THE CANCER LETTER

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Movement To Resolve Patient Care Reimbursement Problems Gains Momentum; NCI Report Adds Fuel

Momentum is building among cancer professional societies and other health related organizations to pursuade Congress, insurance carriers and state legislatures to resolve the issue of reimbursement for patient care costs for patients on

(Continued to page 2)

In Brief

ACS Estimates 502,000 U.S. Cancer Deaths, 178,000 Avoidable With Early Diagnosis

AMERICAN CANCER Society predicts that fewer deaths will result this year from 13 forms of cancer: stomach, rectum, larynx, uterine cervix, bladder, thyroid and four varieties of oral cancer. For 12 other cancers, the number of deaths will remain the same as last year, and for 14 others, the number of deaths will increase. An estimated 502,000 Americans will die from cancer this year, of which 178,000 could be avoided with earlier diagnosis and treatment. The predictions are contained in the society's 1989 edition of "Cancer Facts & Figures". . . . **ISSUE NUMBER** correction: The March 3 issue of **The Cancer Letter** was incorrectly listed as No. 10 of the current volume. It should have been No. 9. Those who maintain files should make that correction on their copies, and also change the March 10 issue from No. 11 to No. 10. This week's issue, March 17, is No. 11. . . . **DEVRA BRESLOW,** director of the Art That Heals program at the UCLA Jonsson Comprehensive Cancer Center, is moving on after 14 years there. She was editor and manager of the UCLA Cancer Center Bulletin and chair of the UCLA Hospice Task Force. . . . **MORE METHODS** workshops will be held this year at the annual American Assn. for Cancer Research meeting, May 27 in San Francisco. Due to the popularity of last year's workshop, three will be held this year. Topics are cloning, expressing and modifying genes and gene products; transgenic mice as a model for oncogenesis; and the polymerase chain reaction, its subtleties and application. Fee is $30 for each session. Advanced registration deadline is March 31, spaces are limited. Contact AACR, 530 Walnut St., 10th Floor, Philadelphia, PA 19106, phone 215/440-9300. . . . **SEN. TED STEVENS** (R-AK) has brought Armand Hammer's Stop Cancer campaign to the attention of Congress. Stevens mentioned the campaign on the floor of the Senate last month and had an article Hammer wrote reprinted in the "Congressional Record."

Reimbursement Momentum Building; ASCO, Others To Lobby Congress

(Continued from page 1)

clinical trials. A report by NIH and NCI obtained this week by **The Cancer Letter** concludes that denial of reimbursement for patient care costs constitutes "a most serious threat" to clinical trials and other investigational therapy.

The American Society of Clinical Oncology and a coalition of other health groups have been working to get the issue before Congress and the Health Care Financing Administration, which administers the Medicare law.

As a result of their work during the past year, the issue is getting more attention:

<>Last year, Karen Antman, associate professor at the Dana Farber Cancer Institute and Harvard Medical School, included the problem in testimony before the Senate Labor-HHS-Education Appropriations Subcommittee on the NCI budget. Antman is chairman of ASCO's Public Issues Committee.

<>The subcommittee included a statement of the problem in its appropriations bill, asking NCI to submit a report in time for this year's budget hearings on "what remedies might be available and the costs involved." The NCI report has been submitted to the Senate.

<>Sen. Edward Kennedy (D-MA), chairman of the Senate Committee on Labor & Human Resources, asked the Institute of Medicine to study the reimbursement issue. That resulted in an IOM report recommending changes in Medicare regulations and actions by state regulatory agencies to pay patient care costs for those enrolled in trials (**The Cancer Letter**, Feb. 24, 1989).

<>NCI sponsored a meeting of several health related organizations to attempt to develop a consensus on a reasonable reimbursement policy. The organizations were ASCO, the Coalition for Cancer Research, the American Medical Assn., the Pharmaceutical Manufacturers Assn., the Assn. of Community Cancer Centers, the Institute of Medicine, FDA, and the Candlelighters.

