THE CANCER LETTER

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NCI TIGHTENS MONITORING, UPGRADES STAFF TRAINING IN ATTEMPTS TO IMPROVE MANAGEMENT OF CONTRACTS

NCI's effort to improve the administration of contracts will emphasize closer monitoring by and improved cooperation between contract and project officers, better education of contract specialists and improved procurement planning, in addition to changes in peer review *(The Cancer Letter,* Dec. 19, 1980).

(Continued to page 2)

In Brief

VINCENT BONO RETIRES AS INVESTIGATIONAL DRUGS BRANCH CHIEF; WEISS TO LEAVE FOR WALTER REED

KEY STAFF changes in NCI's Cancer Therapy Evaluation Program: **VINCENT BONO** is retiring as chief of the Investigational Drug Branch but will remain with CTEP until his retirement from the Public Health Service becomes effective in July. Bono took over the branch during the bitter controversy with FDA, helped develop the agreements which repaired relations between the two agencies. **DANIEL HOTH** is the new branch chief; he has been chief of the section on phase 1 studies. **DANIEL KISNER**, who is with the Div. of Cancer Treatment liaison group in Brussels, will join CTEP in February as deputy to Director John MacDonald. **RAYMOND WEISS** has stepped down as chief of the Clinical Investigations Branch and will join Walter Reed Army Medical Center in April as Director of Medical Oncology. **WILLIAM DEWYS** is acting chief of CIB. . . . **EMIL FREIREICH**, head of the Univ. of Texas System Cancer Center Dept. of Developmental Therapeutics, has been appointed to the Ruth Harriet Ainsworth Research Chair in Developmental Therapeutics. In other UTSCC appointments, **T.L. LOO**, **RONALD HUMPHREY**, **J. LESLIE SMITH** and **SIDNEY WALLACE** were named to Ashbel Smith Professorships, and **RICHARD JESSEE** is the first recipient of the M.G. and Lillie A. Johnson Chair for Cancer Treatment and Research. . . . **NATIONAL CANCER** Advisory Board meeting Feb. 2-4 will include a report on clinical manpower needs by Margaret Edwards, chief of NCI's Clinical Manpower Branch; an update on the Community Based Cancer Control Program by William Terry, acting director of the Div. of Resources, Centers & Community Activities; and a discussion on cancer and black Americans by NCAB member LaSalle Leffall. . . . **ALAN VARLEY**, director of medical affairs for the Domestic Pharmaceutical Medical Division of Upjohn, has been elected chairman of the National Council on Drugs. The council is a consortium of health related organizations which offers advice to the government on use of drugs in humans. **JOEL BENNETT** of New York, who is chairman of President-Elect Reagan's Task Force on Health Advisory Councils, was elected vice chairman of the council.

REPORT TO NCAB CRITICIZES IG, GAO "UNFAIR" CONCLUSIONS ON CONTRACTS

(Continued from page 1)

The draft of a document NCI Director Vincent DeVita will present to the National Cancer Advisory Board next month reviews the history of NCI's use of the contract mechanism, discusses criticism arising out of various investigations of the process, and describes changes recently made or planned to improve it.

Most of the changes involve the Research Contracts Branch, which supplies the contract officers and contract specialists and provides the overall administration of contracts. Project officers are NCI program staff. RCB is part of the Office of Administrative Management in the office of the NCI director and thus is independent of the institute's programs and divisions. James Graalman is chief of the branch.

One of the steps DeVita has initiated is the centralization of RCB staff. Since its inception, RCB staff members have been located with the program areas they supported, with offices in the Landow building in downtown Bethesda and the Blair building in Silver Spring, as well as on the NIH campus.

"It was thought that this was the most effective way to accomplish the partnership of project officer and contract officer, a partnership essential to the success of the contract process," the draft report says. "However, this has caused other problems within RCB. Because the office of the chief, RCB, was physically separated from the contract specialists, the chief's ability to provide the level of direction and supervision needed by the staff was hampered, particularly in the area of contract administration. By mid-October 1980, NCI had centralized gographically the entire RCB. This is expected to foster better management of the workload and of the staff, more effective contract administration, and better training of contract specialists."

Contract personnel will have an incentive to improve their performance in addition to being closer to Graalman's whip. "As a result of the Civil Service Reform Act," the report says, "managers and executives will be evaluated for merit pay on critical job elements. The chief, RCB, has advised his section chiefs and team leaders that contract administration will be an important item in performance appraisal.

