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CONGRESS PASSES BIOMEDICAL RESEARCH AUTHORIZATION, REGULAR APPROPRIATIONS BILL; NCI GETS $1.183 BILLION

Congress, in a last gasp spurt before adjourning last week, managed not only to pass a regular appropriations bill for the Depts. of Labor and HHS, thus permitting NCI to operate in the 1985 fiscal year under normal circumstances rather than with a stop gap "continuing resolution," but also approved a new biomedical research authorization measure which permitted the first substantive changes in the National

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In Brief

SCHMIDT OF GERMANY UICC PRESIDENT ELECT; DAVID KORN APPOINTED NEW DEAN AT STANFORD

C.G. SCHMIDT, of Essen, Germany, was named president elect of the International Union Against Cancer at the UICC biennial meeting in Fukuoka, Japan. Gerald Murphy, director of Roswell Park Memorial Institute, was reelected secretary general; Charles Ebersol, Hartford, Conn., was reelected chairman of the finance committee; and Sandor Eckhardt, Budapest, was elected treasurer. Other new program chairmen elected were F. Clayton, Holland, committee on international collaborative activities; Charles Sherman, U.S., professional education; K. Aoki, Japan, epidemiology and prevention; and W. Bodmer, UK, fellowships.... **DAVID KORN,** chairman of the Dept. of Pathology at Stanford Univ., has been appointed dean of the Stanford School of Medicine. Korn is chairman of the National Cancer Advisory Board .... **NEW STAFF** appointments for NCI's Div. of Cancer Treatment announced this week by Director Bruce Chabner: Donald Poppke, administrative officer of the Cancer Therapy Evaluation Program, replacing Helene Rodriquez who left to accompany her husband to Alabama; MaryAnn Anerino, acting administrative officer of the Clinical Oncology Program, replacing Mark Kochevar, new AO of the Div. of Cancer Etiology; and Barbara Vermillion, acting AO of the Radiation Research Program, replacing Dorothy Tisevich, who was named deputy AO of DCT. Kathy Russell continues as acting AO of the Biological Response Modifiers Program.... **LARRY KUN,** associate professor of radiology at the Medical College of Wisconsin, has joined St. Jude Children's Research Hospital as chairman of radiation oncology. He replaces Omar Hustu, who asked to be relieved as department chairman but will remain at St. Jude as a full time faculty member.... **MARGARET LAYTON,** chief of the Graphics & Audiovisual Section of NCI's Office of Cancer Communications, will retire Dec. 10 after 37 years with the Institute. She is the last of the original members of NCI's first office of public information.... **ONCOLOGY NURSING** Society announced that Boehringer-Ingelheim Ltd., Connecticut pharmaceutical firm, has become the Society's first sustaining member.

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TOTALS FOR CONSTRUCTION, TRAINING, CANCER CONTROL STILL UNDETERMINED

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Cancer Act in six years. Most of the changes will be considered positive by Cancer Program advocates, although a few might cause some problems.

Because the authorization bill was passed, the hang up between the House and Senate over whether NCI programs which require specific authorization—namely construction, cancer control and research training—evaporated. The House had not included money for those programs in its bill; the Senate had. Conferees on the continuing resolution had agreed that those three programs would be funded at the 1984 levels unless authorization renewal could be pushed through.

At the moment, no one is quite sure just what the new levels will be for those three programs. The Senate had earmarked $31 million for training, compared with $24 million in 1984; $64 million for cancer control, up $1 million from 1984; and $13 million for construction, a huge increase over the 1984 figure of $2 million.

Included in the Senate construction total was $4.5 million designated for the proposed new West Virginia Univ. Cancer Center, a project pushed hard by Robert Byrd, Senate Democratic leader, who intended it as a tribute to retiring West Virginia Sen. Jennings Randolph.

It was not clear from the conference report on the appropriations bill if the West Virginia money was still in, or what the construction amount would be whether it was in or not.

What was clear was the total—$1.183 billion, an increase of about $100 million over the 1984 total. There was about $13 million difference between the House and Senate bills, if certain assumptions were made regarding the House's intention on funding training, construction and cancer control. The Senate had asked for a total of $1.188 billion; cutting that by $5 million was somewhat less than splitting the difference.