In the report to the Senate, NCI said the plans of the "consensus group" are to meet directly with insurers to try to resolve the problem. The group also is working on a "consensus statement" that is to be released soon.

<>NCI staff has met twice with HCFA staff to discuss policies for Medicare, according to the NCI report.

<>NCI also is involved in discussions with the Blue Cross Assn. about a meeting this fall of the Blue Cross/Blue Shield medical directors. There will be a session on reimbursement for patient care costs in clinical trials at the meeting.

In addition, the National Committee to Review Current Procedures for Approval of New Drugs for Cancer and AIDS, chaired by Louis Lasagna, is investigating the problem. The committee is scheduled to discuss reimbursement at a meeting this week.

Armed with the NCI report and the IOM study, ASCO will return to Congress during the NIH budget hearings in April and May to press the issue.

"With the base that has been built and the organizations coalescing around the issue, this year will be the best opportunity ever to get this issue resolved," said John Grupenhoff, who represents ASCO in Washington.

However, the work has just begun. The recommendations in the IOM study, which reflect in general those developed by ASCO, will require changes in the Medicare law and its interpretation by HCFA.

"This means the Senate Finance Committee, the House Ways & Means Committee, the House Subcommittee on Health and the Environment all will have to be informed and asked for action," Grupenhoff said.

ASCO does not intend to actually draft legislation, Antman told **The Cancer Letter**. "We can highlight the problem for Congress," she said.

ASCO is talking to a number of insurance companies to try to pursuade them that "it's in their best interests to separate effective and ineffective research" by reimbursing patient care costs for those on NCI sponsored clinical

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trials, Antman said.

"We have to get HCFA to change its policy on reimbursement," Charles Coltman, current president of ASCO and chairman of the Southwest Oncology Group, told **The Cancer Letter.**

"Once HCFA adopts a policy, it spills downward to other third party payers," Coltman said. "But there is no question that this is a state level problem and probably will require legislative action by the states."

According to several sources, Kennedy's interest in the reimbursement problem, which prompted the IOM study, was stimulated by a staff member's personal problem.

The Kennedy staffer was diagnosed with testicular cancer, had failed most standard therapies and wanted to enroll in a clinical trial. But the staff member's insurance company said it would refuse to reimburse for the care. Sources said the young man went into a clinical trial anyway and apparently has been cured, but the insurance company still has refused to reimburse for patient care costs.

"I think Kennedy would have been sympathetic to the issue, whether or not a staff member was involved," said Jane Henney, vice chancellor for health programs and policy at the Univ. of Kansas Medical Center, and a past deputy director of NCI. "That may have triggered a more spontaneous response."

Despite the partial success with lobbying efforts, the reimbursement problem is getting worse, by some accounts.

A senior vice president of one major pharmaceutical company complained recently that three insurers had refused to reimburse for a new prostate cancer drug.

Although the therapy was cheaper, month for month, than conventional therapy, the treatment cost more because the patients lived about seven months longer than under standard care.

Lee Mortenson, executive director of the Assn. of Community Cancer Centers, recounted the drug company executive's story in "Oncology Issues," the ACCC magazine.

"The situation has become absolutely absurd," said Coltman. "Not only do we have the problem of no reimbursement for patient care costs in clinical trials, but there is also this ridiculous situation where they are not reimbursing for off label use of approved drugs.

"FDA says that data often are as good or better for nonapproved uses as they are for approved, but that doesn't cut it with the insurance companies," said Coltman. "FDA approval means only that the drug is approved for marketing for that particular indication. It does not mean that it is unapproved for other uses."

Now, insurance companies are taking nonreimbursement to the next step, Coltman said, by disallowing reimbursement for combinations of approved drugs when the combinations do not have specific FDA approval for a specific indication.

"That is carrying this thing to absurd lengths," Coltman said. "Most of our best treatment involves drug combinations, and FDA rarely is asked to approve them."

