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Report to the President's Cancer Panel on the Reauthorization of the National Cancer Act

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REPORT TO THE PRESIDENT'S CANCER PANEL ON THE REAUTHORIZATION OF THE NATIONAL CANCER ACT

EXECUTIVE SUMMARY

In preparation for congressional hearings regarding the reauthorization of the Health Research Extension Act of 1985, Dr. Armand Hammer, Chairman of the President's Cancer Panel, requested the Director of the National Cancer Institute (NCI) to prepare this report on the special authorities and responsibilities provided specifically to the Director, NCI under Part C Subpart 1 of the Act. This Subpart is commonly referred to as the **National Cancer Act.**

ISSUE: Whether the authorities given to the National Cancer Institute under the National Cancer Act of 1971 and subsequently under the Health Research Extension Act of 1985 should be retained and/or modified.

BACKGROUND: The National Cancer Act of 1971 was designed to provide the Director, NCI with certain unique authorities to remove traditional administrative impediments in an effort to accelerate cancer research and the application of research results in cancer treatment and prevention. It recognized the need to couple authority with responsibility in programs with special priorities. Because some of these authorities have now been extended to the Director of the National Institutes of Health (NIH) and to other NIH institute directors, discussions have ensued concerning the need for the NCI to retain, in law, its special authorities.

POSITION: Cancer has been the number one concern of the American people for over 50 years. It is now the number two killer and even with a marked reduction in mortality, **cancer will become the number one killer** due to the declining mortality from heart disease of the aging population. Basic research findings paid for by NCI's investment in basic research are now voluminous and more than ever require the flexibility to transfer new technology to the public. Therefore, the National Cancer Institute firmly believes that it is critical to retain its special authorities to assure the maintenance and momentum of a coordinated, congressionally mandated National Cancer Program in an effort to reach its Year 2000 Goal of reducing cancer mortality by 50 percent. While some NCI authorities have been extended by legislation to all NIH institutes **through** the Secretary of the Department of Health and Human Services, the NCI still has unique authorities and responsibilities that

are vital to the National Cancer Program. Futhermore, the NCI feels that **ALL** of its authorities should be retained as the need to avoid as many administrative impediments as possible still exists.

Special Authorities of the National Cancer Institute

1. President's Cancer Panel

A three member, presidentially appointed panel oversees the National Cancer Program and brings to the attention of the President any obstacles adversely affecting the operations of the Institute. The law mandates that impediments to the National Cancer Program be debated in public and addressed at the highest level of Government.

Major accomplishments of the Panel include:

- has assured by its very existence, open dialogue, in public if necessary, of problems affecting the progress of the National Cancer Program. Since concerns of the NCI are, at times, also the concerns of the entire NIH, other NIH institutes also have benefitted from the Panel's access to the President and the ability to raise issues in a public forum. As a result, many issues are resolved without need of full, public Panel discussion;

- intervened on behalf of the entire NIH to assure that training authority was re-established in the 1974 authorization legislation;

- brought NIH single **apportionment issue** to the attention of the Office of Managment and Budget (OMB), the scientific community, and the President and was instrumental in separating congressional concern over numbers of competing grants and OMB use of the apportionment process to meet congressional grant targets. The clarification of this issue benefitted the entire NIH;

- has been the primary recommending body to the President for nominees to the National Cancer Advisory Board (NCAB) to assure Board membership without regard to political affiliation and based only on scientific/personal credentials;

- in 1975, brought to the attention of the President the need to increase the personnel ceiling for the Institute commensurate with the large budget increases received since passage of the National Cancer Act of 1971;

- performed management oversight of the 1972 conversion of the Fort Detrick buildings in Frederick, Maryland from a facility dedicated to biological warfare, to a world-class cancer research facility;

- in 1978 led the NCI to separate the peer review process of grants from the program management of grants by consolidating the peer review system in one division and assigning the scientific management of the grant portfolios to the research divisions;

- in 1979, led the Institute to further separate program and review functions by recommending that the contract review function be separated from the contract management/scientific oversight function. Thus, all review activities were merged into a new Division of Extramural Activities thereby assuring unbiased conduct of the peer review system;

- during the period 1975-1977, the Panel recognized the need to merge the treatment activities of the Institute into one division - the Division of Cancer Treatment (DCT). For the first time, all treatment activities of NCI could be coordinated under the direction of one division; and

- in 1983 established **Outstanding Investigator Grants** which are awarded based on an investigator's proven career track record and not on the merits of any one specific project.

2. National Cancer Advisory Board

The NCAB consists of 18 **presidentially** appointed members from the scientific and lay communities. Because the **Chairman** is appointed by the President, the Board is able to set its own agenda and provide independent and objective advice regarding all aspects of the National Cancer Program. All other NIH research boards/councils are chaired by their institute directors.

Major accomplishments/characteristics of the Board are:

- because its members and **Chairman** are appointed by the President, it is more independent and able to give constructive critical advice to the Director, NCI;

- established in 1972 an extramurally managed Organ Systems Program to accelerate and target research on common tumors of major organs. The establishment of this program required the special authorities of the National Cancer Act. In 1981 the Board concluded that appropriate stimulation of the research had been accomplished and therefore, the Board subsequently recommended to internalize the program within the NCI;

- created what is now termed the "RFA" mechanism at the NIH. In 1975 the Board formulated the concept of the NCI soliciting grants to cover areas of research which were perceived to be inadequately addressed. After establishing a reserve of grant funds and identifying specific areas of science, the NCI published announcements for Cancer Research Emphasis Grants (CREG's). This mechanism was the forerunner of the Request for Grant Applications (RFA's) which is now a commonly used method of stimulating science via the grant mechanism by the entire NIH;

- the Board is able to take action on its own initiative, such as:

    a. sponsored Public Participation Hearings targeted toward involving the public in prevention and early detection activities;

    b. sponsored the Black Leadership Initiative to involve black business leaders in educating black populations concerning cancer prevention and control; and,

    c. brought to the attention of the Director, NIH the serious shortage of nursing staff in the Clinical Center and the adverse impact on the operations of the intramural NCI program;

- shortly after passage of the National Cancer Act of 1971, the Board defined the term "center" and the term "comprehensive" through establishing criteria to be used in evaluating and granting the titles "Cancer Center" and "Comprehensive Cancer Research Center;"

- participated in major reorganizations of the NCI including:

    a. the 1980 transition of the Baltimore Cancer Research Program from an intramural research program, to an independent, grant supported, university cancer center;

    b. the 1983 transfer of applied prevention activities from the Division of Cancer Cause and Prevention, to a newly created Division of Cancer Prevention and Control and the assignment of basic science prevention research to the Division of Cancer Etiology; and,

    c. the 1982 transfer of the bioassay component of the National Toxicology Program from the NCI to the National Institute of Environmental Health Sciences (NIEHS). This transfer involved approximately $48 million and 95 positions and moved responsibility for the testing of chemicals in experimental animals for potential

carcinogenic and toxicologic effects from the NCI to the NIEHS.

3. **Presidential Appointment of the Director, NCI**

The Director, NCI is the only Presidentially appointed NIH institute director. This fact, coupled with the President's Cancer Panel, gives the Director, NCI the independent ability to vigorously pursue solutions to administrative obstacles which inhibit the scientific progress and the translation of that progress to the practice of the treatment of cancer.

4. **Professional Judgment Budget (BY-PASS Budget)**

By law, the Director submits **directly** to the President (OMB) a budget for the following fiscal year that will enable the Institute to pursue all scientific opportunities. This budget by-passes all internal administrative offices and informs the President directly as to the needs of the National Cancer Program. The professional judgment budget serves as the end product of an Institute-wide planning process involving Institute staff, the National Cancer Advisory Board, the President's Cancer Panel, and other expert advisors who are closest to the science and able to project the needs for an effective cancer program. The legislative provision for the By-Pass Budget was created in recognition that **cancer has been the number one health concern of the American public for the past 50 years and that sufficient resources for cancer research was a public mandate.** No other NIH institute has this authority.

5. **Authority to Appoint Advisory Committees**

In consultation with the NCAB, the Director, NCI may appoint advisory committees necessary to conduct the business of the Institute. Using this authority and in recognition that management of a program as large and complex as the NCI required a unique management structure, the Director has appointed and established a **Board of Scientific Counselors** for each research division of the Institute as well as for the Frederick Cancer Research Facility (FCRF). Each of these boards has been vested with special authorities and responsibilities unique at the NIH. By his authority under the National Cancer Act, the Director, NCI has delegated to each Board of Scientific Counselors, the authority to:

- review and approve concepts for grant or contract supported activities before issuance of a Request for Applications (RFA) for grants or a Request for Proposals (RFP) for new or recompeting contracts is allowed;

- perform peer review of the intramural research program; and

- review, comment, and advise on all aspects of both the intramural and extramural programs including financial resources.

