THE CANCER LETTER

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"REALISTIC" BYPASS BUDGET FOR 1983 ASKS $1.147 BILLION; ORGAN SITE, TRAINING, CONTROL WOULD GET NO INCREASES

NCI has submitted to the White House its "bypass" budget request for the 1983 fiscal year totaling a "more realistic" $1.147 billion (one billion, 147 million), only $5 million more than asked in the 1982 bypass budget total. The 1983 request is the result of an effort by Director Vincent DeVita and the National Cancer Advisory Board to scale down the bypass total in order to more closely relate priorities within the budget to the real world.

This is the first bypass budget, since it was authorized in the National Cancer Act of 1971, which does not request an amount at or near the full authorized total. There is no authorization total yet for the 1983 fiscal year, but the 1982 authorization was $1.232 billion. The 1983

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In Brief

HOUSE MONEY BILL REPORTEDLY WILL NOT INCREASE NCI FUNDS; AD HOC GROUP APPROVES NCCTG RENEWAL

HOUSE APPROPRIATIONS Health Subcommittee marked up the 1982 money bill last week in closed session; the full committee is scheduled to act next week. Sources said the subcommittee added only $68 million to the President's request for NIH, and little if any of that would filter down to NCI. All of the additional money was earmarked to bring the payline for R01 grants up to 190. NCI expects to be able to pay to that level with the $1.025 billion in the presidential budget. The Senate Health Appropriations Subcommittee was scheduled to mark up its bill this week. . . . **NORTH CENTRAL** Cancer Treatment Group was approved for renewal of its grant at a high priority by the ad hoc review committee established to review regional cooperative groups. "It was a tough review, probably tougher than it would have received from the CCIRC," an NCI staff member told *The Cancer Letter*. The ad hoc committee was established because regional group members and some NCI staff felt regional groups would not get a fair review from the Clinical Cancer Investigation Review Committee. The North Central group, chaired by Charles Moertel, director of the Mayo Comprehensive Cancer Center, operates predominantly in Minnesota, the Dakotas, Montana and Wyoming. . . . **R. LEE CLARK**, president emeritus of the Univ. of Texas System Cancer Center, will be honored at the Univ. Cancer Foundation Board of Visitors Award Dinner Oct. 2 in Houston. Clark has been one of the world's leading figures in the fight against cancer for nearly four decades. . . . **LA JOLLA CANCER** Research Foundation has received a three year, $600,000 grant from NCI as a specialized cancer research center. William Fishman, who organized the foundation five years ago, is president and chief executive officer.

NCI 1983 FISCAL YEAR BYPASS BUDGET BY MECHANISM
(Dollars in Thousands—Add Three Zeroes)

