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P.O. Box 2370 Reston, Virginia 22090 Telephone 703-620-4646

HOUSE SUBCOMMITTEE VOTED $1.011 BILLION FOR NCI 1981 FISCAL YEAR BUDGET IN CLOSED DOOR MEETING

Some good news and some bad news was leaked from the super secret closed markup session of the House Labor-HHS Appropriations Subcommittee last week:

* Good news—The subcommittee ignored President Carter's attempt to fight inflation by slashing $42.7 million from his no-increase request of $1 billion for NCI in the 1981 fiscal year budget.

* Bad news—The subcommittee increased NCI's appropriation by only $11 million over the FY 1980 amount of $1 billion.

An optimist could say that the subcommittee, chaired by William Natcher (D.-Ky.), thus added more than $50 million to the President's

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In Brief

OLDHAM TO HEAD BIOLOGICAL RESPONSE MODIFIERS PROGRAM; WALTER, NAMOVICZ NAMED ACTING HEADS

ROBERT OLDHAM, director of the division of oncology at Vanderbilt Univ., will be the director of NCI's Biological Response Modifiers Program. Oldham will start work in late October or early November with the program, which will include supervision of NCI supported interferon development and testing. . . . **WILLIAM WALTER,** for many years deputy director of NCI's Div. of Extramural Activities and its previous incarnations, is acting director of the division with the departure last week of Thomas King. . . . **ROBERT NAMOVICZ,** who has been Executive Officer Calvin Baldwin's deputy, is acting EO now that Baldwin has moved on to NIH headquarters. . . . **ANN BLUES** has resigned as deputy director of the Ephraim McDowell Community Cancer Network in Kentucky to accept a position with the Oregon Comprehensive Cancer Program. . . . **MICHIGAN CANCER** Foundation staff changes: Marie Swanson to chairman of the department of social oncology and assistant director for medical research; Sharon Klein to chairman of patient and family care; and Joy Harsen to head of the cancer prevention section. . . . **LEUKEMIA PATHOPHYSIOLOGY** concepts is the theme of the Leukemia Society of American annual symposium scheduled for Oct. 24 at the Shamrock Hilton in Houston. Kenneth McCredie is chairman. For registration information, call 713-792-2222. . . . **SEVENTH LATIN** American Cancer Congress will be held in Sao Paulo, Brazil, May 10-15, 1981. It will include the Latin American Chemotherapy Congress. Charles Sherman of the Univ. of Rochester Medical Center, is U.S. liaison. Contact him at the center, 160 Elmwood Ave., Rochester, N.Y. 14642. . . . **MEDICAL COLLEGE** of Virginia started construction this week of a $4.1 million cancer center in Richmond. The new facilities will include space for 30,000 outpatient treatments a year. Additional space for research will be added when a drive under way to collect $1 million in private funds to pay for it is completed.

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NCI WOULD GET ONLY 8.7% OF TOTAL NIH INCREASE IN HOUSE SUBCOMMITTEE BILL

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amended budget request. The pessimist (and in this instance the realist) will point out that the subcommittee figure would increase NCI's budget by only 1 percent in a year in which inflation will be between 10 and 15 percent. A final appropriation of that amount would result in substantial cuts in many program areas, with the elimination of some.

The subcommittee, again departing from the usual practice for congressional appropriations subcommittees of marking up their bills in open sessions, excluded the public and press. The subcommittee sent out word that the marked up bill and accompanying report would not be released until they are presented to the full Appropriations Committee. That probably will not happen until after Congress reconvenes following the Democratic convention.

The Cancer Letter learned, however, that the subcommittee's figure for NCI is $1.011 billion, and that the total for NIH was placed at $126 million more than the 1980 appropriation.

NCI's portion of the total NIH increase is only 8.7 percent despite the fact that it accounts for more than one third of NIH expenditures and personnel. The subcommittee obviously continues to feel that the NIH budget is out of balance in favor of NCI.

That is contrary to remarks by Congressman David Obey, a powerful member of the subcommittee, at hearings earlier this year. Obey said that the President's budget did not allocate enough for NCI and the National Heart, Lung & Blood Institute in relation to the other institutes. That comment represented a major switch for Obey, the subcommittee's most outspoken critic of NCI.

If the full committee and the House allow the $1.011 billion figure to stand, that will become the floor for NCI's 1981 budget. The Senate Labor-HHS Appropriations Subcommittee will not proceed with its markup until the House committee acts, or perhaps not until House floor action. Since the National Cancer Program was established in 1971, the Senate always has added substantially to the House figure for NCI, last year increasing it by $60 million, to an even $1 billion. In previous years, House-Senate conferees split the difference. Last year Senate conferees held firm on NCI.