These boards are comprised of non-Federal advisors to advise and monitor the scientific programs of the divisions and the FCRF. Through the NCI Director's authority to appoint, the membership of these boards represents a cross-section of scientific disciplines with independence of expression encouraged through the appointment of one of its members to serve as chairman.

Major accomplishments/characteristics of the Boards of Scientific Counselors are:

a. in 1976 recognized the need to provide an organized process of peer review of intramural research comparable to grant peer review for program projects (including review of laboratory/branch budgets). This highly successful process has since been required by the Health Research Extension Act of 1985 to apply to all NIH intramural programs;

b. The Boards of Scientific Counselors review both the intramural and extramural activities of NCI's divisions and therefore can judge and advise on the balance of resources between intramural and extramural programs -- advice not only useful to the divisions, but also to the NCAB and the Institute as a whole. This oversight of the total scientific content of both intramural and extramural research is unique to the NCI and is possible only because of the NCI's authority to establish and appoint appropriate members to such committees. Furthermore, it assures that the extramural and intramural programs are complementary and that the resources available to the Institute are utilized in the most effective manner possible;

c. the Boards of Scientific Counselors, in conjunction with the NCAB and the President's Cancer Panel, form a network of advisory committees to the Institute that comprise an infrastructure making possible the governance of science. Through the close relationship between the President's Cancer Panel, the National Cancer Advisory Board, and the divisional Boards of Scientific Counselors, the overall direction, goals, and priorities of the National Cancer Program and National Cancer Institute become matters of public debate and discussion.

For example, in 1985, the Division of Cancer Treatment recommended that the NCI Drug Development Program be restructured from a system using live animals as an initial

screen for potentially active compounds, to a system based on human tumor cell lines. This represented a **major** scientific change. Intensive discussion and debate took place both at the DCT Board of Scientific Counselors as well as at the National Cancer Advisory Board and was reported to the President's Cancer Panel. Through these discussions, changes in staff proposals were adopted with the general recognition that the change would have far reaching ramifications on the development of cancer chemotherapy for decades.

The NCI is convinced that its authority to establish and appoint advisory committees to work in harmony with the Panel and NCAB, is the heart of its ability to conduct business in an open, constructive environment and represents the foundation for free scientific debate and discussion concerning the allocation of scarce resources.

The National Cancer Act, as incorporated in the Health Research Extension Act of 1985, contains many other important special authorities for the National Cancer Institute. This summary has highlighted only the most significant and visible of these authorities, and omission should not be interpreted as insignificance. The attached full report describes the above authorities in more detail as well as numerous others which have served the NCI and American public well in the goal toward the conquest of cancer.

I. INTRODUCTION

For 50 years cancer has been the number one health concern and the second leading cause of death for the American people. Even if NCI achieves its stated goal of decreasing the cancer mortality rate by 50 percent by the beginning of the next century, cancer will become the nation's leading cause of death due to the aging of the population and the declining mortality from heart disease. The public fear of cancer, the perceived failure of the Government to have given its control sufficient priority, and concern that a special initiative on cancer would be met with resistance within the bureaucracy led to the passage of the National Cancer Act in 1971 and to its renewal and amendments in the years since.

In November 1987, in anticipation of the 1988 reauthorization of the National Cancer Act, Dr. Armand Hammer, Chairman of the President's Cancer Panel, directed the National Cancer Institute (NCI) to prepare a report on the impact of the Act and its amendments on progress in cancer research. He asked that this report include:

1. a concise history of the National Cancer Act;
2. a description of the special authorities provided by the Act;
3. how the Act and its amendments have been able to expedite progress in cancer research and treatment;
4. whether any eliminated authorities should be restored;
5. whether any new authorities are needed in 1988 to guarantee the highest quality National Cancer Program; and,
6. the funding deemed necessary to support the National Cancer Program for the next five years.

The body of this report addresses these requests. The Appendices supplement the document with the following materials: 1) a discussion and wording of recommended legislative changes for 1988; 2) a summary listing of authorities given to NCI by the National Cancer Act that have since been extended to other NIH components; 3) examples of President's Cancer Panel activities; 4) examples of National Cancer Advisory Board activities; 5) examples of collaboration with other Federal agencies; 6) examples of public information activities; 7) a 1984 case study of the National Cancer Institute commissioned by the Institute of Medicine as part of its study of the organization of the National Institutes of Health (NIH); and 8) the 1971 Summary of the Report of the National Panel of Consultants on the Conquest of Cancer.

The National Cancer Act of 1971

In 1937, responding to the concern of the American people about cancer, the U.S. Congress created the National Cancer Institute as a division of the United States Public Health Service. NCI was moved in 1944 to the National Institutes of Health. NCI was the first categorical disease institute and served as the prototype of this structure at NIH.

In 1970 Senator Ralph W. Yarborough, Chairman of the Senate Labor and Public Welfare Committee, introduced a resolution, supported by 53 of his Senate colleagues, calling for a study of the status of cancer research. Consequently, the Senate authorized the formation of the **National Panel of Consultants on the Conquest of Cancer**, a committee composed of 26 eminent laymen and scientists. The panel's report, **A National Program for the Conquest of Cancer** (Appendix 8), became the blueprint for the development of the National Cancer Act with the special authorities it provides the NCI to coordinate, expand and expedite cancer research.

The report's bold recommendations called for a new agency reporting directly to the President of the United States with greatly expanded resources of manpower, facilities, and funds to conquer cancer. The resulting legislation represented a masterful compromise, reached after months of public discussion and debate, regarding how best to accelerate progress in cancer research and its application and yet preserve scientific ties within the NIH community. This legislation has governed the relationship of NCI to NIH and other agencies for 16 years. Its durability is a testimony to the wisdom of the architects of the Act.

The Panel of Consultants (the Yarborough Committee) concluded in 1970 that:

> **the National Cancer Institute has done excellent work itself and has supported grants and contracts in the scientific community, which have resulted in much outstanding work, but the overall research effort is fragmented and, for the most part, uncoordinated. The effort in cancer should now be expanded and intensified under an effective administration charged with developing and executing a comprehensive national plan for the conquest of cancer at the earliest possible time.**

The Panel of Consultants laid out three necessary ingredients for the success of an amplified National Cancer Program: **effective administration; a comprehensive and coordinated national plan of action**; and **the necessary financial** resources.

Discussion ensued within congressional and scientific quarters regarding whether it would be possible and beneficial to "plan" in a scientific environment; whether the current state of knowledge about cancer warranted such an adventuresome program; and whether increased resources for cancer research would jeopardize other areas of health research. The latter was the most worrisome, and this concern turned out to be unfounded.

In a paper written on the occasion of the fifteenth anniversary of the Act, Benno Schmidt, the Chairman of the Yarborough Panel of Consultants and the first Chairman of the President's Cancer Panel, (1971 to 1980) noted that **during the 1970's the NCI budget had risen**

from $180 million in 1970 to over $1 billion in 1980 and that during the same period the NIH budget had grown from $1 billion to $3.429 billion, "thus belying the fear so widely expressed in 1970 and 1971 that any increase in the cancer budget would be at the expense of other institutes. Since 1980, the appropriations have increased annually so that by 1986 the NCI budget had reached $1.2 billion and the NIH budget was $5.3 billion.....permitting levels of fundamental biomedical research that were totally unprecedented." (1) Over two-thirds of the cancer program money was spent on basic biomedical research. Figures 1, 2 and 3 show the relative increases for the individual NIH Research Institutes. While increases to the NCI budget were the highest of all the institutes from 1970 to 1979, the rate of growth of the NCI budget slowed considerably and was surpassed by that for all the other institutes between 1980 and 1988.

In 1977, the Director of NIH, Dr. Donald Fredrickson, wrote in a memorandum to the Office of the Assistant Secretary for Health "almost six years after enactment of the special cancer legislation, it is fair to say that few of the predicted problems have materialized, and those not to the extent predicted." Commenting on the four-fold increase in funding that had occurred by 1977, Dr. Fredrickson concluded that the "increase in funding had been extraordinarily well managed."(2)

By far, the most controversial of the National Panel of Consultants' recommendations was the plan to remove the National Cancer Institute from the NIH and the Department of Health, Education and Welfare (DHEW), the predecessor to the current Department of Health and Human Services (DHHS). The impetus for this initial recommendation derived from the Yarborough Committee's strong feelings about the need for an organization designed for action. The Panel of Consultants noted:

> An effective major assault on cancer requires an administrative setup which can efficiently administer the coherent program that is required in this formidable and complex scientific field. Such a setup will not be easy to achieve within the Federal Government. The effective implementation of such a program will require a simplification of organizational arrangements and a drastic reduction in the number of people involved in administrative decisions. This type of straight-line organizational efficiency does not exist today in the National Cancer Institute, the National Institutes of Health, or the Department of Health, Education, and Welfare ... there is real doubt whether the kind of organization that is required for this program can in fact be achieved within the NIH or the DHEW.

