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NCI Will Get $1.3 Billion, But Only If Congress Fends Off GRH Cuts, Reprogramming For Drug War

Congress continued wrangling this week over the massive "continuing resolution" which will keep government agencies funded until regular appropriations bills are passed, with arguing raging right up to the midnight, Sept. 30 deadline,
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In Brief

Kean, Montes Leave DCPC; Smart Heads Early Detection Branch; Costlow Special Assistant

THOMAS KEAN, acting director of the Cancer Control Science Program in NCI's Div. of Cancer Prevention & Control, has left to become vice president for technical operations at the Washington D.C. area management consultant firm of Prospect Associates. DCPC Director Peter Greenwald gave Kean much of the credit for organizing and developing CCSP's activities. **Lillian Gigliotti**, chief of the Health Promotions Science Branch, was named as acting CCSP director until a permanent director is recruited. . . . **HENRY MONTES**, who has overseen NCI's cancer control programs for Hispanic populations while also serving as executive secretary of the DCPC Board of Scientific Counselors, will leave to become associate director for extramural programs in the HHS Office of Minority Health. . . . **CHARLES SMART**, who has been chief of the Community Oncology & Rehabilitation Branch in DCPC, has been named chief of a new Early Detection Branch by Jerome Yates, director of the Centers & Community Oncology Program. Yates is looking for a new CORB chief. . . **RITVA BUTRUM**, who has been acting chief of the Diet & Cancer Branch in DCPC's Prevention Program, has been appointed chief of the branch on a permanent basis. . . . **RICHARD COSTLOW**, longtime chief of the Cancer Detection Branch, has been named special assistant to Greenwald. "He will help us think through several issues," Greenwald said, including whether the division will establish an intramural nutrition research laboratory. . . . **OTHER DCPC** staff changes: **Kenneth Brow**, an engineer in the Research Facilities Branch, has moved up to the facilities and construction office of the Public Health Service; **Terry Pechacek**, director of smoking research at the Univ. of Minnesota, is working in the division's tobacco program; and **Marjorie Perloff** has moved from the Cancer Therapy Evaluation Program in the Div. of Cancer Treatment to the Chemoprevention Branch.

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White House Would Cut NIH, NCI To Help Finance War On Drugs

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the end of the 1986 fiscal year and start of the 1987 year. Theoretically, the entire federal government would have to close down if the continuing resolution is not passed by Congress and signed by the President at that time. None of the 13 regular appropriations bills have yet been cleared by Congress, although the HHS bill, which includes NCI's funds, has been approved by both houses. At press time this week, no conference had been held to work out the differences, and it appears that HHS and NIH-NCI funding will be included in the continuing resolution.

The House approved its version of the continuing resolution last week. It calls for interim spending at the levels of the various House passed appropriations bills. The Senate version, as approved by the Appropriations Committee, calls for spending at the levels of any Senate passed appropriations bills. At press time, the full Senate had not yet acted on the continuing resolution.

To make matters more complicated, President Reagan has threatened to veto the continuing resolution if the House version prevails, objecting to certain foreign policy and defense provisions. If that happens, Congress will have to stay in session around the clock until some type of interim funding is approved.

Members of Congress had hoped to adjourn by this weekend (Oct. 4) so they can hit the campaign trails, but that seemed out of reach this week. A more likely date is Oct. 15.

The House and Senate were very close to agreement on the FY 1987 figure for NCI in their respective bills, so it will not make much difference to the Institute which level prevails in the continuing resolution. The Senate figure is $3 million under $1.4 billion, the House about $7 million over.

NCI would do well with $1.4 billion, although still far from the amount needed to fund all high priority programs. There is no assurance, however, that that will be the final appropriation, even if it survives the continuing resolution problems and veto threat.

Darkest of the clouds hanging over the budget is the prospect that the FY 1987 deficit projections will trigger the automatic, across the board cuts established by the Gramm-Rudman-Hollings Deficity Reduction Act. During the fiscal year just ended, NCI lost more than $55 million to GRH. An early projection on the deficit made in August would require a cut of more than seven percent under 1986 levels, which could cost NCI around $90 million.