NCI's bypass budget request for 1981 was $1.167 billion. An action by the Senate similar to last year would add at least $100 million to the House figure. Even that would barely keep up with inflation.

DRCCA TO BE ORGANIZED INTO THREE PROGRAMS; CENTERS A BRANCH OF ONE

NCI's new Div. of Resources, Centers & Community Activities is still being organized into branches, but the eventual shape of the division is beginning to emerge.

The division includes all of the former Div. of Cancer Control & Rehabilitation, along with the cancer centers, construction, organ site and manpower training programs. Those activities will be grouped into three programs—Prevention, Detection & Diagnosis Program; Treatment, Continuing Care & Rehabilitation Program; and Research Resources.

Grouping of the various activities into branches and locating them in one of those three programs is still underway. DRCCA Acting Director William Terry said "it is fairly clear" at this point that cancer centers will be a branch, possibly located in the Treatment, Continuing Care & Rehabilitation Program.

The manpower training activities will be located for the present in Research Resources. However, consideration is being given to establishing a fourth program for training, or replacing Research Resources entirely with training.

Terry said the organization should be completed by the end of this month.

NCI TO FUND 23 CHOPs, MORE SINGLES THAN MULTIPLES; ACCC "CONCERNED"

NCI's Div. of Resources, Centers & Community Activities will fund 23 Community Hospital Oncology Program proposals—13 with single hospitals, nine with multihospital consortia, and one rural hospital.

The fact that more single than multihospital proposals will be funded, and that the total is less than 30, has aroused some criticism from the Assn. of Community Cancer Centers, which had strongly backed the program.

Robert Frelick, ACCC president, expressed that concern in a letter to NCI Director Vincent DeVita. Excerpts follow:

"As you know, the Association has been a major supporter of the CHOP program since its inception. When the program was first suggested before the DCCR advisory group, Dr. Charles Cobau, then ACCC's president, strongly endorsed the concept. When Congressman David Obey attempted to remove $17 million from the cancer control and construction budget (and which would have jeopardized CHOP's funding), we worked with Senator Bayh to assure its reinstatement. And, as you are no doubt aware, a large portion of the responses to the RFP came from ACCC's members.

"The concern of the membership is generated by several statements which suggest that:

"1. NCI will not fund the CHOPs out of 1980 money, but instead will spread out funding over a period of time.

"2. NCI may fund less than 30 programs.

"3. NCI is not taking into account that there were a large number of urban CHOP submissions and a

new category of potential CHOP models emerge (i.e., it was initially expected that CHOPs would be from isolated urban communities, like Grand Rapids; but in addition to those areas, a number were submitted from major metropolitan areas, thus creating a new category of CHOPs to be tested).

"4. Despite No. 3 above, NCI may actually fund more single hospital CHOPs than multihospital.

"Some congressional sources express concern that NCI may fund as few as 20 to 24 CHOPs, with far less than a dozen multihospital CHOPs receiving funding in the final analysis.

"If this is an accurate analysis, I believe that NCI will receive a negative image among communities despite its good intentions and, of course, the programs that it does intend to fund. This is for several reasons:

"First, much of the emphasis from NCI in the original RFP, the bidders conference and elsewhere was upon the multihopsital concept. Essentially, the RFP stated that a single hospital application was only acceptable if a multi-institution CHOP had been explored and was impossible to develop. Funding more single hospital CHOPs than multihospital flies in the face of all of NCI's very clear signals to emphasize the latter over the former.

"Second, many of the reviewers who participated in the CHOP review, while careful not to mention specifics, have made it clear that a large number of multihospital program applications were outstanding and many were excellent.

"Third, the investment of those individuals and institutions who developed multihospital programs was substantial, since as you are well aware, it is difficult for competitive health care institutions in the same community to cooperate.

"These three factors are likely to combine with the fact that far less than 30 programs are being funded and lead much of the community to several conclusions:

"1. NCI is not to be trusted and is relatively arbitrary in changing signals.

"2. NCI is ignoring the efforts of the community to ensure funding for community programs (especially our efforts to recover money Congressman Obey proposed to transfer from construction and control) and our many other efforts on behalf of the entire National Cancer Program.

"3. Most, if not all, of the unfunded programs will assume that they were among those to be funded if NCI had kept its commitment to fund 30 programs.

"These perceptions, although they may be inaccurate, could readily have a major effect on our ability to gain community cooperation in supporting the NCP in the years ahead.

"Therefore, the Board of Trustees and I hope you will investigate this matter and determine if these statements are accurate and what can be done to correct them.

