

THE

CANCER LETTER

P.O. BOX 15189 WASHINGTON, D.C. 20003 TELEPHONE 202-543-7665

Vol. 21 No. 2
Jan. 13, 1995

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\$250 Per Year Elsewhere

'Rush To Downsize' Is A Danger To NCI, Broder Warns In A Farewell Address

NCI could be substantially weakened through cuts in its highly skilled work force as a result of the "bipartisan rush to downsize government," Samuel Broder, the Institute director, said a final address to an advisory group *this week*.

Broder, who recently announced he will leave NCI in April, likened the Institute to a giant redwood. The redwood is a "delicate ecological" (Continued to page 2)

In Brief

NBCC Wins Grants To Train Breast Cancer Activists In Language, Concepts Of Science

NATIONAL BREAST Cancer Coalition has launched a project to teach breast cancer advocates the language and concepts of science. Funded with grants from the Nathan Cummings Foundation and Wellcome Oncology, Project LEAD (Leadership, Education and Advocacy Development) is expected to provide breast cancer activists scientific and medical expertise in order to influence breast cancer research. "We need to bring the perspective of the patient, the breast cancer activist, to the table where breast cancer research decisions are being made," said Fran Visco, president of the NBCC. . . . **NCI STAFF CHANGES: Judith Karp** has been appointed assistant director for applied science. She will be responsible for identifying basic and preclinical discoveries that can be translated into clinical applications. Karp, a leukemia specialist, has been a special assistant to NCI Director Samuel Broder since 1990, and editor-in-chief of the NCI Bypass Budget. **Edward Sausville** was appointed director of the Developmental Therapeutics Program, succeeding Michael Grever, who left last year. **Saul Schepartz** retired as deputy associate director of the DTP. In the Div. of Cancer Prevention & Control, **Thomas Marciniak** resigned as chief, Computer Systems Branch. **Nicholas Olimpio**, divisional administrative officer, retired. **Jacquelyn Havens** was appointed acting administrative officer. In the Div. of Cancer Etiology, **William Blattner**, chief, Viral Epidemiology Branch, announced his retirement. In the Div. of Cancer Biology, Diagnosis & Centers, **Kenneth Brow** retired as chief, Research Facilities Branch. . . . **CORRECTION:** In the Jan. 6 issue of **The Cancer Letter**, an article misstates when NIH officials learned about the study performed by Gerald Myers comparing the AIDS virus discovered by French scientists to the AIDS virus developed by NCI's Robert Gallo. The Myers data was sent to NIH in 1987, not in 1984 as implied in the article.

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Broder: NCI Is 'A Delicate System' That Requires Balance

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system" that appears strong, but whose roots are easily trampled by curious tourists, he said in an address to the National Cancer Advisory Board this week.

Part of that delicate balance depends upon the public's support, Broder said. The NIH concept of research centered around specific diseases with which people can identify is "brilliant," he said.

"People suffering from cancer throughout the nation look to the National Cancer Institute," Broder said. "To them, the value of research is immediately understood and intuitively obvious. This has been an important principle and one that should not be tampered with."

NCI's research programs should remain balanced between the "three foundation stones" of basic research, clinical trials in prevention and treatment, and the cancer centers, Broder said in his final address to the NCAB as NCI director.

"I do not believe that we are totally in balance, but we have achieved a substantial degree of balance between the needs of basic researchers and clinical researchers," Broder said. "I think this will bode well for my successor."

Broder said that later this spring NCI will have to defend its programs at Congressional appropriations hearings.

"We at NCI will need to carefully articulate that cancer research is essential to the agendas of both political parties," Broder said. "And we will have to forcefully resist the chronic tendency—now much more acute—to use the NCI resources as an administrative reserve to meet shortfall in other areas."

Decline In Breast Cancer Deaths

Broder noted that latest statistics on cancer deaths from 1989 to 1992 shows a decline in deaths due to breast cancer in American women.

The overall death rate from breast cancer for white women has declined a total of six percent, the longest short-term decline in the breast cancer death rate since 1950, he said. There has not been a similar decline in African-American women.

