THE CANCER LETTER

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DEVITA SAYS NCAB SUBCOMMITTEE'S RECOMMENDATION FOR RESHAPING ORGAN SITE PROGRAM IS "REASONABLE"

The recommendation for reshaping the Organ Site Program approved by the National Cancer Advisory Board Subcommittee on Organ Site Programs is "reasonable," NCI Director Vincent DeVita said, but he still wants the NCAB to consider his plan when the full Board debates the issue May 17.

The subcommittee proposal would abolish the four independent headquarters (National Bladder Cancer Project, National Prostatic Cancer Project, National Large Bowel Cancer Project, National Pan-

(Continued to page 2)

In Brief

HATCH RESTORES NCI BUDGET BYPASS AUTHORITY IN HIS BILL RENEWING NATIONAL CANCER ACT

SEN. ORRIN HATCH, declaring his solid support for the Cancer Program, put NCI's budget bypass authority back into his bill renewing the National Cancer Act. Hatch had gone along with a White House request to eliminate the bypass (***The Cancer Letter***, April 9) but had let it be known he was doing so with some reluctance Last week he sent word through his staff aide David Sundwall that he is convinced now the budget bypass is perceived as being of vital importance to the Cancer Program and that he wants renewal of the Act to be accomplished in a way that will not have any adverse effects on the program. Hatch also feels the $42 million increase in his bill in NCI's authorization for FY 1983 over the White House budget request of $956 million, with increases of 5.5 and 5 percent the following two years, should sustain the momentum of the Cancer Program. The bypass authority thus appears safe for another three years, barring an unlikely amendment on the floor of either house. Congressman Henry Waxman's bill renewing the Cancer Act also includes the bypass. Hatch hoped to complete markup on the bill this week by his Committee on Labor & Human Resources. . . . **FDA'S ONCOLOGIC** Drugs Advisory Committee will meet May 7 to discuss the revised preclinical toxicology protocol as well as requirements for additional preclinical studies on drug combinations. FDA is especially concerned about combinations in which more than one drug is investigational and in studies in which one drug interferes with the metabolism of others. The meeting will start at 9 a.m. in the Parklawn Bldg., Rm G and H, and is open. . . . **JONATHAN NEUMANN**, who teamed with reporter Ted Gup to produce the *Washington Post's* much criticized series on testing anticancer drugs, has resigned from the paper. Neumann will return to the *Philadelphia Inquirer*, where he won a Pulitzer Prize before joining the Post. It was "a career decision, one I have planned for some time," he told ***The Cancer Letter***. Gup intends to remain at the Post and is still working on the next cancer series.

DEVITA STILL WANTS NCAB TO CONSIDER HIS ORGAN SITE PROGRAM SUGGESTIONS

(Continued from page 1)

creatic Cancer Project); establish a single headquarters for the entire program, with two divisions—genitourinary and gastrointestinal; return review of OSP grants to NIH, with R01s being reviewed by the Div. of Research Grants, and program projects and clinical grants by NCI's Div. of Extramural Activities; emphasize organ systems, to include other GU and GI malignancies; and open the way for additional organ site systems to be included in the program (***The Cancer Letter,*** April 9).

DeVita's plan differs essentially in only one major respect—it would not continue any headquarters operation outside NCI and would turn over the coordinating-communication functions of the headquarters to the Organ Site Branch in NCI's Div. of Resources, Centers & Community Activities. In that respect, the program would resemble the Breast Cancer Task Force as it is now constituted.

DeVita's proposal also differs in that it does not separate out the clinical grants from R01s and P01s.

DeVita described his proposal and the NCI Executive Committee's rationale for it in a letter to NCAB Chairman Henry Pitot:

"We feel that in view of the budgetary constraints and the comments in the scientific portion of the report that:

"1) Steps be taken to convert the present organ site grants to R01 grants, or, if appropriate, to a mixture of R01 and P01 grants.

