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Progress Toward Year 2000 Goal Slow, But NCAB Says It's Too Early, Only Data Up To '87 Available

It has been only four years since NCI and the National Cancer Advisory Board adopted the goal for the Year 2000 of reducing cancer mortality by 50 percent. At that time it seemed far enough in the future

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In Brief

Bernard Fisher Professorship Endowed By ICI Pharma; Brady Wins RSNA Medal

ICI PHARMA has established the Bernard Fisher-ICI Professorship in Surgery for the advancement of breast cancer treatment and research at the Univ. of Pittsburgh in honor of Fisher's pioneering work in breast cancer treatment. The Wilmington based company has agreed to give the School of Medicine $600,000 over the next six years. Fisher is chairman of the National Surgical Adjuvant Breast & Bowel Project, director of the Cancer Adjuvant Therapy Center at the Univ. of Pittsburgh, a member of the National Cancer Advisory Board and a former member of the President's Cancer Panel. . . . **LUTHER BRADY,** chairman of the department of radiation oncology and nuclear medicine at Hahnemann Univ. received the Gold Medal Award from the Radiological Society of North America. The medal is the society's highest honor, given to those "who have rendered unusual service to the science of radiology." Brady was president of the society in 1985 and has served RSNA in several capacities for more than 20 years. . . . **NATIONAL CANCER** Advisory Board appointments to fill seats vacated by resignations of Louis Sullivan (when he was named HHS secretary) and Louis Gerstner (when he took over the reigns of a major tobacco company) are still languishing in the White House. It appears the Administration now intends to wait until it is time to fill the five seats which will open up after the board's January meeting, and make all seven appointments then. The five whose terms expire then are Roswell Boutwell, Helene Brown, Gertrude Elion, Enrico Mihich, and Louise Strong. . . . **SAMUEL BRODER** on the NCAB's recent practice of having "a two day meeting with a four day agenda. That's not the proper way to deal with NCI business." . . . **COMBINING BIOLOGICAL** Response Modifiers With Cytotoxics is the topic of an NCI conference scheduled for March 5-7 at Omni Inner Harbor Hotel, Baltimore. Deadline for abstract submission is Jan. 19, registration deadline Feb. 2. For information contact Abbe Smith or Debra Casey, Technical Resources Inc., 301/770-3153.

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Progress Toward Year 2000 Goal Slow, But NCAB Says It's Too Early

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to preclude a sense of urgency. Now that the 1990s have arrived, the next millennium does not seem so far away.

NCI and its advisors are starting to consider how much progress has been made on meeting the individual goals in the elements that make up the Year 2000 Plan.

The NCAB's Committee on Information & Cancer Control heard a report on progress toward those goals last month. The general conclusion: Not much has been made that can be measured, but it is too early for that, especially considering that the data presented for the most part only went through 1987.

Larry Kessler, chief of the Applied Research Branch in the Div. of Cancer Prevention & Control, presented an interim report on measurements involved in the goals:

Smoking: The target for the Year 2000 is for no more than 15 percent of Americans to smoke. Considering that in the 1960s, more than 50 percent of American males smoked regularly, the fact that in 1987 only 31 percent of males smoked is astonishing. More recent estimates have placed that figure under 30 percent. The prevalence for women in 1987 was 28 percent.

"It has been a straight line projection, dropping about one percent a year," Kessler said. "If that continues, we still will not quite reach the goal of 15 percent."

The good news is that smoking prevalence among high school seniors "has really turned around," with the upward trend seen into the 1970s having been reversed.

The discouraging news is that the new downward trend among high school seniors appears to have flattened.

Diet: Surveys over time of women age 19-50 show that there has been no change in the percent of calories from fat. In 1971 to 1974, it was 36.5 percent. In 1986, it was 36.4 percent. The Year 2000 goal is 30 percent. "There have been a lot of changes in the diet, but they have not affected this measurement," Kessler said.

