THE CANCER LETTER

Vol. 8 No. 24
June 11, 1982

Subscription $125 year North America/$150 yr elsewhere

P.O. Box 2370 Reston, Virginia 22090 Telephone 703-620-4646

DCT BOARD GIVES CONCEPT APPROVAL TO "NATIONAL DRUG DISCOVERY GROUPS," SUGGESTS FOUR AT $1 MILLION EACH

As many as four "National Cooperative Drug Discovery Groups" will be established, with NCI support of up to $1 million a year each, as the result of action last week by the Board of Scientific Counselors of the Div. of Cancer Treatment.

The Board unanimously approved the concept of the plan drawn up

(Continued to page 2)

In Brief

BRUCE CHABNER IS DEVITA'S CHOICE AS PERMANENT DIRECTOR OF DCT; SIX NEW RCDAs FUNDED IN FY 1982

BRUCE CHABNER, who has been acting director of NCI's Div. of Cancer Treatment for the past year, is NCI Director Vincent DeVita's choice as permanent director of the division, ***The Cancer Letter*** has learned. No formal announcement of the appointment will be made until it has been approved by HHS Secretary Richard Schweiker. . . . **DANIEL KISNER**, who has been acting head of DCT's Cancer Therapy Evaluation Program, will leave July 1 to become associate professor of medicine in the Div. of Medical Oncology at the Univ. of Texas Health Sciences Center in San Antonio. Chabner said he has started a search for a new CTEP director. . . . **PHILIP PIZZO**, who has headed the Infectious Diseases Section of the Pediatric Oncology Branch in DCT, has been named chief of the branch. . . .**ONLY TWO** Research Career Development Awards were funded at last month's meeting of the National Cancer Advisory Board. Both had priority scores of 111 or better, although NCI was able to fund a total of six new RCDAs in the 1982 fiscal year, down to a priority score of 146. Research Manpower Branch Chief Barney Lepovetsky said he hopes to be able to fund at least to the 150 payline in the 1983 fiscal year. NCI supports 110 RCDAs now, and Lepovetsky would like to stabilize the number at 110-113. The awards pay investigators $30,000 a year for five years plus fringe benefits, and up to eight percent in indirect costs, with the provision they spend nearly all their time on research and very little on teaching or administrative duties. During that time they are expected to develop their own research projects which can lead to funding through other mechanisms. . . . **UCLA JONSSON** Comprehensive Cancer Center will replace Joseph Cullen, deputy director for cancer control, with two new appointments—Lester Breslow, who will be co-director for cancer control research of the Div. of Cancer Control; and Helene Brown, co-director for community cancer control applications. Cullen will become deputy director of NCI's Div. of Resources, Centers & Community Activities. . . . **WILLIAM HUTCHINSON**, president and founder of the Fred Hutchinson Cancer Research Center, has received an honorary Doctor of Humanities degree from Seattle Univ.

DCT BOARD APPROVES CONCEPT OF FOUR COOPERATIVE DRUG DISCOVERY GROUPS

(Continued from page 1)

by a subcommittee chaired by Alan Sartorelli, who had originally proposed the plan (***The Cancer Letter,*** Feb. 26). The new groups will attempt to generate new approaches in development of chemical and biological compounds, rapidly translate those concepts into new entities and carry out studies leading to clinical evaluation. Groups will include investigators in chemistry, biology, biochemistry and pharmacology from academia, nonprofit institutions and industry.

The groups will be funded through cooperative agreements, and DCT will issue a request for applications, spelling out details of the program.

There is a possibility that DCT will not be able to set aside $4 million for the new groups in the 1983 fiscal year. "If you can find only $3 million, then fund three groups," Sartorelli said. But John Driscoll, director of DCT's Developmental Therapeutics Program, said it was not yet clear whether the groups would be funded at identical levels. "It may be possible to support four groups for $3 million," he said.

The subcommittee's report appeared to envision the groups as vehicles for development of chemical compounds as anticancer agents, but DCT Director Bruce Chabner said that biologicals would be included. Board member Efraim Racker pointed out development of radiosensitizers also would be an allowable activity.

The subcommittee's report follows:

Chemotherapy has made a major impact towards the cure of cancer over the past two decades. Nevertheless, there is considerable need for the development of new and more efficacious agents with higher therapeutic ratios for the treatment of these diseases. In spite of these considerations, programmatic support for drug discovery has been markedly reduced over the past several years. This decrease has resulted to a large extent from a major reduction in the contract mechanism in this area, and is exacerbated by an inability of the grant program to accommodate in individual project grants the varied disciplines necessary for the discovery process.

