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

Senate Appropriations Includes Cancer Control, Training Money, But Very Little For Construction

The Senate Appropriations Committee has approved nearly $1.6 billion for NCI's 1989 fiscal year budget, an increase of $104 million over the amount in the House appropriations bill which isn't really an increase at all. The amount is about $122 million more than NCI's spending level this year.

(Continued to page 2)

In Brief

DeVita Wins $150,000 Pezcoller Prize; BreastPac To "Storm" Capitol On Bastille Day For More $$

VINCENT DEVITA has been named winner of the first Pezcoller Foundation Award, a $150,000 prize, in recognition of his "innovative work on the curative chemotherapy of lymphoma as well as the overall stimulus and leadership he has given to the field of oncology." He will receive the prize Sept. 10 in Trento, Italy. The Pezcoller Foundation, established this year by Alessio Pezcoller, will recognize outstanding contributions of oncologists every three years. . . . **B.J. KENNEDY** has been awarded a Regent's Professorship by the Univ. of Minnesota, the highest recognition of excellence given by the university to faculty members. . . . **NANCY REAGAN** has been named national recipient of the 1988 Betty Ford Award, presented by the Susan G. Komen Foundation. Nancy Brinker, chairman and founder of the organization, said that the first lady's "quick response and prudent action in dealing with her own illness has contributed immeasurably in educating women throughout the country about the problem of breast cancer and the possible treatment options". . . . **BASTILLE DAY**, July 14, has been selected by Rose Kushner's new political action committee, BreastPac, as the day "to storm the barricades for more money for breast cancer research." The "storm" will take place at the lower west terrace of the Capitol, from 10:30-11:30 a.m. BreastPac is attempting to raise money to help elect candidates who fight for breast cancer research funds. Kushner points out that with 135,000 new cases and 42,300 deaths estimated for this year, the government is spending only $50 for each new case. . . . **BEVERLY NIELSEN**, director of the Oncology Nursing Education Center at the Univ. of Miami School of Nursing, has succeeded Roberta Scofield as president of the Oncology Nursing Certification Corp. **Ellyn Bushkin**, clinical nursing director at Mount Sinai Medical Center in New York, succeeds Connie Yarbro as chairwoman of the foundation's board.

Senate, House Totals Nearly Identical With Cancer Control, Training Included

(Continued from page 1)

The specific amount in the Senate bill is $1,593,536,000. The amount approved by the House was $1,489,897,000, but that did not include any money for cancer control or training. The House position is that those programs have not yet been reauthorized for the next fiscal year; the Senate ignores that point.

The Senate has approved reauthorization, including renewal of the National Cancer Act. The House has not yet acted on reauthorization.

The House also did not include any money for research facilities construction and renovation. The Senate reauthorization bill contains a provision establishing NIH wide extramural construction support as well as continuing the separate construction authorities of NCI and a couple of other institutes.

The Senate Appropriations Committee in the report on its bill specifies that $2.5 million of NCI's appropriations be transferred to the NIH "buildings and facilities account" for renovations at the Frederick Cancer Research Facility. That action apparently was in response to NCI Director Vincent DeVita's complaints that without construction money, NCI could not proceed with development of laboratory and other space at FCRF.

The Administration's request for NCI included $71.3 million for cancer control and $32.4 million for training. The Senate committee report directs that $75 million of the NCI total be allocated to cancer control. Training is not mentioned, but adding the Administration's request to the Senate's cancer control figure, and deducting the $2.5 million for FCRF renovation, amounts to the total in the Senate bill over the House total.

That means that the Senate and House are virtually in agreement on the NCI total. It is not likely that that amount will be increased in the Senate-House conference which will follow the Senate's approval of the bill.

It appears that for the second year in a row, NCI will not be able to support any extramural construction or renovation.

If any facilities support is available at all, it will have to come through the provisions in the Senate reauthorization bill. Whether that would result in a separate allocation for NCI remains to be seen. An NIH-wide program probably could not be organized, implemented and funded during the next fiscal year, even if the House goes along with it.

For the present at least, NCI's highly successful and effective construction program is dead.

The Senate committee expressed concerns about progress in cancer prevention and control.

