

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

September 19, 2007

I. CALL TO ORDER

Dr. Griffin P. Rodgers, Director, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), called to order the 175th meeting of the National Diabetes and Digestive and Kidney Diseases (NDDK) Advisory Council at 8:35 a.m., Wednesday, September 19, 2007, in Conference Room E1/E2, Natcher Building (45), NIH, Bethesda, Maryland.

A. ATTENDANCE – COUNCIL MEMBERS PRESENT

Dr. Janis Abkowitz	Dr. Mark Magnuson
Dr. Janice Arnold	Dr. Juanita Merchant
Dr. Janet Brown	Dr. William Mitch
Dr. Roberto Coquis	Dr. Brian Monahan (Ex Officio)
Dr. Charles Elson	Dr. Jerry Palmer (Ex Officio)
Dr. Jeffrey Flier	Dr. David Perlmutter
Dr. James Freston	Ms. Margery Perry
Dr. William Henrich	Ms. Lisa Richardson
Dr. David Klurfeld (Ex Officio)	Dr. Anthony Schaeffer
Dr. Mitchell Lazar	Dr. Patrick Tso
Dr. Rudolph Leibel	

Also present:

Dr. Griffin Rodgers, Director, NIDDK, and Chairperson,
NDDK Advisory Council

Dr. Brent Stanfield, Executive Secretary, NDDK Advisory Council

B. NIDDK STAFF AND GUESTS

In addition to Council members, others in attendance included NIDDK staff members, Center for Scientific Review (CSR) Scientific Review Administrators, and other NIH staff members. Guests were present during the open sessions of the meeting.

Attendees included the following:

Abraham, Kristin - NIDDK
 Akolkar, Beena - NIDDK
 Arreaza-Rubin, Guillermo - NIDDK
 Beverly, Kevin - Social and Scientific
 Systems
 Bishop, Terry - NIDDK
 Blondel, Oliver - NIDDK
 Castle, Arthur – NIDDK
 Chamberlain, Joan - NIDDK
 Chang, Debuene - NIDDK
 Chianchiano, D. - National Kidney
 Foundation
 Chon-Lee, Angie - NIDDK
 Connaughton, John - NIDDK
 Cowie, Catherine - NIDDK
 Densmore, Christine - NIDDK
 DeSanti, Andrea - Fisher Bio. Services
 Doan, Loretta – The Endocrine Society
 Donohue, Patrick - NIDDK
 Doo, Edward - NIDDK
 Dunlap, T. J. - JTx Co., LLC
 Eggerman, Thomas - NIDDK
 Elder-Leak, Gayla – NIDDK
 Evans, Mary - NIDDK
 Everhart, James - NIDDK
 Farishian, Richard - NIDDK
 Feld, Carol - NIDDK
 Ferguson, Frances - NIDDK
 Fonville, Olaf – NIDDK
 Fradkin, Judith – NIDDK
 Gansheroff, Lisa - NIDDK
 Garfield, Sanford – NIDDK
 Gershengorn, Marvin - NIDDK
 Gladstone, Elisa - NIDDK
 Goter-Robinson, Carol - NIDDK
 Graves, Reed - CSR
 Greene, Lucy – NIDDK
 Greenwel, Patricia - CSR
 Haft, Carol – NIDDK
 Hamilton, Frank - NIDDK
 Hanlon, Mary - NIDDK
 Harmon, Joan - MORI
 Harris, Mary – NIDDK
 Harrison, Barbara – NIDDK
 Hays, Tim - OPASI
 Hilliard, Trude - NIDDK
 Hoff, Eleanor - NIDDK
 Horlick, Mary - NIDDK
 Hubbard, Van - NIDDK
 Hunter, Christine - NIDDK
 Hyde, James – NIDDK
 James, Stephen – NIDDK
 Jerkins, Ann - CSR
 Jones, Teresa – NIDDK
 Karp, Robert - NIDDK
 Ketchum, Christian - NIDDK
 Kim, Sooja - CSR
 Kranzfelder, Kathy - NIDDK
 Krishnan, Krish - CSR
 Kuczarski, Robert - NIDDK
 Kusek, John - NIDDK
 Laughlin, Maren - NIDDK
 Leschek, Ellen - NIDDK
 Linder Barbara - NIDDK
 Malik, Karl - NIDDK
 Manouelian, Denise – NIDDK
 Martinez, Winnie – NIDDK
 May, Michael - NIDDK
 McGowan, Melissa - NIDDK
 McKeon, Catherine – NIDDK
 Miles, Carolyn - NIDDK
 Miller, Megan - NIDDK
 Moen, Laura - NIDDK
 Moxey-Mims, Marva - NIDDK
 Mullins, Christopher - NIDDK
 Narva, Andrew - NIDDK
 Nyberg, Leroy - NIDDK
 Owens, Susan – American Society for
 Nephrology
 Patel, D.G. - NIDDK
 Perry-Jones, Aretina - NIDDK
 Pike, Robert - NIDDK
 Podskalny, Judith - NIDDK
 Pope, Sharon - NIDDK
 Rasooly, Rebekah – NIDDK
 Roberts, Tibor - NIDDK
 Robinson, Terra – NIDDK
 Robuck, Patricia - NIDDK
 Rosenberg, Mary Kay - NIDDK
 Rushing, Paul - NIDDK
 Sahai, Atul - NIDDK
 Salomon, Karen - NIDDK

Sankaran, Lakshmanan - NIDDK
Sato, Cheryl - NIDDK
Sawhney, Ravi - OPASI
Sechi, Salvatore – NIDDK
Seef, Leonard - NIDDK
Sekis, Branca – Social and Scientific
Systems
Sheard, Nancy - CSR
Singer, Elizabeth - NIDDK
Smith, Philip – NIDDK
Smith, Tyrone – NIDDK
Spain, Lisa – NIDDK
Star, Robert – NIDDK

Staten, Myrlene - NIDDK
Tabak, Lawrence - NIDCR
Torrance, Rebecca - NIDDK
Weinstein, Rachel - NIDDK
Wellner, Robert - NIDDK
Williams, Garman - NIDDK
Wojnarowska, Barbara - NIDDK
Wright, Daniel - NIDDK
Wright, Elizabeth - NIDDK
Xie, Yining – RLM Communications,
Inc.
Zellers, Charles - NIDDK

C. ANNOUNCEMENTS

Dr. Griffin P. Rodgers, Director, NIDDK

Members Retiring from the Council: Dr. Rodgers recognized the following members who were retiring from the Council after the September 2007 meeting. He thanked them for their dedication to promoting human health, as reflected in the time they have committed to Council deliberations.

- *Dr. Rudolph Leibel*, Division of Diabetes, Endocrinology, and Metabolic Diseases Subcouncil
- *Dr. Janis Abkowitz*, Division of Kidney, Urologic, and Hematologic Diseases Subcouncil
- *Dr. Roberto Coquis*, Division of Kidney, Urologic, and Hematologic Diseases Subcouncil

Appointments to Deanships: Dr. Rodgers announced that two leaders in the NIDDK research community had recently been appointed deans of major medical schools.

- *Dr. Jeffrey Flier*, a current Council member and long-term NIDDK grantee, has been appointed as the Dean of Harvard Medical School. He is also the Harvard faculty dean for academic programs. He is internationally renowned for his research on the molecular mechanisms of insulin action and insulin resistance, and the pathophysiology of obesity. Dr. Flier is a member of the Institute of Medicine of the National Academy of Sciences, the American Association for the Advancement of Science, and an elected member of the American Society of Clinical Investigation and the Association of American Physicians.
- *Dr. Nancy Andrews*, a long-standing NIDDK grantee, has been named the Dean of the Duke University School of Medicine. Her research has focused on

identifying the key transport pathways involved in maintaining normal iron stores in the body, and on the causes of hemocromatosis and the anemia of chronic diseases. She is a member of the Institute of Medicine of the National Academy of Sciences and was recently elected to the American Academy of Arts and Sciences. Dr. Andrews has also been a Howard Hughes Medical Institute investigator.

