

Meeting Minutes
Department of Health and Human Services
National Institutes of Health
National Institute of Diabetes and Digestive and Kidney Diseases

I. CALL TO ORDER

Dr. Rodgers

Dr. Rodgers called to order the 194th meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council at 8:30 a.m. on Wednesday, February 5, 2014, in Conference Room 10 on the NIH Campus, Bethesda, Maryland.

A. ATTENDANCE – COUNCIL MEMBERS PRESENT

Dr. Domenico Accili
Dr. Sharon Anderson
Dr. Gopal Badlani
Dr. David Brenner
Dr. Eugene Chang
Dr. Judy Cho
Ms. Cindy Hahn
Ms. Ellen Leake
Dr. Kenneth Kaushansky
Dr. David M. Klurfeld

Ms. Robin Nwankwo
Dr. Jerry Palmer
Dr. Craig Peters*
Dr. Thomas Robinson
Dr. Jean Schaffer
Dr. Alan Shuldiner
Dr. Bruce Spiegelman⁺
Dr. Robert Vigersky
Mr. John Walsh
Dr. Mark Zeidel

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

⁺Attended by phone.

B. NIDDK STAFF AND GUESTS

Abankwah, Dora – NIDDK
Abraham, Kristin – NIDDK
Akolkar, Beena – NIDDK
Appel, Michael – NIDDK
Arreaza-Rubin, Guillermo – NIDDK
Barnard, Michele – NIDDK
Bavendam, Tamara – NIDDK
Begum, Najma – NIDDK
Bishop, Terry – NIDDK
Blondel, Olivier – NIDDK
Bourque, Sharon – NIDDK
Brown, Andrew – NIDDK
Buchanan, Sarah – Health & Medicine Council of Washington
Calvo, Francisco – NIDDK
Camp, Dianne – CSR
Carrington, Jill – NIDDK
Castle, Arthur – NIDDK
Cerio, Rebecca – NIDDK
Choy, Janet – IQ Solutions
Connaughton, John – NIDDK
Corsaro, Cheryl – CSR
Cowie, Catherine – NIDDK

Curtis, Leslie – NIDDK
Dayal, Sandeep – NIDDK
Densmore, Christine – NIDDK
Desiderio, Ulyana – Amer. Soc. Hematology
Dirks, Dale – Health and Medicine Counsel of Washington
Donohue, Patrick – NIDDK
Doo, Edward – NIDDK
Drew, Devon – NIDDK
Duggan, Emily – NIDDK
Eggerman, Thomas – NIDDK
Evans, Mary – NIDDK
Farishian, Richard – NIDDK
Feld, Carol – NIDDK
Flessner, Michael – NIDDK
Fonville, Olaf – NIDDK
Fradkin, Judith – NIDDK
Gansheroff, Lisa – NIDDK
Garofalo, Robert – CSR
Giambarresi, Leo – Amer. Urology Assoc.
Goodnight, Joanne – Jackson Laboratory
Graves, Reed – CSR
Grey, Michael – NIDDK

Haft, Carol – NIDDK
Hamilton, Frank – NIDDK
Hanlon, Mary – NIDDK
Harris, Mary – NIDDK
Hoffert, Jason – NHLBI
Hoofnagle, Jay – NIDDK
Hoshizaki, Deborah – NIDDK
Hubbard, Van – NIDDK
Hunter, Christine – NIDDK
Hyde, James – NIDDK
Iaakso, Joseph – The Endocrine Society
James, Stephen – NIDDK
Jenkins, Connie – NIDDK
Jones, Teresa – NIDDK
Karimbakas, Joanne – NIDDK
Karp, Robert – NIDDK
Ketchum, Christian – NIDDK
Kimmel, Paul – NIDDK
Kirkali, Ziya – NIDDK
Kranzfelder, Kathy – NIDDK
Kuczmarski, Robert – NIDDK
Kusek, John – NIDDK
Laughlin, Maren – NIDDK
Leschek, Ellen – NIDDK
Li, Yan – NIDDK
Linder, Barbara – NIDDK
Malik, Karl – NIDDK
Malozowski, Saul – NIDDK
Margolis, Ronald – NIDDK
Martey, Louis – NIDDK
Martinez, Winnie – NIDDK
Maruvada, Padma – NIDDK
McBryde, Kevin – NIDDK
McKeon, Catherine – NIDDK
Moxey-Mims, Marva – NIDDK
Mullins, Christopher – NIDDK
Narva, Andrew – NIDDK
Newman, Eileen – NIDDK
Nguyen, Van – NIDDK
Nurik, Jody – NIDDK
Pawlyk, Aaron – NIDDK
Perry-Jones, Aretina – NIDDK
Pike, Robert – NIDDK

Podskalny, Judith – NIDDK
Rankin, Tracy – NIDDK
Rasooly, Rebekah – NIDDK
Reiter, Amy – NIDDK
Roberts, Tibor – NIDDK
Rosenberg, Mary Kay – NIDDK
Rosendorf, Marilyn – NIDDK
Rushing, Paul – NIDDK
Rys-Sikora, Krystyna – NIDDK
Salaita, Christine – NIDDK
Salgaller, Michael – Conafay Group
Sanovich, Elena – NIDDK
Sato, Sheryl – NIDDK
Savage, Peter – NIDDK
Scanlon, Elizabeth – NIDDK
Sechi, Salvatore – NIDDK
Serrano, Jose – NIDDK
Sheard, Nancy – CSR
Shepherd, Aliecia – NIDDK
Sherker, Averell – NIDDK
Sigmon, Hilary – CSR
Silva, Corrine – NIDDK
Singh, Megan – NIDDK
Smith, Philip – NIDDK
Spain, Lisa – NIDDK
Speir, Ruth Ann – IQ Solutions
Star, Robert – NIDDK
Tatham, Thomas – NIDDK
Teff, Karen – NIDDK
Tilghman, Robert – NIDDK
Torrance, Rebecca – NIDDK
Tuncer, Diane – NIDDK
Turner, Linda – NIDDK
Van Raaphorst, Rebekah – NIDDK
Wallace, Julie – NIDDK
Wellner, Robert – NIDDK
Wilkerson, Anita – NIDDK
Wilkins, Kenneth – NIDDK
Williams, Shimere – Lewis-Burke Associates, LLC.
Wright, Elizabeth – NIDDK
Yang, Jian – NIDDK
Yanovski, Susan – NIDDK

C. ANNOUNCEMENTS

New Council Members

Dr. Rodgers welcomed new Council members and thanked them for contributing their time and expertise.

