

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES**

**MINUTES OF THE ONE HUNDRED THIRTY-FOURTH MEETING OF THE
NATIONAL ADVISORY ENVIRONMENTAL HEALTH SCIENCES COUNCIL**

September 1-2, 2011

The National Advisory Environmental Health Sciences Council convened its one hundred thirty-fourth regular meeting on September 1, 2011 in the Rall Building, Rodbell Auditorium, National Institute of Environmental Health Sciences, Research Triangle Park, NC. Dr. Linda Birnbaum presided as Chair.

The meeting was open to the public on September 1, 2011 from 8:30 a.m. to 2:00 p.m. and on September 2, 2011 from 8:30 a.m. to 12:20 p.m. In accordance with the provisions set forth in Section 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), the meeting was closed to the public on September 1, 2011 from 2:15 p.m. to 5:00 p.m. for consideration of grant applications. Notice of the meeting was published in the *Federal Register*.

Council Members Present

Julia Brody, PhD
Steve Dearwent, PhD
Richard Finnell, PhD
Thomas Gasiewicz, PhD
Andrea Hricko, MPH
Mary M. Lee, MD
Grace LeMasters, PhD
R. Stephen Lloyd, PhD
Yvonne Maddox, PhD
Thomas McKone, PhD
Sem Phan, MD, PhD
Jerald Schnoor, PhD
Palmer Taylor, PhD
Deborah Winn, PhD
Nsedu Obot Witherspoon, MPH
Elizabeth Yeampierre, JD

NIEHS Staff

Janice Allen, PhD
Joellen Austin
Beth Anderson
Trevor Archer, PhD
Eddy Ball, PhD
David Balshaw, PhD
Martha Barnes
Linda Bass, PhD
Linda Birnbaum, PhD
Perry Blackshear, MD, DPhil
John Bucher, PhD
Matthew Burr
Danielle Carlin
Trisha Castranio
Lisa Chadwick, PhD
Pamela Clark
Jennifer Collins
Gwen Collman, PhD
Don Cook, PhD
Helena Davis
Caroline Dilworth, PhD
Christina Drew, PhD
Serena Dudek, PhD
Dorothy Duke
Sally Eckert-Tilotta, PhD
Mitch Eddy, PhD
Lisa Edwards
Don Ellis
Yolanda Eskridge-Nyass
Christine Flowers
Johannes Freudenberg, PhD
Barbara Gittleman
Ashley Godfrey, PhD
Kimberly Gray, PhD
Astrid Haugen
Jerry Heindel, PhD
Heather Henry, PhD
Jill Hesse, PhD
Stephanie Holmgren
Michael Humble, PhD
Laurie Johnson
Paul Jung, MD, MPH
Ed Kang
Annette Kirshner, PhD
Ken Korach, PhD

Cindy Lawler, PhD
Leping Li, PhD
Xiaoling Li, PhD
Stephanie London, MD, DrPH
Chris Long
Robin Mackar
J. Patrick Mastin, PhD
Kim McAllister, PhD
Rose Anne McGee
Liz McNair
Aubrey Miller, MD, MPH
David Miller, PhD
Ellen Moul
Sri Nadadur, PhD
Teresa Nesbitt, DVM, PhD
Sheila Newton, PhD
Heather Nicholas
Liam O'Fallon
Ted Outwater
Michelle Owens
Linh Pham, PhD
Jerry Phelps
Kristi Pettibone
Nicole Popovich
Molly Puente
Scott Redman
Leslie Reinlib, PhD
Charles Romeo, PhD
Margarita Roque
Elizabeth Ruben
Angie Sanders
John Schelp
William Schrader, PhD
Thad Schug, PhD
Daniel Shaughnessy, PhD
William A. Suk, PhD, MPH
Kimberly Thigpen Tart, JD
Raymond Tice, PhD
Cheryl Thompson
Claudia Thompson, PhD
Frederick Tyson, PhD
Carmen Williams, MD, PhD
Mary Wolfe, PhD
Leroy Worth, PhD
Richard Woychik, PhD
Jerrel Yakel, PhD

Darryl Zeldin, MD

Members of the Public Present

Kevin Beverly, SSS
Laura Bono, SafeMinds
Melissa R. Chapman, SSS
Jennifer Freeman, PhD, Purdue University
Sy Garte, PhD, CSR NIH
Ernie Hood, Scribe
Jane Huber, Eastern Research Group
Danielle Hunt, PhD, Epidemiology International
Perry Kirkham, Purdue University
Laine LaPasha, Learning Technologies
Richard Morris, SRA International
Robyn Peoples, Wyle
Michael J. Phillips, RTI International
Maria Sepulveda, Purdue University
Sarah Tishkoff, PhD, University of Pennsylvania

I. Call To Order and Opening Remarks

Dr. Linda Birnbaum, Director of NIEHS and NTP, welcomed attendees and called the meeting to order. She welcomed new Council member Elizabeth Yeampierre, to the meeting. She presented retiring Council members Dr. Richard Finnell, Dr. Jerald Schnoor and Nsedu Obot Witherspoon with certificates recognizing their service. She also acknowledged the service of the retiring members who were absent, Dr. Stephen Baylin and Dr. Christopher Bradfield. She asked the retiring members to attend the February 2012 Council meeting, as it is often a lengthy process to get new members approved and on board. She then asked all present in the room to introduce themselves, which they did.

II. Review of Confidentiality and Conflict of Interest

Dr. Collman reviewed the Conflict of Interest and Confidentiality procedures, which had been provided earlier to Council members in written form, and went over various other administrative matters.

III. Consideration of May 2011 Meeting Minutes

Approval of the May 2011 minutes was moved and seconded, and Council voted unanimously to approve the minutes. Dr. Collman also noted the dates of the upcoming Council meetings for members to put on their calendars.

IV. Report of the Director, NIEHS

Dr. Birnbaum updated Council on staff changes. Joellen Austin started her duties in June as the new NIEHS Executive Officer. She thanked Chris Long for his recent service as Acting Executive Officer prior to Austin's arrival. She reported that after two long, intensive searches for a new Scientific Director, Dr. Darryl Zeldin has been selected to fill that position. She also recognized Dr. David Miller's contribution over the past year as the Acting Scientific Director. Dr. Zeldin has been the Acting Clinical Director for NIEHS, and there is now a search being conducted for a Clinical Director, which will run until at least October 31.

In her summary of FY 2012 appropriations, Dr. Birnbaum noted that the Energy and Water Appropriations Act (HR 2354), which includes provision of the \$10 million funding for the NIEHS/DOE Worker Training Program, has passed the House and is expected to be enacted. The House Interior and Environment Bill has also passed, which provides \$79,054,000 for the NIEHS Superfund programs, which is actually a small increase over FY2011. NIEHS, as is most of NIH, is largely funded through the House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies. Hearings for the NIH director or any institute directors have not been scheduled. There is guarded optimism that the final mark-up of the bill will not revert funding levels to 2008, as has been proposed, but will be close to FY 2011 funding. It is anticipated that a final budget will not be passed by September 30, and that there will be a series of short-term continuing resolutions, eventually leading to passage of an omnibus bill.

