THE CANCER LETTER
RESEARCH EDUCATION CONTROL

Vol. 4 No. 20
May 19, 1978

P.O. BOX 2370 RESTON, VIRGINIA TELEPHONE 703-620-4646

Subscription $100 per year

MOST COMPREHENSIVE CENTERS SCORE HIGH; FEW MAY BE IN TROUBLE; DIRECTORS BACK PROGRAM

Evaluation summaries of the National Cancer Advisory Board site visits to 18 comprehensive cancer centers were released this week, wrapping up the effort by the Board and NCI to determine how well the centers are meeting the 10 characteristics for comprehensiveness established by the Board.

Most of the centers came through with good scores and will not have

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In Brief

BREAST CANCER PROJECTS TO PAY FOR CONCURRENT PATHOLOGY REVIEW; LAETRILE STUDY ENTRY CLOSED

NCI WILL PAY for a concurrent pathology review for women in the Breast Cancer Detection Demonstration Project who are diagnosed as having cancer. "We intend to push the pathology review up front," Div. of Cancer Control & Rehabilitation Director Diane Fink said. "We want to let the women know that a pathology review is available before surgery, especially for small lesions, and it will be paid for out of BCDDP funds" . . . . **TIMOTHY TALBOT**, president of the Fox Chase Cancer Center, on getting various cancer program constituents in Philadelphia to work together: "We sit in the midst of an area with six medical schools. The local ACS division is composed of medical school people. At least we've gotten in bed together. I don't know that we're making love all that well" . . . . **ENTRY INTO NCI's** retrospective laetrile study has been closed, with 220 cases where both the physician and patient agreed that the patient received the substance. Deputy Director Guy Newell said field work is under way to determine if there is any evidence the patients may have received some benefit from laetrile. The answers could form the basis for a clinical trial. . . . **ALAN RABSON**, director of NCI's Div. of Cancer Biology & Diagnosis, has received the Departmental Service Medal, the top award for PHS commissioned officers, for outstanding leadership in cancer research. . . . **STATE OF THE ART** conference in screening and early detection of colorectal cancer has been scheduled by DCCR for June 26-28 at the Bethesda Holiday Inn. The conference will review and evaluate the techniques which have been proposed for colorectal cancer screening, the experience gained in screening programs which have already been undertaken, and the information available on the influence of early detection on the effectiveness of treatment. Starts 9 a.m. each day. . . . **CANCER REHABILITATION** conference will be conducted by the Colorado Regional Cancer Center June 12 at the Univ. of Colorado School of Medicine. The conference will attempt to provide participants with an in depth view of the cancer patient and the rehabilitation process, examine personality variables in relation to treatment programs.

CENTER DIRECTORS RALLY TO DEFENSE OF COMP PROGRAM, 10 CHARACTERISTICS

(Continued from page 1)

to worry about losing their official NCI recognition as comprehensive cancer centers. Two or three centers are on thin ice, however, and in effect are on probation, although no recommendations were made for immediate withdrawal of recognition. Two of those three are the consortium centers—the Colorado Regional Cancer Center and the Illinois Cancer Council. Two others with organizational problems which will not threaten their status but which drew serious criticism were the Georgetown Univ./Howard Univ. Comprehensive Cancer Center and the Fox Chase/Univ. of Pennsylvania Comprehensive Cancer Center.

The evaluation summaries were presented Tuesday to the NCAB Subcommittee on Centers. Chairmen of the site visit teams and directors of each of the comprehensive centers were invited to the meeting.

William Terry, who took over recently as director of the Cancer Centers Program for NCI, used the occasion to challenge the entire concept of comprehensive centers and to question the value of the 10 characteristics.

"Does NCI need a mechanism for recognizing comprehensive cancer centers?" Terry asked. "Is comprehensive recognition valuable? We now have many clinical centers, some with basic science that probably are not too different from the 19 comprehensive centers (the UCLA Jonsson Comprehensive Cancer Center was not reviewed since it received its official recognition after the Board review started). What benefits have you received from being considered comprehensive?"

