

**Department of Health and Human Services  
National Institutes of Health (NIH)  
Office of the Director (OD)  
Office of Portfolio Analysis and Strategic Initiatives (OPASI)**

**Council of Councils Planning Meeting  
November 8, 2007**

**Meeting Minutes**

**I. Welcome**

The Chair, Alan M. Krensky, M.D., opened the meeting at 8:33 a.m. on Thursday, November 8, 2007, in Building 31, Room 6, on the campus of the National Institutes of Health (NIH), Bethesda, Maryland. Dr. Krensky welcomed the Council of Council participants, NIH staff members, and members of the public.

**A. ATTENDANCE – COUNCIL PARTICIPANTS PRESENT**

Chair: ALAN M. KRENSKY, M.D., Director, OPASI, OD, NIH  
Executive Secretary: ELIZABETH L. WILDER, Ph.D., Acting Associate Director, OPASI, OD, NIH  
RONALD L. ARENSON, M.D., University of California, San Francisco  
DONNA BATES BOUCHER, Bates Group, Inc., Denver  
ENRIQUETA C. BOND, Ph.D., Burroughs-Wellcome Fund, Research Triangle Park, North Carolina  
RICHARD CHABRAN, M.L.S., California Community Technology Policy Group, Los Angeles  
COLEEN K. CUNNINGHAM, M.D., Duke University Medical Center, Durham, North Carolina  
ROBERT M. DICKLER, Association of American Medical Colleges, Washington, D.C.  
CECILE A. FELDMAN, D.M.D., M.B.A., University of Medicine and Dentistry of New Jersey, Newark  
EDWIN FLORES, J.D., Ph.D., Chalker Flores, LLP, Dallas  
JOSEPH H. GRAZIANO, Ph.D., College of Physicians and Surgeons, Columbia University, New York  
BEVRA H. HAHN, M.D., David Geffen School of Medicine, University of California – Los Angeles  
MARY J.C. HENDRIX, Ph.D., Children’s Memorial Research Center, Northwestern University  
Feinberg School of Medicine, Chicago  
DILIP V. JESTE, M.D., University of California – San Diego/VAMC, San Diego  
LENWORTH M. JOHNSON, M.D., University of Missouri – Columbia, Missouri  
WARREN A. JONES, M.D., FAAFP, University of Mississippi Medical Center, Jackson  
JOSEPH LOSCALZO, M.D., Ph.D., Brigham and Women’s Hospital, Harvard Medical School, Boston  
MARJORIE K. MAU, M.D., John A. Burns School of Medicine, University of Hawaii at Manoa,  
Honolulu  
JUANITA L. MERCHANT, M.D., Ph.D., University of Michigan, Ann Arbor  
SANDRA MILLON-UNDERWOOD, Ph.D., R.N., College of Nursing, University of Wisconsin –  
Milwaukee  
DARLA MOCHLY-ROSEN, Ph.D., Stanford University School of Medicine  
SERJIO R. OJEDA, D.V.M., Oregon National Primate Research Center, Oregon Health & Science  
University, Beaverton  
ORIEN REID, M.S.W., Alzheimer’s Disease International, Consumer Connection, Laverock,  
Pennsylvania  
MARTIN ROSENBERG, Ph.D., Promega Corporation, Madison, Wisconsin  
RICHARD A. RUDICK, M.D., The Mellen Center, Cleveland Clinic Foundation, Ohio  
HAROLD T. SHAPIRO, Ph.D., The Woodrow Wilson School of Public and International Affairs,  
Princeton University, New Jersey  
PHYLLIS M. WISE, Ph.D., University of Washington, Seattle  
MARINA E. WOLF, Ph.D., Rosalind Franklin University of Medicine and Science, North Chicago

**B. COUNCIL MEMBER ABSENT**

ARTHUR M. KLEINMAN, M.D., Harvard University Medical School, Cambridge

**C. AD HOC REPRESENTATIVES PRESENT**

JOAN E. FOX, Ph.D., Cleveland Clinic, Lerner College of Medicine, Western Reserve University,  
Cleveland

VICTOR M. HESSELBROCK, Ph.D., University of Connecticut Health Center, School of Medicine,  
Farmington

