

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

**MINUTES OF THE NATIONAL ADVISORY ENVIRONMENTAL HEALTH SCIENCES
COUNCIL**

February 19, 2008

The National Advisory Environmental Health Sciences Council was convened for its one hundred twenty-third regular meeting on February 19, 2008 at 8:33 a.m. in the Rall Building, Rodbell Auditorium, National Institute of Environmental Health Sciences, Research Triangle Park, NC. Dr. Samuel Wilson presided as Chair.

The meeting was open to the public on February 19, 2008 from 8.33 a.m. to 2:30 p.m. In accordance with the provisions of Public Law 92—463 the meeting was closed to the public from 2:30 p.m. to 4:00 p.m. for consideration of grant applications. Notice of the meeting was published in the *Federal Register*.

Members Present

Teresa Bowers, PhD
Christopher Bradfield, PhD
Hillary Carpenter, PhD
David Christiani, MD
Kathleen Dixon, PhD
John Essigmann, PhD
Joseph Graziano, PhD

Lisa Greenhill, MPA
Stefani Hines, MS
George Leikauf, PhD
David Losee, JD
Kenneth Ramos, PhD
Peter Spencer, PhD
Kevin Stephens, JD, MD
Altaf Wani, PhD

AD HOC Members

Richard Finnell PhD
Nsedu Obot Witherspoon

NIEHS Staff

Kathy Ahlmark
Janice B. Allen, PhD
Ralph Ball, PhD
David Balshaw, PhD
Linda Bass, PhD
Martha Barnes
Perry Blackshear, PhD
John Bucher, PhD
Gwen Collman, PhD
E. Anne Davis, PhD
Allen Dearry, PhD
Christie Drew, PhD
Dorothy Duke
Sally Eckert-Tilotta, PhD
Benigno Encarnacion
Mary Gant, PhD
Elliot Gilmore
Kimberly Gray, PhD
Thomas Hawkins
Jerrold Heindel, PhD

Marc Hollander
Stephanie Holmgren
Sharon Hrynkow, PhD
Michael Humble, PhD
Ethel Jackson, DDS
Laurie Johnson
Marian Johnson-Thompson, PhD
Annette Kirshner, PhD
Dennis Lang, PhD
Cindy Lawler, PhD
Robin Mackar
Joyce Martin, J.D.
William Martin, MD.
Carolyn Mason
J. Patrick Mastin, PhD
Elizabeth Maull, PhD
Kimberly McAllister, PhD
Rose Anne McGee
Elizabeth McNair
Scott Merkle
Sirkanth Nadadur, PhD

Teresa Nesbitt, PhD
Shelia Newton, PhD
Liam O'Fallon
Theodore Outwater
Michelle Owens
Jerry Phelps
Christopher Portier, PhD
Leslie Reinlib, PhD
Margarita Roque
John Schlep
Barbara Shane, PhD
Daniel Shaughnessy, PhD

Carol Shreffler, PhD
William Suk, PhD
Kristina Thayer, PhD
Ann Thompson
Claudia Thompson, PhD
Hugh Tilson, PhD
Sally Tinkle, PhD
Fred Tyson, PhD
Bennett Van Houten, PhD
Brenda Weis, PhD
Samuel Wilson, MD.
Marva Wood

Members of the Public Present

David Brown, Constella Group
Lindrey Cline, Court Reporting Services
Perry Kirkham, PhD, Purdue University
Christina Makarushka, Social and Scientific Systems, Inc.
Jennifer Sass, National Resource Defense Council
Anne Sassaman, PhD, Consultant
Mary Watson, Social and Scientific Systems, Inc.
Gerri Wolfe, Consultant

OPEN PORTION OF THE MEETING—February 19, 2008 —8:33 A.M.

I. CALL TO ORDER AND OPENING REMARKS

Dr. Samuel Wilson called the one hundred twenty-third regular meeting of the National Advisory Environmental Health Sciences Council to order. He opened the meeting by welcoming those in attendance. Council members and those individuals at the table were asked to introduce themselves and then Dr. Wilson asked NIEHS staff and guests to continue with the introductions.

Dr. Dennis Lang reminded Council members to sign their Conflict of Interest forms and to complete their travel vouchers expeditiously. He noted that Michelle Owens was available to Council members to help with any administrative or logistic matters.

II. REVIEW OF CONFIDENTIALITY AND CONFLICT OF INTEREST PROCEDURES

Dr. Dennis Lang discussed with Council confidentiality and conflict of interest procedures and read the requirements of the Government in the Sunshine Act and the Federal Advisory Committee Acts. All aspects of the meeting were open to the public except those concerned with review, discussion and evaluation of grant applications and related information.

III. CONSIDERATION OF MEETING MINUTES

The minutes of the September meeting were approved as written.

IV. FUTURE COUNCIL MEETING DATES

The following dates were confirmed:

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|----------------------|-------------------------|---------------------|
| May 13-14, 2008 | NIEHS (ONES Interviews) | Tuesday – Wednesday |
| May 29-30, 2008 | NIEHS | Thursday – Friday |
| September 9-10, 2008 | NIEHS | Tuesday – Wednesday |
| February 17-18, 2009 | NIEHS | Tuesday – Wednesday |

V. REPORT OF THE ACTING DIRECTOR – DR. SAMUEL WILSON

Dr. Wilson commenced his presentation by acknowledging Dr. Shelia Newton for composing the report Council received earlier.

Dr. Wilson introduced the theme of his report that would surface several times during the day's discussions. "The general theme of our work here at NIEHS is research excellence in pursuit of disease prevention and better Health. This statement is important in the sense of focusing and emphasizing the theme of research excellence. We need to keep that in mind. At NIEHS we address address "real world" human problems related to environmental exposures and environmental triggers in human disease."

He outlined what would be covered in his presentation; highlights and milestones, comments on noteworthy publications, appropriations, and interactions with the Center for Scientific Review (CSR) and the Society of Toxicology (SOT) Council regarding peer review of proposals assigned to NIEHS.

He interjected that the Office of Management Assessment (OMA) Report has not been completed and submitted; but is expected to be ready for dissemination by April 1, 2008. He announced that Dr. David Schwartz is leaving the NIH and has acquired a position at the National Jewish Medical and Research Center in Denver, Colorado.

Dr. Wilson briefed Council on some of the highlights and milestones since September 2007. Dr. Hugh Tilson was appointed as editor for the Environmental Health Perspectives (EHP) journal. Dr. Wilson acknowledged Dr. William Martin for his time and effort in administrative oversight for the journal during the transition period. A number of workshops and meetings were held: The Exposure Biology Program (within the GEI) has awarded a number of grants and had its first annual grantees meeting; the Interagency Coordination Committee on the Validation of Alternative Methods (ICCVAM) had its ten-year anniversary workshop; the Superfund Basic Research Program/Worker Education and Training Program (SBRP/WETP) had its twenty-year anniversary symposium; and the National Academy of Science /Institute of Medicine (NAS/IOM) had a symposium concerning the effects on health due to energy production. The Institute continues to co-lead in the Roadmap 1.5 Epigenomics Initiative and the initiative on engineered nanomaterials "health and safety research." Last week a press conference was held to announce a partnership between National Institute of Environmental Sciences/National Toxicology Program (NIEHS/NTP), National Human Genome Research Institute (NHGRI), and the Environmental Protection Agency (EPA) on a high-throughput screening collaboration.

Under Noteworthy Publications, Dr. Wilson highlighted approximately a dozen publications from the extramural community as well as the intramural program at NIEHS and the journals they were published in.

Dr. Wilson then commented on appropriations. He mentioned that the NIEHS budget for FY2008 represented a modest increase. The Superfund Basic Research Program budget decreased approximately 2% and the Work Education and Training Program budget remained relatively the same.

