LETTER

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## White House Plans To Name Broder NCI Director, Overruling Wyngaarden, Who Supported Rabson

Samuel Broder, who has been a clinical cancer investigator and scientist manager his entire career but who has gained international fame for finding the only drug so far proven

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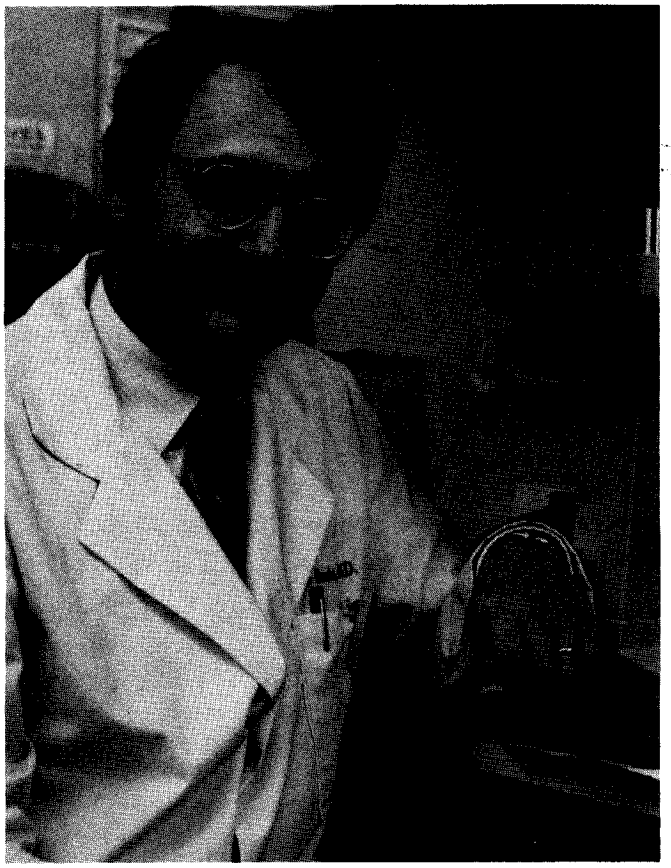
*In Brief*

## Vietti Heads Chairmen's Committee; Chabner Seeks Deputy Candidates; WHO Center At MSK

**TERESA VIETTI**, chairman of the Pediatric Oncology Group, was elected head of the Cooperative Group Chairmen's Committee at last week's meeting of the committee. She replaces Bernard Fisher, who completed a two year term. . . . **BRUCE CHABNER**, director of NCI's Div. of Cancer Treatment, is seeking candidates for the position of deputy director of the division. Former Deputy Gregory Curt left last summer for Roger Williams General Hospital in Rhode Island. Contact Chabner at NCI, Bldg 31 Rm 3A52, Bethesda, MD 20892, phone 301/496-4291. Chabner said his deputy "participates in everything I'm involved in," with additional duties handling DCT grants, small business grants and contracts, licensures, and opportunities for participation in intramural clinical protocols. . . . **CORRECTION:** The new institutional authority NIH has given grantees to extend grants without additional funds and carry over unobligated balances, among others (**The Cancer Letter**, Nov. 11), applies to all R series grants except R10, R18, R43 and R44 grants. . . . **THE WORLD** Health Organization Collaborating Center for the Prevention of Colorectal Cancer has been established at Memorial Sloan-Kettering Cancer Center. Its purpose is to advance understanding of various aspects of prevention of this cancer and to promote worldwide cooperation and collaboration to that goal. Sidney Winawer, chief of MSK's Gastroenterology Service, is head of the WHO center. The center is the result of a series of meetings beginning in 1979 of the International Working Group on Colorectal Cancer, cosponsored by the American Society for Preventive Oncology, American Society for Gastrointestinal Endoscopy, and American College of Gastroenterology. A Board of Scientific Advisors includes members of the MSK Gastroenterology Services, representatives of the departments of clinical chemistry, epidiology and biostatistics, rectal and colon service and solid tumor service, plus distinguished scientists from the U.S. and around the world.



