THE CANCER LETTER

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NCI Disclosure of Walk-Out By DSMB May Be Harmful, Improper, Experts Say

By Paul Goldberg

In the morning of March 26, the members of the Data and Safety Monitoring Board of the National Lung Screening Trial resigned, citing the government's failure to give them protection from lawsuits that may arise in connection with the trial.

In their letter of resignation, board members wrote that their walkout was precipitated by an administrative problem, adding that "once this matter is resolved, we look forward to resuming our participation in this important trial."

Nobody knows of any lawsuits that name members of DSMBs, and

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In Brief:

Kansas Cancer Institute Gets $15M Pledge, Hires Jensen, In Bid For NCI Center Grant

ROY JENSEN, a breast cancer pathologist from Vanderbilt University, was named director of the Kansas Masonic Cancer Research Institute, previously known as the Kansas Cancer Institute, at the University of Kansas Medical Center. The Kansas Masonic Foundation made a $15 million pledge that enabled Jensen's recruitment. Also, KCI was renamed in honor of the gift. The institute's goal is to become an NCI-designated comprehensive cancer center, said University of Kansas Chancellor **Robert Hemenway**. "The combination of Dr. Jensen's arrival and the support from the Masons will lead to tremendous benefits for all of Kansas, including leading edge health care and more research dollars coming into the state," Hemenway said. "The energy that's now in our cancer research program and in all our life sciences research is impressive. We are recruiting top scientists to the Medical Center from all over the country and will continue to do so." Jensen, a native Kansan, also was named the first **William R. Jewell** Distinguished Kansas Masonic Professor in Cancer Research. The professorship was funded by a $500,000 gift from the Kansas Masonic Foundation in honor of Jewell, a surgical oncologist, founder, and director of the institute. Jewell will step down as director, but will continue to teach and practice medicine at KUMC. . . . **RONALD ALVAREZ**, professor and director of the Division of Gynecologic Oncology at the of University of Alabama at Birmingham School of Medicine and director of the Women's Cancer Program of the UAB Comprehensive Cancer Center, was elected chairman of the Integration Panel of the Department of Defense Ovarian Cancer Research Program. He succeeds **David Gershenson**, of University of Texas M.D. Anderson Cancer

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NCI Disclosure Is Invitation To Sue DSMBs, Lawyers Say

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the extent of exposure of personal assets of members of these boards remains unexplored.

The strategies for solving such problems are straightforward. In the case of NLST, a trial where DSMB members are hired as contractors, board members can get liability protection if they are rehired as "special government employees," a designation used for members of the National Cancer Advisory Board and the FDA Oncologic Drugs Advisory Committee. Alternatively, DSMB members could get protection by becoming volunteers, or the government can buy indemnity policies to cover them.

Generally, problems of this sort are resolved quietly, in part because institutions that sponsor clinical trials avoid discussion of their DSMBs, fearing that the public would perceive controversies on these boards as signs of problems with the data or safety.

NCI took a different approach: it publicized the resignation of the DSMB and its replacement with an interim board that consists of federal employees. The Institute disclosed the problem in the lead story in the April 6 issue of the NCI Cancer Bulletin, its official publication.

"If I were a plaintiff's attorney, I'd be very interested in exploring what I could do with the information that was released," said Grace Powers Monaco, an attorney and patient advocate who serves on the DSMBs of Children's Oncology Group and St. Jude Children's Research Hospital. "You can only conjecture what kind of legal exposure this information can lead to for past and present members of these boards."

It was inappropriate for NCI to publicize the resignation of the board, Monaco said. "The proceedings of data and safety monitoring boards are confidential, and the release of any part of those proceedings can be accomplished through a vote of the board, designating the audience to which this information would be provided," Monaco said. "If NCI stated that the board took a walk for a specific reason, that puts other boards on notice, which could have a chilling effect on the work of other boards. It parlays a manageable problem into a major impediment to NIH committee activity, and may jeopardize trials."

The release of this information by NCI doesn't serve the interests of DSMB members, said John Engel, an attorney with the Washington law firm of Engel and Novitt. "Thanks to NCI's dabbling in journalism, a new target has been identified for the plaintiffs' bar," Engel said. "Whatever liability issues may be confronting the DSMBs should have been addressed first by NCI in confidence, in the spirit of the DSMB process."

