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WILL NIEHS' NEW PRIORITIES PROTECT PUBLIC HEALTH?

HEARING

BEFORE THE

SUBCOMMITTEE ON DOMESTIC POLICY

OF THE

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

FIRST SESSION

SEPTEMBER 25, 2007

Serial No. 110–70

Printed for the use of the Committee on Oversight and Government Reform

Available via the World Wide Web: http://www.gpoaccess.gov/congress/index.html
http://www.oversight.house.gov

U.S. GOVERNMENT PRINTING OFFICE

44–007 PDF WASHINGTON : 2008

For sale by the Superintendent of Documents, U.S. Government Printing Office
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WILL NIEHS' NEW PRIORITIES PROTECT PUBLIC HEALTH?

TUESDAY, SEPTEMBER 25, 2007

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON DOMESTIC POLICY,
COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM,
Washington, DC.

The subcommittee met, pursuant to notice, at 2:05 p.m., in room 2154, Rayburn House Office Building, Hon. Dennis J. Kucinich (chairman of the subcommittee) presiding.

Present: Representatives Kucinich, Tierney, Watson, and Issa.

Staff present: Jaron R. Bourke, staff director; Jean Gosa, clerk; Vic Edgerton, senior legislative assistant, Office of Mr. Kucinich; Natalie Laber, press secretary, Office of Mr. Kucinich; Leneal Scott, information systems manager; Alex Cooper, minority professional staff member; and Larry Brady, minority senior investigator and policy advisor.

Mr. KUCINICH. Good afternoon. The committee will come to order.

The Subcommittee on Domestic Policy of the Committee on Oversight and Government Reform will now come to order. Today's hearing will examine the National Institute of Environmental Health Sciences and whether or not it protects public health.

Without objection, the Chair and the ranking minority member will have 5 minutes to make opening statements, followed by opening statements not to exceed 3 minutes by any other Member who arrives and seeks recognition.

Without objection, Members and witnesses may have 5 legislative days to submit a written statement or extraneous materials for the record.

I want to bid a good afternoon to our ranking member, Mr. Issa. I appreciate your presence here today and to our witnesses attending and the audience.

Soon after becoming the Director of NIEHS on April 4, 2005, Dr. David Schwartz set in motion a new set of research priorities for NIEHS, which he articulated throughout his tenure in forums like his Director's Perspective Columns in EHP, as well as the NIEHS 2006 to 2011 Strategic Plan.

A primary goal was to shift significant resources toward research that was clinical in nature and which focused on discoveries that would contribute to treating or curing disease once a patient was already afflicted. There was also an effort to shift resources away from projects or programs that represented anything other than scientific research.

The new plan was fairly well received in the scientific community. Legitimate environmental health research needs would be filled and innovative approaches would be embraced.

Dr. Schwartz's own research was highly respected. His reputation as a top-notch scientist was translated into a strong research agenda which few would argue with, unless the consequences of implementing it were too great, unless the tradeoff was too costly. That is exactly the problem we are faced with today. NIEHS does not have unlimited resources, and Dr. Schwartz's new direction forced cuts in the traditional mission and role of NIEHS in researching and protecting public health.

It should be noted that Dr. Schwartz is not a witness today. Dr. Schwartz departed from NIEH when it became known that an internal investigation was under way into significant charges against him for misconduct, conflict of interest, waste and mismanagement. This committee had opened an investigation into Dr. Schwartz's management practices months earlier, and several other congressional investigations were also in their beginning stages.

Dr. Schwartz is officially on temporary leave, although I don't know if anyone seriously believes he will return as Director. The hearing today does not concern any alleged misconduct, and I want to use the word "alleged" misconduct, however important I believe it is to go into that. However, it will explore the programmatic direction and policy choices Dr. Schwartz made as Director and try to ascertain whether NIEHS' new management intends to sustain them in Dr. Schwartz's absence.

The first question we will explore today is, at what cost has come Dr. Schwartz's new direction for the NIEHS? What are we losing by shifting resources toward new endeavors and in doing so targeting for reductions in other areas? Let me be clear that this is not just a funding question. Several management decisions have also reflected a devaluing of these key areas to restructuring and weakening leadership of certain initiatives.

The second question is this: Should the new NIEHS research direction and priorities, as set out by Dr. Schwartz, continue?

This subcommittee has performed its own analysis of the NIEHS' new research direction and priorities based on information provided by the NIH at our request and from information provided by informants and verified by staff. We have some documents up on the screen that will reflect that.

We found the impact on public health to be significant, with tangible effects on people's health. As suspected, there were funding cuts to preventive research, to outreach and education and to long-term research. There was also a neglect to fill leadership positions or programs representing those interests like in EHP and NTP. There were efforts to change the direction of children's research by stacking a review panel. At the same time, there were several new initiatives, mostly clinical in nature, that were expensive by comparison.

Today, we will hear from witnesses about the programs like community involvement, environmental justice, long-term research, children's health and information dissemination and education that have suffered. These are exactly the kinds of areas that are fundamental to public health.

If we are to make the research translate into preventing disease, instead of trying to treat or cure it after it has already struck, we will need to involve the communities that are affected using proven techniques like community-based participatory research. We will need to make deliberate efforts to get the information out there, using world-class peer review journals like Environmental Health Perspectives.

We will need to focus on populations that are most affected by chemicals and other hazards in our environment, like children and communities of color; and we will need to prioritize environmental hazards for regulatory action with programs like the National Toxicology Program.

With relatively meager funding, NIEHS is viewed as one of the most credible sources in the world of impartial information about health hazards in our environment. NIEHS' work in the public interest is critical at a time when some malfeasant actors in the chemical industry or plastics industry have the funding to turn out their own pseudo-science, following in the footsteps of the tobacco industry. EHP alone is a pillar of truth. Consider the study released in January of this year showing that of all the studies looking for a possible relationship between mobile phone use and any health problem, those funded exclusively by the telecommunications industry were far less likely to find a link. You may also know the National Toxicology Program is a target for those trying to use procedural monkey wrenches to slow the listing of certain chemicals as a cause of cancer or birth defects, which had been made plain in an August report by OMB Watch.

Another reason for the importance of NIEHS and its mission to prevent disease from occurring is that prevention is often far more cost-effective than treatment or cure. The reason is a significant failing of the market system: There is a little profit in prevention when compared to treatment. There is no race for the prevention of breast cancer, only for the cure. There are no public health professionals roaming hospital corridors pitching the latest techniques to reduce exposure to polybrominated diphenylethers [PBDEs], a flame-retardant chemical, to expectant mothers, in the same way there are drug industry reps selling the latest patent drug.

Yet the reach of the NIEHS, given this financial disadvantage, is extraordinary. EHP is the No. 1 journal in its field and adjacent fields. Its Report on Carcinogens, the gold standard of chemicals that cause birth defects and cancer, is relied upon by State, Federal and international agencies whose mission is to help prevent exposure to toxic chemicals.

We must keep in mind that the NIEHS is a world-renowned agency which built its reputation on the excellent preventive and public health work it does. While the agency has not abandoned that authority, it has made significant first steps in that direction.

I want to thank the witnesses who have taken time out of their busy schedules and important work they do in protecting public health to explore this topic. I will note that each of them works with many others who also contribute every day to this noble cause. I thank each of them for their work as well.

[The prepared statement of Hon. Dennis J. Kucinich follows:]

Dennis J. Kucinich
Chairman
Domestic Policy Subcommittee
Oversight and Government Reform Committee
Opening Statement
Hearing on the Direction of NIEHS
2154 Rayburn HOB – 2:00 P. M.
September 25, 2007

Good afternoon.

Soon after becoming the Director of NIEHS on April 4, 2005, Dr. David Schwartz set in motion a new set of research priorities for NIEHS, which he articulated throughout his tenure in forums like his Director's Perspectives Columns in EHP as well as the NIEHS 2006-2011 Strategic Plan. A primary goal was to shift significant resources toward research that was clinical in nature and was focused on discoveries that would contribute to treating or curing disease once the patient was already afflicted. There was also an effort to shift resources away from projects or programs that represented anything other than scientific research.

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argue with – unless the consequences of implementing it were too great. Unless the trade-off was too costly.

That is exactly the problem we're faced with today. NIEHS does not have unlimited resources, and Dr. Schwartz's new direction forced cuts in the traditional mission and role of NIEHS in researching and protecting public health.

It should be noted that Dr. Schwartz is not a witness today. Dr. Schwartz departed from NIEHS when it became known that an internal investigation was under way into significant charges against him for misconduct, conflict of interest, waste, and mismanagement. This Committee had opened an investigation into Dr. Schwartz's management practices months earlier, and several other Congressional investigations were also in their beginning stages.

Dr. Schwartz is officially on temporary leave, though I don't know if anybody seriously believes that he will return as Director. The hearing today does not concern his alleged misconduct, however important I believe that is. Rather, it will explore the programmatic direction and policy choices Dr. Schwartz made as Director and try to ascertain whether NIEHS' new management intends to sustain them in Dr. Schwartz's absence.

The first question we will explore today is; At what cost has come Dr. Schwartz's new direction for NIEHS? What are we losing by shifting

resources toward new endeavors and, in so doing, targeting other areas? Let me clear that this is not just a funding question – several management decisions have also reflected a devaluing of these key areas through restructuring and weakening leadership of certain initiatives. The second question is this; should the new NIEHS research direction and priorities, as set out by Dr. Schwartz, continue?

The Subcommittee has performed its own analysis on NIEHS' new research direction and priorities based on information provided by NIEHS at our request and from information provided by informants and verified by staff. We found the impact on public health to be significant, with tangible effects on people's health. As suspected, there were funding cuts to preventive research, to outreach and education, and to long-term research. There was also a neglect to fill leadership positions of programs representing those interests like in EHP and the NTP. There were efforts to change the direction of children's research by stacking a review panel. At the same time, there were several new initiatives, mostly clinical in nature that were expensive by comparison.

Today, we will hear from witnesses about the programs like community involvement, environmental justice, long-term research children's health, and information dissemination and education that have suffered. These are exactly the kinds of areas that are fundamental to public health. If we are to make the research translate into preventing disease instead of trying to treat or cure it after it has already struck, we will need to involve the communities that are affected using proven techniques like community based participatory research. We will need to make deliberate efforts to get the information out

there using world class peer reviewed journals like *Environmental Health Perspectives*.

We will need to focus on populations that are the most affected by chemicals and other hazards in our environment, like children and communities of color. And we will need to prioritize environmental hazards for regulatory action with programs like the National Toxicology Program.

With relatively meager funding, NIEHS is viewed as one of the most credible sources in the world of impartial information about health hazards in our environment. NIEHS work in the public interest is critical in a time when some malfeasant actors in the chemical industry or plastics industry have the funding to churn out their own pseudo-science, following in the footsteps of the tobacco industry. EHP alone is a pillar of truth. Consider the study released in January of this year showing that of all the studies looking for a possible relationship between mobile phone use and any health problem, those funded exclusively by the telecommunications industry were far less likely to find a link. You may also know that the National Toxicology Program is a target for those trying to use procedural monkey wrenching to slow the listing of certain chemicals as a cause of cancer or birth defects, which was made plain in an August report by OMB Watch.

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Race for the Prevention of Breast Cancer – only for the cure. There are no public health professionals roaming hospital corridors pitching the latest techniques to reduce exposure to PBDEs (poly-brominated-di-phenyl-ethers) – a flame retardant chemical -- in expecting mothers in the same way that there are drug industry reps selling the latest patented drug.

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We must keep in mind that NIEHS is a world renowned agency which built its reputation on the excellent preventive and public health work it does. While the agency has not completely abandoned that priority, it has made significant first steps in that direction.

I want to thank each of the witnesses who has taken time out of their own busy schedules and the important work they do in protecting public health to be her today to help explore this topic. I'll note that each of them works with many others who also contribute every day to this noble cause. So I thank each of them for their work as well.

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MEMORANDUM

September 24, 2007

To: **Majority Members of the Domestic Policy Subcommittee**

From: **Domestic Policy Subcommittee, Majority staff**

Re: **Staff analysis of NIEHS direction under Dr. David Schwartz**

Summary

Before departing under a cloud of a formal internal investigation for misconduct, Dr. David Schwartz initiated a significant change of priorities and research direction at NIEHS.

The Majority Staff of the Domestic Policy Subcommittee investigated the record of Dr. Schwartz's leadership. The record shows that there have been clear winners and losers. In general, programs of a preventive nature, long term population research programs, and education and outreach, were cut. Meanwhile, programs of a clinical nature were increased. A funding summary of select programs is illustrative. But it is only part of the picture which also includes key leadership vacancies and stacking of advisory panels.

PROGRAMS CUT OR ELIMINATED	Difference	
Environmental Justice	($1,747,741)	
Community Based Participatory Research*	($3,122,792)	
Children's Centers	($894,173)	
National Children's Study*	($1,639,485)	
Environmental Health Perspectives	($965,851)	
Centers for Population Health and Health Disparities	($332,506)	
Environmental Health Sciences as an Integrative Context for Learning (K-12 Program)*	($2,424,901)	
	($11,127,449)	**Total**

* Funding Eliminated

NEW PROGRAMS	Difference	
DISCOVER	$10,242,043	
Institutional Patient-Oriented Career Development Program in the Environmental Health Sciences	$1,000,479	
Interdisciplinary Partnerships in Environmental Health Sciences	$1,397,565	
Intramural Clinical Research	$6,598,910	
	$19,238,997	**Total**

These funding losses, restructuring efforts, and instances of programmatic neglect collectively demonstrate the effects of NIEHS new set of priorities. This hearing will examine their impact on public health and the degree to which these priorities will remain under Interim Director Wilson and his successor.

Background

Soon after becoming the Director of NIEHS on April 4, 2005, Dr. David Schwartz set in motion a new set of research priorities for NIEHS, which he articulated throughout his tenure in forums like his Director's Perspectives Columns in EHP as well as the NIEHS 2006-2011 Strategic Plan. A primary goal was to shift significant resources toward research that was clinical in nature and was focused on discoveries that would contribute to treating or curing disease once the patient was already afflicted. There was also an effort to shift resources away from projects or programs that represented anything other than scientific research.

Many in the environmental health community became concerned when it became clear which resources would be redirected toward new proposals. Three general areas were among those that were targeted: education and outreach, prevention of disease and long term epidemiological studies. The impact is exemplified in more specific programs such as community input and participation, environmental justice, children's environmental health, the National Toxicology Program (NTP), and *Environmental Health Perspectives* (EHP). Through document requests and through interviews with informants, the Subcommittee has assembled evidence of the costs to public health of NIEHS' new priorities.

RESEARCH AND PROJECTS CUT OR ELIMINATED

ENVIRONMENTAL JUSTICE and COMMUNITY PARTICIPATION

Environmental Justice: Partnerships for Communication is a program designed to create more effective research that could be translated into preventive efforts and to empower affected communities to act on their own behalf through scientific education and participation in the research about them. Under NIEHS new set of priorities, this program lost half of its funding so far.

FY05	FY06	FY07
$4,384,463	$4,290,187	$2,636,722

Community Based Participatory Research in Environmental Health has lost every dollar of the $4.7 million it had in FY04.

FY05	FY06	FY07
$3,122,792	$357,116	$0

CHILDRENS ENVIRONMENTAL HEALTH and LONG TERM RESEARCH

Centers for Children's Environmental Health and Disease Prevention Research ("Children's Centers") have collectively already resulted in interventions that have protected children's health. [1] The goals of the Children's Centers are "understanding how environmental factors affect children's health, and promoting translation of basic research findings into intervention and prevention methods to prevent adverse health outcomes."[2] Funding has also consistently declined faster that the overall budget of NIEHS as can be seen in the chart below. The number of centers is currently eight, down from thirteen. Dr. Schwartz was reported to have stated his intent to sunset funding for the Centers entirely by 2010.

FY05	FY06	FY07
$7,530,707	$6,634,563	$6,636,534

The Centers not only lost funding but were faced with significant programmatic changes. In April 2007, a panel was assembled to review the effectiveness and future direction of the Children's Centers. Accusations were made that the panel was populated with scientists who would be likely to reach conclusions that were in line with Dr. Schwartz's desire to shift from long term to short term funding mechanisms, to reduce community participation requirements, and to increase lab science over epidemiological science and public health interventions; in short, to reduce the mission of the Centers to one of science only, with options for conducting outreach and interventions that prevent disease. The final recommendations of the review panel reflected those priorities. Public comments on the recommendations were nearly unanimous in their opposition to the fundamental points made in the panel's report. As current recipients of Children's Centers funding, most commenter placed their future funding at risk by speaking out against the recommendations.

One of the review panel's primary objections to the existing direction of the Children's Centers was the costs associated with the long term nature of some of their core research. But some of the best epidemiological science that results in major advances in public health is long term in nature. It follows people for several years, tracking their exposures and diseases along the way. Previous models include the Framingham Heart Study and the Nurses Study, which have both yielded hundreds, if not thousands of published studies and have been credited with changing they we look at major health factors like heart disease and diet.

[1] For example, in Comments to the Panel's Report submitted by Dr. Philip Landrigan of the Mt. Sinai School of Medicine, he said "The scientific findings of the Centers have thus already protected tens of thousands of American children from prenatal brain injury."
[2] http://es.epa.gov/ncer/childrenscenters/, accessed September 19, 2007.

The National Children's Study (NCS) is a separate initiative on the scale of the Framingham and Nurses Studies. It is "designed to examine the effects of environmental influences on the health and development of more than 100,000 children across the United States, following them from before birth until age 21. The goal of the Study is to improve the health and well-being of children. Researchers would analyze how these elements interact with each other and what helpful and/or harmful effects they might have on children's health. By studying children through their different phases of growth and development, researchers would be better able to understand the role of these factors on health and disease."[3] NIEHS collaborates with the EPA and CDC on the National Children's Study.

FY05[4]	FY06[5]	FY07
$1,639,485	$1,643,600	$0

ENVIRONMENTAL HEALTH PERSPECTIVES

Environmental Health Perspectives (EHP) is utilized by scientists, communities, patients, doctors, librarians, students, teachers, corporate research centers, public health professionals, advocates, and Members of Congress. It is read in over 200 countries. All content is free on line. The journal has an 80% rejection rate for papers, which means they publish only the highest quality research. It has some of the strictest conflict of interest provisions of any peer-reviewed journal. EHP is critical to the NIEHS mission to prevent disease and educate the public. However, EHP has been embattled since 2005.

There were two attempts, in 2005 and 2006, to privatize the journal. Free access to the journal's contents, which is essential for accessibility, was at risk from privatization. Privatization also threatened the very reputation of the journal, which is its currency, since content decisions would be in private hands. Both privatization proposals met with significant Congressional and public resistance. Public comments on the first proposal were overwhelmingly opposed (94%). The budget of EHP was also under fire as it decreased from $3.7 million down to $2.4 million, until still more public outcry forced current leadership to promise a full budget again in a public forum designed to solicit feedback on NIEHS from stakeholders.

Some of the cuts undermined the efforts of the journal to stay afloat. For example, press releases had been a low cost way to publicize articles of major public health significance, thereby increasing readership, revenue, and impact factor, a measure of the journal's influence in the field. But the budget was cut for press releases.

FY05	FY06	FY07
$3,389,341	$3,105,581	$2,423,490

5

[3] http://www.nationalchildrensstudy.gov/, accessed September 24, 2007
[4] Source: EPA
[5] Source: EPA

Attempts were also made to trim the content of the Journal. EHP contained sections like Environews, designed to translate the scientific articles into language that the layperson could understand. Other sections explored topics in more depth than could be covered by a scientific article. EHP had an acclaimed Student Edition, which provided content for educators. EHP provided translations for developing countries whose governments were not sponsoring the research but whose potential for lives saved and improved is disproportionately high. A Chinese edition, in particular, which was a partnership with the Chinese CDC, was especially important to alert Chinese residents of the dangers of toxics like lead. Though the Subcommittee has received reports of plans to restore some programs and other non-scientific content that is critical to the Journal's success as a tool to advance public health, a commitment has not yet been made.

Furthermore, there has been a persistent leadership void. Most, if not every one of the leadership positions in the journal is now filled on an "acting" or "interim" basis. Some of those positions have been vacant for well over 6 months and all are currently occupied by staff who were not relieved of their previous duties. The previous Editor in Chief announced his intention to retire well before his departure in December 2006. Yet the Journal is still without an Editor in Chief (EIC). The search now underway for the EIC has elicited significant concern among those close to the Journal. In fact, one of the final candidates publicly supported privatizing the journal during the initial 2005 proposal to do so.

NATIONAL TOXICOLOGY PROGRAM

The National Toxicology Program is responsible for the high quality science that often clarifies the need for regulation of a chemical. Its work is therefore necessarily important for disease prevention. Yet, a nationally recognized leader of the program, Dr. Chris Portier, was suddenly "promoted" into a new position in January 2006 and was not replaced for 18 months, leaving NTP without permanent leadership at a time when the program's work was being challenged by the chemical industry.[6] In addition, NTP's budget may have been declining. The Subcommittee has found budget figures that range from approximately $85 million per year to nearly $200 million per year. Finally, the number of chemicals it reviews appears to have declined. As Dr. Lucier mentions in his testimony, "Only 4 chemicals will be started in cancer bioassays in 2007 while 10 were started in 2005. Moreover no new starts have been reported for reproductive, developmental or neurotoxicity (with the exception of the c. elegans studies) and there does not seem to be a compensatory increase in molecular based toxicology screens and evaluations."

