

THE

# CANCER

RESEARCH  
EDUCATION  
CONTROL

# LETTER

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## WHO WILL DETERMINE PAY LINES FOR EACH PROGRAM AT NCI? UPTON SUGGESTS A COLLECTIVE APPROACH

NCI Director Arthur Upton and his senior staff members are moving closer to a resolution of the major questions that must be answered to implement Upton's proposal for reorganizing the institute. Upton told *The Cancer Letter* this week that most of the issues could be resolved within the next two weeks.

The reorganization primarily involves transfer of grant portfolios and program staff from the Div. of Cancer Research Resources & Centers to the other four NCI divisions, giving those divisions for the first time the use of traditional investigator initiated grants to fund extramural research.

Upton also proposed that all NCI grant and contract review committees be located in DCRRC, thus separating review from program activities.

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### In Brief

#### AACR VOTED ON NAMING DELEGATES TO CONGRESS, NOT ON ATTENDING; ACCC MEMBERSHIP OVER 300

AACR MEMBERS did not vote on the question of whether or not they should attend the XIIth International Cancer Congress in Buenos Aires, as reported by *The Cancer Letter* Feb. 3. The membership was asked to vote on the question of whether or not the American Assn. for Cancer Research should send official delegates to the General Assembly of the Congress. The response: 601 voted for sending official delegates; 159 said no delegates should be named; and 368 voted for informing UICC that AACR does not wish official representation at the Congress. Over 42% of the active members responded to President Gordon Zubrod's request for guidance about the issue of naming delegates. Zubrod said he would abide by the majority vote and would name delegates, but also plans to inform UICC that there are a substantial number of AACR members who are opposed to official representation at the Congress. . . . ORVILLE KELLY, founder of the organization "Make Today Count," received the annual award for service to cancer patients from the Assn. of Community Cancer Centers. Cathy Roche, regional director of the organization, accepted the award for Kelly at the ACCC annual meeting when he was prevented from leaving his home by a snowstorm. Also receiving awards for service to ACCC were C.D. Pruitt and Dick Taylor of CDP Associates. . . . ACCC MEMBERSHIP now totals more than 300 less than four years after it was organized, and its recent annual meeting was its biggest yet in terms of participation, although many who had registered were prevented by bad weather from attending. A regional meeting on Hospice and the Community Cancer Program is scheduled for April 28-29 at Disneyworld. Contact Donna Pace, ACCC Executive Offices, 4733 Bethesda Ave., Bethesda, Md. 20014.

#### DCCR Plans Three Multiple Contracts In Pain Control

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## UPTON, DIVISION AND PROGRAM CHIEFS WOULD DETERMINE PROGRAM PAY LINES

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Main purposes of the reorganization were to channel more money into investigator initiated grants and to permit the program managers to more effectively coordinate extramural research supported by contracts and grants and eliminate undesirable duplication.

A key issue had to be addressed: How will decisions be made regarding priority pay lines for each program, and who will make them?

Some feared that if the program managers and division directors were permitted to make those decisions, unacceptable inconsistencies would develop, with top quality science going unfunded in some areas to permit the funding of lesser science in projects perceived more important by the program staff.

On the other hand, establishing a common pay line without regard to program needs could be equally disastrous.

One solution Upton said is being seriously considered is "the consortial approach to budget development." It would involve one big study section composed of Upton, all division directors and all program managers. Collectively, this group would determine the grants budget for each program and the pay lines for each. This group would be concerned only with grants. After those decisions are made, the division directors and program managers would then determine what else needed to be done, either extramurally through contracts or intramurally.

"We're still exploring the logistics, but we've hit no stone walls yet," Upton said.

One of the major concerns expressed by many interested in the Cancer Program is that NCI intramural and extramural research be totally separated. Upton agreed that this issue is one he and his staff have been thrashing out.

