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

I. CALL TO ORDER

Dr. Rodgers

Dr. Griffin Rodgers, Director, NIDDK, called to order the 205th meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council at 8:30 a.m. on September 6, 2017, in Conference Room E1/E2, Natcher Conference Center, Building 45, the NIH Campus, Bethesda, Maryland.

A. ATTENDANCE – COUNCIL MEMBERS PRESENT

Dr. Joseph Bonventre
Dr. Eugene Chang
Dr. David D'Alessio
Dr. Mark Donowitz
Dr. Joel Elmquist
Dr. Lisa Guay-Woodford
Dr. Caren Heller
Dr. Lee Kaplan
Dr. David Klurfeld
Mr. Richard Knight
Dr. Paul H. Lange
Mr. Thomas Nealon
Dr. Jeffrey Pessin
Dr. Craig Peters
Dr. Alan Saltiel
Dr. Jean Schaffer
Dr. Ian Stewart
Dr. Beverly Torok-Storb +

+Attended KUH Sub Council by phone.

Also Present:

Dr. Griffin Rodgers, Director, NIDDK and Chair of the NIDDK Advisory Council
Dr. Gregory Germino, Deputy Director, NIDDK
Dr. Brent Stanfield, Executive Secretary, NIDDK Advisory Council

B. NIDDK STAFF AND GUESTS

Abbott, Kevin – NIDDK
Ananthanarayanan, Meena – CSR
Andersen, Dana – NIDDK
Arreaza-Rubin, Guillermo – NIDDK
Barnard, Michele – NIDDK
Bavendam, Tamara – NIDDK
Begum, Najma – NIDDK
Berti-Mattera, Liliana – CSR
Best, Caroline – Am. Urol. Assoc.
Bishop, Terry – NIDDK
Blondel, Olivier – NIDDK
Boerboom, Lawrence – CSR
Bourque, Sharon – NIDDK
Bremer, Andrew – NIDDK
Burch, Henry – NIDDK
Burgess-Beusse, Bonnie – NIDDK
Camp, Dianne – NIDDK
Castle, Arthur – NIDDK
Cerio, Rebecca – NIDDK
Chowdhury, Bratati – NIDDK
Connaughton, John – NIDDK
Cowie, Catherine – NIDDK
Curling, Mitchell – NIDDK
Curtis, Leslie – NIDDK
Dayal, Sandeep – NIDDK
Densmore, Christine – NIDDK
Dirks, Dale – Health & Med. Counsel of Washington
Doherty, Dee – NIDDK
Donohue, Patrick – NIDDK
Doo, Edward – NIDDK
Drew, Devon – NIDDK
Duggan, Emily – NIDDK
Evans, Mary – NIDDK
Farishian, Richard – NIDDK
Fisher, Rachel– NIDDK
Fonville, Olaf – NIDDK
Fradkin, Judith – NIDDK
Garcia, Martha – CSR
Gamliel, Dee – NIDDK
Gansheroff, Lisa – NIDDK
Goglas II, Philip – Health & Med. Counsel of Washington
Gossett, Danny – NIDDK
Guo, Xiaodu – NIDDK
Haft, Carol – NIDDK
Hall, Sherry – NIDDK
Hamilton, Frank – NIDDK
Hoff, Eleanor – NIDDK
Hoffert, Jason – NIDDK
Hoshizaki, Deborah – NIDDK
Hu, Jianxin – CSR
Hyde, James – NIDDK
Ivins, Jonathan – CSR
James, Stephen – NIDDK
Jerkins, Ann – NIDDK
Jones, Teresa – NIDDK
Karp, Robert – NIDDK
Ketchum, Christian – NIDDK
Kimmel, Paul – NIDDK
Kirkali, Ziya – NIDDK
Kranzfelder, Kathy – NIDDK
Laakso, Joseph – Endocrine Society
Larkin, Jennie – NIDDK
Laughlin, Maren – NIDDK
Lawlor, Sharon – NIDDK
Lee, Christine – NIDDK
Lee, Jessica – NIDDK
Li, Yan – NIDDK
Linder, Barbara – NIDDK
Lynch, Christopher – NIDDK
Macpherson, Cora – Social and Scientific Systems
Malfait, Anne-Marie – Rush University
Malik, Karl – NIDDK
Marchiolo, Eryn – American College of Rheumatology
Martey, Louis – NIDDK
Martinez, Winnie– NIDDK
Maruvada, Padma – NIDDK
Mendley, Susan – University of Maryland
Morris, Ryan – NIDDK
Mullins, Christopher – NIDDK
Narva, Andrew – NIDDK
Norton, Jenna – NIDDK
Olumi, Aria – – Am. Urol. Assoc.
Osganian, Voula – NIDDK
Otradovec, Heidi – NIDDK
Pawlyk, Aaron – NIDDK
Payne, January – NIDDK
Perrin, Peter – NIDDK
Perry-Jones, Aretina – NIDDK
Pike, Robert – NIDDK
Pileggi, Antonello – CSR
Ramesh, Ganesan – CSR
Rankin, Tracy – NIDDK
Rasouli, Beeta – Lewis-Burke Associates
Regan, Karen – NIDDK
Roberts, Tibor – NIDDK
Rojas, Raul – CSR
Rosenberg, Mary Kay – NIDDK
Roy, Cindy – NIDDK
Rushing, Paul – NIDDK
Sanovich, Elena – NIDDK
Saslowsky, David – NIDDK
Sherker, Averell – NIDDK

Sierra-Rivera, Elaine – CSR
Silva, Corinne – NIDDK
Singh, Megan – NIDDK
Smith, Jaime – NIDDK
Smith, Philip – NIDDK
Spain, Lisa – NIDDK
Star, Robert – NIDDK
Stoeckel, Luke – NIDDK
Tatham, Thomas– NIDDK
Thornton, Pamela – NIDDK
Tilghman, Robert – NIDDK
Torrance, Rebecca – NIDDK
Tuncer, Diane – NIDDK
Turner, Linda – NIDDK
Unalp-Arida, Aynur – NIDDK
Utama, Herman– NIDDK
Van Raaphorst, Rebekah – NIDDK
Vinson, Terra – NIDDK
Waddy, Salina – NIDDK
Wallace, Julie – NIDDK
Weiner, Jeff – NIDDK
Xie, Yining – NIDDK
Yang, Jian– NIDDK
Yanovski, Susan – NIDDK
Zhao, Aiping – CSR

C. ANNOUNCEMENTS

Dr. Rodgers

Council Member News

Dr. Rodgers explained that council members are appointed to serve for a period of three to four years. After this September meeting, five council members are scheduled to complete their terms: ***Dr. David Brenner*** (who was absent), ***Dr. Eugene Chang***, ***Dr. Craig Peters***, ***Dr. Jean Schaffer***, and ***Ms. Ellen Leake***. Dr. Rodgers expressed gratitude for the time they have committed and the thoughtful advice they have given as council members.