The largest decreases in death rates are in the younger age groups. For ages 30-39, there is an 8.7 percent decline. For ages 40-49, there is an 8.1 percent decline, and for ages 50-59, there is a 9.3 percent decline. In women aged 60-69, the death rate declined 4.8 percent, while in women aged 70-79, there is a 3.4 percent decline.

Research is needed to understand the reasons for the decline in white women, Broder said. However, he said several factors, including adjuvant therapy, breast cancer awareness and screening, and changes in risk factors, are most likely involved.

Broder said it might be instructive to review the history of adjuvant therapy, from the first clinical studies published more than 20 years ago, through former NCI director Vincent DeVita's "much-debated" clinical alert in 1988, to the recent consensus conference.

"We can see how truly determined we must be to make a difference in breast cancer death rates," Broder said. "It is clear to me, at least, that Vince DeVita was right to persevere against his critics in the issuance of an appropriately-timed clinical alert."

Broder is taking a top research and development job at IVAX Corp. of Miami.

The excerpted text of Broder's address follows:

It is important that we all remember that progress is made in cancer research only when we have a balance in our research programs. We need the three foundation stones of basic cancer research, clinical trials (in prevention and treatment) and our cancer centers. There is a vital need for each part of the program and for a certain symmetry. Inevitably in the normal course of events, the focus changes as achievements are announced or problems occur. It is to be expected that the spotlight swings from one part of the stage to another. There is a constant, active, living process of stress and adjustment, of quiet work and of heightened scrutiny.

As director, I find it useful in speaking to basic researchers to stress the importance of clinical

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research. When I talk to clinical researchers, I stress the importance of basic research. Strength in both of these areas and a proper sense of balance is the only route to reductions in the suffering and death from cancer.

Whether you come from within NIH or from the outside, one's perspective changes when one assumes the duties of the director of the NCI. I think it is very hard before assuming the post to see exactly how large and strong and yet, paradoxically how fragile this Institute is. The metaphor of the giant redwood comes to mind. Giant redwoods are impressive, but their roots are surpassingly delicate. Roots can be injured or trampled with very little effort, even by an innocent tourist trying to get close to the trunk, and then even the largest and strongest tree can be harmed.

Part of the delicate ecological system for NCI is the American public. I am struck that Mary Lasker's brilliant concept of a governmental research response to human suffering and the expanded concept of a one-to-one linkage of research to a specific disease via the categorical institutes were truly inspired. Everyday people suffering from cancer throughout the nation look to the National Cancer Institute. To them, the value of research is immediately understood and intuitively obvious. This has been an important principle and one that should not be tampered with.

The strength of the NIH is that it supports and shelters the categorical institutes. I would assert that what is good for NCI is good for NIH and what is good for the NIH is good for NCI. We are part of the same research body, the same research body politic, if you will. But the inherent genius behind the establishment of the categorical institutes—of which NCI, founded in 1937, is the prototype—is clear and should be held in the highest regard.

Government Downsizing

I also want to comment on the bipartisan rush to downsize government and the almost compulsive drive to blame government workers for doing the jobs they were recruited to do in the first place. We should be careful that we do not eliminate the things that can be done only as core governmental functions. It is easier to weaken or destroy an NCI or an NIH than to create a new one. The surgeons among us would be the first to remind us that if you do not look carefully where you cut, you can harm the patient, sometimes irreparably. And it doesn't matter if the surgeon is a friend or a stranger.

NCI needs a skilled and highly trained work force.

Everything we do here is done because somewhere along the line intelligent peer groups or astute members of the public have asked us to do it. Everyone here must be above the ordinary—the correct word is extraordinary—in their abilities. The NCI mission demands it.

While I would really like—what we all really would like—is for my successor to be the last Director of the NCI, last because the research mission will have been achieved—because we will have learned to cure and prevent cancer and so we can proudly announce to the nation that our mission has been accomplished. During my tenure, I believe we have come closer to that goal, but alas, I will not be the director who will preside over this moment.

