REPORT TO THE COMMITTEE ON LABOR AND PUBLIC WELFARE UNITED STATES SENATE

Administration Of Contracts And Grants For Cancer Research B-164031(2)

National Institutes of Health
Department of Health, Education, and Welfare

BY THE COMPTROLLER GENERAL OF THE UNITED STATES

MARCH 5, 1971

COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON D C 20548

B-164031(2)

Dear Mr Chairman

This is our report on the administration of contracts and grants for cancer research by the National Institutes of Health, Department of Health, Education, and Welfare Our review was made pursuant to a request dated September 25, 1970, from the former Chairman of the Committee on Labor and Public Welfare, United States Senate, to assist and complement the work of the Committee's Special Staff on Cancer Research

Since we believe that the contents of this report will be of interest to the Congress and to others concerned with cancer research, we have arranged with the former Committee Chairman to make further distribution of the report

Sincerely yours,

Comptroller General
of the United States

The Honorable Harrison A Williams, Jr
Chairman, Committee on Labor
and Public Welfare
United States Senate

COMPTROLLER GENERAL'S REPORT
TO THE COMMITTEE ON
LABOR AND PUBLIC WELFARE
UNITED STATES SENATE

ADMINISTRATION OF CONTRACTS AND GRANTS FOR CANCER RESEARCH
National Institutes of Health
Department of Health, Education, and Welfare B-164031(2)

D I G E S T

WHY THE REVIEW WAS MADE

The Chairman of the Senate Committee on Labor and Public Welfare (hereinafter referred to as the Senate Committee) asked the General Accounting Office (GAO) to assist and complement the work of a special staff established by the Senate Committee to study cancer research.

GAO examined into the administration of the cancer research program within the Department of Health, Education, and Welfare (HEW), the National Institutes of Health, and the National Cancer Institute, including the methods and procedures used for processing, reviewing, and approving contracts and grants for cancer research.

The National Cancer Institute conducts and supports cancer research through (1) research at the National Cancer Institute's laboratories and clinics, (2) contracts for research, and (3) grants-in-aid for research projects The National Cancer Institute received an appropriation of $181 million in fiscal year 1970. It awarded 333 research contracts for $49 7 million and 1,182 research grants for $71.4 million

A committee of consultants appointed by the Senate Committee to study the cancer problem estimated that the program it recommended would require annual Federal expenditures for cancer research of $800 million to $1 billion by 1976

FINDINGS AND CONCLUSIONS

The present system of administering and funding National Cancer Institute research has resulted in delays in the approvals and funding of contracts and grants. GAO was told by the Director of the National Cancer Institute and some officials at research institutions receiving grants that

--the initiation of some research projects was made uncertain because of the inability of some research institutions to provide private funding until final approval and funding was received from the National Cancer Institute and

Tear Sheet

MARCH 5,1971

--such delays could cause problems for the institutions in attracting and retaining qualified researchers (See p. 30)

Approval Delays

The 333 contracts awarded during fiscal year 1970 for cancer research required an average of about 7 months for review and approval. Approximately 1-1/2 months of that time was the result of what GAO believes were unnecessary duplicative reviews by the National Institutes of Health and the National Cancer Institute (See p 21) Specifically, the reviews of contract proposals by the National Institutes of Health--including the qualifications of the proposed contractors, the work specifications, and the amounts of the proposed contracts--duplicate steps in the National Cancer Institute review (See p 23)

Although the Secretary of HEW delegated contract authority to the Director of the National Institutes of Health, he did not delegate such authority to the National Cancer Institute. GAO believes that much delay could be eliminated if the National Cancer Institute program managers were granted research-contracting authority.

Research grants during calendar year 1970 required an average of about 8 months for review and approval A significant portion of this processing time occurs because the study sections which review grant applications for scientific merit and the National Advisory Cancer Council which recommends approval of grant applications each meet only three times a year. (See p. 25)

An application submitted after the deadline for review at one of the three meetings of the applicable study section would require from 3 to 8 months before it could be considered at the next study section meeting.

The National Advisory Cancer Council was established in compliance with the Public Health Service Act The study sections were established by the National Institutes of Health to provide an independent peer review of the scientific merit of all applications to the National Institutes of Health for research grant funds. The study sections are made up of eminent scientists knowledgeable about research in specific areas.

In general, all research grant applications must go through the same review process, including a study section evaluation, and all must receive Council approval (See p. 27) GAO does not question the merits of external scientific reviews of applications for research grants The present system, however, results in significant delays. (See p 28)

Approximately 45 percent of the 1,182 grants awarded in fiscal year 1970 by the National Cancer Institute were for less than $30,000 each. (See p. 27) To expedite approval of grant applications involving moderate

amounts, GAO believes that HEW should consider authorizing program managers to award grants up to a specified amount without review by study sections

Funding Delays

Action on the National Cancer Institute funding request must wait each year until the entire HEW appropriation bill is enacted Cancer research projects, usually from 3 to 5 years in length, are funded annually (See p 30)

During each of the past 6 fiscal years, the HEW appropriations were not approved by the beginning of the fiscal year in which the funds were to be used Such approval has been delayed from 2 to 8 months.

Although ongoing research grants and contracts are funded under a joint congressional resolution making continuing appropriations for a fiscal year pending approval of appropriations for that year, the National Cancer Institute cannot effectively plan for research, particularly new programs and projects, until the National Cancer Institute appropriation request is approved and the total funds appropriated are known

GAO believes that the Congress should consider authorizing appropriations for the National Cancer Institute to be available for the next fiscal year following the usual budget year. This type of advance funding has been authorized for certain other programs, including aid to educationally deprived children under title I of the Elementary and Secondary Education Act of 1965 (See p. 31)

RECOMMENDATIONS OR SUGGESTIONS

The Secretary of HEW should authorize the National Cancer Institute program managers to

--negotiate research contracts (see p 24) and

--award grants up to a specified dollar limit without review by study sections (See p. 29)

AGENCY ACTIONS AND UNRESOLVED ISSUES

The Secretary of HEW stated that action was being taken to extend research-contracting authority to the National Cancer Institute (See p 24) The Secretary said that HEW planned to evaluate the grant review system with a view toward strengthening and expediting the review process He said that the evaluation would include consideration of granting authority to the National Cancer Institute program managers to award grants up to a specified dollar limit without review by study sections (See p 29)

The Secretary stated that, although funding delays are of considerable inconvenience and concern to researchers and research institutions, at the present time the Department did not have any data that indicated any serious disruption to research or any significant or widespread problems for research institutions (See p 31)

He stated also that the delays in appropriation approvals could be a significant deterrent to initiation of the new and sizable cancer program levels visualized by the consultants to the Senate Committee

The Secretary advised GAO that delays in funding had emanated most often from the recent practice followed by both the Congress and the executive branch of establishing annual spending ceilings He said that the effect of these spending ceilings on the timing of grant funding was to delay awards of new grants until a spending plan had been developed for the entire fiscal year, which was very difficult to do until appropriation and expenditure limitations were known He said also that the result was that typically HEW did not fund new projects until well into the fiscal year and that this situation would exist whether or not the grants were advance funded

GAO recognizes that HEW must develop an annual spending plan based upon various expenditure control limitations; however, it seems to GAO that it would not be desirable to delay financing most new projects until appropriation and expenditure limitations for the year are known

GAO believes that, to optimize the Government's research investment, particularly in view of the adverse effect that delays in funding can have on new research programs and projects, consideration should be given to the advance-funding mechanism as a means to plan and program research more effectively

In GAO's opinion, advance funding would enable the National Cancer Institute to make awards on the basis of the amount appropriated for the year covered by the advance funding and would facilitate more timely financing of new programs and projects, rather than limit awards for research to the amounts authorized by a joint resolution making continuing appropriations, which generally provides appropriations up to the prior year's level.

MATTERS FOR CONSIDERATION BY THE CONGRESS

The Congress may wish to consider the enactment of legislation authorizing, in the case of the National Cancer Institute, the making of appropriations to be available for the next fiscal year following the usual budget year (See p. 34)

Contents

ABBREVIATIONS

GAO General Accounting Office

HEW Department of Health, Education, and Welfare

NCI National Cancer Institute

NIH National Institutes of Health

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CHAPTER 1

INTRODUCTION

Pursuant to a request dated September 25, 1970, from the Chairman, Committee on Labor and Public Welfare, United States Senate, and to subsequent discussions with the Committee's special staff on cancer research, the General Accounting Office has reviewed selected aspects of the administration of the cancer program of the National Cancer Institute (NCI) of the National Institutes of Health (NIH), Department of Health, Education, and Welfare (HEW). Our review was made to assist and complement the work of the Senate Committee's special staff on cancer research. A copy of the Chairman's request is included as appendix I.

On April 27, 1970, the Senate passed Senate Resolution 376, authorizing the Senate Committee, with the assistance of an advisory committee, to report to the Senate on (1) the present status of scientific knowledge with respect to the causes of cancer and its treatment, cure, and elimination, (2) the prospect of success in such endeavors, and (3) measures necessary or desirable to facilitate success at the earliest possible time.

Pursuant to this resolution, a committee of consultants on the conquest of cancer, composed of 13 eminent laymen and 13 eminent scientists, was established in June 1970 as the advisory committee to assist the Senate Committee with the new study on cancer and was asked to submit its report and recommendations at the earliest practicable date.

On July 15, 1970, the House of Representatives passed Concurrent Resolution 675, later passed on August 28, 1970, by the Senate, expressing the unanimous sense of the Congress that "the conquest of cancer is a national crusade" and that "the Congress should appropriate the necessary funds so that the citizens of this land and all other lands may be delivered from the greatest medical scourge in history."

On June 29, 1970, the committee of consultants held its first meeting. Since that time the committee of consultants has met 10 full days, subcommittees have met many additional days, and the written or verbal testimony of 289 witnesses

and advisors has been considered. On November 25, 1970, the committee of consultants submitted its report and recommendations to the Chairman of the Senate Committee.

In the foreword to the report of the committee of consultants, the Chairman of the Senate Committee stated that:

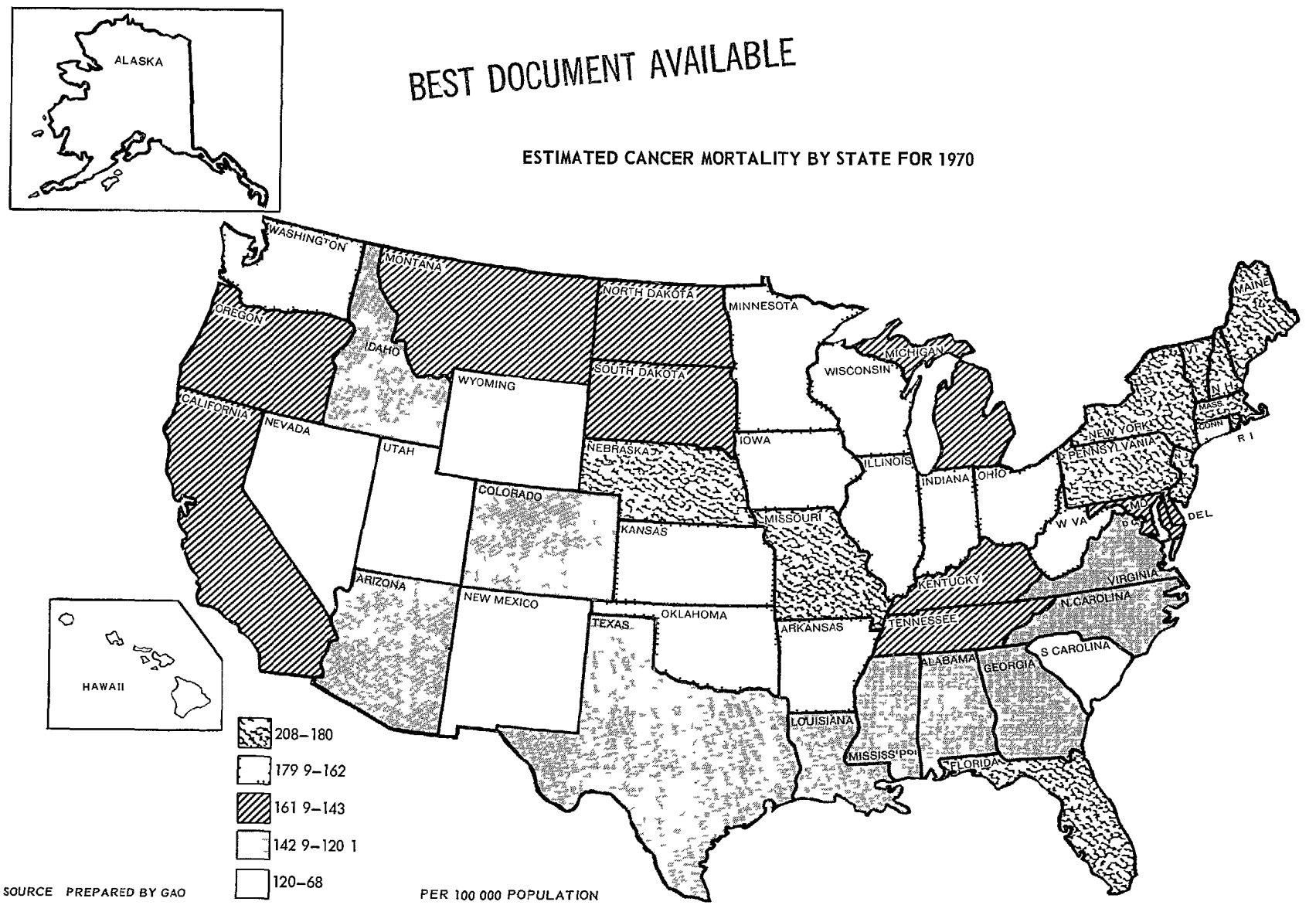
> "After months of intensive and diligent effort, this Panel has prepared the attached report, 'A National Program for the Conquest of Cancer.' The report is dedicated to the proposition, expressed in a recent Concurrent Resolution of the Congress, that the conquest of cancer should be a national crusade. The recommendations are bold and far reaching. They call for a new agency, whose sole mission is the conquest of cancer. They call for adequate resources of manpower, facilities and funds to do the job in accordance with the provisions of a coordinated national program plan."