Appointments of NIDDK Staff Members: Dr. Rodgers announced the new positions accepted by several former and current NIDDK staff members.

- *Dr. Joyce Hunter*, who served as the Deputy Director of NIDDK's Division of Extramural Activities since 2002, was recently appointed the Deputy Director of the National Center on Minority Health and Health Disparities. She was particularly active in NIDDK in coordinating scientific program policies that govern clinical research.
- *Mr. Tyrone Smith*, who was a member of the NIDDK's Division of Extramural Activities, has recently accepted a position as a Grants Management Specialist at the National Heart, Lung, and Blood Institute. He has greatly facilitated NIDDK Council activities during his tenure with the Institute.
- *Dr. Michelle Barnard*, who joined NIDDK's Review Branch in January 2000, has accepted the position of Deputy Chief of the Branch.
- *Ms. Emily Tinkler* has joined the Division of Kidney, Urologic, and Hematologic Diseases as a Writer/Editor. She previously served as a contractor to the National Cancer Institute.

Retirements: Dr. Rodgers announced the retirements of three NIDDK staff members from Government Service.

- *Dr. Neil Musto*, former Deputy Chief of the Review Branch. Dr. Musto has been well-known for his skills as a scientific review administrator and for his many contributions to the planning and operations of the Review Branch. He has also served very capably as a supervisor and a teacher. He continues to be very active in the local community, with a special interest in urban affairs.
- *Ms. Barbara Harrison*, former Director of the Obesity Special Projects Program and Program Director of a major NIDDK clinical trial, Action for Health in Diabetes—the "Look AHEAD" trial. Ms. Harrison has played a pivotal role in the management of this complex, 11-year trial in 5,000 patients with type 2 diabetes. The aim is to determine the effects of a lifestyle intervention designed to achieve and maintain weight loss over the long term through decreased caloric intake and exercise.

- *Ms. Carol Feld*, former Associate Director for Scientific Program and Policy Analysis. Ms. Feld has played a key role in advising Institute management regarding science-policy issues, and in developing NIDDK strategic planning documents, budget justifications, congressional testimony, and a wide range of other policy-significant documents.

II. CONSIDERATION OF SUMMARY MINUTES OF THE 174th COUNCIL MEETING

A motion was made, and unanimously passed by voice vote, to approve the summary minutes of the 174th NIDDK Advisory Council (May 2007) as submitted.

III. FUTURE COUNCIL DATES

Dr. Rodgers emphasized that the Institute is working to increase the efficiency of Council meetings so that they can be reduced to one day. Individual feedback is sought from Council members regarding streamlining approaches so that the Institute can use Council meeting time most productively. However, the NIDDK is continuing to reserve two days on the calendars of Council members for some meetings so that it can retain the flexibility to schedule longer sessions should circumstances warrant. The current schedule is:

January 30, 2008
May 23, 2008
September 24-25, 2008
February 18-19, 2009
May 13-14, 2009
September 9-10, 2009

IV. ANNOUNCEMENTS

Dr. Brent Stanfield, Director, Division of Extramural Activities, NIDDK

Dr. Stanfield outlined the procedures to guarantee confidentiality and avoid conflicts-of-interest, discussed the scope and applicability of these procedures, and requested Council compliance. Members were asked to sign and return a conflict-of-interest statement and were reminded that materials furnished are considered privileged information and are to be used only for the purpose of review and discussion during the closed portions of the meeting. The outcome of the closed-session discussion may be disclosed only by NIDDK staff and only under appropriate circumstances; all communications from investigators to Council members regarding actions on applications must be referred to NIDDK staff.

Furthermore, Council members should recuse themselves when individual applications from their institutions are discussed in order to avoid an actual or perceived conflict-of-interest. This is unnecessary with *en bloc* votes, for which all members may be present and may participate. A Council member from a multi-campus institution of higher

education may participate in discussions of any matter affecting one campus of that multi-campus institution if his or her disqualifying financial interest is employment at a separate campus of the same multi-campus institution and is in a position with no multi-campus responsibilities.

V. REPORT FROM THE NIDDK DIRECTOR
Dr. Griffin P. Rodgers, Director, NIDDK

Reduced Demand in Applications for R01 Grants

Dr. Rodgers reported that the NIDDK has observed reduced applicant demand for R01 grants over the last two Council rounds. The R01 applications received in May 2007 were approximately 10 percent fewer in numbers than in the May Council round a year ago. R01 demand for the current Council round (applications received last winter) was also down compared to the same Council round the previous year. Dr Rodgers suggested that very low paylines in recent years may have discouraged some investigators who have exhausted their opportunities to amend and resubmit their applications for further consideration. As a result of this decreased demand, the NIDDK is able to award early some of the most meritorious competing renewal applications for R01s from the current Council round to aid applicants who have ongoing projects with continuing costs. Moreover, the Institute will similarly be making some early awards for projects for which first or second amendments have been submitted; this decision will help to assist, as quickly as possible, those scientists who have already seen a significant amount of time pass in their application process.

Status of the FY 2008 Budget

To date, the House and Senate action on the FY 2008 NIH budget has resulted in proposed increases, respectively, of 1.5 percent or 2.5 percent for the NIDDK over the preceding year's operating level. These differences have not yet been resolved by a conference committee or other means. House and Senate leaders now appear unlikely to meet their goal of completing work on all 12 appropriations bills by October 1, 2007, which is the beginning of FY 2008. Experts believe that a continuing resolution through the end of the current session of the Congress may be used to provide continuing funding for federal programs until more definitive action can be taken.

Dr. Rodgers underscored that, if an increase is provided in FY 2008, the NIDDK is hoping to increase its general payline, which is a percentile-based funding cutoff point determined at the beginning of the fiscal year by balancing the projected number of applications with the amount of funds available. If possible, the NIDDK would increase its payline by one or two additional points. The Institute also aims to mitigate programmatic adjustments for all categories of competing research project grants. Dr. Rodgers also emphasized that the percentile payline tends to be lower than success rates, which are generally calculated by dividing the number of applications funded by the number of peer-reviewed applications. NIDDK success rates include some grants whose

scores are beyond the general payline because the Council has determined they warrant Special Emphasis.

Attention to New Investigators

New investigators will remain a high priority of the NIH and the Congress in FY 2008, as the agency is likely to continue with last year's target of funding 1,500 R01 awards to these applicants. A related program, the NIH Pathway to Independence Award, has reached its goal of making 171 awards. Initiated in 2007, this Program combines an initial research career award (K99) with a follow-on research project award (R00). The latter award is conditional upon the investigator's achievement of appropriate benchmarks in the initial phase of the work. The NIDDK has been able to reach its target under this program.

Special Statutory Funding Program for Type 1 Diabetes Research

Current funding for this special program extends through FY 2008 at the level of \$150 million annually. Proposals have been introduced in the House and Senate to extend the program for an additional five years and to increase funding to \$200 million annually. The NIDDK has administered this program on behalf of the Secretary, HHS, since its inception in 1998—with the participation of multiple NIH Institutes and Centers, as well as the Centers for Disease Control and Prevention. The NIDDK will convene an *ad hoc* planning and evaluation group on clinical research in early 2008 to perform a mid-course assessment of current clinical projects in order to seek advice and recommendations regarding priorities. This meeting will be useful to the Institute not only in prioritizing and modifying the scope of some existing efforts if the program is not renewed, but also in suggesting new research initiatives if the program is extended. Moreover, if an extension occurs, the NIDDK will also convene two additional *ad hoc* panels—one on fundamental research on autoimmunity and the beta cell, and another on the complications associated with diabetes. The Institute is also exploring the possibility of being able to make multiyear awards if the program is extended, so as to have the greatest management flexibility in pursuing emerging scientific opportunities.