For example, he said, MOPP, for treatment of advanced Hodgkin's disease, has never been approved by FDA. "Can you imagine if third parties refused to reimburse for MOPP?" Coltman asked.

Mortenson said lobbying HCFA to change its policies would have limited results. The problem should be explained to the public and to legislators, he said. Groups also could provide a rating of cancer benefits in insurance plans.

"The idea that living longer is a waste of resources is a national scandal," Mortenson wrote. "It should be in headlines."

Antman said ASCO's approach was based on numbers. "If we can get the government to ensure that goverment employees and Medicare recipients are covered for investigational care, that would cover a large population."

In addition, Antman said, the reimbursement issue is tied in to the problem of inadequate NCI budgets. "This is a problem that we'll be approaching over the next few years."

Grupenhoff praised ASCO's work on the issue. "ASCO's leadership, especially that of Karen Antman, has really made things happen on this issue this last year," he said. "The NIH report, called for I think because of her statements to the appropriations committees last year, plus the upcoming consensus statement, and the IOM study, will certainly have an impact on Congress and HCFA."

The National Coalition for Cancer Research is soliciting a number of proposals from firms to survey cancer centers to provide data on the scope of the problem, according to Marguerite Donoghue, a spokesman for the group.

"We know what's happening anecdotally, but we have no hard core data and Congress

doesn't pass bills and Medicare policy doesn't get changed on anecdotes alone," Donoghue told **The Cancer Letter.** "Unless the cancer community comes forward with the data, people on Capitol Hill will just shrug their shoulders."

Donoghue said the first phase of data collection should begin this spring.

NCI's discussions with HCFA so far have not produced an agreement, according to the report submitted to Congress.

According to the report, Medicare policy is to exlude investigational therapy from coverage because, "HCFA believes that treatment with agents not yet approved by FDA does not satisfy the 'reasonable and necessary' criterion included in the legislative language relating to Medicare."

The NCI report, "Remedies and Costs of Difficulties Hampering Clinical Research," submitted to the Senate by NIH Deputy Director William Raub, provides a concise statement of the reimbursement problem:

"Most third party insurance contracts explicitly exclude payment for patient care costs associated with investigational drug research. The research exclusion has been part of most insurance contracts for many years, but has not been rigorously enforced, probably because of substantial difficulties in monitoring the delivery of medical care.

"Recently, however, with the increased emphasis on cost containment, insurance companies have had an increasing tendency to deny claims where an investigational agent is clearly part of the therapy.

"The claims that are denied are not simply the additional costs of care over and above that of standard therapy, but may include the entire cost of the hospitalization, irrespective of what the cost would be without the investigational treatment."

According to the NCI report, the extramural working group to investigate interleukin-2/LAK therapy has had many denials from insurance companies, "even though this therapy has been placed into a modified Group C category by FDA and seems to be probably the most effective treatment for two malignancies (metastatic melanoma and renal cell carcinoma)."

The reason for the denial, the report said, is the cost, which can reach $30,000 to $35,000 per patient.

Although NCI's Clinical Drug Development Program has not been affected by denials, there have been reports of denials to patients who receive an experimental drug and then are hospitalized due to complications.

"The rationale for the denial, apparently, is that if the drug causing the complication is investigational, then any complications resulting from drug administration should not be reimbursed," the report said.

It is not clear whether investigational therapy on the whole is more expensive than standard therapy. The National Center for Health Services Research and NCI are conducting a retrospective study to arrive at some estimate of the relative costs. Blue Cross is also talking about doing a study.

"NCI's point of view on this problem can be simply stated," the report said. "We believe that, in the treatment of cancer, patients on clinical trials receive therapy that is quite likely to be at least equivalent to or possibly better than standard treatment.

"Patients who are candidates for (clincial trials) have, by definition, desease that is resistant to all known forms of 'standard' therapy," the report continued.