As we discuss these transitional processes, perhaps we can look to the concepts of the contemporary social philosopher, Judith Viorst, as expressed in her book, "Necessary Losses":

"When we think of loss we think of the loss, through death, of people we love. But loss is a far more encompassing theme in our life. For we lose not only through death, but also by leaving and being left, by changing and letting go and moving on. And our losses include not only our separations and departures from those we love, but our conscious and unconscious losses of romantic dreams, impossible expectations, illusions of freedom and power, illusions of safety...."

Her book continues to expand upon the idea that such losses are necessary for change, for personal growth and true maturity. This is true for individuals, and it is equally true for organizations: we gain by letting go, in a process that has its own internal dynamic. I do not believe that any one person is necessary to an organization, but I do believe people collectively are irreplaceable. Each of us makes a unique contribution, but the uniqueness and durability is paradoxically possible only when there is change and renewal—a welcoming of new spirits.

Every successful research enterprise must have a process of renewal, with leaders who will not let go at the wrong time, but who will decisively let go at the right time.

Gratitude to NCI Employees And Advisors

I am the 10th director of the NCI and have served under three Presidents. I have had the privilege of working with exceptional employees and advisors during my tenure as director of the NCI. I want to thank all of you sincerely for all that you have given

individually and collectively to the Institute during my time as director. I doubt there is a better staff anywhere, in any public or private institution. And I doubt if any public or private agency has better men and women who give so much, and receive so little in return, as the men and women around this table.

NCI has an extraordinary group of grantees, far more committed to this Institute than most other grantees are to the health of their granting organization. We have strong private organizations and articulate patient consumer advocates behind us. I want to especially thank all of them and all of you who serve and have served on the National Cancer Advisory Board. Your work is of vital importance to the country and the world....

I want to thank and express my respect and admiration for the members of the President's Cancer Panel: Ms. [Fran] Visco, Dr. [Henry] Pitot and especially, Dr. [Harold] Freeman, the chairman.... He taught me, and I hope he taught you, that poverty is a carcinogen, and I fear that it will be no easy task to eliminate this carcinogen from our society.

A "January Moment"

It takes all of us meeting in mutual regard to assure the health of this Institute. There are tensions, and there should be tensions. In the body, healthy tension strengthens muscles. In the muscles of an institution emitted heat forges truth and allows for change. Dynamic tension, challenges, and the scientific process are essential to our efforts.

This is definitely a perfect January moment—a time of looking back and at the same time, looking forward.

Early in my speech I named some people who have left or who are leaving.

Perhaps in speaking for myself, I can speak for the others who are leaving: we are devoted to the NCI and the level of devotion is immutable. I know that for me it is a life-long affliction. By and large, NCI employees believe it is an extreme honor to work here. We feel that this is no ordinary place and no ordinary work.

We love the larger universe of the National Institutes of Health—but we also especially revere what is rare or unique at the NCI. We know that at NCI we are working to prevent and cure cancer and other terrible diseases and this brings a sense of purpose unlike any other.

Thank you for giving me the privilege of working with you these past six years.

Proposed Deal Could Resolve Key Disputes At NSABP, Pitt

Officials at the Univ. of Pittsburgh and the Allegheny Health, Education and Research Foundation said they are close to finalizing an agreement that is likely to resolve the most significant disputes over who will run the National Surgical Adjuvant Breast & Bowel Project.

The agreement does not refer to the suit brought against Pitt by former NSABP chairman and principal investigator Bernard Fisher and the NSABP Executive Committee.

However, it was expected that once the agreement is executed, the Executive Committee would drop out of the suit. The impact of the proposed agreement on Fisher's claims remained unclear.

The agreement, a copy of which was obtained by **The Cancer Letter**, in effect splits the power at the group, giving tangible responsibilities to Allegheny surgeon Norman Wolmark, who is also the NSABP chairman.

Under the proposed deal:

—Wolmark would become the Principal Investigator-Operations of NSABP. The operations office would remain at Pitt, and Wolmark would be paid by the university .

—The office of the chairman of the cooperative group, also headed by Wolmark, would be moved to Allegheny under a subcontract from Pitt, the document says.

