THE CANCER LETTER

Vol. 11 No. 34
Sept. 6, 1985

Subscription $150 year North America
$175 year elsewhere

P.O. Box 2370 Reston, Virginia 22090 Telephone 703-620-4646

OMB SPECIFIES ONE YEAR ONLY FUNDING FOR 200 GRANTS UNDER SUPPLEMENTAL APPROPRIATIONS LEVEL OF 6,200

The die hards in the Reagan Administration who attempted to slash more than 1,500 grants from the total funded by Congress in 1985 through the illegal forward funding device have not given up.
(Continued to page 2)

In Brief

FOUR MORE O.I. AWARDS ANNOUNCED; PEDIATRIC CLINICAL TRIALS RFP CANCELED

FOUR ADDITIONAL Outstanding Investigator Awards were approved by the NCI Executive Committee last week: Edward Boyse, Memorial Sloan-Kettering; Peter Duesberg, Univ. of California (Berkeley); Anthony Hunter, Salk Institute; and David Goldman, Virginia Commonwealth. Those were in addition to the 21 previously revealed who had scored 158 or better in the unique review by mail established by NCI for the new seven year awards (**The Cancer Letter,** May 24). At least one and perhaps two of those 21 may not receive awards despite their outstanding scores because of a lack of relevance to cancer in their research.... **RFP FOR** pediatric phase 1 clinical trials and pharmacokinetic studies in children has been canceled due to unavailability of funds. RFP NCI-CM-57712-48 was issued in November, 1984 (The Cancer Letter, Nov. 23, 1984). NCI received three proposals for the projects, but lacked the money to fund them, according to Robert Wittes, director of NCI's Cancer Therapy Evaluation Program. NCI officials have no plans to reissue the RFP, but hope the studies can be performed within existing clinical trials groups.... **RANDOLPH FENNINGER,** former legislative counsel and assistant director of congressional relations of the American Medical Assn., joins Grupenhoff, Endicott & Maldonado, Washington based firm that represents various health organizations.... **CHUCK HONAKER,** former director of communications for the American College of Radiology, is the new VP for public affairs at the Pharmaceutical Manufacturers Assn.... **EPIDEMIOLOGY** and public health issues to be discussed at the fourth annual meeting of the American College of Epidemiology in Santa Monica Sept. 19-20 include acquired immune deficiency syndrome, estrogen therapy, cancer risks from exposure to gas and diesel fumes, dietary guidelines to reduce cancer and heart disease, and evaluation of cancer chemotherapy in breast cancer. A one day continuing education seminar on nutritional science and endocrinology for epidemiologists precedes the meeting. Contact Anne Coulson, UCLA School of Public Health, Los Angeles 90024.... **CORRECTION:** The number of scientists who participated in NCI's mail review for Outstanding Investigator Awards was 200, not 2,000 (**The Cancer Letter,** Aug. 16).

OMB RESTRICTS NCI REPROGRAMMING FOR CANCER CENTERS AND CLINICAL RESEARCH

(Continued from page 1)

President Reagan signed the FY 1985 supplemental appropriations bill during the congressional August recess, which included the compromise on funding 6,200 new and competing grants (compared with 6,500 originaly approved by Congress and the 5,000 the White House had tried to enforce with forward funding). However, the Office of Management & Budget last week directed that 200 of the 6,200 must be one year awards only, with no carryover commitments.

That effectively trims the number of regular research projects NIH can fund this year to the 6,000 total agreed upon by OMB and the Senate leadership. The additional 200 were insisted upon by the House Labor-HHS Appropriations Subcommittee and its chairman, William Natcher, who refused to let OMB dictate the number of grants Congress could support. The House 1985 appropriations bill had included money for 6,200 grants; it was increased to 6,500 at the insistence of the Senate.

Limiting 200 grants to one year awards is annoying enough, but NCI and NIH probably can find ways to soften the impact. Another action by OMB last week may be harder to live with.