## DCCR PLANS THREE MULTIPLE CONTRACTS, \$1.2 MILLION A YEAR, IN PAIN RESEARCH

Three new contract programs in the area of cancer pain, for multiple awards totaling \$1.2 million a year, are in the planning stages by NCI's Div. of Cancer Control & Rehabilitation.

DCCR Director Diane Fink told the division's advisory committee last week that three RFPs were being developed:

- Identify the incidence and natural history of cancer pain—\$400,000 per year for three years.
- Patterns of care for cancer pain involving three common cancer sites, pelvis, head and neck and metastatic bone disease—\$200,000 per year for three years.
- Develop multidisciplinary teams for alleviating cancer pain—\$600,000 per year for two years.

DCCR now supports seven grants for research in various aspects of cancer pain, which amount to \$655,000 in FY 1978 funds. These represent about 90% of NCI's total efforts in study of pain and pain control.

Fink and Div. of Cancer Treatment Director Vincent DeVita are members of a federal government committee looking at the problem of pain and possible new approaches. Other committee members are from other NIH institutes, the National Institute of Drug Abuse, FDA, and Drug Enforcement Administration. It is chaired by Seymour Perry, NIH associate director.

The committee was assured by Peter Bourne, President Carter's staff assistant for health, that there will be no obstacles in making available schedule 1 drugs—primarily heroin and marijuana—for clinical studies.

NCI will file an IND for schedule 1 drug use in clinical trials, one of which will be comparing morphine vs. heroin.

"Pain research has not had a home at NIH," Fink said. "We're going to take a look at grant guidelines and who reviews grant applications. There is no appropriate review committee or study section now."

## THE 66 SUSPECTED CASES OF WANTON OR UNNECESSARY SURGERY DOWN TO THREE

Now it turns out that the infamous 66 Breast Cancer Detection Demonstration Project cases in which women supposedly were duped into having mastectomies although their tumors were benign are really only three—if that.

The 66 suspected cases were found by pathologists reviewing 506 cases of minimal cancer—one centimeter or less—of the 2,487 cancers detected so far in the project. This review was conducted by the Behrs Working Group under its contract with NCI to take a hard look at the project, especially the mammography aspects. The pathology review was conducted hastily so that it would be ready for the consensus meeting last September, when a panel of scientists and lay persons was convened to develop recommendations for the project's operation.

The Behrs report noted that the pathology review had found 66 cases in which the working group pathologists, looking only at the slides and without access to any other information about the cases, had determined the tumors were not malignant.

Although Oliver Behrs, head of general surgery at the Mayo Clinic, cautioned that this was a preliminary report and needed further study, critics such as the Nader organization picked it up and rushed out to damn NCI, American Cancer Society and the medical profession in general.

After the consensus meeting, Behrs put his group back to work re-reviewing the 66 cases. The final report will be released next month; here is what it



will say, Beahrs told the Cancer Control & Rehabilitation Advisory Committee:

—Of the 66 cases, two were in the group's first report because of computer error. That cut to 64 the number of cases in which women were treated for breast cancer although their tumors were thought, in the first review, to be benign.

—The group obtained additional, representative slides on 38 of the cases. "Why didn't we get them originally?" Beahrs commented. "Because of time constraints." Also, some slides were not considered because they were not of the original biopsies but of breast tissue after the breast was removed.

In reviewing these additional 38 cases, the Beahrs pathologists agreed that 16 were malignant, after all. That reduced the number of questionable cases to 48.

—Of those 48, the patients' physicians in 11 cases decided that since they were borderline lesions, they would not treat by mastectomy. So 11 of the 66 original suspected cases did not have their breasts removed.

—That reduced to 37 the number of cases in which mastectomies were performed, "recklessly and unnecessarily," the critics charged. However, of those 37, the two stage procedure was followed in 30 cases. This involved biopsy, followed from one day to seven months later, by mastectomy. Presumably during the intervals, pathologists, treating physicians and patients carefully considered the benign vs. malignant issue and treatment alternatives.