Many exciting leads in fundamental science are available for possible exploration and possible extrapolation into new drug classes with unique mechanisms of action, and new approaches to control cancer. Furthermore, considerable research talent is available in the United States that could be employed in a more effective manner, but to accomplish this requires a national support mechanism that would permit the most outstanding investigators in chemistry, biology, biochemistry and pharmacology (all needed for effective drug discovery) to interact in a manner that leads to the efficient invention of new strategies and entities for the treatment of cancer.

Since it is clear that few institutions possess critcal masses of all of the varied talents needed for effective drug discovery, a new instrument that permits the combination of the available expertise from diverse institutions clearly is required. These units, termed by the subcommittee "National Cooperative Drug Discovery Groups" are envisioned to have the capacity to generate new approaches to therapeutic inventions, to rapidly translate their concepts into new chemical entities, to conduct adequate and unique biological evaluations, and to carry out in depth biochemical and pharmacological studies that not only would lead to future new drug discovery but would also permit the most enlightened clinical evaluation supported by the most sophisticated pharmacological and biochemical technology. It is expected that discovery groups will bring new entities to a stage that will allow rapid development and movement into clinical evaluation and usage.

The minimum scientific composition required of a National Cooperative Drug Discovery Group are four disciplines: chemistry, biochemistry and pharmacology. Although more than one component of a discovery group might be derived from a single institution, it was felt that (a) the program project grant is available to single institutions, and (b) the varied talents and commitment required for effective drug discovery are not usually present in most single institutions. Therefore, it was recognized that for the maximum intellectual strength upon which new discovery leaned, leadership individuals from one or more of the required disciplines should be derived from distinct institutions capable of contributing high quality critical masses in a required area.

Discovery groups can consist of scientists from academia, nonprofit institutions, and industry; active participation of industry was viewed as a means of allowing this segment of the research community to possibly invest their considerable intellectual and material resources. Furthermore, the interaction of discovery groups with industry will be essential for ultimate development and marketing of new chemotherapeutic agents. The minimum number of components in a discovery group was considered to be four; however, multiples of a given discipline, for example chemistry, might well be advantageous and most efficient. Also deemed acceptable might be the combination of two disciplines, such as biochemical and pharmacology.

The director was envisioned to be one of the program leaders, with particularly broad dimension in drug discovery and possessing the expertise to communicate effectively in all of the required disciplines; this individual should provide a minimum of 10 hours of coordination time per week. Each of the program leaders should be leaders in their fields with established laboratory programs, who can contribute effectively to the cooperative enterprise envisioned to be required for a National Cooperative Drug Discovery Group.

The strength of such a discovery group relies upon the ability of the program leaders of the individual components to work together to make corporate decisions as to the molecules to be synthesized, the methods to be employed for analysis for biological activity, and the approaches to biochemical and pharmacological studies on mechanism of action. The most effective programs will develop mechanisms for (a) phasing out at the earliest possible time, drug classes which do not fulfill their initial promise, and (b) incorporating new developments and approaches into the discovery group structure. It is expected that to accomplish these types of interactions regularly scheduled meetings consisting of the director and the individual program leaders of each group will be required.

Various potential funding mechanisms were considered; these included the contract, grant and cooperative agreement mechanisms. The cooperative agreement appeared to be the mechanism of choice, since this would permit the discovery groups complete independence with respect to projects and approaches, but would allow substantial involvement of the Div. of Cancer Treatment of the National Cancer Institute. Here, the expectation is that NCI would function as a full partner in corporate discovery group decision making, and would provide resources such as quality animals, screening of new agents in a tumor panel, scale-up synthesis, formulation and toxicology for drugs entering their decision network, and ultimately support for clinical evaluation.

In order to make a significant impact and meet national

needs, it is recommended that a minimum of four National Cooperative Discovery Groups be established. The total yearly cost of such a program is estimated at $4 million. Furthermore, since translation of fundamental concepts into drug entities often requires in excess of five to seven years, it is recommended that each discovery group be funded for a minimum period of five years. . . .

The fact that two or more institutions share in a grant supported project does not alter the grantee institution's responsibilities concerning patents and inventions. Since it is important for ultimate clinical usage of a therapeutic agent to secure a patent, it is expected that adequate mechanisms for patents will be developed, and it is proposed that participating institutions agree in advance to a sharing of royalties derived from any discovery. The grantee institution must obtain appropriate patent agreements to fulfill the requirements from all persons who perform any part of the work under the grant and may be reasonably expected to make inventions. The grantee should insert into each such written agreement a clause making the patent and inventions policy applicable to each cooperating institution and its employees.

