

# The National Institute of Environmental Health Sciences: A Perspective

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This paper attempts to place the programs of the National Institute of Environmental Health Sciences into correct perspective in relation to the other Federal environmental programs. Its goal is to illuminate the field of environmental health as a new field in science that confronts a wide variety of complex and diverse issues.

It is unrealistic to believe these issues can somehow be rendered less complex and diverse. What is hoped is that the Institute will contribute to providing the tools which will make it possible for us to develop principles leading to an understanding of the underlying problems. Then we should be able to build a base for effective public health programs for the years ahead, years that should prove to be as eventful and challenging as those just past.

## Introduction

In 1980 the National Institute of Environmental Health Sciences (NIEHS) will occupy its permanent facilities and begin to develop its research programs fully. For the first time in its history, lack of intramural research space will not be a major inhibitor of program growth. This will give the Institute the opportunity to extend its major intramural areas, thereby permitting them to develop as are the Institute's extramural programs which are expanding and focusing even more sharply on critical environmental health problems.

This seems to be an appropriate time to step back and take a look at the NIEHS, its mission, its history, and the programs it has shaped. But before addressing these specific areas, some general observations are in order. These relate to our varying perceptions of the concept "environment," the nature of environmental problems, and the wide and often contradictory nature of both legislative and executive reactions to environmental problems.

To begin with, the word "environment" is imprecise in its usage. Thus, we speak with equal certainty of the social environment, the outdoor environment, environment as a synonym for ecology and as a word which describes the concept of the

study of man (in whole or part) in relation to the biological and chemical world surrounding him.

There are spheres of significant public interest in each of the areas described above. In general, however, it can be said with some certainty that what we most commonly refer to as environmental problems have their roots in two traditionally major areas of Federal concern. The first of these is the field of public health in which the Federal government has been active for almost 200 years; the second is the field of conservation in which the government has been engaged for three-quarters of a century. It was not until 1962, with the publication of *Silent Spring* (1), however, that most of us began to see that the biology of man is in some way—not yet clear—inextricably intertwined with the biology of the natural environment in which he lives. In addition, we began to perceive, though not fully understand, that man's ability to modify his environment holds out both the promise for his survival and the threat of his destruction.

In the great upsurge of public interest which followed, man was frequently perceived as the villain from whom the environment must somehow be protected. Then in the mid-1970's, with an increased understanding of the nature and mechanisms of action of many toxic agents, we began to see that the public health must be our central concern if we are to protect both the environ-

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ment and man.

Throughout this period both the Legislative and Executive Branches toiled at devising legislative and administrative solutions to parts of much greater problems. These efforts tended to be centered around agents or media. Thus, we wanted to do something about lead in paint and gasoline, and also worry about air and water pollution. This led to the potential for improving one part of the environment at the expense of another.

The passage of the Toxic Substances Control Act (2) in 1976 marked the growing maturity of our view of environmental health problems. For the first time in regulatory legislation we began to look at the whole range of environmental exposures and their potential for adverse effect on man, and focus on the chemical agent regardless of where found.

The National Institute of Environmental Health Sciences was established in 1966\* to serve as the Federal government's focus for research on the ways in which human health can be, and frequently is, adversely affected by the environmental pollution. While the creation of the Institute was the result of years of planning and thought about emerging public health problems, it was clear that this marked a beginning, not an end. What lay ahead was the task of building a program aimed at the resolution of problems of a nature not previously seen in public health.

In the decade just past, the NIEHS has faced two major tasks: the need to create new tools with which to determine the impact of environmental agents on human health; and the need to serve as a consulting and advisory resource to regulatory and legislative bodies.

From the view of the Institute, public accountability forced it to carry out both tasks in concert. This paper describes the actions of the Institute in these broad areas of program responsibility; their relationships to broad national health needs are readily apparent.

## Program Direction

The National Institute of Environmental Health Sciences' program was established in response to the widespread appreciation of the critical need to develop an understanding of the recognized, but scientifically ill-defined problems arising from technological developments since World War I. While for many centuries we believed some toxic substances in the environment could trigger disease

\* NIEHS was originally named the Division of Environmental Health Sciences. In January 1969, it was elevated to institute status and renamed the National Institute of Environmental Health Sciences.

and injury, we did not know all the consequences of long-term, low-level exposures to recognized toxicants and to the hundreds of new substances being developed each year. Nor, in contrast to the situation with respect to infectious and known chronic diseases, had we developed research and clinical methodologies to tackle these problems effectively.