NIH Leadership Forum: Demographic Changes in NIH Pool of Principal Investigators (PIs)

To set the stage for discussions during the Advisory Council Forum, Dr. Rodgers reported on one of the presentations that had been made at the recent NIH Leadership Forum with respect to demographic changes in the pool of NIH principal investigators and in medical school faculty. Dr. Rodgers expressed appreciation to Dr. Norka Ruiz-Bravo, Deputy Director for Extramural Activities, NIH, and Mr. John Bartrum, Director, Office of Budget, NIH, for making the data available to the NIDDK Council.

Size and Age of Investigator and Academic Faculty Pools: Dr. Rodgers presented NIH data that summarized changes in the size and age of the pools of NIH principal investigators and medical school faculty from 1980-2006. During that time, the number

of NIH PIs increased from 14,887 to 25,419 and their average age rose from 39.1 to 50.8 years. The number of NIH new PIs declined by about 500 people, while the average age of this pool increased from 37.2 to 42.4 years. In trends similar to the NIH, medical schools experienced increases in the size and average age of faculty over the same time period. The number of faculty positions rose from 53,552 to 121,468. The average age of the faculty rose from 43.1 to 48.7 years; and the average age of first-time assistant professors rose from 33.9 to 37.7 years.

Concerns for New Extramural Principal Investigators: Dr. Rodgers noted that there have been attempts over the years to give special emphasis to new investigators. In the 1970s, there was a New Investigator Research Award (NIRA) for individuals who received their very first NIH grant. Then, in the 1980s, there was a similar FIRST award (R29). Those awards were discontinued and the NIH is now requesting that applicants check a box on their application to indicate if they are first-time investigators. Dr. Rodgers elaborated on the data on numbers of new extramural principal investigators from 1980 to 2006. The numbers are quite variable, with a high of 1,859 in 1980 and a low of 1,246 in 1993. Numbers were in the 1,500s during the early years of the NIH budget doubling—reaching 1,680 at the end of the doubling in 2003. Since then, however, the numbers have fallen.

Trend Data—1980 to 2006: Dr. Rodgers showed a video clip of graphs that sequentially displayed the percentage of NIH PIs and Medical School Faculty by age for each year from 1980 to 2006 on a scale that ranged from 25-90 years of age. As the animation rapidly unfolded, there was a dramatic movement of the data curves from the younger-ages on the left side of the graph to the older ages on the right. By 2006, there were virtually no investigators under the age of 30 and very few under age 32, while there were a good number beyond age 70. The sources of these data were the NIH IMPAC II Current and History Files, and the Faculty Roster System of the American Association of Medical Colleges.

Future Projections: Taking the analysis a step forward, Dr. Rodgers presented a video clip of projected changes in the age of NIH principal investigators from 2007 through 2020. This analysis was prepared by the NIH in consultation with experts from Price Waterhouse based on various assumptions such as how long people are likely to be employed before they retire. The animation again dramatically demonstrated the continued movement of NIH principal investigators into older age groups as the curve shifted farther to the right side of the graph.

Dr. Rodgers also showed the Council an NIH analysis of the numbers of Principal Investigators in various age clusters at three points in time: 1980, 2006, and projected to 2020. The percentage of those under age 40 was about 46 percent in 1980 and about 11 percent in 2006; it is projected to be about 10 percent in 2020. The comparative data for PIs below the age range of 41-50 were about 34 percent in 1980, 39 percent in 2006, and 35 percent projected to 2020. For those in the 51-60 age group, the corresponding percentages were approximately 15 percent, 34 percent, and 32 percent. In the 61-65 year grouping, the percentages were about 2 percent, 8 percent, and 9 percent. Finally, in the

65-80 age grouping, the percentages were about .8 percent, 6 percent and 11 percent for the three points in time.

VI. ADVISORY COUNCIL FORUM: Part 1 ***NIDDK Extramural Training Programs***

Dr. Rodgers announced that the Advisory Council Forum would begin with NIDDK-generated data analyses presented by two NIDDK training program directors, Drs. Judith Podskalny and Jim Hyde. Next, the Council would hear the perspectives of Drs. Rudolph Leibel and Carol Abkowitz concerning the workings of NIDDK research training programs at their respective institutions.

Overview and Analysis

Dr. Hyde--Status of NIDDK Research Training and Research Career Development Programs: In FY 2006, the NIDDK research training programs, which are National Research Service Awards (NRSA), represented about 3.1 percent of the Institute's budget. This funding included about \$45.2 million for institutional training grants (T awards) and \$7.7 million for individual fellowships (F awards). The NIDDK research career development programs (various K awards) represented about 3.8 percent of the NIDDK budget with expenditures of \$64.5 million. For several programs, Dr. Hyde showed a series of slides (with different scales depending upon program size) that displayed--in two-year intervals from 1996 to 2006--the number of applications, number of awards made from those applications, and total number of awards active at any one time, to give a sense of the overall size of the program.

NRSA Research Training Awards (F and T Grants): Through the NRSA research training program, the NIDDK makes four types of awards: the F31 Individual Predoctoral Fellowship, which is intended to promote diversity; the F32 Individual Postdoctoral Fellowship; the T32 Institutional Research Training Grant; and the T35 Short-Term Institutional Training Grant that NIDDK uses only for medical students—usually in a two-month, summer program. Stipend levels for both predoctoral and postdoctoral students in the NRSA program have increased slightly over 80 percent from 1997 to 2007.

- F Awards--The NIDDK witnessed variable numbers of applications and a decrease in total awards for NRSA Individual Predoctoral Fellowships (F31s) from 1996 to 2000, followed by an upswing in both applications and total awards through 2006. This small F31 program consists of 30 total awards active in FY2006, and one of the NIDDK's goals is to expand it, as possible. In the corresponding category of NRSA Individual Postdoctoral Fellowships (F32s), applications declined from 1996 to 2000--staying relatively stable until a surge in 2004. The total number of awards declined from 1996 to 2004, but began to rise in 2005 and 2006 as the number of applications increased above 2002 levels. There were slightly over 120 active F32 awards in FY 2006.

- T Awards--The number of applications to the NIDDK for NRSA Institutional Research Training Grants (T32s) has remained well above the 1996-1998 level through 2006, and the total number of awards has consistently increased. These awards are for training “slots” to institutions. The bulk of them are used to support postdoctoral training. The NIDDK was able to increase the number of T32 training slots during the five-year NIH budget-doubling period that ended in 2003, and has subsequently maintained the program’s strength. Over 190 total T32 institutional training awards were active in FY 2006, providing slots for over 800 trainees. Turning to Short-term Institutional Training Grants (T35s), Dr. Hyde reported that the number of awards ranged from 10 to 16 from 1996 to 2006.

Research Career Development Awards (K Grants): Dr. Hyde presented data only on those career development programs for which the Institute has the largest demand. In this group is the Mentored Research Scientist Development Award (K01), which the Institute joined in 1999. This mechanism is primarily for Ph.D.-trained scientists and for M.D.s who have no clinical responsibility. Another major, longer-standing program is the Mentored Clinical Scientist Development Award (K08) for clinically-trained scientists who are usually doing a basic research project. Also of importance are the Mentored Patient-oriented Research Career Development Award (K23) and the Mid-Career Investigator Award in Patient-oriented Research (K24). Both of those started in 1999 for clinically-trained scientists. In FY 2006, the NIDDK had about 500 active awards in the four major K programs. The breakout in the major categories was: 139 K01s, 225 K08s, 89 K23s, and 47 K24s. There were about 15 additional awards in other smaller K programs.

K01 and K08 Awards--The NIDDK’s K01 program has experienced good growth in applications, with 2004 a banner year of unexplained large numbers of applications for K01s and also other major K programs. The K01 portfolio increased during the period of the NIH doubling and has now tapered off as the budget has also become relatively level. The much longer-standing K08 program has been relatively stable in awards from 2000 to 2006. The NIDDK was able to maintain the number of awards for this program on an even keel even with the start of new K01, K23 and K24 programs.