**SAMUEL BRODER**
. . . "An outstanding choice"

## Broder Appointment Imminent; Fauci, Sullivan May Be NIH Director, ASH

(Continued from page 1)
effective against AIDS, is likely to be named director of NCI as early as next week, possibly even this week after **The Cancer Letter** has gone to press. The White House had not yet confirmed the appointment by press time.

Broder, director of the Div. of Cancer Treatment's Clinical Oncology Program and deputy clinical director of the Institute, has refused to talk with the media since his impending appointment was leaked by the White House last week.

One White House source told **The Cancer Letter** that the leak was a trial baloon, to find out the reaction of the scientific community. Another source said, however, that Broder had been given the appropriate forms to fill out, a background check was under way and an announcement of the appointment by President Reagan would be made as soon as that has been completed.

Members of the George Bush transition team have participated in the selection, assuring that the new President will retain Broder.

Broder and NCI Acting Director Alan Rabson had been interviewed at the White House the previous week. John Minna, chief of NCI's Navy Medical Oncology Branch, was the third person on the list sent to the White House by the search committee, but he was not called in for an interview.

If the leak was intended as a trial baloon, the scientific community's reaction would be positive, if former Director Vincent DeVita's comments could be considered representative, and they probably are.

"Sam is an outstanding choice," DeVita told **The Cancer Letter**. "I'm very proud of him. Whenever we've needed him, he's been there. He is enormously capable and talented. He will be a great director."

**The Cancer Letter** has learned that NIH Director James Wyngaarden, while not disagreeing with DeVita's assessment of Broder, nevertheless pressed for Rabson. Wyngaarden reportedly felt that Rabson would be easier to get along with than Broder or Minna, both strong defenders of NCI prerogatives conferred by the National Cancer Act and of NCI's Clinical Center activities.

The behind the scenes battle between Wyngaarden and DeVita over those issues flared into the open earlier this year (**The Cancer Letter**, March 18).

Rabson is a gentle speaking, low keyed person not known for combativeness. However, given the opportunity to speak for NCI and a reason to defend it, he might have given Wyngaarden a surprise or two.

Rabson has said all along that he had no burning ambition to be NCI director, and will return happily to the job he has held since 1975, running the Div. of Cancer Biology & Diagnosis.

In the discussions between the search committee, HHS officials and the White House, there was some concern expressed about Broder's youthfullness. There should not be; he will be 44 in three months; DeVita was 44 when he became acting director in 1980.

There are other parallels: Broder and DeVita both had worked at NCI their entire careers (other than, for DeVita a six month hitch in the Marines, and their residencies); both came up through the NCI intramural clinical research program; both achieved world wide acclaim for their creative clinical research at NIH.

Cancer program participants and advocates will be delighted with Broder as a spokesman for their cause. DeVita has been eloquent and

persuasive, with colleagues and congressional committees alike, but Broder could turn out to be his equal, if not in style, possibly in results.

**Wyngaarden may not have** to put up with Broder, or any other NCI director. He also serves at the pleasure of the President, and there are indications that President Elect Bush will want to name his own NIH director.

No. 1 on that list is Anthony Fauci, the highly regarded director of the National Institute of Allergy & Infectious Diseases and coordinator of NIH AIDS research activities. In one of the campaign debates, Bush mentioned Fauci as one of his "heroes."

Higher up in the Dept. of Health & Human Services, the name of Congressman Willis Gradison (R-OH) is the one most frequently mentioned. However, Surgeon General Everett Koop is a contender, along with Dorcas Hardy, commissioner of the Social Security Administration; Monroe Trout, president of American Health Care Systems; and Congresswoman Nancy Johnson (R-CN).

One person who probably won't be HHS secretary, contrary to rumors buzzing around NCI, is DeVita. The rumors have been fueled by the five month hiatus between DeVita's departure Sept. 1 and his starting date, at Memorial Hospital in New York, in February.

"I took the job at Memorial and I expect to go there," DeVita said this week. Beyond that, he offered no comment.

No one, in or out of government, could be a more effective manager of HHS, historically the most difficult of federal departments to manage with the possible exception of Defense. The HHS secretary is responsible for nearly all the federal government's health programs and could have a powerful impact on how they are run, including NIH. DeVita has had serious concerns about the future of NIH.

