THE CANCER LETTER

Vol. 9 No. 3
Jan. 21, 1983

Subscription $125 year North America
$150 year elsewhere

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

FLINT CHOP SHOWS THAT SUCCESSFUL COMMUNITY PROGRAM CAN BE DEVELOPED AND OPERATED WITHOUT NCI FUNDING

There are 192 applications for the Community Clinical Oncology Program now being processed by NCI and awaiting review. In all likelihood, more than 100 of them are destined to disappoint their authors,

(Continued to page 2)

In Brief

SCHWEIKER RESIGNS, PRESIDENT APPOINTS FORMER MASSACHUSETTS CONGRESSWOMAN MARGARET HECKLER

RICHARD SCHWEIKER resigned last week as HHS secretary, and President Reagan immediately nominated **MARGARET HECKLER**, former Republican congresswoman from Massachusetts, to the position. Her confirmation by the Senate should be no problem, since she was an effective legislator and was popular among her colleagues in both parties. Her views on social issues are close to Schweiker's. Whether she can be as effective in battling the budget cutters in the Office of Management & Budget remains to be seen. Schweiker's departure came after his successful fight, for the third year in a row, in opposing drastic cuts in the NIH and NCI budgets proposed by OMB. Schweiker's resignation reportedly was not forced by White House conservatives (*The Cancer Letter*, Nov. 26). He left to accept a high paying job as president of the American Council of Life Insurance, an organization representing the major life insurance companies. . . . **NATIONAL CANCER** Advisory Board's Committee on Cancer Control and the Community meeting Jan. 30 was not included in the month's list of meetings (Jan. 7). It will start at 6 p.m. in NIH Bldg 31 Rm 11A10. Agenda for the full Board meeting Jan. 31 will include a discussion on cancer care costs by Donald Hodgson, chief economist for the National Center for Health Statistics; a presentation on the revolution in diagnostic imaging and its potential impact on the diagnosis of cancer, by David Pistenma, who heads the Radiation Research Program in the Div. of Cancer Treatment, Paul Capp, chairman of the Dept. of Radiation at the Univ. of Arizona, and William Hendee, chairman of the Dept. of Radiation at the Univ. of Colorado; and problems of marker research, by Robert McIntire, chief of the Diagnosis Branch in the Div. of Cancer Biology & Diagnosis. . . . **MICHAEL SPORN**, chief of the Laboratory of Chemoprevention in NCI's Div. of Cancer Cause & Prevention, and **WERNER BOLLAG**, chief of cancer research at Hoffmann-La Roche in Switzerland, shared the 1982 Lila Gruber Memorial Cancer Research Award of the American Academy of Dermatology. . . . **JERRY LEWIS**, Univ. of California (Davis), has succeeded **JOSEPH CASTRO** as president of the Northern California Cancer Program Board of Trustees. **THEODORE PHILLIPS**, chairman of the Northern California Oncology Group, is NCCP vice president.

FLINT CHOP SHOWS THE WAY FOR OTHER PROGRAMS WHICH FAIL TO GET NCI FUNDS

(Continued from page 1)

at least in the first round of CCOP awards. It is doubtful that the $10 million NCI has set aside for CCOP will stretch over more than 50-75 applications.

The unfunded applicants do not necessarily have to fold up their tents, however. When CCOP's predecessor, the Community Hospital Oncology Program (CHOP) was initiated, only 23 of 50 some applicants were funded. Several of the unfunded CHOPs went right ahead and established successful programs without NCI money. The Community Wide Hospital Oncology Program of Flint, Mich., is one of the more shining examples.

The Flint CHOP (which still uses the NCI acronym for the program despite the extra word in the official title) is a consortium of six hospitals in the Flint area—four major hospitals with 500-600 beds each, one a 150 bed hospital and the other with 50 beds.

The Flint CHOP has completed its second full year of operation and is well on its way to meeting the goals and objectives the organizers set out for themselves:

- Development of professional and site specific guidelines to establish a standardized level of patient care in the region.
- Development of continuing education programs for health care providers and the community.
- Development of a regional tumor registry and data system to allow analysis of the program and of the incidence of cancer in the region.
- Development of investigational therapy, with research activities related to cancer care to be performed in the region.
- Active pursuit of resource coordination among cancer related programs, projects, and activities in the region.