- K23 and K24 Awards--According to NIH-wide data, steady increases have occurred in the number of K23 awards from the program’s inception through 2006. The number of NIH-wide K24 awards also rose steadily through 2003, but then tapered off—although the NIDDK is still seeing some growth in the use of this mechanism. Both the K23 and K24 programs exceeded the agency-wide targets that were set for 1999 to 2003. Turning to NIDDK-specific data, Dr. Hyde noted that the K23/K24 programs have enjoyed a good success rate, with a steady climb in the number of awards from 2000 to 2006. However, he emphasized that the K23/24 programs place much less demand on the NIDDK than the K01/K08 programs.

New Programs: In closing, Dr. Hyde mentioned that the NIDDK expects to meet its target of making 15 awards from the 55 applications it received in 2007 for the new NIH Pathway to Independence Award (K99/R00 program) previously described by Dr. Rodgers. This is a five-year, two-phase trans-NIH program targeted toward recent Ph.Ds to aid their transition from postdoctoral level to faculty. Beginning in FY 2008, the Institute is also joining an existing NIH F30 program, which is for individual predoctoral fellowships for M.D./Ph.D. students. These awards will be for medical students who are working toward a Ph.D. in an area relevant to the NIDDK mission.

Dr. Judith Podskalny--Report from an NIDDK Evaluation Working Group: Dr. Podskalny presented data from an NIDDK working group's efforts to evaluate research training and career development programs as recommended at a 2005 extramural staff retreat. Members of the working group represented all of the extramural divisions of the Institute, with leadership from the directors of the training programs. The working group analyzed data indicative of the career status of cohorts of individuals who received training through NRSA Institutional Research Training Grants (T32s), Individual Postdoctoral Fellowship Grants (F32s), Research Career Development Grants (Ks), and two diversity programs (R03s and supplemental T32 slots).

Institutional Training Awards (T32 Grants): Approximately 1,000 trainees were identified from ten-year summary tables that contained data from 59 competing renewal T32 grant applications received in 2004 and 2005. Thus, the data go back to trainees who started their appointments in 1994-1995. It appeared that 60 percent of the trainees supported during that period were still in academics and 9 percent of them had taken positions with industry. Of the M.D. or M.D./Ph.D. trainees, about 14 percent had entered private practice. The Principal Investigators on those grants were unable to locate about 8 percent of their former trainees. Nearly 70 percent of the trainees who could be tracked were physicians, which is consistent with the NIDDK's long history of supporting physician-scientists.

Individual Research Training Awards (F32 Grants) and Research Career Development Awards (K Grants): The working group analyzed data on F32 and K awardees who had completed their funding in the years 1990 to 1995. Data sources were the NIH IMPAC data system and Medline searches on each individual for publications in 2003, 2004, and 2005. If a person's professional affiliation could not be identified due to lack of an active grant, a Google search was performed.

- F32 Awardees—Data were collected on a diverse group of 256 individuals who received fellowships for varying amounts of time, and may or may not have had a previous training experience. Results showed that 75 percent of the subset of these fellows who applied for NIH funding received an award. Of the total group of 256 fellows, 41 percent received NIH funding of some sort in terms of any award on which their names were listed in the IMPAC system. For fellows engaged in research, there was an average of 7 publications per investigator. Six percent of the 256 fellows were lost to follow-up.

- K Awardees—Data were collected on 140 K awardees, who were all M.D.s and were evenly distributed among the three divisions. Results showed that 74 percent of them were still active in research. Eighty-four percent of the subset who applied for NIH funding received an award. Of the total group of 140 individuals, half received NIH funding. This was a more senior group of investigators than the F32 awardees, and they had a few more publications per investigator than the F32 recipients during the same time period analyzed. It was not possible to locate almost 4 percent of the total cohort.

Diversity Programs: The careers of individuals in two diversity-focused programs were also evaluated using spreadsheet data maintained by the NIDDK. The first program made R03 awards to 48 underrepresented investigators to assist them in moving toward successful competition for an R01 grant. The R03 applications were solicited via yearly Requests for Applications from 1996-2000. Some of the 48 awards were made from initial grant applications and some from subsequent resubmissions. Of the 92 percent of the awardees who later applied for NIH funding, 52 percent were successful. Interestingly, the working group also looked at career data on 33 individuals who applied to, but did not compete successfully for this R03 program. Of those, 67 percent later applied for other NIH funding and 64 percent of those were successful. It may well be that they were aided by having participated in the R03 application experience and the feedback they received through the NIH peer review process. If one considers the entire group of individuals who applied either successfully or unsuccessfully for the NIDDK's R03 program, 45 percent of the total remained in research careers and had NIH funding. This program ended in 2000. The second diversity program evaluated is for institutions that hold T32 training grants and whose slots are filled. Under this program, those institutions may receive additional slots for the training of underrepresented minority investigators. The working group considered data on the 53 participants in this program from 1990-2003. Slightly more than half of these individuals remained in research. Of the thirty-four percent of the 53 individuals who applied for NIH funding, 72 percent were successful. These investigators had an average of 5.6 publications per individual from 2003-2005.

Next Steps: Based on the evaluation results, it appears that these training and career development programs are helping many individuals pursue long-term research careers. Moreover, the research career development awards (Ks) appear to be more effective for this purpose than individual fellowship awards (Fs) and institutional training awards (T32s). In the future, the program directors of the three NIDDK extramural divisions plan to look at 5, 10, and 15 year outcomes for F32 and K awardees.

Perspective from Institutions

Dr. Abkowitz--University of Washington: Dr. Abkowitz said she found the results of the NIDDK staff evaluation very impressive. She hopes that the NIDDK will continue to perform this type of analysis and will listen to how it is interpreted in the research community.

Funding Supplementation: Because the NIH is a major source of funding for academic institutions, Dr. Abkowitz believes that it drives many local decisions about training and career development programs and issues. At the academic institutions, issues include not only the number and type of grants, but also the effects of salary caps and other requirements. The institutions have to adjust their actions to many aspects of the NIH training and career development programs. For example, if an M.D. scientist is working to become an assistant professor, a K award will not provide sufficient resources, and therefore other sources of support need to be sought. Supplementation might be through the assumption of additional clinical obligations by the investigator, or support from an endowment. Therefore, for many young investigators at Dr. Abkowitz's institution, which has a low salary profile, what is really needed is "K plus" support before they can move along the research career path. These funding constraints can increase the age at which an investigator can compete for independent support through NIH R01 grants. Whether intended or not, the lack of adequate funding for training and career development is a barrier to an investigator's ability to move forward.

Gaps in Career Development: Another perspective from the institutional level is that funding gaps can occur in an investigator's career when his or her research activities don't fit with the timing of awards. An example is the time between finishing a T32 and applying successfully for a K award. Some individuals may not be quite ready to make the transition between these two awards on their first attempt, and if they don't succeed, they can become discouraged with the revision and re-application process. Similarly, when some investigators complete a K08 or K23 award, they may not be quite ready to compete successfully for their first R01 grant. If a key goal is to have a continuous flow of excellent investigators, then it is important for the NIH and the academic institutions to address those critical gaps. Unfortunately, investigators may not have fundable ideas at the exact time that their current funding runs out, although they may be excellent investigators over the course of their careers. Thus, continuous support is crucial, especially if investigators are being encouraged to undertake innovative research that may have greater inherent risk, and may not provide a rapid career-advancement benefit in terms of publication of results or other kind of professional "credentialing." The goal should be to develop careers, not science projects.

Dr. Leibel--Columbia University College of Physicians and Surgeons: Dr. Leibel found the evaluation report on the training programs very encouraging, and more positive than he would have expected. He underscored that these are critically important programs, not only to the future of biomedical research, but also to the health of the academic institutions that support the development of research investigators.

Fungibility and Flexibility: As an individual experienced with several of the training mechanisms discussed, Dr. Leibel believes it would be advantageous for institutions to have greater flexibility in managing the resources that NIH commits to training—from predoctoral to postdoctoral awards and beyond. Ideally, an institution would have fungibility and flexibility to determine the best path of training for a given individual, and where to place the emphasis from year to year.

