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NCI Preparing RFA For Genetics Network; Patients Want Gene-Environment Studies

NCI staff has begun preparing a proposal for the creation of the Cancer Genetics Network, Institute Director Richard Klausner said this week.

At a meeting of a working group that guided NCI in the creation of the planned network, Klausner said the concept for the network would be ready for presentation to the Board of Scientific Advisors within a

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In Brief

Balch To Head City of Hope; Rowinsky Moves To San Antonio; Klausner's Deputy Joins NCI

CHARLES BALCH, executive vice president for health affairs and professor of surgery at University of Texas M.D. Anderson Cancer Center, was named president and chief executive officer of City of Hope National Medical Center and Beckman Research Institute. The appointment is effective Sept. 1. Balch replaces Sanford Shapero, who left last January after 17 years as the center's president. Balch was one of four finalists for the position of president of M.D. Anderson (**The Cancer Letter**, April 19), a post that went to John Mendelsohn, formerly of Memorial Sloan-Kettering. Balch becomes the fourth president of City of Hope, an NCI-supported clinical cancer center. . . . **ERIC ROWINSKY** was selected to head the clinical research program at the Cancer Therapy & Research Center Institute for Drug Development. Rowinsky, an associate professor of oncology, Johns Hopkins University School of Medicine, begins the new appointment Aug. 15. . . . **JOE HARFORD**, former deputy director of the Cell Biology Metabolism Branch, National Institute for Child Health and Human Development, will join NCI on Sept. 1 as associate director for special projects in the office of **NCI Director Richard Klausner**. Harford spent 14 years at NIH, 10 of those working as Klausner's deputy in the CBMB. He left NIH three years ago to become director of research at RiboGene, a biotechnology firm based in Hayward, CA. . . **FREDERICK BECKER**, vice president for research, M.D. Anderson Cancer Center, is the first American to receive an honorary fellowship from the University of Wales, Bangor. Becker was recognized at graduation ceremonies July 10 by the university's chancellor, **Prince Charles**. The fellowship recognizes Becker's scientific contributions in the field of bioelectronic analysis of cancer cells. . . . **EDWARD CHU** was named director of the newly established VA Cancer Center at the VA Connecticut

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Klausner Favors Phased-In Development Of Network

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month. The next BSA meeting is scheduled for Nov. 21-22.

The Request for Applications, or a series of RFAs, would be completed later this fiscal year, Klausner said at the meeting Aug. 5.

Though the NCI staff has just begun its work on the RFA concept, Klausner said he would favor allowing the network to develop in phases, starting as a demonstration project, and ultimately developing into a nationwide structure.

As a result of a series of meetings and conference calls, the Cancer Genetics Working Group produced three reports, advising the Institute on the components of the network. Components included protocols for genetic testing, an informatics network that would link the investigators, and educational materials for physicians and patients (**The Cancer Letter**, June 28 and April 12).

The study of genetic susceptibility to cancer is one of the "investment opportunities" listed in the Bypass Budget prepared by Klausner's NCI earlier this year. The Bypass document requested $31.5 million of new funds in FY1998 for the creation of cancer genetics centers, training programs, clinical trials, and repositories.

The Institute is yet to announce how much money it plans to devote to the proposed network.

As the working group submitted its report to NCI, several controversial issues appeared to await resolution.

The working group was divided on the questions of how much attention should be given to the study of gene-environment interactions, quality of life issues and design of mechanisms for safeguarding the privacy of study participants.

Advisors were similarly divided on the question of whether there should be follow-up of study participants who expressed an interest in genetic testing, but ultimately chose not to go through with the test.

To be viable, the network would have to earn the support of the patient groups. As the advisory group conveyed its recommendations, the voices of the patient activists were coming through loud and clear:

"We anticipate that the consumer activist groups would be the driving force behind accrual of patients and participants into this project," said Barbara Brenner, head of Breast Cancer Action, a San Francisco-based patient group.

"If you are collecting information that will allow people to do the sorts of studies that, for example, will help us to identify environmental factors that are triggering an existing predisposition, then we are with you," said Brenner, one of four breast cancer patient activists who addressed the working group.

"But if you are talking about having the infrastructure that permits us to know who is doing genetic tests and how those people are doing, I cannot imagine that you can get us on board," Brenner said.