A lesser threat, but one which aroused considerable opposition in Congress, was the Administration's request to fund the new "drug war" initiative by reprogramming money from various agencies. The proposal included taking $88 million from the total NIH budget for that purpose, which would cost NCI $15.2 million.

The NIH cuts would come from research centers, research project grants (RO1s, PO1s), and training. They would not be taken from money allocated for AIDS research.

While most members of Congress support the drug initiative, they were not enthusiastic about how it would be financed.

"The House certainly won't go along with taking money from NIH," one staff member said.

Sen. Lowell Weicker (R-CT), chairman of the Labor-HHS Appropriations Subcommittee, was adamant. "What this type of proposal would mean is not a war on drugs," Weicker said in a statement on the Senate floor. "This then becomes a war on the mentally ill. It becomes a war on the alcoholic. It becomes a war on the poor. . . I would hope with whatever passes this body we would say to ourselves that indeed drug abuse is a priority, and we have to pay for it just as we have to pay for any other real war. . . Anytime that I go to war, I do not want to have media opportunities. You just give me the bullets. I would hope that drug abuse would be a priority, but not at the expense of others who need our special care."

Minority Leader Robert Byrd (D-WVA), commended Weicker for being "realistic. . . He is quite right. We ought not take that money out of programs that are just as necessary and affect people just as severely."

The Administration justified its proposals for reprogramming on the basis that they fit the GRH requirement by offsetting the costs with reductions elsewhere. The total of $165.3 million proposed for reduction in the Public Health Service budget (which includes the $88 million for NIH) is appropriate because "the Administration believes support for drug abuse research and treatment are now more urgent than general areas of biomedical research and health services."

DCPC Board Asks For Increased Cancer Control Funding Of Centers

The Board of Scientific Counselors of NCI's Div. of Cancer Prevention & Control renewed the debate last week over the Institute's decision more than five years ago to abandon support of cancer control activities in cancer centers in favor of cancer control research competed through the various grants mechanisms.

Cancer control research sometimes can be done best by large organizations, BSC Chairman Erwin Bettinghaus noted. "I think (NCI) staff might give careful thought whether there might be narrow areas of cancer control research that are unique to centers, areas that cannot be done easily by CCOPs or through RO1 or PO1 grants."

"Efforts by NCI to stimulate cancer control have fallen on infertile ground," Board member Philip Cole said. "It would be a reasonable approach for this division to rethink an organized, systematic approach to help centers which want to have cancer control programs."

Jerome Yates, DCPC associate director and head of the Centers & Community Oncology Program, referred to the centers-cancer control efforts started about 10 years ago, in which centers received grants specifically for cancer control staff. "When Peter (Greenwald, DCPC director) and I came here (in 1981) there was a strong feeling that just giving the money did not work." The new DCPC leadership, strongly encouraged by the Board of Scientific Counselors, decided that broad based research in cancer control "would stimulate cancer centers to do these things," Yates said.

Board member John Ultmann, director of the Univ. of Chicago Cancer Center, said that the NCI policy of refusing to support cancer control research in the 1970s (in favor of outreach and demonstration programs) caused many investigators to lose interest. Also, "if you keep cutting the amount of money for cancer control, that won't help. The Mickey Mouse shifting of funds on AIDS is an example. Cutting back the budget will not enable us to start new initiatives." Ultmann noted that the President's budget request for NCI translated into a seven percent cut in DCPC's cancer control budget. "That's not going toward the Year 2000 goals. That's going in the opposite direction." Also, while the Year 2000 plan envisions a 50 percent increase in the number of cancer centers, the budget says "we are planning a decrease."

Cole suggested that requiring cancer control grant applicants to compete with laboratory research for support "is unfair. Most cancer control relates to the social sciences. I'm asking what this division can do to develop cancer control? It's not very well developed now."

Yates said that cancer center core grants can include developmental money for cancer control, although he acknowledged that most core grant developmental funds go to laboratory research. "Cancer control probably is not getting its fair share," he said.

