THE CANCER LETTER

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Conferees Set $1.991 Bil. NCI Budget, Ax Earmark For Breast Cancer, But Find $210 Mil. In Defense

Budget conferees last week recommended a $1.991 billion fiscal 1993 appropriation for NCI, $19 million below the President's budget request.

In another budget conference, the Department of Defense was mandated to spend $210 million on breast cancer research, providing a potential influx of new funds into the cancer program, but also creating

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In Brief

White House Names Five To NCAB; Carson Chairs Nursing Foundation; ONF Research Award

WHITE HOUSE appointed five members to the National Cancer Advisory Board, replacing those whose terms have expired: **Zora Kramer Brown**, president of the DC Breast Cancer Resource Committee, was reappointed to the Board for a full term. **Pelayo Correa**, professor of pathology at Louisiana State Univ., succeeds Bernard Fisher. **Robert Day**, president of the Fred Hutchinson Cancer Research Center, succeeds John Durant. **Barbara Gimbel**, chairman of the Advisory Council School of General Studies at Columbia Univ., succeeds Irene Pollin. **Ellen Sigal**, CEO of the Sigal-Zuckerman Co. and chairman of Duke Comprehensive Cancer Center's Board of Overseers, succeeds Phillip Frost. . . . **COLETTE CARSON** has been named chair of the Oncology Nursing Foundation. Carson is an oncology nurse and consultant in San Diego, CA. She succeeds **Ellyn Bushkin**, who completed a three-year term as foundation chair. . . .**ONCOLOGY NURSING** Foundation has established a research grant of $10,000 to stimulate oncology nursing research. Applicants must be a registered nurse actively involved in some aspect of cancer patient care, education or research. The research must be on a clinically oriented topic. Application deadline is Dec. 1. For application information, contact ONF, 501 Holiday Dr., Pittsburgh, PA 15220, phone 412/921-7373. . . **EDWIN MIRAND**, vice president for educational affairs and dean of the Roswell Park Graduate Division of SUNY at Buffalo, received the Margaret Hay Edwards Award at the annual meeting of the American Assn. for Cancer Education last week. The award recognized Mirand's significant contributions in the field of oncology and cancer education throughout his 42-year career. . . . **MILSTEIN AWARD**, given by the International Society for Interferon Research, was shared by **Jordan Gutterman**, M.D. Anderson Cancer Center, and **Hans Strander**, of Sweden. The award is given for contributions to advance interferon research.

Conferees Set $1.99 Bil. NCI Budget, $210 Mil. In DOD For Breast Cancer

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uncertainty about the manner in which the money would be spent.

Both the Labor, HHS and the DOD bills were expected to be sent to the President this week.

Before the conferees met to consider the budget, both the House and Senate mandated NCI to increase spending on breast cancer research at the expense of other programs. During the conference, these provisions were dropped and the final bill required no set increase for breast or any other cancer.

Throughout the session, professional societies opposed congressionally mandated increases in breast cancer spending, saying that such decisions should be left to the discretion of the Institute.

"We were very pleased that there was no earmark for breast cancer," said Terry Lierman, president of Capitol Associates, the lobbying group for the National Coalition for Cancer Research. "It's very important that NCI have a balanced approach to all programs and to all cancers."

Even without a mandated increase, NCI was given a clear message to boost its spending on breast cancer, a message that could well affect the Institute's spending plan for the fiscal year.

The DOD appropriation for breast cancer represents a new kind of creative financing.

Under the measure, introduced by Sen. Tom Harkin (D-IA), chairman of the Senate Labor, HHS, Education Appropriations Subcommittee, the new funds would remain in the DOD budget. This was necessary to avoid the Administration's threat to score the funds as domestic spending.

Hence, the measure that cleared the conference makes no mention of NCI or its grant-making process, thereby casting uncertainty on the manner in which cancer researchers would be able to make use of the DOD money. The language of the bill was not available at press time.

At this writing, the money appears likely to remain in the budget. For one thing, the measure, which was passed by the Senate by an 89-to-4 vote, has more than sufficient support to survive a potential Presidential veto. Also, as demonstrated by the cable television bill earlier this week, the President's vetoes have lost their invulnerability.

Even before the appropriations bill cleared the Senate, professional societies and patient groups expressed readiness to advise DOD. Sources said the American Assn. for Cancer Research had drafted a letter offering DOD guidance in spending the money.