NIEHS was located organizationally within the National Institutes of Health in recognition of the fact that its primary mission is knowledge development. It focuses on gaining a better understanding of the complex, interrelated phenomena underlying man's reactions to the increasing number of environmental influences imposed by modern living. The Institute's ultimate goal is to develop the knowledge base needed for preventive programs for environmentally-related diseases, and for action by regulatory agencies.

Although it has faced great challenges since its inception (including its task of carrying out an extremely broad mission, its responsibility for developing a completely new program where none existed before, and the relative restriction of resources), the Institute is beginning to achieve its goals.

## Current NIEHS Programs

The NIEHS programs are centered around the objective of understanding basic mechanisms of action of environmental agents. This basic objective has dictated the development of the Institute's internal structure, its multidisciplinary research approach, and its focus on particular problems. All of these factors help the Institute achieve its ultimate goal of developing the knowledge base needed in the environmental health sciences.

NIEHS' focus on understanding basic mechanisms of action gives cohesiveness to all the Institute's efforts. It also enables NIEHS to help: (1) develop better test systems for detecting and predicting toxic effects; (2) identify the opportunities its research may offer for counteracting adverse effects, increasing individual tolerance, protecting unusually susceptible segments of the population, and determining the most effective points at which to exercise control; and (3) respond to environmental health emergencies.

To meet its objectives, NIEHS sets research priorities developed through a program planning process that takes into account the changing nature of environmental health problems, the rapidly evolving state-of-the-art in the field, and the opportunities available to the Institute. Because of the breadth and complexity of environmental health problems, this process is deemed the best way to

develop the broad outlines of the NIEHS program for it permits the Institute to take advantage of the best thinking of the academic and scientific communities in addition to that of its own staff. Initially, this process involved planning undertaken to describe the NIEHS mission. Thereafter, concurrent planning, strengthened by two major task force reports, followed to provide ongoing and future guidelines for NIEHS research programs.

In order to gain understanding of the Institute's planning efforts, it is necessary to know something of the forces and events that resulted in its creation over a decade ago.

## Historical Basis

Even before the NIEHS was created, the need for special program development in environmental health was recognized; and a number of planning activities followed that led to the definition of the NIEHS mission and responsibilities.

The concept of a national research center dealing with the scientific aspects of environmental health was first spelled out in the June 1958 report, prepared by a committee headed by Dr. Stanhope Bayne-Jones, entitled, "The Advancement of Medical Research and Education Through the Department of Health, Education, and Welfare" (3). This report indicated the need for a strong Federal public health research program to deal with the emerging health problems related to the increasing number and variety of substances in the environment.

In November 1961, the Surgeon General of the U. S. Public Health Service established a Committee on Environmental Health Problems, headed by Dr. Paul Gross of Duke University, to develop long-range objectives for a PHS environmental health program. The committee recommended creation of an environmental center and a new Office of Environmental Health Sciences. The committee's report said:

"It is the Office of Environmental Health Sciences, in particular, which will make possible an integrated national environmental health program while avoiding unnecessary duplication of effort. It offers a new method of attacking those facets of environmental health problems which are common to many of the operational programs. By its integrated approach it can identify and appraise environmental health problems which are not under consideration. At the same time it can develop protection criteria which are based on all of the environment" (4).

When Congress approved funds in September 1964 for the planning of a central environmental health facility, it was with the understanding that it would be limited to research and with the provision that it be located more than 50 miles from the Dis-

trict of Columbia (5). These limitations led to the decision to set up a National Environmental Health Sciences Center devoted to the kind of study envisioned by the Gross Committee for an Office of Environmental Health Sciences.

At the suggestion of the Office of Science and Technology, staff papers developing the proposal were submitted to a small group drawn from the National Environmental Health Advisory Committee, headed by Detlev W. Bronk, for comment on the mechanism by which such an undertaking would be best activated. In April 1965 this group unanimously recommended that the center be operated by the Public Health Service, that it seek the assistance of qualified scientific organizations in developing its plans, and that it solicit advice from appropriate advisory bodies (6).

Arrangements were made with the Research Triangle Institute for it (in conjunction with a panel of scientists from several national as well as neighboring universities, representing various disciplines relevant to the center's overall purpose) to review staff plans for the center's mission, broad program, scientific components, facility requirements, and staffing needs. This report (7) was delivered on November 1, 1965; and it served as a statement of objectives and a guide to the development of the NIEHS.