—Of the 30 choosing mastectomies, there was concurrence by hospital and project pathologists in the diagnosis in 25 cases. Outside pathologists were consulted in 15 cases, and almost all considered the lesions malignant, Beahrs said. Fifteen of the 30 had simple mastectomies, 14 modified radical and one radical.

—Of the seven cases in which biopsies were followed immediately by mastectomies, BCDDP pathologists agreed with the hospital pathologists that the lesions were malignant in two instances. Slides were not available in two others.

Project pathologists were in disagreement with the hospital pathologists in the remaining three cases—that is, the hospital pathologists determined after biopsy that the tumors were cancers and mastectomies were performed immediately; and project pathologists later said they were benign. Thus, those three were the only apparent cases in which women underwent treatment that may not have been necessary without carefully considering the issues and alternatives.

There are those who will contend that even three is too many, out of 506, and they are probably right. But the final resolution of the 66 cases demonstrates that the earlier polemics were not justified.

DCCR Director Diane Fink pointed out that BCDDP is turning up a large number of the small

lesions, compared with data in the NCI SEER study and the HIP study in New York.

"The Beahrs review tends to dissipate the charges that the project has led to a lot of unnecessary surgery," commented advisory committee member Saul Gusberg. "That's not the main issue. The main issue is whether or not mammography is the alleged hazard." Gusberg noted that women are being screened in the projects with as little as .2 rad, and that the average is now down to .5 rad.

"When they say it is a question of benefit vs. a presumed risk, they should say questionable risk," Gusberg said. "Physical examination does not have the capacity to determine lesions to the same degree of accuracy as mammography. I wonder if we're not neglecting the 40-50 age group (which receives mammography in BCDDP only if they have a personal or familial history of breast cancer), where we could possibly find early lesions and employ more conservative surgery."

Committee member Sam Shapiro said, "There is a strong consensus that there is a risk, although the question of magnitude of risk remains. It was concluded (by the consensus panel and others) that there is no scientific evidence of benefit to the group under age 50. The consensus report said that NCI should give high priority to research on the use of mammography as a screening technique for women under age 50."

"We do have the nugget, that there is a positive benefit for women over 50, as a screening package, including mammography and physical examination. Women over 50 should be aware that there is a benefit."

## CANCER DANGER TO DES-EXPOSED WOMEN MAY NOT BE THE THREAT ONCE THOUGHT

A preliminary report by NCI contractors studying the effects of in utero exposure to diethylstilbesterol indicates that the risk of vaginal cancer in women so exposed may not be nearly as great as feared when the study was undertaken four years ago.

Leonard Kurland, director of the Mayo Clinic coordinating center for the study, told the Cancer Control & Rehabilitation Advisory Committee that the relationship of DES to clear cell carcinoma of the vagina in women whose mothers received the drug during pregnancy was possibly one in 1,000 or even one in 10,000.

"The big question is long term effects," Kurland said. "This type of cancer doesn't usually occur until age 60 to 70. We will want to follow this group to see if there is an increase in incidence at earlier ages."

DCCR contracted with four institutions to conduct the study—Massachusetts General Hospital, Baylor College of Medicine, Univ. of Southern California and Mayo, with Mayo serving as the coordinating center.

The contractors were asked to identify the population of exposed offspring, conduct examinations and collect data. The contract totaled \$1.8 million over three years, and is being recommended for continuation to June, 1982. Since it was initiated, concern has developed that male offspring exposed in utero may have an increased incidence of sterility, and DCCR is considering adding a male cohort to the study.

The study grouped participants into four classifications: Record review, in which the contractors located the exposed young women by searching medical records; documented walk ins, in which participants voluntarily presented themselves with documented exposure; documented referrals, in which participants were referred by their physicians with documented exposure; and participants who presented themselves with abnormalities but with no documentation of exposure.

Kurland, who is chairman of the Dept. of Statistics & Epidemiology at Mayo, said the contractors felt the record review group was the most representative and least likely to be over weighted by participants with existing abnormalities.

