

NCI's Independence To Be Challenged By Edwards When Cancer Act Comes Up For Renewal Next Year

The Administration will ask Congress to strip the National Cancer Institute of the extra powers it was granted by the National Cancer Act of 1971, unless President Nixon over-rules HEW Secretary Caspar Weinberger and Asst. Secretary for Health Charles Edwards.

The three-year authorization of the act expires next June 30. There is no question it will be renewed, but Edwards has publicly denounced the independence NCI enjoys, particularly in development of its budget. The 1971 act prohibits NIH and HEW from making any changes in the institute's budget request. Only the President, through the Office of Management & Budget, may revise NCI's figures before it goes to Congress.

Edwards insists that the cancer program should be part of his overall "national health strategy," competing for funds on an equal basis with other programs.

The Cancer Newsletter has learned that Edwards, with Weinberger's support, intends to press for a revision that will put NCI back on the same level as other NIH institutes. This would give Edwards veto power over every item in the cancer budget. Edwards has left little doubt that he would exercise that power, on some items at least, if he has the chance.

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IN BRIEF

Schmidt Sells OMB On Training Grants, But Weinberger Is The One To Convince

Benno Schmidt, chairman of the President's Cancer Panel, feels he made progress when he argued NCI's case on research training grants and fellowships with Office of Management & Budget. In this instance, however, OMB will not have the last word. HEW Secretary Caspar Weinberger decided, when he headed OMB, to kill the NIH training program and wouldn't change his mind after moving to HEW. Congress may have forced Weinberger to back down (See HEW budget story, page 2) . . . NCI Director Frank Rauscher says the most damaging blow to cancer research has been the Administration's ceiling on positions. NCI scientists are doing clerical work because OMB (or Weinberger) won't permit Rauscher to hire more people. Rauscher may put to use the authority he has to bypass HEW and take his case directly to the President, and Congress . . . Another level of contract review may be superimposed over NIH procedures by HEW. Asst. Secretary for Health Charles Edwards is considering establishing review in his office for contracts over \$1 million. Rauscher fears this would add 1-2 months to review time already requiring 5-7 months.

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President Accepts Compromise On HEW Money Bill; Cancer Gets \$523.6 Million

The President's decision to accept the HEW appropriations bill hammered out by House-Senate conferees has sent NIH morale soaring and has guaranteed increased cancer research efforts for another year.

The bill appropriates at least \$523.6 million and a maximum of \$551.2 million for the National Cancer Institute, depending on whether or not the President exercises the option to impound up to 5% of the funds in any single program. To avoid a veto despite the fact that the entire Labor-HEW bill exceeded Nixon's budget request by \$1.4 billion, Congress agreed to permit him to impound as much as \$400 million. No more than 5% may be cut "from the amount specified in this act for any activity, program or project," the conference report said.

The Administration had requested \$500 million for NCI in the 1974 fiscal year. The House voted \$522.4 million, the Senate \$580 million, and they compromised at \$551.2 million.

Even if the full 5% cut is imposed, it still will be \$90 million more than NCI received in fiscal 1973. The possibility remains that NCI also will get the \$60 million in 1973 money withheld by the Administration from the \$492 million voted by Congress in the twice-vetoed appropriations bill. That bill specifically provided two-year spending authorization for fiscal 1973 cancer funds; NCI executives consider the \$60 million as still lying there, waiting to be picked up if only the Office of Management & Budget will go along.

Some doubt exists that the President can legally withhold any part of the full appropriation, 1974 as well as 1973. The National Cancer Act of 1971 states that the NCI director will "receive from the President and the Office of Management & Budget directly *all funds appropriated by Congress* for obligation and expenditure by the National Cancer Institute." That would seem to block any impoundment; however, the appropriations bill also has the force of law. The conference report lists the amount of money appropriated for each HEW agency and shows the amount each would receive if cut by 5%. NCI is included with the others and is not shown as receiving any special consideration. This probably could be interpreted as a clear indication of Congress' intent, overriding provisions of the cancer act.

Establishing the minimum NCI appropriation at \$523 million means that 548 competing research grants (both new and competing renewals) will be funded in fiscal 1974 at a total of \$34.6 million. In 1973, 431 grants were funded with \$23.8 million.

The percentage of approved grants to be funded will remain almost the same, 52% for 1973 and 51% for 1974. The number of grant applications approved this year is estimated at 1,078, up from 834 the previous year.