"It may be that it is the intent of NCI to fund 30 programs and to do so in short order. If this is the case, I would suggest that the major concerns expressed by the community reflect their confusion over the long review process and lack of information on the outcome of the review. Obviously, many communities are not well aware of the review process. And, at the same time, when so many have built up strong community wide interest and impetus for this program, and when review is delayed, much of the original force of the effort is seriously impaired.

"Obviously the entire CHOP effort is a keystone in NCI's mandate to transfer technology to community settings and to improve cancer management at all levels, including the communities where 85 percent of cancer patients are treated. This is the basis of our concern over this issue."

DeVita's response, if any, was not available by press time. However, DRCCA Acting Director William Terry confirmed that 23 CHOPs would be funded and defended the decision to support 13 single, nine multiple and one rural programs.

The original goal of 30 was established in discussions with the Cancer Control & Rehabilitation Advisory Committee, Terry said, when it was agreed that from five to 10 in each of the three categories would be desirable to demonstrate the effectiveness of the programs. That range later was narrowed to eight to 10.

It developed that a large number of proposals was submitted in the single and multiple categories but only four from rural hospitals. The review committee determined that only one of the four could be funded.

The decision to fund nine and 13, respectively, of the multiple and single hospital proposals was based entirely on priority scores, Terry said. A gap between nine and 10 in the first, and between 13 and 14 in the second made those the logical breaking points.

The multiple hospital proposals competed only against each other, not with those from the single hospitals, Terry said. They were reviewed separately, and there was no way to compare them.

Funding 23, when the original goal was between 15 and 30 and later goal 24 to 30, is not breaking faith with the communities, Terry insisted, especially considering that the response from rural hospitals was so limited.

Terry said he could understand the argument that multiple hospital CHOPs might have more impact than the singles, since they involve more people and greater commitment of local resources and will cost NCI no more than the singles (about $450,000 over five years). But the program did not evolve with that emphasis and the RFP did not emphasize multiples, he pointed out. He did not comment on the "clear signals" Frelick said were given at the bidders' con-

ference.

The review was delayed because of the large number (more than 50) responses and the fact that the executive secretary of the review committee left that job midway through the process.

Terry said the delays would result in only some of the proposals being funded in the current fiscal year, which ends Sept. 30. Negotiations are still being carried on with some of the proposers. NCI also is up against the HHS restirction against jamming through contract awards in the fourth quarter. Those of the 23 not funded in this fiscal year will be funded after Oct. 1, Terry said.

INVESTIGATOR SAYS LYMPHOBLASTOID IF TEST SHOWS TOXICITY NOT FROM IMPURITY

Results of a phase 1 clinical trial of lymphoblastoid interferon in England has led the investigator who conducted it to conclude that toxic effects observed in the study "represent true properties of interferon rather than the action of non-interferon protein impurities."

The study did produce partial tumor regression in two patients which justify further trials to define the extent of anticancer activity, the investigator said.

T.J. Priestman reported on the study in the July 19 issue of *Lancet.* He is with the department of radiotherapy and oncology at Westminster Hospital in London. The human lymphoblastoid interferon was supplied by Wellcome Research Laboratories.

The sometimes severe toxic effects observed in the early studies with leukocyte interferon supported by the American Cancer Society might be attributed, some investigators felt, to impurities in the material they were using. Priestman no longer thinks so.

"In the studies with leukocyte IF," he wrote, "the specific activity of the material was of the order of 1 x 10^6 units IF per mg protein and it has been suggested that the pyrexia, malaise and myelosuppression seen with the preparation might be due to non-IF protein. The human lymphoblastoid IF used in this series was at least 20 to 50 (sic) more pure than the leukocyte IF.

"The fact that the toxic effects of leukocyte and lymphoblastoid IF are so similar, at equivalent doses, although the materials were prepared from different sources and such difference in purity, suggests that these effects represent true properties of IF rather than the action of non-IF protein impurities."

The aims of Priestman's study were to establish the maximum tolerated dose of human lymphoblastoid interferon and to define its side effects when given by intramuscular injection. Pyrexia limited the initial dose to a maximum of 3 mega units per m^2 body surface area but tolerance to that effect developed over four to five days and the dose was increased to 5 to 7.5 mega units per m^2. Subjective disturbance prevented further escalation but a dose of 2.5 to 5 mega units per m^2 daily was well tolerated and appears suitable for long term administration, Priestman said. Other side effects were hypertension, hypotension, myelosuppression and disturbance of liver function tests. All toxic effects were reversible on stopping the interferon.

The two patients in which remissions were seen (one with malignant melanoma, the other with inoperable carcinoma of the stomach) experienced significant tumor regressions—more than 50 percent in the melanoma patient, and a reduction from 15 cm to 10 cm of the stomach tumor.

