THE CANCER LETTER
RESEARCH EDUCATION CONTROL

P.O. BOX 2370 RESTON, VIRGINIA TELEPHONE 703-620-4646

Vol. 4 No. 19

May 12, 1978

Subscription $100 per year

DCCR GETS GO AHEAD FOR NEW COMMUNITY CLINICAL ONCOLOGY PROGRAM, $600,000 - $1 MILLION A YEAR

NCI's Div. of Cancer Control & Rehabilitation plans to extend its Clinical Oncology Program with an additional five to eight contracts with community oncologists. The new RFP probably will be issued by late summer, with first year funding from the fiscal 1979 budget. From $600,000 to $1 million would be required if the new contractors are funded at the same level as the existing ones.

The present program includes seven contracts, some of which will expire at the end of this year. They were the successful proposers out of 20 responses to the RFP issued in 1974. Each received $75,000 for a year of planning and $150,000 for each of two years to implement the programs.

(Continued to page 2)

In Brief

NCI REORGANIZATION ANNOUNCEMENTS COMING UP; NO DECISIONS ON ORGAN SITE, CENTERS PROGRAMS

NCI REORGANIZATION implementation involving various committee and staff transfers will be announced in one to two weeks by Director Arthur Upton. This will involve moving program management staff from the Div. of Cancer Research Resources & Centers to the program divisions, and contract and grant review committees from the other divisions to DCRRC. No decision yet on where the Centers and Organ Site Programs will be housed. The Rumour of the Week was that Centers would be merged into the Div. of Cancer Control & Rehabilitation: Not true. At least, no such decision has been made as of now. Where to put Organ Sites, Centers and training programs are the toughest reorganization decisions Upton will have to make. Possible move of the Carcinogenesis Testing Program from NCI to some other agency is a question HEW Secretary Califano will settle (see story inside). . . .

CORRECTION: *The Cancer Letter* (April 28) indicated the Veterans Administration Surgical Adjuvant Group receives $2 million a year from NCI. That figure is the total amount NCI pays to help support the NCI-VA Medical Oncology Branch under the Div. of Cancer Treatment intramural Clinical Oncology Program (more than $1 million), the VA Lung Cancer Group ($600,000), and VASAG ($390,000). . . .

NATIONAL ASSN. of Life Science Industries annual meeting May 18 will feature an address by Ernest Brisson, FDA deputy associate commissioner for compliance, on proposed regulations for "Good Laboratory Practices." Program includes discussion of regulatory matters, and the status and direction of the Bioassay Program. The meeting will start at 10 a.m. in Stouffer's National Center Hotel, Arlington, Va. . . .

MASSEY FOUNDATION awards of $25,000 each went to Dorothy Rice, director of the National Center for Health Statistics, and the St. Luke's Hospital Center Hospice in New York.

CURRENT PROGRAM SUCCESS PROMPTS DCCR TO SEEK NEW CLINICAL ONCOLOGY EFFORT

(Continued from page 1)

That RFP was limited to oncologists practicing in community hospitals not affiliated with a university or major cancer center. The objective was to develop multidisciplinary teams of oncologists practicing in community hospitals, using proven single and combined modality therapy and management schemes to provide a system of quality care that incorporates new advances in diagnosis and treatment.

Contractors were required to work with a consortium of one to three hospitals, operate a tumor registry, have a minimum of 300 new cancer admissions a year half of which enter the program, have a physician as the principal investigator, and have no affiliation with a university or comprehensive cancer center but develop a relationship with one for assistance and advice.

The seven existing projects are located in San Jose, Walla Walla, Pendleton, Ore., San Antonio, Ada, Okla., Indianapolis, Allentown, Pa., and Grand Rapids.

Edward Moorhead, PI for the Grand Rapids contract, told members of the DCCR Advisory Committee last week of the progress at the five hospitals which make up the consortium involved in his program (expanded from three with DCCR approval).

"We are developing marvelous relationships with centers, as long as we don't ask them for money," Moorhead said, The program is a major advance, permitting cancer patients to receive the best quality care in their own community, he commented.