	1981		1982 Presidential Budget		1983 Current Services (8% over 1982)		1983 Request	
		% of Total		% of Total		% of Total		% of Total
Group I – Investigator Initiated								
Regular Research Grants	$235,265	34.6	$246,232	35.3	$265,197	35.0	$295,226	34.9
Clinical Cooperative Groups	35,459	5.2						
Program Projects	115,356	16.9	111,923	16.0	117,991	15.5	141,962	16.8
Clinical Education Program	8,000	1.2	8,000	1.2	8,000	1.1	9,000	1.1
Research Career Program	5,143	.8	5,367	.8	5,424	.7	5,424	.6
Fellowship and Training Grants	25,526	3.7	19,339	2.8	19,922	2.6	22,922	2.7
Organ Site	15,540	2.3	15,300	2.2	14,000	1.8	15,300	1.8
Cancer Centers – Core Support	70,635	10.4	74,931	10.7	78,825	10.4	80,731	9.6
Other Centers Support	580	0.1	1,480	0.2	1,980	0.3	1,980	0.2
Cooperative Agreements			44,509	6.3	48,470	6.3	52,500	6.2
Subtotal	511,504	75.2	527,081	75.5	559,809	73.5	625,045	73.9
Group II – Co-Initiated								
Cancer Research Emphasis Grants (CREG)/ Requests for Applications (RFA)	6,708	1.0	12,742	1.8	16,992	2.2	18,892	2.2
Research Contracts	38,987	5.7	29,750	4.3	34,002	4.5	36,645	4.3
Subtotal	45,695	6.7	42,492	6.1	50,994	6.7	55,537	6.5
Group III – NCI/NCP Initiated								
Resource Contracts	100,111	14.7	106,986	15.3	112,491	14.8	117,589	13.9
Interagency Agreements	17,486	2.6	15,952	2.3	17,484	2.3	17,501	2.1
Subtotal	117,597	17.3	122,938	17.6	129,975	17.1	135,090	16.0
Group IV – Other Resources								
Cancer Centers – Exploratory Grants			200	.1	700	.1	700	.1
Construction Grants	2,027	.3	1,000	.1	15,000	2.0	25,000	2.9
Construction Contracts	3,090	.5	4,500	.6	5,000	.6	5,000	.6
Subtotal	5,117	.8	5,700	.8	20,700	2.7	30,700	3.6
Total	**$679,913**	**100.0**	**$698,211**	**100.0**	**$761,478**	**100.0**	**$846,372**	**100.0**
% of Total NCI Budget		72.1		71.5		72.0		73.8
In-House Research	109,191	11.6	114,661	11.8	123,065	11.6	124,679	10.8
Management & Support	100,965	10.7	109,949	11.3	118,324	11.2	120,816	10.6
(NIH Management Fund)	(42,149)	(4.5)	(47,004)	(4.8)	(50,818	(4.8)	(52,818)	(4.6)
Cancer Control	52,746	5.6	53,138	5.4	55,146	5.2	55,146	4.8
Subtotal	262,902	27.9	277,748	28.5	296,535	28.0	300,641	26.2
Subtotal NCI	**$942,815**		**$975,959**		**$1,058,013**		**$1,147,013**	
Pending Transfer:								
National Toxicology Program	45,623		49,034		49,034		49,034	
Associated Management Costs	917		953		953		953	
Total, NCI	**$989,355**		**$1,025,946**		**$1,108,000**		**$1,197,000**	

BYPASS BUDGET SEEKS $171 MILLION INCREASE OVER REAGAN'S 1982 REQUEST

(Continued from page 1)

authorization will be at least that much, probably more, when Congress gets around to extending the Cancer Act.

Congress intended for the bypass budget (called that because it goes directly to the White House without alteration by NIH or HHS) to be a statement by NCI and its advisors of the amount it needs and can usefully spend to achieve optimal results toward goals of the National Cancer Program. The new system of developing a request closer to the amount which will show up in the budget the President submits to Congress deviates from that philosophy. In the opinion of some, it waters down the bypass authority and negates the intent of Congress.

In arguing for realism, DeVita pointed out that, while the NCAB is heavily involved in developing the bypass budget, it generally has had very little to say about the budget which NIH and HHS submit to the White House. Because of the wide disparity in dollar requests between the two budgets, the process of adjusting distribution of funds frequently required reprogramming without NCAB advice. The Board has asked that any reductions from the bypass figures be distributed evenly among all programs, but that has not always been possible or desirable, considering the size of the cuts.

There would be no such problem if the White House and its Office of Management & Budget observed the law, as spelled out in the National Cancer Act. Every President, from Nixon through Reagan,

has completely ignored the bypass budget and has done explicitly what Congress was trying to avoid: allow the NIH director and the assistant secretary for health, upon whom enormous presssures are exerted by the entire range of health interests, to write the budget for the National Cancer Program.

The congressional appropriations committees could rectify the situation by insisting on working from the bypass budget, or at least referring to it, in writing their money bills. Cancer Program advocates could be more diligent in pushing the bypass figures when they present their cases to the committees. The bypass budget in the past has been a carefully worked out and peer reviewed document which states the opportunities in cancer research and control and the money required to take advantage of them. It was far more valid than those which merely divided up the money which NIH, HHS and OMB said was all that was available.