Max Dodds, a surgical oncologist who is known as the "grand old man of oncology" in Flint, is the chairman of an 11 member executive committee which runs the CHOP. Peter Levine is the program coordinator.

The NCI CHOP application was not funded, Levine believes, because "we had the reputation of always being at each other's throats in this community. No community was more divided (among cancer care providers) than we were."

Dodd and his colleagues overcame that problem, put together a collaborative program which is succeeding, and did it without NCI money. "The message is there for others," Levine said. "It's not that hard to do. If we can do it here, it can be done anywhere. There is no excuse for not doing it. And it's been a lot of fun."

The failure to get one of the CHOP contracts was the catalyst which brought the feuding institutions and physicians together, Levine said. Hospitals and individuals committed themselves to development of a CHOP, the organizational structure was established and staff hired, and a proposal was submitted to the Flint Area Health Foundation for funding.

The Foundation was established by Arthur Tuuri, an M.D., to help fund innovative health care systems in the county. The budget was set at from $60,000 to $70,000 a year, and the Foundation agreed to provide 80 percent of the budget in the first year, 50 percent in the second, and 20 percent in the third. The hospital members will assume the full cost in the fourth year, which Levine estimates will level off at about $70,000.

The hospitals, physicians, nurses, and allied health personnel provide a substantial amount of in kind contributions, in space, facilities, and time.

The first two annual reports summarized the steps taken to get the organization off the ground (with some editing to conserve space):

The first six months of CHOP activity was spent orienting staff and the provider community to purposes, goals, and objectives of the program, and organizing the structure of the CHOP. During this period, staff met with the chief executive officer of each member hospital and the physician investigator representing each hospital to determine perceptions of direction for the program by key players. Staff met repeatedly with investigators and other key physicians to refine and synthesize their views, and to achieve sufficient consensus to begin operations. A major purpose of these meetings was to solidify the support of the investigators and their key physicians for CHOP activities.

Two things became clear almost immediately. Most of the key actors in the field of oncology were very interested in the program, but there was not a clearcut conception of the amount of time commitment necessary to actualize the CHOP. . . .

Site visits to member hospitals were performed to review organizational, philosophical, and linkage patterns. The site visits clarified the potential for regionalization of cancer care, and the promotion of the area cancer care program to providers outside the region, for the purpose of generating referrals. The level of pride and motivation among physicians, administrators, and allied health providers was determined to be the key to this activity.

During phase 1 (of the first year), the search began for a data collection package which would be used as a tumor registry for the area hospitals. During this period, several organizational formats and software packages were reviewed. Consensus was not achieved on a package or format by the CHOP Data Collection Committee.

Attempts were made to affiliate the CHOP with the Comprehensive Cancer Center of Detroit. Staff felt that an affiliation with the center would provide expertise, funding, and impetus to CHOP activities. It became clear by the end of phase 1 that the center wished to utilize CHOP staff and physicians with no intention of providing any assistance to the CHOP or its member institutions.

(Levine told *The Cancer Letter* that since that time, relations between the CHOP and the center have improved. In fact, the center has agreed to serve as a research base for the

Flint CHOP in its CCOP application and to manage the CHOP's use of the Southwest Oncology Group as another research base. "There was little impetus for them to work with us before. I think they perceived of themselves as having enough to do in Detroit," Levine said.)

Dodds and CHOP staff attended the Assn. of Community Cancer Centers meetings in Washington. The meetings provided an opportunity to meet and form a working relationship with several federally funded CHOP directors from around the country, as well as to learn about central issues in cancer care nationally. During the latter part of phase 1, communications were instituted between the CHOP and national and regional cancer treatment study groups. The purpose of those contacts was to attract attention to the CHOP, as well as attract financial or in kind resources at a later date.

Planning for two educational programs, cosponsored by the CHOP, was carried out during phase 1. Staff began working to create a statewide consortium of community cancer programs including the Kalamazoo CHOP, and the Grand Rapids Clinical Oncology Program. The purpose...was to create a consolidated vehicle with which to apply pressure for funding or services on the comprehensive cancer center and the National Cancer Institute. The consortium did not develop due to the fact that the directors of the three programs wished to complete planning and commence program implementation before committing major amounts of time and energy to this effort. The result of these contacts has been the opening of communication links between the three programs, with constant consultation taking place between the three program directors.