Instead of following the usual practice of releasing funds directly to NCI and the National Heart, Lung & Blood Institute separately from the rest of NIH's appropriation, as has been done since the National Cancer Act of 1971 and its subsequent renewals, OMB instead included all those funds in one block to NIH. At the same time, OMB decreed that NIH could not reduce the amount of money it was given for research projects.

NCI has received its full allocation from NIH, but the restriction on reprogramming will hit the cancer centers and clinical research budgets unless some way can be found around it. NCI had planned to transfer $1 million from the research project pool to cancer center core grants and another $1.4 million to the clinical cooperative groups.

It appears at the moment that the only way that reprogramming can be done is if other institutes can be persuaded to reprogram $2.4 million of their allocations into the research projects pool. While they aren't likely to do that merely to accomodate NCI, they might do so if they determine that is in their own best interests.

NCI and NIH officials declined to discuss OMB's latest deleterious manipulations of the biomedical research budget. One White House source who would talk about it said that it was part of the overall effort to reduce the deficit through 1988.

PROPAC TO REVIEW ACCC COMMENTS ON DRGs AND CANCER CARE

Concerns raised by the Assn. of Community Cancer Centers about the impact of Medicare's prospective payment system on cancer treatment and research will be on the agenda of an upcoming Prospective Payment Assessment Commission meeting in either September or December, ACCC Executive Director Lee Mortenson told **The Cancer Letter.**

The association sent a letter detailing its concerns about the use of diagnosis related groups for cancer treatment to PROPAC Executive Director Donald Young, asking the group to place the matter on its agenda. The letter, dated June 6, was submitted on the behalf of ACCC by the Washington law firm Kaye, Scholer, Fierman, Hays & Handler.

Specific problem areas identified by the association are:

1. "At least several key diagnosis related groups ("DRGs") pertaining to cancer are weighted far too low, with a resulting negative and unintended impact on practice patterns, not only in those particular DRGs but in cancer treatment generally."

2. "The failure of PPS [Prospective Payment System] to recognize the longer stays and greater costs involved in clinical cancer research will not only discourage and eventually eliminate most such research, but will also exert a profound chilling effect on the most successful cancer treatment patterns as currently practiced."

3. "The singling out of only a very limited number of cancer centers for exclusion from PPS will foster serious regional discrimination, distort cancer research and treatment patterns and undermine research and treatment efforts generally."

ACCC notes that "while each of these is a separate problem for hospitals involved in cancer research and treatment, they are interrelated and in combination raise serious questions about the appropriateness of DRGs for oncology."

The association contends that the use of DRGs for cancer diagnoses poses a serious threat to both patient care and clinical research. "Forcing the accepted standard of treatment for oncology patients--increasingly individualized and experimental regimens--into average cost categories is unrealistic and poses a major threat to the present and future practice of oncology, and correspondingly to the hundreds of thousands of Medicare beneficiaries who suffer from cancer."

The letter notes that ACCC is still in the process of collecting data on prospective payment's effects on cancer treatment and research. "Nevertheless," it adds, "we have obtained enough evidence, both anecdotal and statistical, during the course of the past few weeks to convince us that the

matter is one which should be considered by the commission at the earliest possible time."

Accumulating evidence "demonstrates forcefully that PPS is unintentionally placing in jeopardy cancer research and treatment efforts across a broad range of institutions," it maintains. "Because the appropriate treatment for cancer patients is unprofitable under PPS as currently constituted, patients are receiving less than optimal care."

ACCC also maintains that "the ability to deal successfully with cancer in the future is also in doubt as a result of the serious negative impact which the system is having on research incentives." Prospective payment has also "threatened to slow the dramatic progress made in cancer treatment by curtailing necessary clinical research," it says. "The situation is further worsened by the fact that [HHS Secretary Margaret Heckler] has declined to use the authority given her to make exceptions and adjustments in a meaningful way respecting cancer treatment and research."

