

**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 from 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 Burkhardt. 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.