Meeting Minutes
Department of Health and Human Services
National Institutes of Health
National Institute of Diabetes and Digestive and Kidney Diseases
May 16, 2012

I. CALL TO ORDER
Dr. Rodgers

Dr. Griffin P. Rodgers, Director, NIDDK, called to order the 189th meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council at 8:30 a.m., Wednesday, May 16, 2012, in the Natcher Conference Center (Building 45), Conference Rooms E1/E2, on the NIH campus in Bethesda, Maryland.

A. ATTENDANCE – COUNCIL MEMBERS PRESENT

Dr. Domenico Accili
Ms. LaVarne Burton
Dr. Robert C. Flanigan
Dr. Christopher K. Glass
Dr. Gregory J. Gores
Ms. Jane Holt
Ms. Judy M. Hunt
Dr. Thomas Insel
Dr. Francine R. Kaufman
Dr. Kenneth Kaushansky
Dr. David M. Klurfeld
Ms. Robin Nwankwo
Dr. Jerry Palmer
Dr. Thomas N. Robinson
Dr. Anil K. Rustgi
Dr. John R. Sedor
Dr. Alan R. Shuldiner
Dr. William D. Steers
Dr. Robert A. Vigersky
Mr. John W. Walsh
Dr. Mark L. Zeidel

Also Present:
Dr. Griffin P. Rodgers, Director, NIDDK, and Chairperson, NIDDK Advisory Council
Dr. Gregory G. Germino, Deputy Director, NIDDK
Dr. Brent Stanfield, Executive Secretary, NIDDK Advisory Council

B. NIDDK STAFF AND GUESTS

Abankwah, Dora ¬ NIDDK
Abraham, Kristin – NIDDK
Agodoa, Lawrence – NIDDK
Akolkar, Beena – NIDDK
Alimchandani, Meghna – NCI
Anderson, David – NIDDK
Appel, Michael – NIDDK
Arreaza-Rubin, Guillermo – NIDDK
Atkins, Ronald – CSR
Barnard, Michele – NIDDK
Begum, Najma – NIDDK
Bleasdale, John – CSR
Blondel, Olivier – NIDDK
Brown, Sherry – NIDDK
Calvo, Frank – NIDDK
Carrington, Jill – NIDDK

Castle, Arthur – NIDDK
Chen, Hui – CSR
Cowie, Catherine – NIDDK
Curtis, Leslie – NIDDK
Davila-Bloom, Maria – NIDDK
Dayal, Sandeep – NIDDK
Densmore, Christine – NIDDK
Desiderio, Ulyana – Amer. Soc. of Hematology
Doherty, Dee – NIDDK
Donohue, Patrick – NIDDK
Doan, Loretta – CSR
Doo, Edward – NIDDK
Drew, Devon – NIDDK
Duggan, Emily – NIDDK
Edwards, Michael – NIDDK
Eggers, Paul – NIDDK
Evans, Mary – NIDDK
Everhart, James – NIDDK
Farishian, Richard – NIDDK
Fitzsimmons, Stacey – CSR
Flessner, Mike – NIDDK
Fonville, Olaf – NIDDK
Fradkin, Judith – NIDDK
Gansheroff, Lisa – NIDDK
Glessner, Mary – PPD
Grey, Michael – NIDDK
Guo, Xiaodu – NIDDK
Haft, Carol – NIDDK
Hamilton, Frank – NIDDK
Hanlon, Mary – NIDDK
Hoff, Eleanor – NIDDK
Hoofnagle, Jay – NIDDK
Hoover, Camille – NIDDK
Horlick, Mary – NIDDK
Hoshizaki, Deborah – NIDDK
Howard, Stuart – NIDDK
Houchin, Chris – NCCAM
Hubbard, Van – NIDDK
Hunter, Christine – NIDDK
Hyde, James – NIDDK
James, Stephen – NIDDK
Jenkins, Connie – NIDDK
Jerkins, Ann – NIDDK
Jones, Teresa – NIDDK
Jorgenson, Lyric – NCATS
Karp, Robert – NIDDK
Karimbakas, Joanne – NIDDK
Ketchum, Christian – NIDDK
Khan, Mushtaq – CSR
Kim, Sooja – CSR
Kimmel, Paul – NIDDK
Kirkali, Ziya – NIDDK
Klevins, Robin – NIDDK
Kranzfelder, Kathy – NIDDK
Krishnan, Krish – CSR
Kuczmarski, Robert – NIDDK
Kusek, John – NIDDK
Laughlin, Maren – NIDDK
Leschek, Ellen – NIDDK
Linder, Barbara – NIDDK
Malik, Karl – NIDDK
Maruvada, Padma – NIDDK
Margolis, Ronald – NIDDK
Martey, Louis – NIDDK
Martinez, Winnie – NIDDK
McGeehan, Edward – NIDDK
Miller, David – NIDDK
Miller, Megan – NIDDK
Moxey-Mims, Marva – NIDDK
Mowery, Penny – NIDDK
Moy, Nancy – SRI Inter.
Mullins, Chris – NIDDK
Narva, Andrew – NIDDK
Nguyen, Thuthuy – NIDDK
Nurik, Jody – NIDDK
Oppenheimer, Lori – Health & Med. Council of Wash., DC
Patel, D.G. – NIDDK
Pawlyk, Aaron – NIDDK
Pellnitz, Lori – SRI Inter.
Perrin, Peter – CSR
Perry-Jones, Aretina – NIDDK
Pike, Robert – NIDDK
Podskalny, Judith – NIDDK
Pope, Sharon – NIDDK
Rankin, Tracy – NIDDK
Rasooly, Rebekah – NIDDK
Rocky, Sally – OD
Roberts, Tibor – NIDDK
Rosenberg, Mary Kay – NIDDK
Rosendorf, Marilyn – NIDDK
Rushing, Paul – NIDDK
Ryan, Suzanne – CSR
Rys-Sikora, Krystyna – NIDDK
Salaita, Christine – NIDDK
Salomon, Karen – NIDDK
Sankaran, Lakshmanan – NIDDK
Sanovich, Elena – NIDDK
Sato, Sheryl – NIDDK
Savage, Peter – NIDDK
Scanlon, Elizabeth – NIDDK
Sechi, Salvatore – NIDDK
Sheard, Nancy – NIDDK
Shepherd, Aliecia – NIDDK
Sherker, Averell – NIDDK

Shoneck, Ted – Tunnel Gov't Services, Inc.
Silva, Corrine – NIDDK
Smith, Philip – NIDDK
Spain, Lisa – NIDDK
Star, Robert – NIDDK
Steinberg, Jane – NCATS
Sutherland, Margaret – NCATS
Tatham, Thomas – NIDDK
Torrance, Rebecca – NIDDK
Wallace, Julie – NIDDK
Wright, Daniel – NIDDK
Wright, Elizabeth – NIDDK
Yanovski, Susan – NIDDK

C. ANNOUNCEMENTS
Dr. Rodgers and Dr. Germino

NIDDK AND NIH Contributions to HBO Television Series on Obesity

Dr. Rodgers said that the four-part Home Box Office (HBO) television series, *The Weight of the Nation*, is helping to launch a national public awareness initiative about obesity, and that several NIDDK grantees are featured. In association with the Institute of Medicine, HBO collaborated for over two years with the NIH--primarily the NIDDK and the NHLBI--to highlight research efforts to combat obesity. The series features the work of a number of NIDDK grantees. The producers relied heavily on the expertise of the senior leadership group of the NIH Obesity Research Task Force to help edit film, and to develop discussion guides, editorials, and media materials. The NIH Director, Dr. Francis Collins, is the most prominent voice of the research community in the series, which is available free-of-charge on the HBO website. HBO has also asked cable operators to make the series available to all their subscribers. A community kit is available for organizations wishing to host screenings and conduct discussions in community settings. Dr. Rodgers asked Council members to contact Ms. Kathy Kranzfelder, Director, NIDDK Office of Communications and Public Liaison, if they would like to host a screening. He also mentioned that three associated children's films will be released in the Fall. This obesity awareness project was funded by HBO, the Michael and Susan Dell Foundation, and Kaiser Permanente. The NIDDK and the NIH are grateful for their support in underscoring the importance of one of the most pressing health issues facing our country.