—Ronald Herberman, director of Pittsburgh Cancer Institute, would serve as Principal Investigator-Biostatistics at Pitt, the document said. The university is conducting a search for a prominent biostatistician to head that office.

Until the deal is finalized, Herberman will serve as the PI of both the operations office and the biostatistical center.

NCI has given the two institutions the deadline of Feb. 1 to reach an agreement.

In separate interviews, Herberman and Wolmark confirmed that their institutions are close to an agreement, and vowed to cooperate.

"I am pleased that we are about to finalize this agreement, and I look forward to cooperating closely with Dr. Wolmark to make the clinical trials efforts of NSABP as successful and productive as possible," Herberman said to **The Cancer Letter**.

"I am delighted that at long last we can move

forward with the mission of the NCI and of the NSABP in restoring the clinical trials efforts in breast and bowel cancer," Wolmark said.

The issues that remain to be worked out include determining the budget of the chairman's office, which would be financed through a transfer of funds from Pitt to its cross-town rival Allegheny.

The NCI grants supporting NSABP are scheduled for recompetition next August.

Pitt and Allegheny are expected to compete against each other for the NSABP operations center. Allegheny has no plans to compete for the biostatistical center, Wolmark said.

Wolmark said the proposed arrangement is likely to include a role for Fisher.

"Within the context defined by NCI, we will welcome Dr. Fisher with great enthusiasm," Wolmark said. "He will be welcome in whatever capacity he chooses to participate."

The suit by Fisher and the NSABP Executive Committee has been a major stumbling block for Wolmark.

Soon after Wolmark was elected chairman, NCI declined to approve his candidacy, citing a demand in the suit which called for Fisher's reinstatement as chairman.

In December, the NSABP Executive Committee amended the complaint, removing its demand for Fisher's reinstatement.

However, sources said that since that motion was filed, the Executive Committee voted to pull out of the suit altogether, provided that Wolmark would be named PI of the operations office.

According to the draft agreement, as PI for operations, Wolmark would have the following responsibilities:

"1. Provide scientific direction for the Operations Component and establish research and scientific priorities;

"2. Manage and direct the Scope of Work... [including, protocol development, protocol implementation, logistical support and operations of various committees];

"3. Have signature authority over all expenditures of the Operations Component;

"4. Develop budget(s) for the Operations Component, including requests to carry funds over, and to review and approve or deny any non-budgeted expenditure;

"5. Conduct performance reviews of personnel providing services to carry out the functions of the

Operations Component."

According to the document, the duties of the chairman would include:

"1. Scientific direction of the cooperative group;

"2. Setting research and scientific priorities;

"3. Appointment and supervision of Executive Medical Officer; and

"4. Appointment of NSABP Executive Committee in accordance with the NSABP Constitution and Bylaws."

NIH Reconsiders Holding A Closed Meeting Of Advisors

NIH has reversed its decision to conduct a closed meeting of an advisory committee to the deputy director for intramural research.

The meeting of the Chairmen of the Boards of Scientific Counselors, scheduled for Jan. 23, will be open to the public, Anne Thomas, NIH associate director for communications, said to **The Cancer Letter** earlier this week.

Thomas declined to discuss the reasons for this about-face by NIH.

"It was just a determination by a group of us that we would do that," she said. "I just wanted to notify you." Thomas said a formal response to a protest by **The Cancer Letter** was being prepared.

The Cancer Letter had protested an earlier meeting of the group, as well as a similarly closed meeting of the National Cancer Advisory Board's Ad Hoc Working Group on NCI Intramural Programs.

"We welcome the decision by NIH to obey the law governing federal advisory committees," the editors of **The Cancer Letter** said in a statement.

"However, we are puzzled to see that the decision to obey the law, like the earlier decision to disobey it, was made without an adequate explanation and in an arbitrary and capricious manner.

"More importantly, NIH is now in an inconsistent position of declaring that the meeting of the Chairmen of the Boards of Scientific Counselors is open while the NCAB Ad Hoc Working Group on NCI Intramural Programs remains, to our knowledge, closed.

"We see no legal distinction between these two advisory groups, and we are prepared to take our case to court," the statement said.