"In addition, the chief has established a contract administration review team which is responsible for auditing the quality of contract administration within RCB. This team is under the direct supervision of the deputy chief, RCB [David Keefer], and is led by a senior contract specialist [Paul Dickerson]. The first review was completed in August 1980 and within the next 12 to 15 months the performance of each contract specialist within RCB will be reviewed. The results of the team's findings will be presented to the chief, RCB, for consideration. It is expected that, where justified, unfavorable reports will be considered in merit pay evaluation."

NCI has tightened up review and approval procedures for various contractual documents. "In the past, contracting officers have had significant authority in the area of project plans, justifications for noncompetitive procurements, competitive range determinations and source selections. In some cases, the authority delegated to the section level may have led to certain action decisions without consultation with the office of the chief. To provide for more effective direction and leadership, effective Oct. 1, 1980, the number of RCB staff with approval authority was reduced, in many cases by as much as one half."

The draft report discusses recent investigations of NCI contracting operations and presents the institute's somewhat indignant reaction to what staff considered were unfair conclusions those investigations produced.

"During the past three years, NCI has been the subject of several reports on contracting activity. These reports dealt with the more technical aspects of contracting. Several of the reports were unfairly critical of NCI operations. In some cases, there were questions about qualifications of the auditors, the methodology employed, the sampling procedures utilized, and the consensus reached.

"The NIH director, in a memorandum of October 1978 to the assistant secretary for health, stated ". . . [these reports] contain hypotheses and reviewer opinions that have not been subjected to normal post audit dialogue between reviewer and the organization under review. This fact finding and analysis step is critical to establish the validity and reliability of the reviewers' findings and recommendations. It is evident that an auditor or reviewer not required to discuss and explain the basis for his or her findings is given the role of judge, jury and executioner. Unfortunately, this has been the principal mode of operation of the HEW review teams operating at NIH in recent months.' In other cases, NCI and NIH staff agreed with the findings and were able to make, as a result, improvements in the contracting activity.

"The most comprehensive and critical review of the NCI contract program was the May 1978 inspector general's report. NCI disagreed with many aspects of the report but decided not to respond formally to the draft since NCI and IG staffs were to discuss it at a later date. Indeed in a November 1978 memo the IG noted that efforts to resolve differences in presentation were under way. NCI staff met with staff of the IG in 1979. In an April 1979 memo the chief, RCB, stated the purpose of the meeting 'was to give institute impressions of the report and to identify errors. It was agreed that no purpose would be served

by reanalyzing the data to resolve factual discrepancies. Moreover, the IG did not wish to review the report item for item for the following reasons: (1) the IG auditors were not procurement experts and thus could not respond to or perhaps understand NCI philosophic points and (2) the IG's return visit would be designed only to cover recommendations made in the report and would not be another audit.'

"Thus, errors made in the report were never corrected and differences in opinion never resolved. NCI's failure to respond to the report led many in the department and in the scientific community to form inaccurate opinions of the manner in which NCI does business. NCI staff later regretted that it had not rebutted the report more vigorously. In a memorandum to the assistant secretary for health dated November 1978, the NIH director stated, 'Because there are substantial areas of disagreement in portions of the inspector general's report, we regret our earlier decision to not discuss the report in detail on the merits of various issues. Our failure to discuss the draft report when it was issued early in 1978 may have contributed to a misleading impression about the department that we concur in the validity of the IG report without qualification, which we do not.'"

DeVita's draft report reviews the investigation of Div. of Cancer Control & Rehabilitation contracts by the General Accounting Office, which was initiated by Congressman David Obey.

"This is the most recent examination of the NCI contract program. The report, which involved almost six months of field work and several months of drafting was answered by NCI and a copy of the response was included in the GAO publication. However, because of time constraints imposed by Representative Obey, GAO gave the institute approximately 72 hours to review the draft and to prepare its response.

"GAO reviewed a total of five DCCR contracts. Several GAO conclusions were based on three specific contracts which represent 0.9 percent of DCCR's contracts. In many cases, NCI found the GAO conclusions did not give due consideration to the documentation provided. For example, GAO stated that DCCR's contract review groups identified 52 problems and made 43 recommendations. The auditors could not find any indication that NCI directed the contractors to implement the review recommendations. NCI provided GAO with memoranda from the NCI project officers detailing the corrective and followup actions taken by the institute. Although NCI's documentation could have been better, the institute had taken adequate steps to correct the problems."