In Memoriam – Dr. Nancy Boucot Cummings

Dr. Rodgers told the Council that Dr. Nancy Boucot Cummings passed away in Washington, D.C., in March 2012. She served as a former Director of the NIDDK's Division of Kidney, Urologic and Hematologic Diseases (KUH), and she was the first woman to lead an NIDDK Division. Dr. Cummings joined the NIH in 1972 as a Program Officer. A 1951 graduate of the University of Pennsylvania School of Medicine in Philadelphia, Dr. Cummings was the first woman intern at Philadelphia's Pennsylvania Hospital. She was also the first female medical resident at the Hospital of the University of Pennsylvania and the first woman renal fellow at the Peter Bent Brigham Hospital in Boston. During her tenure at the NIH in the 1970s and early 1980s, Dr. Cummings

worked to promote dialysis as a research topic and was effective in using her leadership position to stimulate the field.

Dr. Dana Andersen's Appointment in the Division of Digestive Diseases and Nutrition

Dr. Rodgers announced that Dr. Dana Andersen is joining the Division of Digestive Diseases and Nutrition (DDN) in June 2012 as Director of the Clinical Studies Program. He previously served as Vice Chairman of the Department of Surgery at the Johns Hopkins University and as Surgeon-in-Chief at the Johns Hopkins Bayview Medical Center in Baltimore, Maryland. Dr. Andersen's academic career has included holding the rank of Professor at multiple institutions, including the State University of New York (SUNY) Health Science Center, the University of Chicago, Yale University, and the University of Massachusetts, where he was Chairman of the Department of Surgery. Dr. Andersen has held numerous research grants and is the author of a large body of published original articles, reviews, editorials, and book chapters. He is also co-editor of the leading textbook of surgery, *Schwartz's Principles of Surgery.* Dr. Andersen brings to the NIDDK special expertise in multiple areas of research, including bariatric surgery and diseases of the pancreas, as well as a wealth of experience in education, clinical care and administration.

Dr. Barbara Linder's Selection as a Finalist in Award Program for Outstanding Federal Employees

Dr. Rodgers said that Dr. Barbara Linder, Senior Advisor for Childhood Diabetes Research within the Division of Diabetes, Endocrinology and Metabolic Diseases (DEM), has been selected as a finalist for a prestigious award. The Samuel J. Heyman Service to America award program recognizes outstanding federal employees who have made significant contributions to the U.S. Honorees are selected based on their commitment and innovation, as well as the impact of their work on addressing the needs of the Nation. Dr. Linder's contributions include her work in combating the emerging problem of type 2 diabetes in children--particularly, her leadership roles in the TODAY, HEALTHY and SEARCH studies. Medalists will be chosen in September 2012 from among the finalists.

Dr. Rodgers' Election to the American Academy of Arts and Sciences

Dr. Germino announced that Dr. Rodgers has been elected to the American Academy of Arts and Sciences, one of the most prestigious honorary societies and a leading center for independent policy research. Founded in 1780, the Academy's members have included members of the American Revolution. The current membership includes more than 250 Nobel Laureates and more than 100 Pulitzer Prize winners. Dr. Rodgers joins an especially elite group in the class of 2012, which includes winners of the National Medial of Science, the Lasker Award, and the Pulitzer Prize. Dr. Germino said that the induction

ceremony will be in October 2012 at the Academy's headquarters in Cambridge, Massachusetts.

II. CONSIDERATION OF SUMMARY MINUTES OF THE 188th COUNCIL MEETING
Dr. Rodgers

Following a motion that was made and seconded, the Council approved, by voice vote, the Summary Minutes of the 188th Council meeting, which had been sent to them earlier for review.

III. FUTURE COUNCIL DATES
Dr. Rodgers

Dr. Rodgers reminded the Council of future meeting dates.

2012
September 12-13 (Wednesday and Thursday)
Natcher Building, Conference Rooms E1/E2, D and F1/F2

2013
February 13-14 (Wednesday and Thursday)
May 15-16 (Wednesday and Thursday)
September 26-27 (Thursday and Friday)*
Building 31, Conference Rooms 10, 6 and 7
* Note divergence from familiar Wednesday and Thursday schedule.

The NIDDK expects that most meetings will be a single day. However, Council members were asked to hold two days to ensure flexibility should a situation arise where a longer meeting is required.

IV. ANNOUNCEMENTS
Dr. Stanfield

Confidentiality

Council members were reminded 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

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 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 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. Council members were asked to look at the statement in their folders regarding conflict of interest in their review of applications. Council members were asked to read it carefully, sign it and return it to the NIDDK before leaving the meeting.

Council members were reminded 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: An employee may participate in any particular matter affecting one campus of a multi-campus institution 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.

New NIH Policy

Dr. Stanfield brought to the Council's attention a new NIH policy that will almost certainly be effective at the next Council meeting in September 2012. In recognition of the constrained fiscal times, the new policy will require additional Advisory Council consideration before awarding a grant to a Principal Investigator (PI) who already has annual NIH research support exceeding $1.5 million in total costs. All competing applications will be screened and those affected will be flagged. Dr. Stanfield commented upon the categories of grants that would fall under the new policy.

Dr. Stanfield pointed out that the policy will be developed so that it is flexible. It is expected that Institutes and their Councils will be permitted to develop their own procedures and to weigh different factors affecting a flagged research application. Once the NIH policy is in-place, the NIDDK will develop changes to its operating procedures for the Council's consideration at its meeting in September 2012. In anticipation of the requirement to implement this new policy in September, the NIH has asked the Institutes and Centers to conduct "dry runs." In closed session, the NIDDK Advisory Council will review the list of May 2012 Council round applications from PIs having more than $1.5

million in total annual NIH research support. Members will have an opportunity to discuss the merits of providing additional resources to those PIs by supporting the research proposed, and to express any concerns they may have.