The recommendations Brenner presented are being developed by the Consumer Advisory Committee of the Hereditary Susceptibility Working Group of the National Action Plan on Breast Cancer.

If Klausner's remarks to the working group are an indication, NCI staff is giving serious consideration to letting the network start as a narrowly focused project, which would expand in phases.

"It may well be that the initial time period would be more of a demonstration project that ties centers together," Klausner said. "It's going to have to happen slowly. That gives us the opportunity to ask more questions early on, with the idea that we are going to have to learn to develop tools that are readily usable in short time periods. I don't think the idea of the network precludes the ability to have expanded data sets."

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Klausner said the Institute planned to start work on designing an informatics system that would then be presented to the principal investigators participating in the network.

"We can move ahead in creating some kind of a rudimentary, basic informatics system to present to successful competitors for PIs in the network, so we don't have the process of first going through the competition for being members of the network, and then starting to design the informatics system," Klausner said.

Follow Those Who Decline Testing?

Breast cancer activists were not alone in suggesting that the network address questions that go beyond defining penetrance of mutations and measurement of clinical outcomes.

"I think you are going to have a very hard time explaining if you don't collect [data] on simple things like smoking or use of hormone therapy," said Francis Collins, director of the NIH National Center for Human Genome Research. "Some level of environmental information seems indefensible not to include, so long as it doesn't become unwieldy."

Collins also objected to the proposed protocol's ambiguity on following patients who consider testing, but do not go through with it.

"I can't imagine doing this study and not including people who decide not to be tested," Collins said at the meeting.

Failing to follow the individuals who choose not to get tested eliminates opportunities for comparing the cohorts and sends the erroneous message that NCI endorses genetic susceptibility testing, Collins said.

"I don't see any reason why there could not be some randomization in terms of follow-up of the mutation-negative, or for that matter, mutation-positive people," Collins said. "You need to have some number-crunching to see what that looks like. I think that's well worth it for both scientific reasons and for the coercion aspect, which could be quite dangerous."

Ken Offit, chairman of the protocols development subcommittee, acknowledged that information on people who choose not to be tested is important, but said NCI money would be better spent on following only the individuals who are tested.

"The degree to which one follows those individuals who decline testing is going to be driven fundamentally by the resources," said Offit, chief of the Clinical Genetics Service at Memorial Sloan-Kettering Cancer Center. "It's going to be an enormous effort and expense to follow up all the individuals who opt out of testing, acknowledging that this is important data in the ideal world.

"But to address the specific aims, as they are listed, that information is not as important as the genotyped individuals," Offit said, citing Klausner's mandate to his subcommittee.

The mandate, contained in an April memo from Klausner, asked the subcommittee to describe the essential elements of a protocol that would "provide a mechanism to learn about the outcome for individuals who seek and who receive [cancer genetic] testing through entrance into simple longitudinal observational studies."

While several participants brought up the subject of studies on the interaction between genetic predispositions and the environmental factors, others questioned whether such studies could be performed in the context of a network aiming to determine penetrance and outcomes.

"I question whether this is the place to try to collect a large comprehensive database of environmental exposure information," said Barbara Weber, co-chair of the working group.

"I question whether we need to spend more time thinking about more innovative ways to actually come up with answers to these questions," said Weber, assistant professor of hematology/oncology at the University of Pennsylvania. "If we try to collect a huge number of data points on exposures in this setting to mesh it with the BRCA 1 & 2 mutation carriers in a way that we don't even know how to expect an outcome, will we really end up with quality data?"

The network may not be the ideal forum for answering psychosocial questions, either, Weber said.

"The question of outcomes with regard to cancer incidence and cancer prevention can only be addressed by big numbers," Weber said. "On the other hand, this may or may not be the best format to answer psychosocial questions, in the context of a big, decentralized network.

"I would raise the issue of whether by using a very simplified questionnaire you'd end up with truly the kind of data that you would want. I am not arguing strongly one way or the other, but to just consider whether a better method might be to approach [psychosocial issues] in a different way, smaller

studies, individual investigator-initiated studies that address specific points, where you don't need 6,000 people," she said.

It may be a measure of the complexity of the subject that at the end of what appeared to be a controversy-filled session, Klausner and other participants said the discussions of the working group have identified a broad consensus on genetic testing.