Moorhead said his program operated under three basic principles: Physicians who will be using the multidisciplinary systems should participate in the design of the system; it should be voluntary; and the management of each patient should be retrospectively reviewed.

Donald Buell, DCCR program director for clinical oncology, said one of the biggest problems encountered by the seven contractors was physician acceptance. "Physicians in the communities do not necessarily welcome federally funded programs telling them how to practice medicine," Buell said.

Physicians in San Antonio considered it one of the last areas in the country where they could practice medicine without government interference, Buell said. The project there started by reimbursing physicians for time spent at tumor conferences. "Now physicians find tumor conferences so interesting that they don't want reimbursement. One hospital administrator opposed the program and refused to participate until one of his patients, who happened to be a trustee of the hospital, insisted that he go into it. The administrator found it was quite different than he had anticipated."

Southwest Texas Methodist Hospital, where the San Antonio program is located, now has 88% of its cancer patients treated in the program. "It has evolved into something better than we had planned," Buell said.

Another major problem has been a shortage of nurse oncologists, "and nurses are the key to success of the programs," Buell said. "They can't recruit anyone, and have had to send their own nurses for oncology training."

DCCR views the seven projects as reasonably successful in that the oncology teams have been established and are in general offering better care to their patients. The systems to achieve further improvements are in place, and the overall success of the program is not in doubt.

DCCR Director Diane Fink told ***The Cancer Letter*** that "We felt a need to expand this program, since the majority of cancer patients are treated in a community setting. We started modestly, and it has been very successful. Now we have some growing room."

The total number of communities involved in the program, including the seven existing ones, probably will be between 12 and 15, Fink said. "But we're not sure of that. There are many different types of community settings, and we do want a balance."

Charles Cobau, vice president of the Assn. of Community Cancer Centers and a consultant to the DCCR Advisory Committee, noted that 700,000 of the estimated 750,000 new cancer patients in 1978 will be treated in non-university or center-affiliated institutions, "where the quality ranges from excellent to not so good. One of the missions of DCCR ought to be to improve the quality where it is not so good."

Committee member Diane Komp cautioned that before a new RFP is issued, the question of overlap with other DCCR programs should be considered. "None has bothered me more as far as overlap is concerned," she said, citing the DCCR contracts with Clinical Cooperative Groups to support clinical trials in community hospitals, and the comprehensive center outreach efforts.

Cobau acknowledged that those programs, plus the Community Based Cancer Control Program and others funded by DCCR "account for a significant part of the DCCR budget. Their success is uneven. We've learned something—that different communities respond differently to narrow stimuli. It is important that DCCR support a range of programs."

Cobau said that ACCC favors extension of the Clinical Oncology Program and that many of its members are potential responders to a new RFP. He suggested some changes: Remove the three hospital limit for each consortium; remove the requirement that the responder not be affiliated with a university medical school. "I feel that a workshop to help communities respond would be helpful. Many of us are not sophisticated about grant applications. It would reduce the number of spurious applications and raise the quality of those submitted."

Committee member Helen Burnside said one of her concerns about the original RFP was that its requirement regarding multidisciplinary teams was aimed primarily at physicians. "Nursing and rehabilitation components were only appendages," Burnside said. "I hope the new RFP will allow other personnel as components."

Ralph Engle, chairman of the Cancer Control Prevention, Detection, and Pretreatment Evaluation Review Committee, said, "We need some way to get a handle on the impact of this program. Perhaps we could identify a reasonably limited geographic area, where we feel the cancer program is not particularly good, and set up a concurrent control group that is reasonably comparable, with a goal of identifying all patients with a particular kind of tumor. I don't think we ought to give up so easily on the impact."

"A good evaluation should be done on this one before we issue a new RFP," committee member Harold Rusch said.

"We're always in a dilemma," said Timothy Talbot, chairman of the Cancer Control Grant Review Committee, "considering socially needed programs and a limited amount of money. The Grand Rapids program is most appealing to one's emotions and it meets the goals of the Cancer Program. I don't know what the others are like. We should find that out before we go off on something new."

