THE CANCER LETTER

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NCI LOW FAT DIET STUDY FOR STAGE 2 BREAST CANCER WILL INCLUDE POSTMENOPAUSAL TAMOXIFEN THERAPY

The recommendation of last week's consensus conference on adjuvant treatment of breast cancer — that tamoxifen is the "treatment of choice" for postmenopausal women with positive nodes and positive hormone receptors — apparently has resolved the sticky issue that has

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In Brief

DAVID SUNDWALL NAMED HEALTH DIRECTOR OF SENATE LABOR & HUMAN RESOURCES COMMITTEE'S HHS OFFICE

DAVID SUNDWALL has been named by Sen. Orrin Hatch (R-Utah) as the majority health director of the Health & Human Services office of the Committee on Labor & Human Resources. He replaces Steven Grossman, who was named deputy assistant secretary for health. Sundwall has been Hatch's physician advisor on the committee since 1981. Prior to joining Hatch's staff, he was an associate professor from the Univ. of Utah College of Medicine. He is board certified in internal medicine and family practice, and is currently a clinical associate professor at Georgetown Univ. School of Medicine.... **SEN. DAVE DURENBERGER,** who chairs the Senate Health Subcommittee, proposes using half of the 16 cent per pack federal excise tax on cigarettes to fund programs for health promotion and disease prevention. The tax is scheduled to fall to 8 cents per pack on Oct. 1, unless Congress extends it. Under the bill, 8 cents of the tax would go into a trust fund to be distributed to the states for preventive health care programs.... **CIGARETTE TAX** changes have the greatest impact on the smoking habits of teenagers, according to a report released Sept. 9 by Harvard's Institute for the Study of Smoking Behavior and Policy. The report suggests that allowing the current 16 cents per pack tax to return to 8 cents could help induce hundreds of thousands of teenagers to take up smoking in coming years. The proceedings of a conference on the excise tax held by the institute at the National Academy of Science, the report also concludes that the impact of cigarette prices, and taxes, appears to be on whether or not people smoke, rather than how much they smoke .... **HOSPICE ASSN.** of America new officers in addition to Anne Katterhagen, chairman (**The Cancer Letter**, Aug. 16) are: Robert Enck, Lourdes Hospital, Binghamton, N.Y., vice chairman, and Joan Lowell, Hospice of the Valley, Phoenix, secretary. Other board members are: Mary Fay Verville, Gold Coast Home Health Services, Pompano Beach, Fla.; John Yarbo, Univ. of Missouri Medical Center, Columbia; Nancy Howell Agee, Roanoke (Va.) Memorial Hospital; Arlene Sayers, Blue Cross-Blue Shield, North Haven, Conn.; and Kaye Daniels, Hospital Home Health Care Agency, Torrance, Calif.

PHYSICIAN AND PATIENT PARTICIPATION IN CLINICAL TRIALS URGED BY PANEL

(Continued from page 1)
been holding up NCI's low fat diet study for stage 2 breast cancer. The debate over whether to withhold adjuvant chemotherapy from patients in the study led to the withdrawal of Memorial Sloan Kettering from the planned trial earlier this year.

The Div. of Cancer Prevention & Control, its Board of Scientific Counselors, and the nutrition study's steering committee and advisory committee had all agreed that chemotherapy would pose too much of a threat to protocol compliance and interpretation of results (**The Cancer Letter,** June 21). Although the study was planned to be limited to postmenopausal women because chemotherapy had not been conclusively demonstrated as effective in that group, the issue divided the clinical oncology camp.

DCPC awarded cooperative agreements to the Univ. of Minnesota for the study's nutrition coordinating unit and to eight clinical units, which will accrue the patients and enter them into the program. One of the eight units is the American Health Foundation, whose president, Ernst Wynder, conceived the study. Wynder contends that epidemiology studies in Japan and elsewhere show that low fat diets help reduce the incidence of breast cancer, and also reduce substantially the risk of recurrence in women who get breast cancer. Wynder believes that the study will demonstrate that low fat diet can be more effective than chemotherapy in preventing recurrence.

