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NCI's Chabner Cautions Against 3-Hour Taxol Infusion, May Lower Response Rate

An NCI official who played a key role in the development of Taxol has warned that the recently approved three-hour infusion schedule for the drug may deprive cancer patients of the optimal drug exposure, possibly decreasing the chance of a response.

FDA's Oncologic Drugs Advisory Committee last month recommended a change in the labeling of Taxol (paclitaxel, Bristol-Myers Squibb) from 24-hour infusion at a dose of 135 mg/m^2 to three-hour or 24-hour

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In Brief

Nobel Prize Awarded To Sharp, Roberts For Gene Splicing; ACS Fills Top Positions

NOBEL PRIZE in Medicine was awarded to **Phillip Sharp**, Massachusetts Institute of Technology, and **Richard Roberts**, New England Biolabs, for their independent discoveries of gene splicing. The researchers will share the $825,000 prize. . . **AMERICAN CANCER** Society Executive Vice President **John Seffrin** has made eight more top-level appointments in the society's national office: **Michael Mitchell**, executive director of the American Cancer Society Foundation. He has been vice president of major gifts for ACS since 1988. **Becky Burkett**, national vice president for income development. She was vice president for income development for the ACS Texas Div. **Ruth Corcoran**, national vice president for voluntarism and volunteer/staff partnership. She was director of behavioral and psychosocial research. **James Bell**, strategic group leader for finance. He was senior vice president for support services and senior advisor to the executive vice president. **Michael Heron**, strategic group leader for advocacy and relationship management. He was senior vice president for communications. **Nelson Rivera**, operational group leader for product production. He was director of materials and purchasing. **E. Derrick Wheeler**, information center operational group leader. He was vice president for information systems and customer services. **Faith Stein**, professional services operational group leader. She was vice president for training and development. Five other positions were filled previously (**The Cancer Letter**, Sept. 10), leaving just three more top jobs to be filled. . . **PRESIDENT'S CANCER** Panel is scheduled to meet Nov. 15, LaGuardia Marriott, New York City, from 8 a.m.-5 p.m. to discuss cancer statistics and chronic disaster areas. . . . **PHILIP SALEM**, director of the Cancer Research Program at St. Luke's Episcopal Hospital, Houston, was honored by St. Jude Children's Research Hospital of Memphis for his contributions to cancer research. Salem studied Mediterranean lymphoma, showing it could be reversed by antibiotics when detected early.

NCI Official Warns Against Use Of 3-Hour Taxol Infusion

(Continued from page 1)

infusion at a dose of either 135 mg/m^2 or 175 mg/m^2 for refractory ovarian cancer (**The Cancer Letter**, Oct. 1).

"I have reservations about the decision to relabel Taxol," Div. of Cancer Treatment Director Bruce Chabner said this week. "I realize the logistic advantages of three-hour infusion—it is simpler to give in an out-patient setting. However, preclinical studies clearly indicate that the drug's activity increases with longer durations of drug exposure. Given its rapid half-life of two hours, the three-hour infusion could well be inadequate to give optimal exposure.

"Secondly, there is clinical evidence that longer durations of Taxol infusion have greater activity," Chabner said to the DCT Board of Scientific Counselors this week. In a recently completed trial at NCI, there was a 48 percent response rate in 33 patients with relapsed breast cancer treated with a 96-hour Taxol infusion.

"Significant Lowering Of Response Rate"

"This response rate seems considerably higher than the 22 percent reported by the Memorial Sloan-Kettering group, who studied a similar relapsed group of pre-treated patients," Chabner said. "Thus, I am concerned that the general adoption of the three-hour schedule, which is bound to happen because of its convenience, could lead to a significant lowering of the response rate in ovarian and breast cancer patients."

NCI's Cancer Therapy Evaluation Program is organizing several studies comparing the three-hour infusion to 24-hour and 96-hour infusions, Chabner said.

ODAC's decision was based on results of a study by the National Cancer Institute of Canada in which relapsed ovarian cancer patients were randomized to receive Taxol on one of four schedules, either as a three-hour or 24-hour infusion, and at a dose of either 135 mg/m^2 or 175 mg/m^2.