With fiber consumption, the average for men is 11.5 grams per day, and for women, 8.8 grams. The trend was flat for both, from 1971 to 1986. The target is 20-30 grams per day.

Screening: The goal was to have 90 percent of women in the appropriate age groups screened by Pap smears. The actual figure is 77 percent, with the trend in white women flat. One encouraging trend was that the percentage of black women screened increased from 60 percent in 1973 to more than 71 percent in 1987.

In breast screening for women over age 50, the trend for breast physical examination was flat, with 45 percent having one during the year prior to the survey. The goal for mammography was that 80 percent of women in the recommended age groups; in 1987, it was only 14 to 19 percent. However, there are indications that the trend is positive, especially considering the numbers of dedicated mammography units in use. Those increased from under 1,000 units in 1980 to about 7,000 in 1987. Kessler said that about 2,000 more were estimated to have opened in 1988.

Treatment: Increased adoption of state of the art therapy is a key element of the plan. Interim objectives are related to survival. There have been positive trends in five year survival for some cancers, Kessler noted. Comparing those diagnosed from 1977-1980 with those diagnosed from 1981-1986, those trends were:

- Colon cancer--1980, 40.9 percent five year survival; 1986, 43.4 percent five year survival. Year 2000 goal, 51 percent.
- Rectal cancer: 39.5 percent, 42.6 percent. Year 2000 goal, 59 percent.
- Small cell lung cancer: 9.3 percent, 9.8 percent. Year 2000 goal, 15 percent.
- Testicular cancer: 80.4 percent, 87.5 percent. Year 2000 goal, 94 percent.
- Breast Cancer (over 50): 63.5 percent, 65.3 percent. Year 2000 goal, 72 percent.

For white patients, males and females combined

THE CANCER LETTER

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(where appropriate), statistically significant increases occurred in five year relative survival rates of 15 primary sites--esophagus, stomach, colon, rectum, lung, melanoma, female breast, ovary, prostate, testis, bladder, brain and nervous system, Hodgkin's disease, non-Hodgkin's lymphoma, and multiple myeloma.

For black patients, the only cancer sites for which there were significant increases in survival over time were prostate for males and bladder for males and females.

Committee Chairman Helene Brown commented, "This does not seem to be a very bright report. It's a little dismal."

NCAB Chairman David Korn suggested that "we should be careful about using words like dismal. The Year 2000 goals we adopted were a bit speculative. There was no hard evidence we could reach all of them. The first surgeon general's report on smoking was in 1964. It took an awfully long time for the impact to be realized."

DCPC Director Peter Greenwald noted that "a lot of those statistics came out about the time the goals were established." NCAB member David Bragg agreed: "This is just a snapshot of the start."

Brown suggested that the first data which could measure progress toward the goals would be that for 1989, which will not be available until 1992.

NCAB member Erwin Bettinghaus did not believe the dietary fat data will remain flat. "I am absolutely convinced that we will have a decrease in fat."

Bragg asked if the NCI budget reflects an emphasis on the goals.

"That's a valid criticism," Brown said. "Why not put the money we have on the priority areas?"

The plan for achieving the goals calls for such investments as doubling the number of patients on clinical trials, doubling the number of cancer centers, increased efforts in screening, education, etc.

In none of those areas have the NCI budgets even come close to providing the money needed for the activities called for in the plan.

"We have important opportunities we can't pursue because of the limited resources," Greenwald said.

Bettinghaus suggested that the NCAB consider issuing commendations to various organizations that may contribute significantly toward progress in cancer.

"It would be appropriate for us to heartily congratulate Congress for banning smoking from all domestic flights," he said.

Korn agreed. "That was an incredible accomplishment. We would never have predicted that five years ago."

President And First Lady Visit NIH, Hail 'Commitment To Compassion'

President George Bush and First Lady Barbara Bush visited the NIH Clinical Center the Friday before Christmas to meet with adults and children with AIDS and to commend all NIH employees for their work to combat AIDS, cancer and other diseases.