V. REPORT FROM THE NIDDK DIRECTOR
Dr. Rodgers

Budget Update

The Congress has held hearings on the FY 2013 President's Budget request for the NIH. The NIH Director, Francis Collins, testified on March 20, 2012 and March 28, 2012, respectively, before the House and Senate subcommittees with jurisdiction over the NIH budget. The hearings focused on the Administration's request of $30.86 billion, which is the same overall program level as FY 2012.
http://www.nih.gov/about/director/budgetrequest/fy2013_collins_senate.pdf
Dr. Rodgers accompanied Dr. Collins to the Senate hearing, along with Drs. Fauci, Hodes, Insel, and Varmus. As outlined in Dr. Rodgers' written statement, the proposed FY 2013 budget for the NIDDK is approximately $1.792 billion. This amount is nearly $3 million below the comparable FY 2012 appropriation, which was about 0.3 percent over the FY 2011 funding level.
http://www.nih.gov/about/director/budgetrequest/fy2013_niddk_rodgers_senate.pdf

Dr. Rodgers provided the Council with an update on the following budget issues.

- *Cap on Discretionary Spending:* The FY 2013 President's Budget request was developed within the context of a government-wide cap of $1.047 trillion on discretionary spending. This cap emerged from the process surrounding the Budget Control Act of 2011. Although the Senate was agreeable to this amount, the House has attempted to make the overall cap even more stringent--$1.028 trillion. The House also wants to treat Defense discretionary spending more generously than other spending. A recent White House announcement stated that the President would veto spending bills that align with the proposed House cap, which would "necessitate significant and harmful cuts to critical national priorities."

  Possible Sequestration of Funds: By law, a sequestration of funds could be triggered automatically in January 2013, if legislative steps are not taken before then to reduce the federal deficit by $1.2 trillion over 10 years. This automatic trigger results from the unsuccessful efforts of a Select Committee of the Congress, which was charged with developing a major deficit reduction plan. Senator Tom Harkin, Chairman of the Senate appropriations subcommittee with jurisdiction over the NIH budget, did not downplay the possibility of sequestration during the FY 2013 NIH appropriations hearing. According to Chairman Harkin, the Congressional Budget Office has estimated that most non-defense discretionary programs, such as the NIH, could be cut by 7.8 percent in January 2013 if Congress does not intervene. Other estimates are

even higher. In response to a Council member's question regarding whether sequestration plans were discussed at the House hearing, Dr. Rodgers replied that the main issues there related to Institutional Development Awards (IDeA Program) and the new National Center for Advancing Translational Sciences (NCATS).

When Dr. Collins has been asked about the effects sequestration would have on the NIH, he has said that the agency could lose about $2.4 billion in FY 2013, which would likely require a 25 percent reduction in the number of new research grants. Members of Congress are developing various proposals to avoid sequestration, but a consensus has not yet been reached. One of the most contentious issues is whether a deficit-reduction plan should include revenue enhancements along with spending reductions. Despite the possibility of sequestration expressed at the Senate hearing, many positive comments were made by Chairman Harkin, Ranking Member Richard Shelby, and other members of the subcommittee regarding the high regard in which the NIH is held, and its recognized importance to the country. Members indicated that they would "do their best" for the NIH budget.

Possibility of a Continuing Resolution: Dr. Rodgers noted that FY 2013 appropriations bills for some agencies appear to be moving forward. However, the bill for the Department of Health and Human Services, which includes NIH funding, tends to be one of the last ones taken up because of Medicare provisions and other issues. The prevailing view is that many appropriations bills will not be enacted until after the November national elections, and therefore, one or more Continuing Resolutions may be needed to keep various agencies operating when FY 2012 ends on September 30, 2012.

Dr. Rodgers thanked the Council members for their continuing support of NIH research programs, which advance human health and contribute to the economy. He said that he would keep them informed of further budget developments.

VI. UPDATE ON THE NIDDK CENTERS PROGRAM REVIEW
Dr. Germino

Dr. Germino provided a brief update on the NIDDK's program review of its Research Centers Program, which funds 87 centers throughout the U.S. at a total annual cost of approximately $100 million. The goals of the program review are to strengthen and enhance this important NIDDK program, to re-examine the outcomes of a 2003 Centers evaluation, and to address Council suggestions made in February 2010.

This review was initiated with Dr. James Hyde's presentation on Research Centers at the February 2010 Council meeting. From December 2010 through March 2011, the NIDDK conducted site visits at Centers supported by five research institutions, each of which house at least five NIDDK-supported Centers. Dr. Germino expressed appreciation to the institutions for the enormous amount of work they did in hosting those site visits and

providing follow-up information. In May 2011, Dr. Germino reported to the Council on the site visits. The NIDDK subsequently distilled and analyzed all the input received. In November 2011, the NIDDK invited the Directors of all the Centers in the Program to submit comments on the following major topics in the Institute's preliminary draft report:

- Enhancing synergy and center value;
- Strengthening the pilot and feasibility program;
- Core support and access;
- Core business models;
- Exploring the potential value of more small Centers; *and*
- Defining the research base for Center membership.

Dr. Germino said that the NIDDK has already begun to make some changes to its Research Centers Program based on comments received. These changes include:

- Supporting regional/national cores through the NIDDK's Diabetes Research Centers.
- Reporting grants included in the research base of more than one NIDDK Center (specifically, Diabetes Research Centers and Nutrition-Obesity Research Centers).
- Enhancing information-sharing through Center websites.
- Broadening access to Hematology Research Centers through a summer mini-sabbatical at a Center to use a core (pilot program).
- Increasing NIDDK coordination through regular meetings of NIDDK staff members who manage Centers programs.

After considering the input received throughout the program review process, including the strong recommendation to increase synergy among the Centers, the NIDDK posted a draft report on its website (see http://www2.niddk.nih.gov/Research/Centers/NiddkCtrsPrgReviewDraft.htm) for a broad public comment period extending from May 16 through June 18, 2012.
The NIDDK has also sent emails inviting comments from Center Directors who have participated in the review process, and from the larger NIDDK research community. Following the public comment period, the NIDDK will prepare a final report to give to the Advisory Council and post on the NIDDK website. Dr. Germino plans to make an in-depth presentation of the key points in this report at the September 2012 Council meeting. He expressed the NIDDK's appreciation to the Council members, Center Directors, and others who have participated in this process.

VII. COUNCIL FORUM: "Overview of the NIDDK Portfolio"
Dr. Germino

Dr. Germino said that strategic planning is essential in these times of fiscal uncertainty. Part of that planning is to understand the current NIDDK portfolio and how it has developed. It is also important to see how the NIDDK portfolio relates to the Institute's core values, which were identified by Dr. Griffin Rodgers when he was appointed as the NIDDK Director in 2007. This type of analysis can help to inform the Institute's future research efforts.

The core values put forth by Dr. Rodgers are:

- Maintaining a vigorous, investigator-initiated research portfolio;
- Preserving a stable pool of talented new investigators;
- Supporting pivotal clinical studies and trials;
- Fostering exceptional research training and mentoring; and
- Ensuring dissemination of science-based health information through communications and outreach activities.

These values are intended to help guide program development and resource allocation decisions.

Dr. Germino said that, due to time limitations, his presentation would address the first four core values and defer discussion of the fifth one to a later date. Dr. Germino asked the Council members to consider whether the extramural research portfolio reflects the Institute's core values, whether the NIDDK is moving in the right directions, and whether the values should be adjusted for the future to ensure that the NIDDK is aligning its budgetary investments with its top priorities. For example, if maintaining the size of the investigator pool and enhancing its diversity are important, then how can this value be maintained in tight budget times? The dilemma we begin to face is: Should the NIDDK reduce the size of awards to the point that it becomes difficult for investigators to do the work proposed, or should it reduce the numbers of awards to ensure that funded investigators can reasonably perform their proposed studies? These are the types of difficult decisions and tradeoffs that the NIDDK must make as it moves forward.