Inspector general auditors returned to NCI last year to determine how NCI had responded to recommendations in the 1978 report. A draft of the followup IG report, received in mid November, showed that NCI had taken many corrective actions but that further improvements are needed.

The draft of DeVita's report to the NCAB summarizes those suggestions and corrective actions taken.

1. Pre-Award Process

"The reports suggested that comments made about specific contracts by peer or technical review groups were not used by the project officer and contracting officer in later negotiations, and that weaknesses noted in the peer review process were not always corrected prior to the institute making a contract award. Actually, this is more a problem of inadequate documentation by NCI of its actions, than it is of failure to take the actions. The suggestion did result in improvement in documentation of NCI followup actions on specific suggestions.

"The reports also noted a lack of adequate cost analysis of contracts and suggested that statements of work were too broad and the requirements contained in them were poorly defined. The cost analysis problems are real, due to inadequate numbers of contract staff at NIH, and lack of lead time in processing contracts. NCI is working to correct these problems through better education of contract specialists and improved procurement planning to allow more time for cost analysis.

"Comments about work statements were inappropriate to a great degree, primarily because auditors did not understand that in a research and development environment, the RFP is deliberately broad to allow for innovative and unique approaches to a problem.

2. Peer Review

"The outside audit reports suggested that occasionally review committees did not reach consensus because some committee members were absent from meetings, and that reviewers were not adequately prepared. This is a rare occurrence, and executive secretaries are continually urged to strive for effective operation of review committees. The reports also suggested that peer reviewers often criticized the quality of proposed efforts. In these cases, however, the committees usually voted to continue the project. In addition review committees sometimes take issue with concepts already approved by a Board of Scientific Counselors, suggesting a need to reinforce the roles of various committees to their memberships.

3. Contract Administration

"This is the area of greatest criticism of NCI contracting activity, and the area in which NCI has taken the most corrective actions. The reports made a number of suggestions and comments: (a) contracting officers and project officers should work more closely together; (b) contract monitoring should be more formal and effective; (c) contractors should provide better reports on the amount of time spent on a contract by their personnel; (d) project officers

did not always review progress reports; (e) project officers sometimes provided oral approval to contractors without the contracting officer's knowledge; (f) contracting officers sometimes did not take action after learning that reports had been received; and (g) project officers sometimes did not follow up on their site visit recommendations to contractors.

"In order to correct these deficiencies, NCI has taken a number of actions. Training for both project officers and contract specialists has been increased. Before 1978, there was little emphasis on formal project officer training; now all must receive training, and now 57 percent of project officers have completed required training. A contract administration manual will be issued shortly to project officers and contract specialists, and a guide to principal investigators will be issued in 1981 to help them with administrative duties. Project officers are required now to review their programs semiannually and to advise their supervisors and the contracting officer of progress and problems. Finally, the number of contract specialists certified pursuant to HHS guidelines has risen to 50 percent of those employed, and by next year will reach 75 percent.

4. General Comments

"There were three main general comments made in the reports: that NCI should increase the percentage of awards made competitively; that project officers sometimes exert undue influence over contracting officers; and that the percentage of obligations incurred in the fourth quarter of the year is too large. As to the number of competitive awards, NCI believes if has a good record. It is estimated that about 60 percent of NCI contract dollars were awarded competitively in FY 1980. Imprecise and contradictory definitions from HHS have led to differences in interpreting the NCI record.

"NCI does not agree that project officers unduly influence contracting officers; however, the NCI director has reinforced the contracting officer's independence in the contracting process.

"As to fourth quarter obligations, the implication that contracts issued late in the fiscal year are somehow suspect is unfortunate and inaccurate. All contracts take nine to 12 months of preliminary work before they can be finalized. In FY 1980, NCI obligated 22 percent of its contracts budget in the last quarter. This is not excessive."

The entire Research Contracts Branch now is located in the Blair Building, 8300 Colesville Rd., Silver Spring, Md. 20910.

The office of Graalman and Keefer is Room B16, and the phone number is 427-8810. Section chiefs, room and phone numbers are:

—Biology & Diagnosis (which also handles Office of Director contracts), Hugh Mahanes, Room 332, 427-8877.

—Biological Carcinogenesis & Field Studies, Charles Fafard, Room 114A, 427-8888.

—Carcinogenesis, Daniel Longen, Room 2A07A, 427-8764.

—Control & Rehabilitation, Gary Kelley, Room 1A07, 427-8747.

—Treatment, George Summers, Room 228B, 427-8737.