The committee of consultants estimated that the program that it recommended would require annual appropriations for cancer research of $800 million to $1 billion by 1976. A copy of the report is included as appendix III.

Cancer is one of the major disease problems facing this nation. The American Cancer Society estimated that during 1970 about 330 thousand Americans would die from cancer. Estimated cancer mortality rates by State per 100,000 population for 1970 are shown on the map on page 7, and cancer mortality rates around the world for 1962 and 1963 are shown on the graph on page 8. The map shows a considerable range in the incidence of cancer-caused deaths among the several states. The graph, which shows cancer mortality rates per 100,000 population in 24 countries in 1962 and 1963, shows the United States as ranking 18th for males and 19th for females. Studies are being made concerning the relationship of the environment to cancer all over the world.

On December 4, 1970, the Chairman of the Senate Committee introduced Senate bill 4564 in the Senate, which called for essentially the action recommended by the committee of

ESTIMATED CANCER MORTALITY BY STATE FOR 1970

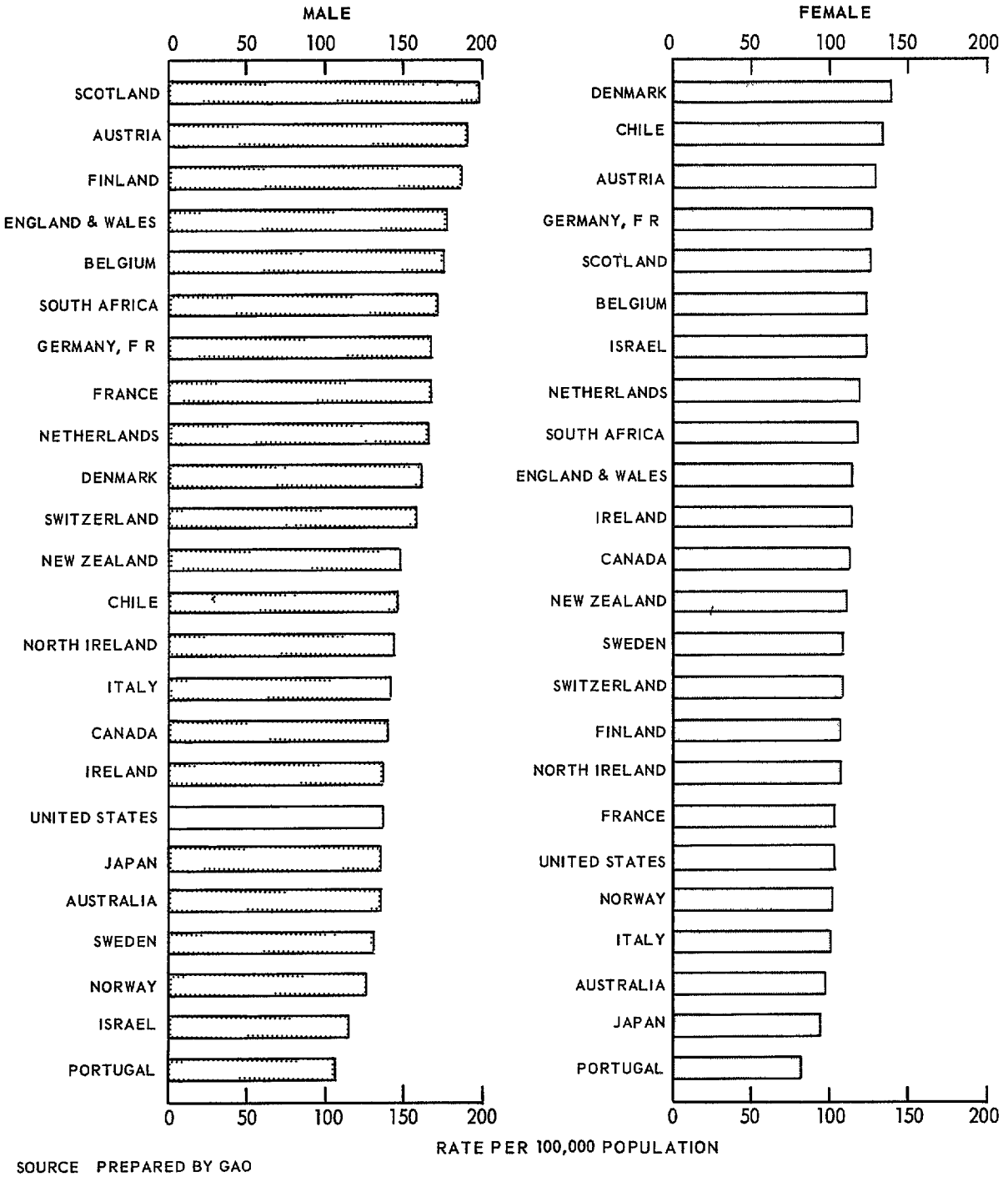


SOURCE PREPARED BY GAO

PER 100 000 POPULATION

CANCER AROUND THE WORLD

AGE-ADJUSTED DEATH RATES FOR SELECTED CANCER SITES IN VARIOUS COUNTRIES, 1962 – 63



SOURCE PREPARED BY GAO

consultants. On January 25, 1971, a similar bill was introduced as Senate bill 34 in the current Congress.

In fulfilling the request of the Senate Committee, we examined into the HEW-NIH-NCI organizational structure and the methods and procedures used for processing, reviewing, and approving contracts and grants for cancer research. The scope of our review is described on page 35.

ESTABLISHMENT AND FUNCTIONS OF NATIONAL CANCER INSTITUTE

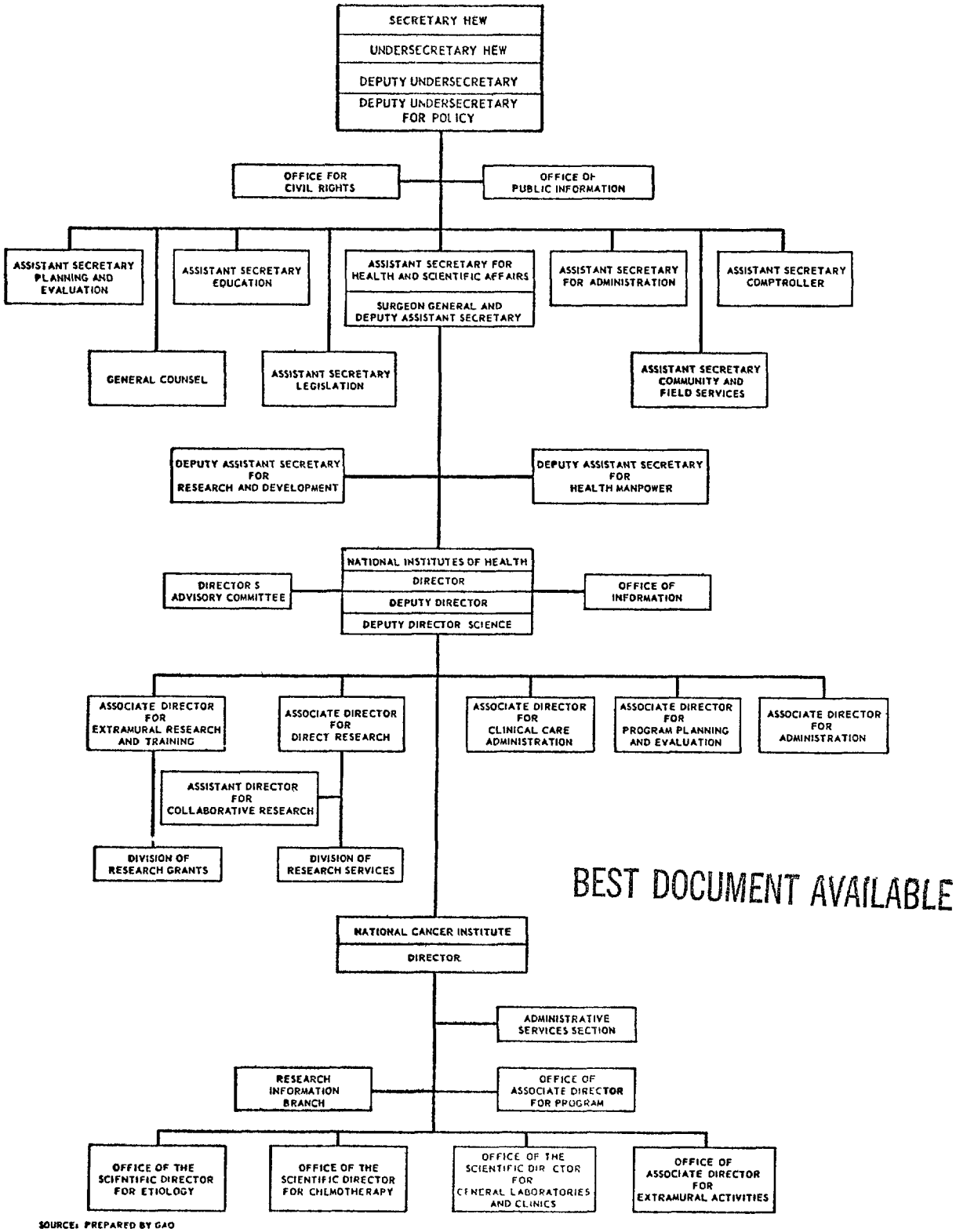
NCI operates within the framework of the HEW-NIH organization and, accordingly, is subject to and must be responsive to HEW-NIH policies, procedures, and requirements. The chart on page 10 illustrates the overall HEW-NIH-NCI organization as of January 1, 1971.

In terms of Federal expenditures, HEW is the largest Government entity other than the Department of Defense. HEW had 102,500 employees as of June 30, 1970, and in fiscal year 1970 made estimated expenditures, including those made from trust funds administered by the Social Security Administration, of $52.7 billion. HEW is, among other things, the Government's principal medical research organization.

NCI was established in 1937. Part A, Title IV, of the Public Health Service Act (42 U.S.C. 281), authorizes the Secretary of HEW, through NCI, to conduct and support research relating to the cause, diagnosis, and treatment of cancer by directly performing such research in-house and by awarding grants-in-aid and contracts to research institutions for performing research projects in the field of cancer. The Public Health Service Act also established a National Advisory Cancer Council, which is a body of 12 members appointed by the Secretary of HEW and three ex officio Government members, to review and recommend appropriate action on applications for grants-in-aid and to recommend general policy and programs.

During fiscal year 1970, NCI employees totaled about 1,400. The NCI administrative work force as of September 30, 1970, consisted of about 260 persons and represented about 19 percent of the total 1,400 NCI employees. The remainder of

ORGANIZATION OF SELECTED OFFICES OF THE DEPARTMENT OF HEALTH, EDUCATION AND WELFARE
NATIONAL INSTITUTES OF HEALTH, AND NATIONAL CANCER INSTITUTE



SOURCE: PREPARED BY GAO

the employees perform principally research and research support activities. This administrative force does not include the various NCI advisory and review committees or NIH-appointed study sections.