Evaluation of applications for the establishment of National Cooperative Drug Discovery Groups should be conducted by a special study section of peers which would employ the following criteria: (a) the broadness of the director as a national leader; (b) the quality of individual program leaders and their staffs; (c) the quality and promise of the initial proposed research; (d) the administrative mechanisms established for program management, including factors such as approaches to decision making as to direction of synthesis, evaluation of new activities, and biochemical and pharmacological studies, as well as the mechanisms to be employed for aborting drug classes and starting new initiatives; and, if and when a competitive renewal is submitted, (e) the productivity of the discovery group. It is further recommended that the Board of Scientific Counselors initiate an evaluation of the effectiveness of this mechanism for drug discovery at the end of a three year period to determine the impact of the program, and the desirability of its expansion or modification.

CCOP RFA DUE OUT IN MID-JULY; DCT BOARD OKs PROGRAM, MAKES SUGGESTIONS

The request for applications for NCI's Community Clinical Oncology Program will be published in mid-July, with letters of intent from organizations planning to apply due by the end of August and the deadline for completed applications in early November.

NCI staff has finished writing the RFA and is now awaiting HHS approval for use of the cooperative agreement mechanism, expected within two weeks.

When the National Cancer Advisory Board gave its blessing to the program last month, its approval took the form of accepting the recommendations of its Subcommittee on Cancer Control & the Community. ***The Cancer Letter*** (May 21) report on the NCAB's action included a summary of the recommendations suggested by Subcommittee Chairman Gale Katterhagen; that summary was not as complete as the recommendations submitted to the Board by the subcommittee. Those recommendations follow:

"The subcommittee proposes the prototype CCOP be a consortia of hospitals, or in some cases a large single institution or large clinic. While 50 patients will remain the minimum number expected, many of these organizations will contribute larger numbers of patients, perhaps as many as 80 to 150.

"CCOPs should be a consortia or a large institution which have already established and developed patient management guidelines through physician committees, and nursing committees, and which have a local cancer data system capable of analysis and data management. Moreover, they have activities, like local physician site committees which actively involve primary care physicians in the cancer program and which will help educate and update them on changes in the state of the art in cancer diagnosis, therapy and continuing care as well as the availability of protocols for certain patients.

"Funding will be provided for clinical research support as was outlined in the original draft of the RFA. In addition, each program will require a full time administrative director, an administrative secretary, and a local data system to support the continuation of community physician, and nurse guideline updates through committee participation, to provide rapid feedback on the patterns of patient care, and to assist in coordination of a larger CCOP program.

"There are likely to be fewer of these programs than first envisioned. At the same time, they are likely to produce a substantial contribution by involving new patients/families with early stage disease thus broadening the clinical research efforts of the National Cancer Program and providing a strong additional base of contributors to assist in meeting our goals for future progress in clinical research."

NCI had resisted including cancer control elements, other than the clinical research itself which the Board and NCI staff agreed must be considered as control. The subcommittee's recommendation was a compromise, avoiding use of the term "cancer control" and limiting "cancer control like elements" to patient management guidelines, physician and nursing committees, programs that involve primary care physicians in the cancer program, etc. The recommendation was specific in requiring each CCOP to support continuation of community activities and guideline updates.

NCI staff prepared a summary of the provisions it planned to include in the RFA and distributed them to NCAB members. The RFA "has been revised five times since the Board meeting," Jerome Yates, associate director of the Div. of Resources, Centers & Community Activities, commented this week. However, the summary still reflects most of the elements that will be in the final RFA. It follows, edited to delete historical and background material:

Participating programs will be required to enter or refer a minimum of 50 evaluable patients annually into NCI approved clinical trials and must be prepared to enter approximately 10 percent of patients available to them to clinical trials designated as high priority by the research base with which the CCOP is affiliated. These research bases may be national or re-

gional cooperative groups, specialized cooperative groups, or cancer centers currently participating in NCI approved, clinical research protocols.

Participants are encouraged to enter or refer, if appropriate, patients with uncommon cancers. Patient entry onto clinical trials will be done through collaboration with one or two primary multimodality research bases having a spectrum of clinical trial protocols available and, if desired, through one or more specialty research bases. Eligible patients in a single disease category should be allocated to one protocol in the case where multiple affiliations have resulted in overlapping protocols.

A Community Clinical Oncology Program may be a single clinic, a group of practicing physicians, a single hospital, or a consortium of physicians and/or clinics and/or hospitals. The consortium approach may be desirable when several such community cancer treatment resources serve the same patient catchment area. Only one of multiple CCOPs competing for the same patient population will be approved.

NCI recognized comprehensive and clinical cancer centers (holding core grants) are not eligible. A university hospital which is the major teaching institution for that university will not be eligible. University hospitals and Veterans Administration hospitals may participate as a non-dominant member of a consortium led by a community institution. University hospitals participating as cooperative group members will not be eligible. Unfunded, non-university group members will be eligible. Those institutions that currently participate as part of the cooperative group outreach program or cancer centers outreach program will be eligible. Dual funding will not be permissable, however, and institutions successful in the CCOP competition will be expected to relinquish their outreach program support.