All phone numbers have the Maryland area code, 301.

CCIRC HOLDS GROUPS TO 1980 LEVELS, BUT THEY MAY END UP WITH EVEN LESS

The Clinical Cancer Investigation Review Committee recommended only modest increases, if any, for Cooperative Group competing renewal grants in 1981 for their 1980 fiscal year budgets, holding the groups for the most part at existing levels. However, if NCI is able to fund at only 70-80 percent of the recommended levels (***The Cancer Letter,*** Jan. 2), most groups will have to operate with less money this year than last.

Groups competing in the first round, with 1980 adjusted awards ("one shot" special funding deleted), total requested, total recommended, and funding at about 80 percent of recommended total:

Children's Cancer Study Group—$3,925,000; $7,405,000; $5,072,000; $4,104,000.

Southwest Oncology Group (adult)—$5,071,000; $9,688,000; $5,561,000; $4,574,000.

Pediatric Oncology Group (a new group consisting of the former SWOG pediatric component, headed by Teresa Vietti)—$2,839,000 requested; $1,335,000 recommended; $1,067,000 at 80 percent.

Smaller grants were approved for the Quality Assurance Review Committee ($144,000); Radiotherapy Hodgkin's Disease Group ($39,000); and miscellaneous awards totaling $539,000.

Groups competing in the second round, with 1980 adjusted awards, total requested, total recommended, and funding at approximately 75 percent of recommended total:

Eastern Cooperative Oncology Group—$5,533,000; $7,875,000; $5,619,000; $4,214,000.

Radiation Therapy Oncology Group—$2,800,000; $4,288,000; $2,890,000; $2,167,000.

Polycythemia Vera Study Group—$388,000; $605,000; $361,000; $271,000.

Lymphoma Pathology Repository Committee—$272,000; $295,000; $251,000; $188,000.

Miscellaneous awards totaling $1,106,000 were requested, $1,013,000 was recommended, and 75 percent would be $760,000.

Groups reviewed in the third round were Northern California Oncology Group, $1,097,000 in 1980, $3,723,000 requested; Radiologic Physics Center, $417,000 in 1980, $556,000 requested; and Ewings intergroup study, $80,000 in 1980, $378,000 re-

quested. Amounts recommended in the third round are not available for release at this time.

Groups with continuing grants not competing for renewal in the 1981 fiscal year are scheduled to receive amounts specified in their negotiated awards. These include approximately seven percent more than they received in 1980, although NCI is considering the recommendation of the Cooperative Group Chairmen's Committee that reductions from recommended levels be applied to all groups. The chairmen also asked that flat percentage cuts not be applied to all groups and instead reductions should be made selectively in consultation among NCI staff and chairmen. NCI is studying that recommendation.

Groups with continuing grants and their negotiated totals are:

Cancer & Leukemia Group B, $4,294,000; Gynecologic Oncology Group, $3,074,000; Wilms Tumor Study Group, $323,000; North Central Cancer Treatment Group, $214,000; Primary Breast Cancer Therapy Group, $1,579,000; Southeastern Cancer Study Group, $4,284,000; Southwestern Oncology Group pediatric component, $1,982,000; EORTC, $213,-000; and Rhabdomyosarcoma intergroup study, $136,000.

Group chairmen were not happy with the method for appealing protocol disapprovals by NCI, a procedure devised by Div. of Cancer Treatment staff to be used when the cooperative agreement mechanism replaces grants in funding the groups. The appeals procedure would use the DCT Board of Scientific Counselors as the final arbiter in disputes between group members and NCI.

CALGB Chairman James Holland objected. "The Board of Scientific Counselors is incompetent to judge those issues," Holland said. He suggested that a procedure for arbitration should be used in which each side selects one representative and the two then choose a third.

Cancer Therapy Evaluation Program Director John MacDonald said that the DCT Board had only approved the concept of protocol appeal and that he would be willing to consider another method for arbitration.

Holland, arguing that the Board has only a minority of members who are experienced in clinical matters and that some disputes might involve areas of specific expertise, offered the motion asking that his plan for arbitration be adopted. It was approved, with ECOG Chairman Paul Carbone and WTSG Chairman Giulio D'Angio abstaining.

"Decisions are being moved from the Cooperative Groups where they belong to someone else," D'Angio said. "Decisions on the conduct of clinical trials belong in the groups. The only areas where approval should be required is ethics and new drugs."