After visiting patients and their families, the President gave a 10 minute talk to about 500 NIH employees. He first spoke briefly about the U.S. military intervention in Panama, expressing his sorrow over loss of life, but saying the intervention was necessary. "We know that nothing is more crucial to peace on Earth than freedom and democracy, and that's what our American soldiers are achieving, freedom and human liberty for those who endured brutal tyranny and brutal oppression," Bush said.

The President and Mrs. Bush were on their way to Camp David, but, Bush said, "In these last days before Christmas, I did want to stop by here and salute what you are doing in biomedical research. For here, too, in your way, you are standing for decency. You are helping to improve the health of millions of Americans, and even more, like those soldiers in Panama, you are giving the greatest gift imaginable, the gift of life.

"Nowhere is this gift more evident that in your work to combat AIDS." Bush noted that two years ago, he had met with AIDS patients at the Clinical Center. This time, he met with a patients' support group and a family support group. Bush said the visits "reminded me of the need for compassion and understanding, and by that I mean the compassion that moves us to care for all those infected with HIV, men and women, adults and children. You, above all, are doing just exactly that. And I want you to know I'm with you and extraordinarily grateful for what you're doing."

Bush noted that some Americans "don't want to help, don't want to become involved because of a misplaced fear. They're afraid of holding an AIDS patient because they're frightened of getting AIDS." These people, he said, are uninformed. "A few minutes ago, we were in a room full of kids with AIDS and we could just feel the courage and character of the doctors and nurses and parents and counselors, and being with them, I thought of how there is no reason to fear for your health, just their health." He said he wished to thank "those who are not afraid" and "those of you here today who do so much for so many."

Bush singled out HHS Secretary Louis Sullivan, Assistant Secretary for Health James Mason, acting

NIH Director William Raub, NIAID Director Anthony Fauci, NCI Director Samuel Broder, NCI Laboratory of Tumor Cell Biology Chief Robert Gallo, and Antonia Novello, the Surgeon General-designate. "Each of these dedicated scientists preaches compassion and understanding," Bush said.

Work on controlling AIDS "has far to go," Bush said, but he also pointed out the advances over the last decade in isolating and treating the disease, including development of AZT and treatment for PCP. "Were did these advances come from?" he asked. "They are rooted in biomedical research conducted and supported by NIH. They show the value of your commitment, and I commend that commitment.

"Too often, we speak of compassion and understanding this time of year," Bush said. NIH employees "embody and live that message all year round. And for that, I thank you, and I want to wish you and your families a warm and happy holiday season. God bless you, and those who are working so hard to save."

HHS, OMB Reach Tentative Budget Accord

HHS and the Office of Management & Budget have tentatively agreed to recommend $7 billion in fiscal 1991 for NIH and an additional $1.7 billion for AIDS research and public health programs.

OMB initially proposed $6.6 billion for NIH and $1.6 billion for AIDS, the same funding level as in FY 1990. HHS Secretary Louis Sullivan is said to have requested $7.2 billion for NIH and $1.75 billion for AIDS.

Under the agreement, HHS and OMB recommended that FDA receive $617 million in FY 1991, about a $33 million increase over the actual amount the agency will receive in FY 1990, about $584 million, when the Gramm-Rudman sequestration is subtracted. Part of the increase would be funded by user fees on industry. Industry has fought and Congress has not approved user fees for FDA services several times in the past, most recently in the President's 1990 budget (**The Cancer Letter,** Jan. 20, 1989).

ASCO Awards Contract For D.C. Office To Washington Law Firm

The Washington D.C. law firm of Fox, Weinberg & Bennett has been awarded the contract to establish an office in the city for the American Society of Clinical Oncology.

To head up the office, ASCO has hired Ellen Schillinglaw, veteran Capitol Hill staff member who most recently was congressional liaison for the Health Care Financing Administration.