"The committee has heard much discussion about how one measures the success of the cancer program, whether incidence, survival or mortality is the best indicator," the report says. "It is important that whenever the data are reviewed, that the increase in population size be considered. For example, when looking at mortality statistics comparing 1950 and 1985, the absolute number of deaths has increased. However, excluding lung cancer, there has been a decrease of almost 45,000 deaths in 1985 from what was predicted to occur based on 1950 rates. Clearly, progress has been significant. However, it is recognized that even if the goal to reduce cancer mortality by 50 percent is achieved, the delining mortality from heart disease will move cancer ahead to the No. 1 cause of death.

"The committee is troubled, however, by the findings of a recent General Accounting Office report entitled 'Application of Breakthrough Therapies.' This report noted that up to two thirds of cancer patients are not getting state of the art treatment [Ed. note: That GAO report and its conclusions have been severely criticized for alleged deficiencies in its methodology and interpretation].

"To complement these findings," the Senate report continues, "The department's year 2000 goal indicated that we could reduce the cancer death rate by 50 percent by (1) reducing the rate of smoking, (2) improving the American diet, (3) better screening and early detection and (4) use of state of the art treatments. The committee is well pleased with the quality of research supported by NCI and the progress being made with this research. Nevertheless, in view of the fact that existing knowledge is not being fully applied and that with the better application of this knowledge we could reduce the cancer death rate by 50 percent, the committee is troubled by the relatively small amount of funding devoted to the Cancer Prevention and Control Program. The committee has, therefore, added language to require that at least $75 million be spent on this program next year.

"Finally, the committee requests that a report be prepared and submitted to the committee outlining the best professional judgment as to what funding and programs neeed to be put in place to maximize Cancer Prevention and Control Program outcomes. This report should be submitted to the committee by Feb. 1, 1989 [Ed. note: That information appears every year in NCI's bypass budget].

"The relationship between health and behavior is quite clear. Critical to cancer control are smoking, diet and nutrition, and cancer screening--all behavioral elements. In furthering the year 2000 goals the committee believes that greater attention should be paid to human behavior and how the behavior variables are critical to the prevention and treatment of cancer. **Accordingly, the committee urges NCI to direct a greater proportion of its funds to health and behavior research this fiscal year."**

After mentioning progress being made in various areas through basic research, and setting out a few directives in treatment programs, the report returns to application.

"The current dilemma facing the institute and the nation is that many state of the art treatments are not being utilized or received. For instance, it is known that if every woman over the age of 50 had an annual mammogram, mortality from breast cancer could be reduced by 30 percent, thereby saving 15,000 lives. The initiation of the physician data query (PDQ), a computerized information system established to disseminate state of the art information in cancer treatment is a major step in the dissemination of these findings and treatments.

"In addition to PDQ, the NCI network also includes an expanded comprehensive Cancer Centers Program, a nationwide clinical trials program, the Surveillance, Epidemiology and End Results Program (SEER) that collects data on cancer incidence and survival, and the Cancer Information Service which provides a toll free number that handles up to 400,000 patient calls annually to provide the latest cancer information to the general public. The mechanisms of education and treatment are in place. The challenge is for full and maximal utilization."

The report emphasizes biologics in the section on treatment.

"The committee is aware of increasing interest in biologics as a form of cancer therapy because of some of the very early and preliminary findings from several studies conducted by NCI as well as independent research facilities. However, the committee recognizes that biologics are in their infancy in terms of development and urges NCI to stregthen its programs in this area. The committee also urges NCI to continue clinical research opportunities in the area of biologics and evaluation of their potential in the management of cancer.

"The development of biologics has revolutionized the scope of cancer treatment. Since 1979, when the Biological Response Modifiers Program was established, over 35 biologics have been identified with potential for cancer treatment. Two biologics that have proven to be effective against several of the more resistant cancers are interferon and interleukin-2. Another important development during the past year was the introduction of colony stimulating factors (CSFs) into clinical trials. CSFs are bone marrow growth factors that are now produced in quantity by molecular biologic techniques and are found to be effective in reducing the toxic and sometimes life threatening side effects of chemotherapy.