Joining the Subcouncil for Digestive Diseases and Nutrition are Dr. David Allen Brenner, Dr. Eugene Chang, and Ms. Cindy Hahn.

Dr. David Allen Brenner is Vice Chancellor for Health Sciences and the Dean of the School of Medicine at the University of California, San Diego. He is a leader in the field of gastroenterological research, specializing in diseases of the liver. He has focused on understanding the molecular pathogenesis of fibrotic liver disease and the genetic basis of liver disorders as the foundation for improving their prevention and treatment. Dr. Brenner is widely recognized as an outstanding clinician and teacher. For five years, he was Editor-in-Chief of the journal *Gastroenterology*, and he currently serves on a number of editorial boards. Dr. Brenner earned his M.D. from the Yale University School of Medicine. After completing his internship and residency at Yale-New Haven Medical Center, he completed fellowships in the Genetics and Biochemistry Branch of the NIDDK, and at the University of California, San Diego. He later joined that university's medical school faculty, and served as a physician at the Veterans Affairs San Diego Healthcare System. In 1993, he became Chief of the Division of Digestive Diseases and Nutrition at the University of North Carolina, Chapel Hill. From 2003 to 2007, he served at the Columbia University Medical Center, College of Physicians and Surgeons, as the Samuel Bard Professor, and the Chair of the Department of Medicine; a Member of the Herbert Irving Comprehensive Cancer Center; a Member of the Columbia University Institute of Nutrition; and Physician-in-Chief of New York Presbyterian Hospital/Columbia. He returned to the University of California, San Diego, in 2007.

Dr. Eugene Chang is the Martin Boyer Professor of Medicine at the University of Chicago. Dr. Chang's research focuses on host-microbial interactions of the intestine, particularly on defining communication signals/pathways that are involved in maintaining intestinal homeostasis. These studies are also aimed at better understanding how perturbations or types of enteric flora contribute to the development of digestive diseases, especially inflammatory bowel disease (IBD). As part of his research, Dr. Chang has defined several novel mechanisms and mediators of action of probiotic organisms that are currently being developed as therapeutic agents. Another research focus is intestinal epithelial biology and pathobiology, including the function and regulation of some major mediators of sodium absorption by the intestine. He is also investigating the acute and chronic effects of immune and inflammatory mediators on epithelial barrier and transport functions. Dr. Chang earned his M.D. at the University of Chicago Pritzker School of Medicine. He completed his residency in internal medicine and a fellowship in gastroenterology at the University of Chicago, before joining the faculty in 1982. Dr. Chang has an exceptional track record in training. He presently has an active NIDDK T32 award that supports a training program for postdoctoral trainees in digestive diseases and nutrition, and pre-doctoral trainees in metabolism and nutrition. Dr. Chang has been an especially staunch supporter of research opportunities for medical students. He has served as Co-Director of the Pritzker School of Medicine's Summer Research Program since 1993.

Ms. Cindy Hahn joins the Council as a public member. Ms. Hahn is the President, CEO, and Founder of the Alagille Syndrome Alliance. The Alliance is an international nonprofit network serving people with Alagille Syndrome (ALGS) and their families. ALGS is a rare genetic disorder that affects about one in every 35,000 people. The genetic mutation in the ALGS gene--JAG1--impacts the Notch signaling pathway. This causes organs in the body to develop abnormally—especially the liver, heart, kidneys and blood vessels. There is no known cure. Associated with her work for the Alagille Syndrome Alliance, Ms. Hahn has performed other substantial service in support of biomedical research efforts. For example, she has served as the

Patient Advocacy Group Committee Chair for the Childhood Liver Disease Research and Education Network (ChiLDREN) and as a member of the Patient Advocacy Group Committee of the Cholestatic Liver Disease Consortium (CLiC). Both of these studies were supported by the NIDDK. Ms. Hahn has also served as a Stakeholder Reviewer of grant applications for the Patient-Centered Outcomes Research Institute.

Joining the Subcouncil for Diabetes, Endocrinology and Metabolic Diseases are Ms. Ellen Leake and Dr. Jean Schaffer.

Ms. Ellen Leake, who will serve as a public member, is the former Chair of the Juvenile Diabetes Research Foundation (JDRF) Lay Review Committee; a current member of the JDRF Research and Executive Committees; and a current member of the Canadian Clinical Trial Network Lay Review Committee. Ms. Leake joined the JDRF International Board of Directors in 2008 and currently serves as Chair of the Development Committee. Ms. Leake is connected to type 1 diabetes research efforts through her child, who was diagnosed at the age of 9 and is now a young adult. Prior to her involvement with the JDRF at a national level, Ms. Leake and her husband joined a group of friends in forming the Mississippi chapter of JDRF in 1999. She has worked in numerous roles in the chapter, including as President in 2002-03. In addition to her work with the JDRF, Ms. Leake co-founded Mississippi Cures, the state advocacy and public policy group in support of stem cell research.

Dr. Jean Schaffer is the Virginia Minnich Distinguished Professor of Medicine at the Washington University School of Medicine in St. Louis. Dr. Schaffer's research is focused on the accumulation of excess fatty acids in non-adipose tissues, which leads to cell dysfunction and death. This health problem, known as lipotoxicity, plays an important role in the pathogenesis of heart failure and other complications of diabetes. Some of the goals of Dr. Schaffer's research include characterization of the fundamental cellular mechanisms of metabolic stress from substrate excess, and understanding how this process contributes to diabetes complications. Through basic studies involving genetic screens in cultured cells, Dr. Schaffer's laboratory has identified critical molecular players in the lipotoxic response. Unexpectedly, this work uncovered a role for small nucleolar RNAs in the response to metabolic and oxidative stress. Dr. Schaffer's research is currently focused, in part, on the molecular mechanisms through which these regulatory RNAs act. Her research group is also focused on translating their basic work to human studies in an effort to define the correlates between altered systemic lipid metabolism and early diabetic cardiomyopathy in asymptomatic individuals with type 2 diabetes. A long-term goal of Dr. Schaffer's research is to develop novel lipid biomarkers for diagnosing the earliest structural and functional abnormalities of the heart in diabetes, and for guiding therapy. Dr. Schaffer earned her M.D. from Harvard Medical School and the Harvard-Massachusetts Institute of Technology, Division of Health Sciences and Technology. She then completed her internship and residency at Brigham and Women's Hospital, and a fellowship within the Cardiovascular Division at Beth Israel Hospital. She completed a post-doctoral fellowship at the Whitehead Institute for Biomedical Research in Cambridge, Massachusetts. Dr. Schaffer joined the faculty at the Washington University in 1995.

