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NCI To Boost Investigator-Initiated Grants Using 5.7% Increase, Cuts In Contracts

NCI is in the process of dramatically increasing funding for investigator-initiated research grants, Institute Director Richard Klausner said in an interview last week.

Though Klausner did not have the final budget figures for fiscal 1996, he said the increase in R01 and P01 grant funding would come from a \$30 million cut in contracts as well as the 5.7 percent budget increase the Institute received this year.

The proposed increase to research project grants would provide greater (Continued to page 2)

In Brief

Wilson Named Director, MCW Cancer Center; UAB Cancer Center Makes Three Appointments

J. FRANK WILSON, professor and chairman of radiation oncology at the Medical College of Wisconsin, has been named director of the Medical College's Cancer Center. Wilson has been acting director of the center since 1994. He is past president and chairman of the board of the American Society for Therapeutic Radiology and Oncology, and is president of the Wisconsin Society of Radiation Oncologists. . . . UNIVERSITY OF **ALABAMA** at Birmingham Comprehensive Cancer Center has made three high-level appointments: **Donald Miller** was named deputy director of the cancer center. Miller succeeds Richard Wheeler, who left for private practice. Miller will continue as director of the Division of Hematology-Oncology in the Dept. of Medicine of the UAB School of Medicine. William Vaughan, associate director for clinical research, was named to the new position of associate director for clinical affairs. He will continue as director of the bone marrow transplant program. Mansoor Saleh, a clinicianscientist at the center, will succeed Vaughan as associate director for clinical research. . . . SUSAN MILLER, a health psychologist, was appointed a senior member of the Fox Chase Cancer Center division of population science. She will direct the psychological and behavioral research program. Miller is leading a project to study how women cope with information about testing for the BRCA1 gene. . . . PEARL MOORE, executive director of the Oncology Nursing Society, was selected for the Achievement Award for Outstanding Contributions to Cancer Care by the Association of Community Cancer Centers. The award will be presented March 15 during the ACCC annual conference in Washington, DC.

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NCI To Boost Grants Funding, Cut \$30 Million From Contracts

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opportunities for cancer researchers to test their ideas, Klausner said.

"We have been sending a very discouraging message about constraint and constriction to all people, but especially young people," Klausner said. "The message I want to send to young people is that there are important opportunities in cancer research."

The Institute also plans to begin a new process for funding a proportion of grant proposals that miss the payline, particularly those involving patientoriented research.

The Institute's funding plans for fiscal 1996 include the following:

- —Investigator-initiated research grants (R01s) would be funded at the 23rd percentile this year, compared to the 15th percentile last year.
- —Program project grants (P01s) would be funded to the priority score of 140, versus 134 last year.
- —Training grants, which have been flat or decreasing for several years, would be increased significantly, Klausner said. Budget numbers were not available at this writing, but would be made public soon, Klausner said.
- —The NCI Executive Committee will begin a new process to review and fund a portion of grants that just miss the payline.



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—Shannon Awards, the small, two-year grants for researchers whose grants missed the payline, will be funded on a "rolling" basis throughout the year.

In fiscal 1995, NCI spent \$920 million to fund research project grants (R01s and P01s), out of a \$2.129 billion appropriation.

The continuing resolution that funds NIH through FY96 provides a 5.7 percent increase. NIH could impose taps on the budgets of the institutes, including a 1 percent transfer for the NIH director's discretionary fund.

Goal To Break "Vicious Cycle" Of Restraint

Providing greater opportunities for investigators to test their own ideas is a high priority for NCI, Klausner said in an interview with **The Cancer Letter** on Jan. 31.

"The whole peer review system gets distorted at paylines of 15 percentile and lower," Klausner said. "The constricted payline forced the Institute to take a more directive, managerial role about what we wanted to fund.

"As funding got more and more constricted, the need for Requests for Applications grew, to make sure we funded very high priority topics," he said. "That further constrained the free availability of competitive funds, in a vicious cycle.

"We need to break that vicious cycle by increasing the funding rate."

Klausner said the proposed increases in funding for R01s and P01s could be sustained over the next several years. "I am convinced that we will be able to sustain funding at that level, in the out-years of the grants," he said.

In addition to funding more grants, NCI plans to fund each grant closer to the level recommended by peer review, Klausner said.