The Breast Cancer Coalition, a patient group that emerged as a major force in Washington cancer politics this year, was talking about exercising control over the way the money is spent.

"While money alone will not cure breast cancer, we need to shake up the status quo at NCI," Fran Visco, president of the Breast Cancer Coalition, said last week at a hearing of the House Select Committee on Aging.

"We need to know that a serious program is in place. The [coalition] wants a formal structure by which advocates and survivors have control over the decisions that affect our lives," Visco said.

The conferees recommended and the Senate approved a $10.363 billion appropriation for NIH, a $216.9 million decrease from the President's budget request.

In other developments:

▶The Senate authorized a national program of cancer registries. The program, which would be operated through the Centers for Disease Control, would fund state programs to establish and upgrade cancer registry systems. Originally, the measure was part of the NIH reauthorization bill, but after that bill was vetoed by the President, Sen. Patrick Leahy (D-VT), in an unusual move, added this authorization measure to the Senate appropriations bill. The money, up to $30 million, would have to come from existing discretionary funds.

▶Facing the threat of a filibuster by Republicans, Sen. George Mitchell (D-MA), the majority leader, withdrew the long-delayed NIH reauthorization measure, pledging to place it at the top of the agenda when Congress returns in January. An attempt at reaching a compromise over the bill's provision for fetal tissue research had failed in the final days of the session, and the 12 Senate members who oppose the

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measure were threatening a filibuster.

▶The Senate passed an amendment by Sen. Bob Dole (R-KS) making up to $10 million available to the Agency for International Development for preventative services including breast and prostate cancer screening.

▶The House-Senate conferees deleted an amendment by Sen. Carl Levin (D-MI) to earmark $1 million for a cyclotron laboratory in Michigan.

In Congress

Harkin Withdraws Amendment Allowing NIH To Bypass IND Process

Thirteen days after introducing an amendment that sought to create a loophole in the FDA Investigational New Drug process, Sen. Tom Harkin (D-IA) quietly withdrew the measure.

Introduced as a correction of a typographical error in a committee report, the amendment to the Senate appropriations bill caused surprise and dismay at NIH and FDA and triggered a protest by Rep. John Dingell (D-MI).

Neither agency took a public stand on the amendment, but both took steps to convince Harkin and other Senate and House conferees to drop the measure, sources said.

Harkin's about-face is important because of its potential effect on the future of the NIH effort to investigate unconventional medical practices.

The amendment was the result of lobbying by former Rep. Berkley Bedell (D-IA), an advocate of unconventional medical practitioners (**The Cancer Letter**, Sept. 25). Last year, Bedell's lobbying convinced Harkin to amend the NIH appropriations bill to mandate creation of an office to study unconventional therapies.

The latest measure, introduced Sept. 17, allowed the NIH director to authorize licensed physicians to use any medicine for investigational purposes, provided that no evidence established that the medicine is unsafe for investigation. Bedell said to **The Cancer Letter** that the NIH director needed such powers to ensure cooperation from unconventional practitioners, many of whom fear repercussions from FDA.

Five days after the amendment was introduced, Dingell attacked Harkin for using the appropriations bill as a vehicle for legislating.

"This is an extremely significant change in current law and is plainly not appropriate for an appropriations bill," Dingell, chairman of the House Committee on Energy and Commerce, wrote to William Natcher (D-KY), chairman of the House Labor, HHS and Education Appropriations Subcommittee.

"I do not agree that such initiatives are warranted through this appropriations bill and without hearings," Dingell wrote.

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In its budget report last month, the Senate Appropriations Committee made a reference to the NIH Office of Alternative Medicine. No such office exists within NIH.

There is an Office for the Study of Unconventional Medical Practices, and there is talk of superimposing the word "alternative" onto its shingle (**The Cancer Letter**, Sept. 25). However, the renaming is yet to occur and, in fact, may not occur if NIH sides with those who believe that the word "alternative" implies that treatments not tested through established scientific procedure are every bit as effective as the standard care.

"Unconventional" became the standard term since a report two years ago by the congressional Office of Technology Assessment.

While preparing that report, OTA considered the linguistic preferences of the parties concerned. Practitioners themselves favored the words "complementary," "noninvasive," "holistic," "wholistic" and "alternative."

The opponents' preferences included "unproven," "fraudulent" and worse.

Seeking a middle ground, OTA chose "nontraditional," but abandoned that term since its opposite, "traditional," refers to tribal healing and similarly untested modalities.