"There is a consensus here," Klausner said to a reported following the meeting. "The disagreements are important, but they are around the margins." Consensus is broad, albeit not complete agrees Mary Jo Kahn, a patient advocate and member of the working group.

"Consumers agree that even though the network has problems, the alternative is worse," Kahn, a member of the Virginia Breast Cancer Foundation and the National Breast Cancer Coalition, said to **The Cancer Letter**. "We agree that [measuring penetrance and outcomes] are the two research questions to be asked."

"However, we want more than that," Kahn said.

Though the working group has submitted its recommendations, it will not be dissolved, Klausner said. The group will be convened whenever NCI needs advice on issues related to cancer genetics.

A similar group is advising the Institute on developmental diagnostics, and two other groups are expected to provide guidance on preclinical models and detection technologies.

The recommendations of the patient advocates and the text of the report of the Protocol Development Subcommittee follow:

Consumer Perspective

These recommendations, developed by the Consumer Advisory Committee of the Hereditary Susceptibility Working Group of the National Action Plan on Breast Cancer, are expected to be presented Sept. 5, at a research workshop sponsored by the Action Plan.

1. The network should be more than a registry of mutation carriers. It must collect data relevant to research into the environmental factors affecting penetrance and expression of gene mutations.

2. NCI has a responsibility to establish a data collection system that provides adequate privacy protection for those tested. Ongoing discussions with consumers will be necessary to establish our trust in the system.

3. NCI must involve consumers in the development of all network protocols and informed consents.

4. To establish the accuracy of research findings, the network must be structured in a way that overcomes ethnic, racial, socioeconomic and geographic barriers to access to cancer genetics research.

5. This initiative must seek new funding so as not to not reduce the already limited funds available for services for those living with breast cancer and for breast cancer detection programs.

6. Protecting women from discrimination by employers and insurers based on their genetic information will be essential to assuring full participation of high risk individuals in genetic studies.

7. To prevent stigmatization of certain groups and to keep genetics research in perspective, a broad-based educational initiative on genetics and on the multiplicity of factors that are implicated in cancer etiology must be funded by the NCI.

8. Education concerning the potential benefits of genetic research must be undertaken, and information must be disseminated regarding who will, and who will not, benefit from genetic susceptibility testing.

9. It is urgent that research be done on the effectiveness of current surveillance and treatment options.

10. A system should be developed to coordinate which researchers should be given access to potential study participants and what information will be provided to them. Overlapping research demands may become burdensome to participants.

11. The network must be structured to assure timely access to all research results, even when those results may adversely affect the economic bottom line of the research entity.

12. The network should establish a feedback mechanism for research participants and the broader public. Consumers should be able to contact NCI with questions through an 800 number and receive a newsletter containing periodic updates. Updates should include information on known and suspected carcinogens.

13. Consumers want cancer dollars to be spent efficiently and research results maximized through coordination and cooperation among NCI, other government agencies, and private research

programs.

Protocol Development Report

The basic charge of the subcommittee was to describe the essential elements of the research protocol that would "provide a mechanism to learn about the outcome for individuals who seek and who receive [cancer genetic] testing through entrance into simple longitudinal observational studies," as described in the April 8 memorandum from Klausner to the working group.

Specific Aims of the Protocol

The protocol was envisioned as forming the common scientific mission linking "a disseminated network of health care providers and researchers" into a "cooperative research group."

The general aims of the protocol were driven by considerations of the critical data necessary to allow the most responsible public health translation of cancer genetic testing. Rapid advances in molecular genetics have culminated in the identification of major cancer susceptibility genes.

However, the clinical application of these discoveries is limited by: 1) the absence of precise data regarding the penetrance of specific mutations, and 2) the absence of data on efficacy of medical, surgical, and other interventions to prevent or detect cancers in those at hereditary risk.

For these reasons, at the initial Working Group meeting, the aims of the protocol were identified as:

1. To define the penetrance of specific mutations in cancer predisposition genes.

2. To measure clinical outcomes in mutant gene carriers after medical and/or surgical interventions, treatments, or behavioral modifications.

It was felt by the subcommittee that options after DNA testing included behavioral change (or no change), as well as medical interventions.

In addition, in those already affected by cancer, treatments may be modified based on genetic test results.