Joining the Subcouncil for Kidney, Urologic and Hematologic Diseases as an ad hoc Council member is Dr. Craig Peters.

Dr. Craig Peters is the chief of the Division of Surgical Innovation, Technology, and Translation at the Joseph E. Robert, Jr. Center for Surgical Care at the Children's National Medical Center in Washington, D.C. Dr. Peters is also a principal investigator at the Sheikh Zayed Institute for Pediatric Surgical Innovation. Dr. Peters has extensive experience with the treatment of pediatric urologic problems, and developing minimally invasive surgical techniques, including robot-assisted procedures. He has conducted NIH-funded research in urinary obstruction, vesicoureteral reflux, and bladder dysfunction. Dr. Peters received his M.D. from the Johns Hopkins University School of Medicine.

Awards

Dr. James Rothman, a former NIDDK Council Member, received the 2013 Nobel Prize in Physiology or Medicine, which he shared with fellow NIH grantees Drs. Randy W. Schekman and Thomas C. Südhof "for their discoveries of machinery regulating vesicle traffic..." The Nobel Assembly stated that: "Without this wonderfully precise organization, the cell would lapse into chaos." At the point when Dr. Rothman began studying vesicles in the late 1970s, it was known that vesicles containing protein cargoes bud from the membranes of compartments inside the cell, and then fuse with another membrane inside the cell or with the cell's outer membrane to release their cargo. However, it was unknown exactly how the cell creates and maintains this information trafficking system. Dr. Rothman worked to isolate and study components of the mechanism biochemically in a "cell-free" system--breaking down each step in the process and recreating it in the laboratory. The NIDDK is one of several NIH Institutes that has supported Dr. Rothman's work.

Dr. Shingo Kajimura, an NIDDK grantee, has been announced as one of 102 researchers who are recipients of the Presidential Early Career Awards for Scientists and Engineers (PECASE). These awards are the highest honor bestowed by the United States Government on science and engineering professionals in the early stages of their independent research careers. Dr. Kajimura is an Assistant Professor at the University of California, San Francisco--the Diabetes Center and Department of Cell and Tissue Biology. His research focuses on the molecular basis of fat cell development and energy homeostasis. Key areas include decoding the transcriptional and epigenetic regulatory networks that govern fate determination and maintenance of brown fat cells, and investigating their roles in controlling whole body energy metabolism under physiological and pathological conditions such as obesity. In 2010, Dr. Kajimura received an NIDDK K99 Pathway to Independence award, which transitioned to an R00 award in 2011. Dr. Kajimura then went on to compete successfully for his first R01 award in 2012.

Dr. Bruce Spiegelman, a current Council member, was the 2013 winner of the Manpei Suzuki International Prize for Diabetes Research. The prize recognizes his extensive and groundbreaking contributions to many landmark discoveries in adipocyte biology and energy homeostasis. These research areas provide a fundamental understanding of type 2 diabetes and obesity.

Dr. Raj K. Goyal is the recipient of the 2013 William S. Middleton Award from the U.S. Department of Veterans Affairs. Dr. Goyal is the Mallinckrodt Professor of Medicine, Harvard

Medical School, and staff physician at the VA Boston Healthcare System. The award is the Biomedical Laboratory Research and Development Service's highest honor for scientific achievement. The award recognizes Dr. Goyal's exemplary record of involvement in, and service to, the VA, and to the biomedical profession, as well as his seminal scientific and clinical contributions to important advances in the understanding of esophageal and gastric physiology and clinical disorders including Barrett's esophagus, gastroesophageal reflux disease (GERD), diffuse esophageal spasm, esophageal pain, and gastroparesis. Dr. Goyal's work has had a broad impact on the clinical care of veterans and the population at large.

NIDDK Annual Compendium of Research Advances and Opportunities

The 2014 edition of the NIDDK's publication, *Recent Advances and Emerging Opportunities*, is being posted on the Institute's website. (<http://www.niddk.nih.gov/about-niddk/strategic-plans-reports/Pages/NIDDK-recent-advances-emerging-opportunities-2014.aspx>) The publication provides examples of NIDDK-supported research advances published in FY 2013. Several stories of discovery also trace research progress over time. The publication contains profiles of patients, and summaries of scientific presentations made by Council members. A new section provides information on funding trends and the support of NIDDK's core values. Production of the publication was an Institute-wide effort, led by the NIDDK Office of Scientific Program and Policy Analysis, with scientific input and guidance from the Divisions.

II. CONSIDERATION OF SUMMARY MINUTES OF THE 193rd COUNCIL MEETING

Dr. Rodgers

The Council approved, by voice vote, the Summary Minutes of the 193rd Council meeting, which had been sent to them in advance of the meeting for review.

III. FUTURE COUNCIL DATES

Dr. Rodgers

2014

May 14-15 (Wednesday and Thursday)
September 3-4 (Wednesday and Thursday)
Building 31, Conference Rooms 10, 6 and 7

2015

January 28-29 (Wednesday and Thursday)
May 13-14 (Wednesday and Thursday)
September 9-10 (Wednesday and Thursday)
Building 31, Conference Rooms 10, 6 and 7

Most meetings are expected to be a single day. However, members are asked to reserve both days to ensure flexibility, if needed.

IV. ANNOUNCEMENTS

Dr. Stanfield

Confidentiality

Dr. Stanfield reminded the Council 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 that advisors and consultants serving as members of public advisory committees, such as the NIDDK National 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 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, partner (including close professional associates), or an organization with which the member is connected.

To ensure that a Council 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 noted that each Council member's folder contained a statement regarding the conflict of interest in his or her review of applications. He said that each Council member should read it carefully, sign it, and return it to the NIDDK before leaving the meeting.

Dr. Stanfield said that, at Council meetings when applications are reviewed in groups without discussion, that is, "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. With respect to multi-campus institutions of higher education, Dr. Stanfield said that: An employee may participate in any particular matter affecting one campus of a multi-campus of higher education, if the employee's financial interest is solely employment in a position at a separate campus of the same multi-campus institution, and the employee has no multi-campus responsibilities.

Annual Approval of the Council Operating Procedures

The Council approved, by voice vote, the Council Operating Procedures, which were sent to members in advance of the meeting for review. Dr. Stanfield said that the Operating Procedures for 2014 are essentially the same as those for 2013.