"In the last year new treatments have been developed for two of the most resistant cancers, bladder cancer and colon cancer. With the addition of these two new therapies, a treatment program that reduces mortality within the study population is available for every common cancer, with the exception of pancreatic and liver cancer. In addition to saving and prolonging lives, treatments today are more tolerable and less morbid, thus enhancing the quality of life. Equal or better survival results now exist in cancers such as breast, colon, bone and soft tissue sarcomas, while preserving breasts, avoiding colostomies, and sparing limbs."

The committee acknowledged NCI's decision to develop a treatment program at a Dept. of Energy facility in Idaho. The decision was made in part, at least, as the result of congressional pressure (**The Cancer Letter**, July 1).

"NCI is encouraged to consider the potential of the power burst facility reactor at the Idaho Nuclear Engineering Laboratory (INEL) in the treatment of cancer. Neutrons from this reactor are used in a form of radiation therapy known as boron neutron capture therapy (BNCT) which unlike more conventional therapies, does not risk damage to normal tissues.

"The committee urges NCI to continue working with, and giving guidance to, INEL. In particular, the committee urges NCI to identify

what types of clinical trials NCI believes INEL could participate in. The committee was pleased that NCI has acknowledged the uniqueness of the PBF and that NCI maintains supporting the PBF in a standby phase."

The Senate report expressed in language almost identical to that in the House Appropriations Committee report interest in diagnostic imaging techniques. It urged NCI to use "a portion of the increased funding to expand its support of research in the field of diagnostic radiology."

In the section of the report dealing with NIH as a whole, the committee called for creating of a Diagnostic Radiology Coordinating Committee "which will be responsible for coordinating ongoing research, as well as to develop an NIH wide long range rsearch plan for diagnostic radiology. The committee requests that it be advised as to the disposition of this matter by Feb. 1, 1989."

All NIH diagnostic imaging research grants were moved into NCI's Radiation Research Program several years ago.

The Senate report mentions problems with clinical trials.

"Clinical research which permits the evaluation of new therapies is a vital element of the Cancer Research Program. However, several difficulties are emerging in the pattern of clinical research which may hamper these valuable studies. For example, there is increasing difficulty in recruiting patients for these trials; additionally, because research patients frequently are more seriously ill than others who might be hospitalized for the same illness, appropriate and needed care for them tends to be more expensive. Currently this additional cost is not reimbursed by research grants, and frequently is also not reimbursed by third party insurance carriers. The committee therefore asks NCI to evaluate the seriousness of these difficulties and to report to the committee, prior to next year's hearings, as to what remedies might be available and the costs involved."

ONS Clout Seen

Oncology nursing was a concern of the committee, reflecting efforts by the Oncology Nursing Society to take their case to Congress.

"The committee again urges NCI to continue its systematic efforts to ensure that professional nurses are actively involved in the programs, advisory boards and committees of NCI [one of ONS' chief lobbying concerns]. The committee further reiterates its support for NCI giving priority to the nursing oncology individual research fellowship award program, the nursing clinical training programs, and the implementation of nursing research initiatives. The committee was especially pleased to note that the NCI Nurse Oncology Training Program which began in 1985 has already doubled the number of baccalaureate nurses who are involved in oncology. The committee requests that NCI and the National Center for Nursing Research submit a joint report, prior to next year's hearings, describing those projects and initiatives which have been supported in the nursing oncology area."

Although the Senate committee did not direct that additional money over the Administration's request go into the Cancer Centers Program, it did lay some groundwork for that next year.

"The committee has heard an ever increasing series of complaints regarding the relative small [this year, about $103 million] allocation of funds to cancer centers. The committee intends to explore this issue thoroughly with NIH and NCI personnel in the upcoming months and focus on the question at hearings next year. Furthermore the committee requests NIH to contract with the Institute of Medicine to undertake a study, to be completed for the committee hearings next yhear, which will report on the present state of the Cancer Centers Program on its funding and organizational needs required to fulfill the role established for cancer centers in the 1971 National Cancer Act. **The committee expects that the Assn. of American Cancer Institutes be consulted during the process of this study."**

The Senate bill has $7.199 billion for NIH, an increase of $321 million over the House figure, but the committee pointed out that the House bill did not include that same amount for unauthorized items.