Dr. Birnbaum told Council that the meeting held at NIEHS earlier in the week (August 29) with Congressman David Price (D-NC) and several NIEHS grantees, designed to be a forum to discuss the economic benefits of federally-funded research, had resulted in a favorable editorial in one of the local newspapers. The article recognized the economic importance to the area of NIEHS, which cumulatively represents a \$500 million engine for the North Carolina economy.

Going over the budget numbers, Dr. Birnbaum noted that FY2010 had been a good year for NIEHS funding, with a 4.1% increase over FY2009 to nearly \$690 million, the largest percentage increase in NIH and a good starting point in the face of anticipated cuts. Superfund was funded at just over \$79 million, with the \$10 million direct pass-through from the Department of Energy for worker training. During FY2011, under the full-year continuing resolution, NIEHS had a 1% cut, which was relatively good given the overall situation. Superfund was cut just .2%, and the \$10 million DOE pass-through again occurred. For the FY2012 mark-up, Superfund was cut just \$10,000 and the DOE pass-through was preserved; all else is currently uncertain.

In other legislative developments, in May the Ad Hoc Group for Medical Research held a Congressional briefing focusing on research assessing the health impact of the Gulf oil spill. Congressman Price also held a town hall meeting at NIEHS in June with institute employees and contractors. Dr. Bucher and his National Toxicology Program (NTP) staff held several Congressional briefings in anticipation of the release of the 12th Report on Carcinogens. Dr. Birnbaum has also been holding a series of briefings for members of Congress. She described the Endocrine Disrupting Chemical Exposure Elimination Act (HR 2521), which would require regulatory agencies to act based on the level of concern for an endocrine-disrupting chemical (EDC). This would be determined by NIEHS, as the lead agency for the evaluation of EDCs, based upon an expert panel charged with reviewing up to 10 chemicals per year. If high concern is expressed, it would trigger regulatory action, including bans on chemicals. Although the bill is unlikely to be enacted, it represents frustration with the difficulty of regulating such potentially harmful chemicals in the environment. She noted that it would create an onerous situation for NIEHS, in that the bill is in authorizing language and would create unfunded mandates for the institute.

She briefly alluded to other current legislation, such as the Combating Autism Act of 2006, which has been extended in the short term, with a proposal for a three-year extension awaiting Congressional action. Two other autism-related bills propose separating the research component from the service component also await action. The Strengthening Protections for Children and Communities from Disease Clusters Act (S76), sponsored by Senator Barbara Boxer, is unlikely to pass this year, said Dr. Birnbaum.

She reported on recent scientific advances associated with NIEHS. The first was from a multi-institute consortium, and it describes the results of a genome-wide association study of prostate cancer in African-American men, which identified a specific, unique susceptibility locus. Another study by a group in Massachusetts that includes NIEHS grantees determined that p53 apoptosis requires normal mitochondrial function. A group at Rutgers University is developing and testing the Pretoddler Inhalable Particulate Environmental Robotic (PIPER) sampler, which is designed to sample the in-home environment in a fashion that would mimic the exposures of pretoddlers.

Studies emerging from the NIEHS intramural program include a study by Dan Shaughnessy (currently in the Division of Extramural Research and Training, but previously in the Division of Intramural Research) and colleagues that showed that diet may protect against mutagens in fried meat, which may have implications for prevention and interventions. Another group that included Serena Dudek and Karen Adelman reported on the impact of poised RNA polymerase II on neuronal gene transcription. A group led by former NIEHS Scientific Director Lutz Birnbaumer found that expanded DNA methylation analysis reveals new functional sequences of the genome, an

important epigenetic finding. Collaborators from the new NTP laboratory, EPA and CDC looked at the effect of drinking water exposures to perfluorooctanoic acid (PFOA) during gestation in mice, using levels similar to environmental levels. They discovered that those chronic low-dose exposures alter mammary gland growth and differentiation. NIEHS grantee David Peden from UNC, in collaboration with EPA, published a study on low-level ozone effects on lung function in healthy young adults, which found deleterious effects on lung function and inflammation at exposure levels below the current regulatory standard.

Turning to other institute news and highlights, Dr. Birnbaum recounted recent developments related to breast cancer research. The Interagency Breast Cancer and Environmental Research Coordinating Committee (IBCERCC) held its second meeting in May and is scheduled to meet again at NIEHS in late September. In July, a meeting was held to integrate the research efforts associated with the Breast Cancer and the Environment Research Program (BCERP), which was attended by more than 80 participants, and was designed to share information from the nine different research programs involved. Dr. Edison Liu, executive director of the Genome Institute of Singapore and president of the Human Genome Organisation, outlined a novel integrative genomics and systems biology approach to breast cancer during his 2010-2011 NIEHS Distinguished Lecture Series presentation on April 22. It was recently announced that Lui will be the new president and CEO of The Jackson Laboratory, succeeding Richard Woychik, who left that position in January to join NIEHS as Deputy Director. An educational video produced by the Bay Area Breast Cancer and the Environment Research Center, "Breast Biologues," has won an Award of Distinction in the 2011 Communicator Awards.

In recent developments related to public health leadership, Dr. Birnbaum noted the release of the 12th Report on Carcinogens and described some of the parameters involved in the listings and the new listings included in the report. Also, NIEHS is taking a leading role in the Global Alliance for Clean Cookstoves. There was an international workshop on this topic organized by a trans-NIH working group in Arlington, Virginia in May. The Partnerships of Environmental Public Health (PEPH) held a workshop in July on environmental health communication methods, research and training, and is to hold another session on engaging policy and decision makers in early September. In the NTP, the Office of Health Assessment and Translation has been established, succeeding CERHR, the Center for the Evaluation of Risks to Human Reproduction.

NIEHS continues its excellent record in environmental sustainability. The institute won an FY2010 Green Champions Award from the US Department of Health and Human Services (HHS) for its composting program. NIEHS has contributed to a new HHS Sustainability and Adaptation Policy Statement and to a new "State of the Practice" related to green chemistry, human health and environmental response. In July, NIEHS

sponsored an Institute of Medicine Roundtable on Global Health and Sustainable Development.

Training and education remain important areas of interest to the institute. Trainees from NIEHS, EPA and area universities attended the 2011 Biomedical Career Fair held in April. EPA and NIEHS co-led a Student Workshop on Climate Change in June. The five-day program featured more than 30 sessions related to environmentalism, health, ecology, sustainability, and communication. Fifty students attended this year's NIEHS Summer Intern Program. In career development, NIEHS continues its Leadership Training Programs. Also, Heather Henry and Kimberly Thigpen Tart of NIEHS have been selected to participate in the inaugural NIH Mid-Level Leadership Program in 2012. NIEHS post-doc Jeffrey Stumpf recently presented a Science Café program at a local restaurant. The Superfund Research Program has begun a series of webinars devoted to enhancing community engagement among its stakeholders.

NIEHS has maintained an active schedule of meetings and events, which Dr. Birnbaum summarized. The 2011 Rodbell Lecture was delivered June by Dr. Brigid L. M. Hogan, from the Department of Cell Biology at Duke University Medical Center. Dr. Birnbaum again alluded to the recent town hall meeting and the roundtable discussion attended by Rep. David Price. The Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) held its annual meeting in June. ICCVAM, the Interagency Coordinating Committee on the Validation of Alternative Methods, will hold a workshop on alternative methods for rabies vaccine potency testing in October. In July, 27 of the 42 grantees from the Outstanding New Environmental Scientist (ONES) Awards program attended the program's annual meeting at NIEHS. Also in July, a workshop on chemical mixtures was held by the National Research Council Standing Committee on the Use of Emerging Science for Environmental Health Decisions. The NIEHS Nanotechnology Consortium held its second official meeting in June at the University of Washington in Seattle. Dr. Zeldin recently participated in a meeting on Developmental Origins of Asthma: Strategies for Primary Prevention, held at NIH in Bethesda.

