COUNCIL MEMBERS PRESENT

Ms. Tracey Brown ⁺	Mr. Richard Knight
Dr. Margot Damaser ⁺	Dr. Paul Lange
Dr. Iain Drummond ⁺	Mr. Thomas Nealon
Dr. Joel Elmquist	Dr. Richard Peek
Dr. Penny Gordon-Larsen ⁺	Dr. Jeffrey Pessin
Dr. Lisa Guay-Woodford	Dr. Michael Snyder ⁺
Dr. Caren Heller	Dr. Ronald Sokol
Dr. Barbara Kahn	Dr. Ian Stewart [*]
Dr. David M. Klurfeld [*]	Ms. Lorraine Stiehl

Also Present:

Dr. Griffin Rodgers, Director, NIDDK and Chair of the NIDDK Advisory Council

Dr. Gregory Germino, Deputy Director, NIDDK

Dr. Karl F. Malik, Executive Secretary, NIDDK Advisory Council

Dr. Stephen P. James, Director, Division of Digestive Diseases and Nutrition, NIDDK

Dr. Robert A. Star, Director, Division of Kidney, Urologic, and Hematologic Diseases, NIDDK

Dr. Philip Smith, Acting Director, Division of Diabetes, Endocrinology, and Metabolic Diseases, NIDDK

^{*} *Ex Officio* member

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

B. NIDDK STAFF AND GUESTS

Abbott, Kevin – NIDDK
Abraham, Kristin – NIDDK
Agodoa, Lawrence – NIDDK
Akolkar, Beena – NIDDK
Anderson, Dana – NIDDK
Arreaza, Guillermo – NIDDK
Barnard, Michele – NIDDK
Bateman, Jessica – American Urological Assoc.
Bavendam, Tamara – NIDDK
Berti-Mattera, Liliana – CSR
Best, Carolyn – American Urological Assoc.
Bishop, Terry – NIDDK
Blondel, Olivier – NIDDK
Boerboom, Lawrence – CSR
Bourque, Sharon – NIDDK
Burch, Henry – NIDDK
Burgess-Beusse, Bonnie – NIDDK
Byrd-Clark, Danita – NIDDK
Castle, Arthur – NIDDK
Cerio, Rebecca – NIDDK
Chan, Kevin – NIDDK
Chen, Hui – CSR
Cheng, Clara – CSR
Chowdhury, Bratati – NIDDK
Cowie, Catherine – NIDDK
Connaughton, John – NIDDK
Curtis, Leslie – NIDDK
Dayal, Sandeep – NIDDK
Denny, Alexis – PKD Foundation
Desiderio, Ulyana – American Soc. of Hematology
Densmore, Christine – NIDDK
Doherty, Dee – NIDDK
Doo, Edward – NIDDK
Drew, Devon – NIDDK
Eggerman, Thomas – NIDDK
Evans, Mary – NIDDK
Fisher, Rachel – NIDDK
Fonville, Olaf – NIDDK
Gansheroff, Lisa – NIDDK
Garcia, Martha – CSR
Gossett, Danny – NIDDK
Greenwel, Patricia – NIDDK
Haft, Carol – NIDDK
Hall, Sherry – NIDDK
Hamilton, Frank – NIDDK
Hanlon-Tilghman, Mary – NIDDK
Herzog, Peter – Digestive Disease Natl.
Coalition
Hoff, Eleanor – NIDDK
Hoffert, Jason – NIDDK
Hoofnagle, Jay – NIDDK
Hoover, Camille – NIDDK
Hoshizaki, Deborah – NIDDK
Hu, Jianxin – CSR
Hyde, James – NIDDK
Ivins, Jonathan – CSR
Jackson, Julia – NIDDK
James, Stephen – NIDDK
Jenkins, Ann – NIDDK
Jenkins, Connie – NIDDK
Jones, Teresa – NIDDK
Ketchum, Christian – NIDDK
Kimmel, Paul – NIDDK
Kirkali, Ziya – NIDDK
Kozel, Peter – NIDDK
Kranzfelder, Kathy – NIDDK
Laakso, Joe – Endocrine Society
Larkin, Jennie – NIDDK
Laughlin, Maren – NIDDK
Lee, Christine – NIDDK
Leschek, Ellen – NIDDK
Li, Yan – NIDDK
Linder, Barbara – NIDDK
Lynch, Christopher – NIDDK
Maric-Bilkan, Christine – NIDDK
Martey, Louis – NIDDK
Martin, Heather – NIDDK
Maruvada, Padma – NIDDK
Mendley, Susan – NIDDK
Morris, Ryan – NIDDK
Mullins, Christopher – NIDDK
Norton, Jenna – NIDDK
Osganian, Voula – NIDDK
Otradovec, Heidi – NIDDK
Parsa, Afshin – NIDDK
Pawlyk, Aaron – NIDDK
Payne, January – NIDDK
Perrin, Peter – NIDDK
Perry Jones, Aretina – NIDDK
Pike, Robert – NIDDK
Pileggi, Antonello – CSR
Rankin, Tracy – NIDDK
Regan, Karen – NIDDK
Reiter, Amy – NIDDK
Repique, Charlene – NIDDK
Roberts, Tibor – NIDDK
Rojas, Raul – CSR
Rooker, Ceciel – NIDDK
Rosenberg, Mary Kay – NIDDK
Roy, Cindy – NIDDK
Saslowsky, David – NIDDK
Sato, Sheryl – NIDDK