Buell said the summaries of the merit reviews conducted on the seven contractors would be available to the committee.

Committee member Louis Leone said that the Grand Rapids program shows the impact it has had. "Technology was being transferred. More people are being treated according to a perception of quality care. It demonstrates the ability to transfer information. To ask if this is better than Toledo is a difficult, sophisticated question. The Clinical Oncology Program budget is not enough to cover a sophisticated impact study."

"Dr. Moorhead, or someone in Grand Rapids, has the secret of dealing with people," said committee member Hamblin Letton. "That's the key to success."

Committee Chairman William Shingleton suggested that action on the proposal to develop a new RFP be delayed until the committee's July meeting, but Fink said she wanted to move faster than that. Reizen's motion that DCCR move ahead with developing a new revised Clinical Oncology Program, with final approval by the committee in July, was approved unanimously.

DCCR had given some consideration to funding the new program with grants instead of contracts. This would appear to fit in with the new NCI policy of using grants as much as possible.

That probably won't happen with the Clinical Oncology Program. Buell said the staff feels that it is the kind of program that needs to be closely monitored, "and you can follow and monitor a contract better than you can a grant."

Some of the existing projects in the program will terminate this year, the rest next year. They will not be eligible to compete for the new contracts. NCI expects them to be carried on with local funding. Moorhead said his program would continue, although perhaps not at the same level.

UPTON PREFERS RETAINING BIOASSAY PROGRAM AT NCI, WITH COORDINATION

The fate of NCI's Carcinogenesis Testing Program (also known as the Bioassay Program) probably will not be determined by HEW Secretary Joseph Califano until next month. Sometime in the next few weeks he will receive an option paper from Director Arthur Upton which will spell out the choices he has as the home for the program.

Those options range from leaving the program where it is, in NCI's Div. of Cancer Cause & Prevention; to moving part or all of it to an existing agency such as the National Institute of Environmental Health Sciences; to making the program the focal point of an entirely new institute or agency.

"My own preference would be not to give up any of it," Upton told ***The Cancer Letter.*** "I would prefer a consortium (to include the regulatory agencies, NIEHS, perhaps others) to assure coordination and cooperation. It would not involve giving away any resources or activities that are now our major responsibilities."

Under that plan, NCI would continue the screening of chemicals for carcinogenicity which it has been doing for a number of years as the nation's only regular, major carcinogenesis screening effort. "But we would see that the needs of the regulatory agencies are adequately met and responded to," Upton said. "We need a closer relationship than has existed in the past."

Another factor, one of the primary reasons for considering a move of the program to another agency, is the need to test chemicals for toxicities other than their carcinogenicity. The animal tests now zero in on neoplasias produced by the chemicals; other end points such as central nervous system damage, loss of fertility, teratogenicity are sometimes observed but are not usually considered in the reports. The tests, or at least the analysis process, probably would have to be redesigned if other toxicities are to be studied concurrently with carcinogenesis. Concurrent tests might not be possible in many cases.

Upton agreed "there is a need to look at other end points. But I think we can do that, join hands, strengthen the program, without giving it away. That is not in our interest or in the national interest."

The Food & Drug Administration operates the National Center for Toxicological Research in Pine Bluff, Ark. (Like Ft. Detrick, Md., now the home of the Frederick Cancer Research Center operated for

NCI under contract by Litton Bionetics, the Pine Bluff facility was formerly as Army biological warfare center.) The center has been mentioned as a possible home for any new federal agency responsible for all chemical toxicity testing, including those that may be performed for the Environmental Protection Agency, National Institute of Occupational Safety & Health, Occupational Safety & Health Administration, NIEHS, and the Consumer Product Safety Commission, as well as FDA. All have some role, either testing, research, or egulation, in federal chemical toxicity control programs.

Some have argued that NIEHS, which is part of NIH but which is located in Research Triangle Park, N.C., would be the more logical agency to conduct combined toxicity tests. That, in fact, is one of the options that will be submitted to Califano.

If that happens, "NCI would not abrogate its responsibilities, but would be joining in a combined effort with NIEHS," Upton said. "I don't see us getting out of the testing business."