Dr. Wilson then illustrated the overall NIH budget from FY2003 to FY2008. He pointed out that the Biomedical Research and Development Price Index (BRDPI) is the index for inflation, and with factoring in such inflation the FY2003 to FY2008 budgets showed a loss in purchasing power equal to approximately 11%. He indicated NIEHS has been able to accommodate for the decrease in spending power by discontinuing certain "capacity-building" programs. However, by FY 2008 the capacity-building programs had ended naturally or had been eliminated; therefore, the Institute is currently under an extreme budget constraint.

Dr. Wilson updated Council on the next topic "Interaction with the Center for Scientific Review (CSR) and the Society of Toxicology (SOT) Council regarding peer review of proposals assigned to NIEHS."

In the year 2000, the NIH study sections were reorganized to answer complaints and concerns from the extramural community. However, many individuals in the NIEHS extramural community were of the opinion that the study sections were not reorganized with enough expertise to give an appropriate, complete and fair peer review to the toxicology and environmental health sciences proposals.

Recently the SOT Council appealed to the CSR-NIH to evaluate whether or not the toxicology and environmental health sciences applications are able to receive a fair and appropriate peer review. An evaluation was conducted by Dr. Toni Scarpa, Director of CSR, and his colleagues, to address the concerns emerging from lack of clustering of ES applications within the study sections.

Dr. Wilson gave details and explanations on the phenomenon of clustering in the review process. He pointed out, for example, that all of the proposals assigned to NIEHS (ES) do not end up in one study section. Instead, the proposals are spread over a large number of study sections, some that have very low numbers of ES applications relative to the total applications to be reviewed, and some that have higher representation. He explained the ES review outcomes for the low and high clustered study sections. Dr. Wilson indicated that the "low clustered" applications did not do as well as the "high clustered" applications. He also pointed out that new principal investigators did not do as well as senior principal investigators. But, in comparison, NIEHS new investigators did not do as well in either the high or low clustered study sections.

Dr. Wilson concluded his presentation by pointing out several ways suggested by CSR to promote better clustering of NIEHS applications, such as, better clustering in study sections within IRGs or assigning ES applications to fewer study sections. Also, CSR plans to form a Special Emphasis Panel as a pilot study. The panel would be called the Systemic Injury by Environmental Exposure (SIEE). The intent would be to evaluate this pilot, and if it is successful to form a working group to consider formation of a new chartered study section that would review certain ES applications.

Council Response and Discussion

Council member (Dr. Leikauf) mentioned his experience in being involved in the creation of the Lung Injury, Repair, and Remodeling (LIRR) study section. He pointed out that it takes

approximately two years for a study section to work effectively; thus any evaluations should be done after two years. He also advised not to take the applications out of the clusters and put them into the new study section, but look at the need, and the design of the study section that meets those needs.

Dr. Lang indicated that the period for the pilot SIEE is for one year (three cycles) and will continue, if necessary, until enough data are generated for an analysis. Therefore, an end date has not been firmly set.

Council member (Dr. Leikauf) made a comment concerning the data from high-throughput screening. He mentioned that it is very easy to collect data, but difficult to appropriately store and make the data available for analysis. Unless the data are stored in an organized way, they will be under utilized.

Dr. Wilson addressed and supported the concerns of Dr. Leikauf. He mentioned that the high-throughput screening data accumulated in the first phase of the collaboration will go into PubChem, which is a database that NHGRI is promoting in association with the high-throughput screening center. However, PubChem is not equipped to integrate all of the information that is already available in the NTP databases and the large amount of new data being generated through the various high-throughput screening efforts. Dr. Wilson acknowledged the inherent problems in amassing large amounts of data.

Council member (Ms. Hines) inquired if Council will be given a copy of the OMA Report and what will be involved in accessing that information.

Dr. Wilson informed Council that it is his understanding that they will be provided a copy of the OMA report.

Council member (Dr. Graziano) mentioned that the information provided on the clustering of applications within study sections and the establishment of a pilot SEP, SIEE, was good news.

Council member (Ms. Hines) queried, in reference to the EHP journal, will the Institute provide Council with an in depth update on the status of the EHP and the EHP contracts.

Dr. Wilson replied that the EHP budget is to be restored to its original level and the individual contract, with regard to the main vendor, is being negotiated. As soon as all the information is available Council will be given an update.

Council member (Dr. Spencer) inquired if the remarks about NIEHS focusing on research excellence and disease prevention, dealing with real world health problems associated with environmental factors, are consistent with the mission that was developed approximately two years ago and are there changes in that mission at this time.

Dr. Wilson replied that the research funded by the Institute is consistent with the mission statement. He pointed out that the fundamental theme is the emphasis on research and scientific excellence. In keeping with the mission of NIH, NIEHS will prioritize its research to gain knowledge that will have an impact on human health.

Council member (Dr. Spencer) noted that the comments of Dr. Wilson were similar to the NIH announcement, with regard to moving medical research from the curative to the preventive. Dr. Spencer remarked that he wondered how important this paradigm is for the future and for the mission of NIH and NIEHS and the commitment to public health.

Dr. Wilson commented that NIEHS, among all the institutes, has a very important role in prevention, and in the early triggers to disease as disease relates to environmental exposures. The Institute has consistently made that point over the years. As for emphasis on prevention, such work historically has not been an emphasis of NIH. However, an NIH emphasis on prevention is the case at the present time.

VI. COUNCIL DISCUSSION ITEMS – COUNCIL MEMBERS

Dr. Dennis Lang opened the discussion by providing an explanation as to the new item marked 'Council Discussions'. Council members had expressed a desire to become more involved in open discussions, and bringing items of interest to the Council. With that intention, Council members, would lead the discussion and inform us about particular topics and items of interest that are relevant to the Institute and the scientific community.

Dr. Lang pointed out that Council members were asked by e-mail for topics that would be of interest; there were no responses from Council members, perhaps, because this is a new process. In the absence of suggestions Dr. Lang suggested that it would be useful to have a general discussion about this agenda item, and how it could be used in the future and what procedures needed to be in place to make it productive.

Dr. Lang then asked if anyone wanted to begin the general discussion. He also pointed out that the Council meeting was being videotaped. This was done to make the discussions from Council more granular, identifiable, and transparent.

Council member (Ms. Hines) gave a brief background on why responses were not submitted for this Council meeting. She pointed out that there were submissions of questions from present Council members and questions that had been accumulated in the past. She noted, at this point in time there isn't a good mechanism to discuss and prioritize questions before coming to Council. She added that it could be disconcerting to bring everything to the table that occurred because some things are more meritorious and timely than others. Although there were questions and items which were tentatively suggested, how do you manage those questions and prioritize them in a responsible way?

Dr. Wilson responded that, at the last Council meeting, Ms. Hines had suggested creating some tools where the Institute could systematically get feedback from the community. The Institute can also get feedback from Council using the same general approach. In response to this suggestion there is now on the Institute's Home Web Page a category "Let us hear from you" or "Do you have comments?" This item is located on the right-hand side of the NIEHS' Web Page. Individuals can write their comments which the Institute tracks and pays attention. If any of them are appropriate for discussion at Council we can use the time allocated on the agenda for "Council Discussion Items" to discuss those items.

Council member (Dr. Leikauf) mentioned that comments from existing members pointed out that the discussions are truncated; many of the presentations are informational and not decision-making or are in the area of Council clearance of initiatives. He suggested that informational items be sent to Council members before the meeting and the presentations should be shorter.

He also stated that a list of approximately 25 questions of major concern by Council members has been circulating among members. Perhaps Council could submit them to Drs. Wilson and Lang and have them prioritized and discuss approximately five or so at each Council. Dr.

Leikauf suggested that the amount of time for presentations be only 15 minutes and Council discussion could also be only 15 minutes.