Part of the increase for research project grants will come from the consolidation or reduction of contracts, Klausner said.

The NCI Executive Committee reviewed \$400 million worth of the Institute's contracts, and identified about \$30 million in reductions. Some contracts which had just begun were not subject to the committee's review.

The reductions affect a wide variety of contracts, Klausner said. "There is no way generalize," he said. "With some contracts, we realized we can fund them at 95 percent rather than a 100 percent."

In particular, NCI officials consolidated contracts

that each division issued separately for support services, Klausner said.

"Sometimes there was a projection of a level of funding that we didn't need, and then [the funds] never got out of the contract line, and some of these were contracts that were being automatically recompeted," Klausner said.

"Accelerated Executive Review"

Another problem NCI plans to address is the lag time in the review process for grants that miss the payline, Klausner said.

Under the current system, investigators whose grants are not funded can amend their grant application and go through the review process again, but the process can take a year or longer.

"We call it the queue, as in waiting in line," Klausner said. "There is a real problem: if you just missed the payline, then you have to go back into the que. You have to write an amendment, and you wait, and often it takes two [review] cycles before you get funded. That's very destabilizing.

"It's particularly disastrous for patient-oriented research," Klausner said. "Often, the patients simply won't be there. It's a very complicated and difficult proposition to organize patient-oriented research, and if you have to wait a year, a year and a half, it just won't be there.

"Your hospital will tell you: 'You're not going to get NIH funding. Go back and see patients.""

To reduce the lag time, the NCI Executive Committee plans to begin "accelerated executive review" of grant proposals that miss the payline, Klausner said.

Any grant application within four percentile points of the payline, and any patient-oriented application within 10 percentile points of the payline would be selected for accelerated executive review.

The prospective grantees would be asked to send a letter to the Executive Committee addressing the questions raised in peer review.

"What does it mean to miss funding by a couple of points?" Klausner said. "We want to respond in an intellectually appropriate way to the fuzziness of the boundary, of the subtle difference between fundable and nonfundable."

Klausner said the Executive Committee will continue to fund some grants by "exception," a process it has used for many years to fund highpriority grants that miss the payline. However, the accelerated executive review would require a written response from the prospective grantee.

"We will ask for a very simple, but clear, pointby-point response—new data, whatever you have to send back in—and the Institute will look at it, and evaluate it, and if we feel that it's correctly answered the objections, we will fund it," Klausner said. "The turnaround could be very rapid."

The committee would conduct an executive review session each month, he said.

"It's analogous to a journal," Klausner said. "When a scientist submits an article to a journal and the reviewers don't quite accept it, an editor will generally say, 'Answer the reviews, and I will evaluate, or the editorial staff will be able to evaluate the quality of your response, and we don't need to send this back out to review.'

If investigators convince the Executive Committee that their grants are fundable, then "everyone wins," Klausner said.

"The grantees get the opportunity to improve their grants in responding.

"The Institute has the opportunity to fund more ideas and more projects, which is what we want to do.

"And the potential disaster of the long queue, the instability, the distress, the discouragement, we hope to get rid of."

Wittes, Fraumeni Appointed

In other developments in the NCI reorganization:

- —Robert Wittes was appointed director of the Division of Cancer Treatment, Diagnosis and Centers. Wittes has been acting director of the division since the departure of Bruce Chabner last spring. He is the former chief of the NCI Medicine Branch.
- —Joseph Fraumeni was appointed director of the Division of Cancer Epidemiology and Genetics. He has been acting director since the division was created last fall. He is the former director of the NCI Epidemiology and Biostatistics Program.
- —NCI has established several working groups of experts from outside the Institute to conduct reviews of major programs. The groups and their chairmen are: Cancer Centers Program, Joseph Simone; Clinical Trials, James Armitage; Cancer Prevention, Edward Bresnick; Developmental Therapeutics Program, Edward Scolnick and Stuart Schreiber; Developmental Diagnostics, Arnold Levine; Cancer Genetics, Joseph Fraumeni and Alfred

Knudson.

—A new, 40-page Bypass budget is nearly complete, and is scheduled for release next month to coincide with appropriations hearings in the House of Representatives. The document is Klausner's first official opportunity as NCI director to lay out his priorities for investment in cancer research.

