

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

**MINUTES OF THE ONE HUNDRED FORTY-THIRD MEETING OF THE
NATIONAL ADVISORY ENVIRONMENTAL HEALTH SCIENCES COUNCIL**

September 9-10, 2014

The National Advisory Environmental Health Sciences Council convened its one hundred forty-third regular meeting on September 9-10, 2014 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 9, 2014 from 8:30 a.m. to 5:00 p.m. and on September 10, 2014 from 8:30 a.m. to 11:30 a.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 10, 2014 from 8:30 a.m. to 11:30 a.m. for consideration of grant applications. Notice of the meeting was published in the *Federal Register*.

Council Members Present

Marie-Francoise Chesselet, MD, PhD
Vivian Cheung, MD
Jeanne Conry, MD
Lisa Conti, DVM (by telephone)
David Eaton, PhD
Kevin Elliot, PhD
Kenneth Fasman, PhD
Andrew Feinberg, PhD
Tomás Guilarte, PhD
Norbert Kaminski, PhD
Randall Kramer, PhD
Linda McCauley, PhD, RN
Donna Mendrick, PhD (*ex officio*)
Marie Lynn Miranda, PhD
Edward Postlethwait, PhD
Viola Waghiyi
Deborah Winn, PhD (*ex officio*)
Elizabeth Yeampierre, JD

NIEHS Staff

Kathy Ahlmark
Janice Allen, PhD
Beth Anderson
Joellen Austin
John Balbus, MD
Joe Balintfy
David Balshaw, PhD
Martha Barnes
Linda Bass, PhD
Sharon Beard
Linda Birnbaum, PhD
Wanda Boggs
John Bucher, PhD
Danielle Carlin, PhD
Natasha Catlin, PhD
Lisa Chadwick, PhD
Pamela Clark
Jennifer Collins
Gwen Collman, PhD
Yuxia Cui, PhD
Christina Drew, PhD
Lisa Edwards
Benny Encarnacion
Sue Fenton
Symma Finn, PhD
Mary Gant
Barbara Gittleman
Astrid Haugen
Michelle Heacock, PhD
Jerry Heindel, PhD
Maile Henson, PhD
Georgia Hinkley, PhD
Jon Hollander, PhD
Michael Humble, PhD
Nina Jaitly, MD
Laurie Johnson
Bonnie Joubert, PhD
Annette Kirshner, PhD
Cindy Lawler, PhD
Alfonso Latoni, PhD
Kelly Lenox
Robin Mackar
J. Patrick Mastin, PhD
Kim McAllister, PhD
Steven McCaw

Liz McNair
David Malarkey, DVM, PhD
Kirsten Mease
Aubrey Miller, MD, MPH
Dan Morgan, PhD
Sri Nadadur, PhD
Sheila Newton, PhD
Liam O'Fallon
Katie Pelch, PhD
Jerry Phelps
Nicole Popovich
Molly Puente
Scott Redman
Les Reinlib, PhD
John Schelp
Thad Schug, PhD
Kevin Selenich
Wynonah Sessoms
Daniel Shaughnessy, PhD
Carol Shreffler, PhD
Robin Stanley, PhD
William A. Suk, PhD, MPH
Ian Thomas
Claudia Thompson, PhD
Sally Eckert-Tilotta, PhD
Frederick Tyson, PhD
Michelle Victolino
Leroy Worth, PhD
Rick Woychik, PhD
Darryl Zeldin, MD

Members of the Public Present

Megan Avakian, MDB, Inc.
Bruce Blumberg, PhD, University of California, Irvine
Jada Brooks, PhD, UNC
Ernie Hood, Bridport Services, LLC
Pia MacDonald, SSS
Jessica Richardson, UC-Davis
Chris Wahlburg, PCRM

I. Call To Order and Opening Remarks

NIEHS/NTP Director and Council Chairman ~~Dr.~~ Dr. Linda Birnbaum welcomed attendees and called the meeting to order. She asked all present in the room to introduce themselves, which they did. She mentioned that Council member Dr. Lisa Conti would be attending by telephone and that Council members Dr. Howard Hu and Dr. Kim Boekelheide and *ex officio* members Dr. Jennifer Orme-Zavaleta and Dr. Kelley Brix would not be in attendance. She also noted that the proceedings were being webcast.

