

[The document below represents the concerted efforts of several member groups of the NIEHS Public Interest Partners. Members developed an issue-oriented letter and discussed it with NIEHS on April 9, 2008. The revised document provided below includes material from the original letter and the April 9 discussion. The perspectives and content included in the document are solely those of the Partners and do not reflect official NIEHS policy.]

May 10, 2008

Dear Dr Wilson and NIEHS Staff;

The Public Interest Partners (PIP) offer you these comments as a way to share with you the important goals that we have identified for priority consideration by NIEHS, and to initiate dialogue with the NIEHS leadership in a spirit of partnership.

The PIP considers these comments to be a living document, to be revised and re-considered as new issues emerge relevant to our members and organizational priorities. We look forward to continued discussions and feedback from the NIEHS staff in an open dialogue that facilitates success of our shared goals to improve human and environmental health.

The PIP represents diverse groups including disease, disability and environmental education and advocacy organizations. Our common interest is in preventing adverse health outcomes from environmental exposures. In our role as PIP members and representatives from our organizations, we lend community perspectives to the research agenda of NIEHS, and serve as a key contributor to the translation of research findings for the public, policy makers and private foundations.

DETAILED COMMENTS

Enhance community-linked environmental research that benefits the public interest

The NIEHS Strategic Plan wisely recognizes that environmentally and occupationally-linked diseases and disabilities occur across the nation. The nation's men, women, and children often must work, live, play, and attend school in environments that are contaminated at levels that exceed national averages, and sometimes even exceed legal limits. These impacted communities require robust, reliable scientific investigations to support mitigation and clean-up measures. NIEHS research and outreach provides critical data to identify and characterize environmental contaminants, including complex mixtures, while researching the health impacts of chemical mixtures and the interactions between chemical and non-chemical stressors like poverty and malnutrition.

We are very pleased with the NIEHS ‘let us hear from you’ link from the home webpage, that invites the public to submit information, as well as find NIEHS contact information (www.niehs.nih.gov/about/od/ocpl/contact/index.cfm). Our understanding is that NIEHS gets about 70 public inquiries per week, mostly focused on community health concerns related to an environmental exposure. Through this mechanism, NIEHS provides relevant and timely information for communities with concerns about health problems that may be linked to toxic exposures. In this way, the public can better inform all agencies involved with the health effects of environmental toxins about potential problems in their communities. This mechanism also creates an opportunity for research needs that are identified by impacted communities and populations to inform the NIEHS research agenda. The PIP will work on helping to publicize this web link.

Enhance translation of research to the public, study participants, and impacted communities

We are very pleased to be reassured by the NIEHS staff and management of the Institutes’ continuing commitment to the prestigious Environmental Health Perspectives (EHP) journal. The journal is one of the top in its field, second of 132 environmental sciences journals and fifth of ninety public, environmental, and occupational health journals. It is the public face of the NIEHS, and therefore is one of the most direct links between the NIEHS, environmental health research, and community health. We hope that it continues to be housed and supported by the NIEHS.

We understand from NIEHS management that there is a great need for exposure data. Disease surveillance or exposure surveillance may be critical to establishing links between environmental exposures and diseases. There are serious chronic illnesses and disabilities that may be attributable to environmental exposures: birth defects, attention disorders, learning disabilities, autism, asthma, chemical and electromagnetic intolerances/sensitivities, autoimmune diseases and depression, for example. Rates for these and many other chronic conditions appear to have been increasing in prevalence. There is need for an increased focus on indoor environmental quality, pesticides and other toxicants, electromagnetic fields, and emerging or under-studied environmental health contaminants such as nanomaterials. Right now, NIEHS has invested about \$10M/yr in nanomaterials research.

We understand from NIEHS management that epidemiology is already about 20% of the research investment (intra and extramural programs), but that it has significant limitations. Epidemiological studies should be done to better identify and characterize populations with chronic illnesses and disabilities that may be attributable to environmental exposures including those with chemical intolerances/sensitivities, birth defects, attention disorders, and autism. NIEHS management points out the need for good indicators of early-disease stages to be included in the epidemiologic study design. PIP strongly supports these initiatives.

Enhance research that characterizes the relationship between early-life exposure to environmental toxicants and later-life health outcomes

The PIP would like to affirm its support for the NIEHS research related to the relationship between environmental contaminants and disease outcomes. There is significant scientific evidence that prenatal and perinatal exposure to environmental toxicants that include hormonally active substances, pesticides, air contaminants, heavy metals, and radiation may induce infertility, diseases and disabilities, some of which are progressive and/or permanent. Since recent reports have suggested that pharmaceutical products may also be polluting some water supplies, research on the health impacts of medications (over-the-counter and prescription) and recreational drugs should be included. Co-factors that involve personal behavior like smoking, alcohol and radiation exposure may influence reproductive outcome so they are also part of the maternal/paternal pre-conceptual and/or prenatal environment. Continued support for research programs focused on children's health and environmental contaminants is a priority for our constituents and for the future of America's health. Examples of this kind of research currently supported by NIEHS include: pesticide impacts on cancer and brain development among children of agricultural communities and of urban communities; air pollution impacts on asthma and allergies among inner city children; and, industrial pollution impacts on learning and behavior among school children.