DOD To Pay For Clinical Trials In Three-Year Deal With NCI

NCI and the Department of Defense announced a three-year project that will give military personnel and their families access to cancer clinical trials.

The agreement, which repeals the DOD policy of denying reimbursement for investigational treatments, may help answer one of the most urgent questions in clinical cancer research:

Do clinical trials cost more than standard care?

The data produced through the collaboration could be used to demonstrate to managed care providers what they could expect from participation in clinical trials.

"We hope an agreement such as this represents the turning of the tide of the challenge to the clinical trials, clinical research, and academic health center system," said NCI Director Richard Klausner.

Model For Managed Care?

The agreement will provide state of the art cancer care for DOD employees, increase the overall enrollment in clinical trials, and provide a model for attracting large managed care providers to clinical trials, Klausner said to **The Cancer Letter**.

"We will also be using this as a demonstration project to study the medical economics, which we all desperately need," Klausner said. "What are the costs? What are the added costs, if any, incurred in a complete and extensive clinical trial system?"

The project could also help derive reliable methods for comparing the costs of clinical trials with the costs of standard care, Klausner said.

"We have to be very careful about what we mean by added costs," he said. "Is it the dollars per month, or is it the value? If people's lives are prolonged, if the cure rates go up, if the outcomes are better, if the quality of life is better, one has to look at the overall costs."

The DOD health system, called Civilian Health & Medical Program of the Uniformed Services

(CHAMPUS), has the enrollment of about 10 million people, which makes it the second largest managed care provider in the US. Based on age-adjusted incidence rates, every year 11,760 people covered by CHAMPUS can be expected to develop cancer, DOD officials estimated.

"While this demonstration provides an exception to current CHAMPUS benefit limitations, the Department hypothesizes that the increased access to innovative cancer therapies will occur at a cost comparable to that the department has experienced in paying for conventional therapies under the standard CHAMPUS program," DOD said in an announcement in the Federal Register Jan 24.

Considering that the vast majority of patients would be randomized to conventional treatment, total enrollment in phase II and phase III trials sponsored by NCI would range between 120 and 350. These patients would get care at NCI designated comprehensive and clinical cancer centers, and, through cooperative groups, at civilian or military hospitals.

"The number [of enrolled patients] may grow as awareness of the [program] increases the potential pool of patients meeting protocol eligibility requirements, and as new NCI studies are established for a wider variety of cancer treatments," DOD said in the announcement.

Additional details of the collaboration are expected to be described in a memorandum of understanding which is currently being negotiated by DOD and NCI officials. Though all the details are yet to be spelled out, the project became effective Jan. 1, and the first CHAMPUS patient has begun treatment at Johns Hopkins Oncology Center, Klausner said.

The demonstration project supersedes an earlier collaboration in which CHAMPUS and NCI sought to assess the safety and efficacy of high dose chemotherapy with stem cell rescue for breast cancer.

That project, which began in November 1994, has now been incorporated into a broader collaboration, officials said.

Under the current arrangement, DOD will reimburse all medical care required as a result of participation in clinical trials, including purchasing and administering all approved chemotherapy agents as well as all inpatient and outpatient care, including diagnostic and laboratory services not otherwise reimbursed under an NCI grant program.

CHAMPUS will not reimburse the costs of investigational drugs as well as the costs of non-treatment research activities associated with the clinical trials. Also, DOD will not provide reimbursement for care at the NIH Clinical Center.

Klausner said the negotiations that led to the expansion of the NCI collaboration with DOD began last August, when he brought a proposal to Stephen Joseph, the DOD undersecretary for health and former New York City health commissioner.

"To me, the enthusiasm with which the Department of Defense entered into this, really reflected their belief that this was the best thing they can do for their community," Klausner said.

Quantifying Impact Of Managed Care

In recent months, NCI has been working to quantify the impact of managed care on clinical trials. However, measuring that impact has been anything but straightforward in the absence of an authoritative cost comparison of clinical trials versus standard care.

Last fall, the controversy came to the attention of the National Cancer Advisory Board, when board member Robert Day presented the surprising results of an NCI survey that demonstrated that enrollment in clinical trials in the cancer centers has remained unharmed (**The Cancer Letter**, Sept. 29, 1995).

At that meeting, on Sept. 14, Klausner said NCI would take on the task of assessing the impact of managed care on clinical trials.

