THE CANCER LETTER INTERACTIVE

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Gore Proposes New War On Cancer, Double Research Funding Over 5 Years

Presidential candidate Al Gore distinguished himself from other candidates and the Administration he serves as vice president by proposing a new war on cancer he would launch if elected.

"No one can promise a cure for cancer; no one can promise what has escaped decades of our best science and our hardest efforts," Gore said in a speech at Thomas Jefferson University June 28. "But we can do better. We must set a national goal: to work tirelessly toward a vision of a 21st Century America that is free of cancer as the killer it is today."

The most notable aspect of the program advanced by Gore is that it addresses cancer specifically. Other initiatives, proposed by Congress

(Continued to page 2)

In Brief:

MSK Opens Laurance Rockefeller Pavilion; Bush Event Raised $10 Million For Anderson

MEMORIAL SLOAN-KETTERING Cancer Center has opened the Laurance S. Rockefeller Outpatient Pavilion, a 190,000-square-foot facility in midtown Manhattan. About 70 percent of the center's outpatient activity is expected to occur at the pavilion. . . . **A BIRTHDAY BASH** for former President **George Bush** and **Barbara Bush** raised $10.1 million for cancer research at the University of Texas M.D. Anderson Cancer Center. More than 3,000 friends of the couple gathered at the Houston Astrodome/Astroarena complex on June 10 for a dinner and concert, proceeds of which will fund The George and Barbara Bush Endowment for Innovative Cancer Research in honor of the couple's birthdays. The Bushes are Lifetime Members of the center's Board of Visitors. . . . **WISTAR INSTITUTE** was awarded a $6.6 million, five-year program project grant by NCI for research on metastatic melanoma. It is the 20th consecutive year Wistar has received an NCI program project grant for this research, directed by biologist **Meenhard Herlyn**. Wistar's melanoma research program is one of the largest in the U.S. The goals of the project are to develop new diagnostic tools and new treatments. Wistar also receives an NCI Cancer Center Support Grant. . . . **LUTHER BRADY** received the American Medical Association 1999 Distinguished Service Award gold medal, the association's highest honor, on June 20 in Chicago during the opening ceremonies of the AMA House of Delegates meeting. Brady is professor of radiation oncology and University Professor at MCP Hahnemann University in Philadelphia. He is also the Hylda Cohn

(Continued to page 8)

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Gore Proposals Consistent With "The March" Agenda

(Continued from page 1)

and the Administration in recent years, address biomedical research in general.

"I believe we should double federal cancer research over five years—which will double our current progress in preventing cancer and saving lives," Gore said in his speech.

The speech comes at the time when President Clinton is advancing a plan to spend the federal surplus to upgrade Medicare and to introduce a prescription drug benefit. The administration plan does not address cancer research specifically.

Several observers said that, regardless of the outcome of the election, Gore's campaign promises, if matched or surpassed by other candidates, could make cancer research a major issue in the year 2000 presidential race.

In addition to doubling funding for cancer research over five years, Gore called for:

—Enhancing diagnostic technology through programs that include the NCI Cancer Genome Anatomy Project and the NIH Human Genome Project;

—Assuring patient access to cancer clinical trials by passing legislation to assure Medicare reimbursement for clinical trials and to require health plans to reimburse patient care costs incurred in clinical trials. "We cannot cure cancer if only two percent of America's cancer patients are enrolled in cutting-edge clinical trials, Gore said. "I want to swing open the doors to the latest cancer clinical trials for Americans of all ages, who don't have the luxury of time. I call for funding to ensure a fivefold increase in the number of cancer patients able to join in clinical trials through our National Cancer Institute."

—Strengthening cancer prevention and early detection by expanding access to proven cancer screening tests, launching a national informational campaign on screening and early detection, and eliminating Medicare deductibles for mammography and colorectal and prostate cancer screening. The initiative also calls for launching a $200-million campaign to prevent children from smoking, penalizing tobacco companies that market to children, and passing legislation that would reaffirm FDA authority to curb tobacco advertising aimed at minors. "It is time to match big tobacco's big advertising campaigns with a national, counter-advertising campaign about the dangers of smoking and the risks of cancer," Gore said.

—Assuring patient access to specialists, protecting privacy of medical information, preventing discrimination against those found to be genetically susceptible to cancer. "We need a law that says to every doctor and health plan in America: Medical records must be kept private, or you will be punished with the full force of our laws," Gore said.