V. REPORT FROM THE NIDDK DIRECTOR

Dr. Rodgers

Fiscal Year 2013 Budget

Dr. Rodgers reviewed the effects of sequestration on the FY 2013 budget. The NIH lost about \$1.5 billion from its 2012 funding level, and the NIDDK absorbed about \$102 million of that loss. In addition, the Special Statutory Funding Program for Type 1 Diabetes Research lost \$7.65 million. These funding losses had program impacts. With respect to Research Project Grants, the NIDDK funded 32 fewer new and competing grants and 97 fewer non-competing grants. The Special Statutory Program for Type 1 Diabetes Research funded six fewer Research Project Grants. In the area of training, the NIDDK funded 14 fewer institutional research training grants (T32s). The funding of applications under the NIDDK's Special Emphasis program was severely constrained, and Collaborative Team Science programs were reduced. The NIDDK's Core Mission Areas were underfunded, and support for a number of emerging scientific areas and opportunities was curtailed.

FY 2014 Budget

In mid-December 2013, the chairs of the House and Senate budget committees, Congressman Paul Ryan and Senator Patti Murray, successfully brokered congressional support for FY 2014 and FY 2015 budget resolutions. These resolutions set funding caps on total discretionary spending. It was agreed that sequestration would not apply to discretionary programs--only to mandated programs. On January 17, the President signed an omnibus FY 2014 appropriations bill consistent with these agreements. While the amount provided is a 3.46 percent increase over the NIH budget for FY 2013, it is a 2.3 percent decrease from the FY 2012 funding level.

For most NIH components, including the NIDDK, the FY 2014 percentage increases over FY 2013 are below the 3.46 percent increase for the NIH as a whole. The main reason is that the Congress provided larger than average increases for some areas. For example, the National Institute on Aging received a 12.6 percent increase for emphasis on Alzheimer's disease research, and the new National Center for Advancing Translational Sciences (NCATS) received a 16.8 percent increase.

Because the Special Statutory Funding Program for Type 1 Diabetes Research is a non-discretionary program mandated by the Congress, it is subject to sequestration and the loss of \$3.15 million in FY 2014 funds.

Within the FY 2014 funds provided, the NIDDK plans to support more competing and non-competing Research Project Grants (RPGs), research training grants, and Special Emphasis grants than in FY 2013, and the Institute may be able to undertake some new research efforts.

Largely because of the delay in finalizing the 2014 budget, coupled with the 16-day government shutdown in October 2013, it is unlikely that the President's Budget Request for 2015 will be submitted to the Congress before March.

Retirements of Members of Congress

Senator Tom Harkin of Iowa has announced that he will retire at the end of his term this year. During his five Senate terms, Senator Harkin has been a champion of the NIH. His service in the Congress included many years as Chair of the Senate Labor-HHS Appropriations Subcommittee, which has jurisdiction over the NIH budget, and also as Chair of the Health, Education, Labor, and Pensions (HELP) Committee, which authorizes NIH programs. In the health arena, the Americans with Disabilities Act is considered one of his signature legislative achievements.

Congressman Henry Waxman of California announced that he will retire at the end of his current term--his 20th. Mr. Waxman has been a champion of the NIH, primarily in his capacities over the years as either Chair or Ranking Member of the House Committee on Energy and Commerce, the House authorizing committee for the NIH. Among his legislative accomplishments is his work to expand health care coverage, including Medicaid coverage for more children.

VI. NIH OFFICE OF EXTRAMURAL RESEARCH: Update on the NIH *Dr. Sally Rockey, Deputy Director for Extramural Research, NIH*

Dr. Rodgers introduced Dr. Sally Rockey, who serves as the principal scientific leader and advisor to the NIH Director on the operations of the NIH extramural research program. He noted that her blog, "Rock Talk," is a valuable, interactive resource for grantees.

Dr. Rockey began her presentation by reflecting on the past year, which has been particularly challenging in terms of both budget uncertainties and the government shutdown. Regarding the budget, she is hopeful that the NIH will be informed of its FY 2015 budget early--given that the Congress has already agreed upon an overall funding level for discretionary programs, which will not be subject to sequestration. Greater budget certainty early in the year would aid program planning and operations. Unfortunately, the effects of the recent budget sequestration are continuing. Most FY 2013 awards faced reductions of five-to-seven percent and the impacts of those reductions are reverberating. Because of sequestration, current funding levels are below what they were in FY 2012, and difficult decisions must therefore be made about the funding of new, competing grant applications, and competitive renewals. However, the NIH will strive to make a higher number of competing awards than last year. With respect to the government shutdown for over two weeks, Dr. Rockey thanked everyone who helped to manage the process as well as possible.

Budget Issues and Grant Activity

The NIH Director, Dr. Francis Collins, has underscored the importance of investments in science, which yield both health and economic benefits. Dr. Rockey emphasized that the NIH must make well-founded decisions about the allocation of precious tax-payers' dollars among competing scientific proposals and activities. She presented some historic data regarding NIH funding and grant activity. These data illustrate a heavy demand on the highly competitive NIH funding system, in which resource constraints and other trends limit the probability of funding success.

Overall, the NIH budget can be considered essentially flat. After the five-year NIH budget doubling period ended in FY 2003, a steady decline in real purchasing power began--thereby reversing the earlier gains. One issue the NIH has been considering lately is the NIH and U.S. position with respect to global scientific leadership. For example, relative to several other nations, the U.S. did not experience a positive change in biomedical purchasing power from 2011-2012 (*Cell* 148, January 20, 2012). The subsequent sequester of funds further eroded purchasing power.

Dr. Rockey presented data on NIH competing grant applications, awards and success rates from 1998 through 2013. In general, the number of applications rose over this time period--from a low of about 25,000 in 1998 to over 50,000 a year from 2011-2013. The number of awards remained relatively constant from 1998-2013, hovering mid-way between 5,000-10,000 annually. Over time, success rates dropped, from about 30 percent during the NIH budget doubling period of 1998-2003, to below 20 percent by 2013. Dr. Rockey reminded the Council that success rates can be expected to fall if applications increase, and other factors, such as the NIH budget, remain relatively constant.

Another important consideration in the NIH funding system is the average total size of NIH Research Project Grants (RPGs), including direct and indirect costs. The average indirect cost rate the NIH pays to various research institutions has remained relatively constant. However, since FY 1999, the average grant size has increased from about \$300,000 to about \$450,000 in current dollars. Despite this increase in current dollars the real purchasing power (constant dollars) of those grants has become substantially less over the years. The NIH is taking a hard look at the average size of awards as a possible means of cutting costs.