The FY 1983 bypass request takes into account the impending transfer of NCI's share of the National Toxicology Program to the National Institute of Environmental Health Sciences.

NCI will contribute nearly $50 million to NTP in the 1982 fiscal year ($49 million in transfer of funds, almost $1 million in associated management costs). The 1983 bypass figure for NTP is identical and is in addition to the $1.147 billion total requested. The President's budget request for NCI in FY 1982 is $1.026 billion, including NTP; the 1983 bypass figure thus represents an increase of $171 million over the previous White House budget–still considerably more than the President is likely to ask when he submits his 1983 budget to Congress in January.

Notable features included in the new bypass budget which went to OMB this week:

- Two levels of funding were included–a "current services level," the President's 1982 request plus an eight percent increase; and the higher optimal level. The current services total would be $1.058 billion, $82 million more than the 1982 Presidential figure.
- R01 and program project grants would be funded at a level of 42 percent of approved new and competing renewals under the higher level, only 29 percent under the current services level.
- Construction grants would get $25 million with the higher level, $15 million with the lower.
- Cooperative Group funding is included with those clinical trials now supported by contract and both are listed under cooperative agreements, starting with the 1982 budget (whether all groups will be transferred to cooperative agreements by 1983, let alone 1982, remains to be seen). The combined total of $44.5 million for 1982 includes $37.5 million for the existing groups, plus another $1.5 million for the new regional groups now in the competition process. Existing groups will be funded at 80 percent of recommended levels in both 1981 and 1982 (the 1981 funding somewhat higher than the 70-75 percent the groups were told earlier this year they would get). The 1983 estimates would fund at full recommended levels, one group less with the lower figure.
- Cancer center core grants, due to get $75 million in 1982, would get $80.7 million in 1983 with the higher level, $78.8 million with the lower. Under both levels, new and competing renewals would be funded at their full recommended levels; the higher level would fund one more center.
- Organ site programs, cancer control and research and clinical training continue to receive lower priorities in the budget process, all with virtually level budgets from 1981 through the 1983 higher figure (cancer control is listed only for a $2 million increase in 1983 over the 1982 estimated total, about half the eight percent average increase; organ site programs would take a $1.3 million cut from 1982 to 1983 with the lower level, remain the same at the higher level).

The low priorities accorded organ site and training programs is somewhat surprising. The NCAB has repeatedly and strongly expressed its support for both. The bypass budget, usually presented to the Board at its May meeting, was not wrapped up until this month to allow Board members more time to offer their opinions, yet organ site and training did not fare well.

The modest increase for cancer control does little to take into account renewed congressional interest in that area. Apparently, Board members agree with DeVita, that any new initiatives (such as the Hospital Oncology Program and chemoprevention clinical trials) will have to be funded by dismantling or not renewing existing programs.

GRAD STUDENT WITHDRAWS FROM CORNELL IN WAKE OF DISCREPANCIES IN STUDY

Mark Spector, the graduate student who co-authored with Efraim Racker a now disputed article on their work which was published in *Science* (***The Cancer Letter,*** Sept. 11), has withdrawn from Cornell Univ.

It was Spector's contribution to the work which was called into question. Racker and his colleague Volker Vogt, who discovered the inconsistency, agree that the experiment had been compromised in some fashion. Spector insists that he did nothing wrong and that his findings will be verified eventually. However, he submitted a one paragraph letter last week which said: "Considering the circumstances that have taken place over the past six weeks, I would like to withdraw my PhD thesis, and, in addition, withdraw from the graduate school."

Racker has submitted the following letter to *Science:*

WARBURG EFFECT REVISITED

"Under the above title I have recently published a paper in *Science,* (213, 303, 1981) coauthored with Mark Spector, a graduate student in my laboratory. I feel compelled to withdraw some of the claims that we have made in this paper. On July 24, 1981, Volker Vogt, an assistant professor in our department with whom I have collaborated, discovered that the data obtained from an experiment involving immune precipitations from extracts of cells transformed with Moloney sarcoma virus were incompatible with the experimental protocol. This important discrepancy, and several others, discovered with the generous help of other tumor virus laboratories, cast doubt on some of the published and unpublished claims we have made. I shall state below which of the basic observations have been repeated by independent tests and which are doubtful.