[6] *An Attack on Cancer Research: Industry's Obstruction of the National Toxicology Program*, OMB Watch, http://www.ombwatch.org/info/NTPDataQuality.pdf, accessed September 18, 2007

OTHER RESEARCH LOST

"**Centers for Population Health and Health Disparities** are designed to support cutting-edge research to understand and reduce differences in health outcomes, access and care. Four NIH institutes or offices the National Institute of Environmental Health Sciences (NIEHS), the National Cancer Institute (NCI), the National Institute on Aging (NIA), and the Office of Behavioral and Social Sciences Research (OBSSR) ? (sic) are supporting this interdisciplinary research to examine how the social and physical environment, behavioral factors, and biologic pathways interact to determine health and disease in populations. These grants, which total $60.5 million over five years, address the recommendations of recent reports from the National Academy of Sciences. The reports called for an approach to health and health disparities that integrates research in the natural, behavioral and social sciences to create a more comprehensive understanding of disease pathways. The reports also stressed the need to examine causation and intervention at the population and environmental levels, rather than solely at the individual level."[7]

FY05	FY06	FY07
$3,816,604	$3,765,459	$3,484,098

Environmental Health Sciences as an Integrative Context for Learning (K-12 Program)

"The Environmental Health Sciences as an Integrative Context for Learning (EHSIC) initiative fosters partnerships among environmental health scientists, educators, and state departments of education with the goal of developing standards-based curricular material that integrate environmental health sciences within a variety of subject areas (e.g. geography, history, math, art). The purpose of the projects is to improve overall academic performance as well as enhance students' comprehension of and interest in environmental health sciences."[8]

FY05	FY06	FY07
$2,424,901	$2,236,213	$0

PROGRAMS STARTED SINCE FY04

At the same time cuts, attempted cuts, or programmatic changes were being implemented, new programs were being created in the extramural program at NIEHS. Please note the familiar theme of clinical research throughout.

[7] http://cancercontrol.cancer.gov/populationhealthcenters/cphhd/index.html, accessed September 22, 2007
[8] http://www.niehs.nih.gov/research/supported/programs/ehsic/index.cfm, accessed September 22, 2007

DISEASE INVESTIGATION THROUGH SPECIALIZED CLINICALLY-ORIENTED VENTURES IN ENVIRONMENTAL RESEARCH (DISCOVER)

"DISCOVER intends to advance our understanding of the role of environmental factors in influencing human disease through an interdisciplinary effort in both basic mechanistic and clinical research. Through an effort in which the findings of mechanistic research and clinical research inform each other, we expect to achieve the long range goal of developing new clinical and public health applications to improve disease prevention, diagnosis, and therapy. This program is the centerpiece of the NIEHS Strategic Plan (http://www.niehs.nih.gov/about/od/director/strategicplan/index.cfm), encompassing aspects of each of the seven goals of the plan within its purview."[9]

FY07	FY08
$4,741,310	$10,242,043

INSTITUTIONAL PATIENT-ORIENTED CAREER DEVELOPMENT PROGRAM IN THE ENVIRONMENTAL HEALTH SCIENCES

The objective of the program is "to increase the number of researchers trained in patient-oriented environmental sciences research. This will be accomplished by establishing programs at universities that are designed to train researchers with MDs or PhDs to do research combining laboratory research and patient-oriented research, and to help promote the career development of these scientists."[10]

FY07	FY08
$682,557	$1,000,479

INTERDISCIPLINARY PARTNERSHIPS IN ENVIRONMENTAL HEALTH SCIENCES

"This initiative is intended to support collaborations between scientists with basic and clinical expertise to advance understanding of the etiology, prevention, and treatment of environmentally-induced human diseases."[11]

FY06	FY07
$752,520	$1,397,565

[9] http://www.niehs.nih.gov/research/supported/centers/discover/index.cfm, accessed September 24, 2007
[10] Description provided to the Subcommittee by NIEHS
[11] http://grants.nih.gov/grants/guide/pa-files/PAR-05-168.html, accessed September 24, 2007

INTRAMURAL CLINICAL FUNDING

Efforts initiated intramurally include a new Clinical Research Unit and several new clinical staff.

FY04	FY07
$500,000	$7,098,910

NATIONAL ADVISORY ENVIRONMENTAL HEALTH COUNCIL (NAEHS)

The National Advisory Environmental Health Sciences Council (NAEHSC) is a Congressionally mandated body that advises the secretary of HHS, the director of NIH, and the director of the NIEHS on matters relating to the direction of research, research support, training, and career development supported by the NIEHS.... Membership of the NAEHSC consists of ex officio members and 18 leaders in the fundamental sciences, medical sciences, education, and public affairs. One-third of the council must be public members."[12] The NAEHSC met last week and expressed concern over the costs to public health of NIEHS new priorities. Stefani Hines is a member of the Council and will discuss the Council's concerns at the hearing.

[12] http://www.niehs.nih.gov/about/orgstructure/boards/naehsc/index.cfm, accessed September 18, 2007

Mr. KUCINICH. At this time, the Chair will recognize the ranking member, distinguished gentleman from California, Mr. Issa.

Mr. ISSA. Thank you, Mr. Chairman, and thank you for many of your opening remarks.

As the witnesses, I am sure, are aware, here on Capitol Hill often you see a chairman and a ranking member as two bookends in their opening statements. Not so here today. Although the chairman and I may disagree on some issues related to other subjects, when it comes to the basic oversight and reform obligations of this committee and this hearing today, no two people could be closer together.

The fact is that Congress relies heavily on NIEHS' ability to do its fundamental job; and a direction change, although well-intended, appears to have done two things: reduced its ability to do core missions, which as of yet Congress has not seen fit, nor have other Federal agencies, to buy in wholesale for those to be abandoned. Second, when a reorganization occurs in any organization and it causes significant internal disruptions, by definition we in Congress feel that we need to ask questions about effectiveness, about whether or not those disruptions are because a new leader is challenging an entrenched bureaucracy, looking for inefficiencies, looking for opportunities to do government's job better, or, in fact, simply trying to make a name for themselves in a community in which reputation has often to do with the number of people supervised and number of reorganizations done.

Today I look forward to this hearing because I believe both in our role as oversight, finding out why there is so much turmoil, and reform, finding out whether or not there are legitimate areas in which new technologies would allow for an effective use of basic clinical science, rather than the traditional roles that have been enjoyed and, if so, what they are and, if so, how should we best fund them.

The chairman and I have worked together on a number of issues. This one probably more than any is one in which we must work out an effective message after this hearing and perhaps follow-on hearings to ensure that this organization right-sizes itself and finds itself on a path toward working to at least accomplish its traditional goals and, if money and efficiencies can be found, to find additional.

I do have just two small points of dissension, and they are limited. Maybe it's in agreement.

The chairman commented that the Director was not here today. Since the Director, Director Schwartz, is, in fact, only on a temporary leave of absence, I would hope that if there is a followup hearing that we insist that somebody who has stepped down temporarily and is still at least partially covered by Federal benefits would be available here today.

That's certainly not to limit your presence or importance, Dr. Wilson.

Second, perhaps to chastise just a little publicly that these opening statements and witness testimony are valuable. I really had wished that we had had at least the minimum 24 hours that the committee requires in order to get those statements analyzed by staff. We will try to do the best we can, having gone through them

just today. If we ask questions that are not fully fact checked or appear to perhaps be asking questions that seem beneath congressional standard, it's because we only received them well after close of business last night.

Mr. Chairman, once again, I thank you for holding this hearing. Once again, I believe we have found a good bipartisan issue to work on.

I yield back.

Mr. KUCINICH. I want to thank the gentleman from California and associate myself with the concerns that you expressed about the necessity of the subcommittee being able to do its work and have staff evaluate these statements that come in. We will do the best we can with the information that you provided us.

At this point, I would like to recognize the representative from Massachusetts, Mr. Tierney, for the purpose of an opening statement.

Mr. TIERNEY. Thank you, Mr. Chairman.

I really have no opening statement to add here. I really came to listen and learn.

I want to thank you and the ranking member for picking this particular subject. I think it has importance to all of us. I am anxious to hear what the witnesses have to present.

Mr. KUCINICH. I thank the gentleman from Massachusetts.

Does the gentlelady from California have any opening statements at all.

Ms. WATSON. I do, if you will give me a second.

Mr. KUCINICH. Sure, just take your time.

Ms. WATSON. I want to thank you, Mr. Chairman. As usual, you are right on time on holding this important hearing with protecting public health.

When I was a State Senator in California, I served as the Chair of Health and Human Services for 17 years, so public health is an issue that is near and dear to my heart.

There are several issues that arise when we discuss the direction of the National Institute of Environmental Health Sciences. The first issue that stands at the forefront is the cuts to the Children's Environmental Health Centers.

In my district, in Los Angeles and Hollywood, there is a joint USC and UCLA Children's Environmental Health Center. Since 1998, this children's center has been investigating the effects of the environment on children's respiratory health.

The center's projects have yielded important information about the effects of air pollution on children. For example, CEHC has reported there has been substantial progress in understanding the effects of ambient air pollutants and environmental tobacco smoke on children's respiratory health, and researchers have identified characteristics that increase the susceptibility of children. This contributes to a growing consensus that current levels of combustion-related air pollutants are more detrimental to children's airways than previously thought.

With significant progress and research on the effects of the environment on children, I am somewhat disturbed to find out that the funding for children's centers has been cut by nearly $900,000.

The other issue that I have with NIEHS is the change of focus from research that was preventive in nature to a more clinical base.

I believe that when we talk about Homeland Security we are talking about protecting the children and the people on the land and not just the infrastructure. Finding preventive measures to catastrophic illnesses should continue to be the main focus of NIEHS and not entirely devoted to treatment and incurring preventable conditions.

My last concern is Dr. David Schwartz, the former Director of NIEHS, who is not here to answer questions about alleged mismanagement and corruption. Mr. Chairman, I hope that we can call on Dr. Schwartz to appear before this committee to answer the questions about these allegations at a subsequent hearing. I know you will see that he is made available.

Thank you so much. I yield back.

Mr. KUCINICH. I thank the gentlelady. I want the gentlelady to know that the ranking member, Mr. Issa, voiced the same concerns that you did. So this committee is united in its intentions.

Ms. WATSON. See, he is a Californian.

Mr. KUCINICH. I just want to thank both Members for focusing on that.

At this time, I would like to introduce our panelist.

Dr. Samuel Wilson is the Acting Director of the National Institute of Environmental Health Sciences. Dr. Wilson joined the NIEHS in his present capacity in 1996. He has fostered basic medical research and disease prevention research during his tenure. He was instrumental in helping develop the NIEHS' programs in genetic susceptibility, functional gnomics, children's health research and minority institutions research and community outreach.

Dr. Wilson has also strengthened partnerships between the NIEHS and other Federal agencies concerned with environmental health. He received his training in medicine and biochemistry at Harvard Medical School and began his research at the NIH in 1970.

In 1991, he moved to the extramural community to found a center focused in the areas of genetic toxicology and structural biology. An active researcher, Dr. Wilson is the principal investigator of the DNA Repair and Nucleic Acid Enzymology Group in the Laboratory of Structural Biology at the NIEHS. He has authored more than 300 research articles.

Doctor, it is the policy of the Committee on Oversight and Government Reform, to swear in all witnesses before they testify. I would ask that you please rise and raise your right hand.

[Witness sworn.]

Mr. KUCINICH. Let the record reflect that the witness answered in the affirmative.

I ask the Doctor to give a brief summary of his testimony and to keep this summary, if you can, under 5 minutes in duration. I want you to know, Doctor, that your complete statement will be included in the hearing record.

The Chair recognizes Dr. Wilson.

STATEMENT OF SAMUEL WILSON, ACTING DIRECTOR OF THE NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES AND THE NATIONAL TOXICOLOGY PROGRAM

Mr. WILSON. Thank you, Mr. Chairman.

Good afternoon. My name is Sam Wilson. At the chairman said, I am the Acting Director of the National Institute of Environmental Health Sciences and the National Toxicology Program. I have long served the interests of the environmental health sciences as a researcher, as director of a center in the extramural community and as the Deputy Director of the NIEHS and National Toxicology Program since 1996.

Dr. Zerhouni asked me to represent NIH today and respond to your questions because Congress has mandated that each Institute and Center comprising the NIH receive direct appropriations, make independent decisions on use of resources, conduct independent strategic planning, and work with its own National Advisory Council. In other words, in terms of allocation of research resources of NIEHS, the buck literally stops here at my desk.

Mr. Chairman, you have expressed concerns that NIEHS is shifting research away from prevention toward clinical approaches to research. I want to state categorically that prevention is a priority of my own and, indeed, all of the NIH. Prevention is a cornerstone of NIH's research strategy. All institutes and centers, especially NIEHS, support medical research that prevents the problem, rather than research that merely addresses acute symptoms or end-stage disease.

Now, the mission of the NIEHS is to support research to define the role of environmental agents in the initiation and progression of human disease. The goal is to use knowledge from this research to reduce adverse exposures and, thus, reduce preventable diseases and conditions. Our understanding of how the environment operates at the molecular level can also provide insights on interventions and early markers for disease. Thus, the NIEHS research is targeted to the "front end" of disease, or disease etiology, and prevention.

The final impact of our research effort, the reduction of human disease and suffering, relies on the efforts of many, including scientists from a variety of scientific disciplines, community groups, policymakers, both within Congress and the administration, along with regulatory agencies throughout the world.

The chart that you see on the screen illustrates this broad spectrum of research translation from fundamental findings in molecular toxicology over here on the left-hand side all the way to the right-hand side of disease, impact, prevention and economic benefit.

Now, all of the components in the continuum that you see here in this rainbow, if you will, are necessary to the efficient transfer of knowledge from fundamental research in molecular toxicology to disease impact, prevention and economic benefit. Our success is highly dependent on public education, as you can see in one sector of the chart here, and also the involvement of community groups.

In the last section of the chart, you can see the importance of formulation of public policy toward the direct application of our research findings.

Also on the chart you see the national toxicology program listed here. This program is one of the crown jewels of the Institute and works on hazard assessment research conducted within the mission of the medical toxicology program.

Every disease has an environmental component. Thus, NIEHS's responsibilities span all human disease, rather than following the model of focus on a specific disease or organ system. This broad spectrum presents challenges, since the public health message of NIEHS must be broad.

Yet the fact is that environmental problems are often local or regional and often complex and often involve involuntary exposures. Such problems engender very passionate responses, both from local communities and the private sector. This multiplicity of stakeholders, as well as the competing economic risks and benefits of our findings, presents NIH with challenging pressures. We have addressed these competing demands by ensuring that stakeholders are included in critical decisions, by providing exhaustive peer review and opportunity for public comment, and by developing innovative approaches by which our research can be relevant to local conditions and needs.

A particular source of pride for me are the novel ways in which NIEHS has sought to recruit the insights of local communities in their research and in the dissemination of research findings. This early inclusion of community groups, in addition to academic medical researchers, has been a particular strength of the NIEHS.

When I joined the NIEHS in 1996, we began to move the Institute's research toward a sharper focus on disease prevention, as well as investigating new ways in which local communities could be more directly involved in the research.

At that time, the Institute had already included the community outreach and education programs in each of its NIEHS Centers of Excellence, and these programs were subsequently reinforced. Working with the Environmental Protection Agency, I helped establish a new children's center program, among other programs. All of these programs are designed to accelerate the discovery of environmental triggers in disease and to include community groups as partners in the research.

I was personally involved in strengthening the community outreach programs by identifying and communicating best practices in individual centers and in ensuring that the centers received extra support for their community outreach efforts and instituting a system where these programs could be evaluated for success in community involvement and education.

Seeing the success of these endeavors convinced me that community based approaches have a very important role to play in the environmental health research enterprise. I was an advocate in developing the NIEHS community based participatory research programs and traveled and spoke extensively to gain the necessary consensus and support for this concept.

As you can imagine, managing an enterprise as diverse and as important as that of NIEHS requires balancing multiple needs and demands. Thus, we are constantly seeking advice from the research community, from a broad spectrum of community groups, and we are open to new approaches not only in laboratory technologies but

also in managing the direction of the environmental health research we support. Because science and technology have changed markedly in recent years, we must be aware of new opportunities in science and incorporate them into our research.

We are looking at how emerging technologies can be used to enhance prevention strategies. For example, in the Exposure Biology Program, which is part of the gene's environment and health initiative, we are developing new genetic tools that will predict risk of disease, along with small monitoring devices that will generate a profile of an individual's environmental exposures.

As we develop new programs, the evaluation of these programs must be an ongoing process at NIEHS. We have recently evaluated the children's centers. We intend to continue to continue to support these centers, at least at their previous level of support or higher.

We also intend to support community based participatory research. A similar program in environmental justice is still undergoing review. However, it is my intent that the NIEHS will continue to support environmental justice research.

Finally, I know that the subcommittee has a strong interest in our journal, Environmental Health Perspectives. In June of this year, NIEHS convened a roundtable discussion on EHP with the community, including a number of investigative journalists. At that time, we expressed—I expressed, our full support for the journal. We are committed to restoring any cuts to the journal, including the Chinese edition and the school edition. I can assure you that the interest of the EHP will be fully represented and supported in the fiscal year 2008 budget.

Now, in closing, NIEHS has a role to play in improving the health of our Nation's citizens. Our research has particular importance because it typically addresses those areas where we can prevent disease and intervene very early in disease development. Thus, we have the ability to provide the Nation with strategies that not only improve health but can greatly reduce health cost.

Such is the power of environmental health research. The full benefit, however, can best be realized when environmental health researchers are part of a team that includes community groups and Congress and other Federal and State agencies. We all have a stake in NIEHS, and we all share as partners in the environmental health research enterprise. It is this relevance to the NIEHS in our everyday lives that motivates me, and it's why I feel privileged to be here today.

Thank you very much for this opportunity to appear today and provide this statement. I shall be happy to answer any of your questions.

Mr. KUCINICH. I want to thank the gentleman.

[The prepared statement of Mr. Wilson follows:]

Good afternoon, I am Dr. Samuel Wilson, currently the Acting Director of the National Institute of Environmental Health Sciences (NIEHS) and of the National Toxicology Program (NTP). NIEHS and NTP are part of the National Institutes of Health (NIH), an agency of the Department of Health and Human Services (HHS). I have long served the interests of environmental health sciences first as a laboratory researcher, then as Director of a Center in the extramural community, and now as the Deputy Director of NIEHS and the National Toxicology Program since 1996.

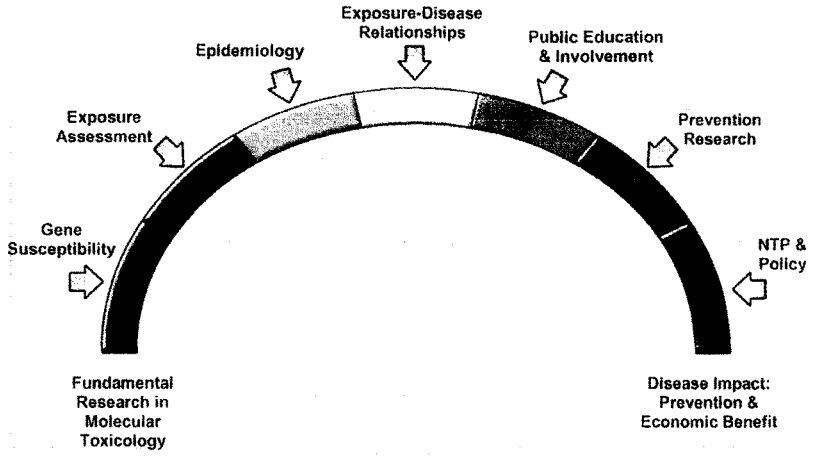
The Director of NIH, Dr. Elias Zerhouni, asked me to represent NIH and respond to your concerns because Congress has provided direct appropriations to each Institute and Center comprising NIH. As Acting Director, I have the primary responsibility for determining how NIEHS makes decisions on the use of its appropriated funds and conducts its strategic planning, working in conjunction with its public advisory council and with the rest of the NIH administration. I have the responsibility for determining how NIEHS's resources are employed both within the Institute and in collaboration with the other NIH Institutes and Centers, as well as other Federal agencies.

Mr. Chairman, you have expressed concerns that NIEHS is shifting research away from prevention and toward clinical approaches to research. I want to state categorically that prevention is a priority of mine and, indeed, all of NIH. Prevention is a cornerstone of NIH's research strategy. All NIH Institutes and Centers support medical research that helps to prevent disease rather than solely how to treat disease once it begins.