Gore's proposals appear to be consistent with the message of The March: Coming Together To Conquer Cancer, an event last September. His initiatives on cancer research appear to restate several key recommendations contained in The March Research Task Force Report, a document that is currently being used as something of a manifesto by professional societies and several members of Congress.

"We are pleased that the Vice President's proposal emphasizes the application of recent findings from molecular genetics and molecular biology to significantly improve the early detection, treatment and prevention of cancer," said Anna Barker, co-chair of The March Research Task Force and a member of the board of directors of the American Association for Cancer Research.

The Gore initiative was applauded by AACR, the American Society of Clinical Oncology, the National Coalition for Cancer Survivorship, and the National Prostate Cancer Coalition.

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Campaign promises notwithstanding, the appropriations picture on Capitol Hill remains uncertain. The House and Senate appropriations subcommittees are yet to act on spending bills that fund NIH as subcommittee leadership is seeking to increase the subcommittees' allocations.

Dave Kohn, a spokesman for Rep. John Porter (R-IL), chairman of the House Labor, HHS and Education Appropriations Subcommittee, said the allocation for the subcommittee is so low that drafting a bill would be a pointless exercise.

"The allocation would require a cut of about $11 billion below current level spending, from about $89 billion to about $78 billion," Kohn said. "This level of reduction is so draconian that if he were to write a bill, that bill would not pass the full House, or even the committee."

Both Porter and his Senate counterpart, Arlen Specter (R-PA) have asked the Republican leadership to increase the allocation.

The budgetary caps that have frustrated the appropriations process were put in place in the 1997 Balanced Budget Act. "When that bill was enacted, there was a great deal of concern about the economy," said Kohn. "In ensuing two years us economy has continued to perform magnificently, and there is, in effect, a pretty good situation."

NCI Grants Funding:

Institute Considers Increase In Support For RFAs, Due To Large Number Of Applications

NCI is considering increasing the set-aside funding for targeted research grants that the Institute invites by Requests for Applications.

The shift may be necessary because the Institute is receiving an unexpectedly large number of grant applications, NCI Director Richard Klausner said to the Institute's Board of Scientific Advisors at a meeting June 23.

Klausner said he may use some of his "Director's reserve" funds to increase support for RFA programs. The reserve is 1 percent of NCI's total appropriation, or about $30 million.

"These initiatives are critical for NCI," Klausner said to the board. "We are going to have to work very hard to deal with this issue of what I suspect will be significant under-funding of what we set out to be some of our major priorities."

Klausner gave the board a list of eight recent RFAS which received large numbers of grant applications. The list indicated that for each RFA program, NCI has set aside funds from the research project grants budget to support about one-fifth to one-third of the applications submitted.

"I am very gratified by the quality and the level of response," Klausner said to the BSA. "The extent to which many of these initiatives have galvanized activities and interests at institutions and centers across the country is exciting."

The response to RFAs raises the issue of the balance between funding these grants versus funding the traditional investigator-initiated grants, Klausner said. "I have no particular conclusion that I want us to come to, but as we plan, and as we work with the board in initiating what we consider high-priority programs, the issue of the size of the [RFA] set-aside relative to the response is something that we are going to need to deal with," Klausner said.

Soon after Klausner was appointed NCI Director in 1995, he said the Institute was "overusing" RFAs, which directed funds away from investigator-initiated research (**The Cancer Letter**, Dec. 8, 1995). He put in place criteria for NCI staff to follow in proposing new RFAs. As a result, many of the new RFAs over the past few years have been recommended by committees Klausner appointed to study the Institute's programs. These RFAs have tended to fund research consortia, centers, and "networks" of investigators.

"These initiatives represent a clear articulation of new approaches and new directions, and we are seeing that these are influential in the community," Klausner said. "These are initiatives that in no way could be looked at as 'R01 set-asides.' The Mouse Models Consortium, the Director's Challenge, the Early Detection Research Network—these are not things that could have just happened."

Klausner listed the following RFAs, the number of responses to them, the funding requested (including estimated indirect costs of 35 percent of the total), and the amount NCI has set aside:

—Mouse Models of Human Cancer Consortia: 31 consortia have applied, requesting an estimated $25 million. NCI set aside $5 million to fund these grants.

—Director's Challenge: 38 applications, many of which are consortia. Estimated total request about $50 million. NCI set aside $10 million.