During phase 2, the CHOP Advisory Committee, Executive Committee, and Data Collection Committee began to meet. This commenced the period of active multi-institutional planning and coordination. . . .

The CHOP cosponsored with Hurley Medical Center the Michigan Tumor Registrar's conference; and cosponsored with the University of Affiliated Hospitals of Flint a cancer workshop for physicians and medical students.

The CHOP Data Collection Committee continued to meet and reached consensus on the concept that all member hospitals would utilize an identical data system for the purpose of tumor registry. It was the consensus of the committee that the system should offer concurrent patient data as well as aggregate data. The system must accommodate entry of CHOP guidelines as well as investigational protocols used by local physicians. The system should accommodate retrieval and analysis of data.

A major action was the decision by the Executive Committee to institute an investigational therapy component as a major CHOP activity. One purpose was to pursue affiliation with a national study group. This will allow the utilization of phase 3 and 4 investigational drugs by all approved physicians who are interested in placing qualified patients on investigational protocols regardless of their hospital affiliations. The second purpose was to place Flint in the position of being a leader in community based programs and to attract federal funds based on that recognition.

The active committee structure was implemented. This required substantial involvement of staff and physicians from the CHOP member hospitals. The committees which began functioning were the breast, lung, lymphoma/hematology, and colorectal site committees; the Investigational Therapy Committee, and the Investigational Therapy Subcommittee on the Colorectal Cancer Study, conducted in conjunction with the Wistar Institute, and the Allied Health Providers Guidelines Criteria Committee.

The process which each site committee followed before producing components of the site specific guidelines was time consuming. Each committee felt a need to define parameters for the guidelines and their application. The committees met monthly. The process of thinking through format and content requirements took from two to five meetings, depending on the site committee considered. Initially, each committee was small, having only one representative from each physician specialist group. As physicians learned of CHOP, all of the committees grew during their initial months of activity. On some committees there are as many as five representatives of a specialty. This has led to some very stimulating discussions on "good patient care" as defined by the various committee members, and will aid in the acceptance of the guidelines by the physician community as a whole. Only the Male Genital Committee completed their guidelines during year one.

The Investigational Therapy Committee began discussion of affiliation with the Southwest Oncology Group. . . . The committee did complete the planning of a structure for multi-institutional activity in placing patients on protocols, and established the format for making investigational drugs available to more physicians than presently have access.

The CHOP was contacted by a fledgling cooperative research group centered in Toledo for affiliation. The organization's goal is the development of therapeutic research protocols. The Investigational Therapy Committee and the Executive Committee decided that there would be nothing to be gained through affiliation with the group, due to the fact that it would be duplicating the efforts of SWOG.

A dinner meeting was held at which Drs. Hilary Koprowski and Zenon Steplewski, of Wistar Institute, spoke, explaining their research utilizing a specific monoclonal antibody to detect colorectal cancer. At that meeting, the CHOP was asked to participate in a prospective study to show its efficacy as a marker. Participation was recommended by the 25 physicians present. The Executive Committee approved participation in the study and referred the project to the Investigational Therapy Committee to work out the details.

An Investigational Therapy Subcommittee was formed to carry out the colorectal cancer study project. The charge of the subcommittee was to work out details of participation in the multi-institutional study, testing the monoclonal antibody produced by the Wistar Institute. The committee completed protocols for data collection activity, and established a mechanism for shipping samples to Wistar Institute. By the end of phase 3, samples were arriving at Wistar for analysis, with participating hospitals utilizing a CHOP patient release form.

The CHOP Data Collection/Registry Committee continued to meet approximately every three weeks to work out the impediments to centralized registry/data collection and to choose a packaged system for cooperative participation. The committee heard presentations by Dr. Brent James, who developed the American College of Surgeons cancer registry; and Randall Thompson, of the Grand Rapids Clinical Oncology Program, who participated in the development of the CHOP Data System. The committee discarded several other registry options due to their cost, or lack of analytical capabilities. Staff spent a substantial amount of time collecting in-

formation on the ACOS system and the CHOPDS packages and talking to programs which had decided on one or the other system. Consensus was not reached on a system during the first year of operation, but substantial progress had been made toward that end. . . .