Dr. Rockey also mentioned new administrative procedures that require the NIH to operate more efficiently, and to find savings. For example, limits have been placed on the NIH by the Department of Health and Human Services regarding the use of appropriated funds for conferences, meetings, food and coffee at meetings, promotional items, printing, and publications. All travel requests must now be approved at the level of the Department.

Ensuring that NIH Funds the Highest Quality Applications

In these times of fiscal constraints, the NIH must ensure that the peer review system identifies the very best science for funding. Although biomedical science is evolving rapidly, the overall structure of the NIH Study Sections that conduct peer review remains static. This disconnect raises many questions. How can the NIH more proactively identify emergent, or especially productive, fields of science? How can the NIH avoid the creation or perpetuation of

“entitlements” to funding in less productive scientific areas? Should a Study Section continue indefinitely if the cutting-edge science has moved to other areas? Do some Study Sections review more high-quality applications than other Study Sections? If so, how can the NIH make sure that those superior applications don’t fall outside the payline? How can the NIH identify and correct for differences in Study Section behavior? Underlying all these questions is uncertainty about the type of metrics that can be used to measure the quality of peer review in light of the many factors involved, including type of science, state of the science a given field, history of applications in a given field, make-up of the Study Sections, and other issues. There are few interim or surrogate markers of research value; citations of “high impact” journals can be over-emphasized; and it is extremely difficult to evaluate characteristics of Study Section behavior or performance.

The NIH is exploring whether there are quantitative and non-quantitative ways to assess the quality of Study Section reviews, while recognizing the importance of doing no harm to the research enterprise. To that end, the NIH is conducting various analyses. The Agency has looked at Study Sections and other Initial Review Groups for their scientific relatedness and performance behavior, and analyzed Study Section inputs and outputs. An NIH group called Analysis of Review Group Outputs (ARGO) has been formed. This group is looking at the bibliometric history of publications or patents attributed to NIH-funded applications, and also performing retrospective “case studies” of important scientific discoveries. One interesting experiment has involved having two different Study Sections review the same applications to see if they will identify the same set of high-quality proposals. Dr. Rockey noted that the NIH has engaged with the research community in some of these analyses, and would welcome ideas from the NIDDK Council. Because peer review is a foundation of NIH research efforts, the agency is constantly seeking ways to identify the best possible science in fields that are rapidly evolving.

Biomedical Research Workforce Working Group

Dr. Rockey reported on the recommendations of a Biomedical Research Workforce Working Group of the Advisory Committee to the Director, NIH (ACD). The report was submitted to the ACD in June 2012. She and Dr. Shirley Tilghman, the former President of Princeton University, served as co-chairs. The charge to the Working Group was to develop a model for a sustainable and diverse U.S. biomedical workforce that can inform decisions about training the optimal number of people for the appropriate types of positions that will advance science and promote health. Based on its analysis and input from the extramural community, the Working Group was asked to make recommendations for actions that the NIH should take to support a future sustainable biomedical infrastructure. The Working Group decided that its focus should be on Ph.D.s because they comprise about 75 percent of the workforce. They recommended a follow-on study of clinician scientists, which is expected to produce a report in June 2014.

The Working Group realized that it was not possible to develop a mathematical, quantitative model within the one-year allotted for the study. Therefore, when they performed their analyses in 2011, they used the latest available data from the National Science Foundation (NSF). Based on NSF survey data from 1970 to 2008 on U.S. Ph.D. and M.D. degrees awarded by field, the Working Group found a huge increase in the number of Ph.D.s engaged in basic biomedical science and in clinical science. They reasoned that, because many people don’t start a Ph.D. program immediately after college, and because of the five-to-seven year post-doctoral period for biomedical researchers, these individuals are probably not starting work as independent

scientists until about age 40--when they may also be facing many family obligations. This view is supported by NIH data that show most Ph.D.s get their first R01 grants around age 42. It is noteworthy that there is about a five-year gap between the time an individual attains a first faculty position and the time he or she receives a first R01 grant award. The average age of NIH investigators has increased substantially from 1980 to 2012.

The Working Group also looked at data with respect to gender, diversity, and earnings. Women and men had the same success rates for their first R01 grants, suggesting that there is no bias against women in peer review. However, the proportion of women as Principal Investigators on NIH grants is relatively flat, even though they are well-represented in post-doctoral programs. The NIH is trying to understand the reasons that women don't submit grant applications for competitive renewals as frequently as men, and don't fare as well as men when they do submit them. Data also show that the biomedical research workforce is lacking in diversity, and the NIH is taking several steps to address that issue. (<http://nexus.od.nih.gov/all/2013/12/30/new-funding-opportunities-with-a-focus-on-workforce-diversity/>)

Regarding earnings, NIH post-doctoral stipends are below those of the National Science Foundation and the Department of Defense. The lifelong earnings potential of a scientist is about one-third that of a person in the business field. Much of that disparity is due to the late age at which someone with a Ph.D. becomes an independent scientist. The low stipends in the post-doctoral period also contribute to lower lifelong earnings for biomedical scientists compared to other types of scientists. These various factors mean that a career in biomedical science may not be particularly attractive to young people.

Dr. Rockey presented a snapshot of the Ph.D. biomedical research workforce, based on data that was available to the Working Group. The snapshot shows the break-out of the post-training workforce in terms of the percentages of U.S.-trained biomedical Ph.D.s who fall into the following categories: science related non-research (18 percent), government research (6 percent), academic research or teaching (43 percent), industrial research (18 percent), non-science related (13 percent), and unemployed (2 percent). Dr. Rockey noted that about 65 percent of post-doctoral scientists who are trained in the U.S. come from other countries, and it is very difficult to track their career paths.

Weighing all the data analyzed, the Working Group reached the following conclusions. The large upsurge in U.S.-trained Ph.D.s, the increased influx of foreign-trained Ph.D.s, and the aging of the academic biomedical research workforce make launching a traditional, independent, academic research career increasingly difficult. The long training time and relatively low early-career salaries, when compared to other scientific disciplines and professional careers, may make a biomedical research career less attractive to the brightest young people. The current training programs do little to prepare people for anything other than an academic research career, despite clear evidence that a declining percentage of graduates will find such positions in the future.

The Working Group's report made specific recommendations regarding graduate students, postdoctoral researchers, information collection/analysis/dissemination, physician scientists, staff scientists, salary support, and diversity. The full Working Group's report can be found at: http://acd.od.nih.gov/Biomedical_research_wgreport.pdf
Additional information is provided on a Supplementary Website at: http://report.nih.gov/investigators_and_trainees/ACD_BWF

Broadening Experiences in Scientific Training

Through an announcement issued by the NIH Common Fund, the NIH received over 100 applications for innovative approaches to complement traditional research training in the biomedical sciences at institutions that receive NIH funds. Ten awards were announced on September 23, 2013.