Sechi, Salvatore – NIDDK
Serrano, Jose – NIDDK
Sheets, Dana – NIDDK
Shepherd, Aliccia – NIDDK
Sherker, Averell – NIDDK
Sierra-Rivera, Elaine – CSR
Silva, Corinne – NIDDK
Singh, Megan – NIDDK
Smith, Jaime – NIDDK
Smith, Philip – NIDDK
Spain, Lisa – NIDDK
Star, Robert – NIDDK
Stoeckel, Luke – NIDDK
Southworth, Linda – NHLBI
Thornton, Pamela – NIDDK
Tilghman, Robert – NIDDK

Torrance, Rebecca – NIDDK
Tuncer, Diane – NIDDK
Turner, Linda – NIDDK
Unalp-Arida, Aynur – NIDDK
Utama, Herman – NIDDK
Van Raaphorst, Rebekah – NIDDK
Voss, Alyssa – NIDDK
Waddy, Salina – NIDDK
Wallace, Julie – NIDDK
Wang, Xujing – NIDDK
White, Vanessa – NIDDK
Wilkins, Kenneth – NIDDK
Woynarowska, Barbara – NIDDK
Wright, Elizabeth – NIDDK
Xia, Ashley – NIDDK
Yang, Jian – NIDDK
Yanovski, Susan – NIDDK

C. ANNOUNCEMENTS

Dr. Rodgers

Council Member News

Dr. Rodgers opened the meeting by welcoming new representatives to the Advisory Council. **Ms. Tracey Brown**, Chief Executive Officer of the American Diabetes Association (ADA) joined as a public member representative and will be serving on the Council's Diabetes, Endocrinology, and Metabolic Diseases (DEM) subcommittee. Ms. Brown joined the ADA in June after serving as Senior Vice President of Operations and Chief Experience Officer for Sam's Club. Ms. Brown started her career as a chemical engineer at Procter & Gamble. She then earned an MBA from Columbia University and has business leader with 25 years of experience working to solve complex issues for large multinational companies. Ms. Brown has been an enthusiastic volunteer and fundraiser for ADA and understands the challenges of the patient community because she lives with type 2 diabetes herself.

Dr. Iain Drummond is associate professor of medicine and genetics and a member of the Program in Developmental and Regenerative Biology at Harvard Medical School. He is also a biologist at Massachusetts General Hospital and a principal faculty member at the Harvard Stem Cell Institute. Dr. Drummond will serve on the Council's Kidney, Urologic, and Hematologic Diseases (KUH) subcommittee. Dr. Drummond earned his Ph.D. at the University of California, Berkeley, and his current research focuses on kidney organogenesis using zebra fish to explore conserved molecular mechanisms underlying cell differentiation, morphogenesis, and regeneration. His lab also studies organ pathologies that result from gene mutations required for cilia biogenesis. This includes kidney cystic disease, retinal degeneration, and left-right asymmetry defects. Dr. Drummond is currently participating in NIDDK's ReBuilding a Kidney initiative and presented about his work at the Regenerative Medicine Council Forum at the September 2018 meeting of the Advisory Council.

Dr. Penny Gordon-Larson is professor of nutrition in the Gillings School of Global Public Health at the University of North Carolina at Chapel Hill. She is joining the Digestive Diseases and Nutrition (DDN) subcommittee. Dr. Gordon-Larson earned her Ph.D. from the University of Pennsylvania. Her NIH-funded research focuses on individual-, household-, and community-level susceptibility to obesity and its health consequences. Her work explores molecular, genetic, environmental, and societal factors relating to obesity over the life cycle, with special focus on ethnicity, disparities, and pathways linking environment and behavior to risk for developing heart disease and diabetes. She is a Past President of The Obesity Society.

Dr. Michael Snyder is Stanford W. Ascherman Professor and Chair, Department of Genetics and Director, Center for Genomics and Personalized Medicine at Stanford University. He is joining the DEM subcommittee. Dr. Snyder earned his Ph.D. at the California Institute of Technology, is a leader in the field of functional genomics and proteomics, and is one of the major participants of the *Encyclopedia of DNA Elements* (ENCODE) project. His laboratory was the first to perform a large-scale functional genomics project in any organism, and has developed many, now familiar,

technologies in genomics and proteomics.

These four members currently serve as *ad hoc* members, but will join the Council as regular members soon.

Dr. Rodgers also made a few additional announcements:

Former NIDDK Council member **Dr. Anil K. Rustgi** has been named director of the Herbert Irving Comprehensive Cancer Center at New York-Presbyterian/Columbia University Irving Medical Center. Pending approval by Columbia University's trustees, Dr. Rustgi will serve as professor of medicine and associate dean of oncology in the Vagelos College of Physicians and Surgeons, and will join the cancer center full-time in early spring of this year. Dr. Rustgi has pursued a multifaceted career at the Perelman School of Medicine at University of Pennsylvania that has included research, patient care, and teaching.

Dr. Stephen Katz, long-time Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) passed away suddenly on December 20, 2018. One of NIH's most respected and beloved leaders, Dr. Katz came to NIH in 1974 as a Senior Investigator in the Dermatology Branch at the National Cancer Institute, and went on to become Branch Chief in 1980. In 1995, Dr. Katz was named Director of NIAMS. Dr. Rodgers said that NIDDK has a special connection to NIAMS because the two ICs both resulted from the division of the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases in 1986. In fact, Dr. Rodgers said that he had invited Dr. Katz to speak at today's meeting to provide an update on NIAMS and some of the shared interests between NIDDK and NIAMS. Dr. Katz was regularly tapped by NIH leadership to help navigate some of its most difficult situations. In announcing Dr. Katz's death, Dr. Francis Collins noted that, "His legacy is simply profound." Dr. Rodgers extended condolences to Dr. Katz's family and colleagues.