"Are you willing to allow someone else to decide on ethics?" Holland asked. That is a matter that is out of NCI's hands because it is in department regulations, D'Angio noted.

In answer to D'Angio's comment that protocol disapproval "should never be in DCT staff hands," MacDonald said he agreed except when the issue was duplication. "When the seventh protocol for looking at radiotherapy for pancreatic cancer comes in, we should be able to say we have enough of that kind of thing."

"When that happens, if a group chooses to go ahead, that group then would be under a cloud. Existing mechanisms can police that," D'Angio said.

"That's not the only issue," SECSG Chairman John Durant said. "Other details of cooperative agreements will have an impact, such as termination of studies with less than 100 patients. It's a question of who does what to whom."

"Let's get off this," Carbone said. "No one is going to stop a protocol. We've got to work with Jack. I've got confidence we can work with him."

Other issues discussed by the group chairmen included:

• Common criteria for toxicity.

Edwin Jacobs, associate chief of the Clinical Investigations Branch of CTEP, submitted the revised criteria for toxicity. Development of common group toxicity ratings has been going on for more than two years. "The effort to finalize this has lagged," Durant said.

Holland moved that approval be tabled until the next meeting of the chairmen's committee. "We received this only yesterday," he said. "This is as important as hell."

"This has been in the works for two years," Jacobs said. "Only minor modifications were made (from previous versions). It was sent out several times, and has been tabled several times. This is the third time it has been here."

SWOG Chairman Barth Hoogstraten suggested that a subcommittee of chairmen study the document and bring it back with suggestions at the next meeting.

GOG Chairman George Lewis said that "this was written for medical oncologists," and suggested that some aspects of surgical and radiotherapy problems be added.

"There are a number of things that are not addressed adequately," NCCTG Chairman Charles Moertel commented.

The motion to table and refer to a subcommittee was approved unanimously.

• Common criteria for response.

"I applaud this effort, but I'm not sure it can be achieved," Holland said. "What we have used is common sense. . . I'm not convinced it makes that much difference whether leukopenia is rated 2 vs. 3 or 1. A 2 may not be leukopenia at all. A lot of the reason for cancer morbidity and mortality is fear of leukopenia by doctors."

"Let's not start diddling around with things that already have numerical values," Moertel said.

MacDonald said he agreed that "when you have a numbering system, you should use it, and find a way to use it better. If it comes out 2.1, but that down and not just 2 plus."

"There are so many common usages in so many areas. I don't see why we can't put them down and use them," Hoogstraten said.

"What's the harm in identifying uniform criteria that exist and using them?" CCSG Chairman Denman Hammond asked.

"People sometimes think they are using common terms but they're not," Carbone said.

Durant, summarizing the discussion, asked if it was the consensus that common criteria for both toxicity and response be developed, and the answer was affirmative.

• Intergroup study guidelines.

Durant noted that there is "a diverse set of opinions" and no consensus on the need for one set of guidelines for intergroup studies. "It's informal, study by study now. Does it need to be formalized?" He concluded that it is "the sense of the group to leave it the way it is."

Contract Awards

NCI ANNOUNCES FOUR MORE CHOPS AWARDED, WITH 13 LEFT TO GO

NCI has announced four more contract awards in the Community Hospital Oncology Program. They are Christ Hospital, Cincinnati, $105,600; Hackensack Hospital, $119,200; Borgess Medical Center, Kalamazoo, $136,244; and St. Louis Park Medical Cancer Research Center, Minneapolis, $116,086.

Six CHOP awards have been announced previously (*The Cancer Letter*, Oct. 24, 1980), and 13 more are still being negotiated.

Title: Coordination program—Centers for Radiological Physics

Contractor: American Assn. of Physicists in Medicine, Chicago, $235,226.

Title: Long term followup of breast cancer screening project participants

Contractor: Mountain States Tumor Institute, Boise, $86,853.

SOLOMON GARB'S QUESTIONS AND ANSWERS ABOUT THE NATIONAL CANCER PROGRAM

The following will complete publication of questions and answers frequently asked of and answered by Solomon Garb, chairman of the Citizens' Committee for the Conquest of Cancer. ***The Cancer Letter*** has published this compilation to assist those who serve as advocates of the National Cancer Program and are often called upon to explain or defend it.

Those who wish to do so may photocopy without further authorization from ***The Cancer Letter*** the questions and answers as they see fit. Publication began in the Dec. 5 issue.

Some of the responses to the questions include opinions which are those of Garb and his fellow committee members. Some Cancer Program supporters may disagree with those opinions.