**The Assistant Secretary for Health** (ASH) is another position likely to change hands. Two being mentioned as possibilities to replace Robert Windom are Louis Sullivan, president of Morehouse School of Medicine and a member of the National Cancer Advisory Board; and William Roper, head of the Health Care Finance Administration.

So far, there has been little if any speculation about change in command at the Food & Drug Administration. But Frank Young has served as commissioner longer than anyone since the 1960s and may be ready to leave without a push from above.

## Review Of Cancer, AIDS Drug Approval To Start With Meeting Jan. 4 At NIH

The National Committee to Review Current Procedures for Approval of New Drugs for Cancer and AIDS will hold its first meeting Jan. 4 at NIH. It will be open.

The meeting will start at 9 a.m., in conference room 10 of Building 31.

This is the committee established by the President's Cancer Panel at the request of Vice President George Bush. Panel Chairman Armand Hammer will present the vice president's charge to the committee, followed by presentations by FDA, the National Institute of Allergy & Infectious Diseases and NCI.

Louis Lasagna, dean of the Sackler School of Graduate Biomedical Sciences at Tufts Univ., is chairman of the committee. Other members are:

Theodore Cooper, chairman and CEO of Upjohn Co., former director of the National Heart, Lung & Blood Institute and former assistant secretary for health; Gertrude Elion, scientist emeritus at Burroughs Wellcome, member of the National Cancer Advisory Board and recent winner of the Nobel Prize; Emil Frei, director and physician in chief of Dana Farber Cancer Institute and member of the Div. of Cancer Treatment Board of Scientific Counselors; Samuel Hellman, dean of Biological Sciences at Pritzker School of medicine, former president of the American Society of Clinical Oncology and former chairman of the DCT Board; Peter Hutt, attorney with Covington & Burling of Washington DC and former general counsel of FDA; Charles Leighton, senior vice president for medical and regulatory affairs worldwide of Merck Sharp & Dohme; Thomas Merigan, professor of medicine at Stanford Univ. Medical Center; and Henry Pitot, director of McArdle Laboratory for Cancer Research at the Univ. of Wisconsin and former chairman of the NCAB.

Other committee meetings, all of which will be open, are scheduled for Feb. 1, March 15 and May 2.

**Meanwhile**, a new organization called the FDA Council established to help strengthen the infrastructure of FDA, has held its first meetings.

The council is managed by Terry Lierman, president of Capitol Associates, a Washington firm which represents health related organizations. Members of the council include ALZA, American Federation for Clinical Research,

American Medical Assn., Cambridge BioScience, Cystic Fibrosis Foundation, Genentech, Joint Council of Allergy & Immunology, Merck and Co., National Multiple Sclerosis Society, National Organization for Rare Disorders, Pfizer, Sandoz, Squibb and Upjohn.

## Group Chairmen Accept Most Terms Changes, Except CTEP Adjustments

Cooperate group chairmen had their first crack at the proposed new terms of award drafted by the Div. of Cancer Treatment's Cancer Therapy Evaluation Program last week. Reluctant as always to endure significant changes in the rules under which they operate, they went along with most of the changes but drew the line at one proposal that would allow CTEP staff to adjust group funding in noncompeting years based on performance.

The proposals are a long way from their final form. CTEP Director Michael Friedman said that concerns of the chairmen would be considered in a new draft, and invited them to submit more detailed recommendations in writing. The new draft will be resubmitted to the chairmen, and also to the DCT Board of Scientific Counselors.

The proposal which drew the most fire was the final sentence of the last provision of the 11 page document. The provision starts:

"Each group will have a mechanism in place for assessing performance of its members, with particular attention to accrual of adequate numbers of eligible patients onto group trials. This mechanism will include a procedure for recommending an adjustment of funds to group members as appropriate for the level of participation in group activities, including (but not limited to) accrual. This procedure can be either prospective (i.e., reimbursement by the case) or retrospective (financial adjustment at the time a noncompeting continuation award is made).

**"NCI decisions on funding in noncompeting years will be based on documentation of satisfactory performance by the group, as manifested, in part, by adequate accrual rates to the clinical trials of the group."**

"Is that legal?" one of the chairmen asked.