Terry pointed out that any center could call itself a "comprehensive cancer center" without NCI's official blessing. At least one has, in fact—the Michigan Cancer Foundation incorporated as the Michigan Comprehensive Cancer Program and has applied for official designation.

The center directors, when faced with what they felt was a threat to the concept of comprehensive cancer centers, rallied unanimously to its defense.

Terry later told ***The Cancer Letter*** that he had not set out to sell the directors on doing away with the comprehensive concept but was attempting to assess their sense of its importance. "They convinced me they perceive it as very important, which is the same as its being important," Terry said.

It was the same when Terry asked for opinions on the 10 characteristics. "That was put up or shut up," he said, referring to frequent criticism of some of the 10 by center representatives in the recent past.

"I wouldn't change a single one," said Charles Moertel, Mayo Clinic, of the characteristics. "We can work with them. We've learned to adapt to them. They're like motherhood and apple pie now."

Some directors asked that review groups and NCI staff remain flexible in applying the characteristics. But when it appeared that Terry might be leading up to asking for a recommendation for changes, they quickly moved to the defense.

"We can live with the characteristics," said David Yohn, Ohio State. "There's no reason why everyone can't strive to meet them."

Richard Steckel, UCLA, said, "I'm afraid of destroying the program by trying to save it. If the comprehensive program were dropped it would have a devastating effect on the UCLA center. The institution has committed millions of dollars, new space and new people are coming to the center, all on the basis of it being a comprehensive center. . . We need stability in the centers program now."

"When our institution decided to apply for comprehensive recognition, I opposed it because I felt we were not ready," Moertel said. "Our basic science was not worth a hoot. But the institution felt threatened by the regional aspect of comprehensive centers, and if another institution were to be designated as the regional center, it was felt that might cut into our base. As a result of that decision, all good things started happening. We got 14 top scientists, starting from zero. We were able to use the wedge as a designated center to achieve a number of goals."

"Adding comprehensive to your center's name will not gain anything," commented John Durant, Alabama. "When the local Chamber of Commerce finds out you don't have NCI designation, they will know it doesn't mean anything."

Albert Owens, Johns Hopkins, argued that the word comprehensive "now has taken on connotations of good science and human service, of congressional intent, of institutional commitment, of community commitment. How would you describe abandoning the adjective without appearing to take a giant step backward? It would be a cop out."

Terry threw to the directors the tough question of what to do about centers which give every indication they will never meet the characteristics. "And what should we do about the comprehensive center which loses its core grant, after re-application if that is what it chooses to do?"

"Bite the bullet, if it had competent review," answered Timothy Talbot, Fox Chase. His meaning was clear—withdraw recognition.

Such a policy would have its most immediate effect on the two consortium centers, Colorado and Illinois. The Illinois Cancer Council was unable to get approval for its core grant application when its planning grant expired. Colorado's review of its grant renewal was conducted recently, and ***The Cancer Letter*** has learned that the Cancer Center Support Grant Review Committee will recommend its disapproval.

Illinois has been operating since last November

without its grant, but losing its core grant could be fatal to the Colorado Regional Cancer Center. One of the major criticisms of the NCAB review team was that the Univ. of Colorado's commitment to the center was dependent upon continuation of the core grant.

If the center loses its core grant, therefore, NCI might be spared the trauma of withdrawing recognition—a pullout by the university would put the center out of business.

Steven Silverberg, director of the Colorado center, told ***The Cancer Letter*** he did not expect that to happen. "We have already corrected more than half the deficiencies the NCAB site visitors found," Silverberg said. He feels the university can be persuaded to remain in the consortium even without the core grant, and is confident other funds will be found to keep it going.

Silverberg and Jan Steiner, director of the Illinois Cancer Council, were severely critical of the Cancer Center Support Grant Review Committee site visit teams which reviewed their applications.

"I would go along with biting the bullet if the review is compete," Steiner said. "The emphasis has been too much on science and not enough on regional capabilities. It could happen, that centers will go down the drain because of inappropriate review. We need center directors involved in the review process."