Dr. Wilson asked for other comments.

Council member (Mr. Losee) clarified that the “resounding silence” regarding lack of items of interest submitted may have been due to the fact that Council members have been communicating and collecting issue items for quite some time. The list is long and would possibly take at least a full day of Council. Mr. Losee had suggested that this be submitted as an agenda item for this Council, but Council members thought time would be better spent looking at procedural detail during this Council meeting. He then pointed out that it was not because of lack of interest or concern or items, it is a matter of how to approach the list.

Council member (Dr. Ramos) suggested that some time be set aside to decide what mechanism, with the help of Drs. Lang and Wilson, can be put in place to help Council bridge the communication gap.

Dr. Wilson responded that this would be an agenda item for the next Council meeting to discuss a structured way that this process could be exercised.

Dr. Ramos agreed with the suggestion.

Council member (Mr. Losee) informed Dr. Wilson that a number of the Council members suggested the following:

- 1) The Council meeting agenda follow the format of the Advisory Committee to the Director of NIH. In that format, there is equal time given for presentations and comment.
- 2) The Council minutes more accurately reflect the specific questions, and are carried forward in some formal way.
- 3) A period of time is allotted at Council for interaction with NIEHS staff.

Dr. Lang suggested that the Council members prioritize their list of items they would like to put forward for discussion in order that they can be addressed at the next Council meeting.

Council member (Ms. Hines) added an additional request to Mr. Losee’s third item. She requested that part of the time be allowed for Council to meet together in order to be able to prioritize the items by a direct dialogue with each other.

Dr. Lang pointed out that Federal Advisory Committee Act (FACA) require that Council meetings are advertised, open to the public, and with government employees present.

Council member (Dr. Essigmann) noted that the Council meetings are shorter than they have been in the recent past. One day and a half allotted for the Council meeting would give more time to address issues. He asked if this is a singularity or the pattern for the future.

Dr. Lang responded by noting that this is a singularity and is dictated by the number of presentations and information to present to Council.

Council member (Dr. Ramos) suggested that in laying the path for the future with regards to requests that have been made by Council; Council would not want to engage in a reactive mode

of questions and answers which would be counterproductive. The dialogue amongst Council and with the Institute should be strategic in nature; because the Council is here to help the Institute strategize and achieve its goals. It would be a waste of time and effort on everyone's part for us to engage in an exercise where points are given, prioritized and then we feel compelled to respond to those points. So at the next Council meeting when a mechanism is formulated as to how Council engages in dialogue, Council should keep in mind that strategy and not reaction is what we are seeking.

Dr. Lang noted that the NIH committee management officer will be presenting at the May Council to give the parameters on how Council should function.

Council Member (Mr. Losee) asked if the NIEHS Council is constituted and given a charge which is different than the other NIH Councils.

Dr. Lang responded that the overall objective and the way councils operate are the same, but the charters are somewhat different. All councils are constituted as FACA committees and need to operate under those requirements. Their main charge is to serve as the second level of review and to provide advice to the Institute. That advice is considered by the Institute in making decisions.

Dr. Wilson then introduced the new Associate Director, Sharon Hrynkow.

VII. REPORT OF THE ASSOCIATE DIRECTOR – DR. SHARON HRYNKOW

Dr. Sharon Hrynkow began her presentation by acknowledging and thanking the Council for their time and effort. She pointed out that she was new to NIEHS but not to NIH. She has been at NIH for 12 years, seven of those years as Deputy Director of the Fogarty International Center (FIC) and two years as Acting Director of FIC.

She explained that her endeavors at NIEHS will fall into three baskets. Items in the first basket will consist of advising Dr. Wilson and the senior team on best practices at NIH, based on her experience at Fogarty and on trans-NIH teams. Items in the second basket will deal with the challenges that persist due to the location of NIEHS and how we can strengthen NIEHS' presence of the NIH campus. Dr. Hrynkow will be enhancing and building upon the foundation which already exists. She will also be enhancing the visibility of NIEHS with groups such as the Global Health Council, the Council on Foundations, and the Pan American Health Organization (PAHO). With PAHO we are working to develop a curriculum for leadership and gender training for women working in Latin America in the Environmental Health Sciences. During March, which is Women's History Month, NIEHS will be dedicating the month to women scientists through lectures and awards. The next item will look at what the Institute is supporting in climate change and identify needs and opportunities. Third basket items will focus on autism. This will include looking at research at NIEHS and obtaining greater communication and connectivity with the autism community. The Institute is in the early stages of considering outreach opportunities and working more closely with autism groups we have previously worked with in the recent past.

Dr. Hrynkow closed her presentation by saying she was excited about being at NIEHS at this point in time and asked for questions.

Council Response and Discussion

Council member (Dr. Spencer) asked about the Council of Councils at NIH and whether the Institute has a representative on that Council.

Council member (Dr. Graziano) responded to Dr. Spencer's statement. Dr. Graziano pointed out that he attended the first meeting of the Council of Councils, which was a meeting to understand the role of the Council. There is a second meeting scheduled. When the NIEHS council convenes again Dr. Graziano should have more information to report.

Council member (Dr. Ramos) asked Dr. Hrynkow if she could give the timeline for the three issues she laid out during her presentation in order to have a sense of when to look for these activities coming forward.

Dr. Hrynkow responded that the World Health Organization will dedicate World Health Day on April 7. Climate change will be in that discussion. NIEHS wants to be sure that health is included in the discussion on climate change and that the Institute is prepared on what research might be supported under that umbrella. In the coming months, numbers and data should be available on what we are doing and we will be looking for input from other groups.

On the gender issue, discussions were started in December. PAHO Curriculum Development meeting will be in April in which the Institute has a pilot program with that effort. We hope to continue to bring together partners and support for this activity and re-launch the pilot program after April. However, the internal discussion on gender has not reached the same level of maturity as the climate change discussion due to the attention we have placed on climate change in the broader global health and global environmental health discussion.

The third issue, autism, has a large inter-agency coordinating committee which is currently developing strategy on research needs and opportunities. In the next few months the Institute will want to interface and have more dialogue with the community as the research agenda moves forward and becomes public and widely available.

All three of the above issues should reach a good level of maturity within six months.

VIII. REPORT OF THE ACTING DEPUTY DIRECTOR, NIEHS – DR. WILLIAM SUK

Dr. Suk began his presentation by highlighting the important components of his role as Acting Deputy Director which are enhancing communication, fostering scientific collaboration and expanding training. His presentation centered on two areas of interest for the Institute; the NIEHS Visualization Center, and the ongoing program in Global Environmental Health (GEH). The Visualization Center, at the Institute, is part of the Library and Informational Services Branch which is rapidly moving towards developing a digital library which will take advantage of new technologies in order to promote science for collaboration and enhance communication. The Visualization Center Components consist of two parts, a Viswall and an Access Grid (AG). The Viswall consist of a large screen display wall, multiple rear-mounted projectors and one seamless high definition (HD) 8' x 10' display which is linked to the an AG which is a state-of-the-art video conferencing center that allows for interactive and real time communication. This screen is linked to other AG sites around the world. The benefits are enhanced communication, discovery, and knowledge. It allows investigators to view data sets at high resolution. It enhances viewing of the Allen Brain Atlas, bioinformatics, comparative genomics, gene expression-disease relationships, epidemiology, molecular modeling, pathology slides, and

protein structures. It allows for a level of detail that is not presently available. Dr. Suk acknowledged the Library and Information Services Branch who are developing this tool.

The next part of the presentation dealt with the GEH program. During the past few years several items were developed. First, the NIEHS Strategic Plan in 2006 (Goal IV) is to improve and expand community-linked research. During the strategic planning activity there were discussions on developing a program in GEH and building capacity to pursue research in GEH. This is addressed in the Strategic plan (Goal VII) fostering the development of partnerships between the NIEHS, other NIH institutes, international research agencies, academia, industry, and community organizations to improve human health.

