

Statement of Stefani D. Hines  
Before the Committee on Oversight and Government Reform  
Subcommittee on Domestic Policy  
September 25, 2007, 2 p.m.  
2154 Rayburn House Office Building

This statement is prepared at the request of the House of Representatives Committee on Oversight and Government Reform, Subcommittee on Domestic Policy, in anticipation of a hearing to be conducted on Tuesday, September 25, 2007. In this statement I describe my personal recollection and understanding of the position/opinions of the National Advisory Environmental Health Sciences Council (herein referred to as Council) regarding the scientific mission and direction of the National Institute of Environmental Health Sciences (NIEHS). Although I am a member of the Council, I offer this testimony solely as an individual and am not speaking on behalf of the Council.

The Council consists of eighteen (18) members appointed by the Secretary of Health and Human Services and six (6) non-voting ex-officio members: the Secretary; the Director of the National Institutes of Health (NIH); the Director of NIEHS; the Chief Medical Director of the Department of Veteran's affairs; the Assistant Secretary of Defense for Health Affairs (or that Department's designees); the Director of National Cancer Institute (or the Director's designee); and any other persons the Secretary deems necessary.

The function of the Council is to advise the Secretary and Assistant Secretary of Health, the NIH Director, and the NIEHS Director on matters relating to research, training, health information dissemination, and other programs with respect to factors in the environment that affect human health, directly or indirectly.

In this capacity, the Council is drafting a letter to Dr. Zerhouni, Director of NIH, to clarify its view of the new 2006-2011 Strategic Plan as it relates to the scientific direction of NIEHS. It is my understanding that the goal of that letter is to underscore the importance of NIEHS's unique mission to advance environmental health-related research and, by communicating the results of that research, to protect public health. The letter to Dr. Zerhouni is intended to highlight the Council's recommendations regarding general research approaches, initiatives, and priorities needed to achieve its critical mission.

Because the letter is still under discussion and subject to change, I cannot reveal its exact content. However, I can share my recollection of the issues, comments, and sentiments expressed by Council members during the public session of the last Council meeting held September 17 and 18, 2007.

Many of the Council members expressed support for the spirit of the 2006-2011 Strategic Plan that Dr. David Schwartz developed in partnership with numerous environmental health scientists. That plan produced a new paradigm shift in environmental health research and called for a multi-disciplinary disease-oriented focus instead of a more-limited chemical-oriented focus.

As I recall from various Council conversations, Council has two main reasons for supporting an integrated disease-oriented research approach. One is that such an approach would stimulate "out-of-the-box" thinking, thereby generating new, unique and potentially significant research results; the other hypothesizes that a disease-oriented approach would bring environmental health research out of the sidelines where research consists only of testing chemicals for toxicity to a more mainstream role where research would investigate how environmental agents contribute to specific diseases that impact public health on a large scale.

With that said, Council members also agree that support of disease-oriented environmental health research does not exclude support of the more historic and traditional methods. This includes testing chemicals for toxicity – indeed these toxic chemicals may contribute to major diseases in a very significant way. It is my understanding that Council scientists envision an interdisciplinary disease-oriented approach to research, including the use of clinical trials, as a context by which to employ all of a scientist's tools to meet the goals of disease prevention, possible treatment, and overall improved public health.

I would like, however, to make a distinction between a vision or concept and implementation of that concept. For example, although the Council has expressed general support for the NIEHS Strategic Plan, three Council members (Lisa Greenhill<sup>1</sup>, Hillary Carpenter<sup>2</sup> and myself) have also expressed concerns about the erosion of disease-prevention educational activities in the NIEHS portfolio. The Strategic Plan makes provisions for such activities, but the reality is that outreach and education programs are being significantly reduced. For example, where Community Outreach and Education Cores in NIEHS Centers were once mandatory programs, they are now optional.

Several of the Council members stated that they were not aware—or made aware—of the extent to which the omission of outreach programs, as well as certain other actions and decisions taken by NIEHS over the past several years, have violated trust within the outreach and educational communities. When this situation was brought to all the Council members' attention, I recall that in our discussions of it, the Council generally concurred that offering scientific and disease-prevention outreach and education to the public was integral in meeting the NIEHS mission.

This lack of awareness among the Council members about the status of environmental health outreach and educational activities within the NIEHS demonstrated

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<sup>1</sup> Lisa M. Greenhill, MPA  
Associate Executive Director for Diversity  
Association of Veterinary Medical Colleges  
Washington, DC 20005

<sup>2</sup> Hillary Carpenter, PhD  
Toxicologist  
Minnesota Department of Health  
St. Paul, MN

to us that there is a weakness in the structure of Council meetings. There is currently not enough time during meetings for in-depth discussions among Council members or between the Council and NIEHS leadership. Thus, in my opinion, Council has had little opportunity to refine its understanding of and position on how the NIEHS Strategic Plan is actually being implemented – i.e. making sure the environment in environmental health is still present in all of its funded activities.

Another shortcoming related to Council meetings and communication is the absence of a mechanism for the outside community (including the scientific community) to formally approach the Council between meetings or for the Council to communicate the public's ideas and concerns to NIEHS so that issues may be appropriately addressed at meetings.