Because this initiative is a forerunner to subsequent cancer control activities, it would be understood that applicants inexperienced in clinical protocl research should demonstrate some proficiency in other areas of cancer control. These may include educational efforts such as tumor board conferences, outreach activities to surrounding areas, and serve activities in the area of prevention, early detection, and continuing care. These activities may include such things as the development of treatment guidelines, the existence of local supportive care protocols, and efforts to upgrade nursing skills in patient education. No one activity should be considered a requirement nor will all activities be expected; however, such participation will provide a global assessment of an institution's potential in participating in future cancer control activities.

Quality controlled clinical research data is a performance requirement. Assurance of quality is the joint responsibility of the CCOP and its research base affiliates. Quality control procedures, operational in the center or group, will be applied to the CCOPs and must be specified in the CCOP-Research Base Affiliation Agreement.

The CCOP is scheduled to begin in fiscal year 1983. In the fully developed program, NCI is prepared to fund CCOP up to a total cost of $10 million per year. Initial awards will be based on the number of qualified, acceptable proposals received. CCOP awards will be made directly to the community programs. Allocation of CCOP funds to support the cost of receipt, handling quality control assurance and analysis of patient data by the affiliated research bases should be mutually agreed upon and specified in the written agreement between the CCOP applicant and its research base. Awards will be in the form of cooperative agreements, now the preferred mechanism for funding NCI clinical trials programs.

The CCOP is intended to be a long term NCI program to involve community oncologists in high priority cancer clinical trials. Individual programs will be expected to apply and pass merit review for competitive renewal every three-five years.

The Board of Scientific Counselors of the Div. of Cancer Treatment last week gave its approval to CCOP, after a review by a Board subcommittee had resolved most of the objections raised at a previous meeting. The DCT Board was not required to approve the concept, since the program will be funded by DRCCA and the DRCCA Board has concept approval authority in this case. However, the program will have considerable impact on DCT supported programs, and the DCT Board insisted on being heard.

Subcommittee members were Theodore Phillips, Sharon Murphy, and Philip DiSaia. Following a meeting with NCI staff, they drew up a list of recommendations which Phillips presented to the DCT Board:

1. Absolute topnotch quality must be assured through continuation of existing cooperative group quality control programs and their application, without dilution to new CCOP members.

2. Some mechanism of uniform criteria for designation of protocols, as high priority should be established.

3. A uniform funding mechanism for the statistical and headquarters operation for the research base should be worked out. It is recommended that a uniform supplementation be given per case actually entered into studies by CCOPs by each of the cooperative group headquarters, and that this not be assessed against the funding given to the CCOP directly. Reimbursement of such funding should come directly from DRCCA to DCT. It should be based on the most economical group within a reasonable limit and should be based on cases actually assessed, not those projected.

4. There should be some real assurance and a program instituted which will prevent unwarranted switching of CCOPs between cooperative groups or centers and which prevents duplicate membership in multimodality cooperative groups.

5. The assessment of a CCOP directly for research base costs should be discouraged, since it will inhibit rather than stimulate case accession.

6. The decision to make existing group members from community hospitals ineligible for the initial round of CCOPs should be reconsidered since they may make up the best pool of eligible institutions.

NCI Deputy Director Jane Henney told the DCT Board that most of those recommendations had been adopted. Unwarranted switching of research bases by CCOPs would be prevented, she said, by permitting changes only when the cooperative agreements are up for renewal.

The somewhat controversial and seemingly complicated issue of how research bases will be funded for costs they incur by participating in the program may have a simple solution—administrative supplements to the cooperative group and cancer center grants. These would be paid directly to the groups

and centers by DRCCA (not through DCT as the Phillips subcommittee recommendation would require).

Editor's note: ***The Cancer Letter*** report on the NCAB's vote approving CCOP listed those members voting for and against it. Not included were the proxy votes of Ann Landers and William Powers, who were not at that session. Those votes were cast by Rose Kushner for approval.

DCCP BOARD GIVES CONCEPT APPROVAL TO NONCOMPETITIVE PROCUREMENTS

Among those concepts acted upon by the Board of Scientific Counselors of the Div. of Cancer Cause & Prevention (***The Cancer Letter,*** June 4), were a variety of noncompetitive procurements. The Board approved:

—Resource for the use of human tissues in carcinogenesis studies, $400,000 first year, total of $1.5 million over three years. These will be made available to qualified investigators. The intent is to identify sources capable of providing well characterized specimens, announce the availability of them, identify those applicants to whom specimens would be provided on a pay back basis, and then make the appropriate contractual arrangements with suppliers for fixed price contracts.

—Continuation of research on effects of varying doses of UV on mammalian skin: stimulation of decreasing stratospheric ozone. This work is being done by Emory Univ. and funded through the NCI-Environmental Protection Agency agreement. The Board approved funding for one more year with the suggestion that Emory be encouraged to seek subsequent support through the grant mechanism.