The mission of NIEHS is to support research to define the role of environmental agents in the initiation and progression of human disease. The goal is to use knowledge from this research to reduce adverse exposures and thus greatly reduce preventable diseases and conditions. Our understanding of how the environment operates at the molecular level can also provide insights on intervention or early markers of disease. Thus, the research at NIEHS is targeted to the "front-end" of disease, disease etiology, and prevention.

The final impact of our research efforts – reduction in human disease and suffering – relies on the efforts of many entities, including scientists from a variety of disciplines, community groups, policy makers within Congress and the Administration, and regulatory agencies throughout the world. The chart below illustrates this fact, and it shows the progression of NIEHS research, from insights developed through Fundamental Research in Molecular Toxicology to Disease Impact: Prevention & Economic Benefit. All components of the continuum presented in this chart are necessary to the efficient transfer of knowledge at each stage of the spectrum. Our success is highly dependent on public education and involvement and on public policy formulations.

National Institute of Environmental Health Sciences



Every disease has an environmental component, thus NIEHS's responsibilities encompass all human diseases, rather than following the more common model of focus on a specific disease or organ system. This broad continuum presents challenges, since the public health message of NIEHS must be all-encompassing. Complicating matters further is that environmental problems are often local or regional, have complex causal patterns, and often involve involuntary exposures to the local community. Such problems engender passionate responses both from local communities and the private sector. This multiplicity of stakeholders, as well as the competing economic risks and benefits of our findings, present NIEHS with challenging pressures. NIEHS has addressed these competing demands by ensuring that all stakeholders are included in critical decisions, by providing quality peer review and opportunity for public comment, and by developing

innovative approaches by which our research can be relevant to local conditions and needs. A particular source of pride for me is the novel ways in which NIEHS has sought to include the insights of local communities in the conduct of research and in the dissemination of research findings. This early inclusion of groups outside of the academic medical research community has been a particular strength of NIEHS.

When I first came to NIEHS in 1996, we began to move the Institute's research in a more disease-oriented direction, as well as investigating new ways in which local communities could more directly benefit from and be involved in our research. At that time, we had included the activity of Community Outreach and Education Programs (COEP) in each NIEHS Center of Excellence. Working with the Environmental Protection Agency (EPA), I helped establish the first Children's Environmental Health Disease and Prevention Center programs. I also worked to create the Breast Cancer and Environmental Research Centers and the Collaborative Centers for Parkinson's Disease Environmental Research; both of these programs are designed to accelerate the discovery of environmental components in disease and to include community groups.

I was personally involved in strengthening the COEP program by identifying and communicating the "best practices" of individual Centers, insuring that Centers received extra support for their community outreach efforts, and instituting a system where these programs were evaluated and expected to include community involvement and education. Seeing the success of these local endeavors has convinced me that community-based approaches have an important role to play in the environmental health research

enterprise. I was a strong advocate for developing the NIEHS Community-Based Participatory Research in Environmental Health program, and I traveled and spoke extensively to develop the necessary consensus and support for this concept.

As you can imagine, managing an enterprise as diverse and as important as NIEHS requires balancing multiple needs and demands. Thus, we are constantly seeking advice from the research community and from a broad spectrum of community groups, and we are open to new approaches, not only in the laboratory, but also in managing the direction of environmental health research. Because science and technology have changed markedly in the years I have been at NIEHS, we want to be cognizant of new opportunities in science and incorporate them in our research enterprise. We are in particular looking at how emerging technologies can be used to enhance public health prevention strategies. For example, in our Exposure Biology Program, we are developing small exposure monitors that people can wear and that generate a personal profile of their environmental exposures.

As we develop new programs, evaluation must be an on-going process at NIEHS. We have recently evaluated our Children's Environmental Health and Disease Prevention Research Centers Program and concluded that it merits continued support. We also intend to support our Community-Based Research program. A similar program, the Environmental Justice Program, is still undergoing review, although it is my intent that NIEHS will continue to support environmental justice research.

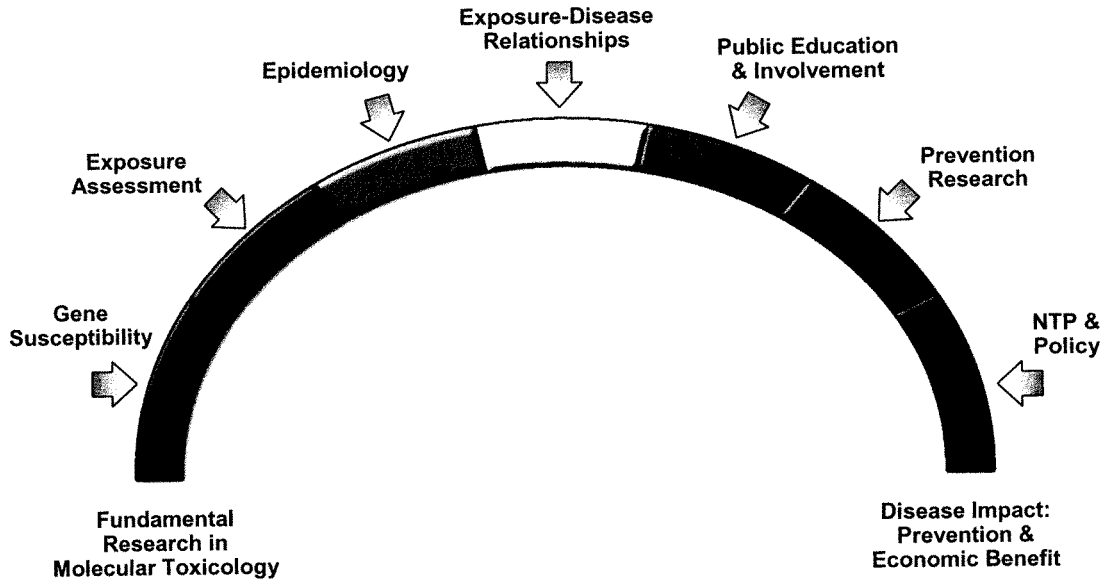
NIEHS has a key role to play in improving the health of our Nation's citizens. Our research has particular importance because it typically addresses those areas where we can prevent disease or intervene very early in its development. Thus, we have the ability to provide the nation with strategies that not only improve health, but would greatly reduce health costs. We cannot, however, do it alone. We must be productively linked to our constituents and the regulatory community in order to fulfill the promise of our mission. When all of us work in partnership, the Nation benefits.

I use the example of environmental lead to illustrate the potential power of this strategy. Research studies supported by NIEHS and NIH's National Institute of Child Health and Human Development showed that even low levels of lead cause decreases in children's intelligence. Evidence such as this, combined with other epidemiological studies, including those conducted at NIH and HHS's Centers for Disease Control and Prevention, has helped to mobilize parents, environmental advocates, environmental health researchers, the EPA, and Congress to remove lead from gasoline, paints, and other sources. The result has been a sharp reduction in blood lead levels throughout the country. The benefit of lead reduction does not stop at childhood; like many environmental agents, lead can affect multiple systems over the lifespan. Recent NIEHS-supported research shows that in adults, higher levels of lead in bones (an indication of life-long lead exposure) are associated with increased risks of hypertension, cataracts, and kidney problems. Clearly, our partnerships to study the effect of lead in the environment represent a major public health success. Such is the power of environmental health research.

The full benefit, however, can only be realized when environmental health researchers are part of a research program that informs community groups and other federal and state agencies. We all have a stake in the NIEHS, and we all serve as partners in the environmental health research enterprise. It is this relevance of the NIEHS to our everyday lives that motivates me as an administrator and why I feel privileged to be here today.

Thank you for this opportunity to appear before you today to provide this statement. I shall be happy to answer any questions you have.

National Institute of Environmental Health Sciences



Mr. KUCINICH. I want to note for the sake of the Members who are curious as to why I didn't call Dr. Wilson's time, and mostly those who are in the audience, this committee has a rule that all witnesses are given 5 minutes. The good doctor has been given 11 minutes, which is double the time that any witness who has come before this committee has been given.

Let me explain to the Members why, and I want members of this committee to know, because this matter is of the utmost importance. Dr. Wilson has a high level of responsibility, and this committee will hold him to a high level of accountability in the questioning. So, because we are going to proceed in that way, I felt it was a prudent approach to make sure that the doctor had ample time to be able to make his presentation without interruption.

I would like to proceed with the first round of questions here, and I want to begin by letting Dr. Wilson know that I am glad to hear that he is going to fully restore environmental health perspectives.

I want to ask you, do you support restoring funding for the children's centers?

Mr. WILSON. Yes, I do. I think the funding for the children's centers has actually been relatively stable.

Mr. KUCINICH. Does that mean full restoration, Dr. Wilson?

Mr. WILSON. Yes.

Mr. KUCINICH. When I ask "full restoration," please be definitive as to what that means to you.

Mr. WILSON. Well, it means that we started the children's centers with 12 individual centers around the country, and the amount of investment was approximately $7 to $8 million at that time, and full restoration of the program would be consistent with that initial investment. We think the program is very successful, and it is an example of this partnership between academic medical researchers and community groups working together to address important problems.

Mr. KUCINICH. Doctor, do you support restoring the program that has been eliminated entirely, which you said you helped create, called the Community Based Participatory Research Environmental Health Program? Is that a yes?

Mr. WILSON. Yes.

Mr. KUCINICH. What about the Centers for Population Health and Health Disparities?

Mr. WILSON. Yes, I support that program.

Mr. KUCINICH. The environmental health sciences as an integrative context for learning, K–12 program?

Mr. WILSON. Uh-huh.

Mr. KUCINICH. Now, when we talk about this, would you be prepared to elucidate? Are you talking about full restoration? Are you talking about restoration in name only, so that you can say there is a program? Or are you talking about really having these programs solid, fully restored, up and running? How would you respond? What would you respond?

Mr. WILSON. I fully support these programs and believe that they are incredibly effective in terms of the successful pursuit of environmental health sciences research.

One thing I would like to add is we are continuing the programs that have recently been discontinued and other mechanisms in our portfolio. So we believe that this research approach is absolutely fundamental and needs to be continued in the interest of successful programs.

But, in some cases, the way that we initiated or sparked research in this field has now matured to the point where it's appropriate to expect to support the research through other mechanisms. So the overall commitment to community based participatory research is absolutely solid and fundamental. The mechanisms that we use to achieve this end point, however, need to be broader than the individual dedicated program that we have previously funded.

Mr. KUCINICH. Let's talk about environmental justice, partnerships for communication to pre-Dr. Schwartz levels. What about that? Do you support restoring that?

Mr. WILSON. Yes, I do.

Mr. KUCINICH. Fully?

Mr. WILSON. Fully, yes.

Mr. KUCINICH. So you would hold it harmless from further cuts?

Mr. WILSON. Yes.

Mr. KUCINICH. I want to read you a quote from a very high-ranking person within the NIEHS who is working with others to put together a search committee that would hire a new editor in chief for environmental health perspectives. I think it summarizes in many ways my concern with the NIH's direction under Dr. Schwartz, who, by the way, had rhetoric that was quite impressive. There was always a concern about his actions being consistent with the rhetoric. So let's get into this. "It would be nice if a candidate actually worked in our field, or can at least consistently spell 'environmental' correctly, but it is more important that they know neuroscience broadly, represent the field and know how journals really work."

That's a direct quote. In other words, this quote seems to put a priority on medical clinical research over environmental and public health, kind of focus on the lab, Petri dish research, as opposed to the studies of large populations for links between chemicals and health problems. What's your perspective on that?

Mr. WILSON. Well, I don't support that statement, first of all. I think the role of the editorship of EHP is an absolutely critical appointment for the Institute in these next several weeks, hopefully. I think the overall——

Mr. KUCINICH. So the candidate will not only be able to spell "environmental" correctly, but will also be able to spell "public health" correctly.

Mr. WILSON. Yes, but to see public health and the importance of the concept of public health, which is a concept that I am very much committed to.

I think an individual who can represent this type of interest and enhance the news section of the journal, plus the broader audience for the journal, to advance the field of public health is fundamental. I am hoping that we can identify an individual of this type. We are in the middle of the search process at the present time and have finalists identified but haven't yet made a choice.

Mr. KUCINICH. Thank you, Doctor.

My 5 minutes is expired. I recognize the ranking member, Mr. Issa.

Mr. ISSA. Thank you, Mr. Chairman. Eleven minutes would have been fine with me. It's not a problem.

Doctor, I will pick up where the chairman left off with a question. Since it's a matter of public record, but I don't have it in front of me, what did the previous editor get paid? Or, if you can, what range are you looking at for the replacement? I just wanted to understand whether spelling comes at a price and what that price is.

Mr. WILSON. Yes, I don't have that number in my mind at the moment.

Mr. ISSA. North of $200,000?

Mr. WILSON. No, no, no.

Mr. ISSA. South of $200,000.

Mr. WILSON. It was way south of $200,000, something in the range of $120- to $130,000 would be my assessment of it.

Mr. ISSA. I ask that because one of the challenges that you have faced and you are facing right now is there have been two attempts to privatize EHP. I would like your thoughts on that. And, quite frankly, one of my reasons for asking that question is a premier, believable, open, transparent, and trustable magazine probably should pay more than $120,000 to get the best and the brightest.

So what I am asking, one, what do you think about privatization? And, if not, two, if you are not able to get privatization, will you recruit the best and the brightest for this within the confines of private pay?

Mr. WILSON. Well, I don't support privatization. I have indicated that on the record at the council meeting for the Institute in May and in other settings.

I am concerned about this level of salary that we have competed this position for. The reason for competing it in the Title 5 GS scale was that the appointment was consistent with the previous individual who occupied the position. We were hoping that we would be able to have a timely appointment by using this mechanism, although I do share the concerns; and I will take a very careful look at these final recommendations by the search committee and by the selecting official in the case of how the search plays out.

Mr. ISSA. If you don't mind elaborating a little bit more, because it appears as though Dr. Schwartz, it was his instigation for this privatization. Can you characterize, and I don't want you to go beyond what you think is fair, but why? Why do you think this was a priority?

Mr. WILSON. Well, I think Dr. Schwartz had a view that the journal could possibly be more successfully operated in the private sector, that the editorship could be more academic in its orientation, and that the typical practices for publication of a journal of this type in the private sector could also benefit the EHP.

I think a secondary factor in his view was the cost of the EHP, the opportunity of maintaining involvement for the Institute and influence over the journal and then, at the same time, having it published in the private sector seemed to be a reasonable opportunity to evaluate.

So I think those were the two main forces driving this idea.

Mr. ISSA. It does appear as though you have to be on both sides of this. On the one hand, you would like to get more dollars for the structure. On the other hand, there isn't.

This privatization—and I want to followup just a little bit more—was more of a public-private scheme, if I understand correctly, because you did want to own and yet not operate, allow it to "float up." Was there any merit to that under your tenure that you would explore to see if you couldn't get a hybrid, one might say, like the post office, which is clearly not private but has a level of autonomy?

Mr. WILSON. Yes, you are right. It was in one stage of the planning conceived as a partnership between NIEHS and a private organization. At another stage of the analysis, it was conceived as a completely private activity, but at the same time the Institute would have some linkage in the editorial process or in the board.

But my view is that the journal really is best served by being published at the Institute. The reason for that is the broad public health orientation of the journal and the opportunity to include very, very high-quality information on what it means to conduct these experiments that we are conducting in our research side of the portfolio, what it means with regard to public health and to the actual daily lives of individuals around the world and here in our country.

Mr. ISSA. I appreciate that.

I will try to close very quickly. You mention in your opening statement about the Chinese. That's a printed Chinese language version?

Mr. WILSON. Yes. Yes, it is.

Mr. ISSA. It's circulated primarily where?

Mr. WILSON. In China, primarily.

Mr. ISSA. OK, so it's an export.

I will just anecdotally say, quite frankly, they can print cheaper in China. I might ask whether helping China by delivering information, and even potentially participating and making sure the translation is correct, might actually be one of the cuts you say you don't want to do that I might question here from the dais, that perhaps the burden of anything other than making the copyrighted material available and a partnership for translation, the balance of it might reasonably be picked up by a Chinese entity. That's why I asked.

I would ask you for the record, because we have run out of time, you said what you wouldn't cut, for the chairman. I would appreciate, assuming no efficiencies—because we all know that efficiencies are mythological sometimes. We know that they exist, but we never see them. Give us those items which you would cut or which you intend to cut or at least those which you are considering in order to balance a set of books while not cutting some very important programs, including the gentlelady from California's questions on the children's centers.

With that, I yield back and thank the chairman.

Mr. KUCINICH. If the gentleman will respond briefly.

Mr. WILSON. Yes, I think the programs that we have funded over the years, especially during the NIH doubling, that represent capacity building in the area of gnomics and various other areas are

areas that we could look at for cutting. So in this broad category of capacity building types of investments.

Mr. KUCINICH. I thank the gentleman.

The Chair recognizes the gentlelady from California, Ms. Watson.

Ms. WATSON. Just very quickly, Mr. Chairman.

I understand that Dr. Schwartz had convened a panel to review the effectiveness of the centers. One of the panelists wrote a letter to him, and he felt that the panel was skewed. Let me just read very quickly, and then you can answer as we flee to the floor to vote. Sorry.

A fundamental problem is that the review panel was highly skewed in its composition. Despite its avowed focus on children's help, the panel did not contain a single pediatrician; and the panel contained an abundance of very senior, highly accomplished laboratory scientists who have studied gnomics and epigenetics and the developmental impacts of environmental toxins in experimental settings.

Given this make-up, it is perhaps not surprising that the panel chose to devaluate child-centered epidemiologic studies and to devalue the primary prevention of environmental diseases.

Would you agree that the composition was unbalanced?

Mr. WILSON. Yes, I would.

Ms. WATSON. How do we then correct that? I think you have been alluding to what you would like to do.

Mr. WILSON. Yes. But let me also point out that the committee, even though not fully balanced, produced an outstanding report, and the report was very strongly supportive of the children's centers. As I said in my earlier comments, I was gratified to see that and view the report as a strong endorsement of the children's centers.

Ms. WATSON. So what will the focus—under your direction, what will the focus be of these children's centers?

Mr. WILSON. Well, in the initial stage of the centers, we first funded eight, and those were focused fairly specifically on childhood asthma. Then we funded, in that first phase, four additional centers; and these were focused on other topics, including autism and various kinds of neurological development problems.

My view is that the structure of the center, for having a partnership between community groups and academic groups, should continue. That is, in each of the centers the structure is this mix of community groups actually working on problems with the academic researchers. So I think that structure is very, very powerful and should continue.

Now, in terms of the topic areas, whether it's asthma or development or some type of other metabolic problem, I see that question as being defined by the community, the children's health research community not originally focused on the topic of asthma, as the original program was heavily focused.

Ms. WATSON. Originally, I think the studies were to be on exposure assessment?

Mr. WILSON. Yes, of course.

Ms. WATSON. I understand that funds had been cut out of that focus, and it has abandoned its commitment to the study by zeroing

out the funding for the study in 2007. Do you plan to continue that?

Mr. WILSON. No, because in the environmental health sciences we have to have exposure science in order to study the front end of disease, so the exposure information is absolutely fundamental in all of our centers. So you really can't do environmental health sciences research supported by our Institute without taking into account the exposures.

Ms. WATSON. Thank you.

Mr. KUCINICH. I thank the gentlelady.

This committee will be in recess until 3:30, where we will reconvene.

Mr. Tierney, do you have any questions of this witness?

Mr. TIERNEY. No, I will waive my questions to the witness. I am sure he would like to move along.

Mr. KUCINICH. What I would like Dr. Wilson to know is that the committee will have followup questions which we will submit to you in writing and ask you to respond to those questions in writing and continue the cooperation which you have shown here today and to ask all of the witnesses to be back here by 3:30—let's make it 3:25, in the interest of conserving time. Be back by 3:25. We will do the best we can to start at that time.

The committee stands in recess.

[The information referred to follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of
Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, N.C. 27709
Website: www.niehs.nih.gov

November 19, 2007

The Honorable Dennis J. Kucinich
Chairman
Committee on Oversight and Government Reform
Subcommittee on Domestic Policy
House of Representatives
Washington, DC 20515

DEC 0 5 2007

Dear Mr. Kucinich:

I am writing you today in response to your recent letter following up on my testimony before the Domestic Policy Subcommittee on September 25, 2007. Your questions are addressed below.