The closed meeting of the Chairmen of the BSCs was held last Aug. 1, called by Michael Gottesman, NIH deputy director for intramural research. The group consists of the chairmen, or their designates,

of the 23 BSCs that advise the scientific directors of the institutes.

NIH officials had maintained that the committee was not subject to the Federal Advisory Committee Act because the purpose of the meeting was to obtain the individual advice of members, not a consensus.

After reporters from **The Cancer Letter** challenged the rationale for closing the meeting, NIH officials opened the meeting for the first hour and a half. Then, saying that personnel issues would be discussed, Gottesman asked the reporters to leave. (**The Cancer Letter**, Aug. 5, 1994).

Subsequent interviews with participants revealed that no confidential personnel matters were discussed. Participants said discussion centered on NIH policy regarding changes in the intramural research program.

In a letter to HHS Secretary Donna Shalala, **The Cancer Letter** protested the closing of the meeting (**The Cancer Letter**, Aug. 12, 1994).

In a Sept. 12 response, Thomas reiterated that the meeting did not fall under FACA because the agency sought individual advice from the participants, not a consensus (**The Cancer Letter**, Sept. 23, 1994).

In a Nov. 29 letter to Thomas, **The Cancer Letter** said this was "a misreading of FACA, and one that we will challenge if applied to any subsequent gathering of the Boards.... The distinction suggested by the agency's position is at best metaphysical, practically unworkable, and entirely inconsistent with the letter, spirit and case law interpreting FACA."

NCAB Working Group's Closed Meetings

The Cancer Letter is also protesting the decision of NIH and NCI officials to close to the public the NCAB working group's meetings (**The Cancer Letter**, Dec. 9 and 16, 1994).

In a letter to Marvin Kalt, director of the NCI Div. of Extramural Activities, who serves as executive secretary of the working group, **The Cancer Letter** said the Dec. 7 meeting of the working group violated the Federal Advisory Committee Act.

"The assertion that FACA's requirements are inapplicable simply because a body is termed a 'working group' is the sort of cynical manipulation of legal text that should be beneath a venerable public institution like the NCI," the letter, dated Dec. 27, said.

"Similarly, the claim that the meetings had to be closed because of uncertainty as to when issues exempted from public airing under [the federal law] might arise is just as unpersuasive," the letter

continued. "The exemption is a narrow one, and issues that fall within it can be readily identified, separated out, and dealt with in separately scheduled meetings."

The Cancer Letter urged NCI to reconsider the decision to close the Jan. 24 meeting of the working group.

The letter concluded: "It would indeed be a *pity* if the limited taxpayer resources available to the NCI are diverted to litigation because the NCI seeks to prevent the public, in direct violation of federal statute, from learning of advice or opinions being furnished the NCI by private individuals."

Bishop: Ground Rules Set By NIH, NCI

Meetings of the NCAB working group should remain closed because the group is examining confidential information, Michael Bishop, the group's co-chairman, said in an interview.

The working group is looking at specific cases of peer review of NCI intramural researchers, Bishop said.

"The underpinning of everything we are doing is quality review," Bishop said.

"We are looking at investigators, their leadership and performance," Bishop said. "We get into individual review and information that would not have been brought to us in open session.... We are looking at peer review as it was performed in the labs and the divisions."

The working group, co-chaired by Bishop, of the Univ. of California, San Francisco, and Paul Calabresi, of Rhode Island Hospital, was established last fall.

The group was established on the initiative of NIH Director Harold Varmus.

The group, which has held two meetings so far, is expected to present a report to the NCAB in May.

"The rules of play for the working group were set by NIH or NCI," Bishop said. "I am grateful for those rules of play."

Describing the panel's meeting Dec. 7, Bishop said, "We heard personal judgments that we would not have heard in public."

Bishop said it would be difficult to separate the working group's meetings into open public sessions and closed sessions. Having entirely closed meetings "is an efficient and cost-effective process of determining how well the science is being done," he said.

Bishop said the working group will communicate

with the NCAB regularly. "I will be as substantive and candid in public as possible, and I am available to chat with anyone to discuss the progress of the committee," he said.