Kurland stressed that his figures were preliminary and subject to change. But in the record review group, with 1,275 participants, there were no cases of invasive adenocarcinoma of the vagina, no cases of carcinoma in situ of the vagina, and no cases of severe squamous dysplasia of the vagina, as detected by biopsy at entry examination.

In the same group, there were no cases of carcinoma in situ of the cervix, and no cases of severe squamous dysplasia of the cervix.

The record review group did have four cases of mild and one moderate squamous dysplasia of the vagina and four mild and five moderate of the cervix.

Of the 815 participants in the documented walk in group, there were two cases of carcinoma in situ of the cervix and one invasive adenocarcinoma of the vagina. The documented referral group had no cases of carcinoma in situ of the cervix or vagina and one invasive adenocarcinoma of the vagina. Those with no documentation of exposure had one carcinoma in situ of the cervix and two invasive adenocarcinomas of the vagina.

Two of the four with adenocarcinoma were referred because of a previous diagnosis of the disease and two were diagnosed at their entry examination.

#### **UCLA'S STECKEL ASKS BETTER USE OF CANCER CENTERS BY NCI DIVISIONS**

Richard Steckel, director of the UCLA Jonsson Comprehensive Cancer Center, called for stricter enforcement of grant guidelines, appealed to NCI Director for more staff in the Cancer Centers Program, criticized NCI divisions for not better utilizing centers, and pleaded, "Don't destroy the Centers Program by well meaning efforts to save it."

Speaking at the recent meeting of the Assn. of American Cancer Institutes, Steckel said, "I may run the risk of offending friends at NCI for whom I have the highest personal regard and who are among our most dedicated and self-effacing public servants."

Starting at the top, Steckel said, "Dr. Upton has stated convincingly that he is committed to the present and future success of the Centers Program. One of the most important deeds that he could effect immediately would be to assign more adequate numbers of qualified staff to the Centers Program, to supplement present staff who now are doing their best under very difficult circumstances. There has simply been inadequate staffing available at NCI to carry out the exhaustive administrative responsibilities of the Centers Program. Administrative reorganization alone, while important, will not solve this problem."

Steckel charged that existing guidelines for cancer center core grant support "have never been successfully advocated nor completely implemented by NCI. The transition from umbrella grants to core grants has still not been accomplished fully in certain centers, in my opinion. While we were recently faced with proposals for major changes in NCI core support guidelines, there is still need for consistent forceful advocacy and direction from NCI to guide peer review bodies in implementing present support guidelines. I am reminded that NCI staff must remain strictly impartial, both during and following peer reviews. However, impartiality is congruous with vigorous personal involvement and guidance by staff during peer reviews, including guidance by staff designed to ensure that peer reviewers follow strictly the guidelines promulgated by NCI and the National Cancer Advisory Board. NCI staff must always be the most explicit advocates of appropriate review procedures and of adherence to established support guidelines. They must also point out inadequacies or inconsistencies in the peer review process when they occur and attempt to rectify the inconsistencies immediately. . . . They must also take a continuing active role after the completion of peer review in interpreting the review groups' recommendations in the context of local and national programmatic needs."

Center directors "should be commended for having taken a pragmatic and a courageous position in advocating funding of new as well as renewal core grants strictly according to the priorities reached through peer review," Steckel said, rather than advocating cuts across the board. But "I think few of us would disagree with the need for highly informed NCI staff to make flexible and reasoned judgments about the absolute levels of core funding for individual centers which are based upon several factors, including (1) perceived local and national programmatic needs, (2) the ability of individual centers to rectify inadequacies in their programs if given limited

interim support, (3) the enormous commitments which certain institutions have already made toward their own centers programs, and (4) other mitigating circumstances which must be taken into account once the intent and the spirit of peer review recommendations have been met. It is unfortunate but perhaps inevitable that procedural impediments which were never mandated by NCI guidelines or by peer review have on rare occasions characterized interactions by centers with NCI staff. There is no justification for the arbitrary imposition by staff of onerous requirements upon core grant awards which have not been mandated or justified by agency regulations, published guidelines or by prior peer review.