Because HHS approved a nomination process for new council members only two weeks before this meeting, new council members have not yet been approved and will probably not be in place before the January council meeting. For this reason, the five departing council members have agreed to extend their service another 180 days to retain appropriate expertise on the council and maintain continuity of operations. Dr. Rodgers thanked Ms. Leake and Drs. Brenner, Chang, Peters, and Shaffer for their service and for their generosity in staying on through the January 2018 meeting.

Dr. Rodgers also pointed out that before individuals can serve as regular council members they must first become a special government employee, or SGE, which requires a hiring action. Because of the government-wide hiring freeze that went into effect in January 2017, NIDDK was not able to complete the hiring action for Dr. Guay-Woodford, Dr. Lange, and Dr. Nealon, and these individuals have technically served as *ad hoc* members since January. However, this administrative obstacle has now been resolved, and they are full members of the council. Dr. Rodgers extended an official welcome.

Dr. Rodgers also welcomed ***Dr. David D'Alessio***, who joined the council as an *ad hoc* member at the May meeting. Dr. D'Alessio has now joined as a regular *ex officio* member, representing the Department of Veterans Affairs.

Dr. Rodgers extended best wishes to ***Dr. Sharon Anderson***, a former council member, on her appointment as the dean of the school of medicine at Oregon Health and Science University (OHSU), effective July 5, 2017. Dr. Anderson will also serve as the executive vice president of OHSU. She has served as chair of the OHSU's department of medicine since March 2015 and will retain that role until a transition plan is enacted. Dr. Anderson's career in academic medicine has included research, education, clinical care, and administration. Previously, she was chief of medical service at the VA Portland Hospital Health Care System, where she maintains a staff appointment.

Dr. Rodgers also extended congratulations to ***Dr. Robert Desnick***, a long-time supporter of NIDDK who was selected by the National Organization for Rare Disorders (NORD) to receive one of two 2017 Rare Impact Awards. Dr. Desnick is dean for genetics and genomics and professor and chairman emeritus of the Department of Genetics and Genomic Sciences at Icahn School of Medicine at Mount Sinai in New York. He is also professor of pediatrics, oncological sciences, and obstetric gynecology and reproductive sciences at Mount Sinai. He has been treating genetic diseases for more than 40 years and helped establish the Porphyria Consortium as part of the Rare Disease Clinical Research Network of the National Center for Advancing Translational Research (NCATS). NIDDK funds the Porphyria Consortium with NCATS, and Dr. Desnick is a principal investigator on that award.

NIDDK Staff News

Dr. Marva Moxey-Mims, a pediatric nephrologist, departed NIDDK in July to become chief of nephrology at Children's National Health System here in Washington, D.C. Dr. Moxey-Mims joined NIDDK's Division of Kidney, Urologic, and Hematologic Diseases (KUH) in 2002 and became deputy division director in clinical sciences in 2008. While at NIDDK, she initiated and oversaw research programs, including the Chronic Kidney Disease in Children study (CKiD), a randomized intervention for children with vesicular urethral reflex trial. She also managed KUH's small business grants for kidney research. Prior to joining NIDDK, Dr. Moxey-Mims served as a nephrologist at the FDA and as a staff nephrologist at Children's National.

Dr. Rebekah Rasooly, program director for NIDDK's Kidney and Urology Genetics and Genomics programs, has moved to a new position within NIH as chief of the Wellness, Technology, and Training branch of the National Institute for Nursing Research. Dr. Rasooly has overseen and managed many important studies since joining NIDDK in 2001. In 2002, she established and has since directed NIDDK's Central Repository, which houses samples and data from major clinical studies supported by NIDDK. Dr. Rasooly has also overseen policy and stepped into many other areas as needed, including serving as deputy division director for KUH, which included the transition of division leadership.

Dr. John Kusek, program director in clinical epidemiological studies for KUH has retired after 28 years at NIDDK. Dr. Kusek managed epidemiological studies of large-scale clinical trials in urology and chronic kidney disease. He advocated for the interests of the research and patient communities and is a nationally recognized expert in epidemiology and clinical and translational research design. Dr. Kusek also acted as a true mentor to many and was recognized at NIDDK for his experience, sound judgement, and high standards for himself and NIDDK program administration.

Dr. Christine Hunter, clinical psychologist, left NIDDK in August to become deputy director for the NIH Office of Behavioral and Social Science Research. Dr. Hunter joined NIDDK in 2006 and served as director of behavioral research in the Division of Diabetes, Endocrinology and Metabolic Diseases. She developed and led NIDDK's Center for Diabetes Translational Research and fostered new areas of behavioral research relevant to obesity and diabetes. Prior to joining NIDDK, Dr. Hunter served in the U.S. Air Force as Chief of the Air Force Substance Abuse Program.

Dr. Rodgers also welcomed ***Dr. Henry Burch*** who has joined NIDDK's Division of Diabetes, Endocrinology and Metabolic Diseases as program director for the diabetes and thyroid grants program. Dr. Burch served more than 20 years at Walter Reed National Medical Center (formerly Walter Reed Army Medical Center) where he served for 11 years as Chief of Endocrinology, Diabetes, and Metabolism service as well as Chair of the Endocrine Division at the Uniform Services University for Health Sciences. He also served for seven years as endocrinology consultant to the U.S. Army Surgeon General. His clinical and research focus is thyroid disorders and he served on the American Thyroid Association's hyperthyroidism practice guideline committee in 2011 and 2016.