Meetings regarding affiliation with the Comprehensive Cancer Center of Michigan continued during phase 3, leading to offers to provide faculty for CHOP educational programs. This offer will be accepted during year two.

The oncology nurses of the hospitals decided to establish a chapter of the Oncology Nursing Society. Several CHOP physicians and institutions provided in kind and financial support for the society. ONS is committed to providing continuing educational programs to local nurses, as well as aiding in the development of CHOP nursing care guidelines.

A patient origin study was approved by the Executive Committee to determine how many cancer patients are receiving their treatment in other areas. The data is being collected by the Commission on Professional & Hospital Activities.

The CHOP moved to incorporate the activities of the allied health providers during phase 3. Staff met with social work directors to determine a strategy for having allied providers develop treatment guidelines. The social work directors immediately began developing social work guidelines. Those draft guidelines were used as a format from which a committee of allied health providers representing nursing, social work, dietary, and home health care professional groups, could begin developing criteria for allied health provider guidelines. The committee began developing criteria at the end of phase 3 and will complete the process during the first quarter of the second year of activity. It is anticipated that profession-specific allied health care guidelines will be completed by the middle of the second year of activity.

The second annual report listed these highlights:

Guidelines for the treatment, diagnosis, staging, and followup of carcinoma of the lung, breast, prostate, and cervix are complete. The guidelines for screening, diagnosis, staging, and followup of cancer of the colon/rectum and lymphoma will be completed within one quarter.

The allied health care professional community has drawn together, with great swiftness, to begin the process of providing allied health provider guidelines which are profession specific. The guidelines for social work, nutrition service, and home care are complete; the work having been provided by the organizations representing those professional groups.

The nursing community has completed guidelines for care of carcinoma of the lung, prostate and multiple myeloma, in draft form.

The CHOP and the American Cancer Society sponsored a multihospital screen of the general population of Genesee County over the age of 45 for occult blood in the stool, an initial screen for colorectal cancer.

The CHOP sponsored several educational programs, including a seminar on "Patient Education Strategies for the Oncology Team."

Four CHOP member hospitals have agreed on a tumor registry/data system which can be implemented in all four hospitals. The system will allow them to collect identical diagnostic, staging, treatment and followup information on all cancer patients. It is hoped that a fifth hospital will participate in this registry activity in the future. The anticipated implementation date is July 1, 1983. The hospital commitment to uniform community wide data collection is envisaged by the substantial capital outlay required to purchase the hardware to run this system. . . .

The CHOP member hospitals and physicians have been participating for over one year with the Wistar Institute studying a specific monoclonal antibody for the diagnosis and, hopefully, ultimately the treatment of colorectal, stomach, and pancreatic carcinoma. The study is ongoing and should lead to further studies.

The CHOP and the Univ. of Michigan School of Public Health's Dept. of Epidemiology began working toward preparation of a proposal to NCI for the study of the impact of vitamin A on the control (prevention) of cancer. It is anticipated that that proposal will be completed during the third year of CHOP operation.

The CHOP and the member hospitals made the decision to prepare a proposal to NCI seeking designation as a CCOP.

This year one of the CHOP investigators was appointed to the SWOG National Lung Protocol Committee. One other participating has been asked to help develop a national study group for carcinoma of the lung.

Three member hospitals have either applied for or received designation as cancer control centers for SWOG.

The components of regional cooperation in oncology services are now truly in place, the report's summary statement noted. Program growth is continuous. The CHOP, with continued baseline funding by the Flint Area Health Foundation and the area hospitals, will ensure continued cooperation among area hospitals and physicians in the area of oncology.

It must be stressed that this program proposes to perform more functions in a larger health care system than any of the federally funded CHOPs with the exception of the Cincinnati program. It is proposing to do this with approximately one-third of the funding that the federal programs receive.

Levine said that the committee meetings, both those of physicians and the allied health personnel, have turned out to be very valuable as continuing education efforts. For the allied health people, it is virtually the only contact they have with their professional colleagues. "The physicians trade therapy ideas, discuss specific patients. It's like a large, diffuse tumor committee. Everyone is communicating."