According to a survey conducted by ACCC, "certain frequently used cancer DRGs are being reimbursed well below costs." The survey also found that when the 46 DRGs used exclusively for cancer diagnoses were analyzed as a group, they still result in actual losses to the hospital. The letter asserts that the discrepancy is likely to become "even greater over time as the data employed by the Health Care Financing Administration (HCFA) lags behind actual treatment patterns in oncology."

The survey collected actual cost, charge and reimbursement data from 16 community based hospitals, all of which are members of ACCC.

Leukemia, DRG 401, and acute leukemia, DRG 403, were identified as the most seriously under-paid cancer DRGs. Of 49 discharges for leukemia analyzed, hospitals experienced a $1,355.43 loss per discharge. Actual DRG payment per discharge was $3,765.16, compared to an actual cost per discharge of $5,120.59, and actual charges per discharge of $6,677.41.

Of 297 discharges for acute leukemia studied, hospitals had a $1,418.05 loss per discharge. Actual DRG payment per discharge amounted to $3,780.21, compared to an actual cost of $5,198.26 per discharge and actual charges of $6,722.85 per discharge.

"Experienced practitioners in oncology have speculated that the imbalance in reimbursement for leukemia diagnoses stems from the data base employed by HCFA in determining DRG weights," the letter says. "The anticipated average length of stay for acute leukemia, for example, is only seven days, a figure that reflects the historical treatment practice with respect to leukemia patients aged 65 or over — i.e., essentially not to treat the disease and simply allow the patient to die."

ACCC notes, however, that "as the state of knowledge respecting treatment of cancer advances, there are increasing opportunities for curative as well as palliative approaches to treatment of aged leukemia victims." The DRG for that diagnosis, however, "not only fails to reimburse for those new treatments, but in doing so in fact discourages their application to the Medicare population," it contends.

The problem of under-reimbursement "is particularly severe in the case of the chemotherapy DRG," the letter states. Of 620 discharges under DRG 410 for chemotherapy, hospitals experienced a loss of $641.49 per discharge, based on actual DRG payment of $1,206.86 per discharge; an actual cost of $1,848.35 per discharge and actual charges of $2,530.20 per discharge, according to ACCC data.

"Significant advances in the use of chemotherapy have occurred during the past few years, so that it is used successfully in treatment of a variety of tumors," ACCC says. Because "it is by far the most frequently used DRG among those involving cancer diagnoses," the group contends, "its drastic under-payment creates a particularly serious disincentive to appropriate treatment."

Even more troubling, "there is a powerful incentive to use chemotherapy in less than optimal ways for patient treatment, ways which might even be harmful to the patient's health," the letter advises.

Cancer treatment in general is in the process of constant evolution, the group notes. "Nowhere is this more true than in the area of chemotherapy. As practitioners become more familiar with an increasing range of chemotherapeutic regimens, the state of the art advances."

Under the prospective payment system, however, "decisions involving the use of chemotherapy are being driven not by the existing state of medical knowledge so much as by the exigencies of the new Medicare reimbursement system."

For example, the letter cites anecdotal evidence suggesting that approximate dosages are being reduced to permit the therapy to be given on an outpatient basis outside the strictures of PPS. The system also creates a "marked disincentive to the use of infusion therapy...if it results in patient stays beyond the average length of stay for the chemotherapy DRG," it maintains.

The letter also suggests that rapidly changing treatment patterns in cancer care make the disease unsuitable for inclusion in the prospective payment system. "There is a distinct possibility that cancer is generally inappropriate for a prospective payment system because treatment patterns are rapidly changing," it advises.

"It is widely recognized among oncology practitioners that there is at present no 'standard' treatment for most cancers." In most instances, the best treatment for a patient will involve "to some degree" the use of new and different procedures from those employed with other patients or at earlier times, it remarks. "Thus, in many cases the current cost of treatment will be more than the historical cost."

If a reimbursement system such as prospective payment does not take that into account, "treatment for cancer will always be behind the reimbursement curve, and cancer will forever be in a disfavored position as compared to other diagnoses," it warns.