Upcoming events include a September meeting sponsored in part by NIEHS called Toxicogenomics Integrated with Environmental Sciences (TIES): The Biology and Bioinformatics behind Environmental and Toxicologic Influences. Also in September, there will be an important meeting on Advancing Research on Mixtures, focusing on advancing research methods and approaches.

Recent awards received by NIEHS staff members include recognition of Captain Lisa Rider of the NIEHS Environmental Autoimmunity Group in Bethesda as the Physician Researcher of the Year in the US Public Health Service. In June, NIH announced its approval for the promotion of NIEHS Principal Investigator Dr. Thomas Kunkel to the rank of NIH Distinguished Investigator, one of the highest honors NIH awards to its

scientists. Staff Scientist Grace Kissling, Ph.D., has been named a fellow of the American Statistical Association. NIEHS Chief of Staff Cmdr. Paul Jung, M.D., was honored on June 22 with the U.S. Public Health Service (USPHS) Asian Pacific American Officers' Committee RADM Samuel Lin Senior Officer Award at the 2011 Minority Officer Liaison Council (MOLC) awards ceremony in New Orleans in recognition of his work mentoring Asian-American physicians. The scientific manuscript mentioned earlier from the NIEHS group led by Serena Dudek, Ph.D., was singled out for commendation by the Faculty of 1000, a post-publication review group of thousands of experts worldwide who identify and evaluate the most important articles in biology and medical research publications. In June, Visiting Fellow Dr. Javier Revollo received the Presidential Poster Award at ENDO Expo 2011, the 93rd Annual Meeting of the Endocrine Society. NIEHS Superfund Research Program (SRP) founder and Director Bill Suk, Ph.D., was recognized by colleagues with the Adel Sarofim Award for Excellence in Combustion Research at the 12th International Congress on Combustion By-Products and Their Health Effects held in June at Zhejiang University in Hanzhou, China. NIEHS postdoctoral fellow Steven Roberts, Ph.D., won best poster recognition at the 2011 Gordon Research Conference on Genetic Toxicology, held in July in Barga, Italy.

Dr. LeMasters suggested to Dr. Birnbaum that it might be fruitful in the effort to replace the Clinical Director to contact each of the Centers supported by NIEHS, including their members. Dr. Birnbaum agreed that that was a good idea and might help to spread the word about the opportunity. She asked Council members to spread the word as well.

Dr. Lloyd asked if there was anything Council could do to help anticipate the passage of bills containing unfunded mandates affecting NIEHS. Dr. Birnbaum suggested that it would be useful for Council members to speak to their members of Congress about the benefits of NIEHS research funding, particularly if they are on appropriations committees. Dr. Winn added that it was important for Congress to be aware that environmental health sciences research can affect a wide variety of diseases and health outcomes, and that it is important that the peer review system not be circumvented by efforts to establish special committees or targeted research.

Dr. Lee wondered why the legislation on endocrine disruptors, which seems primarily regulatory in nature, was targeted at NIEHS, rather than EPA. Dr. Birnbaum explained that the legislation is not primarily regulatory, but focuses on research results that can have a direct regulatory impact. She added that a lack of effective action by EPA over the past several years may have contributed to that impetus as well. Dr. Lloyd asked whether the endocrine disruptors-mandated activity might eventually fall to NTP, similar to its carcinogens reporting. Dr. Birnbaum agreed that it could be a natural activity for the new NTP Office of Health Assessment and Translation to take on at some point. Dr.

Taylor said that someone must have thought NIEHS would do a better job with the activity, having put it into the unfunded mandate.

V. Strategic Plan Process

NIEHS Deputy Director Dr. Richard Woychik updated Council on the status of the institute's Strategic Planning Process, which he leads. He recapped the overall process, which will culminate in a new strategic plan for the institute to help determine the direction for the next five years.

His remarks focused on the Stakeholder Community Workshop, which was held in Research Triangle Park, July 12-14, 2011. Approximately 170 participants attended, who represented a broad-based cross-section of the environmental health sciences community. Under the modified Open Space Technology format, each participant was invited to share an idea, or multiple ideas, by posting a "sticky note" on the agenda board, which resulted in a total of 120 initial postings. That led to the formation of a total of 97 breakout sessions, each of which generated a 1-2 page report. The reports were posted and the topics were voted on and prioritized. Ultimately, 13 priority topics were identified, with others moved under the top vote-getters as subtopics. The final report detailing all of the raw results has been published on the Web.

Following the meeting, Dr. Woychik and Dr. Sheila Newton independently reviewed the 97 reports and developed 8 "overarching themes:"

- Basic Research on Human Health and Disease
- Exposure Science and the Exposome
- Translational Science: Linking Biological Pathways and Bridging the Gaps to Activities that Move toward Actual Health Outcomes
- Collaborative and Integrative Approaches for Conducting Research
- Data Management and Analysis
- Environmental Health Disparities, Environmental Justice, and Climate Change
- Training of the Environmental Health Science Workforce
- Communication and Outreach

Each overarching theme included summaries and subtopics that referenced the pertinent individual workshop reports.

The next major step in the process will be the Strategic Planning Workshop to be held October 13-14, 2011 at Research Triangle Park, which will include approximately 60 NIEHS and external participants. Outcomes from the meeting will be initial drafts of new mission and vision statements, as well as a compilation of strategic goals for the

institute. A draft of those outcomes will be published on the Web, and input will be encouraged.

Dr. Brody expressed her appreciation for the workshop, calling it “exciting and stimulating.” She suggested that the photo in one of Dr. Woychik’s slides illustrating the Translational Science theme be changed to reflect the prevention orientation of NIEHS. Dr. Woychik agreed that would be a good idea.

Dr. Taylor noted that it was good that NIEHS staff members were included in the July workshop, allowing them to communicate directly with external attendees.

Dr. Birnbaum expressed her appreciation to Dr. Woychik for his and his team’s efforts related to the strategic planning process.

Ms. Yeampierre wondered if there had been any discussion at the workshop about the projected changes in demographics in communities of color in waterfront areas, as related to the theme of environmental justice. Dr. Birnbaum said that the topic had not specifically been raised, but that the issue of community resiliency and how it can be fostered had been discussed. Ms. Yeampierre said that while it was good that community engagement had been considered, data collection in the affected areas, particularly regarding clustering of toxicants, would also be important.

Dr. Maddox asked about plans to disseminate the final Strategic Plan. Dr. Woychik replied that the mission, vision, and strategic goals will be published on the website and opened for public comment soon after the October meeting. Eventually, a draft strategic plan will be brought to Council in May 2012. Subsequently, the final plan as approved by Council will be published in *Environmental Health Perspectives*.