"Both remissions were short lived, indicating that longer term treatment is necessary to sustain a response," Priestman wrote. "Further studies are needed to define the spectrum and degree of that activity and to determine the role of IF in relation to presently available treatments."

Lymphoblastoid interferon, unlike the leukocyte variety, can be produced in large quantities, as can fibroblast IF. Wellcome has bet on lymphoblastoid as being at least the equal in effectiveness of leukocyte and superior to fibroblast, and has developed production facilities to back up that bet.

Meanwhile, a California firm—Genentech Inc.—in partnership with Hoffmann-La Roche, has announced that it will be capable of producing large quantities of interferon within a year with recombinant DNA techniques. Also, the Swiss firm, Biogen, partially owned by Schering-Plough, plans to start pilot plant production of recombinant DNA interferon. Previous estimates of the timetable for significant production by recombinant DNA was four to five years.

NCI CONTRACTS CUTBACK RESULTED IN CANCELATION OF SEVEN RFPs

When NCI decided to slash $6.5 million from the FY 1980 contracts budget and move it to cancer center core, program project and R01 grants (***The Cancer Letter,*** June 27), it resulted in the cancelation of seven RFPs which had already been issued. Some had generated proposals which went through the review process, and one had been carried through to the signing of the contracts.

A major portion of the $6.5 million came from the cancelation of programs which had not yet reached the RFP stage. Those RFPs which were released and canceled were:

—Nutritional and other in vitro requirements—human epithelial cell cultures. Canceled before the due date, but several proposals had been submitted. Diet, Nutrition & Cancer Program.

—Support services for the clinical studies section, LVC. Proposals received and reviewed. Div. of Cancer Cause & Prevention.

—Hydroponic cultivation of plants. Canceled be-

fore due date, several proposals received and returned. Div. of Cancer Treatment.

–Systematic evaluation of fungi. Canceled before due date, several proposals received and returned. DCT.

–Hormone receptors in endometrial carcinoma. Proposals received, reviewed, selections made and contracts signed by the contractors. DCT.

–Pathology continuing education in breast, cervical and colorectal cancer. Proposals received, reviewed, selections made but negotiations not completed. Div. of Cancer Control & Rehabilitation.

–Oncology rehabilitation nursing training. Proposals received and reviewed. DCCR.

OBEY SAYS "NCI MUST DO BETTER;" RESPONSE DISPUTES GAO CONCLUSIONS

Congressman David Obey, who had requested the General Accounting Office to investigate NCI's Cancer Control Program, said in a news release issued when the GAO report of its investigation was made public that "the National Cancer Institute must do better."

NCI responded in detail to the GAO report, challenging most of the adverse conclusions and disputing some of the material presented as facts.

Obey's news release and NCI's response follow:

Congressman Dave Obey (D.-Wisc.), today released a report by the General Accounting Office indicating significant problems exist in the operation of the nation's Cancer Control Program.

The GAO which at Obey's request examined the objectives of the program and five major contracts operated under the program found that the objectives of the program were unclear and that serious deficiencies existed in the awarding and the management of four of the five contracts.

GAO found that the benefits from three of the five contracts were considerably less than expected.

The Cancer Control Program is a $70 million-a-year effort contained within the National Cancer Institute at the National Institutes of Health. Federal health research funding is one of the areas under the jurisdiction of the Appropriations Subcommittee on Labor, Health, Education and Welfare on which Obey serves.

"I think this report leaves little doubt that those involved in decision making on cancer control both in Congress and in the executive branch have not had a clear idea of what they specifically expect to achieve with this $70 million-a-year expenditure. Few Americans would argue that any other program of the federal government deserves a higher priority for tax dollars than controlling cancer but the more dollars that are wasted or poorly targeted the fewer dollars that are effectively fighting cancer," Obey said.

"I can't be certain that the five contracts reviewed are representative of all contracts and consulting work being performed by the Cancer Control Program. It would be prohibitively expensive to have auditors do this type of detailed analysis on all or even a large sample of the contracts and consulting fees being awarded and managed under the Cancer Control Program. However, it is certainly disconcerting to see four of the five contracts reviewed handled in such a sloppy manner and the benefits of three of these five contracts being– according to GAO–'substantially less than expected,'" he stated.

Of the $301 million allocated for the Cancer Control Program during the last five fiscal years, about $216 million (72 percent) was obligated for contracts. The five contracts reviewed amounted to about $10.3 million.

Failings in the award and management of the contracts included:

Failure by NCI and its contractors to fully develop plans for the projects before contracts were awarded.

Failure to amend project plans when major changes in the nature of the work being performed under the contract were made.

Failure to revise the project plan when the cost of the contract was significantly altered.

Failure to take action on deficiencies in contract work identified by official review groups.

