National Arthritis and
Musculoskeletal and
Skin Diseases Advisory Council

MINUTES OF MEETING

June 12, 2007

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
NATIONAL ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES ADVISORY COUNCIL

MINUTES OF THE 62nd MEETING

June 12, 2007
8:30 a.m. to 4:00 p.m.

I. CALL TO ORDER

The 62nd meeting of the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council was held on June 12, 2007, at the National Institutes of Health (NIH) Campus, Building 31, Conference Room 10. The meeting was chaired by Dr. Stephen Katz, Director, National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS).

Attendance

Council members present:

Mr. George A. Beach
Ms. Carmen Cheveres DeMummy
Dr. Betty Diamond
Dr. B. Lee Green
Dr. Kathleen Green
Dr. Bevra H. Hahn
Dr. Joshua Jacobs
Dr. Martin J. Kushmerick
Ms. Patricia McCabe
Dr. Robert J. Oglesby (*Ex Officio*)
Dr. Jack E. Parr
Dr. Lawrence G. Raisz
Dr. Clifford J. Rosen
Dr. Raymond Scalettar
Dr. Jouni J. Uitto

Council members not present:

Dr. Kevin Campbell
Dr. Gena Carter
Dr. Brian L. Kotzin
Dr. James Weinstein

Staff and Guests:

The following NIAMS staff and guests attended:

Staff

Dr. Janet Austin
Dr. Carl Baker
Ms. Susan Bettendorf
Dr. Michael Bloom
Dr. Amanda Boyce
Mr. Gahan Breithaupt
Dr. Eric Brown
Ms. Justine Buschman
Mr. Frank Cromwell
Ms. Wilma Peterman Cross
Ms. Teresa Do
Dr. Jonelle Drugan
Mr. Erik Edgerton
Ms. Sharon Fair
Mr. Raymond Fleming
Mr. David Fuller
Ms. Valerie Green
Dr. Elizabeth Gretz
Ms. Gail Hamilton
Ms. Jane Hymiller
Mr. sAji Ijiyemi
Dr. Stephen Katz
Ms. Shahnaz Khan
Dr. Cheryl Lapham
Dr. Gayle Lester
Ms. Anita Linde
Ms. Mimi Lising
Ms. Elizabeth Lordan
Dr. Kan Ma
Dr. Marie Mancini
Dr. Joan McGowan
Ms. Leslie McIntire
Ms. Melinda Nelson
Ms. Anna Nicholson
Ms. Zintesia Page
Dr. James Panagis
Dr. Paul Plotz
Ms. Trish Reynolds
Dr. Louise Rosenbaum
Ms. Beverly Russell

Dr. William Sharrock
Ms. Sheila Simmons
Mr. Yen Thach
Mr. Michael Toland
Dr. Madeline Turkeltaub
Dr. Bernadette Tyree
Dr. Fei Wang
Dr. Ping Wang
Dr. Yan Wang
Dr. Chuck Washabaugh
Ms. Sandra Wearins
Dr. James Witter

Guests

Mr. Dennis Barbour, Esq., Society for Investigative Dermatology
Mr. John Burklow, Office of the Director, NIH
Dr. Luke Evnin, Scleroderma Research Foundation (by teleconference)
Ms. JoAnne Goodnight, Office of the Director, NIH
Ms. Hilary Hansen, National Psoriasis Foundation
Ms. Darlene Kerr, Circle Solutions
Dr. Andrew Kurtz, National Cancer Institute, NIH
Mr. Michael Weingarten, National Cancer Institute, NIH
Ms. Susan Whittier, NIH Osteoporosis and Related Bone Diseases ~ National Resource Center

II. CONSIDERATION OF MINUTES

A motion was made, seconded, and passed to accept the minutes of the 61st Council meeting, held on February 27, 2007, with two changes: (1) the correct spelling for Dr. Angela Christiano's first name on page 6, and (2) the correct spelling of Dr. Hal Dietz's last name on page 7.

III. FUTURE COUNCIL DATES

Future Council meetings are currently planned for the following dates:

September 27, 2007
January 29, 2008
June 6, 2008
September 23, 2008
February 3, 2009
June 2, 2009
September 16, 2009

IV. DIRECTOR'S REPORT AND DISCUSSION

Dr. Katz welcomed Council members and began his report by inviting them to review the NIAMS Shorttakes online, which go into more detail on many of the topics covered in Dr. Katz's comments. The Director's Column this month focuses on efforts to support new investigators, which is a top priority for NIH Director Dr. Elias Zerhouni and for the Institute and Center (IC) Directors.

Personnel Changes at the NIH and NIAMS

At the NIH level, Dr. Griffin Rodgers has been appointed as the Director of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK); Dr. Barbara Alving has been named as the Director of the National Center for Research Resources.

At the NIAMS level, the Institute currently is conducting a nationwide search for a new NIAMS Deputy Director. There has been tremendous response to the vacancy announcement for this position; interviews with top candidates are ongoing, and Dr. Katz will provide an update on this position at the next Council meeting. In the interim, Dr. Paul Plotz continues to serve as the Acting Deputy Director of the NIAMS. Dr. Elizabeth Gretz, who has served as the Director of Immunology and Inflammation Program within NIAMS' Division of Skin and Rheumatic Diseases since 2001, has left the Institute. Justine Buschman has joined the Institute as a Program Analyst in the Skin and Rheumatic Diseases Branch; previously, Ms. Buschman was with St. John's Health System in Springfield, MO. The Institute also welcomes Anna Nicholson as a Clinical Coordinator for the NIAMS Extramural Program. Prior to joining the Institute, Ms. Nicholson worked as a Project Manager for KAI Research, Inc.

In the NIAMS Office of the Director, Helen Simon, Senior Advisor for Program Coordination, has retired after over 30 years of service to the NIH. Stephanie Kreider, who once served as a Management Intern at NIAMS, has joined the NIAMS Budget Office. Karin Rudolph has been named as the Chief of the Public Information Branch within the NIAMS Office of Communications and Public Liaison (OCPL). Mimi Lising has joined the NIAMS OCPL as a Multicultural Health Educator.

Update on Budget and Congressional Activities

As a result of the Joint Resolution from Congress that enhanced the budget for FY07, the NIAMS has been able to move the payline to the 15th percentile for all investigators. The NIAMS payline for new investigators is the 18 percentile. Because the NIH has made the commitment to support 1,500 new investigators in FY07, the Institute will have to go beyond this 18 percent to meet its quota of 41 new investigators. Another effort to support new investigators is the NIH Director's New Innovator Award, a grant program that supports new investigators who propose highly innovative research projects that have the potential for exceptional impact in biomedical or behavioral science. The K99/R00 award also has been established; a K99 converts to an R00 after about 2 years. The NIAMS will award five K99/R00s this year. The NIH recently launched the NIH Director's Bridge Award (NDBA), which is intended to provide continued but limited support to investigators who have submitted

competing renewal grant applications that just miss an IC's nominal payline and who have limited additional support.