"In the study, patients who received 175 mg/m^2 had a higher response rate than those treated at 135," Chabner said to the board. "There was no significant overall difference between the three- and 24-hour schedules when all doses were lumped together. However, when the individual cells of the trial were analyzed, the highest response rate, 26 percent, resulted from 175 mg/m^2 for 24 hours as compared to 19 percent for the three-hour schedule at the same dose.

"The number of patients in each arm was approximately 80, too few to allow the detection of a significant difference between the three-hour and the 24-hour schedules," Chabner continued.

Taxol Incompatible With Most Pumps

Physicians are feeling pressure to go to the shorter infusion because of problems with reimbursement for the hospital stay required for Taxol infusion, sources said.

Longer infusions of Taxol require a hospital stay because the solution Taxol is administered in destroys the tubing on most portable pumps, Chabner said to **The Cancer Letter**. New types of pump tubing are under development and used experimentally at the NIH Clinical Center. If the three-hour infusion becomes the norm, there will not be a market for special tubing, Chabner said.

"I am afraid we may have taken an effective drug on an inconvenient schedule and changed it to an ineffective drug on a convenient schedule," Chabner said. "We need further information before making a decision about the best schedule."

Chabner and his staff in DCT negotiated the Cooperative Research and Development Agreement with Bristol-Myers Squibb for the development of Taxol.

The CRADA was signed in 1991 (**The Cancer Letter**, March 15, 1991), and the drug was approved by FDA for refractory ovarian cancer in 1992 (**The Cancer Letter**, Nov. 20, 1992).

Chabner explained and defended the CRADA in Congressional hearings, and he and the DCT staff were involved in the deals for harvesting the bark of the Pacific yew tree, from which Taxol was originally derived.

THE CANCER LETTER

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Prostate Cancer Prevention Trial Begins At 222 U.S. Sites

NCI last week announced the start of the first large-scale prevention trial for prostate cancer at 222 sites in the U.S., enrolling 18,000 men age 55 and older.

The Prostate Cancer Prevention Trial, an intergroup study designed to test whether taking the drug finasteride will prevent prostate cancer, will be coordinated by the Southwest Oncology Group.

"We are embarking on a very important prevention effort," NCI Director Samuel Broder said. "In 1993, there will be about 165,000 new cases of prostate cancer, and about 35,000 deaths. Prevention of cancer is our highest goal, and the need for effective prevention strategies is clear."

NCI is providlng approximately $60 million to conduct the trial.

Finasteride Approved For BPH

The Food & Drug Administration approved finasteride in 1992 for the treatment of benign prostatic hyperplasia, a non-cancerous enlargement of the prostate gland. Because BPH and prostate cancer are influenced by similar hormonal factors, researchers believe that finasteride may also prevent cancer. More than half a million men in 25 countries are currently taking finasteride for BPH, but the drug has never before been tested for cancer prevention.

"We believe finasteride is a very promising agent that could prove to be of great value in heading off prostate cancer," said Charles Coltman Jr., chairman of SWOG. "But the theory is still untested, and only a large-scale, controlled clinical trial of finasteride can show whether the drug is truly effective for cancer prevention."

SWOG will collaborate with two other cooperative groups, the Eastern Cooperative Oncology Group and the Cancer and Leukemia Group B in recruiting men to the trial.

A minimum age limit of 55 was selected because older men are at highest risk of developing prostate cancer. About 98 percent of prostate cancers are diagnosed in men age 55 or older.

The 18,000 men in the trial will be divided randomly into two groups. Half will take one five-milligram tablet of finasteride per day for seven years, and half will take a placebo. Merck and Co. Inc., Whitehouse Station, NJ, will provide both the finasteride (trade name Proscar) and the placebo without charge. The trial will be double-blinded.

Finasteride controls BPH by reducing levels of the hormone dihydrotestosterone (DHT) in the prostate. The drug works by blocking the activity of an enzyme that converts testosterone to DHT.

"We believe finasteride may help prevent prostate cancer because we know DHT promotes the growth of prostate cancer, and finasteride decreases levels of DHT," said Ian Thompson Jr., study coordinator for SWOG.