"The treatment offered them on ethical, scientifically valid clinical trials represents the best approach medically that can be offered.

"For this reason, we consider it appropriate for third party carriers to reimburse patients for the medical care costs of participating in scientifically valid clinical trials."

The NCI report concludes, "If pressures for cost containment compel the insurance industry to increase enforcement of the research exclusion, then failure to provide reimbursement of patient care costs will constitute a most serious threat to clinical trials."

The report's "executive summary," ends on a more favorable note, however.

"NCI staff is optimistic that further discussion and education will convince at least some carriers of the medical validity of covering patient care costs of investigational therapy."

NCI Patient Accrual Effort Is Getting PR For Clinical Trials, Report Says

Efforts by NCI to increase patient accrual to clinical trials are starting to have some effect, mainly on increasing publicity for clinical trials, according to an NCI report obtained this week by **The Cancer Letter.**

The report, submitted to Congress by NIH Deputy Director William Raub, was requested last year by the Senate Labor-HHS-Education

Appropriations Subcommittee.

According to the report, "Remedies and Costs of Difficulties Hampering Clinical Research," NCI has taken several steps to remedy the problem. NCI's goal is to double participation, from 25,000 patients per year to 50,000 patients per year enrolled in trials.

The clinical trials groups have been asked to "substantially increase" the percentage of eligible patients placed on study, to decrease the complexity of studies, to eliminate the collection of nonessential data and minimize the number of medical tests, the report said.

NCI also is targeting trials in the most prevalent cancers as "high priority" trials, giving them extra funds for accrual. NCI also is talking with health maintenance organizations and for profit health care companies to broaden participation in clinical trials.

The Office of Cancer Communications has launched a public education campaign to promote clinical trials. This has resulted in "many articles" in newspapers about NCI clinical trials, according to the report.

The NCI report gave two reasons for less than optimal accrual. First, delivery of medical care in a clinical trial is more time consuming and difficult for physicians than standard care. For example, physicians must carefully collect data and comply with federal regulations on protection of human subjects.

"In addition, different physicians may have varying degrees of enthusiasm for the research question being addressed in any particular clinical trial and may not feel strongly impelled to accrue all available patients to the trial," the report said.

Three major cooperative groups whose performance was evaluated recently had accrual rates that would result in the extension of studies by 32 percent, 113 percent and 119 percent, compared to the original projected durations, the report said.

The effort to publicize the trials would also help to recruit more physicians, and thus, more patients, the NCI report said.

"Anecdotal experience even at this early stage suggests that enhancing public awareness of, and demand for, access to clinical trials may be one of the most effective means of increasing accrual rates," the NCI report said.

The American College of Surgeons Commission on Cancer is working with NCI on a survey of its members concerning obstacles to participation in clinical trials. ACOS and NCI are planning to produce videotapes for surgeons about trials in particular diseases.

How To Get More Money Without Asking: Broder Faces A Conundrum

When NCI Director Samuel Broder makes his first appearance before Congress next week, he faces an onerous task--to defend an Administration budget that will result in shortfalls in most major programs of NCI.

Broder is scheduled to testify March 22 before the House Labor-HHS-Education Appropriations Subcommittee, chaired by Rep. William Natcher (D-KY). In his public statements during his first two months on the job, Broder indicated his strategy:

"Officially, I must defend the President's budget, but I will do everything I can to signal that we need more money," Broder told the National Cancer Advisory Board last month. (**The Cancer Letter,** Feb. 10, 1989).

Whether he uses flags, sign language, telepathy, or simply asks congressmen to read his lips, Broder must signal that NCI is facing a year of cutbacks.

Examining Impact

NCI is in the process of an extensive examination of the effect of the President's budget on each program area, **The Cancer Letter** has learned.

It has been established that an increase of about 5 to 6 percent over the President's 1990 budget would be required to maintain the current level of services.