"You are not giving yourself enough credit," Board member Paul Engstrom said. "The new CCOP (Community Clinical Oncology Program) competition is stimulating a lot of cancer control (in fact, participation in cancer control protocols is a requirement in the new competition). Suddenly people are seeing there is an interesting opportunity to carry out cancer control in communities."

Greenwald defended the policy of supporting cancer control research through the "stepwise" fashion DCPC now is doing. He also agreed with Ultmann on the need for more cancer control funds. "A very high percentage of our budget is locked up in continuation grants," he added. "That makes it very difficult to start new efforts."

Even so, there are eight to 10 cancer centers "which are doing sound research in cancer control," Greenwald continued. Also, cancer control grant applications are doing very well in study section reviews. "They are measuring up to the basic science applications," Greenwald insisted.

Employment Discrimination

Board member Robert McKenna, pointing out that widespread evidence exists that persons who have had cancer are still being discriminated against in employment, asked for support of House Concurrent Resolution 321. That measure, introduced by Mario Biaggi (D-NY), expresses Congress' opposition to such discrimination.

His resolution affirming the Board's support of the measure was approved unanimously after McKenna said that employment antidiscrimination laws in 45 states do not address the issue. It is strongly supported by the American Cancer Society, McKenna said.

Bettinghaus said the Board's position would be passed on to the National Cancer Advisory Board and members of Congress.

Yates told the Board that seven construction/renovation grants had been approved in the 1986 fiscal year but that none would be funded. Out of a total of $3.1 million appropriated by Congress for construction support by NCI in FY 1986, $1.9 million went for renovation at Frederick Cancer Research Facilities, leaving $1.2 million for extramural construction(**The Cancer Letter**, Sept. 19). That entire amount, however, was awarded to the St. George, UT, radiation screening program, which had previously been through peer review with a fundable priority score.

Organ Systems Extension

NCI's Organ Systems Program, which is operated out of a section of the Cancer Centers Branch in Yates' program, is supported through the Organ Systems Coordinating Center at Roswell Park Memorial Institute. The center coordinates the activities of seven working groups, with NCI support coming through a cooperative agreement which totals about $725,000 a year in direct costs.

That three year cooperative agreement will expire next year. NCI could have requested its advisors--in this case, the National Cancer Advisory Board--to consider whether the cooperative agreement should be recompeted next year. **The Cancer Letter** has learned, however, that instead, NCI intends to extend the award for two more years. When the NCAB approved the concept originally, it was for five years, but NCI decided to limit the award to three years, so extension will be in line with the NCAB's action. Working group members were not pleased by the results of their efforts in the first year of the new program, when most of the concepts were merely "program announcements," which did not provide set aside funds. The situation has changed, however, with the success of their concepts before the BSCs during the past year. "There is no question that everyone is encouraged, and there is an air of enthusiasm," OSCC Director James Karr told **The Cancer Letter** this week. "We have worked hard in getting input from NCI and the four divisions."

The bottom line, Karr noted, is how many grant applications stimulated by the working group's efforts actually are funded. So far, of those which have completed the full cycle in the second year just completed, only three or four, from the Large Bowel Cancer Working Group RFAs, have been approved with fundable priority scores.

Diagnostic Prostate Ultrasound And Markers Studies Concept Approved

The Board of Scientific Counselors of NCI's Div. of Cancer Prevention & Control has approved a concept for the early diagnosis of prostate cancer through the use of ultrasound. The concept would provide first year funds totaling $600,000 for five three year grants to determine the ability of ultrasonography used alone or in combination with biological markers to detect early prostate carcinoma, and to quantify the volume and/or extent of prostate tumor burden and its biologic potential.

The board approved two other concepts, one for assessment of the second phase of the Community Cliical Oncology Program and another for health department data based interventions for cancer control. The contract for the CCOP 2 assessment will be for a period of four years, with an approximate annual budget of $800,000 the first three years, and a fourth year budget of $350,000 for the final analysis and report writing. NCI expects to award eight data based intervention grants with total first year funding of $960,000. Details of the two concepts follow the story below.