The physicians are proud of their affiliation with Wistar in the monoclonal antibody study, which got the community's attention. Levine said it was the single most important coalescing factor in the CHOP's development. That study was supported with a $27,000 grant from the Louis B. Mayer Foundation.

The CHOP has applied to the Fraternal Order of Eagles for a grant to purchase a minicomputer.

The Flint success accomplished without federal funds does not mean the CHOP is not interested in obtaining NCI support. The members hope to get a CCOP award, for the recognition that would mean and for the money. "Even if we don't get a CCOP award, we'll go ahead with it anyway," Levine said. Both the Univ. of Michigan and Wayne State Univ.

have agreed informally to serve as research bases for Flint's clinical research activities. "We'll raise the money locally to pay clinical trial costs, if we have to," Levine said. Some of the CCOP money would be used for travel costs, to encourage physicians to attend national meetings. "If we don't get it, they'll have to pay for that themselves."

But the Flint CHOP members are counting on becoming a funded CCOP. "We want the federal recognition," Levine said. "We need it. We deserve it."

GIGLIOTTI NAMED EDUCATION BRANCH CHIEF; EIGHT OTHERS REMAIN OPEN

Lillian Gigliotti, assistant clinical professor of nursing and nursing coordinator for the Univ. of Pennsylvania Cancer Center, has been appointed chief of the Education Branch in the Cancer Control Applications Program of NCI's Div. of Resources, Centers & Community Activities.

Gigliotti has been a member of DRCCA's Board of Scientific Counselors.

Her appointment still leaves eight permanent branch chief appointments to be made in the division, along with an associate director of the division to head the Cancer Control Applications Program. Joseph Cullen, DRCCA deputy director, is acting head of that program and plans eventually to turn it over to someone else.

DRCCA branches with acting chiefs now are:

Cancer Control Applications Program—Cancer Control Science, presently with Carlos Caban as acting chief; and Career Development, Robert Burnight, acting. Permanent branch chiefs are Barney Lepovetski, Cancer Training, and Sandra Levy, Behavioral Medicine.

Centers & Community Oncology Program, headed by Jerome Yates—Cancer Centers, Yates acting chief; and Community Oncology & Rehabilitation, Yates also acting. Permanent branch chiefs are Donald Fox, Research Facilities, and Andrew Chiarodo, Organ Systems.

Prevention Program, headed by William DeWys—Chemoprevention, Winfred Malone, acting chief; Occupational Cancer, Veronica Conley, acting chief; Diet & Cancer, DeWys, acting; and Cancer Prevention, DeWys acting. Richard Costlow is permanent chief of the Cancer Detection Branch.

CORRECTION: The RFA for Patterns of Care for Elderly Cancer Patients published in last week's issue of ***The Cancer Letter*** incorrectly stated that NCI had committed as much as $1.2 million a year to fund grants generated by the RFA. The correct is $1.2 million total for all three years of those grants.

NCI CONTRACT AWARDS

Title: Carcinogen bioassay of p-Nitrotoluene and 4-chloro-2-nitroaniline

Contractor: Litton Bionetics, $220,504.

NEW PUBLICATIONS

"Antiemetics and Cancer Therapy," edited by John Laszlo. Covers the general mechanisms of nausea and vomiting including the neurophysiology of the process, management of fluid and electrolyte imbalance, and the pharmacologic control of different types of nausea and vomiting with a variety of antiemetics. Williams & Wilkins, Baltimore, phone 301-528-4000, $19.95.

"Brochure of TNM Checklists;" "TNM Classification of Malignant Tumors;" "Classification of Pediatric Tumors;" "TNM Pamphlet on Breast Cancer," all published by the International Union Against Cancer. Prices not available. Contact UICC, Rue du Conseil-General 3, 1205 Geneva, Switzerland.

"13th International Cancer Congress," cassette tapes of the entire meeting held last September in Seattle. For the list by session with prices, contact Audio-Stats, 2639 S. La Cienega Blvd., Los Angeles 90034, phone 213-558-4529.

"Clinical Care of the Terminal Cancer Patient," edited by Barrie Cassileth and Peter Cassileth. Focuses on the understanding and management of symptoms, with chapters on relevant psychosocial and anthropologic issues. Lea & Febiger, 600 S. Washington Square, Philadelphia 19106, $24 ($28.75 in Canada).