"In the series of partnerships called centers between the federal government and individual institutions which are devoted to a high purpose, one would hope that the line between bureaucratic responsibility and unnecessary hindrance would be crossed rarely, if ever. When for an example, an institution has succeeded in establishing a track record over a period of years, reflecting responsible administration of core funds and candor with a federal agency, actions by that agency which seem to indicate a lack of sensitivity to institutional needs or a prior assumption of wrongdoing are unnecessary."

NCI's Div. of Cancer Control & Rehabilitation and Div. of Cancer Treatment were criticized by Steckel for not "using centers actively as resources to carry out their missions. The apparent lack of communication and coordination of responsibilities between NCI divisions in the past, concerning core support for center based community clinical trials and for cancer control, is equally unfortunate."

Steckel asked these questions:

"1. What will actually be the role of centers, particularly comprehensive centers, in fostering cooperative clinical trials involving community institutions and physicians? Does there already exist a cooperative interdivisional framework at NCI which is geared to encourage such trials? If not, why not?"

"2. Is the primary role of centers in cancer control, particularly with respect to cancer screening and prevention, to carry out studies of so called innovative techniques and to conduct limited demonstrations, rather than to cover a region with costly large scale programs? If so, what has DCCR been doing to ensure that data generated from its funded demonstration programs have been and are being widely disseminated to other centers and community institutions around the nation? Are there effective mechanisms in place to foster transitions from successful demonstrations to widespread program applications in cancer control, or do many so called innovative demonstrations simply become dead end programs?"

"3. Should innovativeness still be a major criterion for prioritizing cancer control grant proposals? After all, how many variations can there be on a limited

number of themes? Isn't it time to give well designed studies for the evaluation of known control techniques, even a higher priority than so called innovative projects? Furthermore, how many federally funded control programs which have survived their initial demonstrations and a positive evaluation have achieved independent long term funding in the past three-four years? Perhaps another national conference of center directors, associate directors for cancer control and NCI staff is now needed to consider some of these questions in depth.

"4. At long last, has anyone really defined what constitutes a core planning and coordination unit for cancer control, to serve a regional or a comprehensive cancer center? There are several designated comprehensive centers which, even today, do not have an associate or deputy director for cancer control. The compromise last year between DCCR and DCRRC concerning the core support of associate directors for cancer control did not really answer the support problem. Some might question if the agreement were ever really implemented. What branches or divisions ultimately will support core cancer control activities in major centers?"

Most university based centers are poorly equipped to carry out massive community cancer control programs which include screening of large populations, Steckel said. "Universities should by their nature be best suited for research in new control techniques, for demonstration and intensive evaluation, and for professional education, including training in cancer control. The latter capabilities may well be directed toward professionals and allied health personnel throughout the region served by a center. In fact, the same cancer control functions which are least effectively carried out by voluntary societies, community based programs and local governmental health agencies are the ones which are best suited to university related cancer centers.

"Centers, therefore, are potentially enormous resources for NCI to perform cancer control functions. On the other hand, certain control interventions which include mass cancer screening, large scale public information activities, and community services may in fact be best carried out by community based programs, by voluntary societies and by local governmental agencies."

Pleading for consistency from NCI, Steckel said, "It is difficult if not impossible for a director of a major institutional cancer center program, particularly one that is in the stage of rapid development, to lead that center effectively when existing federal support guidelines are hesitantly applied and continuously changing. The primary concern of the center's director may become to maintain meager gains and to protect them from constant erosion, rather than to concentrate upon further development of the center's program.

"This should not be construed as implying that

little can be accomplished without more money. What it does mean is that there is a paramount need for consistency at the NCI level, and for a feeling of confidence at the level of each center that there is continuous and strong advocacy by NCI staff in the application of existing guidelines to peer review and to the implementation of peer review recommendations.