Transrectal prostate ultrasonography is currently being used for staging of prostatic carcinomas and is considered to offer the greatest potential for both accuracy and economics among imaging modalities currently available, concept presenter Martin Resnick told the board. Resnick is professor and chairman of urology at Case Western Reserve Univ.

The technique has a sensitivity of 71% and specificity of 86%, he said. Although researchers once believed that magnetic resonance imaging would be very specific for prostate cancer, other changes in the prostate such as inflammation will cause changed densities, and persons with prostatic cancer will have normal scans. CT scans also don't offer the accuracy of ultrasound, he said.

In addition, prostate ultrasound may be useful in aiding biopsies in areas of the prostate that are not palpable.

"There is a lot of literature related to these techniques, but a lot is anecdotal," Resnick said. "It is crucial that the final diagnosis is established on the patients studied."

Markers in serum, urine and prostatic

fluid have also been studied and offer potential for staging carcinoma of the prostate. The markers "may substitute or add significantly to the rectal examination as a tool to identify patients with increased risk of the disease early in its course," the concept statement said. "The options for management would therefore be expanded and in all likelihood treatment results could be improved." For example, acid phosphatase has a sensitivity of 70% and a specificity of 95%, with a positive predictive value of 61% and a negative predictive value of 97%, Resnick told the board.

Board member Philip Cole questioned whether the RFA would include both early diagnosis and screening. Fellow member Frank Meyskens also pointed out the need to distinguish between screening and diagnostic procedures. Cole replied that the RFA would look primarily at early diagnosis, and agreed to a suggestion by Board Chairman Erwin Bettinghaus that language in the concept statement be clarified to indicate that the studies are to investigate early diagnosis, not screening.

"We need to see the studies so we can get more accuracy in diagnosis, and hopefully, in the future, screening," board member Paul Engstrom said.

Board member Virgil Loeb noted that the concept was initiated by the Organ Systems Program because of a need expressed by urologists for more research in the area.

Board member John Ultmann questioned whether the concept should be enlarged to include other diagnostic tools in addition to markers, such as needle biopsies, but Resnick said the concept was intended to explore noninvasive procedures for early detection.

A question by board member Lloyd Everson about whether the studies should include a measurement of sperm viability to determine whether there was any effect on fertility was dismissed by Resnick as unnecessary. Although most studies on ultrasound's effects on fertility have been conducted in women, there have been no problems found in those or in the few studies that have looked at men's sperm counts following ultrasound, he said. Noting that the ultrasound does not directly strike the testicles, he said, "I don't think it is an issue." He also speculated that investigators could have a difficult time getting men to provide sperm samples for the study.

The concept statement follows:

This project addresses the need to identify imaging modalities and known biochemical markers in serum, urine and prostatic fluid that will aid in early detection, diagnosis and quantification of prostatic carcinoma. Reports have addressed this problem employing existing radiographic techniques, e.g., computed tomography, ultrasonography, magnetic resonance imaging, but none have utilized these modalities to their full potential. A session on prostate cancer imaging at the 81st annual meeting of the American Urological Assn. revealed a consensus that CT and MRI currently do not appear to have the potential of fulfilling this need, whereas ultrasonography does. It appears that the critical volume for dissemination is associated with tumors greater than 1 ml. Therefore, it appears essential that the detection technique be sensitive enough so as to resolve and identify this volume.

Recent advances combining histopathology and ultrasonographic images reveal the potential capability of diagnosing Stage A lesions and capsular invasion. There is evidence suggesting a correlation of hypoechogenic masses with carcinomas in the peripheral zone of the prostate, while other examples of hyperechogenic and mixed echogenic masses are associated with normal, BPH and malignant tissue. The need to clarify the interpretation of hyper and hypoechogenicity patterns and their correlation with histopathology is timely and important, as there has been confusion and misunderstanding among radiologists and urologists using ultrasound for the diagnosis of prostatic disease. Clearly, the location and echogencity of ultrasonic findings, when combined with ultrasonographically guided needle biopsies, could provide the most useful diagnostic information. Thus, this imaging modality offers the greatest potential for early diagnosis among those currently available.