For FY08, the House of Representatives is slating the NIH to receive a 2.6 percent increase; most ICs will receive a 1.4-1.7 percent increase in their budget. On March 6, 2007, the House Appropriations Subcommittee on Labor, HHS, and Education held its NIH Overview Hearing on the FY08 budget. The Senate Appropriations Committee held its overview hearing on March 19. Dr. Zerhouni's testimony and slides from both hearings are available online at http://officeofbudget.od.nih.gov/ui/homepage.htm. The Senate Appropriations Subcommittee also held a series of theme hearings; Dr. Katz was asked to participate in the theme hearing entitled "Burden of Chronic Diseases," which was held on April 20, 2007 (http://www.niams.nih.gov/ne/reports/congree_rep/cj2008/state_sen_comm.htm). Directors from the National Institute on Aging; National Heart, Lung and Blood Institute; and NIDDK also participated in the hearings.

Dr. Katz noted that an FY05 House Appropriations Committee report directed the NIH to develop a plan to guide the nation's investment in lupus research and to identify opportunities, priorities, and needs in lupus research that should be considered for inclusion in the research plan. A panel of experts in this field was convened for 2 days of presentations and discussion; highlights of their conclusions are reported in the *Future Directions of Lupus Research*. This research plan has been posted on the NIAMS Web site for public comment through June 22; Council members with expertise in lupus were asked to review the plan and provide any comments.

A number of legislative issues related to the NIH are currently pending. Topics include the Psoriasis and Psoriatic Arthritis Research, Care and Cure Act of 2007; the Lupus Research, Education, Awareness, Communication, and Healthcare Amendments of 2007; and the Arthritis Prevention, Control, and Cure Act of 2007.

Highlights of Recent Scientific Advances

- Studies by Dr. Diane Mathis of Harvard Medical School and colleagues showed that mast cells provide a critical link between autoantibodies and inflammation. These researchers have identified the molecular mediator produced by joint mast cells, IL-1, that leads to joint inflammation. This work represents a new focus on mast cells and inflammatory diseases, particularly autoimmune diseases.

- In the area of scleroderma, work by Drs. Laurie Glimcher from the Harvard School of Public Health and Robert Lafyatis from Boston University School of Medicine and colleagues have shown that a mouse model of human scleroderma reveals a molecule that regulates the expression of some immune system genes and suppresses skin sclerosis by its effect on the innate immune system. These researchers demonstrated that activation of IL-13, a cytokine that promotes tissue fibrosis and is specifically associated with the innate immune system, may be a key to the occurrence of skin sclerosis.

- Certain treatments for scleroderma, particularly oral cyclophosphamide, improve the quality of life for scleroderma patients. A study by Dr. Dinesh Khanna from University of Cincinnati and colleagues published in *Arthritis and Rheumatism* showed that treatment with the immunosuppressive drug cyclophosphamide significantly improved the health-related quality of life in patients with scleroderma-related lung disease.

- Dr. Lesley Arnold of the University of Cincinnati College of Medicine and colleagues recently reported in *Arthritis and Rheumatism* that gabapentin is effective for fibromyalgia pain. In a placebo-controlled trial of 150 men and women, subjects taking 1,200-2,400 mg daily doses of gabapentin over 12 weeks displayed significantly less pain than those taking placebo. Those taking gabapentin reported a 50 percent improvement in their pain compared with about 15 percent in the placebo group.

- A series of studies appearing in *Nature* have demonstrated that skin cells can be turned into early progenitor cells. Drs. George Cotsarelis, Sarah Millar, and colleagues at the University of Pennsylvania have demonstrated Wnt-dependent *de novo* hair follicle regeneration in adult mouse skin after wounding. This represents a change in paradigm; these studies broke the long-standing belief that hair follicles only form in development and that adult hair loss is permanent.

- Dr. Michael Rudnicki and colleagues found that satellite cells exist as two distinct populations— as undifferentiated muscle stem cells and as progenitor cells that have begun undergoing molecular changes that will lead to muscle development. These cells have been a tremendous source of interest in terms of regeneration of muscle.

- Dr. Sharmila Majumdar and coworkers have shown that two magnetic resonance imaging (MRI) measurements could be used to assess cartilage integrity in the knees of patients who had early stage osteoarthritis. This relatively small study needs to be replicated in a larger population to determine whether this finding correlates with severity.

- To date, it has been thought that human parathyroid hormone increases the functional lifespan of osteoblasts. A recent paper by Dr. Robert Lindsay and his coworkers in the *Journal of Bone Mineral Research* puts this belief into question with data indicating that parathyroid hormone enhances osteoblast turnover, thereby making them more effective bone-forming cells.

- Council member Dr. James Weinstein published a study entitled "Surgical Versus Non-Surgical Treatment for Lumbar Degenerative Spondylolisthesis." This study, supported by NIAMS and other agencies, along with a previous study on herniated discs, is one of a series of studies in which 12 spine centers from around the country were funded to examine herniated discs, surgical versus non-surgical treatment for lumbar degenerative spondylolisthesis, and spinal stenosis. The study showed that surgery is more effective than other approaches for this common back problem.

- Dr. Rafael Casellas, an investigator in NIAMS' Molecular Immunology and Inflammation Branch, and coworkers created two mouse strains that will permit researchers to trace, in a

live animal, the activity of an enzyme known as activation-induced cytidine deaminase. This enzyme is believed to play a crucial role in the normal immune response as well as in autoimmunity. The study was published in the *Journal of Experimental Medicine.*

- In a recent issue of *Immunity*, Dr. John O'Shea, NIAMS Scientific Director, and colleagues published a paper on the role of interleukin-2 inhibition of autoimmunity by acting on different T cells. The journal also published a study by Dr. Juan Rivera of NIAMS' Molecular Immunology and Inflammation Branch and colleagues on the role of the sphingosine kinase-sphingosine-1-phosphate as it relates to anaphylaxis.

NIH/NIAMS Activities and Plans for the Future

Dr. Katz noted that the NIAMS is leading a mid-course review of the Patient-Reported Outcomes Measurement Information System (PROMIS) initiative, which is one of the currently funded NIH Roadmap projects designed to re-engineer the clinical research enterprise. A supplement to the journal *Medical Care* was distributed to Council members—the supplement includes a number of papers on the PROMIS initiative. Dr. Katz reported that Dr. Lee Simon, a noted rheumatologist and expert in health outcomes research, is chairing an outside panel that is conducting the review. The goal of the PROMIS initiative is to develop ways to measure patient-reported symptoms such as pain, fatigue, and other aspects of health-related quality of life across a wide variety of chronic diseases and conditions. One of its dimensions is to develop a publicly available computer adaptive test for the clinical research community.

With regard to peer review issues, the Center for Scientific Review (CSR) is hosting open house/town meetings and workshops to discuss issues related to CSR's integrated review groups (IRGs) review of the musculoskeletal, oral, and skin sciences (MOSS). The meeting to discuss the MOSS IRG will be held on August 24, 2007.

Dr. Katz noted that recent NIAMS activities include roundtable discussions convened as part of the Institute's annual scientific planning process, and the NIAMS Retreat, which also is part of NIAMS' planning process. David Wofsy of the University of California, San Francisco is chairing an evaluation panel to examine NIAMS' training program and identify possible improvements. He will join the NIAMS September Council meeting to present a report of the evaluation's findings and recommendations.