Here's still another possible option: Leave existing testing programs where they are, with independent management and resources, and hire a single administrator and staff to provide the coordination.

"If some one agency is to be the lead agency, it is immaterial which it is , as long as there is wholehearted commitment," Upton said. "In this day and age, the nation needs the best program we could possibly have, a national program to which the regulatory and the research agencies are committed. I'm anxious to see changes in the NCI Bioassay Program to bring the regulatory agnecies more closely into the administration of it. I believe it is absolutely necessary to see that all testing activities are coordinated."

There are some at NCI and elsewhere who have long felt that the institute should never have become involved in routine screening and who would be pleased to have that job shifted to some other agency. NCI is a research agency; screening is not research, they say, and it detracts from the research mission.

The Carcinogenesis Testing Program, however, is not limited to screening. It has a research component (not to be confused with the Carcinogenesis Research Program, which was split out from the Carcinogenesis Program two years ago). The Carcinogenesis Testing Program was left with the research aspect of testing methodology, including the all-important in vitro testing systems.

Splitting the testing program will not be easy. Program Director Richard Griesemer said he has not even started to consider how any such split would be made. Some NCI executives feel that testing research would have to go along with the testing. That would mean that some very important cancer research would be conducted by a federal agency other than NCI.

"Moving in vitro and other carcinogenesis research would have to be worked out," Upton said. "Obviously, NCI does not want to get out of carcinogenesis research. I do not see us giving up our carcinogenesis research efforts. If the program is combined with others at a new institute, it is logical that it would be doing some testing research. We may have to give up part of it."

On the other side of the coin, if NCI is to retain some carcinogenesis testing research, it will have to perform some carcinogenesis tests. Would it not be economical to do some screening with those tests? Or perhaps testing research might better be performed if it is not burdened with the requirements of a screening program.

When Califano gets around to trying to answer some of these tough questions, he may well conclude that Upton's first choice is the logical one.

There are 52 staff positions in the Bioassay Program, including Griesemer's. Where the people who fill those slots would wind up in the event the program is split up depends on how it is divided. Some might be permitted to remain at NCI, moving to other programs, or perhaps transferring to other agencies. Some undoubtedly would be required to move if they want to remain in the government, and that prospect is looked upon with mixed emotions.

If a new super-agency is established with responsibility for all government toxicity testing, it could open up new career opportunities for some. The government's responsibilities in this area were greatly increased by the Toxic Substances Act which probably will require tests of all the hundreds of new compounds which enter into commerce each year. Tests of a substantial number of those already in use also will be conducted. A new agency, or an existing one given the new responsibilities, would conduct many of the tests but would probably contract with commercial labs for most of them. It would be the leading edge in a major national effort to reduce human exposure to harmful substances in the environment.

Califano urged Upton to proceed with the reorganization of NCI, particularly that part of it aimed at moving those basic research projects now supported by contracts to the grant mechanism.

The HEW Inspector General's office reported on its audit of NCI's contracts and concluded that there was improper use of contracts, weak contract administration and ineffective use of peer review groups. Project officers dominated administration of contracts, relegating contract officers into the background, the report said.

The Inspector General made a number of recommendations, most of which Upton already has implemented or is in the process of implementing as part of his reorganization, including separation of peer review from program.

Many research contracts, particularly those that supported basic research, were deliberately written with broad workscopes to permit the greatest degree of flexibility to contractors. NCI executives and the scientific community pretty much agree now that grants are a more appropriate mechanism for basic research.

However, not all research contracts will be phased out. "We will look at them on a case by case basis," Upton said. "There will be exceptions."

There will even be some basic research carried out with contracts. For instance, the basic research component at Frederick is supported through the contract with Litton. "We won't stop basic research at Frederick merely to stop using a contract that supports basic research," Upton said. Contracts still may be used to stimulate work in areas where it is needed, he said. Drug development and clinical trials are examples of two activities that will continue using contracts in a substantial way. "We've no reason to change those," Upton said.