—Array Facilities: NCI received requests of

direct costs of $11 million. The set-aside is $2.5 million.

—Early Detection Research Network: 45 applications were reviewed and 18 were considered "excellent" or "outstanding." Total amount requested by those 18 are about $20 to $25 million. NCI set aside $3 million.

—Small Animal Imaging Research Program: 29 applications, total request $51 million. NCI set aside $4.5 million.

—Transdisciplinary Tobacco Use Research Centers: 24 applications received, about $50 million requested. NCI set aside $10 million.

—Special Populations Research Networks: 64 letters of intent received. These have not been reviewed and Klausner did not provide an estimate of funds requested. NCI set aside $6 million, which would potentially fund six to eight, or possibly 10 networks.

—In Vivo Cellular and Molecular Imaging Centers: 29 letters of intent received. Set aside was $6.4 million.

"I think you can hear my concern," Klausner said. "I feel very strongly that these are new types of initiatives that are not just particular fields of R01s. We have reoriented our approach to RFAs. All of these emerged after extensive planning processes."

The Director's reserve is used for emergencies or to support unmet needs, Klausner said. "My intention is, as we watch the reviews for these major initiatives, to use some of those [funds] to deal with shortfalls, so that we don't have 7 percent or 10 percent success rates in these initiatives that we're saying we want people to come in for," Klausner said to the board. "This will be a growing issue as we deal with the competing desires for exceptions, for where we set the payline, for honing down on initiatives that are responsive to robust funding levels."

More "Major Initiatives" To Come

BSA Chairman David Livingston, the Emil Frei professor of medicine and genetics at Harvard Medical School, said the funding requests in response to the RFAs Klausner listed came to a total of $200 million, for an available $30 million of set-aside funds. "That's a 7-to-1 gap," Livingston said. "What should the gap roughly be in order to accomplish the capturing of the opportunities?"

KLAUSNER: "I really don't feel comfortable saying, until [the applications] have been reviewed and we look at them and we get more experience," Klausner said. "I raised it because, my qualitative guess is that there is not enough set-aside."

LIVINGSTON: "Fair enough. The fundability gap, call it. Do you think that gap, regardless of whatever it is, will that gap grow? Is the shear volume of opportunity, and the cost of leading that volume of opportunity, likely to grow? Is there an ideal gap?"

KLAUSNER: "I don't know if there is an ideal gap. Not knowing what our budget is going to be, I can't project whether the gap is going to [increase].

"What I can project is that I think we still have a series of major initiatives that are going to be as important to the program as the ones we have. Again, we are looking at what I think is qualitatively a shortfall of these initiatives, in a year with a 15 percent budget increase."

FREDERICK APPELBAUM, BSA member and director of clinical research, Fred Hutchinson Cancer Research Center: "How many RFA [applications] that are not funded will show up later in the [R01] grant pool?"

KLAUSNER: "I would say none. If you had a RFA where you said we want to set aside money to stimulate more R01s studying this aspect of pancreatic cancer because it is not appreciated and under-funded, it's obvious that that could go into the R01 pool. You know that we don't do those RFAs anymore. The RFAs here are highly structured to try to bring people together and give them infrastructure and resources that we've been told by the community isn't going to happen through the grant pool mechanism and through the general review process.

"We set a percentage of the total available funds for new and competing grants which is our ceiling for RFAs, and then the consequence of that, will be under-funding the RFAs, not going over that ceiling. The decision to go over that ceiling is something that needs to be discussed."

FY 1999 Grants Funding Update

NCI plans to spend $1.367 billion in the current fiscal year ending Sept. 30, on extramural research grants, Klausner said to the BSA. The Institute expects to fund a total of 4,419 grants this year, compared to 3,950 last year.

In the research project grants budget, NCI plans to fund approximately:

—2,800 R01 grants, including 873 new and competing grants, a 23 percent increase from FY 1998.

—175 P01 grants, of which 45 are new and competing. The number of new and competing P01s increased 15 percent from FY98.

—156 phased innovation awards (R21/R33s), of which 118 are new and competing, a 200 percent increase over last year. NCI expects to spend $22.6 million on these grants. "We certainly are contemplating expanding this mechanism to a variety of other projects," Klausner said.

—299 Small Business Innovation Research awards (SBIR/STTRs).

—422 FIRST awards (R29s).

—71 MERIT awards.

—450 other awards, which would include RFAs, U01s, R03s, R55 (Shannon awards), and others.

