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Cancer Program Advocates Seek $170 Mil. Above President's Budget, Vow To Close Bypass Gap

Vowing to close in on the bypass budget "incrementally," cancer program advocacy groups delivered a plea for an additional appropriation of $170 million for NCI in fiscal 1993. None of the groups that spoke before the House Appropriations Subcommittee on Labor, HHS, Education & Related Agencies last week asked for the entire bypass budget, which would constitute a $764 million increase over the

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In Brief

Names Submitted For NIH Deputy Director; Gottesman Leads Genome Project Temporarily

NIH SELECTION committee led by NCI Director **Samuel Broder** has submitted the names of four or five candidates to NIH Director **Bernadine Healy** for the post of NIH Deputy Director for Intramural Research, the position vacant since Joseph Rall's retirement last year. One candidate is from NCI; many names have been rumored around NCI offices in the past few weeks, but the committee has been told, "No leaks," sources say. None of NCI's division directors are in the running. . . . **MICHAEL GOTTESMAN**, chief of NCI's Laboratory of Cell Biology, has been named acting director of the NIH Human Genome Project following the recent resignation of **James Watson**. Watson resigned after a feud with NIH Director **Bernadine Healy** over patenting of gene fragments, which Watson opposed, as well as charges--and Watson's denials--of financial conflict of interest. Gottesman does not want the job permanently, NIH sources say. . . . **SKIN CANCER** Foundation has begun a national campaign to teach self-examination of the skin as a way to increase early detection and treatment of the disease, which affects more than 600,000 Americans annually. The Foundation is placing public service announcements with the theme: "Skin cancer: if you can spot it, you can stop it." . . . **PRESIDENT BUSH** presented the American Cancer Society Courage Award to Sen. Connie Mack (R-FL) and his wife, Priscilla Mack, last week. Both have been treated for cancer; he had a malignant mole removed in 1989, and she was diagnosed with breast cancer last fall. Mack co-sponsored legislation to provide tax incentives for use of cancer screening procedures. . . . **52 SCIENTISTS** have been elected members of the National Academy of Sciences, including **Anthony Fauci**, director of the National Institute of Allergy & Infectious Diseases, **JoAnne Stubbe**, MIT and member of NCI's Div. of Cancer Treatment Board of Scientific Counselors, and **Bert Vogelstein**, Johns Hopkins.

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Goal To Close In On Bypass Budget 'Incrementally,' Groups Tell House

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President's budget request of $2.01 billion. The hearing was conducted by Rep. William Natcher (D-KY).

While NCI has never been funded at the bypass budget level, the document submitted annually to the President represents the Institute's determination of its research needs. NCI is the only government agency required to submit such a budget request.

Last year, advocacy groups were not as united in their stance on the bypass budget. The American Cancer Society and the Assn. of American Cancer Institutes asked for the bypass budget, while the National Coalition for Cancer Research asked for $200 million above the President's 1992 budget request. AACI is a member of the coalition. ACS is not.

This year, the AACI and ACS stance on the bypass budget mirrored that of other groups:

"ACS believes that the NCI bypass level is a realistic figure that represents that portion of our national resources which should be spent on cancer this year," said Walter Lawrence, ACS president and emeritus director of the Massey Cancer Center of the Univ. of Virginia Medical College.

"However, we recognize the serious national economic situation and understand the tremendous demand for funding from a number of worthy health programs," Lawrence said.

"Therefore, the American Cancer Society has met with the National Coalition for Cancer Research and has agreed to work for an increase for NCI of at least $170 million.

"This amount would, in our best scientific judgement, allow NCI to continue progress in some of the areas identified above, and would restore needed monies for the cancer prevention and control programs, construction, research training and career development," Lawrence said.

The request of $170 million above the President's 1993 budget is a response to economic hard times and high federal deficits. It does not constitute termination of the quest for the bypass budget, the groups said in their testimony.