Fox, Weinberg & Bennett partner Samuel Turner, former chief counsel for the Dept. of Health & Human Services, is the principal member of the firm for the ASCO contract.

The new ASCO office is located on the 11th floor of the building in which the law firm has its offices, at 750 17th St. NW, Washington DC 20006. The phone is 202/778-2396.

The primary function of the new office is to support expanded ASCO legislative initiatives. "ASCO has reached the size and level of activity where we need this help," ASCO President Robert Young said. The ASCO Board of Directors and the Public Issues and Clinical Practices Committees will closely monitor the office and hire additional staff if needed, Young said.

The RFP ASCO issued (**The Cancer Letter,** Aug. 11) generated 15 responses. After trimming that number in half, review including site visits was carried out, and the board's vote to award the contract to the law firm was unanimous.

Eight Scientists Awarded $800,000 By Milken Family Medical Foundation

For the second year in a row, eight cancer scientists went to dinner and walked out with $800,000 in their collective pockets.

Again, it was both the largest total amount in an annual cancer award program, and the two top prizes of $250,000 each represented the largest single award in the cancer field.

The second annual Milken Family Medical Foundation Cancer Research Awards were presented last month at dinner at the Waldorf Astoria in New York.

Michael Milken, whose family supported foundation funds a broad range of health related research, education, and service programs, told the recipients that "the reason behind these awards is so you can stay in the laboratory and still have a little fun," with the hope that will speed progress in cancer research by encouraging them to avoid the temptations of private practice or industry.

"We have to look at how society allocates its resources," Milken said. "The U.S. military program in Western Europe equals the total pay of all the teachers in the United States. That is $20 billion a year to West Germany, which is loaning that much to the country we are trying to protect West Germany from."

Award winners were (as announced in **The Cancer Letter** Nov. 10):

▸ Bernard Fisher, professor of surgery at the Univ. of Pittsburgh and chairman of the National Surgical Adjuvant Breast & Bowel Project, who received the $250,000 Distinguished Clinician Award.

▸ Thomas Waldmann, chief of the Metabolism Branch in NCI's Div. of Cancer Biology & Diagnosis, who received the $250,000 Distinguished Basic Scientist Award.

▸ Lawrence Einhorn, professor of medicine at Indiana Univ., who received a $50,000 Clinician Award.

▸ Edward Harlow, Cold Spring Harbor Laboratory, who received a $50,000 Basic Scientist Award.

▸ Stephen Howell, professor of medicine at the Univ. of California (San Diego), who received a $50,000 Clinician Award.

▸ John Minna, chief of the NCI Navy Medical Oncology Branch, who received a $50,000 Clinician Award.

▸ Charles Sherr, St. Jude Children's Research Hospital, who received a $50,000 Basic Scientist Award.

▸ Bert Vogelstein, professor of oncology at Johns Hopkins Univ., who received a $50,000 Basic Scientist Award.

Gerald Rosen, Cedars-Sinai Cancer Center, was chairman of the Selection Committee.

Other members were NCI Director Samuel Broder; Alex Fefer, Fred Hutchinson Cancer Center; Emil Frei, Dana-Farber Cancer Institute; David Golde, UCLA Center for Health Sciences; James Holland, Mount Sinai Medical Center; Philip Leder, Harvard Medical School; John Macdonald, Temple Univ. Cancer Center; Lois Murphy, Memorial Sloan-Kettering; and Bernard Salick, Salick Health Care Inc.

Cancer Centers Branch To Be 'More Proactive' In Future, Kimes Says

The Cancer Centers Branch, now ensconced in its new home in the Div. of Cancer Biology & Diagnosis, promises to be "more proactive" after a period of rebuilding staff and, if Congress is so inclined, resources.