Percentage Distribution of FY 2011 Extramural Research Funds by Categories

Using categories commonly understood by the research community, rather than those used by NIH budget specialists, Dr. Germino showed the following percentage distribution of the NIDDK's FY 2011 extramural research funds for competing and non-competing awards, exclusive of intramural research and administrative funds.

- 56.5 percent for "Investigator Initiated R01 Research Project Grants," exclusive of grants that are solicited and funded through research Initiatives that take the form of Requests for Applications (RFAs). Dr. Germino noted that these R01 grants support a wide range of cross-cutting science that can be applied to many disease-specific research areas.
- 11 percent for "Research Initiatives," which are grants solicited through RFAs.
- 7.1 percent for "Research Centers," which include non-Program Project (non-P01) awards and also those Resource-Related Research Project Grants (R24s) that are "mini-centers."
- 6.9 percent for "Other R" research, which includes such grants as R03s, R13s, R15s, R18s, and grants funded through the Small Business Innovation Research (SBIR) Program and Small Business Technology Transfer Research (STTR) Program.
- 5.5 percent for "Research Career" awards, which include all K awards.
- 5.3 percent for "Collaborative Grants," which include Program Project Grants (P01s) and Resource-Related Project Grants (R24s) that are not "mini-centers."
- 3.9 percent for "Research Training" through the National Research Service Award (NRSA) Program, which provides institutional Training awards (Ts) and individual Fellowship awards (Fs).
- 2.3 percent for "Research Contracts and Interagency Agreements."
- 1.5 percent for "Other Research," which includes grants not captured in the other categories.

Analysis of Extramural Research Funding from FY 2003 through FY 2011

Despite changes in the budget landscape, the percentage distribution of extramural research funds among these categories has not changed appreciably from FY 2003 through FY 2011. The percentages have remained relatively constant for R01 Investigator Initiated Grants, Initiatives, Research Centers, Research Training, and Other Research. There has been a noteworthy increase in the percentage for Research Career awards given the program's size, and a marginal increase for the "Other R" category. The percentage for Research Contracts expanded slightly, and then recently contracted back to earlier levels, while that for Collaborative Grants has dropped a little.

Dr. Germino drilled down into the data for the extramural research categories that relate to the NIDDK's first four core values. As a surrogate measure for assessing the NIDDK's adherence to these values, Dr. Germino used "maintenance of a high level of support."

Core Value of Maintaining a Vigorous, Investigator Initiated (Unsolicited) Research Portfolio. Dr. Germino described trends in the portfolio of R01 Investigator Initiated

(unsolicited) research grants. This category has represented between 55 to 58 percent of the NIDDK's extramural research budget from FY 2003 through FY 2011. Largely because of recent significant increases in average grant size, there has been a slight drop in the total numbers of awards, primarily non-competing awards. Within the subset of competing awards, the numbers of first-time awards (type 1s) have remained relatively constant, while the numbers of competing renewals (type 2s) show some downward pressure. Dr. Germino also drew the Council's attention to the juxtaposition of data on grant applications relative to awards. After the end of the NIH five-year budget doubling period in FY 2003, the NIDDK continued to receive very high numbers of unsolicited R01 grant applications--many of which were competing renewal applications from investigators funded when the doubling began. During this post-doubling period, the NIH budget was also flattening out. The resulting mismatch between the limited supply of funds and the high numbers of applications from FY 2003 through FY 2006 translated into a lowering of success rates from percentages that had been in the high 20s to percentages in the mid-teens. When the numbers of applications subsequently tapered off, success rates began to rise slowly. Dr. Germino next presented data on the numbers of PIs supported. The numbers of PIs supported by at least one Investigator Initiated (unsolicited) R01 grant have remained relatively constant over time. If one includes all PIs on awards having multiple PIs, the numbers are higher.

Core Value of Preserving a Stable Pool of Talented New Investigators: Dr. Germino presented data on the numbers of the NIDDK's R01 applications from new investigators and the associated award patterns. In general, a person is considered a new investigator if he/she has not previously competed successfully as a Principal Investigator for a substantial NIH research project award. From FY 2003 through FY 2011, the annual numbers of applications from new investigators hovered in the 600-700 range. However, numbers of new investigator awards began declining annually during the post-doubling period, from 118 in FY 2003 to 86 in FY 2006--a year that was marked by generally low funding rates in many areas. In FY 2007, there was an upswing to 111 awards. This increase reflected a new NIH policy to give special consideration to new investigators by funding them above the payline. The NIDDK more than doubled the numbers of new investigator awards above the payline that fiscal year, thereby enabling the Institute to match the success rate for new investigators to that of established investigators. Since FY 2007, the award numbers have been maintained at over 100 annually, reaching 127 in FY 2011. Dr. Germino underscored that the NIDDK was able to fund additional new investigators above the payline because of the flexibility provided by special emphasis funds. He also noted that more of these grants have recently been falling within the payline. In 2010, concerns about the increasing length of time between when the highest degree is obtained and when the first R01 is awarded led the NIH to emphasize a subset of new investigators termed "early-stage investigators." These are defined as investigators whose grant applications are within 10 years of their terminal degrees. For M.D.s a terminal degree would be the completion of their clinical residencies, and for Ph.D.s, it would be the receipt of their doctorates. In FY 2010, about 35 percent of the

NIDDK's new-investigator awards went to early-stage investigators. By FY 2011, their proportion increased to over 50 percent.

Core Value of Supporting Pivotal Clinical Studies and Trials: The definition the NIDDK uses for analyzing its portfolio relative to this core value is the investigator's identification on his/her application that the proposed research involves human subjects. The proportion of the NIDDK's extramural research funding that constitutes such "human subjects research" has been approximately 40 percent annually from FY 2003 through FY 2011. Dr. Germino presented data showing the contributions of different categories to this clinical research funding. The proportion of R01 funding within the clinical research component of the extramural research budget has increased from about 15 to 17 percent. Initiatives have consistently been a major contributor. They represented over 30 percent of clinical research funding in FY 2011. The percentage contributions have also increased over time for the categories of Research Centers, Collaborative Grants, Research Career awards, and Other Research. Dr. Germino gave the following examples of ongoing or recently completed clinical studies in each of the extramural Divisions.