The new figure, $1 billion, 183 million, is $86.6 million more than was requested for NCI in the President's budget.

Although the new budget represents more than a 10 per cent increase over 1984, the first time in years that NCI's increase has exceeded inflation, it will still leave many programs unfunded or underfunded. The all important issue now is whether Congress can be persuaded to go along with the 1986 bypass budget request of $1.45 billion, an increase over 1985 of about 25 per cent. A budget of that size is crucial to the start of the massive effort to achieve the Year 2000 goals.

The Senate had directed in the report on its appropriations bill that it had added enough money to NCI's budget request to raise the priority score payline of grants from 170, as estimated in the President's budget, to 190, with all grants being paid at full recommended levels. Whether that will be possible depends on where the $5 million cut from the Senate's figure will be applied. In any case, NCI intends to fund all grants, including RO1s, PO1s, cooperative groups and cancer center core grants, at their recommended levels, leaving a little room for the usual negotiations to trim 1-3 per cent on occasion.

Two changes in the National Cancer Act long sought by NCI, the National Cancer Advisory Board, and cancer centers finally made it: center core grants now may be made for up to five years, rather than three; and the maximum amount on individual grants which may be awarded by the NCI director (after appropriate study section review) without approval of the NCAB was increased from $35,000 to $50,000 in direct costs.

Another change not sought by NCI or the NCAB but not opposed either was a directive to appoint an associate director for prevention. That might cause Director Vincent DeVita a bit of a problem, since two divisions—Cancer Etiology and Cancer Prevention * Control—both have prevention as primary missions. An associate director with Institute wide responsibilities possibly could cause some friction. DeVita could handle it by giving one of the division directors a dual appointment.

A major and immediate problem in the new bill will be the authorized maximum appropriation for FY 1986—$1.345 billion. That is about $100 million less than asked in the bypass budget. Even if the White House and its Office of Management & Budget can be persuaded to go along with the bypass figure (an unlikely event, although not impossible given the needs of the Year 2000 effort), they would be precluded from asking for that much unless they accompany it with a request to modify the authorization total.

Another change not likely to sit well with Cancer Program advocates, particularly those who fought for increased authority for NCI in 1971 and jealously guarded it since, is language calling on the NCI director to go through the HHS secretary, rather than directly to the President. In practice, that is the way it usually works, but many have felt that the suggestion of independence from the department has given NCI some additional clout. The new measure leaves intact the presidential appointment of the director, members of the National Cancer Advisory Board, and the President's Cancer Panel.

The definition of the Cancer Control Program was modified to add prevention as one of its activities,

and to direct that students of health professions be offered training in cancer prevention, early detection, and identification of high risk groups. Cancer control also now officially includes continuing care for cancer patients and their families.

Another change requires the NCI director to act "in consultation with" the NCAB. It does not require NCAB approval for any action he may initiate, other than the previous mandate to approve grants. Again, in practice, the director has almost always consulted the Board, and rarely acts contrary to its advice, but for the first time, this is written into law.

The director's authority to call special meetings of the NCAB, never used, was taken out of the Act.

A provision was included requiring NCI to establish or support "at least one clinical or health facility for cancer screening and research, affiliated with a health science center capable of providing clinical research and interdisciplinary technical assistance to such a clinic or facility and is proximate to a preponderance of residents of an area exposed to the greatest amount of fallout from the Nevada nuclear tests." That description, of course, could fit only one state, Utah, which just happens to be the home state of Sen. Orrin Hatch, chairman of the Labor & Human Resources Committee which wrote the Senate's version of the bill.

The legislation also creates two new institutes at NIH—National Institute of Arthritis & Musculoskeletal & Skin Diseases, and the National Institute of Nursing. Both were opposed by the Administration but had overwhelming support in Congress.