Brian Kimes, associate director of the Centers, Training & Resources Program, the new home of the centers, gave the National Cancer Advisory Board a brief review of the issues facing the centers branch, as well as the other branches which were merged into the program--facilities, training and organ systems.

Cancer Centers Branch: "We are faced with a dilemma: we have increasing opportunities for research, but a flat budget. We're going to have to set our priorities carefully."

Kimes stated what he hoped would be the branch's new philosophy: "We hope to be more proactive overall, and more active with center directors and within NCI. We want a strong interactive partnership with center directors, and an effective relationship with the Assn. of American Cancer Institutes. We have a lot of rebuilding to do and a lot of rethinking to do."

The Institute of Medicine report, "A Stronger Cancer Centers Program," made six recommendations (**The Cancer Letter,** April 28). The first three involved budgetary matters, including the recommendation to reprogram money from other areas into cancer centers and appealed to Congress for greater funding for the program.

"I'm not sure we can really deal with those (recommendations), since the 1990 budget process is over, "Kimes said. "I hope we can get more in 1991. I don't see how we can have a 'Stronger Cancer Centers Program' without more money."

The other three recommendations were, first, to develop a comprehensive plan for the centers program. NCI Deputy Director Maryann Roper heads a planning committee that is developing a five year plan for the program. A draft of the plan is expected to be ready in February. In addition, there is an Ad Hoc Advisory Committee to the director, made up of center directors.

Second, the report recommended more representation of centers within NCI. Kimes pointed to the planning committee and ad hoc committee as efforts to increase the representation. Also, three center representatives will be named to the DCBD Board of Scientific Counselors, probably at the winter meeting. Two of those are Ross McIntyre, director of the Norris Cotton Cancer Center, and Walter Eckhart, of Salk Institute. Several other board members are from cancer centers (**The Cancer Letter,** Nov. 17).

Third, the report said the management capabilities of the cancer centers program should be strengthened. Kimes said he is working on rebuilding the staff. Margaret Holmes has been named acting branch chief while a search for a permanent chief is carried out. Kimes said he is looking for "an MD who knows a lot about clinical trials." Alan Schreier, in the Biological Carcinogenesis Branch of the Div. of Cancer Etiology, will become program director of the centers branch.

Research Facilities Program: If a program has no staff and no money, why keep it, Kimes asked rhetorically, referring to the fact that no construction funding was included in the FY 1990 budget and the recent retirement of branch chief Donald Fox (The

Cancer Letter, Oct. 6).

"There are still good reasons to maintain a viable construction program," Kimes said. There are still construction grants that need monitoring, and active construction review of applications is necessary, because even if there is no funding, an NCI approved application can enables an institution to seek funding from other sources, he said.

In addition, the 1990 budget authorized NIH to take a total of $15 million from the institutes for construction grants, part of which is to be used for construction of animal research facilities. With an active research facilities program, NCI has applications on hand and will be able to compete for some of that money, Kimes said.

Kimes said he is recruiting for a replacement for a new branch chief. "We will maintain an active program," he said.

Cancer Training Branch: Kimes said that in the past, the training branch has been "in isolation" from the rest of NCI except for prevention and control and surgical oncology. Noting that the branch has made only 13 physician-scientists awards this year, he said, "We need to analyze what's going on in training. We need to see more physicians doing research. We can take a closer look at what we're doing."

Organ Systems Coordinating Branch: The branch this year went from being primarily a grant program to a program that sponsors workshops to coordinate research across divisions. The branch is still adjusting, Kimes said. Some upcoming workshops: a planning group will be meeting on myeloma and a workshop on 5-FU and levamisole adjuvant therapy for colon cancer will be held to discuss research on the mechanism.

US Tobacco Program Loses $505 Mil. In Loan Principal To Tobacco Farms

U.S. taxpayers provided an estimated $505 million in loan principal to tobacco farmers in fiscal 1988 that will never be repaid, according to a report published by health organizations.

