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Report to Sen. Dale Bumpers; Carmie Henry, Office of the late Sen. John L. McClellan; by Elmer B. Staats, Comptroller General.

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A review was conducted at the National Center for Toxicological Research (NCTR), Jefferson, Arkansas, and the National Institute of Environmental Health Sciences (NIEHS), near Durham, North Carolina, concerning planned changes in research activities and the need for additional facilities during the next 10 years, estimated costs of the planned facilities, and unnecessary overlap of research between the two activities. NCTR is jointly funded by the Food and Drug Administration and the Environmental Protection Agency. NIEHS is one of the research institutes of the National Institutes of Health. Findings/Conclusions: Research at NCTR is divided into three phases over the 10-year period beginning in fiscal year 1978. Phase I includes programs in 12 major areas; Phase II will continue previous programs and will add programs in inhalation toxicology and behavioral toxicology. Phase III will continue research and will add the capability to test a total of 50 possible cancer-causing chemicals a year. NCTR will need its existing facilities and new facilities. Renovation is planned to cost \$45,822,631, and new construction, \$63,252,014. A cost of \$13,042,536 for other items such as site utilities and electrical work is also planned. NIEHS plans for fiscal years 1979-83 provide for increased staffing of six major areas of current research when a new permanent facility is completed. NIEHS officials plan to continue to occupy existing facilities and to complete construction of a new permanent facility. As of July 30, 1977, \$70,892,500 had been appropriated for the design and construction of the permanent facilities. No unintentional overlap of research between the two organizations was identified; however, their missions are similar. NCTR approaches the problems of toxicity based on the needs of the regulatory agencies. NIEHS' research objective is to increase the body of knowledge in the field of toxicity. (SW)



COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

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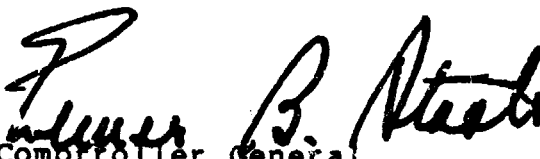
The Honorable Dale Bumpers
United States Senate

Mr. Carmie Henry
Office of the late
John L. McClellan
United States Senate

Pursuant to an April 27, 1977, letter and later discussions with your offices, we reviewed the proposed facility requirements for the National Center for Toxicological Research and the National Institute of Environmental Health Sciences. Specifically, we obtained information on (1) planned changes in research activities and the need for additional facilities during the next 10 years, (2) estimated costs of the planned facilities, and (3) potential for unnecessary overlap of research between the two organizations.

The results of our review, presented to your offices during a September 30, 1977, briefing, are summarized in the enclosure.

As agreed, copies of this report will be made available to the Department of Health, Education, and Welfare and to interested congressional committees, Members of Congress, and others upon request.


Comptroller General
of the United States

Enclosure

HRD-78-29
(10386)

PROPOSED FACILITY REQUIREMENTS FOR THE
NATIONAL CENTER FOR TOXICOLOGICAL
RESEARCH AND THE NATIONAL INSTITUTE
OF ENVIRONMENTAL HEALTH SCIENCES

We made a review at the National Center for Toxicological Research (NCTR), Jefferson, Arkansas, and the National Institute of Environmental Health Sciences (NIEHS), near Durham, North Carolina. NCTR is an activity of the Food and Drug Administration, Department of Health, Education, and Welfare (HEW), but is jointly funded by the Food and Drug Administration and the Environmental Protection Agency. NIEHS is one of the 11 research institutes that make up HEW's National Institutes of Health. Both NCTR and NIEHS have environmental health-related missions.

Our work concerned (1) planned changes in research activities and the need for additional facilities during the next 10 years, (2) estimated costs of the planned facilities, and (3) unnecessary overlap of research between the two activities.

WHAT ARE THE PLANNED CHANGES IN NCTR AND
NIEHS ACTIVITIES OVER THE NEXT 10 YEARS
AND WHAT ADDITIONAL FACILITIES WILL BE
NEEDED TO ACCOMPLISH THESE ACTIVITIES?