1) **Children's Centers**

A) *One of the recommendations of the "skewed" (your testimony) panel convened to review Children's Centers was to shift toward much shorter funding cycles in "R01" grants. Long term funding commitments had previously been a hallmark of Children's Centers, and had been the primary means of funding long term projects. For example, under the existing Children's Center long term funding structure, a link was found between exposure to the controversial pesticide, chlopyrifos, in the womb, and head circumference and delays in cognitive development. The studies that made such links frequently relied on a long term funding commitment so that biological samples could be stored and used by other researchers. In which circumstance will you use the R01 funding mechanism in the Children's Centers? Do you agree that the R01 funding mechanism presents a challenge to the continuation of certain research, such as that cited above, which seem to require long term funding commitments? If not, why not? Do you intend to implement any of the recommended changes to the Children's Centers that were outlined in the Children's Center reports? If so which ones and why?*

Answer: NIEHS is committed to the long-term funding of research in the field of Children's Environmental Health. We are currently speaking with our partners in the Environmental Protection Agency (EPA) and the Centers for Disease Control and Prevention (CDC) about the details of the continuation of the successful Centers for Children's Environmental Health and Disease Prevention Research Program. At the same time, however, we believe a mix of appropriate funding mechanisms will provide the most flexible and responsive program, and we intend to fund both single project research grants (R01s) as well as support the multi-project research and translation centers (P01s). We also currently support and will continue to support smaller grants to assess the feasibility of novel approaches to emerging issues in Children's Environmental Health. It has been our experience that R01 funding in

addition to the Centers program has been successful in supporting new advances in children's environmental health. We will continue to bring multidisciplinary teams together to address important questions using diverse scientific methodologies such as epidemiology, exposure sciences, development of biomarkers of exposure and effect, genetics, and toxicology. In addition, we will encourage the engagement of communities which have high levels of exposures and/or disease risk and promote opportunities for researchers and community members to work together. It is our goal to bring these groups together and to create synergy which will result in new information and methodology to protect children from environmental hazards.

B) *As you know, the weakest link in epidemiological studies is often exposure assessment. It is difficult to identify what someone has been exposed to over a few weeks, let alone a lifetime. It is also difficult in many studies to make sure the exposure precedes the disease. One of the best ways to overcome both problems is the prospective study, where people are followed - and their exposures are assessed - over a long time period. You also know that the National Children's Study will follow 100,000 people from pre-conception all the way to adulthood. That study has enormous promise since its predecessors, the Framingham Heart Study and the National Nurses Study, yielded major contributions to public health. Yet under Dr. Schwartz, NIEHS abandoned its commitment to the study by zeroing out funding for the study in FY07. Do you plan to fund the National Children's Study?*

Answer: NIEHS concurs wholeheartedly that exposure assessment is a critical need in environmental studies, and one for which the tools at our disposal are woefully inadequate. That is why we prioritized the funding of the Exposure Biology Program, which we hope will add substantially to the technologies that can be used to measure participants' exposures in studies like the National Children's Study (NCS). NIEHS made the decision to use the funds which, in previous years, it had provided to the NCS to support planning efforts (about $1.5M/year) to jump-start this critical work in exposure assessment technology so that it would be available for use by studies. NIEHS is still very much engaged with the NCS. NIEHS staff sits on the NCS Interagency Coordinating Committee, and other staff are being detailed part-time to the NCS Program Office to assist with the workload associated with awarding and monitoring the new study centers. Also, as the Exposure Biology awards are made, NIEHS staff will be facilitating interactions between those awardees and the scientists to discuss the validation and field-testing of the new exposure assessment technologies as they are developed.

2) Environmental Health Science (EHC) Core Centers

A) *The following changes were made to the Core Centers program under Dr. Schwartz. Please detail which changes will persist. Of those changes that will not persist, please describe the changes you will make, and which stakeholder participants will be included in the decision making process?*

i) *"The program endeavors to focus investigators to a greater extent on clinical applications, translation, and interdisciplinary research that will have a greater impact on human disease and public health."*
ii) *"In order to provide increased flexibility in organization and structure of the EHS Core Center, the Director may develop a dynamic structure which meets the on-going intellectual needs of the Center. This structure can change as the intellectual needs change to accommodate new opportunities for collaboration. Research Cores are no longer required as organizational units in the Center. The proposed Center organization must include the required components outlined above, but, beyond those, no additional structure is imposed by NIEHS."*
iii) *"An Integrative Health Sciences Facility Core is required."*
iv) *"Community Outreach and Education Cores (COEC) which focus on partnering with stakeholders in order to disseminate EHS Center research results are optional. Centers that choose to develop a Community Outreach and Education Core are eligible for an additional $100,000 direct costs. Kindergarten-Grade 12 curriculum development is not allowed as a COEC activity."*

Answer: The Environmental Health Science (EHS) core centers program supports the infrastructure for research in environmental health sciences at many universities across the U.S. Our purpose in re-engineering the program was to bring a sharper focus on human disease and to promote integrative research, while continuing to provide the infrastructure for a wide spectrum of science, including toxicology, epidemiology, and cellular and molecular biology. Our goal was to promote scientific advances along the spectrum from basic cellular studies, to animal and other models of human disease, to clinical work in patients, and to populations at high risk of environmentally induced diseases. All of these approaches are important to further our understanding of the role of the environmental exposures in human disease, exposure sciences, and prevention and intervention research.

Our plan is to keep these current guidelines in place for two more years (that is, two more rounds of applications) in order to promote fairness across the program. Since Center grants must be re-competed every five years and the new guidelines have been in place for 3 years, this will allow all of the Centers to compete under the same objectives and guidelines. If we redesign the program at this time, it could be unfair and detrimental to the current centers and applicants.

We will assess the implementation of these changes after the 2010 awards are made. At that time, we will get input from a variety of stakeholders, researchers, administrators at the universities, community outreach and education partners, and

program staff to guide the next set of revisions. We will be assessing and revising our P30 EHS Centers program at regular intervals in order to keep pace with the ever changing world of environmental health science and to keep it vibrant and current.

3) Environmental Health Perspectives (EHP)

A) *There has been a dearth of permanent leadership at the Journal. Most, if not every one of the leadership positions in the journal is now filled on an "acting" or "interim" basis. Some of those positions have been vacant for well over 6 months and all are currently occupied by staffs who were not relieved of their previous duties. Several rank and file staff have also not been replaced. What is your plan and timeline to correct this? Please detail which positions will be filled and when.*

Answer: The NIEHS has completed a lengthy and open recruitment process for the position of Editor-in-Chief of the Environmental Health Perspectives (EHP). Hugh A. Tilson, Ph.D., will join the agency on November 26, 2007, and will assume the full responsibility of the Editor-in-Chief of EHP on January 1, 2008. We have assured Dr. Tilson that he will have the full administrative and budgetary support of the NIEHS so that EHP will remain the premier environmental science journal.

B) *More than two months after the closing of the Request for Proposals a contract still has not been awarded. Is this unusual? If not, what is the cause of the delay?*

Answer: It is not unusual for it to take longer than two months to award a contract after the closing of a Request for Proposal. The National Library of Medicine's (NLM) Consolidated Operations Acquisition Center is managing the acquisition process which will result in the award of the new EHP contract for publication services. The NIEHS staff has not been directly involved in the technical evaluation process since receipt of proposals but will be given the opportunity to participate in the selection of the contractor following the completion of the formal technical evaluation. The technical evaluation is being coordinated and conducted by a professional Scientific Review Administrator (SRA) following the unique requirements for reviewing proposals in support of a peer reviewed scientific journal. This review will result in an independent evaluation of the proposals and will be used as part of the best value determination when a contractor is selected.

C) *The National Library of Medicine (NLM) was given responsibility for the EHP contract in response to Dr. Schwartz's recusal from all matters pertaining to the journal. This protective measure had the unfortunate consequence of preventing the end users of the contract (i.e., EHP and other NIEHS staff) from having any input into the selection of the contractor. Given that Dr. Schwartz is no longer director of the institute, is there a reason that NIEHS should continue to be excluded from the EHP contract selection process? If not, what should NIEHS' role be?*

Answer: The EHP staff and NIEHS leadership were consulted during the preparation of the Statement of Work (SOW) for the Request for Proposals (RFP) for the proposed contract. The NLM Contracting Officer will attend the technical evaluation meeting of the independent peer review panel assembled by the SRA, and will consult NIEHS staff in relation to any questions the reviewers may have. In addition, NIEHS staff will have the opportunity to provide input in the final selection process.

D) *How can you ensure that the best interests of EHP, not just the contracting bottom line, will be served despite the exclusion of EHP/NIEHS staff from the contract selection process?*

Answer: We have been assured by NIH and the Contracting Officer that the best interests of EHP will be protected through the contract process and in the future administration of the journal. NIEHS will be available at any time to discuss with the Contracting Officer any issues relevant to the contract selection process. NIEHS is fully supportive of the continued success of EHP as the premier journal in its field.

E) *The primary focus of EHP is not to make a profit but to serve the community, and the journal should be supported in this endeavor. What will you do to ensure that EHP will not be derailed again and that it remains unencumbered in fulfilling its mission of broadly disseminating information to the public? What is your plan to continue to expand EHP's influence, reputation and readership?*

Answer: NIEHS stated unequivocally at the Roundtable held in June 2007, and I testified at the September hearing before this Subcommittee, that the best interests of EHP are a top priority for NIEHS and will remain so for the foreseeable future. The new Editor–in-Chief and our EHP staff will commit to enhancing the reputation and readership of EHP by continuing the successful policies that have markedly increased the "impact factor" of EHP so that it is now the number one environmental health science journal in the world. We have also provided additional funds for travel and other strategies to augment awareness of the journal to the scientific community and the public.

F) *EHP suffered from cutbacks and neglect under Dr. Schwartz. Have you ever had any indication that his desire to weaken the journal resulted from pressure from NIH? From any party external to NIH?*

Answer: To my knowledge there has been no exertion of pressure from NIH or any party external to NIH to anyone within NIEHS to weaken the journal.

G) *Which EHP features will be continued, reinstated, strengthened, or cut?*

Answer: The proposed budget for EHP for 2008 includes full support for the news section of the journal, for the student edition, and for international outreach activities of the journal, plus additional support for the new editor to expand awareness of the journal.

H) *Will the promotion of EHP through press releases be reinstituted?*

Answer: We will ask the new Editor-in–Chief to look carefully at this option for promoting the journal and will support his decision.

4) National Toxicology Program (NTP)

A) *Under Dr. Schwartz, there was concern about the level of support for the National Toxicology Program. The NTP is important for prevention as it generates the solid science that informs priorities for chemical regulation.*

I am concerned about a lack of transparency in the NTP budget. Your analysis provided to the committee says the NTP budget is about $114M in FY04 and $109M in FY08. But your website says "in 2004, the total budget for the NTP was approximately $192.2M (direct plus indirect cost)"[2]. And our committee reports that the actual number is closer to $85M. My concern is that such a lack of transparency and consistency makes it possible to obfuscate funding decreases. In fact, there is some evidence that it has already happened: In 1981, the NTP budget was about $65M. By 1993, the budget had grown to about $80M. Then the NTP was folded into NIEHS and was no longer a Congressional line item. NTP has reportedly remained flat since then - around $85M - despite the recent doubling of NIEHS' budget. If that is true, the difference between the $200M NTP is getting according to some of your budget figures and the $85M they are reportedly actually spending on NTP (about $115 million per year) is going somewhere. Where is that money going? How will you ensure consistently and clarity in the NTP budget in the future?

Answer: The National Toxicology Program (NTP) has traditionally received more than 95% of its funding from the NIEHS. Before 1993, this funding was an amount designated as a line item in the Congressional budget, and after 1993, it was an amount set at the discretion of the NIEHS Director, who is also the Director of the NTP. The vast majority of NTP funding is used to cover expenses in three general areas: 1) research and development contracts (R&D contracts); 2) research or special initiatives carried out by the NIEHS on issues considered relevant to the NTP; and 3) costs associated with personnel salaries, supplies, benefits, etc. The differences in the NTP budget numbers over time reflect, in part, differences in the number of NIEHS staff assigned to NTP, the amount of research carried out by the NIEHS Division of Intramural Research attributed to the NTP, and any special NIEHS research initiatives begun and/or concluded that were considered relevant to

the NTP. The majority of the NTP toxicology research and testing activities, including the rodent cancer bioassays conducted in response to nominations to the program, are designed and interpreted by a core of NIEHS/NTP staff scientists and are performed under R&D contracts.

The NTP R&D contracts budget at its peak in 2004 was $95,583,323. In 2004, salaries and expenses related to personnel in that segment of the NIEHS Division of Intramural Research assigned to NTP (Environmental Toxicology Program (ETP)) were $18,794,117. The NTP budget of approximately $114,000,000, which was provided to the committee, reflects R&D contracts and ETP staff costs (#1 and #3 above). The NTP budget of $192,200,000, which is referenced on the website, also includes the costs of research carried out within the NIEHS Division of Intramural Research attributed to NTP-relevant nominations or issues, plus the costs of an Institute initiative for developing a new technology termed "toxicogenomics," which is currently receiving widespread use in the field of toxicology (#2 above). In addition, it includes the contributions by the National Institute for Occupational Safety and Health (NIOSH), administered by CDC, and FDA's National Center for Toxicological Research (NCTR) to the NTP ($22,300,000) as reported to the NIEHS; these agencies, along with NIEHS, form the core contributing to the NTP.

The NTP R&D contracts budget for 2007 was $87,353,000 and intramural staff costs within the Extramural Toxicology Program (ETP) were $22,056,700, for a total of approximately $109,000,000, which was reported to the committee. NIEHS recognizes the past difficulties and complexities in understanding the NTP budget and has undertaken steps to increase the transparency of the NTP budget and staffing in the future. As of October 28, 2007, the NTP exists as a separate program operationally within the NIEHS Division of Intramural Research. The NTP budget will comprise the NTP R&D contracts plus associated personnel costs and will be tracked and reported as a distinct program. The NTP will include 94 staff devoted to running the research and testing program and specialized evaluation activities (e.g., the Report on Carcinogens), as well as continuing to provide basic pathology support services which benefit NTP and NIEHS, a role NTP has played since its inception.

B) *We heard testimony in the hearing stating that there has been a decline in the number of chemicals being studied for possible regulation. In particular, we understand there has been a decline in the areas of cancer bioassays and reproductive, developmental, and neurotoxicity assays. Please detail the number of toxicology starts annually since FY00 as well as any projected for the future. What is the cause of the decline in existing starts? Will you perpetuate that trend or reverse it? If the decline in starts is due to a diversion of resources to fund other research, how is NIEHS translating the results of that research into improvements in the science and the efficiency of toxicological testing?*

Answer: Overall, the number of substances studied by the NTP since 2000 has remained relatively constant. Fluctuations in the number of substances studied in any given area have occurred throughout the years; however, these differences have primarily reflected changes in the types of studies that were needed to address gaps in the toxicology and cancer databases for particular substances rather than a lack of funding. As shown in the table below, cancer study starts from FY 2000 – 2006 averaged 8.4 per year and ranged from a peak of 14 in 2003 to a low of 6 in 2004. In 2007, however, the number of cancer study starts declined to 3 because the anticipated budget would be insufficient to start more studies while maintaining ongoing cancer studies (approximately 50 at any given time; an NTP cancer study in rodents typically takes 5 years from initiation to reporting of the findings). This decrease in cancer study starts reflects a flat budget for FY 2007 and 2008 and not a specific or intentional diversion of funds. The cost of performing these studies has increased over time also. The 2007 NTP R&D contracts budget of $87,353,000 is projected to be the same in 2008.

The recent decline in the number of starts for reproductive and developmental toxicology studies is related to the small number of contract laboratories that have the capability to do these types of studies. NTP has selected a contract laboratory to conduct its reproductive and toxicology studies and is currently working to build and support the laboratory's capacity to conduct the NTP's studies successfully. However, initiation of these studies will impact the NTP research and testing program overall due to the budgetary constraints noted above.

NTP has conducted neurotoxicity studies as an adjunct to other studies, but not as an area of primary focus.

NTP Study Starts FY 2000 – 2007

	2000	2001	2002	2003	2004	2005	2006	2007
Carcinogenicity studies	9	7	7	14	6	9	7	3
Subchronic toxicology studies	27	21	16	19	16	14	23	26

C) *What is the status of the Report on Carcinogens? It is due this year and there is a concern that it will not come out on time. What are the reasons for the delay? Have Data Quality Act challenges been a significant cause for the Report's delay?*

Answer: The process for preparation of the 12th Report on Carcinogens has begun. The final review process was announced in the Federal Register (72 FR 18999, April 16, 2007), and 13 candidate substances are under consideration for possible listing in the report. Meetings to review the candidate substances are underway and NTP anticipates publication of the 12th Report on Carcinogens in 2009. Preparation of the

12th Report was delayed due to efforts by the NTP toward development of a process for review of substances for the Report on Carcinogens that enhanced scientific development of the Report and addressed issues raised by the Office of Management and Budget/Office of Information and Regulatory Affairs and guidance in the *OMB Final Information Quality Bulletin for Peer Review.*

5) Other Programs

A) *The Union of Concerned Scientists has conducted surveys of scientists at nine agencies, not including NIH. Of the more than 1,800 respondents, almost 700 scientists reported that they fear retaliation for openly expressing concerns about their agency's mission-related work. This number should be zero. The Subcommittee has heard allegations of suppression of scientific freedom by, for example, requiring an excessive amount of preapproval to publish a scientific paper. Do you know of cases where scientists at NIEHS have reported political interference in their work or have been afraid to speak? How do you propose to lead NIEHS to create a culture of scientific openness and impartiality? How will you solicit the concerns of scientists about working at NIEHS?*

Answer: I know of no cases at the NIEHS in which there was political interference in anybody's research. There are many forums at which scientists can make their views known to the scientific leadership. For example, we solicit the concerns of scientists through frequent, open meetings between the administration of the Division of Intramural Research (DIR) and several different scientific interest groups, including: 1) The Assembly of Scientists, representing all Principal Investigators and Staff Scientists at the NIEHS; 2) the Tenure Track Investigators' Association; 3) the Women Scientists' Association; and 4) the Trainees' Assembly. The Assembly of Scientists also has a Council that can relay members' concerns anonymously to DIR administration. In addition, there are frequent meetings between the DIR administration and the Lab and Branch chiefs, known as the DIR Council meeting. At these meetings, the Lab and Branch chiefs represent the members of their labs and branches and communicate important information back to them. Finally, the DIR administration meets regularly with the Program Directors, a group that represents the four major intramural programs within DIR. The DIR also sends an elected representative to the NIH Assembly of Scientists meeting, so that the views of the NIEHS Assembly of Scientists are communicated to the senior NIH administration. Thus, we feel that NIEHS scientists have ample opportunity to communicate their views to the administration in a variety of open forums and are free from political interference in their work.

The NIEHS follows the NIH policy regarding review and approval of scientific and technical information by NIH employees, a process that has been in place since 1993. NIH, as does NIEHS, encourages professional dissemination of scientific research and other information on behalf of the public health by its employees. The

NIEHS has developed a convenient on-line manuscript approval process for this internal review. The operation of this review mechanism was discussed as recently as October 23, 2007 by the DIR Council and the Council agreed to continue the process in its present form. During this discussion, there were no complaints that the NIEHS process was "excessive."

The NIEHS process for the DIR is very similar to that outlined by the NIH Office of Intramural Research (http://www1.od.nih.gov/oir/sourcebook/oversight/pub-clear.htm) and NIH Manual Chapter 1184: Scientific, Technical, and Other Professional Information Presented by NIH Employees. The NIEHS system requires completion of an on-line form at https://dir-apps.niehs.nih.gov/msmanager/index.cfm?action=manuscript.new, approval by two peer reviewers of the author's choice, the Laboratory or Branch Chief, and the Scientific Director. There have been times when one or more of the reviewers has recommended changes or revisions to a manuscript, but this is in the spirit of trying to improve the quality of the scientific publications coming from the DIR. None of the reviewers in this process is a political appointee.

B) *During our hearing, you committed to restore funding for the Environmental Justice: Partnerships for Communication program. You also committed to fund Community Based Participatory research. In that context, you mentioned an interest in reexamining the funding mechanism of CBPR. Please elaborate on other potential funding mechanisms or sources. How does that compare to prior funding mechanisms? How will the funding mechanisms be selected?*

Answer: We hope that many of the principles developed and utilized in these programs will become standard practice in community-based participatory research (CBPR). We plan to continue and combine all of these programs into a comprehensive overarching new program of "Environmental Public Health" that may utilize a number of appropriate funding mechanisms including R03s, R21s, and R01s, as well as supplements and/or components of other established programs such as the NIEHS Core Centers. We cannot be certain at this point what the totality of this program will be, as we have just begun discussions of it. Our deliberations will include public input, including input from grantees and the communities that would be expected to participate. It is important to note that we have supported community involvement in research by requiring the inclusion of community partners in a number of our programs including the Children's Environmental Health Centers and the Breast Cancer and Environment Research Centers. We intend to continue to emphasize the use of CBPR methods when appropriate for community-based and population-based research. We believe there are distinct advantages to using these methods to gain a richer understanding of community concerns and incorporating them into hypothesis-driven research.