After much hairsplitting, OTA chose the word "unorthodox," but that, too, failed to fly. Unveiling its ultimate choice in the final report, OTA implored: "We intend no implicit message in the use of the word 'unconventional...'"

Trading In U.S. Bioscience Stock Halted Due To Analyst's Rating Drop

An investment rating by a Wall Street analyst quoting a report in **The Clinical Cancer Letter** caused an order imbalance and led to a halt in trading of shares of U.S. Bioscience Inc. last week.

Alex. Brown & Sons analyst David Webber issued an opinion that his confidence in U.S. Bioscience stock had fallen based on an FDA review of studies of the company's key drug, Ethyol, developed to protect cancer patients from the toxic effects of chemotherapy.

Webber cited an article in the July 1992 issue of **The Clinical Cancer Letter**, which reported that a

Food & Drug Administration literature review found a number of animal studies which suggested that Ethyol also protected tumors from radiation and chemotherapy.

The newsletter reported that the literature review of Ethyol was discussed in a closed session of FDA's Oncologic Drugs Advisory Committee last June, prior to the committee's consideration of another chemoprotector, Zinecard, by Adria Laboratories. The committee recommended against approval of the Adria drug based on evidence that it protected tumors from doxorubicin, though it encouraged the company to conduct more studies.

The newsletter also reported that the studies of Ethyol (also known as WR2721) in the FDA review had not been presented to the committee when it considered U.S. Bioscience's New Drug Application for Ethyol last January.

In his rating report, Webber said he believed Ethyol does not protect human tumors and that the drug eventually will be approved. However, he said, U.S. Bioscience stock is not likely to perform well until the FDA committee reviews Ethyol again. The existence of the animal studies, which had not been included in the company's original New Drug Application, could delay the approval, Webber said.

The analyst lowered the rating for the stock from a "strong buy" to "neutral."

Responding to the stock analyst's rating, U.S. Bioscience, based in West Conshohocken, PA, issued a statement that the company was not privy to what was discussed at the FDA committee's closed session, but that the review may have involved "isolated reports, in older literature, of Ethyol uptake in some rodent tumors."

The company said that there have been no data from human studies to suggest that Ethyol blunts the antitumor effects of chemotherapy or radiation.

"We were disappointed to hear of Alex. Brown's change in investment rating of our stock, and believe that careful examination of the facts of the situation does not merit this decision," the company said in a statement.

FDA Literature Search

The Cancer Letter last week obtained a copy of the FDA literature review that was discussed in the closed session of the June ODAC meeting.

The review was presented by Gregory Burke, director of oncology and pulmonary drug products, according to sources present at the meeting. Burke had no comment to **The Cancer Letter.**

The literature review, prepared by Wendelyn Schmidt of FDA's Div. of Oncology & Pulmonary Drug Products, listed 25 papers from 1981-1992 in a Medline search. None of the studies were included in the company's NDA submitted in October 1991. Schmidt reviewed 15 of the most pertinent papers.

Following is an excerpt from the review:

"Conclusions: From a survey of the following papers it is clear that some tumors are protected from various chemotherapeutic agents and radiation by WR2721. Protection tends to be low (DMF less than 1.7), but in a similar range to protection afforded to some normal tissue. Tumors exhibiting maximal anti-oncolytic effect were usually micrometastases where oxygenation was adequate. Protection with WR2721 occurs within 10-15 minutes after treatment and remains significant for several hours, although the manifestations of the protection may be seen throughout the observation period. WR2721 protection of tumor is also dose dependent.

"None of the papers or citations reviewed here were included in the original NDA submission. The only data submitted to the NDA suggesting the above findings were 1) Washburn et al., 1974, which indicated that Morris hepatoma accumulated more WR2721 than some normal tissue, 2) Millar et al., 1982, which showed no difference in uptake between normal bone marrow cells and Lewis lung carcinoma cells and 3) Yuhas and Storer, 1969, which found a DMF of 1.15 for mammary tumor protection from irradiation; two other papers showed a non-statistically significant reduction in time to tumor regrowth. Fifteen papers in the preclinical pharmacology/ ADME sections of the NDA submission addressed the issue of tumor protection in whole animals, of those papers, 9/15 were coauthored by Yuhas. Based on those papers, the sponsor stated:

"'Pretreatment with WR2721 has also shown significant protection of bone marrow toxicities induced by a broad range of antineoplastic agents including cisplatin, carboplatin, cyclophosphamide, nitrogen mustard, melphalan, mitomycin C, BCNU, and 5-fluorouracil, as well as ionizing radiation, without any reduction in the antitumor activity of these antineoplastic drugs or radiation. In fact, several preclinical models have demonstrated synergistic antitumor effects when WR2721 was administered prior to chemotherapy.'