II. Review of Confidentiality and Conflict of Interest

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

III. Consideration of May 2014 Meeting Minutes

Approval of the May 2014 minutes was moved and seconded, and Council voted unanimously to approve the minutes. Dr. Collman 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 Institute developments since the May 2014 Council meeting.

She introduced Dr. Robin Stanley, the first new tenure-track investigator in the Division of Intramural Research in more than four years. She recognized outgoing Council members Kim Boekelheide, Marie-Francoise Chesselet, and Elizabeth Yeampierre and thanked them for their service.

She noted that there is still no budget passed by Congress, and that the expectation is that there will soon be a Continuing Resolution that will carry the government's needs through mid-December. In terms of the potential NIEHS appropriation, she pointed out that the President's request for FY 2015 is essentially flat compared to FY 2014.

In her legislative report, Dr. Birnbaum described several recent Congressional hearings and briefings. She described the status of relevant pending legislation of interest to NIEHS, none of which is expected to pass in the near future.

Turning to science advances, she briefly summarized several recent publications by NIEHS/NTP personnel or grantees. She also described recent publications from DERT, DNTP and DIR researchers, including collaborations fitting the "One NIEHS" concept.

Dr. Birnbaum related several recent items of NIEHS news and highlights, including new technologies fostered by NIEHS, an SRP-EPA course on passive sampling devices, a new Tox21 study on bioactivity of chemicals in human cells, and a new website for the Agricultural Health Study. She announced the funding of two new centers – the Center for Urban Responses to Environmental Stressors in Michigan, and the Center for Translational Environmental Health Research in Texas. She also updated Council on recent NTP activities, including several concept clearances and National Academy of Sciences validation of Report on Carcinogens calls on formaldehyde and styrene.

She described recent distinguished visitors to NIEHS: Professor Dr. Her Royal Highness Chulabhorn Mahidol of Thailand, and Dr. David Murray, head of the Office of Prevention in the NIH Director's Office, who leads the NIH/FDA tobacco research program. She went over several recent meetings and events with NIEHS participation, along with a rundown of upcoming meetings and events of NIEHS interest or sponsorship.

Dr. Birnbaum related several awards and recognitions recently gained by NIEHS personnel and grantees, including her receipt of a U.S. Surgeon General's Commendation Medal awarded by the U.S. Public Health Service, several NIEHS/NTP recipients of NIH Director's Awards, and several fellows who won NIH FARE awards.

Dr. Feinberg commented on how NIH often does not receive the appropriate public credit for the projects it has funded, particularly at the local level. Dr. Birnbaum praised Dr. Collins for his efforts to get the word out on the NIH level. She noted that part of that has been to more closely coordinate messaging efforts, including branding. She said that sometimes grantees will put out materials about studies without crediting the funding institution. She added that she does make a concerted effort to get out in the community, participating in community forums across the country. Dr. Feinberg suggested that investigators should be required to give community-based talks about what they do. Dr. Birnbaum said that all of the NIEHS centers programs are required to have a community core.

Dr. Miranda said that NIH and NIEHS should reach out more to the scientific journals to ensure that NIH and NIEHS are properly credited. Ms. Mackar noted that NIEHS works with grantees to make sure that they include reference NIEHS in their press releases. Dr. Birnbaum said that the institute does quite a bit of outreach in that area.

V. Report of the Director, DERT

Dr. Collman briefed the council on recent activities and developments within DERT. Her presentation focused largely on the new NIH Genomic Data Sharing Policy, the new R35 grant mechanism, and how recent DERT activities have promoted and advanced the 11 goals of the NIEHS Strategic Plan.