Silverberg said CCSG site visitors displayed little interest in the center and appeared more concerned with the science programs at the university. Steiner and Silverberg made the point that reviewers fail to appreciate the nature and value of a consortium as a focal point for creating multidisciplinary clinical care and basic research conducted by several institutions into programs that reach into community hospitals throughout a region.

The NCAB reviewers were aware of those situations but remained critical of both Colorado and Illinois centers. Following are overviews on each, as presented in the evaluation summaries (edited to conserve space):

The Colorado Regional Cancer Center Inc (CRCC) is a consortiun of 33 member institutions, agencies, and hospitals, including the Univ. of Colorado Medical Center (UCMC), the Univ. of Colorado at Boulder, the Colorado State Univ., the Colorado Div. of the American Cancer Society, the Colorado State Dept. of Health, and 28 community hospitals within a six-state region. The management of the consortium is headquartered at UCMC, where the director of the CRCC, Dr. Steven Silverberg, has his academic appointment. The major basic and clinical resources are housed at UCMC, including the majority of the peer-reviewed, funded programs for the CRCC.

Operationally, the center is still in the developing state and must be categorized as an emerging organization. Although there is potential for this community-oriented regional comprehensive cancer center, it has yet to be realized. The difficulties inherent in defining and delineating programmatic activities and establishing working relationships with participating members of the consortium make it imperative that certain organizational prerequisites be fulfilled:

1. The role of UCMC in this consortium, i.e., whether the CRCC's gravitation toward greater involvement, and hence control, by the Univ. of Colorado Medical School, will continue, and if so, how should the center be established within the framework of the UCMC.

2. Whether the participating institutions will be represented in the CRCC's management of activities and goals.

3. Whether the consortium can develop a quality control mechanism, capable of review and evaluation of CRCC programs.

Although Dr. Silverberg has been in office slightly more than a year, it is clear that he is committed to directing the center. He and his associates are fully cognizant of the constraints caused by the complications of center organization definition for the consortium arrangement, the question over the role of UCMC, and the lack of sustained leadership over the past several years.

The core budget for this center is about $300,000 per year. This is a major portion of the support for the CRCC. Therefore, it is of concern that the center trustees have not taken steps to provide additional funds. Fund raising efforts are being programmed, but largely for construction purposes.

A major advantage of the consortium concept is the potential for developing effective outreach programs involving community hospitals and other agencies. CCRC is developing an outreach program involving a large number of community hospitals in a vast geographical region of the western United States. The program has enormous potential for improved impact on the health delivery system for the cancer patient in this region. However, there is concern about the program planning and organizational structuring for a program in cancer control.

The CRCC has progressed slowly in its clinical activities within various affiliated hospitals, and although they have had some success in motivating these hospitals toward working on the cancer problem in a coordinated manner and have planned efforts for future programs, many deficiencies exist, particularly in clinical research.

In basic science, the CRCC can be very proud of the quality of the basic science programs at the affiliated participating institutions, particularly the program led by Dr. Ernest Borek. Because the program in basic oncology exists at UCMC, it is questionable that the CRCC will be able to impact on the program in any significant way. The CRCC has not yet developed an administrative structure to direct or coordinate the basic oncology program, nor do they contribute financially to the program. There is con-

cern over the fact that Dr. Borek is planning to retire in the next few years, and the question evolves as to what role UCMC will have in the CRCC's basic science program after his retirement.

The epidemiological and statistical activities at the CRCC are excellent and have good potential for future development. The staff is considered to be well trained, talented, and strong in their areas of expertise. It has been recommended, however, that a biostatistician be recruited to complement the fine efforts of Dr. John Berg.

Training and education efforts are weak at the CRCC. Although ther is much excellence and quality in the various programs within the affiliated institutions, few of their accomplishments can be attributed to the CRCC. The CRCC needs leadership in order to develop and coordinate the various isolated training and education efforts within the UCMC and other institutions.