The research programs at NIEHS are planned through 1983. NCTR's research programs and the required facilities are projected through 1987.

NIEHS

Research programs

NIEHS' intramural research programs are directed toward developing a reliable data base for establishing standards and methods to identify and treat the adverse effects of environmental and occupational chemicals and physical factors on human beings. The programs focus on several environmental agents that, on the whole, are considered the greatest potential hazards now and in the future. Those agents include airborne toxicants, metal toxicants, persistent chemicals and pesticides, compounds causing hereditary birth defects, physical factors, and other hazardous compounds. The major areas of current research, according to an NIEHS official, are:

- Genetic damage by chemicals. NIEHS is developing new methods to test for such damage.
- Reproduction and teratology (nonhereditary birth defects). NIEHS is evaluating birth defects caused by selected chemicals and the effects of chemicals on postnatal development.
- Rates and processes of absorption, distribution, and excretion of chemicals in the body (pharmacokinetics). Studies are focusing on the kinetics of the chemical polychlorinated biphenyl and are attempting to extrapolate the test results from one animal species to another and to humans.
- Lung damage by chemicals (pulmonary toxicology). Studies concern the effects of chemicals on the lung's regulation and use of certain enzymes.
- Balance between body systems metabolizing ingested chemicals (toxication-detoxication). Scientists know that a substance may metabolize in one body system to form a toxic agent but harm may not occur because another body system may excrete or detoxify the substance. They also know that the balance between toxication and detoxication may be altered by various drugs, chemicals, and physiological or hormonal changes. NIEHS studies concern the characterization of certain chemical metabolizing systems in a few tissues and the effects of pollutants on these systems.
- Techniques for estimation of the human risk from long-term exposure to low doses of environmental agents, identification of potential health hazards in the environment, and mathematical modeling of biological processes (biometry).

NIEHS plans for fiscal years 1979-83 provide for increased staffing of these research areas when its new permanent facility is completed. This will allow NIEHS to strengthen its programs in the effects of noise and nonionizing radiation, behavioral toxicology, neurotoxicology, organ toxicology, reproductive toxicology, marine and aquatic biomedical research, pharmacokinetics, toxication-detoxication mechanisms, and epidemiology. NIEHS plans to expand research studies in the effects of chemicals on the lungs; the rates and processes of absorption, distribution, metabolism, and elimination of chemicals in the body; and the effects of chemicals on behavior and the nervous system by establishing laboratories in

each subject area. Genetic damage caused by chemicals will also be emphasized.

Through its extramural program, NIEHS provides funds to support research and research training activities at educational institutions, research institutes, and other public and private nonprofit organizations. NIEHS supports research and training in four primary program areas: etiology of environmental diseases and disorders, environmental pharmacology and toxicology, environmental pathogenesis, and environmental mutagenesis and reproductive toxicology.

The etiology program attempts to identify and understand causal associations between hazardous chemical, physical, and biological factors in the human environment and human illness and death. The pharmacology-toxicology program studies the principles and mechanisms involved in the toxicity of environmental agents. The pathogenesis program focuses on the details and time sequence of molecular and cellular events that culminate in recognizable diseases upon exposure to toxic agents. Mutagenesis and reproductive toxicology studies deal with the potential roles of environmental agents in altering the genetic makeup of human beings, their reproductive capability, and the development of the embryo or fetus. NIEHS plans to continue studies in each of these four areas.

Facilities

NIEHS officials plan to continue to occupy existing facilities and complete construction of a new permanent facility.

Permanent facilities

In November 1961 the Committee on Environmental Health Problems recommended that a national center be established to do research in environmental health problems. This committee was established by the Surgeon General, in response to a House Appropriations Committee request, to develop long-range objectives for the Public Health Service's environmental health program. In the fiscal year 1965 budget, the Congress authorized planning funds for the facility and appropriated design funds with a requirement that the facility be located more than 50 miles from Washington, D.C.