President Reagan's farewell budget requests $1.6 billion for NCI, only a 4.7 percent increase over FY 1989. Part of the increase, $28.5 million, is slated for AIDS research.

That would leave NCI with $46 million more for cancer activities than the current year, an increase of only 3.2 percent. NCI would need an additional 5 to 6 percent increase, or $90 million, to sustain the current level of services.

What's more, there is no guarantee NCI will receive even the amount in the President's budget. In fiscal 1989, NCI received $20 million less than the President's budget had proposed, Broder reminded the NCAB.

Here is the budgetary outlook for NCI's major programs:

Cancer Centers: The President's budget allocates $101.3 million, unchanged from FY 1989. Excluding AIDS funding, the centers' budget falls to $97 million, a $1.2 million decrease. NCI estimates that to operate the centers at the recommended levels and to restore previously awarded grants, the program would need additional funding of nearly $20.6

million. That would not include funding for any new centers.

Cancer Prevention & Control: The President's budget asks for $74 million, the same level as the current year. Using the estimate of adding 6 percent to the President's budget, cancer control would be entitled to an increase of about $4.5 million.

The President's budget includes $11.5 million for the Community Clinical Oncology Program. That amount is currently funding 52 CCOPs and 17 research bases.

NCI wants to add eight more CCOPs in FY 1990, which would cost another $3.5 million. In addition, the new minority CCOPs program would need $1.2 million for FY 1990 (**The Cancer Letter,** Feb. 3, 1989).

Neither the $3.5 million for the additional CCOPs, nor the $1.2 million for the minority CCOPS, are included in the $74 million cancer control budget.

Training: The National Research Service Awards program is slated to receive $33 million, $1 million more than last year. That increase is enough to maintain the current level, according to NCI.

However, the training program and the career education program may be restructured this year, which could mean that not enough funding would be available.

In addition, an NIH mandated stipend increase for NRSA fellows has complicated matters. NCI's training branch is waiting for word for more specific information on the program's outlook for 1990.

Clinical education got $2 million in the President's budget, no increase from the current year.

Research management & support: The President's budget includes $70.5 million for management and support, a cut of $3 million, or 4 percent. Excluding funding for AIDS research support, the cut is even greater, about 5 percent. Under the 6 percent formula, the mechanism should get an increase of $4.2 million over the President's budget to maintain current services.

Clinical cooperative groups: The President's budget asks for nearly $60 million, about $279,000 more than the current year, an increase of 0.5 percent. Under the 6 percent formula to maintain the current level, funding should be $3.6 million more than the President's budget allows.

Construction: There is no money for construction in the President's budget. Last year, Congress put in only $2.8 million for construction at theFrederick Cancer Research Facility.

Research project grants (RO1s and PO1s), which have always been given the highest priority at NCI, are listed for a 6 percent increase over FY 1989. However, that is still not enough to fund more than 29 percent of approved grants.

The President's budget gives the grants program a total of $768 million. Under the 6 percent estimate, the grants program should get about $46 million more than the President's budget allocates.

NCI estimates funding about 822 competing grants in FY 1990, about 100 more than this year. That is due to money being freed up from the expiration of more noncompetitive grants this year, and to downward negotiations in grant budgets approved by review committees. Competing grants will be negotiated down 10 percent, and noncompeting grants about 4 percent.

The President's budget gives intramural research a total of $312 million, a 9 percent increase. However, AIDS funding gets the largest piece of the increase, about $26 million. Intramural cancer research would receive $14 million more than the current year, a 5.8 percent increase.

In addition to those program areas, NCI is facing a shortage of positions, or FTEs. Under the President's budget, NCI would lose 28 FTEs for cancer in FY 1990, but would receive 32 additional FTEs for AIDS. The result is an overall increase of four FTEs.

Since FY 1984, NCI has lost 400 FTEs, a 20 percent reduction, Broder told the NCAB.