A line item authorization, with a dollar figure, for cancer centers did not survive. The American Assn. of Cancer Institutes lobbied hard for the line item, along with behind the scenes efforts by other representatives of cancer centers. They had convinced Congressman Henry Waxman (D.-Calif.), chairman of the House Health Subcommittee which wrote the House version of the legislation, to include it. However, Waxman was forced by strong opposition when the bill went to the floor to accept a series of modifications, one of which dropped the line item. In its place was a provision putting a "floor" under the number of centers supported by NCI, at 55. Even that modest achievement did not get through the conference with the Senate. Instead, strong language supportive of centers was included in the conferees' report:

"The House amendment included specification that the National Cancer Institute maintain support for at least 55 cancer centers. The House receded to the Senate provision which does not specify the number of centers to be funded. However, conferees are in unanimous support for the cancer center program and several members in both the Senate and House had expressed strong support for maintenance and expansion of the NCI cancer center program.

"In expanding the number of cancer centers the conferees believe high priority should be given to those areas which are currently underserved or demographically unique. An example of such is the state of Utah which offers a number of specialized opportunities for cancer research. Scientific literature has documented that the Mormon population offers unique research opportunities in cancer prevention related to diet and nutrition. Low rates of cancer found in this population appear to be related to specific dietary factors. Utah is also the site of exposure to low level radiation which occurred secondary to above ground testing of nuclear weapons in the 1940s and 1950s. Therefore, this state's population offers distinct epidemiological opportunities to study the consequence of radiation exposure. Cancer screening is a logical extension of this activity, and the establishment of a cancer center in Utah will assist in serving not only the state, but the central northwest region of the country by providing treatment now unavailable to patients in large rural areas in this region of the country. Conferees recognized that at present, plans are under way to establish a regional cancer center in West Virginia, which would serve the Appalachian Plateau. This area has been identified as being significantly underserved regarding modern cancer therapy, and development of this center at West Virginia Univ. will accomplish a great deal to serve the citizens of this area.

Although conferees agreed not to mandate a minimum level of support for the cancer center program, there is strong bipartisan support and encouragement for the director of the National Cancer Institute to maintain current programs and expland this effort as resources permit."

Sen. Arlen Specter (R.-Pa.), made this statement in support of centers during debate on the appropriations bill:

"The committee has provided an additional $12,410,000 over the Administration's request for NCI research centers. This amount would support one additional center, for a total of 60, and restore close to full estimated costs for research centers in 1985. Cancer center core grants are essential for the stability and continued excellence of cancer centers, and directly enhance the effectiveness of research grants at the centers. The committee is aware that during the past year such core grants have been treated differently from other grants and have been decreased on the average of 15 per cent below the peer review levels, and desires that these core grants be funded at full peer review levels.

"Research activities in the field of cancer have produced tremendous breakthroughs recently and the role of the cancer centers is extremely important in continuing and expanding this trend."

The National Cancer Act of 1971 and subsequent revisions contained authority for NCI to establish and operate what has become known as the International Cancer Research Data Bank. Sen. Claiborne Pell (D.-R.I.) was the principal sponsor of that initiative. The modification of the Act this time officially gives ICRDB its name and spells out its mission:

"The International Cancer Research Data Bank shall collect, catalog, store, and disseminate insofar as feasible through the use of information systems accessible to the public, general practitioners, and oncologic investigators, the results of cancer research and treatment undertaken in any country for the use of any person involved in cancer research and treatment in any country."

DCPC DEFERS TWO CONCEPTS ON CERVICAL CANCER PREVENTION, WORKPLACE STUDY

Two concept proposals recommended by Div. of Cancer Prevention & Control staff were deferred by the division's Board of Scientific Counselors at its meeting earlier this month after some members objected to various aspects of the projects, including cost.

Staff had asked for a five year noncompetitive extension of contracts for chemoprevention of cervical cancer with Univ. of Arizona, Albert Einstein College of Medicine, and Georgetown Univ. Medical School. Total estimated cost was over $750,000 a year.

Cooper, Kuller and Ultmann argued that the cost per patient would be in the range of $6,000 a year. Mary Ann Sestili, project officer, said it would be closer to $4,000. "That is still extraordinarily high," Kuller said.

"I can't believe it costs that much," Ultmann said.