A site selection committee for the national center was appointed and, following its recommendations, the Secretary of HEW announced in January 1965 that the center would be located in the Research Triangle Park of North Carolina. The proximity to three major universities--North Carolina State

University, the University of North Carolina, and Duke University--was a major factor in selecting this location. In addition, the Research Triangle Foundation of North Carolina donated 509.2 acres of land to the Federal Government contingent upon the national center being built on the site.

In 1968 a contract for a master plan for the 509.2-acre tract was awarded for \$215,000. The plan, completed in March 1971, provided for four research centers to be located on the tract. Two centers were named in the plan--the National Environmental Health Sciences Center and the Air Pollution Control Office-Environmental Protection Agency center. The design contracts for the permanent facility were awarded in February 1974 and completed in 1976.

The NIEHS permanent facilities will consist of a five-module program facility and a central support services complex. The program facility will include laboratories, animal rooms, and offices. Two of the modules will have three floors, and the other three modules will have four floors and a basement. An NIEHS official said the central support services complex will consist of six buildings, which will be large enough to accommodate the other research centers proposed for the tract. The NIEHS permanent facilities will provide 452,273 gross square feet of floor space. Of the total, 74 percent (334,000 square feet) will be for the program facility and 26 percent (118,273 square feet) for the support services complex.

In November 1976, construction to extend the water and sewer lines to the permanent site began, and in April 1977, clearing and grading of the site began. The HEW resident engineer said construction of the permanent facilities is on schedule for planned occupancy in February 1980.

Existing facilities

Since June 1966 NIEHS has occupied buildings on leased property about one-fourth of a mile north of the permanent facility site. In addition, it has leased two off-site warehouses for storage and 4,246 square feet of floor space in Raleigh for staff administering its extramural programs. As of August 1977 the leased facilities had a total of 179,763 gross square feet of floor space. Of this space

--72 percent (129,170 square feet) is used for research programs;

--26 percent (46,347 square feet) is used for support services, such as the power plant and maintenance shops; and

--2 percent (4,246 square feet) is the leased space in Raleigh used for staff administering the extramural programs.

Four buildings on the leased property were built to NIEHS specifications in 1971 after delays in constructing the permanent facility. An NIEHS official said that one of these buildings was specifically designed for research in inhalation toxicology and that this space will not be duplicated in the permanent facility. The four buildings are under a 20-year lease expiring in 1991. The lease for the other buildings on this property will expire in May 1978 and will be renegotiated for a 3-year period.

An NIEHS official said staff administering the extramural program, now in Raleigh, will move to the Research Triangle Park when the permanent facilities are completed.

The space currently used and under construction at NIEHS is summarized below.

	<u>Gross square feet</u>
Space currently used:	
Research programs (program facility)	a/129,170
Support services	<u>46,347</u>
	175,517
Leased space in Raleigh for staff administering the extramural program	<u>4,246</u>
	<u><u>179,763</u></u>
Space under construction:	
Research programs (program facility)	a/334,000
Support services	<u>118,273</u>
	<u><u>452,273</u></u>
Space available after completion of permanent facilities:	
Currently used	175,517
Under construction	<u>452,273</u>
	<u><u>627,790</u></u>

a/Includes cafeteria space.

The officials believe these facilities will be adequate for the research programs planned through 1983. However, according to an official at NIEHS, it anticipates a shortage of about 15,000 square feet of animal rooms by 1985 or 1986 for planned research in hereditary birth defects if each planned research program is allowed to develop optimally. Officials said the emphasis on this type of research increased after the design for the permanent facilities was completed. To meet the shortage of animal space, an official said NIEHS plans to consider either contracting with private laboratories or other Government agencies for the animal facilities. The official further stated that there are no plans to build any facilities beyond those under construction.

NCTR

Research programs

An NCTR official said that the master plan is the guide for developing its research program. Research development is divided into three phases over the 10-year period beginning in fiscal year 1978. Research in phase I, currently underway, includes programs in 12 major areas:

- Cancer effects of aromatic amines.
- Evaluation of liver tumors in rodents in cancer bioassays.
- Causes of bladder cancer in experimental animals and humans.
- Adverse effects of hormones.
- Causes of prenatal cancer.
- Techniques for estimating health effects on humans exposed to low levels of environmental chemicals.
- Development of methods for providing quantitative data on the various aspects of cancer.
- Hereditary birth defects.
- Nonhereditary birth defects.
- Chemistry.
- Microbiology.