"It is indeed true that we are all competing for the limited federal dollars. However, for NCI and the NCAB to take a public stance which in effect pits the funding of one program or group of programs against another is self defeating. There is, or certainly should be, in most centers a complementary relationship between program projects, individual research grants, and core support. To imply that one type of program is eroding support for the other is unintentionally to create a problem and possibly to encourage dissension. I think that steps recently proposed at NCI to increase funds available for program projects at the expense of core support was potentially divisive and should not have been made. . . . I hope there is no implication that core support dollars are not being used to support productive research. This is simply not so. Core research developmental support and research core services are important components of most core programs. To imply that core funding takes away from research support is again to create a dichotomy that does not exist.

" . . . I believe that there is such a thing as an individual core within a core for each cancer center—that is, an irreducible minimum constellation of core activities which are peculiar to that center and which are not necessarily generalizable to other centers. Core support for key professional staff is essential for some centers. On the other hand, biostatistical core support and an administrative core unit are at the heart of most center programs. The availability of core research development funds, administered through a carefully delineated intramural peer review process, may also be of critical importance, particularly in younger centers."

#### **SIX NEW GRANT AWARDS ANNOUNCED BY COUNCIL FOR TOBACCO RESEARCH**

The relationship of childhood respiratory disease to the development of adult chronic lung disease will be studied under one of six new grants announced by the Council for Tobacco Research—USA, Inc. The council is supported by the tobacco industry.

Grants are awarded by the council following recommendations by a Scientific Advisory Board currently consisting of 11 physicians and scientists.

Recipients of new grants, their institutions and the titles of their research projects:

Mario Aceto, Virginia Commonwealth Univ.,  
"Steriospecific binding of nicotine."

Leslie Baer, Columbia Univ. College of Physicians & Surgeons, "Cigarette smoking in normotensive and hypertensive subjects: blood pressure, renin, aldosterone and catecholamine response."

Francis Chao, Center for Blood Research, Boston, "Platelet activation and blood hypercoagulability."

Ronald Gillette, Univ. of Hawaii Cancer Center, "Effect of tobacco byproducts and other environmental contaminants on lymphoid cell homing and function."

Caroline Hall, Univ. of Rochester School of Medicine, "The relationship of lower respiratory tract disease in infancy to the development of chronic lung disease in adults: development and time course of physiologic abnormalities indicative of early obstructive airways disease."

A.M. Tometsko, Lotron Laboratories Ltd., Rochester, N.Y., "Probing nicotine receptor sites."

#### **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. Some listings will show the phone number of the Contract Specialist, who will respond to questions. Listings identify the respective sections of the Research Contracts Branch which are issuing the RFPs. Their addresses, all followed by NIH, Bethesda, Md. 20014, are:*

*Biology & Diagnosis Section — Landow Building*

*Viral Oncology & Field Studies Section — Landow Building*

*Control & Rehabilitation Section — Blair Building*

*Carcinogenesis Section — Blair Building*

*Treatment Section — Blair Building*

*Office of the Director Section — Blair Building*

*Deadline date shown for each listing is the final day for receipt of the completed proposal unless otherwise indicated.*

#### **RFP NCI-CM-87192**

**Title:** *Support services for maintenance and operation of a drug distribution and protocol monitoring system*

**Deadline:** *March 31*

The distribution of these drugs and the data generated therefrom must be recorded in compliance with FDA regulations. To meet these requirements, a Drug Distribution Authorization & Protocol Information System has been developed. Assistance is being sought to maintain the system and modify it as necessary.

The Drug Distribution Authorization & Protocol Information System is an automated procedure having an established data base. It is used to verify the accuracy of requests for drug supplies made by investigators. The system is also used to monitor protocol information, study reports and historical drug shipment information. The NIH computer facilities are utilized with programs written in PL/1, Conversational Programming, or Inquiry Reporting system. A majority of the work on this system will be performed on site.