Division of Diabetes, Endocrinology and Metabolic Diseases:

- Diabetes Prevention Program Outcomes Study (DPPOS)
- Epidemiology of Diabetes Interventions and Complications (EDIC);
- Treatment Options for Type 2 Diabetes in Adolescents and Youth (TODAY)
- HEALTHY Study
- Plans for studies on Glycemic Reduction Approaches in Diabetes, and on Vitamin D for Type 2 Diabetes Prevention

Division of Digestive Diseases and Nutrition:

- Longitudinal Assessment of Bariatric Surgery (LABS) and Adolescent Bariatrics: Assessing Health Benefits and Risks (Teen LABS)
- Action for Health in Diabetes (Look AHEAD)
- Nonalcoholic Steatohepatitis Clinical Research Network (NASH CRN) Hepatitis B Research Network (HBRN)
- Gastroparesis Clinical Research Consortium (GpCRC)
- Inflammatory Bowel Disease Genetic Consortium (IBDGC)

Division of Kidney, Urologic and Hematologic Diseases:

- Acute Renal Failure Trial (ATN); Chronic Kidney Disease in Children (CKid) and Chronic Renal Insufficiency Cohort (CRIC)
- Consortium for Radiologic Imaging Studies of Polycystic Kidney Disease (CRISP) and HALT Polycystic Kidney Disease (HALT PKD)
- Randomized Intervention for Vesicoureteral Reflux (RIVUR)
- Urinary Incontinence Treatment Network (UITN)
- Multidisciplinary Approach To the Study of Chronic Pelvic Pain (MAPP) Research Network.

Core Value of Fostering Exceptional Research Training and Mentoring Opportunities: Dr. Germino presented FY 2003 through FY 2011 extramural research data on institutional Research Training awards (Ts), individual Fellowship awards (Fs), and Research Career awards (Ks). During this time, the percentages of extramural research funds expended on both F and K awards have grown considerably, while the percentage of funds for T awards has dropped off a bit. In terms of numbers of awards, the T awards have remained relatively constant, as have the numbers of training slots they support. The numbers of F awards have increased from nearly 130 to almost 270. Turning to Research Career awards, Dr. Germino said that the annual numbers have grown from the high 400s to a relatively stable level of over 500 annually since FY 2006. Major expansion has occurred in the Mentored Patient-Oriented Research Career Development Award (K23) program, for which the numbers have almost doubled. In contrast, the numbers of Clinical Investigator Awards (K08s) have declined from around 240 in FY 2003 to around 160 in FY 2011. There has been growth in the numbers of Research Scientist Development Awards (K01s) over time, and in a new type of K award, the Pathway to Independence award (K99/R00), which was initiated by the NIH in FY 2007. The latter award facilitates a timely transition of early-stage post-doctoral investigators from a mentored postdoctoral research position to a stable independent research position. This program has now stabilized in terms of numbers and funding level, which is about $10 million annually.

In closing, Dr. Germino asked the Council to consider several questions. Does the extramural research portfolio reflect the NIDDK's core values, as measured by the maintenance of a high level of support for these values? Has the NIDDK given appropriate weighting to the values in terms of resource allocation decisions? Given the tight fiscal environment, should the NIDDK adjust its values? If difficult decisions are necessary, what should be the top priorities, and where should adjustments be made to align the budget with these priorities? Dr. Germino thanked Dr. Karl Malik and his staff within the Office of Research Evaluation and Operations for their assistance in preparing for his presentation.

Council Questions and Comments

During the discussion period, Council members expressed support for the core values and noted that the NIDDK has taken important steps to buffer the research community, to the extent possible, from budget hardships. It was noted that the NIDDK and other NIH components have unique opportunities to be a forum for not only preserving core values, but also for articulating a vision about biomedical research and its interface with patient care. Society and government look to the NIH to be a visionary leader and to sustain the biomedical research enterprise in difficult times. A recurring theme in Council comments was that the NIDDK needs to engage in fiscal modeling and to assess return on investment in order to determine the relative funding priorities for different research categories. Other comments from Council members included the following:

Investigator-Initiated Research: The NIDDK is one of the most important basic science Institutes at the NIH, and it should continue to maintain a vigorous investigator-initiated research portfolio.

Initiatives: Research solicited through initiatives funded via RFAs is worthy of support, but these initiatives need to be considered carefully to ensure that they are well-developed, address important topics, and provide sufficient response time so that all investigators have an opportunity to compete for the funding.

Clinical Studies: Support for pivotal clinical studies is a key aspect of the Institute. Has the NIDDK included correlative basic science questions in its clinical studies? That could be a way to involve young or new investigators. If so, has the NIDDK looked at the success of these studies? Dr. Germino responded that the NIDDK has fostered ancillary studies associated with its major clinical trials as a means of capitalizing fully on the research investment in the trials, and has also encouraged optimal research use of its clinical repositories. Many important scientific results have been linked to the NIDDK primary clinical trials and studies. The NIDDK often funds the ancillary studies through PARs--that is, Program Announcements with special receipt, referral and/or review considerations, as described in the announcement. The Institute believes that is important for the community and the peer reviewers to understand the link to the primary studies and the research opportunities presented.

Research Training and Research Career awards:

- *Special consideration for new investigators is crucial. At the same time, if new investigators remain a priority during periods of flat or reduced budgets, then funds will have to be taken from other programs to support that priority.*
- *Awards that help investigators transition from post-doctoral fellowships to research independence are valuable, as is the Loan Repayment Program.*
- *It is essential to understand the reasons for and the effects of shifts that are occurring in the system, such as the decrease in K08 awards and the increase in K23 awards, as well as the relative success of these awardees in the job market.*
- *The K-to-R success rates need analysis, which could help the NIH predict the R01 success rates of its K programs. Research institutions should also study the conversion rate from K to R programs and encourage their investigators to include that information when they apply for K grants.*
- *The NIDDK should emphasize the continuum of career development opportunities it offers, and highlight interdisciplinary Research Training, not only across the biomedical sciences, but also with other fields.*
- *It is important to have a realistic view of the way that NIDDK and NIH Research Training and Career Development programs intersect with the job market, but also to*

recognize that the NIH cannot control that market, nor academic salaries and promotions. Vagaries in the job market should not dictate NIH programs. Moreover, academic research centers have proven very robust enterprises in meeting biomedical workforce challenges.

- *Given that many research advances arise from serendipity, having a pool of talented young researchers and spreading funds across many small research projects may be a more advisable investment strategy than funding big science projects or a limited number of research institutions.*
- *Fiscal modeling can help the NIDDK analyze the potential effects of difficult decisions.*
- *For all programs, it is imperative to analyze alternative management strategies in terms of return on investment.*

Dr. Germino said that there are many difficult choices and tradeoffs ahead and the NIDDK needs the Council's advice. New investigators are viewed as critically important because they will provide the pool of talent to drive the future of Investigator Initiated research. He said that some planning can be done in transitioning investigators from Research Training awards (Ts) to Research Career awards (Ks) to help them prepare for becoming independent investigators and for the job opportunities that exist. The NIDDK also has a program to help those who receive their first R01 grant to prepare for obtaining subsequent grants so that they will not drop out of the research enterprise.

Functionality of Laboratories: Rather than making global reductions, the NIDDK should consider the return on investment from funding individual laboratories. One issue the NIDDK might try to address is to define the critical mass of resources that is needed for a laboratory to be functional and productive. This information would help to inform NIDDK's resource allocation decisions.

Additional Council Consideration of Applications from Grantees Holding More than $1.5 Million Annually in NIH Awards (Total Costs): It is difficult to predict the effects of this additional scrutiny, which will likely work as a funding cap. It is possible that those investigators affected will be able to find funding elsewhere at their institutions, or move to different institutions. The NIDDK emphasized that the new policy requires additional Council consideration of these grants, but it does not constitute a funding cap.