Dr. Lloyd noted that several of the topics would have overlapping areas of emphasis with other NIH institutes. He wondered whether coordination or synergism between NIEHS and other institutes regarding strategic plans might take place. Dr. Woychik replied that increased collaboration among ICs was one of the topics of discussion at the workshop, with NIEHS bringing the environmental perspective while other institutes would have more of a disease focus. He said it will be a topic of discussion at the upcoming workshop as well, so that NIEHS is not isolated in terms of its goals and plans. Dr. Birnbaum added that recently more and more ICs have begun to consider the environment as playing a role in their diseases, and that will encourage more opportunities for collaboration and integration. Dr. Woychik said “we’re taking this beyond lip service,” and that there have been specific contacts over the past several months that will enhance collaborations with other ICs.

Dr. Gasiewicz asked about other considerations that might affect the prioritization of the overarching themes. Dr. Woychik said that budgetary issues will certainly have an

impact, and that everything, obviously, cannot be done. When the realities of limited budgets are assessed, the impact on the institute's overall plans will be clarified.

VI. Report of the Executive Officer

In her first presentation to Council, the new NIEHS Executive Officer, Joellen Austin, briefed council members on her background and the role and organization of the Office of Management, which she leads.

She had been with NIH on the Bethesda campus for 22 years, most recently as Executive Officer of the National Institute of Neurological Disorders and Stroke. She started at NIEHS at the end of June. Although she had considerable experience in the standard executive officer role with NIH, she was attracted to the NIEHS executive officer position because it has several additional areas of responsibility, including campus security and operations.

Organizationally, the Office of Management reports to the Office of the Director. She serves as the Associate Director for Management, overseeing the functions of the Office of Management. She sees her role as Executive Officer, along with the staff of the Office of Management, as being in service to the entire institute. Within the Office of Management, the Financial Management Branch receives appropriations from Congress, and is subject to a variety of limitations and requirements about how funds are allocated. The Computer Technology Branch equips institute personnel with computers and software and ensures that they operate properly and remain up to date. The Administrative Management Branch provides help to institute scientists with a wide variety of administrative needs. The Office of Acquisitions has the authority to enter into contracts in support of the NIEHS mission, for items such as equipment, furniture, and research and development. The Administrative Services and Analysis Branch oversees the cafeteria, inventory of government property on campus, the supply store, administrative and management staff training, and risk management, among other duties. The Operations and Security Branch undertakes a variety of activities to provide a safe environment for employees, visitors and property. The Health and Safety Branch provides the programs that address chemical, biological, radiation and physical safety, hazardous waste management, occupational health, and health and safety training. Some staff functions are organized under the Deputy Executive Officer, including liaison with the US Environmental Protection Agency. She recognized the many contributions of Christopher Long, the Deputy Executive Officer.

As Executive Officer, Ms. Austin maintains liaison relationships with several other entities within NIH, including sitting on various committees, and helping to ensure that NIEHS interests are represented at the NIH level. She said that her number one job is to maintain responsible and excellent stewardship in support of the NIEHS

mission. “Sometimes that means saying no,” she said. “More often, that means finding a creative way to make something happen in support of our mission.” Her operational priorities include assessing and re-competing information technology, streamlining various processes, and planning implementation of ideas gleaned from the PULSE climate survey that was conducted last year.

VII. Report of the Director, DERT

DERT Director Dr. Gwen Collman updated Council on DERT developments and activities, beginning with staff changes. New arrivals include Dr. Molly Puente, a former Presidential Management Fellow, who has joined the Grants Management Branch as a Grants Specialist; Nicole Popovich, who has joined DERT as a Management Analyst in the Office of the Director; Angie Sanders, who has joined the Administrative Management Branch (AMB) as Lead Administrative Officer for DERT; and Mitsue Parish of the AMB, who has recently been assigned to DERT. Recent departures include Dr. Janet Cakir, Dr. Elizabeth Maull, Michelle Mayo, and Margarita Roque.

Recent NIEHS grantees honors and awards included the award given to the “Breast Biologues” video previously mentioned by Dr. Birnbaum. Also, grantee Dr. Patricia Hoyer of the University of Arizona received the 2011 Trainee Mentoring Award from the Society for the Study of Reproduction, and grantee Dr. Adam Spanier of Penn State was awarded the Michael Shannon Research Award and the Clinical Young Investigator Award from the Academic Pediatric Association.

Dr. Collman reported that NIH has issued a Request for Information (RFI) asking for input on the deliberations of the Advisory Committee to the NIH Director Working Group on the Future of Biomedical Research. The RFI was released August 17; responses were due by October 7. The committee was established to examine issues related to future planning and resources needed for the biomedical research workforce. It is gathering information from various sources, including the extramural community, to develop a model to help inform decisions about how to train the optimal number of people for the appropriate types of scientific positions. Dr. Collman listed several considerations for developing the model, such as balance between supply and demand, characteristics of Ph.D. training and clinical research training, and how to increase the attractiveness of biomedical research careers.

Dr. Collman described the NIH Common Fund, and its strategic planning process, which is currently underway. Created by NIH in 2004, the Common Fund supports exceptionally innovative programs that are inherently high-risk but have the potential for high payoff by catalyzing research across NIH and in the biomedical research community. They are typically transformative, cross-cutting, trans-NIH programs, developed and prioritized in collaboration by IC directors and NIH leadership. Dr.

Collman shared a list of selected current Common Fund programs, including several in which NIEHS has been involved, such as epigenomics, the Gulf oil spill, a knock-out mouse repository, metabolomics, and molecular libraries and imaging. A flow chart graphic illustrated the path to development of new ideas for Common Fund support, including two phases. In the first phase, external and internal input is gathered; in the second phase, ideas are refined and decisions are ultimately made, leading to the establishment of new Common Fund programs. She described the criteria for Common Fund programs, which must be transformative, synergistic, cross-cutting, and must involve broad benefit to public health. Whether a proposed program is truly transformative is assessed by a series of questions used by staff members as part of their evaluation process.

In May, the Common Fund Office sponsored a workshop called “Innovation Brainstorm: Transforming Discovery into Impact” in Potomac, Maryland, which was attended by exciting new junior investigators in their fields identified by each of the ICs. Several new ideas for potential support by the Common Fund next year were put forward. Also, ICs were asked this year to submit ideas developed by staff members that would meet the criteria for Common Fund programs. Dr. Collman showed the list of nearly 20 submitted ideas to illustrate the diversity of topics involved. Most pertinent to NIEHS is an idea developed in partnership by NIEHS, NICHD, and colleagues from several other institutes, *Developmental Origins of Health and Disease: Disease Prevention Across Generations*. The full list is available on the Common Fund website, <http://commonfund.nih.gov> and there is currently an opportunity for comments, which were due by September 14, 2011. She urged Council members to look at the ideas and share their comments.

Dr. Collman briefed Council about the NIH Blueprint for Neuroscience Research, which is a collaborative effort among the NIH Office of the Director and the 16 NIH ICs that support neuroscience research, including NIEHS. The goals of the program are to develop research tools, to create research resources shared by the entire neuroscience community, to train a new generation of cross-disciplinary neuroscientists, and to develop a cooperative framework for the ICs to plan and implement their neuroscience efforts. Organizationally, the IC directors are involved, including Dr. Birnbaum, who is often represented at the Blueprint meetings by Dr. Aubrey Miller or Dr. Woychik. There is a coordinating committee which is more at the staff level; NIEHS is represented by Dr. Cindy Lawler and Dr. Annette Kirshner. They and Dr. Kimberly Gray have been involved in several of the initiative working groups over the last few years. Dr. Collman cited several examples of Blueprint products that have emerged over the past several years, such as the NIH Toolbox for Assessment of Neurological and Behavioral Function, the Neuroscience Information Framework, the Gene Expression Nervous System Atlas, and the Neuroimaging Informatics Tools and Resources Clearinghouse.