The Senate added $31 million for NIH AIDS research, and the committee specifically rejected the Administration's request that all Dept. of Health & Human Services AIDS funds go through the assistant secretary for health. Unlike the House, however, the Senate did not allocate specific sums of AIDS money to the institutes, at least not as shown in report.

Other items related to NIH overall, with implications for NCI, included:

NIH staffing--"The committee continues to be very concerned about the reduction in full time equivalent staff positions below the levels cited in report language. Therefore, for the

third year in a row, the committee has included bill language specifying a minimum range of FTEs to be allocated for the dollars appropriated for the programs and agencies in HHS.

[Bill language does have the force of law; the committee reports do not, although agencies generally try to comply with them, especially if the same directives appear in both House and Senate reports].

"The committee was particularly alarmed to learn that a lack of staff has delayed AIDS drug clinical trials. To ensure appropriate staffing levels for these trials and other AIDS related activities, the committee has specified a separate FTE number for AIDS related activities. Include in the AIDS related FTE number is an increase of 200 positions for AIDS research conducted at NIH."

Funding priorities--"The committee continues to give the highest priority to the support of investigator initiated research project grants and requests that the director balance the competing goals of maintaining the highest possible number of grants with the interest of limiting the amount of downward negotiations.

Spending Directives Minimized

"Beyond expressing its specific directions with respect to numbers of grants and policies on downward negotiations, the committee has attempted to minimize its directions to the institutes regarding the specific allocations related to individual diseases or research mechanisms. It is the committee's view that these decisions are best made by the scientists and science managers at NIH based on the quality of the opportunities as they present themselves during the year. Based on the testimony of the NIH director, however, the committee believes that the amount recommended is sufficient to support approximately 11,600 research trainees and to provide for approximately 580 research centers. Furthermore, the committee expects approximately $56.8 million to be available for the Biomedical Research Support Program and that approximately $28 million will be available for major new clinical trials."

Gene mapping--"The committee has approved the NIH request for $28 million for the gene mapping program in fiscal year 1989, an increase of $10.5 million or 60 percent over the $17.5 million provided in fiscal year 1988. An NIH sponsored conference earlier this year suggested that this amount should increase each year up to $200 million a year for 15 years, for a $3 billion effort. In some quarters this effort has been hailed as the Manhattan project of the life sciences.

"Gene maps that scientists are just beginning to construct could become one of the most important scientific tools ever created. The many and varied efforts under way to advance gene mapping, and America's ability to take advantage of the research, have created complex issues that the scientific community, industry, Congress and our society at large must sort out.

"In order to address these issues, and also to ensure that the Federal effort is coordinated, NIH is directed to establish a Human Genome Advisory Panel.

"The committee feels strongly that the advisory panel should be appointed as quickly as possible. Recent reports from the Office of Technology Assessment and the National Research Council strongly support the development of genetic and physical maps of the full human genome, leading to the complete sequencing of the genome. Those reports point out the extensive activities in this area on the part of NIH, the Dept. of Energy, the National Science Foundation and other agencies.

"The advisory panel shall consist of the director of NIH, the secretary of Energy, the director of NSF and the director of the National Library of Medicine, or their designees, along with four individuals representing the biotechnology industry, four individuals representing the biotechnology industry, four individuals representing the research community,, one individual with expertise in biomedical ethics and one individual representing national foundations, medical institutes and other philanthropic organizations involved in biomedical research. The panel shall be cochaired by the representatives of NIH and the Dept. of Energy. While a single lead agency would be ideal, the committee recognizes the considerable current funding and commitment to achieve a map and sequence of the human genome on the part of both DOE and NIH. The cochair arrangement will draw upon the unique expertise and resources of the national laboratories supported by DOE, and the strength of peer review biomedical research projects supported by NIH.

"The committee has noted the recent creation of the Office of Human Genome Research within the NIH director's office. The committee has included $28 million for enhanced human genome research in the appropriations for fiscal year 1989. The

committee is concerned, however, that genome research being conducted by various agencies be carefully coordinated so as not to waste scarce resources or detract from other research goals.