Priority-Setting and Planning: Priorities will probably emerge from open discussion and fiscal modeling, not from a formulaic approach. The fact that the NIH receives its funding annually makes priority setting difficult; however, modeling can enable the NIDDK to see the potential effects of different funding scenarios on its core values. The NIH and the broad research community need to preserve these core values and decide what the emphases should be in austere times. If funding shrinks, should all programs be equally curtailed, or are some of them more important or productive than others? Investigators also need to adopt behaviors that increase productivity and efficiency. At the same time, it is important for the research community to continue advocating for

funding, but with the recognition that the NIH has fared well relative to many other agencies, and that public policy makers may find other parts of the economy of greater concern right now. Dr. Germino said that the NIDDK does fiscal modeling several times throughout the year to gauge the effects of different funding scenarios. The Institute also recognizes that decisions involve opportunity costs and unintended consequences. Special emphasis funding enables the NIDDK to support some areas that have particular vulnerabilities.

VIII. NIH OFFICE OF EXTRAMURAL RESEARCH UPDATE: "Managing in Hard Times, and the Workforce Working Group"

Dr. Sally Rockey, Deputy Director for Extramural Research, and Director, Office of Extramural Research (OER), NIH

Dr. Rockey directs the NIH Office of Extramural Research (OER), which provides leadership, oversight, tools and guidance needed to administer and manage NIH grants policies and operations. The mission of the Office is to provide the corporate framework for NIH research administration--ensuring scientific integrity, public accountability, and effective stewardship of the NIH extramural research portfolio. The Office also serves as a vital interface between the NIH and the biomedical research community by guiding investigators through the process of attaining grants funding and helping them understand and navigate through federal policies and procedures.

Dr. Rockey said that she welcomes the opportunity to present to the National Advisory Councils because the members are a channel for sharing important information with the research community and obtaining its feedback. Dr. Rockey also noted that the NIH appreciates the strong bi-partisan support it receives from public policy makers, and their recognition that science is a positive driver of the economy. She said that her presentation would focus on managing research in challenging times, and on biomedical workforce issues that are being addressed by a subcommittee of the Advisory Committee to the Director, NIH.

NIH Budget Analysis

Dr. Rockey presented several slides that displayed NIH budget trends. From FY 1998 through FY 2003, the NIH experienced a period of budget doubling wherein funding rose from about $13 billion to $27 billion. Since then, NIH funding has remained relatively level. The President's request for FY 2013 is $30.86 billion, which is the same overall program level as the current FY 2012 budget. Dr. Rockey used the Biomedical Price Index to demonstrate the purchasing power of the NIH budget over time. On average, this Index rises three to four percent each year--reflecting the effects of inflation on conducting research. When this index is applied to the NIH budget, it becomes clear that inflation has eroded the benefits of the budget doubling period. In terms of purchasing power, the NIH has essentially returned to the 1998 level. Had a modest, sustained budget growth occurred instead of the rapid budget doubling, the NIH would probably

have reached the same budget that it has today; however, gradual growth may have provided more opportunities for strategic planning.

Another major event in NIH budget history was the American Recovery and Reinvestment Act (ARRA), through which the NIH received a total of $10 billion in special additional funds for expenditure over the two-year period of FY 2009 and FY 2010. The NIH was able to set and clearly communicate expectations to the research community about ARRA because of the agency's experiences with the budget doubling period and the knowledge that the ARRA funding would definitely cease at the end of two years. The NIH solicited research projects that could produce major accomplishments within two years, and as a result, both the NIH and the research institutions adjusted their procedures and financial systems to deal with this short-term funding.

Both the five-year budget doubling period and the two-year ARRA funding enabled the NIH to support important scientific work. However, the investigator community seemed to adjust better to the end of ARRA funding, which was widely known to be absolute, than it did to uncertainties surrounding the budget doubling period. In both cases, the NIH was concerned that an abrupt end to the increased funding would lead to a difficult budget transition marked by piles of unfunded research applications. While that occurred during the initial post-doubling years, the end of ARRA placed less stress on the system.

Dr. Rockey said that the effects of the flattening of the NIH budget can be seen in the drop in success rates, which are calculated by dividing the number of applications received by the number of awards made. Compared to the 1970's and 1980's, success rate dipped in the early 1990s, but then rose to be consistently above 30 percent during the budget doubling period. Success rates subsequently fell from FY 2004 through FY 2006, then remained relatively constant at about 20 percent through FY 2010 (excluding the effects of the special ARRA funding, which was tracked separately from regularly appropriated funds). The success rate was slightly below 20 percent in FY 2011 and is likely to be around 18 percent in FY 2012.

Dr. Rockey described some aspects of the FY 2013 President's budget, which reflects difficult choices made within constraints. Some of the proposed emphases include increasing the number of new and competing Research Project Grants, and ramping up support for the newly created Cures Acceleration Network and for Alzheimer's disease research. In considering strategies for FY 2013 and beyond, Dr. Rockey said that it is helpful to review the way the NIH grant system is currently managed. She presented data in the following areas:

- *Number of Grants Held by an Individual Investigator:* Contrary to a commonly held belief that individual investigators hold many grants, an individual investigator holds, on average, 1.4 NIH grants at any given time. A large percentage of investigators hold only one grant.

- *Profile of NIH Funding in Terms of Investigators and Research Institutions:* Approximately 20 percent of NIH investigators hold 50 percent of NIH funds. These investigators typically hold very large awards. They might be part of a large Program Project Grant or a multicenter clinical trial network. Moreover, investigators in this subset of grantees tend to hold two to three grants per individual. Dr. Rockey said that the distribution of funds to individual investigators probably reflects the way that the biomedical research community is structured. About 50 research institutions hold about 70 percent of NIH funds. Most of these institutions are medical schools that house large numbers of investigators who apply for and succeed in obtaining NIH grants.

- *Project-Based System:* The NIH peer review system for research grants is largely based on the competition of meritorious ideas put forth in proposed research projects, not on the assessment of the individual applicant or his/her institution. Of course, consideration is given to whether the applicant has sufficient expertise and resources to carry out the proposed work. The average NIH research grant is currently $414,000 per year, with an average duration of 4.3 years.

Dr. Rockey noted that the NIH and the Office of Management and Budget (OMB) have engaged in discussions about possible ways to manage the budget in challenging times. To this end, the OMB issued the following guidance to the NIH for addressing the President's Budget request for FY 2013.

- Reduce non-competing Research Project Grants (RPGs) by one percent from the FY 2012 level. Dr. Rockey pointed out that, in FY 2012, the NIH made one percent reductions in RPGs from the FY 2011 level.
- Negotiate budgets of competing RPGs to avoid growth in average award size.
- Eliminate inflationary increases in out-year budgets of both competing and non-competing RPGs. Dr. Rockey said that this is not a new approach; the NIH has not been providing inflationary out-year increases for several years.
- Give additional scrutiny and review by the National Advisory Councils to applications from Principal Investigators (PIs) who already receive in excess of $1.5 million per year in total costs.
- Continue the policy of funding applications from early-stage investigators at the same success rate as established investigators for new R01-equivalent applications.