Identification of biochemical or immunological characteristics of carcinoma of the prostate could, in combination with ultrasonographic imaging, add to current capabilities to detect the disease and accurately assess its extent and potential. This approach is both timely and possible. Many of the biochemical markers that have been detected in serum, urine and prostatic fluid have not been sufficiently explored for this purpose, even though they are readily available and the technology exists for their proper and full evaluation. Such biochemical determinations as, for example, prostate specific antigen, prostatic acid phosphatase, LDH isoenzymes, etc., offer the potential of assessing tumor burden quantitatively. Additionally, prostatic fluid protein patterns and techniques of quantitative pattern recognition of fluid components could be applied to evaluating this disease. Further investigations may reveal that these techniques have varied and multiple applications.

Assessment of the implementation of the Community Clinical Oncology Program Phase 2 - Cancer control research in communities. One four year contract will be awarded, with approximate annual funding of $800,000 for the first three years, and $350,000 for the fourth year, during which time the final analysis and writing of the report will be conducted.

The awardee will assess 1) the degree to which the CCOPs 2, research bases and NCI implement and manage the new requirements for CCOPs; 2) the impact of the CCOP 2 program on the state of cancer control research and 3) the impact of the cancer control interventions on community practices and cancer control activities.

DCPC will be responsible for monitoring the CCOPs 2 as well as establishing a mechanism for the management and review of cancer control research projects. Clinical treatment protocols will continue to be reviewed by the Div. of Cancer Treatment.

The assessment of the implementation and impact of CCOP 2 will examine three major areas and their interaction.

First is the CCOP response to the new program requirements. At one level, NCI wants to look at the mechanics of implementing the new CCOPs. Such questions include: What happens to the CCOPs participation in treatment protocols as the new cancer control requirements are phased in? What type of cancer control research is done in the CCOPs? What type of data management and support staff is needed? Who and how does the CCOP mobilize the necessary patient population and expertise to implement cancer control research? At the next level, it will consider the impact of the CCOP 2 on community practice. This could range from the narrow view of impact on treatment patterns of care to the broader view of the impact of cancer control interventions on community practices; what approaches are adopted or discarded and why did this occur. Finally, it would look at the CCOPs 2 as organizations in a changing environment. How have the CCOPs evolved as organizations and what is necessary to be a successful CCOP 2?

The second major area is the research base response to CCOP 2. "The release of the new RFA has caused a considerable amount of new activity at the research bases," the concept statement noted. "At most research bases there has been the formation of a cancer control committee and heightened interest in cancer control research. Experts in the field are being recruited to augment the existing group structure. Compilation of past cancer control research and development of new cancer control research concepts is underway. Alliances between CCOPs and research bases are forming. Group (university) members are developing an interest in cancer control as well." The evaluation will consider the impact of CCOP 2 on the research bases: 1) the protocols available for CCOP participation, 2) the intellectual expertise available and recruited in cancer control by the research bases, 3) the ability to develop and carry out complex interventions, 4) the skill of the research bases to monitor and control the quality of new types of CCOP data, and 5) the extent to which university members elect to participate in cancer control. An opportunity to stimulate cross education through the development and adoption of cancer control methodology by participating scientists is likely, based on knowledge of the impact of treatment trial participation.

While in the current Community Cancer Care Evaluation, NCI considers the funded research bases as successful based on CCIRC review, in CCOP 2 the research base, as well as the CCOP, will be under scrutiny for the science and extent of their cancer control participation. In addition, the quality of cancer control efforts from centers, health departments and the CCOPs themselves must be examined.

The third area for appraisal is NCI participation in CCOP 2. There will be new requirements placed on DCPC and to a limited degree DCT staff in the area of protocol review. A protocol credit system must be developed and standardized. A mechanism in DCPC to review and track cancer control research projects, analogous to CTEPs, must be developed. Outside experts will be used to assure peer review of protocols along with some DCPC staff. The use of state of the art computer technology to manage protocol data and to transmit comments from review for protocol revision is expected to result in a more rapid turnaround. The management of the protocol review process and the extent to which this proves to be an educational tool for DCPC staff will be examined.