GARY L. WESTBROOK, M.D., Oregon Health & Science University, Portland

**D. PRESENTERS IN ATTENDANCE**

Norka Ruiz Bravo, Ph.D., Deputy Director for Extramural Research, OD, NIH

James Ostell, Ph.D., Chief, Information Engineering Branch, National Center for Biotechnology  
Information, National Library of Medicine (NLM), NIH

Rebekah Rasooly, Ph.D., Deputy Director, Division of Kidney, Urologic, and Hematologic Diseases,  
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH

William Riley, Ph.D., Deputy Director, Division of AIDS and Health & Behavior Research, National  
Institute of Mental Health (NIMH), NIH

Peter C. Scheidt, M.D., M.P.H., Director, National Children's Study, National Institute of Child  
Health and Human Development (NICHD), NIH

Marc Smolonsky, Director, Office of Legislative Policy and Analysis (OLPA), OD, NIH

Elias A. Zerhouni, M.D., Director, NIH

**E. ATTENDANCE – NIH STAFF AND GUESTS**

In addition to Council of Councils participants and meeting presenters, others in attendance included  
NIH staff and interested members of the public.

## I. INTRODUCTION TO OPASI AND TODAY'S GOALS

Dr. Krensky presented overviews of the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI); the Common Fund; the Council of Councils (Council); and the Office of Portfolio Analysis and Strategic Initiatives (OPASI). Dr. Krensky's slide presentation is available at <http://opasi.nih.gov/council/pdf/01-Introduction.pdf>.

Highlights of Dr. Krensky's presentation:

- Institute and Center (IC) contributions to support trans-NIH initiatives were replaced by the NIH Reform Act of 2006 that codified the Common Fund (originally set up by Dr. Zerhouni to support NIH Roadmap initiatives) as a line item in the NIH budget.
- DPCPSI's role is to identify potential trans-NIH initiatives and provide a biennial report on trans-NIH research. DPCPSI is composed of a cooperative "sibling" relationship of offices within the Office of the Director, NIH, with these offices retaining their original authorized missions. These offices are Office of Aids Research (OAR), Office of Behavioral and Social Sciences Research (OBSSR), Office of Disease Prevention (including Office of Dietary Supplements (ODS), Office of Medical Applications of Research (OMAR), and Office of Rare Diseases (ORD)), and Office of Research on Women's Health (ORWH).
- The Council's role is to advise the NIH Director on DPCPSI policies and activities and make recommendations regarding proposed trans-NIH research to be supported by the Common Fund.
- OPASI's mission is to (1) provide NIH and its ICs with methods, tools, and information to manage their portfolios; (2) identify—in concert with multiple other inputs—important areas of emerging scientific opportunities or rising public health challenges; (3) help accelerate investments in these areas, focusing on those involving multiple ICs; and (4) coordinate and make more effective use of NIH-wide evaluation processes.
- OPASI is organized into three functional divisions reflecting its mission: Division of Resource Development and Analysis (DRDA); Division of Strategic Coordination (DSC); and Division of Evaluation and Systematic Assessment (DESA).
- All Roadmap-type initiatives are trans-NIH, cross-cutting, and at the edges or front wave of science. Examples are the NIH Director's Pioneer and New Innovators Awards that provide a real opportunity to bring change and test new ideas rapidly, evaluate them, and export them to the ICs.

### Discussion

During the discussion period, Dr. Krensky stressed that the factors for OPASI's success are:

- Science first—all planning is evidence-based
- Transparency and communication
- Managing change
- Ability to fill gaps, alleviate redundancies, and add value to the strategic planning portfolio.

## II. HISTORY OF THE NIH REFORM ACT OF 2006

Mr. Marc Smolonsky, Director, Office of Legislative Policy and Analysis, provided an overview of the evolution of NIH authorizations and of the NIH Reform Act of 2006, passed by Congress in December 2006, and signed into law by the President in January 2007. A major element of this Act was the new authority it gave to the NIH Director to improve program coordination, assemble accurate data, implement strategic plans based on IC-determined priorities, ensure resources are properly allocated, and further maximize investigator-initiated research. Mr. Smolonsky's presentation is available at <http://opasi.nih.gov/council/pdf/02-ReformAct.pdf>.