Highlights of Information Dissemination Efforts

Dr. Katz noted that this Council meeting features a presentation by John Burklow, who heads the NIH Office of Communications and Public Liaison. Mr. Burklow discussed NIH efforts to raise awareness about its role in medical research with a particular focus on media outreach.

Recent events have placed a special emphasis on underserved populations. NIAMS has recently released a number of new patient publications in Chinese, as well as additional materials in Spanish.

The Institute also has created an interactive Web tool, "Check Up On Your Bones," to help people identify the most common red flags that put their bones at risk and give pointers on how to make bones stronger and healthier. Dr. Katz noted that a number of experts provided input while the tool was being built. This publicly accessible tool also provides numerous resources for osteoporosis and bone health.

Discussion

In response to a question from Council member Dr. Joshua Jacobs, an orthopaedic surgeon at Rush University Medical Center, Dr. Katz explained that the Arthritis Prevention, Control, and Cure Act of 2007 was primarily motivated by the Arthritis Foundation and has a focus on juvenile rheumatic diseases, as well as a component geared towards increasing the number of pediatric rheumatologists. There has been discussion about having the Health Resources and Services Administration provide an incentive (e.g., loan repayment) to encourage medical students to enter the field of pediatric rheumatology.

Council member Dr. Lawrence Raisz, Director of the Center for Osteoporosis at the University of Connecticut Health Center, asked about the NIH Director's New Innovator Award. Dr. Katz explained that applications are currently being received, and a limited number will be awarded from FY07 funds. The applications are being reviewed centrally, in the same way that the NIH Pioneer Awards have been reviewed and awarded. He added that these are basically R01 awards with an average time of 4-5 years. It is expected that only 10-20 of these highly competitive awards will be funded.

Dr. Bevra Hahn, Professor in the Department of Medicine at the University of California, Los Angeles School of Medicine and a member of the Council, asked about the NDBA. Dr. Katz responded that these awards are focused on established, vulnerable investigators, with an emphasis on first-time R01 recipients applying for their first renewal. Applicants also cannot have other sources of funding for their research. The NIAMS had six investigators eligible for this award, and has allocated Joint Resolution funding for all six of them. Council member Dr. Clifford Rosen, Executive Director of the Maine Center for Osteoporosis Research and Education, asked whether the NDBAs are selected by the Program Officers and whether these awards are publicized to the scientific community. Dr. Katz explained that Program Directors play a critical role in identifying candidates, as does the Budget Office.

Council member Dr. Jouni Uitto, Professor and Chair of the Department of Dermatology and Cutaneous Biology at Thomas Jefferson Medical College, asked about NIH's 2.6 budget increase for FY08. Dr. Katz noted that the scientific community, as well as the public and lay communities, plays an important role in helping to educate Congress in terms of prioritizing tax dollars. He emphasized that it is not just the scientific community that benefits from increased NIH funding; the public and voluntary organizations benefit as well. The Senate is on record as indicating that it will promote an increase in the NIH budget; but the amount of this increase is unclear. Educating Congress on scientific needs and priorities in a time of shrinking budgets is critical.

George Beach, Chairman and CEO of Beach Creative Communications and a member of the Council, complimented NIAMS on its "Check Up On Your Bones" Web tool and asked whether it is possible to pool information on users. Dr. Katz indicated that no data are accumulated from the tool.

V. REPORT ON THE NIAMS EXTRAMURAL PROGRAM SCIENTIFIC RETREAT

NIAMS holds an Extramural Program Scientific Retreat each year; these retreats are part of the Institute's regular planning process. Council members Drs. Rosen and Kathleen Green, the Joseph L. Mayberry Professor in the Department of Pathology/Cancer Center at Northwestern University Medical School, presented an overall summary of this year's retreat to the Council.

Imaging Modalities for Musculoskeletal Soft Tissues

Dr. Rosen first discussed the application of imaging modalities to musculoskeletal soft tissues, noting that this is an exciting, but challenging area. Various modalities were discussed, including MRI, ultrasound, computed tomography (CT), and positron emission tomography CT. Applications for these modalities include identifying at-risk populations, early detection of disease, conclusive diagnosis of disease or injury, and evaluation of tissue repair or regeneration. Research gaps associated with musculoskeletal soft tissue imaging include: (1) standardization of methods; (2) correlation between signs and symptoms; (3) collection of images during movement; and (4) visualization of tissues, cells, and cell processes. Dr. Rosen noted that the future of musculoskeletal soft tissue imaging may include the ability to:

- Examine multiple tissues that compose joints (e.g., muscle atrophy and symptomatic back pain, not just intervertebral disc; soft tissue pathology and osteoarthritis symptoms, not just cartilage).

- Measure functional indices to quantify disease severity (e.g., intervertebral disc degeneration, tissue regeneration).

- Understand cell processes (e.g., stem cell propagation, migration, and differentiation; tissue regeneration).

- Evaluate therapies (e.g., conventional pharmacologic, surgical, and physical therapies; engineered tissue constructs; stem cells or other regenerative strategies).

Systems Biology of Inflammation

Dr. Rosen then discussed systems biology of inflammation, noting that a systems biology approach is an iterative process that includes: (1) identification of component parts and interactions, (2) integration of the information into a model of system behavior (usually a mathematical model), (3) experimental testing of the model, and (4) refinement of the model based on experimental results. He added that systems biology identifies properties that have not been predicted, using knowledge of component parts. For example, some aspects of inflammation that can be addressed using a systems biology approach include triggers of

inflammation, cytokine/chemokine networks, resolution/control of inflammation, and genetic or regulatory networks. Systems biology uses a multidisciplinary team to approach a single problem. This "team-based approach" requires leadership from the senior-level managers. Interaction is more important than physical proximity, and the involvement of statisticians in microarray analysis is critical. Dr. Rosen added that the newer generation of scientists may be more amenable to such a team approach, but this attitude must be matched by promotion committees.

Challenges associated with systems biology include recruiting biologists to test models developed by others, and the cost/benefit assessment of the effort to create, validate, and test a model with a minimal number of available components.

Discussion

Council member Dr. Betty Diamond, Chief of the Laboratory of Autoimmune Diseases at the Feinstein Institute of Medical Research and Professor at Albert Einstein College of Medicine, asked if there are any notable successes of systems biology, particularly in terms of being able to predict the results of a particular perturbation. Dr. Rosen replied that there are no classic examples of systems biology, but there probably are successful examples. In his laboratory, it has been extremely helpful in mapping networks that are important in bone cell state. Systems biology requires a working experience, and it is very early in the process, as researchers are being trained to share knowledge rather than keep it within their respective laboratories and groups. Outcome measures are needed to demonstrate that this approach can be successful. Dr. Katz added that the biggest paradigm shift in this regard is the sharing aspect. Dr. Rosen agreed, adding that complex pathways and models represent particular challenges facing the systems biology approach.

Dr. Hahn asked if there is a central resource that an NIH-funded investigator can use to assist with this issue. Dr. Katz indicated that there is not; Dr. Ron Germain of the National Institute of Allergy and Infectious Diseases has set this approach up as a potential model, and there is funding available for his work to move ahead. Dr. Rosen explained that having a collaborative biostatistician who can speak some of the biologists' language is incredibly important. Dr. Katz noted that this type of interaction can be encouraged at the NIH level. Dr. Diamond commented that it might be useful to create microarray databases for raw data—the analysis of microarrays can be very different depending on which biostatistician is conducting the analysis. A central bank for this data could be a very important resource for this systems analysis approach. Dr. Rosen added that journals are becoming stricter about what they allow when it comes to microarray studies; standardized formats are becoming a requirement.