<http://www.nih.gov/news/health/sep2013/od-23.htm>

The awards will help institutions to leverage funds with existing institutional offices and programs, with local resources outside the institution, or with organizations that partner with industry or other entities. The awardees must conduct a rigorous analysis to demonstrate the program's impact. Proven approaches will be widely disseminated throughout the biomedical research community, and awardees will meet to exchange ideas.

Dr. Rockey also mentioned other steps the NIH is taking or plans to take. These include:

- Improving research training for graduate students and post-docs by requesting institutions to put in place Individual Development Plans for anyone receiving NIH support (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-093.html>); reducing the length of graduate training; and providing individual pre-doctoral fellowship opportunities (F30 and F31 grants) through all Institutes and Centers--fully implemented for applications received after April 2014.
- Increasing postdoctoral stipends--to be implemented in FY 2014.
- Considering policies on benefits--developing a comprehensive survey.
- Shortening the eligibility period and increasing support for the NIH Pathway to Independence Awards (K99/R00 awards)--implemented for applications received after February 2014. It is hoped that investigators will apply for this program early and reduce their post-doctoral periods.
- Developing a simple and comprehensive tracking system for trainees. This system would use unique identifiers for better tracking of individual scientists. There would also be a system of science CVs that could operate along the lines of LinkedIn.
- Initiating discussions with the community to assess NIH support of faculty salaries, and whether the current construct is sustainable in times when the NIH is not receiving budget increases. From a pilot survey, the NIH learned that it provides about 50 percent of the salary support of investigators.
- Creating a functional unit at NIH to assess the biomedical research workforce.

Dr. Rockey closed her presentation by mentioning her blog, "RockTalk," and her tweeting @RockTalking. She said that the interactive feature of her blog has been enormously helpful in gaining input from the research community. (<http://nexus.od.nih.gov/all/rock-talk>)

Council Questions and Discussion

Has the NIH looked at great ideas that didn't get presented to Study Sections, or that didn't get funded? What was their funding source? Dr. Rockey responded that the NIH checks the funding source for major discoveries and awards, and that the vast majority of the investigators involved have received NIH support at some time. Otherwise, tracing the evolution of a scientific advance over time can be difficult. She added that greater scientific risk-taking and even greater ideas might be possible if sustained funding were provided based on scientific track records. However, it would be important to ensure diversity among the scientists and institutions funded; to give opportunities to young scientists; and to avoid the perpetual funding of already well-supported scientists. Given the current NIH budget, the implementation of a funding approach based on track records would require shifting some funds from project-based studies, which have long been the mainstay of the NIH. Maintaining a balance among approaches would be important. A perennial question faced by the NIH and the Institutes is whether to fund more investigators with smaller awards, or fewer investigators with larger awards.

Why does the NIH believe that there may be an over-emphasis on analyzing publications in high-impact journals? How can data analysis and social media approaches help to identify the highest quality science? Dr. Rockey said that, in a world of increasing digital communication, new ways of measuring scientific impact are emerging. For example, scientists are now using as evidence of the impact of their work the reviews and comments that are posted on Internet blogs by their scientific peers. It is also noteworthy that Pub Med Central is now permitting comments on the publications it makes available. The scientific world will also change as more journals provide open access. Collectively, these changes are contributing to the development of a new social media for science. The NIH and the research community may need to find new methods to evaluate the quality of science being conducted by investigators who present themselves and their work in such non-traditional ways.

Isn't the issue whether to evaluate the science of investigators retrospectively, based on their past achievements, or prospectively, based on their future plans? Dr. Rockey agreed that the issue could be framed that way. She also noted that a retrospective funding approach recognizes that the length of award may be more important than the size of award--so that investigators are not always on a grant-writing treadmill. However, Dr. Rockey pointed out the difficulty in retrospectively evaluating young, new investigators who have not yet had time to establish a track record. Therefore, built-in funding opportunities are needed for them in the NIH system.

What can be done about the difficulty faced by currently constituted Study Sections in differentiating among grants that are extremely close in scientific quality? Also, what can be done about investigators who just miss the payline? Dr. Rockey agreed that the applications reviewed by Study Sections are generally of very high scientific quality, which can lead to a clustering of scores. When that happens, it is extremely difficult to make differential funding decisions among applications that are just a few points apart. Differences in Study Section behavior and performance can make this situation even worse. It is hoped that NIH-conducted analyses and experiments in peer review may point to possible improvements in the system. Regarding investigators who just miss the payline, Dr. Rockey noted that the NIH decided to limit amended applications because data showed that high-quality applications ultimately get funded. That being the case, it makes sense to fund them as early as possible, rather than to put them into what is essentially a long funding queue created by an extended amendment process.

However, many investigators would still prefer to have the option of submitting amendments. They believe in the merits of their initial ideas and would prefer to refine them via amendments rather than to submit new applications with entirely different ideas. The NIH is currently engaged in discussions with the community on this issue.

Is the loan burden of biomedical education directing individuals into different career paths? Dr. Rockey said that the NIH has not yet analyzed data to answer that question, but would like to do so. The NIH is aware from communications with young investigators that the NIH Loan Repayment Program has enabled them to stay in science. Dr. Rockey also noted that the educational loan burden may persist for many years because of the long time it takes for a Ph.D. to become an independent investigator, with a sufficiently high salary to apply to reductions in loan debt.

Shouldn't the focus of NIH research training programs be to teach people to do science? Trying to teach them to do too many things can diffuse the quality of science education. Dr. Rockey agreed that teaching people to do science should be the foundation of research training programs. She also noted that there is a Catch 22 in training. On the one hand, the NIH would like to shorten the time it takes for a Ph.D. to become an independent investigator. On the other hand, the NIH offers support for a variety of training experiences that can extend that time. Academic institutions are also offering different educational experiences. By studying best practices, the NIH hopes to learn what works optimally in terms of producing success, and how to balance and dovetail the agency's goals and programs. It is also important to listen to Ph.D.s to learn about the career paths they want to pursue. Dr. Rockey noted that academic institutions can help graduate students make early decisions about whether a Ph.D. in the biomedical sciences is a reasonable career path for them, given their talents and objectives.