At least one delightful problem has been created for NIH by the availability of more money than the President had sought. His budget had omitted funds for research training grants and fellowships, since the Administration had decided to terminate those programs. Congress insisted on including money for them, however; the caveat against cutting more than 5% is in the law; and now it is up to HEW Secretary Caspar Weinberger and OMB to decide what to do about it.

The token training grant program offered by Weinberger after the House had overwhelmingly approved the Rogers bill mandating continuation of the old one satisfied no one. The Senate added so many new items to the Rogers bill that it was referred back to Rogers' Health Subcommittee, where it is languishing.

Meanwhile, Weinberger must decide what to do about all the money he has been ordered by Congress to spend on a program he has tried to kill.

NIH will enjoy a minimum increase over the budget request of \$191.4 million, which was cause for celebration among the staff after a year of suffering through dreary Administration efforts to make biomedical research and other health programs bear the brunt of anti-inflation austerity. "It's just like the good old days," one NIH executive said gleefully.

Research Opportunities In Pancreas Cancer Described; Top Priority Set

The "surging incidence" of pancreatic cancer, which will cause 20,000 deaths a year by 1975 making it the fourth leading cancer killer, "has put this cancer site" in the major leagues," James A. Peters, director of NCI's Division of Cancer Cause & Prevention, told the National Cancer Advisory Board.

Cancer of the pancreas thus has gained a spot in the national cancer program as a major priority for concentrated, sharply targeted action. A big increase in research activity may be expected during the next year, Peters and others emphasized in their presentations to the NCAB.

Extremely low survival rates, difficulty of early diagnosis and lack of response to treatment and surgery characterize the disease. But a growing number of clues indicate it is an "essentially man-made disease, and therefore by definition a preventable one," Peters said.

"The profile of the individual at high risk for cancer of the pancreas is that of a heavy smoker on a western diet high in cholesterol and fat. Other minor factors may be city living, race, a family history of multiple polyposis, and the ataxiatelangectasia syndrome," Peters said.

"Desirable and feasible research" Peters said is needed includes:

— Consideration of anatomical characteristics of the tumor; whether it originates in acinar or duct

cells. Acinar origin would lend credibility to endogenous etiologic theories, perhaps incriminating viruses, while a duct cell origin would be more consistent with carcinogenic origination outside of the pancreas itself.

- General location of the cancer in the pancreas.
- Close scrutiny of the biochemistry and fate of biliary acids.
- Chemical configuration of bile acids, and determination of how smoking, high cholesterol and fat consumption affect bile composition, perhaps adding to its carcinogenic load. The role of betanaphthylamine should also be investigated since chemists exposed to this compound have shown a higher risk to pancreas cancer.

Research opportunities in etiology and prevention listed by Peters were:

- Epidemiology—environmental and host related factors, prospective studies of high-risk groups.
- Tumor biology—morphology, biochemistry, physiologic and metabolic conditions.
- Development of experimental models—total models of metabolic and physiologic characteristics similar to man; organ and cell cultures; partial models for carcinogen bioassay.

- Testing of etiologic hypotheses—bile reflux, liver metabolism, bile acids; dietary etiology, nitrosamines, B-naphthylamine, other diet carcinogens; viral etiology.

Diagnosis research opportunities listed were:

- Prospective studies of high-risk groups to discover early symptoms or disease markers, predisposing conditions.
- Tumor biology—biochemical markers, proteins, t-RNA, enzymes; immunological markers, CEA virus antigens.

Therapy research opportunities listed were:

- Tumor biology, to identify characteristics amenable to optimum therapy.
- Clinical trials, chemotherapy.
- Surgical management.
- Radiotherapy.

One of the big problems to be overcome to achieve significant progress is development of a suitable animal model. "If the reflux theory is as significant as it appears to be," Peters said, "then experimental models must be physiologically close to the human situation." Small animals are not suitable, and even the dog does not provide biliary composition and metabolism relevant to man.

Some primates may be acceptable, although adding complications to research logistics. Smaller animals may be used as partial models.

Joseph F. Fraumeni, associate chief of epidemiology, discussed epidemiologic considerations:

- Incidence and mortality from pancreatic cancer in the U.S. has risen more rapidly in blacks than whites.
- It is relatively rare in Japan, but Japanese mig-

rating to the U.S. reach a risk close to prevailing rates here.