"Followup of the Cancer Patient," by Ben Eiseman, William Robinson and Glenn Steele Jr. A clinical manual that provides information on the determination of efficient strategies for maintenance and early detection of recurrence. Thieme-Stratton Inc., 381 Park Ave. South, New York 10016, phone 212-683-5088; $38.

"Vital Signs," by Fitzhugh Mullan. A young doctor's struggle with cancer. Farrar, Straus & Giroux Inc., 19 Union Square West, New York 10003, phone 212-741-6900; $12.50.

PROGRAM ANNOUNCEMENT

Smokeless Tobacco and Non-Tobacco Smoking Product Use: Identification of Initiation Mechanisms in Children and Adolescents

The Div. of Resources, Centers & Community Activities of NCI is expanding its program initiatives under the Smoking, Cancer & Health Program which has been designed to facilitate the development of effective approaches to smoking prevention and cessation. The purpose of this announcement is to encourage research activities which will: (1) identify factors that lead to the use of smokeless tobacco and/or nontobacco smoking products (NTSP) by children and adolescents; (2) identify those conditions which may lead to shifts in tobacco usage patterns; and (3) develop prevention and cessation strategies which can be integrated into school based

health and/or antismoking programs.

For purposes of this announcement smokeless tobacco is defined as chewing, dipping, or snuffing commercial tobacco products; nontobacco smoking products are defined as commercially sold "smokes."

Shifts in tobacco usage patterns and initiation of nontobacco smoking behaviors have been reported by the research community. Data published by the USDA indicate that 11 million Americans use smokeless tobacco annually. This figure represents a 12% increase in smokeless tobacco use since 1974. In addition, the recent introduction of NTSP increases the potential for recruitment to smoker behavior by offering alternate smoking products.

Epidemiological evidence suggests that use of smokeless tobacco increases the risk of oral cancer. While little scientific evidence is available on NTSP, preliminary reports suggest that constituents in the gas phase of the smoke are suspected contributors to impairment of lung functioning, as well as acting as potential promoters of neoplastic disease. In addition multiple tobacco use (e.g. dipping and smoking), is a likely contributor to an increased cancer risk.

These projects should focus on the development of research strategies to identify, within well defined population group(s)—e.g., junior high school students—the antecedents and correlates associated with initiation of smokeless tobacco and/or nontobacco smoking product use and identification of those concurrent or interacting conditions which may lead to shifts from these products to regular tobacco cigarette smoking. Evaluation of possible changes in knowledge, attitudes, beliefs, and behavior concerning the use of nontraditional smoking and smokeless tobacco products and/or the decision to shift from these products to regular tobacco cigarette smoking will be considered a major component of the research design. Due to the generally similar behavior correlates between use of these products and cigarette smoking, demonstrated knowledge of the relevance and significance of current smoking prevention and cessation strategies aimed at children and adolescents is to be included in the research design. Knowledge of the psychological and social mechanisms potentially inherent in recruitment to these products is a general requirement.

In addition, the investigators must demonstrate an in depth knowledge of state of the art research in the areas of smokeless tobacco and NTSP as well as regular cigarette smoking as it relates to the research population. In addition to self report, the study design should include biochemical measurements to increase the validity of self reports, as well as to provide independent estimates of levels of tobacco use.

Description of the research populations, rationale for the method of sampling, definition of the variables and size of the group, as well as proven access and cooperation from intended research population, school authorities, parents, will be required.

This program is seeking grant applications concerned with basic and applied studies in prevention of disease with emphasis on behavioral, cognitive, attitudinal and motivational factors, as well as other appropriate research areas.

It should be emphasized that this statement of interest in developing new grant applications is neither a request for applications (RFA-Grants) nor a request for proposals (RFP-Contracts), but rather an announcement of the NCI's intent to stimulate investigator initiated research in the stated area. As such, proposals are reviewed by the usual NIH peer review groups for technical merit and recommendation to the National Cancer Advisory Board.

Additional needs for specific, in depth activity in any or all of the programs may be met in the future with issuance of RFAs and/or RFPs.

The announcement leaves the choice of specific research objective, identification of specific aims, development of appropriate protocols and methodology, and the procedures of analysis and interpretation of data to the investigators' initiative. However, once the award is made under the program, any substantial modification of the research originally proposed must be mutually agreed upon by the investigator and the respective NCI division.