NIDDK Intramural Program

While most Council business focuses on NIDDK's extramural research program, the Council also provides advice for the Institute's intramural program. The intramural program conducts basic,

translational, and clinical biomedical research related to diabetes, endocrine, bone, metabolic diseases, digestive diseases (including liver disease), nutritional disorders, kidney diseases, and hematologic diseases. This research ranges from basic science to clinical studies and is conducted in Bethesda and at NIDDK's clinical facility in Phoenix, Arizona. NIH policy requires that the scientific director who oversees intramural research report to the Council annually. Dr. Michael Krause will give the Council this update later during executive closed session, since the update includes sensitive and confidential information regarding the reviews and review outcomes of individuals within the intramural program.

NIH policy also requires review of the scientific director's leadership every four to six years. These reviews are conducted by an *ad hoc* committee established by and reporting to the NIDDK Advisory Council. The committee may include Council members, former intramural scientists, or senior scientific administrators. Dr. Rodgers has requested that Dr. Krause start developing reports in preparation for his first review, and he asked for a motion from the Council to establish an *ad hoc* committee to conduct this review and report back to the Council at the May meeting. The motion was made, seconded, and with no objections council indicated its concurrence with the request.

II. CONSIDERATION OF SUMMARY MINUTES OF THE 204th COUNCIL MEETING

Dr. Rodgers

The Council approved, by voice vote, the Summary Minutes of the 204th Council meeting, which had been sent to them in advance for review.

III. FUTURE COUNCIL DATES

2018

January 24-25 (Wednesday and Thursday)
Natcher Conference Center (Building 45)
Conference Rooms E1/E2, D and F1/F2

May 16-17 (Wednesday and Thursday)
Natcher Conference Center (Building 45)
Conference Rooms E1/E2, D and F1/F2

September 7 (Friday)
Building 10, details TBA

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

While the conference room in Building 10 is being renovated, the Council will meet in Natcher Conference Center for the January and May meetings, moving to Building 10 (Clinical Center) for the September meeting, which will be held on a Friday. More details regarding the September meeting will be forthcoming.

IV. ANNOUNCEMENTS

Dr. Karl Malik

Confidentiality

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

Conflict of Interest

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

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

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

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

V. REPORT FROM THE NIDDK DIRECTOR

Dr. Rodgers

Budget Update

Dr. Rodgers reported that just before the Council's May meeting, the President signed into law the Consolidated Appropriations Act of 2017, funding government agencies through September 30, 2017. This law provides the NIH with an additional $2 billion over the 2016 appropriation. NIDDK specifically will get an increase of 2.9 percent. This amount does not include the Special Statutory Funding Program for Type 1 Diabetes Research (Special Diabetes Program), which is a separate appropriation that requires periodic authorization. This appropriation was subject to the sequestration, which reduced the amount.

For fiscal year 2017, NIDDK established a nominal pay line for new and competing R01s at the 12th percentile. R01 applications requesting $500,000 or more in direct costs for any year were held to a more stringent pay line set at the seventh percentile for both type 1 and type 2 applications. Early Stage Investigators (ESIs) benefited from a more generous payline set at the 17th percentile. First competitive renewal applications for R01 awards to researchers who were ESIs when they competed for the initial NIDDK Type 1 R01 award received a payline set at the 15th percentile. These and other aspects of the 2017 funding policy are on the NIDDK website (https://www.niddk.nih.gov/research-funding/process/award-funding-policy).

Looking next at FY 2018, Dr. Rodgers reported that after releasing a budget blueprint in March, the President released his full budget request for all executive agencies on May 23 and Congressional hearings for NIH funding were held in May and June. The hearings went well and both parties in the House and Senate were very supportive of NIH.

The full House appropriations committee passed its FY 2018 bill for NIH in July, and the Senate appropriations subcommittee was scheduled to consider the bill within the week, and it was expected that the Senate's intention for NIH would be known soon.

In May, the President requested $26.7 billion for NIH in his FY 2018 budget. The House recommendation is $35.18 billion, or 3.19 percent over the FY 2017 level of $34.1 billion. The level for NIDDK would be $1.899 billion, $29 million (1.56 percent) over the FY 2017 appropriation of $1.87 billion. Dr. Rodgers pointed out a few features of the President's request. The administration has a plan for government reorganization that includes changes to the NIH. This plan calls for the consolidation of the Agency for Healthcare Research and Quality with the NIH as well as the dissolution of the Fogarty International Center. Reflecting the administration's objective of efficiency in government, indirect costs would be capped at 10 percent of the total costs of all research grants. Currently, NIH spends about 28 percent of the extramural budget on indirect costs.

The President's request is the starting of the budget process and reflects administrative priorities. Budgets and policy directives for federal agencies are determined by Congress, and we won't

know their response until the bill for the fiscal year 2018 appropriation is passed.

Dr. Rodgers pointed out that Congress has a full docket of issues and concerns to address. These issues include the national debt ceiling; emergency disaster relief for Texas, Louisiana, and other states; a fix for the Deferred Action for Child Arrivals (DACA) program; and government funding beyond September 30 to avoid a shutdown. With little time remaining in this fiscal year, the solution may be to pass a Continuing Resolution to fund the government at fiscal year 2017 levels at least through December 1 and possibly the end of the calendar year.

The Special Statutory Program for Type 1 Diabetes Research (SDP) has enabled NIDDK to provide funding for research that has made great strides in the quest to prevent, treat, and ultimately cure type 1 diabetes. Dr. Rodgers explained that the SDP requires periodic reauthorization, which it has received nine times during its 20-year history. The authorization for fiscal years 2016 and 2017 occurred as part of the Children's Health Insurance Program (CHIP); authority beyond 2017 has not yet come through. The SDP historically has had strong bipartisan support in Congress, but funding is still a challenge. Dr. Rodgers remained hopeful that funding will come through and, in anticipation, NIDDK held a planning meeting to discuss potential funding opportunity announcements that could be released if the funds are indeed renewed. During a two-day meeting, non-federal experts provided input on a host of proposals for new and expanded research developed by NIDDK and other NIH institutes.