"In summary, in contrast to the statement in the Ethyol NDA, there is evidence from in vivo preclinical studies indicating Ethyol may protect some tumors to an extent comparable to protection of some normal tissue from the toxicities of cyclophosphamide, cisplatin, melphalan, and radiation."

The four papers FDA considered "most germane to

the issue of tumor protection by WR2721" were:

Clement, J.J., and R.K. Johnson. 1981. Influence of WR2721 on the efficacy of radiotherapy and chemotherapy of murine tumors. Int. J. Radiat. Oncol. Biol. Phys. 8: 539-542.

Milas, L., Ito, H. and N. Hunter, 1983. Effect of tumor size on S-2-(3-aminopropylamino) ethylphos-phorothioic acid and misonidazole alteration of tumor response to cyclophosphamide. Cancer Research. 43: 3050-3056.

Twentyman, P.R. 1983. Modification by WR2721 of the response to chemotherapy of tumors and normal tissues in the mouse. Br. J. Cancer 47:57-63.

Wist, E.A. 1985. Effect of the radioprotector WR2721 on the response of metastatic Lewis lung carcinoma colonies to alkylating agents. Acta Radiol. Oncol. 24:259-306.

The FDA review summarized these and 11 other papers. Fourteen papers involved research in mice; one involved hamster cells. The most recent of the papers was dated 1987, while most were dated from 1979 to 1985.

Ultimate Proof From Human Studies

U.S. Bioscience, in its statement, said: "The ultimate proof of efficacy of any drug is derived from the results of appropriately designed controlled clinical trials in humans. To the knowledge of the company, based upon studies sponsored by U.S. Bioscience, as well as studies by the National Cancer Institute, there have been no data to suggest that Ethyol pretreatment blunts the antitumor effects of chemotherapy or radiation therapy in patients.

"In addition, during phase 2 clinical trials exploring the efficacy of Ethyol/anticancer drug combinations, unexpectedly high tumor response rates have been observed in such tumors as melanoma and lung cancer.

"U.S. Bioscience's New Drug Application was built upon the National Cancer Institute's Investigational New Drug Exemption, which contained a large data base of preclinical and clinical information that did not, in the company's opinion, present evidence of tumor protection.

"U.S. Bioscience has prospectively conducted an extensive international program of preclinical research which emphasized the testing of human tumors, including ovarian cancer, melanoma, breast cancer, leukemia and lung cancer.

"The work has been complemented by company-sponsored studies in rodent tumors, as well as the work of independent investigators. All these data are consistent with our previously reported and ongoing clinical observations with no evidence of tumor protection.

"In older literature, there have been isolated reports of Ethyol uptake into some rodent tumors. However, even in these reports, given relevant conditions of dose and schedule, the protective effect on normal tissue greatly exceeds any effect on tumor," the company said.

Robert Capizzi, U.S. Bioscience's executive vice president, said he had no comment other than the company's statement about the FDA literature review, but he did discuss the company's key clinical trial, a phase 3 randomized study of cyclophosphamide and cisplatin with or without pretreatment with WR2721 for ovarian cancer.

"Our conduct is in full accord with the FDA," Capizzi said to **The Cancer Letter.** "Our clinical trial is moving along nicely. Response rates are equivalent in both arms; the two survival curves are 31 months in the experimental arm and 30 months in the control arm. They look very comparable in terms of response, and that speaks to the therapeutic value of the combination. That with the decrease in hospitalization and decrease in antibiotics, are the most critical aspects of the study. These will be the most compelling features of the drug's efficacy."

In his investment report, Webber said: "We reason that a) the question of tumor protection has always been an important one to FDA; b) the fact that the company did not bring the studies to the agency's attention will not reduce interest in the issue; and c) that, whatever the ultimate conclusion regarding the significance of these studies, the studies constitute an issue with which the company will have to deal. More often than not, we believe, the existence of new issues regarding a New Drug Application translates into delays."