MSK, which had agreed to work with the American Health Foundation on entering patients into the study, wrote Wynder that the study design was unacceptable, due to the lack of therapy for the control group of women with stage 2 breast cancer.

DCPC Director Peter Greenwald said after last week's conference that he thinks all the original participants in the study will go along with giving tamoxifen to all patients, with cytotoxic chemotherapy to remain excluded. The study's steering committee met immediately after the consensus conference and agreed to limit the study to patients age 50 and over, and that all patients would receive tamoxifen, including those with both positive and negative estrogen receptors.

Half the patients will be randomized to a control group that will continue with normal diets, the other half to a diet in which the percentage of fat will be reduced from the average 40% in most Americans' diets to 20%. The hypothesis being tested is that reduced fat levels will help prevent breast cancer recurrence.

A comparison study, to test if the same low fat diet can prevent breast cancer, has already started.

The study's Policy Advisory Committee, a committee of DCPC's Board of Scientific Counselors, was scheduled to meet this week prior to the BSC meeting Sept. 19-20. Recommendations of that group and the Steering Committee were to be considered by the full BSC. Greenwald also said that the BSC's decision will be final, provided the NCI Executive Committee concurs.

The full study still must await completion of a feasibility study, which will determine if patient compliance can be achieved. Greenwald said that would require a year and 250 patients.

Consensus Conference Recommendations for Adjuvant Chemotherapy

The consensus conference's draft statement released Sept. 11 advises that "tamoxifen should now be regarded as standard therapy for postmenopausal patients with positive axillary lymph nodes and positive hormone receptor status."

Although the panel notes that "the optimal duration of tamoxifen therapy remains to be defined," it suggests that a minimum two year course be considered. "It appears that a longer duration of adjuvant tamoxifen (e.g., at least two years) may be more effective than one year," the statement says, adding that current trials are evaluating tamoxifen given for four or more years. The panel also advises that "there is no evidence to suggest that a dose of tamoxifen higher than 20 mg per day is indicated."

The panel also strengthened an earlier recommendation for adjuvant cytotoxic therapy in premenopausal women with positive nodes made by a similar panel in 1980, concluding that "adjuvant chemotherapy can now be considered standard care for these patients." The panel recommends treatment with "established combination chemotherapy," but advises that single agent therapy "should be avoided outside a clinical trial."

Patients who are ineligible for an investigational protocol should receive an adjuvant chemotherapy combination "that has demonstrated efficacy in major clinical trials." The protocol regimen "should be followed in detail," the panel says, adding that "arbitrary dose reductions to circumvent moderate and manageable toxicity may reduce the effectiveness of adjuvant therapy and should not be made."

Although the panel notes that "an optimal duration of adjuvant chemotherapy has not been defined," it suggests that six months may be as effective as 12. "Some clinical trials have demonstrated that a duration of more than one year is not indicated," it says, adding, "regimens of shorter duration (e.g., six months) may be equally effective." It emphasizes that "full doses of adjuvant chemotherapy should be administered."

The panel does not recommend a specific cytotoxic regimen. During the discussion following the presentation of the draft statement, however, National Surgical Adjuvant Breast Project Chairman Bernard Fisher suggested that the panel's reference to six versus 12 month therapy should clarify that it refers to CMF containing regimens.

The panel does not endorse routine administration of adjuvant chemotherapy for either pre or postmenopausal women with histologically negative lymph nodes, explaining that "at present, there is not adequate information from randomized clinical trials of adjuvant therapy to demonstrate a signficant survival benefit for women with negative nodes."

Women with negative lymph nodes "are encouraged to participate in randomized clinical trials comparing observation with adjuvant therapy." The panel does, however, identify high risk node negative patients who may benefit from adjuvant chemotherapy and for whom chemotherapy "should be considered" if they cannot be entered into an ongoing trial. High risk patients may be identified by "large tumor size, negative hormone receptors, and cell differentiation pattern, including high degree of anaplasia, high thymidine labeling index, and aneuploidy."