Congress should enact legislation to eliminate the direct or indirect expenditure of federal funds to support the growth of tobacco, the American Medical Assn., the American Cancer Society, the American Heart Assn. and the American Lung Assn. said in a report released as a result of a national conference on tobacco held earlier this year.

"The federal government's policies on tobacco are inconsistent," the organizations said. While the government acknowledges that tobacco use is the single most preventable cause of death, Dept. of Agriculture policies "assure that federal assistance and tax dollars support the growth and use of tobacco."

In addition, the federal tobacco program costs taxpayers $15 million a year in administrative costs, according to "U.S. Agricultural Policy on Tobacco," prepared by Fran Du Melle, director of government relations for ALA. The report is a chapter of a larger document on the conference, "Tobacco Use In America."

In 1982, Congress passed the No Net Cost Tobacco Program Act which altered the tobacco program that had been in place since the 1930s.

The origin of the tobacco program is the Agricultural Adjustment Act of 1938, which set an average support price for each type of tobacco. The law made non recourse government loans available through local cooperative associations to farmers whose crops did not bring a price from a buyer above the average support price for each type of tobacco. The government then charged interest on the loans and held the tobacco until it could be sold for a profit. Each class of tobacco had its own similar price support program.

Tobacco supply was also controlled through a national acreage allotment system.

According to the conference report, costs of the pre-1982 tobacco program were significant.

"If a local cooperative was unable to sell the tobacco it held as collateral for unpaid loans, the federal government bore all losses. By April 1982, past losses totaled $57 million in unpaid loan principal."

Cooperatives were allowed to make loan payments on the principal first, rather than on principal and interest. This resulted in additional losses. The cooperatives were charged below market rates and the interest was not compounded.

"By the end of 1981, these loan policies had cost the federal government $591 million in interest losses." The program's administration cost $13.1 million in 1981.

The legislation passed in 1982 imposed an assessment on growers for every pound of tobacco marketed with the borrowed funds. The money raised by assessments was supposed to reimburse the government for any future financial losses from tobacco loans.

"In theory, except for administrative costs, the tobacco program was to be run at no net cost to the taxpayer," the report says. However, the administrative cost of managing the price support program, including inspection, grading standards and crop insurance subsidies was $15 million in 1988.

"The grower assessment under the no net cost legislation was not expected to ever exceed one or two cents per pound since past losses were low," the report says. "However, loan prices were legislated higher than market prices in the late 1970s and early 1980s, resulting in a large increase in imported tobacco. Further, the statutory limits on marketing quotas could only be reduced so much each year. This allowed production which continuously exceeded utilization--and the surplus went under government loan. As stocks increased, so did the assessments until they reached 25 cents per pound for flue cured tobacco and 30 cents per pound on burley tobacco in 1985."

The high assessments, declining market quota and accumulating surplus tobacco stocks created a crisis for farmers and tobacco program, the report says. In early 1986, Congress enacted legislation to lower tobacco loan prices by 26 cents per pound, and cigarette manufacturers agreed to buy the surplus tobacco stocks over the next five years at discount prices of up to 90 percent.

The deep discounts are expected to generate loan losses of $1 billion for U.S. taxpayers, the report says.

"Ironically, as it operates today, the tobacco support program benefits least the people it was designed to assist: small family farmers," the report says. Those that benefit the most are tobacco allotment holders, 74 percent of whom do not grow tobacco. Allotment holders charge the family farmer for permission to lease their allotment, a cost that can increase production expenses by 30 to 60 percent. About 84 percent of family tobacco farmers rent allotments, the report says.

A spokesman for the USDA tobacco program told **The Cancer Letter** that in a recent vote among producers, over 95 percent of the farmers voted in favor of having the price support system.

As a result of higher American prices created by the price support system, foreign grown tobacco makes up 35 percent of all tobacco used by American manufacturers, the report says.

