Testimony
National Institute of Environmental Health Sciences

Domestic Policy Subcommittee, Oversight and Government Reform Committee
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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.