- Highest rate in the world is reported for the Maoris of New Zealand. Hawaiians, also a Polynesian group, have rates nearly as high. American Indian females have rates significantly higher than whites.
- Diabetics have significantly increased risk.
- About 20% of patients dying with hereditary pancreatitis have pancreatic cancer at autopsy.
- No environmental exposure has been proven to cause pancreatic cancer. Only tobacco has been consistently implicated.

Stephen K. Carter, associate director for cancer therapy evaluation, pointed out that "survival rates are so poor . . . that aggressive therapeutic procedures are worthy of trial."

The cure potential of surgery is limited, Carter said. Only 7 to 10% of patients undergoing surgery are alive after five years. There is hope that surgery plus radiation plus chemotherapy will work.

Clinical trials cited by Carter:

- Fluorouracil (15 studies, 212 patients), 60 responses.
- Streptozotocin (2 studies, 18 patients), 7 responses.
- Mitomycin C (4 studies, 44 patients), 12 responses.
- Radiotherapy plus 5-fluorouracil. Radiotherapy plus 5FU, 32 patients, mean survival 10.4 months; radiotherapy plus placebo, 32 patients, mean survival 6.3 months.
- High dose (6,000R) plus 5-FU, 29 patients, 21% surviving after 30 months.

H. Marvin Pollard, Univ. of Michigan, reported on an American Cancer Society symposium on pancreatic cancer. "There is very little first class research in the field," Pollard quoted one symposium participant. Basic research needs include effects of secretagogues on exocrine function, attention to the question of whether calcium is required or discharged in the secretory process, and recovery of pancreatic cells from injury.

NCAB Asks Government To Take Steps Aimed At Reducing Health Hazards From Cigarettes

The National Cancer Advisory Board, declining to seek specific legislation to establish maximum tar and nicotine levels in cigarettes, has called on the federal government to take steps "for reducing the health hazard from smoking cigarettes."

These steps should include efforts to reduce cigarette smoking, the board resolution said. It also recommended that federal regulatory agencies in the health field should be utilized both to reduce smoking and to enforce hazard-reduction measures. Where necessary, the President and Congress should consider legislation to strengthen powers of the regulatory agencies, the resolution said.

RFPs AVAILABLE

All requests for proposal described here pertain to contracts planned for award by the National Cancer Institute, unless otherwise noted. Write to the Contracting Officer indicated or phone the Contract Specialist. NCI's address is Bethesda, Md. 20014. All requests for copies of RFPs should cite the RFP number.

RFP NCI-CN-74-11

Title: *Oncology nursing programs in community hospitals*

Deadline: Jan. 29, 1974

Only community hospitals will be considered for this project of the Office of Cancer Control. To meet the serious need for greater numbers of personnel to provide specialized nursing care for cancer patients, the program will enlist the assistance of specially qualified nurses to train other nurses in cancer care at the undergraduate, inservice and continuing education levels.

Program objectives: increase knowledge and understanding of cancer in all of its aspects—prevention, detection, treatment and rehabilitation; augment existing skills and practices in cancer care; and promote new methods, approaches, and techniques consistent with the latest cancer and related research findings.

To qualify for consideration, a community hospital must provide evidence of:

- Strong support for this educational program from other hospitals, nursing schools, and other agencies in the same geographic area that would use or otherwise benefit from the training program.
- A minimum of 300 beds.
- An organized nursing service consistent with the standards of the Joint Commission for the Accreditation of Hospitals.
- A yearly census of cancer patients sufficiently high in numbers and varied as to cancer sites, to provide clinical experience in the most commonly occurring cancers.
- Both inpatient and outpatient services and linkages with a community facility such as a nursing home so that experience can include primary, acute and extended care.
- Teaching programs for cancer patients and their families.
- An orientation program for new employees.
- A cancer program and tumor clinic approved by the American College of Surgeons.
- An active nursing audit committee.
- An ongoing inservice education program for nursing personnel with an educational director appropriately qualified to direct such a program.
- A minimum of two physicians in different specialties who through postgraduate courses, self-study or specialized experience have become especially qualified to treat cancer patients.

— A faculty responsible for affiliating student nurses (professional or practical) receiving clinical experience in the hospital which is supportive of the proposed continuing and inservice education program.

Costs eligible for government funding include salaries of personnel involved in the training program (but not stipends for trainees); travel expenses and per diem for trainees attending workshops, conferences and courses away from the training institution; and equipment and supplies required by the program.