The proposed project director should have experi-

ence with information systems and be familiar with medical terminology. Data technician and programming skills are required. The level of effort is estimated at approximately 10,000 man-hours per year. It is anticipated that an incrementally funded contract will be awarded for a period of three years.

**Contracting Officer:** Charles Lerner  
Cancer Treatment  
301-427-8125

#### RFP NCI-CP-VO-81023-66

**Title:** *Production, purification and concentration of potentially oncogenic DNA viruses*

**Deadline:** March 24

A total of 30 liters/week of Epstein-Barr virus (EBV). Of this weekly total, 1/3 is to be primarily infectious virus, 1/3 primarily transforming virus, and the remaining 1/3 is to contain sufficient high molecular weight DNA for biochemical/molecular biology studies. It is expected that a 1000X concentration final product shall yield biologically active material with either a minimum of  $10^6$  transforming units/ml on cord lymphocytes of  $10^6$  ea inducing units/ml on RAJI cells. The final products must be characterized by appropriate tests including electron microscopy, and biochemical and immunological determinations.

**Contracting Officer:** Fred Shaw  
Viral Oncology & Field  
Studies  
301-496-6496

#### RFP NCI-CM-87182

**Title:** *Preparation of plant extracts*

**Deadline:** March 27

The Div. of Cancer Treatment, NCI, will make available to interested organizations a request for proposal concerning a project to prepare extracts of approximately 3,600 plants per year for anticancer screening. The contractor must provide an extraction laboratory, have capacity for storage of approximately 10,000 plant samples, and show evidence of experience in extract preparation. All samples of dried plant materials (3 lbs. each) will be supplied by the government.

It is expected that one incrementally funded contract will be awarded for a three-year period of performance. It is estimated that the level of effort required during each year of contract performance will consist of a minimum of  $4\frac{1}{2}$  man years.

**Contracting Officer:** John Palmieri  
Cancer Treatment  
301-427-8125

#### RFP NCI-CM-87208-6

**Title:** *Phase I and phase II studies of new anticancer agents*

**Deadline:** March 31

The Cancer Therapy Evaluation Program (CTEP),

Div. of Cancer Treatment (DCT), NCI, is seeking organizations having capabilities and facilities to conduct and report the clinical evaluation of investigational new anticancer agents in phase I and phase II clinical trial studies. All offerors must propose to conduct phase I studies. In addition, they may choose to propose to conduct in-depth clinical pharmacology studies and/or phase II studies. However, all phase I studies may include an evaluation of clinical pharmacokinetics.

It is planned to make multiple awards for the phase I clinical portions of this project, with or without phase II studies. Of those offerors receiving phase I clinical or phase I/phase II awards, a limited number (possibly only one) will be selected for award of the in-depth clinical pharmacology studies portion of the project. It is anticipated that incrementally funded contracts will be awarded for a period of three years.

**Contracting Officer:** Carolyn Swift  
Cancer Treatment  
301-427-8125

#### RFP 210-78-0025-0000

**Title:** *Teratogenic assessment of butylene oxide, styrene oxide and methyl bromide*

**Deadline:** *Approximately March 25*

The National Institute for Occupational Safety & Health is soliciting proposals from organizations interested in evaluating the potential teratogenicity of styrene oxide, butylene oxide and methyl bromide by exposing rats and rabbits to these chemicals through inhalation.

#### RFP 210-78-0026-0000

**Title:** *Mutagenic screening of 13 NIOSH priority compounds*

**Deadline:** *Approximately March 25*

Rats, mice and insects will be used for this test. The inhalation route of exposure will be used whenever feasible.

**Contracting Officer  
for above 2 RFPs:** M. Stitely  
NIOSH  
5600 Fishers Ln. Rm 8-29  
Rockville, Md. 20857

#### CONTRACT AWARDS

**Title:** Study transplantability of human breast cancer in nude thymusless mice, continuation  
**Contractor:** Stehlin Foundation for Cancer Research, \$149,700.

**Title:** New techniques for the study of cell kinetics of breast cancer, continuation  
**Contractor:** Allegheny General Hospital, \$116,000.