The panel concludes that "while significant advances have been made in the past five years" in adjuvant therapy, "optimal therapy has not been defined for any subset of patients."It adds, "for this reason, **all patients and their physicians are strongly encouraged to participate in controlled clinical trials.**"

Outside the context of a clinical trial, the panel addresses five subgroups of breast cancer patients:

* For premenopausal women with positive nodes, regardless of hormone receptor status, treatment with established combination chemotherapy should become standard care.

*For premenopausal patients with negative nodes, adjuvant therapy is not generally recommended. For certain high risk patients in this group, adjuvant chemotherapy should be considered.

*For postmenopausal women with positive nodes and positive hormone receptor levels, tamoxifen is the treatment of choice.

*For postmenopausal women with positive nodes and negative hormone receptor levels, chemotherapy may be considered but cannot be recommended as standard practice.

*For postmenopausal women with negative nodes, regardless of hormone receptor levels, there is no indication for routine adjuvant treatment. For certain high risk patients in this group, adjuvant therapy may be considered.

The consensus statement was based in large part on massive amounts of clinical trial data presented at the two and a half day conference. The panel also appeared to rely heavily on a statistical overview of breast cancer trials presented by statistician Richard Peto, a reader in cancer studies at Oxford Univ.'s Radcliffe Infirmary.

Peto reviewed several dozen trials involving approximately 40,000 women, including results of trials conducted in the USSR. The statistical overview found a "definite delay of recurrence and a highly statistically significant reduction in mortality" for women over 50 given tamoxifen. A two year prophylatic course of tamoxifen for older women could, he said, reduce five year mortality from 30% to 25%, thereby avoiding about one fifth of early deaths. Results from three or four dozen randomized trials in which patients received tamoxifen for an average of 20 months demonstrated a five year survival of 72% for women over 50 treated with tamoxifen compared to 67% for the control group.

"This benefit of tamoxifen for women older than 50 years of age is even more important because it can be achieved without serious short term toxicity," the panel says.

Tamoxifen's therapeutic benefit "may correlate with increasing quantity of hormone receptors, but further investigation of this is required," the panel concludes. It also notes that the drug "may have its greatest benefit in patients with four or more positive nodes."

The panel also concluded that "adjuvant tamoxifen in [postmenopausal]patients with negative estrogen receptors is generally regarded as ineffective, and a large cooperative group trial in the United States has verified this point." It acknowledges, however, that "data from some European centers suggest that the effects of tamoxifen in patients with negative estrogen receptors may be worthy of further investigation."

Adjuvant chemotherapy "may be considered" for postmenopausal women with positive nodes and negative hormone receptor levels, the panel says, but it "cannot be recommended as standard practice." Although many adjuvant chemotherapy trials have not shown an increase in overall survival for postmenopausal patients with positive lymph nodes, one cooperative group series demonstrated "a modest increase in disease free and overall survival." The overview of all randomized trials showed a small but statistically significant increase in disease free and overall survival.

The panel stresses that "survival advantages that accrue from current adjuvant chemotherapy programs must be improved upon through careful clinical research, and when possible, all patients should be offered entry into such trials."

NCI's SMALL BUSINESS AWARDS PAYLINE NEARS REGULAR RESEARCH PROJECTS'

NCI executives were feeling considerably better about the Small Business Innovation Research Program after the most recent round of awards were sorted out during the summer than they did in the program's first round last year.

The disastrous first round generated so few proposals, and even fewer with much scientific merit, that NCI was forced to fund some with almost the worst possible priority scores. The law which established the program decrees that all of those approved must be funded as long as the set aside money holds out. Any money left over reverts to the Treasurey.

NCI was so successful in drumming up interest in the program among the scientific community and research oriented small businesses that more than 200 grant and contract proposals were submitted. Even better, their quality was such that the grant payline approximated that of the regular research projects. And, no money will be left on the table.