The R01 pool includes 112 grants funded through the Accelerated Executive Review process, compared to 61 last year. Funding will increase from $8 million last year to $20 million this year. The grants funded include 84 that do not involve patient-oriented research and 28 that do include patient-oriented research.

Klausner said the NCI Executive Committee plans to analyze why the AER exceptions mechanism funded so many fewer patient-oriented applications than basic research applications.

The success rate for AERs this year is expected to be 68 percent, compared to the overall grants success rate of 32.8 percent.

NCI Programs:

BSA Approves Recompetition Of Contracts For Phase II Trials

The NCI Board of Scientific Advisors gave unanimous approval to the recompetition of contracts for the phase II studies of cancer therapeutics.

The contracts represent the Institute's major mechanism for conducting phase II research on NCI-sponsored therapeutics.

NCI will spend an estimated $2.6 million on the phase II contracts this fiscal year. Under the recompetition, the Institute plans to spend $7.58 million in FY 2000, increasing to $8.8 million in 2004. The Translational Research Fund would cost NCI an additional $6.3 million in FY 2000.

The contract program would allocate $4,750 per patient, an amount that would include pharmacodynamic and pharmacology studies, Christian said to the board.

The contracts are held by some of the largest cancer centers and research institutions in the U.S.

The text of the concept statement follows:

Early Therapeutics Development With Phase II Emphasis.

Concept for an RFP, recompetition of contracts held by Sloan-Kettering Institute for Cancer Research, University of Texas M.D. Anderson Cancer Center, Ohio State University, University of Chicago, Case Western Reserve University, City of Hope National Medical Center, Montefiore Medical Center, and Johns Hopkins University. Eight contracts, estimated total cost $7.58 million for the first year. Estimated cost for the Translational Research Fund, $6.3 million. Project officer: Susan Arbuck, phone 301-496-1196, email: arbucks@ctep.nci.nih.gov

The Early Therapeutics Development with Phase II emphasis ("Phase II") contracts and the Translational Research Fund (TRF) will create early clinical trials consortia poised to rapidly evaluate the biologic effect of NCI-sponsored anticancer agents on their molecular targets and determine clinically-relevant correlates. They will provide the essential clinical trials infrastructure and laboratory support to the Cancer Therapy Evaluation Program. One critical role of CTEP is to bring the NCI-held IND anticancer agents into clinical trials. NCI has collaborative agreements with 65 industry partners for 160 investigational agents. CTEP has filed approximately 20 IND applications annually in recent years and already has 22 in preparation this year. All but two are for early clinical trials.

Eight U01s have provided the clinical expertise and infrastructure to conduct phase II clinical trials of NCI-sponsored investigational agents since 1995, and they will expire in March 2000. The primary endpoint of these single institution phase II trials has been clinical tumor response.

They have evaluated 1446 patients on 53 completed trials with 12 investigational agents and 14 combinations that included investigational agents. The annual patient accrual was 331 in 1995, 381 in 1996, 372 in 1997 and 362 in 1998. In addition to the 53 completed trials, 39 trials that remain open to accrual are evaluating l l investigational agents and 12 combinations that include investigational agents. Four trials that did not accrue well are closed, 9 trials are on hold due to drug supply problems, and 17 trials are in the process of review.

The ability to answer clinical trial questions quickly is important, and this is suboptimal in the current system. For the 53 completed trials, the median time per trial from NCI approval of a letter of intent to the time the first patient accrued was 314 days. The median rate of accrual was 1.7 patients per month. The median time from the first patient accrued to the last patient accrued was 318 days. Thus, the median time from LOI approval to last patient accrued is approximately 2 years. Thirty of the completed trials

included pharmacology studies and 27 trials planned correlative science components. Although many of these studies included plans for correlative studies, in practice they were performed on the few patients with visually accessible tumor for biopsy. Thirty-one of the 39 ongoing trials have either pharmacology or planned correlative science components. Ninety-five reports from phase II trials supported by this initiative have been published since 1995.

Although speed was suboptimal, and insightful laboratory correlates were lacking, there are a variety of examples where important activity of new agents was first demonstrated in these NCI-sponsored trials. Several examples where this activity prompted important phase III trials are discussed below. Some of these have already altered the standard of care; with additional time for completion of definitive phase III trials, others are likely to do so.