The disclosure constituted an invitation to sue, said Michael Clark, a healthcare lawyer with the Houston firm of Hamel, Bowers & Clark and a former federal prosecutor. "Theoretically, there is a class action suit here," Clark said. "NCI is certainly putting a spotlight on it; isn't it? The way it's going to play out is that soon you are going to have only government employees on these committees. How are you going to get qualified people to serve on these committees when you subject them to risk of being outed and turned into potential targets for lawsuits?"

NCI decided to release this information to respond to concerns raised by the lung screening trial's DSMB, said Dorothy Foellmer, chief of staff at the Institute.

"Obviously, this is an issue that's on the minds of a lot of people, for an entire group to have taken the action of resigning as a signal to NCI," Foellmer said. "This is something we need to pay attention to. Putting it into the [NCI] Cancer Bulletin is a way of letting the community know that we are aware that it's a concern, and that we will try to come up with a workable solution.

"We had hoped that we could come up with a solution very quickly, and, as it turns out, we haven't been able to come up with a quick fix that addresses all of the concerns about different mechanisms, different levels of coverage, different situations," Foellmer said. "The more time goes by, the more responsibility

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there is to be clear with the community about what's happening. I am still hoping that we will be able to get this resolved quickly, but I really don't know how long it will take."

Foellmer said NCI is trying to determine the magnitude of the problem, and was unable to project how soon the problem would be resolved.

Some members of DSMBs are protected by the government, she said. "There are some people who serve on these committees who are covered by their institution, and know they are covered," she said. "There are some people who are covered by their institution and don't know whether they are covered.

"I think the only thing that changed is the heightened level of concern. The issue has been there, but it's probably more a reflection of a more litigious society that's driving the concern rather than any precedent."

Foellmer said there was no concern about the disclosure harming the trial, "because we had already put an interim DSMB in place." Asked about the risk of inviting litigation by making the disclosure, Foellmer said, "I don't know. I haven't had those conversations."

"A Global Issue"

"My view is that it's a global issue, not just for NCI, but I bet you the same sort of vulnerability exists throughout NIH, and there is an assumption on the part of people who participate in things like this that the risk would be covered by the federal government," said Robert Young, president of Fox Chase Cancer Center and chairman of the oversight committee for NLST.

Young said the government should protect board members and their institutions from such risk.

Similar problems may affect the DSMB members at cooperative groups. Like NCI and its contractors, most cooperative groups offer no liability protection to DSMB members. The question of liability was raised on April 2, during the meeting of the DSMB for the Stud of Tamoxifen and Raloxifene, conducted by the National Surgical Adjuvant Breast & Bowel Project.

DSMBs should be independent committees formed to monitor data through the duration of studies, to determine whether continuation of studies is appropriate scientifically and ethically.

Though NIH and FDA have issued guidance documents on these boards, they aren't defined in any federal regulations, and it's unclear who should form these groups, who should serve on them, and how often they should meet. Requirements for disclosure and reimbursement also vary. In some cases, at cooperative groups, DSMB members serve with no contractual agreements, sources said.

Though the problem of liability protection may be global, NCI chose to disclose it in the context of NLST, a trial that compares survival in 50,000 current or former smokers screened with spiral CT or chest x-rays.

The question was first raised by Sylvan Green, chairman of the DSMB and professor of public health and director of biometry at the Arizona Cancer Center. Sources said Green requested information on liability of DSMB members sometime in early March, and the question was quickly forwarded to NIH attorneys.

As contractors, board members couldn't be assured of protection, attorneys said.

The Federal Tort Claims Act covers government employees, special government employees, and volunteers.

"Therefore DSMB members serving as volunteers should be covered, subject to the Department of Justice approval," NIH spokesman Don Ralbovsky said to **The Cancer Letter**.

Though the law doesn't cover contractors, the decisions of the DSMB would be defended by the government regardless of the board's composition. "The decision to defend individual non-employees or contractors would be made by the Department of Justice if and when a lawsuit arises," Ralbovsky said.

The memo from NIH attorneys was dated March 22, sources said.

Sources said John Gohagan, the widely respected project officer on the trial, flagged the problem for his supervisor, Peter Greenwald, director of the Division of Cancer Prevention.

The NCI Executive Committee would have been the perfect venue for addressing this problem, but the DSMB meeting was scheduled for Friday, March 26, and the next Executive Committee meeting was scheduled for Tuesday, March 30.

At the time, many NCI officials, including Greenwald and Institute Director Andrew von Eschebach were leaving for the annual meeting of the American Association for Cancer Research in Orlando.