NCI had set aside $9.1 million for the program from the FY 1985 budget. Approximately 100 contracts (out of more than 150 approved) will be funded for a total of $5.7 million. Thirty four grants are being funded, totaling $3.4 million. Most of the grants have been awarded; negotiations are still going on for some of the contracts, most of which also have been awarded.

The January round of grants showed considerable improvement from those in the first round, with the payline dropping to 300. The range was 156-300. Those that went to the May National Cancer Advisory Board had an even more remarkable improvement, with the range of priority scores from 129-187. There may be one or two exceptions over that, for proposals with notable program relevance.

There are two types of awards—phase 1, for $50,000 and six months; and phase 2, up to $250,000 a year for two years. In the January round, 11 of 21 approved phase 1 grants and all three of the approved phase 2 grants were funded. In the May round, the percentage dropped as the number of proposals increased—10 of 40 approved phase 1 grants and one of five phase 2 grants were funded. The four phase 2 grants not funded had priority scores ranging from 210 to 339.

The SBIR budget for FY 1986 will go up, with 1.25% of each institute's budget to be set aside for it (compared to 1% in 1985). The NCAB will consider the next round at its October meeting, with those awards to be gleaned from the 140 grant applications submitted by the April 15 deadline.

A new SBIR contract solicitation was scheduled for release this week by NIH, with 75 suggested topics. NCI intends to emphasize contracts over grants, for one reason: the grants will count against the overall limit imposed by the Office of Management & Budget, while the contracts will not. Thus, contracts will not detract from the number of RO1s and PO1s NIH may award, while the grants will.

The Div. of Cancer Biology & Diagnosis still will award only grants in the program, while the other divisions will emphasize contracts.

Those interested in participating in the program may contact Vincent Oliverio, associate director for program coordination in the Div. of Extramural Activities, NCI, Bldg 31 Rm 10A05, Bethesda, Md. 20892, phone 301-496-9138.

OMB REPROGRAMMING RESTRICTIONS CRITICIZED BY NCCR's ULTMANN

The ill-advised decision by the White House to restrict reprogramming of remaining 1985 fiscal year funds by NIH institute directors and to limit 200 grants to one year awards was criticized this week by the chairman of the National Coalition for Cancer Research.

John Ultmann, who is also director of the Univ. of Chicago Cancer Center, said the new Office of Management & Budget restrictions "will have a serious detrimental impact" on biomedical research.

The order limiting reprogramming would hit cancer centers and cancer clinical research harder than any other NIH programs. NCI had planned to move $1.4 million to the cooperative groups and $1 million to center core grants. Both programs already are being funded at levels up to 15-20% under the peer review recommended levels; the restriction on reprogramming would further depress those awards.

"The news of further funding problems as conveyed in the OMB proposals present a continuing saga of difficult problems in assuring continuity of funding biomedical research," Ultmann told **The Cancer Letter.** "Not only the National Cancer Institute but the entire National Institutes of Health, it appears, will be affected.

"The National Coalition for Cancer Research views these developments with great concern, for we believe that a further negative impact on research will have detrimental consequences, not only immediately but also in the long run. Science is a fragile enterprise. Although subject to the same fiscal overview as any federally funded program, its long range welfare depends on a broad perspective of its needs. The proposed restrictions in reprogramming, heretofore permitted to institutes of NIH, will have a serious detrimental impact. The recent experience with the rapid reprogramming of funds in order to focus on AIDS illustrates what

knowledgeable scientists and wise administrators can do cooperatively.

"The micromanagement of science by fiscal authorities cannot serve science well and can lead to serious consequences in the development of scientific information necessary to improve the health of American citizens," Ultmann concluded.

OMB also has decreed that 200 of the 6,200 grants which Congress directed NIH to fund in language contained in the 1985 supplemental appropriations bill could be only one year awards. While the impact of that maneuver probably will not be great (most of the 200 could be special purpose awards or one year extensions of grants which fell above the payline), NIH executives and their scientific colleagues are alarmed by the precedent the order establishes. Ultmann's concern about the "micromanagement of science" by the budget cutters is well founded.