C) *The establishment of a clinical center at NIEHS raises several concerns in addition to costs. First, a hospital is not in close proximity, in case an unforeseen health problem arises. Second, it is inappropriate to expose people to hazardous agents to induce an adverse response, especially at a government facility that is not in close proximity to a hospital. Third, clinical research centers exist at nearby hospitals (Duke and UNC) where approved studies could be performed. What is the construction status of the new clinical research center at NIEHS? Will it be continued? If the program and building are to continue, have alternatives been explored, such as partnering with EPA and the University of North Carolina and/or conducting such research in Bethesda?*

Answer: Regarding the three concerns listed in this question: 1) Two major teaching hospitals are within 15 minutes driving time of the planned Clinical Research Unit (CRU). In addition, we will have a physician on site at all times who is board certified in internal medicine and pulmonary and critical care medicine, as well as registered nurses and respiratory technicians. As part of the NIH credentialing process for the new CRU, all NIEHS physicians wishing to be credentialed to use this facility will need to be certified and keep current their training in cardiopulmonary resuscitation. 2) We have no plans to expose our subjects to truly hazardous agents. However, as part of our mission to investigate common, environmentally sensitive diseases such as asthma, we plan to expose research subjects to the kinds of exposures that are either in the environment (such as ozone) or are considered routine in pulmonary research involving pulmonary function testing (such as drugs that expand or contract the airways). Agents of this type are commonly used in environmental exposure chambers at Duke, or the EPA "government facility" housed at the University of North Carolina at Chapel Hill (UNC). 3) We are aware of the clinical research centers at UNC and Duke but decided that the best way to maximize the interactions between basic scientists and clinical investigators at the NIEHS was to construct our own outpatient facility within convenient walking distance of the laboratories within the main NIEHS campus.

NIEHS' Board of Scientific Counselors (BSC), which advises the NIEHS Director and the Director and Deputy Director for Intramural Research, regularly reviews the research of all intramural investigators conducting clinical research as well as basic research. All Institutes of the NIH have similar Boards, which are composed of distinguished non-government scientists. These Boards provide input on intramural initiatives as well as in-depth reviews of the intramural laboratories (each lab undergoes this review every four years.) The BSC was apprised of the planned development of the Clinical Research Unit and the expansion of the Clinical Research Program in a discussion with Dr. David Schwartz at one of the Board's regular meetings. Our Clinical Director has described the planned construction of

the CRU, and the expansion of the Program in Clinical Research, at three consecutive open meetings of the National Advisory Environmental Health Sciences Council, at which members of the Council were encouraged to ask questions about this new initiative, and did so.

The current status of the NIEHS CRU is that it is scheduled for completion on December 7, 2007, with doors to open early in the new year. We plan to continue this process. Prior to the decision to construct the CRU, we explored alternative mechanisms for conducting clinical research, such as using the General Clinical Research Centers at Duke or UNC. However, we decided to build our own center on site, both because of major cost savings compared to leasing laboratory space on campus at Duke or UNC and because of the need for an integrated, collaborative program.

D) How long have the positions for the Directors of both intramural and extramural research been vacant? How long has the Scientific Director position been vacant? When do you expect them to be filled?

Answer: The former Director, Division of Extramural Research and Training, retired on November 8, 2006, after a very long and rewarding career, and the former Director, Division of Intramural Research, resigned from the position of Scientific Director on February 1, 2007, to focus on his personal research program here at NIEHS.

The Scientific Director Search Committee conducted the recruitment for the Director, Intramural Research, and interviews have been completed. The final recommendation has been forwarded to the NIH Director. The Director, Extramural Research and Training, search was extended until December 3 of this year to allow more time for candidates to apply.

E) *The Subcommittee has received reports over the loss of lab funding for Dr. Retha Newbold, who performed groundbreaking work on endocrine disruptors. Was the same review by the Scientific Board of Counselors that reportedly preceded Dr. Newbold's defunding also performed on other labs/research? Which ones? Was it performed on any of the newly created clinical initiatives?*

Answer: At the same meeting at which Retha Newbold's research was most recently reviewed, the research of the following groups was also reviewed: Jean Harry, Dori Germolec, Heinrich Malling, and John French. All research groups within the Division of Intramural Research (DIR) are reviewed approximately every four years by essentially the same Board of Scientific Counselors (BSC) that conducted this specific review. These extremely stringent reviews are the mechanism by which

the BSC recommends to the Scientific Director that the resources of a given laboratory be increased or decreased, or that the laboratory be discontinued. The reviews apply to all investigators –clinical and bench - with independent laboratory resources within the DIR.

The same Board of Scientific Counselors (BSC) regularly reviews the research of all principal investigators conducting clinical research as well as basic research.

F) *The Subcommittee is concerned with infrastructure and processes that provide oversight of the Institute. In particular, we heard testimony about significant errors in the meeting minutes of the NAEHSC (Council). Please explain the reasons for the errors. What processes are in place to ensure the accuracy of the minutes? Are all members of the Council entitled to view the minutes and any supporting information such as audio/video recordings of the meetings? Because the Council provides scientific advice to NIEHS leadership, it is crucial that the information members receive is complete, easily accessible, and accurate. What information about the Institute is off limits to members of the Council, if any?*

Answer: We do not agree that there were errors in the minutes of the May 2007 meeting of the National Advisory Environmental Health Sciences Council (NAEHSC). The minutes have always been prepared as a brief summary of the council discussion. Minutes are always approved by Council by vote. At the September 2007 meeting, several Council members objected to the fact that the minutes for the May 2007 meeting were not detailed enough and failed to include some of the discussion points and recommendations that they believed should have been included. The minutes for that meeting have subsequently been revised to include those details, and have been circulated to the council members for their approval. On a vote of 14 in favor, 1 against, and 2 abstentions those revised minutes have been approved by the Council. For future meetings, we will make every effort to include more detail in the minutes, and as always, they will be subject to approval. Additionally, we hope to begin videotaping the entire public portion of Council meetings and to archive those videos as permanent and complete records of the Council deliberations.

6) Workforce

A) *Please explain how you will protect employees (or whistleblowers) from reprisal? What will you do to ensure that employees feel free to come forward to appropriate authorities with concerns of waste, fraud, and abuse? What will you do to ensure fairness and equity and a workplace free of reprisal, favoritism, and/or discrimination?*

Answer: Dr. Zerhouni addressed the issue of whistleblower protection in a memo to the Director of NIEHS, and Dr. Schwartz issued an email to all staff supporting an open atmosphere for NIH and NIEHS and reassuring employees that they work in a workplace free of reprisal, favoritism, and discrimination. During my recent all-hands NIEHS meeting, I reiterated the policy and my strong commitment to upholding the protections of the federal whistleblower statutes. I re-affirmed that no NIH or NIEHS employee will be subject to retaliation, directly or indirectly, for exercising their rights under federal law. I am committed to fostering an environment where these protections are not inhibited.

B) *As you know, morale at NIEHS is exceedingly low. Please explain your plan to revitalize the Institute's most valuable asset - its employees. Please include a description of the people/entities you will engage in this process.*

Answer: My plan is to provide ongoing information to employees and ask for and value their suggestions and input. Immediately after Dr. Schwartz stepped aside from his role as director, I met with small groups of employees and explained the situation to them as well as responded to their questions. Since then I have instituted periodic "all hands" meetings to provide continuing information and ask for comments and suggestions.

I am in the process of developing an inclusive committee structure to provide transparent cooperative governance of the Institute as appropriate.

C) *In 2006, supervisors were reportedly instructed to not discuss final ratings for any job element with employees because this required input and approval by upper management. Consequently, many employees never learned the basis for their performance ratings. As one supervisor noted, the performance management system "clearly wasn't managed well last year and lots of folks got lower ratings than usual." If the performance system was poorly managed last year, then NIEHS management should have acknowledged the flaws and corrected the errors. Will you determine what errors were made last year and correct the 2006 ratings where appropriate?*

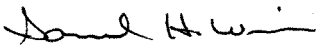
Answer: For the 2005 review period, the NIH/NIEHS used a long-standing pass/fail rating system. For 2006, however, implementation of a new NIH-wide four-tiered rating system – Exceptional, Fully Satisfactory, Minimally Successful and Unacceptable – was implemented. There is no way to draw any parallels between the old and new systems.

Supervisors were asked to postpone discussions of specific performance award recommendations until they had conducted all of their direct report ratings. This way they would be able to make the determination for award amounts. To ensure full understanding of the performance review process for the upcoming 2007 rating

period, the NIEHS has chartered an institute-wide committee comprised of management representatives from across the institute to develop a process to ensure consistent application of the standards for personnel reviews. This group anticipates issuing their recommendations later this month.

Thank you for this opportunity to respond to your questions. An identical letter will be sent to Representative Issa who was a co-signatory on your letter.

Sincerely,



Samuel H. Wilson, M.D.
Acting Director

cc: Darrell E. Issa
Ranking Minority Member
Domestic Policy Subcommittee

[Recess.]

Mr. KUCINICH. The committee will come to order. There was a vote call on the way back here, and so we're mindful of Dr. Lucier's time constraints. And what we're going to do is this: I'm going to ask the witnesses to be sworn. I will go to Dr. Lucier so he can get his statement in the record, and then we will discharge him as a witness, provided he's open to some written questions from the committee, and then we will continue with the testimony of the other witnesses.

I'm going to ask all the witnesses if they would please stand. It is the custom and purpose of this committee to make sure the witnesses are sworn. I would ask that you raise your right hands.

[Witnesses sworn.]

Mr. KUCINICH. Let the record reflect that the witnesses have answered in the affirmative.

Dr. Lucier has a very extensive background, which we will submit for the record, but in the interest of facilitating his schedule, I'm going to go to him for testimony right now.

You may proceed, Doctor. And please pull that mic up close to you so we can hear you.

Mr. LUCIER. Thank you, Chairman Kucinich.

Mr. ISSA. See if the green light is on.

Mr. KUCINICH. Would staff assist Dr. Lucier in making sure that he can get his testimony in the record?

I want to thank all of you for waiting.

Please proceed.

STATEMENTS OF GEORGE W. LUCIER, FORMER EDITOR IN CHIEF OF EHP, FORMER ASSOCIATE DIRECTOR OF NTP; LYNN R. GOLDMAN, PROFESSOR, JOHNS HOPKINS UNIVERSITY, BLOOMBERG SCHOOL OF PUBLIC HEALTH; PEGGY M. SHEPARD, EXECUTIVE DIRECTOR, WE ACT FOR ENVIRONMENTAL JUSTICE; AND STEFANI D. HINES, MEMBER, NATIONAL ADVISORY ENVIRONMENTAL HEALTH SCIENCES COUNCIL [NAEHSC], ENVIRONMENTAL SPECIALIST, ALBUQUERQUE, UNIVERSITY OF NEW MEXICO

STATEMENT OF GEORGE W. LUCIER

Mr. LUCIER. Thank you, Chairman Kucinich, and thank you, Chairman Issa. It is certainly an honor for me to testify here today about my views on NIEHS' support of environmental perspectives in the National Toxicology Program. I worked at NIEHS for 30 years, and when I left, when I retired in 2000, I was Associate Director of the NTP and coeditor of Environmental Health Perspectives, a position that I had held for 28 years.

First let me begin by making some comments on EHP. In 2005, when Dr. Schwartz came to NIEHS, EHP was considered the leading environmental health journal in the world. Its impacts by all measures were steadily increasing, while at the same time costs were decreasing. Dr. Schwartz, in a puzzling series of moves, attempted to dismantle the EHP under the false guise of saving money.

Here are some relevant facts from my perspective. EHP is comprised of several sections, articles, science articles, news, the stu-

dent edition, international editions, Chinese, Spanish editions. Each has important readership, and each has an important impact. Dr. Schwartz attempted to cut or eliminate all but the science articles.

The impact factor, scientific impact factor, in the last 5 years has nearly doubled. The mentions of EHP articles in the lay press has increased from one per day to six per day. The last 3 months the Web site was visited by 305,000 individuals from 207 countries. At the same time, the cost was decreasing. The proportion of the NIH budget taken by EHP was 0.67 percent in 2001; it was 0.46 percent in 2005, a 50 percent decrease.

There has been a significant loss of senior staff. In 2001, EHP had an editor in chief, two science editors and a news editor. Today there is an interim editor on a part-time basis, no science editor, and the news editor has been detailed to the Director's office for the last 9 months. It is amazing the journal still comes out and is as good as it is.

I have a series of recommendations for you and the NIEHS, and Dr. Wilson has addressed many of these. Restore the EHP budget to 2005 levels. Restore the staffing levels. Fully fund the news section. Fund the Chinese and Spanish editions. Restore the student edition. Establish a budget process for EHP that is consistent with its important role in the NIEHS; don't treat it as a second-class citizen.

Let me now make some comments regarding the National Toxicology Program. This program was established by Congress in 1978 as an interagency effort to provide toxicological evaluations on substances of public health concern. It is not a regulatory agency or program, but it does provide key scientific information for those who must make regulatory decisions. It has a primary role in disease prevention by identifying hazards in the environment and in the workplace, in the home that may cause toxicity, and by characterizing those toxicities. We have to remember that a positive epidemiology or clinical finding really is a failure of public health policy.

Over its 29 years of existence, NTP has been considered the world's leading and most comprehensive toxicology research and testing program. Many programs are still doing well in the NTP, but there are several problems.

Dr. Schwartz seemed to view his dual role as NTP/NIEHS Director as an annoying inconvenience. NTP needs a Director who is willing and wants to be enthusiastic about NTP and its important mission in public health.

Two, Dr. Schwartz appeared to have a lackluster commitment to the interagency activities of the NTP, and this is critical for its success. He appeared to prefer a go-it-alone approach.

Regarding the budget, it is hard to get a handle on the NTP budget, but it does seem as a proportion of the NIH budget it is going down. I recommend that the NTP budget be explicitly identified by Congress. Right now it's not discernible as a separate budget entity. And the fact that the budget seems to be decreasing shows up in the productivity of the NTP.

In 2005, 10 substances were begun for testing in the 2-year bioassay. In 2007, that had been diminished to four. Currently there's

no studies being initiated for reproductive and developmental toxicity, and no study is being initiated for neurological toxicity.

Clearly this has to stop, and it doesn't appear to me at this point in time, even though there's some mechanism-based toxicology initiatives, that there has been a compensatory increase in toxicological evaluations being done through mechanistic toxicology approaches.

And the last point is that there are a lot of vacancies in key staff. It is important that the NTP and the NIEHS recruit top-notch people to fill those vacancies, because you can't run a top-notch program without top-notch people.

So with that, let me conclude my oral testimony. The details are found to a greater extent in my written testimony.

I apologize for having to go, but I'm in my new life. I am an elected official. I'm a Chatham County commissioner in North Carolina, and we are holding an important public hearing tonight on zoning a part of the county that has not been zoned previously, so you could expect that my constituents might not be happy if I didn't show up. So I apologize for running out the door, but thank you for giving me this opportunity.

[The prepared statement of Mr. Lucier follows:]

Domestic Policy Subcommittee
Oversight and Government Reform Committee
"Will NIEHS' new direction protects public health?"
George W. Lucier, Ph.
Tuesday, September 25, 2007
2154 Rayburn HOB – 2:00 p.m.

Chairman Kucinich, and Ranking Minority Member Issa and distinguished members of the Domestic Policy Subcommittee on Oversight and Government Reform Committee. I am honored to provide testimony to you on recent directions of the National Institute of Environmental Health Sciences (NIEHS) including its flagship journal, Environmental Health Perspectives (EHP) and its leadership and stewardship of the National Toxicology Program.

Relevant qualifications and current positions: I retired from the NIEHS in 2000 after serving as Director of the Environmental Toxicology program (1993-2000), Associate Director of the NTP (1993-2000), head of a research group in molecular epidemiology and dosimetry and co-editor in chief of EHP (1972-2000). In my NTP role, I was responsible for coordinating toxicological research and testing across Federal agencies including EPA, FDA and CDC. I also served as Chair of the North Carolina Science Advisory Board for the regulation of Air Toxics (1991-2006). Currently, I am a consultant in toxicology, consulting editor to EHP and a member of EPA's Science advisory Board. In 2006, I was elected Commissioner in Chatham County North Carolina where I have resided for 34 years. My biosketch and full cv have been provided previously for your review.

Environmental Health Perspectives

Let me begin by saying that I am proud to have worked at the NIEHS for 30 years including 28 years as editor of EHP because I felt part of remarkable effort to establish the environmental health sciences as a major contributor to the prevention of human diseases.

During my 28 years as editor, EHP grew form a fledgling journal publishing workshops and conference proceedings to a leading journal in environmental health. After, I left EHP continued to grow in stature under the editorial leadership of Drs Gary Hook, Tom Goehl and James Burkhart. In 2005, when Dr Schwarz was selected as Director of the NIEHS and NTP, EHP was widely recognized as the world's leading environmental health journal. Its impact as measured by any and all benchmarks was steadily increasing while at the same time its costs were steadily decreasing. This kind of situation is a manager's dream. However, in a puzzling series of moves, Dr Schwarz began to systematically dismantle the journal under the false guise of saving money. I and most others in the scientific and public health communities believe that his actions toward EHP were inconsistent with the mission of the NIEHS, his own statements on global health

and education, and strategies for effective communication of critical environmental health information to those who need it most. More detailed information to substantiate these statements is as follows:

1. The mission of the NIEHS is to understand and prevent environmentally-mediated diseases and to communicate this information to the scientific community, general public and public health agencies in a timely manner. Therefore, publication of a high quality journal such as EHP should be considered a priority for institutional support.
2. EHP was comprised of several sections including regular scientific articles, environmental health news, international versions (Chinese and Spanish), the student edition, children's health and environmental medicine. Taken together, these sections provided comprehensive and understandable scientific information to scientists, the global community, educators, journalists and clinicians. It was the only journal providing such a comprehensive and integrated approach to environmental health and it was widely acclaimed for the broad scope and quality of its coverage. Why would a new NIEHS Director want to undermine this successful endeavor as a first step in his administration rather than concentrating on more problematical parts of the Institute?
3. Impact factors for scientific journals are derived each year by independent analysis. These factors measure the impact of the science published in those journals. The impact factor for EHP has steadily grown (3.0 in 2001; 5.2 in 2006) and it now stands as the world's leading environmental health journal. This vital measure of success was apparently ignored by Dr Schwarz as he sought to restructure and privatize EHP. In addition, visibility in the lay press increased substantially, from 1 mention per day in 2001 to 6 mentions per day in 2006. The Society of Environmental Journalists is a strong advocate of EHP as they believe it to be a reliable and informative source for environmental health information. In the last three months the EHP website was visited by 305,000 individuals from 207 countries.
4. In 2002, the total cost of EHP was $3.8 million. By 2005, the cost had decreased to $3.3 million even though the NIEHS budget was increasing during that period. Thus, in 2001 the EHP budget was 0.67% of the NIEHS total and in 2005 it had decreased to 0.46% of the NIEHS total. During this same period, the total number of pages increased from 1900 to 3200 per year for the monthly EHP. Moreover, EHP went to an open access journal in 2004 which cost $0.5 million in lost revenue. Why would Dr Schwarz attempt to dismantle EHP when it's scientific and public health impacts were increasing, its visibility and productivity increasing and its costs decreasing? The old saying goes; if it's not broke don't fix it. Dr Schwarz had a different approach; if it's working well, break it. One has to ask, why?
5. One of the stated goals of the NIEHS strategic plan for 2006-2011 is to develop a program in global environmental health. It further states that "the NIEHS is in the process of cultivating partnerships to better leverage resources in pursuit of new and emerging opportunities in global environmental research." This is an admirable goal and I support it but coming from Dr Schwarz it seems

disingenuous. In 2005, EHP had partnerships to publish EHP in Chinese and Spanish. These partnerships were incredibly important because of the growing recognition that environmental problems are global problems and it is important for the United States to share environmental health information with countries who need it and want it. The cost cutting mandates imposed by Dr Schwarz have severely impacted the global health initiatives developed by EHP staff.

6. Another stated goal in the NIEHS Strategic Plan is to "recruit and train the next generation of environmental health scientists." This like the global health goal is laudable but actions taken by the NIEHS towards EHP are in direct contradiction of this goal. In 2001, EHP developed a student edition aimed at helping teachers teach environmental health and to encourage students to become interested in environmental health. By all accounts and surveys, the student edition was remarkably successful. Teachers liked it, students liked it and I know from personal experience (when giving high school and middle school lectures) the student edition was an excellent teaching tool in an area to often neglected in our public schools. Inexplicably, the NIEHS cut the student edition from the EHP budget. It needs to be restored.
7. In 2001, the leadership of EHP was comprised of an editor in chief, two Science Editors and a News Editor. Now, EHP has an interim editor, no science editor and the News Editor has been detailed to the Director's office for the past nine months. While, the interim editor, Dr Korach, is performing admirably on a part time basis, EHP has suffered because of the heavy loss of senior positions. The previous editor, Jim Burkhart, was forced to be both editor in chief and science editor. This situation is not sustainable if EHP is to keep its place as a top rank journal.

I and the vast majority of environmental health professionals urge the NIEHS to restore funding to EHP so that the NIEHS can fulfill its mission of timely dissemination of environmental health information. I offer the following recommendations:

1. Restore the EHP budget to 2005 levels in 2005 dollars
2. Restore staffing levels to include an editor in chief, a science editor and a news editor
3. Restore the global environmental health initiatives including funding of the Chinese and Spanish editions
4. Restore the student edition
5. Establish a budget process for EHP that is consistent with its important role within NIEHS

The National Toxicology Program

The NTP was established in 1978 as an interagency program to be headquartered at the NIEHS. This action represented a restructuring and an expansion of the former cancer bioassay program of the National Cancer Institute(NCI).