As the budgets of the medical institutions become tighter--partly due to NIH budget constraints and partly due to other factors--the predoctoral programs are experiencing greater pressure. Disruptions in these predoctoral programs may result because the academic institutions are no longer subsidizing them to the extent they did previously. To address this, it would be helpful if the institutions could quickly allocate and reallocate training funds internally.

Mentoring: Dr. Leibel expressed his belief that trainees do not receive sufficient mentoring with respect to some of the most important career issues—even on K awards for which mentoring is explicitly required. This lack of adequate mentoring may be most pervasive in the early years of an investigator's career, when it may be needed most. The NIH may wish to consider a new type of funding to encourage established faculty to take on a much more explicit role as mentors. This funding could be provided within the training grant itself, or through a separate award. Enhanced mentoring could aid many individuals who have very little understanding of the clockwork and nomenclature of the NIH, or knowledge of whom they should contact for assistance with career development issues.

Council Questions and Discussion

Several Council members made positive comments about the results of the NIDDK staff's evaluation report on the Institute's research training and career-development programs. These efforts are considered very important throughout the research community.

Clarifying Terminology: In the NIDDK staff's presentation, does achievement of NIH funding mean that the individual was a Principal Investigator? Also, if someone has two NIH grants is he or she counted twice? Dr. Podskany responded that the working group considered any trainee or fellow to have achieved NIH funding if his or her name was in the IMPAC system as an investigator. The investigator could be on a subproject to a P01 grant, but not on supplements to grants. Dr. Fradkin noted that, for the NRSA awardees, success in obtaining NIH funding could have been receipt of a K award. Dr. Podalsky also noted that the data reflect people, not numbers of grants.

Sub-analyses: Were there any differences in the evaluation results among the NIDDK divisions? Dr. Podskalny responded that there did not appear to be noteworthy differences.

Mentoring: The NIH should consider funding to encourage established faculty to take on a much more explicit role as mentors. Vital mentor-trainee relationships are already being forged at some institutions--but generally not in any organized way--and most of them are informal and are not being directly funded.

Return on Investment—Predoctoral vs. Postdoctoral Programs: Are there any comparative data to show whether investing more in predoctoral training programs vs. postdoctoral programs would be more effective in terms of building the cadre of future

successful investigators? One Council member commented that, although data may not exist or may be limited to specific institutions, he is aware of anecdotal reports favoring predoctoral training from faculty involved in training programs. There may be different views on this issue within different academic settings; that is one of the reasons that the institutions should have flexibility in their internal allocation of research training funds.

Portability of Training Awards: With respect to flexibility, talented trainees should probably be permitted to carry their awards with them to different institutions during their career development process, as opportunities emerge. Dr. Rodgers noted that the K99/R00 awards incorporate this concept.

Reducing Anxiety: Providing institutions with greater flexibility in administering training funds would help them quell the anxiety of some trainees about their long-term career prospects. With greater flexibility, institutions would have the resources to fund an individual during periods of uncertainty.

Effect of Research Career Development Awards on Demographics: The introduction of K awards has probably contributed to the increasing age of the investigator pool. While the K programs are valuable, they require several years of an investigator's time between completion of a training program (F or T award) and receipt of a first independent R01 grant. This fact should be kept in mind when reviewing the data that show the average age of investigators shifting to older-age categories.

Case Studies of Individuals Who Have Left Research: While the evaluation data presented are very positive, can NIH do even better? It would be useful to have some case studies of individuals who have dropped out of the research system in order to identify their reasons and to devise ways to prevent such losses.

Comments by Assigned Discussants

To gain additional input, Dr. Rodgers turned to four assigned discussants who had been asked to address specific topics: Drs. Mitchell Lazar, David Perlmutter, Jeffrey Flier, and Jerry Palmer.

Dr. Lazar--Articulation between NIDDK Training Programs and Centers: Dr. Lazar's comments were based on his perspective as a Principal Investigator on a Diabetes Research Center grant, as well as his affiliation with an institution that has two NIDDK-funded research training grants. One training grant has almost no involvement with the diabetes research center, while the other one has an active relationship with it. He reminded the Council that research center grants do not have training components.

Dr. Lazar said that one of the first questions that needs to be addressed is: "What are the potential barriers to synergizing research training with research centers programs?" As in most other areas, limitations in time and money are major barriers that immediately come to mind. However, an important, often forgotten barrier is the imposition of new, unfunded mandates that compete for the time and funds available to a program. If new

initiatives are sought to synergize training and center programs, they will require additional investments, rather than simply a rearrangement of existing funds in a zero-sum game.

Dr. Lazar suggested that increased synergy could be fostered through various joint meetings. For example, there could be regional meetings for cross-fertilization among investigators from both training and center programs. Investigators on training grants could be involved in a seminar series sponsored through the academic enrichment programs that are found in most centers, but are not typically built into training grants. It may be possible to incentivize leaders of the training grants and the centers to join in one special lecture each year that would be center-based, with predoctoral or postdoctoral student speakers, including underrepresented minority students. Another way to promote synergy would be to increase the pipeline for the training grants via the centers by fostering center-based programs, particularly for underrepresented minorities, but also in general. Such programs for undergraduates would need to be scheduled in the summer, but those for medical students could be at any point in the year. Based on Dr. Lazar's experience with a summer program of this type, he thinks that the enthusiasm of students would be the greatest if they themselves could identify the preferred center/institution they wish to attend and then successfully compete for placement there. To that end, he recommended the establishment of a central clearinghouse for the receipt of applications to a program that would be advertised nationally. The clearinghouse would develop a priority placement list for the student applicants based on their own institutional preferences and a competitive process.

Dr. Perlmutter--Training Hurdles in Pediatrics: Dr. Perlmutter presented four recommendations for the NIDDK: (1) to continue and, if possible, strengthen the T32 program, (2) to carefully consider starting up a K12 program (which in other Institutes is the junior faculty scholar awards with a center approach); (3) to serve as a "net" for struggling investigators based on a global view of the elements of effective training; and (4) to emphasize the importance of teaching the scientific method. Dr. Perlmutter then elaborated on these recommendations. He noted that his views are based on his long-term experience as a Principal Investigator on T32 training grants with a pediatrics focus; as a Principal Investigator on a K12 research career development award for junior faculty in pediatrics; and as a Department Chair.

Strengthening the T32 Mechanism: From Dr. Perlmutter's perspective, the T32 mechanism is extremely valuable, but it is likely to be less successful than other research training and career development mechanisms. One reason is that it takes seven or ten years to establish the ethic of the T32 program. By that time, the leaders who have shaped the programs are usually moving on to other positions, as Dr. Perlmutter himself moved on to become a Department Chair. These leadership changes can cause a loss of momentum in the T32 programs. Another factor contributing to the complexity of the T32 mechanism is that the initial pool of candidates has a variety of different interests with no specific commitment to science. Therefore, the expectations for success in T32 programs should not be set unrealistically high; Dr. Perlmutter believes that achieving 30 percent success in these programs would be commendable. The difficulties of the T32

mechanism should be accepted, along with the recognition that these programs need continuing strong support and enhancement.

Considering the K12 Mechanism: The K12 mechanism provides an important means of support for junior faculty. It gives the institutions greater flexibility in filling junior faculty scholar positions with individuals who may not yet be ready for another type of K award or may need to develop further. The K12 grant increases the number of potential ways to provide support to individuals who are moving along the continuum of research career development.

Providing a “Net”: Dr. Perlmutter believes that problems for research training in pediatrics are the same as for other training areas--except that they are amplified because there is a smaller pool of pediatric training candidates, mentors and subspecialists. As a member of an NIH study section, Dr. Perlmutter has also observed a recent unevenness in the review process as the number of grant applications has increased. This unevenness will likely affect pediatrics more than other fields. The NIDDK can help address these issues by serving as a “net” for struggling investigators, some of whom can be saved from falling out of the system through the Council’s decisions about funding.