Opportunity For Follow-up

It is estimated that one-third of all men over age 50 have early, undiagnosed prostate cancer. Most of these cancers are destined to remain harmless, but some will progress to clinically significant disease. Finasteride might prevent the progression of these early cancers to advanced, life-threatening stages, Thompson said. Men taking the drug could benefit if finasteride prevented prostate cancer or simply halted or slowed its progression.

"There's no guarantee that a man who enrolls in the trial won't develop prostate cancer," Thompson said. "But all men in the study, whether they get finasteride or a placebo, will have the opportunity for close follow-up for the detection of prostate cancer."

One of the main advantages of using finasteride in a prevention trial is that the drug works only in the prostate, and its side effects are relatively rare and relatively mild. In previous clinical trials performed by Merck, small numbers of men in both the finasteride and placebo groups had sexual complaints. Impotence, decreased sexual desire, and decreased ejaculatory volume were all observed slightly more frequently in men taking finasteride than in men taking a placebo. But none of these side effects was reported by more than 5 percent of men in either group. In addition, a recent study suggests that these problems frequently diminish over time in men who continue to take the drug.

Minority Recruitment Emphasized

Any man age 55 or older who is in good health may be eligible to participate in the study. To find out if he is eligible, a man must go to a study site to have a digital rectal exam and a blood test for prostate-specific antigen.

The death rate from prostate cancer among

African-American men is twice as high as the rate for white men.

"For reasons not currently understood, African-American men have the highest prostate cancer mortality rate in the world," Broder said. The higher death rate among black men may be partly due to the fact that blacks tend to be diagnosed with prostate cancer at later stages than whites.

NCI officials stressed the importance of obtaining a representative sample of the entire U.S. male population.

"Ideally, we'd like to recruit men from all racial and ethnic groups--African-Americans, whites, Native Americans, Hispanics, Asian-Americans--roughly in proportion to their risk of developing the disease," said Otis Brawley, of NCI's Community Oncology and Rehabilitation Branch, and the NCI official responsible for the PCPT. "The better the representation we have from all these groups, the more confident we can be in applying the results of the trial to the population at large."

All men in the trial will have a prostate biopsy at the end of seven years to determine whether they have developed prostate cancer. Participants' self-reports will be used to assess the effects of the drug on men's sexual and urinary functioning and other quality-of-life measures.

Men who are interested in participating in the trial should contact the site nearest them. To locate the nearest site, they can call NCI's Cancer Information Service at 1-800-4-CANCER.

Capitol Notes

Duke Physician, BMT Patients Lobby For Reimbursement

William Peters didn't travel alone when he came to Washington last week.

With him the Duke Univ. physician brought a bus full of women who had received high dose chemotherapy and bone marrow transplantation for breast cancer in his clinic.

At a Capitol Hill luncheon Oct. 14, under the gleaming chandeliers, the physician took a microphone to emcee a program that included testimonials from patients, accounts of their battles for reimbursement as well as Peters' own advocacy of the investigational procedure.

"I could give you a lot of statistics about the effectiveness of this treatment protocol," Peters said. "But I think it would be easier to do this with a simple demonstration: 'Would the women who received the transplants please stand up!'"

More than 70 women stood up.

Peters said that at least half of the patients present would have died if not for the high dose chemotherapy with bone marrow transplants. The results of a prospective, randomized trial in which Peters is the principal investigator are yet to be published.

Peters and his patients came to Capitol Hill to argue that patient care costs under the impending health reform should be reimbursed for patients enrolled in clinical trials and that innovative therapies that appear expensive at the outset ultimately become less expensive.

After many of the procedures started to be performed on the outpatient basis, the price of bone marrow transplantation at Duke has dropped from about $140,000 to about $65,000, roughly the price of a Lexis automobile, Peters said.

"As you look at a woman across the table from you, ask yourself, 'Is the price of this woman's life worth the price of a car?'" Peters asked at the luncheon.

Altogether, 850 patients received transplants at Duke.

In June, the "Journal of Clinical Oncology" published the results of Peters's study of 85 patients whose cancer had spread to over 10 lymph nodes. At a median followup of 2.5 years, disease free survival was 72%.

Comparison to three historical or concurrent Cancer and Leukemia Group B adjuvant chemotherapy trials for similar patients was between 38% and 52%. Therapy related mortality for bone marrow transplant patients was 12%.