OTHER QUESTIONS AND ANSWERS

141. Is it true that in early times, cancer was a rare disease?

No. It was underdiagnosed since prior to surgery, diagnosis of internal cancer was often impossible. Even when the doctor did diagnose it, the aura of guilt and shame surrounding it led to covering up the diagnosis. Often, the term "died of natural causes" was used.

142. How does the U.S. compare with other nations in cancer death rate?

Only 44 nations report their age adjusted cancer death rates to the World Health Organization. In that group, the U.S. is the 22nd.

143. Does a reordering of society to eliminate corporations eliminate or reduce cancer death rates?

Among the nations with higher age adjusted cancer death rates than the U.S. are the communist nations, Czechoslovakia and Hungary. Poland has about the same rate as the U.S. Romania has a lower rate for men, but a much higher cancer death rate for women—second highest in the world.

144. Does a higher cancer death rate always come from a high level of industry?

No. Uruguay which is almost entirely an agricultural-pastoral nation has a much higher age adjusted cancer death rate than the U.S. The highest level in the world of cancer death rates for women is in Holland. Geneva, Switzerland, the cleanest city in the world, has a higher age-adjusted cancer death rate than Birmingham, England.

145. What about Russia and China?

There are no statistics for those nations, but we know they have a high level of cancer and they are both eager to cooperate with the U.S. in fighting cancer. Mao Tze Tung and Chou En Lai both died of cancer.

146. Why did Congress make the conquest of cancer a national priority?

Because health consistently shows up in polls as the foremost long term interest of the citizens of this country. On top of that, cancer is the most feared disease. Congress knows that cancer is probably the most costly disease. (Estimates range from $24 billion to $35 billion per year in terms of doctor and hospital bills, and income lost.) All these reasons were discussed on the floors of both houses of Congress when cancer was made a national priority.

147. A vocal critic of the Cancer Program complains that too much effort and funds go to finding treatments and not enough to prevention. How do you respond?

Both treatment research and prevention research are underfunded. Both should receive more funds.

148. The same critic complained before the Kennedy subcommittee in 1979 that the "prevention lobby" was diffuse and relatively weak, and that there is an absence of a grass roots constituency for prevention. Is this correct?

Yes.

149. What about the grass roots national constituency of those who support the search for better, less toxic treatments? How strong is that?

It's one of the largest and strongest constituencies in the nation. One element of that constituency, the American Cancer Society, has over two million members. They contri-

bute and raise over $100 million per year to supplement the national cancer effort. There are other, smaller groups and there are many donors to cancer hospitals. Then there are those who actively support the Cancer Program but who are not members of any group.

150. Can you estimate how many people constitute the grass roots constituency of the move to get more effective, less toxic treatments?

Almost everyone who knows about cancer wants to see it conquered without delay. At least 100 million Americans.

151. Do you see any possible barriers to continuing progress in finding better treatments for cancer?

Yes. There are recurring attempts to return the National Cancer Institute to the rule of the National Institutes of Health and the department of HHS. This would mean that the advances of the Cancer Act of 1971 would be lost. Vital clinical research studies could, as in the past, be vetoed by people in the NIH who are not experts in cancer, and by people in HHS who are neither physicians nor scientists. Furthermore, the notorious and admitted bureaucratic inefficiency of HHS would then blanket all the National Cancer Institute programs.

152. Then you oppose the return of the National Cancer Institute to the operational control of NIH and HHS?

Absolutely. This is an issue on which we cannot compromise or negotiate. Millions of lives depend on our preventing this disaster. Shortage of funding delays the conquest of cancer. Surrendering NCI back to NIH and HHS means abandonment of cancer victims and is far worse.

153. Do you dislike NIH and HHS?

No. NIH and HHS have their good side which we appreciate. However, we know that when they dominated the National Cancer Institute, clinical progress was impeded and often halted. The critical studies on breast cancer could not be done until NCI received substantial independence.

154. Is the National Cancer Institute doing an excellent job in all respects?

No. It is doing an excellent job overall, but there are areas of marginal performance. Most are due to constraints imposed by higher level agencies.

155. Which areas of poor performance are due to constraints imposed by other agencies?

Research grants must be approved by study sections chosen by the Div. of Research Grants (DRG), a division of the National Institutes of Health. The grant funds disbursed by all the operating institutes must be based on approval and priorities set by study sections chosen by DRG. At times, DRG chooses study section persons who are opposed to some NCI program. For example, the dearth of NCI research grants for cancer prevention research is not the fault of NCI. It is the fault of a DRG study section that turned down applications NCI would have approved. To some extent, the same is true in nutrition research.