Board Members Learn of Problem on March 26

Though Green was interested in the question of liability protection, members of his board said they first learned about the potential problem in the morning of March 26.

"It was an issue that had never even crossed my mind, and I think it had been a tacit assumption that those

sorts of issues were taken care of," said DSMB member David Johnstone, a cardiothoracic surgeon at the University of Rochester Medical Center. "Looking back on it, I guess I assumed that it had been addressed."

Though discussion of liability protection was placed on the agenda of the DSMB, Green chose not to convene the board, and raised the question outside the meeting, delineating this administrative issue from issues connected with the trial.

After the trial project officer Gohagan relayed the answers of the NIH attorneys, he was asked to leave, and the board members met separately to consider their options.

"They certainly weren't prepared to fix that problem prior to convening the meeting," Johnstone said. "The decision was difficult for us to make. Though we perceived the liability risk as a very small one, we felt strongly that it needed to be resolved before we proceeded, and the most logical way to behave at that point was to terminate our status with the trial, pending the correction. We decided that until that was clarified, we didn't want to expose ourselves to personal liability."

DSMB member Joe Selby, director of the division of research at Kaiser Permanente for Northern California, said he, too, first became aware of the problem the day of the meeting.

"We spent a good deal of time deliberating it, but in the end, we did conclude that the most reasonable step was just to call a brief halt to our participation until this could be dealt with," he said.

While Gohagan and NCI staff waited outside, the board composed a letter of resignation.

"John was not in the room when that discussion took place, nor was he present when the letter was being composed," said Robert Mayer, a member of the DSMB and director of the Center for Gastrointestinal Oncology and vice chairman for academic affairs in the department of medical oncology at the Dana-Farber Cancer Institute. "The members of the committee—myself included—were concerned that, at a time when the data were beginning to emerge from the study, such a situation was unacceptable."

Board members said their actions had nothing to do with the data or the conduct of the trial, and that they wanted to return as soon as the liability problem was solved.

"The whole issue regarding this meeting and the resignations is a tempest in a teapot," Mayer said. "None of the members of the DSMB have any desire to do anything other than serve on this committee, and we look forward and anticipate rejoining the effort as soon as the liability issues are clarified."

"It had nothing to do with the data," said Russell Harris, associate professor at the University of North Carolina Lineberger Comprehensive Cancer Center. "This is a very important trial, and it's very important that this action not hurt the trial. The people already involved with this trial are doing a great job. That's not what it's all about."

Members of the DSMB receive a small honorarium, $60 an hour. With some board members requiring up to two unreimbursed travel days, this is a nominal payment. Yet, while board members were willing to devote their time to this endeavor, they were unwilling to risk their personal assets.

"The key issue is that we were personally liable if someone sued the study for some reason, and had included us," Harris said. "I wasn't representing any institution. I am a part of UNC, but my participation on the board had to do with me participating as an individual. If there were some way that I could simply volunteer, and not be paid a penny, I would do that.

"I am hopeful that there is a way it will be worked out," Harris said. "This has nothing to do with making money."

Unlike treatment trials, which specify follow-up and therapy, NLST leaves work-up to the judgment of physicians as they try to interpret the clinical meaning of small nodules in the lungs of trial participants. The Prostate, Lung, Colorectal & Ovarian Cancer Screening Trial, a study of 154,000, similarly refrains from prescribing and controlling follow-up.

"[NLST] is one of the most important trials going these days," said DSMB member Selby. "This is a technology that wants to proliferate, and it would probably like to proliferate before the trial results are in.

"If helical CT works and really does reduce mortality from lung cancer, that would be a really major contribution to public health. On the other hand, it's entirely uncertain whether it does.

"It's a perfect setting for a trial, and this is a very well designed trial. But in both arms of the trial, because of the complete uncertainty, either finding nodules or not finding nodules could lead to adverse events," Selby said.

"Until the trial is done, we will not truly know whether the right thing was to screen, treat, or observe when something is found. But lawyers will not be willing to wait until the end of the trial. They will try to convince juries that clinicians and the DSMBs should have known

what to do in advance.

"That's the irony: this trial is perfectly timed, because of the complete uncertainty of benefits versus the risks of this screening, but it will not come out that way when we get to court."

No Pressure To Disclose

NCI was under no pressure to announce the NLST board's resignation.