"The policy issue before the health community should not be whether federal financial assistance for the tobacco support program should be ended, but when--and how best to accomplish this task quickly and fairly," the report says.

The report notes that allotment holders will lose income from the lease of allotments when the program is phased out. However, that would only benefit small farmers.

Many observers say the price of cigarettes will fall if the price supports are eliminated, resulting in increased sales and exports. "Reduced costs will not necessarily increase use, because only three cents of the price of a package of cigarettes is the actual cost of tobacco," the report argues. "However, phasing out the tobacco support program should be accompanied by a comprehensive package of proposals to reduce the use of tobacco products."

The report concludes that, "While it is inappropriate to fund the tobacco price support program through general revenues, the health community finds nothing objectionable about requiring those who manufacture or use tobacco products to fund the tobacco price support system through a system of user fees. Such a system should fund all associated administrative expenses."

The health groups made the following recommendations:

<>No federal expenditures should be permitted to pay for, administer or otherwise support the tobacco price support program. No federal funds should be pledged to guarantee tobacco loans or the sale of tobacco for export. To the extent the program continues to exist, a system of user fees on tobacco manufacturers should be developed to replace federal financial support.

<>Federal financial assistance should be available for farmers who wish to stop growing tobacco. Such an assistance program might be funded from a portion of revenues generated by the federal excise tax on cigarettes. Tobacco allotments owned by farmers who participate in the program would be retired, thereby decreasing the overall number of tobacco allotments and the total acreage devoted to the growth of tobacco.

RFPs Available

Requests for proposals described here pertain to contracts planned for award by the National Cancer Institute unless otherwise noted. NCI listings will show the phone number of the Contracting Officer or Contract Specialist who will respond to questions. Address requests for NCI RFPs, citing the RFP number, to the individual named, the 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 announcements from other agencies will include the complete mailing address at the end of each.

RFP NCI-CN-05249-20

Title: Efficacy studies of chemopreventive agents in animal models
Deadline: Approximately Feb. 13

Master agreements will be awarded for contractors capable of evaluating the efficacy of various designated chemopreventive agents at several dose levels in animal models and the refinement and improvement of animal test models for chemopreventive studies.

The emphasis of the activity will be to take initial leads on designated agents and expand the data base as to the spectrum

of carcinogens, spectrum of target sites and range of species. These agents have previously been evaluated for chemopreventive activity in various in vitro tests and in a limited number of in vivo studies. However, before a decision can be made as to their suitability for phase 1 clinical trials, their efficacy and bioavailability must be evaluated in various animal models.

Agents to be tested are potentially hazardous. The animal model systems also involve the use of carcinogens. Laboratory practices shall be employed which will keep any element of risk to personnel at an absolute minimum. Where indicated, tissue and compound handling must be performed in at least Class I laminar flow cabinets which must meet NIH specs for work with carcinogen agents.

It shall be required that the animal facilities be maintained in accordance with the NIH Guide for the Care and Use of Laboratory Animals, the Animal Welfare Act as administered by the USDA and the U.S. Government Principles for Utilization and Care of Vertebrate Animals Used for Testing Research and Training.

This research will be performed under cost reimbursement and/or fixed price MAOs. Offerors will not be considered eligible for award unless they can conduct specific individual MAOs in accordance with FDA Good Laboratory Practice Regulations.

The contractor shall have all the equipment necessary to accomplish the studies, including but not limited to animal racks and caging, hazardous chemical storage cabinets and refrigerators, pathology equipment such as microscopes and microtomes, and miscellaneous laboratory equipment. The laboratory shall have or have access to appropriate terminal and computer facilities and equipment for data collection and storage.

The purpose of this acquisition is to qualify additional contractors to an existing pool of master agreement holders. There are currently eight qualified contractors in the pool.

The period of performance of the master agreement pool runs through Aug. 19, 1993, which would be the expiration date for new master agreement holders, too. It is estimated that up to four task orders per year will be issued pursuant to the master agreement contracts.