The need for a compromise was seen by all, including the Yarborough Committee and its Senate supporters, when intense opposition to elevating the NCI to an independent agency, separate from the NIH, threatened to jeopardize all of the Panel's recommendations.

Representative Ancher Nelson from Minnesota solved the dilemma by suggesting that Congress create a three-person President's Cancer Panel, appointed by the President, to supervise and monitor the National Cancer Program and to report directly to the President any delays or blockages in its rapid execution as well as on progress. Further, the NCI would have a "budget bypass" which would permit the Institute, with review by the National Cancer Advisory Board, to submit its budget directly to the President without change by the NIH and the Department.

This compromise was struck by providing special authorities to NCI, while leaving it within NIH, and by creating an enhanced and accelerated National Cancer Program. On December 23, 1971, President Nixon signed the National Cancer Act of 1971 into law.

The Cancer Act mandated that NCI pursue basic research and take responsibility for the application of the results of that research in an organized program to reduce incidence, morbidity and mortality from cancer. The mandate to apply the results of basic research necessitated authorization for special programs and the ability to undertake initiatives not traditional for an NIH institute. Congress gave the clear signal that the NCI was to move ahead on all fronts with minimal interference from higher levels in the bureaucratic structure.

II. THE SPECIAL AUTHORITIES OF THE NATIONAL CANCER ACT

The special authorities of the National Cancer Act and its subsequent amendments fall into three major categories: strengthening the National Cancer Program's access to the President; facilitating an expedited cancer program; and expanding existing programs.

Although the NCI legally could have carried out some activities such as training, information dissemination, constructing or leasing facilities, and appointing advisory committees, all such activities had been severely limited by higher level policy or had failed to develop at the Institute. The Act mandates that activities such as information dissemination and training be developed and allowed to proceed. Other special authorities assured that the NCI would create a national program with as wide an impact as possible.

The Act remains essentially intact, and no major authorities have been deleted during the past 16 years. However, minor modifications would assist the Institute in meeting its responsibilities or clarify existing authorities, and are discussed in this report and detailed in Appendix 1. Congress considered a number of authorities so useful to NCI and NIH that the Health Research Extension Act (HREA) of 1985 extended them to other components of NIH as well (Appendix 2). Others remain unique to NCI.

Two points relative to reauthorization of the Cancer Act deserve emphasis. As the architects of the Act had hoped, the biologic revolution, fostered by the infusion of resources that followed passage of the legislation, has created unprecedented opportunities to apply the results of the new biology to reduce incidence, morbidity and mortality from cancer. Special authorities are necessary, especially in the current NIH climate, to couple responsibility for a program of the size and scope of the National Cancer Program with the authority to fulfill the dual mandate to support basic research and to apply rapidly the results of research to decrease the incidence, morbidity, and mortality of cancer.

A. Strengthening Access to the President

President's Cancer Panel

This three-member Panel, appointed by the President, with the Chairman named by the President, is charged **"to monitor the development and execution of the National Cancer Program... and report directly to the President. Any delays or blockages in rapid execution of the Program shall immediately be brought to the attention of the President."**

The Panel is required to submit progress reports to the President, as well as an annual evaluation of the efficacy of the National Cancer Program, including recommendations, to the President, the Secretary and the Congress. The Panel also advises the President on the selection and performance of the Director, NCI and plays an essential role in identifying and advising the President on candidates for the National Cancer Advisory Board.

The statutory requirement that the Panel immediately report to the President delays or blockages in the rapid execution of the National Cancer Program also makes it incumbent upon the Director, NCI to report such problems to the Panel. **An important consequence of the existence of the Panel and the requirement of the Federal Advisory Committee Act that it hold its meetings in public to discuss impediments, solve problems and review priorities, is that dialogue is often stimulated at all levels of government and in the private sector. This promotes early resolution of problems that might otherwise have required actual Panel discussion.**

Throughout its existence the Panel has monitored problems faced by the National Cancer Institute and NIH and intervened when necessary on subjects such as budget, staffing levels, the grant and contract review process, and the cancer centers program. (Appendix 3)

National Cancer Advisory Board

The National Cancer Act of 1971 replaced the National Advisory Cancer Council, a standard research institute council, with the National Cancer Advisory Board (NCAB). Its 18 members would now be appointed by the President from the scientific and lay communities, with ex-

officio members (now 11) from other Federal agencies with responsibilities related to cancer research, and therefore part of the National Cancer Program. Unlike advisory councils for the other NIH institutes and the Office of the Director, NIH which are appointed by the Secretary **and chaired by the Institute Director**, the Chairman of the NCAB is selected by the President from among the appointed members, which promotes more objective advice and review. Until the 1985 amendments, the law specified that the ex officio members were non-voting. Removing this stipulation has resulted in voting status for the 11 Federal ex officio members.

In addition to the customary role of NIH councils in the review and approval of grants, the NCAB was authorized to hold public hearings and to investigate programs and activities of the National Cancer Program. In doing so, the NCAB has played a significant role in establishing and restructuring major programs such as: developing the initial criteria for comprehensive cancer centers and later modifying them as necessary, the Organ Site Program, the Biological Response Modifiers Program and, most recently, the NCI's program of AIDS research. The 1985 HREA provided similar authorities to other NIH councils.

The NCAB advises on policy and resource allocation and reviews in detail the development of the By-Pass Budget. All major initiatives which affect the entire Institute or the Cancer Program are first brought to the NCAB for advice and guidance. A number of these are discussed in Appendix 4.

Recommended legislative changes:

Restore the provision that ex officio members are non-voting to preserve the authority of the presidential appointees.

Add an ex officio member from the Department of Energy, which did not exist at the time the Act was passed, and which supports cancer-related research activities.

<u>Presidential Appointment of the Director, NCI</u>

As part of the legislative compromise which kept the NCI within the NIH, but provided it special autonomy, the National Cancer Act specified that the NCI Director should be appointed by the President. This indicated the priority of the National Cancer Program and the need for the Institute Director to have independent authority. To preserve the relationship at NIH, the Act also made the Director, NIH a presidential appointee and specified that the Director, NCI should report to him in all matters except budget.

The exclusion of budget matters was deleted in the 1985 HREA.

By-Pass Budget - the Professional Judgment Budget

The NCI was required to submit an annual budget to the President developed on the basis of scientific opportunity after consultation with the National Cancer Advisory Board, but without modification at other levels in the Executive Branch. This provision is unique to NCI and is also a result of the decision of the authors of the National Cancer Act to keep NCI within NIH, while providing special autonomy as though it were an independent agency. Direct submission allows the President and the Congress to consider NCI funding priorities in the light of the professional judgment of both lay and scientific advisors who are closest to cancer research advances. The By-Pass Budget is also used by the Panel in advising the President.

The By-Pass Budget is a clear statement not only of the level of funding which could be productively utilized, but of priorities. In recent years, the National Cancer Advisory Board has directed that the need for support for construction and renovation of biomedical research facilities be clearly articulated in the By-Pass Budget.

NCI simultaneously develops a budget within the NIH structure for submission, through the Department, to the Office of Management and Budget (OMB). NCI develops its initial request to the Department based on the By-Pass Budget priorities. However, this request is often altered at NIH, the Department, and OMB.

The By-Pass Budget also serves as a planning document, as it results from a forward planning process used by the NCI since 1980. Since 1984 when the Institute announced the Goal for the Year 2000 of reducing cancer mortality rates by 50 percent by applying what is now known about cancer prevention, early detection and treatment, the By-Pass Budget has served as the document which links resource requirements to attaining this goal. (3)

Optimum funding to operate the National Cancer Program for the next five years is shown in the By-Pass Budget requests for FY 1989 through FY 1992.