Dr. Martin Kushmerick, a member of the Council and Professor in the Department of Radiology at the University of Washington, applauded this approach but cautioned that one of the consequences of the enthusiasm of gene arrays, proteomics, etc., is that one tends to forget existing knowledge. A lot of classical knowledge is not being built in to newer approaches. Taking the model described by Dr. Rosen would include prior knowledge and new knowledge and can be very powerful. Dr. Rosen reinforced the importance of the literature base as a foundation.

Dr. Kathleen Green noted that one topic discussed at the retreat was the need to change the culture with regard to giving credit to investigators who are part of these multidisciplinary teams. This goes beyond promotions committees and extends to the peer review issues. In biology, first-author papers are extremely important for the career of a researcher; this will have to change. Dr. Katz agreed, adding that most of the responsibility for this culture shift falls on the academic health centers. Dr. Green also noted that peer reviewers from the extramural community on study sections will have to be educated by their academic health centers. Dr. Rosen commented that there are rarely, if ever, methodologists or other experts on study sections who can critique or propose how to approach a specific process in a systems way.

Dr. Jacobs explained that an investigator at Stanford University is proposing to have journals maintain image banks or archives, and allow investigators from different institutions to pool image results and hopefully provide more power to individual studies. The NIH potentially could take this approach.

Before moving on with the agenda, Dr. Katz commented that the topics selected for discussion at the retreat were chosen based on relevance to existing or proposed Roadmap initiatives.

Epigenetics

Dr. Kathleen Green reported on the discussion on epigenetics and noted that epigenetics involves heritable changes in gene expression that are not accompanied by changes in DNA sequence. An epigenetic state involves covalent and non-covalent modifications of DNA and histone proteins that influence chromatin structure and gene expression patterns. There are three primary modifications that give rise to the epigenetic state: (1) DNA methylation, (2) histone methylation, and (3) histone acetylation. Dr. Kathleen Green added that there has been a recent explosion of interest in this area by the scientific community; epigenetics is the topic of a new NIH Roadmap initiative. She cited the May 24, 2007, issue of *Nature* as having a number of contributions on the subject. Epigenetics has a tremendous impact on the final phenotype of an organism; these changes are going to be an important target for gene therapy.

In terms of the enzymes and proteins that affect the epigenome, the focus has been on histone deacetylases, histone acetyl transferases, and methyl transferases. In addition, the roles of microRNAs and non-coding single nucleotide polymorphisms are emerging as important contributing factors to the epigenetic state. New technologies have launched large-scale efforts to map the epigenome. At the NIAMS Extramural Program Scientific Retreat, topics discussed included epigenetics and lupus, epigenetics and bone biology, technologies driving the field, and epigenetics as a new NIH Roadmap initiative.

Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs

Dr. Kathleen Green explained that the SBIR and STTR Programs also were discussed at the retreat. SBIR is a set-aside program for small businesses to engage in federal research and development with the potential for commercialization. Approximately 2.5 percent of the NIH extramural research budget is set aside for SBIR. STTR is a set-aside program to facilitate

cooperative research and development between small businesses and U.S. research institutions with the potential for commercialization. STTR represents 0.3 percent of the NIH extramural research budget. A more detailed discussion of these programs took place later in the day. The SBIR and STTR Programs were selected for discussion at the retreat to address how their processes can be optimized at the NIAMS. The National Cancer Institute's (NCI) model for SBIR and STTR was presented at the retreat.

Discussion

Dr. Katz added that another reason for discussing the SBIR and STTR Programs at the retreat was to consider ways to enhance their potential benefit. He noted that these programs are congressionally mandated; NIAMS is searching for ways to optimize the opportunities they present.

VI. REPORT OF NIAMS ROUNDTABLE SUMMARIES AND DISCUSSIONS

Dr. Madeline Turkeltaub, Deputy Director of the NIAMS Extramural Program and Council Executive Secretary, gave this presentation in the absence of Dr. Susana Serrate-Sztein, Director of the NIAMS Division of Skin and Rheumatic Diseases. Dr. Turkeltaub explained that the NIAMS Roundtables are an important part of the Institute's planning process. These meetings pull together experts from outside and within the NIH to examine NIAMS' current and future directions. These meetings help inform the Institute's long-range strategic planning. The NIAMS Roundtables provide consultation on scientific issues/areas of special interest, with a particular focus on research fields, disciplines/programs, and trans-NIH interests. Council members are often invited to participate in the Roundtables, each of which is a small group (of about 10) that considers broad questions for discussion. No formal presentations are given; rather, high-level interactions occur. The Roundtables lead to recommendations and advice for setting new priorities and considering special initiatives; identifying new programs; informing funding decisions; examining criteria for portfolio evaluation; and responding to inquiries from Congress, the public, and the press.

Dr. Turkeltaub explained that the Roundtables often help the Institute identify interests of the communities NIAMS represents, such as the need for fellowships in certain areas, the need to increase education of specialty groups, clinical outcomes and outcomes that need standardization, etc. This year, the Roundtables have been particularly interdisciplinary and multidisciplinary. The four 2007 NIAMS Roundtables were: (1) Musculoskeletal Injury and Trauma; (2) Wound Healing; (3) Sex, Inflammation and Immune-Mediated Disease; and (4) Rheumatoid Arthritis, Psoriasis, and Psoriatic Arthritis. Dr. Turkeltaub noted that an additional function of the Roundtables is to help bring the community into the NIAMS planning process. Some common themes have emerged from the Roundtables, including enhancing collaborative work, standardization of methodologies, partnerships, ensuring clinical relevance, and topic-specific needs and opportunities. Council members were provided with summaries of the four 2007 NIAMS Roundtables.

Discussion

Dr. Diamond commented that the NIAMS Roundtables appear to represent a logical interface with the NIH Office of Portfolio Analysis and Strategic Initiatives (OPASI) because of the trans-NIH, multidisciplinary involvement. She asked if at the next series of Roundtables there would be any consideration of the overall NIH portfolio. Dr. Katz explained that the NIAMS Extramural Program Scientific Retreat was specifically designed to address how NIAMS could take advantage of initiatives being released under the NIH Roadmap 1.5. The Institute is constantly considering ways to initiate activities that coincide with Roadmap priorities. Dr. Katz clarified that OPASI is the structure under which the NIH Roadmap exists.

VII. ROADMAP 1.5

Due to time constraints, a discussion of Roadmap 1.5 was tabled until the next Council meeting.

VIII. FACILITATING INTERDISCIPLINARY RESEARCH

Dr. Fei Wang, Health Science Administrator in NIAMS' Division of Musculoskeletal Diseases, discussed enhancing collaborations and facilitating multidisciplinary/interdisciplinary research. There is a strong need for this type of research approach because of the complexity of the science being conducted today. Emerging scientific research requires team approaches. As an example, Dr. Wang described the establishment of the Musculoskeletal Development, Tissue Engineering, and Regenerative Medicine Program, which integrates developmental biologists with tissue engineers. The overall purpose of interdisciplinary research is to promote collaborations among groups of investigators that have not interacted traditionally but have a clear shared scientific area of interest.