Kuller moved to defer the proposal to permit "better justification of the budget." The motion was approved unanimously.

A plan to conduct an assessment of occupational nursing practices and educational needs in the primary prevention of cancer, at a cost of $150,000 a year for two years, was deferred when some members expressed doubt that management would allow nurses enough time to effectively participate.

Additional concepts approved by the Board follow (the other concept approvals appeared in last week's issue of **The Cancer Letter**):

Title: Primary prevention studies within defined small business occupational settings. This will involve an interagency agreement with the Occupational Safety & Health Administration. OSHA will perform most of the studies, but a contract will be awarded through competitive processes to an academic institution for evaluation. The anticipated annual budget ranges from $700,000 to $850,000 a year, for three to five years. The staff description and justification of the project:

Goal of this proposed study is to test the hypothesis that primary cancer prevention interventions in defined work environments can effect changes which reduce or eliminate exposures to cancer hazards. The focus of this study is on a population of managers and employees in work environments defined as small business with 250 or fewer employees.

Major objectives are to identify effective methods and approaches to primary cancer prevention interventions in small business work environments; to develop measurable criteria by which to evaluate the impact of the prevention interventions; to describe organizational and administrative structures which can serve as reinforcements or deterrents to effective cancer control efforts; and to develop new hypotheses relative to the design of models for primary prevention interventions in occupational environments in general.

This study proposes to utilize the OSHA On Site Consultation Network in sample states to develop and evaluate a model cancer prevention intervention program. As one example of the usefulness of the end product of this study, a tested and proven model could be incorporated into the OSHA nationwide consultation system so that cancer hazards could be specifically, systematically and expeditiously addressed.

This collaboration will provide NCI with the following elements critical to this scientific inquiry: (1) the means of access to the workplace for evaluation purposes; (2) health oriented trained consultants who have experience in dealing with small business managers; and (3) the data to target high risk small businesses. From the standpoint of OSHA, this collaborative project has the potential of providing a tested cancer prevention model which can be implemented in the 50 states by OSHA in meeting its mandate to assist managers to meet cancer prevention responsibilities under both the Consultation Regulation and the Hazards Communications Standard. The latter will go into effect in 1985.

Under the regulations, OSHA provides funding to states through grants to administer and provide safety and health consultative services upon request to small businesses. The state agency may be a state health department, state labor department, or a university. The OSHA funded state consultants, who are industrial hygienists or safety specialists, visit workplaces to identify safety and health hazards, suggest methods for correction, and make recommendations regarding the employer's management system for the prevention of a broad range of occupational injuries and illnesses. The training

aspect of the regulation has just been authorized and has not been implemented, especially in relation to carcinogenic hazards.

Experience has demonstrated that small businesses (250 or fewer employees) have the highest injury and illness rate, the least knowledgeable managers and employees and the fewest resources for assistance. In the workforce, these workplaces represent the neediest component from the overall health viewpoint. For this reason, Congress mandated in 1976 that OSHA provide for consultation services.

Based on estimates published in 1979, there are approximately 4 million businesses employing 250 or fewer employees. Of these, approximately 300,000 businesses with 9.9 million employees are engaged in manufacturing or chemical processes. As high as 25 per cent of the latter workplaces are suspected of having exposures to cancer hazards. A literature search documents the fact that there have been few if any studies which focus on the application and evaluation of primary cancer prevention in these occupational settings. A major problem is lack of access to these work environments. This problem will be overcome by collaborating with OSHA.

This study will evaluate the impact of primary prevention interventions on the reduction or elimination of exposures to cancer hazards in work environments of defined size. The intervention will be carried out by OSHA consultants in sample states selected on the basis of criteria determined by NCI and OSHA. The initial target population will be managers in these work environments. A phased approach will be used in this study. The major tasks are:

Development of eligibility criteria and selection of study populations:

1. Selection of states within which the study will be implemented. Griteria will include among others the state agency's past performance in administering the Consultation Network, the competencies of the consultants and the density of cancer hazard workplaces.