The new NIH Genomic Data Sharing Policy sets expectations that ensure the broad and responsible sharing of genomic data. Dr. Collman noted that the new policy follows on efforts that have been in place at NIH for some years encouraging sharing of data, in an effort to make data publicly available in a timely manner from the research activities that it funds. With the production of larger volumes of genomic data from studies funded by NIH, due to recent technological advances, a new policy is required to expand NIH data-sharing expectations while continuing to protect human genomic data. The Genomic Data Sharing (GDS) policy extends and replaces the Genome-Wide Associations Studies (GWAS) data sharing policy, and applies to all NIH-funded research that generates large-scale human or non-human genomic data, as well as the use of those data for subsequent research. The new policy takes effect for competing grant applications submitted for the January 25, 2015 receipt date, for FY 2016 funding. It incorporates new data submission and release expectations. Genomic data sharing plans will be included in grant applications, but peer reviewers' comments on the plans will not be factored into scores. If an award is funded, the genomic data sharing plan will be reviewed and approved by the Program Officer and referenced as a term and condition of the award.

Dr. Kaminski asked where are the repositories to which investigators are asked to submit. Dr. Collman said that the National Library of Medicine hosts the dbGaP database, and that several others that can be accessed through the genomic policy website.

Dr. Eaton asked whether there are clear guidelines about confidentiality issues related to data submissions, particularly given HIPAA. Dr. Collman said that the types and sharing availability of the data collected should be described in the data sharing plans. She noted that Data Use Agreements will serve as safeguards against improper use of shared data. Dr. Feinberg asked if the Data Use Agreements include publication restrictions. Dr. Collman said that situations specific to a laboratory should be described in data sharing plans, with particular attention paid to privacy issues.

Dr. Cheung asked how to deal with privacy issues in terms of exposure. Dr. Collman said that is a concern, and described some of the strategies used by various investigators to protect privacy of data, as well as some new strategies that have emerged. Dr. Cheung said it seemed like a problem that is impossible to solve, in that some data are very difficult or impossible to de-identify. Dr. Collman agreed, and said that in some situations there may be compelling reasons for not sharing data. Dr. Winn said that in the case of human data, the depositing institution must run its plan through its IRB, which will take into account consent issues and potential risks to individuals and populations.

Dr. Elliott asked how the genomic data sharing policy would compare with policies applicable to other sorts of data. Dr. Collman replied that NIH has focused on genetic and genomic data in terms of policy, but investigators are encouraged to share all types of data when appropriate.

Dr. Collman continued her presentation with information about the new R35 funding mechanism, which is a new approach to funding research by outstanding investigators. The award is designed to provide sustained and flexible support to experienced investigators, providing them with more freedom to perform research that breaks new ground or extends previous discoveries in new directions. NIH ICs could use the R35 to support areas that are underrepresented in their research portfolio, that are of particular importance to the institute's mission, or for research projects that require more than 5 years to complete. The award period can be up to 8 years, with direct costs up to \$750,000 per year. The PI's effort is expected to be at least 50%. Dr. Collman described the elements of the application, review criteria, and post-award management and reporting requirements. ICs wishing to use the R35 activity code will initially become part of a pilot study being conducted by NIH.

Dr. Chesselet noted that the R35 is very different from the MERIT Award. She said that it would fund projects that would be long by their nature and would require more time, and it would provide flexibility to researchers to go in different directions unexpected at the time of application. She asked how those two very different types of extended funding were combined into one program. Dr. Collman said the mechanism was created with many different kinds of science in mind, and that each institute could use it to meet the various needs of its community.

Dr. Kramer asked about trade-offs, as in how the funding of R35s might result in reductions in other areas of the extramural portfolio. Dr. Collman acknowledged that that question was the "elephant in the room," in that there clearly would be an impact with larger commitments for longer periods of time. She noted that it would be challenging to have enough of the R35 grants to satisfy the community while still being able to accomplish the institute's other research funding goals.

Dr. McCauley asked whether the "safety net" Dr. Collman had mentioned referred to protecting the science in a particular field or to protecting the time and efforts of the scientist by providing longer-term funding. Dr. Collman said that the working group she had participated in was quite concerned about the stewardship of the dollars involved. She noted that the issue of the safety of the science was important, but that it was still an open question as to how that should be assessed as the long-term grant progresses.