The Senate Finance Committee, which oversees the section of the CHIP bill that contains the reauthorization for the Special Diabetes Program, is holding a hearing on September 7th, and the House Ways and Means Committee (the counterpart of the Senate Finance Committee) is also planning to hold hearings on CHIP. NIDDK will keep a watchful eye on the hearings and other deliberations involving the Program

Council Questions and Discussion

Dr. Donowitz asked about the Grant Support Index (GSI) system presented by Dr. Tabak at a previous Council meeting. The system would limit total funding given to any investigator based on a scoring system. Dr. Rodgers said that the policy received lots of feedback, especially about potential downsides, and it has been put aside in favor of another approach. Dr. Rodgers said that now the emphasis is on Early Stage Investigators (ESIs), who are investigators who have received their terminal degree or completed post-graduate clinical training within the past 10 years, and ways to ensure the number is right-sized for the projected workforce of the future. The new emphasis also considers Early Established Investigators (EEIs), who are within 10-years of receiving their first competing NIH R01 equivalent award. NIDDK has been active in fostering the careers of early career investigators for some time by establishing extended paylines for ESIs and more recently by extending the R01 payline for former ESIs who are seeking their first competitive renewal award. The emphasis that NIH has placed on supporting ESIs and EEIs is consistent with NIDDK's focused efforts and NIDDK will continue to adhere to all NIH policy requirements and embrace efforts to appropriately support the next generation of researchers.

VI. UPDATE FROM THE DIRECTOR, NATIONAL LIBRARY OF MEDICINE
Dr. Brennan

*Dr. Rodgers introduced **Patricia Flatley Brennan, R.N., Ph.D.**, Director of the National Library of Medicine since August 2016. As of January 2017, Dr. Brennan has also assumed the role of the NIH's Interim Associate Director for Data Science following the transfer of the Trans-NIH Data Science Initiative to NLM.*

Dr. Brennan came to the NIH from the University of Wisconsin at Madison, where she was the Lillian L. Moehlman Bascom professor at the School of Nursing and College of Engineering. She has also led the Living Environments Laboratory at the Wisconsin Institute for Discovery, which develops new ways for effective visualization of high-dimensional data. She received her Masters of Science degree in Nursing from the University of Pennsylvania and a Ph.D. in Industrial Engineering from the University of Wisconsin at Madison. She has been on faculty at Marquette University and Case Western Reserve University. Among her many honors, Dr. Brennan was elected as a member of the National Academy of Medicine.

Dr. Brennan's presentation focused on her vision for the NLM and the importance of its resources, including ClinicalTrials.gov, the flagship trial registry system. She also discussed data science, why data science matters to NIH, and the Trans-NIH Data Science Initiative. She began by noting that, since the late 1990s, the realization has emerged that the data generated in the course of a research project are inherently valuable. The Data Science Initiative explores ways to make effective use of these data, how to manage the data, and how to ensure that they can be leveraged for future research projects.

The Trans-NIH Data Science Initiative will help create a unified approach to managing scientific data resulting from NIH supported research. Standardized ways of managing identity, ensuring security, and making datasets accessible for both NIH and non-NIH users will be developed. Dr. Brennan noted that some data science policy issues will still need to be handled by individual Institutes and Centers (ICs) within NIH, while being careful to avoid duplication of efforts or creating data siloes in individual ICs. The NLM has specific resources that will be likely to be helpful in this area, given its long history of curation, cataloging, and making literature and genomics data widely available.

As an example of institutional flexibility and refined purpose, Dr. Brennan reminded the Council of the Big Data to Knowledge (BD2K) program that began in 2009. BD2K was intended to have about a $400 million to $500 million investment over eight years to generate new solutions to data science and data science challenges. Led initially by Eric Greene and then later by Phil Bourne, the BD2K program stimulated extramural research through various types of research programs and training grants. After four years, the investment shifted to address more explicitly data science needs, specifically, pivoting from an extramural program supporting new investigations to development of NIH resources. One of BD2K's lasting contributions has been the commitment at NIH that all data generated in the course of research projects should be FAIR: Findable, Accessible, Interoperable

and Reusable. These are the four fundamental principles that now drive how all the Institutes should acquire and then later make use of data.

Dr. Brennan issued a cautionary note regarding interest among ICs at NIH to create institute-specific approaches to data science, including training programs for staff or analytics to answer questions relevant to that IC. While it's appropriate in the sense that domain scientists know best how to move data science forward in their area, this approach is also dangerous in the sense that solutions created for one dataset may not scale to other datasets; or, more importantly, solutions scaled in a familiar fashion may make unsupported and unsupportable assumptions about the data.

Dr. Brennan reviewed the NLM's history, mission, and data resources, which attract more than 4 million users daily. The most widely used resource is PubMed as well as PubMed Central (PMC), the full-text publication database. Molecular and clinical data draw about 300,000 users daily to resources including Gene, Nucleotide, Protein Structure, BLAST, PubChem, and Clinical Trials. Finally, specialized datasets, including SNP, GEO, SRA dbGaP, and ClinVar, attract about 15,000 users daily.

Dr. Brennan traced the NLM's evolution from the card catalogue era to that of the cloud-based storage. She defined data science as the scholarly work that creates algorithms, discovery services, and computational tools to explore, interrogate, and analyze data. In contrast, advanced data management makes sure that the records are secure, identifiable, and accessible. Advances in science don't necessarily improve data management, and focusing on data management alone won't advance science, so it is ideal that these two be brought together within the NLM, she said.

Rather than becoming the data resource for the world, Dr. Brennan said the NLM will emphasize preserving its datasets and their physical locations throughout the world, always with an eye to appropriate preservation. Preservation issues become crucial as the NIH ICs begin to ask investigators to deposit data at the end of their studies. Many details regarding data preservation need to be resolved and trans-NIH consensus must develop. The NLM plans to be at the forefront of these decisions.