2. Selection of OSHA consultants within participant states. Criteria will include among others, educational background, quality of performance and interest in study participation.

3. Selection of workplaces. Currently, the information available on the presence of carcinogens and, in particular, on levels of exposure in the states' workplaces is fragmentary and comes from various sources. NCI and OSHA staffs will coordinate information for the purposes of improving methods of targeting study workplaces. In addition to the presence of known or suspected carcinogens, other criteria such as the past record of cooperation with the OSHA Consultation Service, and the willingness of managers to participate in the study will be included. NCI and OSHA will develop approaches, techniques, and instruments to assess the needs of the OSHA funded consultants and the targeted small businesses, both in terms of the needs of the managers and employees.

Development of the study evaluation process:

The evaluation protocols will be developed under a subcontract with an academic institution, selected The evaluation protocols will address the total system of workplace primary prevention, since end points will be measured in terms of changes which result in the reduction or elimination of cancer hazards. The protocols will also address the various groups within the framework of the study; namely, the OSHA consultants, the study managers and employees. For example, the consultants and managers may be evaluated in terms of their knowledge of cancer control sciences, their performance as teachers and their impact on environmental changes, such as the substitution of less hazardous chemicals and the correction of engineering deficiencies, etc. Workers may be evaluated in terms of changes in work practices such as the identification of hazardous substances, the selection, use and maintenance of personal protective equipment, personal hygiene habits, and the identification of engineering control deficiencies, among others.

Title: Double blind evaluation trial of slit scan flow cytometer. One three year award is anticipated, at an estimated cost of about $250,000 a year.

Objective will be to test and evaluate the performance of a multidimensional slit scan flow system in a double blind study using clinical gynecologic specimens in order to determine its applicability as an automated screening device.

It is estimated that there will be 6,800 deaths from cervical cancer in 1984. The use of Pap smears to detect cancer of the uterine cervix has been shown to be cost effective and has shown a significant reduction in morbidity and mortality. Once dysplasia and carcinoma in situ have been identified, further progression of disease can in general be prevented by appropriate therapeutic procedures and continuing surveillance. It is also believed that without therapeutic intervention, severe dysplasia and carcinoma in situ frequently progress to invasive cancer. There are, however, reports of rapidly growing malignant lesions that were detected between screening intervals, in some cases less than one year after a negative examination.

The impact that a more aggressive screening program might have on the reduction of mortality due to cervical cancer might be deduced from a small study of 97 women that showed that 52 per cent of new invasive cancer cases were found in women who never had Pap smears. Of the remaining 48 per cent of the new cancer cases, 10 per cent had their last Pap smears more than five years previously and 38 per cent of the cancer cases were missed by Pap smear screening. The reasons for these 38 per cent missed cases might be due to fast growing cancer that developed after the last negative Pap smears (10 per cent) or false negative reporting of the smears, 28 per cent. Reported false negative rates range widely. Evans, et al, found the range of false negative from 2.1 to 11.1 per cent and false positive from 0 to 17.1 per cent in a study involving 120 slides examined by six laboratories. In a state mandated proficiency testing program, false negative and false positive rates among pathologists examining 1.659 cervicovaginal smears (in 237 labora-

tories) were 6.3 and 5.8 per cent respectively. In a recent examination given by the International Academy of Cytology, of the 243 U.S. examiners, the false negative rate was 7.4 per cent when 21 slides containing malignant cells were read. In a stratified random sample of 100 cervical smears examined by three laboratories, it was found that the sensitivity of the smear test for detecting cervical malignancies ranged from 72 to 88 per cent and for all severe epithelial abnormalities the sensitivity varied from 52 to 71 per cent. The lowest false negative value of 1.1 per cent was reported by Richard on the rescreening of patients with known neoplasia. Reagan and Scott found a false negative rate of less than 5 per cent, Graham and Meigs 10 per cent, Fidler et all 13 per cent, and Friedell et all estimated the range of false negatives at 19 per cent in vaginal and 11 per cent in cervical smears. Nyirjesy found 24 per cent negative results on repeat smears from known cases of cervical neoplasia. These reports have been from institutions where quality control should be better than average. Across all laboratories, the false negative rate is estimated to be around 25 per cent.