If NCI receives the $170 million increase, the Coalition would like to see the additional funds distributed in the following way:

Cancer Prevention and Control--$48 million
Clinical Research--$17 million
Construction--$40 million
Cancer Centers--$18 million
Specialized Programs of Research Excellence--$10 mil.
Training and Education--$7 million
Research Project Grants--$30 million

"The NCCR fully supports the bypass budget," said Albert Owens, past chairman of the coalition and director of the Johns Hopkins Oncology Center.

"However, the disparity between the bypass budget and the Administration's proposal is $764 million. Therefore the NCCR recommends incrementally increasing spending for the National Cancer Program," Owens said.

Symbol Endures

"We wish to be clearly on record with the Congress that it is essential not to abandon the bypass budget as the long term goal to adequately address the magnitude of a growing epidemic of cancer in this country," said Brigid Leventhal, professor of oncology and pediatrics and director of clinical research administration at Johns Hopkins Oncology Center.

Leventhal testified for the American Assn. for Cancer Research.

Along with asking for a funding increase for NCI as a whole, witnesses spoke on behalf of particular programs.

Thus, Lawrence of ACS asked for an additional $30 million for the Centers for Disease Control program of grants to states to improve breast and cervical cancer screening, referral and education among disadvantaged women.

Under the 1993 budget request, the program is slated to receive $70 million, a $20 million increase from 1992. Lawrence also asked for an unspecified funding increase for the Office on Smoking and Health.

Similarly, AACR's Leventhal asked for an additional $85 million for the National Institute of

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Environmental Health Sciences, partly to pursue collaborative research with NCI.

▶**Vincent DeVita**, president of the International Council for Coordinating Cancer Research and clinical professor at Memorial Sloan-Kettering Cancer Center, and former NCI director, focused on funding of NCI's prevention and control programs.

"I have to tell you that my greatest frustration as NCI director was to come to Congress and tell them enthusiastically about our plans for prevention and have them react enthusiastically to those plans and provide resources and then find that the money never went into this particular program, which is the way that you would lower the incidence of cancer," DeVita said.

"I am here to suggest that the President's budget of $91 million for [cancer prevention and control programs] in 1993, which is a $15 million reduction from the $106 million of the previous year, is insufficient and would respectfully submit that the Congress add about $48 million to that particular budget so these kind of studies--the tamoxifen study and nutrition studies such as the Woman's Health Initiative--can in fact receive the support they need so we can take those advances from the laboratory to the bedside."

In his written testimony, DeVita noted that, "The framers of the National Cancer Act had the wisdom to isolate a portion of the NCI program, the cancer control budget, and protect it from other than its intended use, to serve as the effector arm of our applied prevention program." That line item accounts for less than 4.5 percent of NCI's budget, he said.

▶Speaking for American Society of Clinical Oncology, **Harmon Eyre**, chairman of the association's Public Issues Committee and Chief of Medicine at the Veterans Administration Medical Center in Salt Lake City, said that the President's budget request cuts into support for the Community Clinical Oncology Program and holds funding for the Clinical Cooperative Groups flat.

"Despite our own efforts and those of NCI, there remains a tremendous shortfall in funds for large scale clinical studies," said Eyre. "The number of clinical trials open in a given year has decreased from 527 in 1988 to about 500 in 1990.

"As a result of limited resources, some clinical research teams have already been forced to cap patient accruals and delay the initiation studies," Eyre said.

Fewer than 3 percent of all cancer patients in the U.S. are enrolled in NCI sponsored or approved clinical trials, he said, citing NCI figures.

ASCO also made an unusual plea for the House Appropriation Committee to address the problem of the public and private insurance plans' policies of denying reimbursement for nonresearch costs of treating patients enrolled in clinical trials.

"We are mindful that the Appropriations Committees are hesitant to deal with matters outside their jurisdiction, Eyre said. "However, we urge you to direct the attention of the relevant authorizing committees to the urgent need to address this problem within the context of health care reform.

"Without appropriate coverage for patient care costs associated with clinical trials, efforts to enhance funding for clinical research will be undermined. Our success in improving cancer treatment is dependent upon a joint effort that brings research funding to the NCI programs that coordinate clinical research and provides reimbursement for the patient care costs associated with those trials," Eyre said.