The subcommittee considered broadening the specific aims to reflect hypotheses driven by gene-gene or gene-environment interactions which were felt to be of critical scientific importance. It was concluded that these questions would best be addressed through the Cooperative Cancer Family Registries and other mechanisms, and that the network goals should be as focused as possible.

A number of ancillary aims of the network were defined:

1. Increase access to testing.

2. Develop an infrastructure to exchange educational information.

3. Develop a mechanism to standardize informed consent.

These goals could be regarded as spin-offs from the primary scientific aims indicated above, in that they were prerequisites for adequate study design.

Protocol Design

The subcommittee considered several research designs. The first was a prospective ascertainment of mutant gene carriers as well as carriers of unaltered cancer predisposition genes (controls) through a population-based longitudinal study.

Such a design would be well suited to address questions of outcomes after medical or surgical interventions (e.g. prophylactic surgery, chemoprevention, behavioral changes). However, it was observed that determination of penetrance utilizing this design could be subject to distortion by "censored events."

These "censored events could include, for example, prophylactic surgery interfering with an estimate of the breast or ovarian cancer risk in a mutant gene carrier. For these reasons, nested case control studies might be better suited for analysis of penetrance for certain syndromes. Retrospective studies, however, are also vulnerable to selection bias.

For these reasons, it was recommended by the subcommittee that the precise research design of the protocol should be flexible as long as certain features were present. Regardless of whether the design is prospective or retrospective, a basic feature of the network protocol should be a baseline clinical assessment at an initial time-point and follow-up clinical assessment(s) at later time-points for both mutant and unaltered cancer predisposition gene carriers.

These assessments, plus the genotype, should be collected in a uniform manner, and entered onto a national database specific for each hereditary cancer syndrome. The very large sample sizes achieved by a national study will allow penetrance estimates for infrequent mutations, as well as robust estimates of outcome after medical interventions in mutant gene carriers.

Enrollment In the Protocol

At a minimum, eligibility for the protocol should include all individuals seeking genetic testing for hereditary cancer syndromes, including: breast/ovarian cancer syndromes, colon cancer syndromes, multiple endocrine neoplasias, Li-Fraumeni syndrome, retinoblastoma, Wilms tumor syndromes, Von Hippel Lindau syndrome, nevoid basal cell carcinoma syndrome, neurofibromatosis, ataxia telangiectasia, and other rare cancer susceptibility syndromes.

Eligibility would include both individuals with or at risk for cancer, individuals with mutant or normal cancer predisposition genes, and individuals with or without a family history of cancer. Precise eligibility criteria for "high risk" individuals should be defined cautiously or not at all, since the phenotypes of even the common syndromes of breast and colon cancer susceptibility have not been fully defined. In addition, founder-effect mutations are still being described, defining new "high risk" groups.

While it was agreed that enrollment in the protocol should be offered to those considering genetic testing, it was unclear as to the level of follow-up of individuals who opt not to be tested. Some committee members felt that tracking of these individuals should be included, while others felt that this effort would be enormous and of unclear scientific validity for the central aims of the study. At a minimum, tracking of family members who opt not to be tested should be attempted through family history report of (genotyped) probands participating in the study. Under specific circumstances (e.g. obligate heterozygotes) these data will be useful to refine penetrance estimates.

Eligible individuals could be jointly enrolled in the Cooperative Family Registries, or in institutional IRB approved trials, etc. In these cases, the baseline and follow-up data would be a small subset of the more extensive data already collected for these studies. The vast majority of probands, however, would be enrolled by health care providers across the nation who are participating in the network, and who would not have otherwise collected these data on individuals being tested.

Enrollment would require giving of informed consent in the setting of pre-test genetic counseling. Consents could be modeled on those developed by the ELSI Cancer Studies Consortium, and should contain, at a minimum, the elements outlined in the recent Statement on Cancer Genetic Testing by the American Society of Clinical Oncology. Consents should include an option to know or not to know results. All testing should be performed in the setting of an IRB-approved longitudinal research study.

Baseline and Follow-up Data

The subcommittee agreed that the "core" data should be kept to a minimum in order for the network infrastructure to be as simple as possible. It was also recommended that common "instruments" should be utilized throughout the network so as to guarantee an ability to pool common data to give the largest possible denominators.

The following baseline clinical data were viewed as those suggested, at a minimum, to meet the two specific aims of the protocol: sex, date of birth, geographical region where born, ancestry (country of origin of ancestors), prior surgery on organ at risk, family history of cancer, personal history of cancer, history of type of treatment for cancer, status of cancer at time of enrollment.