"1. I have confirmed the phosphorylation of the β subunit of the Na^+K^+ ATPase by a protein kinase from Ehrlich ascites tumor cells prepared by Mark Spector. I have established that the phosphorylated amino acid on the β subunit is tyrosine.

"2. We have mentioned in our paper a 6,000 dalton polypeptide which was isolated in my laboratory by Mark Spector and was claimed to activate one of the enzymes of the protein kinase cascade (PK_S) by another (PK_L). I have performed these experiments several times with preparations of PK_S, PK_L and activator, supplied to me by Mark Spector, and observed at least a 3 to 5-fold stimulation of protein phosphorylation in the presence of the activator. Mr. Spector has also given to Dr. George Todaro, chief of the Laboratory of Viral Carcinogenesis at the National Cancer Institute, a preparation of the activator (now shown in Dr. Todaro's laboratory to be a mixture of several small polypeptides) which was found to be active in inducing phenotypic transformation of normal cells to cells that show achorage-independence of growth. I have also tested a preparation of a transforming growth factor given to Mark Spector by Dr. Todaro and I have found it to be very active in the above described system of phosphorylation with PK_S and PK_L. It is obvious that these experiments will have to be repeated with enzyme preparations and an activator of known purity.

"On the other hand, I have been unable to verify the effectiveness of the rabbit antisera that supposedly neutralize and precipitate the four protein kinases. Since I know that some of these sera were shipped to other laboratories, I suggest that no further experiments be conducted with these samples.

"I am also not certain of the correctness of some of the physical-chemical properties ascribed to the protein kinases, but I cannot state that they are wrong. We are now checking all published data and it will take us many months before we know what is correct. We suspect that some of the data dealing with cells transformed by various tumor viruses are incorrect. We have not dealt with these experiments in the *Science* article but they were subjects of a paper in press which we are withdrawing. They were also presented by me and others in seminars and I wish to withdraw these claims until we can verify them."

NCI PUSHES FOR HOP CONCEPT REVIEW IN OCTOBER; CHOPs SEEK CONTROL GROUP

The staff of NCI's Div. of Resources, Centers & Community Activities is making every effort to prepare a concept review for the Hospital Oncology Program in time for the division's Board of Scientific Counselors meeting Oct. 22-23, contrary to the report in last week's ***Cancer Letter.***

NCI Director Vincent DeVita has assured Sen. Paula Hawkins (R.-Fla.) that the HOP concept review would be held in October and the program started in the 1982 fiscal year.

DeVita also has let it be known that much of the $10 million (or more) HOP will require will have to come from existing programs. Prime candidates would include the Cooperative Group Cancer Control Program, in which more than $4 million a year has been supporting efforts by selected groups to bring community hospitals into their protocols; and cancer control outreach grants to cancer centers. The Div. of Cancer Treatment also may be asked to help fund the clinical research portions of HOP.

Additional money may be made available with the expiration of the Community Based Cancer Control Program and others which are due to end next year.

Meanwhile, HOP's predecessor, the Community Hospital Oncology Program (CHOP), is getting under way. Fourteen of the 23 CHOP contractors have joined to conduct an in depth evaluation of the program and are looking for other institutions to serve as a control group for their study. Paul Anderson, chairman of the group, sent this letter to institutions he felt might wish to participate:

"Fourteen of the National Cancer Institute's funded Community Hospital Oncology Programs (CHOPs) are developing an in depth evaluation of the program. Since this evaluation is funded by the CHOPs themselves, we intend the evaluation to be sound, serve national ends, and be comparable to the Patterns of Care study sponsored by the American College of Radiology.

"The project will require a like number of institutions interested in answering questions with regard to the quality of care available to the cancer patients served in this nation's community cancer centers. Over 40 institutions are represented by the participating CHOPs. Thus, we seek a number of qualified institutions to serve as a comparison/control group.