BY-PASS BUDGET REQUEST
FY 1989 - FY 1993
(in Thousands)

	Cancer Research	Cancer Prevention and Control	Total
FY 1989	$1,968,629	$111,371	$2,080,000
FY 1990	$2,169,000	$135,000	$2,304,000
FY 1991	$2,454,000	$155,000	$2,609,000
FY 1992	$2,702,000	$175,000	$2,877,000
FY 1993	$2,924,126	$200,000	$3,124,126
	President's Budget Request		
FY 1989	$1,396,978	$ 71,278	$1,468,256

The Act required that NCI submit its budget request to the President and that it receive, directly from the President and the Office of Management and Budget, all funds appropriated by Congress for obligation and expenditure by the Institute. The 1985 HREA permitted, but **no longer required** that funds be apportioned directly to NCI.

In 1985, OMB pooled all NIH funding into one centralized apportionment tied to funding mechanisms, a dramatic change from the past when funds were apportioned to each Institute. OMB made this change in response to a congressional mandate to fund a specific number of new and competing grants, stimulated by the 1979 initiative of the NIH Director to stabilize support for research. (4) This single change resulted in a marked decrease in flexibility in the day-to-day management of research resources, especially deleterious for an institute of the size and breadth of NCI. Had the language of the original Act, requiring that NCI funds be received directly by the Institute been retained, it would not have been possible for OMB to consolidate the entire NIH apportionment.

The requirement for a fixed number of grants, without the necessary funds to support them, finally resulted in awards so markedly below recommended levels, that it, in essence, negated the value of peer review judgment. Recognizing this, the President's Cancer Panel, and the National Cancer Advisory Board, intervened in 1986 on behalf of the NIH and NCI. Congress, as a result of these and others' efforts, has not since required a fixed number of grants in law and, in turn, OMB has reverted to the former apportionment process.

Recommended legislative changes:

Authorize appropriations at the levels requested in the By-Pass Budget.

Restore the original language of the National Cancer Act stating that the Director, NCI **shall** receive directly all funds appropriated to the Institute, replacing the current "**may**" with "**shall.**"

B. Facilitating an Expedited National Cancer Program

Authority to Appoint Advisory Committees

The Congress recognized that the Director, NCI had been charged with a large and complex mission and had to be able, independently, to appoint advisors based on his own assessment of program and scientific need. The National Cancer Act therefore permits the Director, NCI, to appoint advisory committees composed of private citizens and officials of Federal, State and local governments.

This authority is used to appoint **Boards of Scientific Counselors (BSCs)** to the four program divisions of the NCI and the **Frederick Cancer Research Facility (FCRF) Advisory Committee**, as well as other

advisory committees when needed. The function of these advisory bodies is unique to the NCI at NIH and forms the basis for the governance of science in the cancer program and NCI's planning process. This is discussed more fully below.

The Boards of Scientific Counselors review extramural and intramural research and must approve all extramural research initiatives of an NCI division. They also conduct regular site visits of the intramural programs with written documentation, including budgets, analogous to the review of extramural program project grants. Their advice is critical in decisions concerning priorities, resource allocation, promotions, and reorganizations.

NCI's intramural site visit process, with its display of budgets, has been received with enthusiasm by the extramural community. As a result, the HREA of 1985 requires the Director, NIH to establish procedures for review of research at the NIH. This requirement is modeled on the NCI process. The NIH Legal Advisor has interpreted the 1985 Act to permit NCI to continue to use advisory committees appointed under its own authority, rather than the NIH Director's authority, to conduct the now mandated intramural reviews, but the language is unclear.

Recommended legislative change:

The reauthorization should specify that advisory committees appointed under the authority of the Director, NCI may conduct the required peer review of the NCI intramural program.

Peer Review Authority

Congress required NCI to provide for scientific peer review of its research grants and programs. This was to assure that NCI would fund projects of high merit and that activities authorized by the Act, but atypical for the rest of the NIH, would receive expert peer evaluation. Authority to establish peer review groups permitted the creation, in 1972, of the unique Organ Site Program, now the Organ Systems Program, with its own authority to review grants.

Prior to 1985, establishment of scientific peer review groups by the Director, NCI required approval of the Director, NIH and the NCAB. HREA extended authority for peer review of extramural research to all NIH institute directors. However, HREA required that **appointment** rather than **establishment** of peer review groups be approved by the advisory council of an institute and the Director, NIH. This could be construed to mean that the appointment of individual members requires approval. It would be inappropriate for the NCAB to approve the appointment of individual members of peer review committees for which it is the second level reviewer.

Recommended legislative change:

Clarify that the requirement for approval of the NCAB and the Director, NIH applies only to the establishment of peer review committees, but not to **appointment** of their members.

Construction Authority

Although construction authorities had existed at the NIH since 1948, they had become inactive or had been transferred elsewhere within the Public Health Service by 1968. The National Cancer Act of 1971 provided NCI with both intramural and extramural construction authority, making it the only NIH research institute with such authorities. The 1974 amendments clarified that this authority was for basic, as well as clinical, research facility construction and could include construction of biohazard and animal facilities. Extramural construction authority subsequently has been provided to two other institutes. An NIH committee, recently convened in response to a Senate directive, has recommended that authority also be given to the NIH for a general extramural construction program. Construction grants are awarded through the peer review system based on the scientific merit of the research to be conducted in the facility.

Construction authority supported the development of cancer research facilities across the country and has had a remarkable impact on the ability to attract private sector support for construction projects. Construction grants initially required 25 percent matching funds, later changed to 50 percent. NCI construction grants of $208 million generated $205 million of matching funds between 1972 and 1980. The authority has also enabled the NCI to modernize its own facilities. In the period 1972 to 1987, the NCI expended $299,268,097 for construction: $246,682,509 or 82 percent was awarded for extramural grants and contracts while $52,585,588 or 18 percent was spent on the Bethesda campus and at the Frederick Cancer Research Facility.

Construction authority enabled the NCI to utilize fully the facilities at Fort Detrick, Maryland that President Nixon transferred from the Department of Defense to NCI. Today the Frederick facility houses special containment laboratories for virus research, including research on AIDS; a modern fermentation facility to produce anti-cancer agents for clinical evaluation and analysis; and the only supercomputer facility in the United States dedicated solely to biomedical research. The NCI construction authority and associated funds remain the only means by which the NCI can maintain the physical plant at the Frederick Cancer Research Facility.

In recent years, appropriations for cancer research facility construction have been much more modest. Nevertheless, an NCI construction grant places a peer review seal of approval on a project which declares it to be a "winner," facilitating fund raising. Recently, grantees have successfully raised matching funds which exceeded NCI awards by as much as nine to one.

Authority to Award Contracts

The National Cancer Act of 1971 gave the Director, NCI independent authority to enter into contracts for research. The need for this authority was documented in a 1970 Government Accounting Office (GAO) report, requested by Senator Yarborough, that reported delays due to duplicate reviews by the NIH. The new authority made it possible to award contracts more rapidly. Contracts have served as a means to launch a research effort when speed is important. NCI has used the contracting authority to act quickly on priority programs as exemplified by; the establishment and operation of the Frederick Cancer Research Facility including the supercomputer facility, the International Cancer Research Data Bank (ICRDB), the Surveillance, Epidemiology and End Results (SEER) Program, the Physician Data Query (PDQ) system, the Chemoprevention Program, the Smoking, Tobacco and Cancer Program and NCI AIDS efforts in drug and vaccine development. The contracting authority was also used to expand rapidly such programs as the Virus Cancer Program, the Cancer Drug Development Program, the Clinical Trials Programs (treatment and prevention trials) and the Chemical Carcinogen Bioassay Program.

An NCI-sponsored study to evaluate the mechanisms that supported major research advances, showed that contracts have played a significant role in some phase of almost all of the major basic and clinical advances, as identified by an expert advisory panel. Contracts also have proven useful in stimulating research effort in a particular field to a level sufficient to generate support through investigator-initiated grants. (5)

The Director, NCI also uses his contracting authority to issue Contracting Officer Warrants which allow a contracting officer to award contracts and to authorize advance payment to a contractor as necessary. The National Heart, Lung and Blood Institute also has received its own contracting authority, but all other Institutes receive contracting authority through a delegation from the Secretary, DHHS.

Award of Small Grants

In 1971, the Congress gave the Director, NCI the authority to award grants up to $35,000, and since 1985 up to $50,000, after peer review, but without review and approval by the National Cancer Advisory Board. This has allowed the NCI to expedite the award of small grants, often used to fund first-time and minority awardees and special programs to stimulate prevention research, including small grants programs in epidemiology and cancer prevention.

This authority has since been extended to other NIH institute directors.