—Breeding and production of 129/J and NFR mice. Two years at $130,000 a year, to the California Dept. of Health, the only source with specialized physical facilities capable of breeding and maintaining those mouse strains pathogen-free.

—Collection, separation and elucidation of the components of cigarette smoke. Interagency agreement with the Energy Research Development Agency, three years at $400,000 a year.

—Continuous work history samples. Social Security Administration interagency agreement, three years, $386,900.

—Population estimates for U.S. counties. Bureau of the Census, five years, $110,000, interagency agreement.

—Application of biological markers to carcinogen testing, workshop. EPA interagency agreement, $15,000.

The Board disapproved only one concept, continuation of the NCI-EPA study by Gulf Breeze Research Lab on effects of carcinogens, mutagens and teratogens on aquatic animals. The cost was estimated at $300,000 a year, for two years; Board members felt aquatic animals are not good models for human cancer.

NEWS COUNCIL SAYS POST DRUG TESTING SERIES "FLAWED BY SENSATIONALISM"

The National News Council, an independent organization which serves as a forum for complaints about inaccuracies and unfairness in reporting news, has found the *Washington Post* series on anticancer drug testing "flawed to some extent by sensationalism and failure to supply important information that would allow the reader to put the defects of the testing program into reasonable context. The series, therefore, falls below the Post's own standards for journalistic fairness."

The Council commended the Post for devoting resources to the series and for publishing letters critical of the series.

The Council undertook its investigation of the Post series in response to a complaint by Herbert Kerman, Daytona Beach radiologist who at that time was president of the Assn. of Community Cancer Centers. Kerman also objected to the ABC television program "20/20" which also was critical of the National Cancer Program.

The Council's report on its action included comments from Post Editor Ben Bradlee, who refused to discuss the series with Council representatives because, he said, the complaint was part of a "full court press" against the articles by "the cancer establishment."

The Council's action was reported by the Associated Press and appeared in some newspapers, but the Post to date has not carried the story.

Excerpts from the Council's report:

The Washington Post articles focused on defects in the testing of experimental cancer drugs by the National Cancer Institute. Dr. Kerman called the articles lurid recitals of of complications and deaths which "may be partially factual," but "are written in a manner as to substantially impugn the entire effort of drug development of the NCI." He said, "The positive results which have occurred in the fight against cancer, while mentioned, are de-emphasized. The articles show no evenhandedness or fairness in presentation, and are so distorted as to deny the very great advances made in the experimental drug research effort."

Dr. Kerman said, "The ABC '20/20' show also de-emphasized the benefits of cancer research and the National Cancer Program and emphasized some scientifically unproven drugs and methods. In essence, a pro and con report was lacking." He said a more recent "MacNeil-Lehrer Report" from WNET/Thirteen on cancer research "was more evenhanded and afforced an opportunity for open debate between scientists with differences of opinion and an opportunity for a reasonable discussion on controversial issues ensued."

Dr. Kerman said his concern about the reports grew out of 30 years of treating cancer patients during which he has seen "slow but progressive positive results of ever increasing small improvements and sophistication in care, techniques, equipment and drug management of cancer which translates into improved survival and lessened morbidity for patients. He feared that:

"The present interest of the media in cancer and the way it is being presented results in erosion of confidence and questions the credibility and integrity of, not only the medical research scientists, but also the practicing community oncologists who apply the methodology evolved from the research efforts in the treatment of over 85 percent of all patients with cancer. While the public eagerly awaits a monumental 'breakthrough' in cancer management, this is more than likely never to occur and the benefits and progress of treatment methods must rely on small increments of increasing knowledge which can be applied to cancer management only through the present methods of investigation.

"It would be my hope that the media itself, perhaps through the influence of the National News Council, could be urged to develop a more evenhanded approach to their reports and give as much emphasis to the compassion, quality of patient care and support, and concern of the investigators who overwhelmingly are concerned with the humanistic factors as well as the scientific factors of research which involves patients and their families. The medical and bioscientific community has little opportunity to be heard in the same forum and under the same circumstances as the media, and we can only rely on the journalistic profession to improve the characteristics of professionalism and ethical behavior in journalism."

The News Council employed two people with specialized knowledge to analyze this complaint. They are David Zimmerman, a free lance science writer, and Gerald Delaney, director of public affairs for Memorial Sloan-Kettering Cancer Center. Zimmerman was recommended by Barbara Culliton, news editor of *Science* magazine and president of the National Assn. of Science Writers, after Culliton discovered that she did not have time to do the analysis herself. She recommended Zimmerman as an experienced science writer who enjoyed the respect of his colleagues for his integrity and his concern with the ethics of science writing. Delaney was recommended by Lewis Cope, science editor of the *Minneapolis Tribune,* as a person within the cancer establishment who had enough detachment to make a reliable evaluation of attacks on that establishment.