For purposes of tracing responses to this program announcement, investigators should indicate its title on line 2, page 1 of the PHS 398 grant application form. A letter of intent and requests for additional information should be sent to: Catherine S. Bell, MS, Program Director for Behavioral Smoking Projects, NCI, DRCCA, Blair Bldg. Rm. 629, 8300 Colesville Rd., Silver Spring Md. 20910; phone 301-427-8656.

Application receipt dates for grants submitted under this program announcement are those indicated in PHS form 398. Completed applications are to be sent to: Div. of Research Grants, NIH, Westwood Bldg. Rm. 240, 5333 Westbard Ave., Bethesda, Md. 20205.

PROGRAM ANNOUNCEMENT

Tobacco and the Blue Collar Worker

The purpose of this announcement is to encourage research activities which will: (1) identify those factors that lead to recruitment, maintenance, cessation, and recidivism as related to tobacco use in the blue collar population; (2) identify concurrent and interacting conditions which may lead to shifts in tobacco usage patterns; and (3) develop prevention and cessation strategies which can be integrated into planned or ongoing workplace based health and/or antismoking programs.

This program announcement was developed in response to survey research data which indicate that

51 percent of blue collar workers are smokers as contrasted with 37 percent of the total smokers in the U.S. population. In addition, research data suggest that blue collar workers have a potentially greater risk of exposure to known and suspected carcinogenic substances in the workplace. This occupational exposure may act in synergy with smoking behavior thus exacerbating the risk of cancer for this population.

These projects will focus on the development of research strategies to identify, wtihin a well defined population group(s)—e.g., asbestos workers, who are tobacco users—the antecedents, correlates and consequences that are related to recruitment, maintenance, recidivism, and cessation of tobacco use in blue collar workers. The study design should include identification of those concurrent and interacting conditions which may lead to shifts in tobacco usage patterns—e.g., from nonuser to user, occasional user to regular user, regular user to nonuser, cigarette smoker to smokeless tobacco user, etc. The project should focus on the individual, social, and environmental factors that determine the influences affecting tobacco use in the blue collar workers, e.g., occupational related stress, social support and interaction effects, need for stimulation, maintenance of status, etc. Knowledge of the adverse health effects that result from the interaction between tobacco use and exposure to known and suspected carcinogens in the workplace will be a general requirement.

The study design should include a reliable definition of the status of tobacco usage among blue collar workers and should consider multiple forms of tobacco use, e.g., regular tobacco cigarettes, cigars and pipes, nontobacco smoking products, chewing and dipping. In addition to self report, the study design should include biomedical measurements to validate self reporting, as well as to provide independent estimates of levels of tobacco use. The investigator should address application of research results to future prevention and cessation strategies.

Description of the research population, rationale for the method of sampling, definition of the variables and size of the sample, as well as proven access and cooperation from the intended research sample and appropriate labor and management representatives will be required.

A letter of intent is encouraged and requests for additional information should be sent to Catherine Bell at the address on the previous announcement.

Completed applications are to be sent to DRG at the address on the previous announcement.

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 NCI-CM-37580-09

Title: *Detailed drug evaluation and development of treatment strategies for chemotherapeutic agents*

Deadline: *Approximately March 31*

The Drug Evaluation Branch of the Developmental Therapeutics Program, Div. of Cancer Treatment, NCI, is seeking a contractor with the expertise to design and conduct detailed drug evaluation studies in a variety of murine leukemic and solid tumor models. Studies will focus on compounds identified as active in primary screening in the DCT tumor panel, which is currently comprised of the L1210 leukemia, and B16 melanoma, the M5076 tumor, and the MX-1 mammary human tumor xenograft. The primary screen uses routine schedules of drug administration and liberal endpoints to enhance the opportunity of identifying active materials.

This contract will emphasize the design of sequentially more challenging tests involving a variety of in vivo and in vitro tumor systems in an effort to select the most promising agents for clinical trial. In primary screening drugs are usually injected intraperitoneally to treat intraperitoneally implanted tumors. In detailed drug evaluation a number of paramenters may be altered, such as tumor system, site of tumor implantation, timing of treatment (early or delayed treatment of tumor bearing animals), and route and schedule of drug administration.