On a happier note, Dr. Rodgers announced that **Dr. Ad Bax**, a Senior Investigator in NIDDK's Intramural Research Program's Laboratory of Chemical Physics, was selected as recipient of the 2018 Robert A. Welch Award in Chemistry. This award recognizes his development of the novel methods for structure determination, which have led to important advances in the understanding of basic biological systems at the molecular level. NIDDK congratulated Dr. Bax for this prestigious recognition of his research accomplishments, his contributions to the field of nuclear magnetic resonance, and the impact of his career on the biomedical research community.

NIDDK Staff News

Dr. Rodgers reported several staffing changes within NIDDK:

With the retirement of Dr. Judith Fradkin, **Dr. Philip Smith** is currently serving as Acting Director of DEM. Dr. Smith has served as DEM's Deputy Director for many years and is also co-director of NIDDK's Office of Obesity Research. As Acting DEM Director, Dr. Smith will serve as Chair of the Council's DEM subcommittee. Dr. Rodgers thanked Dr. Smith for stepping in during the search for a new DEM director and commented that DEM is in excellent hands.

Dr. Rodgers also announced the appointment of **Dr. Karl Malik** as Director of the Division of Extramural Activities (DEA). In this position, Dr. Malik will coordinate and oversee the receipt, referral, and scientific review of extramural research grants before they are funded, and process/manage research and training awards. Dr. Malik will oversee several distinct but related functions involving extramural science programs and activities and provide executive and managerial leadership for integrated program planning and development, policy development, and resource allocation, in collaboration with the leadership of the various offices within DEA and in other NIDDK divisions. He will also continue to serve as Dr. Rodgers's principal advisor on the Institute's extramural scientific programs.

Dr. Malik earned his Ph.D. in neuroscience from Rutgers University and completed a postdoctoral fellowship in the Laboratory of Molecular and Cellular Biology at the National Institute of Mental Health. With two partners, he founded MarkSport, Inc., an America Online (AOL) partner company, rising to become MarkSport's president, working with diverse partners and customers. Dr. Malik returned to the NIH in 2001 to the NIH Center for Scientific Review (CSR), where he spent four years at CSR before joining NIDDK in 2005. He has served as Deputy Director, DEA and Director, Office of Research Evaluation and Operations (OREO) and served as the Acting Director, DEA for almost all of 2018.

Vikas Khator has been appointed NIDDK's Chief Information Officer. Mr. Khator brings over 23 years of experience in information technology in both the private and public sectors. He was formerly Service Area Manager for Network Security Services at the NIH Center for Information Technology. He joined NIDDK as Deputy CIO, and stepped into the role of Acting CIO within two months. He has served in that acting capacity for nearly two years and has impressed NIDDK staff and leadership with his technical knowledge and his gift for customer service. As our CIO, Mr. Khator leads the Computer Technology Branch's services and operations, oversees NIDDK's IT infrastructure and security, and works closely with the intramural and extramural communities to reinforce CTB's commitment to customer service and programmatic support.

Dr. Rodgers also announced the appointment of **Dr. Heather Rieff** as Director, Office of Science Program and Policy Analysis (OSPPA). Dr. Rieff will act as primary science policy advisor to Dr. Rodgers and senior scientific managers on policy, planning, legislative and reporting matters. She will also provide support to Dr. Rodgers by researching relevant scientific and policy issues and facilitating dialogue with representatives of professional organizations, patient-advocacy groups, and members of Congress and their staffs. Dr. Rieff earned her Ph.D. in neurobiology from Harvard University and completed a postdoctoral fellowship in the Department of Neuroscience and department of biology at the University of Virginia. She began her career as a science policy analyst in the Office of Public Affairs at the Federation of American Societies for Experimental Biology. At NIH, she has served at the National Institute of Neurological Disorders and Stroke (NINDS) as a health science policy analyst in the Office of Science Policy and Planning. At NINDS, she led an institute-wide program of legislative activities and disease-specific and strategic planning efforts, program evaluation, and assessments.

Dr. Kevin Chan has joined NIDDK to oversee clinical and epidemiologic studies in KUH and provide expertise on chronic kidney disease, dialysis, and clinical informatics. Dr. Chan received his M.S. degree in epidemiology at Stanford University, and earned his M.D. from the University of Ottawa. After his residency at UCLA Medical Center, and a fellowship in nephrology at Stanford University, he was senior director of outcomes research at Fresenius Medical Care North America, as well as assistant professor at Harvard Medical School/Massachusetts General Hospital. He is a previously-NIH-funded principal investigator and a nationally recognized thought leader in clinical dialysis.

Dr. Rodgers also welcomed **Vanessa White**, program analyst for DDN. Ms. White earned her M.P.H. from Boston University, and previously was a program analyst in the Office of AIDS Research in the NIH Office of the Director.

Dr. Rodgers also showed the results of a “renovation” of the NIDDK website, which should make NIDDK’s online resources easier to find and use. The website will now resize to different types of devices, including mobile devices. Other improvements include:

- redesigned extramural research content with streamlined presentation of research funding opportunities
- a new intramural research page, showcasing NIDDK labs and science, training, and employment opportunities
- mobile-friendly content for the general public, including updated information on prevention and management of acute and chronic diseases and conditions.

These web enhancements have improved NIDDK’s customer satisfaction from a baseline of 64 (out of 100) in 2012 to 84 today.