Dr. Wang described the concept, tentatively titled as the Method to Enhance Collaborative Activities Program, an initiative under development at NIAMS that may provide limited funds to:

- Develop a new interdisciplinary collaboration between funded projects in different laboratories;
- Expand the scope of a funded project, adding expertise or approaches from another discipline; or
- Explore the feasibility of a new collaborative, interdisciplinary project.

Examples relevant to this program could include a pilot program in specific scientific areas, such as musculoskeletal soft tissue biology and imaging techniques, tissue engineering and developmental biology, tissue engineering and immunology, and developmental biology and systems biology. Dr. Wang noted that systems biology may play a role in this initiative.

NIAMS Program Directors will be asked to provide input; Council members were asked to provide any suggestions for additional options for this program.

Discussion

Dr. Raisz commented that the program discussed by Dr. Wang could play an important role in the Institute's future. He suggested possible inclusion of a training support option that could help enhance an investigator's understanding and use of multidisciplinary work (i.e., possibly through sabbatical-type work). He also noted that in the bone field, there are two areas currently in need of and beginning to engage in collaborative activity—the emerging fields of osteoimmunology and neuro-osteology. He asked what type of resources, timetable, and structures NIAMS is considering. Dr. Katz commented that there is only a certain amount of funds available, and if funds are put into one area, it necessitates removing funds from another area. The only initiatives that NIAMS can fund in the current budget climate are those that are very compelling—the concept is felt to be a compelling issue. The Institute is still considering how broad this program should be, and how much funding should be involved. The community's response and the Institute's budget will be primary factors dictating how this program will evolve.

Dr. Diamond asked about sponsoring more small meetings to bring experts together. She offered the perspective that collaborations arise from the people and their passion. Bringing people together and introducing them to areas that NIAMS feels could be connected might be an effective approach—for example, to discuss pain and inflammation, and why some people feel pain with inflammation and others do not. This approach might be well worth the effort and accomplish the program's goals in a more expanded way. Dr. Hahn commented that she was unsure whether this is the best way to use NIAMS funds. When calling for proposals, it is possible to encourage interdisciplinary applications and supplement the budget to facilitate this approach. It also could be possible to plan on the front end of an application and include experts who are equally enthusiastic about the idea. Dr. Kathleen Green echoed Dr. Hahn's comments regarding the encouragement of interdisciplinary approaches in research solicitations, adding that it may be helpful to provide instructions to study sections for evaluating the interdisciplinary portions of grants in a slightly different way. Dr. Katz noted that it is very difficult to educate the more than 150 study sections about these types of issues and bring in appropriate experts who are qualified to evaluate them. Dr. Kathleen Green noted that some of the more novel interdisciplinary applications often are viewed as too high risk—if special consideration were given to the interdisciplinary components, it could help get more research using this approach funded. Another idea would be to add *ad hoc* members to study sections who can evaluate interdisciplinary research. Dr. Katz commented that the interdisciplinary aspect or dimension of an application is not one of the five criteria currently used for review. Dr. Kathleen Green suggested that interdisciplinary research should not be added as a criterion, but rather possibly be considered as an extra "bonus." Dr. Wang noted that the NIAMS does fund interdisciplinary proposals, but the majority of funded applications typically involve grants for work in a limited environment. The limited funding over a limited time associated with the proposed program is intended to bridge areas of expertise among researchers working in specific research areas.

Dr. Kushmerick suggested that existing programs and funded researchers could be encouraged to participate in interdisciplinary endeavors if some type of supplemental funding was available. Dr. Katz explained that the proposed program is being viewed in this way, as a supplement to researchers already being funded by NIAMS to reach out to different laboratories and enhance interactions. Dr. Kushmerick added that the program proposed by Dr. Wang will indicate that interdisciplinary research is a serious endeavor that can be beneficial.

Dr. Raisz indicated that the Institute may want to consider not being too focused on specific areas, because it may limit the possibility of promoting other innovative ideas. He asked about the mechanism for review envisioned by the Institute. Dr. Katz explained that NIAMS has identified having tissue engineering experts collaborate with biologists as an important challenge to address. In terms of review, a pilot will allow the Institute to examine priority areas and determine whether these areas should be pursued further; therefore, a limited approach might be the best option to start with. Dr. Diamond expressed concern that this pilot program will not forge new relationships if experts already doing this work are funded. She suggested that it may be more effective to focus on training programs for researchers and/or groups of researchers interested in conducting interdisciplinary research. Dr. Katz explained that training may be a component of this initiative. He emphasized that this initiative is meant to enhance what the Institute is already getting back from its grantees, rather than starting an entirely new program.

Dr. Kathleen Green asked about whether the Institute had considered the possibility of partnering with the National Science Foundation (NSF) to both expand the program, as well as identify experts who might not normally collaborate. Dr. Katz noted that this is an excellent idea and will be pursued if this program moves forward. Dr. Wang explained that the NIH has active collaborations with the NSF, and that many applicants for NIH funding are current or former NSF grantees.

Dr. Katz concluded this discussion session by noting that the Institute will utilize this input at future internal discussions to determine whether a pilot project will be proposed for FY2008.

IX. SBIR/STTR HISTORY AND MECHANISM

Ms. JoAnne Goodnight, SBIR/STTR Program Manager, NIH Office of Extramural Research, noted that this year marks the 25th anniversary of the SBIR Program. SBIR was established because Congress recognized that small businesses are an important source of technological innovation. Per the Small Business Innovation Development Act of 1982, SBIR was formed with the following four goals: (1) stimulate technological innovation, (2) use small businesses to meet federal research and development needs, (3) foster and encourage participation by minorities and disadvantaged persons in technological innovation, and (4) increase private-sector commercialization innovations derived from federal research and development. Ms. Goodnight commented that for the NIH to fully meet its mission and translate scientific knowledge and findings to real-world practice, small business concerns will be instrumental.

Both SBIR and STTR are three-phase programs. Phase I consists of a feasibility or proof-of-concept study, with $100,000 in funding and a 6-month period of performance for SBIR awards

and a 1-year period of performance for STTR awards. Phase II represents a full research and development endeavor based on the results of Phase I. Phase II includes $750,000 for 2 years and requires a commercialization plan. Phase III is the commercialization stage, which cannot use SBIR/STTR funding. Ms. Goodnight acknowledged that biomedical research is not linear but rather cyclical in nature, which has presented some challenges.

There are eligibility criteria that SBIR companies must meet. These criteria have been set by the U.S. Small Business Administration (SBA). For example, they must be organized as a for-profit U.S. business that is small (500 or fewer employees, including affiliates). The Principal Investigator's (PI) primary place of employment must be with the small business concern at the time of award and for the duration of the project. In addition, SBIR companies must be at least 51 percent U.S. owned by individuals and independently operated, or at least 51 percent owned and controlled by another (one) business concern that is at least 51 percent owned and controlled by one or more individuals. As SBIR companies receive their Phase I and Phase II funding, they leverage those dollars for attracting other resources to help transition through the commercialization period. Oftentimes, these companies receive venture capital funding and/or other investments. At that point, very often these companies must give up ownership to multiple venture capital firms. These companies then are ineligible for participation in the program. The NIH is examining some different approaches to retaining successful companies in the program, possibly by giving preference to new entrants to the program and those who respond to programs and IC-specific priorities and areas.

