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Congress of the United States

House of Representatives

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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 than 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 commenters 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 the way 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

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