"To coordinate the group, to devise the specific questions, hypothesis, collection and analysis

strategy, and overall research design, the group sought out and contracted with ELM Services Inc. ELM's considerable knowledge of the CHOPs, national evaluation techniques, and the underlying purposes of the demonstrations made it uniquely qualified to work with us on this effort. Lee Mortenson, director of ELM's Cancer Program Group, is serving as the study's project manager.

"If your program is interested in the possibility of serving as a member of this control group, you must understand out the outset that we are not offering any funding to participate in the study. Only the recognition and satisfaction that at last we are beginning to tackle some of the basic questions regarding community cancer care can be offered as a reward. Whether or not we can obtain future funding for the effort is undetermined at this time. To indicate your interest, we ask that you fill out the accompanying form and return it to Mr. Mortenson. Mr. Mortenson can also be contacted directly at any time for information on the progress of the study or on the details of serving as a control member of the National Study Group. You may also contact me for further information.

"I hope you will consider joining us in developing an evaluation of high quality and great importance to our mutual goal of improved patient care and documentation of the quality care available to the 85 percent of cancer patients treated in our nation's communities."

Mortenson's address is: ELM Services Inc., 11600 Nebel St., Suite 201, Rockville, Md. 20852, phone 301-984-1242. Anderson's address is: Southern Colorado Cancer Program, 2215 N. Cascade Ave., Colorado Springs, Colo. 80907, phone 303-830-5781.

At the recent meeting of the Assn. of Community Cancer Centers Clinical Research Committee, in which an ACCC position on the organization and direction of HOP began to take shape, Anderson presented an analysis of models proposed by Charles Moertel, chairman of the DRCCA Board's Clinical Research Committee, and by Edward Moorhead, chairman of the ACCC committee (excerpts follow):

"The basic approach of both models links cancer control projects in the community to the receipt of money for patient accrual to national cancer treatment protocols. Both propose new center-type programs of varying size, and of varying degrees of comprehensiveness, in the community. All of the new program community centers would add at least a small number (30-50) of patients to national protocols, and with increasing size, ambitiousness, and funding, would be required to add on cumulative numbers of cancer control projects.

"Both models envision a cancer treatment and control unit consisting of a single currently designated 'support unit' (comprehensive center, university center, regional or national cooperative group) plus five or more community hospitals or clinics aligned with the central support unit.

"The Moertel plan more clearly pictures these as originating in and more or less controlled by the support unit, much like expansion of current comprehensive center outreach and control mandates. The Moorhead model, on the other hand, encourages more initiative on the part of the community hospitals or clinics, and appears to designate the community as the agent which selects the degree, size, scope, and comprehensiveness of its own programs before negotiating with the NCI and the support units for funding and other services and collaborative activities.

"It is recognized that there is a need to realize some cancer control results from the expanded program for community clinical research, and to show that this program has, in the public health context, some cancer control impact. It is recognized further, that as communities are where most of the patients are treated (and therefore where clinical investigation is needed), in addition, the communities are where most of the population is who comprise the targets for the whole comprehensive spectrum of cancer control.

"The communities, however, need special consideration. Previously most community physicians have had little or no contact with NCI, with comprehensive centers, or with cooperative treatment groups, so these contacts will need careful development. Length of time between idea initiation and project initiation is crucial in the community (not usually federally funded or dependent) in order to maintain enthusiasm and participation. The community physicians, their professional staffs, their institutions and agencies, all desire best care for their patients. Clinical investigation has very strong appeal, but must not carry too much other weight if it is to be realistically achieved.

"Hospital relationships to their physicians, communities and to their patients are not as clearly defined (or manipulable) as comprehensive centers, cooperative groups and NCI organizations with a history of organized cancer efforts. Only some of the recently established Community Hospital Oncology Programs have started to develop hospitalwide, interhospital, or community level broad spectrum efforts (with NCI formalization) in what could be called cancer control. The CHOP efforts are early, have not been evaluated, and are not yet proven models for exporting control programs from support unit to community, although they probably represent the pioneer efforts for this new program.