Authority to Hire Expert Consultants

The National Cancer Act of 1971 gave the NCI Director, in consultation with the NCAB, special authority to hire experts (originally 50 and currently 151) without regard to employment ceilings or certain Civil Service requirements. This mechanism allowed quick expansion during the 1970's and the employment of people with selected skills for specific program needs who would not necessarily become permanent staff. The effectiveness of this mechanism led the NIH to request and receive a similar authority in the mid-1970's. It has also specifically been provided to the National Heart, Lung and Blood Institute.

In 1982 the Office of Management and Budget, contrary to congressional report language, required that experts be counted against employment ceilings. A one-time ceiling increase was provided to the NCI for the 114 experts employed at the time, but not the 151 authorized, thus reducing flexibility in using this authority. NIH would benefit as a whole if Congress stated in law that expert consultant appointments are not to be counted against employment ceilings, allowing use of these appointments to be managed within available budgets.

The 1971 Act required the Director, NCI to consult with the NCAB in exercising this authority. In 1985 the law was changed to require that the NCAB **approve** expert consultant appointments. The NCAB has expressed the opinion that approval of individual temporary personnel appointments is not an appropriate Board role.

Recommended legislative change:

Restore the consultative rather than approval role of the NCAB for expert appointments.

Mandate to Expand, Intensify and Coordinate Federal and Non-Federal Cancer Research

The National Cancer Act of 1971 and subsequent amendments directed the NCI to plan and develop an expanded, intensified and coordinated cancer research program encompassing the programs of the NCI, related programs of the other NIH research institutes, and other Federal and non-Federal programs. The Congress used the word shall in describing such a role, requiring the NCI to develop a true national program. Responsibility for the coordination of a national program is not a traditional NIH mission. Simultaneously, the NCI was authorized to utilize, **with their consent**, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies.

Federal Coordination Since 1971, the NCI has developed important working agreements with a large number of other Federal agencies with activities relevant to the National Cancer Program. It currently supports activities through interagency agreements with 16 other

Federal organizations. (Appendix 5)

Collaboration with State and Local Governments In the early 1970's the Institute worked with State and territorial health departments on programs to reduce radiation exposure from mammography and promote screening for cervical cancer. Today, NCI provides technical assistance and grants to State health departments to expand capabilities and help them use their own funds most effectively for cancer prevention and control and address specific local and regional cancer problems. As more State legislatures develop cancer plans, the NCI advises them regarding effective strategies and maintains a central information resource on State and local cancer legislation.

Mandate to Collaborate with Private Industry

In a prescient move, the original National Cancer Act and all amendments have directed the NCI to encourage and coordinate cancer research by industry. NCI contracts for cancer drug development in the 1960's established the precedent at NIH for encouraging collaboration with private industry. The Institute developed commercial discreet agreements to protect proprietary rights to agents submitted for testing at NCI, and was given authority to use an "alternate patent clause" which allowed companies to obtain patents for work done with Government support, while preserving Government "march in" rights to develop resulting drugs should industry fail to do so. Such arrangements have been codified in law with the passage of the Stevenson-Wydler Act.

NCI collaborates with industry in cancer and AIDS drug screening, and development and conduct of clinical trials. NCI's drug development program, unique at NIH, has been involved in some phase of the development of almost all currently available anti-cancer drugs. It was the model for the AIDS drug development program, also managed by NCI, which has developed azidothymidine, dideoxyadenosine, dideoxyinosine and dideoxycytidine for the treatment of AIDS.

Mandate to Develop and Update a National Cancer Plan

Congress recognized that along with the new authorities provided by the 1971 Act, there would be a large influx of new monies, often for activities uncommon at NIH. Therefore, it required the development of a National Cancer Plan to be updated annually. The National Cancer Plan listed areas of scientific investigation thought to be key to eradicating human cancer. Its development and publication attracted more scientists with diverse interests to cancer research.

In 1980 the National Cancer Institute established integrated Institute-wide mechanisms for executive management and advisory structures to carry out its mandate through the day to day management of the Institute. The Institute's system of boards, described below, and the NCI Executive Committee conduct the annual planning process. Priorities and associated resource allocations are expressed in the

annual By-Pass Budget which includes projected requirements for a total five year period.

In 1985, Congress deleted the requirement for annual five year plans and asked for a biennial report from the entire NIH for which NCI prepares a section.

Authority to Accept Unconditional Gifts

The 1971 National Cancer Act authorized NCI to accept unconditional gifts, such as donations of money and property. The NCI Gift Fund can be used to support any activity for which the Institute is authorized to use appropriated funds and provides a valuable resource for special projects.

In 1985, this authority was extended to all the directors of NIH Institutes.

Authority to Accept Voluntary and Uncompensated Services

In addition to the authority to accept gifts, the 1971 Act permitted the Director, NCI to accept volunteer services.

In 1985, this was extended to the Directors of all NIH Institutes.

C. Program Expansion

Mandate to Conduct Cancer Control Activities

Congress has always been intent on assuring that the results of cancer research are translated rapidly into prevention and treatment benefits for the public. NCI's 1937 authorization included cancer control activities. However, in 1957 State cancer control activities were transferred to the Public Health Service Bureau of State Services and cancer control programs at the NCI ceased. In 1965 cancer control was moved to the new Regional Medical Program, and by 1970 no cancer control programs were sponsored by the Federal government.

The 1971 National Cancer Act explicitly mandated cancer control, which forms the bridge between new knowledge gained from research and the application of that knowledge to the prevention, early diagnosis and treatment of cancer. Funding for cancer control was to be considered separately from the competition for basic research dollars. This separation was described as a most useful provision in the previously cited Fredrickson memorandum.

NCI's cancer control programs provided a prototype for the 1977 NIH initiative to develop demonstration, education, and technology transfer activities in the new Office of the Medical Application of Research, which includes the Consensus Development Conferences. However, NCI is the only NIH component with a separate budget line for control activities.

The cancer control programs are now used as the effector arm for applied prevention research and the cancer control budget is the source of funding for:

the **Smoking, Tobacco and Cancer Program**, which supports studies of smoking prevention and cessation methods involving 10 million Americans;

the **Chemoprevention Program**, which identifies micronutrients which may be able to inhibit or reverse the promotion stage of carcinogenesis and includes 24 clinical trials of the ability of micronutrients to reduce cancer incidence, with an additional 14 trials soon to begin;

the **Diet, Nutrition and Cancer Program**, which seeks to understand how diet is related to cancer, and to learn how to modify diets to reduce cancer risk;

the **Early Detection Program**, which promotes full utilization of effective early detection and screening technologies and collaborates with the American Cancer Society in the development of scientifically sound national screening recommendations;

the **Community Clinical Oncology Program**, which attempts to improve the effectiveness of cancer detection, treatment, prevention and rehabilitation at the community level; and

the **Cancer Control Science Program**, which supports intervention research on effective applications of existing knowledge, research to reduce the cancer burden in special populations, training for professionals in prevention and control activities, and large grants for Cancer Control Research Units and Cancer Control Science Programs.

Authority to Establish National Cancer Research and Demonstration Centers

During its deliberations in 1970, the National Panel of Consultants on the Conquest of Cancer was impressed with the contributions made by the three existing comprehensive cancer centers and NCI's research at the NIH Clinical Center. It determined that **"the comprehensive cancer center offers the best organizational structure for the expanded attack on cancer."** Consequently, the Panel recommended that

> **Existing cancer centers should be strengthened and additional cancer centers in different parts of the country should be created...In addition to the few comprehensive cancer centers that exist in the United States today, there are a number of other institutions which combine all or most of the capabilities for a multidisciplinary effort in cancer. These could serve as a base for the creation of additional centers...**

The National Cancer Act authorized the Director of the Institute to "pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for centers for basic and clinical research into, training in, and demonstration of advanced diagnostic, prevention, and treatment methods for cancer."

The major intent of the Congress in establishing the Cancer Centers Program was to erect a nationwide structure to promote these ends. Today, the United States has 60 comprehensive, clinical, laboratory, and consortium centers which are a unique national resource and compete successfully for about half of the research and training support awarded annually by NCI.

Mandate to Enhance and Expand Information Dissemination

The 1971 Act authorized the Director, NCI "to take necessary action to insure that all channels for the dissemination and exchange of scientific knowledge and information are maintained between the NCI and the other scientific, medical, and biomedical disciplines and organizations nationally and internationally."

While the original Act authorized NCI information dissemination, this activity proved controversial and was often impeded. The Congress therefore explicitly required information dissemination programs for the public, health professionals and the scientific community in the 1974 Amendments. Congressional reports accompanying those amendments made it clear that it was the intent of the House that "the new authority and its exercise by the NCI should not be restricted or curtailed by HEW." The Senate report stated that

> The Committee is concerned about the loss of the independent authorities of the Director, NCI, to conduct a full range of communications, information and public affairs activities in support of the National Cancer Program. These authorities are important to the effective implementation of the Act, and are not to be subject to regulation or modification within DHEW.