One of the major reasons for placing the NTP at the NIEHS was a recognition that toxicological evaluations were needed not only on cancer-causing substances but also on agents causing other forms of toxicity such as reproductive toxicity, birth defects, neurological toxicity, immunotoxicity and other endpoints of toxicity. The Director of the NIEHS was appointed to the position of Director of NTP. The Director of NIEHS reports to the Director of the NIH while the Director of NTP reports to the Secretary of DHHS. Placing the NTP Director under the Secretary of DHHS emphasizes the interagency nature of the NTP. The Executive Board of the NTP provides policy oversight for NTP programs and priorities. The Executive Committee is comprised of representatives from the Agency for Toxic Substances Disease Registry, the Consumer Products Safety Commission, EPA, FDA, National Center for Environmental Health (part of CDC), NCI, NIEHS, the National institute of Occupational Safety and Health and the Occupational Safety and Health Administration. Additional information on the NTP can be found on its website; http://ntp.niehs.nih.gov.

The NTP has fulfilled its expectations during the 29 years since its inception. It is considered a world class toxicology research and testing program and reports from the NTP are widely used around the world for strengthening the science base for regulatory decisions and for informing the public on health issues. Its role in disease prevention should not be minimized.

The dual role the NIEHS/NTP Director works well provided that the Director fully embraces both positions and recognizes that the purpose of the NTP is to prevent environmentally-mediated diseases. This is done by identifying potential as well as actual hazards in the environment and the workplace. The earlier these hazards are identified and exposure to them minimized, the greater will be the impact on disease prevention. We should keep in mind that a positive finding in an epidemiology or clinical study is, in reality, a failure of preventive medicine policy.

It is also critical that NIEHS/NTP Director fully embrace the interagency nature of the NTP and to foster effective collaborations between those agencies working on different aspects of research and regulation on substances found in the home, environment, workplace and in drugs and medical products. This is needed because NIEHS is not a regulatory agency but its role is to provide regulatory agencies with sound scientific data for decision-making.

While several programs and initiatives in the NTP appear to be functioning well, I believe that Dr Schwarz has failed his NTP responsibilities in three ways:

1. There is little evidence that Dr Schwarz has embraced his dual role as Director of NTP and NIEHS. From my perspective, he appears to view the NTP as an inconvenient annoyance rather than an integral part of his job. This attitude is in stark contrast to previous NIEHS/NTP Directors (Drs Rall and Olden) who were ardent champions of the NTP mission.

2. There appears to be only lackluster attempts in fostering interagency collaborations and to leverage resources to maximize productivity of the NTP. He seems to prefer "a go it alone" approach.
3. Technological innovations and molecular biology are offering exciting opportunities for the NTP. From my perspective, Dr Schwarz has not taken a leadership role in fostering mechanism-based toxicology in the NTP.

I will come back to a more detailed explanation of these criticisms later in my testimony but I also want to compliment the NTP for several initiatives that seem to be moving forward with good progress in most cases.

1. **Toxicology studies on nanoscale materials.** This is an incredibly difficult task but nevertheless incredibly important. The NTP is appropriately taking a leadership role in the design and conduct of toxicology studies to address potential health hazards arising from the manufacture and use of nanoscale materials
2. **Herbal medicines.** Herbal medicines are not subject to FDA premarket approval for safety so it falls to the NTP to provide toxicological data on those substances so that appropriate regulatory actions can be taken if they are shown to pose health risks. Again this is a difficult problem but the NTP progress has been good.
3. **Safe Drinking Water.** NTP has taken a comprehensive approach to its toxicology studies and appropriate interagency collaborations are in place.
4. **DNA based products.** DNA based products are being used to treat a wide range of diseases but FDA has only limited authority to require long-term evaluation of these therapies. Studies are needed and the NTP is working with other agencies to address this issue but progress has been slow due to limited funds and the difficulty of the problem.
5. **Databases.** The NTP has done an outstanding job in making their databases publicly available.

These initiatives and several others (found on the NTP website) were begun prior to Dr Schwarz's arrival at the NIEHS. He has however, been involved with restructuring NTP to form two new units; the Biomolecular Screening Branch and the Host Susceptibility Branch. These new branches offer several important opportunities and challenges for the NTP. Adequate funding and leadership will be needed if they are to be successful.

I will now come back to the issues that I find troubling or in need of attention including my recommendations for consideration by you and the NIEHS/NTP.

1. In 2005, the NTP finalized a Roadmap for the Future. This roadmap was developed with the involvement of NTPs stakeholders including the general public. This roadmap should be followed to the extent possible and of course modified when circumstances and scientific information dictate. Adequate funding is needed to insure its success.
2. The NTP budget is hard to follow. During the last five years it has ranged from 84 to 192 million dollars. Much of this fluctuation seems to be related to changes in

accounting procedures but it does seem that the NTP budget as a proportion of the NIEHS budget is decreasing. The NTP is key to the NIEHS mission to prevent environmentally-mediated diseases. It should not be shortchanged. For purposes of clarity and transparency, I recommend that the NTP budget be specifically designated by Congress.

3. The number of new chemicals studied by the NTP is decreasing. Only 4 chemicals will be started in cancer bioassays in 2007 while 10 were started in 2005. Moreover no new starts have been reported for reproductive, developmental or neurotoxicity (with the exception of the c. elegans studies) and there does not seem to be a compensatory increase in molecular based toxicology screens and evaluations. Dr Schwarz has a personal focus on lung toxicity but he does not seem to be taking a broad view of all the toxic endpoints of public health concern. I recommend that adequate funds need to be provided to increase the number of chemicals studied for the endpoints of interest so that this vital measure of output by the NTP is back where it belongs.
4. The NIEHS recently announced a $40 million program on Genes, the Environment and Monitoring through the Extramural Program. While these activities are needed, it is not clear how this initiative will be linked to the NTP in terms of priority setting and the generation of toxicological evaluations on substances of public health concern. It is also not clear how this initiative will be linked to ongoing exposure assessment programs of the EPA and CDC. This is needed to help leverage resources and to insure that the NIEHS initiative is not just an ivory tower exercise. I recommend that the NTP Executive Committee examine the NIEHS initiative in order to maximize use of funds devoted to exposure assessment in the United States.
5. The NIEHS is apparently constructing a Clinical Center on its campus. I must ask why, since the NIEHS is adjacent to two world class hospitals at UNC and Duke. Moreover the EPA has an exposure assessment facility on the UNC Campus which I understand is a shared resource and open to other government organizations. Will the NIEHS clinical center duplicate, in part, resources already available in the Research Triangle area? If so, those funds might be better spent on other projects.
6. In 2005, Dr Chris Portier, the Associate Director of NTP was reassigned and an interim Director was appointed. The NTP languished during this period and from my perspective Dr Schwarz did not seem to place a high priority on finding a permanent replacement. Dr John Bucher has just been hired and I am confident that he will do a good job. My recommendation is that replacements for important vacancies in the NTP be filled with qualified individuals as soon as possible.

Thank you for providing an opportunity to testify before you on my views regarding the status of the NTP and EHP. I would be pleased to answer your questions to the best of my ability.

Mr. KUCINICH. We completely understand. We thank you for testifying. You are dismissed as a witness, but you are greatly appreciated for your presence here. Thank you.

Mr. LUCIER. Thank you. And I look forward to your questions and will respond promptly with answers.

Mr. ISSA. I also want to thank you, Doctor. Like all county commissioners, I know that you are not going to allow too much packing of density within the county within this new zoning. We trust you to protect the Carolinas.

Thank you, Chairman.

Mr. LUCIER. I will do my best, Congressman.

Mr. ISSA. I am just lobbying for a beautiful place in a beautiful State.

Mr. KUCINICH. Thank you.

Dr. Lynn Goldman is a pediatrician and professor at the Johns Hopkins University Bloomberg School of Public Health where she specializes in environmental health policy, public health practice and children's environmental health. She was appointed and confirmed in 1993 to be the Assistant Administrator for the Environmental Protection Agency's Office of Prevention, Pesticides and Toxic Substances where she was responsible for the Nation's pesticide, toxic substances and pollution prevention laws.

Dr. Goldman has conducted public health investigations on pesticides, childhood lead poisoning and other environmental hazards. Dr. Goldman has served on numerous boards and expert committees, including the Committee on Environmental Health for the American Academy for Pediatrics, the Centers for Disease Control Lead Poisoning Prevention Advisory Committee, and numerous expert committees for the National Research Council. She is currently vice chair of the Institute of Medicine Roundtable on Environmental Health Sciences, and chair of the IOM Gulf War and health study. She'll testify about the research and programmatic priorities of the NIEHS.

Dr. Goldman, thank you. You may proceed.

STATEMENT OF LYNN R. GOLDMAN

Dr. GOLDMAN. Thank you very much, Mr. Chairman, Mr. Issa, members of the committee. It is my honor to testify about the National Institute of Environmental Health Sciences. I will put my full written testimony in the record with your consent.

As vice chair of the Roundtable on Environmental Health Sciences, Research and Medicine, I know that environmental protection needs to be informed by environmental health science and by the best science possible. And by environmental health I mean a very broad view of environmental health that encompasses the built environment, including places where we work. That encompasses the natural as well as the social environment. All of these are important to promoting our health.

We know that the stakes are very high. We know that the cost of regulation is very high. We also know that the cost of environmentally related diseases are very high, and therefore it is important that we have a sound basis for science on which to make decisions.

The NIEHS is the preeminent institution within our government that does provide that science. It is the global center for toxicological research. And I think I can associate myself with the comments that Dr. Lucier made about its journal Environmental Health Perspectives and about the work of the National Toxicology Program.

When I was at the EPA for 2 years, I chaired the Executive Board for the National Toxicology Program, and unique in my experience in government was the way that the NTP coordinates among the agencies in Health and Human Services to make sure that they are working together to assess toxic chemicals, as well as bringing on board EPA, CPSC, OSHA, the regulatory agencies, so that people are working together, sharing the science, sharing the assessments.

NIEHS research has been so important not only in terms of diseases like cancer and respiratory diseases related to the environment, but also impacts that are more subtle, impacts on development of the brain, immune system, endocrine system that affect populations, perhaps don't cause disease, but perhaps are very important in terms of public health.

In the area of children's health, along with EPA, NIEHS established the Centers of Excellence for Children's Environmental Health Research. These have been very important. It also participated in efforts to establish the National Children's Study, but unfortunately these efforts have had reduced support over the last few years.

NTP also has had reduced support, I think, in terms of fewer starts; but on the other hand, one thing that's a good thing that has been happening is that the NIEHS has been supporting research so that we develop a better understanding of the mechanisms that are involved in the toxic action of agents. This is very important for doing better assessments of risk, doing better epidemiology and so forth.

So I think that Congress may have put some expectations on the NIEHS to show tangible results that may have resulted in the strategic plan that was issued in 2006. I thought that the process of developing the strategic plan was a very open process and involved the community of people in environmental health. However, there were some puzzling aspects, and one in particular was the idea of expanding the role of clinical research in environmental health.

We all would like to improve the way treatment is done at the bedside. As a pediatrician I care about that terribly, but that is not what the NIEHS has been known for. NIEHS has tended to make its impact at other levels, translation of research to policy, to action of communities, to things that in some instances are at a neighborhood level that can make an enormous difference for health.

I think the role of the NIEHS is very important today. Just to name a few things, in a university such as mine, the NIEHS provides the bulk of the support for the cutting-edge research and environment health that we do, but it also enables us to train the next generation of scientists. These scientists are not only needed in the university, they are needed for government, for industry, across society.

You heard about the Environmental Health Perspectives and the role in providing judgment on chemical hazards, obviously improving actions for the public's health.

The path forward, though, is not a simple one. There are enormous challenges for the NIEHS as it moves forward in the future. There are thousands of chemicals that are in commerce, and despite the wonderful approaches that have been developed in the 2-year bioassay and other assays, those approaches are no way robust enough to face up to the challenge that we have with all of the things that we need to be able to look at. So the NIEHS does need to have some balance. It needs to balance its traditional mission and responsibilities with a need to be creative and a need to innovate and push forward the leading active environmental science.

Thank you again.

Mr. ISSA [presiding]. Thank you.

[The prepared statement of Dr. Goldman follows:]

Testimony
National Institute of Environmental Health Sciences

Domestic Policy Subcommittee, Oversight and Government Reform Committee
U.S. House of Representatives
Lynn R. Goldman, M.D., M.P.H.
Professor, Environmental Health Sciences,
Johns Hopkins University, Bloomberg School of Public Health
September 24, 2007- 2154 Rayburn HOB
2:00 P. M.

Mr. Chairman and members of the U.S. House of Representatives Domestic Policy Subcommittee, Oversight and Government Reform Committee, it is my honor to testify today about the research direction of the National Institute of Environmental Health Sciences (NIEHS). In so doing, you have asked me to specifically address the public health related research at the NIEHS. This testimony provides background on the work of the NIEHS, the role of the NIEHS in environmental public health, and conclusions about future directions.

Introduction

I am a professor of environmental health at the Johns Hopkins Bloomberg School of Public Health. From 1993-98, I served as Assistant Administrator for Prevention, Pesticides and Toxic Substances at the US EPA Prior to that I worked for eight years in public health with the California Department of Health Services. During the time I served at the EPA, for two years I chaired the Executive Committee for the National Toxicology Program (NTP). Later, after leaving the federal government, I served on the NTP Board of Scientific Counselors. This testimony reflects my personal opinions and not the views of Johns Hopkins University nor any of the governmental agencies where I have been employed previously.

For the last 9 years I have been Vice Chair of the Institute of Medicine Roundtable on Environmental Health Sciences, Research, and Medicine. The Roundtable provides a mechanism for those from academic, industrial, and federal research perspectives to engage in dialogue and discussion about the full range of environmental health science, policy, regulatory and educational issues. In particular we have been concerned about developing innovative clinical and environmental health research strategies and improving the understanding of issues concerning susceptible populations. In our work over the years it has been clear that environmental protection needs to be strongly informed by environmental health science. A broad definition of environmental health, encompassing the built environment (including occupational environments), the natural environment and the social environment is key to our efforts to assure the health of the public. An improved understanding of environmental health risks is important because economic development plays a vital role in the US and world economy and to human welfare. Regulation needs to be informed by the best available scientific information to assure that it is directed to assurance of the public's health, especially the most vulnerable among us such as children.

Background

According to an article published in *Environmental Health Perspectives* by Muir et al in 2001, the cumulative costs of environmentally-related diseases are very large, totaling around $520 billion to $740 billion per year for the United States. Moreover, according to Landrigan, et al in 2002, total costs from environmental pollution for children's health are at least around $55 billion (range $50-65 billion) every year or 2.8% of total U.S. health care costs in 2002. Although both of these studies gave only a very partial accounting of the costs, it is obvious that the stakes are very high in financial terms alone.

The NIEHS was established by NIH in 1966, in recognition of an emerging understanding of the role of the environment in health. In 1971, Dr. David Rall joined the

institute and under his leadership the NIEHS became the world's preeminent center for toxicological research. The Institute's scientific journal *Environmental Health Perspectives* published its first issue in 1972. That journal has become possibly the most important scientific forum in the field of environmental health sciences. It presents the state of the art of research from the many disparate fields of study that comprise environmental health including environmental medicine, toxicology, exposure sciences, environmental epidemiology, risk sciences and many other disciplines that contribute to this field. Under Dr. Rall's leadership the NIEHS developed preeminent research programs within the NIEHS. Its excellent extramural grant program enabled the establishment of environmental health research programs in universities across our nation. NIEHS provided critical funding support for university trainees and faculty needed to build the environmental health workforce, not only in universities but also in industry, not-for-profits and governmental settings. Particularly valuable are the core centers of environmental health science that the NIEHS has funded on a competitive basis for many years. These centers have created and sustained a critical mass of expertise within major universities across the US, allowing for the multidisciplinary collaborative environment that is needed for in environmental health sciences.

In 1978, Health and Human Services was mandated by Congress to develop a list of agents that are "known" or "reasonably anticipated" to be human carcinogens to which a significant number of people in the United States are exposed. The National Toxicology Program (NTP) was created not only to fulfill this function but also to bring together the disparate toxicology programs of the DHHS into a coherent Program to identify environmental hazards. The NIEHS was delegated to coordinate the work of the NTP and the NIEHS Director serves as Director of the NTP. The NTP coordinates toxicology evaluations conducted by the Food and Drug Administration (FDA), National Institute for Occupational Safety and Health and the National Cancer Institutes. Importantly, officials from the Environmental Protection Agency, the Occupational Safety and Health Administration, the US Centers for Disease Control and Prevention (CDC) and Agency for Toxic Substances and Disease Registries (ATSDR), the Consumer Products Safety Commission and FDA are members of the Executive committee of the NTP, so that the activities can relate to the needs of those agencies. This work has been successful in that the methods developed by the NTP for cancer assessment are the "gold standard" worldwide. The 11th Report on Carcinogens published January 31, 2005 provides a comprehensive and authoritative assessment of 246 agents, 58 of which are listed as known to be human carcinogens and with the remaining 188 being listed as reasonably anticipated to be human carcinogens. Currently 11 substances are under consideration for the 12th Report on Carcinogens. As an example of the potential public health impact of this report, the evidence for the carcinogenicity of formaldehyde in humans, an issue of recent concern because of its presence in mobile homes sold to Katrina refugees, is under consideration to decide whether the US should upgrade it from "reasonably anticipated" to "known to be" a human carcinogen.

Dr. Ken Olden became Director of the NIEHS in 1992 and very much expanded the public health role of the institute. He recognized that the nation's environmental regulatory burdens had increased to hundreds of billions of dollars, even while medical care costs for treating diseases were skyrocketing. He believed that the prevention-oriented or public health-oriented research agenda of the environmental health sciences was critical at a time when our understanding of human genetics presented the opportunities to determine the causes and

prevention of devastating diseases. Thus, in addition to continuing the Institute's focus on cancer prevention and toxicology, Dr. Olden led the development of a number of new directions. NIEHS directed research to prevention of chronic neurological diseases, such as Parkinson's and autism. It expanded research related to air pollution and health. It began research to better understand how nongenetic factors--environmental and dietary exposures, behavior, lifestyle, and infectious agents -- may work in concert with genetic susceptibilities to promote the development of disease, thus offering the potential to improve human health through public health prevention efforts. NIEHS not only created new basic science programs, such as the Environmental Genome Program and the Toxicogenomics Research Consortium, but also led the way in areas of environmental justice and community-based participatory research. This latter focus is appropriate because of disparities in exposures to chemicals and air pollution as well as in rates of disease. It was a stellar example of how the results of federally funded research can be translated to communities, so that they can take appropriate actions to protect health.

In the area of children's health, the NTP also established the Center for the Evaluation of Risks to Human Reproduction; under this program 15 NTP monographs have been completed, 6 reviews are underway, and 8 nominated chemicals have been deferred for later review. This is the only national or international effort in the world making judgments about agents harmful to reproduction and development. NIEHS partnered with the US Environmental Protection Agency to fund innovative Centers of Excellence in Children's Environmental Health Research. NIEHS later participated in the NICHD-led effort to establish the National Children's Study. Unfortunately, NIEHS support for both the research centers and the National Children's Study (NCS) was recently ended. The NCS has received strong congressional support and continues with the involvement of the NICHD and other federal agencies, but it is difficult to understand why the NIEHS has not been supportive, either with resources or contributions of scientific expertise, in recent years.

In the area of chemical hazards assessment, the NTP has reduced its reliance on standard toxicology bioassays. Over time, the NIEHS has tended to shift resources away from the NTP and into the NIEHS intramural research program. While some would hope that a shift to more basic research will result in new toxicology assays that can replace the standard bioassays, others are concerned that, in the meanwhile, the NTP has produced fewer chemical assessments and less applied research. The NTP has received little guidance in recent years from HHS in this and other areas, because HHS is no longer coordinating such public health related efforts among its agencies (as it once did through the Environmental Health Policy Committee).

More recently, the NIEHS has supported important research that is beginning to develop a mechanistic understanding of the toxic action of environmental agents. Insight into molecular mechanisms is important in the following three ways: 1) to provide a more rational basis for assessing human risk based on data obtained in animals; 2) to enhance our ability to conduct epidemiologic studies to more precisely identify the causes of human illnesses; 3) and to increase understanding of the wide person-to-person variation in risk to disease. As an example of the fundamental way this has altered our understanding of the toxicology of environmental agents, one need look no further than endocrine disruption. Whereas, in the past, it was believed that chemical exposure-related cancer was caused only by damage to cellular DNA, we now understand that endocrine and other modes of action also are involved. As we make advances in

other areas of genetics and systems biology, it will be important for the NIEHS to further the understanding of the complex biological phenomena that are related to toxicity and disease risk. This kind of research is needed not only for understanding environmental diseases like cancer and respiratory diseases, but also for understanding more subtle neurological, developmental, cardiovascular and endocrine effects that may have profound impacts on the health of the US population.