Since January 2007, a number of events have occurred. In San Francisco, a workshop was held to look at GEH. In May, a Concept Clearance document was presented for Council's approval looking at the broader issues of GEH. In September, there was a partnering meeting at NIH in Bethesda. All of these events are moving the Institute toward the vision it has for GEH: all vulnerable populations in every country and every community have the right to be protected against environmental threats to their health, and training is needed due to the critical shortage of researchers and clinicians trained in environmental health. Therefore, the NIEHS GEH program plans to enhance communication and direct knowledge, facilitate, and coordinate activities to meet scientific, public health, and disease burden outcomes.

Dr. Suk pointed out that at the last Council there was a presentation by Dr. Van Houten as to our investments in GEH. Over a three year period (2005 – 2007) the Institute using the criteria of scientific research and collaboration, outreach capacity, service to the community, as well as training, there are 57 projects in 35 countries in the extramural community and 31 projects in 12 countries intramurally. The Institute is supporting a total of 88 individual research projects in 47 countries. In some countries there are both intramural and extramural activities taking place. The investment for the extramural is approximately 30 million dollars.

Concerning training at NIEHS, approximately 100 international postdoctoral fellows are currently being trained. Approximately half of the fellows are from foreign countries. A data base is being developed to track these fellows. NIEHS also funds Fogarty International Center's International Training and Research Program in Environmental and Occupational Health (ITREOH). Also the institute has a supplemental program for ongoing research capacity in developing countries. Researchers who have an R01 from NIEHS can receive supplemental funding by collaborating with investigators in a developing country.

In the area of outreach and capacity building three items were mentioned: The Environmental Health Perspectives (EHP) journal, GEH Conference and meeting support, and the World Health Organization (WHO) International Program on Chemical Safety.

The EHP journal has a broad audience, open access, its contents are shared, and it has partnerships with a variety of journals. Specific portions of the journal are translated into Chinese, Portuguese, and Spanish.

There have been a number of GEH conferences and workshops in which their proceeding and meeting reports will help the Institute define research recommendations.

For the last 27 years NIEHS has had a cooperative agreement with the WHO International Program on chemical Safety.

Under Scientific Service, Dr. Suk mentioned that NIEHS scientists and staff are engaged in a variety of activities that impact GEH. The following individuals are serving on advisory panels, international scientific review panels, and policy committees: Dr. John Drake, President of the International Genetic Federation; Dr. Dori Germolec, Environmental Health Criteria Document on the contribution of environmental factors in auto immune disease, WHO Center for Autoimmunity, Bilthoven, Netherlands; Dr. Fred Miller, The International Myositis Collaboration Study Group; and Dr. Samuel Wilson, Scientific Advisory Board to the Radiation Effects Research Foundation, Hiroshima, Japan. These activities contribute to the international activities of the NIH.

Dr. Suk familiarized Council with the portal concept. The GEH portal will be an internet-based tool for communication and coordination of research, training, and public health efforts. It will provide a venue for communicating the outcomes and value of the Institute's GEH investment to the public. It will leverage the research being supported by connecting interested parties around the world who are looking at the same or similar problem. It will enhance visibility of funding mechanisms for international research and training programs. It will eventually provide a networking space including online collaboration tools and interactive research technologies to connect scientists around the world in real time.

Dr. Suk indicated that the overall future direction for the NIEHS GEH Program is to continue these ongoing efforts and recommit to existing global partnerships and establish new collaborative opportunities. With the goal of facilitating basic, fundamental research involving networked teams in global regions and fostering population-based research involving networked teams to address specific diseases.

So the overall idea is to bring interested parties together using a web-based approach. At the moment the Institute does not support this technology, but the technology does exist and networks already exist in specific regions dealing with asthma with an emphasis in children. The key is to bring these investigators together and to link them in a dynamic way in order to support the basic science and infrastructure research that needs to be done. This could also be done in an expanded way for all investigators in the environmental health sciences.

Dr. Suk concluded his presentation by stating he had discussed two areas, which use two distinctly different tools to bring people together for enhancing communication, fostering collaborations, and establishing and reestablishing NIEHS' presence in the environmental health sciences. He acknowledged and thanked the Environmental Health Program Working Group for their support.

Dr. Wilson asked for questions.

Council member (Dr. Dixon) asked whether there is any movement towards an NIH-wide policy to support extramural training for international trainees, since the intramural program is able to support international trainees.

Dr. Shreffler explained that the National Research Service Award authorizing legislation indicates that trainees have to be U. S. citizens or permanent residents. Therefore, the authorizing legislation or rule making would have to be changed before this could be done, it would have to go out for public comment.

Council member (Dr. Graziano) noted that the ITREOH program sponsored by the Fogarty International Center does allow support for foreign trainees.

Dr. Graziano mentioned that the January 2007 retreat prioritized indoor air pollution due to combustion and biomass burning as number one and arsenic as number two. According to the WHO Global Burden of Disease the third largest killer in Asia and the fourth in Africa is air pollution due to combustion and biomass. He speculated that the NIEHS portfolio on this topic is very small.

Dr. Suk acknowledged that NIEHS portfolio is very small in these areas.

Dr. Graziano encouraged an analysis that would look at that these areas for continued prioritization, concerning portfolio development.

Dr. Suk indicated data is available on the where research is being done globally on indoor air pollution and biomass burning. He would report back to Council with an update on the web-based tools, specifically to let Council look at the website, navigate, and query it. At this time Council could provide thoughts on the future directions for GEH.

IX. REPORT OF ACTING DIRECTOR, DERT – DR DENNIS LANG

Dr. Lang outlined the topics he would be presenting to Council: Extramural Funding Trends in 2007; Extramural Awards Made in 2007; Council Delegated Authorities; PubMed Central Requirements; Financial Conflict of Interest; and Council Participation – Formation of Work Groups.

The extramural funding trends in FY2007 were presented in three different pie charts. These pie charts laid out the Institute's extramural grants distribution from the previous year. The first showed the breakdown of extramural grants. Research Project Grants (RPGs) comprise the largest segment of the budget at 57.9%. The Small Business Initiative Program (SBIR) (2.9%) is an identified percentage of monies that are universally applied across the government to agencies that award research grants. The Superfund Basic Research Program (Superfund) (19.4%) is a separate appropriation. Additional distributions are Other Research (3.2%), Centers Program (11.6%); and Training (5.0%). The second pie chart without the inclusion of Superfund had a slightly different distribution. RPGs constituted 71.8% of the Institutes total expenditures; SBIRs (3.7%), Other Research (4.0%), Centers Program (14.4%); and Training (6.2%). The third pie chart gave a break down of how RPGs were distributed by mechanism.

Dr. Lang spoke about the NIH success rate from FY2001 – FY2007. He indicated there has been a steady decline in the success rate across NIH due to the flattening of the budget after FY2003. In spite of this, in FY2006, NIEHS' success rate was a little better than the NIH average and in FY2007 a little less.

Dr. Lang noted from FY2002 – FY2007 the average monies set aside at NIEHS for targeted solicitations (RFAs) were between 30% – 33% of the total budget. The actual dollars spent for solicited awards was \$36.8 million and for unsolicited awards \$57.7 million. He also indicated the success rate for the unsolicited applications is better than that for the solicited applications.

Dr. Lang asked for questions on this portion of the presentation.

Council member (Dr. Leikauf) mentioned unsolicited grant applications are able to have three attempts when applying for an award; thus, the success rate is after three attempts, whereas solicited grant applications have only one attempt in applying for an award.

His second comment dealt with a possible 10% reduction in spending due to inflation and the increased costs of grants; for that reason, the Institute needs to begin to look three years ahead on how the portfolio is going to be adjusted, what initiatives will remain, and what will be diminished.