"The committee therefore expects the advisory panel to report within 18 months after enactment of this appropriations measure the optimal strategy for the mapping and sequencing of the human genome. It expects that the advisory panel will coordinate the activities currently under way by federal agencies. The committee strongly encourages the panel to carefully consider how best to provide resources for this project, and how best to assure U.S. competitiveness in achieving this goal."

Nutrition--The Senate committee rejected, gently but firmly, the House committee's directive that all statements and guidelines related to nutrition be funneled through the Dept. of Agriculture (**The Cancer Letter**, June 24). That would have resulted in all sorts of delays and frustrations in reaching the public with nutrition and health messages.

The Senate report says, "Agencies of the Dept. of Health & Human Services, through their preeminence in health research, have traditionally played a leading role in the conduct of nutrition research and dissemination of the resulting information. The U.S. Dept. of Agriculture Human Nutrition Information Service has a complementary role. No change in their respective roles should be made without full examination and authorization by Congress."

Scientific fraud--"The committee is concerned with the increasing allegations about scientific fraud in programs and projects supported with NIH funds. The committee is pleased that NIH has moved quickly to respond with the development of guidelines and regulations on scientific fraud and by commissioning an Institute of Medicine study on the subject.

"The IOM study will highlight priorities among publication practices, peer review, data retention, training and supervisory practices and other topics which need to be addressed to assure quality in research. The study will also identify mechanisms for future exploration of selected topics, and will recommend how NIH and the general community of scientists, science editors, professional societies, academic institutions, and others can promote the proper conduct of research and discourage misconduct in science.

"The committee also expects NIH to strengthen its internal investigative responsibilities and fully explore the possibility of requiring the many peer review panels that evaluate research proposals to also on a random basis evaluate the results of that NIH sponsored research with a focus on the broad area of scientific misconduct.

"The committee directs that a report detailing the NIH proposed remedial steps be prepared and submitted to the committee by Feb. 1, 1989."

National Biotechnology Policy Board--NIH is directed to establish a National Biotechnology Policy Board which should include representatives from all federal agencies funding or promoting biotechnology related research or regulation (including NIH, NSF, Dept. of Agriculture, Dept. of Commerce, Dept. of Defense, Dept. of Energy, FDA and the Environmental Protection Agency). Representatives of the Office of Management & Budget and the Office of Science & Technology Policy should be ex officio members of the board.

Four individuals representing the university research community should be appointed, based on recommendations from the National Academy of Sciences. A biomedical ethicist and a representative of national foundations, medical institutes or other philanthropic organizations should also be appointed based on NAS recommendations. Four representatives of the U.S. biotechnology industry should be appointed following consultation with relevant industry groups. Two representatives of state biotechnology development programs should also be appointed. Members of the board are to elect a chairman from their members to serve for a two year period, and who may be reelected by the board at its discretion.

"The committee expects the board to review and appraise the programs and activities of the federal government relating to biotechnology, including the amount and type of biotechnology research. It should also review and appraise nonconfidential, privately funded biotechnology activities, including both basic and applied research, and the development of commercial biotechnology related industries and products. The board shall make recommendations to the President and to Congress on policies:

--To enhance basic and applied research.

--To enhance the competitiveness of the U.S. in development of commercial biotechnology related industries and products.

--To assure the training of sufficient scientists, engineers and laboratory personnel

for both research and commercial development.

--To enhance the transfer of technology from university and federal research laboratories to commercial laboratories.

"The board shall also make recommendations regarding federal participation in cooperative research initiatives involving governmental and private entities; and regulatory policies which affect biotechnology industries and products, ensuring that the regulatory system protects the public health, safety and environment without unduly impeding academic and commercial activities."

ECOG Disputes DeVita Accrual Figures; Numbers Up 17% This Year

Paul Carbone, chairman of the Eastern Cooperative Oncology Group, and Marvin Zelen, ECOG statistician, took exception to figures cited by NCI Director Vincent DeVita on ECOG patient accrual (**The Cancer Letter**, June 3). In a letter to **The Cancer Letter**, Carbone and Zelen wrote:

"The discussion of accrual problems to clinical trials is a timely and largely accurate treatment of a very important issue in cancer research.