Administrative services are also furnished by NIH to the NCI program. For example, the NIH Research Contracts Branch is involved in the negotiation of NCI contracts, and NIH offices--such as the associate directors' offices for Extramural Research and Training, Program Planning and Evaluation, Direct Research, Clinical Care Administration, and Administration--provide administrative services.

Presently NCI conducts, fosters, and supports studies of the occurrence and distribution of cancer and laboratory and clinical research on the cause, prevention, and methods of diagnosis and treatment of cancer through four major organizational components--Extramural Activities, Etiology, Chemotherapy, and General Laboratories and Clinics. Two of these organizational components--Etiology and Chemotherapy--are referred to as collaborative research programs in that they consist of both in-house and contract research. An associate director is in charge of extramural activities. The other three major organizational components are each headed by a scientific director.

The Office of the Associate Director for Extramural Activities plans and directs NCI's grant-supported activities and recommends NCI policies relating to the administration of grant and contract programs. This Office also develops and coordinates plans, reviews, and criteria for the implementation of NCI grants and research contracts; evaluates the effectiveness of grant-supported activities; and advises NCI's Director, the National Advisory Cancer Council, and other scientific advisory bodies of grant and contract activities and developments.

The Office of the Scientific Director for Etiology is charged with the responsibility for the major share of NCI's collaborative research on cancer causation and prevention. Its investigations are aimed at finding means to prevent human cancers and encompass studies of the cancer risks to defined human and animal populations. Investigations are also directed toward identifying viral and chemical

cancer-causing agents and the means by which these agents produce alterations in living systems. The program involves collaboration with investigators in industry, universities, and other research institutions in this country and abroad.

The Office of the Scientific Director for Chemotherapy plans, directs, and coordinates NCI's integrated cancer chemotherapy activities, including intramural laboratory and clinical studies, contracted research, and research conducted in cooperation with other Federal agencies. The chemotherapy program is concerned with finding the best methods of treating cancer through the screening, testing, and clinical evaluation of drugs.

The Office of the Scientific Director for General Laboratories and Clinics has general responsibility for the planning and direction of all in-house laboratory and clinical studies, other than the research performed in-house by the Offices of Scientific Director of Etiology or Chemotherapy. General laboratories and clinics provide broad research support for the various scientific disciplines generating knowledge basic to the advancement of cancer research.

The chart on page 14 shows the NCI appropriations from 1960 through 1970. The fiscal year 1970 appropriation[1] by program for NCI is shown on the chart on page 15, and the fiscal year 1970 estimated funds obligated by each of the four major organizational components of NCI and the Office of the Director, NCI, are shown below.

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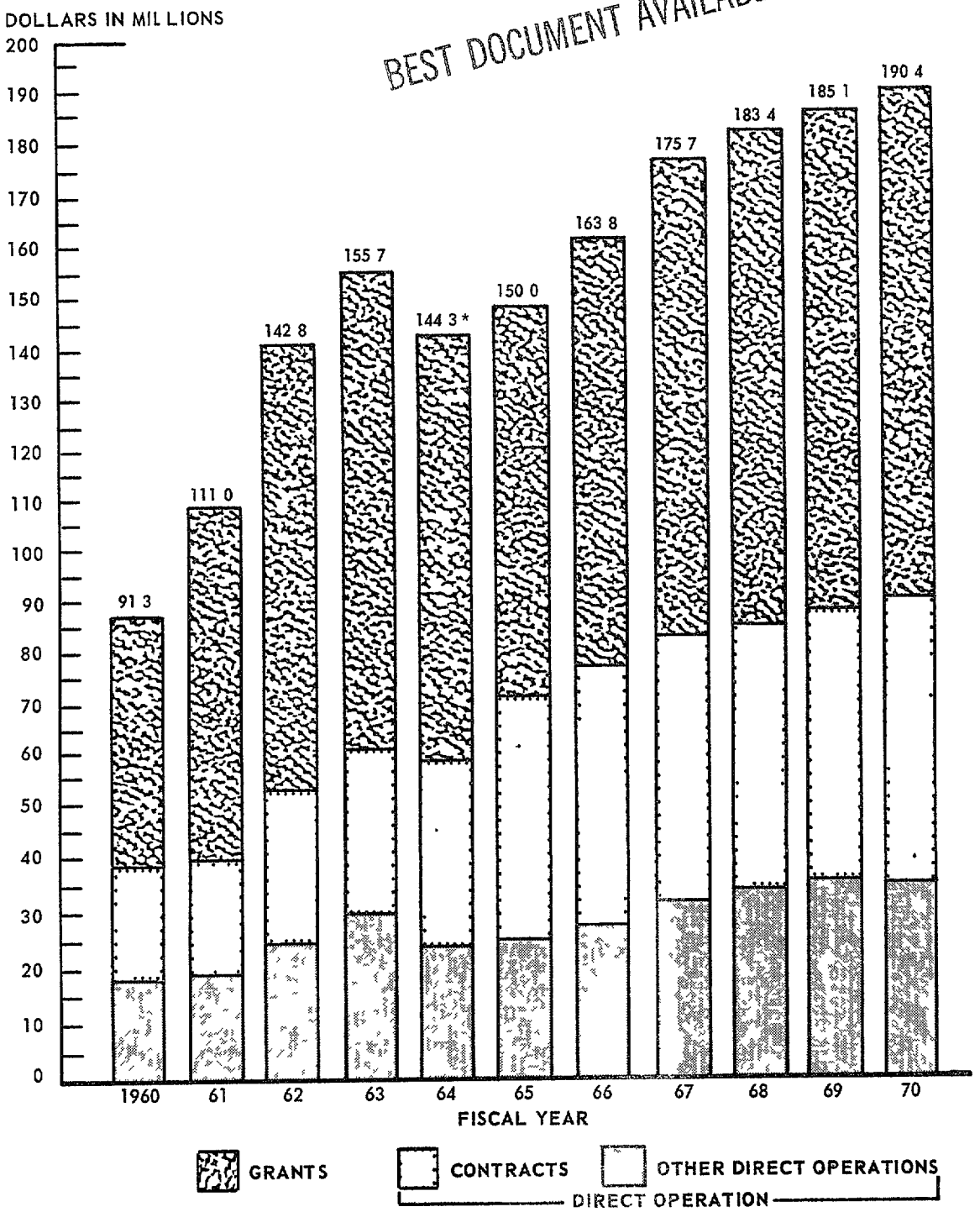
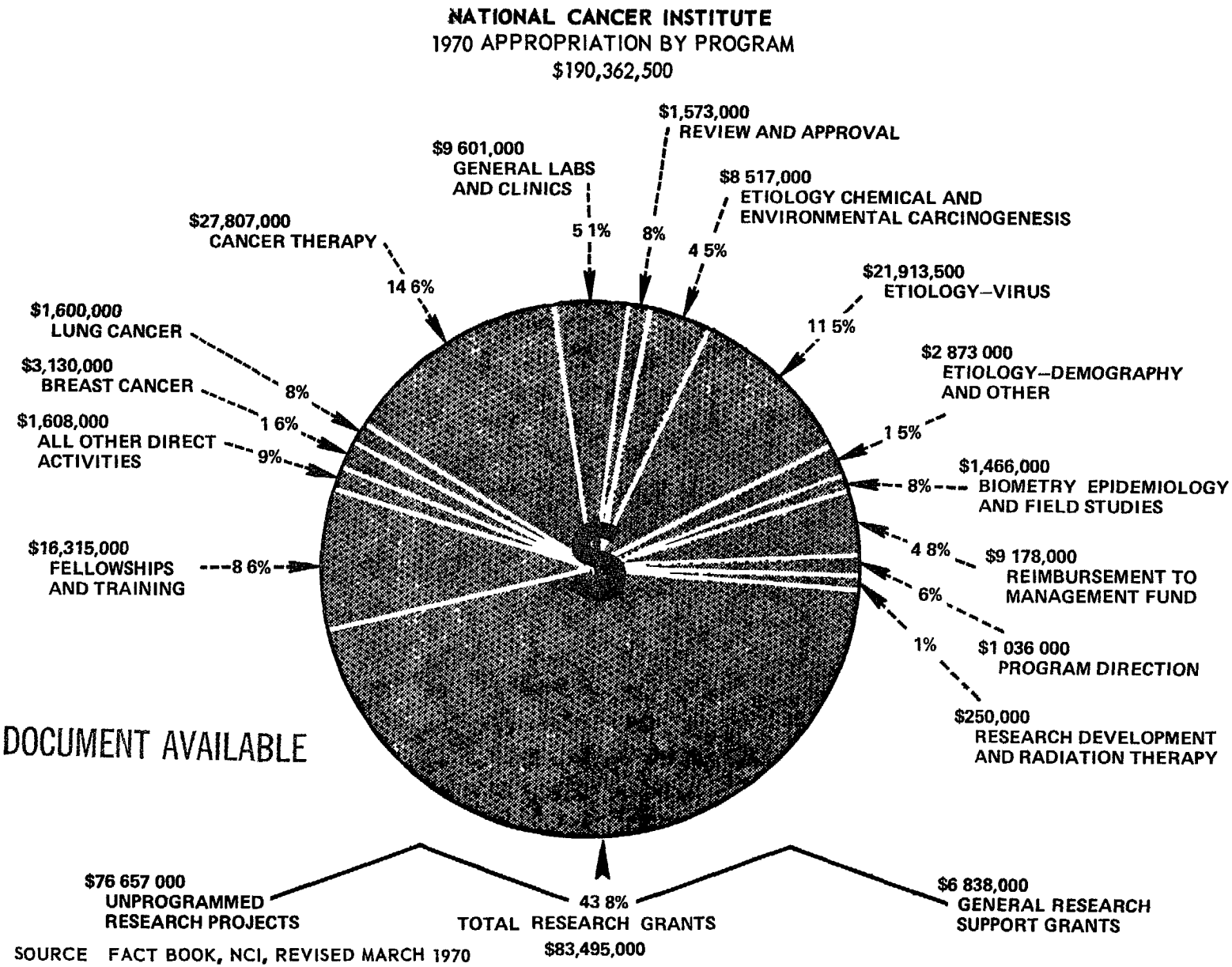
[1]The amount in the chart on page 15 was subsequently cut back by $9.6 million to comply with section 410 of the Labor-HEW Appropriation Act for fiscal year 1970 (Pub. L. 91-204, March 5, 1970). The amount appropriated less the cut back plus net transfers in, totaling $0.6 million from other NIH appropriations, equals the $181.3 million of funds obligated.

	Estimated obligated funds for fiscal year 1970 (millions)
Extramural Activities	$ 95.3
Collaborative research:	
Etiology	40.0
Chemotherapy	26.1
General Laboratories and Clinics	18.8
Office of the Director	1.1
Total	$181.3

NATIONAL CANCER INSTITUTE
APPROPRIATIONS
1960 – 1970



*$14 6 MILLION FOR CANCER CONTROL HOW APPROPRIATED ELSEWHERE
SOURCE FACT BOOK, NCI, REVISED MARCH 1970



CHAPTER 2

ADMINISTRATION OF CANCER RESEARCH BY THE NATIONAL CANCER INSTITUTE

The present system of administering NCI research and the method of funding the research has resulted in significant delays in approving and funding contracts and grants for cancer research.

NIH awarded 333 cancer research contracts, totaling $49.7 million, during fiscal year 1970. These contracts required an average of about 7 months for review and approval. About 1½ months of this review and approval time was the result of what we believe were unnecessary duplicative reviews by NIH and NCI.

During calendar year 1970 the review and approval process for applications for research grants required an average of about 8 months. This processing time was due, to a large extent, to the fact that both the study sections which must review grant applications and the National Advisory Cancer Council which must approve grant applications met only three times annually for recommending grant approvals.

During each of the past 6 fiscal years, the HEW appropriations were not approved by the beginning of the fiscal year in which the funds were to be used. The delays of such approvals, which ranged from 2 to 8 months, hindered effective planning for research, particularly for new programs and projects.

We were told by the Director, NCI, and by some grantee officials at research institutions that, because of the inability of some research institutions to provide interim private funding until final approval and funding is received from NCI, the initiation of some research projects was made uncertain.

UTILIZATION OF REVIEW COMMITTEES FOR DECISIONMAKING

There are 25 committees or groups, with approximately 279 members, which advise and assist NCI in the management of the cancer program. NIH has 47 study sections, with about 700 persons who are primarily nonfederally employed persons, which review the research grant applications of all institutes, including NCI, for scientific merit within the broad fields of medicine and public health. Each grant application, however, is reviewed by only one study section.