The NIEHS four "Discover" centers were set up to study complex human disease. The main research of these centers is asthma. These centers are intended to provide new opportunities to enhance research on environmental contributors to children's health, disease, and disabilities. Compared with adults, prenatal and later periods of development are uniquely vulnerable to many pollutants in both the outdoor and indoor environments, due in part to rapid growth and development, behaviors and activities, eating patterns, and physiology. Understanding and preventing the severity and/or incidence of childhood and adult diseases and disabilities are vitally important to society and the economy, and will require sustained investment in research on childhood exposures to environmental factors that disrupt the immune system, brain development and function, reproduction, and hormone activity. We understand from the NIEHS management that the cost of these Centers is very high, and that the value of this type of approach is still somewhat untested. We will look forward to revisiting the 'Discover Centers' mechanism in the future. NIEHS has informed us that the direct costs of the 'Discover Centers' is roughly twice the NIEHS investment in the Children's Centers (below) whose costs are shared with the EPA. In addition, the research from these Centers may be redundant with the Children's Centers (below), which are being expanded.

The NIEHS-supported Centers for Children's Environmental Health and Disease Prevention Research (the Children's Centers), and the National Children's Study are two important programs that generate critical information about environmental impacts on children's health. The PIP is very pleased to hear from the NIEHS management that the Institute intends to continue and even expand its investment in the Children's Centers, including adding new Centers. We are pleased to learn that the community-based participatory research component is being expanded. The information from these studies

will enhance global understanding of interactions between environmental exposures, genetic factors, and structural and developmental disabilities present at birth as well as the onset of childhood disorders, dysfunction and diseases such as obesity, autism, early-onset diabetes, developmental delay, mental illness, learning disorders, lead poisoning, asthma, autoimmune disease, and chemical and electromagnetic intolerance/sensitivity. Many of these are interconnected. The data from these and similar initiatives will be of particular help to economically disadvantaged communities whose members often must play, work, and learn in polluted outdoor and indoor environments. These research initiatives are a priority for our members, and we encourage the NIEHS to consider expansion of these or similar programs.

Develop and validate exposure methods for biological media and environmental media, to support health-protective regulations

In response to the needs of health-affected populations, the NIEHS could provide validated tools to document exposure(s) such as the Quick Environmental Exposure and Sensitivity Inventory (QEESI), a screening questionnaire for multiple chemical intolerances (MCI), asthma questionnaires, etc.

Hospital-based environmental medical research units (EMUs) are a much needed and long overdue technology that will enable NIEHS, researchers, and physicians to make all-important links between exposures and symptoms, and to understand gene-environment interactions in real time. Japan has already established several units; NIEHS has hosted meetings on this topic over the past decade, including in Japan, but has yet to commit to developing this essential new medical tool. Initially the EMU would be a research tool, and if validated for particular illnesses, the EMU needs to be made available in most hospitals as a way to diagnose and treat environmentally related illness of all kinds.

Develop and validate rapid high through-put tests to characterize hazardous environmental pollutants and support health-protective regulations

The validation of rapid high-throughput methods for characterizing environmental pollutants, including mixtures, is critical work that The National Toxicology Program (NTP) is already positioned to perform. We are pleased that the NIEHS management sees this as a priority. We support developing non-animal testing techniques, which promise to be cost effective, and to reduce the need for whole animal testing. Wikipedia describes high-throughput screens (HTS) as methods that, “allows a researcher to quickly conduct millions of biochemical, genetic or pharmacological tests. Through this process one can rapidly identify active compounds, antibodies or genes which modulate a particular biomolecular pathway. The results of these experiments provide starting points for drug design and for understanding the interaction or role of a particular biochemical process in biology. In essence, HTS uses a brute-force approach to collect a large amount of experimental data -- usually observations about how some biological entity reacts to

exposure to various chemical compounds -- in a relatively short time.”¹ These methods are capable of testing up to 100,000 compounds in a day. We are pleased to learn that the NTP will continue to develop its HTS methods. The approach could address nanomaterials and other new or under-studied contaminants.

However, while HTS methods offer great future promise as rapid screens, they cannot at this time replace the information provided by whole animal tests, such as toxic impacts on complex biological systems and chronic effects. As the tests are approved by the federal government (the NTP Interagency Center for the Evaluation of Alternative Toxicological Methods, NICEATM, and the Interagency Coordinating Committee on the Validation of Alternative Methods, ICCVAM), they will hopefully be used by regulators to allocate resources wisely in the protection of human health and the environment.