As to the center's involvement in the National Cancer Program, it is agreed that the CRCC is committed to serving the region as a demonstration facility. The center has many agreements with other institutions in the area as well as with other cancer centers, and there are notable examples of individual contributions. However, the lack of sustained leadership in recent years and the embryonic status of the center has not allowed the CRCC to become involved with the National Cancer Program as much as some other comprehensive cancer centers. They have evidenced a strong commitment to focus their efforts on becoming heavily involved in the future.

Due to the embryonic status of the CRCC and its serious deficiencies in several areas, it is recommended that this center be reviewed again within two years.

The Illinois Cancer Council (ICC) is not based at a single institution but comprises a number of institutions throughout Illinois with major contributions from four medical schools in Chicago. These are the Univ. of Illinois School of Medicine, Rush-Presbyterian Medical Center, Northwestern Medical School and the Univ. of Chicago Medical Center. This consortium is clearly quite different from most other comprehensive cancer centers in that specific control of cancer patients, and most of the programs, space and finances are totally or largely outside of the influence and control of the director of the ICC. Basically the center consists of a loos confederation of medical schools and other institutions, several of which have specialized cancer centers with cancer center core grants. The headquarters of the ICC appears to control or regulate in some manner certain components essential to a comprehensive center such as the cancer patient data base and has grants and contracts in cancer control, education, and cooperative group studies.

The ICC consortial model appears entirely appropriate to the region, its need and institutions. The ICC has demonstrated substantive progress in meeting its stated major goals of two years ago: recruitment of an effective, dedicated director and evolution of a meaningful administrative structure. The consortium's major programmatic achievements to date are almost exclusively in the EPI/STAT and cancer control arenas, activities which are, in fact, those most appropriate to its mission. The impact of the ICC in other areas has been minimal or non-existent.

Despite this record of partial achievement and progress, several serious problems cloud the horizon of the ICC. Most important of these are the failure to define the director's tenure and personal appointment, the director's conditional, part-time acceptance of his directorship, and the emergent conflict situation with the American Cancer Society. Concern over these problems was tempered substantially by the director's lucid statement of his goals and priorities, by the clear and unequivocal support of the directors of the specialized cancer centers, and by the confidence of the director and his major advisors that these problems could and would be equitably resolved.

Thus, despite the significant weaknesses identified, the ICC has made major progress toward establishing and implementing a viable consortial model for the state of Illinois and continued recognition of the ICC as a comprehensive cancer center is justified.

Summary overviews of the other comprehensive centers produced in the evaluation will appear in subsequent issues of ***The Cancer Letter.***

MILLERS SHARE BRISTOL-MYERS AWARD FOR DISTINGUISHED CANCER RESEARCH

Elizabeth and James Miller, professors of oncology at the Univ. of Wisconsin's McArdle Laboratory, won the first Bristol-Myers Award for Distinguished Achievement in Cancer Research. The award, a $25,000 prize, was presented by Richard Gelb, chairman and chief executive officer of Bristol-Myers, at a luncheon this week in New York.

The Millers, who have done pioneering research in chemical carcinogenesis, were selected by a five member panel of judges from cancer research centers at Baylor, Chicago, Johns Hopkins, Stanford and Yale. Each of those schools participates in a $2.5 million grant program funded by Bristol-Myers to promote unrestricted, innovative cancer research. John Ultmann, director of the Univ. of Chicago Cancer Research Center, was chairman of the selection panel. Other members of the panel were Harris Busch, Baylor; Albert Owens, Johns Hopkins; Saul Rosenberg, Stanford; and Alan Sartorelli, Yale.

CLEARINGHOUSE REVIEWS BACKLOG, FINDS CAUSES, REPORTS ON PROGRAM'S VALUE

The Clearinghouse on Environmental Carcinogens, reporting on a review of how the bioassay backlog developed in Carcinogenesis Testing Program and the

current status of the program, concluded that chief among the factors was an abrupt increase in the number of bioassays started in 1971-73, inadequate management by NCI of contractors performing the bioassays, lack of adequate contractual reporting requirements, and minimal responsiveness on the part of some contractors.