Emphasizing the Scientific Method: At the core of effective training is the mentor who helps students learn about the method of science. Much of today’s research is technology-driven rather than hypothesis-driven. Nonetheless, the teaching of the scientific method is a key to the sustainability of training.

In concluding, Dr. Perlmutter noted several characteristics of institutions that tend to have successful research training programs in which there is a good return on investment. Such institutions usually have a successful track record; have resources in addition to the NIH training grants to fund individuals; and have used mentors external to the department in which the training grant is located.

Dr. Jeffrey Flier--Multidisciplinary Training--Beyond a Disease-Specific Focus: As the newly appointed Dean of the Harvard Medical School, Dr. Flier said he is thinking in new ways about issues, including that of multidisciplinary/interdisciplinary training, which has long been an interest of his. As he looks at this issue from a different perspective, he will come back to the Council with more refined ideas. Dr. Flier noted that there is general agreement about the value of multidisciplinary/interdisciplinary research as a way that much of the best science is done. However, there are inadequacies in training individuals to optimize their capacity to do such research. A key question is: “How can the NIH better support such optimization?” given that it is seen as an obvious, inherently important way to promote the best research for human health.

New Approaches To Fostering Interdisciplinary Research at Harvard University: The University has broadly recognized the need for new collaborative approaches across fields of inquiry. For example, the new Harvard University Science and Engineering Committee, on which Dr. Flier serves, is bringing together deans and faculty leaders from all parts of the University involved in research and teaching in the sciences to help the

University plan and coordinate major new investments for collaborative, cross-disciplinary endeavors. The University has committed \$50 million to provide initial support for the Committee's efforts. Moreover, Harvard is creating a new Department of Developmental and Regenerative Biology, which cuts across the Schools and reports to both the Medical School and the Faculty of Arts and Sciences. Other fields that may follow this model include systems biology, chemical biology, and bioengineering. Harvard is also committed to fostering clinical and translational science. The University is seeking to align research training with this new way of thinking about cross-cutting science---from undergraduate work to the clinical work in hospitals and courses in the Medical School. An institutional goal is to create new courses, new methods of teaching, and new ways of bringing hospital-based Harvard medical professors into the classroom--both to teach undergraduates and to learn from them.

Mentorship: Improved mentorship is an essential component of these efforts. Right now, mentorship is largely left to individuals; however, institutional arrangements are needed to facilitate mentorship, especially for interdisciplinary studies. The range of NIH research training programs and their results are encouraging; however, they are not optimized to support interdisciplinary research in a sustainable fashion. One reason may be that there is tension between the disease-focus of NIH components and the need for training that cuts across NIH organizational lines. A major challenge will be to develop and implement new approaches during times of constrained budgets. Perhaps joint efforts should be encouraged among Institutes and Centers to support interdisciplinary training that doesn't have to begin with relevance to a particular disease. That way, the training experience could be enhanced, with resulting benefits to all fields of research. There are reasons why this approach may be difficult, in terms of program management and organizational issues. Nonetheless, all of NIH would benefit from improving the culture of training, which would in turn increase the ability of investigators to successfully compete for the funds necessary to capitalize on scientific opportunities. It would be very helpful for the NIH to forge alignments along these lines of mutual interest.

Dr. Palmer--Career Development for Clinical Researchers: Dr. Palmer commented on some of the advantages of the new NIH Clinical and Translational Science Award (CTSA) program. The program draws attention to the full spectrum of activities encompassed by clinical research—from what used to be considered disease pathophysiology to clinical trials, and beyond that, to outcomes research. The CTSA program also underscores the importance of research that is directly relevant to humans and human disease, not just research to answer important scientific questions. Furthermore, the CTSA program has a mandate to think about the training of future researchers. This issue includes the demographic changes in the investigative pool that have been presented to the Council, as well as the disincentives of low paylines, which may relate to some problems with the peer review system. Today, trainees and junior investigators see excellent, senior investigators struggling for funding. This struggle translates into a sense of job insecurity at the very time that the junior investigators are thinking about a long-term career in clinical research. Another major problem for career development of clinical researchers is the regulatory burden. While it may not be possible to reduce this burden, academic institutions and the NIH may find ways to assist junior

investigators in walking the regulatory pathway. Other suggestions for enhancing clinical research career development include involving trainees in large clinical trials, and removing the disincentive of salary caps on research grants. It is also important that the peer review process consider an applicant's future potential along with past productivity. Steps need to be taken to make research careers more attractive to junior investigators as they look down the pipeline to where they may find themselves at later stages in their professional lives.

Dr. Rodgers noted that a number of important points had been raised with respect to issues such as salary caps on the K awards, the desire for greater institutional flexibility in administering NIH training funds, ways to promote greater mentorship, the benefits of the new CTSA program, and other topics. The NIDDK will compile the comments of all the participants and share them with the full Council for additional thoughts and expansions.

Council Questions and Discussion

Advantage/Disadvantages of CTSA Awards: At institutions that have CTSA awards, what do program directors think about their effectiveness in leveraging the ability of medical students and other investigators to succeed in obtaining grants? For clinical investigation, outcomes research, and clinical trials requiring shared skill sets, the CTSA mechanism is considered a powerful approach because these activities can be connected and there is sufficient flexibility for mentorship. There are important opportunities to capitalize on the ability of CTSA programs to develop robust, meaningful educational programs that include substantial mentoring. The CTSA is probably less successful in addressing more traditional patient-oriented research that is the focus of some of the K awards, for which the NIDDK review process provides important feedback and should be retained.

Advantages of K12 Awards: The K12 awards can help to fill gaps in timing between the five-year CTSA awards and the regular K awards that are generally 2-3 years in duration. They are also a flexible, relatively inexpensive mechanism that enables a focus on particular areas that need pursuit by physician-scientists. The K12 mechanism enables institutions to support under-served clinical research areas and to galvanize the research community around those areas. This attribute is particularly valuable for small groups of aspiring applicants who can interact and gain mentorship in their specific avenues of research.

VII. ADVISORY COUNCIL FORUM: PART 2

Update: NIH Steering Committee and Advisory Committee to the Director Working Groups on Peer Review

Dr. Lawrence Tabak

In introducing Part 2 of the Council Forum, Dr. Rodgers noted that NIH considers its peer review system the cornerstone supporting the extraordinary success of its extramural programs. However, no system is perfect and times and technologies change. Recognizing this, the NIH is taking a critical look at its peer review system and considering how it might be made more effective in supporting the NIH mission and, as appropriate, how it might become more efficient. In an effort to gain broad input on possible improvements, the NIH Director, Dr. Elias Zerhouni, has established two *ad hoc* working groups. An internal working group reports to the NIH Steering Committee, while an external working group reports to the Advisory Committee to the Director, NIH (ACD). Dr. Lawrence Tabak, Director of the National Institute of Dental and Craniofacial Research, is a co-chair of both working groups.

At the outset of his presentation, Dr. Tabak described some of the principles that underlie the self-study that the NIH has undertaken, in partnership with the scientific community, to strengthen peer review in changing times. Because of the challenges posed by the increasing scope, complexity, and interdisciplinary nature of biomedical science, the NIH is taking a new look at the system that supports its research efforts. Peer review is an essential key part of this system. To avoid untoward consequences, the NIH is taking a systems-wide approach that recognizes the need to adapt to both the changing fields in science and the ever-growing public health challenges. At the same time, approaches need to be efficient and effective for both applicants and reviewers alike, and the NIH needs to continue to draw upon the expertise of the most talented reviewers. Dr. Tabak listed the members of the external and internal *ad hoc* working groups that are guiding this self-study. In this process, the NIH is seeking input from many stakeholders including investigators, scientific societies, grantee institutions, voluntary health organizations, and agency staff. At the same time, the NIH Center for Scientific Review (CSR) is undertaking several initiatives with regard to: shortening the review cycle; immediate assignment of applications to Initial Review Groups; realignment of Study Sections; electronic reviews; and shortening the length of applications. The internal working group is coordinating its efforts with these CSR initiatives.