"Absolutely," Friedman answered.

Those funding decisions would be based on annual reports to be submitted to NCI "in a format developed by CTEP staff and will include at a minimum summary data on protocol performance by each member and affiliate and other relevant data. Performance will be reviewed annually by CTEP staff," another new provision states.

"That's so we can identify those who need additional funding and those who are not performing and should be cut back," Friedman said.

Emil Frei, chairman of Cancer & Leukemia Group B, said "We've been doing that for the last four to five years. Accrual is important but not everything. There is a redistribution within the group. Those who are doing better and could use more money get it. We do it both ways."

"The money stays within the group," Chairman Charles Coltman of the Southwest Oncology Group said. "It would not come back to NCI's pool in the sky."

"This is something we have fought for," Bernard Fisher, chairman of the National Surgical Adjuvant Breast & Bowel Project said.

But Marvin Zelen, who heads the Eastern Cooperative Oncology Group statistical center, objected.

"It's one thing to say the cooperative groups have the authority to redistribute funds within their own groups, but it's another to say that NCI can direct that redistribution," Zelen said.

"That's germane to the whole issue," Friedman insisted. "If performance of individual members is not satisfactory, it's our responsibility to make adjustments," Friedman said.

"You're interfering with peer review," Zelen said. "People need long term commitments. At peer review, you can look at it and make plans. But if you can make adjustments every year, with NCI staff making the decisions, there's no stability."

Friedman made the point that that policy has been followed, and that writing it into the terms of award "codifies" the policy and makes its application uniform for all groups.

"You're introducing something new," Zelen insisted. "This will be NCI staff making the annual review and adjustments."

"That's not true, Marvin," Friedman said. "This is the way business has been carried out during the five years I've been at NCI."

Zelen also objected to the proposal for protocol closure. Friedman acknowledged that "there should be some discussion and controversy about this." The proposal states:

"CTEP staff will review mechanisms for interim monitoring of results and will take part in such monitoring. CTEP staff may request that a protocol study be closed for reasons including: (a) insufficient accrual rate

(e.g. <50% of the estimated accrual rate for any year after the first year); (b) accrual goal met; (c) poor performance (such as poor protocol compliance or high ineligibility rate); (d) patient safety; (e) results are already conclusive; and (f) emergence of new information which diminishes the importance of the study question.

"NCI will not provide investigational agents or permit expenditures of NCI funds for a study after requesting closure (except for patients already on study). For any study, whether involving an investigational drug or not, NCI will establish an arbitration process for investigators who wish to appeal protocol closure. This process will be identical to that described for protocol approval (see below).

"If a group wishes to close accrual to a study prior to meeting the initially established accrual goal, the interim data should be made available to NCI staff for review and concurrence prior to implementation of the decision by the group. It is recommended that statistical guidelines for early closure be presented as explicitly as possible in the protocol in order to facilitate these decisions. In all cases, the group will provide NCI with documentation of the reasons for the decision to close the study.

"Unresolved disagreements between NCI staff and group investigators regarding the appropriateness of early study closure will be submitted to artibration."

**"This presumes**, A, that you do not trust the groups to make these decisions, or B, that NCI has a mandate to do this," Zelen said. "If it is the latter, where is the mandate from?"

"It does not have to be either/or," Friedman said.

"These are joint responsibilities, to design studies to get reliable answers and to terminate them when it is obvious you are not going to get the answers," Richard Simon, chief of CTEP's Biometric Research Branch, said.

"The problem is not when an NCI staff member follows completely the development of a protocol," Zelen said. "Otherwise, it is not appropriate. If NCI can be involved with early closure, then you should have people involved in group discussions and decisions. If this is to satisfy some mandated responsibility, fine, but if NCI feels it can have more insight than group members without being involved in the process from the start, I disagree."

"There is a third option," Friedman said. "People working together, participating as colleagues and statisticians. In the node negative study (which was closed early), there was NCI participation."

"It seems as if NCI is getting involved more in the detail of group operations," Frei said. "It seems to me that you should get more involved in procedure and not in details."