"2) Should recommendation (1) be accepted by the NCAB, the funds currently allocated to the organ site program in FY 1983 be transferred to the R01/-P01 grant pools in some proportion that seems appropriate to the Board.

"3) If (1) and (2) are implemented, all grant applications assigned to the organ site program subsequent to the May, 1982 NCAB meeting be reviewed for scientific merit by the appropriate chartered NIH or NCI initial review groups.

"4) Headquarters operations for each organ site be phased out but that the current program focus at NCI, the Organ Site Branch, continue in operation and remain responsible for maintaining the momentum these programs have achieved and for tracking the progress of grants in these areas.

"There are several points I wish to make in reference to these general recommendations:

"1) First, NCI is not opposed, conceptually, to the organ site programs. In fact, we believe they have successfully accomplished a significant portion of their mission.

"2) Soon after I became acting director of NCI, in 1980, we discussed the organ site issue at the first Board meeting. I raised the question as to whether the creation of the Organ Site Program was intended to stimulate research in the field or to stimulate research and remain active until incidence and mortality figures improved for each of the cancers involved.

"While the answer to this question is still not entirely clear, the staff and I have accepted the conclusion that the individual programs were probably meant to stay active as long as the targeted diseases represented a significant problem to American citizens, which they still do.

"The question the Executive Committee faced at our program planning session was whether the relative priority given the Organ Site Program in our various surveys should now change our attitude toward these programs in view of our more limited resources. We believe that there is now a broad interest in the research community in studying all tumors, including the sites which now have organ site programs.

"Two major factors influenced this conclusion:

"1) The rapidly evolving new technology is readily applicable to so many different organ sites simultaneously that there no longer seems to be a preference by investigators to study only the uncommon cancers. An example is the application of phenotyping of malignancies other than lymphomas using monoclonal antibodies. Compartmentalization of resources by organ site could actually inhibit the application of new technologies for diagnosis, treatment, etc., for a specific site.

"2) More importantly there is now ample budgetary evidence that there is considerable research going on in each of the organ site areas, outside of the formal organ site programs. A brief survey of our budget has identified $200 million devoted to 17 single organ sites. In each case, when funds allocated to the specific organ site programs are related to the amount of general monies at NCI devoted to the same organ site, the Institute-wide figure is more than double and sometimes several times larger than the amount devoted to the specific organ site program.

"There is an estimated additional $290 million devoted to research on multiple sites which has not been analyzed as to specific organ sites. Nonetheless, it seems safe to assume that more dollars are allocated to organ specific research than are in the current organ site programs.

"We conclude then that after a decade of stimulation, research is proceeding on all kinds of cancers in a satisfactory way. Given the budget circumstances, we feel those dollars allocated to maintaining the rather special structure afforded this program would be more appropriately devoted to further support of investigator initiated research using the traditional mechanisms. . . .

"We realize that if a decision is made to convert the Organ Site Program to a regular grant program, using the existing review system, the options for conversion may vary for each [project]. Subsequent dis-

cussions can deal with various options for conversion which could be considered as a second step."

There appears to be strong support among NCAB members for continuing the planning and coordination function outside of NCAB. That was the recommendation of the Ad Hoc Review Committee which at the direction of the NCAB conducted an independent review of each of the four projects.

Others have suggested that even more of NCI's resources should go into off-campus directed studies. Their view is that a little decentralization is healthy, and that NCI is getting a bargain when nongovernment scientists and administrators donate their time to help run a program.

DeVita does not dispute that an "outside focus" may be useful, but said that the Board should take a look at the original reasons for establishing that focus and determine if those reasons are still valid.