The National Advisory Cancer Council was established in compliance with the Public Health Service Act. The various study sections were established by NIH to provide an independent peer review of the scientific merit of all applications to NIH for research grant funds. The study sections are made up of eminent scientists knowledgeable about research in specific areas.

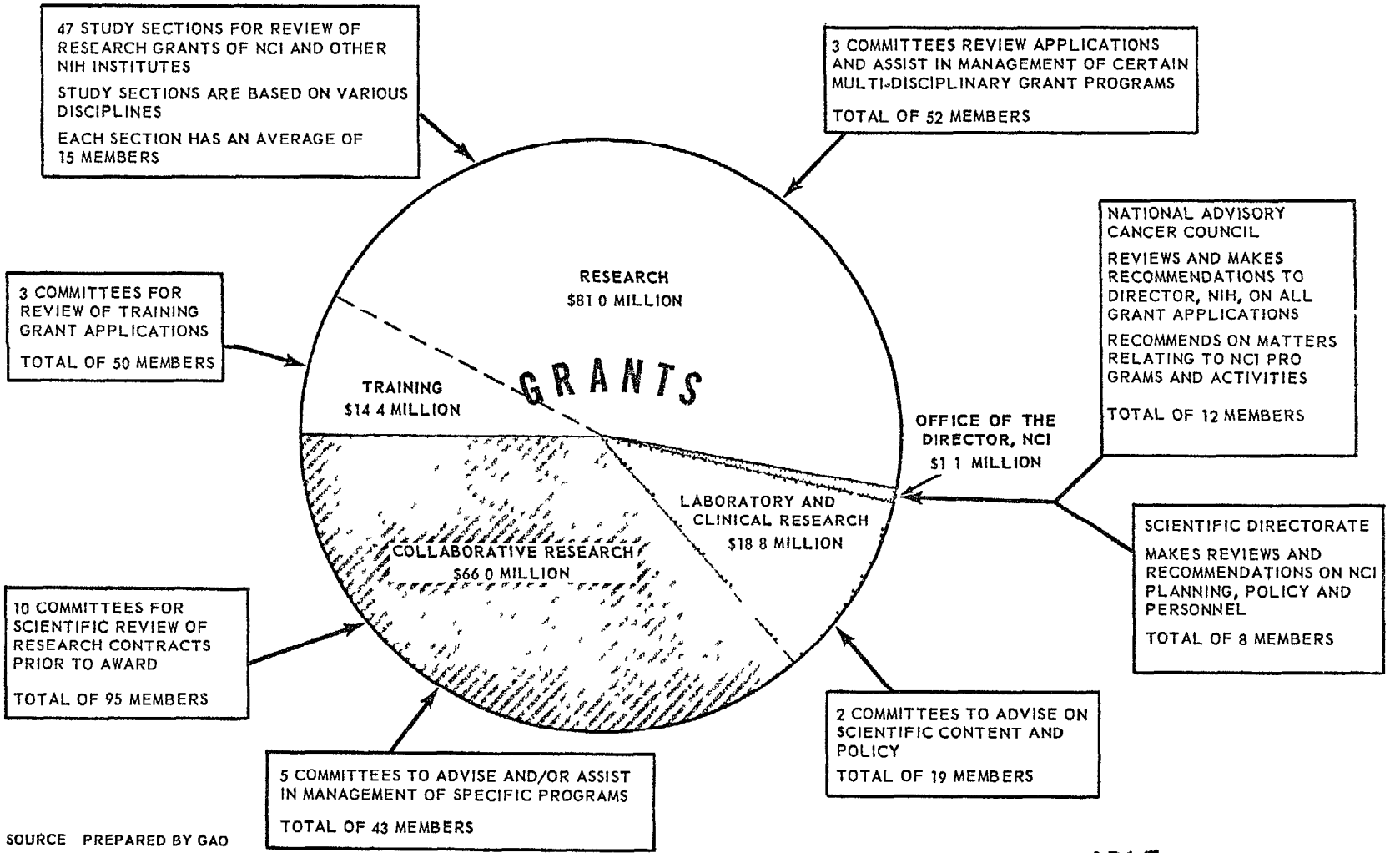
The chart on page 18 illustrates the review and advisory groups which have responsibilities for cancer programs. The study sections, depending on the specific research area involved, review NCI research grant applications. Also, three committees review NCI research grant applications, three committees review NCI training-grant applications, 15 committees advise or assist in the management of NCI collaborative research, including contract research, two committees advise on NCI laboratory and clinical research, and two groups (the National Advisory Cancer Council and the Scientific Directorate) advise on the overall program.

The review and advisory groups' members are selected primarily from outside the Government and represent leading medical or scientific authorities in the study, diagnosis, or treatment of cancer and in specialized areas of health-related research, fundamental sciences, or medical sciences. Several of the committees have NIH or NCI employees represented on the committees, and a few committees are comprised entirely of NIH or NCI employees.

The chart on page 20 illustrates the organizational and administrative arrangements within HEW, including the advisory and review groups, relating to the etiology program.

NATIONAL CANCER INSTITUTE

REVIEW AND ADVISORY COMMITTEES AND FISCAL YEAR 1970
OBLIGATIONS BY PROGRAM AREA

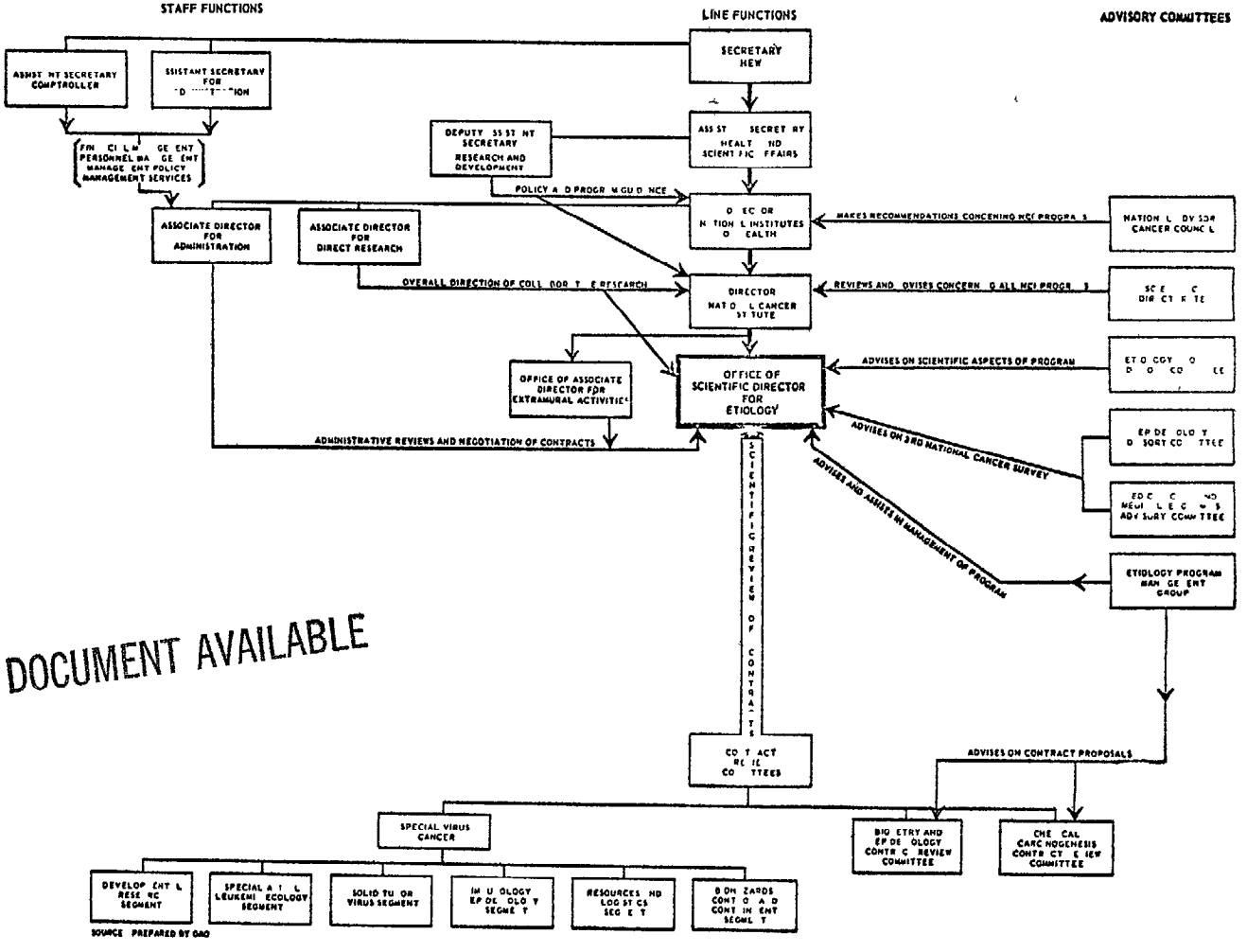


SOURCE PREPARED BY GAO

The Scientific Director for Etiology receives advice directly from four committees and indirectly from two committees. In addition to receiving direction from the Secretary of HEW through normal channels, the Director, NCI, receives policy direction or program advice from several staff organizations within HEW-NIH. Both the Deputy Assistant Secretary, Research and Development, HEW, and the Associate Director for Direct Research, NIH, have policy and program guidance responsibilities for the etiology program.

In the area of contracting, a number of internal and external groups are involved. The Assistant Secretary, Comptroller, HEW, and the Assistant Secretary for Administration, HEW, establish overall financial and administrative policy for contracting. The Research Contracts Branch under the Associate Director for Administration, NIH, performs administrative review and negotiation of contracts. Scientific review of etiology research contracts is the responsibility of eight contract review committees made up of NCI and NIH employees and non-Government consultants.

ORGANIZATIONAL AND ADMINISTRATIVE ARRANGEMENTS ON THE NATIONAL CANCER INSTITUTE'S ETIOLOGY PROGRAM



SOURCE PREPARED BY GAO

PROCESS USED FOR REVIEWING AND APPROVING CONTRACTS FOR CANCER RESEARCH

In recent years NCI has made extensive use of research contracts in its collaborative research programs. Of its $181 million of fiscal year 1970 obligations, NCI awarded 333 research contracts for $49.7 million.

The 333 contracts required an average of about 7 months for review and approval. Approximately 1-1/2 months of that time was the result of what we believe were unnecessary duplicative reviews by NIH and NCI.

The contractor selection and proposal review process commences with an NCI scientist's proposal to establish a specific project under contract support and ends upon award of a contract. Contract proposals are reviewed by the appropriate scientific review committee. The review covers the scientific aspects of the proposal and the propriety of the selection of the contractor. Each review committee is responsible for the review of contract proposals relating to a given type or phase of scientific research.

The process of contract development and award can be divided into two phases: the development of a project and the preaward procedures leading up to the award of a contract.

The program scientific director, a program scientific coordinator (project officer or project originator), and an NCI program contract specialist determine that a proposed project is relevant to their established program. Then a recommendation is developed on the source of potential contractors and on the scope of the work to be solicited. Approval of the scientific director for the program area is then obtained to proceed with the contract selection and proposal review process.

The schedule on page 22 shows that it takes an average of about 7 months of processing time from advertising to the award of a contract when the contractor selection involves multiple solicitation of prospective contractors. The processing time is broken down by steps, and the number of days required for each step and the cumulative days at each step are shown.

After advertising and obtaining the proposals, the NCI project officer and contract specialist make a preliminary screening of all proposals to eliminate those which are not responsive to the requirements of the project or which are otherwise unacceptable.

Schedule of Processing Time for NCI
Research Contracts from Initiation to Award

Step	Days per step	Cumulative days	Procedure
1	30	30	Advertising the effort--Initiation of a research contract normally consists of advertising the scope and objectives of the proposed project and requesting interested contractors to submit resumes of their qualifications rather than proposals for the effort. This period includes the time when the Grants and Research Contracts Operations Branch receives word from the specific program officials to advertise through the time when the program officials advise the Contracts Operations Branch on which of the resumes received merit request for proposals.
2	21	51	Obtaining proposals and forwarding them to program officials.
3	34	85	Contractor selection (when multiple solicitation is involved)--Preliminary screening by project officer and contract specialist. Evaluation by an ad hoc group of the proposals received on a project and its recommendation of one of these proposals.
4	28	113	Review of proposal by program officials.
5	14	127	Preparation of review committee "package" by the Contracts Operation Branch--Delivered 1 week prior to committee meeting
6	14	141	Contract review committee review--Allows 1 week to review "packages" and 1 week to prepare minutes.
7	14	155	Preparation of final review committee "package" by the Contracts Operation Branch
8	18	173	Review by final review committee.
9	4	177	Approval by NCI Director
10	47	224	Preparation of program memo to NIH. Negotiation of contract by NIH. Finalization of contract Work begins.