"I don't think that Congress, the White House, major insurers would be sanguine about the complete destruction of academic health centers," Klausner said at that meeting. "[However], we do have to demonstrate the extent to which academic health centers are threatened, and in what ways, and on what time scale."

Praise For An "Important Development"

NCAB chairman Barbara Rimer said the difficulties of obtaining reimbursement for clinical research warrant a proactive role by NCI.

"This is really an important development because it extends coverage for clinical trials to one of our most significant populations, and, hopefully, will provide a model for interacting with other defined populations, especially managed care organizations," Rimer said of the CHAMPUS program.

Bruce Ross, chief executive officer of the

National Comprehensive Cancer Network, said the collaboration with CHAMPUS would benefit clinical trials by helping accrue patients as well as by yielding vitally important cost data.

"This speaks well for the NCI leadership," Ross said to **The Cancer Letter**. "When we are looking at the total cost of care, it is our thesis that academic centers provide the most cost-effective care over the long term of this disease.

"The more data we have on costs and outcomes, the better it is for everybody," Ross said.

Fox Chase Cancer Center Forms Physician Network

Fox Chase Cancer Center has organized a group of community oncologists that would negotiate with third party payers, engage in group purchasing and have access to practice guidelines now being developed at the major academic cancer centers.

Fox Chase officials said 90 medical oncologists who work in 38 practices in Pennsylvania, New Jersey and Delaware have been invited to join the non-profit group called the Oncology Physician Network.

The network will be independent, and guided by physicians rather than by health care institutions. However, during the start-up phase, the network will purchase administrative services from the Fox Chase Network, the cancer center's outreach program.

Initially, the group will be governed by a sixmember interim board of directors that will include physicians who are not employed by Fox Chase, as well as Paul Engstrom, senior vice president for population sciences at the cancer center and medical director of the Fox Chase Network.

"OPN was created in response to changes in the regional health care environment," Engstrom said. "Fox Chase has a large medical oncology practice that would benefit from formal relationships with other oncologists in the region."

According to Fox Chase officials, the new network would recruit members who are committed to developing clinical protocols and practice guidelines. The group would also use the cancer center as a source of expertise and access to cancer treatment and research, officials said.

OPN members will have access to the guidelines now under development by the National Comprehensive Cancer Network, an alliance of 13 academic cancer centers nationwide.

"OPN is unique because it is physician directed and controlled, and links medical oncologists practicing in both academic and community setting," said John Sprandio, a member of the interim board and co-medical director of Delaware County Regional Cancer Center in Drexel Hill.

"Building upon the successful relationship that has developed among Fox Chase Network members, we are now expanding to include oncologists outside this hospital-based network," Sprandio said.

The Fox Chase Network has the membership of 19 community hospitals in Pennsylvania and New Jersey.

At this stage, the membership is limited to medical oncologists and hematologists. However, in the future, membership will be extended to other specialties, officials said.

In addition to Engstrom and Sprandio, members of the interim board include Alan Weinstein, medical director of Memorial Regional Cancer center in Mt. Holly, NJ; Stephen Fox, medical director of the Cancer Center at Paoli Memorial Hospital in Paoli, PA; Richard Kosierowski, medical director of North Penn Cancer Program in Lansdale, PA, and Carl Minniti, a medical oncologist at the South Jersey Regional Cancer Center in Millville, NJ.

Komen Foundation Offers Postdoctoral Fellowships

The Susan G. Komen Breast Cancer Foundation is accepting applications for its 1996 National Grant Program for postdoctoral fellowship research and project grants.

The National Research Fellowship Program offers postdoctoral fellowship grants for breast cancer research to qualified applicants with MD or PhD degrees. The three-year program offers an experienced breast cancer investigator the opportunity to select a postdoctoral fellow to train in his or her laboratory. The fellowship candidate must be no more than three years postdoctoral graduate. Ten grants will be awarded, of which each will receive a stipend of \$35,000 a year. Fellowship applications must be submitted by the sponsoring principal investigator.

In addition to funding the postdoctoral fellowship grants, the foundation awards grants to qualified applicants and institutions promoting early detection and treatment of breast cancer through education, survivor support and outreach, particularly to the medically underserved population.

Application deadline is March 15. Applicants are available from Elda Railey, tel: 214/450-1789.