Janet Rowley, professor of medicine at the Univ. of Chicago and an NCAB member who felt strongly that all review of Organ Site Program grants should be returned to NIH, still supported continuation of some outside functions. The motion she presented at the Board's February meeting calling for review of all the grants by DRG (which was tabled) also recommended "that the Organ Site Program be reorganized so that some of the planning and management functions continue to be carried out by leadership groups located outside of NCI; these groups should be responsible for organizing the various scientific activities such as symposia and workshops that pertain to focused organ site programs. However, these programs should be expanded to include relevant investigators whose support is outside of the Organ Site Program."

Rowley is not a member of the Subcommittee on Organ Site Programs but attended the meeting in which the recommendation, drafted by Harold Amos and Pitot, was approved. She said that she supported it.

A number of issues remain, if the Board goes along with the subcommittee's recommendation, the most important of which involve the responsibilities of the headquarters and advisory groups:

- What specifically will be included in "planning and management functions"? Will one advisory committee be made up from the existing working cadre groups which advise each of the four projects, or will there be one each for GU and GI systems?
- Who will they advise? With both the subcommittee and DeVita plans, organ site grants will be funded out of the R01-P01-clinical research pools in the budgets of NCI's divisions. Would a concept approval by the Organ Systems Program Headquarters Advisory Committee for an RFA or program announcement have to go to the appropriate NCI division's Board of Scientific Counselors?
- Would other NCI supported efforts involving organ sites be brought under the wing of the outside headquarters, such as the Brain Tumor Study Group and the Breast Cancer Task Force? How about the clinical studies involving specific sites by the cooperative groups?
- How will the headquarters award be competed and funded? Through an RFA as a grant, or an RFP as a contract?

NCI staff and the NCAB will have to tackle those issues after the basic decision is made on reshaping the program.

During the subcommittee's discussion, Amos summarized the Board's rationale for establishing the Organ Site Program:

"These grants were somewhat sheltered, not because someone wanted to apply less restrictive standards, but because we wanted studies in these areas to get funded. Some were mundane but were necessary. The blind push to throw most of our money into R01s is blind faith that innovative research is needed to get things done."

Amos agreed that "quite a few of these grants probably wouldn't get funded in the R01 pool, not necessarily because they are less meritorious. Some may not be the type of ideas that get funded."

"Dr. Amos synthesized this committee's concern and also the recommendation of the ad hoc group," Subcommittee Chairman William Powers said. "There is a place for the Organ Site Program, with outside administration."

Gilbert Friedell, who heads the National Bladder Cancer Project, took issue with a number of points in the Ad Hoc Review Committee's report. Excerpts from his letter to Andrew Chiarodo, chief of NCI's Organ Site Programs Branch:

We of the NBCP headquarters staff wish to acknowledge through you our appreciation of the efforts of the Ad Hoc Review Committee. The seriousness and diligence with which the members undertook their evaluation of the four organ site projects is commendable. However, the task was of such magnitude, and the time frame within which the work had to be accomplished was so limited, that several facets of the NBCP program were evidently misunderstood and/or evaluated with insufficient information. For your information we would like to clarify a few of these areas of apparent misunderstanding.

"The consensus was that most of the research being supported did not originate in the individual project, but was 'derivative of work accomplished elsewhere."

We would suggest that as much initiative is required to build on state of the art knowledge as to establish new approaches. It was never the intent of the NBCP to limit the program to novel approaches, but rather to focus attention on the problems of bladder cancer with the purpose of reducing the mor-

tality and morbidity from the disease. More specifically, the intent of the National Cancer Advisory Board and NCI was to develop the best possible program of research on the basis of investigator initiated projects supported through the granting mechanism in contrast to a program comprised of research projects directed through the contract mechanism.

"No useful models for bladder cancer have been developed in this project."

We regret that during the review on Nov. 23 the scientific presentation dealing with the development and uses of various models in bladder cancer was abbreviated. This circumstance may have been at least partially responsible for the lack of enthusiasm for NBCP models expressed in the written summary.