Contracting Officer: Hugh E. Mahanes Jr.
Cancer Control Contracts
Section

Contract Specialist: Patricia A. Eigler
301-496-6991

RFP NCI-DCBD-74-2

Title: *Development of a simple, quick, accurate (98%) method of the detection of small amounts or more (over 7-10 mls per 24 hrs) of human blood in human feces*

Deadline: Jan. 14, 1974.

Cancer of the large bowel and the entire gastrointestinal tract is frequently first detected by finding either gross or occult blood in the stool. Food derived from animal sources ingested causes present (non-specific) tests to be falsely positive in about 5% of screenees. True positive rate should be about 1% if only human blood is present. Meat free and high roughage diets do not lend themselves to large-scale screening; blood cell tagging by radioisotopes also is not desirable for large groups.

The contractor shall develop detection procedures utilizing some of the following methods:

1. Detection of globins specific for human blood.
2. Detect red or blood cell surface antigens specific for human blood.
3. Detect other antigens specific for human blood cells.
4. Other and innovative methods more feasible for screening.
5. Application of the test to an adequate number of persons both known to be bleeding and thought not to be bleeding is essential. An adequate number of controls must have been on high meat, poultry and fish diets and be truly negative by the proposed test.

The diagnostic procedure developed should be capable of being used by screenees so that they can collect and mail in specimens to be examined.

NCI anticipates the contract will span two years; offerors should furnish their own estimates of the time required.

Contracting Officer: H.P. Simpson
Div. of Cancer Biology &
Diagnosis

Contract Specialist: J.H. Reynolds
301-496-5565

The following RFPs are available from the Contracting Officer, Division of Cancer Biology & Diagnosis:

RFP NCI-CB-43920-31—Biochemistry of normal and tumor cell surface antigens.

RFP NCI-CB-43921-31—Human tumor-associated antigens and corresponding antibodies.

RFP NCI-CB-43922-31—Organization and dynamics of cell surface membrane components relevant to tumor immunology.

RFP NCI-CB-43923-31—Specificity of antigen-binding receptors on T-cells.

RFP NCI-CB-43924-31—Detection of antigen-binding activity of transplantable T-cell tumors.

RFP NCI-CB-43925-31—Serologic and immunogenetic investigations of tumor associated or normal cell surface antigens.

RFP NCI-CB-43926-31—Chemical characterization of purified thymic products or other agents promoting lymphocyte differentiation.

RFP NCI-CB-43927-31—Mechanisms of lymphoid cell differentiation.

RFP NCI-CB-43928-31—Identification, separation, quantification and characterization of lymphocytes and macrophages.

RFP NCI-CB-43929-31—Selective stimulation or suppression of humoral or cellular immunologic responses.

RFP NCI-CB-43930-31—Studies of the mechanisms by which tumors avoid destruction by the immune system.

RFP NCI-CB-43931-31—Investigations of the nature and function of immune-related cells in tumor masses.

RFP NCI-CB-43932-31—Mechanisms for cell-mediated destruction of tumor cells.

RFP NCI-CB-43933-31—Development or improvement techniques for in vitro sensitization of human lymphocytes.

RFP NCI-CB-43934-31—Genetic control of immune responses in relation to cancer.

RFP NCI-CB-43935-31—Production and distribution of H-2 recombinant or mutant congenic strains of mice.

RFP NCI-CB-43936-31—Improved detection and development of H-2 recombinant strains.

SOURCES SOUGHT

These RFPs will be sent only to organizations NCI considers as qualified to perform the work described. Submit the indicated copies of resumes to the Contracting Officer or Contract Specialist. Note deadlines for receipt of resumes.

RFP NCI-CM-75-5

Title: *Clinical trials on carcinoma of the breast*

Deadline: *Jan. 15, 1974*

Multiple contracts will be awarded to organizations

with the capability of carrying out clinical research programs in patients with disseminated carcinoma of the breast. These studies will entail evaluations of new drugs which are ready for Phase II trials as well as new combination therapy programs. Protocols would be determined jointly by NCI and the contractors. To qualify, institutions must be capable of entering at least 75 patients per year, previously untreated with cytotoxic chemotherapy, into the protocol. Consideration will also be given to smaller institutions which combine their resources to meet the 75 patient requirement. Each such smaller institution must indicate in its resume with whom it is combining resources and plans for coordinating research.