Activity of paclitaxel in advanced, metastatic cancer was first demonstrated through these trials in a variety of different tumor types. Subsequent phase III trials have confirmed the importance of this agent in ovary, breast, and lung cancer and phase III trials are ongoing in a variety of other tumor types. Even more exciting are early results that were reported at ASCO in 1998, from the first trial incorporating paclitaxel in the adjuvant treatment of women with lymph node positive breast cancer. A significant survival advantage was observed in women who received paclitaxel in addition to standard chemotherapy compared with those who received standard chemotherapy. Paclitaxel is now also undergoing evaluation in the adjuvant setting in a phase III trial for women with negative lymph nodes. The first adjuvant phase III trial with paclitaxel in non-small cell lung cancer is in progress.

Additional phase II trials were completed demonstrating that paclitaxel has a 25% response rate in cervical cancer, a disease for which available chemotherapy has limited effectiveness. Thirty-seven percent of patients with esophageal cancer responded, providing an important new agent for this disease. Funding also supported a phase II triple combination trial in esophageal cancer.

Topotecan either alone or in combination with cytosine arabinoside, achieves the highest response rates (including complete response rates), observed with any combination therapy for aggressive myelodysplasia and chronic myelomonocytic leukemia. Single agent response rate of 41% (28% CR) was first reported through a study funded under these UO1s. In a follow-up phase II trial, a response rate of 83% was observed with the combination of topotecan and cytosine arabinoside. Based upon these impressive results, a phase III trial incorporating this active regimen is under development.

An NDA-directed phase III trial of homoharringtonine vs hydroxyurea in patients with CML who have progressed following interferon therapy is underway. Patients with CML that is resistant to interferon have limited therapeutic options. Palliative therapy with hydroxyurea is frequently used. UO1 investigators demonstrated that 88 % of 58 patients with poor prognosis CML achieved a hematologic remission with homoharringtonine; 72% achieved a complete hematologic remission. Furthermore, 31% developed a cytogenetic response, (complete cytogenetic response in 7%). Some responses have been prolonged. The combination of homoharringtonine and interferon is also under development.

Although the phase II cooperative agreements have contributed to early therapeutics development, they were not conducted efficiently or rapidly, and often lacked potentially informative correlative laboratory studies. Very few trials were conducted on molecularly targeted agents. There are several reasons that may account for these deficiencies. Single institutions may not have sufficient numbers of eligible patients for rapid trial completion. Other causes for slow accrual may include lack of investigator or patient interest in the NCI-IND agent under study, or other competing studies of higher priority in the same population of patients. NCI had placed little emphasis on molecular targets and provided no funding for laboratory or non-invasive imaging evaluation of those agents. The ability to do correlative studies has been hampered by the need to do invasive biopsies for tissue evaluation and lack of funding for the procedures, personnel time, and laboratory evaluation. There may also be a lack of scientific expertise for molecular targeted research, as this had not been specifically emphasized in the existing cooperative agreements. Lack of appropriate assays and research tools to evaluate the biologic endpoints may be another problem.

The "Phase II" contracts and the TRF will create early clinical trials consortia poised to rapidly evaluate the biologic effect of NCI-sponsored anticancer agents on their molecular targets and determine clinically-relevant correlates.

The objectives of this program are:

—to rapidly conduct clinical trials necessary to assess the anti-tumor activity and carry out the development plans for NCI sponsored agents of varying classes, many of which are directed at new cancer targets.

—to characterize the effects of new agents on their targets through biopsies and suitable assays, functional imaging, and other appropriate technologies and correlate those effects with clinicallyrelevant endpoints

· to develop new scientific insights into drug mechanisms and determinants of response.

The "Phase II" contracts will fund 8 multi-institutional consortia each of which will commit to accruing a minimum of 100 to 200 patients per year (800-1600 total patients) with different tumor types. These will provide sufficient patients for approximately 4 to 8 trials per contract, or 32 to 64 trials each year for all 8 contracts (averaging about 25 patients per trial) testing a variety of new agents with different targets. These contracts will

require rapid implementation and completion of trials and they will require the ability to implement correlative studies testing the effects of the investigational agent on their target in tumors.