We have been very pleased at the wide range of models which investigators within the program have utilized, viz., animal models for screening chemical carcinogens, for studying initiation, promotion and progression, and for the study of bladder cancer pathogenesis, detection, diagnosis and treatment. Moreover, grants awarded under the NBCP have supported efforts in the use of heterotopically transplanted bladder, in vitro culture of normal differentiating transitional epithelial cells, and soft agar cloning of tumor cells as the basis of a system of chemotherapy drug selection. Ironically, previous reviews of the overall program have specifically singled out the development and application of models as a significant positive feature of the NBCP program. In the original NBCP plan, it was clearly indicated—and agreed to by other segments of the NCI—that this program would take primary responsibility for model development in bladder cancer research in order to prevent unnecessary duplication of effort within NCI. This effort led to the well characterized and clearly defined models which have in particular contributed significantly to our understanding of bladder cancer, and in general to our knowledge of two stage carcinogenesis, the roles of promoting agents, and ultrastructural changes and other morphologic characteristics of the neoplastic state. Indeed, although it is true that bladder cancer models have not yet reached the level of sophistication of those relating to liver and skin, it is also true that increasingly the results of bladder carcinogenesis studies are quoted along with the results of carcinogenesis studies employing liver and skin cancer models.

It was gratifying to note that the models dealing with clinical aspects of bladder cancer were viewed favorably by the committee.

"All the projects have attempted to develop radioimmunoassays at some time but none of the studies has been fruitful."

No radioimmunoassay effort has been evident in the NBCP.

"It was the unanimous and strong opinion of the reviewers that the organ site programs should limit their support of long term, expensive phase 2 and phase 3 trials. Instead, they should emphasize innovative site-specific developmental therapy and phase 1 studies, leaving further trials to the clinical cooperative groups supported by NCI through other mechanisms."

Clinical therapy trials in bladder cancer outside the NBCCGA consist largely of case reports and small pilot studies. A few institutions, e.g., Memorial Hospital, M.D. Anderson, and the Mayo Clinic do have enough cases in any given stage to conduct phase 2 clinical trials by themselves. The failure of other large institutions to carry out appropriate studies is not so much for lack of interest as it is for the lack of their individual capability to accrue sufficient numbers of patients in a reasonably brief period of time. It was the insight/foresight of such eminent biomedical scientists/urologists as Drs. Rubin Flocks and Willet Whitmore who participated in the initial Bladder-Prostate Advisory Committee which led to the concept of a clinical cooperative group large enough to access in a realistic time frame the number of cases that would be needed for meaningful clinical investigations. It was recognized and stated clearly by the Advisory Committee and the National Cancer Advisory Board that a need existed for an organizational structure to conduct phase 3 randomized clinical trials. It was evident that this would require the active participation of dedicated urologists in leadership roles in order to accrue the necessary patient resources. Moreover, the Advisory Committee recommended that close communication be maintained between the NBCP Headquarters and the Collaborative Group to assure effective interaction between basic scientists within the NBCP and the clinical specialists working within the NBCCGA. There is a dearth of phase 3 clinical trials in bladder cancer. To our knowledge, other existing cooperative groups, directed for the most part by medical oncologists, have not been able to obtain sufficient multispecialty involvement or recruit sufficient numbers of patients to conduct randomized clinical trials on bladder cancer as effectively as the NBCCGA, and they seem unlikely to develop this capability in the forseeable future.

"The NBCP headquarters staff is not directly involved in therapeutic trials except to administer grants to the National Bladder Cancer Cooperative (sic) Group A...."