The Act established the Council of Councils to advise the Director on matters related to the policies and activities of DPCPSI, including trans-NIH research; the Common Fund to support cutting-edge trans-NIH

initiatives; and the Scientific Management Review Board (SMRB) to conduct an organizational review of NIH every 7 years.

An ongoing NIH effort to establish an electronic coding system to uniformly code research grants and activities was codified in the Act. The Act also created two demonstration programs for bridging the sciences and high-risk, high-reward research. An important congressionally mandated responsibility of the Council will be to conduct the second-level review of grants in the high-risk, high-reward research program.

The Act also eliminated approximately 30 of NIH's reports and created a single biennial report, along with some additional reports, including a report on NIH's collaborations with other HHS agencies, the use of experts and consultants at NIH, the number of whistleblower complaints at NIH, how NIH tracks and stores human tissue samples, the number of clinical trials registered on clinicaltrials.gov, and a report from extramural institutions on length of time people are in Ph.D. programs.

Congress views the Council as a check in the balance system of NIH by ensuring that NIH receives input from the broad scientific community before proceeding with trans-NIH research identified by DPCPSI. The Act set up staggered terms for service on the Council. NIH plans to make a technical adjustment to 4 years to make it easier for members to co-serve on their IC advisory councils and this Council. NIH is also asking that the Council be increased to 30 members to include three ICs being represented by ad hoc persons at this planning meeting.

During the discussion that followed Mr. Smolonsky's presentation, several members raised questions regarding the process for growth of the Common Fund and its effect on the ICs' budgets and on research project grants. Summaries follow:

- The Common Fund will be subject to the usual NIH budget process; the growth is ultimately up to Congress.
- Although there is not a formula for growth, the annual allotted amount cannot go below the percentage reserved from the prior fiscal year.
- The Act also emphasizes preservation of investigator-initiated grants.
- Because appropriations legislation includes a line item amount for the Common Fund, the percentage contributions from the ICs for Common Fund initiatives were eliminated, resulting in the increase of the ICs' funding base for FY 07 (and this practice will continue in FY 08).
- The Common Fund is intended to enhance the work of the ICs by providing them with new tools.

Other Discussion Highlights:

- The Council will not be responsible for reviewing the SMRB report.
- The new NIH biennial report does not replace the separate Government Performance and Results Act (GPRA) requirement.
- As OPASI existed before the enactment of the NIH Reform Act, it will remain a transition structure within DPCPSI.
- The Advisory Council to the Director has very broad responsibilities regarding policy matters pertinent to NIH. The Council of Councils' role focuses on trans-NIH initiatives and specific research mandated by the Act. The two councils function separately.

### **III. REMARKS FROM THE NIH DIRECTOR**

Dr. Elias A. Zerhouni, Director of NIH, further expanded on the role of the Council of Councils and the benefits from establishment of the Common Fund. He expressed his appreciation to the members for their participation in this additional duty and noted that nearly 31,000 scientists assist NIH through peer review, councils, workshops, and white papers and stated that NIH could not do its job without them.

Dr. Zerhouni presented the case for the creation of the Roadmap and the reauthorization of the NIH. In emphasizing how science has changed in the past 50 years, he pointed out that the concept that biological systems have a unifying underpinning did not exist previously. As science continues to change at a rapid pace, the need to have a mechanism such as the Common Fund initiatives to serve as the “glue” between the ICs is essential.

Dr. Zerhouni’s first charge to the Council in their advisory role to the Director, to the IC Directors, and to OPASI is to be bold, to define experiments that NIH can do and fund reasonably, to engage the community, to effectively use and expand the venture space, to foster incubation of new ideas, and to build resources as needed—all driven by analysis of the science. The need for this analysis led to the creation of OPASI. NIH has a mechanism of governance shared by the ICs, a common resource, and a modus operandi for experimental space. NIH now needs evaluation of these programs. Dr. Zerhouni stated that this will be a fundamental question for the Council of Councils to address.