The trial had completed accrual, and the data were starting to come in. The DSMB members were eager to return to the board, and therefore motivated to refrain from discussion of their action.

Since DSMBs usually operate outside public view, it is unlikely that any publication would have written about the board's resignation. It was too deep inside the Institute to attract attention, and seemed to be a manageable administrative problem.

Making the disclosure, the NCI Cancer Bulletin apparently misrepresented that DSMB chairman Green had "explained" that the board resigned "because individual members do not have liability insurance coverage as part of the professional services contract under which they were secured for the trial."

This is inaccurate, said board members who were present during the closed-door discussion. DSMB members were concerned about the lack of legal protection, not the absence of "insurance coverage." Clearly, Green, who raised the question of liability in the first place, knows the difference.

While it's possible that liability insurance could solve the problem, the committee had no solution to recommend.

"It's an administrative issue involving DSMBs at NCI, and I have no information on it," Green said to **The Cancer Letter**.

Young said he didn't know why NCI decided to publicize the board's resignation.

"I don't know the answer to that, except that I think they felt that it would be made public in **The Cancer Letter**, and they wanted to get ahead of the wave on it," he said.

The Aftermath

Von Eschenbach first learned about the board's resignation while he was at the AACR meeting, Young said.

"I got an email from Andy, who was at AACR at the time, saying that this is a new issue, and we need to take some steps, and I want to talk to you about it," said Young. "Obviously, Andy realized that this was a serious problem."

Recently, Young took part in a meeting that included von Eschenbach, Foellmer, Deputy Director Karen Antman, Division of Cancer Treatment and Diagnosis Director James Doroshow, and several NIH lawyers.

"My understanding is that they are going to go the route first of trying to simply build in this kind of insurance in the contract through which these people were hired," Young said. "If that doesn't work, they will probably go the temporary government employee route. The other mechanism that exists is that they can be volunteers."

The special government employee status has the drawback of requiring extensive disclosures and annual ethics training, while the volunteer status may preclude travel reimbursement, sources said.

"This needs a global solution, but in order to get a global solution, you need to bring it to the attention of people who are capable of doing that," said Young.

Global solutions take time, Foellmer said.

"The problem with trying to put a new process or procedure in place, you've got to look at it from all possible angles, so you don't make a decision to move in some direction, and find out later that there is some unanticipated complication," Foellmer said. "It could be that there is not just one answer. It could be that, depending on the way the trial is funded, or where the actual jurisdictional responsibility is for convening the DSMB, could be a factor.

"We still don't know exactly where the problem exists," Foellmer continued. "Apparently, for this particular DSMB, because of the way people were engaged, this was an issue, where it perhaps isn't an issue in other situations, where people are brought in differently.

"That's part of the challenge here," Foellmer said. "We are still in the phase of trying to figure out how much of a problem this is, and then, more broadly, what's being done across NIH. We certainly don't want to do anything that will be out of line with where NIH is going.

"It clearly is an issue that goes beyond cancer," Foellmer said. "So, maybe somebody else has come up with other ways of addressing this problem that we are just not aware of. And we are actively trying to get this information."

Foellmer said NCI is exploring the possibility of buying liability insurance through a contractor to enable the lung screening trial DSMB to return. "As far as I know, we don't have an answer yet," she said.

Gohagan Reassigned

The Institute has reassigned Gohagan from his position as chief administrator of NLST and PLCO.

"NCI is in the process of making some changes in management aspects of NLST and PLCO," Greenwald said in a statement. "Managing NLST and PLCO is an intense job. I have great respect for Dr. John Gohagan, and believe that with these changes, he will be able to continue his scientific participation in NLST and PLCO, as well as work on other important issues for DCP."

Greenwald said Gohagan's work has been exemplary. "For more than 10 years, since before accrual began to the PLCO trial in 1992, Dr. Gohagan has provided scientific leadership and experienced management of the PLCO and the NLST trials."

Foellmer declined to discuss the reasons for Gohagan's reassignment. Gohagan, too, declined to discuss the matter.

Mayer said he was saddened by Gohagan's departure as the project officer.

"All of us serve on the DSBM, in essence, in a voluntary way," Mayer said. "Particularly for me, joining yet another DSMB was in large part due to my respect, gathered over the years, for John Gohagan, for his forthrightness, clarity of thought, respect within the scientific community, and general collegiality. I also find him someone who critically views the big picture in looking at cancer screening, and has a very good sense for reality, the limits of trials of this sort, and where we ought to be going in the future.