Dr. Rodgers also brought to the Council’s attention the 2019 edition of [NIDDK's Recent Advances and Emerging Opportunities](#), which highlights examples of NIDDK-supported research progress published in Fiscal Year 2018. He pointed out the cover art, which shows the villi of the small intestine. Recent NIDDK-supported research shows that within these structures are cells called telocytes that play an important role in supporting intestinal stem cells. The volume also includes summaries of the three scientific presentations from 2018 Council meetings as well as stories of research discoveries and personal stories of patients living with or at risk for diseases that are part of NIDDK’s mission. It also features data on NIDDK’s funding trends. Dr. Rodgers thanked all involved in this effort, particularly the Office of Scientific Program and Policy Analysis, which developed the content and managed the project, as well as the extramural and intramural divisions, which provided input and guidance. NIDDK welcomes comments from the Council on the report.

Dr. Germino announced that in October 2018, Dr. Rodgers received the President’s Medal from the American Society of Nephrology (ASN) during the ASN Kidney Week Meeting in San Diego. This is the highest award bestowed by the Society, and adds to the list of awards and recognitions Dr. Rodgers continues to garner for his vision and dedication to advancing NIDDK’s scientific research mission. The Council joined Dr. Germino in congratulating Dr. Rodgers on his award.

II. CONSIDERATION OF SUMMARY MINUTES OF THE 208th COUNCIL MEETING

Dr. Rodgers

The Council approved, by voice vote, the Summary Minutes of the 208th Council meeting, which had been sent to them in advance for review.

III. FUTURE COUNCIL DATES

2019

May 8-9 (Wednesday and Thursday)
Porter Neuroscience Building, Building 35

September 11 (Wednesday)
Natcher Conference Center, Building 45

2020

January 29-30 (Wednesday and Thursday)
Building 31, Conference Rooms 10, 6 and 7

May 20-21 (Wednesday and Thursday)
Building 31, Conference Rooms 10, 6 and 7

September 9-10 (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. Karl Malik

Confidentiality

Dr. Malik 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. Malik 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. Malik 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. Malik pointed out that when the Council reviews applications in groups without discussion--also called "*en bloc*" actions--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. Malik 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.

V. ITEMS FOR CONSIDERATION

Dr. Malik

Dr. Malik introduced two items for consideration. The first was the annual approval of council operating procedures. Dr. Malik pointed out some minor updates to the procedures to clarify some existing information. The motion to approve was made and accepted without concerns.

Dr. Malik also explained that the NIH Revitalization Act of 1993 (Public Law 103-43) directed NIH to establish guidelines for inclusion of women and minorities in clinical research. The law also requires the advisory council of each national research institute to prepare reports outlining the institute's compliance with those guidelines. The 21st Century Cures Act of 2016 (Public Law 114-255) amended the frequency of those reports from every two years to every three years. Dr. Malik asked whether the Council had any questions on the 2018 Triennial Advisory Council Report on Inclusion of Women and Minorities in Clinical Research, which was provided to council members for review prior to the meeting. He then asked for a motion to accept the report. The motion was made and accepted.

VI. REPORT FROM THE NIDDK DIRECTOR

Dr. Rodgers

Budget Update

In late September 2018, the House and Senate passed, and the President signed into law, the 2019 Labor-HHS-Education appropriations bill coupled with the 2019 Department of Defense appropriations bill—collectively referred to as a “minibus.” The appropriations included in this minibus comprise 72 percent of federal discretionary spending, including the NIH budget. As a result of this legislation, the defense, labor, HHS, and education agencies were spared the effects of the government shutdown, which was still underway.

Dr. Rodgers reviewed the funding numbers for NIH and NIDDK. NIH received an increase of \$2 billion (5.4 percent) over the fiscal year 2018 level, and NIDDK received an increase of \$67 million (3.4 percent). The larger percentage for NIH is partially due to the 21st Century Cures Act of 2016, which designated targeted funding for certain projects, which represent about one-third of the overall increase in NIH’s budget. NIH institutes and centers (ICs) that did not receive this targeted funding received similar increases to NIDDK’s 3.4 percent. Most agencies that received targeted funding saw increases of up to 6.6 percent. Because of targeted appropriations for Alzheimer’s Disease, the National Institute on Aging received a budget increase of nearly 20 percent. Since 1996, both NIH and NIDDK funding have risen steadily, although NIH as a whole has increased at a slightly higher rate, rising from \$30 billion to \$40 billion in the last five years. However, adjusted for inflation, NIH’s and NIDDK’s budgets peaked in 2003 and have not kept up with the rate of inflation. Thanks to budget increases since 2016, NIH has regained more than half of its lost purchasing power since 2003. NIDDK has recovered some but not as much of its purchasing power. Although this is an improvement, it is not where NIDDK or the scientific community would like it to be.

Looking ahead to the coming fiscal year, the President is supposed to submit his budget proposal for Fiscal Year 2020 to Congress in early February. Since the last Congressional Budget Resolution covered both fiscal years 2018 and 2019, the new budget resolution—which is the foundation for appropriations—should be forthcoming around April 2019. Budget hearings should occur between March and June, with the goal of a new budget being in place by October 1, 2019. If a budget for FY 2020 is not passed and signed into law by October 1, there will either be a continuing resolution or, worst case, another government shutdown.

Dr. Rodgers also reviewed the results of the November 2018 election, which has led to many changes in the makeup of Congress. The Democrats now hold the majority in the House, while the Republicans retained their control of the Senate and even picked up a couple of seats. Dr. Rodgers noted the record number of women who ran for and won office. He also pointed out that a total of 35 physicians and scientists serve in the 116th Congress (up from 29). Looking at the committees with jurisdiction of NIH, the chairs and ranking members remain the same in the Senate, but in the House the chair and ranking members shift to the Democrats, but the specific membership had not been announced yet.