Some committee members felt that "key" exposure data (e.g. cigarette smoking, diet) should also be collected. Most members felt that gene-environment studies would fall under the domain of other funded mechanisms. In any event, the experience of the Cooperative Family Registries suggests that such questions may add considerable length to the instruments utilized.

Follow-up data. at a minimum, should include: interval preventive or prophylactic intervention, interval development of cancer, interval treatment for cancer, interval change in family history, outcome (survival, relapse).

In additional psycho-social assessments of impact of counseling and testing were viewed as vital, but were already being addressed by a number of large studies funded by the Ethical, Social, and Legal Implications Branch of the NCHGR.

Mechanisms for Follow-up

It was concluded that mechanisms for follow-up will depend to a large part on the nature of the participating network component. Options include centralized data managers, questionnaires to primary care health care providers, exporting of data from clinical trials, etc.

Mechanisms of Confidentiality

Two general approaches were discussed:

1. Data forms contain a code which is linked to

personal identifiers in a centralized, secure database. Advantages: This allows for fidelity of data, ability for follow-up from a central source. Disadvantages: Security risks; misuse of data.

2. Key linking personal identifiers and codes reside only in hands of the enrolling health care provider, or the local institution. Advantages: Less risk for security breakdown. Disadvantages: Limited ability to track multiple members of a common kindred if the kindred is geographically dispersed; no possibility for centralized performing of follow-up.

The subcommittee discussed the pros and cons of the above two models at length, realizing that the outcome would have major implications for the informatics component. It was concluded that for a variety of reasons, including acceptability by consumers as well as large provider organizations, the increased confidentiality protection of model 2 was appealing. It was recognized that many of the potential disadvantages of each of the models could possibly be addressed by the Informatics subcommittee.

Quality of Data

Quality of genetic data, pathologic data, and clinical counseling were considered of paramount importance. The committee recommended that the network should consider including a centralized mechanism to oversee quality of testing and clinical counseling.

It was specifically proposed that a "core lab" send blinded test specimens to labs participating in the network, as a basic test of proficiency. Method of mutation detection, as well as the name of the laboratory providing testing, should be included as fields in the network database. It was proposed that the network also include specific guidelines and methods to guarantee uniform interpretation of test results and counseling. It was recommended that defined "proficiency standards" be determined by mechanisms specified by the Education Subcommittee in concert with professional organizations.

Documentation of meeting of these standards should comprise an eligibility requirement for participation of health care providers in the network. It was observed that the obtaining of this proficiency documentation would in itself serve as a major incentive for participation by health care providers in the network. With respect to pathology data, it was felt that central pathology review would be too great an effort, but that a reference pathologist at each network "hub" be recommended.

Counseling, Testing, and Preventive Services

It was recommended by the subcommittee that a two-tiered approach be undertaken to address the issue of access to services. First, it was recommended that a supplemental fund, modeled on the one created for the Tamoxifen Prevention Trial, be created to underwrite costs genotyping individuals who meet simple means tests devised to document inability to afford the cost of these studies. It was recognized, however, that the costs for many of the screening procedures commonly employed in high-risk groups (e.g. colonoscopy) are not routinely reimbursed by third-party carriers. Second, it was recommended that "hubs" of the network should be created in traditionally underserved areas, with an effort made to maximize the diversity of participants in the Network. Genetic diversity is a prerequisite for the scientific success of the study.

Friends Of Cancer Research To Launch Public Education

A newly formed coalition of cancer advocacy groups is preparing to launch a public education campaign to commemorate the 25th anniversary of the signing of the National Cancer Act of 1971.

The new group, called Friends of Cancer Research, is expected to begin a one-year campaign aimed at raising the public awareness of the need for cancer research.

"We have a focused message: the importance of cancer research," said Ellen Sigal, chairman of the new group and a member of the National Cancer Advisory Board. "We have a wide coalition of the cancer patient and professional groups, as well as some new thinkers. We are going to be selective and target the opinion leaders."

Friends of Cancer Research is planning a series of media events around the country, organized primarily by patient advocacy groups. The theme of the events would be, "Only Research Cures Cancer."

The nonprofit organization, based in Washington, DC, expects to raise $600,000 in donations to finance the campaign, Sigal said.