Failure to require contractors to complete tasks under the terms of the contract.

Failure of contractors to accomplish tasks specified in the contract.

"The GAO interviewed the chairman of the Cancer Control Merit Review Committee who told the GAO he believes problems similar to the ones found exist in about 50 percent of the national cancer control contracts," Obey said.

Obey said the Cancer Control Program is not involved directly in finding cures for cancer but in transferring information about new means of cancer treatment and cancer prevention once they become available.

"We have several problems with the transfer of knowledge that I think the Congress must consider when it decides how much money to allocate to this area and how much to allocate to learning more about cancer and how to treat it and prevent it," Obey said.

"First, because we have made less progress in developing effective new forms of treatment than we originally expected, there is less information to transmit. The former director of this program indicated to my subcommittee that a major mission of the program has in fact become the prevention of the situation where new forms of treatment are transferred into general use before they are proven to be relatively safe and effective," he said.

"Secondly, new methods of treatment and information about cancer treatment seem to disseminate through the medical community rather quickly without the involvement of the Cancer Control Program. The report indicates that it is difficult for the government to retain physicians at current wage schedules who have the technical competence to intervene in the highly complex issues of what treatments are appropriate for use by the highly skilled and paid practitioners in the field of cancer treatment. It is questionable, given the low probability that these wage schedules will change, whether the government should continue to allocate such large sums of money for this purpose," Obey continued.

"Finally, the report indicates that much of the money spent on the contracts reviewed by the GAO was wasted on silly and ill-conceived notions. For example, money was provided in New York and other states to demonstrate the use of Pap tests for low-income individuals. Year after year after year NCI demonstrated and continued to demonstrate those Pap tests despite the fact that the Cancer Institute and the Cancer Control Program are not supposed to be involved in the delivery of health services. More importantly, the services that were being provided were already available under the states' medicare program at a considerably lower cost. Yet, there was no effort made to evaluate the 'demonstration' and to see that it was either terminated if a failure or converted into an ongoing and non-NCI supported part of the health care delivery system in the state if it were successful," he explained.

"What makes this whole report particularly damaging is that it comes on top of an earlier GAO report, an HEW Inspec-

tor General's investigation and a House Appropriations Committee Surveys and Investigations report all finding much the same thing at NCI," Obey noted.

"Cancer is a terrible disease," he concluded, "and the Congress must guarantee to the taxpayers that we are getting the best efforts our tax dollars can buy to prevent it, to treat it and to cure it. Too much of the money spent by the Div. of Cancer Control and Rehabilitation does not fit that requirement. The National Cancer Institute must do better."

NCI RESPONSE TO THE GAO REPORT ON THE CANCER CONTROL PROGRAM

Summary of Issues and NCI Response

This is a response to the undated draft of a proposed report to Representative David R. Obey entitled "Cancer Control Program—The Congress Should Examine Its Objectives and HEW Should Investigate Its Contracting Practices," which was received by the National Cancer Institute on February 11, 1980. On February 14, NCI staff had the opportunity to discuss this draft report with the General Accounting Office staff. This response summarizes points raised during those discussions and adds some additional information.

NCI disagrees with many of the interpretations, "facts" and conclusions, and all of the recommendations of the Feb. 11 draft report.

The report states that the premises upon which the legislation establishing the Cancer Control Program was based were incorrect, that NCI has modified the mission of the program without fully explaining this to Congress, and that GAO therefore recommends that Congress redetermine what the objectives of the Cancer Control Program should be and what level of effort is needed to accomplish the Program's objectives.

NCI contends that the premises upon which the Cancer Control Program legislation was based were correct in 1971 and continue to be correct in 1980, that the mission of this program has not been modified except at the specific direction of Congress. Also, NCI contends that Congress, the President's Cancer Panel, the Presidentially appointed National Cancer Advisory Board, have been kept fully informed about this program and its resources and, therefore, oversight hearings are unnecessary. It should be noted that NCI proposes to increase the emphasis on applied prevention activities within the Cancer Control Program in future years. This will be a shift in emphasis within the mandate of cancer control but will not be a modification of mission.

The report further stated that the five cancer control contracts reviewed revealed improper and weak administration in awarding and monitoring practices; that NCI did not include provisions in contracts requiring the contractor to encourage or assist localities to continue projects after federal funding ceased; that the deficiencies in contract administration were believed not to be limited to the five contracts reviewed; and that, therefore, the secretary of HEW should require the Inspector General to conduct a review of NCI's administration of cancer control contracts in order to determine if there are program-wide problems.