Lastly, Dr. Rodgers spoke of budget caps, the dollar amount that limits the total federal discretionary appropriations, pointing out that the budget resolution determines specific funding amounts. The statutory budget caps that were negotiated in 2011 are due to expire in 2021. Two budget deals (in 2018 and 2019) raised non-defense discretionary caps to \$597 billion, but another two-year deal is needed to cover fiscal years 2020 and 2021. Without it, the cap will go down by \$19 billion. The defense discretionary cap faces a similar situation. Both defense and non-defense advocates are aligning around a new budget for later this year. Even if the Congressional leadership reaches an agreement to reopen the government and fund it for the rest of this fiscal year, they must still agree on spending limits for fiscal 2020.

VII. STRATEGIC PLAN FOR NIH NUTRITION RESEARCH

Dr. Christopher Lynch

Dr. Rodgers introduced Dr. Christopher Lynch, Director of NIDDK's Office of Nutrition Research who has served as executive secretary of the NIH Nutrition Research Task Force, which is currently developing a strategic plan for NIH nutrition research. This plan will emphasize innovative opportunities to advance nutrition research and complement and enhance ongoing efforts across NIH to prevent and combat disease and conditions affected by nutrition. The plan recently went through a public comment period and the draft is now undergoing revisions and final clearance before being released in early 2019.

Dr. Lynch began by explaining that Dr. Collins formed the trans-NIH Nutrition Research Task force in 2016 to develop a strategic plan to help guide NIH-supported nutrition research. This marked the first time NIH has convened representatives from all institutes, centers, and offices to develop a strategic plan for nutrition research.

Interest in diet and nutrition spans many institutes, centers, and offices within the NIH. Chronic disease treatment accounts for more than 75 percent of national health care costs, and four out of 10 leading causes of death are diet-related, including heart disease, some cancers, stroke, and type 2 diabetes. For many other diseases, diet is a major factor. While other factors that affect disease risk—such as genes or the environment—are largely out of a person's control, most people have some choice over diet and eating patterns.

Certain dietary patterns and behaviors have been linked to the improvement or prevention of more than one condition, and people frequently have more than one diet-related condition at one time. Dietary exposures *in utero* or childhood can have life-long consequences that sometimes can pass to the next generation. Additionally, methodologies that improve the rigor of nutrition research also benefit investigations sponsored by multiple ICs. The growing interest in nutrition research is reflected in the increase in NIH funding for this line of research. NIDDK leads NIH funding in this area, followed by National Heart, Lung, and Blood Institute; National Cancer Institute; and National Institutes on Aging.

The NIH Nutrition Research Task force is co-chaired by four institute directors: Dr. Rodgers from NIDDK, Dr. Gary H. Gibbons from NHLBI, Dr. Norman E. Sharpless from NCI, and Dr. Diana W.

Bianchi from the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development. Senior leadership includes Dr. Andrew Narva and Dr. Lynch from NIDDK, Drs. Victor Kipnis and Amy Subar from NCI; Dr. Charlotte Pratt from NHLBI, and Dr. Andrew Bremer from NICHD. In addition, more than 40 intramural and extramural scientist volunteers from 17 different ICs make up the Writing/Working Group.

The group started with a literature search and review of white papers outlining recommendations for federal action. In early 2017, the Task Force wrote to every scientist who had applied for nutrition research funding in the last five years (12,000 total) to solicit their ideas and other input. Also in 2017, a panel of thought leaders nominated by the writing group provided additional input. The literature search yielded 300 ideas, as did the letter campaign. The Task Force then consolidated that number to 200 ideas, and then asked the thought leader panel to further prioritize those to a more manageable number. In addition, both NIH and the National Academy of Science have recently held workshops on nutrition research and those sessions provided some additional ideas. The result was 26 research priorities that were presented for public comment. The polished version of the strategic plan will be published later this year, and the group has now held its first implementation meeting.

The strategic plan identifies a framework of seven themes and four research areas that span these themes. These cross-cutting areas include:

- Minority Health and Health Disparities
- Women's Health
- Rigor and Reproducibility, including
 - Harmonization of research methods and common data elements
 - Nutrition as a relevant variable influencing all biological responses
 - Transparency in conducting nutrition research
- Systems Science

Dr. Lynch then described the seven themes:

1. **Investigate nutritional biochemistry, physiology, behavior, and the microbiome:** This foundational and fundamental theme will address bioinformatic gaps in nutrition-related pathways, genes, and chemistry. This would include investigations into nutrient transporters and their role in nutrition, fatty acids and their physiological effects, nutrition “dark matter” (metabolites in food and in the microbiome that bear further investigation), and integrative physiology of ingestive behaviors, gut-brain communication, and the role and location of different taste receptors in the body. This theme also encompasses the interrelationship between diet, hosts, and the microbiome and how that can be leveraged to promote health.
2. **Assess the role of nutrition and dietary patterns in development, health, and disease across life stages:** This includes examining the role of preconception and prenatal nutrition in maternal and child health, and addressing gaps in nutrition research at different stages of development, from birth, through childhood and adolescence, and to older adulthood. It would also include study of dietary patterns (including preparation, timing, and quantity) and their role in health promotion and disease prevention.