ASCO OBJECTS TO PROPOSED MEDICARE GRADUATE MEDICAL EDUCATION BILL

The American Society of Clinical Oncology has registered its objection to a provision in a Medicare bill that would limit Medicare's contribution for graduate medical education costs to the lesser of five years or the minimum number of years required for initial board eligibility.

The provision is contained in S. 1158, which was scheduled for mark up this week by the Senate Finance Committee.

ASCO President John Durant, in a letter to Finance Committee Chairman Robert Packwood (R.-Ore.), said the provision would in effect terminate Medicare direct support for residency training programs in clinical oncology.

"Any physician who decides to enter an internal medicine subspecialty, such as clinical oncology, must first obtain board certification in internal medicine," Durant wrote. "Thus, under the terms of S. 1158, no resident in internal medicine could receive any Medicare funds beyond the first three years of internal medicine training. It is necessary for clinical oncologists to receive at least two more years of training in order to be qualified. The loss of these funds would severely hamper our ability to train new physicians to treat cancer patients.

"The members of the Society are all specialists involved in providing cancer patient care, conducting clinical cancer research and training cancer physician specialists. Our members are involved in the care of the majority of the cancer patients in the United States.

"The Society deeply appreciates the commitment of Congress to improved cancer treatment and research. The generosity of the federal government over the years has led to tremendous strides in cancer cure rates. Nonetheless, much work remains to be done.

"We recognize that the current federal budget situation requires careful review of all federal spending; however, it would be tragic if we allowed those circumstances to undermine our efforts to improve cancer treatment by severely limiting the number of qualified specialists in oncology.

"The Society also is concerned that the manpower policy decisions inherent in S. 1158 may not be in the best interests of patients, especially the elderly who often face chronic and complex illnesses as they get older. The management of these conditions frequently demands a high level of medical skill and sophistication.

"We hope as the Finance Committee proceeds with its consideration of S. 1158 that the Members will act to address these concerns."

NCI FISCAL 1985 CONSTRUCTION GRANTS EXCLUDE CITY OF HOPE

Here is the (almost) final breakdown on how NCI's construction grant money is being distributed in the 1985 fiscal year now coming to a close:

*Univ. of Pennsylvania, Richard Cooper, principal investigator (but now dean of the Medical College of Wisconsin), $2.5 million. That is the entire amount requested in the grant application.

*Univ. of Rochester, $900,000. The amount requested and approved was $1.4 million; $500,000 was awarded in FY 1984.

*La Jolla Cancer Research Center, $306,900. The amount requested and approved was $606,900; $300,000 was paid in FY 1984.

*Sloan Kettering Cancer Center, Richard Rifkind, PI, $1,139, 250. The entire amount was provided through reallocation of funds from a previous NCI grant to MSK which had not been spent. It is the entire amount requested.

*Univ. of Arizona, Sydney Salmon, PI, $774,000. The amount requested and approved was $1,724,000; the balance was paid with FY 1984 funds.

Those awards expend all but $269,100 of the money in the construction grant budget. That money had been approved for the Beckman Research Institute at City of Hope, but NCI decided it could not make that award while the institution was under restrictions placed by the Dept. of Health & Human Services because of alleged deficiencies in the laboratory animal operations (**The Cancer Letter**, Sept. 13). NCI must commit the money before Sept. 30, when the fiscal year ends. That money now probably will go to Albert Einstein School of Medicine. City of Hope officials say they expect the moratorium to be lifted by November.

NEW PUBLICATIONS

The massive (2,416 pages) second edition of "Cancer: Principles and Practice of Oncology" edited by the triumvirate of Vincent DeVita, Samuel Hellman and Steven Rosenberg is now available from J.B. Lippincott Co. It would appear that if there is anything that could be said about the practice of oncology which does not appear in the new edition, it must have been an oversight.