NCI contends that the five contracts reviewed by GAO represent approximately 1.5 percent of the cancer control contracts and that the contracts were not selected at random and cannot be taken as a representative sample; that these five contracts were initiated more than 4½ years ago and therefore are not representative of recent or current contract practices; that there is no federal rule or regulation that requires contractors to encourage or assist in the continuation of projects after federal funding stops and therefore NCI does not include a provision to this effect in all demonstration project contracts; that any contract administration problems described are not representative of recent or current contract procedures and do not take into account either the large number of substantial changes in contracting practices that have been introduced in the past several years or rational explanations for situations that were described by the GAO as deficiencies; and that, therefore, there is no need for the Inspector General to conduct a special review of NCI's administration of cancer control contracts.

The report also stated that staff available for the Cancer Control Program has not kept pace with increased program funding.

NCI agrees with this observation, but contends that it is representative of a larger NCI problem in which funding (including cancer control funding) has increased from $699 million to $937 million in the past five years, while authorized personnel ceilings have remained essentially level (1,889 to 1,915). This overall pattern, which was acknowledged in the GAO report, causes problems for the entire National Cancer Program, not just for the Cancer Control Program.

The report finally stated that the Div. of Cancer Control & Rehabilitation, NCI, had acted to implement recommendations made by policy advisors.

NCI is pleased to acknowledge this observation.

1. The Cancer Control Program was founded on an incorrect premise and program officials and advisors agree there weren't many unused research advances

The GAO report alleged that the Cancer Control Program was established ". . . to rapidly transfer research advances to general medical use" and that ". . . the thinking of scientists and Congress was that serious delays existed in putting the advances into practice. Medical experts estimated that once these existing advances were put into use and all cancer patients received the same level of care, about 50 percent of all cancers could be cured. However, the premise that many advances existed but were not being used proved incorrect." The implication of this statement is either that scientists testifying before Congress were misinformed or that they intentionally misrepresented the facts to Congress, but that in either case, Congress was misled and passed inappropriate legislation.

The statement projecting that "about 50 percent of all cancers could be cured" was quoted numerous times in the GAO report. It is therefore important to provide the complete quotation from the report of the National Panel of Consultants on the Conquest of Cancer, 1970. Recommendation 5 states, "The cure rate for cancer is gradually improving. In 1930 we were able to cure only about 1 case in 5; today we cure 1 case in 3; and it is estimated that the cure rate could be brought close to 1 case in 2 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." This statement is quite accurate and not misleading. The facts indicate that the cure rate of 33 percent in 1970 has improved to better than 40 percent in 1977 (the last year for which figures are available). Thus, the cure rate has been brought closer to 50 percent and there is no reason to believe that the cure rate will not continue to improve. It should be noted that this has been accomplished without ". . . an extension to all citizens of the same quality of diagnosis and treatment now available at the best treatment centers."

As further evidence that the information presented by the Panel of Consultants was appropriately cautious, it is worth quoting another portion of the report: "Because of these new possibilities, a number of different specific approaches are becoming recognized that make cancer control conceivable. The variety of these promising approaches affords confidence that at least some of them will prove successful. Present research cannot promise a single miraculous breakthrough. It is more

likely to lead to progressive improvements over a number of years. Effective control will be achieved for increasing numbers of particular forms of cancer—as indeed it has already been for a few of them—before it will become a reality for all."

It also must clearly be stated that there were research advances available in 1971 that had not effectively been put into practice. As examples, one can cite the following:

Prevention. The research advance was the identification of cigarette smoking as a major cause of lung cancer. The effective application of that knowledge had not occurred in 1971 and, although progress has been made, considerably more must be done to decrease cigarette smoking now so that the 125,000 cancer deaths annually attributed to cigarette smoking can be decreased in the future.

Detection. The research advance was the development of exfoliative cytology which made possible early detection of cervical cancer. The effective applicaiton of that research advance had not occurred in 1971 and, although progress has been made since then, approximately 7,500 women still die each year from invasive carcinoma of the cervix, a disease whose incidence could be sharply curtailed.

These are just two of the advances to which the Panel of Consultants referred. The issue was not whether there were advances that weren't being used at all as was implied in the GAO report. Rather, the issue was whether cancer could be controlled through better information dissemination and demonstration of research advances that were being applied, but being applied ineffectively. Congress acknoweldged this issue in House Report 92-659, page 24 (1971) where the report of the House Committee on Interstate & Foreign Commerce contains the following explanation of the control legislation: "Cancer Control Programs. The Committee was very disturbed to find in its study of the cancer problem that identifiable funding for cancer control programs ceased with fiscal year 1970, and that a number of the activities previously supported through these programs have in one way or another been terminated or allowed to lapse. Disease control programs in cancer and other areas have long been a part of the public health scene, and their importance is incontrovertible, for they are a means of bringing into general medical applications the most practical fruits of research in terms of improved methods of treatment and control. Especially when a major national effort is being mounted to develop new cancer knowledge, it seems ill advised if not irresponsible to eliminate any useful means for speeding that new knowledge to application for the benefit of the public." Further, the committee report states, "Accordingly, in order that states and other public or nonprofit agencies can once again receive funding for cancer control activities, the committee has inserted in its bill authority for the Director of the National Cancer Institute to 'establish programs in the prevention, control, and eradication of cancer'; and has included specific authorizations to help make sure that these funds intended to help in the attack on cancer are not diverted."