The interaction and relationships that exist and will develop between the CCOPs 2, research bases and DCPC will be monitored to provide data for future program planning. The effect on cancer control research and practices is a critical feature of any assessment of CCOP 2.

The project will be divided into several different areas to complement the breadth of activities taking place as part of CCOP 2. The major functions will be:

1. Analyze the performance of CCOP 2 grantees. Establish a data base to track CCOP 2 participation in treatment protocols and other cancer control research including application and annual report dates, types of protocols available, types of protocols used, numbers of patients (subjects) registered, extent of physician participation, quality of CCOP performance and other management information related to CCOP 2 performance.

2. Develop a computerized system to coordinate the resources needed to facilitate the following: cancer control research; protocol development and review; implementation of standardized formats, electronic transmission of protocols, reviewer's comments and revisions; and management of information regarding progress of ongoing and completed cancer control research. The ability to categorize study designs, methods, and outcomes into a useful reference resource for future cancer control studies is planned.

3. Assess the changes that occur in the CCOP and research base relationships including the efficiency of protocol development, implementation, and the adoption of state of the art computer technology for protocol management.

4. Conduct special studies that may be general in nature or based on the expected influence of a specific intervention in selected CCOPs and/or research bases to assess such areas as:

a.CCOP 2 implementation and operation. How does a CCOP organize to implement cancer control research; what happens to the successful clinical trials program when cancer control research requirements are added; how are the resources mobilized and interventions implemented; what motivates physicians to participate?

b.Interventions to change physician practice patterns. Using the patterns of care data collected in the CCCE design and implement targeted cancer control interventions (feedback only, feedback plus target education) to examine possible changes in physician practice patterns and effect beneficial influences on quality of care for cancer patients.

c.Effects of CCOP 2 on community practices; involvement of primary care physicians in community cancer control research; effective ways of implementing cancer control research in community settings and its limitations. This may include local physician surveys to assess knowledge and attitudes as well as other approaches that may define physician behavior.

d.Changes in the mission of research bases as a result of CCOP 2; the interest of other cooperative group members in cancer control research; the role of state and local health departments in CCOPs; the extent to which cancer centers become more active in cancer control research.

e.Impact of cancer control research in community medical practice patterns; and attempted measurement of diffusion of proven cancer control interventions into practice.

Many of these special studies will depend on the specific cancer control research proposed by the CCOPs 2 and their results.

During the discussion following the presentation of the concept, Cole questioned the evaluation's inclusion of special studies. "Part of the evaluation is evaluation of research," Leslie Ford, medical officer of the Community Oncology and Rehabilitation Branch, replied. "It's not just do they implement the requirements, but is there a cancer control benefit?"

Jerome Yates, who heads NCI's Centers and Community Oncology Program, said, "We do plan on extending

beyond evaluation. We have a unique opportunity here to look at some of these community environments, both in terms of clinical research and the patterns of care activities that are going on, make some comparisons and then institute an occasional intervention to see whether or not things change in those environments. We have a very unique opportunity in terms of the cancer control efforts, because in many of these places there is virtually no cancer control research going on at the present time. Yet we expect that these will track at variable speed in terms of success and we anticipate that during the course of the collection of the baseline information during the course of this evaluation, that we will use appropriate advisors to help us develop some interventions to test whether or not we can alter the speed, and presumably increase the speed, and the efficiency with which there is participation in cancer control."

"You really can't evaluate a program simultaneously for improvement and effect or impact because you're shooting at a moving target," board member Donald Iverson said. The former head of DCPC's Cancer Control Science Program, Iverson suggested that in the last year of the project "then you look at the impact on two or three questions at the most, not look at 20 or 30."

Yates explained that "when one tracks the protocols we expect that we're going to see some evolution in the types of protocols that are being used. We also expect to see some evolution in the other cancer control activities that may be going on in these communities as a result of the exposure to new expertise from the cooperative groups, of the centers and health departments. I would call that impact, not improvement. Improvement to me means that you're starting from the baseline, you're going to find activity, then you watch how the accrual increases or how the numbers of protocols increase, or the number of investigators increase. But we're looking for qualitative differences in terms of the types of protocols and the relative participation in the protocols, the quality and also the influence on other cancer control activities, both in terms of the groups as well as communities."