DeVita is director of the National Cancer Institute; Hellman is physician in chief of Memorial Sloan-Kettering Cancer Center; and Rosenberg is chief of surgery at NCI. Their first edition was published in 1982 and sold more than 20,000 copies.

They didn't do it by themselves—124 other clinicians and scientists contributed to this edition, and they had the help of nine associate editors—for surgery, Murray Brennan, Bernard Fisher, and Paul Sugarbaker; for radiation therapy, Rodney Million, Carlos Perez and Theodore Phillips; and for medical oncology, Daniel Bergsagel, George Canellos and John Ultmann.

In their preface, the editors said their work "has been designed to be of value not only to the oncologist but to all physicians who care for cancer patients. We believe that the presentation of the scientific principles underlying the practice of oncology and the integrated treatment approaches described in this textbook are unique. We hope that, by virtue of this presentation and the freshness of the information, this textbook can play a role in improving the care of patients with cancer."

The book as a single volume sells for $125, and $157.50 for the two volume set. A deluxe two volume set is priced at $245.

J.B. Lippincott, East Washington Square, Philadelphia 19105.

"If You've Ever Thought About Breast Cancer...," by Rose Kushner. Available free from NCI, Office of Cancer Communications, Bldg 31 Rm 10A18, Bethesda 20892. Latest treatment information, explanations of what a woman should do and expect if she should find a symptom of what might be breast cancer.

"Early Breast Cancer," edited by J. Zander and J. Baltzer. Springer-Verlag, 44 Hartz Way, Secaucus, N.J. 07094.

"The New Human Genetics," published by the National Institute of General Medical Sciences. Free booklet from NIGMS, Office of Research Reports, Bldg 31 Rm 4A52, Bethesda 20892, phone 301-496-7301.

The following are available from Raven Press, 1140 Avenue of the Americas, New York 10036:

"Mammalian Cell Transformation: Mechanisms of Carcinogenesis and Assays for Carcinogens," edited by Carl Barrett and Raymond Tennant, $59.50.

"The Cytobiology of Leukemias and Lymphomas," edited by Dennis Quaglino and F.G. Hayhoe, $59.50

"Peptide Hormones as Mediators in Immunology and Oncology," edited by R.D. Hesch and M.J. Atkinson, $42.

SKIN CANCER SCREENING PROGRAM FINDS "EXTRAORDINARILY HIGH" CANCER RATE

A skin cancer screening program conducted by the Greater Flint Area Hospital Assembly's Community Wide Hospital Oncology Program (CHOP) has found an "extraordinarily high" rate of skin cancer, according to Peter Levine, program manager for the CHOP.

Of the initial 97 men and women screened, 61 were found to have significant abnormalities of the skin, representing a .628 ratio of abnormalities per person screened. The screens were performed during National Skin Cancer Week the final week in March, and during the month of June.

About one fourth of people (25.7%) attending the screens were found to have actinici keratosis, a precancerous condition. Basal cell carcinomas were discovered in 11.3% of those attending the screen, as well as two melanomas.

A significant number of non malignant abnormalities requiring physician care were also discovered during the screens.

The number of abnormalities discovered during the screens is consistent with those found in male urogenital cancer screening programs, which produced a .978 ratio of abnormalities per person screened. In that screening, a significant number of non malignant abnormalities requiring physician care were also discovered.

The screening program was implemented in conjunction with the American Academy of Dermatology and area dermatologists.

Ratio totals of abnormalities discovered during both skin cancer screens are:

Moles FU at 6 mos.	.05
Seborrheic Keratosis:	.062
Actinic Keratosis:	.257
Basal Cell Ca	.113
Melanoma	.02
Bowens Disease	.01
Granuloma	.01
Dyplasic Nevi	.02
Intra Dermal Nevi	.02
Fungal Infection	.01
Blue Nevus	.02
Keloid	.01
Squamous Cell Ca	.01
Adnex al Neoplasm	.01

RFPs AVAILABLE

Requests for proposal 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 Blair building room number shown, National Cancer Institute, NIH, Bethesda, MD. 20205. Proposals may be hand delivered to the Blair building, 8300 Colesville Rd., Silver Spring, Md., but the U.S. Postal Service will not deliver there. RFP announcements from other agencies will include the complete mailing address at the end of each.