156. Are NCI statistics valid?

They lag behind the clinical facts, since like all statistics, it takes time to collect and analyse them. They disregard some cancers that have over a 95 percent cure rate. Specifically, both their incidence and survival data omit skin cancer and in situ cancer of the cervix. However, these are real cancers. If not treated, they will spread and kill the victim. In some countries, they are significant causes of death after they spread.

157. If the statistics did take those cancers into consideration, what then?

It would be clear that cancer is even more frequent than has been stated, and that the cure rate is higher than is realized.

158. How high?

Counting skin cancers and in situ cervical cancers, we are now curing between 50 percent and 58 percent of cancer victims. (The figures are approximate because national statistics are not computed this way.)

159. Why are there differences in the reported survival rates of cancer patients?

There are several reasons. One is the exclusion of skin cancers and in situ cancers of the cervix from the statistical base. Another is the difference between relative and observed rates of survival in statistical analyses. Using the relative rate, one compares the survival of a large number of patients with cancer to the survival of the same number of healthy people matched by age, sex, occupation and other factors. If at the end of, say, five years, the numbers alive in both groups are the same, we can say that in five years, the cancer did not cause a measurable change in survival rate. If only half as many cancer patients are alive compared to the matched group after five years, we can say the survival rate is 50 percent. This method is the most valid, but it requires complex comparisons.

The observed rate approach simply measures the number of cancer patients left alive after a period of time—say five years. If, out of 100 patients, 60 are alive, the observed survival rate is given as 60 percent. The problem is that of the 40 deaths, several may have been due to natural disasters, some to strokes, some to heart attacks, and only 20 to cancer. No matter. In this system, no corrections are permitted. Although only 20 deaths were due to cancer, cancer is blamed statistically for all 40 deaths and the five year survival is listed as 60 percent, not 80 percent or some intermediate figure.

The observed rate approach is the easiest and is most commonly used. The net result is an exaggerated figure for cancer death rates. Actually, we are doing much better than the statistics indicate.

160. Why don't we have a more accurate, uniform method of statistical analysis?

Statistical analysis is quite complex. Different groups use different approaches. We hope that they will adopt uniform methods that give an accurate picture. However, many groups use and publish statistics including government agencies, universities, life insurance companies, public interest groups and so forth. Each group has its own focus.

161. Which statistics are the most accurate, then?

That depends on whom you ask. Each group believes theirs is. We believe that the most accurate statistics are the crude figures compiled by physician groups and cancer centers who actually treat cancer patients. They have good observations on how many of their patients survive for long periods, and they know years before the statisticians can amass and analyse the data. For example, the physicians treating testicular cancer at the Univ. of Indiana knew they had a breakthrough long before any national statistics showed it.

162. There have been references to a "Disease of the Month Club." How does this apply to the Cancer Program?

Cancer is not a "disease of the month." To the patient in pain, it is a disease of every second, minute, hour, day, and week. To too many, it is the disease of their remaining lifetimes. The phrase "disease of the month" is highly misleading. It was developed and promoted as a means of criticising research that concentrated on the diseases that afflict people.

163. You said that cancer is not a "disease of the month." Are any of the other diseases that the Congress has directed the National Institutes of Health to work on?

No. All are serious afflictions that deserve attention. We support efforts to improve prevention and treatment of all of them.

164. Do you feel that Congress was correct in setting up a series of institutes, each concentrating on a particular kind of disease?

Absolutely. This approach has already saved many thousands of lives and will soon be saving more. Congress showed foresight and courage in supporting the individual institutes

within NIH and every congressperson and senator who provided such support deserves the gratitude of all Americans for generations to come.

165. I have heard that many scientists have slanted their research proposals to emphasize a relationship to cancer and thereby become eligible for a grant from the National Cancer Institute. Is this true?

To a certain extent. It is difficult to tell how many scientists have done this, since we cannot analyze their inner motives.

166. Isn't this a problem?

No. If the research is of high quality and relevant to the Cancer Program, it could be of critical importance. There is also the other side of the coin. Before the Cancer Act of 1971, when cancer research was being funded at about 1/5 to 1/10 of a reasonable level, many scientists who wanted to do cancer research were unable to do so. Now, many of them are able to do so, but more than a third of scientists who are ready, willing and able to do worthwhile cancer research cannot because of inadequate funding.