▶"The Cancer Centers Program is no further along in terms of actual buying power than it was nearly a decade ago," said **Jerome Yates**, president of the Assn. of American Cancer Institutes and associate institute director, clinical affairs, at Roswell Park Cancer Institute in Buffalo.

The appropriations for the cancer centers and the Specialized Programs of Research Excellence was increased by $33.5 million to $143.9 million in fiscal 1992 and remains at the same level in the President's 1993 budget request.

"From the increase for FY 1991 and FY 1992, $17.5 million will be deducted for the new SPOREs program, $750,000 will be deducted for the 12 planning grants, leaving approximately $14.3 million for the 58 centers previously funded," Yates said.

"From this total figure, travel, salary and expenses, holdbacks and funds held in reserve for potential redistribution to other institutes at the NIH will reduce the increase further," Yates said.

AACI asked for an increase of $28 million in fiscal 1993. Of that increase, $18 million would go to cancer centers and $10 million to the SPOREs program.

Yates said AACI supports the NCCR request for a $7 million increase for "K series" awards for physicians and PhD's prior to receiving their first R01 grant.

"This is the time when young physician researchers are typically discouraged from pursuing a research career due to highly competitive environment, and many decide to leave research and follow career in clinical practice," Yates said.

Breast Cancer Prevention Trial Launched, Enrollment Begins May 15

NCI and the National Surgical Adjuvant Breast & Bowel Project last week formally launched the Breast Cancer Prevention Trial to evaluate the preventive effects of tamoxifen in 16,000 women over age 35 who are at increased risk for the disease.

This year, over 180,000 women will be diagnosed with breast cancer. Over the next 10 years, about 1.5 million U.S. women will be told they have the disease, and almost half a million will die of it.

"We see breast cancer as an urgent priority," NCI Director Samuel Broder said at a press conference announcing the trial. "We need to develop important preventive strategies allowing individuals to make choices."

Broder stressed that tamoxifen may have risks as well as benefits for healthy women. "Tamoxifen certainly is not a miracle cure or preventive agent," he said. "Even if this trial should ultimately point the way, NCI will not necessarily advise women or doctors to use it in all cases, but to weigh and consider individual risks for each woman."

The $60 million randomized, placebo controlled trial will be conducted at more than 270 sites in the U.S. and Canada over the next five to eight years.

'Time Is Right'

Bernard Fisher, chairman of the NSABP and principal investigator for the trial, said the study is designed to demonstrate a 35 to 40 percent reduction in breast cancer and coronary heart disease, a 30 to 33 percent reduction in osteoporosis, and a mortality reduction of 30 to 35 percent for those women taking tamoxifen.

"We feel the time is right to embark on a trial to evaluate the efficacy of using a drug to impact on promotion or initiation of a tumor," Fisher said.

The National Heart, Lung & Blood Institute will provide nearly $8 million for analysis of heart disease, and the National Institute of Arthritis & Musculoskeletal & Skin Diseases will provide support for studies of osteoporosis and bone fractures in the trial participants.

The trial represents a number of "firsts": it is the first large scale prevention trial for women at increased risk of breast cancer, the first large prevention trial with substantial involvement of NCI-funded Community Clinical Oncology Programs, and the first trial to enroll subjects based on a disease risk assessment model developed at NCI.

All women 60 or over are be eligible for the trial, as are all women over 35 who have been diagnosed with lobular carcinoma in situ. Women with LCIS are at nine times the risk of an average woman for development of breast cancer.

Other women aged 35-59 will be enrolled based on how high they score on a breast cancer risk assessment model created by Mitchell Gail, chief of the Epidemiologic Methods Section in the Biostatistics Branch of NCI's Div. of Cancer Etiology.

A woman's risk will be determined by: age, number of first degree relatives with breast cancer (mother, sister, daughter), age at first live birth, number of benign breast biopsies, age at first menarche, and presence of atypical hyperplasia.

Entry Criteria

According to Carol Redmond, director of NSABP's biostatistical center, the minimum criteria for entry for women under 60 is as follows:

▶Age 35: one or more first degree relatives with breast cancer and two benign breast biopsies, or lobular carcinoma in situ (LCIS).