"I, for one, will miss him greatly."

Gene Therapy:

NIH, FDA Open Web Site For Adverse Event Reporting

NIH and FDA have formed a Genetic Modification Clinical Research Information System (GeMCRIS) to improve the reporting and analysis of adverse events on gene therapy trials.

The agencies said the Web-based GeMCRIS will enable patients, research participants, scientists, sponsors, and the public to become better informed about human gene transfer research. GeMCRIS users can learn where trials are taking place, which diseases or health conditions are being studied, and what investigational approaches are being taken.

Investigators and sponsors conducting human gene transfer trials will be able to report adverse events using a secure electronic interface. The GeMCRIS site is available at: www.gemcris.od.nih.gov/.

Funding Opportunities:

RFPs Available

RFP N02-CM-47030-45: Manufacture of Oral and Topical Dosage Forms

Response Due Date: June 30

Pharmaceutical Resources Branch, NCI Division of Cancer Treatment and Diagnosis, is seeking contractors to furnish services for formulation, manufacture, analysis, packaging and labeling of pharmaceutically acceptable oral and topical dosage forms of new anticancer agents in support of NCI-sponsored clinical trials. The most common dosage forms will include capsules, tablets, enteric-coated tablets, ointment and cream. The contractor will perform formulation and process development, manufacture and controls, packaging and labeling of oral and topical drug products to be used in clinical trials. Batch sizes will range from very small batches required for toxicology studies (e.g. 100s of capsules), to larger batches required for Phase II clinical trials (e.g. several thousand capsules or tablets). Data obtained from the contractors will be used to prepare IND application to submit to the FDA. The RFP is available at http://www.fbodaily.com/archive/2004/04-April/10-Apr-2004/FBO-00562360.htm.

Inquiries: Kathy Giuliano, phone 301 435-3821; fax 301 402-6699; e-mail kg109o@nih.gov.

RFP N02-PC-45002-61: Surveillance Support Services for NCI

Response Due Date: May 17, 2004

NCI Division of Cancer Control and Population Sciences anticipates making four awards for Task Order Contracts. The contractors that receive a basic contract award will compete for specific Task Order requirements as they are developed. The RFP is available at http://www.fbodaily.com/archive/2004/04-April/07-Apr-2004/FBO-00559953.htm.

Inquiries: Charles Jackson, phone 301-435-3829; fax 301-402-8579; e-mail cj14k@nih.gov, sh191h@nih.gov; or Susan Hoffman, phone 301-435-3799, fax 301- 402-8579.

RFP N01-CM-37039-19: Preclinical Toxicology and Pharmacology of Drugs Developed for Cancer, AIDS and AIDS Related Illnesses

NCI Developmental Therapeutics Program is seeking organizations to carry out pharmacology and toxicology studies, the data from which must be suitable for filing with FDA part of IND applications. Work assignments will be issued under cost-reimbursement completion contracts. Assignments are estimated to involve two to three chemical agents annually per contract. Offerors are required to propose both levels of effort (64,015 and 127,960 hours over a 7 year period). RFP is available at http://www.fbodaily.com/archive/2004/04-April/09-Apr-2004/FBO-00562158.htm.

Inquiries: Diane Stalder, phone 301- 435-3822; e-mail ds88b@nih.gov, mg345x@nih.gov or MaryAnne Golling, phone 301-435-3819.

RFAs Available

RFA-CA-05-009: The Early Detection Research Network: Biomarker Reference laboratories

Letter of Intent Receipt Date: July 16, 2004

Application Receipt Date: Aug. 16, 2004

NCI Division of Cancer Prevention invites new and competing renewal cooperative agreement applications to develop, evaluate, and validate of biomarkers for earlier cancer detection and risk assessment. Biomarkers are defined as cellular, biochemical, and molecular (genetic and epigenetic) alterations by which a normal or abnormal biologic process can be recognized or monitored. Biomarkers are measurable in biological media, such as in tissues, cells, or fluids. The Network has four main components: Biomarker Developmental Laboratories, Biomarker Reference Laboratories (formerly known as Biomarker Validation Laboratories), Clinical Epidemiology and Validation Centers (formerly known as Clinical and Epidemiologic Centers), and a Data Management and Coordinating Center. The BDLs have responsibility for the development and characterization of new or the refinement of existing biomarkers and assays. The BRLs serve as a Network resource for clinical and laboratory validation of biomarkers, which include technological development and refinement. The CECs collaboratively conduct clinical and epidemiological research on the Network-wide clinical validation of biomarkers. The DMCC supports statistical and computational analysis and informatics infrastructure and coordinates network-wide meetings and conferences. The RFA will use the NIH Cooperative Agreement U24 award mechanism. The RFA is available at http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-05-009.html

Inquiries: Sudhir Srivastava, phone 301-435-1594; e-mail srivasts@mail.nih.gov. and Jacob Kagan, phone 301-496-8397; e-mail kaganj@mail.nih.gov.