U.S. Bioscience stock (AMEX: US Bio s) fell 1 1/2 and closed at 7 1/4 on Oct. 1, the day following a "Wall Street Journal" article on the investment report, and was listed as most active in share volume on the exchange. On Oct. 2, the stock rose 1/8. The 52-week high was 44, the low was 6 1/8.

The company further stated that the article in the July 1992 issue of **The Clinical Cancer Letter** "contains inaccurate information" concerning ODAC's recommendation to FDA last January not to approve Ethyol.

The Clinical Cancer Letter reported that, at the January ODAC meeting, "the reasons cited for the decision were that the protective effects had not yet been convincingly established, and that the key study [in ovarian cancer] may have been compromised by protocol violations.... The committee said that more information was needed from ongoing trials." The paragraph summarized a more lengthy report contained in the February issue.

In its statement, U.S. Bioscience said, "Although the committee requested completion of the ovarian cancer trial, Chairman [Craig] Henderson reported ODAC's

consensus that the ovarian cancer study provides evidence that toxicity has been significantly decreased, specifically as related to hospitalizations associated with neutropenic fever."

Capizzi told **The Cancer Letter**, "Henderson made a very strong statement that, 'We believe that this particular trial does provide evidence that toxicities have been decreased. Specifically convincing are neutropenia less than 500 and granulocytes less than 500, and hospitalizations.' That is a very strong statement and has been basis of our emphasis in the trials.... The overarching concern on this is balance."

"We do not dispute Dr. Capizzi's statement; however, we feel that the paragraph at issue is accurate as a general description of the committee's deliberations. We stand by our story," said Kirsten Goldberg, editor of **The Clinical Cancer Letter** monthly and **The Cancer Letter** weekly.

NCI Issues Eight SPORE Awards, 12 Feasibility Grants, In 3 Cancers

NCI has issued the first awards for the new Specialized Programs of Research Excellence, which will direct $17.5 million annually to 17 institutions over the next three years for research in breast, prostate, and lung cancer.

Eight full SPORE awards were made to seven institutions, while 12 feasibility grants were made to 10 institutions.

NCI devised the program to stimulate research in the most prevalent cancers in women, in men, and in both. The grants are designed to stimulate translational efforts between laboratory and clinical scientists, and to encourage young investigators to pursue careers in translational research. Each SPORE also is responsible for developing a tissue resource that can be made available to scientists.

NCI originally advertised the grant program as offering nine SPORE awards, three in each disease site, based on merit. However, priority scores were such that the Institute decided to fund four breast cancer SPOREs and two SPOREs each in prostate and lung cancer, and to distribute the remaining funds for feasibility grants.

Centers, Training & Resources Program Director Brian Kimes said there was a "clear cutoff" in the priority scores between the disease sites.

"We wanted to encourage other organizations to get better and work on their prostate and lung cancer, so we decided to go with feasibility awards," Kimes said to **The Cancer Letter**. "We're trying to keep as many people in the game as possible."

SPORE Awards

Four awards were made for breast cancer SPOREs, out of 19 applications submitted. First year funds were:

--Lombardi Cancer Research Center, Georgetown Univ. Medical Center, Marc Lippman, $2.1 million.

--Univ. of Texas, San Antonio, Kent Osborne, $1.7 million.

--Lineberger Comprehensive Cancer Center, Univ. of North Carolina, Edison Liu, $1.9 million.

--Univ. of California, San Francisco, Craig Henderson, $1.7 million.

Two awards were made for prostate cancer SPOREs:

--Baylor Univ., Peter Scardino, $2 million.

--Johns Hopkins Oncology Center, Donald Coffey, $2.3 million.

Baylor Univ. will be officially designated as the Matsunaga/Conte Prostate Cancer Research Center after Sen. Spark Matsunaga (D-HI) and Rep. Silvio Conte (R-MA), both of whom died of the disease. The designation was madated in the FY92 appropriations for NCI.

Two awards were made for lung cancer SPOREs:

--Univ. of Colorado Cancer Center, Paul Bunn, $1.8 million.

--Johns Hopkins Oncology Center, Stephen Baylin, $2.1 million.

Feasibility Awards

Three-year feasibility grants of $200,000 annually went to:

--Dana-Farber Cancer Institute, David Kufe, for breast cancer.

--Univ. of California, Los Angeles, Dennis Slamon, for breast cancer.

--Memorial Sloan-Kettering Cancer Center, William Fair, for prostate cancer.