The TRF will fund investigators with correlative studies characterizing the effects of new agents on their targets and identifying correlates of clinically-relevant endpoints. The TRF will also provide funding directly to the phase II contractors for procedures and assays directly tied to the evaluation of the clinical endpoints (e.g., pharmacokinetic studies). The anticipated product is the development of new scientific insights into drug mechanisms and determinants of response that will be useful in determining the future drug development plans of the agents under study. The correlative studies must be linked to the clinical trials being conducted by the "Phase II" contractors. The TRF will fund the costs of personnel time, procedures directly related to the laboratory correlative investigations, and the laboratory studies. It is anticipated that each of the clinical trials will have at least one correlative laboratory investigation, for a total of 32 to 64 laboratory correlates per year.

Structure of Funding/Review:

"Phase II" Contracts: The request for proposals will solicit multi-institutional consortia arrangements of clinicians, statisticians, data managers, and research nurses with early phase clinical trial expertise with investigational agents in cancer. Offerors for these contracts must demonstrate that they have expertise in cancer drug development, and knowledge in the clinical management of specific tumor types, phase II clinical trials, pharmacology and pharmacodynamics. They need to provide evidence of their own expertise, or access to such expertise, in diagnostic and functional imaging, interventional radiology, pathology, and other potentially relevant laboratory methodologies.

Each contract applicant needs to show evidence of sufficient numbers of patients to be able to conduct 4 to 8 clinical trials using NCI-held IND anticancer agents. The size of each trial may vary depending upon whether the first phase demonstrates activity resulting in expansion from 12 to 35 or 40 patients. The average size of each trial is estimated to be 25 patients, necessitating approximately 100 to 200 patients per contract. For common tumors, such as breast, colon, prostate and lung, studies must take no more than one year from approval of a Letter of Intent (LOI) to completion of accrual. For less common tumors, studies should be completed no more than 18 months after LOI approval. To ensure efficient conduct of studies, full contract credit will not be given unless patients are accrued and trials completed in the time specified, with the quality of the data assured. Quarterly progress reports on accrual will be reported to CTEP, and future funding will be based on the quarterly numbers of patients accrued. Per capita costs per patient will be provided.

The Research Contracts Branch of the NCI will formulate the request for proposals in conjunction with the CTEP project officer, and the initial peer review will be administered through DEA, NCI. Subsequent selection and negotiation will then ensue after the peer review has been completed.

Scientific Review of Clinical Studies: CTEP will call for solicitation of proposals to conduct clinical trials with specific NCI-held IND agents. Investigators will submit a letter of intent to conduct the trial, which will receive internal review by the protocol review committee (PRC) of CTEP. The LOI may be rejected, approved with the requirement for recommendations to be incorporated, or fully approved. Upon approval of the LOI, the contractor will write the clinical protocol within 30 days, and this protocol will be reviewed by the PRC of CTEP within two weeks. After protocol approval, the contractor will have up to one year or some timeline mutually agreed upon by the CTEP project officer and the contractor, to complete the trial.

Scientific Review of Translational Research Studies: The TRF will primarily be administered through NCI's existing Science Applications International Corporation (SAIC) contract, which has within its work scope the types of clinical and laboratory studies that will be required for these early clinical trials consortia. SAIC will broadcast a request for proposals in correlative studies at the same time there is a request for the clinical trial solicitation by CTEP. In circumstances where appropriate, SAIC will allow sole-sourcing for the correlative studies.

Competition will be open and announced in the appropriate journals in addition to notifying the "Phase II" contractors and other investigators with the anticipated expertise. The proposed translational studies will be reviewed by external expertise, and will be administered through SAIC. A rigorous description of the rationale and methodology for the laboratory components of the study, as well as a description of how the results will be analyzed in conjunction with the results of the clinical trial, will be provided at the time of protocol submission. Laboratory studies using patient specimens from the clinical trial may include patient monitoring studies (i.e., pharmacokinetics, immune response, etc) or clinical correlative studies that may guide clinical development of the new agent or approach or identify patient subsets for specific therapies. Statistical design issues should be addressed in the research plan for both the clinical protocol and the laboratory analyses.

TRF funds will be committed for correlative studies that are approved following scientific review. The TRF will fund the personnel, procedures, and laboratory costs associated with the assessment of target effects. Supplementation of existing "phase II" contractors will be administered through the Research Contracts branch, and subcontracts to investigators funded via other means or who are currently unfunded would be administered through SAIC.

Funding Opportunities:

NCI Extends Deadline For Applications For 3 RFAs

NCI has extended the deadline for the receipt date for applications submitted in response to:

RFA CA-99-007, The Early Detection Research Network: Clinical And Epidemiologic Centers;

RFA CA-99-008, The Early Detection Research Network: Biomarkers Validation Laboratories;

RFA CA-99-011,The Early Detection Research Network: Data Management And Coordinating Center.