Based upon these earlier reports and studies, the mission of the Institute was evolved, taking into account several considerations. First, NIEHS would take a broad view and not consider only disease end-points, vehicles by which hazards are transmitted, or particular population groups affected. Its approach would be holistic, requiring multidisciplinary research efforts. Such an approach would be necessary to identify the consequences of the interaction of biological systems with chemical, biological, and physical agents in the environment. In this connection, the need was twofold: (1) there would have to be vigorous and integrated study of the effects of environmental factors on human health and well-being; and (2) there would be an overriding need to establish the basic information upon which realistic control measures could be based.

Second, NIEHS research objectives would be to determine how environmental agents produce deleterious effects in exposed persons and the circumstances that influence the expression of these effects. This would permit principles to be developed through which the probable toxicity of new as well as existing compounds could be predicted. Individual bioassay of every agent would be impossible because of the enormous expenses involved in testing the 700-1000 new compounds introduced in

commercial quantities every year, as well as the approximately 15,000 synthetic chemicals already in the environment. Moreover, it was clear that the nation did not possess the capacity, in terms of physical facilities or manpower, to test more than a fraction of these compounds using classical approaches. This meant interest would be focused upon the fundamental nature of the body's response to these agents and the ultimate consequences for health and longevity. In addition, programs would be directed to investigating and identifying the opportunities that such basic knowledge may offer for preventing environmentally related disease.

Several factors would make achieving these objectives difficult. NIEHS' investigation would not be directed only to exposure of overwhelming concentrations of environmental agents producing immediate or short-term responses that are relatively easy to detect and understand. Rather, and more difficult, the Institute would also investigate the health effects of exposure to low-level concentrations over longer periods of time. These may produce adverse effects which are usually difficult to associate with specific causes. The Institute would also have to determine the significance of the effect of multiple agents or combinations of agents, because additive or synergistic effects interacting at a common site may be important in disease development.

Finally, because of the broad nature of the problems to be addressed, NIEHS would be called on to carry out a wide range of coordination efforts, including collaborative programs with other Federal and non-Federal organizations. It would also have to engage in a high degree of cooperation with academic institutions to advance understanding of the relationship of environment to health and to stimulate recruitment and training of research personnel.

### **First Five Years**

To convert the results of the early planning activities into action during the first five years of its existence, NIEHS was given responsibility for a variety of efforts to assist in program definition and priority setting. One was the Office of Science and Technology/Council on Environmental Quality Ad Hoc Committee on Environmental Health Research, a committee organized by the President's Science Advisor and chaired by the NIEHS Director in 1972. This committee surveyed the various environmental research activities and information sources within the Federal structure; considered how the products of research are used in decision-making, especially regulatory decision-making; and

considered the need for coordination. It found that the time was ripe for an expansion of research in environmental health. This would result in better predictive tools which would provide a much firmer basis for critical and potentially costly regulatory decisions and for public health protection (8).

The major planning effort undertaken during this time was work leading to the development of the report of the first Task Force on Research Planning in Environmental Health Science, a task force established by NIEHS' National Advisory Environmental Health Sciences Council (NAEHSC). This report provided an essential resource for Institute staff in selecting particular program areas for special emphasis and expansion (9).

Through guidance supplied by the task force, it was recognized that the lack of knowledge relevant to human health and environmentally related diseases must lead to an initial emphasis on strengthening the base of knowledge upon which progress in resolving the major health problems is entirely dependent. Accordingly, the Institute's programs were designed with emphasis on: acquiring and analyzing existing information on national problems, needs, and activities in the environmental health field; determining the best ways to encourage scientific research in environmental health at other agencies, organizations, and universities; constructing a strong foundation of general environmental health competencies at the Institute upon which highly focused programs of critical and immediate importance would be based; and establishing those relationships with other activities in the Public Health Service and with the academic community that would enable NIEHS to enter most effectively into a national appraisal of environmental problems.

### **Second Five Years**

The stringency of the budget situation in the early 1970's created a gulf between expectations and realities for the Institute. But this same challenge that required NIEHS to reexamine its plans and limit some of its efforts also made it essential that the Institute continue its careful program planning. Through these planning efforts, the Institute identified the major course its programs would follow through the end of its first decade.