NOT-AI-04-024: Inter-Institute Program for the Development of AIDS-related Therapeutics

Letter of Intent Receipt Date: May 1, 2004

Application Receipt Date: June 1, 2004

The IIP, which is co-sponsored by the National Institute of Allergy and Infectious Diseases and NCI, invites investigators to submit proposals to facilitate the pre-clinical development of: 1) therapies for the treatment of HIV disease, AIDS-associated malignancies, opportunistic infections and tuberculosis associated with AIDS, and 2) microbicide-based prevention strategies for HIV. IIP does not fund grants. Instead, applications to the program are requests to use IIP drug development resources to conduct specific tasks the applicants themselves are unable to carry out in their efforts to translate basic research findings to applied or clinical practice. Examples of tasks that may be requested include High Throughput Screen assay development, evaluation in animal efficacy models, GMP scale-up synthesis of small molecules and biologics, clinical dosage formulation and manufacturing, and GLP toxicology. Program proposals are solicited on June 1 and Dec. 1. Information is available at http://dtp.nci.nih.gov/docs/dart.html.

Inquiries: Inter-Institute Program Coordinator, phone 301-496-8720; e-mail iip@dtpax2.ncifcrf.gov.

NOT-CA-04-011: Notice of Availability of Administrative Supplements for Disseminating Evidence-Based Intervention Research Products

NCI requests applications for administrative supplements for NCI-funded cancer control intervention research R01, P01, P50, U01, and U19 grants. The supplements provide 1-year funding to cancer control investigators whose intervention efficacy data have been analyzed and who are conducting peer-reviewed research (with an active NCI grant award) related to the intervention program proposed for dissemination. Intervention research across the cancer control continuum that may be eligible for these supplements, includes: tobacco use prevention and cessation; promotion of appropriate changes in diet and physical activity; reduction of sun exposure and ultraviolet radiation exposure; facilitation of informed decisions about genetic testing for cancer susceptibility; enhancement of screening for breast, cervix and colorectal cancers; quality of care; and improvements in coping skills and quality-of-life for cancer survivors and their families.

The earliest anticipated award date for this program will be Sept. 1, 2004. Inquiries should be addressed to the NCI Program Director for the particular R01, P01, P50, U01, or U19 for which the supplement is being requested.

Inquiries: Jon Kerner, deputy director for research dissemination and diffusion, Division of Cancer Control and Population Sciences, phone 301-594-7294; e-mail jon.kerner@nih.gov.

Program Announcement

PAS-04-079: Understanding and Preventing Brain Tumor Dispersal

Applications should focus on either: (1) determining the causes of brain tumor dispersal; (2) understanding the interactions of migrating tumor cells with normal brain elements; or (3) developing interventions that target migrating tumor cells. Analysis of either pediatric or adult brain tumors is appropriate. Studies that apply insights from other fields (e.g. developmental neuroscience, glial cell biology, stem or precursor cell biology) to the analysis of tumor spread are within the scope of this PAS and are encouraged. Translational studies using cell or animal models of brain tumor migration to test possible therapeutic interventions are also encouraged. The PAS is intended to promote interdisciplinary collaborations, as well as interactions between basic scientists and clinicians. The PAS will use the NIH R01 and exploratory/developmental grant R21 award mechanisms. The PAS is available at http://grants.nih.gov/grants/guide/pa-files/PAS-04-079.html.

Inquiries: For NCI--Steven Krosnick, Clinical Grants and Contracts Branch, Cancer Therapy Evaluation Program, Division of Cancer Treatment and Diagnosis, phone 301-496-8866; e-mail krosnicks@mail.nih.gov.