Their analyses were sent to Council members as background material. So were an article from the January-February, 1982, issue of the *Washington Journalism Review* and an "explainer" article from the October 23, 1981, issue of the *Boston Globe.* Richard Knox, the Globe's medical writer, felt compelled to write the explanatory article because he and the Globe's ombudsman received a number of phone calls and questions after the Globe published parts of the Post series.

The Post series consisted of four articles and a number of sidebars about the National Cancer Institute's phase 1 testing program for experimental cancer drugs.

Ben Bradlee, editor of the Post, said it was unsophisticated to take Kerman's complaint seriously. He implied that the complaint was part of a "full court press" mounted against the articles by "the cancer establishment." He noted that the complaint did not allege inaccuracy and said, "I see no reason why, in the absence of anything like a specific charge, the Washington Post or any of its staff should share its thinking and insights or anything else with you."

Staff replied that the complaint did allege that the articles were unfair and that unfairness, as much as inaccuracy, was a concern of the News Council. Bradlee replied that the complaint, to the extent that it it implied that the cancer series was not fair or not in the proper context, differed little from hundreds of other complaints he received in the course of a year. He said, "If you want to investigate us, be my guest," but he did not offer his thinking or that of his staff on the allegations in the complaint. That being the case, Council staff did not consider that his second response differed significantly from his first.

The Council received on April 6 from Vincent DeVita, director of the National Cancer Institute, a 52-page list of what he called "inaccuracies, omissions, or distortions of fact" in the Post series. Council staff was concerned that the list might consist of new criticisms that the Post had not had an opportunity to answer. However, it appeared from references within the DeVita list that the gravamen of the criticisms had been communicated to the Post in one or more of three letters from DeVita—one that was published in the Post Oct. 19, and two others dated Oct. 19 and 21, which were not published. Nonetheless, the appearance of the DeVita criticisms at the last minute led Council staff to try again to elicit a response from the Post to the DeVita complaints and to the original Kerman complaint. Richard Cunningham called Bradlee April 9; told him about the DeVita material; said he was uncomfortable about not having a response from the Post, and offered to make himself and the material available to receive a response from Bradlee and/or his staff. Bradlee declined. He said it ought to be clear that DeVita had an axe to grind.

Cunningham sent a copy of DeVita's criticisms to Bradlee. Bradlee replied with a letter noting that in his view the DeVita material did not constitute a challenge to the accuracy of the series and that the complaints had been largely dealt with in a statement from DeVita published by the Post.

Hard-hitting reporting on the battle against cancer has been overdue. The news reports complained of represent attempts to provide that kind of reporting.

The News Council finds that it is neither necessary nor desirable to establish special standards for the reporting of medical research in general or cancer research in particular. However, it is most important to be accurate and fair in reporting these fields.

The Council rejects the suggestion of the complainant that the medical and bioscientific communities are somehow cheated in the arena of public discussion of their programs. The press has developed some specialized reporters and editors competent to handle the complexities and subtleties of bioscientific subjects. The bioscientific community has developed public relations skills. Unfortunately those skills have often been used to limit rather than increase public discussion of the ethical issues in medical science. The cancer research program appears to both of the experts employed by the News Council to be one of the areas in which there has been too little public discussion.

The News Council commends the Washington Post for spending months of reporting time on a series of articles focused specifically and in depth at the complex and little known experimental drug testing program of the National Cancer Institute.

Unfortunately the Post adopted a sensational, accusatory tone and failed in some cases to supply information that would help the reader make up his or her mind independently about the issues involved in the experimental drug program.

As one example of the inappropriate tone of the articles: "Cancer did not kill Sheri Beck. Her treatment for cancer did. She died of congestive heart failure brought on my mitoxantrone, an experimental drug derived from the dye used in ballpoint pen ink." The article does not report what the Beck child's doctor said: That the child was not responding to any other chemical therapy; had received maximum radiation treatment, and had survived under treatment with mitoxantrone with a diminution of tumor size for five months before her death. The mention of ballpoint dye is egregrious. Many drugs are related to harmful substances—nitroglycerin to explosives, coumadin to rat poison, and the cancer drug, MOPP, to mustard nerve gas—yet the reporters mention the relationship of mitoxantrone to ballpoint ink three times. Furthermore, they report at one point that the drug changes the color of bodily secretions; so do a number of other conventional drugs.

The Post series left no doubt that the writers found it un-

acceptable that some experimental drugs were continued in testing long after the Post writers thought they should be discontinued. But the Post writers, perhaps because they are not science reporters, did not present NCI's explanation of how a drug might legitimately be under test against one type of cancer long after it had proved ineffective against other types: NCI selects six to eight of the more than 100 types of cancer for testing. Tests are conducted in 30 patients with each type of cancer, and they are tested at different dose levels and different schedules of administration. With only two dose levels and two schedules of administration almost 1,000 patients are required and the full test may take years.