Another focus area for NLM will be promotion of interoperability through standards. The NLM has had a long history with clinical standards, including promoting the use of common data elements (CDEs) in clinical research, patient registries, and other human subject research to improve data quality and opportunities for comparison and combination of data from multiple studies and with electronic health records. Another example is NLM's Value Set Authority Center, which brings together the indicators of clinical outcomes so that terminology and standards can guide the work of external institutions.

Another challenge for NLM is identification of high-value datasets that must be preserved. Dr. Brennan favors adding an econometric perspective to evaluate the future value of datasets to help provide guidance regarding how much data should be maintained as readily accessible and what can be moved into cold storage. Dr. Brennan also wants to see conversations within the scientific community change from investigator-centric views of data and data-driven discovery, to a cooperative group view or a society-based view where each study contributes to the knowledge of

the country in the way that articles contribute to this knowledge base. This requires developing structures for integrating and linking datasets similar to those that currently exist for scientific literature. Also, since datasets can range in size up to millions of petabytes that are not able to be easily moved from one physical location to another for use by other scholars, new analytical strategies will have to adapt from bringing the data together for analysis to sending out analytical tools to the far-flung data elements and then resynthesizing them.

Dr. Brennan has targeted four areas for developing discovery and analysis tools.

- *Curation, catalogs, and indexing.* This will involve performing these activities at scale, mapping scientific vocabularies to data vocabularies, and determining when a human-driven versus automated solution is appropriate.
- *Analytics.* Statistics and biostatistics will remain important but there is a need for better-best principles regarding their application, particularly using a distributed model. Dr. Brennan sees investments in artificial intelligence, machine learning, and deep learning as critical for harvesting knowledge from data. She also wants to enhance existing optimization tools to help with better study and protocol planning.
- *Visualization.* As datasets become ever-more sophisticated, data visualization needs to keep up so that findings can reach their broadest audience, said Dr. Brennan.
- *Management practices.* This area includes better data tracking and accounting, as well as preserving the provenance of analytical strategies and data.

The NLM has good foundational tools in each of these areas, and Dr. Brennan's goal is to make them more robust and accessible, and to continue to drive the NLM to contribute to global data science and open science solutions. Other points of pride are NLM's participation with ELIXIR and the creation of the Open Science Prize in partnership with the Wellcome Trust.

Dr. Brennan believes the NLM has a responsibility to build workforce capacity targeting the needs of scientists, clinicians, and patients. She also noted that 6,500 libraries across the United States participate in the National Network of Libraries of Medicine.

Dr. Brennan shared the NLM's top three priorities for 2018. First is the Commons Pilots, a three-year, $60 million program to develop the infrastructure for cloud instant storage. NLM is partnering with three key dataset contributors to explore the analytical, ethical, social, legal, technical, computational, and financial cost of this type of investment. Some of the key questions are: How do we make data FAIR? How do we make these large datasets discoverable? How do we do that in a way that preserves the conditions under which the data were originally collected?

As an example, Dr. Brennan explained that the dbGaP is running out of space because broad reads from human studies are so large that they are "choking" the system, leaving NLM unable to meet the ICs' demands for safe data storage. In cooperation with Andrea Norris, and under the Commons Pilots, NLM has built the NIH/CIT Cloud Instance, a remote storage environment, where rarely used but important large raw datasets can be kept and stored under IC control. Dr. Brennan envisions this as the future foundation of the NIH Data Commons, under an NIH-wide governance system, including the Scientific Data Council.

The second priority is data deposit and discovery via PubMed Central, which currently contains 4 million full-text articles and has a daily download total of about 1 million articles. Dr. Brennan told the Council that NLM will soon offer direct deposit of data in support of any PubMed Central article. This first step into large-scale data sharing will allow datasets of 2 gigabytes or smaller to be shared immediately and curated by the original investigator. The NLM group is working on an indexing strategy and metadata structure so that the data will be searchable as well as the article itself. The hope is that this project will inform future efforts to store and coordinate larger data sets.

The third priority is ClinicalTrials.gov, the clinical trials reporting system, which currently contains about 250,000 active and closed studies. Dr. Brennan demonstrated site improvements by showing screenshots and noted that there are a number of pathways into the system for different audiences. For example, a member of the public may enter through one pathway to find appropriate studies for participation, while investigators who deposit data and those who use analytical tools have separate pathways. Dr. Brennan noted that NLM partners with other NIH groups to facilitate patients' exploration of clinical trials. One such example is BreastCancer.gov, which downloads the entire clinical trials dataset every night and has created an easy-to-use interface for patients looking to participate in special kinds of breast cancer trials.

ClinicalTrials.gov has added several features in the last year, including the disclaimer, "This site does not reflect endorsements by the National Institutes of Health," which has been much discussed from both policy and political perspectives. Search options have also been improved, so that a user can search by disease or physical location. There is more description about each study as well.

Investigators register trials in ClinicalTrials.gov at the beginning of their studies (prospective registration) with the intended protocol and other information. Staff verify key protocol information. Summary results reporting was added to the database in January 2017. This provides "minimum results reporting set" for each trial based on its registered protocol information. Structured data enable accurate search and retrieval based on elements of the study design. With these features, ClinicalTrials.gov gives a good survey of the research landscape.

As of now, ClinicalTrials.gov does not include individual participant data (IPD), only aggregate data. However, this is an area of great interest because of the rich data available in IPD. While Dr. Brennan does not envision that ClinicalTrials.gov will become a repository for IPD, she did think it was possible that the database may one day link out to IPD. This may help create an audit trail for summary reporting and would allow for combining trial data with other trials and may enable better use of some individual repositories at NIH, including the NIDDK central repository. In this way, ClinicalTrials.gov would act as the integrating point for data from initial declaration of the study to protocol information, results data, final publications, abstract, conference presentations, and access to individual participant data.

Dr. Brennan then shared with the Council the NLM 2017 Strategic Plan process, which started in September 2016 and is ongoing. The process has included expert panels, functional audits to make sure resources are well used, and site visits to all NLM training programs. She received input from around the country and from staff here on campus and other NIH investigators. The areas examined

included:

- Advancing biomedical discovery and translation;
- Advancing data science, open science and informatics;
- Supporting the public's health; and
- Building the 21st century collections for discovery and health.