Along with strategic analysis and evaluation, a third function of OPASI is to develop tools to look at all the grants across the ICs and the world literature to get a complete picture of the scientific environment. The intention is for the new process and the Council’s role not to be a top-down mechanism or a rigid one. Dr. Zerhouni also encouraged the Council’s members that in fulfilling their new advisory role they act to represent, not the specific areas of the individual ICs, but the interests of NIH as a whole.

#### Discussion

In responding to a question about whether the Common Fund would support funding for training, Dr. Zerhouni replied that it covers all NIH mission areas. He stated that he has two passions: his top priority is “new investigators, new investigators, new investigators.” The second is to remove the barriers between scientists, between disciplines of science, and between stages of science.

In response to questions about the growth of the Common Fund, the establishment of evaluation metrics, and the setting of priorities for research and training of the workforce, Dr. Zerhouni emphasized the need for balance. He also stressed the need for a very clear message as to where science is headed and what NIH is trying to accomplish.

Dr. Zerhouni pointed out that the Council of Councils may have a more visible role than any other council. Therefore, the Council’s ability to communicate its vision is going to be a strong determinant in addressing the issues listed above. It will be important not to oversell or over promise expectations.

Dr. Zerhouni noted that leveraging the Common Fund and avoiding overlap with the ICs’ missions requires an open process. Evaluation metrics for training programs or for reviewing bold ideas or for measuring the success of the Council itself are core elements.

The structural review of NIH falls under the SMRB and the intramural activities under the Advisory Council to the Director, although intramural programs are a part of the overall portfolio analysis. The Council is not an oversight group. Its focus is on interacting with the IC Directors and OPASI divisions and advising the Director on matters related to the policies and activities of DPCPSI (trans-NIH program coordination, planning, and strategic initiatives) and recommending the conduct of and support of trans-NIH proposals supported by the Common Fund.

#### **IV. INNOVATION**

Dr. Krensky suggested that the Council of Councils have as its brand the definition for innovation that reads “Innovation is the process that translates knowledge into economic growth and social well-being.” Along with all the ICs, fostering innovation is one of OPASI’s goals. On December 5, 2007, NIH will hold a workshop on how to foster innovation to come up with a priority list of ideas on how to do this. Dr. Krensky’s slide presentation is available at <http://opasi.nih.gov/council/pdf/03-Innovation.pdf>.

The following points were raised by the Council:

- Dr. Krensky's definition itself generated some responses. It was thought that promotion of economic growth and human well-being would require some elements of commercialization to bring the new knowledge or invention to the public. This would mean overcoming a number of academia-industry issues such as proprietary information and conflict of interest. Likewise, a review group for an idea to create new knowledge may need to be different from one to evaluate if an idea will promote economic growth or translate into social well being.
- Institutions tend to build knowledge silos by communicating and interacting only among their own colleagues and students instead of engaging others. This impedes the interdisciplinary approach that can bridge the gaps in basic science. Unfortunately, we are training students to mirror this behavior. We need to identify what is needed and how to train a new type of scientist. It was suggested that there be new review groups with new paradigms to evaluate bold ideas. Others added that innovation requires experienced persons at the table as well as those without preconceived notions.
- Multi-pronged approaches were recommended as key to innovation. One such approach would be getting new investigators independent sooner; this would help to break the pattern of mirroring one's mentor. Short-term, starter-type awards for innovative ideas with minimal investment and early evaluation of benchmarks were suggested. Some questioned whether this short-term period was sufficient to jump start an innovator's career.
- It is important to consider what inhibits innovation. In addition to limited expertise that drives the need to collaborate across disciplines and the difficulties collaborating across disciplines mentioned earlier, ingrained thinking was named. For another inhibitor—the risk-reward equation—it was suggested that a phased innovation award with a two-phase level of support might be a solution. The investigator might be required to work with skilled collaborators to learn about a new field. As an incentive, if the researcher meets certain targets in the first phase, then funds are awarded for the second phase. This would reduce risk and encourage cross-disciplinary interactions and possibly stimulate answers.
- According to some, the process of innovation begins with generating ideas, which is really a low-tech, low-cost activity in which people who do not normally interact are brought together to think of things they haven't thought about before. Next, instead of waiting for the originator of the idea to spontaneously pursue it, a champion is recruited for a selected idea and provided with resources and partnerships to develop the idea. It was felt that not enough time and effort are spent on question generation and champion preparation; there is a tendency to move too quickly to the review process and resource allocation. The involvement of senior investigators can be helpful here because they are likely to be more aware of how broad the interdisciplinary base needs to be and what multi-disciplinary tools are out there. Access to tools such as high-density, complex data sets was considered a requisite to change data into information, information into knowledge, and knowledge into understanding.
- A related suggestion was to proactively identify some bold, highly intelligent thinkers and present them with major questions to be answered and the support to pursue the questions. They could enlist others and work collaboratively, possibly in a center of innovation.
- One needs first to remove the issue of resources from the table before asking someone to think big. To remove the resource question and have a level playing field, it may be necessary to require the big centers and institutions, as part of their competitive applications, to set aside funds for small innovative grants. It was noted, however, that innovation and innovative people are not limited to large institutions.
- Communication was high on the list of what is needed to foster innovation. Bringing people together for free-flowing talk about a problem from a variety of perspectives was key. Communicating to the public, to experienced and new researchers, to Congress, and to study sections what the vision of innovation is was deemed necessary to foster innovation. Again, there was concern as to whether this could be applied by the average study section given their traditional review criteria and non-multidisciplinary membership.