RFP NCI-CM-57757-09
Title: Quality control of rodents and tumor cell lines
Deadline: Approximately Nov. 22

NCI's Div. of Cancer Treatment's Developmental Therapeutics Program is seeking an organization to provide assistance in quality control for rodent host tumor systems and protocol development. An organization is sought that will supply the necessary equipment, personnel and facilities to maintain experimental animals and conduct quality control studies aimed at assuring the integrity of a wide variety of murine and human tumor lines and hosts used by DTP screening contractors.

Tasks will include tumor cell kinetic studies, development of working protocols for large scale use of tumor systems, evaluations of animal supply sources as to host response to appropriate tumor lines, verification of tumor line performance and, historical base lines and evaluation of specific protocol procedures. The principal investigator should be at either the M.S., M.A., PhD or DVM level and should be trained in an appropriate biological science. Other investigators should include a qualified cell kineticist. The level of effort is 11,688 staff hours per annum. NCI expects to award one incrementally funded contract for a period of three and a half years.
Contract Specialist: William Roberts
RCB Blair Bldg Rm 224
301-427-8737

RFP NCI-CM-57755-09
Title: Computer support task orders
Deadline: Approximately Dec. 13

NCI's Div. of Cancer Treatment's Developmental Therapeutics Program's Information Technology Branch is seeking organizations to provide system designs, development and programming services, under a task order managed level of effort contract.

NCI expects to award the contract for a five year incrementally funded period of performance, with each period comprising a level of effort of 6,438 staff hours for each of the five periods. In general, the programs will be required for maintenance support, operations suppport or development support.

While NCI has no specific details available for any particular task, it notes that objectives "may be the conversion of a file from one graphic format to another, the interfacing of a software package or new equipment with an existing system, or the resolution of specific operating problems."

Experience is required in planning and designing scientific information systems, with information management and principles, in implementing large and complex data bases; with graphics terminals such as the HPA-2623A or the Tektronic 4112, with robots and their controllers, with the HP-2685 laser printer, with the HP-3000 computer and its operating system, and with similar equipment. Experience is also required with data communication, the selection of multipoint networks, data concentrators and various types of multiplexers, etc.

Personnel proposed should include programmers, a chemist/biologist and a statistician/mathematician.
Contract Specialist: William Roberts
RCB Blair Bldg Rm 224
301-427-8737

RFP NCI-CM-57771-16
Title: Synthesis of compounds for preclinical toxicology and phase 1 clinical studies
Deadline: Approximately Nov. 12

NCI expects to award two cost reimbursement contracts to contractors with the capability to provide and operate a synthesis laboratory for (a) the development of existing or new processes, procedures and techniques for the synthesis of compounds, and (b) the synthesis of varying amounts of materials, not readily available from other sources in the quantity and/or quality needed by NCI.

The successful operator shall provide an operating facility with one small (20-50 gallons) and one large (100 gallons or larger) glass lined reactor and the necessary supporting equipment and facilities.

Quantities of drug requested will usually range from 50 grams to five kilograms. NCI will make specific assignment of the materials for preparation, which may include a wide variety of medicinal compounds. Quality specifications will be determined by NCI's Pharmaceutical Resources Branch. All materials must be assayed for identity and purity before being submitted to NCI.

Offerors must be registered with FDA as a manufacturer of bulk drugs, and should have submitted a facilities Drug Master File to FDA. Facilities should also meet FDA standards in accordance with the current good manufacturing practices.

The principal investigator should be trained in organic or medicinal chemistry, preferably at the PhD level, and have extensive experience in chemical synthesis and synthetic process development.

Two related RFPs are currently available. This RFP is an open competition. RFP NCI-CM-57798-16, "synthesis of compounds by small business for preclinical toxicology and phase I clinical studies" is a 100% set aside for small business.