In Brief:

Edge Elected To NCCN Board; Boman Heads Colon Ca Group

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Center. . . . **STEPHEN EDGE,** professor of surgery at the State University of New York at Buffalo School of Medicine and Biomedical Sciences, was elected to the National Comprehensive Cancer Network board of directors executive committee. Edge is chairman of the Breast and Soft Tissue Surgery at Roswell Park Cancer Institute, as well as medical director of the Lymphedema Treatment Program, and co-director of the Breast Cancer Risk Evaluation Program at Roswell Park. . . . **BRUCE BOMAN** was elected president of the Collaborative Group of the Americas on Inherited Colorectal Cancer for 2003-2004. Boman is professor of medicine and of immunology and microbiology and director of the Division of Genetic and Preventive Medicine at Jefferson Medical College of Thomas Jefferson University. He directs the Hereditary Cancer and the Gastrointestinal Cancer Program at Jefferson's Kimmel Cancer Center. . . . **SHARON COHEN,** vice president for government relations and chairman of the health care cluster at the Biotechnology Industry Organization, has joined PodestaMattoon, a government affairs and public relations firm based in Washington, D.C. She will serve as a lead lobbyist and manage the federal government relations department. . . . **EPPLEY Cancer Center** at the University of Nebraska Medical Center has added two faculty members. **Marcel DeVetten,** of the School of Medicine, Blood and Marrow Transplantation Program at West Virginia University, was named assistant professor of medicine and head of the Allogeneic Transplantation Program. **Tadayoshi Bessho,** of the Institute for Biotechnology at the University of Texas Health Science Center in San Antonio, was named assistant professor. . . . **EHAB HANNA** has joined M. D. Anderson Cancer Center as professor and co-director of the skull base tumor program in the Head and Neck Center. Hanna was professor and vice-chairman of the Department of Otolaryngology, Head and Neck Surgery at the University of Arkansas for Medical Sciences. Hanna will work with **Franco DeMonte,** director of the Department of Neurosurgery, to coordinate the skull base tumor program. . . . **CANCER RESEARCH and Prevention Foundation** has published the Digest of Innovative Strategies, aimed at increasing screening rates among diverse and underserved populations. The digest is available through CRPF at phone 703-836-4412 or www.preventcancer.org/colorectal/conference

. . . . **ARMAND KEATING**, chief of medical services at Princess Margaret Hospital/Ontario Cancer Institute, was elected president of the American Society for Blood and Marrow Transplantation. He is also director, Division of Hematology at the University of Toronto, and professor and head of the Department of Medical Oncology and Hematology. **Nelson Chao**, professor of medicine and director, Division of Hematology at Duke University Medical Center, is president-elect, and will assume the presidency in 2005. **Robert Negrin**, associate professor of medicine and director, Division of Bone Marrow Transplantation at Stanford University, was elected vice president, to become president in 2006. **Daniel Weisdorf ,** professor of medicine, University of Minnesota, director of the Adult blood and Marrow Transplant Program, was re-elected secretary. Newly elected directors are: **Claudio Anasetti**, Fred Hutchinson Cancer Research Center; **Samuel Silver**, University of Michigan, Ann Arbor; **Robert Truitt**, Medical College of Wisconsin Cancer Center. . . . **ASBMT** and five other stem cell therapy and blood and marrow transplant organizations have adopted a unified policy for legislative and regulatory advocacy. The platform includes seven areas of common interest: access to care, cost of care, patient and donor rights, confidentiality, clinical research, safety, and patient and public awareness and education. The policy was developed to help the organizations act as a coalition. The five other groups include American Association of Blood Banks, Foundation for the Accreditation of Cellular Therapy, International Bone Marrow Transplant Registry/Autologous Blood and Marrow Transplant Registry, International Society for Cellular Therapy, and National Marrow Donor Program. . . . **PATRICIA NEWMAN**, former chief of the NCI press office, retired after 33 years with the Institute. She joined the press office in 1971 as a science writer, and in 1981 was named chief of the press office. In 2001, she joined the NCI Center to Reduce Cancer Health Disparities to coordinate its communications. Starting in 1999, she also served as program advisor to the planning committee for the President's Cancer Panel. . . . **CONSTANCE PERCY**, 89, a former NCI statistician, died March 24 of lung cancer at her home in Rockville, Md. Percy joined NCI in 1970 and worked for 31 years on cancer nomenclature and classification standards, and was instrumental in the development of the Surveillance, Epidemiology, and End Results Program. Before joining NCI, she worked at the American Cancer Society for 22 years. She was on the research team that produced the study linking smoking with lung cancer and heart disease.

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