Dr. Luke Evnin, a venture capitalist and Chairman of the Scleroderma Research Foundation, and who participated in this year's NIAMS Extramural Program Scientific Retreat, commented that it would be rare for venture capitalists to become involved in a company in any meaningful way without having a majority ownership. Often, venture capitalists will invest significantly to help create infrastructure and cover laboratory and overhead expenses.

Ms. Goodnight emphasized that the Phase I and Phase II dollars that go to small businesses represent funds that these companies cannot obtain elsewhere. These same companies have innovative ideas that fall back into the early stage of the pipeline, and are not in a position to attract venture capitalists at this point because they have not yet proven the feasibility of their idea. Dr. Evnin noted that given the risks involved with Phase I and Phase II concepts, it is difficult in a corporate culture to get consensus around funding early-stage high-risk projects. It is not uncommon for mid-stage companies that have the ability to address an early-stage idea that could be synergistic with NIH and leverage existing work, to be ineligible because of SBA ownership issues.

Ms. Goodnight explained that 10 years after the SBIR Program was established, Congress recognized that a great deal of technology was being developed at universities without viable avenues for moving these technologies to the marketplace. The STTR Program provides that opportunity for universities to partner with small businesses in a formal, collaborative setting. The company must do at least 40 percent of the work, while the university must do at least 30 percent of the work. The two entities must work out intellectual property agreements, rights to follow on, and so forth. About 70 percent of SBIR programs have university involvement; 100 percent of STTR programs have university involvement (because it is a requirement).

The SBIR budget at NIH has increased from $352.1 million in FY00 to $563.3 million in FY04, and has leveled off at $580.7 million in FY07. For FY07, NIAMS' SBIR/STTR allocation of $12.1 million represents approximately 2 percent of the overall NIH SBIR/STTR set-aside. In terms of success rates at the NIH, about 19 percent of Phase I applicants and 41 percent of Phase II applicants were funded in FY06. The success rates for the NIAMS' SBIR/STTR Program were slightly higher in FY06 than those for the NIH (22 percent for Phase I and 48 percent for Phase II).

Ms. Goodnight explained that there are 11 federal agencies that participate in these programs; each agency administers their respective programs differently. She commented that the NIH is viewed as one of the most flexible agencies across the government, in large part because of the science that is supported. The NIH issues multiple solicitations and encourages ICs to develop specific funding opportunities. Multiple award mechanisms are used (about 95 percent are done through the grant mechanism, about 5 percent through contracts, and less than 1 percent through cooperative agreements). The NIH also offers multiple submission dates, a competitive peer review process, a multiple PI option, larger award amounts, a Phase I/II fast track option, and Phase II competing renewals. Ms. Goodnight noted that the multiple PI option is believed to be a strong incentive for companies and universities to collaborate and participate in the program.

The number of NIH SBIR awardees with U.S. Food and Drug Administration (FDA) approved products increased by 51 percent, from 59 in 2002 to 89 in March 2007. The estimated cumulative sales to date for SBIR-funded projects increased by more than 200 percent; from $821 million in 2002 to $1.95 billion in March 2007. In addition, the number of awardees receiving additional non-SBIR funding or capital increased by 33 percent, from 281 in 2002 to 375 in March 2007.

Ms. Goodnight discussed efforts to enhance SBIR/STTR outcomes and described the Performance Outcomes Data System (PODS), which is a dynamic monitoring database searchable by award number, award title, institute code, etc. PODS allows NIH staff to research SBIR companies, contact them, and query them about sales and other outcomes. Technical Assistance Programs are in place to help companies transition between Phase II and Phase III. The three Technical Assistance Programs are: (1) Niche Assessment (Phase I), (2) Commercialization Assistance (Phase II), and (3) Manufacturing Assistance (Phase III). The NIH also has established a new initiative called Pipeline to Partnerships (P2P). P2P is a virtual space where NIH SBIR/STTR awardees and NIH licensees can showcase their technologies and product development. P2P also provides information on where companies are in the commercialization pipeline (e.g., research, clinical Phase I, Phase II, etc.), http://www.ott.nih.gov/P2P/index.asp.

Ms. Goodnight closed her presentation with a list of compelling reasons for companies to take advantage of the SBIR/STTR Programs:

- Across the 11 participating federal agencies, there is more than $2.2 billion in funding available annually.

- SBIR and STTR are not loan programs, there are no requirements for repaying grant money if Phase I or Phase II fails.

- Participation provides recognition, verification, and visibility to use as potential leveraging tools for attracting venture capital or other resources.

- They foster partnerships with universities, large corporations, and others to enhance the competitiveness of the small businesses.

- Participation creates jobs and stimulates local and state economies, as well as the national economy.

- The program provides seed money to fund high-risk projects that the company might not otherwise have been willing or able to fund.

- The intellectual property rights generally are retained by the small business.

- Small businesses are recognized as a unique national resource of technological innovation; they are making technological, economic, and societal contributions while helping the NIH meet its mission of improving health and extending life.

Discussion

Council member Dr. Lee Green, Executive Director of the Office of Institutional Diversity and Research, and Professor of Health Outcomes and Behavior at the H. Lee Moffitt Cancer & Research Institute, asked about strategies for fostering participation by minorities and women. Ms. Goodnight explained that most of these efforts are carried out through outreach. Fewer than 10 percent of NIH SBIR/STTR Program awards go to small women-owned businesses; less than 5 percent are awarded to small disadvantaged businesses. Part of the outreach efforts involves encouraging these businesses to attend conferences and become aware of the programs to help them identify a fit with their core technology areas. Two conferences were held this year to help inform small and disadvantaged businesses about these opportunities. In addition, the NIH offers diversity supplements; embedded in these supplements are the SBIR and STTR mechanisms.

Dr. Jack Parr, Consultant for Medical Technology Development, Inc., and a member of the Council, asked about what happens when a company receives additional ownership equity during Phase II and loses the 51 percent ownership criterion set by the SBA. Ms. Goodnight responded that according to the SBA, eligibility is determined at the time of award, so at the time the Phase II award is made, even if the company is acquired a short time later, it gets to keep the entire award.

X. ENHANCING THE NIAMS SMALL BUSINESS RESEARCH PROGRAM

Dr. James Panagis, Director of the Orthopaedics Program within NIAMS' Division of Musculoskeletal Diseases, noted that discussions on the subject of small business research at the Institute's recent Extramural Program Scientific Retreat were guided by the following questions:

- How do we define success of NIAMS' Small Business Research Program?
- How can we enhance NIAMS' support of meritorious small business research to better meet Institute mission needs and opportunities?
- What administrative strategies can be implemented to facilitate mentoring, coordination, program development and management, and improved commercialization?
- Is there a role for targeted initiatives? How could these be best implemented?
- Are there opportunities for partnership to leverage our support of meritorious small business research?