The Clearinghouse review, requested by Director Arthur Upton, detailed the buildup of 207 chemicals on which the bioassays were completed but not reported before July 15, 1976. The backlog became a matter of acute embarrassment to NCI, was the subject of congressional hearings, and played a role in the dismissal of former Div. of Cancer Cause & Prevention Director James Peters.

"A plan to dispose of the backlog did not anticipate the problems which were encountered, but provided a mechanism which has become efficient for gathering and verifying data and writing reports," the Clearinghouse report summarized. The personnel and management plan now in operation are satisfactory. The current program should allay the development of future backlogs. Additional personnel are recommended for the program in the areas related to data analysis and contractor monitoring.

"The quality of the studies has varied, largely due to the reasons cited above for development of the backlog. The studies were intended to provide yes/no answers on carcinogenicity at maximum tolerated doses and MTD/2. For the most part, they have provided such answers. The reports have been of considerable value to the regulatory agencies."

Although the regulatory agencies told the Clearinghouse Executive Subgroup, which conducted the review, that the bioassay reports have been of considerable value in a general sense, they also said the reports have not been much help in assessing human risk. The Subgroup's draft report contained language which said the backlog reports "provided little help" in that regard.

Clearinghouse member Michael Shimkin pointed out the inconsistency and succeeded in changing the language to "provided limited help," despite Chairman Arnold Brown's statement that "They told us the reports were of little help. Little help means not much help. Limited help means some help."

The Clearinghouse report offered these conclusions and recommendations:

- The backlog studies were designed and conducted to provide a yes/no answer to the question of a compound's carcinogenicity. Their success has been variable in this regard due, in large part, to the lack of a formal bioassay protocol and control system. Greater confidence can be expected in data generated under current protocols and conditions of test, although equivocal results may still be anticipated due to the vagaries of bioassay and to the test chemical's activity. It is concluded that the bioassay data do have value when properly evaluated with respect to conditions of test and biological and statistical considerations.
- While the regulatory agencies appear to value and use the bioassay reports, they have differing concepts of the type of carcinogenicity data of most immediate need to them.
- Estimates of human risk of carcinogens would be useful to the regulatory agencies, though the backlog reports provide limited help in this regard. It is concluded that, at this time, in depth risk assessments are not feasible as a function of the Carcinogenesis Testing Program.
- It is recommended that (a) the present efforts by the Program to expand the design of bioassays to include additional observations, particularly as they may be of use in risk assessment, be continued and expanded, (b) the suggestions made by the NCI statistics group, with respect to changes in bioassay reports, be given due consideration, (c) the good rapport now apparent between the regulatory agencies and the Program be maintained in order that NCI can continue to provide data useful to those agencies, (d) the Program consider the needs and feasibility for risk assessment.

The Executive Subgroup collected the views of the Program staff, the regulatory agencies and Clearinghouse members in writing an assessment of the utilization of bioassay data.

"The Program staff stated one way of viewing the usefulness of the bioassay data is in terms of their impact on the regulatory agencies. Regulatory actions have resulted or are under consideration as a result of data generated in bioassays sponsored by the Program. It was pointed out that whenever there is an indication that a compound may be carcinogenic, the relevant regulatory agencies are notified and the preliminary results made available to them.

"One NCI group commented on the statistics used to evaluate bioassay data. In general, the Clearinghouse agrees with those suggestions made with respect to changes in the bioassay reports.

"Some concern about the meaningfulness of the animal data for humans was expressed. It is clearly too early to determine whether action based on results of the bioassay studies will lead to a lessening in human cancer mortality or morbidity. However, it was agreed that the prudent approach is to consider relevant animal data as predictive of possible public health problems.

"The Program staff felt that not all future bioassays should be focused on the production of data for regulatory use. It was their opinion that a defined percentage of the Program's resources should be committed for the development of new and improved testing methods. In this regard, the Clearinghouse concurs with the Program staff. Areas identified by the Program as requiring investigation include the predictability of carcinogenicity from short term in vivo and in vitro prescreening tests; protocols to

detect tumor promoters and other modifying agents affecting carcinogenesis; and ways in which environmental chemicals can be more systematically selected for bioassay."