It is regrettable that from the printed material or the presentations given to the committee the significant involvement of the NBCP headquarters staff in the NBCCGA activities was not evident. In fact, from the beginning of the program close working relationship between these two groups was mandated by the original Advisory Committee. The headquarters staff played a major role in facilitating and coordinating the initial planning efforts of the NBCCGA; including the development of the "Treatment Decision Net-

work" (matrix of diagnostic and therapeutic options) which provided the basis for the surveillance protocol and for the several clinical management protocols followed by the group. The staff also took a major part in developing the organizational structure and management procedures which led to the multidisciplinary makeup of the group. The staff played a leading role in the evaluation of the original data management system of the group and following the assessment of consultants recommended restructuring the statistical services. There has also been active participation by the staff in all executive committee and group meetings, with the directors of the administrative center, statistical coordinating center and the central cytology and pathology laborlatory, and as liaison between the NBCCGA and the Div. of Cancer Treatment, NCI.

". . . Seven of the 13 institutions participating in the bladder studies also serve as a source of patients for the prostate studies. . . ."

Two of the seven institutions cited for overlapping bladder and prostate patient studies are no longer supported by the NBCP. We have no information regarding their support by the NPCP.

"The four offices. . . without exception are overstaffed. . . ."

The administrative structure of the NBCP has never increased from that proposed, recommended and approved in the original planning and management documents. The staff has been meeting its basic obligations over the 10 years with an average of 2.5 professional and 1.25 support personnel. For most of its history, at least one position has been vacant. This has not been due to any one circumstance, and the understaffing has—despite what we believe to be significant accomplishments by NBCP—not allowed us to reach an optimal level of operations. However, we do not agree at all with the committee's assessment that the NBCP Headquarters is overstaffed.

In general, the recommendations of the committee regarding the future direction of the Organ Site Programs are reasonable, and they reflect much thoughtful consideration of both the past effort and future potential. We wish to comment briefly on a few of the recommendations as follows:

"The program should continue to constitute only a small fraction of the NCI budget (approximately five percent)."

It would indeed be a boon to the Organ Site Program to limit the budget to a small (five percent) fraction of the NCI budget since the current budget for all four projects constitutes only 1.5 percent of the total NCI funds!

"The program should phase out support for long term clinical trials which place a disproportionate burden on its resources and are often repetitious. Instead it should support highly innovative pilot studies in patients and focus attention on basic research."

We have carefully noted above the problem of patient accrual for any clinical trials in bladder cancer and what we perceive as a major continuing need for the existence of a multispecialty research organization headed by—and with major input from—urologists for the conduct of phase 3 studies of bladder cancer. We do not view our current activities as duplicative. In fact, we are not aware of any other group in this country carrying out clinical studies of this type or of this scope. However, future interaction with other cooperative groups to avoid undesireable overlap of activities would be both feasible and advisable.

It should be noted that NBCP does support innovative pilot studies of various kinds in patient populations, and has tried to encourage other cooperative groups to conduct studies in human patients and to share data from such studies as much as possible. The truth of the matter is, however, thus far no other cooperative group has been able to convince reviewers to support it primarily for phase 3 studies of bladder cancer.

"The review process should be streamlined in order to reduce the costs and time required by busy scientists for grant review and to foster communication among the groups. Following are some alternatives suggested by the review committee for further consideration in the near future. a) Form one review committee for all NOSP grants, with representatives expert in each of the sites; b) consolidate the review into bladder-prostate and large bowel-pancreas groups; c) use the established study sections at NIH for review."

The review process may indeed have to be modified, a judgment that will be made by others. However, we would like to note that one of the great advantages of our having had a review function in the past was that it provided the best possible continuous education about all aspects of bladder cancer research for the scientists involved, yielding in turn a much more knowledgeable set of reviewers as well as a much stronger basis for program evaluation by the Working Cadre. Perhaps providing a strongly committed board of scientific advisors with access to all NCI or NIH applications dealing with bladder cancer would help to compensate for its loss of the review function.

"To bring more new innovative investigators into the program, projects should be supported for a limited period, perhaps one to three years. Subsequent renewal should only occur in exceptional cases where continuity of support was essential to complete an objective."