The number of missed cases may be reduced by more frequent screening and improving the quality of screening, i.e., decreasing the number of false negative cases. One approach to this problem is the use of an automated screening system. An automated screening device would potentially identify a large percentage of the negative specimens leaving the remainder to be screened and diagnosed by conventional procedures, i.e., by cytotechnologists and cytopathologists. Thus, the availability of an automated screening system for early cervical cancer detection should augment the curren screening by cytotechnologists, reach far more women, and reduce the cytotechnologists chance of missing cancers. The number of certified cytotechnologists has decreased in recent years. This trend is expected to continue due to the lack of enrollees in the training program and the closing of many training facilities. Furthermore, an automated screening system should increase the uniformity and quality of cervical cancer screening in those laboratories with poor quality control and should reduce the mortality due to cervical cancer.

Currently, there are a few automated systems that have been evaluated using clinical cervical materials. At the Univ. of Rochester, for example, the flow system shows a false negative rate of 2.6 per cent and a false positive rate of 17.6 per cent in a single blind clinical study. This information is based on a total of 740 specimens including 156 that were abnormal. The few missed cases by the instrument (false negative cases) were in the category of mild and slight dysplasia. The instrument classified correctly all cases in the moderate and marked dysplasia and malignant categories which included carcinoma in situ, squamous cell carcinoma, adenocarcinoma and sarcoma. The instrument appears sensitive to the entire spectrum of abnormality existing in the female genital tract and can classify as abnormal any specimen containing on the order of 0.1 per cent or greater abnormal cells.

Recently, the Cancer Detection Branch held a workshop on cervical cancer detection. The participants in this workshop included cytotechnologists, cytopathologists, gynecologists and pathologists. The discussions at the workshop delineated five major determinants that might be related to cervical cancer deaths. Using the Delphi technique, the relative contribution of each determinant was estimated. The following determinants were considered to play a significant role in cervical cancer deaths: not screened (46 per cent); inadequate sample collection (16 per cent); laboratory reading error (13 per cent); inadequate pretreatment evaluation (11 per cent); and lack of treatment planning and followup (14 per cent).

As the Board recommended last May, the subject of automated cytology was also discussed at length. The development of an automated cytology system has the potential for impacting on several of these determinants. Foremost, it has the potential for reducing the incidence of false negative readings from reported values down to 2.6 per cent. Second, it has the potential of identifying some of the failures to obtain an adequate specimen by setting objective criteria for cell number and other characteristics. Finally, a machine could reduce the failure to be screened category and it could lower the screening costs.

It was determined at the workshop that the current high resolution image analysis systems are too slow for automated cell analysis at this time and that at least one flow system has now reached the level that a single blind study is being performed. It was generally agreed that the slit scan flow system could not be adequately assessed until a double blind study is done.

In addition, cellular quantitative analysis may yield subcellular pathologic changes not readily discernible by routine light microscopic examination. Quantitative analysis by flow cytometric measurements have been applied to many cancer sites. Some examples may be cited: Wolley, et al, found that the determination of DNA distribution in colon carcinomas may be of prognostic value. Goerttler, et al, concluded that "it should be possible for diagnostic purposes to combine the technique of fine needle aspiration biopsy of the prostate with flow cytometry." Significant differences in DNA distribution of prostate cancer were observed according to tumor grade. Zetterberg and Esposti showed that a diploid amount of DNA correlated well with a good survival of the patients, while a nondiploid distribution pattern was correlated with poor prognosis. Olszewski applied flow cytometry to mammary carcinoma and showed that breast cancer with diploid and near diploid distribution tended to be histologically low grade and differentiated and contained estrogen binding receptors. Others investigated the DNA content in tumors of the urinary bladder. The diploid or near diploid patterns corresponded to low grade tumors, whereas aneuploid pattern corresponded to high grade tumors.