Jill Eikenberry To Receive ACCC Award; Breast Cancer Symposium Set

Actress Jill Eikenberry will receive the Assn. of Community Cancer Centers' Outstanding Community Service Award at the association's luncheon April 1, during its 15th annual meeting in Washington.

Eikenberry, star of television's "L.A. Law" series, will be honored for the TV special on breast cancer which she hosted. Since she will not be able to attend, the presentation by ACCC President David King was videotaped in Hollywood and will be shown at the luncheon.

A breast cancer symposium will make up the program for the entire day April 1, with discussions on epidemiology, prevention, screening, treatment, rehabilitation, reimbursement and ethical issues.

Program Announcements

Title: Specific cancer cell targeting using molecular genetic technology
Application receipt dates: Feb. 1, June 1, Oct. 1

The Developmental Therapeutics Program and the Biological Response Modifiers Program of NCI's Div. of Cancer Treatment invite grant applications for basic and applied molecular biological studies concerned with specific targeting of cancer cells. The goal is to develop and evaluate novel methods for killing tumor cells while sparing normal cells in vivo.

Specific targeting of cytotoxic agents to tumor cells and not to normal cell populations continues to be a major goal in the treatment of cancer. Although many cytotoxic agents are effective against rapidly dividing cells such as in leukemia, where a large percentage of the tumor cell population is undergoing proliferation, these same agents cause undesirable toxicity often associated with damage to normal rapidly proliferating cells such as those in the bone marrow and the gastrointestinal tract.

Approaches have been taken to achieve specificity o cancer treatment by exploiting unique features of the tumor type. Immunotoxin (a specific antibody covalently coupled to a toxin) therapy has the theoretical capability of restricting cell killing to a defined antigen bearing cell population, but several problems have been identified which may limit the use of this technique. These problems include the rapid emergence of nonantigenic variants within a tumor, the shedding of antigens from the tumor surface, and the development of a human anti-immunoglobulin response. Recent advances in molecular genetic technology now allow the consideration of new approaches to cancer treatment which circumvent these problems. One example is the use of tissue specific promoters and enhancers to regulate selectively the expression of inserted genes coding for cytotoxic molecules, such as the A subunit of diptheria toxin. Another strategy is the use of gene splicing to produce hybrid molecules consisting of segments of toxins and cell surface receptor ligands or the variable region of immunoglobulins. These agents target cells at the level of the plasma membrane. The success of these approaches for the specific killing of tumor cells depend upon the identification of either unique regulatory regions for a specific tumor gene or tumor specific surface receptor ligands.

Recent experiments have shown that the specific cell targeting using gene transfer or genetically engineered molecules can result in selective toxicity in vitro. However, successful use of these techniques for the treatment of cancer patients will depend upon the efficient delivery of the genes or toxic molecules to the tumor in vivo, the expression of the genes within the cells of the tumor, and the limitation of gene expression or ligand binding in nontarget tissues.

This program announcement is intended to encourage novel approaches to specific cancer cell targeting using recombinant DNA technlogy. Construction of appropriate molecules or genes which would specifically alter the function of tumor cells is encouraged. Proposed studies could include the isolation of cell specific genes with unique promoter and enhancer regions, the design of multifunctional proteins with specific cell surface receptor ligands, or the development of theoretical models which predict functionality of the molecules. These molecules or genes should then be tested for efficacy in vivo in appropriate tumor bearing animal models addressing questions of delivery and specificity. The overall aim of this initiative is the stimulation of new therapeutic approaches to cancer using molecular genetic technology which can be tested in a relevant experimental animal model.

Although outside the scope of this program announcement, resources are available within BRMP and DTP to facilitate further development of interesting and efficacious therapeutic agents. Resources include scale up production, pharmacokinetic assessment, toxicology studies and clinical evaluation of the agent.

For further information, contact Dr. George Johnson, Grants & Contracts Operations Branch, DTP, DCT, NCI, Executive Plaza North Suite 832, Bethesda, MD 20892, phone 301/496-8783.