▶Age 40: two or more first degree relatives, or two biopsies, or LCIS.

▶Age 45: one or more first degree relatives, or two biopsies, or LCIS.

▶Age 50: same as age 45.

▶Age 55: one or more first degree relatives, or first live birth at age 30 or older, or LCIS.

Breast cancer risk assessment will be done over the next few weeks and randomization will begin on May 15, Redmond said. She also said that for non-white women, the risk assessment would consider rates specific for them, "to the extent we have that information available."

Tamoxifen, the most widely prescribed cancer drug in the world, has been used for 20 years to treat advanced breast cancer patients and since 1985 as adjuvant therapy for early stage breast cancer.

Half of the women will take a 20 mg dose of tamoxifen daily for five years while the other half take a placebo pill. ICI Americas Inc. of Wilmington, DE, will provide tamoxifen and the placebo without charge. The study will be double-blinded.

The protocol was reviewed last summer by FDA's Oncologic Drugs Advisory Committee, which approved the study on the condition that the eligibility criteria would be tightened to ensure that only high risk women would be enrolled (**The Cancer Letter,** Aug. 2, 1991).

The revised protocol received unanimous approval late last year after the informed consent form was modified to make clear there were tradeoff risks.

Toxicity data from NSABP B-14, a trial of tamoxifen

as prevention of secondary breast cancer in the contralateral breast showed that 1.5 percent of the women on tamoxifen experienced serious thromboembolic reactions, including two deaths. Six patients taking the drug developed early-stage endometrial cancer; three had prior hormone intake.

At the press conference, Fisher said the risk of thromboembolic disease is "slightly increased, primarily in postmenopausal women who have had previous thromboembolic events."

For endometrial cancer, "our conclusion is that the risk is greater than what would occur following estrogen replacement therapy," he said.

Therefore, women taking hormone replacement therapy are not eligible for the study unless they go off therapy for three months prior to the study and stay off. Other inclusion criteria include normal physical and mammogram, absence of pulmonary embolism, life expectancy of 10 years, and normal biochemical and hematological profile.

Benefits Outweigh Risks, Fisher Says

A Swedish study last year reported two cases of liver cancer in patients taking a tamoxifen dose greater than that usually taken in the U.S. However, no other study has found an increased risk of liver cancer in humans taking the drug.

"Therefore, we feel that the risk from liver cancer does not justify a concern in this trial relative to the risk-benefit outcomes," Fisher said.

A representative of the National Women's Health Network asked whether all 16,000 women "will be monitored for uterine cancer."

NSABP officials said all women will have routine gynecologic exam prior to the study, and will be asked about gynecologic abnormalities during follow-up. If they report abnormalities, they will be given an endometrial exam.

The Women's Health Network testified before ODAC in opposition to the trial last summer.

Last November, the group wrote to Gregory Burke, director of FDA's Div. of Metabolic Drugs, arguing that the trial should not begin due to questions about efficacy, feasibility, lack of a prior pilot study, definition of high risk women, and potential risk of tamoxifen.

Most importantly, the letter said, the group questioned whether all women over age 60 are at high risk of developing breast cancer.

"The NWHN does not advise women whose only risk factor is being over the age of 60 to participate," the group said in material distributed at the press conference.

Asked his response to critics of the trial, Broder said, "We should present the facts to the woman and let her make the best judgement. I'd like to point out that out of 100,000 women over age 60, there will be 300 cases of breast cancer annually. Between ages 60 and 65, the risk in 100,000 jumps to 400 cases. I think those are noteworthy figures." In addition, for women aged 40-45, breast cancer is the leading cause of death, he said.

Broder noted that no clinical study "is completely devoid of risks."

Broder: Trial Could Stop Due To Heart Attacks

A CBS reporter asked Broder, "How safe is it to unleash this drug on a healthy population?"

"One has to weigh the issues," Broder said. "Breast cancer is a formidable disease once it occurs. In Dr. Fisher's experience, hepatic cancer has not occurred. I personally believe that this study could require an early stopping point on cardiovascular disease due to heart attacks [in the placebo group]. Others don't believe it will."