NIEHS Strategic Plan

Of particular concern in the context of this hearing is the traditional focus of the NIEHS on prevention and public health. In 2006, the year of its fortieth anniversary, the NIEHS issued a new strategic plan *New Frontiers in Environmental Sciences and Human Health: The 2006-2011 NIEHS Strategic Plan.* The 2006 plan was created with the input of multiple stakeholders; its stated purpose was "to prevent disease and improve human health by using environmental sciences to understand human biology and human disease", implying a continuation of the NIEHS focus on public health, and prevention. One successful initiative stemming from this strategic plan is the co-leadership by NIEHS with the National Human Genome Research Institute (NHGRI) for the Genes and Environment Initiative. As scientists began to sequence the human genome, they discovered that less than 5% of cancers and cardiovascular diseases are associated with single gene mutations; in fact, most diseases are of complex etiology involving multiple genetic as well as environmental factors. Recognition that environmental and behavioral factors interact with genetic variation and influence susceptibility or resistance to various disease states is long overdue.

It is clear that the NIEHS must respond to Congress's expectations for tangible results through an increased focus on translating science for the public good. The first of the seven goals of the 2006 NIEHS strategic plan to "expand the role of clinical research in environmental health sciences" has created some concern in the community. NIEHS has long embraced research relevant to clinical disease (most notably, cancer, and in more recent years including respiratory and neurological diseases as well). The NIEHS needs to continue its efforts to fund research that is relevant to a broad array of human disease processes. However, the NIEHS has appeared to be encouraging a focus on clinical research relevant at the bedside. Certainly all would welcome research that improves patient care. The concern has been that this should not be at the expense of environmental health research program that addresses disease risks on a population basis. Although this was not the sole direction taken, it has been of concern that the historic strengths of the institute will not be diminished by this and other new directions outlined in the strategic plan. The NIEHS makes major impacts on human health through research translation to public policy, not to the bedside. All NIH institutes conduct research related to disease prevention, but the NIEHS is the only institute with a primary mission of public health rather than clinical medicine. The reorientation to clinical medicine not only reallocated resources, it also has been viewed as a major shift in mission. In this regard, Congress may wish to work with the NIEHS on the development of measurements of results that focus on the ways that the research done at the NIEHS supports societal decisions about environmental health and informs policy. A secondary question is whether the NIH Clinical and Translational Science Award (CTSA) model is an appropriate fit for the NIEHS. In my discussions with colleagues, the cross-disciplinary CTSA format -- basic science-to-bedside-to-population--is not a universal

fit. The diseases and conditions that meet a narrow environmental focus may not be the best targets for a prevention-oriented clinical focus. Other models for cross-disciplinary collaboration may be more appropriate for the NIEHS.

Conclusions

Thank you for this hearing today. I know that I speak for many in the field of environmental health science when I say that the role of the NIEHS is, if anything, even more important today than it was when it was founded 40 years ago.

- We rely on it to fund and to carry out cutting edge research in toxicology, environmental epidemiology and exposure science to inform public health.
- The NIEHS is positioned to harness the next generation of scientific advances, such as in molecular biology and genetics, in the service of advancing environmental health sciences.
- Only the NIEHS funds the development of the next generation of environmental scientists who will fill important roles in academia, government and industry.
- The academic community relies on the NIEHS for funding not only individual research projects but also for funding centers that create core capacity, opportunities for transdisciplinary collaboration, and foci for new areas of knowledge such as children's health.
- We depend on the NIEHS journal, *Environmental Health Perspectives*, to provide a center of communications for the environmental health community.
- There is untapped potential for greater collaboration between the NIEHS and more prevention-oriented environmental science agencies, such as, the CDC National Center for Environmental Health, ATSDR and the EPA, particularly in areas related to the NTP, environmental exposure assessment and biomonitoring.
- We depend on its expert judgment on carcinogens and developmental toxicants.
- Most of all, we rely on the science generated by NIEHS to support societal decisions and actions to improve the public's health.

As part of fulfilling these many missions, the path forward for the NIEHS is not simple. The challenges of addressing environmental health issues are enormous and there are significant limitations of the traditional approaches to assessing the thousands of agents that are in commerce but to reducing public health risks. The NIEHS will need to balance its traditional mission and responsibilities with the need to promote creativity and innovation in the field of environmental health science. In this regard, NIEHS will continue to need strong scientific leadership and management.

Mr. ISSA. And now we go to Ms. Peggy Shepard. I will do my best to be fair to your background as executive director and cofounder of We Act for Environmental Justice, founded in 1988—you're not old enough to have been there then. Are you one of the founders?

Ms. SHEPARD. Yes, I am.

Mr. KUCINICH. Congratulations.

In West Harlem, We Act works to build community power, to improve environmental health policy and protection in communities of color. She is the recipient of the 10th annual Heinz Award for the Environment, and the Dean's Distinguished Award from Columbia School of Public Health in 2004.

We Act is a nationally recognized organization in the field of community-based participatory research in partnership with the Mailman School of Public Health at Columbia University.

She is a member of the National Children's Study Federation Advisory Committee to the National Institutes of Health. Ms. Shepard serves as guest editor for EHP, which we've already established is a tremendous magazine and periodical that we intend as a body up here on a bipartisan basis to continue to support.

And with that, we look forward to your testimony.

STATEMENT OF PEGGY M. SHEPARD

Ms. SHEPARD. Thank you. Good afternoon, Chair and committee members. I'm Peggy Shepard, cofounder and executive director of We Act for Environmental Justice.

I've had the opportunity in the past to serve as Chair of the National Environmental Justice Advisory Committee to the EPA and as a member of the NIEHS Advisory Council. Currently I'm a member of the NIEHS Public Interest Liaison Group.

When I first began organizing around the disproportionate impact of pollution on my community in northern Manhattan, I recognized that the lack of scientific literacy, information, data and context was and is a serious void that contributes to the systemic exclusion of communities of color and low income from decision-making that affects their families and their communities.

Evidence-based campaigns move policymakers and empower residents. Science and technology are important tools that can impact on our ability to develop safe, sustainable communities. To achieve these aims, we had to begin a process of inquiry that led to collaborative research projects over the last 12 years with research centers at the Columbia Mailman School of Public Health.

We've had a total of 10 years of these partnership grants that have allowed us and other partnerships nationally to develop capacity. As a result of these partnership programs, there is policy and system change with all levels of government, academic institutions and community groups who want to work with us. And importantly, we are having impact on the field through our trainings, findings, publications, policy changes, new models of action and the new perception that it can be beneficial to work with affected communities.

Three years ago the Kellogg Foundation identified the We Act-Columbia partnership as one of 10 community-based participatory research projects that document the impact of CBPR on health policy. In a peer-reviewed article published last January in the Jour-

nal of Urban Health, the authors found the carefully designed CBPR that is committed to strong science, high-level community involvement, engagement in policy steps and activities, and the strategic use of study findings to help impact policy can be an important part of the broader struggle for urban health and environmental justice.

Conversion of New York City's buses to clean diesel and installation by the EPA of permanent of air monitoring in Harlem and other hot spots were among outcomes for which the partnership's research and policy work was given substantial credit.

The effects of Dr. Schwartz's new research direction have certainly being chilling. We know that the NIEHS has been the source of key information regarding the health impacts of pollution. The information that generates in its research is used daily in setting protective Federal, State and local policies; in arguing for the protection of children, the elderly and our communities.

Though the NIEHS strategic plan states that they are committed to research on populations that are exposed to high levels of environmental agents; however, it appears that the Director has cut funding for CBPR and environmental justice partnerships, all of those programs. It has made community partnerships optional with the research centers, like the children's centers that have been so effective.

Prevention and environmental intervention represent the most effective and efficient ways to improve human health, and this core principle should not be lost in favor of technical, individually oriented medical solutions.

To answer the question of why some communities are more affected by some disease, NIEHS must continue to assess the degree to which environmental exposures disproportionately impact specific communities, to understand the effects of multiple and cumulative exposures, and ultimately what types of intervention will effectively reduce those disparities in health burdens.

At one point the NIEHS had begun to look at the built environment as a key environmental exposure that merited further investment. We would hope that they would further consider that relationship between urban, suburban and rural built environments and their relationship to obesity, respiratory health and cardiovascular health.

In addition, the NIEHS should continue training and research programs that educate researchers and communities on ethical issues associated with environmental health research.

The Children's Environmental Health Centers Program has catalyzed development of the new subspecialty of environmental pediatrics and has provided an evidence base for a solid children's environmental health and place-based advocacy movement here and abroad, yet they recommended a cut in funding and a radical change in the funding mechanism for the centers. And rather than seek innovative opportunities to translate these developments in lab science to the community and to field-test them, the NIEHS proposes a retreat to the lab.

Review panels and study sections of the EJ, CBPR, and children's centers research programs need to embody a broader range of perspectives that include senior scientists from the fields of pedi-

atrics, public health, preventive medicine, as well as public interest advocates of environmental justice, CBPR, and public health.

And finally, the translation begins at home. The NIEHS peer-reviewed journal EHP, which has a solid scientific constituency, needs to continue to create accessible and user-friendly environmental health resources and references for the media and other lay consumers. They must continue to make EHP accessible in terms of cost and its lay language reports and news articles to the public, which in turn will bolster public support for the NIEHS.

I thank you for the opportunity to share with you the significant public impact that NIEHS has had in the past and I hope will continue to have. I would like to urge this committee to ensure their commitment to these remarkable and unparalleled programs, to restore the Environmental Justice and CBPR research programs at 2005 levels, to designate staff to participate and lead Federal interagency EJ and CBPR efforts, and to invite community representatives to engage in the strategic planning process.

The NIEHS has had a legacy of responding effectively to identified research needs of the most vulnerable. I hope it will return to that legacy and to improving the health of this Nation's residents.

Thank you, and you will have my full testimony.

Mr. KUCINICH [presiding]. Thank you for your testimony.

[The prepared statement of Ms. Shepard follows:]

Domestic Policy Subcommittee
Oversight and Government Reform Committee
Effects of the New NIEHS Research Direction
Peggy M. Shepard
Executive Director Co-Founder
WE ACT For Environmental Justice
Tuesday, September 25, 2007
2154 Rayburn HOB -2:00 P.M.

Good afternoon Chairman Kucinich and committee members. I am Peggy Shepard, co-founder and executive director of WE ACT For Environmental Justice, a 19-year old non-profit environmental justice organization based in Harlem, New York City. WE ACT works to build community power to fight environmental racism and to improve environmental health, protection and policy in communities of color. WE ACT has developed a national reputation for its community-based participatory research partnerships to improve environmental health locally, to develop a national environmental health research agenda to address a broad array of community-based environmental exposures, and to translate research findings into reformed public policy. I have also had the opportunity, in the past, to serve as chair of the National Environmental Justice Advisory Committee (NEJAC) to the EPA , and as a member of the NIEHS Advisory Council. Currently, I am a member of the NIEHS Public Interest Liaison Group.

My aim today is to portray an urban community of color and low income that is disproportionately impacted by pollution, and to address the impact of NIEHS programs on community capacity to advance environmental justice and children's environmental health through community-based participatory research (CBPR)..

The Environmental Justice Movement has challenged the current environmental protection model to address environmental inequities, unequal protection, and the disparate and cumulative impacts of pollution. The vision of Environmental Justice places human health at the center of environmental struggles understanding that communities of color and low income are home to more susceptible populations, that multiple environmental exposures must be addressed by studying their cumulative impact and synergistic effects on health, that children, in their early stages of development, are more vulnerable to environmental exposures, and that children of color living in communities of color disproportionately impacted by pollution are the most disadvantaged. The frame is precautionary. It seeks to prevent environmental threats before they occur and shift the burden of proof to the polluter.

I have lived and worked for 22 years in Northern Manhattan which comprises four neighborhoods of mostly African-American and Latino residents with a median household income of $16,000. There are multiple environmental exposures, high rates of learning disabilities and low birth weight, and excess mortality from asthma, cancer, and heart disease. One of these neighborhoods East Harlem, has the highest asthma rates in the nation. Significant broader impacts are that Manhattan is a non-attainment area for clean air standards and is ranked #1 in cancer risk from air toxics by the EPA.

Peggy Shepard Testimony to Domestic Policy Subcommittee

In 1988, WE ACT was born out of community struggles around the use of Northern Manhattan as the dumping ground for the downtown elite neighborhoods. With my neighbors, we began organizing around the operations of the North River sewage treatment plant whose odors and emissions were exacerbating respiratory disease. And in 2000, WE ACT filed a Title VI Civil Administrative Complaint with federal DOT against the Metropolitan Transit Authority because Northern Manhattan neighborhoods bear the disproportionate burden of hosting one third of the largest diesel bus fleet in the nation. There are six diesel bus depots in Manhattan and Northern Manhattan communities host five of those.

When I first began organizing around these issues, I recognized that the lack of scientific literacy, information, data, and context was and is a serious void that contributes to the systemic exclusion of communities of color and low income from decision making that affects their families and their communities. Around the nation, environmental justice advocates have realized that evidence-based campaigns move policymakers and empower residents. Though we understand that science cannot always correlate exposures with suspected point sources, or confirm community suspicions about exposures and outcomes, we recognize that science and technology are important tools that can impact our ability to develop safe, sustainable communities.

To achieve that goal, we must ensure translation of research findings, scientific data, health information and government regulations into policy reform and educational materials for a broad range of stakeholders including research participants, residents, health care providers, elected officials, policy makers and civic and advocacy organizations. For that information exchange to be effective, we need to build and expand the capacity of low-income communities of color to improve public health and children's environmental health pre-natally and post-natally by training area residents and organizations to apply this information in ways that will help to inform individual choices and to modify current policies to improve community environmental conditions.

To achieve those aims, WE ACT began a process of inquiry that led to collaborative research projects over the last 12 years, with research centers at the Columbia Mailman School of Public Health. In 1995, WE ACT and Columbia's Harlem Health Promotion Center were awarded an EPA Community-University Partnership grant that allowed us to begin relationship building and community identification of concerns with our academic partners. In 1997, WE ACT was awarded a three-year grant from the National Institute of Environmental Health Sciences (NIEHS) new grant program, Environmental Justice: Partnerships for Communication, and received a competitive renewal in 1999. We began work with the understanding that there was room for us to shape the research agenda to include community concerns. Through trainings that have developed 200 environmental health leaders, involved scores of community-based organizations and housing groups, and through briefings to elected officials, WE ACT and our academic partners have translated the scientific and regulatory foundation of environmental health issues that affect community residents.

The NIEHS EJ grant program supported our efforts and those of other partnerships to raise the profile of environmental health research and particular disease burdens not only for the communities of Northern Manhattan but throughout New York City, and the nation. I thank the

NIEHS for their support of the EJ and CBPR grant programs. Nationally, researchers point to the NIEHS as providing the vanguard support for health disparities research that really does address issues that matter in low income and communities of color.

Our engagement in community-based participatory research (CBPR) -- a method where scientists work closely with community partners involved in all phases of research, from inception of research questions, to study design, to collection of data, monitoring of ethics, and participation in the interpretation and communication of study results -- has allowed us to answer community residents questions regarding their exposures from a variety of sources of pollution.

We have had a total of 10 years of these partnership grants that have allowed us to develop capacity. We have been able to hire staff with advanced degrees in environmental health and science and provide technical assistance within our local, regional and national environmental justice community. WE ACT has leveraged additional funding for our research partnerships, and one Columbia Center alone has leveraged over $6 million in grants, due, according to them, to the effective community component. We have sustained the partnership for a decade and continue to develop collaborative projects. We have developed new tools such as GIS, curricula, and air monitoring procedures. There is policy and system change with all levels of government, academic institutions and community groups who want to consult or work with us. And importantly, we are having impact on the field through our trainings, findings, publications, policy changes, new models of action, and the new perception -- that it can be beneficial to work with affected communities.

Three years ago, the Kellogg Foundation identified the WE ACT/Columbia partnership as one of 10 CBPR projects that document the impact of CBPR on health policy. In a peer-reviewed article published last January 2007 in the Journal of Urban Health, a bulletin of the NY Academy of Medicine, the authors found that *"carefully designed CBPR that is committed to strong science, high level community involvement, engagement in policy steps and activities, and the strategic use of study findings to help impact policy, can be an important part of the broader struggle for urban health and environmental justice... "Conversion of NYC's bus fleet to clean diesel and installation by the EPA of permanent air monitors in Harlem and other hot spots were among outcomes for which the partnership's research and policy work was given substantial credit."--.* (Promoting Environmental Health Policy Through Community Based Participatory Research: A Case Study from Harlem, New York by Vasquez V., Minkler M., Shepard P., Jan.2007,Journal of Urban Health, NY Academy of Medicine.)

Today, we are here to review the effects of the NIEHS director's new research direction. Well recently, I spoke to a Boston toxicologist who works in the field of environmental health who expressed her concern and that of her colleagues regarding the co-opting of many federal agencies that we rely on for information and basic protections. She observed that the "hijacking of NIEHS's research agenda to divert it away from environmental health hazards is anti-public health and works against any sense of justice. I think it is possible and necessary to restore an independent technical team at NIEHS that we can rely on to provide accurate information on some of our most challenging public health problems.

The NIEHS has been the source of key information regarding the health impacts of pollution. The information it generates in its research in chemicals is used daily in setting protective federal, state, and local policies, in arguing for the protection of children, the elderly, and our communities. It provides much of the evidence necessary to adequately regulate polluters, require disclosure and cleanup, obtain enforcement actions, and obtain just settlements for those who have been harmed. While something as seemingly obscure as research results may have little interest for most people, accurate evidence regarding chemicals can make the difference between safe children and sick children, between an intact family or the loss of a parent, or between being able to work or being chronically ill.

Community-Based Participatory Research (CBPR), with its emphasis on translation i.e. approaching research with the goal of converting it into information, resources or tools that can be used by public health and medical professionals and by the public to improve overall health and well being especially in vulnerable populations, has demonstrated the ability to improve the accuracy, precision, reliability and relevance of environmental health data. CBPR and translational research play a key role in achieving NIEHS's mission of reducing the burden of human illness and dysfunction from environmental causes. That role must continue.

Regarding environmental justice, the NIEHS strategic plan states that the NIEHS is committed to research on populations that are exposed to high levels of environmental agents; however, it has been said, that the director has cut funding for CBPR and the Environmental Justice: Partnerships for Communications grants programs. Prevention and environmental interventions represent the most effective and efficient ways to improve human health,, and this core principle should not be lost in favor of technical, individually- oriented medical solutions. To answer the question of, why some communities are more affected by some diseases, NIEHS must continue to assess the degree to which environmental exposures disproportionately impact specific communities, whether the interaction of multiple exposures plays a role in those health disparities, and, ultimately, what types of interventions will effectively reduce those disparities in health burdens.

At one point, the NIEHS had begun to look at the built environment as a key environmental exposure that merited further investment of resources. We would hope that the NIEHS will further consider the relationship between urban, suburban, and rural built environments and their relationship to obesity, respiratory health, and cardiovascular health as mediated by exercise. Access to healthy and nutritious foods is also an important environmental health issue given the key role that food supply infrastructure plays in defining the living environment (where we live, play, pray and go to school) of most Americans. The research agenda will be strongest if it includes the prioritization of developing better ways to understand the effects of multiple and cumulative exposures. In addition, NIEHS should continue training and research programs that educate researchers and communities on ethical issues associated with environmental health research (as distinct from the biomedical research model of ethics training that most academic institutions provide.)

The NIEHS Children's Environmental Health Centers Program (which WE ACT has been a part of through our partnership at the Columbia Children's Environmental Health Center and as an advisory board member of the Mt. Sinai Children's Center) has catalyzed development of the

new subspecialty of environmental pediatrics, and has provided an evidence base for a solid children's environmental health and place-based advocacy movement here and abroad. The children centers program has been highly productive, contributed greatly to our enhanced understanding of the environmental causes of childhood disease, and successfully translated state-of –the- art information on developmental toxicology and environmental genomics to exploration of the causes and mechanisms of disease in children living across this country. This multi-disciplinary program was intentionally designed to over-sample populations of color and low income who live in toxic environments disproportionately impacted by pollution.

Yet, NIEHS has recommended a cut in funding and a radical change in the funding mechanism for the children's centers which have provided robust scientific data on both exposure and health outcomes for thousands of individuals followed from birth through childhood. They propose to change these centers from operating centers that directly support multidisciplinary research such as the birth cohort studies into centers that support only research infrastructure. This funding mechanism is problematic because it favors laboratory research at the expense of clinical translation and primary prevention. Rather than seek innovative opportunities to translate the latest developments in laboratory science into the community and to field-test them in these well-characterized cohorts for the betterment of children's environmental health, the NIEHS proposes a retreat to the laboratory.

Review panels and study sections of the EJ, CBPR, and children's centers research programs need to embody a broader range of perspectives that include senior scientists from the fields of pediatrics, public health, preventive medicine, as well as public interest advocates of environmental justice, CBPR, and public health.

And finally, translation begins at home. The NIEHS peer-reviewed journal EHP which has a solid scientific constituency, needs to continue its move to create accessible and user-friendly environmental health references and resources for the media and other lay consumers. NIEHS must continue to make EHP accessible (in terms of cost and its lay language reports and news articles) to the public which, in turn, will bolster public support for the work of NIEHS.