Title: Regulation of prostatic involution as related to prostatic cancer
Application receipt date: June 1, Oct. 1, Feb. 1

The Tumor Biology Program of the Div. of Cancer Biology & Diagnosis of NCI seeks applications to study the relationship between prostate involution and prostatic cancer. The major objectives are to understand the nature of both the morphological and functional heterogeneity of the ductal acinar network in the intact prostate, to study the regulation of gene expression during prostatic involution, to study the activities and functions of specific gene products in the prostate following androgen deprivation and the nature of their substrates, to study the biochemical properties and genetic regulation of cells in the prostate following involution, and to develop appropriate tumor models that mimic stages of the involution process and which will allow direct comparison between malignant and normal cells.

Standard treatments to block cell proliferation in fast growing tumors cannot be utilized effectively in prostate cancer because of the slow growth of these tumors. In addition, prostate cancer is usually androgen sensitive but not androgen dependent, rendering treatment by androgen blockage only partially effective. Because of these limitations, new approaches must be explored in order to understand how to enhance cell death in these tumors. Since it is becoming increasingly obvious that treatment of prostatic carcinoma by androgen blockage, whether by castration or by more elaborate therapeutic combinations, is only partially successful at best, the elucidation of the mechanism of prostatic involution could herald a second generation of therapies designed to enhance the rate and degree of involution and to ensure the continued suppression of growth. Many elements of the process already have been described in some detail. A concerted effort to unravel the remaining links in the processes which control involution in the prostate may lead to new ways of treating prostate cancer.

The cellular and functional heterogeneity of the prostate has recently emerged as a major feature of the prostate gland. A broad range of experimental approaches is needed if the relationship of this heterogeneity to the pathology of the gland, especially the pathology of prostatic cancer, is to be understood. Of particular interest to the tumor biology program is how these variables relate to prostatic involution and androgen dependent and androgen independent responses. The role of cell-cell interactions, including stromal cells, and the extracellular matrix may be important to evaluate in order to fully understand the process of involution. In view of the poor overall success of antiandrogen therapy, it may be important to examine the fully regressed prostate to determine unique features of the gland which are responsible for its refractoriness to antiandrogens.

There are numerous possible approaches to these problems and the tumor biology program encourages all novel research strategies with appropriate rationales which will help to reveal relationships between prostatic involution and prostatic cancer. Researchers using a number of techniques from a variety of disciplines are likely to contribute to these studies. The disciplines considered important, but not all inclusive, are struc-

tural morphology, cell biology, endocrinology, protein biochemistry, molecular biology and genetics, and immunology. Since it is unlikely that any one laboratory has all the requisite skills to investigate these complex biological phenomena, multi-institutional and inter-disciplinary collaborations may greatly facilitate the conduct of this research.

For additional information, contact Dr. Colette Freeman, Chief, Cancer Biology Branch, Division of Cancer Biology & Diagnosis, NCI, Executive Plaza South Room 630, NIH, Bethesda, MD 20892, phone 301/496-7028.

RFPs Available

Requests for proposals described here pertain to contracts planned for award by the National Cancer Institute unless otherwise noted. NCI listings will show the phone number of the Contracting Officer or Contract Specialist who will respond to questions. Address requests for NCI RFPs, citing the RFP number, to the individual named, the Executive Plaza room number shown, National Cancer Institute, NIH, Bethesda, MD 20892. Proposals may be hand delivered to the Executive Plaza, 6130 Executive Blvd., Rockville, MD. RFP announcements from other agencies will include the complete mailing address at the end of each.

RFP NCI-CM-97580-30T
Title: Operation and maintenance of the DTP biological data processing system
Deadline: April 30

NCI's Div. of Cancer Treatment, Developmental Therapeutics Program, Information Technology Branch, is seeking an organization to provide support for DTP's biological data processing system. This system provides laboratory microcomputer support, and large scale database management for NCI's anticancer and anti-AIDS drug discovery activities which include the annual in vitro screening of many thousands of synthetic compounds and natural product extracts.