The NIH has shared these management ideas with the research community and has received a wide range of comments. The NIH has also considered the following scenarios for grants management:

- *Trim Program Budgets Across-the-Board:* Instead of the initiation of systematic changes, this approach would focus on annual belt-tightening for all programs, which would scramble to survive. Further declines in success rates would be likely, as the

system adjusts itself. Also, research applicants and peer review panels might place less emphasis on innovative science, which is inherently risky.

- *Evaluate and Reorder Research Portfolio:* Based on a rigorous evaluation of its entire research portfolio, the NIH could concentrate resources on the highest scientific priorities, eliminate duplicative research, and promote highly innovative research. This type of portfolio analysis and priority-setting is done now by the Institutes and Centers within their respective budget levels.

- *Reduce or Limit Average Size of Awards:* This approach would not result in major budget savings for the NIH, but it could have serious negative impacts on individual labs. For example, a hypothetical reduction of $25,000 on the FY 2010 average grant size would have saved about $232 million, which could then have been used to increase the number of competing RPG awards by slightly over 600 grants, and to increase the RPG success rate by about 1.2 percent.

- *Limit Number of Awards Held by a Principal Investigator (PI):* This strategy would not produce major budget savings that could be applied to boost grant numbers and success rates. For example, based on FY 2010 data, if the NIH had imposed an extreme limitation of no more than 2 awards per PI, the savings could have funded only 956 additional competitive RPGs. The overall RPG success rate would have been 22.6 percent instead of 20.6 percent.

- *Limit the Amount of Funds that a PI Can Hold:* Considerable savings could be achieved through this strategy. For example, assuming an average RPG grant size of $400,000, a limit of $1 million on a PI's total RPG support would save $3.1 billion that could be applied to fund about 2,000 additional competing RPGs (one-fourth of the savings being available for competing awards in any given year). Dr. Rockey emphasized that this strategy does not result in the funding of more science; rather, it would fund essentially the same amount of science, but it would probably be conducted by different investigators.

- *Limit Salaries of PIs:* The NIH supports an estimated 30 to 50 percent of the salaries of the PIs on its grants. This estimate is based on "level of effort" as a surrogate measure of salary support. The PIs generally depend for other salary support on their research institutions and other organizations. Dr. Rockey said that these very complex funding relationships are fundamental to the way that biomedical research is conducted in the U.S., and that any changes would have to be long-term in nature. She noted that the FY 2012 NIH appropriations language lowered the existing cap on PI salary from Executive Level 1 to Executive Level 2. The resulting salary shortfalls had to be absorbed by the research institutions, which are probably in the best position to approach the Congress on this issue. In a sense, the strategy of lowering NIH contributions to PI salary was pilot-tested by these FY 2012 events.

Dr. Rockey emphasized that each of these possible management approaches needs to be evaluated, not only in terms of the savings that could be realized and potentially applied to priorities elsewhere, but also relative to the goals sought and possible unintended consequences. If there is a sequestration of funds in FY 2013, then the NIH would have to find ways to absorb an estimated 8 to 10 percent reduction in funds--whether through one of the approaches described, or through some other means, such as limiting or eliminating new Initiatives undertaken through Requests for Applications. In planning for a "worst-case scenario," investigators should be thinking about what they would do within their own research projects to absorb an 8 to 10 percent funding cutback.

Workforce Working Group of Advisory Committee to the Director, NIH

Based on analyses and input from the extramural community, a Working Group of the Advisory Committee to the Director, NIH, will soon issue a report recommending that the NIH take actions to support a future sustainable biomedical infrastructure. The Workforce Working Group, which Dr. Rockey co-chairs, is developing a model that can inform decisions about training an optimal number of people for the appropriate types of positions that will advance science and promote health. Dr. Rockey presented some of the data that have informed the Working Group's deliberations:

- *Distribution of NIH PIs on Research Project Grants by Degree Type:* Ph.D.s are by far the largest subset of NIH PIs. From 1986 through 2009, they consistently represented about 70 percent of NIH PIs (excluding ARRA data). During this time period, the proportion of PIs with just an MD degree has gone down slightly and the proportion of M.D./Ph.Ds has risen slightly.

- *Average Age of PIs Receiving their First R01-Equivalent Awards:* In FY 2011, the average age of Ph.D. scientists receiving their first R01-equivalent award was 42 years. This average age has risen fairly consistently since 1980, when it was in the mid-30s. Since 2001, the average age for Ph.D.s to receive their first R01-equivalent award has remained fairly consistent. However, the average age for M.D.s and M.D./Ph.Ds. to receive their first R01-equivalent award has continued to increase and is now exceeding 44 years. A major factor underlying these data is the long amount of time investigators devote to research training and career development prior to becoming fully independent PIs. The NIH has tried to address this issue by increasing the proportion of early stage investigators in its new-investigator pool.

- *Numbers of Positions the NIH Supports on Research Training Grants (Ts) and Fellowship Grants (Fs) under the National Research Service Award (NRSA) Program:* From 1998 through 2011, the NIH has supported roughly 16,000 positions annually on Research Training grants and Fellowship grants (includes pre-doctoral and post-doctoral positions). The numbers have not changed significantly for each type of grant. However, these data do not reflect the training that also occurs on NIH regular research grants, which support about 30,000 graduate students and about 35,000 post-doctoral

investigators. Dr. Rockey pointed out that data on post-doctoral investigators are generally unreliable because many people who are post-docs are not categorized as such. The NIH knows that about 60 to 70 percent of its extramurally funded post-docs come from other countries.

Dr. Rockey also shared some 1993-2008 National Science Foundation (NSF) survey data on doctorate recipients who were trained in the U.S. There has been a huge growth in basic biomedical Ph.D.s. over time. The NIH knows that there has not been a corresponding growth in jobs available to these individuals, particularly since the economic downturn that started in 2008. Also, those who are already employed are tending to stay in their positions. The NSF survey also shows that, in the basic biomedical area, the numbers of tenured employees or tenure-track employees have been going down, while the numbers of non-tenure track employees have been going up. In the biological/life sciences, the percentage of Ph.D.s working in an occupation related to their doctorate has dropped from about 65 percent, as reported in 1997, to below 60 percent, as reported in 2008. However, it is encouraging that 60 percent of those with biomedical Ph.D.s who were surveyed in 2008 said that they were working in their fields 11 or more years after obtaining their degrees. Nonetheless, this percentage is not as high as in the past.

Dr. Rockey closed her presentation by mentioning several web-based resources that the NIH Office of Extramural Activities provides.