Among the key findings:

- The library must change to support data driven discovery and data-powered health in the community.
- NLM must continue the digitization process, but must also maintain its history (i.e., collections include an original manuscript from ancient Abyssinia and 10th-century Chinese resources).
- Training for librarians, clinicians and researchers is needed.
- The most precious aspect of the NLM is the trust the public has placed in it.

Dr. Brennan closed her presentation by sharing NLM's goals for the next five to 10 years. The NLM will become an integrated information pathway for health and discovery in the 21st century. The NLM will create pathways for dissemination and engagement to technology, to machines, to people and to clinicians and researchers. Finally, the NLM will foster workforce development for accelerated discovery and for the better health of the world.

Council Questions and Discussion

Will there be NLM resources to help young investigators become more proficient in all aspects of data science, including big data applications?

Dr. Brennan pointed out that one resource available currently is BigDataU.org, a product of the BD2K program. However, BigDataU.org is for individual, self-paced study, and therefore is not adequately suited for the widespread sea change that must occur within scientific fields. She believes that the bigger issue will be to create model curricula focusing on the application of data science, possibly in partnership with other ICs. She drew a parallel between this need and the NIH 10-week session on ethics: a course standardized to be used throughout NIH, avoiding the need for each IC to create its own material.

Dr. Brennan also encouraged Council members and IC leaders to work with their own faculty on data science issues to ensure appropriate cross-pollination and training as well as foster a full appreciation of the difference between data science and statistics. She also called for partnerships to make sure faculty understand available resources and provide appropriate guidance for trainees.

Dr. Brennan asked the group whether there would be interest in a common curriculum in data science for trainees. Council members responded that a focused, limited set of lectures that won't interfere with trainees learning their specialty would be very helpful and that the curriculum should provide meaningful feedback and assessment of learning.

Dr. Brennan said she has been talking with the head of NIGMS as well as the contractor Booz Allen

about developing training for program officers who must evaluate the data science proposals that are coming in. Although the content of that training may be different from that of NIH trainees, some of the challenges and approaches may be similar.

What types of quality control processes do you have in place to assess these large datasets?

Dr. Brennan explained that the NLM uses quality assurance and quality control (QA/QC) processes developed for genomics. She realizes that NLM needs to develop processes for image data, environmental science data, and, eventually, for electronic medical record entries. She also noted that the ingest process, where data is taken into the system, is the point where the quality control is accountable, and that National Center for Biotechnology Information (within NLM) has developed a very strong and high-quality ingest process. However, in this context, she would like to see more recognition that both science and analytics change and develop. She added that some of the newer data science analytic approaches are more robust to perturbations in the data than are standard deviation statistics. So, there is a chance to leverage data differently with the new analytics.

But these gains also underscore the need to be able to return to a dataset at will, to address issues like machine calibration problems and to overcome variables like idiosyncratic naming tendencies that vary by discipline. So, the first part of QA is data accuracy, followed by data reusability. Part of the process is also to maintain meticulous use records so that errata can be identified, and the sponsoring institution informed of the need for revision. But there's also a need to protect trust in the datasets themselves, she noted.

Dr. Brennan believes that, over time, a greater understanding of the relative importance of different errors will develop, and understanding of scientific quality can change, too, over time. She pointed out that, in experimental studies, quality is built into the design phase: adequate power, the right measurement scheme, and validated instruments. But in data science explorations, quality is built in at the evaluation stage. Some of the more robust machine learning tools can classify and extract perpetuated errors, helping to balance quality challenges.

Please explain whether NLM uses its own proprietary cloud or a commercial cloud, and what security precautions NLM is taking to protect and control data.

Dr. Brennan clarified that all clouds are by definition commercial clouds, at least for now. She said that NIH has made a commitment to a more formal process of risk assessment and of identifying data integrity as part of the NIH mandate for risk assessment of the Trans-NIH solution. One example of NLM's efforts is that they are building a double cloud resource in Amazon and in Google for the Commons Pilots projects. She noted that there was federal implementation that is FISMA (Federal Information Security Management Act) compliant within Amazon that, if it's used to its fullest extent, provides a level of security and business agreement that is as reliable as can be right now.

Dr. Brennan said that it is possible that NIH will develop its own cloud, perhaps replicating it with two or more cloud providers. She anticipates that there would be significant efficiencies coming from that arrangement and individual choice about how long to preserve data could be given to the

institutes. Most importantly, this development would yield a controlled access process that would allow for some robustness such as new partners coming in, for example, or real-time authentication. Dr. Brennan said that the NLM is working with NSA (National Security Agency) on security and authorization issues.

Dr. Brennan closed by suggesting three points to consider in the move to cloud-based computing, starting with long-term scalability. Compliance with NIH data security requirements is also vital so that NLM can ensure that access is controlled. Finally, each scientist and institution will have to consider the value of any given dataset to the larger scientific world. Resources that might also be useful to scientists who work in other fields may mean that it may make less sense to do an NIDDK investment and more sense to move to an NIH investment. She welcomes the guidance of Council members in this and notes that this will be a long conversation.

VII. COFFEE BREAK

VIII. NIH OFFICE OF PORTFOLIO ANALYSIS: OVERVIEW AND TOOLS
Dr. George Santangelo

Dr. Rodgers explained that the Office of Portfolio Analysis (OPA) was established in 2011 as part of the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) within the Office of the Director of the National Institutes of Health. OPA develops portfolio analysis metrics and tools for NIH staff, including a relative citation ratio (RCR) metric to measure the influence of a journal article and a web tool (called iCite) that calculates the RCR of articles listed in PubMed.