The contractor shall take responsibility for the current biological data processing system and all of its subsystems. The responsibility shall include design and/or redesign of system programs as well as initial coding, revising, testing, debugging, documentation, operation, and/or maintenance of all system software.

The contractor shall also provide support for installation and operation of the systems and development of new hardware and software systems as required for further development of the DTP drug discovery and development programs. The current system involves a series of Intel 80386 based laboratory microcomputers running SCO XENIX connected via Ethernet. The in vitro drug screening database resides in a relational database management system on a VAX 8820 computer running VMS. Some components of the system also utilize IBM 370 facilities at NIH's Div. of Computer Research & Technology.

All responsible sources may submit a proposal which shall be considered by NCI. It is anticipated that one level of effort contract shall be awarded for a five year period, with incremental funding each year. Offerors will be invited to submit proposals at two levels of effort--18,800 or 9,400 direct labor hours per year.

The proposed contract is a 100 percent small business set aside. For the purposes of this acquisition, a small business is defined as a firm, including its affiliates, that is independently owned and operated, is not dominant in the field of operations in which it is proposing on government contracts, and its average annual receipts for the preceding three fiscal years do not exceed $12.5 million. This is a recompetition of a contract currently held by VSE Corp.
Contract Specialist: Elsa Carlton
RCB Executive Plaza Rm 603
301/496-8620.

RFP NCI-CM-07315-72
Title: Detailed drug evaluation and development of treatment strategies for chemotherapeutic agents
Deadline: April 25

The Developmental Therapeutics Program of NCI's Div. of Cancer Treatment is seeking a contractor to evaluate compounds for anticancer activity in experimental in vivo tumor models. Studies will focus on agents identified by the program's disease oriented in vitro drug screen and will employ human tumors growing in immune deficient (athymic) mice.

Experiments will be designed and conducted to optimize drug activity and evaluate the drug's therapeutic potential. Some in vivo studies may involve mouse tumors growing in pathogen free immune competent mice and some cell culture support will be required for use of the human tumors.

Compounds to be studied will be selected by the government. As compounds of a commercially confidential nature (discreet) may be evaluated, pharmaceutical and chemical firms will be excluded from the competition. Also, since structural formulas of discreet materials may be provided by the government on occasion, the organization must be willing to sign a confidentiality of information statement.

Facilities for handling pathogen free immune competent and immune deficient mice and utilize methods to protect the facilities from pathogenic organisms are required. Additionally, facilities and equipment for frozen storage of tumors, tumor transplanatation, drug preparation, and treatment; for the handling of potentially carcinogenic or hazardous materials; and for propagation and testing human tumor lines in vitro are required.

One incrementally funded contract will be awarded for five years, on a level of effort basis specifying approximately 95,000 labor hours over five years. The current contract is held by Southern Research Institute.
Contracting Office: Jacqueline Ballard
RCB Executive Plaza South Rm 603c
301/496-8620

RFP NCI-CM-97596-19
Title: Provision, maintenance and transfer of tumor bearing animal models for investigation

The deadline for proposals under this RFP, originally listed as approximately March 15 (**The Cancer Letter**, Jan. 20), has been extended to April 28. The original announcement listed the RFP number incorrectly; the above number is correct.
Contract Specialist: Zetherine Gore
RCB Executive Plaza South Rm 603
301/496-8620

NCI Contract Awards

Title: Precancerous gastric lesions: study of determinants and rates of transition in a population in China at high risk of stomach cancer, Epidemiology & Biostatistical Program, Div. of Cancer Etiology
Contractor: Beijing Institute for Cancer Research, $355,479

Title: Literature surveillance and selection of promising natural products by small business
Contractor: Naprotech Inc., $140,555

Title: DTP AIDS screening database support
Contractor: Capitol Technology & Information Services, $1,043,492