Executive Subgroup members had extensive discussions with representatives of the Food & Drug Administration, Environmental Protection Agency and Consumer Product Safety Commission. They also had a short meeting with a representative of the Occupational Safety & Health Administration.

"There was general agreement that the bioassay reports, so far released on the backlog studies, have been useful to the regulatory agencies. It was stated that the critiques provided by the Clearinghouse Data Evaluation/Risk Assessment Subgroup were helpful in evaluating the studies and gave the regulatory agencies additional confidence in their consideration of the reports. "The view was expressed that additional sections could make the bioassay reports more useful to the regulatory agencies. It was pointed out that the agencies frequently communicate with the Program staff to determine the adequacy of the experimental conditions and contractor performance. Although the assessment is difficult to communicate in the reports, it was suggested that more specifics in these matters would be helpful. It also was suggested that a statement on the implications for human risk should be included in reports on compounds found to be carcinogenic."

(Ed. note: Clearinghouse members discussed at length the question that has confronted them since the body was established two years ago: How far should NCI and the Clearinghouse go in attempting to determine risk assessment, and should that even be considered as one of their responsibilities? The following sentence was agreed upon, although some minor changes in the language may be made.)

"Clearinghouse Executive Subgroup members and agency representatives agreed that risk assessment is within the purview of NCI but that application of risk assessment is the responsibility of the various regulatory agencies.

"The problems involved in an additional bioassay of a compound that had already been tested once was discussed. It was agreed that the present Program structure was adequate for considering such situations. However, if an agency requested further testing it was incumbent upon it to indicate the type of information now required of the study.

"The representatives of the agencies disagreed as to whether the present bioassay protocol was adequate. FDA and CPSC representatives argued that more dose response information was highly desirable. The EPA representative stated satisfaction with the present level of information."

Views of Clearinghouse members:

"The Clearinghouse Executive Subgroup considered that one approach for assessing the value of bioassay data might be based on the power of a study to detect a carcinogen. As a result, a member of the Field Studies & Statistics Section was enlisted to assist the Subgroup in regard to data generated under the experimental design used in backlog studies. Since no single experimental design typified these studies, as a model, a control group size of 20 and a treatment group size of 35 were chosen. Nine tissues were selected on which power calculations were to be based.

"The evaluation clearly shows that relatively large increases over the spontaneous tumor incidence must occur in the treated animals before an acceptable level of sensitivity is achieved. The increase need not be as large, however, if it occurs in more than one sex or strain. Based on this evaluation, the Clearinghouse Executive Subgroup concludes that, given the limited sensitivity of bioassays conducted under past protocols, 1) the meaningfulness of negative data must be viewed with even greater caution than such data generated under current protocols, and 2) the meaningfulness of positive data takes on greater significance with respect to the confidence that a carcinogenic response was detected."

Critique by Clearinghouse Executive Subgroup:

"Any assessment of the value of bioassay data is dependent upon whether such data answers the questions being asked. There is general agreement that the single question being asked of the bioassay studies is whether a compound is carcinogenic in the test system. For operational purposes, a carcinogen is a material which significantly increases the incidence of tumors in exposed groups above that in controls.

"The Clearinghouse has found the value of past studies quite variable, ranging from entirely useless to entirely adequate. Past bioassays, subject to many uncertainties and degrees of performance, must be individually judged after thorough examination of its strengths and weaknesses. Bioassay data presently being generated, under revised protocols and monitoring conditions, will have a greatly increased level of confidence over those data from past studies. It must be noted, however, that certain chemicals will produce only 'borderline' results given the nature and sensitivity of the bioassay system. It may be expected that the value of the bioassay data will continue to increase as refinements of experimental design are introduced. These may include a wider exploration of other routes of administration; greater utilization of in vitro testing data; systematic development and use of metabolic and pharmacokinetic studies; and investigation of dose-response relationships."

The report detailed reasons for the backlog buildup.