Another reporter asked what would be the rationale for stopping the study "before you find an answer to the breast cancer question."

"The purpose of studies is not to play intellectual games," Broder said. "The purpose is to find out if a variable has the effect of decreasing disease. If the Data Safety and Monitoring Board looked at the decreased death rate due to decreased myocardial infarction events and found it to be significant, I do not know how you would ethically continue the study."

Broder said other scientists involved in the study do not share his view that the cardiovascular data will require an early end to the trial.

CCOP Participation: Leslie Ford, director of NCI's Community Oncology & Rehabilitation Program in the Div. of Cancer Prevention & Control, said 80 percent of the NCI-supported CCOPs will enroll patients on the study.

Of the 20 percent not involved, some chose not to apply and others did not have the background to qualify for the study, Ford told **The Cancer Letter.** Of the 12 minority CCOPs, "three or four" are involved in the breast cancer prevention trial, Ford said.

"Women will be taken care of in their routine care setting," Ford said. "By forging this alliance between cancer specialists and primary care providers, we have found in the past that primary providers have an increased awareness of cancer."

Persons seeking information about the trial can call NCI's Cancer Information Service, 800/4-Cancer, or the American Cancer Society, 800/ACS-2345.

Space Station Attacked By Advocates For Earth-Bound Health Research

NASA's proposed space station was attacked from the ground last week as health research advocates told the House Committee on the Budget that the $2.3 billion the program would cost in FY 1993 would be better spent on earth.

At a hearing chaired by Rep. Richard Durbin (D-IL) advocates of research in cancer, Alzheimer's disease and arthritis took issue with claims that the space station "Freedom" has the potential to advance medical research.

"We do not agree that a strong case has been made for choosing to do cancer research in space over critically needed research here on earth," said David Rosenthal of Harvard Medical School, speaking for the American Cancer Society.

"At this time it does not appear that the type of microgravity experiments and medical research that could be conducted on board a space station would yield benefits matching, much less exceeding, the benefits to be gained from pursuing research in established laboratories, clinics and other facilities around the country," Rosenthal said.

In a document prepared last year NASA said that the space station "will provide significant advances in science technology and commerce, establishing a man tended research in a microgravity environment."

During last year's budget debates Senate and House members argued that experiments conducted on the space station would be likely to lead to advances in osteoporosis, cancer and AIDS research.

"Our nation already has a first class medical research facility--the National Institutes of Health," said Durbin at the hearing. "Unfortunately, the NIH is unable to fund all of the promising avenues of research identified by the medical community. For some institutes, such as NCI, the portion of the approved research grants drops to less than 20 percent."

Speaking for the Arthritis Foundation, Shaun Ruddy, professor at the Medical College of Virginia, struck a similar back-to-earth note: "Simply put, there is no osteoporosis research that will be conducted in space that could not be carried out in laboratories here on the ground."

"NASA's life science research proposals are not bad science," said Veronica Catanese, a member of the National Council of the American Federation for Clinical Research.

"They are just not good enough to be ranked above the long list of existing research that is standing in line waiting for funding from the NIH and VA."

Attempts to kill the space station--along with the proposed supercollider, a portion of the strategic defense initiative and parts of the intelligence budget--are expected to be introduced during floor debates by Sen. Dale Bumpers (D-AR), who is then expected to put a portion of the money into the NIH budget (**The Cancer Letter,** April 24).

The "Bumpers initiative," as the expected Senate measures are called since for the time being they are not elaborated in any bill, has the support of over 50 research groups. ACS is not on that list of supporters (**The Cancer Letter,** May 1).

Addressing the space station's relevance to health research, astronaut Rhea Seddon said that the loss of blood cell mass during space flight has been observed since the Skylab era.

"Just what causes this is not fully known," she said. "It may be that the change is hormone mediated or could be occasioned by a reduced rate of red cell release into the circulation.

"Understanding what triggers this loss may help us gain new insights into anemias which plague so many individuals on earth," she said.

While medical research on the space station could well bring about advances in medicine, Robert Moser, clinical professor of Medicine at the Univ. of New Mexico School of Medicine, said medicine on earth should not be the sole justification for the station.