3. **Explore individual variability in response to diet to inform nutrition science, improve health, and prevent disease:** This line of research includes biological and environmental factors that influence nutrition.
4. **Enhance clinical nutrition to improve health outcomes in patients:** This area focuses on clinical nutrition, or the connection between nutritional status and disease states, and the role of nutrition in clinical care. Lines of inquiry might include improved methods to assess nutritional status and better criteria and expanded evidence base for nutritional intervention, including in premature and low-birthweight infants and individuals with special nutrition requirements. This latter category includes people with disorders that affect metabolism and digestion (inflammatory bowel disease, irritable bowel syndrome, and celiac disease), and also people who have undergone bariatric surgery.
5. **Advance research on implementation of nutrition-related programs, practices, and behaviors:** Research under this theme would examine real-world applications of increasing the uptake of evidence-based diet plans, such as NHLBI's DASH diet. It would also look at multidimensional strategies to implement and sustain nutrition-related behaviors that promote health.
6. **Develop and refine research methods and tools.** Accurate documentation of dietary intake is an ongoing challenge in nutrition research. Emerging technologies, biomarkers, and assessment methodology offer some new possibilities. Could biomarkers be used to identify those at risk for diabetes or cardiovascular disease even earlier and assess effectiveness of nutritional interventions to address that risk? This theme includes the development and improvement of tools for using big data to collect and analyze information from various sources (patient health records, grocery store sales) and take a systems science approach to nutrition research. It might also include development of sensors for continuous monitoring of nutrients and metabolites (including blood glucose in people with diabetes). The development of predictive epigenetic tools may help increase understanding of factors involved in changes in gene expression. Encouraging controlled feeding studies may help establish the biology in a controlled situation before implementation in real-world settings.
7. **Support research training to build an outstanding nutrition research workforce:** This theme emphasizes the development and facilitation of training new scientists, especially in the areas of hosts, microbiome metabolism, diet interrelationships, and big data approaches to nutrition science.

Dr. Lynch ended by referring Council members to the Task Force's webpage, where the finalized plan will be released soon. He then took questions from the audience.

Council Questions and Discussion

What are the initial implementation plans for this? Are you working with the Food and Drug Administration on what evidence they need to build evidence for special nutritional requirements and nutritional supplements? This affects insurance coverage and patient access to these therapies.

Dr. Lynch explained that the usual NIH approaches will be used to implement the Task Force's recommendations. Dr. Collins and FDA Commissioner Dr. Scott Gottlieb have organized the Joint Agency Nutrition Group that includes representatives from FDA and NIH to address what evidence

the FDA needs to approve nutritional supplements and dietary approaches to treating disease. Dr. Lynch pointed out that special diets to address specific health conditions can be very expensive and burdensome to families.

An increasing number of physicians and wellness programs are “prescribing” fruits and vegetables as a “medication” to promote health. What are the possibilities for insurance coverage or subsidy for people who can’t afford quality foods? Paying for food would be cheaper than a lot of the drugs available to treat disease.

Dr. Lynch said that a member of the Task Force is working to increase nutrition curricula in medical schools, but the best place to include this learning may be in residency when physicians are most likely to retain and use the knowledge. The Task Force is not getting involved directly in recommendations for insurance coverage, but they would be interested in considering research proposals that leverage natural experiments or pragmatic trials to investigate whether using specific diets and nutritional approaches as “medicine” is effective.

Would having a reference map for the human metabolome and the human “foodome”—like we now have for the human genome—be valuable foundational information for this research? This seems like a good project for the NIH Common Fund.

Dr. Lynch pointed out that recently the glycoscience program has started work to develop an assay to measure oligosaccharides as new drug targets. Increasing bioinformatics of biochemicals is definitely a goal of this initiative. Dr. Phillip Smith, who chairs the Metabolomics Common Fund Program, said that one of the primary goals of that program is to identify as much of the metabolome as possible. Currently the components have been identified represent the tip of a large iceberg.

The U.S. has a large nutraceutical industry, with sales in the hundreds of billions of dollars. Has NIH thought about partnering with these large companies?

Dr. Lynch pointed out that many nutraceuticals are not FDA approved. Currently, NIH spends about \$1.8 billion on nutrition research. The industry spends close to \$12 billion. It would be desirable to leverage these efforts. However, partnering with industry presents a variety of challenges for NIH. We hope, where possible, industry representatives would share the results of their research and discuss research needs with us as stakeholders.

Where does obesity research fit in this plan?

Dr. Lynch pointed out that there is a separate Obesity Research Task Force, and the two task forces are working closely together. The Nutrition Research plan is designed to be disease-neutral because the goal is for all institutes and centers to work on it.

VIII. UPDATE: CENTER FOR SCIENTIFIC REVIEW (CSR)

Dr. Byrnes

Dr. Rodgers introduced Dr. Noni Byrnes, Acting Director, Center for Scientific Review (CSR). Dr. Rodgers informed Council members that the CSR reviews all NIH grant applications to ensure that they receive a fair, independent, expert and timely review, free from inappropriate influence. It refers grant applications to the appropriate initial peer review and institute funding components and performs the initial peer review for slightly more than 70 percent of all NIH applications. Dr. Byrnes has served in several positions at CSR, including Scientific Review officer, Integrated Review Group chief, division director, and now acting director.

Dr. Byrnes began by noting that while most of the other 27 institutes in NIH have their own review branch that performs specific types of review in the interest of that institute, CSR does not have funding authority and instead focuses entirely on review and ensuring that institutes can identify the most promising research. The CSR Advisory Council advises the CSR director on peer review design and processes.

Dr. Byrnes outlined CSR's funding and budgetary structure, noting that its \$135 million budget is 0.38 percent of NIH's total \$37.3 billion budget. CSR allocates 56 percent of its budget for staff, 31 percent for reviewers, and 13 percent for operations.

In a typical year, CSR handles 77 percent of NIH's 81,000 applications, organizes more than 200 chartered or recurring study sections that meet three times per year, and annually holds 1,600 review panel meetings. CSR uses more than 18,000 outside reviewers each year. Currently, CSR has a staff of 245 Scientific Review Officers (SROs).