The ability to bring more new, innovative investigators into the program would be an obvious advantage under the right circumstances. One of the most important functions of the NBCP, however, is to facilitate communication between all investigators of

bladder cancer, not just new ones. Currently our ability to bring about a high level of communication within the program is at least partially related to the fact that renewal (type II) applications as well as new ones (type I) are handled by the NBCP headquarters and the Working Cadre. At present the work of "old" as well as new investigators is monitored by the headquarters and the Working Cadre, and the headquarters has sufficient funds to bring together all principal investigators funded by the program at least annually, with the ability to convene small group meetings as necessary or desireable to meet programmatic needs. If competitive renewal applications were handled by some other mechanism, it is hoped that a means would be found to provide appropriate opportunities for meaningful interaction between new and "old" investigators.

MARIE LOMBARDI DIES; HHS HOLDING UP NCAB APPOINTMENTS FOR SIX VACANCIES

Marie Lombardi, widow of football coach Vincent Lombardi and a member of the National Cancer Advisory Board, died April 17 at a West Palm Beach hospital. She was 66. She had been ill for two months with a lung infection.

Mrs. Lombardi had not been attending NCAB meetings during the last two years, reportedly because of failing health and also because she felt she had not been contributing much to the Board's deliberations. Her term expired last February, along with those of five others.

The Dept. of Health & Human Services has refused to forward to the President nominations from NCI and NIH for the six vacancies, four times returning the list with the request for "additional information" about the prospective appointees.

The result is that the surviving five whose terms have expired will remain as members until replaced. Apparently there is little chance new appointments will be announced now before the Board's next meeting May 17-19.

The five include the chairman of the Board, Henry Pitot. Others are Bruce Ames, Harold Amos, Frederick Seitz, and Philippe Shubik. Mrs. Lombardi and Seitz were two of the Board's six lay members. Ames and Shubik are two considered as experts in environmental carcinogenesis.

An amendment to the National Cancer Act requires that five members be experts in envornmental or occupational cancer.

Although Amos will not be a member of the Board he will continue as an ex officio member because he is one of three members of the President's Cancer Panel.

President Reagan will have the opportunity to appoint the new chairman of the Board. He could name one of the new appointees or select from the holdover members—Maureen Henderson, Robert Hickey, Gale Katterhagen, Rose Kushner, Ann Landers, LaSalle Leffall, William Powers, Janet Rowley, Sheldon Samuels, Morris Schrier, Irving Selikoff, and Gerald Wogan. Kushner, Landers, Samuels and Schrier are lay members.

Since the NCAB was established by the National Cancer Act of 1971, those who have served as its chairmen—Jonathan Rhoads and Pitot—were scientific members, but the Act does not preclude lay members from the chairmanship.

Two major issues will be brought before the Board in May—the Organ Site Program (see previous article), and the Community Clinical Oncology Program. The Organ Site Program discussion is scheduled for May 17, at 3:30 p.m., while the CCOP discussion will be May 19 at 8:30 a.m.

Other items on the May agenda are a discussion of the NIH grant review process; a presentation on the International Agency for Research on Cancer by its new director, Lorenzo Tomatos; and a discussion on the significance and use of relative cancer survival rates.

ETHICS COMMISSION ACKNOWLEDGES WEAK CASE FOR COMPENSATION

The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research will issue a report later this year on the touchy issue of compensation for subjects injured in research which will acknowledge that there is little data to justify a mandatory compensation plan.

The report also will admit that a compensation plan would face serious administrative difficulties and that the moral issue does not appear to be all that convincing.

Nevertheless, the commission will recommend that a small pilot study involving a few institutions be undertaken to establish whether a need exists for a compensation program.

The commission's charter is due to expire at the end of this year, although legislation authorizing biomedical research (including the National Cancer Act) now in Congress would extend it for at least one more year.

The commission recently summarized the reports which it will be turning out this year, including:

COMPENSATION OF SUBJECTS INJURED IN RESEARCH

Compensation for research related injuries, as considered by the commission, encompasses the provision of, or payment for, necessary medical and rehabilitative services, and payment for lost wages and other direct expenses, but not for pain and suffering or other intangibles. It is distinct from remuneration, which is payment for the time and trouble of being a research subject.