Financial support for the group's work has come from cancer centers, professional societies, the pharmaceutical industry, and other corporate sponsors, she said.

The Cancer Act authorized several special authorities for the NCI director, including the

director's appointment by the President. The Act was signed into law by President Nixon on Dec. 23, 1971.

Besides Sigal, officers of the group are Joseph Bertino, of Memorial Sloan-Kettering Cancer Center, John Glick, of University of Pennsylvania Cancer Center, and Ellen Stovall, executive director of the National Coalition for Cancer Survivorship.

The group hired Podesta Associates Inc., a public relations firm based in Washington, to coordinate the campaign.

Board of Directors

The board of directors of Friends of Cancer Research includes Sigal, Bertino, Glick, Stovall, Patrick Butler, an executive at The Washington Post; Paul Calabresi, President's Cancer Panel; Debbie Dingell, G.M. Foundation; John Durant, American Society of Clinical Oncology; Margaret Foti, American Association for Cancer Research; Barbara Gimbel, NCAB; Amy Langer, National Alliance of Breast Cancer Organizations; Sherry Lansing, president of Paramount; Marlene Malek, NCAB; Pearl Moore, Oncology Nursing Society; Albert Owens Jr., National Coalition for Cancer Research; Ivor Royston, San Diego Regional Cancer Center; Philip Schein, NCAB, U.S. Bioscience Inc.; John Seffrin, American Cancer Society; Dianne Shaw, NCI Cancer Centers Public Affairs Network, Lineberger Comprehensive Cancer Center; Fran Trachtenberg, WETA; Fran Visco, President's Cancer Panel; Mary Woolley, Research!America; and Robert Young, Fox Chase Cancer Center.

NCAB To Commemorate Cancer Act

In a related development, the National Cancer Advisory Board said it would work with other organizations to conduct a public education campaign to commemorate the Cancer Act.

The resolution, approved during a telephone conference call on July 29, did not refer specifically to Friends of Cancer Research.

The NCAB would conduct the campaign with "organizations whose purpose is to inform the public about the benefits of cancer research and organizations who strive to increase public understanding of the disease," the resolution said.

"The goal of the campaign would be to demonstrate the benefits of cancer research and increase public understanding of the disease through grassroots education," the resolution said.

In Brief:

George Peters Moves To UT Southwestern Center

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Medical Center, West Haven, CT, chief of Medical Oncology-Hematology at the VA, and co-director of the Developmental Therapeutics Program at Yale Cancer Center. Chu was a senior investigator at the NCI-Navy Medical Oncology Branch. The new cancer program was formed to strengthen clinical and basic research at the VA and integrate research with Yale Cancer Center programs. Emphasis will be on new drug therapies, Chu said. In addition, Yale's Developmental Therapeutics Program has recruited **Lorrin Yee**, previously an assistant professor of medicine, Rhode Island Hospital, Brown University. . . . **GEORGE PETERS**, a prominent Texas surgeon, was named executive director of the University of Texas Southwestern Center for Breast Care, and a professor of surgery at the university. Peters has been on staff and served as clinical instructor in surgery and surgical oncology at Baylor University Medical Center in Dallas since 1980. He is a past president of the American Cancer Society's Texas Division. . . . **BARBARA ANN KARMANOS** Cancer Institute at the Detroit Medical Center plans to establish the Hudson-Webber Cancer Research Center with a $7.5 million grant from the Hudson-Webber Foundation and $2.5 million from Wayne State University. The 60,000-square-foot research tower will house 300 investigators in 50 new clinical laboratories. The center plans for the building to be operational in 1998 and completed in the year 2000. The grant is part of the Institute's Cancer Care & Cure Campaign, a five-year, $75 million effort to fund new facilities, research, community outreach and education projects. . . . **RESEARCH!AMERICA**, an advocacy organization for medical research, based in Alexandria, VA, has elected four new board members: **John Seffrin**, chief executive officer of the American Cancer Society; **Jay Gershen**, acting dean, School of Dentistry, University of California, Los Angeles; **Richard Lerner**, president, Scripps Research Institute; and **David Mahoney**, chairman and CEO, Charles A. Dana Foundation, the Eleanor Naylor Dana Charitable Trust, the Dana Alliance for Brain Initiatives, and David Mahoney Ventures, New York.