The in-depth review by the program officials (step 4 on p. 22) involves both the scientific and the administrative aspects of the proposal, such as the capability of the contractor, the type of contract proposed, the proposed budget of the contractor, and a check for scientific duplication of effort.

The method of reviewing prospective contracts for cancer research had its inception in the early days of the chemotherapy program, which was initiated in 1955. At that time it was believed that a review system similar to the study section-National Advisory Cancer Council concept used in reviewing grants was needed. Chemotherapy panels (composed of outside consultants) and the Chemotherapy Review Board (composed of the chairmen of the panels plus some members of the National Advisory Cancer Council) were established. As time went on, however, difficulty was experienced in recruiting outside consultants with no appearance of conflicts of interest. As a result, a system was established in which preaward reviews were made first by standing program committees comprised of NCI staff and then by the Scientific Directorate.

Subsequently, early in 1965 Congress gave consideration to adding to the HEW appropriation bill a requirement that the National Advisory Cancer Council review each contract before award. As a compromise, it was agreed that NCI periodically would provide the National Advisory Cancer Council with information regarding the plans for and status of the contractual program. This procedure is still being used.

After the Director, NCI, approves the contract proposals, the Research Contracts Branch in the Office of the Associate Director for Administration, NIH, negotiates and finalizes the contracts. The Secretary, HEW, has formally delegated contracting authority to the Director, NIH, who in turn has delegated this authority to certain NIH officials but not to any NCI officials.

Contract negotiations by NIH take approximately 1-1/2 months and duplicate several of the review steps previously taken by NCI. Specifically, the reviews of contract proposals by the NIH contracting officers--including the

qualifications of the proposed contractors, the work specifications, and the amounts of the proposed contracts--duplicate certain work in steps 3, 4, and 6 of the NCI review in the schedule shown on page 22.

Conclusion

We believe that about 1-1/2 months of the 7-month period required to review and approve an NCI research contract consisted of an unnecessary duplication of review by NIH and NCI. We believe also that much of the 1-1/2 months could be eliminated if NIH gave research-contracting authority to NCI program managers.

Recommendation to the Secretary of HEW

Accordingly, we recommend that the Secretary of HEW authorize NCI program managers to negotiate research contracts.

- - - -

In his comments dated January 21, 1971 (see app. II), on a draft of this report, the Secretary of HEW stated that action was being taken to extend research-contracting authority to NCI. The Secretary noted that HEW studies had recommended decentralization of research-contracting authority to NCI and other NIH components which have a large volume of research contracts.

PROCESS USED FOR REVIEWING AND APPROVING GRANTS FOR CANCER RESEARCH

In fiscal year 1970 NCI awarded 1,182 research grants amounting to $71.4 million. The research grant review and approval process, which is summarized in the chart on page 26, took an average of about 8 months during calendar year 1970.

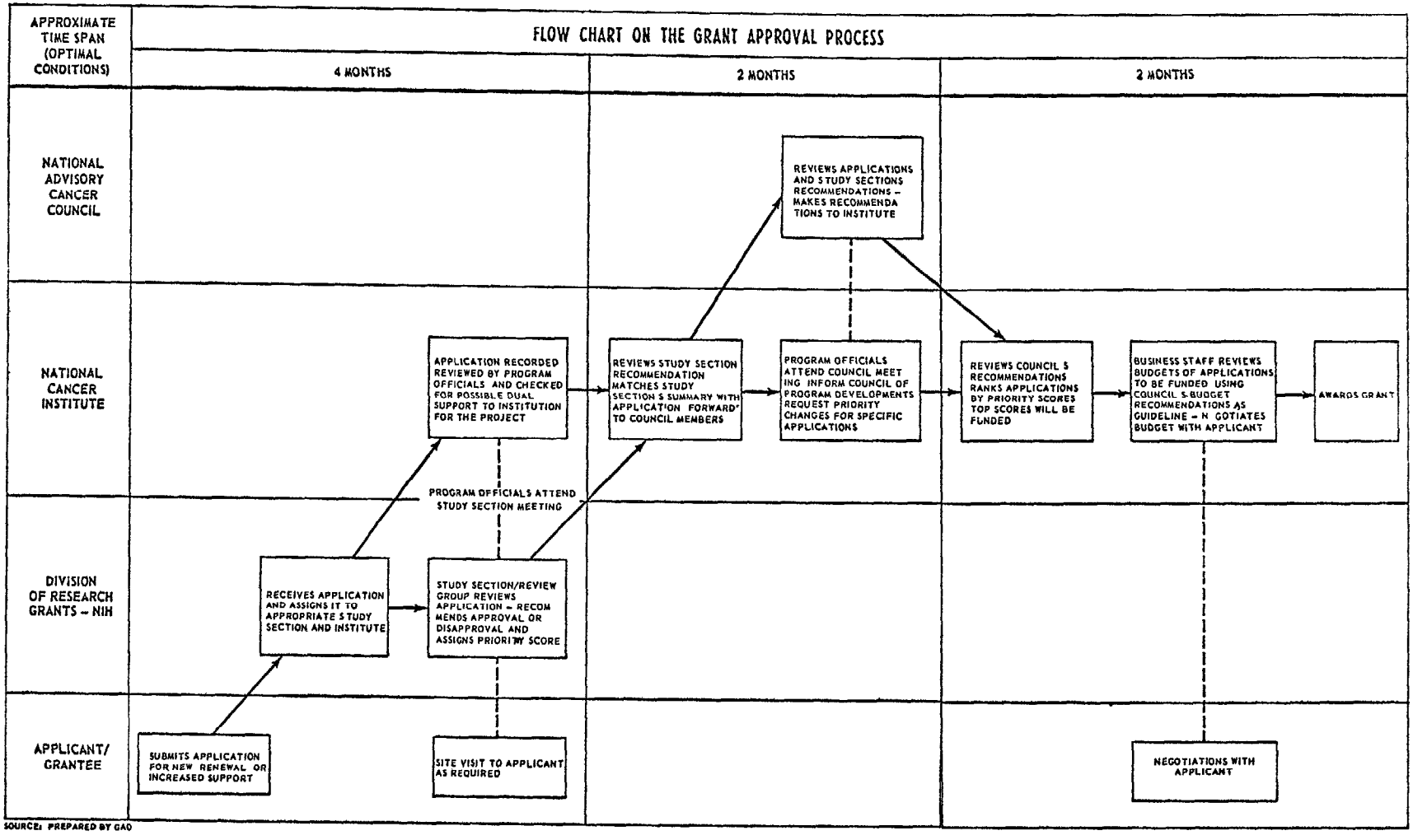
A significant portion of this processing time occurs because the study sections that review grant applications and the National Advisory Cancer Council that recommends approval of grant applications each meet only three times a year. All applications, regardless of amounts involved or complexity, are held for some period of time, the amount of time depending upon when the applicable study sections and the National Advisory Cancer Council will meet.

Inherent in such a review process is a certain amount of time when most applications are just waiting for the next step without being processed. For example, as indicated below, an application for a new project submitted between February 2 and the June 1 deadline for submission of an application would take from 3 to 8 months to reach the study section review. It would then have a 6- to 10-week wait before consideration by the National Advisory Cancer Council.

The National Advisory Cancer Council meets three times annually to consider grant applications. The frequency of its meetings determines, to a great extent, the timing of the grant review process. The following table illustrates key dates in the grant review process for fiscal year 1969 Council meetings.

Deadline for submission of application to NIH:			
Renewal	May 1	Sept. 1	Jan. 1
New and supplemental	June 1	Oct. 1	Feb. 1
Period of study sections meetings	Aug. 28 to Sept. 29	Jan. 5 to Feb. 1	Apr. 12 to May 3
Period of National Advisory Cancer Council meetings	Nov. 18 to Nov. 20	Mar. 10 to Mar. 12	June 16 to June 18

NATIONAL CANCER INSTITUTE



SOURCE: PREPARED BY GAO

In reply to a GAO suggestion in a draft of this report that meetings of study sections and the National Advisory Cancer Council be scheduled more frequently, the Secretary of HEW stated that there was a serious danger that an increase in the frequency of these meetings would jeopardize the ability of NIH to obtain the kind of expert advice needed to ensure the quality of its programs. He said that the eminent scientists involved would be most reluctant to commit significant additional time away from their schools and laboratories and that, in any case, the time saved by additional meetings would be minimal. (See app. II.)

In general, all research grant applications, regardless of the complexity of the project or the amount of funds requested, must go through the same review process and therefore require approximately the same overall processing time.

In fiscal year 1970 NCI awarded 1,182 research grants totaling about $71.4 million. Grants of under $30,000 each made up 45 percent of the number of grants and about 12 percent of the dollar amount.

Amount of individual grant award	Percent of total number of grants awarded	Percent of total amount of grants awarded
$ 0 to $ 9,999	13	1
10,000 to 19,999	13	3
20,000 to 29,999	19	8
Total	45	12
In excess of $30,000	55	88
Total	100	100

The review process for grant applications starts with the Division of Research Grants of NIH, which is the central receiving point for all grant applications. The Division designates, on the basis of program relevance, the institute to which applications are referred and assigns the applications for scientific review to one of the study sections which are organized along scientific discipline lines. (See app. IV.)

To ensure scientific excellence in the review of grant proposals, NIH and NCI use study sections made up of such experts as scientists, educators, and others in the scientific area of the research covered by the grant application being considered The responsibility of the study sections and the special review committees reviewing NCI grant proposals includes determining the scientific merit of the proposed research. Priorities are established by these groups on the basis of scientific merit.

The grant applications relevant to cancer, along with the study sections evaluations, are forwarded to the National Advisory Cancer Council. About 400 to 500 applications are considered at each meeting. The National Advisory Cancer Council usually has approved the study sections' recommendations without any material change. The proposals recommended by the National Advisory Cancer Council with the highest priorities are funded within the limitations of available appropriations.

All applications to be funded are sent to NCI's business staff, which reviews the funding level in the application for reasonableness of the amounts involved. Council recommendations are used as a guideline. The remaining applications are grouped into two categories, those which may be funded later if sufficient money is available and those not to be funded. During fiscal year 1970 the chance of not obtaining funds for newly approved projects for cancer research was about 50 percent.

Conclusion

We do not question the concept or the merits of scientific reviews by outside committees in approving research proposals for the purpose of setting priorities on the basis of scientific merit. However, the fact that the system of review and approval of proposals for research projects has reached the point at which proposals for NCI grants take an average of about 8 months to process raises the question of whether the present system should be continued. We believe that, unless some measures are taken to streamline and expedite the review and approval process, the problem of delays in the review and approval process probably would be made worse if the substantial increases in the amount of

cancer research recommended by the committee of consultants are appropriated by the Congress.

Recommendation to the Secretary of HEW

Accordingly, we recommend that the Secretary of HEW authorize the NCI program managers to award grants up to a specified dollar limit without review by study sections but with the review and recommendations of the National Advisory Cancer Council.

- - - -

In commenting on this matter, the Secretary of HEW informed us that the Department planned to review all aspects of the grant review system with a view toward strengthening and expediting the review process. He also stated that the Department's evaluation of the grant review system would include consideration of granting authority to NCI program managers to award grants up to a specified dollar limit without review by study sections. (See app. II.)

DELAYS IN FUNDING CANCER RESEARCH PROGRAM

Because the NCI budget is part of the HEW budget, action on NCI funding requests must wait until the entire HEW appropriation bill is enacted. Cancer research projects, usually from 3 to 5 years in length, are funded annually. Although ongoing research grants and contracts are funded under a joint congressional resolution making continuing appropriations for a fiscal year pending approval of appropriations for that year, NCI cannot effectively plan for research, particularly new programs and projects, until the NCI appropriation request is approved and the total funds appropriated are known.

The Director, NCI, and some grantee officials advised us that, because of the inability of some research institutions to provide interim private funding until final approval and funding is received from NCI, the initiation of some research projects was made uncertain. Also, the Director, NCI, and the grantee officials informed us that such delays could cause problems for research institutions in attracting and retaining qualified researchers.

Effect of HEW budget process on funding cancer research

Each of the 10 institutes at NIH has separate appropriations, and each must be considered during the budget process by various levels within HEW and the Executive Office of the President, as well as by the appropriation committees of Congress. For example, in fiscal year 1970 HEW had a total of 88 appropriation requests to prepare and justify. Consideration of the HEW appropriation request takes substantial time each year, as shown below by the dates of enactment for the past 6 years.