HOUSE SUBCOMMITTEE ADDS $30 MILLION TO NCI '79 TOTAL OVER BUDGET REQUEST

The House HEW Appropriations Subcommittee added $30 million to the amount requested by the Carter Administration for NCI in FY 1979, substantially more than expected based on the Subcommittee's actions in recent years.

The Administration had requested $878 million, only $11 million more than NCI is getting this year ($6 million more, if it receives the $5 million it should get from a supplemental appropriation to cover the cost of pay increases). That would have meant a severe cutback in some programs, since NCI would need between $910-920 million just to stay even with inflation.

Chairman Dan Flood of the Subcommittee had penciled in a $19 million increase over the Carter request. Of that $19 million, Flood had earmarked $10.5 million for support of basic research through R01 (traditional investigator initiated) grants.

Congressmen Joseph Early (D.-Mass.) and Silvio Conte (R.-Mass.) submitted an amendment adding $11 million to Flood's figure, all of it earmarked for R01s. That brings the amount NCI must allocate to R01s to not less than $209 million, Early pointed out.

"We're willing to go along with the new gentleman (Director Arthur Upton) at NCI," Early said. "When he has completed the reorganization, I'm willing to give him more than a billion dollars if he can show us it is being well spent."

Conte said he concurred, although "I was prepared to submit an amendment adding $100 million over the President's budget. NCI needs $50 million to develop second generation anticancer drugs, and $50 million for epidemiological studies. What we're approving is way short of the mark. But I listened to Secretary Califano's plea, and the idea that we will set out this amount for basic research is one of the greatest things that could happen. I'll go along with this meager increase."

"That means NCI will have the highest pay line (priority score up to which approved grants will be funded) of any NIH institute," Congressman David Obey (D.-Wisc.) said.

"That does give NCI a little higher pay line," Early responded. "But NCI spends less than 22% of its budget on basic research, while others spend 50%." Early repeated that he is willing to "hold the line at $30 million increase for NCI until the reorganization is completed."

Obey said, "You can make a good case that they have been fairly responsible at NCI in funding high quality basic research."

What was that? The same David Obey, who used the same occasions the last two years to blast NCI and who has argued that NCI could not spend wisely all the money it was getting?

This time Obey was a pussycat. There's more.

Obey took up the cause of inadequate staffing throughout NIH, including NCI, and the overload placed on existing study sections. "Before we get into the question of individual institutes," Obey said, "there's the question of the staffing base at NIH and the study section problem. Dr. (Donald) Fredrickson (NIH director) indicated there is a serious problem with the tremendous burden on peer review. They are unable to get additional study sections approved (by HEW). I suggest that we add $570,000 to provide the equivalent of 19 additional study sections."

"How about doing that within available funds?" Flood suggested.

"Okay, just as long as it's in."

That will probably turn up in the House report on the bill which will not have the same force of law that it would spelled out in the bill itself. But HEW officials will ignore it at their peril.

Obey also shifted the blame from NCI to Congress for inadequacies the General Accounting Office found in its investigation of the Eppley Institute contract. "This is what happens when we lay out money to NIH and do not provide positions necessary to administer it," Obey said. After reading from a section of the GAO report, he said, "I'm sure the same thing has happened with other contracts at NIH. . . . We can't pretend we're helping NIH when we don't give them the positions to monitor the programs. NCI had only one staff member monitoring the Eppley contract. That's not NCI's problem, that's our problem."

Obey asked that 200 additional positions be mandated to NIH. "We'll leave it to Dr. Fredrickson to distribute as he sees fit." The subcommittee agreed,

and also accepted an additional appropriation of $5.2 million for NIH to cover the cost of the new positions.

Overall, the subcommittee added $305 million to the President's budget for NIH, probably the most generous increase it has approved in years. The Senate has invariably had to provide the major impetus for significant increases in the NIH budget. Cancer Program advocates now are optimistic that the Senate HEW Appropriations Subcommittee, with Edward Brooke (R.-Mass.) insisting on $1 billion for NCI, will come in with something more than $950 million. The compromise then could be in the range of $930 million or more, which would help relieve the stifling effects of the 1975-78 budget crunch in nearly every program area.