In addition to reviewing the vast majority of R01 grant applications, CSR handles all reviews for the institutes that have no review branch, and most of the trans-NIH reviews initiated by the Office of the Director. CSR also oversees reviews for various interagency collaborations, including NIH's All of Us (precision medicine), FDA tobacco research, Brain Research through Advancing Innovative Neurotechnologies (BRAIN), Cancer Moonshot, and Global Alliance for Chronic Disease.

Dr. Byrnes stated that CSR intends to become more transparent to the scientific community regarding their activities. An important part of this effort was to launch a new CSR website in August 2018 that uses plain language and seeks to make the NIH easier to navigate for scientists who are seeking grant support. The website revision includes updated guidelines for all 178 study sections. Each section now also contains shared interest or overlap statements to assist scientists in determining which review panel might be most suitable for their project.

CSR also launched last summer an orientation program for incoming study section chairs delivered via video streaming. Study section chairs serve for two years, so each year about half of them rotate in or out of that role. Training topics included the role of the section, fostering a culture of review integrity, upcoming NIH policies affecting review, and addressing significance/impact in scoring.

Facilitated breakout sessions explored leadership strategies new section chairs can bring to their roles.

Since 2011, CSR's Early Career Reviewer (ECR) Program has helped enrich the pool of NIH reviewers. Promising junior faculty who have not received a R01 grant and have never served on a study section are invited to attend a peer review meeting and serve as a third reviewer on a small number of applications. To date, 3,111 scientists have received ECR training and then served on study sections. Nearly half of these are women, 19 percent are from underrepresented racial/ethnic groups; 143 former ECRs are now members of standing study sections who have received their own R01 funding. CSR's goal is to have one ECR on every standing study section for every council round.

CSR Evaluations

A full evaluation of the ECR program is underway and will include demographic analysis (gender, race, ethnicity, geographic distribution, institution type for both database and ECRs used in review), analysis of success rates for R01s submitted by ECRs compared to other early career researchers matched for relevant demographic and career characteristics, and a survey of ECRs to identify areas of improvement for the program.

Dr. Byrnes also updated the Council on the CSR Anonymization Study, which has been designed to examine potential sources of bias. In this pilot, a contractor has redacted reviewer information from 1,200 previously considered applications and then resubmitted them for review. The study's experimental approach, results, and data will be peer-reviewed and shared, with an anticipated date of completion of fall 2019. In particular, Dr. Byrnes thanked Dr. Richard Nakamura, the former director of CSR, who initiated the study and who is still involved in it as a volunteer.

Dr. Byrnes shared with the Council that following years of study, CSR has developed a new framework for CSR study section evaluations. By way of background, she explained that in 2003, the Panel on Scientific Boundaries of Review (PSBR) recommended wholesale reorganization and mandated recurring evaluations of study sections.

For the next 10 or so years, internal evaluations focused on integrated review groups (IRGs), CSR's organizational/management grouping of study sections.

In the next stage of evolution, external working groups operated within the existing IRG organizational structure and provided bibliometric and scientific overlap data and conferred with SROs to evaluate quality and processes. These working groups did not provide feedback about how the study sections were structured or if they were still relevant.

In 2015, CSR piloted an evaluation process that no longer considered the IRG organizational structure. They formed 10-20 scientific clusters based on text analysis and an overlap between study sections, and assembled a blue-ribbon working group of scientifically broad, senior scientists with interest in more than one scientific review group (SRG). Staff provided background information like current scientific guidelines for all study sections, titles, abstracts, specific aims, and workload trends and ensured the working group received enough time and guidance for

meaningful evaluation and recommendation.

SRGs were instructed to answer one question designed to focus discussion on the science, not the process: *How well does the scientific scope of the study sections align with the current state of the science?* If a study section was currently over- or under-subscribed or the scope of the science reviewed by a study section was not adequately representative of the scope of the field and emerging fields, the working group could recommend merging or eliminating study sections. They could also recommend moving an area of science from one study section to another or even creating new study sections in response to the emergence of new areas of science. In the past several years, CSR has successfully reorganized and reimagined several areas, including bioengineering, imaging, basic cancer biology, visual sciences, and AIDS.

New Process for Study Section Evaluation

Dr. Byrnes also informed the Council that between December 2017 and June 2018, the Trans-NIH Working Group on Peer Review developed a robust study section evaluation process. The Working Group, co-led by CSR and representatives from NIH institutes and centers, carefully considered data/metrics, multiple inputs, and measures to design a process that CSR could reasonably implement. They built on successful model of scientific review by external model, by adding an examination of bibliometric and publication data to determine if published research funded by each section is of the expected quantity and quality. It also adds a process evaluation component to look at scoring patterns, conduct surveys of reviewer and program officers, and hold site visits and discussions. For example, low numbers of early-stage investigators funded may indicate unusually critical reviewing, insufficient applications, or perhaps a declining area of research.

Overall, the new evaluation process combines the strength of expert opinion and objective metrics while increasing engagement with the scientific community, Council, and ICs. In the continuous, systematic review process, 20 percent of the study sections are evaluated each year, with each section undergoing evaluation once every five years. This new processes addresses both the NIH Strategic Plan element “Optimize approaches to inform funding decisions” and CSR’s mandate to continually examine the functions.

Two clusters are currently under evaluation. The External Scientific Evaluation Group Meeting occurred shortly before the NIDDK Council Meeting and the Internal Process Evaluation Group Meeting was to have occurred shortly afterward. A presentation to the CSR Advisory Council is planned for March 2019.