Role of NIEHS in guiding regulatory agencies to make policy decisions in the absence of scientific certainty

An agency’s ability to collect robust data on exposure and hazard is often very limited. It cannot, for instance, go out and intentionally expose people to precise, measurable levels of carcinogens and then document the increase in cancer rates. Most often, an agency must collect data through other means, often using experimental data from well-designed animal and non-animal studies conducted under controlled laboratory conditions. Still, uncertainties and data gaps abound when extrapolating experimental data to risk for the general population that includes people of diverse ages, lifestyles, nutritional status, genetic make-up, and health status. As a practical matter, however, a regulatory agency must protect the public from preventable risks. To do this in a systematic and scientifically supported manner, an agency collects the available data, and then fills in identified data gaps with adjustment factors, estimates, extrapolations from the observed range of data to the unobserved range, and with the use of mathematical models. All of these approaches rely heavily on expert judgment, untested assumptions, extrapolations, and sometimes perilous leaps of faith. Regulatory agencies knows that the realities of constantly emerging new science and the frailties inherent in available evidence dictate that it will never eliminate all major assumptions and judgments from its decision-making. Our public health and environmental programs, however, would not be effective if incontrovertible evidence of harm were a prerequisite of regulatory action. To quote Bradford Hill, the father of knowledge criteria for epidemiology:

"All scientific work is incomplete-whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have, or to postpone the action it appears to demand at a given time." (Bradford Hill, 1965)

However, without scientific support for regulatory decisions, the courts will strike down any proposed protections for lack of sufficient evidence. The terrible paradox is that waiting for “evidence” is usually a matter of waiting for an increase in disease and death

¹ Wikipedia on high-throughput screening. http://en.wikipedia.org/wiki/High-throughput_screening

among the exposed population. Thus, a significant role for NIEHS is to provide the scientific review and validation of methods for use in regulatory decisions.

Develop and implement an environmental health education program

We are very pleased to learn from NIEHS leadership that it would like to work further with the PIP to find ways to promote educating medical students, residents, nurses, public health professionals and others about environmental health. In the South Texas Environmental Education and Research (STEER) Program offered through the University of Texas Health Science Center at San Antonio's border campuses in Laredo and Harlingen, participants are taught about air, water, indoor environmental quality issues and gene-environment interactions/individual differences in susceptibility. The STEER Program, which has been operational for thirteen years and has won national awards for educating hundreds of medical professionals, is a model for such programs. The National Environmental Education Foundation's Health Care Provider Initiative which employs a strategic framework involving a wide range of partners to integrate environmental health into health care is another model for educating medical professionals.

Global climate change and health

We understand from NIEHS leadership that it is not intending to invest in this topic specifically, but is invested in related research such as air pollution and asthma. Right now, NIEHS is involved in a communication effort to begin to conceptualize its message and role, and insert the issue of environmental health. At this time, the NIEHS may feel that it is too early to define its role. PIP will look forward to working with NIEHS to help the Institute find its contribution to this important area of environmental health research. NIEHS leadership suggests that areas of energy production and impacts may be a topic for further discussion.

A Bulletin of the World Health Organization in spring of 2007 warns that human-induced climate change is an emerging threat that rightly commands widespread policy and public attention. This message is also being carried by the EPA, CDC, and other public health institutes. Along with other rapid changes associated with global population and economic growth, climate change strains existing weak points in health protection systems and calls for reconsideration of public health priorities. The most effective responses are likely to be strengthening of the key functions of environmental management, surveillance and response to safeguard health from environmental contamination likely to increase with natural disasters, and a more pro-active approach to ensure that development decisions serve the ultimate goal of improving human health.² While recognizing that NIEHS is not a health services institute, its research will be an

² Global climate change: implications for international public health policy. March, 2007. <http://www.who.int/bulletin/volumes/85/3/06-039503/en/>

important contributor to strengthening the health sector's ability to respond in a timely and effective manner. Some areas of note may be:

- The US is already seeing declining sources of potable water in part due to chemical and other contaminants. Increased storms and floods are predicted to increase contamination from these events and other extreme weather conditions. NIEHS research may be increasingly critical to supporting enforcement of environmental clean-up statutes.
- Climate shifts are predicted to favor disease outbreaks, including diseases of humans, wildlife, and agriculture animals. NIEHS research can support effective surveillance and response systems that will be essential for disease management.
- The impacts of current and future natural disasters could be reduced by developing integrated measures from the health sector that identify vulnerable communities, regions, and populations and support preventative or rapid response measures. NIEHS can support the capacity of the health sector to respond by providing timely and accurate hazard information, developing validated exposure monitoring methods, and sharing this information with other relevant public agencies.

Thank you for your consideration of these comments. We look forward to discussing these and related issues with you further.

Respectfully,

American College of Preventive Medicine (Michele Surricchio)
Alliance for Healthy Homes (Ralph Scott)
Asthma and Allergy Foundation of America (Charlotte W. Collins, JD)
Birth Defect Research for Children (Betty Mekdeci)
Children's Environmental Health Network (Nsedu Obot Witherspoon)
DES Action (Kari Christianson)
Huntington Breast Cancer Action Coalition, Inc. (Karen Miller)
Learning Disabilities Association of America (Lynne Cannon)
National Center for Environmental Health Strategies, Inc (Mary Lamielle)
Natural Resources Defense Council (Jennifer Sass, PhD)
Prevention Is The Cure, Inc. (Karen Miller)
West Harlem Environmental Action, Inc. (Peggy Shepard)