"A number of factors contributed directly to or exacerbated the development of the backlog. In 1971 the National Cancer Act was passed which provided

the impetus and financial resources to expand research into all aspects of cancer. At approximately the same time, an increased awareness of the environmental etiology of cancer and the availability of greater resources resulted in a stimulus to identify chemical carcinogens to which humans were exposed. Finally, the lack of federal legislation, with respect to the testing of environmental chemicals for carcinogenicity, meant that the burden for such studies fell to the government and, in particular, to NCI.

"Given the above circumstances, the extramural Bioassay Segment of the NCI Carcinogenesis Program was authorized to initiate a number of contracts to investigate the carcinogenicity of environmental chemicals in large-scale, long-term bioassay.

"The contract awards resulted in chronic bioassays being started on a large number of chemicals from the latter part of 1971 through most of 1973, with the majority being placed on test during mid-1972. As a consequence, the bioassay activities became not only a major effort in itself, but also the focal point for carcinogenicity data on which the regulatory agencies could base their actions. In 1973, in recognition of the importance of the bioassay effort and the workload it was creating, the Bioassay Segment was split into a Metabolism & Toxicology Segment and a Bioassay Operations Segment.

"A review was undertaken by the branch to evaluate the bioassay protocols and procedures and to formalize them whenever practical. An outcome of the review was the establishment of a formal pathology procedure. It required that some 32 tissues from every control and treated animal be examined histopathologically. Previously, a more limited number of tissues were examined and, depending upon the findings, all the treated animal groups may or may not have been subjected to histopathology.

"The expanded pathology procotol coupled with the termination of the chronic studies over a relatively short time period resulted in a massive pathology backlog. The situation was exacerbated by the limited number of qualified pathologists, inconsistencies in pathological interpretation and in nomenclature, and associated logistical problems. At the same time, demands were placed on contractors for the formal submission of data into a computerized storage system and for their active participation in preparing reports. Until then, contractual provisions had not been made with respect to reporting requirements. As a result, significant delays were encountered in locating data and ensuring their integrity. The problem was compounded by changes in personnel and the intervening time between the generation of the data and their later use in developing reports. These factors culminated in a workload that far exceeded the capacity of the system to handle within a reasonable time frame. As a result, the backlog was created.

"In summary, the creation of the backlog was a result of a combination of factors. Chief among these was the initiation of a large number of bioassays within a relatively short time span, lack of an adequately planned and staffed program, implementation of expanded pathology requirements, and establishment of formal reporting procedures."

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 of Contract Specialist for copies of the RFP, citing the RFP number. Some listings will show the phone number of the Contract Specialist, who will respond to questions. Listings identify the respective sections of the Research Contracts Branch which are issuing the RFPs. Their addresses, all followed by NIH, Bethesda, Md. 20014, are:
Biology & Diagnosis Section — Landow Building
Viral Oncology & Field Studies Section — Landow Building
Control & Rehabilitation Section — Blair Building
Carcinogenesis Section — Blair Building
Treatment Section — Blair Building
Office of the Director Section — Blair Building
Deadline date shown for each listing is the final day for receipt of the completed proposal unless otherwise indicated.

RFP NCI-CP-FS-81038-65

Title: *Epidemiological studies of lung cancer in communities with nonferrous smelters*
Deadline: *June 19*

The Environmental Epidemiology Branch of NCI in conjunction with the Environmental Protection Agency, plans to conduct a case-control interview study in Pennsylvania counties in the vicinity of a nonferrous zinc smelter.

This investigation is designed to assess the roles of occupation, environment, and tobacco consumption in relation to the high lung cancer rates in these counties.

This will be accomplished through personal interviews of the next-of-kin of persons who died of lung cancer (cases) during the years 1974-77, and of persons who died of other causes (controls) during that same period. Controls will include other cancers and non-cancers (lung-related diseases will be excluded). Approximately 1,000 death certificates will be abstracted to elicit identifying information and cause of death for each case and control.

Contractor will function in a purely supportive role assisting in the establishment, administration and conduct of this field study which was designed by the Environmental Epidemiology Branch in association with EPA. Contractor must have:

(1) Its established offices and technical equipment in one of three Pennsylvania counties, Carbon, Lehigh or Northampton.