This project will test the performance of a flow system in a double blind study using clinical gynecologic specimens in order to determine its appli-

cability as an automated screening device. The clinical gynecologic specimens will be collected through the existing health care system as well as through special efforts to reach high risk populations. After double blind reading, the results of the flow system reading will be compared to those of conventional cytology and to the results of biopsy when available. Positive predictive value will be ascertained to document effectiveness of the screening device.

It is expected that an automated system must be sensitive to the entire spectrum of cellular abnormality existing in the female genital tract; have a sufficiently low false positive rate to justify the instrument economically; have a false negative rate equal to or less than that of a good cytopathology laboratory; and recognize the inadequate specimen, i.e. a specimen containing insufficient number of epithelial cells.

Bill Bunag is the project officer and program director for cytopathology.

"I have problems with this," Board member Philip Archer said. Noting that it had been deferred from the May meeting because of Board criticism, Archer said "it still doesn't address the issue of comparability with regular cytometry. It doesn't say here how it would be compared. It would use a different type of sampling procedure. It's a good idea to test this thing, but it is not clear how to achieve comparability and specificity."

"An automated system has the capability of quantitative criteria," William DeWys, director of DCPC's Prevention Program, said. "It would address that issue. Samples will be collected by the same method in each individual."

"We will look at the content of each specimen," Bunnag said. "The portion read by the flow system will also be read by the conventional system."

"Okay," Archer said. "That didn't come across here." Bunnag noted that the RFP would spell out that requirement.

Board Chairman Barbara Hulka asked why the contract would be for three years, why it would cost so much, and why only one award is anticipated.

Bunnag said only one award would be made because of the cost and because there are only a few labs doing flow cytometry. Three years is the time it will take one lab to collect a sufficient number of samples, at 1,000 a year.

"You're comparing the standard Pap technique with your method," Board member John Ultmann said. "If I were to design the experiment, I would place the patient in the normal position for the standard Pap, then scrape, then do your technique. I would also limit it to high risk populations with no previous Pap test."

"The fundamental problem is failure of 50 per cent of women to get the Pap test," Board member Robert Cooper said. "I don't understand how this will address that problem."

"We're developing two concepts," DeWys said. "The other one is to remove what impediments there are. We will present that to the Board in January."

"It will be a major contribution if you get a small percentage reduction (in the determinants playing significant roles in cervical cancer deaths)," Board member Jerome DeCosse commented.

"The real issue is that we have a large population of women not being screened," Board member Lewis Kuller said. "Part of the problem may be that there are a lot of people involved in the screening. This reduces the number involved in screening, and could centralize it."

"If it can be shown to reduce costs, the reduction in false negatives makes it worthwhile," Board member Loretta Itri said. "This needs to be compared with the scrape smear."

Itri's motion to approve with that provision was approved by the Board.

Title: Support for program tracking data base. One award, estimated cost $250,000 a year, five years.

In order to guide program planning for the Year 2000 goals and objectives, DCPC intends to develop a system of cancer control monitoring. While the specific goals for the Year 2000 are not yet formulated, the planning process has progressed to the point where it is possible to identify the necessary elements of the system. First, there is a need for surveillance of disease outcomes. This will be addressed via the Surveillance, Epidemiology & End Results (SEER) program. Second, there is a need to monitor the knowledge, attitudes and behavior of the public related to cancer prevention and control. This need will be addressed via national probability sample surveys of the general population. The first such survey is being contracted for by the Health Promotion Sciences Branch. The third element necessary for the monitoring system is a means of collecting data on the prevention, screening, and treatment programs and other activities that are a part of the nation's cancer prevention and control efforts. The purpose of this concept is to purchase support services that will enable DCPC staff to develop this element of the total monitoring system. This part of the system, referred to as the Program Tracking Data Base, will allow for the collection of information on cancer control programs and activities in the federal, nonfederal, and private sectors.

It is anticipated that the support services contractor, under the direction of CCAB staff, will:

1. Identify existing federal, nonfederal and private sector data bases that might include information pertinent to the Year 2000 goals. Examples of existing data bases include: the National Ambulatory Medical Care Survey, the Health Interview Survey, CDC state surveys, data bases of private organizations such as the Assn. of State and Territorial Health Officers.