Dr. Panagis described the so-called "valley of death," the period between Phase II of an SBIR/STTR award, when federal funding supports the research, and Phase III, which is funded by for-profit entities. This transition is the target of many enhancement strategies (i.e., those discussed previously by Ms. Goodnight). A review of previously funded NIH Phase II SBIR awards issued in 2003 found that of 768 Phase II awards, 220 products, services, and usages emerged (roughly a 29 percent success rate). Only 40 (or 5 percent) of these products, services, and usages resulted in devices, biologics, or drugs that required FDA approval. A bridge over this "valley of death" is needed to increase commercial success and potential of SBIR/STTR-funded projects.

Dr. Panagis indicated with regard to the NIAMS Small Business Research Program from 2001 to 2006 that the Institute generally averages between 170-200 grant applications per year, with the number of awards made ranging from a low of 22 in 2002 to 51 in 2006. The 51 awards from FY06 can be broken down into the following scientific focus areas: Treatments (23 awards), Diagnostics (9 awards), Implants (6 awards), Computer Software/Simulations (5 awards), Devices (4 awards), and Tissue Engineering (4 awards). In terms of success rates for NIAMS SBIR/STTR awards in FY06, there were a total of 177 Phase I and II SBIR/STTR applications in FY06; 46 of them were funded for an overall success rate of 26 percent. Funding for these 46 awards totaled $10.9 million (generally, 90 percent of the awards are SBIR and 10 percent are STTR).

Dr. Panagis discussed some possible administrative strategies to enhance the SBIR/STTR Programs at NIAMS. For example, administrative supplements could be used in Phase I or Phase II as one-time provisions of up to $50,000 for a scientific need. Another option is a competitive supplement for Phase II that requires a formal application for a significant expansion of the original scope of work; the work may not extend beyond the original term of the grant. Dr. Panagis noted that some of the larger NIH ICs have used a Type II, Phase II application,

which provides additional time and money to move an already identified drug or device requiring regulatory approval into clinical trials. Funding for these applications ranges from $750,000 to $1 million per year for a maximum of 3 years; they typically are awarded in response to a targeted initiative and most require prior discussions with program staff before submission. Targeted initiatives in response to Program Announcements, RFAs, or RFPs are another alternative to help enhance the SBIR/STTR Programs at NIAMS.

Michael Weingarten, Director of the SBIR and STTR Programs at the National Cancer Institute (NCI), gave a presentation at the NIAMS Extramural Program Scientific Retreat on steps the NCI plans to take to enhance its small business program, which he briefly summarized for Council members. These include: (1) centralizing the scientific administration of their small business grants from 42 programs to 6-8 more specialized programs that focus specifically on small business research, (2) assembling SBIR Development Centers that blend current scientific expertise with business and marketing expertise, (3) assembling an external SBIR Advisory Committee, and (4) co-investing with the private sector to "bridge" SBIR projects towards commercialization. Overall, the NCI plans to increase its support of small business research from grant dollars to contracts, moving from 4 percent today to approximately 50 percent funded by contracts in the next 5 years.

Dr. Panagis closed this presentation by posing the following questions to Council members:

- Should NIAMS consider Type II, Phase II awards?

- Is there a role for targeted initiatives? If yes, what percent of NIAMS' small business program? How can the Council assist in identifying the most promising areas of research?

- Should NIAMS consider "operational involvement" with small business centers now being developed within some of the NIH ICs?

Discussion

Dr. Panagis noted that NIAMS currently excludes Type II, Phase II awards. Small business investigators have approached the Institute and asked about these awards; NIAMS is beginning internal discussions to determine whether the Institute will begin to utilize these awards. Dr. Katz noted that NIAMS funds those applications that have been rated as the most highly meritorious and there is a tremendous amount of interest in this area by the skin and musculoskeletal communities. What are the opportunities for NIAMS in this area? Dr. Katz asked Council members to consider the role for targeted initiatives as they relate to NIAMS' SBIR and STTR Programs and the needs of the Institute.

In response to a question from Dr. Uitto, Dr. Panagis indicated that the success of an SBIR/STTR award can be defined as commercialization. Mr. Weingarten commented that the NCI is moving more of its programs toward directed research; the NCI envisions that 25-50 percent of its program over the next 3-5 years will be in more targeted, focused areas, with 50 percent of the program being investigator-initiated. Contracts will be one mechanism for achieving this; other targeted grant mechanisms will be utilized as well. Pending Council

agreement, Dr. Katz suggested forming a subcommittee of the Council to examine what the Institute can do in terms of targeted areas and possibly taking the same approach that the NCI is taking. Dr. Hahn agreed that this would be a good idea and suggested identifying some specific targets. Dr. Parr suggested that this approach is a workable model for addressing translational research, in which an idea moves from concept to treatment. He strongly encouraged having NIAMS enhance its Small Business Program. Dr. Raisz asked if it would be feasible to ask NIAMS grantees about potential business opportunities that they see. Dr. Katz noted that it could be possible to establish a pilot program that could be moved from year-to-year depending on what needs are identified. Ms. Goodnight noted that an RFA could be issued for targeted research identified by the Council, NIAMS, and the overall scientific community. Dr. Jacobs indicated that many in the research community may not be aware that these programs exist. Having targeted programs and RFAs may raise the level of awareness and increase the number of applications.

Dr. Panagis asked Ms. Goodnight about the potential for NIAMS to receive an increase in funds from NIH's overall SBIR/STTR Programs, noting that the Institute's SBIR/STTR applications tend to receive higher priority scores in the review process than other ICs. Ms. Goodnight indicated that the NIH has discretion in allocating these funds. Overall, the NIH must spend a total of $650 million on these programs. Despite the high-profile fields in NIAMS communities such as tissue engineering, the Institute receives a small portion of these funds, 2 percent. The NIH has an SBIR "think tank" that identifies trans-NIH strategies; one idea is to allocate the funds differently. Dr. Katz noted that many ICs look to other places to invest some of their SBIR money. Ms. Goodnight added that because the applications are percentiled, there is wide variability across the study sections in terms of scoring.

XI. NIH COMMUNICATION PLAN REQUEST FOR INPUT

John Burklow, Associate Director for Communications and Public Liaison at the NIH, serves as the chief advisor to the NIH Director, Deputy Director, and senior staff on communications and public liaison issues. Mr. Burklow noted that approximately 5 years ago, shortly after Dr. Zerhouni was appointed NIH Director, Dr. Zerhouni challenged all NIH staff to improve communications about the NIH, specifically the work done at NIH, who the NIH represents, etc. He explained that the NIH in its communication efforts has sometimes inadvertently put information out of people's reach, either by the language used, or by putting information where the public doesn't look for it. The major communications challenge facing the NIH is making information understandable, relevant, tailored to specific audiences, and accessible. Tied to this challenge is increasing legislators' awareness of the NIH, the work it carries out, and how its funds are distributed and for what purpose.

Mr. Burklow reviewed the goals of communication for the NIH, which are to increase: (1) benefits received by every American from the public investment in biomedical research, (2) the role research will play in transforming medicine in the 21st century, (3) the public and private sector agreement to advance biomedical discovery, and (4) the connection between the NIH and the nation's research community. Gateway audiences for promoting these goals to the public

and Congress include NIH leadership and staff, the scientific community, members of the public actively interested in health issues, the media, and constituency/patient organizations.