The self-study is still in its diagnostic stage in which comments and suggestions are being sought through various means. This phase has featured the issuance of a Request for Information (RFI) with an interactive web site for soliciting input from the extramural community on such topics as challenges of the overall NIH research support system, challenges of the NIH peer review process, solutions to challenges, core values of peer review, review criteria, peer review scoring, and career pathways. With respect to pathways, a key question is whether or not the current process is appropriate for investigators at all stages of their careers. Although the formal period for input was July to September 7, 2007, Dr. Tabak told the Council that they could still provide comments that would be read and considered. In addition to this web-based process, Dr. Zerhouni,

Dr. Tabak, and Dr. Keith Yamamoto—the other co-chair of the external working group—have solicited the views of institutions by holding two deans’ conferences with about 100 participants. Moreover, a series of regional town meetings will be held with professional organizations and patient advocacy groups. Working group members are also selecting a series of individuals to serve as science liaisons to further enhance these outreach efforts to stakeholders. Furthermore, the working groups are conducting a very extensive search of the literature on peer review and also analyzing approaches taken by other agencies, such as the recently released report by the National Science Foundation. Experts in psychometrics will help to identify the positive and negative consequences that might emerge as different models of peer review are considered for the future.

When all this information is assembled, it will be reported to the Advisory Council to the Director, NIH, in December 2007, and also to the full NIH Steering Committee. Informed by this input, NIH leadership will frame a series of pilot interventions to design and initiate in the Spring of 2008—with associated evaluations. Essentially, these will be scientific experiments to see if the interventions have the desired effects and whether there are any unanticipated, untoward consequences. Ultimately, an implementation plan will be developed to brief NIH stakeholders of the results. There will be briefings for NIH staff, scientific societies, advocacy groups, NIH Advisory Councils, the Congress, and the relevant media. It is expected that successful pilot studies will be expanded and will likely lead to the development of new policies.

Dr. Tabak gave the Council some sense of the emerging ideas that have been submitted by various stakeholders. These concepts are from the first 10 percent or so of the over 2,500 responses received thus far. With regard to review criteria and focus, some concepts are: review of the project vs. the person; retrospective vs. prospective review; and separate application modes and review criteria for projects that lack preliminary data or precedent. On the subject of reviewer mechanisms/mechanics, some individuals have suggested the “editorial board model;” electronic review; virtual electronic dialogue between applicants and reviewers to address questions; and different types of review for different types of science, such as interdisciplinary research. Other emerging ideas include whether an investigator should designate one application as his or her primary one, with different criteria for the review and funding of “non-primary” applications.

One major concern is the long queue that is developing within Study Sections. As an agency, the NIH funds fewer than 10 percent of the initial submissions it receives. Perhaps a pre-application process could enable rapid identification and separation of submissions that are competitive vs. non-competitive and enable more meaningful advice to applicants. Scoring is a major issue as there is increasing concern that it is difficult to determine funding based on differences between grants that have extremely close scores. Moreover, investigators are frustrated if they receive only marginally better scores on applications they have revised and resubmitted based on the comments from Study Sections. Perhaps two sets of scores should be given at the outset—a score for the application as received and the “best potential score” the application might subsequently receive upon revision. Various scoring alternatives have been suggested.

To maximize review and reviewer quality, suggested concepts include limitations on extraneous information; incentives for reviewers; mandatory service vs. more flexible service; ratings for reviewers and NIH Scientific Review Administrators (SRAs); and providing or withholding reviewer identification.

Dr. Tabak noted that the Council discussion on his presentation would be extracted for consideration by the working groups.

Council Questions and Discussion

Triage Approach: What is gained by the triage of grant applications? Are there devastating effects on investigators when told that their applications are so deficient that they are not even being scored? What is the benefit of saving reviewers' time through triage if there are fewer applications—perhaps there are fewer applications because applicants are being discouraged by triage and other aspects of the peer review system? Dr. Tabak responded that many individuals have commented about the shortcomings of the triage system, which will certainly be examined by the peer review working groups. One suggestion is that scores be provided to all applicants because, currently, they don't know if they just missed receiving a score. Balance is needed between the time demands put on reviewers and the type of feedback given to applicants so as to avoid psychological damage to investigators, as well as their loss from the scientific enterprise.

Changing the Application Format: Would shortening the application, permitting a video presentation, or changing the appendix be beneficial? Dr. Tabak responded that changes in application format is one of the mechanical issues of peer review that is being examined by the Center for Scientific Review (CSR). Dr. Tony Scarpa, the Director of CSR, is an *ex officio* member on the external working group and a member of the internal working group. Thus, there is crosstalk between both working groups.

Continuity of Review: Has thought been given to enhancing continuity of review so that, to the extent possible, the same reviewers who assessed the initial application would also perform any re-reviews? Dr. Tabak replied that this point has been reflected in comments the working groups have received. However, initial reviewers are often unavailable for subsequent reviews. The NIH will explore whether there are more facile ways of arranging reviews so as to encourage continuity.

Lay Reviewers: Has the NIH given thought to including a lay review component, as is the practice in the peer review processes of some other agencies and patient-advocacy groups? According to Dr. Tabak, one of the reasons that NIH is having a meeting specifically devoted to patient advocacy groups is to hear their views on the value of including lay reviewers. Thus far, most of the comments received by the working groups have been from practitioners of science, and the NIH is seeking greater input in the peer-review self-study process from patient advocates, who have a very important perspective to contribute.

Review of Interdisciplinary Applications: What creative steps can NIH take to ensure that reviewers are fully capable of assessing applications that have the most interesting interdisciplinary approaches? Dr. Tabak described one approach that involves bringing in reviewers with an overarching perspective. For example, if the review panel includes a

dentist and a biophysicist because the application spans those domains, a third person would be brought in who can speak the lexicon of both fields and be an interpreter between them. However, it seems that often that person wants to be considered an “expert,” not an “interpreter.” The key is to find individuals who are facile across multiple scientific domains. This approach could be a potential pilot to emerge from the current NIH self-study of the peer review process. A variant would be to employ the “editorial board model” in which the electronically prepared assessments of individual experts in specific scientific fields would be integrated by a group of individuals who have a broader view. However, it would be a challenge to ensure that review groups do not become so unwieldy as to be inefficient.

In closing, Dr. Tabak said that, as this process moves forward, the NIH is aware that some apparently beneficial changes in the peer review process could have some negative effects elsewhere in the system. Ultimately, the NIH is looking for a balanced and coherent strategy for moving forward. He thanked the Council members for the contributions.

VIII. SCIENTIFIC PRESENTATION

Systemic Implications of Nephrolithiasis

Dr. Gary Curhan, Brigham and Women’s Hospital, Harvard University



Nephrolithiasis.ppt

IX. ADVISORY COUNCIL FORUM: PART 3

NIDDK Intramural Program Update

Dr. Marvin Gershengorn, Director, Division of Intramural Research, NIDDK

Intramural Budget: Dr. Gershengorn displayed a slide showing FY 2006 funding for the NIDDK Division of Intramural Research relative to other NIH intramural components. The Intramural Programs of the National Cancer Institute and the National Institute of Allergy and Infectious Diseases have the largest budgets in absolute dollars. The NIDDK Intramural Program registers fourth in absolute funding, at \$163.2 million in FY 2006, including a \$2.5 million addition from the Office of the NIH Director for a new obesity research program. About \$54 million of the NIDDK intramural budget is for indirect costs under the NIH “Management Fund,” about half of which supports the NIH Clinical Center. The other major components of the NIDDK intramural budget are “Salaries/Benefits/Stipends” of about \$61 million, and “Operating Expenses” of about \$48 million. The latter category includes direct consumable supply budgets for NIDDK laboratories, as well as some renovation and other costs.