Dr. Vivian W. Pinn, Director, ORWH, briefly described projects fostering careers for women in science. The NIH Working Group on Women in Biomedical Careers, co-chaired by Drs. Zerhouni and Pinn, is compiling resources, working in various areas such as mentoring, and developing two workshops. The working group's website is <http://womeninscience.nih.gov/workinggroup/index.asp>.

## V. INITIATIVES ON THE HORIZON I: SCIENTISTS IN THE PIPELINE

Dr. Norka Ruiz Bravo, Deputy Director for Extramural Research, reiterated that new investigators and a stable, sustainable scientific workforce are one of Dr. Zerhouni's top priorities and of major interest to the IC directors. Two concerns are the health of the pipeline and the increasing age at which new investigators are able to become independent. A major question is whether there are going to be enough new investigators to replace the "baby boomers" who are exiting the field. The pipeline is an ongoing issue, not a new one. However, the world junior scientists are entering is a new one, not the one of their mentors. Dr. Ruiz Bravo's presentation of major trends affecting the pipeline is available at <http://opasi.nih.gov/council/pdf/04-Horizon1.pdf>. Dr. Ruiz Bravo acknowledged Dr. Howard Garrison's assistance in analyzing data from the Federation of American Societies for Experimental Biology (FASEB), the National Science Foundation, NIH, and other sources for these slides. Highlights included:

- There is a relative decline in persons entering academia versus industry.
- From 1980 to 2006, the characteristics of the population of Principal Investigators (PIs) of a research project grant, such as an R01, has changed significantly. In 1980, the age at which someone became medical school faculty *and* received their first R01 was very similar. In 2006, the average age of a PI was 50.8 versus 39.1 in 1990. There is a similar trend in the average age of medical school faculty and first-time assistant professors, indicating that the demographics have changed, the PI pools have changed, and the available jobs have changed.
- There has been a sharp decline over the last 3 years in the number of first-time R01s. When NIH noted this, the ICs committed a target of 1,500 new R01 investigators in 2007 and actually funded 1,602. For experienced investigators with little other support, NIH provided 1-year bridge funding so they could retool and respond to study sections. In addition to the New Investigators Program and the Pathway to Independence Awards that NIH has developed to encourage scientific research careers, the Center for Scientific Review has accelerated notification of review outcomes to reduce the time that a new investigator can reapply. The Director's limited number of New Innovator Awards also targets new investigators. There are also Career Development Awards and K awards.