(2) Expertise in conducting interview studies through personal face-to-face interviews. Experience with telephone and mail questionnaires is not acceptable as a substitute.

(3) Support services including a project director (5-20% time), a full-time field supervisor, 42-person months of working time for locally hired medical abstractors and interviewers, a computer programmer/analyst (25% time) with experience in epidemiologic studies or equivalent, and a half-time secretary with experience in typing scientific reports. Computer facilities are necessary. However, the contractor may subcontract for such services.

Contracting Officer: Sydney Jones
Viral Oncology & Field Studies
301-496-1781

RFP NCI-CP-FS-81036-65

Title: *Cancer in Southern Louisiana: A case-control study of lung, pancreas, and stomach cancers*

Deadline: *June 19*

The Environmental Epidemiology Branch of NCI, in conjunction with the Environmental Protection Agency, is planning a case-control interview study of environmental determinants of lung, pancreas, and stomach cancers in southern Louisiana. This will be an investigation into several variables that may explain the high incidence rates of lung cancer, pancreatic cancer among whites, and stomach cancer among blacks in this area. These variables will include occupational, dietary, and ethnic factors, in addition to possible community exposures to environmental agents. Only one contract award will be made.

The contractor shall serve primarily as a field-operating research/service collaboratory on in-house studies undertaken and designed by the Environmental Epidemiology Branch in association with EPA, with data processing services as required. The contractor must have:

(1) Offices permanently based in the state of Louisiana, and established and in operation at the time of this advertisement. There will be no exception to this requirement, therefore organizations permanently based outside the state of Louisiana should not reply, as they will not be considered.

(2) Expertise in conducting stratified case-control interview studies. The present study will involve an estimated 3,000 interviews in the field through personal face-to-face interviews. Experience with telephone and mail questionnaires is not acceptable as a substitute.

(3) Support services including experienced interviewers (a minimum of 4), a full-time management specialist for field supervision of interviewing and abstracting, computer facilities, and data processing personnel with experience in epidemiologic studies. The contractor may subcontract for field interviewing services in the western parishes, if he so desires.

(4) An established ongoing close working relationship with state and local health officials and the medical community to ensure accurate identification of cases (incident cases, if possible) and selection of controls.

(5) Close familiarity with the population of southern Louisiana so that the contractor might assist in the detailed design of this study.

Among other duties, the potential collaborator is expected to assist in the design phase of the project; identify appropriate cancer cases and controls, and obtain informed consent for interviews from the patients, their physicians, and hospitals; interview subjects utilizing an approved detailed Field Studies questionnaire; gather data from medical records as required; assign personnel anywhere in southern Louisiana for long or short periods as applicable for the purpose of conducting their interviews or abstracting; computerize and summarize the data in order to permit detailed analyses of such data.

Contracting Officer: Sydney Jones
Viral Oncology & Field Studies
301-496-1781

RFP NCI-CP-VO-81040-60

Title: *Retroviral expression during primate carcinogenesis*

Deadline: *June 23*

NCI will make available to interested contractors a request for proposal for studying retroviral expression during primate carcinogenesis. This project will focus on the utilization of primate cell model systems to determine cellular control of integration and expression of these sequences and on identification and characterization of retrovirus-related molecules in human tissues.

Specific experience in the following areas is required: (1) Purification and characterization of probes for retroviral information in cells; (2) In vitro culture of primate tissues; characterization of cell cultures; (3) Nucleic acid hybridization assays; (4) Reverse transcriptase assays; (5) Protein purification and characterization; (6) Detection of integrated proviral genomes in cellular genome; (7) Detection of viral mRNA in cells; (8) Detection of retrovirus proteins in cells; and (9) Systems for detection of cellular control of virogene expression.

Contracting Officer: Charles Fafard
Viral Oncology & Field Studies
301-496-1781

The Cancer Letter —*Editor* JERRY D. BOYD

Published fifty times a year by The Cancer Letter, Inc., P.O. Box 2370, Reston, Virginia 22090.