Dr. Rodgers introduced ***Dr. George Santangelo****, the director of OPA. Dr. Santangelo is trained in genomics and data science, with a bachelor's degree from the University of Pennsylvania and a doctorate from Yale University. He began his career with NIH in 2009 at the National Institute of General Medical Sciences (NIGMS). In 2011, he became the first director of the OPA and leads a team of analysts, data scientists, and software developers to enable data-driven decision making.*

Dr. Santangelo explained that the OPA develops data-driven approaches to support NIH staff in decision making. By using data analysis, program managers and other NIH administrators can identify and overcome unintentional bias that can arise when evaluating portfolios or programs. He pointed to the work of Daniel Kahneman, who won the Nobel Prize in economics, in describing two systems of thinking. System 1 thinking is fast, intuitive, and unconscious. This type of thinking is subject to bias. System 2 thinking, on the other hand, is slow, logical, analytical, and conscious. This is the type of objective thinking that scientists aspire to attain. Although Kahneman was not the first to understand this dichotomy, he was the first to lay out and demonstrate how the two systems differ from each other.

OPA's goal is to provide data to combat bias and foster objective decision making. For example, in 2016 the NIH Deputy Director for Extramural Research asked OPA to investigate whether there

was a relationship between the amount of NIH support to researchers and the number of trainees from those labs who go on to apply and receive research grants. They did this by conducting a longitudinal study that analyzed the publications listed in the biosketches and looked at which awardees co-authored publications with early stage investigators (ESI) to identify ESI applicants and their mentors. It turned out that there was no linear relationship between the funding level of mentors and the number of ESI applicants that they train.

Dr. Santangelo explained that OPA has a four-faceted mission:

- To coordinate portfolio analysis activities across NIH (including planning and hosting seminars, workshops, and symposia) and encouraging "crosstalk" within the NIH community through the Portfolio Analysis Interest Group and a blog (*The Analyst*);
- To provide training and disseminate information via formal classes, *ad hoc* sessions, office hours, and the OPA website and other publications;
- To provide consultation, analyses, data acquisition and management, and other services to the Institutes and Centers for the NIH, including NIH senior leadership and NIH staff; and
- To develop a science of portfolio analysis, including establishment and dissemination of best practices, developing new tools and approaches, and building a community of experts representing government, academia, and the private sector.

He pointed out that this last piece is the most challenging because portfolio analysis is a relatively new field and the computational resources for this work are still being developed. He pointed out that NIH is a model for studying "the science of science," i.e., understanding how science progresses and applying scientific methodology and the scientific method to answering questions about how to improve and recognize opportunities to invest in science.

OPA has a suite of tools, some of which are still in development, for portfolio analysis. These include:

- IN-SPIRE and Word2vec for content analysis;
- iClean for efficient disambiguation (or connecting principal investigators with their research, publications, patents) (in progress);
- iCite for effective bibliometrics;
- iTrans to map translational science;
- iSearch, the NextGen portfolio analysis platform;
- iNet for network analysis (in development); and
- iTech to track patents, licensing, and start-up activity (in development).

Dr. Santangelo went on to describe further some of these tools, including two in detail: iSearch and iTrans.

iSearch

iSearch is the NextGen portfolio analysis platform. *iSearch* was developed by OPA to enable

NIH staff to answer analytical questions and improve data-driven decision making by using computational resources. It was developed in 2015-2016 and in September 2016 a beta version was made available. The official release took place in January 2017, with the release of version 2.0 slated for October 2017.

iSearch provides comprehensive and easy-to-use access to carefully curated and extensively linked datasets of publications (PubMed), clinical trials (ClinicalTrials.gov), patents, approved drugs, investigators (including mentor/mentee relationships and longitudinal studies), and awards made by other funders (both domestic and international). Some modules are still under development, but the program already offers NIH staff a wide range of functionality. Some of the areas still being worked on include: investigators, clinical trials, and drugs. OPA is considering making some modules of *iSearch* publicly available.

The platform provides sub-second query times over millions of funded and unfunded grants, tens of millions of publications, tens of millions of patents, and hundreds of thousands of clinical trial and drug records. It uses Google-like free-text queries, NIH-specific search filters, and real-time drill down, to make data exploration quick and accurate. The datasets are constantly updated. Currently the program has more than 600 active users with 460 sessions a day.

Some of the features of the updated version include the ability to save user preferences and transfer data between modules, which allows someone to search for grants, then look at the papers associated with those grants. Users can view QVR (Query/View/Report System) and PubMed pages directly from within the tool and they are able to select visualization clusters to view the corresponding records.

OPA has held several training sessions on the *iSearch* 2.0 platform, and it has been well received.

iCite

iCite is OPA's tool for effective bibliometrics. When judging science, staff members want to read the papers, understand the experiments, and judge the work on that basis. But when staff are faced with 400 applications in a hiring search or in response to a funding announcement, they don't have the time to read all the papers. *iCite* is designed to measure the influence of the work by calculating the Relative Citation Ratio (RCR) of a particular journal article. It measures the actual citation rate, then divides that by the expected citation rate for that field. This tool is available publicly and is used by librarians and others across the country. The tool has been validated through meticulous research and an article documenting the validation ran in June 2017 in *PLOS Biology*.

iTrans

Dr. Santangelo pointed out that influence is just one measure of the value of an individual's work or of a collection of grants awarded. Dr. Griffin Weber, who is the Chief Information Officer at Harvard Medical School, has developed another way to evaluate research using the MeSH terms developed by the NLM. Ninety five percent of research papers fall into one of three MeSH categories: molecular/cellular, animal, or human medical subject —which are the three stages of translation of research from bench to bedside. Using these three categories, Dr. Weber has

generated a “triangle of biomedicine” which reflects the diversified metrics needed in research assessment. Dr. Weber published his findings in the *Journal of Translational Medicine* in 2013.

Dr. Santangelo explained that OPA has collaborated with Dr. Weber to tweak his ideas to analyze the research portfolios of a department, individual, or group or articles on a particular topic to show how basic discoveries on cells and molecules translate to animal research and, finally, clinical trials that impact human health. He showed an example of research into Voraxaze, a drug that treats methotrexate buildup in patients with kidney failure. The development of the drug started with the cloning of the CPDG2 gene (molecular/cellular), then moved to a mouse model (animal), case studies (human), toxicity (animal), and then into clinical trial (human). This progression does not always occur in a straight line. Sometimes human research stimulates basic research, so knowledge and drug development can flow both ways.