Fiscal year	Date of enactment	Budget delay from June 30 (months)
1966	8-31-65	2
1967	11- 7-66	4
1968	11- 8-67	4
1969	10-11-68	3
1970	3- 5-70	8
1971	1-11-71	6

Although NCI has a separate appropriation, the NCI budget is consolidated with the NIH budget and included in the overall HEW budget, so that the NCI budget must compete with all other HEW research and health, education, and welfare programs. The budgetary process takes 24 months and is presented in the chart on page 32.

Many scientific researchers depend primarily upon NCI for research funds. Research experiments take several years to perform; therefore grants generally are awarded for periods ranging from 3 to 5 years, subject to annual funding. About a year prior to the expiration of the grant award, the researcher must begin the application process anew to finance a new experiment or series of experiments or a continuation of the prior experiment that was not completed within the estimated time. Officials of some research institutions informed us that they were unable to fund new projects for periods of time because of delays in Federal appropriations.

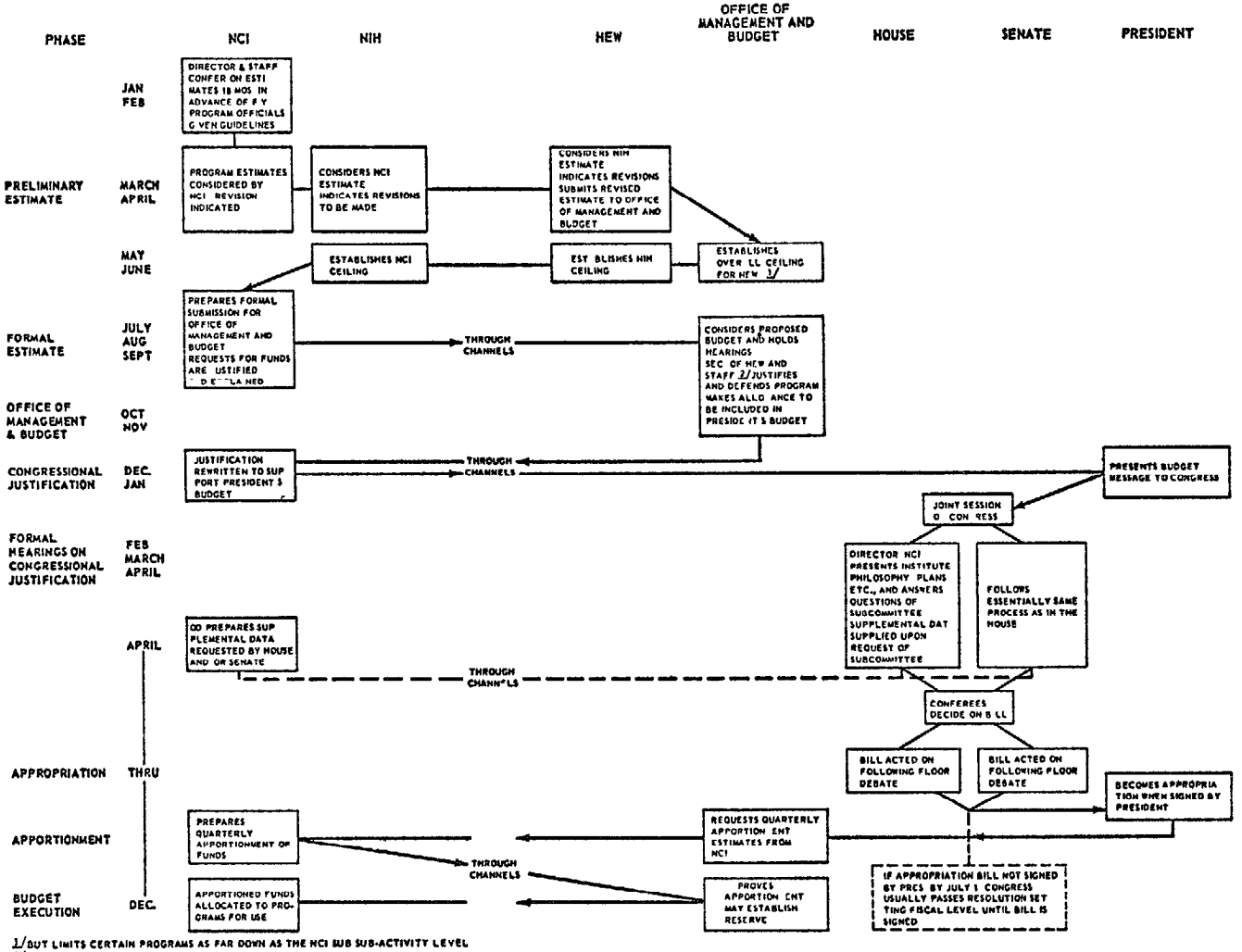
HEW's comments and our evaluation

We believe that, to minimize the effect of the substantial time delays in obtaining appropriations and funding for NCI grants and contracts each year, the possibility of adopting the practice of authorizing advance funding should be considered by the Congress. This can be accomplished through authorizing and making appropriations to be available for the next fiscal year following the usual budget year. This type of advance funding was authorized by title I of the Elementary and Secondary Education Act of 1965, as amended, for the program of aid to educationally deprived children and by the Economic Opportunity Amendments of 1969.

The Secretary of HEW advised us that, at the present time, despite delays in the funding of new grants and contracts, HEW did not have any data that indicated any serious disruption to research under the funding mechanism and that HEW was not aware of any significant or widespread problems encountered by research institutions in attracting qualified staff. He stated that funding delays were a considerable inconvenience and concern to the research institutions and to individual investigators, not only in the cancer program but also throughout the programs administered by HEW. The Secretary concluded that the delays in appropriation

NATIONAL CANCER INSTITUTE

BUDGET PROCESS



1/BUT LIMITS CERTAIN PROGRAMS AS FAR DOWN AS THE NCI SUB SUB-ACTIVITY LEVEL
2/INCLUDING DIRECTOR NIH
SOURCE FACT BOOK NCI REVISED MARCH 1978

approvals could be a significant deterrent to initiation of the new and sizable cancer program levels visualized by the consultants to the Senate Committee.

Also, the Secretary of HEW advised us that delays in funding had emanated most often from the recent practice followed by both the Congress and the executive branch of establishing annual spending ceilings. For example, in regard to the fiscal year 1970 appropriations, funds were withheld from HEW by the Office of Management and Budget to keep 1970 Federal outlays within the overall budget estimate for the year, and funds were also withheld as a result of limitations placed by the Congress on the expenditure of appropriations.

The Secretary stated that the effect of these spending ceilings on the timing of grant funding was to delay awards of new grants until a spending plan had been developed for the entire fiscal year, which was very difficult to do until appropriation and expenditure limitations were known. He also said that the result was that typically HEW did not fund new projects until well into the fiscal year and that this situation would exist whether or not the grants were advance funded.

We recognize that HEW must develop an annual spending plan based upon various expenditure control limitations; however, it seems to us that it would not be desirable to delay financing most new projects until appropriation and expenditure limitations for the year are known. We believe that it would be desirable to begin financing new projects as soon as possible after the beginning of each fiscal year within the authority of either a joint congressional resolution making continuing appropriations for the fiscal year which generally limits appropriations to the prior years level, or advance funding. In either case provision could be made to hold back a reasonable amount of funds to cover any estimated expenditure limitations that might be imposed subsequently.

We believe that, to optimize the Government's investment in terms of both facilities and the scientific knowledge accumulated by professional researchers, particularly in view of the adverse effect which delays in funding can

have on the implementation of new research programs and projects, consideration should be given to the advance-funding mechanism as a means to plan and program research more effectively. In our opinion, advance funding would enable NCI to make awards on the basis of the amount appropriated for the year covered by the advance funding and would facilitate more timely planning and financing of new programs and projects, rather than limit awards for research to the amounts authorized by a joint resolution making continuing appropriations

Matter for consideration by the Congress.

In consideration of the foregoing observations concerning the problems of funding cancer research, the Congress may wish to consider the enactment of legislation authorizing, in the case of NCI, the making of appropriations to be available for the next fiscal year following the usual budget year.

CHAPTER 3

SCOPE OF REVIEW

Our review was directed toward obtaining information concerning the organizational and administrative problems associated with implementing a large-scale, mission-oriented program to conquer cancer within the present structure of NIH, as expressed to us in a letter dated September 25, 1970, from the Chairman of the Senate Committee on Labor and Public Welfare. Our review also was concerned with the use of grants and contracts in financing cancer research.

Our review was accomplished through discussions with officials of NIH, NCI, and various grantee institutions and through the use of available records and documents relating to the administration of research contracts and grants, the organization and administration of HEW-NIH-NCI, and the HEW budget process.

APPENDIXES

United States Senate
COMMITTEE ON
LABOR AND PUBLIC WELFARE
WASHINGTON D C 20510

September 25, 1970

Honorable Elmer B. Staats
Comptroller General of the United States
General Accounting Office
441 G Street
Washington, D.C. 20548

Dear General Staats

Pursuant to Senate Resolution 376 (copy enclosed), a Special Staff of the Senate Committee on Labor and Public Welfare is conducting a study of our current efforts in cancer research to determine the best way to implement a major national effort to conquer cancer.

The problems associated with implementing a large scale, mission-oriented program within the present structure of the National Institutes of Health must be examined in considerable detail. It is my understanding that your staff has been resident in NIH for a considerable period of time and therefore has background and experience that can be very helpful to the Special Senate Staff I further understand that our staffs have discussed the problem and agree that your people should be able to contribute in an important way to this effort.

It is therefore requested that the General Accounting Office provide such assistance as you consider appropriate to the Special Staff on Cancer of the Senate Committee on Labor and Public Welfare in developing background and support for its report on implementing a major effort on cancer. It would be particularly helpful if preliminary information could be made available before the end of October 1970 with a final report submitted by the end of the year.

Please be assured of my personal appreciation for any assistance you may give in this matter.

Sincerely,

Ralph W. Yarborough
Chairman

Enclosure
RWY/mmb

THE SECRETARY OF HEALTH EDUCATION AND WELFARE
WASHINGTON D C 20201

JAN 21 1971

Mr. Dean K. Crowther
Assistant Director
United States General Accounting Office
Washington, D.C. 20548

Dear Mr. Crowther:

Thank you for the opportunity to comment on the draft report of the Comptroller General's Review of Selected Aspects of Administration of Cancer Research.

This draft report examines the organizational structure of the Department of Health, Education, and Welfare (HEW), the National Institutes of Health (NIH), and the National Cancer Institute (NCI) relating to the administration of the cancer research program, and the method and procedures used for processing, reviewing and approving grants and contracts for cancer research; and considers alternative approaches to such methods and procedures. The basic aim of the report appears to be the identification of problems of organization and processes that might inhibit or deter the proper administration of a cancer research program of a much larger size or that recommended by the Committee of Consultants appointed by the Committee on Labor and Public Welfare.

The report's finding is that significant delays in approving and funding grants and contracts for cancer research are caused by long delays in Congressional approval of HEW fiscal year budgets and by problems in the internal review and approval procedures. Because of the delays "the initiation of some research projects was uncertain...and that GAO was told that the delays can cause problems to research institutions in attracting and retaining qualified researchers." We assume that the delays in funding of grants and contracts as noted by the GAO, applies to new programs and applications since all on-going grants and contracts are funded under a continuing resolution pending approval of appropriations.

Page 2 - Mr. Dean K. Crowther

At the present time, despite delays in the funding of new grants and contracts we have no data that indicate any serious disruption to research conducted under these mechanisms nor are we aware of any significant or widespread problems encountered by research institutions in attracting qualified staff. We are, of course, aware that funding delays of new grants and contracts are a considerable inconvenience and concern to the research institutions and individual investigators, not only in the Cancer program, but throughout the programs administered by this Department Every effort has and will continue to be made to minimize the inconvenience and problems involved. However, the delay in appropriation approvals could be a significant deterrent to initiation of the new and sizable Cancer program levels visualized by the Consultants to the Committee

In our view, the funding delays in the awards of grants and contracts are caused primarily by events outside the control of this Department, such as the lag in approval of annual budgets as mentioned in the report. The delays caused by Office of the Secretary-Office of the Director, National Institutes of Health-National Cancer Institute internal review and approval procedures are minimal. As outlined further in this letter, the speed-up of the processes involved may do damage to the scientific review necessary to fund only research projects of high scientific merit without achieving significant time savings.

The following are the Department's comments on the recommendations cited in the report. For convenience, the response to each is listed directly below the recommendation, as follows:

1. Provide for more frequent meetings of NIH study sections and the National Cancer Advisory Council to minimize approval delays.