- Information on funding opportunities, award data, NIH research initiatives and other aspects of the NIH grants process can be accessed at http://www.grants.nih.gov/.
- Data on funded NIH research can be accessed through the Research Portfolio Online Reporting Tools provided at http://RePORT.NIH.Gov.
- Regular updates on NIH grants policies and activities that impact the entire grants community can be found through the NIH Extramural Nexus, which includes Dr. Rockey's blog, "RockTalk." The NIH Extramural Nexus can be accessed at http://grants1.nih.gov/grants/nexus.htm

Council Questions and Comments

Indirect Costs: Is the NIH considering budget savings by restricting the indirect costs the research institutions expect the NIH to pay? Administrative staff has grown far more than the number of people with advanced degrees at universities and it is unclear how this is helping to speed the pace of science. Dr. Rockey described the complexity of the issue. There is a dichotomy of views in the community about indirect costs, and reluctance by the Office of Management and Budget to make changes to the present system. Research institutions must have funds to manage scientific programs and support them administratively, including complying with the growth in regulations. The institutions are therefore heavily dependent on a partnership with the NIH, which includes indirect costs. However, working scientists at those institutions often don't understand exactly how

those funds are used. Dr. Rockey said that divisiveness on this issue can be very harmful to the research community. It is important to keep several points in mind. Institutions must negotiate their indirect cost rates with the Division of Cost Accounting within the Department of Health and Human Services. Some parts of indirect cost rates on research grants are already capped and have been for many years. The NIH also caps the indirect cost rates on Training and Fellowship grants at a very low level, which is difficult for the institutions. It is also important to consider that the research institutions contribute cost sharing to indirect cost rates. Another consideration is that, when institutions cannot recover their management costs, they are likely to pass them along to students via tuition increases. Dr. Rockey said that, because the costs of doing research are both direct and indirect, she finds it most useful to focus on total costs.

Profile of Funding to Research Institutions: Based on the data showing that a relatively small number of research institutions receive most NIH research funds, should society focus on supporting these powerhouse institutions? Alternatively, is it the case that great ideas can arise anywhere, but that a small institution may need to have the collaborators, infrastructure, and facilities to execute those ideas? There should be an open dialogue to promote informed decisions about the trends that are occurring and the needs they present. Dr. Rockey said that additional open dialogue would help to illuminate these issues.

Clinician Salaries: Has the NIH considered that clinicians often obtain salaries from their clinical duties? They may be willing to accept awards that provide only research support because they can obtain their salaries elsewhere. For physician-scientists, preserving high numbers of awards and a viable core of researchers in a field may be more important than preserving salary support, especially in sub-specialty areas. Dr. Rockey replied that the NIH recognizes that salary approaches may need to be tailored to different circumstances. For example, the National Science Foundation supports awards that provide a summer salary for individuals whose primary salary comes from their nine-month academic appointments. Consideration should also be given to research institutes that don't have clinical revenues or other sources of revenues to support teaching activities when research grant support is lost or curtailed. There is no solution regarding salary support that fits all circumstances; therefore, a long-term approach is needed.

Strategies To Maximize Investments and Buffer Budget Reductions: In these challenging times, the NIH should consider ways to maximize its research investments through data-sharing policies that foster the harvesting and mining of the extensive amounts of data that its grantees have already produced. The biomedical research workforce would benefit from the training of individuals in informatics, biostatics, epidemiology and public health to do this harvesting. Another strategy would be to promote multidisciplinary scientific teams as a means of buffering budget impacts. If one or two investigators on a team are not funded, the team may still be able to continue its work.

Comparisons with Other Professions: How does the biomedical workforce compare with other professions? Should there be concerns that only 60 percent of biomedical Ph.D.s have occupations related to their degrees? Dr. Rockey responded that the NIH has primarily made comparisons with other science professions. The life-long earning potential for biomedical scientists is almost the lowest of any science profession, although individuals catch up at the end of their careers. Very long periods of biomedical Research Training, coupled with the very low salaries during the post-doc years, contribute to the low life-long earning potential. These factors can be disincentives for individuals to start pursuing or to remain in a biomedical research career.

Post-Doc Issues: Does the NIH track international post-docs? Has the NIH considered diversifying its post-doc training programs--possibly through a cross-disciplinary pilot program? Dr. Rockey replied that NIH data include all post-docs who receive NIH funding, and about 60 to 70 percent of them are international. However, the NIH cannot continue to track their careers if they do not move into academic positions and are not applying for grants. One idea under discussion is whether it might be feasible to have a Federal Government researcher profile, with an individual identifier that would permit tracking of each researcher's publications, as well as his/her career--whether within or outside of the Federal research system. Dr. Rockey noted that the NSF's survey data only include information on post-docs trained in the U.S. There are other post-docs that are not captured by either the NIH or NSF data systems and for whom it is difficult to obtain data. There is even a great debate over the definition of post-docs. When they are on research grants, are they trainees or employees? The NIH treats them as employees, but they may not be receiving full employee benefits at their research institutions. Steps to shorten their training periods and make them more competitive for the job market would be beneficial.

How does the NIH define training success? What are its goals? If NIH-trained scientists move into business careers, or if the NIH Research Training and Research Career award programs produce more Americans who are savvy biomedically, is that success? It is important to study the transition from training programs to investigative independence, to track trainees throughout their careers, and to have a robust and broader view of success. Dr. Rockey agreed. She said that it is necessary to address the role of the NIH in funding alternative careers in such areas as industry, education, and science policy, and in fostering a scientifically literate society. The NIH also needs to find additional ways to build a diverse workforce.

Analyzing Drop-Outs from the Research Enterprise: In assessing return on research investments, does the NIH seek to understand the reasons that individuals fall out of the NIH funding system? For example, was it the wrong mentor, the wrong institution, or personal reasons? Dr. Rockey replied that the NIH knows points at which people fall out of the system. For example, racial and ethnic minorities generally fall out between undergraduate and graduate training, whereas women fall out between a graduate career and a tenured career.

Public Dialogue for Informed Decision-Making: The NIH should promote more data sharing and public dialogue about some of these workforce issues. The intent would not be to convey a pessimistic message detrimental to morale, but rather to provide data that will aid in career decisions. Dr. Rockey agreed. She noted that some academic institutions are providing information to students regarding the fields in which their graduates eventually work. Unfortunately, the NIH finds that data in all areas are sparse, and that it is very difficult to track people, especially when they leave the NIH funding system. The Workforce Working Group and a parallel Diversity Working Group will be addressing this issue in their reports.

IX. SCIENTIFIC PRESENTATION: "Emerging Strategies to Combat Beta Cell Failure in Diabetes"

Dr. Domenico Accili, Professor of Medicine at Columbia University and Director of the Columbia University Diabetes and Endocrinology Research Center in NewYork City

Council member Dr. Domenico Accili is a graduate of the University of Rome, who trained in Internal Medicine at the University Hospital Gemelli, also in Rome. Following a Fogarty Fellowship in the Diabetes Branch within the NIDDK's Intramural Program, he became Chief of the Section on Genetics and Hormone action of the National Institute of Child Health and Human Development at the NIH. Since 1999, Dr. Accili has served on the faculty of Columbia University College of Physicians and Surgeons and as an Attending Physician at Columbia-Presbyterian Hospital. Dr. Accili's research interests include the pathogenesis of diabetes, the integrated physiology of insulin action, and mechanisms of pancreatic beta dysfunction. He is best known for the identification of a family of DNA-binding proteins that collectively regulate diverse pathophysiological processes, including liver glucose and lipid production, food intake, insulin production and adipogenesis. Dr. Accili's work is supported by the NIH, and also by the American Diabetes Association, the Russ Berrie Foundation, and the Brehm Coalition.

X. ADJOURNMENT

Dr. Rodgers expressed appreciation to all the presenters. He thanked the Council members for their attendance and valuable discussion. There being no other business, the 189th meeting of the NIDDK Advisory Council was adjourned at 4:30 p.m., May 16, 2012.

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