### Discussion

- It was noted that workforce projections are among the most difficult.
- Because they are trained in new techniques and have a wider range of experiences, new investigators may have very innovative ideas that are not necessarily high-risk.
- Attention to the pipeline at an earlier stage such as middle school or high school was another idea, especially to recruit minorities.
- The Burroughs-Wellcome Fund has been examining workforce issues. They are following a cohort of 600 trainees drawn from physics, chemistry, and mathematics into biology to see what happens with their careers and whether they leave research for other careers. NIH is developing a database to look at post-docs and graduate students on research grants.
- The change in the Ph.D. and medical school demographics might be related to a fundamental change in America's demographics, such as ethnic data. Of concern is the motivational factor of the length of time and the effort needed to establish a biomedical research career versus the length of time to establish a business or legal career.
- Calculating how many new investigators will be needed in 2020 is very complex. NIH has a baseline and a "simple" statistical model, but a more system dynamic model has to take into account population trends and changing dynamics to responsibly predict numbers.
- There is a need to project not just the number of persons but the skill sets that they will require.

## VI. INITIATIVES ON THE HORIZON II: PHENOTYPING

Four NIH staff members discussed phenotyping initiatives as examples of early to mid-stage concept development, an area where the Council will be providing its advice. Phenotyping is one of the subjects that the IC directors will be revisiting in February 2008 as a potential Roadmap initiative. It is currently undergoing further concept development. Dr. Krensky suggested that the Council as an advisory body comment on these concepts with the understanding that the ultimate decision will be made by the IC Directors and the NIH Director.

The four presenters were Dr. William Riley, Deputy Director, Division of AIDS and Health and Behavioral Research, National Institute of Mental Health; Dr. Rebekah Rasooly, Deputy Director, Division of Kidney, Urologic, and Hematologic Diseases, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK); Dr. James Ostell, Chief, Information Engineering Branch, National Center for Biotechnology Information (NCBI), National Library of Medicine; and Dr. Peter Scheidt, Director, National Children's Study, National Institute of Child Health and Human Development. Their presentations are available at <http://opasi.nih.gov/council/pdf/05-Horizon2.pdf>.

**Dr. Riley** overviewed the Patient-Reported Outcomes Measurement Information System (PROMIS) and its relevance to a phenotyping effort. The three broad objectives of PROMIS are (1) to develop a large item bank measuring patient-reported outcomes (PROs); (2) create a computerized adaptive testing system for robust assessment of PROs for a wide range of chronic disease research; and (3) create a publicly available system that can be expanded and provide precise, dynamic rather than static scales to clinical researchers. The 5-year project is in year 4.

**Dr. Rasooly** offered two approaches for obtaining information about diseases and conditions. The approach of the future is to design very large studies with carefully selected measurements that have been validated and look at different things in a large number of people, as is being done with the National Children's Study. In the past, interventional and observational studies, each of which focused on a particular disease or condition and generated a large amount of data with relatively idiosyncratic measurements and little comparability with other studies, was the norm. In considering phenotype initiatives, Dr. Rasooly explained that we do not need to discard all the data from the past in order to move forward. We can combine the data and use it in different ways. She stressed two points: (1) NIH needs to support investigators in their efforts to move outside their comfort zone to look at other studies; and (2) data and samples from clinical studies need to be made more accessible and easier to work with.

**Dr. Ostell** introduced dbGAP as a phenotyping initiative that is "leveraging past investments to build a functional future." Previously, researchers interested in blood pressure went to the National Heart, Lung, and Blood Institute's Framingham study and those interested in visual acuity to the Age-Related Eye Disease Study (AREDS), the National Eye Institute's macular degeneration study. Then genomics showed that what all studies have in common is the human chromosome. Dr. Ostell pointed out that by looking at the pattern of markers, for example, surprising relationships within phenotypes are seen and these surprises are what discovery is about. Thus, it became important to capture existing studies. dbGAP provides a base for examining a variable, such as systolic blood pressure, across multiple independent studies. Thus the scientific literature can be used to reach consensus on how to do phenotyping and develop standards, which can change as new information is added to the base. By the end of 2008, there will be almost 100,000 persons and tens of thousands of phenotype variables in dbGAP just from studies doing whole genome associations.

**Dr. Scheidt** briefly reviewed the National Children's Study, which is studying 100,000 children, their families, and their environment from pre-conception or early pregnancy until the children reach age 21. This is the largest long-term study of children's health and development ever conducted in the United States. One goal is to study high priority but relatively infrequent outcomes such as autism and certain birth defects. Another goal is to examine the complex ways in which environment interacts with genetic expression. It is both hypotheses-driven (priority exposures and priority outcomes) and a rich natural



resource for future studies. There are approximately 30 hypotheses and many measures associated with testing them. Additional information on the National Children's Study is available at <http://www.nationalchildrensstudy.gov/>.