Early in 1980, the commission was asked by the Dept. of Health & Human Services to review the

1977 report of the HEW Secretary's Task Force on Compensation for Injured Research Subjects. The report favored compensation for subjects of therapeutic as well as nontherapeutic research who were "on balance" made worse off through their participation in research. The commission has questioned three of the Task Force's premises. First, present data do not establish whether injuries are frequent or severe enough to justify a mandatory compensation plan; second, a number of practical administrative difficulties appear likely under the proposals of the Task Force; and third, the moral claims of injured subjects in many circumstances (particularly for therapeutic research that aims to find a new and better treatment for patient-subjects' disease or disability) appear less convincing than acknowledged by the Task Force.

The commission will instead recommend to HHS that it conduct a small experiment in which a few research institutions would be given funds for several years to establish nonfault compensation programs with varying features. Such an experiment should establish the need for, and the feasibility and expense of, such programs. It would also mean that the incidence of reported injuries in these institutions could be compared with the experience of other institutions where research injuries would be tabulated but where subjects would not be offered compensation.

INFORMED CONSENT IN RESEARCH AND TREATMENT

The commission's statutory mandate calls for a study of "the ethical and legal implications of the requirements for informed consent to participation in research projects and to otherwise undergo medical procedures." The project reflects two decisions by the commission at an early stage of its work. First, the commission will focus the "informed consent" project on health care rather than upon research. (The research aspects will be taken up as part of the commission's separate biennial report on the protection of human research subjects.) Second, the commission, though recognizing that "informed consent" is a doctrine developed by the law, decided that it could make a larger contribution on the subject if it did not limit its study solely to the legal aspects of informed consent. Instead, the commission is looking more broadly at relationships between patients and health care providers and the role that communication plays in promoting "better" or "more autonomous" decisions by patients.

Some of the questions being addressed include:

—What role do medical schools and other training programs play in shaping providers' attitudes and behavior regarding consent and their relationship with their patients generally? What changes might be brought about and how?

—What influence does the treatment setting (private office, clinic, hospital, etc.) have on provider-patient communication? Is change possible here?

—What role has the law (e.g., malpractice litigation) played in shaping the provider's attitude and behavior and the patient's response?

—Does "informed consent" offer any remedy for problems in this area, especially in allowing patients to avoid excessive or otherwise undesired treatment that is prompted by "defensive medicine"?

—What factors determine the "incompetence" of various groups to consent to biomedical interventions (children, the aged, mental patients, prisoners in research settings, etc.) and are they explained by any one set of criteria?

RESEARCH WITH HUMAN SUBJECTS

The commission released its first biennial report on the protection of human research subjects in December 1981. A second report will be published in December of this year.

Response to the first report has been very positive. All affected agencies but one have formally endorsed the commission's recommendation of a uniform set of regulations to govern all federally supported research with human subjects. A government wide committee has been established to draw up these "core" regulations, based upon the current rules of the Dept. of Health & Human Services.

The commission found that present federal oversight of the process of research review and approval is inadequate. Although the Food & Drug Administration inspects institutions at which research is conducted, this process is not keyed closely to the HHS requirements. The department itself has promised adequate compliance activities, but has yet to develop a program. In the absence of systematic review of the quality of institutional review boards, reliable, generalized information on whether these bodies are adequately protecting human research subjects does not exist.

To overcome this inertia, the commission is trying out various forms of site visits to IRBs. A report on the outcome of this study will be included in the second biennial report. The commissioners will decide whether to recommend a site visit system, and if they do, what elements should be included, how institutions should be selected, and under what auspices the visits should be conducted. In addition, the report will discuss the extent to which objective standards of performance can be developed.