"It is likely that cancer control projects in the community will not, in any single community, be able to cover as broad a spectrum of control efforts as in a comprehensive center. At least for some sized community groups, there may be need for more for-

mally organized, centrally administered, control programs, (for example by NCI or by the relevant support unit) as the time, sophistication and ability to produce worthwhile control projects initiated in the community may result in diminished desire to participate in the clinical investigation programs.

"As proposed in both the Moertel and Moorhead models, there will need to be several different possibilities for a given community to participate in cancer control projects, including:

"(1) Some communities may desire to do no control, only clinical investigation. This group should probably be limited, but it is needed.

"(2) Many communities in an intermediate group will be able to, and want to do some, a few, or limited control projects. These may either propose a project of their own, or (more likely) elect to participate in an NCI, center, or cooperative group initiated cancer control program. This should provide a good field test for control projects previously tried at centers. This group of communities might request a catalogue or laundry list of existing control projects from which they might select one for participation.

"(3) A smaller number of communities will probably want to do cancer control projects from several points on the spectrum, but not all, and perhaps not primary control research. They should compete for cancer control funds on a peer evaluation basis, but should (by virtue of participating in the clinical investigation program) have some advantage over communities not involved in the clinical investigation program. An alternative would be, as suggested by the Moorhead model, to link clinical research funding to the requirement for some cancer control project initiation.

"(4) A small number of communities may well desire to become true comprehensive community cancer control and research centers. These programs will have almost (except for basic research) the same commitment and level of organization and administration as the comprehensive cancer centers. It is not certain how many communities have such desire or resources. This group probably needs to be the target of an RFP similar to those directed to potential comprehensive or university centers. Such centers could have enormous potential in expanding the National Cancer Program. This concept should be encouraged, but possibly not in this program aimed primarily at increasing cancer clinical investigations and limited cancer control objectives.

"In addition to discussing the various levels of community cancer control and clinical investigation programs, some general proposals related to control may be pertinent. Questions of cancer control importance related to clinical research include:

"(1) Does participation in, and placing 50 or more patients on, national protocols improve the overall cancer care in communities so participating?

"(2) Can the pattern of clinical cancer care be documented in the communities participating in the program, and how does this pattern of care compare to other components in the national cancer program (so that changes can be made as needed)?

"(3) Does the implementation of clinical investigation alone in the community constitute an adequate (or significant) cancer control effort at the same time, or does linkage with formalized cancer control projects decrease cancer mortality and morbidity in any additive evaluable way?

"While recognizing that there are many other significant questions relevant to the program, it might be proposed that all participants might be required to participate in exploring these three questions at a minimum. It supposes that different communities will 'buy in' at different levels, that different levels of participation are acceptable, and that adequate technology and funding are available to deal with the cancer control component of the whole program.

"Specifically, recommendations could include:

"(a) That each participating community program regardless of size, or of spectrum of control activities, provide data (in addition to that requirement for protocol compliance) for either all patients or all patients with specified diagnoses to CCPDS for inclusion in the national program data set. (Funding for data collection would need to be budgeted for both functions.) Comparison of patients on protocol to those with the same diagnosis not on protocol could be compared at the CCPDS level. Reasons for not adding a patient to protocol would be required of the participating hospital. Similar requirements for protocol vs. nonprotocol CCPDS reporting should be requested for some set of the comprehensive centers, to make this meaningful. Multiple acceptable reasons for not placing patients on protocol should be made available to encourage realistic reporting.

"(b) That either an in depth set of CCPDS data, or a mutually developed management guidelines data set for selected major diseases be developed, and data related to that set of guidelines be collected by each involved support unit and its community collaborators. Development of such a set may be difficult but the need for collaboration between support unit and community may be enhanced, as well as answering the ever recurring questions related to adequacy of technology transfer.

"(c) That each community and each support unit define individually and collectively, the specific projects and spectrum of cancer control projects that they will develop, and develop plans for comparing either clinical research efforts with control programs to those with no control projects, or the sum total of the control activities in their institutions to a population defined area with neither research or control activities.