"This is the way things are being done now," Friedman said. "We're just putting it on paper to get some consistency. It's not a matter of trust. Some of these are difficult decisions."

"The SWOG phase 3 trial data monitoring committee includes NCI staff at all its meetings," Coltman said. "The question is moot as far as we're concerned. NCI does participate in those decisions."

"If you are serious about NCI involvement in closure, then an NCI persons should be involved from the beginning," Zelen said. That appeared to be a point NCI would concede.

The protocol development proposals drew some fire, particularly the requirement for "concept review" of phase 3 protocols prior to submission:

"All phase 3 protocol submissions to NCI should be preceded by a concept review by CTEP staff. It is also highly recommended that submissions of studies utilizing IND agents be preceded by an approved letter of intent. These two mechanisms for preliminary review expedite protocol development and implementation."

Teresa Vietti, chairman of the Pediatric Oncology Group, said that statisticians frequently "won't help until we get everything in order." She made the point that information for a concept review would be incomplete without that provided by statisticians, to the extent that a concept proposal would not be acceptable. "It's a Catch 22 situation."

"Statisticians do want more definitive information before approving the concept," Simon agreed. "Somehow, we have to find a way."

Charles Moertel, chairman of the North Central Cancer Treatment Group, said "We've done this voluntarily. But we've been asked for details not appropriate at that stage, in effect a complete protocol. We need some ground rules on what is reasonable."

Zelen said the concept should be limited to one or two pages, covering "the main scientific idea. It's a burden on the statistical centers to keep grinding through figures that won't be appropriate in the protocol."

Friedman agreed the concepts should be "just general, with such things as accrual

expected, the scientific question, and not a lot more than that."

The protocol approval procedures drew some criticism. Cooperative group protocols are reviewed by CTEP staff, with external ad hoc reviewers when appropriate. Review and approval are required for all protocols utilizing IND drugs; all protocols that permit entry of 100 or more patients; and all phase 3 studies. Other protocols will be filed with CTEP for information purposes but will not require specific approval. The draft terms of award states:

"The major considerations relevant to protocol review include (a) the strength of the scientific rationale supporting the study; (b) the medical importance of the question being posed; (c) the absence of undesirable duplication with other ongoing work; (d) the adequacy of study design; (e) a satisfactory projected accrual rate (e.g., for common adult malignancies, no more than three years to complete the accrual for phase 3 and two years or less for phase 2 studies; (f) patient safety; (g) compliance with federal regulatory requirements; (h) adequacy of data management; (i) appropriateness of patient selection, workup and followup."

Zelen objected to specifying accrual periods, suggesting more general language such as a requirement for "satisfactory" accrual periods.

"The reason the numbers were put in is precisely to provide a more specific framework," Friedman said. He said that there have been too many incidences where studies "were initially planned to take a long time. There is no way to deal with that in protocol review."

Zelen insisted that use of specific numbers "is not defensible," but Friedman disagreed. "The numbers (in the terms of award proposal) may not be the correct ones, but we need a discussion on what they should be."

Moertel expressed the general opinion of the chairmen that CTEP is to blame for what they consider unreasonable delays in approval of protocols by NCI. Another Catch 22 situation: "We can't get (local IRB) approval until we have yours." But CTEP holds up approval because of various modifications it asks. The protocol goes back and forth, finally is approved by CTEP, and then the IRB process starts.

"If you would say, 'This will be approved if you do such and such,' we could go ahead (and get institutional approval)."

"I would like to see data on where the major delays are," Friedman said. "What I am hearing is that a tremendous amount of time is required to get them through locally." His statement that CTEP intended to complete its part of the approval process within 30 days was greeted with skepticism by the chairmen.

The suggestion was made that NCI should be required to document objections to a protocol. Friedman argued that many of the discussions relating to objections are done by phone. "We have hundreds of phone calls and discussions" on that subject, he said.

"I don't think we should change the scientific thrust of a group on the basis of a phone call," Coltman said. "It isn't necessary to document every random phone call. But on substantive matters, you should be able to ask for documentation."

"That's reasonabale," Friedmen said.