2. Develop new systems of data collection. In instances where data are needed but no valid sources exist, the contractor might develop, test, and implement the necessary data collection systems. Development of a system to monitor the adoption of nonsmoking policies by local and state governments is an example of the type of activity that could be conducted.

3. Analyze, integrate, and disseminate informa-

tion related to the Year 2000 goals. In addition, reports on selected cancer prevention and control activities could be written and disseminated: for example, reports on state legislation related to cancer prevention and control.

"How will you evaluate this after you spend $1.25 million in five years, when you come back and want to do another five years? How will you know if this has been useful?" Cooper asked.

"We don't have the basic information on what exists," DCPC Director Peter Greenwald answered. "We need to know what else exists."

"Once you know it, how will you know if it impacts decisions?" Cooper persisted.

Greenwald argued that information the project would provide "will help us know what works."

"So you are persuaded that it will affect your decision making?" Cooper asked, and Greenwald said he was.

"I would like to do a double blind study, with one group using the data base and another not," Cooper said. "It might be fun to see if their decisions are any different."

The Board approved the concept without further discussion.

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CONCEPT REVIEW FIGURES ARE ESTIMATES ONLY: RFPs, RFAs NOT YET AVAILABLE

The dollar estimates with each concept review brought before the various boards of scientific counselors are not intended to represent maximum or exact amounts which will be spent on those projects. They are intended only as guides for board members to help in determining the value of the projects in relation to resources available to the entire program or division. Responses should be based on the workscope and description of goals and methods included in the RFPs (contracts) and RFAs (grants and cooperative agreements). Availability of RFPs and RFAs will be announced when the Institute is ready to release them.

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NCI CONTRACT AWARDS

TITLE: Technical writing, publication distribution and telephone answering service in response to cancer-related inquiries, modification
CONTRACTOR: Biospherics Inc., $1,242,131.

TITLE: Methodology & analysis of fiber components in food
CONTRACTORS: Univ. of Wisconsin, $825,487; and Cornell Univ., $766,077.

TITLE: Studies of iatrogenic cancer and radiation dosimetry
CONTRACTOR: M.D. Anderson Hospital, $547,085. n

TITLE: Resource to support the chemical, economic and biological information needs of the Div. of Cancer Etiology and to provide chemical process, production and economic information as support to the Internaitonal Agency for Research on Cancer
CONTRACTOR: Tracor Jitco Inc., $1,494,217.

TITLE: Toxicology & pharmacology of anticarcinogenic agents
CONTRACTORS: IIT Research Institute, $1,372,533; Southern Research Institute, $1,367,747.

TITLE: Data management & analysis center for the Breast Cancer Detection Demonstration Project, continuation
CONTRACTOR: University City Science Center, $1,388,426.

TITLE: Phase I studies of new chemopreventive agents
CONTRACTOR: Michigan State Univ., $453,971.

TITLE: Cancer Information & Dissemination & Analysis Center (CIDAC)--Diagnosis & Therapy, renewal.
CONTRACTOR: M.D. Anderson Hospital & Tumor Institute, $1,727,052.

TITLE: Technical & logistical support services for Div. of Cancer Prevention & Control
CONTRACTOR: Technassociates Inc., $3,297,896.

TITLE: Studies on environmental cancer utilizing pre-paid health plans
CONTRACTORS: Kaiser Foundation Research Institute, Los Angeles, $929,793; Kaiser Foundation Research Institute, Oakland, Calif., $1,178,812, and Kaiser Foundation Research Institute, Portland, Ore., $1,481,396.

TITLE: Biomedical computing support services
CONTRACTOR: Information Management Services Inc., Rockville, Md., $1,715,065.

TITLE: Biomedical computing support in cancer control & prevention
CONTRACTOR: Information Management Services, $2,788,432.

TITLE: Systems planning support services, modification
CONTRACTOR: JRB Associates, McLean, Va., $173,968.

TITLE: Epidemiologic study of black/white differences in cancer patient survival experience--data collection center
CONTRACTOR: Northern California Cancer Program, $904,947.

The Cancer Letter _Editor Jerry D. Boyd

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