Contracting Officer: Charles Lerner
RCB Executive Plaza South Rm 635
301/496-8603

RFP NCI-CN-05248-20

Title: Evaluation of chemopreventive agents by in vivo screening assays

Deadline: Approximately Feb. 13

Master agreements will be awarded for contractors capable of conducting in vivo screening studies in laboratory animals, primarily rats and mice, using gavage and other routes of administration to administer the designated chemopreventive agents in animal models using any carcinogenic mechanism that is consistent with the Evaluation Criteria, such as the administration of carcinogens, promoters, hormones, irradiation, cells or other carcinogenic agents.

This research will be performed under cost reimbursement or fixed price MAOs. Offerors will not be considered eligible for award unless they can conduct specific individual MAOs in accordance with the FDA Good Laboratory Practice Regulations in facilities that are operated in compliance with the NIH Guide for Care and Use of Laboratory Animals, the Animal Welfare Act as administered by the USDA and the U.S. Government Principles for Utilization and Care of Vertebrate Animals Used for Testing Research and Training.

The purpose of this acquisition is to qualify additional contractors to an existing pool of master agreement holders. There are currently eight qualified contractors in the pool. The period of performance of the master agreement pool runs through Dec. 30, 1991, which would be the expiration date for new master agreement holders, too. It is estimated that up to four task orders per year will be issued pursuant to the master agreement contracts.

Contracting Officer: Charles Lerner
RCB Executive Plaza South Rm 635
301/496-8603

RFAs Available

RFA 90-CA-02

Title: Prevention clinical trials utilizing intermediate endpoints and their modulation by chemopreventive agents

Application Receipt Date: March 15

NCI's Div. of Cancer Prevention & Control invites applications for cooperative agreements to support clinical trials that are directed toward examining the role of various chemopreventive agents and/or diet in the prevention of cancer. This is a followup to earlier RFAs that requested grants, and then later, cooperative agreement proposals in this area.

The major objective of this solicitation is to encourage cancer chemoprevention clinical trials that utilize biochemical and/or biological markers to identify populations at risk and/or to provide intermediate endpoints that may predict later reduction in cancer incidence rates.

These studies may be developed in phases, including a pilot phase, which could later proceed to a full scale intervention. The main emphasis should be on small, efficient studies aimed at improving future research designs of chemoprevention trials, providing biologic understanding of what is happening in the trials, or providing better, more quantitative and more efficient endpoints for these trials.

After successful completion of the pilot phase (i.e. demonstrated modulation of marker endpoints by the intervention), subsequent studies can include phase 3 clinical trials involving the designated agent, the utilization of the monitoring test system and a cancer incidence or mortality endpoint.

Investigators may apply at this time for the pilot phase or submit an application for both phases. However, if the application is for the pilot phase only, the proposed study must describe its relevance to a clinical application and utilize a chemopreventive agent, marker test system and study population that later could be the subject of a full scale, double blind, randomized, risk reduction clinical trial.

Applicants funded will be supported through the cooperative agreement mechanism. The recipients will have primary responsibility for the development and performance of the activity. However, there will be government involvement with regard to 1) securing investigational new drug approval from the FDA, 2) monitoring of safety and toxicity, 3) coordination and assistance in obtaining the chemopreventive agent and 4) quality assurance with regard to the clinical chemistry aspects of the study.

Awards will not be made until all arrangements for obtaining the IND, agent and its delivery are completed. Final awards will also consider not only the cost of the clinical trial, but also the cost of the agent and its formulation if necessary. Applications should include a suitable representation of women and minority populations of individuals such as those aforementioned. If the applicant cannot comply, a reasonable explanation should be provided.

Inquiries may be directed to: Dr. Marjorie Perloff, Chemoprevention Branch, Executive Plaza North, Suite 201, NCI, Bethesda, MD 20892-4200; phone 301/496-8563.