--Mayo Comprehensive Cancer Center, Donald Tindall, for prostate cancer.

--Pittsburgh Cancer Institute, Ronald Herberman, for lung cancer.

--Univ. of Texas Southwestern Medical Center, John Minna, for lung cancer.

Three-year feasibility grants of $75,000 annually were awarded to:

--Memorial Sloan-Kettering Cancer Center, Lawrence Norton, for breast cancer.

--Univ. of Texas M.D. Anderson Cancer Center, Gabriel Hortobagyi, for breast cancer.

--Yale Comprehensive Cancer Center, William Hait, for breast cancer.

--Washington Univ., St. Louis, William Catalona, for prostate cancer.

--Lombardi Cancer Research Center, Edward Gelman, for prostate cancer.

--Duke Comprehensive Cancer Center, David Paulson, for prostate cancer.

Cancer Act Impact: Decline In Mortality, DeVita Tells ACCC

The wave of discoveries and the scientific yield from those discoveries which followed adoption of the National Cancer Act of 1971 have resulted in a significant decline in cancer mortality for patients up to age 65, and for those up to 85 when smoking related tumors are excluded. But the greatest impact of the National Cancer Program has yet to hit the clinic, in the form of molecular medicine and new therapies under development.

That was the message Vincent DeVita gave to members of the Assn. of Community Cancer Centers when he accepted the ACCC annual award for contribution to community based clinical research. The award was presented at ACCC's Fall Leadership Conference in San Diego late last month.

DeVita pointed out that in the last 20 years, pediatric cancer mortality has declined 63 percent. He gave much of the credit for that to the fact that two thirds of children with cancer are entered onto clinical trials.

The continued increase in cancer mortality is primarily from smoking related cancers, DeVita said. This will level off and ultimately decline, as the impact of reduced levels of tobacco use is felt. That is already being seen in persons under age 55.

"Breast cancer incidence has increased 32 percent since 1980, but it is virtually certain that this is a total artifact of screening," DeVita said. The widespread use of mammography screening has resulted in early detection of tumors that would not have been found until much later, in more advanced stages. "We'll see the results of that, in decreased mortality from breast cancer, by the year 2001," DeVita said.

The "scientific yield" from the National Cancer Program, DeVita suggested, include discovery of restriction enzymes and reverse transcriptase, DNA hybridization and sequencing, recombinant DNA, hybridomas and monoclonal antibodies, a "cascade" of oncogenes, discovery of suppressor genes, and much more.

Development of a national network to facilitate application of research results, as called for in the Cancer Act, occurred in the 12 years following passage of the Act. This included, in 1972, major expansion of cancer centers, increased number of clinical trials, expansion of training programs, and initiation of the Cancer Control Program.

The Cancer Information Service and International Cancer Research Data Bank were established in 1974; the SEER Program in 1975; new epidemiology programs in 1978; the Community Clinical Oncology Program in 1981; prevention clinical trials in 1983; and PDQ in 1984.

DeVita said that he has "fond memories" of events following his proposal of CCOP, not long after he became director of NCI in 1980.

"It was controversial within this organization (ACCC)," he said. "It replaced CHOP (Community Hospital Oncology Program), which consisted of a one time, three year award (while CCOP was planned as a permanent program with three to five year, competitively renewable awards). But CHOP was a bird in hand. CCOP was also controversial among cancer centers and the cooperative groups. But it has turned out to be the most successful treatment program in the history of NCI. All of you had a role in its success, and for that, I thank you."

DeVita described present major limitations on cancer treatment: inability to determine when an apparently localized tumor has metastasized ("We will soon have genetic probes to help with that"); inability to detect minimal residual disease; inability to explore the full range of dose response; inability to monitor the impact of cancer treatment on cancer cells in vivo, on a moment to moment basis; specific and permanent resistance to anticancer drugs; lack of clinical assay systems.

Continuing and future logistical problems include speciality competition ("Who will be the oncologist in the future?"); tradition; economic considerations; public understanding of clinical trials, including fear of randomization.

Finally, "The health care system is a mess. It is cumbersome, and is our biggest problem. I hope this will be corrected by the next President, whoever that is."

Before he was appointed NCI director, DeVita had seen, as director of the Div. of Cancer Treatment, the increasing difficulty of enrolling patients in clinical trials by the clinical cooperative groups and academic centers.