Dr. Lang noted that in times of flat budgets, an active discussion is needed on what the portfolio boundaries and targets will be in the future. He suggested that this topic be one for a Council working group discussion.

Dr. Wilson responded that this is a critical point, especially if the President's budget request for FY2009 stands as presented. Therefore, there needs to be careful thought about the appropriate balance and emphasis for both the extramural and intramural programs.

Dr. Wilson pointed out that the 20% success rate is a target the Institute has tried to maintain for the past several years.

Dr. Lang agreed with Dr. Wilson's statement and underscored that this continues to be the case. He pointed out as the number of applications increases; it is going to be difficult to keep the success rate at 20% with the same amount of money.

Council member (Dr. Leikauf) indicated the success rate for all the RPG mechanisms is different than for just R01s; thus, he is requesting data on the success rate for the R01 applications. Also, he would like to know if more R01 applications are being submitted three times, because he believes this trend is increasing, but will level off.

Dr. Lang pointed out that program staff encourages extramural investigators to submit new applications (unsolicited) that incorporate suggestions made by the review committee during review of the solicited application.

Ms. Mary Gant asked, given the President's budget request for FY2009, what would be the possible success rate for non-RFAs.

Dr. Lang responded the success rate would be lower than this year.

He then preceded to the topic Council Delegated Authorities. He informed Council that the language for the Council Delegated Authorities has been changed. These changes can be found under staff actions number four, five, and thirteen, and under special review of grant applications item number nine. "Excluding consortium and fiscal and administrative (F&A) costs" is the new language that has been inserted into these actions.

A question regarding the meaning of the language was posed.

Ms. Duke explained that a designated ceiling cost on grant applications consist only of direct cost. Thus, this cost does not include consortium F&A indirect cost. To include indirect cost in the direct cost would put the grantee over any designated ceiling cost, thus penalizing the grantee when they are collaborating with other institutions.

A motion was requested for approval of the language "excluding consortium and F&A costs". The motion was approved and seconded with one abstention.

Dr. Lang brought to the attention of Council a NIH website, Office of Extramural Research (OER) Nexus. He mentioned several items that would be of interest to Council that can be

viewed at this website. The first concerns applicants who are members of a chartered study section; they will be able to submit their applications at any time. The second is an advisory committee on peer review, organized by Dr. Zerhouni. The overall goal is to reduce the workload for those submitting applications and for those who are reviewing them. There will be a series of pilot studies focusing on shortening the length of an application and having remote meetings.

Dr. Lang then updated Council on the new requirements for manuscript submission to PubMed Central. The new law states, "The Director of the National Institutes of Health (NIH) shall 'require' that all investigators funded by NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication. The publications are to be made publicly available no later than 12 months after the official date of publication, provided the NIH implements the public access policy in a manner consistent with copyright law."

Dr. Lang pointed out for FY2006 approximately 20% of the peer reviewed articles were published in PubMed Central. Consequently, the language has been changed from a 'request' of investigator to a 'requirement' of investigators. This will include new enforcement and monitoring. Compliance with Public Access is a condition of award whether it is a grant or contract. Beginning April 7, 2008, all articles arising from NIH funds must be submitted to PubMed Central upon acceptance for publication. Beginning May 25, 2008, anyone submitting an application, proposal or progress report must include the PubMed Central or NIH manuscript submission reference number when citing applicable articles that arise from their NIH funded research. Compliance will be enforced by NIH staff and colleagues who will be aware of investigators participation.

Council member (Dr. Leikauf) mentioned that this is not an easy process. It is the journal's editorial decision to publish the article. This may skew the process and it may under-represent the work being done by the environmental health community.

Dr. Lang mentioned that the Office of the Inspector General (OIG), over the past year, has been looking at conflict of interest statements from 50 institutions. The OIG came up with the following recommendations: 1) increase oversight of grantee institutions to ensure they are complying with Federal financial conflict of interest regulations; 2) require grantee institutions to provide details regarding the nature of financial conflicts of interest and how they are managed, reduced, or eliminated; and 3) require Institutes to forward to the OER all financial conflict of interest reports that they receive from grantee institutions and ensure that OER's conflict of interest data base contains information on all conflict of interest reports provided by grantee institutions. These recommendations will require the attention of the investigators and institutions to a more granular collection of conflict of interest information, a more granular dissemination on a standard report form to NIH of the data, and a more uniform way that the NIH Institutes apply the information to identify conflicts and participation by the extramural community.

Dr. Lang concluded his presentation with the topic, Council Participation – Formation of Working Groups. He updated the Council on the purpose of the Council Working Groups. The purpose is to engage Council members early in the process for workshop planning, initiative development, and to obtain their input in their areas of expertise and interest.

The NIEHS Council Committee consists of the following individuals: Drs. Lang (Chairperson), Collman, Hughes, Mastin, Suk, Thompson, and Tinkle. These individuals will determine which

topics are appropriate for Council participation. Council will nominate two members for each working group according to expertise, interest, and time available.

Dr. Lang pointed out there are sensitivities about which Council members are expected to be knowledgeable. Council members serve as special government employees, in addition to being extramural researchers and grantees, and the potential for conflict of interest exists. Confidentiality regarding the discussions and deliberations of the working group must be maintained. Some groups will just gather information; therefore, there will be few or no conflicts. Nevertheless, it should be underscored that too much information on new initiatives may preclude the Council member from applying for support under that initiative. Unofficial notification to the extramural community concerning an initiative will jeopardize its release. As the development of the initiative moves forward, participation from Council members will end. Normally the Council member of a working group will be the reviewer and discussant when the Concept Clearance is presented to Council.

The first Council working group is 'Partnerships in Environmental Public Health'. NIEHS staff consists of Dr. Collman, Mr. O'Fallon, Dr. Gray, Dr. Drew, Dr. Mastin, Ms. Anderson, Mr. Hughes, Dr. Nesbitt, Ms. Duke, Ms. Mason, Dr. Eckert-Tilotta, Mr. Phelps, Dr. Humble, Ms. Beard, Dr. Lawler, and Dr. Tyson. The two Council Members are Dr. Carpenter and Ms. Hines.

Dr. Lang asked for questions.

Council member (Ms. Greenhill) mentioned that a year and a half ago she was named to lead a Council group on minority researchers and development. After the initial discussions, nothing transpired. Her question is will this be revisited under this new format.

Dr. Wilson responded that the initiative is being looked at in the Office of the Director, NIEHS and if the budget permits, more concrete planning will be done.

Dr. Blackshear was introduced as the next speaker.

X. REPORT OF ACTING SCIENTIFIC DIRECTOR, DIR – DR PERRY BLACKSHEAR

Dr. Blackshear began with an outline of what he would be covering in his presentation to Council [Division of Intramural Research (DIR) Leadership Changes, NIEHS Science Awards Day, Fellows Award for Research Excellence (FARE) Awards, Top DIR Papers for 2007, and Board of Scientific Counselors (BSC) Reviews].

Dr. Blackshear updated Council on DIR leadership changes. Effective December 1, 2007, Darryl Zeldin, MD became the Acting Clinical Director. A brief biographic sketch was presented. Dr. Zeldin is a senior tenure-track investigator and holds joint appointments in the Department of Medicine at Duke University and Durham Veterans Administration Medical Center. Currently he is clinically active in pulmonary and critical care medicine. His research interests include the role of eicosanoids in lung and heart function, and indoor allergens and asthma pathogenesis.

The next topic presented was NIEHS Science Awards Day. This took place November 1, 2007. The following awards went to Dr. James W. Putney, Scientist of the Year; Dr. Stephanie A. Nick-McElhinny, Best Poster Presentation in Environmental Biology; Dr. Karina F. Rodriguez, Best Poster Presentation in Environmental Diseases and Medicine; Dr. Matthew T. Miller, Best Oral Presentation; and Dr. M. Garcia-Diaz, et al., Paper of the Year.