--Effects of chemicals on biological mechanisms that help resist diseases.

Phase II of the research program will be a continuation of the phase I programs and the addition of programs in inhalation toxicology and behavioral toxicology. Under phase III, programs initiated in phases I and II will be continued and the capability to test a total of 50 possible cancer-causing chemicals a year will be added.

Facilities

To accomplish the research programs planned through 1987, the master plan indicates that NCTR will need its existing facilities and new facilities.

Existing facilities

NCTR occupies the Army's former biological warfare production complex at Jefferson, Arkansas. The complex, located on a 500-acre site, includes 33 buildings with about 1 million gross square feet of floor space. NCTR has used about half of the floor space for its research programs. According to an NCTR official, this space has been made usable for \$10,926,583. However, some of the space was easily adapted from its former Army use and an NCTR official said it used such space first.

Master plan

In October 1975 the Congress authorized NCTR to make a long-range planning study for its research programs to insure the most effective use of existing facilities and future laboratories. In June 1976 NCTR contracted with a management and technical consulting firm to develop a 10-year master plan. In August 1977 an NCTR official said the master plan had been completed except for the final printing; however, it has not been approved above the NCTR level within HEW or by the Environmental Protection Agency.

NCTR officials said the plan represents the best information available on the proposed future activities for the center. It provides for a total of 1.7 million gross square feet of space upon completion of the plan in 1987. The total construction cost of the recommended facilities is estimated at \$122.1 million in 1977 dollars. The facilities are to be built in six phases over a 10-year period.

Renovation

The plan provides for renovating 614,868 square feet of floor space for \$45,822,631. Most of the buildings at NCTR are 25 years old and were built for highly specialized functions. In developing the master plan, the consultants assessed the condition of the existing facilities and their suitability for renovation. The structure was found to be in good condition; however, most of the interior spaces and building systems (for example, plumbing, electrical, heating, and air-conditioning) were in fair or poor condition. Of the total space planned for renovation, NCTR officials estimate that about 22 percent (137,493 square feet) is currently used but will require some renovation to be suitable for a different use. For example, the space now used as a cafeteria will be converted to a computer facility. The estimated cost for renovating the space currently used is about \$8,397,000.

New construction

The master plan also proposes expansion of some buildings and construction of eight new buildings. A total of 719,434 gross square feet of new construction is planned for an estimated cost of \$63,252,014. The plan also proposes demolishing seven existing buildings containing about 25,500 square feet.

In addition to renovation and new construction, the plan indicates a cost of \$13,042,536 for other items, such as site utilities, site electrical work, and architectural fees, which will benefit both renovated and new facilities.

NCTR officials said about \$31,804,690 of renovation and new construction would be necessary to continue NCTR's current operations even if the master plan is ignored. Examples of items that would be needed are a new animal diet preparation facility and a waste disposal system.

The space offered by the existing facilities and the planned renovation and new construction at NCTR is summarized on the following page.

	<u>Gross square feet</u>	
Existing space:		
Currently used	509,398	
Planned for renovation		137,493
Unused	502,685	
Planned for renovation		<u>477,375</u>
Total existing space	<u>1,012,083</u>	
Total existing space planned for renovation		<u>614,868</u>
New construction		<u>719,434</u>
Space planned to be available in 1987		<u>1,731,517</u>

PERSONNEL INCREASES--NIEHS AND NCTR

In 1977 NIEHS was authorized 331 permanent and 125 temporary positions. NIEHS projects that the permanent staff will increase to 1,000 and the temporary staff to 180 by September 1983. NCTR had 629 personnel (356 contract employees and 273 Government employees) in August 1977. The master plan for NCTR projects an increase to 2,013 personnel by 1987.