Since 1974, the Department has honored the intent of Congress, and has not required clearances for NCI information programs.

Because of the strong legislative mandate and the attendant flexibility, NCI, through its Office of Cancer Communications, has a strong integrated information program for patients and the public which has gone from distributing a few thousand copies of educational materials in 1974 to responding to 600,000 inquiries in 1987 and distributing 20 million pieces of public and patient education materials in 1987. (Appendix 6) The legal requirement that all printing be contracted through the Government Printing Office (GPO) has resulted in delays in printing education materials. Actual costs are sometimes far in excess of estimates, making it difficult to manage the printing budget.

Recommended legislative change:

Remove the legal requirement that NCI use the Government Printing Office as the agent for all commercial printing and typesetting to promote speed, and potentially reduce costs. Congress has exempted the National Science Foundation from this requirement.

International Cancer Research Data Bank

The International Cancer Research Data Bank (ICRDB) was mandated in the 1971 Act which required it to **collect, catalog, store and disseminate, insofar as feasible the results of cancer research undertaken in any country for the use of any person involved in cancer research throughout the world.** Today, information services for investigators and medical practitioners are consolidated in the **International Cancer Information Center (ICIC)** including:

A. the **CANCERLINE** computer database, which contains:

CANCERLIT: which contains approximately 600,000 citations/abstracts of cancer literature, updated monthly;
CLINPROT: which contains detailed summaries of investigational clinical cancer therapy protocols in the U.S. and other countries;

B. three series of publications with over 24,000 subscribers;

CANCERGRAMS: monthly publications with 65 different series in Diagnosis and Therapy, Carcinogenesis, and Basic Cancer Biology, listing 30 to 100 abstracts in each issue;

ONCOLOGY OVERVIEWS: 15 specialized bibliographies per year with abstracts and an editorial commentary on selected area of cancer literature; and

RECENT REVIEWS; three issues a year which compile abstracts of 250 to 400 review articles on cancer research.

C. the **Physician Data Query (PDQ)**, which was completed in 1984 utilizing the authorities of the Act, facilitates transfer of advances in cancer treatment to clinical practice through an online database available through the National Library of Medicine and private information vendors. Updated monthly, it provides state-of-the-art treatment statements for almost all cancers, geographically matrixed information on over 1,000 investigational clinical protocols open for patient referral, names of physicians specializing in cancer treatment as well as hospitals with organized cancer programs; and

D. the **Journal of the National Cancer Institute**, which is a bi-weekly publication read by about 10,000 investigators, and is dedicated to the rapid publication of both clinical and basic

cancer research reports.

Special Training Authority

The 1971 National Cancer Act, building upon efforts begun in 1938, mandated support for training programs in fundamental sciences and clinical disciplines to provide an expanded and continuing manpower base for participation in clinical and basic research and treatment programs relating to cancer, including, where appropriate, the use of training stipends, fellowships, and career awards. Other NIH Institutes were authorized to support research, but not clinical training.

The Act authorized clinical training programs for health professionals including training in "advanced diagnostic, prevention and treatment methods," thus assuring an adequate supply of trained cancer specialists. These programs are a significant part of NCI's network for the application of the results of research. Since 1971, through training funds provided by NCI, pediatric and medical oncology were established as new specialties and their numbers grew from fewer than 100 to over 4,000; likewise, the number of radiation oncologists grew from a few hundred to 1,500.

In response to an Administration decision that all federally funded research training activities were "not appropriate," and should cease, Congress passed the National Research Service Act (NRSA) of 1974 which is the authority for all NIH extramural research training. The 1974 Amendments to the National Cancer Act also reinforced the authority of the Director, NCI to support clinical as well as research training and allow the Institute flexibility to restructure its training programs to meet evolving needs.

NCI training authorities are used to target training efforts in high priority areas which are not covered under the NRSA or the general NIH research training authority and to support specialized intramural training activities.

The NCI Cancer Education Program, which originally was used to support the development of oncology curricula in health professions schools, is now used to support:

training for doctoral level practitioners in chronic disease prevention and control, emphasizing cancer;

short research experiences for health professions and minority students;

the development and implementation of nutrition curricula for health professions schools; and

selected short courses to meet identified needs.

Other special training programs which NCI is able to conduct under the authorities provided by the Act include:

the **NCI Student Research Training Program**, which provides training in NCI laboratories for high school, college and graduate students;

the **Biotechnology Fellowship Program**, which supports postdoctoral training in the clinical application of biotechnology;

the **Cancer Nurse Training Program**, which trains nurses in the care and treatment of cancer patients in a clinical research setting, addressing the critically short supply of trained oncology nurses; and

the **Cancer Prevention Training Program**, which trains scientists and other professionals to conduct cancer prevention research and meet the need for State and local health agency cancer control staff.

Foreign Research and Training

The National Cancer Act of 1971 required the NCI to support cancer research outside the U.S. by highly qualified foreign nationals; collaborative research involving American and foreign participants; and the training of American scientists abroad as well as foreign scientists in the U.S. As a result of this mandate, the NCI awards research grants to leading scientists in other countries, undertakes international collaborative epidemiology, prevention, and clinical trials studies and develops bilateral agreements with foreign governments. All other foreign activities at the NIH are conducted under the authority of the Secretary. NCI international activities include:

The execution of a bilateral agreement with the Union of Soviet Socialist Republics (USSR) which was initiated by President Nixon and General Secretary Brezhnev in 1972. Currently, agreements are in effect between the U.S. and Japan, Egypt, France, Poland, the Federal Republic of Germany, Italy, China and Hungary;

support to international agencies concerned with cancer including the **International Agency for Research on Cancer (IARC)** and the **European Organization for Research on Treatment for Cancer (EORTC)**; .

the conduct of epidemiologic studies and investigations of the effects of diet on cancer and the ability of micronutrients to reduce incidence in defined populations in other countries including China and Finland; and

the cosponsorship of the **EORTC Research Training Program** which allows exchanges between the U.S. and EORTC member nations. A similar program is being started with Japan.

Foreign travel is controlled by strict ceilings, imposed externally. Effective management of these programs and the conduct of cancer and AIDS research in other countries requires that NCI scientists travel abroad. Foreign travel should be controlled by program requirements and budget availability.

Recommended legislative change:

Exempt the NCI from externally imposed foreign travel ceilings beyond those naturally imposed by budget levels to facilitate effective utilization of this authority.

III. THE GOVERNANCE OF SCIENCE AT THE NATIONAL CANCER INSTITUTE

Because of its size and complexity, and its unique programs and mandates, the National Cancer Institute has required an organizational structure not only different from, but neither required, desired, or appropriate for other NIH Institutes. Using the provisions of the National Cancer Act, NCI has developed a **system of boards** which includes the **President's Cancer Panel** and the **National Cancer Advisory Board**, both appointed by the President, and the four **Boards of Scientific Counselors (BSCs)** to the four NCI program divisions responsible for research in cancer biology, causation, prevention, detection, diagnosis and treatment as well as the **Frederick Cancer Research Facility Advisory Committee (FCRFAC)**, appointed by the Director, NCI. (6)

The BSCs and the FCRF Advisory Committee have been vested, by NCI, with the requisite authorities to serve as effective monitors of program development and implementation within the context of a rapidly changing scientific environment. The BSCs, each chaired by one of the appointed members, are charged with reviewing and advising on both intramural and extramural programs. This range of responsibility exists only at NCI which has consolidated management of related intramural and extramural science programs within each division.

Since 1980, each of the four NCI Board of Scientific Counselors has:

-been chaired by one of its own members;

-held its meetings in public;

-conducted an annual review of the entire divisional budget;

-performed concept review for each new and recompeting contract support project prior to the solicitation of proposals;

-performed concept review for Request for Applications for grant supported projects;

-provided advice on management problems of the division;

-conducted scientific peer review of all of the 58 laboratories and branches in the intramural program through a process of site visits similar to peer review of program project grants;

-provided advice on important areas for future research or the termination of less productive areas of research; and

-sponsored workshops/seminars to facilitate the dissemination of scientific information.

For example, the BSC for the Division of Cancer Treatment was heavily involved in the 1978 development of a Master Plan for Drug Development and a Memorandum of Understanding with the FDA and an FDA-approved NCI distribution system for anti-cancer drugs which is more fully described in Appendix 5. The BSC is currently working with the Commissioner of Food and Drugs to discuss the process for approval of marketing of cancer drugs, a problem recognized by the Yarborough Committee. The BSC proposed, in conjunction with the treatment research community, new approval criteria.