All resumes must include:

1. Name, qualifications and experience of scientists, and technical personnel available for the project.
2. Published or unpublished data related to this work.
3. Availability of clinical facilities.
4. Evidence of at least 75 eligible patients per year.
5. Capability to carry out controlled clinical trials and provide necessary initial and follow-up information.
6. Availability and description of facilities required to perform in the technical area under consideration.
7. Proficiency in the technical procedures.

Submit 15 copies of the resume to:

Contracting Officer: George E. Summers
Cancer Treatment Contracts
Section

RFP NCI-CM-74-55

Title: *Phase II and Phase III studies in patients with disseminated solid tumors*

Deadline: *Jan. 7, 1974*

Qualified institutions must produce at least 400 patients per year with large bowel cancer, bronchogenic carcinoma, breast carcinoma, pancreatic carcinoma, gastric carcinoma, prostatic carcinoma, bladder carcinoma, renal carcinoma, ovarian carcinoma, malignant melanoma, or soft tissue and bone sarcomas. A minimum of 25 patients per year must come from each tumor type.

Protocols will include Phase II testing of new investigational drugs, Phase II testing of standard anti-tumor drugs not previously tested against the particular tumor type, and Phase II testing of new combination chemotherapy regimens as well as Phase III trials to determine the definitive activity of the above regimens. Protocols also may include combined modality approaches in which chemotherapy is combined with surgery, radiotherapy, or immunotherapy. Multiple awards will be made.

Resumes must include:

1. Experience and capabilities of proposed project manager and all key personnel.

2. Past experience of the institution in similar or related projects including published and unpublished articles.

3. A plan for the implementation and operation of clinical trials.

4. Evidence of ability to obtain the required number of patients.

5. Availability and description of facilities.

Submit 10 copies of the resume to:

Contracting Officer: George E. Summers
Cancer Treatment Contracts
Section

RFP NCI-CB-43938-37 (Project No. CB-43938-S)

Title: Investigation of possible correlations between morphological and epidemiological characteristics of breast cancer.

Deadline: Feb. 5, 1974

Proposals are solicited from organizations capable of combined morphological and epidemiological studies of human mammary cancer to evaluate relationships between the morphological characteristics of breast cancer, the natural history of the disease, and specific epidemiological factors such as geographic locale, race, familial history, age at diagnosis, and parity.

RFPs will be available Dec. 26 from:

(List both RFP and Project numbers)

Contracting Officer: H.P. Simpson
Cancer Biology & Diagnosis
Section

RFP NCI-CB-43939-37 (Project No. CB-43939-S)

Title: Biochemical and physiological investigations based on familial genetic patterns

Deadline: Feb. 5, 1974

Proposals are solicited from organizations for selected endocrine and biochemical measurements (study 1) on blood and urine specimens from premenopausal female members of families with a high incidence of breast cancer and from premenopausal members from matched control families. Endocrine assays are to be performed as follows: Urine—11-13 metabolites of estrogens, androgens and corticosteroids; blood—follicle stimulating hormone (FSH), luteinizing hormone (LH), progesterone and prolactin; estradiol (E2) estrone (E1) and estriol (E3).

In addition, measurements will be made of physiological markers (study 2) such as enzyme, aryl hydrocarbon hydroxylase (AHH). These may be done in conjunction with the endocrine studies or separately.

These studies will be carried out by separate investigators or a collaborative group using its own patient resource or the patient resource of the Breast Cancer Task Force. Proposals may be submitted on one or both of the above studies, and awards may be

made on an individual basis or as a total unit.

RFPs will be available Dec. 26 from:
(see above).

RFP NCI-CB-43940-37 (Project No. CB-43940-S)

Title: Investigations of histocompatibility antigens and other genetic polymorphisms in high and low risk breast cancer families.

Deadline: Feb. 5, 1974

Proposals are solicited for lab studies of genetic markers in about 75-multiple-case families with breast cancer and matching controls from low risk breast cancer families. Tests should include: (A) measurement of histocompatibility (HL-A) antigens; (B) studies of the immunoglobulins (Gm, Inv & A2m), red cell enzyme (PGM), blood groups (ABO, Rh, K, Fy, Jk, MNS) and serum markers (haptoglobins, phosphatases); (C) karyotyping of selected individuals should be conducted to assist in chromosomal localization of genetic markers of breast cancer susceptibility.

Studies may be carried out by separate investigators or a collaborative group, using its own patient resource or that of the Breast Cancer Task Force. Proposals may be submitted on one or all of the above studies, and awards may be made on an individual basis or as a total unit.