Although restricted in developing the program originally envisioned, the Institute would be able to support fundamental and applied research in selected areas of central concern. This would enable NIEHS to serve as a bridge between the other basic research organizations and the regulatory agencies. In addition it would provide the

framework for constructing responses to emergency situations (such as the Kepone exposure incident in Virginia) to meet national needs.

In its work, the Institute chose to concentrate on chemical factors in the environment, focusing on studies on the cause of disease and the effect of organic and inorganic chemicals on the human body. NIEHS' emphasis is on understanding the basic principles of metabolism of xenobiotics, identifying toxic levels, and understanding the movement and sites of action of toxic agents. Ultimate objectives are to: develop better test systems for detecting, identifying, and quantifying low-level chronic effects (mutagenic, teratogenic, carcinogenic, and other chronic toxicities), which would make prediction of effects of new or poorly studied old chemicals possible; develop better understanding of species differences in pharmacokinetics so that animal data can be extrapolated to man; provide means of identifying susceptible population subgroups; and prevent, or provide means for treating, diseases related to environmental factors.

## The NIEHS Today

With its permanent facilities under construction, NIEHS is entering another phase in its evolution, which has led to a new period of reappraisal and planning for growth. To guide the Institute during this period, NIEHS has undertaken a number of efforts aimed at helping it determine research priorities. The most significant of these is the Second Task Force on Research Planning in Environmental Health Science, established by NIEHS' advisory council at the direction of the House Appropriations Committee.

This task force was specifically asked to reexamine the needs, goals, and resources appropriate to the NIEHS research program. In developing its report (Human Health and the Environment—Some Research Needs) which was published in January 1977, the task force operated under the philosophy of "... not restricting the realm of coverage according to current patterns of assigned Federal responsibility for either research or regulation, but to give attention, to the extent practicable, to a broad range of concerns in environmental health regardless of current jurisdictional boundaries" (10). Because of this, the recommendations contained in the report are not limited to the programs of the NIEHS. Rather they range across the entire field of environmental health and by implication the various Federal programs with responsibilities in this area.

In order to convert this wide-ranging report to a set of program plans for NIEHS, the Institute

started an indepth planning effort based on that report. The Director, NIEHS, established a Planning Work Group, composed of both Federal and non-Federal scientists to take a thorough look at: what is ongoing in research in the environmental health field that is related to the responsibilities of the NIEHS; what is the total annual cost of this research (NIEHS vs. others); what areas of research should NIEHS not include as part of its priorities; what areas of the ongoing NIEHS intramural and extramural research need increased support, what areas are receiving sufficient support, and what areas, if any, should receive less support; whether NIEHS should launch new programs or actively solicit research applications in areas not currently being supported; what would be the cost in dollars and manpower of these new and enlarged research efforts, and how and where should NIEHS obtain the necessary manpower; and in what directions should the NIEHS program be moving.

The report of this group will serve as a basis for determining research priorities at the NIEHS for the next five years.

In addition to taking advantage of these planning efforts for guiding its programs, the Institute will continue to rely on the review mechanisms that have served it well in the past.

## NIEHS Review Mechanisms

In making decisions about its program emphases and direction, NIEHS carries out continuing examinations of its activities and solicits input from the entire scientific community. In these efforts, the Institute considers the impact of new research programs on ongoing research and efforts required to fill the national needs.

The NIEHS uses the following mechanisms for internal review and evaluation of its ongoing research: Laboratory chiefs and program directors regularly meet with the Scientific Director to review ongoing and proposed research; the Scientific Director, Associate Directors, and other Office of the Director staff meet regularly with the Director to review programs and goals; the Scientific Director and laboratory and branch chiefs hold an annual program review to evaluate the entire Institute's intramural research effort; the NIH Director conducts an annual program review at which the NIEHS programs and goals are examined; and at a higher level of generality, the Institute develops a five-year forward plan each year which includes the information on its major research goals and objectives, its research programs, and an estimate of resource requirements for achievement of its long- and short-term goals.

The Institute also uses procedures whereby all research programs are critically and regularly reviewed by scientists outside the Institute.

The National Advisory Environmental Health Sciences Council (NAEHSC) meets three times a year to advise NIEHS on overall program strategy and content in the area of environmental health sciences. It reviews grant applications for research and research training projects and recommends approval of those that merit support. The NAEHSC has a Centers Subcommittee which meets semiannually to review the adequacy of management and the quality of research and training at the seven university-based NIEHS-supported Environmental Health Sciences Centers.