Dr. Gershengorn also provided data regarding the percentage of each NIH component’s budget that is directed to intramural research. The NIDDK expends approximately 9.4 percent of its total appropriation on its Intramural Program. Several NIH components direct a much larger percentage of their budgets to intramural efforts. During the five-year doubling of the NIH budget, the NIDDK Intramural Program increased about 94

percent and just about kept pace with the overall growth of the Institute's budget. However, even with the extra \$2.5 million from the Office of the NIH Director, the NIDDK intramural budget has remained relatively flat since the NIH budget doubling period concluded at the end of FY 2003, and it is expected to remain essentially level in the near future. Therefore, the NIDDK is giving considerable thought to ways to allocate and reallocate funds and to identify programs that can be curtailed or closed. The challenge is to maintain the quality of intramural scientific endeavors and programs in an environment in which inflation continues--particularly with respect to personnel costs, most of which are beyond control and continue to rise.

One way the NIDDK Intramural Program may need to control costs is by reducing the number of principal investigators. Reporting on the current staffing of scientists by category, Dr. Gershengorn noted that, in FY 2007, the Intramural Program had 175 doctoral-level scientists, including 80 tenured investigators, 17 tenure-track investigators, 62 staff scientists, and 16 staff clinicians. In addition to the clinicians who do their own research, the Program also supports consultations in endocrinology, diabetes, gastroenterology, kidney diseases and liver diseases throughout the NIH Clinical Research Center.

Any steps taken to reduce the number of principal investigators are based on the expert external review of the Board of Scientific Counselors. This board of experts reviews each intramural scientist about once every four years. Although the Board members are advisory, their evaluation is critically important in helping NIDDK leadership determine the allocation of budgetary resources. While there are low levels of attrition, it has been possible to change the profile of the scientific staff over the past 5-6 years. The total number of independent investigators has been reduced, while other scientists have retired or left the NIDDK for their own reasons. At the same time, the NIDDK has granted tenure status to 15 young investigators and has undertaken efforts to build up the clinical side of its Intramural Program. A goal is to enhance the translational and patient-oriented programs to match the level of excellence in the basic science laboratories.

Within its Intramural Program, the NIDDK maintains high scientific quality with great efficiency. Of the total of 175 scientists in FY 2007, 106 scientists received independent budgets. Using available data, Dr. Gershengorn has done a preliminary analysis showing that the average NIDDK *per capita* funding for these 106 scientists falls below comparable funding levels for other Institutes and Centers.

Office of Fellow Recruitment and Career Development: This Office was established a little over four years ago to help train the next generation of scientists. Dr. Louis Simchowicz was recruited from the Howard Hughes Medical Institute as its Director.

The NIDDK has approximately 500 intramural fellows in different categories. In the largest group are about 180 postdoctoral visiting fellows who are not U.S. citizens or green-card holders. Another 60 postdoctoral fellows are citizens or have green cards. An additional 70 research fellows are more senior trainees on their way to becoming senior investigators. There are 25 clinical fellows in four separate training programs certified by

the American Board of Internal Medicine (ABIM). The remaining fellows fall into the category of predoctoral, post baccalaureate, or technical fellows--all of whom are in the Intramural Research Training Assistant (IRTA) Program--as well as the category of summer student interns. The post-baccalaureate IRTAs are usually students who want to enter medical or graduate school, but would like first to spend a year or two gaining some research experience. The technical IRTAs are usually post-baccalaureates who are also seeking laboratory experience, but who don't plan to obtain a doctoral degree. The Summer Student Interns are usually college or even high school students who become acquainted with NIH scientific programs during the summer months; participation of minority students is strongly encouraged in these programs.

Dr. Simchowicz has oriented the fellows in multiple ways. He established a "buddy system" through which experienced fellows orient new fellows. He also set up an NIDDK fellowship office website; arranged for staff of the fellowship office to provide monthly orientation sessions; and furthered social interactions among fellows. He has taken the lead for the entire NIH in establishing fellowship connections with science and education offices at foreign embassies. Importantly, NIDDK fellows can participate in an off-site, three-day research conference/retreat. This opportunity fosters the interchange of ideas through oral and poster presentations; provides a career-development session featuring a panel of former fellows; encourages networking with peers; and introduces the fellows to the NIDDK's core scientific facilities. Fellows are encouraged to develop a mentality/spirit of research collaboration, with a focus on interdisciplinary and multidisciplinary science. Dr. Simchowicz has set up a number of career-development programs that feature mentoring and career planning, grant writing workshops, laboratory management skills, career counseling, job placement and alumni networks, and an educational program in conjunction with Duke University that leads to a master's degree in health sciences. The NIDDK Intramural Program also encourages fellows to submit K99/R00 applications. Lastly, the Program promotes career transition via the NIH opportunity to receive faculty development awards.

Office of Technology Transfer and Development: Established about four years ago to support both the intramural and extramural programs, this office is directed by a patent attorney, Ms. Rochelle Blaustein. Dr. Gershengorn elaborated on the structure and functions of the office. Its main functions are to provide services and foster formal arrangements concerning matters of intellectual property for propriety materials and information; to perform oversight for the protection and development of NIDDK-created technologies; and to give advice to NIDDK investigators and senior management on matters within the scope of the staff's expertise. Ms. Blaustein is defining a set of metrics to better quantify the practices within her office, and their effectiveness. She educates NIDDK scientists about patent-related issues and provides related materials specific to research and development programs. Under her leadership, technology transfer information has been centralized in a single, accessible, searchable database. There is a balance between protection of the commercial value of government-funded research tools and the scientific community's access to those resources for further research and exploration. In other words, there are protections of intellectual property, not for monetary profit, but so that commercial partners can bring inventions to the clinics and

the patients as rapidly as possible. The Office is a bridge with industry through formal collaborations, and also a liaison with similar offices in other Institutes and Centers and at the NIH level. The Intramural Program is aided by formal, well-defined and appropriate agreements with industry such as clinical trials agreements, Cooperative Research and Development Agreements (CRADAs), and confidential disclosure agreements. On an ongoing basis, Ms. Blaustein resolves many issues with NIDDK scientists regarding assessment of intellectual property rights, patentability, commercialization, and other legal aspects of scientific discovery.

Council Questions and Discussion

Funding Levels: Isn't the funding level for an NIDDK intramural scientist higher than for an extramural scientist? Dr. Gershengorn responded that, although it may look that way at first blush, that is not really the case since the budgets include what would be considered indirect costs at institutions. Also, one needs to consider that the NIH Clinical Research Center is totally supported by the intramural budgets of the Institutes and Centers. Another consideration is that, for the most part, this is the entirety of the support received by intramural scientists. They do not have the range of options available to extramural scientists for securing other sources of support.

How many of the high school and college students being trained come from out-of-state and how are arrangements made for their stay in Bethesda, Maryland? Dr. Gershengorn replied that more of the younger students tend to be local. About 50 percent of those who are above high-school level live in the area. Out-of-state students have access to NIH-arranged housing at Georgetown University and the American University.

How productive are the relationships with the foreign embassies located in the Washington, D.C. area? These liaison activities are viewed as very beneficial. The NIDDK's idea of forging scientific relationships with the embassies quickly expanded throughout the NIH, and the activity is now located under the NIH Deputy Director for Intramural Research.

X. CONSIDERATION OF REVIEW OF GRANT APPLICATIONS

A total of 1,503 grant applications, requesting support of \$360,176,294 were reviewed for consideration at the September 19, 2007 meeting. Funding for these 1,503 applications was recommended at the Scientific Review Group recommended level. Prior to the Advisory Council meeting, an additional 1,135 applications requesting \$253,511,362 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 September 19, 2007 meeting.

XI. ADJOURNMENT

Dr. Rodgers thanked the Council members for their attendance and efforts. There being no other business, the 175th meeting of the NIDDK's National Advisory Council was adjourned at 5:00 p.m., September 19, 2007.

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

A handwritten signature in black ink that reads "Griffin Rodgers". The signature is written in a cursive, flowing style.

Griffin P. Rodgers, M.D., M.A.C.P.

Director, National Institute of Diabetes and Digestive and Kidney Diseases,
Chairman, National Diabetes and Digestive and Kidney Diseases Advisory Council