RFPs will be available Dec. 26 from:
(see above).

SOLE SOURCE

These are proposed contract renewals, listed here for information purposes only. RFPs are not available.

Title: *Development and production of oral and parenteral dosage forms*

Expiration date: *March 31, 1974*

Contractor: *Univ. of Tennessee*

Renewal Budget Estimate: *Not to exceed \$75,000*

Balance on hand as of Nov. 30, 1973: *\$67,954*

Contract Specialist: *Thomas R. Hardy*
Cancer Treatment Contracts
Section

Title: *Development of Parenteral Dosage Forms for Clinical Investigation*

Expiration date: *March 21, 1974*

Contractor: *Univ. of Kansas*

Renewal Budget Estimate: *Not to exceed \$90,000 for first year of a three-year contract; total anticipated cost for three years not to exceed \$285,000.*

Balance on hand as of Nov. 30, 1973: *\$57,183.*

Contract Specialist: *Thomas R. Hardy*
Cancer Treatment Contracts
Section

Frederick Center Should Have Top Scientist As Director, 20% Of Budget For Basic Research

Basic research should have at least 20% of the budget at the Frederick Cancer Research Center and should be directed by a person "of outstanding caliber and stature . . . whose personality, philosophy and attitudes will set the tone of the whole program and whose inspiration and leadership will create an esprit de corps that is essential to success."

That is the conclusion of the ad hoc advisory committee on the Frederick Center in its final report to the National Cancer Advisory Board. The committee was headed by Sidney Weinhouse, director of Fels Research Institute.

The committee reviewed the program and facilities at the former biological warfare center in Ft. Detrick, Md., where Litton-Bionetics, Inc. operates the facility for NCI on a \$10-million contract. The committee found that research programs there now are targeted toward specific objectives of the National Cancer Program "in a reasonably satisfactory manner."

If that is to be the only purpose of the center, the report says, it needs only some organizational improvements to clarify the lines of authority, responsibility and communication. "The center would then have a worthwhile, well-defined but limited role as a provider of products and services, both to NCI and to the outside scientific community."

That wasn't what President Nixon or the NCAB had in mind in the sword-to-ploughshare conversion of Ft. Detrick. It was to become an international center of leadership in the cancer program. The Weinhouse committee found that the present structure does not provide the kind of effective scientific leadership such a goal requires.

The present Litton staff is competent for the scientific management of the present program, the report says. "But neither the general manager, Robert Stevenson, nor the director of science, John Landon, fulfill the requirements of a director whose "judgement, foresight, and reputation will make it possible to recruit the top-flight scientists" needed to give the center the role envisioned for it.

The director of the basic science program would be "a leader of a team of innovative scientists, each of whom has the freedom to pursue his own project without specific direction from above," the report says.

The director should have a high-level status within the NCI administration, the report notes. In a preliminary report to NCAB last June, Weinhouse had suggested that the director would be the equivalent of an NCI division director. That drew fire from existing division directors who have their own programs at the center. The final report suggests that the entire operation of the center be under the Division of Cancer Cause & Prevention, which already funds about 80% of the center's total budget.

The present budget for service-oriented research is about \$9.5 million. Twenty per cent (\$2.5 million) should support 10-20 independent investigators and their staffs, the report says. "This would establish a reasonable balance with the targeted research."

The center should be free to develop appropriate academic affiliations, the report suggests. It is within an hour's drive of Johns Hopkins, Univ. of Maryland, George Washington Univ., and the Hershey Medical Center. Affiliation need not be with a single institution.

The committee objected to the fact that NCI awards the contract to Litton on a year-to-year basis, fearing that lack of security and continuity could impair the search for a top-flight scientist to run the program. Carl Fretts pointed out that a provision exists in the Litton contract permitting its Frederick staff to switch to the successful contractor if Litton loses the job.

NCI Director Frank Rauscher asked what the director's special field of interest should be. "A microbiologist? An expert in chemical carcinogenesis? Perhaps we should determine that before we start looking for someone? Does the country need another lab for viral oncology more than one in chemical carcinogenesis?"

"Those are the wrong questions to ask," said Sol Spiegelman, Columbia, an NCAB member. "Get the best guy you can."

The report said the committee considered the fact that "this unique facility was made available to the National Cancer Program with high hopes and expectations that it would become an internationally renowned institution, at the forefront of the cancer effort, providing both research and service functions of the highest quality."