Dr. Blackshear acknowledge Dr. Joel O'Bramowitz for preparing the FARE awards report that was presented to Council. These travel awards were awarded to fifteen fellows for their research excellence.

Dr. Blackshear pointed out that each year the top papers from the intramural program are selected and submitted to NIH. This year there were 528 publications with 80 principal investigators from DIR. Seven papers were selected. The selected papers were, Muse GW, et al. RNA polymerase is poised for activation across the genome, *Nature genetics* 39: 1507–11, 2007; Henley DV, et al. Prepubertal gynecomastia linked to lavender and tea tree oils, *N Engl J Med* 356: 479–85, 2007; Moon AF, et al. Structural insight into the substrate specificity of DNA polymerase mu, *Nature Struct Mol Biol* 14: 45–53, 2007; Bushel PR, et al. Blood gene expression signatures predict exposure levels, *Proc Natl Acad Sci USA* 104:18211–6, 2007; Storici F, et al. RNA-templated DNA repair, *Nature* 447:338–41, 2007; Pursell ZF, et al. Yeast DNA polymerase epsilon participates in leading-strand DNA replication, *Science* 317: 127–30, 2007; and Prasad R, et al. HMGB1 is a cofactor in mammalian base excision repair, *Mol Cell* 27: 829–41, 2007.

This group of papers included clinical publications on prenatal stress (PNS) on exposure biology, blood gene expressions signatures that predict exposure levels, and DNA repair, which is a major interest of the DIR program.

Dr. Blackshear concluded with an update on the BSC reviews. The following laboratories were or will be reviewed. Laboratory of Respiratory Biology, December 2–4, 2007; Laboratory of Neurobiology, February 25–26, 2008; and the Laboratory of Structural Biology, July 22, 2008.

There were no comments or questions.

XI. REPORT OF THE ASSOCIATE, DIRECTOR – DR. BUCHER

Dr. Bucher's presented an update of the National Toxicology Program (NTP), focusing on toxicology in the 21st century. He began his presentation by displaying the cover of the NTP Center for Evaluation of Alternative Toxicological Methods – Interagency Coordination Committee on the Validation of Alternative Methods (NICEATM-ICCVAM) five-year plan, which was requested in the appropriation language for the last several years by Congress. This plan was delivered to Congress approximately one week ago and it was also presented at the Ten-Year Anniversary Symposium of the NICEATM-ICCVAM. The symposium was held on February 5, 2008 at the Consumer Product Safety Commission in Bethesda, Maryland. The program consisted of the presentation of the NICEATM-ICCVAM five-year plan. Speakers were Drs. Bern Schwetz and Dan Krewski. Dr. Schwetz gave an overview on the history of the development of alternative methods in toxicology testing and Dr. Krewski spoke about toxicology testing in the 21st century. The information presented was very informative for the ICCVAM programs. Other agenda items included "Future Directions in Test Method Development" which include National Institute of Environmental Health Sciences/National Toxicology Program, Food and Drug Administration, and Environmental Protection Agency and a panel which discussed the "Way Forward for ICCVAM and its Stakeholders".

Dr. Bucher mentioned that the two National Research Council (NRC) reports were published last year: *Toxicity Testing In the 21st Century, a Vision and a Strategy, and Applications of Toxicogenomic Technologies to Predictive Toxicology and Risk Assessment*. Together these documents deal with the implications of the emerging technologies in producing massive

amounts of information from high-throughput screening and the “omic” technologies. Challenges were mentioned in these documents, e.g., database issues.

He pointed out in the report; *Toxicity Testing in the 21st Century, a Vision and a Strategy*, a number of areas were articulated that had been outlined in the NTP Roadmap (2004). These essential elements of the NTP Roadmap were further evaluating and refining the use of non-mammalian animal models in toxicology testing; developing high-throughput capabilities for assessing mechanistic targets *in vitro*, and creating analytic capabilities to integrate diverse types of toxicology information to add value and understanding.

Dr. Bucher highlighted one of the ways NTP is implementing the NTP Roadmap in regards to the development of alternative assays. NTP has an in-house *C. elegans* screening core that is looking to develop automated methods to measure toxicity in *C. elegans* with regard to developmental and neurological toxicants. This work is in its early stages, but the goal is to create or obtain green fluorescent protein (GFP)-based, stress-responsive transgenic *C. elegans*. NTP is also looking to develop the capabilities of doing microarray analysis to evaluate a subset of chemicals, and adapting methods for high-throughput analysis to assess toxicological responses in *C. elegans* in which each gene has been inactivated by using RNA interference.

With regards to high-throughput screening, the NTP Roadmap includes a major initiative to develop a high-throughput screening program with three goals: to identify mechanisms of action; develop predictive models for *in vivo* biological response; and prioritize substances for further in-depth toxicological evaluations.

NTP has done this through partnering with the NIH Molecular Libraries Initiative (MLI), specifically in 2005 with the NIH Chemical Genomics Center (NCGC). NTP is working to identify batteries of cell-based and biochemical assays to probe toxicity pathways which are a concept which is articulated in great detail in the NRC report, *Toxicity Testing In the 21st Century, a Vision and a Strategy*. This partnership supplied chemicals, assays and financial support to the MLI for developing tools to link data generated from these assays with data that are produced and housed in NTP’s toxicology testing program. , The current focus of this testing effort is to probe critical pathways in immune function and cancer.

Dr. Bucher reported that some of the early results from the partnership with MLI that have been published in the *Environmental Health Perspectives* in 2007. The study was basically a proof of principle study in which 1353 compounds were tested for cytotoxicity in 13 different human and rodent cell lines. The patterns were reproducible. Some chemicals were uniformly toxic across all 13 cell lines. Some were cell-type specific and some were not consistent in cells of similar tissue origin from rodents and humans. The paper showed it was technically feasible to run large series of compounds through multiple assays using a 15-point-dose response curve; the data provided some challenges in the interpretation, and there will be a great deal of complexity involved in the computation methods required to sort through this kind of information.

As recommended in the NRC Toxicology in the 21st Century Symposium, NTP has signed a Memorandum of Understanding on High-Throughput Screening, Toxicity Pathway Profiling and Biological Interpretation of Findings with the National Toxicology Program/National Institute of Environmental Health Sciences, NIH Chemical Genomics Center/National Human Genome Research Institute, and the Office of Research and Development /Environmental Protection Agency.

He pointed out that a paper (*Transforming Environmental Health Protection*) was recently published in *Science*. The three partners laid out the research goals and plans for transforming toxicology in the 21st century.

In closing, Dr. Bucher foresees the expectations of the NTP continuing to refine traditional methods and develop new ones to provide basic toxicology information for public health protection. All the new methods that NTP develops and old methods that NTP continues to refine must continue to incorporate mechanistic information and exposure response information. The new methods must be predictive of toxicity to humans, animals, and the environment. They must take into consideration life stage susceptibility and genetic susceptibilities. The results from the data rich techniques; genomics, proteomics, and high-throughput screening must be reconciled with existing testing information for conceptual validation. If these new assays are generating information that is reasonable and fits within scientific expectations, at that point the approaches need to be formally validated in coordination with regulatory agencies, so these new methods can be used and incorporated into regulatory science.

Dr. Bucher asked for questions.

Council Response and Discussion

Council member (Dr. Dixon) asked for the rationale for choosing the organism *C. elegans* rather than the zebrafish or *Drosophila*.