"Unfortunately, the summary given of ECOG accrual in that article is substantially in error. Accrual to ECOG trials has been steadily increasing since 1986, and preliminary figures for 1988 show that these increases will continue during the next year. Dr. DeVita's projections are apparently based on comparing accrual in the first six months of 1987 with accrual in the first quarter of 1988. In the first six months of 1987, ECOG recorded 2,044 registrations to the Group's studies, and during the first three months of 1988 there were 1,194 registrations. We thus anticipate 2,388 registrations during the first half of 1988, or a 17 percent increase in accrual. Actual registrations beyond March 31, 1988 show that we are in fact exceeding the estimated 17 percent increase. The total number of registrations in 1987 was 4,069, a 24 percent increase from 1986. It is important to note that the increase in accrual has come in all types of ECOG studies. We are not completely sure of the source of Dr. DeVita's accrual data, but we know that he will be pleased to learn that ECOG has made substantial progress with the issue of increasing accrual to cooperative group clinical trials.

"We agree with Dr. (Charles) Coltman's comments earlier in that same article on the importance of community oncologist participation in cooperative group trials. ECOG has had a strong commitment to the CGOP (Cooperative Group Outreach Program) and CCOP (Community Clinical Oncology Program) programs since their inception. During 1987 60 percent of our 4,069 registrations came from CGOP or CCOP institutions, and we believe that this important source of accrual can be expanded if more funds are made available. We have had a strong response from oncologists not now members of cooperative groups but who wish to participate in NCI designated high priority trials, and are waiting funding decisions on that initiative."

713 Nurses Pass Oncology Certification Examination During ONS Congress

Beverly Nielsen, president of the Oncology Nursing Certification Corp., announced that 713 registered nurses passed the certification examination administered during the Oncology Nursing Society's 13th annual Congress in May.

Seventy nine percent of those who took the exam passed. They represented 46 states, the District of Columbia and Puerto Rico. Those who received certification included staff and head nurses, clinicians, educators, supervisors, assistant directors and directors of nursing. The majority of those who became certified work in a hospital or clinic setting with nurses also representing schools of nursing, community or public health nursing, private group practice, office nursing and comprehensive cancer centers.

Certification for oncology nursing was introduced at the 1986 ONS Congress in Los Aangeles, where 1,384 registered nurses passed the exam. There are now more than 3,600 oncology certified nurses.

Oncology nursing certification is available to nurses who have a current RN license, three years of experience as an RN within the last five years, and a minimum of 1,000 hours of oncology nursing practice within the last three years.

Additional testing this year will be held Oct. 15 in Phoenix, New Orleans, Minneapolis, New York City and Seattle. Also, more than 15 groups have arranged special test sites for the same date. The registration deadline is Sept. 15. Those interested should contact the Oncology Nursing Certification Corp., 1016 Greentree Rd., Pittsburgh, PA 15220, phone 412/921-7373.

RFPs Available

Requests for proposals described here pertain to contracts planned for award by the National Cancer Institute unless otherwise noted. NCI listings will show the phone number of the Contracting Officer or Contract Specialist who will respond to questions. Address requests for NCI RFPs, citing the RFP number, to the individual named, the Blair Building room number shown, National Cancer Institute, NIH, Bethesda, MD 20892. Proposals may be hand delivered to the Blair Building, 8300 Colesville Rd., Silver Spring, MD, but the U.S. Postal Service will not deliver there. RFP announcements from other agencies will include the complete mailing address at the end of each.

RFP NCI-CM-97567-29
Title: Human breast cancer cell lines
Deadline: Aug. 26

The Developmental Therapeutics Program of NCI's Div. of Cancer Treatment is seeking organizations to develop and characterize new human breast carcinoma cell lines for use in the DTP antitumor drug screening project.