**Title:** Conduct biomolecular studies of herpes saimiri  
**Contractor:** Harvard College, \$395,140.

**Title:** Population-Based Cancer Registry for Surveillance, Epidemiology and End Results (SEER), continuation

**Contractor:** Commonwealth of Puerto Rico, \$71,597.

**Title:** Production and detection of antibodies to chemical carcinogens and other small molecules of interest in cancer research

**Contractor:** Brandeis Univ., \$126,421.

**Title:** Transplantation and preservation of plasma cell tumors in mice

**Contractor:** Litton Bionetics, \$141,802.

**Title:** Tumor registry training program and allied activities, continuation

**Contractor:** Univ. of California (San Francisco), \$123,109.

**Title:** Sequencing of the 3' end of RSV 35S RNA: Implications for replication integration and chemotherapy, continuation

**Contractor:** Massachusetts General Hospital, \$208,550.

**Title:** Development, management and support services to the Diet, Nutrition and Cancer Program, continuation

**Contractor:** Enviro Control Inc., \$580,008.

**Title:** Support for studies of spontaneous and virus induced neoplastic transformation, continuation

**Contractor:** Meloy Laboratories, \$114,839.

**Title:** Maintenance of mouse mammary tumor virus facility, continuation

**Contractor:** Meloy Laboratories, \$75,000.

**Title:** Study the effect of environmental factors on endogenous MMTV expression

**Contractor:** Michigan Cancer Foundation, \$347,102.

**Title:** San Francisco Bay Area resource for cancer epidemiology, continuation

**Contractor:** California Dept. of Health, \$727,299.

**Title:** Mouse typing and diagnostic reagents, continuation

**Contractor:** Microbiological Associates, \$520,538.

**Title:** Development of mammalian cell lines, continuation

**Contractor:** Microbiological Associates, \$38,630.

**Title:** Support services for studies on the role of viruses and experimental oncogenesis, continuation

**Contractor:** Hazleton Laboratories, \$689,500.

**Title:** Studies on mammary tumor viruses  
**Contractor:** Hahnemann Medical College, \$115,000.

**Title:** Services to maintain studies of type C RNA tumor viruses, continuation

**Contractor:** Microbiological Associates, \$110,000.

**Title:** Measurement of aryl hydrocarbon hydroxylase in human lymphocytes, supplemental

**Contractor:** New York Dept. of Health, \$42,745.

**Title:** Cervical Cancer Screening Program, renewal

**Contractor:** Georgia Dept. of Human Resources, \$256,184.

**Title:** FDA/NCI special study of the role of saccharin in bladder cancer of the general population

**Contractor:** Westat Inc.

### SOLE SOURCE NEGOTIATIONS

*Proposals are listed here for information purposes only. RFPs are not available.*

**Title:** Breast Cancer Detection Demonstration Project, renewal

**Contractor:** St. Vincent's Medical Center.

**Title:** Induced perinatal alterations and their influence on carcinogenesis, continuation

**Contractor:** Aichi Cancer Center/Research Institute, Nagoya, Japan.

**Title:** Technical support services for the ICRDB program, modification

**Contractor:** The Franklin Institute.

**Title:** Support of the U.S. National Committee on the International Council of Societies of Pathology, modification

**Contractor:** National Academy of Sciences.

**Title:** Clinical oncology program

**Contractor:** Butterworth Hospital, Grand Rapids, Mich.

**Title:** Study of hormonal factors of human and animal prostate, continuation

**Contractor:** Southwest Foundation.

**Title:** FDA/NCI special study of the role of saccharin in bladder cancer of the general population

**Contractor:** Michigan Cancer Foundation.

**Title:** Immunoprevention of spontaneously occurring neoplasms

**Contractor:** Microbiological Associates.

**Title:** Implementation of Cervical Cancer Screening Program

**Contractor:** Massachusetts Dept. of Health.

### **The Cancer Letter** —Editor JERRY D. BOYD

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