These RFAs can be accessed at the following URLs:

http://www.nih.gov/grants/guide/rfa-files/RFA-CA-99-007.html

http://www.nih.gov/grants/guide/rfa-files/RFA-CA-99-008.html

http://www.nih.gov/grants/guide/rfa-files/RFA-CA-99-011.html

For all three RFAs, the previous receipt date of July 16, 1999 has been changed to July 28, 1999. All other aspects of these three RFAs remain the same.

Inquiries: Sudhir Srivastava, Division of Cancer Prevention, NCI, Executive Plaza North Room 330F, Bethesda, MD 20892, phone 301-496-3983, fax 301-402-0816, email: ss1a@nih.gov

Program Announcement

PA-99-122: Individual Postdoctoral Fellowships In Genomics And Related ELSI Topics

Application Receipt Dates: Aug. 5; Dec. 5; April 5

Scientist and scholars who are well-trained in one or more of a variety of disciplines will be needed to accomplish the goals of the Human Genome Project and to use the knowledge, resources and data that will be generated for further research. Further, as more institutes and centers at the NIH begin to develop additional similar projects, such as the Environmental Genome Project, functional genomics projects, etc. that will use the resources generated by the HGP, the need for additional interdisciplinary-trained scientists will only increase. To ensure that there is a trained cadre of scientists to take advantages of the resources being generated by the HGP, several NIH institutes are announcing the availability of individual postdoctoral fellowships. The purpose of these fellowships will be to train scientists who will have the multi-disciplinary skills that will enable them to engage in research to accomplish the short- and long-term objectives of the HGP and similar genomic projects and to take full advantage of the resulting genomic data and resources to solve biomedical and bioethical problems. Broad areas of research that are relevant include genomic analysis (including technology development) and the ethical, legal and social implications of human genetics research.

Inquiries: Bettie Graham, Division of Extramural Research, National Human Genome Research Institute, Building 38A, Room 614, Bethesda, MD 20892-6050, phone 301-496-7531, email: Bettie_Graham@nih.gov or Lisa Begg, Office of Centers, Training and Resources, National Cancer Institute, 6130 Executive Boulevard, Room 520, MSC 7383, Bethesda, MD 20892-7383, phone 301-496-8580, email: begg1@mail.nih.gov

In Brief:

Winawer Honored By ADHF; Seeger Promoted At Fox Chase

(Continued from page 1)

American Cancer Society Professor of Clinical Oncology. . . . **SIDNEY WINAWER**, the Paul Sherlock Chair, Memorial Sloan-Kettering Cancer Center, received the 1999 Miles and Shirley Fiterman Foundation, Joseph B. Kirsner Award in Gastroenterology from the American Digestive Health Foundation. . . . **CHRISTOPH SEEGER** was promoted to senior member of Fox Chase Cancer Center's division of basic science. Seeger, a virologist, joins a select group of only 35 current staff members previously honored as senior members in one of the center's three research divisions. The honor is based on the consensus of peers and receives approval of the center's Board of Directors. Seeger conducts research on the hepatitis B virus. . . **THREE MEMBERS** of the NCI Board of Scientific Advisors have completed their terms: **Robert Greenberg**, director, Norris Cotton Cancer Center; **Sharon Murphy**, chief of the Division of Hematology/Oncology, Children's Memorial Hospital, and professor of pediatrics, Northwestern University School of Medicine; and **Stuart Schreiber**, professor of chemistry and chemical biology, and co-director, Institute of Chemistry and Cell Biology, Harvard University. . . . **"CLINICAL TRIALS:** A Blueprint for the Future," is the title of a new NCI booklet describing the pilot projects that the Institute has begun with the goal of restructuring its national cancer clinical trials system. The 40-page booklet is available at no charge by sending an email request to Jana Johnston at johnstoj@occ.nci.nih.gov or calling the NCI Cancer Information Service at 800-4-CANCER (800-422-6237). Or, read the text online at: http://cancertrials.nci.nih.gov/NCI_CANCER_TRIALS/zones/Tools/Booklets/Plan/index.html. Another option for learning about the clinical trials restructuring is to listen to or read the text of lectures by NCI officials about the plans at: http://www.webtie.org/nciinitiatives/.

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