The Board of Scientific Counselors functions as the peer review body for all intramural projects and contracts. Every laboratory or branch program is subjected to critical indepth review at least once every three years. These appraisals deal with scientific merit, progress and its relationship to resources committed, and relevance to the overall needs of that subdiscipline, as well as of the overall field of environmental health research. The recommendations of the Board are taken into account in allocating new resources and in reassigning directions and priorities.

Grant applications funded by NIEHS come through the NIH-wide scientific peer review system where they are judged according to scientific merit. Approved applications then go to the Institute and to the NAEHSC for review for relevance to the NIEHS programs. Although external to NIEHS, this mechanism serves as an integral part of the Institute's program review and evaluation system.

The NIEHS decision-making process depends on a continuous flow of information within the Institute structure and on an exchange of information between NIEHS and its advisors, as well as with other organizations and individuals concerned with environmental health problems. These other sources provide directives, advice and information that impact on Institute decisions.

The Administration and the Congress set the broad goals and boundaries for NIEHS research in the course of substantive legislation activity and in the political give-and-take involved in deciding appropriations. For example, the Toxic Substances Control Act contains the implicit expectation that Federal research agencies—primarily within HEW—will provide the basic knowledge and technology to permit the conduct of faster, simpler, more accurate, and less expensive toxicity testing. The Congressional authorization and appropriation process is the primary mechanism by which the legislature, and through it the public, influences

NIEHS program decisions and priorities. Thus, appropriations which result from the political process are a measure of the perceived social significance of environmental health problems.

The NIEHS parent organizations, HEW and NIH, and the President make the decisions regarding the resources the Institute can request. Moreover, NIH, working along with the other Institutes, develops a broad consensus as to what the NIH-wide pattern of goals and relative emphases should be.

NIEHS has played a major role in a number of intergovernmental liaison activities that impact on its decision-making process. For example, the DHEW Committee to Coordinate Toxicology and Related Programs (for which the NIEHS Director is chairman) identified the need for a study on the effects of PCBs in mother's milk, which NIEHS scientists are currently undertaking. Other such activities include the Environmental Protection Agency/National Institute for Occupational Safety and Health/Department of Energy/National Institute of Environmental Health Sciences collaborative efforts on adverse health effects of alternative energy sources; the National Cancer Institute/National Institute of Environmental Health Sciences joint programs in environmental mutagenesis and carcinogenesis; and international efforts such as activities relating to NIEHS' leadership as a World Health Organization Collaborating Center and to joint agreements with Japan (mutagenesis, carcinogenesis), the Soviet Union (general environmental health problems), and Egypt (general environmental health problems).

Still another source of information and advice that can affect NIEHS program decisions are the conferences sponsored by the Institute on potential or emerging environmental health problems. The goal of these conferences is to develop consensus among scientists from industry, government, and academia, as well as the science press (as surrogates for the general public), public interest groups, and Congress, on the state-of-the-art, needs, opportunities, and responsibility for particular research problems.

A variety of other sources can also influence the Institute's decision-making process. These include consultants retained on an as-needed basis; participants at scientific meetings, especially those related to toxicology, industrial hygiene, public health, and specific diseases; scientist-to-scientist interactions (within and outside the Institute); contacts with constituent groups, including voluntary health groups; and findings from Government Accounting Office studies.

## What Lies Ahead

While the ongoing activities of the Planning Work Group will result in more definitive plans for the Institute's programs for the years ahead, the Second Task Force on Research Planning in Environmental Health Science did identify some major needs in the environmental health research area NIEHS will be addressing in the near term. These include the need to: increase emphasis on the search for environmental factors in the etiology of major chronic diseases and disorders, particularly cardiovascular and pulmonary diseases, cancer, neurologic defects, and structural and functional birth defects; devote greater resources to chronic disease epidemiology which is crucial to inferences regarding the effects of toxicants on human health and for validating laboratory and animal test systems; provide increased support for research manpower training programs, especially for epidemiologists, pathologists, and toxicologists; and increase emphasis on research on mechanisms of action of toxic agents in order to facilitate both the understanding of disease production by chemicals and the development of better toxicologic test methods and remedial actions.

Furthermore, the NIEHS will continue to invest a growing percentage of its efforts in coordinated research with other agencies and in support of regulatory efforts, thereby maintaining close ties with the regulatory agencies and categorical programs for which it must provide much of the research base in the environmental health sciences.

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