The BSC of the Division of Cancer Etiology reviews the concepts for division agreements with the National Institute of Occupational Safety and Health, the Environmental Protection Agency and the National Oceanic and Atmospheric Adminstration. Individual BSC members also serve on special advisory committees to other agencies on occupational carcinogens.

The Interface

The Panel, Board, and BSC/FCRFAC all have specific roles, and each relates to the other. The BSCs, whose members are selected for their expertise in the areas of science supported by the division, advise on specific intramural and extramural undertakings, prioritizing competing projects for resources within the division, and annually present their deliberations/advice to the National Cancer Advisory Board. Taking into consideration input thus received from the divisional Boards of Scientific Counselors, the NCAB is able to advise the Director, NCI, on policy regarding major program and administrative issues and resource allocation among competing priorities across the Institute. Through regular attendance at NCAB meetings, as well as its own meetings both in Bethesda and nationwide, the Panel is able to monitor the National Cancer Program and to ascertain any blockages or delays in its execution which may be reported by the advisory boards or uncovered through public meetings held at the major cancer centers across the Nation.

This interlocking network of communications amongst the Panel, NCAB, and Boards of Scientific Counselors, culminates at the annual Program Review meeting of the NCAB when the plans for the entire NCI program are examined. At this time the BSC Chairs report to the Board and

Panel on their activities in the past year and plans for the coming year. This Program Review provides a single, comprehensive overview of all the programs of the NCI, their balance and interrelationship and assists the NCAB in recommending budget allocations for the Institute as a whole and in identifying gaps. (6)

The Director, NCI with his Executive Committee, is responsible, under the National Cancer Act, for acting on this guidance and for the execution of the National Cancer Program. The independence granted to the NCI reduces unnecessarily duplicative review of scientific decisions at levels of government both removed from the actual science and/or lacking the necessary extensive and open advisory structure, developed by NCI, required to operate a complex organization like the National Cancer Institute.

From their inception, the Panel, the Board, the Boards of Scientific Counselors and the FCRF Advisory Committee have played a major role in solving problems related to the National Cancer Plan, Cancer Centers, the Frederick Cancer Research Facility, the Biological Response Modifiers Program, redirection of the Cancer Prevention Program and transfer of the Bioassay Program, the human tumor cell line screen, the supercomputer facility, and the Goals for the Year 2000, among many others.

IV. CONCLUSION

The extraordinary scientific advances from basic research, the resultant opportunities they offer to develop prevention strategies, the increasingly sensitive diagnostic procedures, and the new treatment approaches developed since 1971, more than justify the creation and maintenance of the National Cancer Act. The architects of the Act may be fairly credited with saving hundreds of thousands of lives.

The Act mandated an investment and the means to accelerate basic research and to apply the results of that research insofar as feasible and as quickly as possible. A case study of the NCI which was commissioned by the Institute of Medicine in 1984 as part of its overall study of the NIH concluded (Appendix 7):

> **As a result of NCI's broad mandate to support research on the cause, prevention, and treatment of cancer in the 1937 Act, and its additional authority to plan and develop a National Cancer Program following the 1971 Act, the NCI has been extremely adaptive in using a variety of administrative and funding mechanisms to meet its Congressional mandates. The NCI has emerged into an expanded, coordinated international cancer research and control program that supports a significant amount of basic research, training, and demonstration of advanced methods of controlling cancer.**

Through its special authorities, the NCI has been able to establish a nationwide coordinated network to apply the results of basic research. Today the network includes Cancer Centers, trained physicians, an expanded Clinical Trials Program, the Cooperative Group Outreach Program, the Community Clinical Oncology Program, the Cancer Control Program, Physician Data Query (PDQ) and the Surveillance, Epidemiology and End Results (SEER) program to collect data on cancer incidence and survival.

The Yarborough Committee showed exceptional wisdom and foresight in anticipating that the conquest of the fearsome group of diseases we call cancer would require a coordinated program that went far beyond what had previously been attempted and that the traditional structure and mandates of other NIH institutes would not suffice. They weighed the risk to NCI's ability to meet the challenge and risk of being an atypical institute within the NIH. Wisely, the framers of the Act judged the benefits of remaining within the NIH, for both the NCI and the NIH, would outweigh any disadvantages.

The compromise was a good one. The 1971 National Cancer Act has been reauthorized in 1974, 1977, 1978, 1980 and 1985. Minor changes have accompanied each reauthorization, while the major authorities and mandates have remained unchanged. The Act is an extraordinary experiment in biomedical science that is a model for the management of the highest priority research initiatives. It has served the nation and the research community well for 16 years and has brought us to the point originally envisioned by its framers.

Because half of all cancers occur in people 65 and older, the aging of the population and the successes in controlling heart disease will make cancer the number one health problem in the United States. By the beginning of the next century, it will kill ten times more people in a year than AIDS has killed in five years. This will happen despite the major progress that has been made in research and treatment over the past 16 years and even if the Institute attains its Goal for the Year 2000 of reducing the mortality rate from cancer by 50 percent.

Because of this pressing need, the National Cancer Program requires the continued mechanisms and authorities that the 1971 National Cancer Act set in motion.