NCI concludes, therefore, that Congress established cancer control legislation on correct premises, that there were research advances that required dissemination in 1971, that there are research advances that require dissemination in 1980 and we anticipate additional research advances that will require dissemination as long as there is a National Cancer Program.

The GAO report further alleged that the former director of DCCR, NCI, considered premature application of cancer technology a more significant problem than lags in transferring technology. The former director disagrees with this interpretation of her comments, which were only intended to indicate that premature or inappropriate application is **also** a problem and that the Cancer Control Program must address this problem to assure optimal and safe technology transfer.

The report alleged that the "control program was modified to focus on supporting projects to prevent the premature application of technology and also to promote technology aimed at an early detection of cancer. Thus, NCI has adjusted the basic mission of the Cancer Control Program authorized by the Congress." NCI believes that the mission to foster technology transfer certainly implies that only appropriate technology should be transferred and that information disseminated to the public and the health profession must help them to distinguish appropriate from inappropriate technology. Congress has made this explicit in the amendments to the Community Mental Health Centers Act, 1978, where the cancer control legislation was significantly modified and where the legislation states in part: that "Programs established and supported under this section shall include: . . . 2. the demonstration of and the education of health professionals in (A) effective methods for the early detection of cancer and the identification of individuals with high risks of developing cancer . . . 3. the demonstration of new methods for the dissemination to the general public concerning the early detection and treatment of cancer and information concerning unapproved and ineffective methods, drugs, and devices for the diagnosis, prevention, treatment and control of cancer."

Moreover, Congress affirmed its intention that "early detection of cancer" was mandated under the Cancer Control Program when it specifically amended the legislation in 1974 to state "The director of the National Cancer Institute shall establish programs as necessary for cooperation with state and other health agencies in the diagnosis, prevention, and treatment of cancer, including programs to provide appropriate trials of programs of routine exfoliative cytology tests conducted for the diagnosis of uterine cancer."

In summary, there has been no modification in the focus of the Cancer Control Program, and NCI has not adjusted the basic mission. Congress has been fully informed, as evidenced by discussions of the Control Program in the House Reports of 1971, House, Senate and Conference Reports of 1974, House and Senate Reprots of 1977, and the House Report of 1978.

2. Advisors have mixed opinions on the Cancer Control Program and its future

GAO discussed this matter with the former chairmen of the President's Cancer Panel, the Cancer Control & Rehabilitation Advisory Committee, and the Cancer Control Merit Review Committee, and also with the current chairmen of the National Cancer Advisory Board and the Cancer Control & Rehabilitation Advisory Committee. The responses were supportive of the program and "four of the five said the Cancer Control Program was worthwhile and should be continued." One of these advisors, the former chairman of the Cancer Control Merit Review Committee is quoted in the report as saying that ". . . the program had accomplished little that the medical community would not have done anyway and had not increased the body of knowledge needed to control cancer." Subsequent conversations with the former chairman indicate that what he intended to convey was that the control program focused on diagnostic and treatment procedures that were already being performed and that the program helped disseminate them more rapidly. He feels that for at least some of these procedures, dissemination would have happened anyway, "sooner or later." NCI contends that this statement confirms that the program was doing what it was supposed to do, namely, identifying effective diagnostic and treatment procedures and accelerating their dissemination into general medical application.

In response to a request for a listing of significant accomplishments of this program, NCI provided a list of 57 items, four of which were included in the GAO report. The items

selected by GAO are not representative of the major program accomplishments.

3. Cancer Control Program's effect has never been evaluated

The program itself has been evaluated by the Cancer Control & Rehabilitation Advisory Committee and also by the National Cancer Advisory Board in 1978. The GAO report is correct, however, in indicating that the congrol program's effect has not been evaluated. NCI maintains that the National Cancer Program is an integrated effort including the control program and a quantitative evaluation of the impact on morbidity or mortality of one segment of the program is not possible without considering the entire program. For example, a decrease in mortality from lung cancer could result from decreased incidence due to decreased smoking attributable to the control program, and/or from earlier diagnosis due to improved cytology techniques developed by the diagnosis program of the Div. of Cancer Biology & Diagnosis, and/or improved chemotherapy or radiotherapy developed by the Div. of Cancer Treatment program. It is almost impossible to single out a segment of the NCP and evaluate the effectiveness of its efforts to reduce morbidity and/or mortality without evaluating the entire NCP.