NIH Sets Tuition Cost Policy For NRSA Training Grants

NIH will implement a new policy for the support of tuition costs, beginning with competing National Research Service Act (NRSA) research training grants made in fiscal year 1996.

Implementation for NRSA fellowships will begin with competing awards made in fiscal year 1997, NIH said in an announcement in the NIH Guide to Grants and Contracts on Feb. 2. The tuition policy is based on recommendations from the NIH Task Force on NIH Tuition Policy.

The complete text of the recommendations is available under the NIH Home Page on the World Wide Web (http://www.nih.gov).

Tuition, for the purpose of this policy, means the combined cost of tuition, fees and self-only health insurance. The new tuition policy will be phased in with competing (Type 1, Type 2) awards.

Support for tuition costs of training grants and fellowships for which the new (Type 1) or competing renewal (Type 2) award was made prior to the implementation dates will remain consistent with policies in effect at the time of the competitive award.

For competing training grant awards made in fiscal year 1996 and henceforth, the NIH will reimburse 100 percent of the cost of tuition up to \$2,000 and 60 percent of tuition costs above \$2,000 for each predoctoral trainee and each undergraduate trainee supported by the Minority Access to Research Careers and Career Opportunities in Research training grants. This policy will also apply to individual predoctoral fellowships awarded in fiscal year 1997 and henceforth.

As in the past, support for the tuition costs of postdoctoral trainees are limited to the cost of self-only health insurance and the costs of specific courses in support of the approved research training program. Postdoctoral tuition costs for a trainee will continue to require prior approval on a case-by-case basis by the NIH awarding component and will be paid according to the policy described above for predoctoral trainees and fellows. This policy also

will apply to postdoctoral fellowship awards beginning in fiscal year 1997.

Non-competing (Type 5) of awards of Type 1 and Type 2 awards made under this policy will reimburse tuition costs in the amount paid in the previous award year, unless there is a change in scope of the award.

Carry over of unobligated training grant funds will continue to be permissible only with the prior written approval of the NIH awarding component.

The awardee institution retains full authority to rebudget funds into or within the stipend and tuition cost categories of an institutional training grant. Rebudgeting funds into the trainee travel and the institutional cost categories will continue to require the prior written approval of the NIH awarding component.

ORI Finds UNC Researcher Falsified Research Records

The HHS Office of Research Integrity has made final findings of scientific misconduct in the following case:

Durga K. Paruchuri, University of North Carolina, Chapel Hill: Based on an investigation conducted by the University of North Carolina, Chapel Hill and information obtained during its oversight review, ORI concluded that Paruchuri committed scientific misconduct by falsifying research records and falsely reporting to her supervisor and in a grant application submitted to the Public Health Service that she had produced a clone of meningococcal bacteria transferrin binding protein 1, labeled "pUNCH 701," and used it to obtain a second clone, "pUNCH 702." Furthermore, ORI accepted the UNC finding that Paruchuri falsified research records at the Lineberger Cancer Research Center oligonucleotide synthesis facility in an attempt to support her false claim. The research was supported by PHS grant R37 AI26837 and reported in grant application 1 R01 AI32115-01A1.

Paruchuri accepted the ORI findings and agreed to exclude herself voluntarily for a period of two years beginning December 21, 1995, from any federal grant or contract. Paruchuri further agreed that for a period of one year in addition to and immediately following the two year exclusion period, any institution which submits an application for PHS support for a research project on which Paruchuri's participation is

proposed, or which uses Paruchuri in any capacity on PHS supported research, or which submits a report of PHS funded research in which Paruchuri is involved, must concurrently submit a plan of supervision and certification of data accuracy. The HHS Office of Research Integrity has announced final findings of scientific misconduct in the following cases:

—Victoria Santa Cruz, University of Arizona. Based on an investigation conducted by the institution, ORI found that Santa Cruz, former program coordinator at the University of Arizona College of Nursing, engaged in scientific misconduct by fabricating interview data on a questionnaire intended for use in two studies funded by two Public Health Service grants.

Santa Cruz did not contest the ORI findings or administrative actions, which require that, for three years, any institution that proposes her participation in PHS-supported research must submit a supervisory plan designed to ensure the scientific integrity of her contribution.