National Cancer Institute
Percentage Growth FY 1970-1988

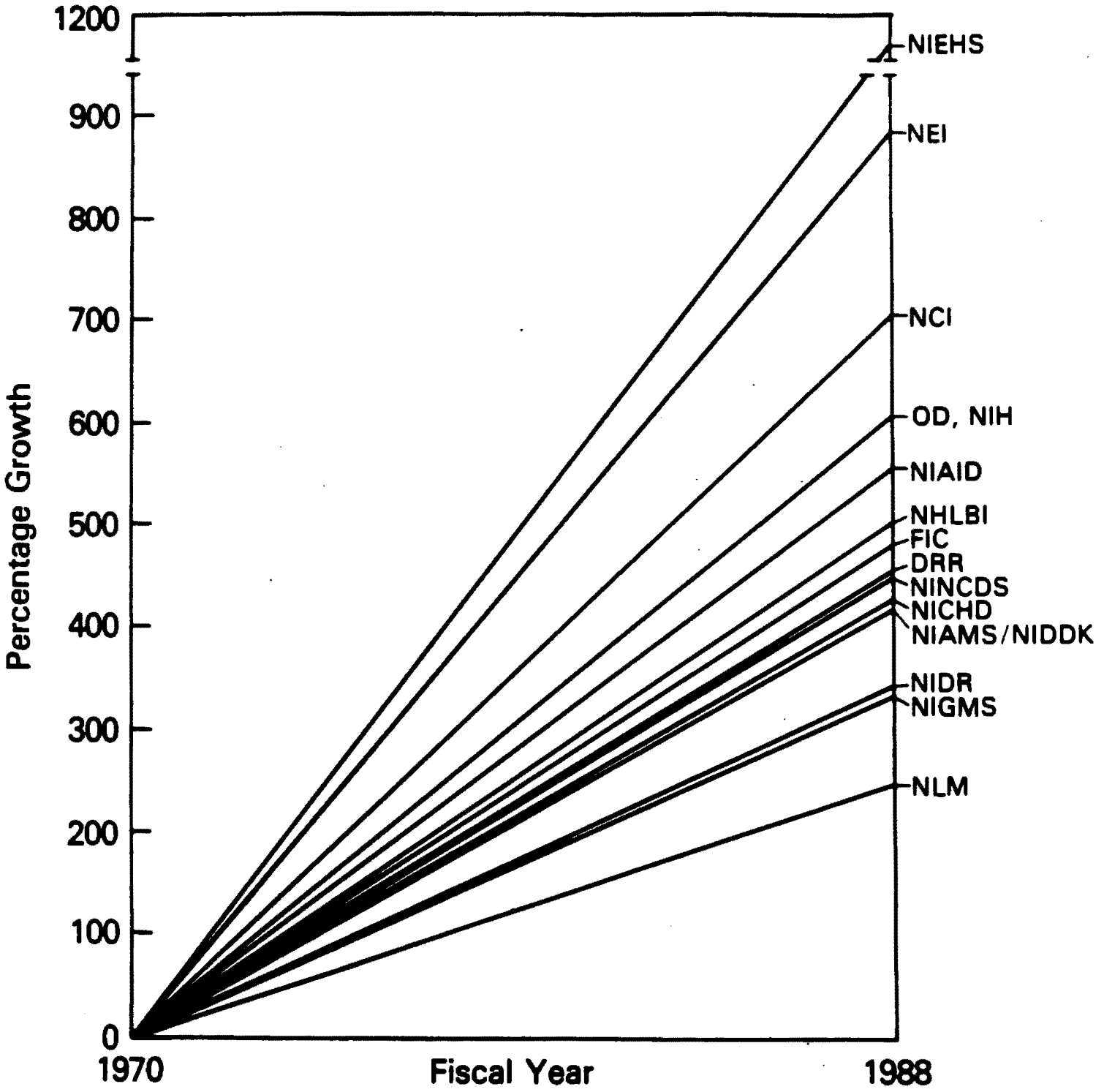

Figure 1

National Cancer Institute
Percentage Growth FY 1970-1979

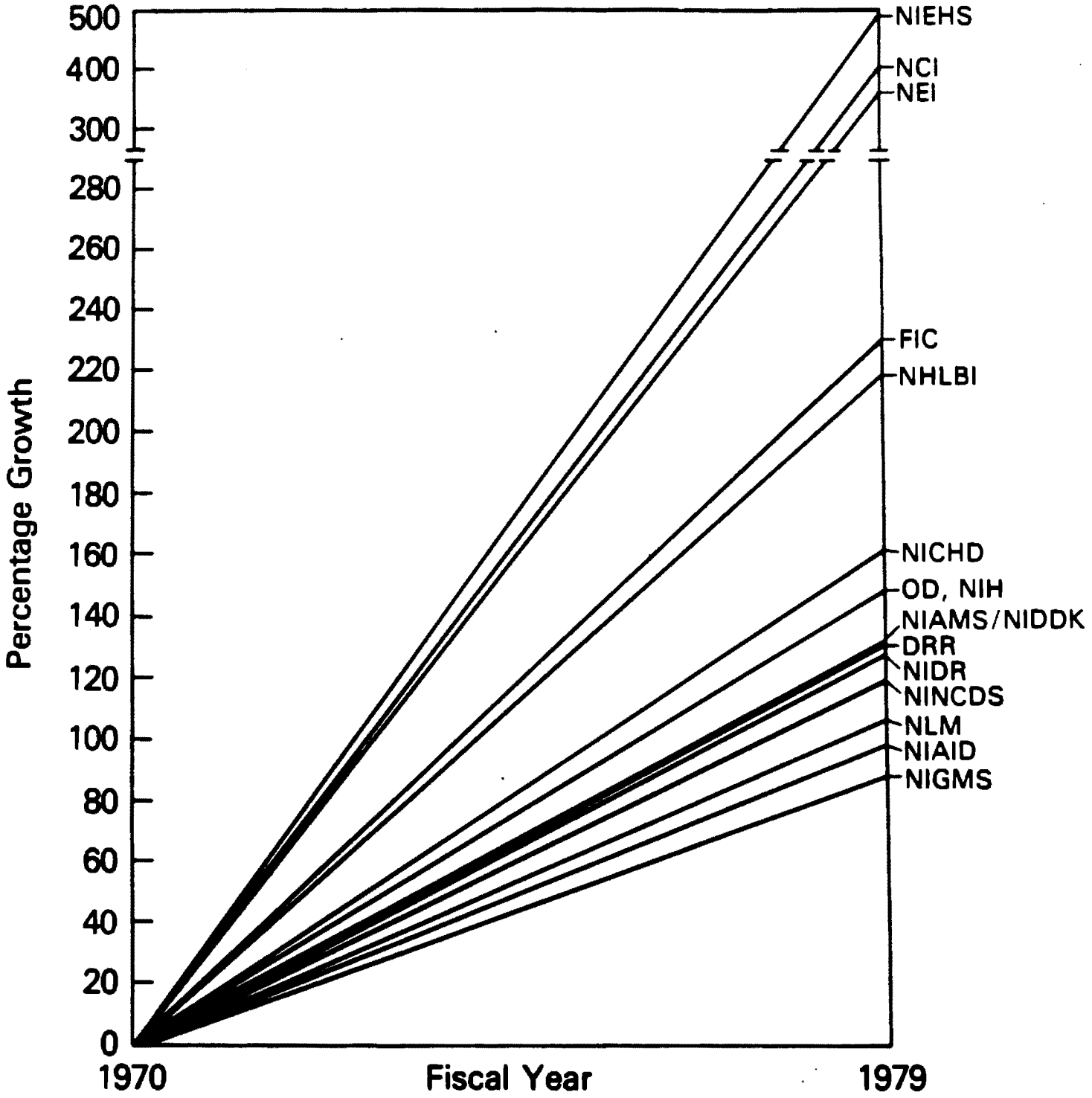

Figure 2

National Cancer Institute
Percentage Growth FY 1979-1988

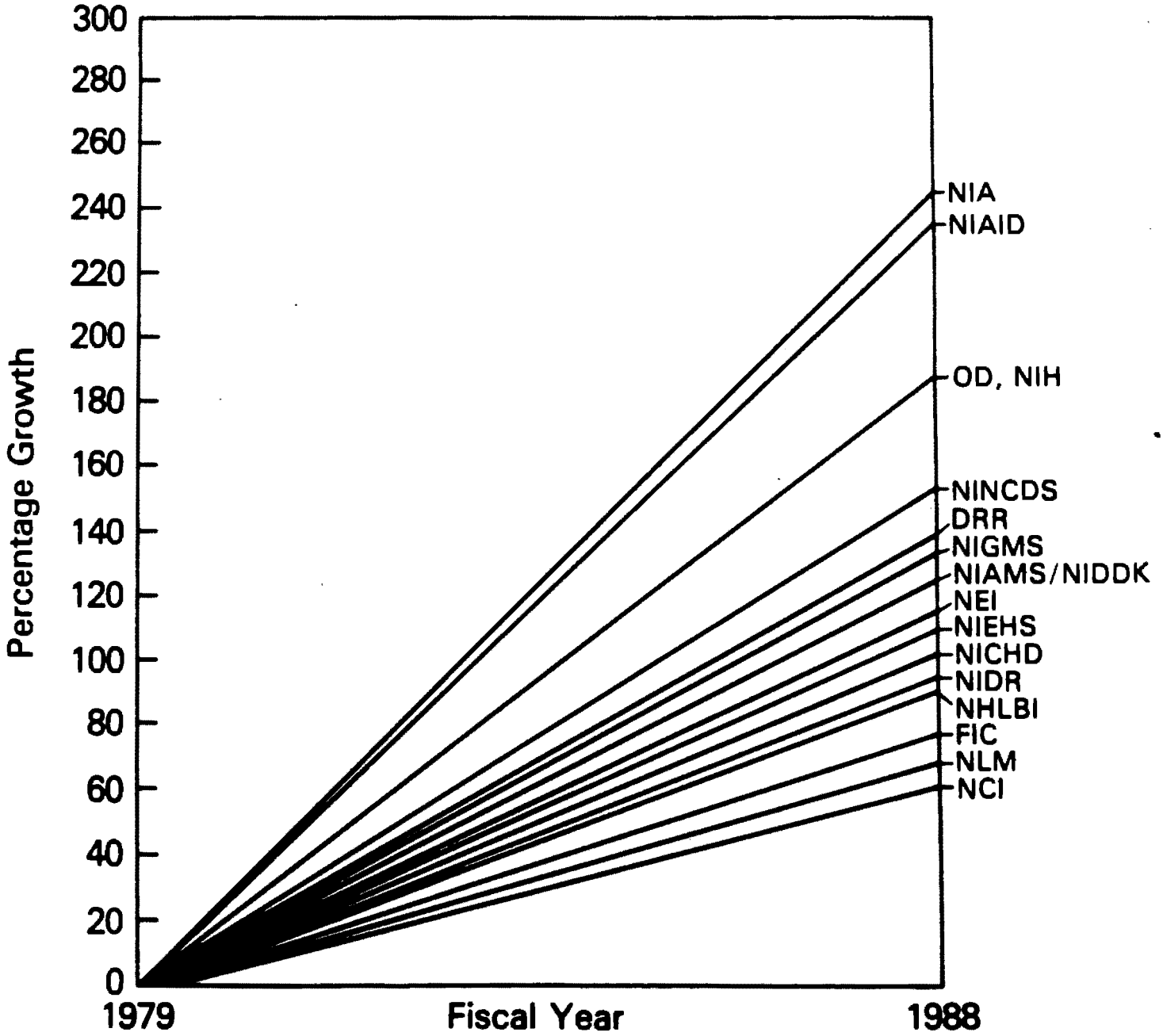

Figure 3

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