Similarly the Post writers in many cases use numbers to draw a negative picture of a drug when numbers might be used to draw a positive picture. As an example, DeVita cites the Post report that mitoxantrone had been tested on 586 people with only one complete and five partial responses—and many cases of heart toxicity. The Post failed to note that the reporting was complete on only 314 patients—not 586—and the Post did not report that the one complete response and three of the partial responses were among a group of only 84 terminal breast cancer patients, a quite different picture of the drug, which is still considered promising as an anticancer therapy. In general the Post does not put the number of drug related deaths it discovered into a context that might suggest what is an appropriate number of deaths.

The reporters also point out that some of the drugs they judge to be unacceptable were on a "high priority" list created by DeVita. They do not describe the process by which those drugs were selected for testing from hundreds of other experimental drugs, nor do they make clear that "high priority" indicated only that the drugs had had some effect against animal cancers, not that they had aroused unusual hope that they might be effective in humans.

Furthermore, the Post writers do not emphasize adequately that therapies now accepted in cancer treatment once produced the same kind of side effects the writers deplore; or that any response at all in a terminally ill patient may warrant using a drug in combination with others. Nor do the writers provide adequate information on animal testing of experimental drugs or on the system that does exist to supervise testing.

It is a significant demonstration of accountability that the Post did publish well displayed along with the third article in the series a protest by the head of NCI and that it did publish letters to the editor critical of the reporting.

While the News Council cannot accept the broad charges of the complainant against the useful and important Post series, it does find the series flawed to some extent by sensationalism and failure to supply important information that would allow the reader to put the defects of the testing program into reasonable context. The series, therefore, falls below the Post's own standards for journalistic fairness.

COMPLAINT AGAINST ABC NEWS "20/20"

Kerman complained that "20/20" unfairly and irresponsibly de-emphasized the benefits of cancer research and overemphasized a couple of "scientifically unproven drugs and methods." Robert Hutter, president of the American Cancer Society, charged more specifically that the program was wrong in saying that cancer is epidemic in the United States; in implying that our ability to treat and cure cancer has not advanced, and in suggesting that ACS and NCI have formed a monopoly on cancer research funds that has denied a chance to at least two researchers with promising therapies.

The News Council commends ABC News for investing months of reporting time in what "20/20" calls a "hard, cold look" at the "well intended efforts" of the national war on cancer.

The impression comes through clearly that "20/20" believes that although billions of dollars have been spent, little "establishment" consisting of ACS and NCI. However, the program's use of innuendo and its failure to supply adequate samples of contrary views raises suspicion about the validity of that message.

The program makes statements that cancer is "no longer the other guy's disease;" that we are in a cancer epidemic, and that cure rates have not improved. Yet there are no figures from biostatisticians who would dispute those conclusions; "epidemic" has a specific meaning not justified by the present incidence of cancer, and viewers are not given an opportunity to hear and judge for themselves the NCI's argument for leaving 85 percent of lung cancer out of the death rate statistics.

An example of tilting the information is provided by the "20/20" treatment of Frank Rauscher's assertion, "We're winning this war. . . ." The reporter translates that statement into a "claim that victory is at hand."

"20/20" clearly believes that the NCI-ACS 'monopoly' has shouldered researchers with promising therapies out of the path of research grants and has denied them recognition. The report appears to place the blame on the peer review system, which, whatever its shortcomings, is essential to the prudent expenditure of research funds and to the reliable evaluation and supervision of research.

The report did not answer any number of "why" questions as it detailed the difficulties of two cancer researchers in obtaining funds or peer acceptance of their work. Such failure, which frequently occurs in adversarial reporting, tends to detract from the believability of the reporting.

The ABC News response to Hutter indicates that the program's treatment of two outsiders with promising therapies did prompt queries from the public about those therapies. Those calls illustrate the sensitivity that news media must take to the task of reporting on medical research.

A news program that takes a point of view has a right, the Council has held, to marshal fact in support of that point of view. However, the producers must be accurate and fair.

The Council rejects the charge that ABC was deliberately unfair. However, it finds that this program fell short in accuracy and responsibility.

The National News Council is an independent nonprofit organization, supported by contributions from a number of newspapers and other media, corporations, and foundations. The Council consists of 18 members representing varying occupations and shades of opinion.