The ACCC survey also refutes the argument that hospitals' reimbursements will average what they would under cost containment because some DRGs are "winners," and some "losers." The averaging concept, ACCC argues, "works only if the winners and losers are spread fairly evenly throughout the DRGs."

Of 4,510 discharges under all "pure" cancer DRGs, ACCC found that hospitals lost $160.49 per discharge. Hospitals received DRG payments of $3,199.29 per discharge, as compared with an actual cost per discharge of $3,359.78, and actual charges of $4,330.22 per discharge.

"It is well known that PPS has encouraged hospitals to be more business like in their administration," the letter acknowledges. However, "when faced with an unprofitable product line, hospitals thus will react as any other business and find ways to concentrate their marketing, recruiting and other efforts elsewhere, notwithstanding the significant and growing demand for cancer treatment," it says.

"The ironic and unfortunate result will be that Medicare beneficiaries will likely be deprived of cancer treatment just as that treatment is becoming more effective in dealing with their disease."

The letter also warns of a decline in necessary clinical trials. Patients enrolled in trials "invariably will have longer hospital stays than the average stay prescribed by the DRGs, thus ensuring that participation in such trials will cost the hospitals money well beyond the designated PPS payment rate," ACCC notes.

In addition, PPS motivates hospitals to act more businesslike in their administration, the letter says. "When faced with an unprofitable product line, hospitals thus will react as any other business, they will cease to participate in clinical trials which will be an even more unprofitable product line than cancer treatment generally," it warns. "Fewer clinical trials plainly translates into longer delays in applying research breakthroughs to help save the lives of cancer victims."

Although Medicare did not specifically pay for clinical research under the cost reimbursement system, it did reimburse the cost of hospitalization "largely without reference to length of stay," thereby covering the greatest part of the expense of clinical trials, the letter says.

Because DRG payments are based on historical costs, past reimbursement for clinical trials is reflected in the national PPS rates, it notes. "The result, however, is that dollars formerly supporting clinical research are now dispersed in small amounts to every hospital, leaving hospitals that actually wish to engage in clinical research with insufficient funds to do so in a meaningful way," it asserts.

The system offers no incentive to continue clinical research, and in fact "encourages the abandonment of research efforts as fiscally unprofitable," the letter says.

In addition to hindering future therapies development, a decline in clinical trials will also have an adverse effect on patient care, it says. The letter cites studies showing that patients involved in approved cancer protocols have significantly improved survival rates. "Oncologists involved in clinical research are on the cutting edge of cancer treatment, and the clinical trial is most likely consistent with the best available treatment for that patient," it asserts.

ACCC also maintains that HHS' interpretation of the Congressionally-mandated exemption for cancer centers is too restrictive. The PPS legislation allows HHS to make exceptions and adjustments "that may be appropriate with respect to hospitals involved extensively in treatment for and research on cancer."

To be eligible for an exemption, a hospital must demonstrate that: 1. it was recognized as a comprehensive cancer center or clinical center by NCI as of April 20, 1983; 2. the entire facility is organized primarily for treatment of and research on cancer (i.e., not a subunit of an acute general hospital or university-based medical center); and 3. at least 50% of its total discharges reflect a principal diagnosis of neoplastic disease.

As of April, only four hospitals had been granted exemptions from prospective pay.

ACCC asserts that the statute "is couched not in terms of exceptions **for** hospitals but in terms of exceptions **with respect to** hospitals involved extensively in treatment for and research on cancer." A hospital with a large and active oncology unit "still may be 'involved extensively' in cancer treatment and research" even though 50% of total discharges do not reflect a principal diagnosis of neoplastic disease, it contends.

"At the very least, the exception should be

available to all NCI-recognized cancer centers or clinical research centers," the letter advises. "Anything less will not only frustrate research efforts at those facilities but will thwart the will of Congress that efforts against cancer not be undermined by PPS."

Although ACCC acknowledges that "the final contours of the Commission's recommendations should await further data collection and study," it suggests preliminary refinements necessary for the payment system.