Ford pointed out that the evaluation is starting with three years of information on practice patterns from CCOP 1 and that it wouldn't make any sense to go back to where the other review started.

She also explained that DCPC staff will monitor the CCOP program and work with individual CCOPs. "What we're talking about here is a CCOP program evaluation, the evaluation of the program as a whole, not monitoring 60 different programs and seeing how they come along."

Health department data based interventions for cancer control. NCI anticipates making eight awards with approximately $120,000 per award the first year for a total first year funding of $960,000. It expects that four awards would be continued into the later phases, with each of the four awards receiving approximately $200,000 per year for the second phase of the award, and about $12,500 per year during the third phase of the five year project. The approximate annual total budget would be $960,000 the first year, $800,000 the second and third years, and $50,000 the fourth and fifth years.

NCI estimates that only four awardees would be able to develop the demonstration programs and models required in the second phase, but if all eight awardees were able to conduct quality phase 2 interventions, NCI staff could come back to the board to approve additional funding, Thomas Kean told the board in response to questioning by board member William Darity.

The goal of the program is to fully utilize existing data for the planning and execution of cancer control programs on the state level that are consistent with NCI's Year 2000 goals and to develop demonstration projects in the use of such data for planning and execution of cancer control intervention programs.

This is the second program proposed under DCPC's public health agency initiative for capacity building. The aim of the program is to stimulate the utilization of the large amount of data related to cancer control that currently exists in states while providing a demonstration to other states of effective use of data for cancer control purposes. It is a three phase project:

1. The first phase will require the identification and evaluation by health department personnel of data available at the state level that is pertinent to the Year 2000 goals. Examples of such data include demographic data from the census, cancer mortality data from state vital statistics records, cancer incidence and survival data from incidence registries, risk factor prevalence data (e.g. CDC's Risk Factor Prevalence Survey in 37 states), health services utilization data (e.g. National Ambulatory Medical Care Survey), hospital discharge data, and information on knowledge, attitudes and practices (e.g. regional data from the National Health Interview Survey) of the population regarding cancer risk factors and cancer control intervention strategies.

Phase one will last one year and will include:

1. The determination of the usefulness of the specific data examined and of additional data needs, and feedback to the sources of the original data;

2. The development of a cancer control action plan for the state or integration of state specific cancer data into an already existing plan.

The action plan will be evaluated through a program review using peer level consultants and program staff to determine those proposals to be funded for the additional phases.

The second phase will involve the use of the data from phase one by health departments for a cancer prevention and control program. As a minimum, this will include the initiation of new or improvement of existing cancer control intervention programs at the state and local health department levels and the education of state legislators as to the nature of the cancer problem and the resource needs for cancer control.

Phase two will last two years.

Phase three will be an evaluation period during which the implementation of the state and local cancer control programs and/or legislation and other expected programmatic outcomes of the project will be identified and catalogued.

Phase three will be accomplished over a two year period.

Two products are expected at the end of the project:

1. Intervention programs that are consistent with the Year 2000 goals but targeted to the specific needs of the state as defined by existing data;

2. Documentation and evaluation of the data sources examined, analytic findings, decisions made based on the data, and descriptions of programs initiated to be made available to other states as potential models of data use.

The concept statement emphasizes that collection of data is not supported under phase one of the project, rather it focuses on the utilization of existing data. Mortality data is one data source available to all states, and must be utilized as part of this research. Applicants must be health departments of states or territories, and cannot have received an award under the previous RFA "technical Development in Health Agencies."

RFA Available

RFA 86-CA-12

Application receipt date: Dec. 15
Letter of intent receipt date: Oct. 31

NCI's Div. of Cancer Prevention & Control invites grant applications for development of intervention projects to reduce avoidable mortality from cancers. The goal is to identify and remedy key factors that contribute to avoidable mortality from specific cancer sites in defined populations.

The focus of this RFA is limited to patterns of medical care use and provision. Studies related to primary prevention of cancer (e.g., prevention of smoking) are funded elsewhere in DCPC and will not be supported through this RFA.