Thank you for the opportunity to share with you the significant public health impact that NIEHS has had, and I hope will continue to have on our communities. I would like to urge this committee to ensure NIEHS's commitment to these remarkable and unparalleled programs, to fund the Environmental Justice and CBPR research programs at $6 million per year, to designate staff to participate and lead federal inter-agency EJ and CBPR efforts, and to invite community representatives to engage in the NIEHS strategic planning process. The NIEHS has had a legacy of responding effectively to identified research needs of the most vulnerable among us. I hope that it will return to that legacy, and to improving the environmental health of all this nation's residents.

Mr. KUCINICH. At this point I would like to introduce Ms. Stefani Hines. Ms. Hines is a member of the National Advisory Environmental Health Sciences Council. She's a senior curriculum and assessment specialist and environmental health specialist at the College of Pharmacy, University of New Mexico, and the National Advisory Environmental Health Sciences Council. She is a congressionally mandated body that advises the Secretary of the Department of Health and Human Services, the Director of the National Institutes of Health, and the Director of the NIEHS in matters relating to the direction of research, research support, training and career development supported by the NIEHS.

Membership of the NAEHSC consists of ex officio members and 18 leaders in the fundamental sciences, medical sciences, education and public affairs. One-third of the Council must be public members. The Council will release a letter expressing concern for the cost of public health as a result of the stated NIEHS set of priorities.

Thank you. Proceed.

STATEMENT OF STEFANI D. HINES

Ms. HINES. Good afternoon, Chairman Kucinich and Congressman Issa. It is an honor to be here today to share my testimony regarding the scientific direction of the National Institute for Environmental Health Sciences. Of course, this is a CliffsNotes version of my written testimony. In this testimony I describe my personal recollection of an understanding of the position and opinions of the National Advisory Environmental Health Sciences Council, which is the advisory council for NIEHS.

I'd actually like to note that we have two Council members with us today, Dr. Joe Graziano and Lisa Greenhill.

Mr. KUCINICH. Thank you for being here.

Ms. HINES. Although I am a member of the Council, I need to clearly state that I am testifying as an individual, and that I am not speaking in any formal capacity on behalf of Council.

With that said, I would like to inform you that the Council is currently drafting a letter to Dr. Zerhouni, the Director of NIH, to clarify its view on the new NIEHS 2006–2011 strategic plan. Because the letter is still under discussion and subject to change, I cannot reveal its exact content, but I can share my recollection of the issues, comments and sentiments expressed by Council.

It's my understanding that the goal of the letter to Dr. Zerhouni is to underscore the importance of NIEHS's unique mission to advance environmental health-related research, as well as to emphasize the Council support of the new disease-oriented vision of the NIEHS. This is a vision that is inclusive of multiple research tools and approaches, including mechanistic research, prevention-based research, clinical trials, population studies, and the communication of NIEHS research for public benefit.

As I recall from various Council conversation, Council has two main reasons for supporting an integrated disease-oriented research approach. One is to stimulate out-of-the-box thinking, hopefully generating new, and unique, and potentially significant research results. The other hypothesizes that a disease-oriented approach would bring environmental health research out of the side-

lines where it consists only of testing chemicals for toxicity into a more mainstream rule where research would investigate how environmental agents contribute to specific diseases that impact public health on a large scale.

Thus the support of disease-oriented environmental health research does not exclude support of the more historic and the traditional methods that have been used, including testing chemicals for toxicity, the valuable role of NTP and other research. Indeed, these toxic chemicals may be contributing to major diseases in significant ways. But I would like to make a distinction between a vision or a concept and an implementation of that concept. Although Council has expressed general support for the strategic plan, three Council members, Lisa, Hilary Carpenter and myself, have expressed concerns about the erosion of disease-prevention educational activities in the NIEHS portfolio. The strategic plan makes provisions for those activities, but the reality is that outreach and education programs, for example, and other things that it paints have been eliminated, so it is not implemented in the way that—what is said.

To conclude this part of my testimony, the Council recognizes it is important in an advisory role to NIEHS. We have an incredible group of minds and a diversity of experience on this Council that really could be utilized more than it is. Thus Council has identified several ways it can strengthen its advisory role within NIEHS.

The Council is currently assembling a formal list of requests for NIEHS, including requesting specific information similar to what was provided here, so it will be very helpful for us, and also requesting some procedural changes such as having Council provide inquiry on the time allocation, the content of meeting agendas, and to allow for our questions and in-depth discussions.

The letter to Dr. Zerhouni that I previously mentioned as well as this list of Council requests are being written and circulated currently among Council members. We anticipate to have those completed in the next 2 to 3 weeks.

I thank you very much for your time and consideration of these important matters and for recognizing the value and the unique mission of NIEHS. The environment plays a significant role in the etiology of disease, in teasing out the nature of that role through innovative interdisciplinary research, and then providing mechanisms for the communication of that information will go a long, long way toward protecting public health.

Mr. KUCINICH. Thank you very much for your testimony.

[The prepared statement of Ms. Hines follows:]

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[1], Hillary Carpenter[2] 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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[1] Lisa M. Greenhill, MPA
Associate Executive Director for Diversity
Association of Veterinary Medical Colleges
Washington, DC 20005

[2] 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 inquires 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.

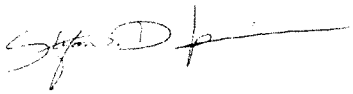
To conclude my testimony, I would like to thank the Committee on Oversight and Government Reform and the Subcommittee on Domestic Policy for their interest in the well-being of NIEHS—the only NIH institute that focuses on the contribution of environmental health to disease.

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



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

Mr. KUCINICH. At this point we're going to go to at least one round, if not two, of questions of the witnesses. And we thank you for your cooperation.

You have now heard Dr. Wilson's testimony, and I'm glad that Dr. Wilson remains with us. Did Dr. Wilson allay your concerns about the research direction and priorities of NIEHS? You heard his statement, and you also heard him respond to questions. Did he allay your concerns?

I would just like to start with Dr. Goldman and get a brief response from each of the witnesses.

Dr. GOLDMAN. I should start by saying, and I should have said before, that the views I'm expressing are my own and not of Johns Hopkins University.

I was very heartened by what I heard Dr. Wilson say about the journal, about the commitment to children's health, Environmental Justice community-based participatory research. But did it allay my concerns? It did not, because I'm very concerned that through this whole process there has been a breakdown in morale at NIEHS, and also there has been a breakdown in some of the communication with the broader environmental health community.

I know that Dr. Wilson and the other leadership at the institute understand this. I think some time and some effort is going to be needed to rebuild those bridges and to bring the community back together again. And a lot of listening with many communities is going to be needed, not just Peggy Shepard's community, but many other communities that have been in one way or another impacted by this. I really had a sense that things could be moving in the right direction. I'm very encouraged.

Mr. KUCINICH. Thank you very much.

Ms. Shepard.

Ms. SHEPARD. Yes. I am very heartened. I know that Mr. Wilson helped develop some of these key programs that have been so beneficial, and I certainly believe that he's sincere in wanting to continue them.

I'm a little concerned about sort of the fine print. You know, I'd like to know that not only will moneys be restored to the EJ and CBPR programs, but that new RFAs will continue to be published.

I'd also like to ensure that the funding mechanism for the children's centers is not simply the RO1 mechanism, which is a problematic mechanism, but that there will continue to be a pool of moneys that funds centers.

Mr. KUCINICH. Thank you.

Ms. Hines.

Ms. HINES. I, too, am encouraged by what Dr. Wilson had to say. I think the—as we have seen, the implementation of action is where the rubber hits the road, and the details and how this is done, of course, is very important. And citing the children's center as an example, restoring funding is part of it.

However, Council expressed concerns about the children's center report on the evaluation related to that. Actually the evaluation and the summary of it was quite good. It was the recommendations that came out of it that there was a real disconnect. And if—and so I don't know how supportive Council would be if those rec-

ommendations were implemented. I think that would be a real cost to the center.

Also I think that the Council can have—play a very important role in helping to provide connections to the community and provide guidance with respect to prioritization, because I don't know that we're going to be able to do everything unless funding is increased.

Mr. KUCINICH. Of course. Thank you.

I would just like to go down the line again and ask this question: Are there any programs that have been cut since about fiscal year 2005 that are critical to NIEHS's ability to protect public health, but that we have not heard about today? Anything that we should have covered that we didn't that you'd like to make a statement about?

Dr. Goldman.

Dr. GOLDMAN. I can't really think of any programs that have been eliminated. I think that it might be that it could be a good thing to take a careful look at that. I have a sense in looking at the charts that you showed that there's been a lot of movement of money around from here to there. And even as knowledgeable as I am about the NIEHS, I'm having a hard time understanding where some of that came from.

For example, there was coverage in the science press about the funding for the NIEHS Director's laboratory. I have wondered where did that come from? I did not see that in the charts. And so I think it would be—and I suspect that some of that may have come from some of intramural activity, some of the activities of the NIEHS scientists, and I think it might be well worth looking at some of that.

Mr. KUCINICH. Thank you.

Ms. Shepard, is there anything that has been cut that has been critical that we haven't heard about?

Ms. SHEPARD. I wouldn't like to address that specifically, but I would say that the larger strategic plan that has been worked on the last year or so needs to be reassessed. I would hope that there would not be a signup by the Council on that plan without a strong review and reassessment of new directions, as well as where they need to return.

Mr. KUCINICH. Thank you.

Ms. Hines, do you have anything that you'd like to add to that?

Ms. HINES. I don't—if you define "critically," I don't at this point. I would need to take a look at it to be better able to——

Mr. KUCINICH. We would like to you stay engaged with us on this question as this develops.

I do want to note as I go to my colleague that it is encouraging that Dr. Wilson has stayed in the hearing to listen to this testimony. That's—that, I believe, is an encouraging sign.

Mr. Issa.

Mr. ISSA. Thank you, Mr. Chairman.

Ms. Hines, I'm—to get a grip on what's happening here, let me ask a question that's not intended to be rhetorical. As a semi-insider, semi-outsider you may be the best witness to answer this.

The strategic plan that looked good on paper a year ago, and you said it quite eloquently so I won't try to repeat it, if I see it cor-

rectly, that was a great plan assuming that as one of the stepchildren of NIH, 1 of 27, the money was there to do it. In a nutshell is that the basis under which you say it is a great idea, but you didn't tell us what you were going to cut to do it if you didn't get money?

Ms. HINES. I would say that's a fair summary, yes.

Mr. ISSA. And, Dr. Goldman, based on your past experience in this ever vast bureaucracy, but looking at NIH and its 27 separate grants within its own government institutes, shouldn't the process that Dr. Schwartz have bought—got buy into been as much up for the funding as down for the approval with peers in the community? Is that one of the fundamental failures?

He's not here. I'm hoping the chairman will allow us to send written questions or possibly ask the doctor to come in to defend himself, but isn't that essentially what this hearing is about today? If there were enough money to your cake and eat it, too, and I mean that in the best possible sense, we wouldn't be having this hearing, because none of the things that he wanted to do, as I understand here today, were inherently bad. The problem is the sacrifices made in the name of doing those other things.

Dr. GOLDMAN. I think that one of the fundamental rules of managing a complex agency like NIEHS, and it is very complex, is that you don't want to have any surprises between you and those above you. In Congress there needs to be completely open communication. And also——

Mr. ISSA. The next administration, if you're in it, I'm going to keep those lines, because we only get surprises on the Committee on Oversight and Government Reform.

Dr. GOLDMAN. I know.

I think the other thing, too, though, is that you can't make decisions alone. I've been the head of a large governmental agency, and you do have a lot of power, but you are not able to make decisions unilaterally; you work together with people in a team, and both the team that you're with and the agency, the people below you, the people above you, the constituencies. And if there's anything that I could point to in terms of the implementation, it was, as you would say, ideas, bad ideas on paper, great ideas, and more kind of the mode of making decisions, of going it alone on issues where you really can't be successful if you go it alone.

Mr. ISSA. I appreciate that.

Ms. Hines, let me ask you to speculate for a moment. Having worked with Dr. Schwartz, do you think he had or thought he had buy-in from NIH for this reshuffling?

Ms. HINES. Um, that would be entirely a speculative response.

Mr. ISSA. Let me ask you another question. Within the National Institutes of Health, many of the programs that—the directions he was going, in fact, are covered or could be covered by many of the other institutes that make up NIH; is that correct?

Ms. HINES. As long as the health and the environment, the environmental health is kept as a primary focus, and all of the research and all of the activities, then it is a unique role. If you remove the E in the EH, then sure, it could potentially be——

Mr. ISSA. Well, the reason I ask, this is the most effective place, but for the chairman and myself as we—if the chairman would

allow a followup hearing, do we need to move upstream to the NIH and ask the bigger picture of what is your plan to cover what I said, "cake and eat it, too," earlier, but to cover two important issues, the areas that Dr. Schwartz was anticipating going into and the ones that have historically been critical to this organization; is it fair to say that we should as an organization of oversight ask is there a plan, what is the plan, how would you do it? Would you propose more funds for this organization or, in fact, other efficiencies, because that seems to be to be one of my questions that's unresolved. Nobody here is saying what he wanted to do was bad. What we're saying is what he had to cut to do it took him away from some core critical items without any way to make it up.

Ms. Shepard, I wasn't leaving you out, but you are one of the core critical items that was being left out, so I take for granted that we know you believe it is important, this dais, on both sides of the aisle agree that it is important. I'm trying to see where we go from here. Your testimony has been very compelling to me and to all of us, but we have to figure out do we do both, and, if so, where do we get it from what has been a growing pot of money?

NIEHS has not been starved by anyone's definition, but the question is how did this happen? Is there a management problem not just at this one institute, but at the bigger NIH?

If anyone has any comments, I obviously yield back. I've expired my time.

Ms. HINES. Well, I think that there are some partnerships that are occurring between NIEHS and some of the other institutes at NIH, and that seems to be one mechanism for sort of leveraging some of the kind of research.

As far as the question you're asking is important, and it really is beyond my individual ability just to say it, to provide an adequate answer other than I think that Council with—can provide—can be one resource to help think through these things.

Mr. ISSA. Yes, Dr. Goldman.

Dr. GOLDMAN. I think what Dr. Wilson said in his testimony suggested one strategy; which is, that over the last few years I have been very well aware—and most of the community have—the NIEHS has been undertaking some fairly large investments in new infrastructure related to newer technologies with genomics and so forth.

That might be a place where, once those investments are in place, the infrastructure is in place, there might be revenues freed up for it.

But the reality is, of course—and if scientists have a lot of good ideas, there will always be more good ideas than there is money. So it will always have to be painful to students about what things are funded and what aren't funded. Everything doesn't get funded. That is just a reality.

But, again, it gets back, then, to how do you do that; how do you do that so that you have the support of the people you work with, the community, Congress and all of that? I think that, again, is the problem.

Mr. ISSA. Thank you.

Mr. Chairman, if I can ask unanimous consent for my team to put together some followup questions directed through Dr. Wilson,

but in an attempt to get answers, so that we can consider on a bipartisan basis whether to hold a followup hearing that might involve more of NIH.

Mr. KUCINICH. I am certainly interested in working with you on this, so if our staffs could collaborate on this and come up with some agreement as to how we proceed, I would like to do that.

Mr. ISSA. I look forward to that, Mr. Chairman.

Of course, we have Dr. Wilson still here, so he could agree to take the questions right now.

Mr. KUCINICH. I think Dr. Wilson has acquitted himself well today, and he should rest on his first testimony and see if we can progress from there.

I would like to just have a brief second round, if we may, and to begin with asking Ms. Hines, you mentioned inaccuracies in the minutes of the council meeting, but you didn't address the reason for that.

Why do you think the inaccuracies occurred? Is there is any reason to think management was altering meeting minutes or reporting them inaccurately? They just happened to be inaccurate? What do you think happened?

Ms. HINES. I don't know. I really am hesitant to speculate on that. I think that sometimes there can be errors in just omission, or perhaps misunderstanding of what is communicated, or emphasizing one small piece of it. I do think that it is important that the minutes accurately reflect what took place at a council meeting, because it is a public record. If the minutes are going to be referred to in the future some way—for example, the children's study. That section on the children's study and our discussion related to that was something you can't adequately capture the sentiment of council related to the recommendations of the review. So should somebody come back to those minutes and say, well, what did council think of it, it just was not a fair representation of what council said.

Mr. KUCINICH. We in the Congress occasionally have a moment where we will actually vote on approval of the journal. We take this very seriously. It is this issue of minutes.

So I would hope that the council and others who are involved in meeting processes would understand that this Chair—and I would ask the ranking member if he would weigh in on this—that we feel very strongly about the accuracy of minutes, because there is a point at which it does have legal bearing and there is legal responsibility taken. If someone at some point deliberately changes the minutes of the meeting or misreports them, there are legal consequences. In the interests of maintaining the kind of felicity with which this committee is proceeding, it would be good, I think, for people to take note of that.

Mr. Issa, would you like to add?

Mr. ISSA. I couldn't agree more with the chairman. To make the matter even more so, often, when we get done passing laws, people look to our debate to figure out what they meant. We would hope that it not be so, but it has been so since the beginning of our Founding Fathers where they read the Federalist papers to figure out what the Constitution meant.

So I think it is important. Words do matter. We would hope that it would be accurate and that it be sustained by all Members.

Mr. KUCINICH. I want to thank my colleague.

I just have one final question of Dr. Goldman. It has been said that small clinical research studies, like those proposed in the children's center and elsewhere in the institute under Dr. Schwartz, will not give us enough quantitative information that is necessary to create reduced exposure standards for the general public.

What is your opinion on that?

Dr. GOLDMAN. I think it is very difficult to make that kind of a generalization.

Mr. KUCINICH. Could you refine it, then?

Dr. GOLDMAN. I will refine it. I think there are certain situations under which clinical studies have been appropriate and they have been helpful. But many environmental exposures you would never learn about by doing small clinical studies. I think where you might have more to gain is, for example, some of the studies that have been done, people who have asthma, that is triggered by very low levels of pollutants. Small clinical studies can tell you how that happens.

One of the questions I had was why it was necessary to invest so much in that particular initiative at this time at the NIEHS, and, for a couple of reasons. One is that within RTP, there is a clinical research center that is run by the EPA at their lab that I have been through, and very little research was occurring. I always wondered whether or not there would have been an opportunity to share in that resource, why a new test lab needed to be developed.

There was also a clinical research facility at NIH in Bethesda, and what was wrong with that? I never really understood why a new center needed to be built, especially in a location that is in a hospital within a hospital. I would never doubt that under some circumstances these small clinical studies can provide us with some valuable information, but I don't have a perception that we have a lack of capacity of places to perform them.

Mr. KUCINICH. I would just like to make this final comment and then turn it over to Mr. Issa for a closing round of questions, if he so desires, and that is that this hearing inevitably reflects on the philosophy of research. The way in which research is conducted depends on philosophical questions and also the manner of research. Do you proceed inductively or deductively? Is the research longitudinal, is it quantitative or qualitative, or a merger of both?

These reflect on some of the questions that are raised here. And while I don't think this committee has any interest in pointing people in the direction of how they should do their research, because it is kind of outside the scope of this, we certainly want to make sure that the research that is done can hold up to a peer review.

I just wanted to offer that for your consideration and for the good doctor's consideration as to this committee's concern that we not exclude a certain body of research that would then change the findings; for example, the effect of certain types of pollutants on public health.

Mr. Issa.

Mr. ISSA. Mr. Chairman, I don't have any further questions.

I would close, though, in thanking the witnesses, both first and second panel. I found this to be very informative. Like often happens with our committee, though, it has opened more questions than it has answered. I think, Dr. Goldman, we talked beforehand, just a little bit about how nice it was to hold a hearing for this important organization.

At the end of it, I can't say that we can't look at 27 institutes. What we can do, I believe, is use this as a springboard to look at NIH and whether or not each institute is treated as a CEO, autonomous—in which case Dr. Schwartz's buy-in and direction probably was within his purview—and, if, in fact, there has to be coordination, leveraging, real collaborative efforts, which there are some, obviously, but it has to be part of the culture of the NIH. And they have to promote it with 27 pockets of money plus some other grants.

It sounds like that may be the question for this committee that really can delve into whether or not NIH has the plan to leverage, as Ms. Hines and others have said; and, Dr. Goldman, you said it too. You have been to these other facilities, you have seen these other capabilities. And leveraging, and a plan to leverage them can't be from the division vice president of this entity, it has to come from the overall NIH down, in a way that encourages all those segments to work together and, of course, rewards them in their funding for leveraging technology.

So I would hope that is the message that we close with today, and I look forward to working with the chairman on this important issue.

Mr. KUCINICH. I thank the gentleman from California for his cooperation. When we cooperate from this chair, it really has the ability to create new policies or to strengthen one that needs to be strengthened.

On behalf of the committee, we thank the witnesses and everyone in the audience who stayed with us during the course of this hearing. We ask you to be available for an exchange of questions from the committee.

If there is no further business before this committee, this committee, Subcommittee on Domestic Policy, stands adjourned.

[Whereupon, at 4:55 p.m., the subcommittee was adjourned.]

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