Specific recommendations are:

*First, either make specific adjustments to seriously underfunded cancer DRGs or provide additional payments for chemotherapy, or both;

*Second, develop a new fee schedule for chemotherapy so as to remove the financial disincentives for appropriate use of this basic treatment technique;

*Third, provide additional payments for care provided to Medicare beneficiaries under NCI-approved research protocols;

*Fourth, develop a special outlier category for NCI-approved research protocols to alleviate the burden of gross under-reimbursement; and

*Fifth, make available to a broader range of hospitals extensively involved in cancer treatment and research the option to be reimbursed in a manner other than PPS.

LITTON'S FEDERAL CONTRACTS TRANSFER TO NEW OWNERS UNDER DISCUSSION BY NCI

Discussions are currently underway between NCI and Litton Bionetics officials regarding the status of government contracts held by the Kensington, Md. based firm. The company holds a number of government contracts, including a $7.6 million per year contract for research at the Frederick Cancer Research Facility.

Litton has sold all of its biotechnology subsidiary, with the largest portion, 50%, going to the Dutch firm Organon Technica. Under the terms of the sale, Organon Technica will acquire R&D operations, as well as those involved in manufacture of human and veterinary diagnostic products.

About 25% of Litton Bionetics has been sold to Corning Glass Works' subsidiary MetPath Inc., of Teeterboro, N.J. MetPath acquired Litton's clinical laboratories network in the mid Atlantic and chemical analysis equipment. Atlantic and chemical analysis equip-

The remaining 25% of Litton Bionetics was sold to Hazleton Laboratories Corp. of Vienna, Va. That company acquired the animal and molecular toxicology units of Litton Bionetics.

The sale of the company's research component to a foreign firm has raised additional questions to be considered in the formal procedure for the transfer of government contracts to a different organization, according to Peter Fischinger, director of NCI's Frederick Cancer Research Facility.

The patent rights for important discoveries from the center is a major consideration for NCI officials, Fischinger said. Because NCI has had no experience with a foreign company taking over a government contract in a high technology area, the institute plans to take the matter to NIH and the HHS assistant secretary for health for consideration.

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-57725
Title: Support services for extramural clinical trials
Deadline: Approximately Sept. 24

The announcement for this RFP appeared in the July 19 Cancer Letter. It is being amended to restrict the solicitation to small business.

For the purposes of this procurement, 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 its preceding three fiscal years do not exceed $3.5 million.
Contract Specialist: Thompkins Weaver
RCB Blair Bldg Rm 228
301-427-8737

RFP NCI-CM-57774-16
Title: Preparation of bulk chemicals and drugs for Phase II and III clinical trials
Deadline: Approximately Nov. 1

Two cost reimbursement contracts are expected to be awarded to contractors with the capability to provide and operate a materials preparation laboratory for (a) the development of existing or new processes, procedures and techniques for the preparation 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.

Present incumbents are Aerojet Strategic

Propulsion, Aldrich Chemical, Monsanto Research, and Warner Lambert.

The scale of the work to be performed under this solicitation is subdivided into the following two categories that relate primarily to the capacity of the offerors' facilities:

Project A: An operating large scale facility with one small (20-50 gallons) and one large (100 gallons or larger) glass lined reactor and the necessary suppporting equipment and facilities.

Project B: An operating pilot plant with a wide variety of glass lined reactors up to and including 500 gallons and the necessary supporting equipment and facilities.

Quantities of drug requested will usualy range from 50 grams to multi-kilograms. Process development for scale-up and access to pilot plant equipment is essential.

Specific assignment of the materials for preparation will be made by NCI and may include synthesis of all types of chemicals and drugs. Quality specifications will be determined by NCI's Pharmaceutical Resources Branch. All materials must be evaluated by the synthesis laboratory 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, or equivalent in experience, and have extensive experience in chemical synthesis and synthetic process development.