The recognition of these shortcomings and the revelation of several Council members' perceptions regarding the implementation of the Strategic Plan led to the initiation of several actions at the September 2007 meeting. The NAEHS Council is:

1. Drafting a letter to Dr. Zerhouni emphasizing the Council's support of the new disease-oriented vision for NIEHS that is inclusive of multiple research tools and approaches, including prevention-based research as well as the communication of NIEHS research for public benefit;
2. Making requests to Dr. Sam Wilson, Acting Director of NIEHS, for Council input on the time allocation and content of meeting agendas to allow for questions and the adequate discussion of agenda items and emerging issues; and
3. Assembling a formal list of requests to Dr. Wilson for information and other procedural changes regarding the Council, so that the Council may provide the best, most educated opinions and guidance to NIEHS leadership.

The letter to Dr. Zerhouni, as well as the Council's requests, are being written by and circulated among Council members. It is anticipated that final versions of these documents will be available within the next 2-3 weeks.

Before closing this testimony, I would like to bring up an additional item of importance. Upon reviewing the May 2007 Council meeting minutes, I, as well as other Council members, noted there were inaccuracies in the minutes and omissions of some of Council's comments. Specifically, these omissions and inaccuracies related to (1) paragraph 8 of Section V, the Director's Report, concerning Congressional inquiries, (2) Section VII which covered our discussion of the review panel's recommendations presented by Dr. Daniel Krewski for the restructuring of the Children's Centers, (3) Section XI concerning a concept clearance for Global Environmental Health, and (4) Section XIV covering our discussion of the National Toxicology Program's Epigenetics Initiative. As a result of these noted omissions and inaccuracies, the Council did not approve the May 2007 minutes at the September 2007 meeting.

I would like to provide some additional details regarding two of the inaccuracies in the May 2007 minutes. The first concerns a discrepancy in the section containing the Director's Report (Section V). The minutes for that section state "A lengthy discussion

ensued over the details of congressional requests, Council's obligations, and Dr. Schwartz's response." In contrast to what the minutes stated, several of the Council members remembered that very little information had been provided about the congressional inquiries and NIEHS's response to them and, as a result of that lack of information as well as the time constraints imposed by the structure of Council meetings, very little if any discussion ensued. Council member Teresa Bowers stated on record at the open portion of the September 2007 Council meeting that the word "lengthy" should be struck and replaced with "cursory."

The second item I would like to highlight is my recollection of Council's response to Dr. Daniel Krewski's May 2007 presentation of the review panel's evaluation and recommendations for the Children's Centers (Section VII of the minutes). Prior to Council's open discussion of the matter, Drs. Graziano and Philbert summarized the public comments submitted regarding the review panel's report and its recommendations. I recall that Drs. Graziano and Philbert noted the very strong concern expressed by the extramural community regarding the composition of the review panel, the panel's recommendation to shift to an RO1 emphasis—in effect moving away from population-based studies and altering what is perceived to be a functional Center design—and the recommendation to eliminate the Community Outreach and Translation Core. From what I also recall, Drs. Graziano, Philbert, and the rest of Council, echoed the concerns expressed by the extramural community related to the review recommendations, in particular the review panel's recommendations to eliminate or modify the very features that the review had identified as strengths of the Centers.

Unfortunately the May 2007 minutes do not adequately reflect my memory of the Council's strong opinion against some of the Children's Center review recommendations. For example, in the "Council Response and Discussion" section under heading VII of the minutes, regarding Children's Health Research Evaluation, it states:

Council noted, while change is sometimes painful, there are some good things to take away from this report....If the institute is to move toward the RO1 Mechanism and coalescence [*sic*] them into a Center, one has to think carefully how one bridges the already valuable and existing cohort that has been put together. (page 8)

Both of these statements insinuate that the Council concurred with the review recommendations or, at the very least, did not express any notable concern about them. I recall the opposite being true – that there was very strong concern among Council members about the conflicting nature of the review panel's evaluations and attending recommendations, as well as the feasibility of implementing them.

During the September 2007 meeting the Council requested that NIEHS staff revise the May 2007 minutes to accurately reflect the dialogue, recommendations, and sentiment expressed by Council. To that end, I have asked for copies of the written transcripts and the audio recording of the May 2007 meeting so that the revision process will be as accurate and detailed as possible.

To conclude my testimony, I would like to thank the Committee on Oversight and Government Reform and the Subcommittee on Domestic Policy for their interest in the well-being of NIEHS—the only NIH institute that focuses on the contribution of environmental health to disease.

Should the committee have specific questions regarding the Council's opinions on the scientific direction of NIEHS and its commitment to communicate research findings to the public, I invite the Committee to submit those questions to the Council at least two weeks before one of its meetings. This will allow enough time for Council members to individually consider the question(s), meet and discuss the question(s) as a group, and thoughtfully construct a response on behalf of the Council.

Future NAEHS Council meeting dates are:

February 19-20, 2008

May 29-30, 2008

September 9-10, 2008

Sincerely

A handwritten signature in black ink, appearing to read "Stefani D. Hines", with a long horizontal flourish extending to the right.

Stefani D. Hines, M.A., M.S.  
Associate Scientist III, Environmental Health Specialist,  
Senior Curriculum and Assessment Specialist  
University of New Mexico, College of Pharmacy