Bishop and Calabresi were scheduled to discuss the working group's activities at the NCAB meeting later this week.

RFP Available

RFP NIH-AG-95-04

Title: **Dynamics Of Health, Aging & Body Composition-Field Center**

Deadline: Approximately Feb. 28

The National Institute on Aging will support an epidemiologic study, Dynamics of Health, Aging and Body Composition. Objective is to examine incidence of *physical disability in relation to body composition and weight-related health conditions in healthier older persons*. HEALTH ABC will include 3,000 noninstitutionalized white and African-American men and women ages 70-79. Incident change in physical function and related disability are major outcomes. Serial measurement of body composition using dual energy x-ray absorptiometry will be accompanied by measures of anthropometry, strength, fitness, and physical function. Key component is assessment by objective measures of weight-related health conditions including osteoarthritis, cardiovascular disease, osteoporosis, pulmonary disease, diabetes, selected cancers, and depression. An 8-year cost-reimbursement contract is anticipated. Two awards.

Inquiries: Donna Winters, Div. of Contracts and Grants, NIH, 6100 Executive Blvd, Rm 6E01 (MSC 7540), Bethesda, MD 20892-7540, Tel: 301/496-4487.

NIH Extramural Office Lists Reinvention Initiatives

The NIH Office of Extramural Research recently outlined the ways in which it is responding to the White House directive to "reinvent" the Federal government and reduce the size of the Federal workforce:

Peer Review and Processing of Applications:

Triage--Beginning with the February 1995 round of review (review of applications submitted Oct./Nov. 1994), all DRG study sections will employ the triage process routinely, and Initial Review Groups within Institutes and Centers (ICs) may use it at their option.

In triage, peer reviewers are asked to identify the pending applications (about half) that are "unrealistic candidates for funding in the present budgetary environment" (not to be equated with "disapproval" or "not recommended for further consideration"). Those applications are not discussed, and are not given priority scores. If one member of the study section believes that the application has some chance of being funded, the

application is discussed and scored.

Modified Summary Statement--The modified summary statement format will be used for all applications reviewed by DRG study sections beginning with the February 1995 round.

Applicants whose projects are unscored will receive a critique that is essentially unabridged comments from the reviewers. This is expected to allow for a quicker return of the critiques and provide the applicant more time to amend and resubmit the application, if desired.

Expedited Release of Summary Statements to Applicants--(concept under discussion). Currently, summary statements prepared by Scientific Review Administrators are routed to program staff at the ICs, who review and then release them to the applicants. This introduces a time lag.

Now that full implementation of triage and the use of modified summary statements are in place, it has been suggested that summary statements for unscored applications, which consist of the unedited reviewers' comments, might be released directly from DRG.

Retrospective versus Prospective Review--(concept under discussion). The usual NIH peer review process is primarily prospective in that it focuses on a detailed proposal of the specific research studies for which the applicant is seeking support.

However, some contend that a retrospective review, focussing primarily on the investigator's recent accomplishments, would be advantageous. Researchers would be relieved of the burden of writing detailed plans that are likely to change in the course of conducting their investigations; evaluation of past scientific record could afford the precision of hindsight and is believed by some to be the best predictor of creativity and accomplishment; and success could be less dependent on grantsmanship skills.

On the other hand, there are concerns that investigators just beginning their careers or at career turning-points may not be well served by retrospective review.

Restructuring DRG Review Groups--(concept under discussion). Ideas are being considered about how the new Initial Review Group-based organization of DRG can be exploited to broaden the range of expertise represented on individual study sections without sacrificing focus. Also, periodic review of the IRGs and their study sections is being considered to ensure that they evolve in pace with scientific advances.

"Just in Time"--(pilot experiments currently under way). "Just-in-Time" postpones the collection of a substantial amount of information that must be provided for all competitive applications. Data on other support and complete budget detail would not be requested at the time of application, and the biographical sketch would instruct applicants to provide only information related to research background and experience, including, at the

option of the applicant, the sponsored support relevant to the proposed research. Detailed information relevant to the award of the project would be exchanged "just in time" prior to award.