Dr. Eaton felt that the R35 concept would increase efficiency and innovation, which comes at the expense of the number of grants that could be funded. He asked if there had been any retroactive assessment of the impact of such a mechanism if it had been in place ten years ago. Dr. Collman said no such analysis had been conducted, but that it was a good idea.

Dr. Feinberg, relating some of his own experiences, felt that the R35 would be a mechanism to ensure that worthy projects that may not score highly in a study section but were the products of experienced investigators could be funded. Dr. Collman noted that the award can be renewed, with no maximum number of awards over time.

Dr. Miranda asked if there was just a single set of numbers in the program, i.e. the \$750,000 and 50% effort. Dr. Collman said that they exist as overall general guidelines.

Dr. Fasman added his support for the program. He suggested that early on, the program should focus on aspects of environmental health sciences where NIEHS wishes to foster innovative thinking, as part of a strategy to overcome the increasing conservatism of study sections.

Dr. Postlethwait suggested that it should be clarified how the R35 applications would be reviewed. He asked if there would be a specific R35 RFA. Dr. Collman said there would, and that it would be reviewed by a Special Emphasis Panel run by NIEHS.

Dr. Birnbaum thanked Council for its input, noting that the program is modeled after the Howard Hughes Medical Investigator program and the NIEHS intramural program. She asked for further input from Council members following the meeting.

Dr. Collman continued her presentation with the third section of her talk, outlining DERT activities during the past year that promote and advance each of the 11 strategic plan goals. She related several specific activities for each of the goals, including funding announcements, workshops, lecture series (e.g., the Keystone Science Lecture Series), webinars, research conference grants, professional conference participation, and other internal and external communications and engagement efforts. She noted that such activities are key to successful research translation and improving public health.

VI. NIH Budget Process (Budget 101)

Scott Redman and Laurie Johnson from the NIEHS Financial Management Branch provided Council with an overview of the NIH budget process.

Mr. Redman described the budget process calendar, which consists of three phases that overlap over the course of succeeding fiscal years: formulation, presentation, and execution. He outlined the appropriation process for FY 2015, showing how it progresses from its initial formulation phase in March 2013, through the presentation

phase in Congress, to final appropriation by the President in October 2014. He provided a more detailed timeline of the steps involved in the formulation and presentation phases.

Ms. Johnson noted that the new fiscal year begins October 1. In the ideal world, that would involve an appropriation, but the more likely scenario is a Continuing Resolution through December 2014. She provided details about the execution phase of the budget process, which begins in early October and runs through the end of the fiscal year, followed by collection and reporting of official data for the preceding year. She described the history of NIEHS appropriations, and showed data on how NIEHS spends its money and how its expenditures compare to those of NIH overall.

Dr. Eaton asked about the intramural program's relative percentage of the budget if NTP was subtracted. Ms. Johnson said that the largest portion of the NTP budget is contracts, and that its intramural program is relatively small compared with the rest of the institute. Dr. Birnbaum noted that given NIEHS's location, many elements have to be provided here that are included and shared at the main NIH campus, such as Security and the Clinical Research Unit.

VII. Bronchiolitis Obliterans and Artificial Butter Flavoring

Dr. Bucher introduced Dr. Dan Morgan from the Respiratory Toxicology Group in the NTP Laboratories, who has studied artificial butter flavoring and its relationship with the devastating, irreversible respiratory ailment called bronchiolitis obliterans (BO), which has been seen in workers in industries where butter flavoring is used or made.

Diacetyl is the major volatile component of artificial butter flavoring. It was deemed "generally recognized as safe" as a food component, but when several workers in a microwave popcorn packaging facility were diagnosed with BO, the toxicity of inhaled diacetyl vapors became a concern. Little is known about BO pathogenesis, as research has previously been limited due to the lack of an animal model. The Respiratory Toxicology Group has developed an animal model of chemical-induced BO, and is using the model to investigate BO pathogenesis. The group has also characterized inhalation toxicity of diacetyl vapors, and has obtained inhalation toxicity data for regulatory agencies. Future studies will include continued analysis of microarray data, identification of pathways leading to airway fibrosis, identification of key targets in those pathways, and evaluation of potential pharmacological treatments.