The increase for NIH amounted to 10.6% over the President's budget, while the $30 million increase for NCI was only 3.4%.

NCI financial management chief Earle Browning suggested to the President's Cancer Panel this week that since Obey had indicated the 200 new positions should be for contract management, and since NCI awards more than half of all contracts supported by NIH, "we should get half of those positions."

"We want the positions," commented Panel Chairman Benno Schmidt (who still has not been replaced, although his term expired in February), "but I don't think we should push for them on the basis of contract monitoring."

PANEL OBJECTS TO CANCER ACT CHANGE REQUIRING NCI REPORT ON CARCINOGENS

The annual report on carcinogens and evaluation of regulatory standards which would be required of NCI by an amendment to the National Cancer Act (*The Cancer Letter*, April 21) was the only change made in the Act by the House Health Subcommittee that drew opposition from the President's Cancer Panel.

The amendment, submitted by Rep. Andrew Maguire (D.-N.J.), reads:

NCI will "publish an annual report which contains (A) a list of all known or suspected carcinogens to which a significant number of persons residing in the United States are exposed; (B) information concerning the nature of such exposure and the estimated number of persons exposed to such carcinogens; and (C) an evaluation of the efficacy of the existing regulatory recommendations respecting ways in which such standards could be improved."

"If we leave out 'suspected' carcinogens and just list all known carcinogens, or those thought to be carcinogenic on the best science available, how much of a problem would it be to list them, evaluate exposure and regulatory action?" asked Panel Chairman Benno Schmidt.

"Listing them would not be a major problem. We get into the gray area on suspected carcinogens," Director Arthur Upton replied.

"That would create real trouble," Schmidt said. "Suspected by whom, and to what degree? We need to talk with Paul (Rogers, chairman of the Health Subcommittee) and other members of the committee," Schmidt said.

Panel member Elizabeth Miller said that the Environmental Protection Agency published in 1975 a list of known and suspected carcinogens. "That was a problem. It contained everything, without too much respect for what happened in control groups. It was not a scientifically sound list," Miller said.

Maguire's amendment grew out of a suggestion by Sidney Wolfe, director of the Nader organization's Health Research Group, who offered it at the hearings by Congressman L.H. Fountain last year as a means of keeping tabs on compounds entered into the regulatory pipeline and prodding the regulatory agencies.

BOURNE TELLS ACCC WHITE HOUSE BACKS HEROIN, THC RESEARCH, HOSPICE CONCEPT

The National Institute on Drug Abuse will make heroin and marijuana's active ingredient, THC, available to "legitimate researchers" in standard dosage units, Peter Bourne, President Carter's advisor on health affairs, said at a regional meeting of the Assn. of Community Cancer Centers.

The meeting in Orlando was devoted to discussions of hospices. Bourne said that an Interagency Committee on New Therapies for Pain and Discomfort has been set up to establish a national policy for the treatment of those in pain and the terminally ill.

One of its tasks is to define how the federal government can be supportive and helpful "without being over-zealous. We are aware that an excess of federal zeal has been known to provide the kiss of death to many perfectly viable efforts, through over-regulation and bureaucratization."

"Obviously, the humane treatment of the terminally ill is a broad topic, involving changes in the public attitude, in the role of medicine and the physician, changes in education and research emphasis, and in government policy," Bourne said. He then described what the White House is doing to support that movement.

"The first area where we were able to help was on the issue of the use of restricted drugs for the terminally ill. Heroin has been used since early in this century in England and other European countries, in combination with other drugs, as an apparently successful treatment for the pain of terminal cancer. However, due to fears of illicit use and an almost mystical dread of the substance in the U.S., we have banned heroin in this country for over 50 years.

"This Administration feels strongly that research into the possible therapeutic benefits of any drug should not be restricted by that drug's bad historical reputation. The decision on making a drug available

to patients should be based on medical evidence, not on its history of abuse in non-medical circumstances. Likewise, the fear of addiction and uninformed biases against selected potent narcotics should not be allowed to interfere with the humane treatment of the terminally ill.