—Ruth Lupu, Georgetown University Medical Center. Based on an investigation conducted by Georgetown University Medical Center, ORI found that Lupu committed scientific misconduct by submitting a false letter of collaboration in an unfunded application to PHS.

Lupu has entered into a voluntary exclusion agreement with ORI, accepting the finding and agreeing to exclude herself voluntarily from serving in any advisory capacity to PHS through Jan. 30, 1997.

In addition, Lupu has voluntarily agreed to accept the sanctions imposed by Georgetown. These included a letter of reprimand and a requirement that her grant applications, proposals, and other publications be subject to monitoring and review for two years.

—Harry June, Indiana University-Purdue University at Indianapolis. ORI found that June committed scientific misconduct by falsifying three letters of recommendation submitted with and in support of a an award application to PHS.

June has entered into a Voluntary Exclusion Agreement with ORI in which he has agreed to exclude himself for the three year period beginning Nov. 21, 1995, from serving in advisory capacity to PHS.

Also, June has voluntarily agreed to accept the administrative sanctions imposed by IUPUI, which include requirements that he take a course in research

ethics, be supervised by a senior faculty member for not less than three years, and submit all grant applications to his supervisor for review.

Oncology Nursing Foundation Offers Research Grants

The Oncology Nursing Foundation will award two investigator research grants, funded by Rhone-Poulenc Rorer Pharmaceuticals Inc.

The \$4,250 grants are designed to encourage new researchers in oncology nursing.

Applicants must be registered nurses involved in some aspect of cancer patient care, education or research. The principal investigator must have less than a doctoral level education and should have received no previous research funding.

Applications are available from the foundation, tel: 412/921-7373, extension 231.

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The Oncology Nursing Society will offer a series of pain workshops in 1996.

The course is designed to improve the ability of nurses to successfully manage pain.

The workshops will be held at a variety of sites in the spring and fall: April 20, Birmingham, AL; May 17, Des Moines, IO; May 18, Boise, ID; Sept. 20, Warwick, RI; Sept. 21, Richmond, VA; Oct. 25, Tulsa, OK; and Oct. 26, Albuquerque, NM. Additional sites are to be determined.

ONS will award 6.9 contact hours to registered nurses who attend the workshop.

For information on the pain workshops, contact ONS, tel: 412/921-7373, ext. 553, fax: 412/921-6565, or e-mail: meeting@nauticom.net.

Program Announcement

PA-96-020

Title: Academic Research Enhancement Award

Application Receipt Date: June 26

NIH is continuing to make a special effort to stimulate research in educational institutions that provide baccalaureate training for a significant number of the nation's research scientists, but historically have not been major recipients of NIH support.

Since FY1985, Congressional appropriations for

the NIH have included funds for this initiative, the Academic Research Enhancement Award (AREA) program.

The AREA funds are intended to support new research projects or expand ongoing research activities proposed by faculty members of eligible institutions in areas related to the health sciences.

Applications received in June 1995 for AREA grants to be awarded this year (FY1996) have been reviewed for scientific merit and program relevance. Approximately \$14 million will be available for the NIH AREA program in FY 1996. As a result, about 140 AREA grants will be made from the applications received June 1995.

Since it is anticipated that additional funds will be available next year, the NIH is inviting grant applications at this time for AREA grants to be awarded competitively in FY 1997.

Inquiries: Office of Extramural Outreach and Information Resources, Office of Extramural Research, NIH, 6701 Rockledge Dr., Rm 6207-MSC 7910, Bethesda, MD 20892-7910, tel: 301/435-0714, fax: 301/480-3963, e-mail: girg@drgpo.drg.nih.gov

The Cancer Letter Establishes World Wide Web Home Page

The Cancer Letter Inc. has established a presence on the World Wide Web with a "home page" and pages for each of its newsletters.

The pages are designed to reach prospective readers of the company's independent newsletters, The Cancer Letter, Cancer Economics and The Clinical Cancer Letter.

The pages are accessable at the following URL address: http://www.cancerletter.com.

The pages contain general information about the newsletters, sample issues, and forms for requesting information or to order a subscription.

Future plans are to provide subscribers with online access to the newsletters.

The Cancer Letter editors welcome other suggestions from readers for useful additions to the Web pages. Suggestions may be sent to kirsten@www.cancerletter.com or to webmaster@www.cancerletter.com.

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