WHY DOES INFORMATION INDICATE THAT IT WOULD COST MORE PER SQUARE FOOT TO RENOVATE VACANT NCTR FACILITIES THAN TO BUILD NEW FACILITIES AT NIEHS?

More current and reliable information than was available in June 1977 indicates that it is cheaper per square foot to renovate the existing facilities at NCTR than to build the new permanent facility at NIEHS.

March 1975 report

When we met with the offices of Senators McClellan and Bumpers in June, we did not have the master plan for NCTR. However, a report entitled "Physical Facilities and Scientific Programs of the National Center for Toxicological Research," prepared in March 1975 by the House Appropriations Committee's Surveys and Investigation Staff was available. This report indicated that renovating 478,037 square feet not used by NCTR would cost about \$76 million, or \$158.98 per square foot. An NCTR official said the \$76 million estimate was developed in-house without the benefit of a professional architectural

engineering study. In addition, an NCTR official said the cost estimate was to renovate all the remaining space, although about 100,000 square feet, including the space scheduled for demolition and basement and other space in buildings planned for continued use, was considered unsuitable for renovation by the consultants who developed the master plan.

NCTR master plan

The master plan indicates a cost of \$84.29 per square foot in 1977 dollars and \$111.21 per square foot in year-funded dollars for the planned renovation. The plan also indicates a cost of \$97.69 per square foot in 1977 dollars and \$141.35 per square foot in year-funded dollars for the planned new construction.

Cost of NIEHS permanent facilities

As of July 30, 1977, \$70,892,500 had been appropriated for the design and construction of the NIEHS permanent facilities. About 98 percent (\$69,251,491) of the appropriations had been obligated and 7 percent (\$4,855,235) had been spent. Of the appropriations, \$67 million is for construction of the facilities. In May 1977 the construction manager established a guaranteed maximum price of \$65,394,000 for facility construction. An NIEHS official said the difference of \$1.6 million between the construction appropriations and the guaranteed maximum price will cover the Government's cost for administering the contract and any necessary design modifications.

According to NIEHS officials, the new facility will include costs associated with future development for the 509.2-acre tract in the master plan. For example, NIEHS is paying the cost of clearing and grading the roadway into the research complex, the total construction cost for the support services complex, the cost for larger and more utility lines than normally would have been required, and the cost of a small lake for the complex (estimated to be about \$68,800). The HEW resident engineer for the new facilities estimated that the construction cost of the NIEHS permanent facilities is about \$8,829,700 higher than it would have been had the master plan not been followed to permit construction of the other research centers on the site.

The cost per square foot for the design and construction of the NIEHS permanent facility is \$156.27. However, this cost drops to \$136.75 if the \$8.8 million additional construction cost for following the master plan is deducted.

The NEV resident engineer for the NIEHS permanent facilities said the Government would incur substantial penalties for canceling the construction contracts and stopping construction of the permanent facilities at this time. In addition, the NIEHS permanent facilities were justified and all of the construction funds appropriated before enactment of the Toxic Substances Control Act.

Differences in cost estimates

The cost for the NIEHS permanent facilities is based on firm contracts and appropriations, whereas the cost of planned renovation and new construction at NCTR is based on architectural estimates. In addition, differences in the quality of facilities at NCTR and NIEHS could affect their costs. Although we did not evaluate quality, the NIEHS program facility will reportedly include interstitial space between floors to house the electrical and utility systems for easier maintenance and maximum flexibility.

The estimated costs for planned renovation and new construction at NCTR and NIEHS are summarized below.

NCTR facilities

Renovation (note a)	\$ 45,822,631
New construction (note a)	63,252,014
Other (note a)	<u>13,042,536</u>
	<u>\$122,117,181</u>
Cost per square foot in 1977 dollars:	
Renovation	\$84.29
New construction	\$97.59

NIEHS permanent facilities

Appropriations (July 30, 1977)	\$70,892,500
Cost per square foot	\$156.27

a/Architectural estimates in the NCTR master plan.