The final speaker at the luncheon, Sen. Tom Harkin (D-IA), urged the patients to lobby for his plan for funding biomedical research through a trust fund financed through surcharges on health insurance premiums.

Harkin, chairman of the Labor, HHS and Education Appropriations Subcommittee, also vowed to amend the Administration's health reform to make mammograms available to all women, "not just women over 50," requiring no copayment.

Harkin Fights For Unconventional Medicine

At another recent event, Harkin vowed to fight for reimbursement of another of his interests: unconventional medicine.

At a hearing of the Senate Labor and Human Re-

sources Committee, Harkin said the Administration's health plan would be deficient unless it includes reimbursement for unconventional practitioners.

Dingell: Structured Referral For Reform Bills

The Administration's health reform, once it's formulated into legislative proposals, is expected to come before 16 House and Senate committees and more than 20 subcommittees.

In a recent letter, Rep. John Dingell (D-MI), chairman of the Energy and Commerce Committee, warned against the bill's submission to all appropriate committees at the same time, calling instead for a structured referral.

"To date, no coherent procedural strategy has been discussed or devised for processing the President's bill," Dingell wrote in an Oct. 7 letter to Rep. Thomas Foley (D-WA), Speaker of the House.

"In the absence of such a strategy, the process for consideration of the bill will become so chaotic as to destroy any opportunity to develop, consider, or pass a serious bill next year," Dingell wrote.

Referring to the potential for turf battles between congressional committees, Dingell wrote, "I believe that unmanaged competition is no more appropriate here than in the health field."

The Administration's bill was expected to be delivered to Congress within a week.

Hill observers note that a sequential submission would greatly reinforce Dingell's turf claims on the legislation.

Greenpeace: Chemicals Cause Breast Cancer

Greenpeace and former House member Bella Abzug issued a report claiming that industrial and agricultural chemicals made from chlorine are an important cause of breast cancer.

"The new evidence that links chlorine-based poisons to breast cancer reinforces the urgent need to begin their phase-out right away," said Joe Thornton, the report's author.

"Although the organochloride-breast cancer link has not yet been proven beyond a doubt, it would be irresponsible and unethical to delay action any longer: these chemicals already blanket the planet, and a woman's lifetime breast cancer risk is one in nine," Thornton said.

Greenpeace and Abzug's group, Women's Environment Development Organization (WEDO), also announced plans to hold a series of meetings and workshops on environmental exposures to chemicals and the cancers that affect women.

The recent report was endorsed by 20 scientists, including Samuel Epstein, professor of occupational and environmental medicine at the Univ. of Illinois School of Public Health and the key proponent of the theory that the majority of cancers are caused by industrial pollutants and occupational exposures.

DCT Board Ok's Recompetition Of Drug Discovery Groups

NCI's Div. of Cancer Treatment Board of Scientific Counselors this week approved the recompetition of the National Cooperative Drug Discovery Groups and the National Cooperative Natural Products Drug Discovery Groups.

The Board agreed to set aside $4 million for each of the grant programs in the first year.

Following are the concept statements:

National Cooperative Drug Discovery Groups. Recompetition for cooperative agreements (RFA). Proposed first year award $4 million, project period five years, announcement date planned for Jan. 1994.

The National Cooperative Drug Discovery Group program was implemented 10 years ago at the recommendation of the Board of Scientific Counselors to attain a more desirable balance between rational approaches to the discovery of new and improved anticancer treatments and the traditional, more empiric in vitro and in vivo screening approaches in operation at the Frederick Cancer Research and Development Center and other contract laboratories. The NCDDG program with its emphasis on multidisciplinary and investigator-initiated approaches is ideally suited for the timely exploitation of new advances and their translation into more effective clinical treatments. The NCDDG cooperative agreement mechanism provides a framework for DCT to support and facilitate the efforts of diverse and often high-risk approaches to identify and develop clinical trial candidates.

Since 1983, the NCDDG program has been recompeted several times using different themes: mechanism-of-action approaches, disease-oriented approaches, model development, and a search for new agents from natural sources, such as plants and marine organisms. The program was launched with two projects in 1984 at a cost of almost $600,000 and was expanded to a total of 23 groups in FY 1992 at a yearly total of about $16 million. The greatest expansion occurred during FY 1990 when expenditures went from a little over $5 million to almost $14 million.