The Center now has programs in three major project areas—chemical carcinogenesis, viral oncology, and animal production and holding. Chemical carcinogenesis projects are:

1. Bioassay and studies on bowel cancer, investigating metabolism of selected bacterial species.
2. Large-scale bioassay, involving selected compounds and effects on mice and rats.
3. Preparation and characterization of carcinogens.
4. Bioassay methodology for potential carcinogens.

Viral oncology projects include:

1. Virus production. 150 liters per week of oncogenic or suspected oncogenic viruses.
2. Development research, development of protocols for virus production.
3. Preparation of viral diagnosis and test reagents from selected viruses.
4. Viral oncology research, basic research in direct support of existing programs in the viral etiology of human neoplasia.

Cancer Control Program Guidelines Developed For Payment Of Patient Costs

Guidelines to be used in determining when patient care costs will be paid by funds allocated from NCI's Cancer Control Program have been adopted and are now in force.

The Cancer Control Program was mandated by Congress in the National Cancer Act as a major effort to spread the fruits of research as widely as possible. The program is not designed to support treatment of patients. It will involve demonstration projects and community outreach programs. Since there were no clear definitions of the program's parameters, regulations were needed relating to patient costs before NCI could start awarding the \$30 million in contracts and grants CCP will have in fiscal 1974.

The guidelines provide that:

— CCP funds may be used for patient costs only when such costs have been approved and budgeted. Participation in a project does not relieve the patient or third party carrier of responsibility for "ordinary and routine medical care."

— CCP funds may pay costs that are specifically required by the protocol. This may include support of personnel and other operational costs for a specific unit which provides the service, or by payment of individual procedure costs as performed. It also may include payment for specific lab and other procedures which would not have been performed except for participation in the project.

— In most cases projects will be carried on as outpatient projects. In those cases where the protocol specifically requires hospitalization, CCP funds may support such inpatient costs.

— Transportation costs of screenees will not be provided. Transportation costs of cancer patients enrolled in CCP projects will be provided only in special cases where the patient cannot participate unless such costs are paid.

— When CCP funds are used to provide for procedures or professional fees, no other party may be charged for such costs.

Cost sharing will be encouraged for both CCP contracts and grants.

1. Where an institutional cost sharing agreement is in effect, the cost sharing arrangement for CCP contracts or grants will be consistent with such institutional agreement.

2. If there is no institutional agreement, cost sharing arrangements will be negotiated on a case by case basis.

Edwards To Challenge NCI's Independence When Congress Reviews Cancer Act

(continued from page 1)

The provision permitting NCI to bypass NIH and HEW in the budget making process was a compromise engineered by Rep. Paul Rogers, chairman of the House Health Subcommittee. The Senate had previously passed a bill that would have taken NCI completely out of NIH and made it virtually an independent agency, responsible only to the President and Congress. Nixon supported that plan, later changing his mind when Rogers prevailed on Congress to go along with his less drastic measure.

The National Cancer Advisory Board has recommended only minor changes in the act—minor except for new authorized expenditures. The act authorized \$400 million in fiscal 1972, \$500 million in 1973 and \$600 million in 1974. (Actual appropriations were considerably less—\$378 million the first year, \$432 million the second and no more than \$551 million the third.)

NCAB's recommendations would permit spending \$750 million in fiscal 1975, \$830 million in 1976 and \$985 million in 1977. "We wanted to avoid the \$1 billion barrier for psychological reasons," said Sol Spiegelman, NCAB member who headed the subcommittee that made up the recommendations. Spiegelman is director of Columbia's Institute of Cancer Research.

Other proposed changes included increasing authorization for cancer control programs (\$40 million authorized in 1974 to \$50 million in fiscal 1975, \$65 million in 1976 and \$85 million in 1977). Another would remove the limit of 15 placed on the number of new research and demonstration centers, permitting the director to approve more than 15 if he sees fit.

Rep. Jack Brinkley (D.-Ga.) has introduced a bill (H.R. 10746) that would go much farther than the original Senate measure. It would: establish an independent agency, the "National Cancer Research Administration"; impose a "cancer eradication tax surcharge" on individual and corporate income for five years; devote income derived therefrom, an estimated total of \$15 billion, to cancer research.

This bill has practically no chance, probably will not even be called up for consideration by Rogers' subcommittee.

3. Federal revenue sharing funds may not be used as a source of contribution under cost sharing agreements.