IS THERE UNNECESSARY OVERLAP OF RESEARCH BETWEEN NCTR AND NIEHS?

As agreed with the Senators' offices, we limited our work in answering this question to discussions with branch chiefs and the director of each facility. In addition, we obtained a list of chemicals being used or tested at each

facility; compared the lists; and for chemicals on both lists, we asked how they are being used or tested.

We did not identify any unintentional overlap of research between NCTR and NIEHS. However, the missions of the two organizations are similar. The NCTR director said NCTR approaches the problems of toxicity based on the needs of the regulatory agencies--the Environmental Protection Agency and the Food and Drug Administration--whereas NIEHS' research objective is to increase the body of knowledge in the field of toxicity.

Missions

The mission of NIEHS is to determine how and why chemical, physical, and biological factors in the environment affect the health and well-being of humans. It also develops basic knowledge necessary for devising protection against these environmental agents.

NCTR has a two-fold mission. Its primary mission is to study the biological effects of potentially toxic chemical substances, with major emphasis on

- determining adverse health effects resulting from long-term, low-level exposure to chemical toxicants;
- determining basic processes for chemical toxicants in animal organisms;
- developing improved methodology and test protocols for safety evaluation of chemical toxicants; and
- developing data to facilitate extrapolation of toxicological data from laboratory animals to humans.

NCTR's secondary mission is to do other research that will contribute to the overall scientific capability of the center without distracting from the primary mission. These programs include research requests from the sponsoring regulatory agencies.

Similar research areas

NIEHS and NCTR are doing research in several of the same areas. However, branch chiefs and the director at both agencies generally said there is no unintentional overlap or duplication in research projects between the two centers. The areas of similar research are:

- Hereditary birth defects caused by toxic agents in the environment (mutagenesis).
- Nonhereditary birth defects induced by environmental factors (teratology).
- Estimation of the risk to man from long-term, low-dose exposure to environmental toxicants and development of mathematical models for extrapolating test data for animal experiments between animal species and to human beings (biometry/risk analysis).
- Rates and processes of absorption, distribution, metabolism, and elimination of chemicals from the body (pharmacokinetics).

We compared chemicals used by NCTR and NIEHS and identified 27 that were used in tests at both activities. However, NCTR and NIEHS officials said many of these chemicals are used as model chemicals in experiments to induce known effects in experimental animals or to compare test results using similar chemicals. The officials do not consider the use of these chemicals by both agencies to be unnecessary overlap.

Mechanisms to prevent unnecessary overlap

Branch chiefs at the two centers said that some research duplication or overlap is necessary and desirable to verify test results and serve as groundwork for further research. The NCTR director said the intense competition between scientists to publish new findings causes them to avoid unnecessary research duplication. However, the similarity of the two agencies' research missions permits a strong potential for duplication.

Both formal and informal mechanisms exist to prevent unnecessary and unintentional duplication. The primary formal mechanism is the HEW Committee to Coordinate Toxicology and Related Programs. This committee is composed of high-level representatives from HEW agencies doing toxicological research. The NIEHS director is chairman of the committee. However, officials at both NIEHS and NCTR said the committee's effect in preventing research duplication or overlap is limited. These officials view the committee primarily as a policy board, whose members are unaware of individual research projects.

Another formal mechanism is the NCTR Science Advisory Board. This board, which has a representative from NIEHS, is responsible for reviewing and evaluating the scientific validity of NCTR's research programs. NCTR and NIEHS officials added that communication between scientists doing similar research also prevents unnecessary overlap. In addition, both agencies sponsor conferences and symposia that are attended by research scientists from the two agencies.

STAFF ASSISTANCE WE PROVIDED TO NCTR

Because of the Senators' request, we found ourselves in a position to assist NCTR officials by pointing out inconsistencies in facilities requirements shown in NCTR's draft master plan documents. An NCTR official said that the consultants had agreed to correct the inconsistencies and provide sources for the data used in preparing the executive summary, the part of the master plan most subject to use by congressional and agency officials who review budget requests. According to the NCTR director, NCTR benefited from the early identification of the inconsistencies.