These targeted projects have been very successful in identifying new leads, some of which are currently in development to clinical trial or in clinical trial. In addition,

their concerted activities have facilitated the introduction of other therapies into clinical trial by providing additional in-depth and critical preclinical data. Some examples of NCDDG achievements are listed below:

• Dr. Porter's NCDDG synthesized a polyamine analog, N',N"-bis(ethyl)norspermine (BENSPM), which induces the polyamine catabolizing enzyme spermidine/spermine N^1-acetyltransferase (SSAT) in many tumors but not in normal tissues. SSAT induction leads to profound polyamine depletion and eventual cell death. This compound, which was recently licensed to Warner-Lambert/Parke-Davis, is in development to clinical trial. A second compound, a discreet spermine analog, does not induce SSAT, but is also being developed through the NCI Decision Network (DN) based on its antitumor efficacy against several human tumor xenograft models and its ability to induce conformational changes in DNA.

• Dr. Pegg's group studied O^6-benzylguanine, a potent inhibitor of the enzyme alkylguanine transferase, which is involved in the repair of damage to alkylating agents and is a major factor in the resistance of certain tumors to this class of agents. O^6-benzylguanine is under development by the DN in combination with BCNU for the treatment of brain and other tumors.

• Dr. Houston's NCDDG has isolated the binding region of a monoclonal antibody that recognizes the oncogene c-erbB-2. This genetically derived single chain product is currently undergoing antitumor efficacy testing. In distribution studies in tumorbearing mice, this product has shown more tumor-selective binding than full-size IgG monoclonal antibodies.

• Dr. Wahl's group developed a technique for identifying double minutes (DMs) in human solid tumor biopsies. DMs, which are found only in cancer tissues and are a poor prognostic indicator, are a sign of gene amplification. Their preclinical studies demonstrated that hydroxyurea (HU) reduced the copy number of the extrachromosomal c-myc oncogene and the corresponding tumorigenicity of a DM-containing colon tumor line. This work has provided a new rationale for initiation of a clinical trial of HU in ovarian cancer patients.

• Dr. Mendelsohn's group found that a combination of two antitransferrin receptor IgG monoclonal antibodies (MAbs), A27.15 and E2.3, caused complete regressions of 10-day established CCRF-CEM tumors. Based on these results, the DN has accepted this pair of MAbs for clinical development and is currently arranging for additional material through the Biological Response Modifiers Program.

• Dr. Murphy's NCDDG project has focused on developing a second-generation novel diphtheria toxin-related interleukin-2 fusion protein called DAB389-IL-2. This product is delivered more efficiently to the cytosol of target cells than the primary lead and has been approved by FDA for clinical trials for the treatment of patients with T-cell leukemias or lymphomas bearing high-affinity interleukin-2 receptors.

• Dr. Brem's group is pioneering a new approach to the treatment of brain tumors using biodegradable polymers impregnated with drugs. Based on a successful clinical trial with BCNU, trials with other anticancer agents, such as carboplatin, 4-hydroperoxycyclophosphamide (4-HC), Taxol, and camptothecin are projected.

• Dr. Ross headed one of the earliest and most successful NCDDG projects. This group synthesized and developed topotecan, an analog of camptothecin with improved water solubility that forms a complex with topoisomerase I and DNA. Based on its activity in phase II clinical trials, this agent may be the first from an NCDDG to receive market approval.

Although likelihood of success in identifying a novel entity for clinical development will be paramount, emphasis will be given to projects in high-priority areas, such as breast and prostate cancer. Both incumbent groups and new groups will be encouraged to compete. Ongoing and recently expired groups totaling $9.32 million for projects related to this RFA are up for competition, but only $4 million is requested for this solicitation.

Newer approaches, such as those involving tumor vaccines and gene therapy, will be especially encouraged. Each group will be assembled by a principal investigator to form a multidisciplinary and multi-institutional consortium of those skills needed to execute successfully the conceptualization, development, and preclinical investigation of new, rationally based treatments. The biological or biochemical targets of attack will be selected by the applying group. If a specific tumor type is selected by an applicant as a target, the applicant will be expected to show the relationship between the proposed research and the anticipated preferential efficacy against the chosen malignant disease.