There is a serious danger that an increase in the frequency of NIH study section and council meetings would jeopardize the ability of the NIH to obtain the kind of expert advice needed to assure the quality of its programs. The eminent scientists involved would be most reluctant to commit significant additional time away from their schools and laboratories. In any case, the time saved by additional meetings would be minimal.

2 Grant authority to NCI program managers to award grants up to a specified dollar limit without review by study sections.

We will include consideration of this idea in our future evaluations of the project grant review system. We are planning to review all aspects of this system with a view toward strengthening it in a number of areas, including expediting the process.

3. Grant authority to NCI program managers to negotiate contracts.

Studies conducted by my office have recommended decentralization of research contracting authority to NCI and other NIH components which have a large volume of research contracts Steps are being taken to effect this recommendation.

4 Congress consider legislation authorizing, in the case of NCI, the making of appropriations for the fiscal year next following the usual budget year.

We doubt that this recommendation goes to the true source of the problem. We believe that delays in funding have emanated most often from the recent practice followed by both the Congress and the Executive Branch of establishing annual spending ceilings The effect of these ceilings on the timing of grant funding is to delay new awards until a spending plan has been developed for the entire fiscal year. This is very difficult to do until final appropriations are known. The result has been that typically we do not fund new projects until well into the fiscal year This situation would exist whether or not the grants were forward funded.

We believe that as we gain experience with the execution of expenditure control devices we can overcome the impact on the timing of grant awards. On the other hand, there is not much that we can do to speed-up the appropriation process.

Page 4 - Mr. Dean K. Crowther

In summary, the real problem lies in the fact that appropriation action has been occurring later and later with each fiscal year. This, coupled with the requirements for expenditure controls, has occasioned the problem with which both the Department and your report are concerned.

We trust that these comments will be helpful in your reporting to the Committee Chairman.

Sincerely,

Secretary

91st Congress
2d Session

COMMITTEE PRINT

NATIONAL PROGRAM FOR THE CONQUEST OF CANCER

REPORT

OF THE

NATIONAL PANEL OF CONSULTANTS ON THE CONQUEST OF CANCER

AUTHORIZED BY

S Res 376

(Agreed to by Senate April 27, 1970)

PREPARED FOR THE

COMMITTEE ON LABOR AND PUBLIC WELFARE UNITED STATES SENATE

NOVEMBER 1970

PART 1

Printed for the use of the Committee on Labor and Public Welfare

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(III)

Foreword

U S SENATE,
COMMITTEE ON LABOR AND PUBLIC WELFARE,
November 27, 1970

Cancer is a disease which can be conquered Our advances in the field of cancer research have brought us to the verge of important and exciting developments in the early detection and control of this dread disease; but as a nation we have not put forth the effort necessary to exploit the full potential of these gains, nor have we made the proper effort to ascertain what additional avenues of research should be opened

In March of this year, I introduced a resolution supported by 53 of my colleagues in the Senate, calling for a completely new study of cancer, cancer research, and the cause and cure of cancer The intent of this resolution is to make the conquest of cancer a national goal of the highest priority

The resolution authorized the Committee on Labor and Public Welfare to study cancer research activities It specifically charged the committee to "examine, investigate, and make a complete study of any and all matters pertaining to (1) the present status and extent of scientific research conducted by governmental and nongovernmental agencies to ascertain the causes and develop means for the treatment, cure and elimination of cancer, (2) the prospect for success in such endeavors, and (3) means and measures necessary or desirable to facilitate success in such endeavors at the earliest possible time "

As a result of this resolution a Panel of Consultants on the Conquest of Cancer, composed of 13 eminent laymen and 13 eminent scientists, was established to assist the Committee with the new study on cancer After months of intensive and diligent effort, this Panel has prepared the attached report, "A National Program for the Conquest of Cancer " The report is dedicated to the proposition, expressed in a recent Concurrent Resolution of the Congress, that the conquest of cancer should be a national crusade The recommendations are bold and far reaching They call for a new agency, whose sole mission is the conquest of cancer They call for adequate resources of manpower, facilities and funds to do the job in accordance with the provisions of a coordinated national program plan The recommendations, along with the supporting findings, are spelled out in detail in the attached report

I intend to introduce in this session of Congress major legislation to implement these recommendations and I therefore commend this report to the committee and to the Senate for early consideration

RALPH W YARBOROUGH, *Chairman*

Letter of Transmittal

NEW YORK, N Y, *November 25, 1970*

Hon RALPH W YARBOROUGH,
Chairman, Committee on Labor and Public Welfare,
U S Senate, Washington, D C

DEAR MR CHAIRMAN I am pleased to present herewith the report and recommendations of the Committee of Consultants on Cancer appointed pursuant to Senate Resolution 376 Part I of the report sets forth in 12 brief paragraphs a summary of the cancer problem, the areas of special promise which offer unusual opportunities for intensified effort, and the recommendations of the committee Part II of the report sets forth the scientific and medical background in more detail For the convenience of your committee, this part of the report is also preceded by a summary of the scientific material

Of the $250,000 appropriated by the Senate for this study, you will be pleased to learn that we have committed or spent only approximately $75,000 This has been possible because of the generous contribution of time and effort of many persons who would not have been available at all on a reimbursement basis, but who, because of their dedication to the goals of this study, have given most generously of their time and talents These included not only members of the committee, but several hundred members of the scientific community whose lives are devoted in a large measure to work related to the conquest of cancer

I would like to express my personal appreciation to the members of the committee, not only for their splendid cooperation and 100-percent dedication to our task, but more particularly for the unprecedented hours of work which they have devoted without reservation The scientific and professional members of the committee have borne by far the largest burden of the work of our committee, and no group could have given more unselfishly of their time and talent The committee is most appreciative to the members of the scientific community, including those at the National Cancer Institute, and to the members of our staff for the information, views, and suggestions which they have so generously made available to the committee

The committee was most fortunate in the diverse views and backgrounds represented, and in such a group one would not expect nor did we have unanimous agreement on all points However, there has been unanimous commitment to the objective of the study as set forth in the Senate resolution Out of our discussions and differences we have been able to crystallize a consensus This report represents that consensus

The committee is unanimously of the view that the conquest of cancer is a realistic goal if an effective national program along the lines recommended in the report is promptly initiated and relentlessly pursued

Respectfully,

BENNO C SCHMIDT, *Chairman*

A NATIONAL PROGRAM FOR THE CONQUEST OF CANCER

Introduction

On April 27, 1970, the Senate passed Senate Resolution 376 authorizing the Senate Committee on Labor and Public Welfare, with the assistance of an advisory committee, to report to the Senate on (1) the present status of scientific knowledge with respect to the causes of cancer and its treatment, cure, and elimination, (2) the prospect of success in such endeavors, and (3) measures necessary or desirable to facilitate success at the earliest possible time Pursuant to that resolution, the Committee of Consultants was designated in June 1970, and was asked to submit its report and recommendations at the earliest practicable date

On July 15, 1970, the House of Representatives passed Concurrent Resolution 675, later passed by the Senate, expressing the unanimous sense of the Congress that "the conquest of cancer is a national crusade" and that "the Congress should appropriate the necessary funds so that the citizens of this land and all other lands may be delivered from the greatest medical scourge in history "

On June 29, 1970, the Committee of Consultants held its first meeting Since that time the Committee has met 10 full days, subcommittees have met many additional days and the written or verbal testimony of 289 witnesses and advisors has been considered The Committee is pleased to present herewith its report and recommendations

Summary and Recommendations

1 Cancer is the No 1 health concern of the American people A poll conducted in 1966 showed that 62 percent of the public feared cancer more than any other disease Of the 200 million Americans alive today, 50 million will develop cancer at present rates of incidence, and 34 million will die of this painful and often ugly disease, if better methods of prevention and treatment are not discovered About one-half of cancer deaths occur before the age of 65, and cancer causes more deaths among children under age 15 than any other disease Over 16 percent of all deaths in the United States are caused by cancer, making it by a wide margin our second greatest killer (after cardiovascular diseases) Cancer often strikes as harshly at human dignity as at human life, and more often than not it represents financial catastrophe for the family in which it strikes

2 The amount spent on cancer research is grossly inadequate today For every man, woman, and child in the United States, we spent in 1969 $410 on national defense, $125 on the war in Vietnam, $19 on the space program, $19 on foreign aid and only $0 89 on cancer research Cancer deaths last year were 8 times the number of lives lost in 6 years in Vietnam, 5½ times the number killed in automobile acci-

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dents, and greater than the number of Americans killed in battle in all 4 years of World War II Given the seriousness of the cancer problem to the health and morale of our society, this allocation of national priorities seems open to serious question In addition to the poignancy of the disease, and the death and suffering that it causes, the economic loss is staggering, with estimates of its costs to the Nation running as high as $15 billion per year, of which some $3 to $5 billion represents direct care and treatment costs and the balance is loss of earning power and productivity

3 The incidence of cancer is increasing This is partly due to the fact that a greater number of our citizens are reaching more advanced ages, where cancer strikes more frequently, but it is also due to the sharp increase in lung cancer, undoubtedly attributable to the air pollution in certain environments and most importantly to the self-pollution of those who smoke cigarettes It is estimated that if the American people stopped smoking cigarettes this alone would eliminate about 15 percent of all cancer deaths

4 The nature of cancer is not yet fully known We know that human cancers are caused by certain chemicals, by certain types of radiation, and probably by viruses The precise mechanisms by which these carcinogenic agents cause, or interact to cause, cancer is not known, and very little is known about the natural defense mechanisms that prevent cancer in some cases and not in others A great deal more must be learned about chemical carcinogens, radiation, and viruses, and how they work We must also learn more about what takes place at the cellular level when cancer occurs There is very strong suggestive evidence that viruses cause some human cancers, but which viruses, how they are transmitted, and how they operate are unknown It is erroneous to think of cancer as a single disease with a single cause that will be subject to a single form of immunization (as in the case of polio) or a single cure Cancer comprises many diseases and results from a variety of causes that will have to be dealt with in a variety of ways However, as our knowledge is expanded, more and more cancers will become preventable or curable

5 The cure rate for cancer is gradually improving In 1930 we were able to cure only about one case in five, today we cure one case in three, and it is estimated that the cure rate could be brought close to one in two by a better application of knowledge which exists today, i e detection at an earlier stage through the more widespread use of existing techniques (such as the Papanicolaou test for women and mammography), coupled with an extension to all citizens of the same quality of diagnosis and treatment now available at the best treatment centers There are three methods for curing cancer today surgery, radiation therapy, and chemotherapy Often two or even three of these methods are used in combination Some types of cancer are far more curable than others For example, early breast cancer treated by surgery, cancer of the cervix by radiation or surgery, and choriocarcinoma and Burkitt's tumor by chemotherapy, are among those most susceptible to cure today Treatment techniques are improving markedly, particularly in radiation therapy and chemotherapy, and more widespread availability of the best quality detection and treatment will give us more and more cures However, it is still true that those cancers which disseminate rapidly are seldom curable today, and this represents a major gap in our existing knowledge Where we stand today in our knowledge of the causes, nature, prevention, diagnosis,

treatment, and control of cancer is set forth in detail in part II of this report

6 There have been major advances in the fundamental knowledge of cancer in the past decade, and these advances in knowledge have opened up far more promising areas for intensive investigation than have ever heretofore existed These areas of special promise must be explored with vigor, if we are to exploit the great opportunities that lie before us They are examined in detail in part II of this report

Among the areas of special promise which must be aggressively pursued are

(*a*) The identification and study of the chemical, physical, and other environmental factors that cause cancer (food additives, air pollutants, industrial hazards, radiation, and other carcinogens),

(*b*) Viruses causing cancer (what viruses cause cancer, how are they transmitted, and how do they act),

(*c*) Cell and tumor biology (including cell surface phenomena, molecular functions, differentiation and genic expression, controls of cell division, mechanisms of metastasis, nutritional requirements and other biological factors),

(*d*) Immunology (host resistance against cancer, its nature, causes and therapeutic use),

(*e*) Epidemiology (the variables in cancer incidence and types stemming from geographic, social, economic, nutritional, occupational, and constitutional differences)

(*f*) Cancer prevention (more effective utilization of existing knowledge and intensified research on preventive measures),

(*g*) Diagnosis (the development of new and improved diagnostic techniques),

(*h*) Chemotherapy (the development of new and better drugs and improvement in their uses),

(*i*) Radiotherapy (development of new and better techniques and apparatus for radiation therapy),

(*j*) Surgery (the best techniques in cancer surgery coupled with earlier diagnosis must be made generally available in order to further increase the cure of cancer Better rehabilitation techniques must be further developed and utilized to return the cancer patient to an active and full life),