Dr. Eaton asked what is known about the isomer composition of commercial 2,3-hexandione, a potential diacetyl substitute. Dr. Morgan said that the flavorings are food-grade products. Dr. Eaton noted that it would be of concern if the products were simply swapped without knowing the isomer composition of the materials.

Dr. Postlethwait said that the original characterization of BO came from nitrogen dioxide exposure. He asked if there were different mechanisms in place for the various exposures that could cause airway fibrosis. Dr. Morgan agreed that there are a number of chemicals that can cause BO, and said he felt that the mechanisms are “pretty much the same.” He noted that BO also occurs in lung transplant patients. Dr. Postlethwait asked if there were any potential therapeutic interventions, given that fibrotic lesions tend to be irreversible. Dr. Morgan replied that BO has few symptoms until it is too late for treatment. Steroids appear to have no effect, he added.

Dr. Kaminski mentioned the differing responses Dr. Morgan’s group had seen in mice and rats, and wondered why. Dr. Morgan said that in exposure to highly reactive chemicals, mice tend to change their breathing pattern, going to shallow, rapid breathing. He said the question warrants further research.

Dr. Cheung asked about the possibility of using angiotensin antagonists, given the involvement of TGF β . Dr. Morgan said that in the literature, no agents appeared to help in these cases, resulting in looking at different pathways. Dr. Bucher compared Dr. Morgan’s experiences with diacetyl to studies conducted years ago with methyl isocyanate, which saw similar rat/mouse differences. He said the key event is the denuding of the epithelium. Dr. Birnbaum added that the effects could still be seen if a number of different strains of mice were tested. Dr. Morgan said his group had tested a number of mouse strains, and still did not see anything.

VIII. Transgenerational Inheritance of Prenatal Obesogen Exposure

Dr. Bruce Blumberg from the University of California, Irvine, presented some of his research on obesogens, chemicals that likely contribute to the obesity epidemic. Obesogen action may involve reprogramming of stem cells. His research is exploring whether the effects of obesogen exposure are permanent, and even transgenerational, and involves the hunt for new obesogens. He has concentrated on the impact of endocrine-disrupting chemicals (EDCs) on adipogenesis and obesity, particularly organotins such as tributyltin (TBT). TBT is a high-affinity agonistic ligand for both the retinoid X receptor (RXR) and peroxisome proliferator activated receptor gamma (PPAR γ). RXR-PPAR γ signaling is a key component of adipogenesis, and inappropriate activation can directly alter adipose tissue homeostasis. Dr. Blumberg’s group hypothesized that organotin exposure during prenatal adipose tissue development may favor the subsequent development of adipocytes. They found that prenatal TBT exposure altered the balance of progenitor cell types in the multipotent stromal stem cell (MSC) compartment, predisposing them to form adipocytes at the expense of bone. Prenatal exposure to low, environmentally relevant doses of TBT led to transgenerational effects on adipose depot weight, adipocyte size, and gene expression in MSCs in F1, F2, and F3 animals.

Dr. Postlethwait asked if there is any evidence that people taking fish oil supplements are becoming obese. Dr. Blumberg said that if such evidence exists, he was not aware of it, but that the theory seemed reasonable.

Dr. Conry, as an obstetrician, asked what she should tell her patients when faced with the information presented by Dr. Blumberg. He said he has a simple message: make real food, from known components, so much the better if the components are organic. Minimize exposure to chemicals and maximize beneficial practices like exercise. Dr. Birnbaum noted that that was not a very helpful answer for disadvantaged populations living in food deserts. She said what to say to people in those circumstances should be thought about.

Dr. Feinberg asked Dr. Blumberg to comment on Anne Ferguson's recent paper about the effects of starvation on the epigenome, which he said had very convincing evidence against the existence of a transgenerational effect. Dr. Blumberg said he thought the paper had been arguing for transgenerational effects. Dr. Feinberg said it had not. He and Dr. Feinberg discussed germ-line reprogramming.