The second biennial report will also provide a summary of the commission's efforts to develop a guidebook for IRBs, as a form of ongoing education for IRB members.

CONFIDENTIALITY OF, AND PATIENT ACCESS TO, MEDICAL RECORDS

The commission has held hearings on the ethical aspects of (1) the privacy and confidentiality of treatment and research records and (2) patient access

to such records. The commissioners heard from representatives of several previous groups concerned with privacy, including counsel for the Privacy Protection Study Commission (1974-77), the Royal Commission of Inquiry into the Confidentiality of Medical Records in Ontario (which issued its final report in 1980), and the National Commission on the Confidentiality of Medical Records (which was active in the late 1970s). Testimony was also presented by representatives of patient groups, hospital administrators, and epidemiologists. Finally, the commission was informed of the legislative proposals made in recent years.

The commission has decided to divide the study into three parts:

1. Issues relating to the privacy of research records and to the use of patient records in research will be incorporated into the second biennial report on the protection of human research subjects.

2. Issues relating to patient access and third party (e.g., insurance companies and employers) access to records will be incorporated into the report on informed consent. Matters regarding genetic information in patient records will be included under the informed consent study or the study on genetic screening and counseling.

3. A brief report will be prepared on the core issues of philosophy and policy, such as the nature and importance of preserving privacy (as these factors enter into rules about the confidentiality of records), whether there are intangible harms in invasions of privacy distinct from loss of income and the like, and why health information is of special sensitivity.

NCI CONTRACT AWARDS

Title: One additional alteration/renovation project at Frederick Cancer Research Facility, modification

Contractor: Litton Bionetics, $2,200,000.

RFPs AVAILABLE

Requests for proposal described here pertain to contracts planned for award by the National Cancer Institute unless otherwise noted. Write to the Contracting Officer or Contract Specialist for copies of the RFP, citing the RFP number. NCI listings will show the phone number of the Contracting Officer or Contract Specialist who will respond to questions. Address requests for NCI RFPs to the individual named, the Blair Building room number shown, National Cancer Institute, 8300 Colesville Rd., Silver Spring, Md. 20910. RFP announcements from other agencies reported here will include the complete mailing address at the end of each.

SOURCES SOUGHT

NCI-CB-23918-42

Title: *Central statistical group for a collaborative study in early lung cancer detection screening*

Deadline for Statement of Capabilities: *Approximately May 12*

NCI is issuing this announcement to identify interested organizations capable of serving as a central statistical group for the ongoing Early Lung Cancer Program which was initiated in 1974. This program involves three clinical centers (namely, Mayo Clinic, Johns Hopkins and Memorial Hospital).

Approximately 30,000 men were entered into this program. The study consists of a screening phase and a followup phase. The screening phase will end later in 1982 with a subsequent followup phase of up to five additional years. The central statistical group would be involved in the continuation of the data collection from the three clinical centers and data analysis and reporting. Specifically, the contractor would be involved in the transfer of the data bank and the maintenance of the existing program and computer system for data collection, editing and analysis.

Experience and capabilities must cover:

1. Experience in biostatistics and epidemiology relevant to analysis and evaluation of cancer screening studies.

2. Access to computer facilities and experience in data management and processing related to the computer aspects of the study.

3. Coordination, implementation and participation in procedures for the determination of cause of death among study participants.

4. Familiarity in design and logistics of multi-institutional cooperative studies.

5. Published and unpublished data related to this type of work.

This announcement is not a request for proposal and does not commit NCI to award a contract now or in the future. No RFP is available at this time.

Interested organizations are invited to respond to this announcement. Responses should include sufficient information to demonstrate capability and facilities of the respondent to carry out the data collection and reporting from the three clinical centers.

Respondents should limit their responses to 10 pages. Ten copies of this document must be submitted to:

Contracting Officer: Dorothy Coleman
RCB, Blair Bldg. Rm. 332
301-427-8877

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