VII. THE NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES (NIGMS): The View from the NIGMS Dr. Jon R. Lorsch, Director

Dr. Rodgers introduced Dr. Lorsch, who became the Director of the NIGMS in August 2013. Dr. Lorsch came to the NIH from the Johns Hopkins University School of Medicine, where he was a Professor in the Department of Biophysics and Biophysical Chemistry. He is a leading researcher in RNA biology, and has received funding support from the NIDDK and several other organizations. His studies have focused on the initiation of translation, a key step in controlling gene expression. Dr. Lorsch earned his Ph.D. in Biochemistry from Harvard in 1995, and did postdoctoral research at Stanford. As the NIGMS Director, Dr. Lorsch is leading the fourth largest NIH component. The Institute is dedicated to cross-cutting fundamental research. The NIGMS also has a large research training program, and other programs designed to increase the diversity of the biomedical and behavioral research workforce.

Dr. Lorsch began his presentation by describing the two-fold mission of the NIGMS. The first part of the mission is to promote fundamental research on living systems to lay the foundation for advances in disease diagnosis, treatment and prevention. The second part is to enable the development of the best trained, most innovative, and productive biomedical workforce possible. By pursuing its mission, the NIGMS lays a foundation for the work of all the other Institutes that support research on specific diseases and organ systems. The NIGMS has five scientific divisions: (1) Cell Biology and Biophysics; (2) Pharmacology, Physiology, Biological

Chemistry; (3) Biomedical Technology, Bioinformatics, and Computational Biology; (4) Training, Workforce Development, Diversity; and (5) Genetics and Developmental Biology.

New Strategic Planning Process

Dr. Lorsch commented on the new NIGMS strategic planning process. The purpose is to identify optimal models for future investments that can promote a thriving and sustainable biomedical research enterprise. Strategic planning can make the NIGMS a more agile research organization that can adapt rapidly to scientific developments and societal changes, and also help the larger biomedical research community do the same. The process will feature data-driven approaches to provide an evidence base for guiding investment decisions and program development. An essential aspect of the process is close, interactive communication with the biomedical community, including scientific societies, and other stakeholders. To ensure that taxpayers' money is invested well, the watchwords for the NIGMS strategic planning effort are efficacy, efficiency, and adaptability.

Renewed Commitment to Investigator-Initiated Research

As an Institute dedicated to fundamental research, the NIGMS is renewing and reinvigorating its commitment to investigator-initiated, question-driven studies. In basic science, it is not possible to know exactly how or where the next major discovery will emerge. It therefore makes sense to have a distributed research portfolio, with investigators themselves determining the most productive lines of research. This does not mean that the NIGMS is drawing a distinction between investigator-initiated research and “big science.” Rather, it means that more decisions about the most promising avenues of scientific inquiry will be made by investigators themselves, and not in a top-down fashion by the NIGMS. Dr. Lorsch noted that investigator-initiated research can be done by single Principal Investigators, in the historic model of the R01 grant, or by teams of investigators. Teams can conduct investigator-initiated research by driving the questions to be answered, as well as the operational framework that works best for finding answers.

Dr. Lorsch presented data showing that the NIGMS supported very little targeted research until the five-year NIH budget doubling period, from 1998 through 2003. During that time, the Institute began to use many more targeted Funding Opportunity Announcements or FOAs. As targeted research increased, investigator-initiated research declined as a percentage of the NIGMS budget--to the point where it now represents about 80 percent of NIGMS funds. According to Dr. Lorsch, these data underscore the need for the NIGMS to renew its commitment to investigator-initiated research. The question now being debated is what percentage of the NIGMS budget should fund targeted vs. non-targeted research. It is hoped that the strategic planning process will help the Institute answer that question.

Development of More Stable, Efficient Funding Approaches

The NIGMS is exploring ways to provide more sustainable, flexible funding to investigators. A research system that funds four-year projects that have specific aims is constantly in flux. Moreover, investigators may tend to be more conservative in their scientific proposals because of the need to compete for funding every four years. It is also more difficult for investigators to pursue new research directions within the confines of highly specific project grants, which

require that their work be consistent with their stated aims. One possible way to address these issues is to undertake an experimental program that would permit investigators to apply for grants to support an overall laboratory program, without the restrictions now attached to individual projects. Investigators could then use their time more efficiently in conducting science, rather than writing grant applications.

Research Resources and Technology Development

The NIGMS is also seeking more efficient and effective ways to support research resources and technology development. Although these programs are typically established through management decisions, they serve the needs of investigator-initiated research and promote efficiency. Regional centers further the studies of many investigators in different fields, and avoid the duplication of resources at individual institutions. Technology development can both drive and be driven by scientific questions. For example, when a new measuring technique is developed, whole new worlds of scientific inquiry open up for investigator-initiated studies. Dr. Lorsch pointed out that support for research resources and technology development has grown within the NIGMS portfolio. Part of the reason is that several biotechnology research programs were transferred to the NIGMS when the National Center for Research Resources was disbanded. Dr. Lorsch hopes to tap the NIDDK's extensive experience in managing these types of programs.

Research Training and Research Career Development

Dr. Lorsch said that the NIGMS is committed to the careful investment of tax payers' money in research training programs in order to develop the best possible biomedical research workforce for the future. He presented 2012 data showing that, relative to other Institutes with large training programs, the NIGMS expends the most funds and supports the largest number of NIH full-time research training positions (slots)--primarily in the form of pre-doctoral positions. Dr. Lorsch also presented data from 1984-2013 showing the evolution NIGMS support for pre-doctoral research training efforts. Each year since 1984, NIGMS has supported more than 40 percent of the NIH total of T32 award training slots. However, during the NIH budget doubling period, the NIGMS made the decision to expend new funds on increasing stipend levels, rather than number of positions. Thus, there was a dramatic increase in the NIGMS investment in pre-doctoral research that is not readily apparent if one looks only at the number of slots funded.

Major issues and questions surround NIH research training efforts. For example, while it is widely recognized that diversity of participation at all levels will strengthen the research enterprise, little is known about the best ways to promote and achieve diversity. There are similar questions about the best approaches for furthering innovation and experimentation in education and training. An overriding issue is the need to identify meaningful ways to measure the short- and long-term outcomes of research training.

The search for appropriate metrics has been a continuing issue in biomedical science generally. Achievements in the acquisition of biomedical knowledge can be assessed in several ways. For example, one could evaluate the numbers and impact of scientific publications in databases such as PubMed. One could also consider the genetic sequence depositions in different databases, the discovery of three-dimensional structures, or other indicators of scientific progress. Interestingly, the trajectories for these indicators of scientific progress are very similar--with high levels of

achievement seen within the last few decades. Although science has changed dramatically during that period of time, research training has not. It is therefore important to find better models that can address the research training and manpower development needs of the scientific enterprise in the 21st century, and which will allow the U.S. to retain its pre-eminent global position in biomedical research.