Investigators will (1) determine the cancer site(s) to be studied; (2) identify factors that contribute to avoidable mortality for that cancer site in cases drawn from a defined population; (3) implement an intervention program to reduce mortality from the identified site; (4) evaluate the results of the intervention program in the defined population; (5) identify prototype approaches to the reduction of avoidable mortality based on the findings of this project.

Applicants are strongly encouraged to submit a letter of intent and consult with NCI program staff before submitting an application because of the need for a clear understanding of the cancer control research issues involved and to facilitate planning for the review of applications.

Nonprofit and for profit institutions in the U.S. are eligible to apply for project periods of up to five years. It is anticipated that a miximum of two awards will be made as a result of this RFA.

Copies of the complete RFA may be obtained from Dr. Knut Ringen, NCI Blair Bldg Rm 1A01, Bethesda, MD 20892, phone 301-427-8597.

RFPs Available

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

RFP NCI-CM-73712-22

Title: Shelf life evaluation of clinical drugs
Deadline: Approximately Dec. 1

The Pharmaceutical Resources Branch of the Developmental Therapeutics Program in NCI's Div. of Cancer Treatment is seeking a contractor to properly store, adequately evaluate shelf life samples of investigational clinical drug formulations (including both injectable and oral dosage forms), and report the results to PRB. Shelf life samples shall be stored at four temperature levels: freezer, refrigeration, room temperature, and elevated temperature. Evaluations shall be performed at the following intervals: 0, 3, 6, 9, 12, 24, 36, 48, and 60 months.

In addition, storage and inspection of reserve samples as defined by the FDA current good manufacturing practices shall be performed annually. Also, solution stability studies of injectable products shall be performed at the 24 and 60 month intervals to validate label stability claims.

Currently, there are about 115 lots encompassing 45 different chemical entities undergoing shelf life evaluation. The contractor shall validate each of the analytical methods prior to use. In addition, it is expected that about 36 to 40 additional lots (including 10 to 12 lots requiring analytical method validation) will be added during this year, and each subsequent year of contract operation. The contractor shall ensure that no scheduled time points are delayed or missed. There are about 250 lots of reserve samples presently stored. About 50 to 60 new lots of reserve samples are expected during this year, and each subsequent year of contract operation. The contractor shall ensure that no scheduled time points are delayed or missed.

The contract period will be for five years, beginning approximately Aug. 16, 1987. The current contractor is the Univ. of Georgia.
Contract Specialist: Elizabeth Moore
RCB Blair Bldg Rm 216
301-427-8737

RFP NCI-CM-73708-17

Title: Synthesis of radiosensitizing agents
Deadline: Dec. 8

NCI's Div. of Cancer Treatment is recompeting a contract for the design, synthesis and characterization of new and novel non-nitro radiosensitizers. The project also requires development of designated in vitro data on synthesized compounds and data regarding the in vivo efficacy of designated radiosensitizers. This contract is currently performed by SRI International.

A three year period of performance is anticipated for this project. The offeror must be accredited or equivalent and be capable of maintaining a conventional rodent colony of at least 200 mice. The offeror must also have radiation capability suitable for irradiating mice and cell cultures. Physical chemical analytical, polargraphic or pulse radiolysis capability to measure electron affinities and determine physiochemical parameters of chemicals that would be sythesized is also required.
Contract Specialist: Elaine Larison
RCB Blair Bldg Rm 228
301-427-8737

NCI CONTRACT AWARDS

Title: Preclinical toxicology studies of anti-AIDS agents
Contractors: Battelle Memorial Institute, $924,977; Midwest Research Institute, $781,999; Hazleton Laboratories America Inc., $953,516.

Title: Development and production of parenteral dosage forms of anti-AIDS agents
Contractor: Ben Venue Laboratories Inc., $3,274,545

Title: Study of thyroid cancer and nodularity in high background radiation areas of China
Contractor: China Ministry of Public Health, $209,625

Title: CTEP information system
Contractor: Information Management Svcs., $2,577,954

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