Grand Challenge initiatives have included the Human Connectome Project, the Blueprint Neurotherapeutic Network, and the Grand Challenge on Pain RFAs.

NIEHS supports the Neuro Blueprint with a contribution of approximately \$600,000. This represents about 2% of Blueprint funding, which totals \$40 million, with the larger contributions coming from the ICs with much larger portfolios of neuroscience research. The NIEHS contribution is actually double what it has been in the past, due to growth in institute funding in this area, particularly focused on the impact of early life exposures on neurodevelopment. Dr. Collman said there is an effort underway to increase awareness of the program in the NIEHS grantee community, to encourage more investigators to apply. That will be accomplished with targeted emails to NIEHS neuroscience grantees and through publicity at relevant extramural meetings.

Ms. Hricko asked Dr. Collman whether the neurological and/or other health effects of noise had been considered by NIEHS. Dr. Birnbaum replied that noise is certainly one of many environmental stressors, but that it probably would not be at the top of the NIEHS list.

Dr. LeMasters suggested that the plan to target neuroscience grantees might be too narrow, in that there may be environmental health science (EHS) researchers with an interest in the Neuro Blueprint information who would not necessarily be primarily considered to be neuroscientists. She suggested that all NIEHS grantees should be alerted.

Dr. Lloyd asked whether any of the topics that arose in the Strategic Planning workshop identified topic areas that might come up for Common Fund initiatives or programs. Dr. Birnbaum replied that there might be some that could emerge from the 97 ideas that came up. She reiterated that the focus of the strategic planning is to identify high-level ideas and programs that should be the most important to NIEHS. Dr. Collman added that many of the themes and ideas discussed in the workshop were included in the proposal to the Common Fund that spawned the Developmental Origins initiative, and that if the proposal is successful, trans-NIH programs in several of those areas could be developed.

Dr. Maddox supported Dr. Collman's point that too often the outside constituency groups of individual ICs may not be fully aware of the institute's participation in particular trans-NIH initiatives such as the Common Fund or the Neuro Blueprint. She said that presenting such information to Council is one good way of spreading the word about such projects.

Dr. Woychik pointed out that once the new strategic plan is in place, it will help guide decisions about what NIEHS will put forward as potential Common Fund projects.

VIII. CSR Review of Toxicology and Environmental Health Grant Applications

Dr. Seymour “Sy” Garte, Director of the Division of Physiological and Pathological Sciences at the Council for Scientific Review (CSR) at NIH, updated Council on data he had collected and actions he had taken regarding peer review of toxicology and environmental health-related grant applications at CSR.

Dr. Garte explained that he had joined CSR two years ago, and that before that he was an environmental health science researcher. He was given the mission of working on the situation regarding toxicology and environmental health science (EHS) applications by CSR’s (then) Director Dr. Toni Scarpa, who recently retired from the position and has been replaced by Acting Director Dr. Richard Nakamura. There had been substantial concern in the community that review of toxicology and EHS applications was not being conducted well because they were being spread out across numerous study sections at CSR, particularly since the elimination in 2004 of the dedicated toxicology study sections when CSR was re-organized. This led to predominantly organ-specific study sections, and feelings in the community grew that their applications were not being appropriately addressed and were at a disadvantage.

In response to the situation, CSR initiated a trial Special Emphasis Panel (SEP) called Systemic Injury from Environmental Exposure (SIEE). The plan was for the SEP to be run for three funding rounds, and then the data from it would be reviewed and analyzed to assess its impact, and to determine whether it should become a chartered study section or be discontinued. By Dr. Garte’s arrival at CSR, the decision had already been made to discontinue it. He was asked to review the SIEE data and propose ideas about what to do about the ongoing situation, which the SIEE had not ameliorated.

To facilitate the analysis incorporating scores from two different systems, Dr. Garte worked out an Integrated Score Metric, ranging from 1-4, with a “fair average” score of 2.8 in a given study section. His retrospective data analysis confirmed that there in fact had been a problem with the review of toxicology and EHS applications. He found that in one round, toxicology and ES applications had been reviewed in 109 different chartered study sections and 178 different SEPs, for a total of 287 different panels. That alone led to the issue of whether the panels had the right expertise. Prior to re-organization of the study sections, the average score for those applications was 2.4. Following re-organization, the average score rose to 2.8 (i.e., a less favorable result). Dr. Garte noted that that was a significant shift. He also showed a graph of the toxicology application results, which depicted a sharply rising line from 2004 to 2008, prior to the establishment of the SIEE SEP.

He also looked at toxicology applications reviewed in SIEE over its three rounds, which totaled 125 investigators, and then looked at all of the 1,012 applications from those

investigators. Looking at the outcomes of those “toxicology applications,” from 2004-2009, he discovered that only about half of the applications were reviewed by the SIEE—52% in 2009, with the others reviewed by non-SIEE study sections. Less than half, 41%, were EHS—many were cancer-related, or distributed to other ICs. Dr. Garte showed a bar chart depicting the range of scores from that data, according to their distribution by study section. The SIEE study section was not one of the best in terms of its average scoring of toxicology applications. Several of the other study sections gave toxicology applications superior average scores. A few were lower than SIEE. Another bar chart showed that the 2009 SIEE was “pretty tough” compared to other study sections, with a higher average score than 2002-2004 study sections, 2004-2008 study sections, other 2009 study sections, and 2009 non-toxicology applications. The data showed that ultimately, the SEP was probably not helping the toxicology and EHS community as had been intended.

Concluding the introductory portion of his remarks, Dr. Garte summarized the main points thus far:

- SIEE reviewed only about half of all relevant applications
- Applications reviewed by SIEE had a less favorable outcome than those reviewed by most other SRGs (Scientific Review Groups, i.e., study sections)
- Outcome of review for toxicology and EHS applications was highly dependent on study section

As a potential solution, an approach called *cluster and cross-assign* was proposed, under which toxicology and EHS applications would be concentrated in four target study sections to create clusters, while maintaining the overall breadth of the study sections. Also, reviewers with expertise in toxicology and EHS would be recruited, who would also have expertise in other areas, allowing for integration and cross-assignment. The four study sections identified as targets for toxicology and EHS applications were:

- XNDA for digestive and multi-organ modeling and general toxicology
- III for immunotoxicology
- ICER for endocrine and reproductive toxicology
- LIRR for respiratory toxicology

The new CSR guidelines for the study sections now include toxicology so that applications including toxicology will naturally go to the targeted study sections. Also, reviewers and chairs with toxicology experience have been recruited.

Having taken those actions, the question was whether they worked. Did they have any effect? Dr. Garte did not have data from the current round of funding, but presented data from the previous round. More specifically, the questions at hand were:

- How many applications are being assigned to target study sections (clustered)?
- How well do these applications do?
- How do toxicology and EHS applications do in target study sections as compared to other study sections?

The data show that there is increased understanding in the community about where the applications should go, and there is an increase in applications to the target SRGs themselves. Post-SIEE data for SRG scores for toxicology applications clearly show that applications going to the target SRGs had significantly more favorable scores than those that went to non-target SRGs, indicating that they may be getting a fairer review in the target study sections. Scores of toxicology applications relative to controls over the years also clearly showed improvement since the institution of the clustering approach.