"If the administration of any drug could help alleviate pain or relieve anxiety, it should be available to the medical profession. In addition, different patients react differently to various analgesics; the doctor should be allowed to judge the patient's response to the drugs that he thinks may be appropriate, and select the most effective.

"The relative merit of heroin versus morphine, which is legally used in our country, is not the real question. Rather, it is whether the treatment of dying patients, using all practical means, is responsive to their individual needs for dignity, compassion and understanding and that they are not depersonalized and merely dismissed as failures of medical technology.

"Late last year we instructed the Dept. of Health, Education & Welfare to change their policies in this area and they are now facilitating research opportunities and access to restricted drugs.

"We originally considered amending the Controlled Substances Act to permit the manufacture of heroin in this country, but this turned out to be unnecessary at this time. The issue of whether morphine is equally effective in this kind of treatment needs to be resolved first.

"We are making every effort to facilitate research into the therapeutic value of abused drugs such as heroin, marijuana and marijuana's active ingredient, tetrahydrocannabinol or THC. The Food & Drug Administration has streamlined its process for the approval of investigational new drug applications, which any researcher into schedule I, the most tightly restricted drugs, must have. In fact, they have established an umbrella IND in the National Cancer Institute for research on heroin and THC. The National Institute on Drug Abuse will make these drugs available to legitimate researchers in standard dosage units.

"In addition, there are federal grants available for research into the therapeutic uses of heroin and THC from the National Institute on Drug Abuse, and the National Institutes of Health. Marijuana is being looked into as both a treatment for glaucoma, as THC apparently lowers intraocular pressure, and as an antiemetic during chemotherapy treatment for cancer.

"We are also looking into the marketing problems of the so-called "orphan" drugs. Orphan drugs are those which have a proven medical use, but which are not commercially advantageous to produce, either because the amounts used are so small, or because they are unusually expensive to make. It is not enough to foster research on a drug which, after its effectiveness is proven, will not be available to physicians because of lack of supply. Both THC and heroin are non-patentable and, therefore, are of little commercial value to the pharmaceutical companies. If either drug proves to be of medical use, we will work with the pharmaceutical industry to ensure an adequate supply. We have already been discussing these issues with the industry.

"We also support educational programs for physicians who are dealing with individuals suffering with terminal illness of having intractable pain to ensure that they use those drugs that are available and which are effective for the control of pain. Studies show that many physicians underprescribe narcotic analgesics for pain. Not only are doses lower than those recommended, but the time between doses is longer, allowing the patient to become anxious about the recurrence of pain, and thus enhancing the pain when it is felt. In one study, many physicians had exaggerated ideas of the dangers of addiction to narcotic analgesics, and those who did were likely to prescribe low drug doses even for the terminally ill.

"I certainly do not believe that it is callousness on the part of physicians that results in patients being kept needlessly in pain. Rather, it is their reaction to the stigma and fear of addiction which has, in large part, been fostered by government policies. Our physicians are the world's best, and, if there is indeed a failure to use analgesics to the patient's best advantage, it may be because we have no uniform policy about providing medication to the dying. One of the goals of this Administration is to establish a clear policy of humane treatment for those in pain or terminally ill, and then, perhaps, our physicians can be more innovative with medicines and less fearful of malpractice suits or bad press.

"We have convened the Interagency Committee on New Therapies for Pain & Discomfort to establish a national policy for the treatment of those in pain and the terminally ill. The membership of the committee includes representatives from the National Institute on the Dying, FDA, Health Resources Administration, National Institute of Mental Health, and the Drug Enforcement Administration, as well as representatives from the National Committee on the Treatment of Intractable Pain, the National Academy of Sciences, Institute of Medicine and members of Congress.

"This varied membership illustrates both the need for coordination and the great amount of interest that has already developed on this important issue. The focus of the committee is broad and their inquiry will not be limited to the use of heroin or cannabis. Rather, they will foster research on developing better methods for the treatment of death, dying and chronic pain, including all forms of therapy, not just chemotherapy. They will look at the mechanics of pain, the proper use of analgesics, and non-chemical therapies. They will see that research findings are

shared widely and promote a coherent government policy toward the treatment of the terminally ill.