CONCLUSION

NCI contends that:

* Congress authorized the Cancer Control Program to accomplish an appropriate objective.
* Congress has supplied resources appropriate to this objective.
* NCI has used the resources to address that objective.
* NCI has not used the resources to address objectives other than those authorized by Congress.

Congress has periodically and systematically exercised its right to be informed concerning the past performance and future direction of the Cancer Control Program.

NCI considers, therefore, that there is no need for Congress to hold additional hearings to again decide on objectives of the Cancer Control Program or the level of effort needed to accomplish those objectives.

The main thrust of this enclosure of the GAO report is that the NCI Research Contracts Branch and Div. of Cancer Control & Rehabilitation have performed poorly with regard to initiation and management of contracts and that this performance was so poor that the Inspector General should conduct a complete review of NCI administration of cancer control contracts.

This sweeping conclusion was based on a review of five contracts—two selected by Mr. Obey, three presumably selected at random. Between 1974 and 1979, 325 contracts were initiated in DCCR. The sample surveyed represents, therefore, 1.5 percent of the contracts initiated in the division. Moreover, all of these contracts were initiated in or before 1975, while about one-third of the DCCR contracts have been initiated in 1976 or later. The sample is thus not only small, but also not representative of current, or even recent, practices. Based on a review of this inadequate and nonrepresentative sample, numerous serious allegations are made. NCI believes these allegations to be based at least in part on errors of fact and/or interpretation.

1. NCI practices in awarding some Cancer Control contracts have been improper or unsound

The GAO report alleged that DCCR failed to adhere to proper procedures in awarding three of the five reviewed contracts.

PROJECT PLAN REVIEW NOT PROPERLY MADE

Specifically, it alleged that, in the case of the Univ. of Arizona, DCCR failed to review the project plan for relevance, need, and priority. In fact, this contract was one of 27 breast cancer detection projects initiated in the Div. of Cancer Biology & Diagnosis in 1973 and 1974, and subsequently transferred to DCCR in July 1976. DCCR therefore could not have carried out the review for relevance, need, and priority, since the contract was initiated in another division of the Institute. Furthermore, the contract with the Univ. of Arizona was part of a larger program known as the Breast Cancer Detection Demonstration Projects. The entire program was reviewed for need and relevance by the Diagnostic Research Advisory Group on Dec. 21, 1972, and documentation to that effect was supplied to the GAO on Feb. 14, 1980.

[Ed. note: GAO deleted from its final report that portion of its criticism of the Arizona contract related to inadequate review.]

The GAO report also alleged that DCCR failed to review the project plan for relevance, need, and priority for a contract with the Illinois Cancer Council. NCI disagrees with this allegation. The contract record contains an approved project plan. This plan contains a statement of relevance, need, and priority. The plan also identifies the committee that reviewed the project plan and the date of the committee meeting. The project plan was signed by all the appropriate responsible officials. DCCR therefore did review the project plan, and the project plan itself contains the evidence. It is true that there are no minutes to document the meeting of the committee that reviewed the project plan, but at the time of that meeting, there was no policy requiring the preparation of such minutes. Subsequent procedures, developed within DCCP, established a system of minutes for these meetings and this procedure has been followed since that time.

The GAO report further stated that, in the case of the New York State Dept. of Health contract, NCI used an unchartered committee to review the proposal. GAO indicated that this was an incorrect procedure, since NCI's Committee Management Procedures and Guidelines state that ad hoc groups called together to give group advice or act as advisory committees should be chartered. The governing phrase, however, is "to give **group** advice." The ad hoc review group did not function to give group advice and did not reach a consensus. Rather, individual opinions (votes) were provided which were used by the executive secretary to prepare the review summary sheet. The use of ad hoc consultants meeting as an unchartered group is a well recognized NIH procedure, and is reaffirmed in NIH Insturction and Information Memorandum No. OD 78-2 "Implementation of PHS Peer Review Regulations—42CFR52h Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects." The only restriction is that the group should not function to reach a consensus but should provide individual opinions. The ad hoc group reviewing the New York state contract met that criterion and, therefore, the conclusion reached by GAO that the committee should have been chartered is not correct according to NIH policies. There may, however, be a discrepancy between NIH policy and the statement in NCI's Committee Management Procedures and Guidelines, since the latter were developed in April 1973 and have never been updated.

The rest of NCI's response will be published next week.

The Cancer Letter _Editor Jerry D. Boyd

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