Dr. Lorsch expressed his belief that the best way to discover new models is to empower the scientists and educators who are actually conducting research training programs to engage in experiments, and to ensure that they have the assessment tools to identify the models that work well. It is likely that market forces will then disseminate the most efficient and effective models throughout the research community. The overarching goal should be to produce researchers who make important discoveries that advance science and medicine. Dr. Lorsch said that the NIH will be partnering with other agencies and organizations to address these training issues and to achieve shared goals.

Contributions of Small, Efficient, Investigator-Initiated Science

In closing, Dr. Lorsch shared with the Council an example of the way that small, efficient, investigator-initiated science can save lives. He recounted the fundamental research of the chemist, Dr. Barnett Rosenberg, who used different types of metal electrodes to study the effect of electrical fields on DNA replication in the bacterium *E. coli*. This curiosity-driven research led to Dr. Rosenberg's discovery, in collaboration with clinical colleagues, that certain platinum-containing compounds inhibit cell division and can cure solid tumors in humans. Dr. Lorsch said that the cisplatin therapy pioneered by Dr. Rosenberg's investigator-initiated research has extended the lives of many thousands of cancer patients.

Council Questions and Discussion

Is the NIGMS taking on greater responsibility and leadership for NIH basic research given that the disease-oriented Institutes and Centers are increasingly being expected to emphasize clinical research? Doesn't the entire NIH research portfolio largely depend on the fundamental science base provided by the NIGMS? Dr. Lorsch replied that NIH Study Sections are requiring more clinical relevance in applications, even for some basic research studies. From conversations with his counterparts, he believes that the disease-oriented Institutes consider basic science to be an important part of their portfolios. The overarching message for the research community should be that basic research is critically important for understanding disease processes.

What will be the future of the Medical Scientist Training Program (MSTP Program)--the combined M.D./Ph.D. training program supported by the NIGMS? Are the outcomes of this program commensurate with its expectations and the resources expended? Dr. Lorsch responded that the MSTP program is a long-standing, very popular program, and that many MSTP awardees are widely recognized for their productive careers in science. However, there are no studies to see if other models might be more efficient or effective. Certainly, there are many productive scientists who do not hold both an M.D. and a Ph.D. Dr. Lorsch said that the Advisory Committee to the NIH Director is currently looking at issues related to the education and training of clinician scientists, and that group may help shed light on the questions raised.

Has the NIGMS considered funding a research pathway in which Ph.D. students acquire clinical experience--along the lines of an approach taken for many years by the Howard Hughes Medical Institute (HHMI)? Dr. Lorsch replied that the NIGMS has a molecular training grant program along the lines described, and that the model suggested by the NIDDK Council member is one that should be explored. As with other types of programs, outcomes should be evaluated in terms of efficiency and effectiveness.

How does the NIGMS decide on investments in technologies or regional resource centers? Does the NIGMS make these decisions alone, or in partnership with other NIH components? Dr. Lorsch said that the large scope of these types of scientific investments precludes decision-making by a single Institute. The NIH is currently taking steps to ensure NIH-wide and interagency coordination in this area, in order to promote efficiencies and avoid duplicative efforts. One example of a collaborative model involving the NIH and the Department of Defense is use of the synchrotron tool for studies of structural biology. It is hoped that knowledge gained with successful models may be applied to other resources in order to achieve cost-savings. Dr. Lorsch noted that some top-down management approaches can work well in the areas of regional centers and technology development, where a particular resource can benefit a large number of scientists who will use it to help answer their respective research questions.

The NIGMS data seem to present an extreme dichotomy between targeted research and investigator-initiated research. How do you treat research that falls somewhere in the middle of those extremes? Dr. Lorsch responded that there are certainly definitional questions when categorizing research. With respect to the NIGMS data presented, if the Institute targeted any area of science in a research solicitation or announcement, it considered the resulting awards to be targeted research. He added that the NIGMS is exploring ways to have “sunset provisions” for targeted research areas that may need a short-term infusion of funds to ignite a field or address a problem, but that should not be given indefinite funding.

Are the topics for Requests for Applications (RFAs) or Funding Opportunity Announcements (FOAs) developed internally by the NIGMS or with input from the research community? Dr. Lorsch said that the NIGMS always seeks input from the community at some point in the development of a research initiative. However, he believes that community input should be very broad--reaching beyond those who would benefit directly from the initiative.

What interaction does the NIGMS have with the Department of Defense (DOD), especially in the area of technology? Dr. Lorsch said that he would like to enhance NIGMS interactions with the DOD, and is looking for a DOD representative to serve on the NIGMS Council. He said he would welcome suggestions from the NIDDK Council.

What does the NIGMS mean by the term “data-driven?” Dr. Lorsch responded that he is referring to the NIGMS strategic planning process, which he believes should be based on data and analysis. Science itself is inherently data-driven.

VIII. SCIENTIFIC PRESENTATION: Beige Fat, Brown Fat and Exercise: Toward a New Generation of Therapeutics

Dr. Bruce Spiegelman

Dr. Rodgers introduced the scientific presentation of Council member, Dr. Bruce Spiegelman, who is the Stanley J. Korsmeyer Professor of Cell Biology and Medicine at Harvard Medical School. He is also Professor of Cancer Biology at the Dana-Farber Cancer Institute. After receiving his Ph.D. from Princeton University, Dr. Spiegelman conducted postdoctoral work at the Massachusetts Institute of Technology. His research is focused on the regulation of energy homeostasis in mammals, primarily at the level of gene transcription. He is widely recognized for the importance of his work to diabetes research. Among his many accolades, Dr. Spiegelman was elected to the National Academy of Sciences in 2002.

IX. CONSIDERATION OF REVIEW OF GRANT APPLICATIONS

A total of 1265 grant applications, requesting support of \$ 361,846,282 were reviewed for consideration at the February 5, 2014 meeting. Funding for these applications was recommended at the Scientific Review Group recommended level. Prior to the Advisory Council meeting, an additional 941 applications requesting \$ 251,841,092 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 February 5, 2014 meeting.

X. ADJOURNMENT

Dr. Rodgers

Dr. Rodgers expressed appreciation on behalf of the NIDDK to all the presenters and discussants. He thanked the Council members for their attendance and valuable input. There being no other business, the 194th meeting of the NIDDK Advisory Council was adjourned at 4:30 p.m. on February 5, 2014.

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