"Undoubtedly, there will be benefits from space life science research that will be beneficial to patients on Earth," said Moser, a member of the Space Studies Board of the National Research Council.

"This will be information largely peripheral to the sole purpose of space medicine--to learn enough to ensure reasonable lack of risk to space faring crews. Benefits derived for Earth bound medicine must not be construed as the primary driver of space medicine," he said.

NCI To Begin Study Of Augmentation Mammaplasty This Fall: Adamson

NCI has developed a retrospective cohort study of 12,000 women with augmentation mammaplasty to determine the long term health effects of the controversial procedure.

The study will not focus on cancer patients who received reconstructive implants, said Richard Adamson, NCI Director of the Div. of Cancer Etiology. Adamson described the study at a hearing of the House Subcommittee on Housing and Consumer Interests of the Select Committee on Aging.

According to Adamson the study will begin this fall and will take four years to complete.

Adamson and Jane Henney, FDA Deputy Commissioner for Operations, are co-chairmen a Public Health Service task force developing a research strategy for the study of issues related to silicone gel filled implants.

The women in the NCI designed study will be recruited from plastic surgery practices and the cohort assembled to achieve 10 years of followup, Adamson said.

The study will focus on women who received augmentation mammoplasty and will not include breast cancer patients. Studies of cancer patients who had received implants would be complicated by the need to evaluate the effects of stage at diagnosis and the role of breast cancer treatments, Adamson said.

"We are currently exploring the possibility of conducting such a study within the context of a number of large clinical trials for breast cancer," Adamson said.

The medical records of women included in the study will be abstracted for details on the implants, information on short term complications and risk factors for a number of diseases. Reported breast procedures will be validated by retrieving medical records.

To draw comparisons, the expected values for cancer rates in these women will be determined in the following ways:

--Through comparison with the NCI Surveillance, Epidemiology and End Results program;

--By developing internal rates by assembling a comparison group of about 3,000 women who have undergone other types of plastic surgery at the same practices as the mammaplasty patients. These women will be followed up in the same way as the mammaplasty patients so that cancer incidence rates in this comparison cohort would be determined.

"These patients may be a more appropriate comparison group than the general population since we will be able to control for factors associated with the choice of plastic surgery," Adamson said.

Incidence rates of the connective tissue disorders which have been reported in connection to breast implants are not available currently available and NCI is considering expanding the comparison cohort to achieve statistical power to compare rates of connective tissue disorders with implant patients, Adamson said.

"Given the publicity in recent months about possible adverse effects of implants, we feel that validation of self reports of connective tissue disorders through retrieval of medical records is essential," Adamson said. "Since the connective tissue disorders experienced by implant patients are often not clearly defined, it may also be desirable to consider detailed clinical examinations and blood tests of a sample of study subjects."

Senate Appropriations Committee recommended recently that NCI "develop a strategy for conducting longitudinal studies on women with various types of silicone breast implants."

A similar study sponsored by manufacturers of breast implants is underway at New York Univ. That study will include 5,000 implant patients and 5,000 comparison patients.

Another study, which involved passive follow up of patients, was begun in Los Angeles some time ago and is continuing with grant support from NCI. Recently NCI recommended that a methodologic component be added to that study to interview the subjects about diseases other than cancer and about risk factors for a variety of disorders.

AIDS Research

FDA Advisors Recommend Approval Of DDC In Combination With AZT

FDA's Antiviral Drug Products Advisory Committee has recommended approval of dideoxycytidine (DDC) for use in combination with zidovudine (AZT) in AIDS patients.

However, the committee recommended against DDC's approval as monotherapy in treating AIDS patients who are intolerant to, or who have not responded to AZT and didanosine (DDI).

In reaching its decision on the question of monotherapy, the committee considered a study conducted jointly by the drug's manufacturer, Hoffmann-LaRoche Inc., and the AIDS Clinical Trials Group of the National Institute of Allergy & Infections Diseases. That study, ACTG 114, comparing DDC with AZT, indicated that the patients given AZT did better than patients on DDC in terms of their length of survival and the avoidance of serious opportunistic infections.