NIH's strategic approach in terms of communications draws on the following principles: (1) stay fact-based and people-focused; (2) draw a clear connection between discovery and health; (3) tell real stories about people (both patients and scientists); (4) connect the NIH and extramural research; (5) sustain constant, compelling communications; and (6) continue proactive, dynamic communications with the public, stakeholders, grantees, Congress, etc. Mr. Burklow discussed recent efforts to improve NIH's communications through presentations, the media, resources, and community outreach.

Dr. Zerhouni has spoken to almost all NIH Councils about improving NIH communications. He also has given presentations on this topic at a large number (approximately 135) of IC and professional societies/organizations meetings over the past year. An article written by Dr. Zerhouni and published in the November 17, 2006, issue of *Science* explains the NIH budget and future implications. There has been growing national press coverage regarding the NIH, coupled with an increase in the number of media stories about medical research. Mr. Burklow commented that about 65 percent of the public when surveyed indicate that they obtain most of their health information from local television news. His office has worked with the ICs to reach out to local television stations and television outlets around the country. Consumer magazines also are a valuable communication tool. NIH staff have met with 15 consumer magazines (e.g., *Prevention*, *Men's Health*, *Redbook*, *Good Housekeeping*, etc.). Top editors were briefed on the clinical research awareness campaign, new NIH initiatives, programs, and research. Last year, the NIH collaborated with the Discovery Channel to create a 1-hour special focused on a science competition involving middle school students.

Mr. Burklow indicated that his office is making efforts to have NIH staff become more comfortable conducting television interviews, which can be a challenge. The NIH has been working with the American Association of Medical Colleges (AAMC) over the last few years on the "Fulfilling the Promise Campaign" to educate the public and encourage grantees to mention the NIH support associated with their research. The NIH is contacting these institutions directly; all of the public information officers at these institutions participate in quarterly conference calls to discuss ways to foster closer collaboration with NIH communications offices.

Frank Brady, Chairman and Founder of Medical Missions for Children, has invited Dr. Zerhouni and all of the IC Directors to participate in a videotaped discussion about what the NIH does. A total of 12 shows have been taped to date; it is hoped that these discussions will be part of a Public Broadcasting Service program in New Jersey. This effort also presents an opportunity for the NIH to repackage these interviews for other uses. Mr. Burklow indicated Dr. Katz participated in an interview as part of this project.

On the NIH homepage, there are more than 100 fact sheets that have been produced by the ICs. The site also contains state-by-state funding data, as well as a newsletter from the NIH Director. The NIH homepage itself has been redesigned and will be released in the next few weeks. A consumer newsletter, *NIH News in Health*, is distributed to hospitals and clinics around the country. A new magazine has been launched, titled *NIH Medline Plus*, through the Friends of

the National Library of Medicine. The magazine has print and online versions, is filled with NIH-related information, and is distributed to doctors' offices. In addition, the NIH is working on a pilot television program for teenagers. Examples of topics for this program include steroid use, childhood obesity, and addiction. The NIH also is using Spanish language radio outreach, Podcasts, and Vodcasts (video Podcasts) to reach its audiences. The NIH has opened a kiosk at the Jackson, MS, Medical Mall to determine how the NIH can enter the community with health information.

Mr. Burklow noted that mentions of the term "National Institutes of Health" in LexisNexis averaged about 4,200 per month from April-August 2006 (not including specific ICs or programs). He also commented that during Dr. Zerhouni's 5-year tenure as Director, media mentions for the term "National Institutes of Health" have increased by almost 62 percent, from an average of 11,688 mentions in 2002-2003 to 18,883 in 2006-2007.

Discussion

Council member Dr. Raymond Scalettar, Clinical Professor of Medicine at George Washington University, noted that there was an NIH communication "moat" before Dr. Zerhouni arrived. In the practicing medical community, little was known about NIH activities, and in the last 5 years, that gap has been narrowed to a large extent. He suggested that the NIH expand its outreach to broad-based medical and health care organizations, such as the American Association of Nurse Practitioners, American Nurses Association, American Medical Association (AMA), etc. He noted that Dr. Zerhouni is a Delegate to the AMA; he could potentially introduce resolutions that would focus on some of the science being done. He also suggested that the NIH consider reaching out to editorial boards and give thought to using satellite radio and/or talk radio to get its messages out. Dr. Jacobs noted that many medical professional societies and organizations have robust media teams in place that could work with NIH's Office of Communications and Public Liaison. Many of these organizations have new communications vehicles and likely would be willing to provide space to allow NIH content to be distributed to their members.

Dr. Kushmerick suggested that the NIH could also get its message out through primary school education. He reported great success in giving a presentation on the heart to a group of second graders. Mr. Burklow noted that the NIH has different programs and curricula for younger children, but more could be done in this area. There are a number of Web sites across the NIH geared toward children, and there are discussions about having a central NIH site for children. Dr. Kushmerick suggested that NIH staff could participate as judges for school science fairs. Dr. Katz noted that NIH staff do participate in this activity locally, but not on a more national level.

Patient advocate and Council member Patricia McCabe commented that from the patient advocate's perspective, the NIH is doing an incredibly good job with its communications efforts. She noted that the NIH Web site is very accessible and provides a wealth of information. She also noted that there has been a great deal of news media coverage regarding the NIH budget. She asked how active the NIH Office of Communications and Public Liaison is in terms of correcting inaccurate information that is relayed through the news media or through non-NIH Web sites. Mr. Burklow commented that the NIH does make efforts to correct inaccuracies in the media and on the Internet. Dr. Katz noted that NIAMS decided early on not to link to other

sites from the NIAMS Web site because it would be too labor intensive to check the accuracy of the information on these other sites.

Dr. Rosen suggested that the NIH could do more when grants are announced by legislators, particularly in local newspapers. Often, the only information that appears is the grant title and cost, with no information for the public about what these grants mean. It would be helpful for the NIH to provide some information on the public health impact of these projects. Mr. Beach emphasized the need for the NIH to reach out to all constituencies, particularly the consumer. Many initiatives in this country are driven by happy or unhappy consumers. Mr. Burklow noted that he will be participating in a conference call with the Web site You Tube, which has 65 million viewers per month; this represents an enormous opportunity to expand NIH's communication efforts.

Dr. Hahn noted that one recent study indicates that 85 percent of rheumatology patients coming to their physician's office for an appointment had been online during the week prior to the appointment. She asked if the NIH and NIAMS were linked to Google. Mr. Burklow indicated that the NIH web site uses Google as its search engine.

XII. ELECTRONIC COUNCIL BOOK UPDATE

An update on the electronic Council book was presented during closed session.

XIII. PORTFOLIO

A discussion of the NIAMS portfolio took place during closed session.

XIV. CONSIDERATION OF APPLICATIONS

The Council reviewed a total of 698 applications in closed session requesting $157,441,039 and recommended 698 for $157,441,039.

XV. ADJOURNMENT

The 62nd National Arthritis and Musculoskeletal and Skin Diseases Advisory Council Meeting was adjourned at 4:00 p.m. Proceedings of the public portion of this meeting are recorded in this summary.