The PI will be the conceptual focus of the group and, depending on the needs of the project, will extend invitation to appropriate scientists, regardless of their institutional affiliations, to participate as group members.

National Cooperative Natural Products Drug Discovery Groups. Recompetition. Proposed first year award $4 million; project period five years; planned announcement January.

The availability of new molecular screens, many of which are highly automated, has enabled the large-scale screening of crude extracts of organisms of plant, animal, and microbial origins. The importance of drugs of natural origin to cancer treatment is well recognized and has been emphasized in the last few years by drugs such as Taxol and the camptothecin derivatives.

The NCNPDDG program began with the first

rounds of awards in 1989 (three awards) and 1990 (four additional awards).

The time frames of these grants have roughly been one year to get the initial collections of organisms, the group logistics, and the screens fully functional; a second year to get viable leads with potential for novel chemicals, re-collections of the promising crude leads to get enough material for fractionation studies to isolate the active principles, debugging the screens for false positive "nuisance" compounds in crude extracts, and multiple rounds of bioassay-guided fractionation; and a third year to isolate and characterize the first active compounds, perform additional biochemical and cellular level studies, determine which are worthy of in vivo evaluation, and begin to acquire animal data. By the fourth year of the award, it is expected that each successful NCNPDDG will have leads worthy of patenting and chemical analogue follow up, and this has been the case for the three groups who are currently in their fourth year.

The Hecht group has a series of topoisomerase I inhibitors in analogue development, the Chang group has a series of heterocyclic analogues with specific cytotoxicity to renal cell lines under study, and the Clardy group is currently patenting an EGF receptor antagonist. The four NCNPDDGs funded in 1990 are at appropriate stages in lead discovery and development and are making good progress.

Recompetition is being sought at this time because by the time of the projected award, awards to the three original groups will have been expired for over a year and the awards of the four later groups will have been expired for several months. The seven extant NCNPDDGs are currently (FY 1993) funded at a level of $4.59 million total costs. The $4 million requested in the RFA thus represents a 13 percent decrease in funding level.

Emphasis will be given to projects in high-priority areas such as breast and prostate cancer. Both incumbent groups and new groups will be encouraged to compete. NCI expects to fund only those projects that offer the most creative approaches and have the greatest potential to result in products for development to clinical trial.

Each group will be assembled by a principal investigator to form a multidisciplinary and multi-institutional consortium of those skills needed to develop and execute the screening concepts, the natural products collection strategies, the chemical isolation and characterization, secondary evaluation in vitro and in vivo, analogue development, and selection of preclinical development candidates. While developmental studies towards clinical trials, including bulk supply, formulation, detailed pharmacology, and protocol toxicology, are beyond the scope of these drug discovery grants, each applicant will be required to have a plan for such subsequent development of agents discovered in the NCNPDDG program. The inclusion of industrial partners in the NCNPDDGs to pursue such efforts will be strongly encouraged. Groups will also be encouraged to bring their candidate compounds to NCI for development through the Decision Network process.

NCI Communications Office To Contract Media Campaigns

NCI's Office of Cancer Communications plans to hire a contractor to help conduct mass media campaigns such as announcements of research news and national educational efforts.

The National Cancer Advisory Board's Subcommittee on Information and Cancer Control approved the plan in concept and agreed to a budget of $3.9 million over five years for the contract.

The OCC Reports Section, also known as NCI's press office, develops and disseminates information about cancer research conducted by NCI and deals daily with the media and the public.

"A mass media contract would provide the Office of Cancer Communications with the means to plan and execute a strategic program of targeted public education using the mass media," according to the concept statement approved by the subcommittee. "These activities could include help in coordinating major press announcements of research news and national kick-off educational efforts."

According to the concept statement, "The contractor would help with logistical arrangements for press briefings and educational seminars for reporters and edtiors; multicultural activities using print, audio and video media, in conjunction with major research or educational announcements; video and audio news releases for the traditional news media; satellite media tours and media training for selected spokespersons; and contacts with selected national and local media outlets to gain visibility for educational information."

Project officer for the new contract is Patricia Newman.