**Moertel called** attention to a provision making groups responsible for "assuring accurate and timely knowledge of the progress of each study through (a) tracking and reporting of patient accrual and adherence to defined accrual goals; (b) ongoing assessment of case eligibility and evaluability; (c) timely medical review and assessment of patient data; (d) rapid reporting of treatment related morbidity and measures to ensure communication of this information to all parties; (e) interim evaluation and consideration of measures of outcome, as consistent with patient safety and good clinical trials practice; and (f) an on site monitoring program which assures that a sampling of records at each member institution, CCOP, CGOP or other affiliate is audited at least once every three years. The on site audit will address issues of data verification and compliance with regulatory requirements for the protection of human subjects and investigational agent accountability. Any disagreements between CTEP and the group relating to quality control or study monitoring that cannot be resolved by discussion will be submitted to the arbitration process."

"I can't conceive of this being done without additional investigators, more computer time, and other things that are going to be costly," Moertel said. "How can you do that with a level budget?"

"I don't have the answer now," Friedman said. "There may be ways to do things more efficiently."

"I hate to speak up for the bureaucracy," Moertel said. "But we've found on site monitoring is not as bad as I had expected. It

has allowed us to maintain contact with members which we never had before. It is helpful to us and to members."

"I endorse that completely," Coltman said. "There is no doubt it is an excellent education program."

The protocol disapproval and arbitration process is spelled out in the terms of award proposals:

"If a proposed protocol is disapproved, the specific reasons for lack of approval will be communicated to the group chairperson as a consensus review within 30 days of protocol receipt by NCI. NCI will not provide investigational drugs or permit expenditure of NCI funds for a protocol that it has not approved. NCI staff reporting to the associate director, CTEP, will assist the group in developing a mutually acceptable protocol, compatible with the research interests, abilities and strategic plans of the group and of NCI.

"If requested by the awardee, NCI will establish an arbitration process for determining the suitability of a protocol which has been disapproved. An arbitration panel composed of one group nominee, one NCI nominee, and a third member with clinical trials expertise chosen by the other two will be formed to review the CTEP decision and recommend an appropriate course of action to the DCT director. The arbitration procedures in no way affect the awardee's right to appeal an adverse determination under the terms of (federal grants appeals regulations)."

**Friedman** discussed the plan for annual meetings of CTEP staff with group leaders, three months prior to noncompeting renewal and nine months before competing renewal. He suggested that budgets be developed using "modular scopes of work," ranked by priority to permit consideration of those projects likely to be funded and those of lesser priority which would be funded if the money becomes available.

"All of us are used to dealing with budget cuts," Moertel said. "I'm not sure your intervention will be helpful. That's adding another layer of bureaucracy to do something I would rather work out myself."

"Reviewers have to look at $14 million applications," Friedman responded. "For us to do our job, it would be helpful to look at your plans. We'll explain, and it will be a guess, how much money will be available, so you won't construct a budget that's a fantasy."

"Why don't you just tell us how much is available and stop at that?" Moertel asked.

"That's what we will do," Friedman said. "It would be helpful if we had some idea how you're going to spend it."

"Responsible groups shouldn't have to have us do this," Ungerleider said.

"A group that isn't responsible will be taken care of at peer review," Frei said.

## "Tough Year" Seen For Groups; High Priority Trials Payment Questioned

"This is going to be a very tough year," Cancer Therapy Evaluation Program Director Michael Friedman said following a presentation by Div. of Cancer Treatment Director Bruce Chabner on the 1989 fiscal year budget for the cooperative groups.

Chabner told group chairmen that the flat budget for NCI means a flat budget for the groups. "By reprogramming, NCI has identified $10 million for reserves and allocation to other programs," he said. "That is incredible, that we could squeeze only $10 million out of a budget of $1.5 billion."

Clinical trials will get $3 million out of the reprogrammed $10 million, Chabner said. DCT had requested an extra $6 million for the high priority patient accrual effort alone. Instead, that effort will get $1.4 million, with another $700,000 going to the Community Clinical Oncology Program and $900,000 for biological agent clinical trials.

If the entire $6 million had become available, DCT planned to support two more CCOPs (in addition to the 52 now funded), and four more cooperative groups, Chabner said.