Promising agents will be further evaluated singly or in combination in an effort to elucidate treatment strategies to address the following causes of treatment failure: (1) failure to control metastatic spread of disease and (2) failure to control the overgrowth of drug resistant tumor cell populations. Recognizing that tumors are comprised of heterogeneous populations of cells with different biological properties, such as growth rates, metastatic potential, and responses to chemotherapy, efforts will be made to develop treatment strategies to achieve total cure of neoplastic disease.

After removing primary tumors (or in some cases before removal), animals will be treated with chemotherapy using simultaneous, sequential or alternating schedules of drug administration. New agents will be evaluated in culture and in vivo for their cross resistance to standard agents in an effort to find synergistic combinations of new agents which are not cross resistant with currently utilized drug combinations.

Data generated from this contract will be used by DCT to set priorities for development of individual agents to clinical trial, as an inclusion in investiga-

tional new drug applications to the Food & Drug Administration prior to the initiation of clinical trials, and as a guide in the design of clinical protocols. The contractor also will be expected to devise appropriate laboratory experiments in response to questions that might arise during the toxicological evaluation or clinical trial of specific drugs, or in response to questions raised by the FDA in the course of reviewing IND applications. The offeror may not be a pharmaceutical firm because commercially confidential materials may be evaluated.

It is anticipated that one incrementally funded contract will be awarded for a period of three years.

Contracting Officer: William Roberts
RCB, Blair Bldg. Rm. 228
301-427-8737

RFP NCI-CM-37584

Title: *Preparation of bulk chemicals and drugs*
Deadline: *Approximately March 11*

The Pharmaceutical Resources Branch, Div. of Cancer Treatment, NCI, is seeking organizations having capabilities, resources and facilities for the preparation of bulk chemicals and drugs. The objective of the project is the preparation by synthesis of quantities of bulk chemicals and drugs (one gram to multikilograms) for use as potential anticancer agents.

The major emphasis will be on process development and will involve resynthesis and scale-up from the chemical literature. Methods will be available for small scale runs in many but not all instances. The facilities must have the capacity for performing all types of chemical synthesis and must be able to demonstrate organizational experience in this area.

A variety of large and pilot plant facilities will be needed. The size of the chemical reactors needed will vary with the contract. The minimum requirement for all contracts is one small (20, 30 or 50 gallons) and one large (100 gallons or larger) glasslined reactor and necessary supporting equipment and facilities. The requirements go up to a well equipped pilot plant with equipment up to and including a 500 gallon glasslined reactor and necessary supporting equipment and facilities. All products must be completely assayed as to identity and purity. A well instrumented analysis laboratory including an in house HPLC and adequate library facilities must be available.

All contractors must be registered with the FDA as bulk drug manufacturer and be in accordance with current good manufacturing practices. The principal investigator must be trained in organic or medicinal chemistry, preferably at the PhD level or equivalent, from an accredited school with extensive experience in chemical synthesis and process development. The principal investigator must be named and all technical personnel must be assigned to the project a minimum of 50 percent of the time, preferably 100 percent of the time.

The effort will be undertaken in multiple contracts with the effort of the various contracts varying from 3.5 to 9 staff years of effort per year. The proposal may be submitted for any one contract or for more than one contract and should clearly indicate the contract(s) for which it is being submitted. However, only one award will be made to any single organization.

Three of the contracts to be awarded shall be totally set aside for award to small business concerns. A small business concern for the purposes of this procurement is one that employs 750 employees or less.

Contracting Officer: John Palmieri
RCB, Blair Bldg. Rm. 228
301-427-8737

RFP NCI-CM-37581-09

Title: *Quality control and protocol development*
Deadline: *March 31*

NCI's Div. of Cancer Treatment, Developmental Therapeutics Program, Drug Evaluation Branch, is seeking an organization to provide assistance in quality control for rodent host tumor systems and protocol development. An organization is sought which 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 DEB 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 as historical base lines and evaluation of specific protocol procedures.

This is a level of effort of 5.5 man years per annum. It is anticipated that one incrementally funded contract will be awarded for a period of three years.

Contracting Officer: William Roberts
RCB, Blair Bldg. Rm. 228
301-427-8737

The Cancer Letter _Editor Jerry D. Boyd
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.