Peer Review Integrity

Although Dr. Byrnes emphasized that most reviewers maintain integrity, there are a small number of concerning reports. The integrity of the peer review process is critically important for everyone in the scientific community and a vital part of maintaining the public trust in the NIH’s stewardship of taxpayer dollars to support U.S. biomedical research. Because confidentiality is critical for candor in discussion and evaluation, and thus impacts the very basis of the peer review process. Support will be needed from the entire research community—investigators, reviewers, chairs, NIH staff, and institutional officials—to create the necessary culture change.

Dr. Byrnes reported that the NIH follows up on every alleged breach of confidentiality. That means referring cases to the Office of Management Assessment (OMA)—which investigates and then issues a report with their findings. Actions have included deferral of application, withdrawal of application, removal from serving on a peer review committee, and notifying the PI's or reviewer's institution, which in turn has led to personnel actions, pursuing government-wide suspension and disbarment, or referral to other agencies for criminal violations.

CSR requires that each scientific review officer add a statement to their email signature: "Integrity matters. Say something! For concerns or questions about possible violations of peer review integrity, please contact your Scientific Review Officer, or the CSR Review Integrity Officer at csrrio@mail.nih.gov, or the NIH Review Policy Officer at reviewpolicyofficer@mail.nih.gov. See the NIH Guide Notice on integrity in review."

Council Questions and Discussion

Does CSR have a mechanism for evaluating individual members of each study section?

Dr. Byrnes explained that CSR is currently developing computational methods to identify reviewers who consistently score more leniently or more harshly than their peers. Additionally, CSR relies on reviewer questionnaires that are part of each section review. Some reviewers are using the free-choice area of that survey to identify peers whose scoring may be disparate compared to others'.

On the staff level, division directors conduct study section visits in which they attend meetings outside their own disciplines and take note of section members who may be displaying bias or otherwise not providing quality reviews. Scientific review officers also note inadequate critiques and may not invite that reviewer back.

What can CSR do to incentivize reviewers? Would it be possible to extend a reviewer's grant support via continuing noncompetitive renewal for the duration of section service?

Dr. Byrnes agreed on the need to do more to attract senior reviewers. However, due to legal issues, there are strict limits on compensating reviewers for service. CSR staff currently are consulting with counsel, and Dr. Byrnes is working with the Extramural Activities Working Group to research possible solutions as well.

If CSR oversees 77 percent of the reviews in NIH, who oversees the other 23 percent?

Each funding institute has its own review staff and process.

How do you identify candidates for the Early Career Reviewer program?

Candidates apply. They must have a faculty position and have published in the field, although they needn't have received a grant of their own. Candidates who meet the criteria are added to CSR's

database. Currently, more people wish to serve on a section than can be accommodated, so the process is becoming more competitive.

It seems that the composition of the study sections is focused on attaining geographic diversity. Does this effort come at the expense of getting the most experienced reviewers in a field?

Dr. Byrnes noted that federal advisory committees are required to have geographic as well as other types of diversity, such as race and gender, but study sections are not. To become a member of a study section, candidates are nominated in a slate by each scientific review officer based on publications, grant support, and breadth of experience. That slate must go to the review group chief, the division director, and then the director of CRS. With 190 sections, it is possible that section members who lack experience and credentials could be nominated. If that's the case, interested parties should notify the relevant scientific review officer or escalate to a higher level using the CSR organization chart posted on the website.

Can you elaborate on the make-up and functioning of CSR's Special Emphasis Panels (SEPs)?

Dr. Byrnes said that recurring SEPs have been included in the external review process. The external review panels were encouraged to fold SEPs into larger groups that have recurring membership whenever possible.

Has CSR considered alternate metrics for reviewers to use, such as forced ranking systems?

Dr. Byrnes noted that the current system is absolute scoring based on descriptors. Once CSR staff receive scores from their study section, they attach percentiles, which effectively ranks the grants. At one point, CSR did a pilot study that allowed reviewers to both score and rank studies but Dr. Byrnes did not know the pilot's results. Another possible option would be to have the entire committee provide one set of joint rankings with their recommendations.

CSR's current formula is to take three rounds of scores for R01s for a given study section to form a base and then put in score order and ranked. In case of ties, the percentile will increase. So then the percentile is simply that rank minus a factor, divided by the total number in the base, times 100.

Has CSR considered incorporating patient values and the patient voice as stakeholders in the review process, as NIDDK does on our grant review committees?

As the first level of review, CSR is very much focused on scientific merit, which is why much of the patient advocacy representation occurs at the second level of review, which has broader goals.

Are comparisons made across study sections?

No.

Dr. Rodgers then thanked Dr. Byrnes for her presentation.

IX. SCIENTIFIC PRESENTATION: Mediator Complex Regulation of Liver Metabolic Gene Expression
Dr. Pessin

Dr. Rodgers introduced Dr. Jeffery Pessin, professor in both the Department of Medicine and Department of Molecular Pharmacology at Albert Einstein College of Medicine. His research interests focus on the molecular mechanism of adipose tissue inflammation leading to fibrosis and programmed cell death; the regulation of insulin/nutrient signaling in the regulation of liver gluconeogenesis and lipogenesis; and dysregulation in states of insulin resistance.

X. REPORTS OF SUBCOMMITTEES
CONSIDERATION OF REVIEW OF GRANT APPLICATIONS.

A total of 1,067 grant applications (231 primary and 836 dual), requesting support of \$346,553,067 were reviewed for consideration at the January 16, 2019, meeting. An additional 63 Common Fund applications requesting \$72,114,221 were presented to Council. Funding for these applications was recommended at the Scientific Review Group recommended level. Prior to the Advisory Council meeting, 1,268 applications requesting \$381,133,371 received second-level review through expedited concurrence. All of 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 January 16, 2019, meeting.

XII. 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 209th 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