As another example, Dr. Santangelo tracked the progress of cancer immunotherapeutic agents, including Nivolumab. These agents kicked off an entire class of agents called checkpoint inhibitors that stimulate the immune system to attack tumors. The basic research was done in the late 1980s through mid-1990s. The translational work took place from 2003-2007, and the clinical trials research has taken place since 2010.

iTrans, the OPA tool based on this method, automates the process, mapping the “knowledge flow,” which can be used in decision making to figure out what research is likely to be successful based on the flow of knowledge as science progresses. Dr. Santangelo showed *iTrans* plots of articles about cancer immunotherapeutic agents published in 1987-1996 focused on the base of the triangle (between cell and molecular and animal studies). During the years 2003-2007, the research published on this topic tended to be in the middle in the zone for translational research. Articles published in 2010-2014 were at the peak of the triangle because they focused on human health.

The *iTrans* tool is now available to NIH staff. Dr. Santangelo admitted that it’s not appropriate for every area of science that NIH invests in, but it can be very valuable in understanding what a portfolio looks like in terms of publication output.

He pointed out that these tools are not the endpoint, but rather a starting point for further inspection and analysis of a body of work. The different tools can be combined—say *iTrans* and *iCite*—to get a more complete picture. Dr. Santangelo has published a paper about how these tools can be used to shift from journal-level to article-level assessments in portfolio analysis and in decision making. These tools are used mostly on research portfolios in aggregate, rather than focusing on the work of individual researchers.

Dr. Santangelo ended by pointing out that data-based decision-making tools do not replace decisions made by instinct and intuition, but that instincts supplemented by data result in better decisions than instinct alone. He thanked the OPA team for their work in developing, disseminating, and supporting these tools for the NIH community.

Council Questions and Discussion

Does the article-level assessment consider the number of publications or articles published by a journal in an annual cycle?

Dr. Santangelo explained that in the paper describing the relative citation ratio method, he and his colleagues found that only a small proportion of the high-RCR articles were published in journals deemed highly influential. This was due in part to the large number of articles published in the other journals combined and the relatively small number of articles published by journals such as *Nature*, *Cell*, and *Science*. A fraction method, he pointed out, would find a higher proportion of high-RCR papers in the well-known journals that make a point to publish provocative discoveries and papers that they expect to be influential.

As NIH looks at its training programs, we need to assess the number of trainees per budget. Clinical research is expensive both in time and money, and many investigators consider it a less-optimal training vehicles for individuals because trainees don't get enough time in the lab. In addition, relying on information from researchers' biosketches has a lot of potential for artifact because investigators are limited in the number of papers they can enter, and older articles may not capture the most trainees.

Dr. Santangelo pointed out that the biosketches that were analyzed were those of early-stage investigators without long track records. The information was used only to identify people who may have been a mentor to that early-stage investigator because they were listed as a last author on at least two papers in the biosketch.

He agreed that different areas of science must be judged differently, and those using data to make decisions must take into consideration these different caveats in drawing conclusions.

Is the objective of this work to influence funding decisions? Is there any thought to expand the use of these metrics to other funders or to pulling together a group to think about how to expand this approach?

Dr. Santangelo said that the goal is to improve data-driven approaches to decision making. It remains up to the individual decision maker to make the judgement of whether and how to use data for a particular decision. The goal of OPA is to provide them with the best data and to communicate any appropriate caveats about using the data.

Although the vast majority of the output from NIH's investments in research is in the form of publications, there are other outputs as well, including patents, clinical trials, and clinical outcomes, which also need to be considered. But for decision makers looking at a large number of papers, it's useful to have a metric. He pointed out that it's also important to track the information flow of science to understand how much influence a paper is having and if it is going in a direction that will lead to an impact on human health, which is ultimately the mission of NIH.

Dr. Santangelo pointed out that OPA has collaborated with other funding organizations, academic

organizations, and private sector partners to use and develop these methods and tools to understand the global investment in biomedical research. The *iCite* database and tool is available publicly. Transparency is an important value of the work.

Questions come up about the relative value of investigator-driven science versus initiative-driven science. Have you applied these technologies to looking at the differences between R01s that come through a program announcement versus through a Request for Applications?

Dr. Santangelo said this is something that OPA has looked at but has not attempted to do comprehensively. Different ICs have different approaches for generating specific funding opportunity announcements (FOAs) for specific investments that lead to variability in the degree of responses. He said this is something that he would like to pursue in collaboration with analysts within the Institutes and Centers.

IX. SCIENTIFIC PRESENTATION

Dr. Rodgers introduced the scientific presentation. Because the NIDDK scientific director will later in the day give an update on the intramural program, Dr. Rodgers invited an NIDDK intramural scientist, ***Jurrien Dean, M.D.****, to present his work on the* ***Molecular Biology of Fertilization****.*

Dr. Dean is chief of the Laboratory of Cellular and Developmental Biology within NIDDK's Division of Intramural Research. He earned his MD at Columbia University's College of Physicians and Surgeons. His laboratory uses a mouse paradigm for investigating developmental biology of spermatogenesis and pre-implantation development. His current research focuses specifically on the molecular mechanisms used by germ cell specific factors to promote spermatogenesis in males and folliculogenesis in females to ensure fertilization and sustained preimplantation development.

X. CONSIDERATION OF REVIEW OF GRANT APPLICATIONS

A total of 1153 grant applications (233 primary and 920 dual), requesting support of $370,021,145 were reviewed for consideration at the September 6, 2017 meeting. An additional 65 Common Fund applications requesting $11,536,278 were presented to Council. Funding for these applications was recommended at the Scientific Review Group recommended level. Prior to the Advisory Council meeting, 1380 applications requesting $444,891,864 received second-level review through expedited concurrence. All the expedited concurrence applications were recommended for funding at the Scientific Review Group recommended level. The expedited concurrence actions were reported to the full Advisory Council at the September 6, 2017, meeting.

XI. ADJOURNMENT

Dr. Rodgers

Dr. Rodgers expressed appreciation on behalf of the NIDDK to the Council members, presenters, and other participants. He thanked the Council members for their valuable input. There being no other business, the 205th meeting of the NIDDK Advisory Council was adjourned at 4:30 p.m.

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

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