"Among the issues that the committee will address is the hospice concept. The hospice movement has great momentum on its own, and a tremendous amount of extremely valuable work is being done by groups such as yours, in the private community. . . .

"There is strong congressional interest in hospices. Senators Hathaway, Kennedy, Dole and Ribicoff are studying hospices very closely, and plan to do so in the coming year. There is a feeling that much of the data that we have on hospices is scattered, and we need to bring it together in order to get a comprehensive picture. Such issues as relative cost effectiveness, licensing—how it's done now and how it might be done—and the reimbursement for hospice-type home care services need to be researched.

"There are provocative reports that hospices provide care for the dying at much less expense than acute-care hospitals, especially when the home care services are emphasized. In one study of about 500 patients served by the New Haven Hospice at home, the average cost of services for the last three months was only $750, less than the cost of a typical week in a hospital. Another study reports that full standing hospices cost about 27% less than acute-care hospitals.

"These reports are heartening, particularly at a time when all medical costs are skyrocketing, and when one of this Administration's most important goals is to bring them under control. I share the concern of many members of Congress that we need to make more comprehensive studies of the possible cost savings of hospices, and carefully determine how to support them and integrate their services into our general health care system. We must bear in mind that we currently have wasteful excess hospital beds—a problem which we don't want to exacerbate. We must also carefully avoid encouraging profiteering in hospices, as has occasionally occurred in the nursing home business. It is not a pleasant thought to consider, but we must guard against commercial exploitation of hospices, and a lowering of standards and supervision. You, as major leaders in the hospice movement, also need to be aware of, and concerned for these issues.

"Reimbursement for hospice-type services is also not a simple question. For example, the average age of a New Haven hospice resident is 60—too young for Medicare—and whose income is, usually, too high for Medicaid. In addition private insurance companies are waiting until standards and certification procedures are set before they extend full coverage. We also need to consider how to integrate hospice-type home care into any national health insurance scheme. All of these questions will take some time to resolve and it would be wise for us to move slowly rather than precipitously. In general, though, there is enormous support for the concept of home care and hospices both in the Congress and the Administration, and an appreciation of the humanitarian values that hospices have come to represent.

"Finally, the Interagency Committee is interested in keeping its focus as broad as possible, dealing with any policies and programs which develop a humanitarian method of dealing with people who are suffering. As a nation, we need to re-educate ourselves about death and the dying. Most Americans reach maturity without experiencing the death of a loved one, and we must begin to rely on our schools and family education to re-familiarize ourselves with death as a natural process. There is a growing trend in the country to educate children in school at a young age about death, and I think this is a healthy change. Doctors also need to be told more about death, how to deal with it and not to avoid it and regard it as a personal failure. We all need to give some thought to dying—our own, and that of others—and how to approach it with compassion, frankness, and humanitarian concern."

CONTRACT AWARDS

Title: Cervical cancer screening program, renewal
Contractor: Hawaii State Dept of Health, $232,117.

Title: Cancer Control program for clinical cooperative groups—National Surgical Adjuvant Breast Project
Contractor: Univ. of Pittsburgh, $1,161,300.

Title: Analysis of cell proliferation in familial polyposis, continuation
Contractor: Memorial Hospital, $456,959.

Title: Support services to maintain studies of type C RNA tumor viruses, continuation
Contractor: Microbiological Associates, Bethesda, $226,557.

Title: Maintenance of an irradiated monkey colony, continuation
Contractor: Emory Univ., $29,047.

SOLE SOURCE NEGOTIATIONS

Proposals are listed here for information purposes only. RFPs are not available.

Title: Program planning, evaluation and related support services for the Div. of Cancer Control & Rehabilitation, renewal
Contractor: JRB Associates Inc.

The Cancer Letter —*Editor* JERRY D. BOYD

Published fifty times a year by The Cancer Letter, Inc., P.O. Box 2370, Reston, Virginia 22090.