"(d) That NCI, representatives of the control units

involved, and representatives of community programs be required before total program implementation to jointly develop both individual evaluation plans to measure local and regional impact, and a national common data set and evaluation plan, so that this overall effort can be adequately evaluated. The effort is too large, too unprecedented, and of too much long range potential impact on the national cancer efforts to be allowed to develop without adequate preplanned evaluation."

NCI CONTRACT AWARDS

Title: Technical support services for the International Cancer Research Data Bank Program
Contractor: Informatics Inc., Rockville, Md., $873,141.

Title: Cancer Information Dissemination and Analysis Center (CIDAC)—covering cancer diagnosis, treatment and rehabilitation
Contractor: M.D. Anderson Hospital, $997,393.

RFPs AVAILABLE

Requests for proposal described here pertain to contracts planned for award by the National Cancer Institute unless otherwise noted. Write to the Contracting Officer or Contract Specialist for copies of the RFP, citing the RFP number. NCI listings will show the phone number of the Contracting Officer or Contract Specialist who will respond to questions. Address requests for NCI RFPs to the individual named, the Blair Building room number shown, National Cancer Institute, 8300 Colesville Rd., Silver Spring, Md. 20910. RFP announcements from other agencies reported here will include the complete mailing address at the end of each.

RFP N01-CM-15801-58

Title: *Efforts to develop new prognostic and therapeutic modalities based on studies on cell transformation and on transformed cells*
Deadline: *Oct. 21*

NCI is soliciting proposals for a support service contract providing much of the raw materials on which the experimental procedures of the intramural research program depend. The project will be concerned with providing purified and partially purified factors promoting the growth of human hematopoietic cells, assays for these factors and assays for the selective growth of human leukemic leukocytes compared to normal bone marrow cells; providing cultures and cells containing specific genetic components introduced by infection and transfection; providing purified viral and cellular proteins and enzymes and providing monoclonal antisera to them; in addition, performing primary structure analyses of these proteins for the purpose of comparing the relatedness of subhuman primate viruses and human type-C virus isolates; supplying radiolabelled complementary DNA and viral RNA sequence-relatedness probes from mammalian type-C viruses, putative human type-C and human leukemic "virus like" particles.

It is expected that one award will be made for a five year period. The contractor's facilities must be within a 35 mile radius of the NIH campus in Bethesda, Md. in order to deliver the cells to the government within one hour of harvesting. This is a recompetition of ongoing efforts being conducted by Litton Bionetics Inc.

Karlene Wakefield
Contract Specialist
RCB, Blair Bldg. Rm. 212A
301-427-8764

RFP NCI-CM-27505

Title: *Storage and distribution of chemicals and drugs used in cancer chemotherapy*
Deadline: *Approximately Oct. 26*

The Drug Synthesis & Chemistry Branch of the Developmental Therapeutics Program, Div. of Cancer Treatment, NCI, is seeking support services to operate and maintain DS&CB's chemical and drug repository. The principal objectives of the project are the receipt, storage, inventory, distribution, documentation and control of synthetic compounds, crystalline natural products and bulk clinical drugs.

The Drug Synthesis & Chemistry Branch is actively involved in the acquisition of a large number of diverse chemicals and drugs for evaluation as potential anticancer agents. Presently, there are approximately 400,000 compounds in storage and approximately 13,000 addition new ones enter the program annually. Approximately 1,500 compounds are shipped monthly to NCI screening laboratories and research investigators both in the U.S. and foreign countries.

The following are considered minimum requirements:

A. Eight thousand square feet of space containing 900 cubic feet of refrigerator space (2-8 degrees C), 1,500 cubic feet of freezer space (-20 to -10 degrees C), and a safe (approximately 10 cubic feet) weighing more than 700 lbs.

B. Sufficient nonrecirculating air conditioning to provide controlled room temperature storage space.

C. Licenses and permits for the storage and distribution of chemicals and drugs:

1) Registration under Controlled Substance Act of 1970 from the Drug Enforcement Administration, Dept. of Justice, P.O. Box 28003, Central Station, Washington, D.C. 20005.