Trend data show that the SIEE helped the situation in terms of assignment and scoring, but post-SIEE, the implementation of the four target SRGs was superior, and scores were significantly better than applications that went to the non-target SRGs. “So I think there’s no question that the clustering and cross-assigning technique...has been helpful in terms of a fair and useful review of toxicology and EHS applications,” Dr. Garte said. The target SRG scores were also better than those from the SIEE.

In conclusion, Dr. Garte outlined CSR’s plans for the future in this area:

- Increase the flow of toxicology and EHS applications to the targeted study sections
- Continue the cycle of recruiting toxicology reviewers for the targeted study sections to meet the increased demand
- Consider additional (or different) target toxicology study sections for other areas
- Revisit the concept of an SEP devoted to EHS

Dr. Taylor asked Dr. Garte whether he sees this as a larger issue than just toxicology. Dr. Garte replied by sharing a list of “orphan application topics,” which all have advocates who raise the same sorts of issues raised by the toxicology community. The list includes topics such as sociocultural factors and bone density, circadian rhythms, sleep disorders, gastrointestinal epidemiology, and many more. He noted that if a study section is devoted to a certain field of science, it inherently guarantees a certain amount of funding for that field. He said one associated issue is the quality of the field of science, and noted that some applications may get a fundable score by a certain study section that would not be given a good score by another, simply because they are not as good. He said that issue does not apply to any of the orphan topics he had listed, or to toxicology. Quantity is another issue, in that some of the orphan topics just would not generate enough applications to warrant a targeted study section. There needs to be

60-100 applications per round to justify a study section, he added, or approximately a minimum of 180 applications per year.

Dr. Phan asked whether there was actually a need for the targeted study section approach, given that toxicology and EHS applications seemed to be treated roughly similarly by the other study sections in the past and by the SIEE. Dr. Garte reiterated the history of the issue, which emanated from perceived problems in the toxicology and EHS research communities, and agreed that some had argued that the SIEE had actually done a good job reviewing toxicology and EHS applications. He noted, however, that that analysis was not the basis for the decision to remove the SIEE.

Dr. Birnbaum thanked Dr. Garte for his efforts, noting that from her previous experience as part of the the leadership of the Society of Toxicology (SOT) and upon her assumption of the directorship of NIEHS, she had seen that this was a serious problem in the field. She said that Dr. Garte was the first CSR official who was willing to listen to concerns. She asked if perhaps more clustering is called for with some of the other areas, perhaps two more SRGs, and hopefully within some of the other CSR divisions. Dr. Garte replied that three of the four current targeted SRGs fell within his division due to his interest in addressing the issue, and that although there could be others, caution was warranted to avoid creating the original problem of too widespread targets for the applications. He noted that the change of leadership at CSR had allowed him to discuss the possibility of revisiting the concept of a SEP or eventually a chartered study section devoted to the field. He said that Dr. Nakamura had indicated that he was willing to listen to the idea. Dr. Birnbaum added that the breadth of EHS is a strength, and that a single SEP focused on EHS may not be adequate. Dr. Garte said that had been one of the problems with the SIEE, reiterating that only about half of the toxicology applications had gone to the SIEE. Dr. Birnbaum said that EHS is much more than toxicology, encompassing a wide range of other areas such as community-based participatory research and exposure assessment for example, and that the current efforts to change the situation at CSR seem to have focused on toxicology, while the other areas still have not had “a healthy home.” Dr. Garte strongly agreed.

Dr. Lloyd asked about the topic areas encompassed by the four targeted study sections, noting that most of them seemed to be animal-driven. He commented that obviously the NIEHS portfolio is much broader, and that the topic areas listed did not appear to cover much of that portfolio. Dr. Garte agreed, noting that he had done much human work himself, which had no home either. He said that the reason his presentation was focused on toxicology is because CSR had mainly been dealing with SOT representatives regarding the ongoing problems. He said that the entire spectrum of EHS would be incorporated into the process going forward, and that it would be important for all members of the community to make their opinions known to the new

CSR Acting Director, Dr. Nakamura, who has indicated a willingness to listen to input on these matters.

Dr. Birnbaum mentioned one area in particular, a growth area for NIH that is currently having a hard time—regulatory science. She said it may be good to consider a SEP for that area. She also noted that tobacco-related research is another growth area, with much new funding taking place. Dr. Garte agreed, particularly with the need for improvement in consideration of regulatory science grants. Dr. Birnbaum noted that this was an issue of interest to Dr. Collins at NIH.

Dr. Maddox noted that assignment to study section process takes place at NIH, and so it is critical to let the outside community know what the clustered study sections cover. Dr. Garte agreed about the importance of investigators being able to direct their applications to the appropriate study sections.

Dr. Gasiewicz said that NIEHS leadership needs to keep abreast of these issues and communicate effectively with the new CSR director, particularly during the strategic planning process, as a number of issues could emerge from that process that would not be adequately considered under the current CSR configuration. Dr. Birnbaum agreed that carrying on a dialogue with CSR would be exciting and important.

Dr. Heindel said that most of his applications go to the ICER study section, and that he has seen “a huge improvement” within the last year or so.

Dr. Birnbaum asked that a summary of the information Dr. Garte had presented be included in the NIEHS newsletter.

IX. Consideration of Grant Applications

This portion of the meeting was closed to the public in accordance with the provisions set forth in Section 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2).

X. Report of the Office of Communications

Ms. Christine Flowers, Director of the NIEHS/NTP Office of Communications and Public Liaison (OCPL), updated Council on activities and achievements. Her presentation was entitled, “Communicating Our Research.”

Media coverage of the institute has increased substantially. There were 6321 citations of NIEHS/NTP in the media in 2010. As of July 31, 2011, NIEHS/NTP had been cited in more than 3,500 news stories. Also, OCPL responded to more than 300 media requests during that period and arranged more than 150 interviews with NIEHS scientists. The NIEHS email news listserv now has more than 800 subscribers, and a

new effort to reach out to the local media has resulted in more than 70 subscribers to the listserv devoted to that effort.

Ms. Flowers highlighted several prominent examples of media coverage, including pieces in the *CBS Evening News* (on flame retardants in baby products), *Voice of America* (on climate change and allergies), and *NIH Medline Plus* (an entire issue devoted to environmental health).

Local media coverage has been beefed up considerably. “We think it’s important to remind our neighbors that we’re here and we’re part of this community,” said Flowers, also noting that it was important for NIEHS staff to see their accomplishments covered in the local press. She shared examples of local coverage, including outlets such as *Triangle Business Journal* and the *News and Observer*, Raleigh’s local newspaper.

OCPL has been very active in promoting NIEHS/NTP response efforts associated with the Gulf Oil spill. Activities have included the establishment of a trademark for the GuLF STUDY, webinars for public input on GuLF STUDY protocols, a press release on February 28 when the study was launched, and media tours in Alabama, Florida, Mississippi and Louisiana to increase recruitment, which included radio ads; television, radio and print interviews, and community meetings. A detailed website also includes information about the Deepwater Horizon Research Consortia grants, as well as fact sheets and talking points related to spill follow-up.