In their presentation before the committee, Hoffmann-LaRoche researchers contended that data from this study as well as other large-scale DDC protocols suggested that some patients on DDC did appear to derive some quality of life benefits from the drug, including weight gain. The committee was not convinced that these benefits were clear and well substantiated and concluded that approval for DDC

monotherapy was not warranted at this time.

The committee also reviewed several small studies testing the efficacy of combination DDC/AZT, comparing the combination to AZT alone. The majority of these studies used only patients who had not previously been treated with AZT.

The results of these trials indicated that the combination therapy had a beneficial effect in some patients through increased CD4 cell levels.

In addition, AZT manufacturer Burroughs Wellcome Co. presented data from a randomized study that produced results consistent with those found in the smaller Hoffmann-La Roche studies.

The committee in its recommendation concluded that data from these studies, when considered together, warranted FDA's approval of DDC for use in combination with AZT. The committee emphasized, however, that since most of the DDC/AZT combination therapy trials involved patients who had not previously received AZT therapy, the approved indication for combination DDC/AZT should be limited to patients who had similarly not been treated with AZT.

The committee said the benefits of DDC/AZT combination therapy need to be studied in persons already treated with AZT before its indication can be extended to this group.

The committee strongly urged continuation of a large ongoing, double-blind trial, ACTG 155, which compares patients on combination therapy with patients being treated with either AZT or DDC. The committee argued that breaking the codes so that an analysis can be done would be premature and would irrevocably harm any chance to acquire reliable efficacy data on DDC/AZT combination therapy.

FDA officials said the agency intends to act quickly in its evaluation of the drug; the agency rarely acts against recommendations of its advisory committees.

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-CO-25611-18
Title: Eating Hints
Deadline: Approximately June 15

Single award for a fixed price contract. Inspection of source material will be on or about June 8 at NIH, Bethesda, MD. Book, 96 pages with separate wraparound cover. Five color printing on covers and four color printing in text. 750,724 books and films used in printing. Level II printing and finishing attributes. Trim size, 5-7/8 x 9", bind on the 9" dimension. Material furnished: 50 mechanicals with tissue overlays, 72 color reflective art illustrations and sample for style only. Proofs require two sets of book dylux and one set composite matchprint or equal color proof of covers and all four color process pages. Must be composite proofs with all elements in position. Inks will be four color process, PMS 325 aqua, PMS 155 tan and black. Operations include binding, separations, printing, coating, margins, packing, mailing and shipping.
Contract Specialist: Catherine Baker
RCB Executive Plaza South Rm 620
301/496-8611

NCI Contract Awards

Title: When someone in your family has cancer
Contractor: Monarch Litho Inc., Nontebello, CA; $82,000.

Title: Synthesis of selected chemical carcinogens and chemopreventive agents
Contractor: Chemsyn Science Laboratories, Lenexa, KS; $1,466,182.

Title: Synthesis of selected chemical carcinogens and chemopreventive agents
Contractor: American Health Foundation, $1,305,259.

Title: Booklet, Taking Time
Contractor: Stephenson Inc, Alexandria, VA; $346,450.

Cancer Prevention Fellowship Program Accepting Applications

NCI's Div. of Cancer Prevention & Control is accepting applications for its Cancer Prevention Fellowship Program. The purpose of the program is to train individuals from a multiplicity of health science disciplines in the field of cancer prevention and control.

The program provides for:

--Master of Public Health training (at accredited university programs).

--Participation in the DCPC Cancer Prevention and Control Academic Summer Course.

--Working at NCI directly with individual preceptors on cancer prevention and control projects.

--Field assignments in cancer prevention and control programs at other institutions.

Funds permitting, as many as 10 fellows will be accepted for up to three years of training, beginning July 1, 1993.

Deadline for receipt of applications is Sept. 1, 1992.

For application information, send postcard or letter with name and home address to: Dr. Douglas Weed, Director, Cancer Prevention Fellowship Program, Div. of Cancer Prevention & Control, National Cancer Institute, Executive Plaza South T-41, Bethesda, MD 20892.

For further inquiries, contact Barbara Redding, 301/496-8640.