## **Discussion**

Dr. Krensky asked that the discussion focus on phenotyping as a potential Roadmap-type trans-NIH initiative. Discussion highlights included:

- The potential of being able to define human genotypes and phenotypes was considered very exciting, particularly if it includes all sectors of the sociocultural environment both in the sample and in the future investigators who review the data.
- Many, if not most, diseases of primary interest are extremely complex, with multiple genes contributing small effects and with the phenotype itself changing significantly throughout life. Thus, it is likely different genes will affect the phenotype over time. It was stated that current data sets will miss the dynamic properties of these changes in phenotype. Another concern was the possible effect of such studies on people and their beliefs. Dr. Krensky agreed that there are many psychosocial and ethical issues to be considered in looking at proposed studies.
- It was thought that the National Children's Study provided the Council an excellent opportunity to encourage next steps in trans-NIH initiatives, especially with the focus on epigenetics. Dr. Krensky said that, in his view, the study would be a platform like the Framingham study for research not only 21 years from now but in the meantime, and not only for NIH but for other funders and for industry. Dr. Scheidt agreed that it does represent a platform for building more intense investigations with more intense measures. NIH also is engaged with an international cohort consortium to actively merge data sets from other very large cohorts worldwide to look at outcomes such as cancer and less common birth defects having exposure variables and genetic factors in common, areas in which one needs a sample size of half a million.

## **VII. DEMONSTRATION OVERSIGHT GROUPS**

Dr. Krensky defined the two congressionally mandated demonstration oversight groups included in the NIH Reform Act of 2006. Bridging the Sciences is aimed at grants for biomedical research at the interface between biological, behavioral, and social sciences and the physical, chemical, mathematical, and computational sciences. Bridging the Sciences projects will include consultations with the National Science Foundation, the Department of Energy, and other Federal agencies as necessary. High-risk, high-reward grants, contracts, or "other transactions" are for high-impact, cutting-edge research that fosters scientific creativity and increases fundamental biological understanding leading to the prevention, diagnosis, and treatment of diseases and disorders. Partnerships between public and private entities and coordination with the Foundation for NIH are a part of the high-risk, high-reward projects. Two oversight groups of senior NIH officials have been formed. Dr. Krensky's slides are available at <http://opasi.nih.gov/council/pdf/06-Demonstration.pdf>.

## **VIII. NEXT STEPS**

Since the Council is a new entity, Dr. Krensky concluded the day's events by asking the participants what they wanted to do next. The discussion first centered on meetings. The consensus was that at least two face-to-face meetings a year were needed and that one day was not long enough to deal with the Council's agenda and mandate. It was decided to have spring and fall in-person meetings annually, each at least a day and a half long. Given that the IC directors would be meeting in February to discuss proposed initiatives, March 2008 was selected for the next Council of Councils meeting. Dr. Krensky's slides are available at <http://opasi.nih.gov/council/pdf/07-Next%20Steps.pdf>.

The Council decided to conduct its assigned activities between meetings through standing subcommittees and short-term working groups communicating primarily by email, conference call, and possibly

videoconferencing. Suggestions for areas of focus included measurement and evaluation metrics, portfolio analysis, workforce issues, and strategic initiatives such as phenotyping. Dr. Krensky said that additional information and documentation would be provided to the members. He urged them to concentrate on approaches and processes, the science of science, the balance between bottom-up versus top-down, and on cutting-edge and tool-based ideas.

Dr. Krensky spoke of the opportunities for multiple inputs and cross-fertilization of ideas from the members' service on the IC advisory councils and their function as members of this Council. He emphasized that this was to be a dynamic advisory body for NIH as a whole that would be a powerful voice on the NIH campus and a champion for trans-NIH research.

Dr. Krensky adjourned the meeting at 4:43 p.m.

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

Alan M. Krensky, M.D.  
Chair, NIH Council of Councils  
Director, Office of Portfolio Analysis and Strategic Initiatives  
Office of the Director  
National Institutes of Health