The *Environmental Factor* newsletter continues to be very popular, and is an excellent vehicle for promoting institute activities, such as the NTP Workshop on Diabetes and Obesity, which was held in January in Raleigh. The workshop also received considerable national news coverage. *Factor* also covered the Tox21 robot dedication in March in Maryland. That event also generated national press.

The June 10 release of the 12th Report on Carcinogens (RoC) was a major news event. OCPL initiated a highly coordinated communication plan aligned with the release, including fact sheets, a dedicated website, a media teleconference, and extensive news coverage. The five RoC fact sheets, one for each new chemical listed in the report, were downloaded more than 14,500 times in the first month following their release. The RoC dedicated website generated more than 16,000 pdf downloads within two hours of the report’s release. Within the first month after release, there were more than 49,000 visits to the site, 38,000 views of all web pages, and 45,800 pdf downloads of RoC profiles. There were 515 news stories written within the first month following the report’s release, and OCPL arranged 15 media interviews, including major media such as the *New York Times*, *Prevention Magazine*, the Associated Press, and more.

Ms. Flowers reported continued progress with the NIEHS website. The homepage is updated daily, just like a daily newspaper, and now includes more multimedia and social

media features. From January 1, 2011 through July 31, 2011, the site received more than 800,000 visits, with more than 2,000,000 pages viewed. The most visited topics have included pages devoted to bioethics, bisphenol A, electric and magnetic fields, environmental topics A to Z in Spanish, and jobs at NIEHS. The NIEHS Kids' Pages have been very popular (4 million hits per year), and a re-design of the sites will be rolled out in fall 2011.

OCPL is increasing use of social media, including activities such as Twitter feeds, a YouTube channel, a Flickr photostream, and more. Generally, those vehicles are used to communicate information about activities at the institute, to advertise for jobs, to recruit for clinical trials and studies, to announce items of interest, and to conduct outreach and education. Ms. Flowers described a growing library of NIEHS videos being shared on the NIEHS YouTube channel, and played two recent examples for Council. The recently established NIEHS Flickr page has made NIEHS images, photos and graphics more accessible and searchable. OCPL is currently evaluating other social media channels, including Facebook, widgets, and mobile apps.

The popularity of the *Environmental Factor* newsletter is growing—as of July 31, this year there had been more than 69,000 page views and nearly 1100 subscribers. Ms. Flowers recognized the outstanding mentoring that has been provided by Eddy Ball, the writer/editor of the newsletter, who has mentored 21 post-docs, scientists, and summer interns over the past three years, some of whom have gone on to get jobs in science writing.

OCPL also works to train scientists in the art of communication, by conducting media training sessions and news and web writing workshops for the scientific staff. On average, 20 scientists are trained each year.

OCPL provides communication services associated with several scientific conferences and exhibits annually. This year, the major event was the Society of Toxicology 50th anniversary annual meeting held in March in Washington, DC. OCPL conducted “Live at SOT,” a meeting-long series of real-time web posts, with 19 people contributing 81 posts. OCPL also produced a *Benchmarks in Toxicology* poster which documents the history of toxicology and commemorates the 50th annual meeting of the SOT. More than 5,000 copies of the poster have been distributed thus far.

OCPL has produced several new fact sheets, which are available on line, as well as a popular new pocket card with quick-reference facts about the institute for personnel to use in a variety of settings.

The office received 5 NIH Plain Language/Clear Communication Awards at a ceremony in May. Also, OCPL team members were recognized in August as part of the group who received an NIH Director's Award for their efforts related to the Gulf oil spill.

Ms. Flowers concluded her presentation by recognizing the members of the OCPL team and thanking them for their work.

Dr. Lloyd noted that there had been considerable attention in the press regarding the banning of formaldehyde in hair straightening products in many countries, and whether there had been any coordination with NTP and its listing of formaldehyde in the latest RoC. Dr. Birnbaum replied that both the CPSC and the FDA are both on the Executive Board of the NTP, and so were aware of the information in the report prior to its public release. Dr. Bucher added that the Occupational Safety and Health Administration (OSHA) has a web page dedicated to the problem mentioned by Dr. Lloyd. Ms. Flowers added that OCPL monitors press accounts and works to help ensure accuracy.

Dr. Lloyd asked whether the NIEHS P30 Centers had been solicited for input on the Kids' Page website. Ms. Flowers replied that OCPL has worked closely on the project with the Partnerships for Environmental Public Health, which pulls educational materials from grantees and centers, and the resources are incorporated as appropriate on a regular basis.

Ms. Witherspoon noted the progress that has been made by OCPL, including increasing visibility and outreach to students.

XI. Report from the Division of the National Toxicology Program

NTP Associate Director Dr. John Bucher updated Council on recent NTP activities.

In February, the Division of the NTP was established as a second intramural division within NIEHS, recognizing the unique mission of the NTP, its unique research approach, its unique training requirements and staff capabilities, and its unique place on the NIEHS organizational chart, which Dr. Bucher outlined for Council.

In March, it was announced at the SOT Annual Meeting that the Center for the Evaluation of Risks to Human Reproduction (CERHR) would be replaced by the newly established Office of Health Assessment and Translation (OHAT). This recognizes the expanded role of the office, which is grounded in reproduction and development assessments but also considers a broad range of human health effects. It is also designed to be a venue for integration and translation of data from new technologies and new methodologies for human health assessment.

Along with NIEHS colleagues, NTP had a major presence at the SOT 2011 Annual Meeting, with more than 100 staff presentations from the division, and an information session on the International Cooperation on Alternative Test Methods (ICATM). There was also a special session to roll out the Chemical Effects in Biological Systems (CEBS) database. ICATM also held a signing ceremony at SOT, officially welcoming

the Korean Center for the Validation of Alternative Methods (KoCVAM) to its ranks, joining centers from Canada, the US, the European Union, and Japan.

The ribbon-cutting for the new Tox21 robot was also held in March, at the NIH Chemical Genomics Center. Dr. Bucher recounted a timeline synopsis of the Tox21 program, which started in 2004. All of the Tox21 activities are focused on chemical probing of biological space. Phase II of the program is now underway. Dr. Bucher also described the assays that had been conducted in Phase I of Tox21, and showed data from the overall output of Phase I, during which more than 2800 compounds were screened.

Draft NTP Technical Reports were peer reviewed in April. They included reports on senna, combinations of AIDS therapeutics, acrylamide, and non-decolorized whole leaf extract aloe vera. Dr. Bucher illustrated the Technical Report conclusions for each substance.

As Dr. Birnbaum had mentioned, the 12th Report on Carcinogens (RoC) was released in June, as mandated by law. The RoC is cumulative, with each edition adding newly listed substances since the prior report. The RoC now has 240 listings, including 54 known human carcinogens and 186 substances reasonably anticipated to be human carcinogens. The RoC is not a regulatory document, but merely identifies hazards. Substances are evaluated using established criteria.

The NTP Board of Scientific Counselors (BSC) met April 13. They considered a modified one generational reproduction study design, evaluated new statistical methods, heard a report about nanomaterials exposure assessment efforts at NIOSH being supported by NTP, evaluated a concept on increased utilization of NTP resources to analyze chemicals in existing biospecimen repositories, and were briefed about a concept for an OHAT workshop on the potential health effects of excess folic acid intake.

The Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) met in June. The group evaluated an *in vitro* estrogen receptor transcriptional activation assay, was updated on NIH activities relevant to the ICCVAM five-year plan, discussed methods nominated for review, and heard reports on best practices workshops for chemically induced eye injuries and contact dermatitis held in January, as well as an upcoming workshop on alternative test methods to assess vaccine potency to be held in October.

Dr. Bucher described another workshop, *Advancing Research on Mixtures*, to be held September 26-27 in Chapel Hill, NC. It is being co-organized by DERT and DNTP. The workshop's goals are to identify and focus on key issues that present challenges in mixtures research, and to inform the development of an intramural and extramural strategy for mixtures research.

Dr. Brody asked about the outcome of the BSC's consideration of biospecimen analysis. Dr. Bucher said that the concept was discussed and tentatively approved, and that it could potentially be a very valuable activity, leveraging existing resources to advance prioritization of exposure analysis.

Dr. Lloyd noted that in Dr. Bucher's presentation of the qHTS Phase I Tox21 data, there appeared to be "a huge clustering" around cytochrome p450s. He wondered if that came as a surprise, or whether the compounds included could have been predicted to be strong inhibitors of a broad class of p450s. Dr. Bucher felt that with the NTP compounds, that would not be surprising, and that that would be seen with almost any cluster of Xenobiotic chemicals chosen for study.

Dr. Maddox asked whether NTP research with AZT and some of the other antiretrovirals had looked at carcinogenesis across generations, or birth defects. Dr. Bucher replied that there had been no transgenerational studies, except for one study many years ago of infants of mothers who had received AZT, who showed an increase in micronuclei in the blood.

XII. Report from DIR Board of Scientific Counselors

NIEHS Acting Scientific Director Dr. David Miller briefly reviewed the scope and organization of DIR for new Council members, noting that each branch and each investigator is reviewed by the NIEHS Board of Scientific Counselors (BSC) roughly every four years. Dr. Miller introduced Dr. Jack Keene of Duke University Medical Center, Chair of the BSC.

With a recent restructuring of the BSC membership, Dr. Keene listed the prior and current members. With the need to abide globally by NIH requirements, the BSC always includes an *ex officio* member from the NIH Office of Intramural Research, and that role is now being filled by Dr. Roland Owens, Assistant Director of that office. Another challenge faced by the BSC is to ensure inclusion of underrepresented groups such as women and minorities, representatives from diverse geographic areas, and members with diverse scientific backgrounds. He noted that part of his job is to lend continuity to the process, particularly when new members are added.

Dr. Keene outlined the board's recent and upcoming agenda:

- May 23-24, 2011: Review of the Laboratory of Molecular Carcinogenesis (LMC) and Leping Li of the Biostatistics Branch [COMPLETED]
- October 16-18, 2011: Review of the Laboratory of Respiratory Biology (LRB)
- March 18-20, 2012: Review of the Laboratory of Neurobiology (LN) and James Mason and Marilyn Diaz

- June 3-5, 2012: Review of the Laboratory of Structural Biology (LSB) and Xiaoling Li
- Fall 2012: Review of the Biostatistics Branch (BSB)

He related several outcomes for the BSC over the past year:

- Successful conversion to an all-electronic format for the BSC review process
- Use of BSC reviews for one promotion to tenure and dossier preparation for tenure review of another tenure-track investigator
- Some underperforming research efforts have been recommended for reduction in scope
- Two contract needs assessments were carried out
- Two new board members were added, and additional member recommendations will be considered by the new Scientific Director in the fall of 2011 and will be invited to join by Dr. Birnbaum

Dr. Keene noted that the BSC intramural review process differs significantly from the extramural grants review process. According to NIH Deputy Director for Intramural Research Dr. Michael Gottesman, it “evaluates scientists predominantly on the basis of accomplishments since the last review ... [it] should evaluate the overall research program of each investigator for its distinctive quality, impact, and long-term objectives.” Thus, the BSC evaluates scientists on the basis of previous work (2/3) and future proposed work (1/3). Also, investigators are rewarded for high risk/high impact more than conservative research. The BSC focuses on quality more than quantity of scientific progress, and encourages collaboration.

Dr. Keene reviewed the steps involved in the review process, noting that the success rate for continued funding far exceeds that of extramural investigators. He also related the categories used for reviews of individuals and programs: significance, approach, innovation, environment, support, investigator training, productivity, and mentoring. Those evaluations culminate in the board’s recommendations. The BSC uses scoring descriptors of Outstanding, Excellent, Very Good, Good, and Poor. Category scores may be split, for example, Outstanding/Excellent. Dr. Keene mentioned that most of the scores are in the Outstanding and Excellent range, that being “a sincere critical opinion.”

He listed the matters that the BSC wishes to advance:

- To emphasize the mission of NIEHS
- To recruit members of underrepresented American populations to BSC and to NIEHS
- To foster interdisciplinary research efforts and mentoring

- To reward the highest-quality research

He also related serious issues facing the BSC and the institute, including limited resources and budgetary issues, an aging senior staff and government rules of employment and retirement, and the fact that a plan of succession for each unit is needed, because it is not always possible to bring in an external senior leader. He felt that good progress has been made in the latter concept.

Dr. Taylor asked whether the NIEHS BSC reviews depart significantly or are in roughly the same format as those employed by other NIH ICs. Dr. Keene replied that they are very different, because the sizes of the institutes vary greatly, and because of the isolation of NIEHS due to its location away from Bethesda. He noted that the annual meeting of the BSC chairs, held in Bethesda, is designed to discuss Dr. Taylor's question, exploring the differences and how the BSCs can help each other.

XIII. Nicotine Acetylcholine Receptor Function in the Brain: Role in Synaptic Excitability, Plasticity, and Disease

Dr. Jerrold Yakel from the NIEHS Laboratory of Neurobiology presented a summary of his latest research results to Council. His group has used electrophysiological techniques and the newer optogenetic methods to look at the relationship between the timing of receptor channels turning on and off and the ability of neurons to make connections with other neurons. They are exploring the role of nicotinic receptors in the brain in cognitive function and disease. Results of their experiments have revealed the temporal precision of cholinergic functions, providing a mechanism to information processing in cholinergic-dependent higher cognitive functions and impairment by amyloid β .

XIV. African Integrative Genomics: Implications for Studies of Human Origins and Disease

Dr. Sarah Tishkoff of the University of Pennsylvania School of Medicine Department of Genetics and Biology (and a 2009 NIH Director's Pioneer Award recipient) presented a summary of her work to Council. She and her colleagues use integrative methods to investigate human genomic variation and its influence on traits of clinical and evolutionary interest. She is developing a systems biology approach to explore the interactive effects of genomic variation, gene expression, metabolism, and the environment on normal variable traits and disease susceptibility in ethnically diverse African populations. This work will produce fundamental insights into the genetic, epigenetic, and environmental factors influencing complex traits that play a role in health and disease and will expand our understanding of human evolutionary history.

XV. Adjournment

Dr. Birnbaum thanked Council for its efforts and officially adjourned the meeting.

The meeting was adjourned at 12:20pm on September 2, 2011.

CERTIFICATION:

Linda S. Birnbaum, PhD, DABT, ATS
Chairperson
National Advisory Environmental
Health Sciences Council

Gwen W. Collman, PhD
Executive Secretary
National Advisory Environmental
Health Sciences Council

Attachment:
Council Roster