167. When can we expect to see a downturn in the death rate from one of the common cancers?

Now. The death rate from breast cancer in women under 50 has already started to move down because of newer, better treatments.

168. Is there anything else about the National Cancer Institute that needs correction and improvement?

As in any organization, there are things that could be done better. However, within the limitations of human performance, the National Cancer Institute is doing an excellent job overall. We would prefer to have a greater emphasis on cooperation and less emphasis on competition among researchers. However, we recognize that an entire generation of researchers has been indoctrinated with highly competitive attitudes by the NIH policies. Fortunately, many cancer researchers have a natural tendency to cooperation.

169. Isn't it true that the cancer death rate is increasing despite the National Cancer Program?

Yes, but not because the program is at fault. The latent period between exposure and development of cancer in adults is usually 20 to 40 years. Therefore, the increased cancer rate in the 1970s came from increased exposure in the 1940s and 1950s. The Cancer Act of 1971, which took effect in 1972, couldn't be expected to turn the tide that quickly.

170. What is the relationship of the National Cancer Institute and the American Cancer Society?

The National Cancer Institute is a U.S. government agency. The American Cancer Society is a volunteer group. Both are trying to conquer cancer. They complement each other. To the extent that the law allows, they cooperate with each other.

171. Isn't the American Cancer Society dominated by industrialists?

No. The American Cancer Society has about 5,000 units. Each unit consists of volunteers, most of whom have had cancer themselves, or have observed cancer in a close relative. These people are the true, legitimate consumers in the area of cancer. The officers of each unit are democratically elected by the volunteer members and serve without pay. The higher level is the division and there are about 57 divisions. Their officers are elected by the units in a thoroughly democratic fashion. The divisions have full time salaried staff in addition to their volunteers. The American Cancer Society is as representative a cross section of the nation as any organization.

172. Didn't the supporters of the Cancer Program overpromise in 1970 and 1971?

No. Opponents of the program have falsely claimed that the program was overpromised. Fortunately, however, there is a written record of what the proponents said in the report of the National Panel of Consultants on the Conquest of Cancer—Document 92-9, U.S. Senate. The Panel said, among other things, "Cancer is an implacable foe and the difficulty of eliminating it as a major disease must not be underestimated," and "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." Nowhere in the report is there any overpromise.

173. What can a person do to help the National Cancer Program succeed?

Join one or more of the organizations that are working to fight cancer and participate in their programs.

174. Which organizations, and what do they do?

American Cancer Society. Divisions in each state. Primary function: collecting money to be used in education, research, and service. If you can't find the address of your state's division, write to the Washington office—1825 Connecticut Ave., Washington D.C. 20009.

Leukemia Society. Primary function: collecting money to be used in research and service to leukemia victims. 211 East 43rd St., New York N.Y. 10017.

Citizens' Committee for the Conquest of Cancer, 7159 S. Franklin Way, Littleton, Colo. 80122. A public interest group devoted to helping citizens inform their congressmen and senators of the people's wish to see cancer conquered without delay. Provides information for this purpose, such as this pamphlet. No dues. This group encourages the formation of local chapters. A local chapter can be formed by a group of friends and neighbors, or an existing club of any kind can volunteer to add the conquest of cancer to its mission.

National Cancer Petition, P.O. Box 85, Watertown, Mass 02172. A public interest group that circulates petitions asking Congress to speed up the fight against cancer. No dues.

Candlelighters, 123 C St. S.E., Washington, D.C. 20003. A group of parents of children with cancer and leukemia. Scores of chapters around the nation. Founded by Dr. Richard Wolk. Functions include mutual psychologic support. Some chapters have been active in persuading congressmen and senators to support the National Cancer Program.

Your nearest regional cancer center.

175. Which research area do you believe deserves the greatest added emphasis and support?

Finding more effective, less toxic treatments for cancer patients. This includes the treatment related research done by basic scientists and the clinical studies of the new agents on patients. The two are inseparable.

176. In your opinion, how much should be appropriated during the next four years for the National Cancer Institute, and how much for treatment and treatment related research?

For a reasonable, not a maximum, program, we recommend the following:

Fiscal Year	National Cancer Institute	Div. of Cancer Treatment*
1981	$1.6 billion	$0.5 billion
1982	1.7 billion	0.6 billion
1983	1.8 billion	0.7 billion
1984	2.0 billion	0.9 billion

* Included in National Cancer Institute total

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