The NCAB subcommittee, at its meeting last month, also gave concept approval to recompetition

of four support contracts within the NCI director's office:

Editorial support services for the Scientific Publications Branch, $1.794 million over five years, first-year award $328,000 (FY95). Current funding level is $167,820. Project officer: Edwin Haugh. Recompetition will include technical proofreading and review, technical and editorial cold reading/review, and copy editing for the "Journal of the National Cancer Institute" and "JNCI Monographs." A separate requirement for data checking will be added .

Budget execution and formulation support system, $1.886 million over five years, first-year award $341,000 (FY95). Project officer: Ann Fitzpatrick. The contract will provide computer programming support and operation of the existing system in the Financial Management Branch.

Office of Cancer Communications program support, $20 million over five years, first-year award $3.6 million (FY95). Project officer: Sharyn Sutton. The support contract will continue to provide comprehensive services for the planning, development, implementation, promotion and assessment of current and future education and communications efforts targeted to public, patient, professional, and other audiences.

Cancer communications research and program evaluation, $2.9 million over five years, first-year award $533,616 (FY95). Project officer: Sharyn Sutton. The contract supports all cancer communications research and program evaluation with OCC. Role of the contract will be expanded to provide support for the enhanced Cancer Information Service. This expands the contract's scope by coordinating all communication research activities including those that had been supported under other mechanisms. The contract will support collection of process and outcome data sources from NCI education initiatives. The contract will support training for CIS outreach coordinators.

RFA Available

RFA DK-94-007

Title: **Hormonal regulation of breast-specific growth factors**

Letter of Intent Receipt Date: Jan. 21

Application Receipt Date: Feb. 18

The National Institute of Diabetes and Digestive and Kidney Diseases intends to promote investigations of the biology, physiology, and pathophysiology of systemic hormones and their role in the regulation of growth factors and their receptors, in both normal and abnormal endocrine regulatory activity of breast tissue.

Applications may be submitted by domestic and foreign for-profit and non-profit organizations. Suport will be through the NIH research project grant (R01) or FIRST (R29) award. The total project period may not exceed five years. A maximum of three years may be requested for foreign awards. Earliest possible award date will be Sept. 30, 1994.

For FY 1994, NIDDK intends to commit $ 2.5 million to fund applications. Applicants must limit their requests to not more than $160,000 direct costs for the initial budget period.

This solicitation is intended to address new issues in molecular endocrinology and medicine that have resulted from recent advances in the understanding of the actions of hormones and growth factors in the physiological regulation of breast tissues.

A letter of intent is to be sent to: Chief, Review Branch, Div. of Extramural Activities, NIDDK, Westwood Bldg. Rm 605, Bethesda, MD 20892, Tel. 301/594-7515.

Inquiries may be directed to: Dr. W. Lorenzo Jackson, Div. of Diabetes, Endocrinology and Metabolic Diseases, National Institutes of Diabetes and Digestive and Kidney Diseases, Westwood Bldg, Rm 621, Bethesda, MD 20892, Tel. 301/594-7576, Fax 301/594-9011.

Program Announcement

PAR-94-004

Title: **Cancer Education**

NCI invites applications to its Cancer Education Grant Program designed to support innovative educational efforts to reduce, directly or indirectly, cancer incidence, morbidity, and mortality. It also wishes to encourage effective programs that promise improvement in the quality of life of cancer patients.

Any not-for-profit or for-profit organization engaged in health-related education, research, or training and located in the U.S. or its territories may apply. The mechanism of support is the Cancer Education (R25) grant award. In general, allowable costs must be consistent with PHS policy and recommended by peer reviewers. All applicants may request up to five years of support in a single grant period in order to develop or maintain a specific education program.

Reorganized in 1993, the Cancer Education Grant Program (CEGP) plans to accomplish its objectives by providing institutions a wide range of opportunities to develop and sustain unique, innovative curriculum-driven programs that focus on various cancer education activities. These will be projects not normally supported by other NIH grant mechanisms. The target audiences for these programs can range from biomedical researchers; health professionals; medical, dental, nursing, and other health professional students; college and high school students; to members of the lay community.

Inquiries: Dr. Robert Adams, Div. of Cancer Biology, Diagnosis and Centers, NCI, Executive Plaza North, Rm 520, Bethesda, MD 20892, Tel. 301/496-8580, Fax 301/402-4472.