(*k*) Combinations of treatment modalities (improvement in treatment results by better combinations of surgery, radiotherapy, chemotherapy, and immunotherapy)

7 A national program for the conquest of cancer is now essential if we are to exploit effectively the great opportunities which are presented as a result of recent advances in our knowledge However, such a program will require three major ingredients that are not present today

First, effective administration with clearly defined authority and responsibility,

Second, the development of a comprehensive national plan for a coherent and systematic attack on the vastly complex problems of cancer Such a plan would include not only programmatic research where that is appropriate, but also major segments of much more loosely coordinated research where plans cannot be definitively laid out nor long-range objectives clearly specified, and

Third, the necessary financial resources

At the present time there is no coordinated national program or program plan 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 three foregoing elements are considered separately in more detail in the succeeding paragraphs 8, 9, and 10

8 *Administration*—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 Obviously, from many standpoints it can be argued that any cancer program should be in the Department of Health, Education, and Welfare and indeed that it should be in the National Institutes of Health However, there is real doubt whether the kind of organization that is required for this program can in fact be achieved within the National Institutes of Health or within the Department of Health, Education, and Welfare Apart from the question of whether it can be done, there is also the question of whether it would be wise to require the Secretary of Health, Education, and Welfare to attempt to give cancer the priority necessary to carry out the congressional mandate in a department charged with the multiple health and other responsibilities of that Department

In the past when the Federal Government has desired to give top priority to a major scientific project of the magnitude of that involved in the conquest of cancer, it has on occasion, with considerable success, given the responsibility for the project to an independent agency Such an agency provides a degree of independence in management, planning, budget presentation, and assessment of progress which is difficult if not impossible to achieve in a large government department Accordingly, if the Congress and the administration are truly committed to making the conquest of cancer a "national crusade", as expressed in the concurrent resolution of the Congress it is the view of the Committee that a National Cancer Authority should be established whose mission is defined by statute to be the conquest of cancer at the earliest possible time All the functions, personnel, facilities, appropriations, programs, and authorities of the National Cancer Institute should be transferred to the National Cancer Authority The Authority should be headed by an Administrator appointed by the President with the advice and consent of the Senate, and he should report directly to the President and present his budgets and programs to the Congress In considering the feasibility of an independent agency, it should be borne in mind that we are talking about a major scientific program and, as pointed out in subsequent paragraphs, not the delivery of patient care generally in cancer cases The only patient care involved in this program will be that associated with clinical research and teaching and the development and demonstration of improved methods in the de-

livery of patient care undertaken as a part of the comprehensive program plan

The powers of such a National Cancer Authority should be very broadly defined in order to accomplish a mission of this complexity It would not be useful to attempt to enumerate here all the powers that such an Authority should have and in the writing of the implementing legislation, the Committee believes that the powers should be broadly defined and not enumerated However, the following are illustrative of the kinds of powers which the National Cancer Authority will have to be able to exercise in order to carry out a comprehensive program of the type envisaged

(*a*) The power to enter into prime contracts with authority in the prime contractor to enter into subcontracts,

(*b*) The power to commit available funds until expended rather than on a year-to-year basis,

(*c*) The power to authorize exceptions to existing regulations, where necessary, to permit the use of experimental drugs, biologicals, and devices in cancer research,

(*d*) The power to establish or support the large-scale production of specialized biological materials for cancer research, such as viruses, cell cultures, animals, and the like, as well as the power to set standards of safety and care for those using such materials,

(*e*) The power to support research outside the United States by highly qualified foreign nationals, collaborative research involving American and foreign participants, and training of American scientists abroad and foreign scientists in the United States, to the extent that such activities will promote the accomplishment of the mission The Committee believes that cancer research offers a particularly fruitful field for collaboration with other nations, including those nations with whom present cooperation is limited but with whom greater collaboration is desired,

(*f*) The power to fund by loan, grant, contract, or otherwise any facilities or programs, or to take such other actions, as may be required for the accomplishment of the mission

9 *Program plan*—A comprehensive national plan for the conquest of cancer should be developed as promptly as possible The development of a coherent overall program plan should include the following features

(*a*) The present research activities now being carried forward under the National Cancer Institute should in no way be impeded or interrupted while plans are being made for the expansion, intensification, and coordination of the cancer research program,

(*b*) Existing research facilities and manpower should be used as promptly as possible for the accelerated exploitation of the opportunities in the areas of special promise There is substantial unused capacity in this country today that should be utilized in order to attract and retain the manpower that is needed It is a myth that we could not spend effectively on cancer very much more than is now being spent The fact that Federal support for cancer research has leveled off since 1967 and that, due to inflation, the actual amount of work done has decreased has created a serious gap between what we are doing now and what we could and should be doing in cancer research It is estimated that current expenditures could be doubled within the framework of the existing facilities and manpower potential of this country

today, exclusive of the great industrial research capability in this field which should be brought to bear on an appreciable scale in high priority areas to which this type of capability is particularly suited

(*c*) Existing cancer centers should be strengthen and additional cancer centers in different parts of the country should be created The solution of the cancer problem lends itself to a multidisciplinary effort, where teams of highly qualified specialists are available to interact on problems of research, both clinical and nonclinical, teaching, diagnosis, preventive programs, and the development of improved methods in the delivery of patient care, including rehabilitation Among those who work in the cancer field, there is great emphasis on the advantages of critical mass—a critical mass of scientists and physicians committed to the cooperative solution of the cancer problem, of research facilities, of patients, and of financial and other resources This is simply another way of saying that the comprehensive cancer center offers the best organizational structure for the expanded attack on cancer 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 new centers should have appropriate geographic distribution and should, wherever possible, be created where a nucleus of scientific, professional and managerial personnel already exists and preferably where a university or a medical school affiliation exists or is planned

In the creation of new cancer centers, manpower limitations should be taken into account, and new centers should not be created where there would be a dilution in the effectiveness of existing centers which would offset any gain from the new center There should be a realistic operating plan for each new center which assures the scientific and managerial commitment and ability necessary to the creation and operation of a successful center

It should be emphasized that the strengthening of existing cancer centers and the creation of new cancer centers does not mean that under this program general responsibility should be undertaken for the care of the Nation's cancer patients The delivery of patient care in cancer cases is a part of the general problem of the delivery of patient care and should be so dealt with However, this inhibition must not prevent the cancer centers from including such patient care facilities as are necessary for clinical research and teaching and for the development and demonstration of the best methods of treatment in cancer cases

(*d*) The cancer centers should also serve as administrative coordinators of those programs which require regional coordination Such centers should support and assist clinics and community medical centers in their own geographic areas in order to assure the widespread use of the best available methods for early detection and treatment of cancer They should also serve to collect data useful in the prevention and cure of cancer, including patient follow-up information, and be responsible for the dissemination of information, both at the lay and professional levels, that is useful in the prevention, diagnosis and cure of cancer The effective dissemination and utilization of such information is a most important part of any national plan to conquer cancer

(*e*) A national plan of the type envisaged must take account of the manpower requirements for this effort There is a critical need for

training and career opportunities for young scientists, physicians, and other personnel in this program We must reaffirm to young investigators our confidence in the future of American science and in our national dedication to success in the conquest of cancer A manpower program in this field should include training stipends, predoctoral fellowships for particularly promising candidates, postdoctoral fellowships for brilliant investigators, and career positions where appropriate through career initiation awards, career development awards, and senior career awards

(*f*) A national plan for the conquest of cancer should provide for the generous use of grants as well as contracts and other methods of funding There should be increased emphasis on the grants mechanism in order to stimulate continued independent exploration, particularly in those areas where knowledge is not sufficiently mature for a coordinated program aimed at reaching defined objectives

(*g*) A comprehensive national program requires optimum communication and centralized banks of information There must be an accurate and prompt information flow in both directions This will call for integrated data processing, storage, and retrieval in order to rationalize the decision-making and to make information available when and where needed As indicated above, the centers can be important foci in both the collection and dissemination of this information

(*h*) A coordinated national program plan should, to the greatest possible extent, be generated by the voluntary productive interaction and joint planning of the scientists who will be responsible for doing the work The program should not be the result of the happenstance of a multitude of random decisions independently arrived at An integrated and coherent plan resulting from the joint effort of representative scientists who will be responsible for its execution is fundamentally different from the hierarchical imposition or direction of a research program from above However, the effective use of collective planning does not mean that centralized administration or management of resources should be sacrificed

10 *Funding*—The Committee estimates that a coordinated national program aimed at the conquest of cancer at the earliest possible time, as envisaged by the concurrent resolution of the Congress, would require an appropriation in fiscal 1972 of approximately $400 million Thereafter, the cost of the program would increase at the rate of approximately $100 to $150 million per year, reaching a level of $800 million to $1 billion in 1976 These sums are not large in terms of our national resources or of the human suffering and economic loss attributable to cancer A program of the type herein recommended is so important to the American people and to the world that we feel that the amounts called for should be provided even if this necessitates the raising of additional revenues It is of utmost importance that the financing of this program not result in cutbacks in other health programs

11 *National Cancer Advisory Board*—Both the public and the scientific community must be effectively represented in this effort, and must have a part in its planning as well as its execution To this end, a National Cancer Advisory Board should be created with 18 members, nine of whom are distinguished scientists and doctors in the field of cancer, and nine of whom are distinguished laymen The members should serve for a term of 6 years with the terms of one-third of the

members expiring every 2 years Members of the Board should be appointed by the President of the United States with the advice and consent of the Senate The Chairman of the Board should be elected by the members and should serve for a term of 2 years The Board should meet not less than once each quarter and its function should be to advise and assist the National Cancer Authority and its Administrator in the development and execution of the program The Administrator should be an ex-officicio member of the Board The Board should have statutory responsibility for the approval of each year's program plan and budget, but the responsibility for administering the program should rest with the Administrator The Board should have full investigatory powers and should be required to report once each year to the President and the Congress on the progress of the National Cancer Authority in the accomplishment of its mission This Board should supersede the presently existing National Advisory Cancer Council, and the members of that Council should serve as additional members of the National Cancer Advisory Board for the duration of their present terms

12 Cancer is an implacable foe and the difficulty of eliminating it as a major disease must not be underestimated A top priority commitment by the Congress, the President, and the American people is required if we are to mount and sustain an assault on cancer of the magnitude envisaged by Senate Resolution 376 and the concurrent resolution of the Congress Such a commitment involves a recognition not only of the difficulty and complexity of cancer but also of the time and resources required to attack it effectively While it is probably unrealistic at this time to talk about the total elimination of cancer within a short period of time or to expect a single vaccine or cure that will eradicate the disease completely, the progress that has been made in the past decade provides a strong basis for the belief that an accelerated and intensified assault on cancer at this time will produce extraordinary rewards The Committee is unanimously of the view that an effective national program for the conquest of cancer should be promptly initiated and relentlessly pursued

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DIVISION OF RESEARCH GRANTS

NATIONAL INSTITUTES OF HEALTH

LIST OF STUDY SECTIONS AS OF JULY 1, 1970

1. Allergy and Immunology Study Section
2. Applied Physiology Study Section
3. Arthritis and Metabolic Diseases Program-Project Committee
4. Bacteriology and Mycology Study Section
5. Biochemistry Study Section
6. Biomedical Communications Study Section
7 Biophysics and Biophysical Chemistry A Study Section
8. Biophysics and Biophysical Chemistry B Study Section
9. Cardiovascular A Study Section
10. Cardiovascular B Study Section
11. Cell Biology Study Section
12. Communicative Sciences Study Section
13. Computer and Biomathematical Sciences Study Section
14. Dental Study Section
15. Developmental Behavioral Sciences Study Section
16. Endocrinology Study Section
17. Epidemiology and Disease Control Study Section
18. Experimental Psychology Study Section
19. General Medicine A Study Section
20. General Medicine B Study Section
21. Genetics Study Section
22. Hematology Study Section
23. History of the Life Sciences Study Section
24. Human Embryology and Development Study Section
25. Immunobiology Study Section
26. Medicinal Chemistry A Study Section
27. Medicinal Chemistry B Study Section
28. Metabolism Study Section
29. Microbial Chemistry Study Section
30. Molecular Biology Study Section
31. Neurology A Study Section
32. Neurology B Study Section
33. Nutrition Study Section
34. Pathology A Study Section
35. Pathology B Study Section
36. Pharmacology A Study Section
37. Pharmacology B Study Section

38. Physiological Chemistry Study Section
39. Physiology Study Section
40. Radiation Study Section
41. Reproductive Biology Study Section
42. Surgery A Study Section
43. Surgery B Study Section
44. Toxicology Study Section
45. Tropical Medicine and Parasitology Study Section
46. Virology Study Section
47. Visual Sciences Study Section

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