Dr. Kaminski said he had been fascinated by Dr. Blumberg's slide that showed that PVC has a very high level of TBT, and asked if there was any evidence that TBT might be leaching out from PVC. Dr. Birnbaum noted that TBT can be found in dust.

IX. An Overview of Scientific Peer Review at the NIEHS

Dr. Collman introduced Dr. Alfonso R. Latoni, Chief of the Scientific Review Branch (SRB), who briefed Council on the various review approaches available, the differences between review at CSR and NIEHS, and other elements of scientific peer review.

Dr. Latoni began with an overview of the scientific peer review process, sketching the process at CSR, which receives approximately 80,000 solicited and unsolicited grant applications annually. The majority are reviewed at the CSR level; others are referred to individual ICs for review. NIEHS reviews several types of grant applications, including those submitted in response to specific IC mission-related RFAs, as well as proposals for Research and Development Contracts.

For each application, there is a pre-review meeting, a review meeting, and a post-review meeting, encompassing the many steps of the review process from inception to completion. Dr. Latoni reported that so far in 2014, the SRB had conducted 32 review meetings and had reviewed 435 grant applications, with 600 reviewers having participated out of 1,800 who had been contacted. He also described the duties and composition of the NIEHS Special Emphasis Panels, and the Environmental Health Sciences Review Committee. He discussed the various review meeting formats currently being used, outlining the advantages and disadvantages of each format. He

also went over the challenges facing the process and potential solutions to those challenges.

Dr. Latoni summarized the Early Career Reviewer Program currently in place at CSR, which trains and educates qualified scientists to become effective reviewers. He also detailed the SRB's personnel and duties.

Dr. Fasman asked what measures are used to assess the quality of reviewers. Dr. Latoni said that CSR does have data, as well as written critiques of reviewers over time. He said that consistency in scoring is one of the criteria, as is service in peer review over the years.

Dr. Postlethwait said that in his experience, he had noticed the inconsistency in reviews, in terms of scoring relative to the guidelines, and whether the critiques are helpful. He said he is not enthralled with the new formula for reviewing grant applications. He asked whether there had been any consideration of a balance between lightening the reviewers' workloads relative to the value of the information the applicant is receiving. Dr. Latoni said there had been much reaction when the bullets system was introduced, and that although the general feedback about the new system had been positive, the Overall Impact paragraph was introduced for information over and above the five NIH standard review criteria.

Dr. Chesselet asked where the jury stands now on the web-assisted review. She said she had been part of the trials, and felt that the method did not work. She asked how it is used, and how often. Dr. Latoni said he could only speak to the NIEHS experience, and said he had heard positive and constructive feedback from the personnel involved in internet-assisted meetings. He said they certainly could be refined and improved, but had not heard from anyone that the method simply did not work. Dr. Collman mentioned that the method had been used in certain situations, and allowed the opportunity to bring in some reviewers who had been difficult to recruit. She noted that some people are in more of a comfort zone in chatting and similar communication modes.

Dr. McCauley asked about the impact of the new re-submission policy. She felt that investigators were being encouraged to "shake the dust off of old proposals," and wondered what the rationale was. Dr. Latoni replied that part of the reasoning occurred during higher-level discussions about bringing back the A2. Dr. Collman added that she had not heard about anyone taking proposals that are ten years old and resubmitting them. She said that the most important piece of advice for applicants considering re-submission would be to talk to their program administrator for guidance.