Small businesses are encouraged to submit proposals under both RFPs, however, not more than one award of the available three awards under both RFPs will be made to any single offering organization.

The contract period is for four and a half years, beginning approximately Aug. 1, 1986.

To expedite requests for solicitation, furnish three self addressed labels with request. Individual requests should be submitted for each application required.

Contract Specialist: Patricia Shifflett
RCB Blair Bldg Rm 228
301-427-8737

RFP NCI-CM-57798-16
Title: Synthesis of compounds by small business for preclinical toxicology and phase 1 clinical studies
Deadline: Approximately Nov. 12

NCI expects to award one cost reimbursement contract to a small business with the capability to provide and operate a synthesis laboratory for (a) the development of existing or new processes, procedures and techniques for the synthesis of compounds, and (b) the synthesis of varying amounts of materials, not readily available from other sources in the quantity and/or quality needed by NCI.

The proposed contract is under a 100% small business set aside, the size standard for which is 750 employees. The contract period is to be four and a half years, beginning approximately Aug. 1, 1986.

The successful offeror shall provde an operating facility with one small (20-50 gallons) and one large (100 gallons or larger) glass lined reactor and the necessary supporting equipment and facilities.

Quantities of drug requested will usually range from 50 grams to five kilograms. NCI will make specific assignment of the materials for preparation, which may include a wide variety of medicinal compounds. NCI's Pharmaceutical Resources Branch will determine quality specifications. All materials must be assayed for identity and purity before being submitted to NCI.

The principal investigator should be trained in organic or medicinal chemistry, preferably at the PhD level, and have extensive experience in chemical synthesis and synthetic process development.

The offeror must be registered with FDA as a manufacturer of bulk drugs and should have submitted a facilities Drug Master File to FDA. Facilities should also meet FDA standards for current good manufacturing practices.

This RFP is a 100% set aside for small business. The related RFP NCI-CM-5771-16 described on page 7 is an open competition. Offerors who qualify as a small business are encouraged to submit proposals under both RFPs, however, not more than one award of the three under both RFPs will be made to any single offering organization.

To expedite requests for solicitation, furnish three self addressed labels with request. Individual requests should be submitted for each solicitation required.

Contract Specialist: Patricia Shifflett
RCB Blair Bldg Rm 228
301-427-8737

MAA NCI-CM-57758-22
Title: Master agreement for chemical synthesis
Deadline: Approximately Nov. 22

NCI's Div. of Cancer Treatment's Developmental Therapeutics Program is interested in receiving contract proposals from, and establishing master agreements with, offerors with the capability to provide services for the synthesis of a variety of organic/inorganic compounds. Primary focus will be on synthesis of organic compounds.

The objective of the project is the resynthesis of known compounds of varying degrees of complexity for confirmatory testing identified by both the new in vitro screen and the in vivo screens. Approximately 200 to 250 compounds will be synthesized during each contract year and these will comprise approximately 35 indiviudal master agreement orders.

Master agreements are competitively negotiated and awarded to more than one contractor. NCI expects to award an unspecified number of master agreements on or about Sept. 12, 1986 for a three year period of performance. The agreements will not be funded per se, but master agreement holders will be invited to bid competitively on appropriate Master Agreement Orders (MAOs) as they are issued.

NCI expects to issue MAOs quarterly. Each MAO will be designed to accomplish a specific task as promptly as possible and will be awarded on a completion level of effort basis, as determined by the contracting officer.

Contract Specialist: Elizabeth Clark Moore
RCB Blair Bldg Rm 216
301-427-8727

NCI CONTRACT AWARDS

Title: Support services for occupational studies
Contractor: Westat, Inc., Rockville, Md., $3,631,936

Title: Operation of a human serum bank for diagnostic studies
Contractor: Mayo Foundation, $1,351,644

Title: Cancer communications system
Contractor: Johns Hopkins University School of Medicine, $936,134

The Cancer Letter _Editor Jerry D. Boyd Associate Editor Patricia Williams
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