Identification of High Risk/High Impact Research Applications--Since June/July, 1994, reviewers serving on DRG study sections have been asked to identify those applications that both involve high risk research and have the potential for high scientific impact. This identification occurs after the merit review and assignment of priority scores, and will require agreement of at least two members of the IRG. The goal is to determine whether IRGs can better identify HR/HI applications when specifically asked to, and if the information they provide will aid program staff and the National Advisory Councils to better identify special research opportunities for consideration.

Amended Applications--(concept under discussion). Currently, there is no limit to the number of times an unsuccessful application can be resubmitted in an amended version. This impacts on review burden. Applicants with intrinsically weak proposals have been known to incorporate reviewers' suggestions into amended versions, cycle after cycle. Applications that are very strong overall, but for which reviewers have raised a few relatively minor questions or criticisms, are frequently voted scores that put them beyond the nominal payline for funding. Those applicants must then resubmit an amended version and go through review again.

A proposal to limit the number of amended versions to two (no more than three submissions of the same project) is under discussion. Other ways to avoid resubmission of promising applications also are being considered, including the increased use of deferral and request for additional information by study sections and/or by Program staff.

Cost Management--Budgeting for total costs rather than direct costs (concept under discussion). The current practice is for applicants to request, and for reviewers and program staff to recommend, grant budgets in terms of direct costs. Indirect costs usually increase total costs by approximately 30 percent. However, indirect cost amounts may vary unpredictably over the duration of a multi-year grant, as institutional indirect cost rates change. Thus, it is difficult to estimate true out-year funding commitments. An approach which is standard practice in several other Federal agencies is to consider the requested and recommended budgets at all stages of the process in terms of total costs.

Modular Grants--(pilot experiments under way). Applications would be submitted and/or awards would be made with direct (or possibly total) costs in modules of a given amount, e.g., \$50,000, with work proposed within these incremental categories. Or, a series of capped award levels (\$100,000, \$200,000) might be used.

A feasibility test is being undertaken by the National Heart, Blood, and Lung Institute through an RFA for R01

applications. A second pilot is planned, also at NHLBI, in conjunction with an RFA for multi-project applications.

Post-Council Notification--(limited implementation in place). Several Institutes have eliminated routine use of post-council letters. Instead, applicants are informed of the status of their applications in letters that accompany the summary statements. The use of post-council letters is reserved for only the small group of applicants for whom the National Advisory Council takes a separate action. Full implementation would eliminate the mailing more than 25,000 letters from NIH each year.

Electronic Research Administration--(some pilot experiments under way). Electronic files would be created to serve as the repository for all information generated during the life cycle of each grant. This data base would be accessible to authorized institutional and NIH staff. This should streamline grants administration.

An experiment in which R01 applications were submitted electronically in their entirety, using software provided by NIH, was carried out for five review cycles (February 1993 through July 1994) in cooperation with seven major grantee institutions. Analysis of the results is not completed. However, the experiment was limited by the fact that internal NIH procedures for the handling of applications are not yet electronic. These trials illuminated the diversity in the way applicant organizations use automation to create applications and to capture relevant data for use within their inhouse systems.

NIH has adjusted its plan to emphasize the publication of transmission stream specifications. This will open opportunities for independent software vendors to develop grant application creation software.

Post-Award Management of Grants:

Notice of Grant Awards--Institutes and Centers have implemented a new procedure whereby only a single copy of the NGA is mailed to the grantee institution's administrative official, with the instruction that the institution distribute copies to the Principal Investigator and other interested parties. This eliminates the mailing of copies from NIH.

Streamlining the Non-Competing Award Process--(implementation begun October 1994). Since last October, financial reporting for Type 5 applications has been streamlined. All out-year budgets are provided to NIH program staff at the time of initial award. Instead of submitting four different financial documents each year, only the Financial Status Report and the Federal Cash Transaction Reports are required. Annual reports are still required, but these should focus on scientific progress, changes in scientific direction, changes in other support, and other matters relevant to the programmatic management of the grant. Further streamlining is under consideration, notably the possibility of eliminating the annual Financial Status Report.