Organizations should have the necessaary facilities and staff to carry out the required work. While complying with local and state laws, the contractors will be required to 91) obtain fresh biopsy or surgical specimens suitable for establishment of breast cancer cell lines together with appropriate clinical and pathological documentation; (2) process tissues aseptically to establish primary cell cultures and/or xenograft; (3) establish in vitro tumor cells lines; and 94) characterize in vitro breast cancer cell lines.

Characterization shall include demonstration that the cell line is free of contamination with adventitious agents, of human origin, tumorigenic in athymic mice, and that it retains features of the tumor of origin.

Contractors should be able to collect material from the patient, process and implant in vitro and/or as xenograft in athymic mice within one hour. A detailed patient history with all necessary consent forms, treatment history, etc. is essential for the performance of this contract.

Incrementally funded contract swill be awarded for periods of three years.
Contracting Officer: Clyde Williams
RCB Blair Bldg Rm 224
301-427-8737

RFP NCI-CM-97568-29
Title: Human prostate cancer cell lines
Deadline: Aug. 26

The Developmental Therapeutics Program is seeking organizations to develop and characterize new human prostate carcinoma cell lines for use in the DTP antitumor drug screening project.

Organizations should have the necessary facilities and staff to carry out the required work. While complying with local and state laws, the contractors will be required to (1) obtain fresh biopsy or surgical specimens suitable for establishment of prostate cancer cell lines together with appropriate clinical and pathological documentation; (2) process tissues aseptically to establish primary cell cultures and/or xenograft; (3) establish in vitro tumor cell lines; and (4) characterize in vitro prostate cancer cell lines.

Characterization shall include demonstration that the cell line is free of contamination with adventitious agents, of human origin, tumorigenic in athymic mice, and that it retains features of the tumor of origin.

Contractors should be able to collect material from the patient, process and implant in vitro and/or as xenograft in athymic mice within one hour. A detailed patient history with all the necessary consent forms, treatment history, etc. is essential for the performance of this contract.

Multiple contract awards, for periods of three years, incrementally funded, are expected to be made.
Contracting Officer: Clyde Williams
RCB Blair Bldg Rm 224
301-427-8737

RFP NCI-CM-97577-27
Title: Development and production of pharmaceutical dosage forms
Deadline: Approximately Sept. 22

The Pharmaceutical Resources Branch of the Developmental Therapeutics Program is seeking organizations capable of providing pharmaceutical services in development of freeze dried and liquid small volume parenterals; development of tablet and capsule solid oral dosage forms; and production of sterile freeze dried dosage forms, small volume parenterals, tablets and capsules.

Batch sizes of injectables will be in the 4,000-6,000 vial range and batches of tablets and capsules will likely range from 10,000-50,000 units. The government will select and provide the antitumor agents for dosage form development and production. The dosage forms will be used in preclinical toxicology evaluation, in pharmacology studies and in clinical trials.

As a minimum requirement, the contractor and subcontractor must be registered with FDA as a pharmaceutical manufacturing facility for both sterile products and solid oral dosage forms at time of best and final offer. Annual work load estimates for development are: injectable, 3,000 technical staff hours; oral dosage forms, 1,000 technical staff hours per year. Annual workload estimates for production are 10 injectable batches and six tablet/capsule production runs.

The orgal dosage form aspects may be subcontracted in part or in total to a manufacturing concern that meets FDA's good manufacturing practice requirements and is acceptable to NCI. Shelf life monitoring of production batches will not be required.

Data obtained from this contract will be used to support IND applications submitted by NCI to FDA; will be provided to other NCI contractors engaged in large scale dosage form manufacture and analytical evaluation of these dosage forms; and will be provided to physicians, pharmacists, nurses and other medical personnel handling these products in a clinical setting.

The contractor selected for this work must prepare products in accord with FDA's good manufacturing practice regulations and NCI's product specifications. The contractor will be responsible for the quality control testing of all formulations components including the active ingredients, excipients, container closure system, as well as the finished products.

All products will be labeled and packaged according to the government's specifications. Label preparation may be subcontracted, but labeling must be performed at the manufacturing site.

It is anticipated that an incrementally funded contract will be awarded for a period of three years beginning on or about June 15, 1989.
Contract Specialist: Johnny Jordan
RCB Blair Bldg Rm 216
301/427-8737

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