At the time of submission of proposal, the offeror must be registered with FDA as a manufacturer of bulk drugs and shall have submitted a facilities drug master file to FDA. Facilities shall meet FDA standards in accordance with the current good manufacturing practices. Noncompliance with the above requirement shall immediately render the proposal technically unacceptable without the consideration of other evaluation criteria.

Two related RFPs are currently available. This RFP No. NCI-CM-57774-16 is an open competetion. RFP No. NCI-CM-57756-16, "Preparation of bulk chemicals and drugs by small business for phase 2 and 3 clinical trials," is a 100% set aside for small business.

Offerors who qualify as a small business are encouraged to submit proposals under both RFPs. However, not more than one award of the available four awards (two under each RFP) will be made to any single offering organization.

To expedite requests for solicitation, three self addressed labels should be furnished with requests. In addition, individual requests should be submitted for each solicitation required. The contract period is four and one half years, beginning approximately Aug. 1, 1986.

Contract Specialist: Patricia Shifflett
RCB Blair Bldg Rm 228
301-427-8737 g Rm 228lf years,

RFP NCI-CM-57756-16
Title: Preparation of bulk chemicals and drugs by small business for phase 2 and 3 clinical trials
Deadline: Approximately Nov. 1

The proposed procurement is under a 100% small business set aside. The size standard is 750 employees. Present incumbents are Ash Stevens, Pharm-Eco Labs and Starks Associates.

Two cost reimbursement contracts are expected to be awarded to small businesses with the capability to provide and operate a materials preparation laboratory for (a) the development of existing or new proceses, procedures and techniques for the preparation 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 offeror shall provide an operating large scale facility with at least 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 multi-kilograms. Process development for scale up and access to pilot plant equipment is essential. NCI will make specific assignment of the materials for preparation, which may include synthesis of all types of chemicals and drugs. Quality specifications will be determined by NCI's Pharmaceutical Resources Branch. All materials must be evaluated by the synthesis laboratory 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, or equivalent in experience, and have extensive experience in chemical synthesis and synthetic process development.

Offerors must be registered with FDA as a manufacturer of bulk drugs and have submitted a facilities drug master file to FDA at the time of submission of proposal.

Facilities shall also meet FDA standards in accordance with the current good manufacturing practices. Non compliance with the above requirement shall immediately render the proposal technically unacceptable without the consideration of other evaluation criteria.

Small businesses may submit proposals under both this RFP and the related RFP NCI-CM-57774-16 described above. However, not more than one award of the available four awards (two under each RFP) will be made to any single offering organization.

To expedite requests for solicitation, respondents should furnish three self addressed labels with requests. In addition, individual requests should be submitted for each solicitation required. The contract period is to be four and one-half years, beginning approximately Aug. 1. 1986.

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

RFP NCI-CM-57749-16
Title: Cultivation of marine microorganisms
Deadline: Approximately Nov. 29

One cost reimbursement contract is expected to be awarded to a contractor with the capability to furnish and operate a microbiological and small

extraction laboratory to isolate various groups of microorganisms from the marine environment, to grow and extract them, and to optimize and scale up production as needed to provide NCI with a repository of both extracts and cell extracts to be evaluated in future screens for antitumor activity. The ultimate goal is to provide NCI with potential sources of antineoplastic agents of novel structural types from marine microorganisms that would be developed for the treatment of cancer in humans.

The specific objectives of this project are to (1) collect source samples, (2) isolate various species from various classes of marine microorganisms, grow them under conditions suitable to produce 3-5g of broth extracts and cell extracts, and (3) to optimize and scale up production as needed by NCI.

The principal investigator should be trained in microbiology, preferably at the PhD level, with at least three to five years experience, and with an emphasis in marine microbiology. The PI should have wide knowledge of and experience with microbiological techniques in culture cultivation, including scale up. The PI will be responsible for the overall implementation of the contract and will be NCI's key contact for the technical aspects of the program. Overall, the technical team should have training and experience in culture isolation, taxonomy, culture preservation and cultivation, optimization and scale up production, and chemical extraction.