Richard Ungerleider, chief of the Clinical Investigations Branch, presented the funding plan for cooperative group awards in FY '89. Noncompeting groups take up $36.7 million of the $56.8 million available, leaving only $20 million for the competing groups. Those competing groups, however, are requesting $45 million.

To help cover the shortfall, noncompeting groups will receive the same amounts they did in 1988, which Ungerleider said is 96 percent of the 1989 commitment. The competing groups, asking for major increases, will instead receive the same amounts they did in 1988. That still leaves a projected deficit of $877,000. CTEP generally recoups about $1 million at the end of each fiscal year, from various unexpended funds.

Six groups plus the EORTC Data Center in Brussels are being recompeted this year. The

groups are Eastern Cooperative Oncology Group, North Central Cancer Treatment Group, Childrens Cancer Study Group, Brain Tumor Study Group, Gynecologic Oncology Group and the Radiation Therapy Oncology Group. There will be miscellaneous supplemental requests, and probably one or more applications from new groups.

"Groups will have to prioritize their research agendas," Ungerleider said. "Concentrate on the finest scientific activities, reduce costs, increase efficiency, consider additional financial sources such as charities and drug companies, and develop realistic budgets."

In turn, Ungerleider said, CTEP will emphasize fiscal austerity, make every effort to recoup unexpended funds, adjust funds up or down based on accomplishments or lack of accomplishments, and will fight for more money for the program.

George Lewis, chairman of the Gynecologic Oncology Group, pointed out that some groups are receiving per case reimbursement and asked if downward adjustments would be made for them as well as for the institutional awards.

Charles Moertel, NCCTG chairman, said "CTEP staff has created a bit of a problem for us. You have strongly motivated us to increase accrual. These are largely surgical adjuvant trials, requiring long term investment. If we have successfully done this, and with a level budget, you are penalizing those who are most successful."

Friedman said that the high priority trials are not the problem. "We've been able to eke out a little for those. My concern is not about those but for the larger number of trials. Your point is well taken there. Continued increase in accrual demands an increased budget. Why do it, then? The strongest possible argument for more money is to show you are increasing accrual, and doing better science."

"But there is a disproportionate burden on those most successful," Moertel insisted.

"Dr. Chabner felt the additional $1.4 million should go to high priority trials," Ungerleider said. "You could argue that the base program should get the $1.4 million, but Dr. Chabner disagrees."

Marvin Zelen, ECOG statistical chief, said that the institutions recruited to participate in the high priority trials are getting paid while some long term members are not [the point Lewis was making]. "You should broaden the policy and pay everyone on a per capita basis," Zelen said.

"If we do, there would be no money to encourage high priority accrual," Ungerleider said, adding that institutions receiving regular funding should be contributing patients without the extra incentive.

"You don't know how many the outside institutions will contribute, and you don't know about the quality of data, or other problems they may have," Zelen argued.

Charles Coltman, chairman of the Southwest Oncology Group, sided with Ungerleider. "Institutions that accept funding for participation in the NCI clinical trials program are obligated to contribute." He suggested that to pay them additional money for case accrual "is paying double."

"It's not paying double to give them additional funds for additional accrual," Zelen said.

"Auditors would look at that as double dipping," Coltman insisted.

"The problem is that we need to get more money in the system," Emil Frei, chairman of Cancer & Leukemia Group B, said. He suggested that groups could compete for program project (PO1) grants.

Moertel said that NCCTG has received a PO1 grant for cancer control studies.

Ungerleider said grants management staff has advised that groups could apply for PO1s "but they have to have very good priority scores. Our experience is that they are difficult [for cooperative groups] to get."

Frei observed that groups are doing some "tremendous science" which should be acknowledged by NCI and taken into account by reviewers.

Moertel had the last word on the issue. "The high priority program is is being funded at only a small percentage of the projection and in a piecemeal way. It can be destructive to groups. Surgeons in our group now get $700 a case. They could move over into the high priority trials and get $1,000 for the same case. If we can't do this well, we shouldn't do it at all. Right now, we're not doing it well."

**The Cancer Letter** _Editor Jerry D. Boyd Associate Editor Patricia Williams

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