Dr. Eaton discussed Level 2 reviews, in the context of the role of Council. He said it is impossible to provide meaningful feedback without actually being able to see the grant

application. That is particularly a problem when there are disparate review scores. He said he could envision a situation where there are disparate reviews that put a grant application in the gray zone, with the grant being assigned to 2 or 3 Council members working with an SRO to look at the disparate reviews and come to a conclusion about which scores are correct. Without looking at the application, that would not be possible. Dr. Collman noted that in the newer process, Council members are being provided with staff members' thinking in terms of selections in the gray zone. She added that Council members should communicate their interest in particular applications early, upon receipt of the Electronic Council Book, so that it becomes evident that there are applications worthy of further discussion. Perhaps, as per Dr. Eaton's suggestion, further information on those applications could be provided to one or two members. Dr. Eaton reiterated that his suggestion pertained to gray zone applications where there were disparate scores, indicated disagreement among the reviewers. He suggested that those application be assigned to identified Council members with specific scientific knowledge in the pertinent areas. Dr. Miranda suggested a spreadsheet for easy reference to variance in the scores. Dr. Latoni said that the concern in the past is that Council members should not become initial reviewers. Dr. Feinberg added that Council members' expertise could be best used to help distinguish the "jewels" embedded in gray zone applications.

Dr. Miranda asked the status of the discussion about requiring people with significant NIH funding to serve as peer reviewers. She said it was her impression that often the most qualified people to serve as peer reviewers on particular RFAs are actually submitting to those RFAs. Dr. Birnbaum mentioned a recent NSF pilot project in which anyone submitting to an RFA would be given the opportunity to review other submissions. She said that one concern with that approach would be reviewers scoring competitive applications poorly. Another concern would be that reviewers forced to participate might deliberately do a poor job. Dr. Collman asked Council what it would recommend if NIEHS could design policy in the area. Dr. Miranda said she had a hard time believing that any of the most senior and talented scientists would sit on a study section and do a mediocre job, if the task was characterized as part of their service to the scientific community. Dr. Birnbaum noted that it was not necessarily the senior investigators who are less willing to serve, and that sometimes it is the junior or mid-level investigators who claim they are too busy to serve or are unwilling for other reasons. Dr. Birnbaum suggested that there should be an evaluation of the issues, which NIH continues to discuss.

Dr. Chesselet said that the best scientists are not always the best reviewers, so it might be problematic to impose reviewers based on their receipt of grants. She also noted that it is difficult to maintain distance between reviewers and applicants, with that distance being one of the beauties of the present system. Dr. Latoni agreed that it is a

fine line, with reviewer recruitment being an art as well as a science. Dr. Collman recalled the high demand for reviewers during the ARRA stimulus, and that very few people declined. As a result, the workload burden was fairly light, because it was widely distributed across the community. Dr. Chesselet asked Dr. Collman if she had any experience with her colleagues at NSF, and whether they were satisfied with their model. Dr. Collman said it was likely that there was a similar diversity of opinions about how reviews are conducted, which is quite different from the NIH approach. She said it would be interesting to compare the two side by side. Although no system is perfect, each must get the program to the end that it needs, and people must feel that it is fair.

Dr. Guilarte asked for clarification on the ability to see staff recommendations on Raise-to-Pays. Dr. Collman explained that in the new procedure put forward for this Council round, raise to pay forms were included.

Dr. Cheung asked about plans for reviewing R35 applications. Dr. Collman said she would be watching to see how it was being approached across NIH. She added that she and her colleagues has asked CSR to design a process to ensure that the review criteria would match the R35 mechanism, and to provide instruction and best practices as ICs start funding R35 grants. She said that if the application is an RFA, it would be reviewed in-house; if it is a Program Announcement, CSR would review it.

Dr. Postlethwait asked if there would be opportunity to discuss the gray zone recommendations. Dr. Collman replied that part of the process is that Council members are being asked to provide their feedback electronically in advance of the meeting.

Dr. Mastin provided Council members with brief instruction on how to access raise-to-pay and gray zone information in their Electronic Council Books. He was asked to prepare slides illustrating the process to share in the meeting's second day. Dr. Postlethwait asked Dr. Mastin to explain the mechanism used to select raise to pay grants.

X. Environmental Health Disparities in Tribal Communities

Dr. Birnbaum reported to Council on her recent visits to tribal areas, where she learned more about the issue of environmental health disparities (EHDs). Native Americans and Alaska Natives experience some of the greatest EHDs on tribal lands and in urban settings. Those vulnerable communities remain vulnerable because of exposures that affect them throughout the lifespan, often involving multiple and interacting exposures to both household and external pollutants.