The successful offeror will be required to provide and grow approximately 1,500 species from various classes of marine microorganisms over a period of five years. Approximately 300 cultures shall be provided during the first contract year, with the remainder (approximately 1,200 cultures) to be provided in years two through five and which should be freshly isolated from the marine environment.

The offeror shall use ingenuity in systematic culture isolation techniques. Taxonomy is fundamental to all branches of biology and is of utmost importance when working with microorganisms. It is essential to know what organisms are being grown. It shall be essential to include various species of bacteria, fungi, actinomycetes or unicellular algae. The successful offeror shall use ingenuity in maintenance and preservation techniques, in selecting suitable media and conditions to encourage growth and production of marine microorganisms.

It is anticipated that NCI will require optimization and regrowth of five to 10 cultures per year. The contractor shall document accurately and in detail the cultures being grown, including source, habitat, growth parameters, optimization and scale up condititions, including media ingredients, pH, temperature, aeration, agitation, light source and intensity (where applicable), growth period, harvest times, method of harvest, cell/broth ratio, extraction solvents, culture preservation, and pertinent observations, including toxicity or any allergenic reactions, Any special growth setup shall be described.

To expedite requests for solicitation, three self addressed labels should be furnished with requests. In addition, individual requests should be submitted for each solicitation required. The contract period is to be five years, beginning approximately Sept. 1, 1986.

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

Recompetition Announcement
Title: Operation of NCI's Frederick Cancer Research Facility to provide research, technical support and other services.

The Frederick Cancer Research Facility (FCRF) intends to recompete the work and services identified and presently being performed as follows:

Research, Contract NO1-CO-23909, Litton Bionetics Inc.;

Operations and Technical Suppport, Contract NO1-CO-23910, Program Resources Inc.;

Animal Production, Contract NO1-CM-23911, Harlan Sprague Dawley Inc.; and

Scientific Library Services, Contract NO1-CO-23913, Data Management Services Inc.

All contracts are expected to be cost type in nature, and with the possible exception of the research component, will be cost plus award fee. Offerors will have the perogative of submitting multiple proposals or combinatorial proposals depending upon their business "size" status. The anticipated beginning date of new contracts is Sept. 26, 1987. Further notice, including RFP availability will be published on or around June of 1986. The estimated term of the new contract(s) may either be seven or 10 years. Present contractors have indicated their intention to participate in the recompetition.

Approximate current annual negotiated amounts for each of the contract components areas are: Research: $7,623,593; Operations and Technical Support: $35,622,633; Animal Production: $1,790,153; Computer Services: $813,235; and Scientific Library Services: $602,197. The announcement is intended to apprise all interested organizations of this future full and open competition opportunity.

Contracting Officer: Ronald Defelice
Frederick Cancer Research Facility, Bldg 427
301-695-1113

RFP NIH-ES-85-18
Title: Genetic monitoring of inbred rodents
Deadline: Approximately Oct. 31

The National Institute of Environmental Health Sciences (NIEHS) is soliciting proposals from offerors having the capability for the genetic monitoring of inbred rodents. The objective of this project is to determine the genetic integrity of rodents used in NTP chemical exposure studies.

The contractor will be required to monitor up to 15 designated loci for each strain or hybrid by electrophoresis of erthrocyte lysates, kidney, liver, pancreas and lung homogenates and serum proteins. Immunochemical methods may also be employed.

The contractor will receive up to 1,000 live inbred rodents per year at a rate of 20 mice and 10 rats per week (40 to 60 mice and 20 to 30 rats per month) for genetic monitoring by biochemical procedures.

In addition, frozen tissues (usually kidneys) from approximately 300 mice per year (kidneys from 20 to 30 mice per month) will be shipped to the contractor by the NIEHS/NTP toxicology testing laboratories for genetic marker isozyme analyses.

The contractor will be required to evaluate up to 240 inbred rodents per year by skin graft procedure; develop and utilize biochemical or immunological procedures to detect genetic drift; and develop and utilize biochemical monitoring procedures for inbred hamsters.