More patients were being treated in community hospitals by the growing number of clinical oncologists in private practice, many of whom had been trained to do clinical research and were frustrated by the lack of access to clinical trials.

Two earlier programs, CHOP and the Cooperative Group Outreach Program, had demonstrated that

community oncologists could participate effectively in clinical trials. DeVita proposed CCOP as a permanent followup to CHOP, with CGOP continuing its role in fostering collaborations of the cooperative groups with smaller hospitals. Their twin goals were to help increase accrual to clinical trials while making available the best and latest treatment to patients in community hospitals.

CCOP now consists of about 60 institutions and, with CGOP, provides more than half of all patients enrolled in cooperative group trials.

DeVita left NCI in 1988 to become physician in chief of Memorial Sloan-Kettering Cancer Center. He resigned that position three years later but remains there as attending physician and member of the Program of Molecular Pharmacology and Therapeutics. He also holds the Benno Schmidt Chair in clinical oncology and services as professor of medicine at Cornell Univ. Medical College.

RFPs Available

Requests for proposals described here pertain to contracts planned for award by the National Cancer Institute unless otherwise noted. Address requests for NCI RFPs, citing the RFP number, to the individual named, the Executive Plaza South room number shown, National Cancer Institute, Bethesda MD 20892. Proposals may be hand delivered to the Executive Plaza South Building, 6130 Executive Blvd., Rockville MD.

RFP NCI-CB-33036-36
Title: Enzyme linked immunoassay of soluble receptors, antibodies and immunoglobulin molecules
Deadline: Approximately Dec. 10

NCI is soliciting proposals for enzyme linked immunoassay of soluble receptors and antibodies and immunoglobulin molecules. A four year award is estimated.

An offeror must meet a mandatory qualification criteria which requires that the offeror 1) demonstrate how it will accomplish the task of attendance at frequent face-to-face discussions between the NCI project officer and the contractor's project director (and other key personnel) in Bethesda, MD, in order to monitor and review progress on project activities, 2) demonstrate how it will accomplish the task of picking up samples from Bethesda, MD, perform the assays, and provide a written report of the results of the assays within a maximum of eight hours from the time of pickup, 3) have biocontainment facilities (BL-2) to conduct work in vitro with human and nonhuman primate viruses (such as HIV, SIV, and HTLV). The incumbent contractor is Hazleton Laboratories Inc.
Contracing officer: Patricia Rainey
RCB Executive Plaza South Rm 620
301/496-8611

NCI Contract Awards

Title: Dietary fat, cooking practices, indoor radon, and lung cancer among women
Contractor: Survey Research Associates Inc., Baltimore, MD; $1,876,269

Title: Epidemiological studies of cancer among atomic bomb survivors
Contractor: National Academy of Sciences, $1,926,314.

Title: A prospective cohort study of cancer among men and women in agriculture
Contractor: SRA Technologies Inc., Alexandria, VA; $3,737,626.

Title: Continuation of followup of DES exposed cohorts
Contractors: Dartmouth College, $288,833; Univ. of Chicago, $633,547; Baylor College of Medicine, $420,179; Univ. of Massachusetts Medical Center, $933,385; Boston Univ. School of Public Health, $618,553.

Title: A case-control study of hormonal, nutritional, and genetic risk factors in breast and prostate cancer
Contractor: SRA Technologies Inc., Alexandria, VA; $499,919.

Title: Cancer in relatives of children with Li-Fraumeni syndrome
Contractor: Danish Cancer Registry, $523,005.

Title: Cancer in patients with ataxia telangiectasia, xeroderma pigmentosum and fanconi anemia, and in their relatives
Contractor: Danish Cancer Registry, $366,545.

Title: Cancer following bone marrow transplantation
Contractors: Fred Hutchinson Cancer Research Center, $406,984; Medical College of Wisconsin, $482,392.

Title: Population based natural history of cervical neoplasia in high risk region of Latin America
Contractor: Fundacion Costarricense Para La Docencia En Ciencias De La Salud, Costa Rica; $383,514.

Title: Cancer risk in women with augmentation mammoplasty
Contractor: ABT Associates Inc., Cambridge, MA; $2,543,920.

Title: Operation and coordination of a nationwide, multistudy, high volume death certificate acquisition and management system
Contractor: Westat Inc., Rockville, MD; $778,929.

Title: A case-control study of stomach cancer in Polish Americans.
Contractor: Univ. of Illinois at Chicago, $1,034,077.