In June, 2014 Dr. Birnbaum and other NIEHS personnel conducted a site visit to Salish Kootenai College, a tribal college in Pablo, Montana. The visit included meetings with

students, faculty and college leadership, as well as with researchers working to address tribal community health concerns in tribal lands across the U.S. and Canada.

Dr. Birnbaum also described her recent journey to Alaska, where she had eight speaking engagements and twelve community meetings over the course of a busy five days. On St. Lawrence Island, the home of Council member Viola Waghiyi, residents are faced with a triple environmental threat: an abandoned military base, air pollution from Asia and North America, and toxins in their traditional marine diet. Thus, the Yupik people are exposed to mercury, arsenic, PCBs, and other toxins. Dr. Birnbaum met extensively with tribal elders on St. Lawrence Island during her visit.

Following Dr. Birnbaum's presentation, Dr. Cheung asked whether there was a prioritized order for clean-up on the island. Dr. Birnbaum said that as far as the government is concerned, at this point they are not interested in doing any more clean-up at the abandoned military base, which is a major source of contamination. She added that climate change is pressuring the tribe's traditional walrus hunt. She concluded that there is no simple answer to the many disparities facing the local population.

Dr. Feinberg said that the effects of the environmental problems could reach beyond the island itself, in that it is a breeding ground for fish supplies. Dr. Birnbaum noted that Scientific American had a lead article recently on climate change in the Arctic that featured St. Lawrence Island.

Next, Dr. Birnbaum introduced Ms. Waghiyi, who is Environmental Justice Program Director of Alaska Community Action on Toxics, an environmental justice group based in Anchorage. Ms. Waghiyi presented several photographs depicting her family members and other people from the local population of St. Lawrence Island, which illustrated her narrative about the many environmental issues they face. Other photos documented Dr. Birnbaum's visit to the island, as Ms. Waghiyi described several of the meetings and events that took place. She discussed the ongoing threats to the traditional way of life on the island, and the deteriorating health status of many of its residents.

Dr. Cheung asked Ms. Waghiyi to elaborate on the types of cancers seen in the St. Lawrence Island population. Mr. Waghiyi replied that all forms of cancer are seen. She said that research in the 1950s had suggested that cancer was quite rare in the population, but that 2011 and 2012 averaged 19 cancer deaths, with the rate doubling in 2013. Dr. Birnbaum added that the cancer issue was one reason it had been so gratifying to get a commitment from the CEO of the Norton Sound Health Corporation in Nome to send a team of health care professionals to the island to evaluate residents' health.

Dr. McCauley asked how many people live on St. Lawrence Island. Ms. Waghiyi said there were about 1500 residents, on an island the same size as Puerto Rico. Dr. McCauley said she had noticed that some of the children in Ms. Waghiyi's photos were obese. Ms. Waghiyi also noted that some of the boys are also becoming feminized as a result of exposures to endocrine disrupting chemicals.

Dr. Birnbaum added that some of the community members, including young people, had recently gone to Geneva, Switzerland to testify before the Stockholm Convention.

Ms. Yeampierre said that when she was in her twenties, she had had the opportunity to spend three months in Alaska, working on a prisoners' rights initiative. She said she had learned that cancer is a result of historical oppression and abuse, along with many other diseases and social ills that require an interdisciplinary intervention. Such interventions should not concentrate on one condition such as cancer, and should be sustained over time. She felt that Ms. Waghiyi's story is central to the environmental justice movement, and is not told enough. She related some of the many positive messages she had received on Facebook during Dr. Birnbaum's Alaska trip, and thanked Ms. Waghiyi and Dr. Birnbaum for sharing their accounts.

XII. Consideration of Grant Applications

This portion of the meeting (8:30 a.m. – 11:30 a.m., September 10, 2014) 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).

XIII. Adjournment

The meeting was officially adjourned at 11:30 a.m., September 10, 2014.

CERTIFICATION:

/s/

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

/s/

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

Attachment:
Council Roster