The government estimates that 0.2 professional person years and 1.6 technical person years will be required per year for this project. The project period is five years.

Contract Specialists: Elizabeth Ford
Contracts Management Office
OAM, NIEHS
P.O. Box 12874
Research Triangle Park, N.C.
27709

RFP NIH-NIAID-IAIDP-86-6
Title: A clinical trial for the use of monoclonal antibodies in bone marrow transplantation
Tentative deadline: Dec. 13

The Genetics and Transplantation Biology Branch of the Immunology, Allergy and Immunologic Diseases Prorgam of the National Institute of Allergy and Infectious Diseases (NIAID) is soliciting contract proposals from organizatons having the capabilities and facilities for conducting a clinical trial on the use of monoclonal anitbody(ies) in allogeneic bone marrow transplantation.

Offerors should have demonstrated expertise in allogeneic bone marrow transplantation and monoclonal antibody technologies as well as experience in the conduct of clinical trials.

The NIAID sponsored project shall take approximately three years to complete. The work will require clinical and immunologic monitoring of study populations, monoclonal antibody treatment of bone marrow, assessment of graft versus host disease and lymphocyte profiles and data analysis of efficacy of treatment.

Multi-institutional collaborative agreements to conduct the clinical trial are encouraged although this does not preclude an award to a single qualified institution. NIAID expects to award two contracts.

To receive a copy of the RFP, send two self addressed mailing labels with a written inquiry to: NIAID, NIH, 5333 Westbard Ave., Rm 707, Bethesda, Md. 20205. Telephone inquiries will not be honored.

RFP NIH-NIAID-IAIDP-86-7
Title: Maintenance of an international bone marrow transplant registry
Tentative deadline: Dec. 6

The Genetics and Transplantation Biology Branch of the Immunology, Allergy and Immunologic Diseases Program of the National Institute of Allergy and Infectious Diseases (NIAID) has a requirement for the maintenance of a statistical center for the collection, organization and analysis of clinical data provided by bone marrow transplant teams throughout the world. Offerors should have demonstrated expertise in statistical analysis and large-scale data management, utilizing computer technology.

The NIAID sponsored project will take approximately five years to complete. This will be a cost reimbursement (cost sharing) type contract.

The work will require knowledge of immunogenetics, bone marrow transplantation, immunodeficiencies, collaboration with bone marrow transplant centers, and analysis of data from clinical studies.

To receive a copy of the RFP, supply two self addressed mailing labels along with a written inquiry to: NIAID, NIH, 5333 Westbard Ave., Rm 707, Bethesda, Md. 20205. Telephone inquiries will not be honored. Md. 20205. Telephone inquiries will not be

RFP NIH-NIAID-IAIDP-86-8
Title: Screening, characterization and acquisition of anti-idiotypic reagents for histocompatability testing of Blacks, Native American and/or Hispanic Americans
Tentative deadline: Nov. 7

NIH has a requirement for the screening, characterization and acquisition of anti-idiotypic reagents for histocompatibility testing of Blacks, Native American and/or Hispanic Americans. The Genetics and Transplantation Biology Branch of the National Institute of Allergy and Infectious Diseases (NIAID) requires improved characterization of transplantation antigens in the three populations.

The successful offeror should have demonstrated capabilities in screening for anti-idotypic sera useful in identifying transplantation antigens, and in other aspects of histocompatability testing. The capability to manage and analyze pooled typing data with the purpose of defining new antigenic specificities is also desirable.

To receive a copy of the RFP, supply two self-addresssed mailing labels with a written inquiry to: NIAID, NIH, 5333 Westbard Ave., Rm 707, Bethesda, Md. 20205. Telephone inquiries will not be honored.

The Cancer Letter _Editor Jerry D. Boyd Associate Editor Patricia Williams
Published forty-eight times a year by The Cancer Letter, Inc., P.O. Box 2370, Reston, Virginia 22090. Also publisher of The Clinical Cancer Letter.