Dr. Bucher responded there are a couple reasons for the choice. First, Dr. John Friedman who was working with NTP earlier to develop the technology now heads the *C. elegans* testing core at NIEHS and this was a choice of convenience. Second, work is currently being done on the zebrafish as part of the EPA ToxCast program. Third, NTP has not explored *Drosophila*. The testing core being developed in-house is looking at developing the capabilities of looking at yeast as another alternative.

Council member (Dr. Spencer) pointed out it was mentioned earlier that neurotoxicity would be addressed with regards to *C. elegans*. How is NTP approaching this and are large numbers of positive controls being run through the system to understand what the biological signatures are that might relate man to *C. elegans*?

Dr. Bucher responded that the first aspect of this is to look at developing assay systems that are reproducible, at the moment there are difficulties in that regard. On the other hand NTP is running a large number of known neurotoxicants through this system and looking at aspects of how they are affecting reproduction, movement, feeding behaviors, and other things of that nature. Progress has been limited insofar as looking at specific outcomes that would reflect neurological effects.

Council member (Dr. Leikauf) mentioned the report from Toxicogenomic Panel suggested little progress would be made if this project was done piecemeal and large amounts of resources would be utilized with very little accomplishment. Therefore, a comprehensive database needs to be developed.

Dr. Bucher responded that both the NCGC and the EPA have computational capabilities. NTP is taking advantage of the EPA Computational Toxicology Center and they are putting together tools to extract this type of data. NTP recognizes complexities and requirements to take this effort forward are greater than any of the individual agencies can accomplish on its own.

In addressing the genomic databases NTP has put together an internal committee that is evaluating the output of the Toxicogenomic report and is beginning to put together some response that will hopefully be able to provide some coordinated institutional responses.

Dr. Wilson pointed out that NTP is willing to respond to the suggestions and advice given in the Toxicogenomic report, but at the present time resources are limited. But, NTP will move forward in terms of conceptualizing ways to respond. Nevertheless, there is agreement that some suggestions are not quite as resource-intensive, so there is a possibility of moving forward on those.

Council member (Dr. Essigmann) reiterated the point that there will be limited success in creating reproducible model systems unless there is computationally an effective way to extrapolate the data.

Council member (Dr. Ramos) asked when reference is made to computational toxicology collaboration, how is Chemical Effects in Biological Systems (CEBS) going to be integrated into the process.

Dr. Bucher indicated that the individuals who are looking at developing the computational tools in the CompTox Program were also involved in the development of the CEBS database. The integration of the two databases is already in progress.

Council member (Dr. Bradfield) asked if the data files could be downloaded and individuals can download the tab-limited sets so they can utilize their own software.

Dr. Bucher indicated that this was the goal and he believed this could be done.

With no more comments or questions Dr. Gray was introduced as the next speaker.

XII. CONCEPT CLEARANCE

CHILDREN'S ENVIRONMENTAL HEALTH CENTERS – DR. KIMBERLEY GRAY

Dr. Gray introduced herself and colleagues, Drs. Annette Kirshner and Cindy Lawler, who are also involved in directing the Children's Environmental Health Centers (Children's Centers).

Dr. Gray informed Council she was presenting the Children's Centers Concept for their approval. She mentioned that over the past ten years there have been four announcements for funding opportunities sponsored by the United States Environmental Protection Agency (USEPA) and National Institute of Environmental Health Sciences (NIEHS). Eight Children's Centers are currently being funded by NIEHS and EPA and one additional center at Duke University is funded by EPA alone.

Dr. Gray gave a brief update on the activities concerning the Children's Centers. In December 2006, NIEHS Council convened a working group to evaluate the use of the program project mechanism to facilitate children's environmental health research. This report was presented to NIEHS June 2007 Council by Dr. Krewski, Chair of the working group. In this report, several opportunities to enhance the effectiveness of the program were discussed and presented.

In conjunction with this evaluation, NIEHS sponsored and hosted a workshop to develop new strategies for research, exposure and effects monitoring, and intervention and prevention in the Children's Centers. This workshop presented two case studies that demonstrated successful

implementation of evidence based prevention strategies that identified links between environmental exposure and disease in children. The second day focused on applying the lessons learned from the lead and asthma research to two new emerging areas of research in children's health: metabolic syndrome and Attention Deficient and Hyperactivity Disorder. The barriers and challenges were identified and new approaches and partnerships were proposed.

In the summer of 2007, EPA established a working group comprised of selected members of their Children's Health Protection Advisory Committee and the Office of Research and Development's Board of Scientific Counselors to assess the Children's Centers program's effectiveness in translating research results that are informative in making public health decisions. The committee recommended continued emphasis on community-based participatory research and the Community Outreach Translation Centers but noted a need for supplemental funding for program enhancements with focus on evaluation and risk communication.

In October 2007, EPA hosted a workshop on Children's Environmental Health: Discover, Treat, Prevent, and Prepare held in Washington DC. This workshop brought together expertise of the Pediatric Environmental Health Specialty Units of North America and the Children's Environmental Health Centers to explore the latest research findings and their practical application in community settings. This meeting was sponsored by the United States Environmental Protection Agency Office of Research and Development, the Office of Children's Health Protection, the Agency for Toxic Substances and Disease Registry, the National Institute of Environmental Health Sciences, and the Association of Occupational and Environmental Clinics in recognition of the ten years of federal effort to protect children's environmental health. This workshop was a good opportunity for the agencies and researchers to reflect on past accomplishments, the current progress, and to formulate a vision for the future of children's environmental health.

Following the October 2007 workshop, NIEHS convened a meeting which included program and review staff from USEPA, ATSDR, Centers for Disease Control (CDC), and the National Center for Birth Defects and Developmental Disabilities. The purpose of the meeting was to stimulate and support the focus on children's environmental health that would be responsive to the mission of the participating agencies and encourage partnership and participation from the CDC.

Dr. Gray outlined the Children's Center Program goals, which are to incorporate new, emerging areas of science, strengthen basic science, continue emphasis of dissemination and translation, enhance training opportunities, and to existing and develop new partnerships with communities to enhance the effectiveness of the research and to facilitate the translation of research into policy and practice.

In the reissue of the Children's Center Program, several essential elements were identified that would enhance the success of the program. These elements include (1) active participation of a clinical pediatric specialist as an integral member of the research and outreach team to ensure the science under investigation will translate to clinical practice and impact public health; (2) training opportunities; and (3) the inclusion and participation of communities affected by environmentally induced diseases under study. This Concept is responsive to the mission of both the NIEHS and the USEPA and will ultimately have a measureable effect on alleviating the burden of childhood disease related to environmental exposures.

Each Center must include an interdisciplinary team of investigators to produce a synergistic research environment incorporating all of the essential elements to accelerate the understanding of the environmental threats to children and the translation of that knowledge to clinical practice and to improve public health.

Maximum flexibility will be given to investigative teams to determine the scientific approach and specific Center structure best suited to meet the goals of their proposed Center.

Once the Centers are established, possible supplemental funding opportunities to enhance collaborations among Centers and/or with outside investigators to take advantage of unique scientific findings and resources that would complement or extend Center activities will be explored.

Program staff will work closely with other federal partners to assure that the network of Children's Centers researchers are integrated into other larger complementary ongoing efforts such as the Clinical Training Science Awards, National Children's Study, and the Pediatric Environmental Specialty Health Units.

Program representatives will create a model for data and biospecimen sharing that will encourage the development of new discoveries and provide better data for health policy and action, while retaining the strengths of the original program whose roots are deeply grounded in community, training and public health.

In closing, Dr. Gray acknowledged those individuals who played a key role in the preparation of the Concept. She then introduced Drs. Ramos and Carpenter as the reviewers for this Concept.

Dr. Ramos was gratified to see that the recommendations from the evaluation of the Children's Centers were included in the Concept. He also pointed out that the essential elements, the leveraging for supplemental funding, and the added emphasis on the quality of the science are all appropriate within the new structuring of the Children's Centers. Dr. Ramos commented that the high expectations for the program should also have the appropriate dollars for adequate funding; otherwise this could be a problem for Children's Centers that are currently funded.