2) Registration for controlled dangerous substances from the state in which the repository will be located.

3) Permit to distribute from the state in which the repository will be located.

D. Must be within a 35 mile radius of DS&CB, NCI, Silver Spring, Md.

The principal investigator should be trained in organic chemistry at the master's level or higher from

an accredited school and have experience in areas relevant to this work including supervisory or managerial level responsibilities. The principal investigator and all key personnel should be assigned to the project 100 percent of the time. There should be at least one additional project team member at the bachelor's level whose primary responsibility will be as a backup to the principal investigator.

Maria Decker
Contract Specialist
RCB, Blair Bldg. Rm. 228
301-427-8737

RFP NCI-CM-27508

Title: *Development and production of investigational parenteral dosage forms of anticancer agents*

Deadline: *Approximately Oct. 26*

The Pharmaceutical Resources Branch, Developmental Therapeutics Program, Div. of Cancer Treatment, is seeking a contractor to develop, produce, quality control test, package, label and ship to NCI investigational parenteral drug products formulated as liquids (ampules/vials) or lyophilized vials suitable for clinical trials.

The number of development assignments is expected to be between six to 10 annually. It is expected that 48 formulation projects will be required annually (36 lyophilized and 12 liquid filled ampules/vials). A production project may involve the manufacture of 4,000 to 30,000 freeze dried vials or 15,000 to 30,000 liquid filled ampules, although greater or lesser amounts may also be required. Production projects will periodically involve the technique of low temperature vacuum drying from non-aqueous solvents such as ethanol. All work performed under this contract must be in accordance with Food & Drug Administration's Current Good Manufacturing Practices.

The contractor selected must meet at least the following minimum requirements:

1. Be currently engaged in sterile manufacturing of clinical products involving freeze drying, ampuling and liquid filling of vials.

2. Be required to have operational equipment and capabilities for all production and quality control tasks at the time of contract award. The following is a list of equipment that must be in-house at the time of contract award: High pressure liquid chromatograph, recording ultraviolet-visible spectrophotometer, pH meter, Karl Fischer water analyzer, infrared spectrophotometer, pilot freeze drier, paper and thin layer chromatography equipment, oven/water baths for kinetic studies, melting point apparatus, analytical and manufacturing balances, ampule filling and sealing equipment, vial washing facility, autoclaves, FDA approved sterile water holding and distribution system, hot air sterilizer, two production size freeze driers (must be operational), compounding tanks (routine and temperature controlled), sterile preparation area, inspection stations, and emergency electrical support for freeze driers. Also, low temperature storage facility for storing products prior to shipment to NCI (2-8 degrees C, -20 to -10 degrees C).

3. Have in house capability and experience in working with the equipment noted above. In addition, the offeror must have the in-house capability of performing USP sterility testing.

4. Possess mixing equipment that will maintain the temperature of a solution of an unstable drug at 1-3 degrees C.

5. Must be FDA approved to manufacture parenteral products.

John Palmieri
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RFP NCI-CB-15001-46

Title: *Maintenance and development of inbred and congenic resistant mouse strains*

Deadline: *Oct. 30*

The Div. of Cancer Biology & Diagnosis, NCI, is seeking proposals for provision of a support facility capable of (1) maintaining a colony of approximately 40 strains of inbred mice by strict pedigreed brother-sister matings; (2) breeding and developing new congenic mouse strains; (3) making selective crosses and backcrosses between these strains; (4) producing antisera by immunization between these strains; and (5) performing quality control testing by serology and skin grafting of pedigreed animals in the colony. A maximum of 4,000 mice will be maintained under this contract. All animals will be supplied by the government.

The successful offeror will be required to have this facility located within 50 miles of the NIH campus in Bethesda, Md. Other minimum facility, equipment and personnel reuqirements are included in the RFP.

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The Cancer Letter _Editor Jerry D. Boyd

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