The Council's finding against the Post was unanimous among those members present—Norman Isaacs, Council chairman, who is former president of the American Society of Newspaper Editors; William Brady, W.H. Brady Co., Milwaukee; William Scott, senior vice president, Radio State Group, Westinghouse Broadcasting Co.; Elie Abel, Stanford Univ. professor; Lucy Benson, former under secretary of state and former president of the League of Women Voters; William Hornby, editor and vice president of the *Denver Post;* Margo Huston, editorial writer, *Milwaukee Journal;* Michael Pulitzer, editor and publisher of the *Arizona Daily Star;* Ernest van den Haag, professor at New York Law School; and Franklin Williams, president, Phelps-Stokes Fund and former ambassador to Ghana.

TIM LEE CARTER NAMED NCAB CHAIRMAN, WHITE HOUSE LISTS OTHER APPOINTEES

Tim Lee Carter, one of the architects of the National Cancer Act of 1971, will be the new chairman of the National Cancer Advisory Board.

The White House announced this week that Carter and five others had been appointed to fill the six vacancies on the Board. The others are:

–Richard Bloch, of the H & R Block income tax service company. Bloch is a former cancer patient and founded the R.A. Bloch Cancer Management Center in Kansas City. He is 56.

–Angel Bradley, North Miami, Fla., homemaker and community activist. She is 61.

Bradley and Bloch will take over the two lay seats vacated by Frederick Seitz and the late Marie Lombardi.

–Victor Braren, associate professor of urology and assistant professor of pediatrics at Vanderbilt Univ. School of Medicine. He is 41.

–Ed Calhoun, general practitioner and general surgeon in Beaver, Okla. He is Oklahoma's delegate to the American Medical Assn. He is 59.

–Geza Jako, professor of otolaryngology at Boston Univ. He is a surgeon, and is president of the Institute of Applied Ear Research in Boston. He has been a member of the National Institute of General Medical Sciences Advisory Council, and is 51.

Carter replaces Henry Pitot as chairman of the NCAB. He is an M.D. in private practice in Tompinsville, Ky., after retiring two years ago from a long and distinguished career in Congress. Carter was the ranking Republican on the House Health Subcommittee when the National Cancer Act came before it in 1971. His work with Subcommittee Chairman Paul Rogers played a key role in securing passage of the Act, and he was supportive of the National Cancer Program in following years.

The scientific members retiring from the Board are in addition to Pitot, Bruce Ames, Harold Amos, and Philippe Shubik.

RFPs AVAILABLE

Requests for proposal described here pertain to contracts planned for award by the National Cancer Institute unless otherwise noted. Write to the Contracting Officer or Contract Specialist for copies of the RFP, citing the RFP number. NCI listings will show the phone number of the Contracting Officer or Contract Specialist who will respond to questions. Address requests for NCI RFPs to the individual named, the Blair Building room number shown, National Cancer Institute, 8300 Colesville Rd., Silver Spring, Md. 20910. RFP announcements from other agencies reported here will include the complete mailing address at the end of each.

RFP NCI-CB-25007-48

Title: *Support to the Diet, Nutrition and Cancer Program*

Deadline: *July 1*

The Div. of Resources, Centers & Community Activities, NCI, is seeking proposals for contractor support in three general areas: (1) assistance for statistical analysis, data processing, and data coordinating for the Diet, Nutrition & Cancer Program (DNCP); (2) technical assistance for the planning and formation of technical documents for the DNCP; and (3) workshop, conference and meeting support.

The successful contractor must be located within a 35-mile radius of the Blair Bldg., 8300 Colesville Rd., Silver Spring, Md.

This requirement is set aside 100 percent for small business with a size standard that annual receipts for the preceding three fiscal years do not exceed $4 million.

Contract Specialist: Thomkins Weaver
RCB, Blair Bldg., Rm. 105
301-427-8745

RFP NIH-ES-82-12

Title: *Refine and use of a short term in vivo rat liver tumor model in investigation of mechanisms of carcinogenesis*

Deadline: *Approximately Aug. 2*

The National Institute of Environmental Health Sciences is soliciting qualified sources having the capability to refine and use a short term in vivo rat liver model to investigate the mechanisms of hepatocarcinogenesis. Successful offerors will (a) refine a short term in vivo rat liver tumor model, such as that described by Pitot (Nature 1978:27, 456), (b) determine the utility of preneoplastic hepatocellular foci and other early endpoints as indicators of hepatocarcinogenicity, (c) investigate specific mechanisms of carcinogenesis using the model, and (d) over a three year period test 18 chemicals as complete carcinogens, initiators, and promotors in the refined model.

Only one award will be made under this solicitation.

National Institute of Environmental Health Sciences
Procurement Office, Attn: Glen Hentschel
PO Box 12874
Research Triangle Park, N.C. 27709

The Cancer Letter _Editor Jerry D. Boyd

Published forty-eight times a year by The Cancer Letter, Inc., P.O. Box 2370, Reston, Virginia 22090. Also publisher of The Clinical Cancer Letter.