Dr. Carpenter agreed totally with Dr. Ramos' assessment of the Concept and had nothing further to add.

Council Response and Discussion

Council member (Dr. Carpenter) inquired if there had been any feedback from the re-competing Centers, who were ultimately not funded, on the positive and negative aspects of the program.

Dr. Collman responded that with the requirements and restrictions of the original program, and also requiring the community-based participatory component, investigators had to make difficult choices about resources. When the Centers were peer-reviewed it became apparent that some of the better programs in the basic sciences didn't have the available resources to do population-based research or vice versa. The major lessons learned were that the program must be flexible and let the investigators decide where to put their resources and efforts, as long as they implement the essential elements.

Council member (Dr. Carpenter) emphasized the need for a strong community-based component.

Dr. Collman responded that the community-based-component can be implemented in many different ways. She pointed out that there can be problems and adverse outcomes when the Centers are dictated to.

Council member (Dr. Carpenter) expressed concern if this might also be the case for the clinical component where there is a tremendous shortage of clinicians trained in environmental health sciences.

Dr. Gray responded that the clinician does not need to be trained in environmental health science, but provide some oversight that the research being conducted in the Centers has some implication for clinical or public health. For example, a Center could be all basic science, but would have a clinician to make sure the research is going in the right direction.

Council member (Dr. Carpenter) remarked that what was missing was the idea of intervention and prevention strategies which are an essential part of public health and environmental health and are not necessarily a part of clinical medicine.

Dr. Collman responded that the first iteration had a very strong focus on intervention and prevention, but the studies were not of the highest quality because the funds available per Center did not provide for a well-designed intervention study. Therefore, we are leaving the design to the investigators to put together the components in a way that promotes the best-quality science.

Council member (Dr. Carpenter) asked if there are plans to collaborate with the National Children's Study.

Dr. Gray stated they would be able to do some parallel work when they get their ancillary studies done, but the National Children's Study is just beginning their feasibility study this summer.

Dr. Graziano pointed out that the RFA for the Children's Center would be announced in March 2008 with a receipt date of September. When looking at the funding cycle for the existing seven Centers, would there be a discontinuation of funding?

Dr. Gray replied that the seven Centers will end September 31, 2008, and we are in a discussion of what the fate will be. Some of the Centers have acquired funding through R01s and some have very large carry-overs. We will be monitoring what the Center's needs are during that period and what we can do to help sustain the Centers.

Council member (Dr. Graziano) remarked that it would be a shame to have a gap in funding for those Centers that have performed successfully.

Dr. Gray stated that we are looking at time lines to try to avoid a gap in funding for those Centers.

Council member (Dr. Christiani) asked about the autism Centers within the Children's program.

Dr. Gray answered that there is currently one autism Center at University of California, Davis. It is in its second year funding and has three more years of support.

Council member (Ms. Hines) inquired if there were plans to track the composition of the Centers and if they were potentially all basic science or community-based participatory Centers or vice versa how would this be addressed.

Dr. Gray replied the Centers portfolio would be addressed through program balance.

With no more comments or questions Dr. Gray asked for a motion to approve the Concept Clearance. A motion was made for approval with a second. The motion carried unanimously

XIII. DISCUSSION OF REPORTS

Dr. Lang informed Council that this portion of the meeting was set aside to discuss any of the reports that were given during the open session.

Council member (Dr. Leikauf) asked for a clear definition of public health. He pointed out that public health is being defined in a number of ways and with limited resources not much can be accomplished with a million dollars.

Dr. Wilson indicated this item would come under the definition of the current and future “Environmental Public Health” portfolio, emphasizing both the breadth of the current portfolio and where the future emphasis areas will be. He pointed out this subject is a dialogue that is just beginning, will be actively pursued for several months, and will include Council members in the discussion. For that reason a more specific answer can not be given at this time.

Council member (Mr. Losee) inquired about the web format database of the first responders of Katrina and 9/11. He indicated the materials presented in the databases were excellent and if this information was made available to other communities that might have similar events if engaged in a problem with natural disasters or terrorists.

Mr. Hughes pointed out that the Institute would like to have the capacity to identify environmental and occupational health problems instantaneously, characterize the risk for responders and then be able to have the capacity in the longer term to monitor and survey individuals who have been exposed. NIEHS is trying to make this happen, but as yet, it has not. He pointed out it is unfortunate that public health and research information is not being conveyed when decisions are being made.

Dr. Wilson remarked that there were lessons learned from 9/11 that were incorporated into the response to Katrina. One of the things done was the development of a website, essentially overnight. This capability was possible because the Institute had a critical mass of researchers within the Centers and Superfund programs; in addition, grantees at the University of California at San Diego had access to resources at a National Science Foundation Super Computing Center that allowed the Institute to put information together and develop the portal very quickly. He stressed that it is far more effective to have systems in place, than to have to develop them, almost instantaneously. The issue being raised (by Mr. Hughes) is the sustainability of capabilities such as this.

Council member (Dr. Essigmann) commented that a key issue is where the Institute will focus. Emphasis should be placed on doing things well and not being too broad.

Dr. Wilson followed up on the earlier comment of Dr. Leikauf’s concerning public health. Dr. Wilson pointed out that NIEHS has investments across a wide spectrum, from policy research,

to translational research and hazard identification, to fundamental basic research in areas such as structural biology, etc. Dr. Wilson indicated “environmental public health” is a theme with a lot of potential to identify important information gaps where there is a health burden, areas where there is insufficient information to understand an efficient course toward intervention. Addressing this type of challenge is the kind of basic, strategic thinking role and communications role the Institute is able to take part in. At this time, the Institute is essentially a research funding organization, yet the Institute has opportunities and responsibilities in translating the information emerging from the research investments to public health impact. The Institute has a broad mandate to conduct and support the highest quality research and then to see it translated to benefit the public health.

Council member (Dr. Leikauf) responded to Dr. Wilson’s remarks by pointing out that agencies such as EPA and CDC are not chartered to do science, but NIH is. Thus, he would like to see public health driven by a theory that can be tested, evaluated, and judged, and not just a description of an idea. Consequently, he would like a clear definition of public health and a refining of the mission.

Council member (Dr. Stephens) emphasized that the intersection between science and public health is very important. The role is to obtain objective evidence to show how science and technology interface, especially when it comes to environmental concerns. The public health component should be defined and how the Institute will participate should be very clear.

The open portion of the meeting was adjourned at 2:30 p.m.

CLOSED PORTION OF THE MEETING – February 19, 2008 – 2:30 p.m.

XIX. Consideration of Grant Applications

This portion of the meeting was closed to the public in accordance with the determination that it was concerned with matters exempt from mandatory disclosure under Sections 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 regulations concerning conflict of interest were reviewed. Council members were reminded that materials furnished for review purposes and discussion during the closed portions of the meeting are considered privileged information. All Council members present signed a statement certifying that they did not participate in the discussion of, or vote on, an application from any organization, institution, or any part of a university system, of which they are an employee, consultant, officer, director or trustee, or in which they have a financial interest. Institutions or organizations which have multi-campus institution waivers, or are specifically designated as separate organizations under 18 U.S.C. 208(a), are exempt from this provision.

XXI. ADJOURNMENT OF THE NAEHS COUNCIL

The meeting was adjourned at 4:00 p.m. on February 19, 2008.

CERTIFICATION

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

Samuel Wilson, MD
Acting Chairperson
National Advisory Environmental
Health Sciences Council

Dennis Lang, PhD
Acting Executive Secretary
National Advisory Environmental
Health Sciences Council

Attachment:
Council Roster