THE CANCER LETTER

Vol. 23 No. 3
Jan. 24, 1997

Price $265 Per Year US
$285 Per Year Elsewhere

PO Box 9905 Washington DC 20016 Telephone 202-362-1809

New CEO Brings Managed Care Expertise To Network Of Academic Cancer Centers

William McGivney, an insurance company executive, was named CEO of the National Comprehensive Cancer Network, an organization formed by 15 academic cancer centers to enhance their ability to compete for managed care contracts.

McGivney, vice president for clinical and coverage policy at Aetna Health Plans, replaces Bruce Ross, who led NCCN through its initial two years, as the network recruited new members, drafted its clinical

(Continued to page 2)

In Brief

Friends of Cancer Research Honor Specter; Dole Tapes Announcement For CaP CURE

SEN. ARLEN SPECTER (R-PA) received an award from **Friends of Cancer Research**, a non-profit organization formed to mark the 25th anniversary of the signing of the National Cancer Act. Specter, chairman of the Labor, HHS & Education Appropriations Subcommittee, received at the award at the Fox Chase Cancer Center... **BOB DOLE**, a prostate cancer survivor and former senator and presidential candidate, recorded a public service announcement for CaP CURE, an organization started by the financier **Michael Milken**. "I may have lost the race to the White House, but five years ago I won an important one against prostate cancer," Dole says in the announcement. "For me, early detection was the key, so I urge all men to discuss prostate cancer with their doctors. Every 90 seconds a man in America is diagnosed with prostate cancer. We need more intensive research to find a cure."... **PAUL TSONGAS**, the former senator who briefly became the Democratic presidential front-runner in 1992, died Jan. 18 of pneumonia. He was 55. Running for the presidency after having been treated for non-Hodgkin's lymphoma, Tsongas drew attention to the issue of a candidate's health disclosure. He won the New Hampshire primary in February 1992 and went on to win in Maryland, Utah, Arizona, Massachusetts and Rhode Island. He quit the race in March. Tsongas was elected to Congress in 1974 and served two terms before his election to the Senate in 1978. . . . **NATIONAL HUMAN** Genome Research Institute is the new name of the NIH National Center for Human Genome Research after HHS Secretary **Donna Shalala** signed documents Jan. 14, giving institute status to the center established seven years ago. With the new status, the Institute can better form collaborations with

(Continued to page 4)

NCCN's Next Step: Marketing The Services Of Centers

(Continued from page 1)

guidelines, and developed outcomes research capabilities.

Ross, who resigned effective Dec. 31, is scheduled to undergo kidney transplant surgery at Johns Hopkins University Hospital March 18.

McGivney's skills and connections are very different from Ross's. Ross, who came to NCCN after retiring from Bristol-Myers Squibb, brought to the table his strong personal connection to the key players in academic oncology and the pharmaceutical industry.

McGivney, by contrast, brings an expertise and contacts in managed care, technology assessment and public policy.

"I think our two most significant accomplishments were the treatment guidelines and the beginning of the outcomes studies," Ross said to **The Cancer Letter.** "Now it is up to Dr. McGivney to take the network to the next level: marketing the services of our 15 cancer centers."

Ross, who will remain a consultant to NCCN, was a member of the search committee that selected McGivney.

"Were it not for health issues, I am sure Bruce would have continued," said Robert Young, vice chairman of NCCN and president of the Fox Chase Cancer Center.

"What Bruce brought to the organization was a wonderful ability to translate a business outlook to institutions that have been organized along scientific and academic lines. What Dr. McGivney brings is in-depth expertise from the insurance side, and the knowledge about national insurance strategies and marketing," Young said.

Common Theme: Outcomes Data

McGivney has stated consistently that academic cancer centers and managed care companies have a common interest: developing the capability to make decisions based on outcomes data.

"Both communities, in terms of decision-making, are interested in basing their decisions on outcomes data, and that's a common theme that we need to sit down and talk about more," McGivney said to **The Cancer Letter.**

"There is a potential for a better relationship, if you can get by some of the historical standoffishness and doubts about the other side," he said.

McGivney said NCCN marketing will be aimed at insurance and managed care companies as well as employers.

"Employers are always willing to sit down and listen to issues being raised by exactly what type of care they are buying," McGivney said. "I think they are a very important audience for NCCN, and I intend to make them a major focus of our early days and months there."

McGivney, who holds a Ph.D. in pharmacology, has had considerable impact on issues of managed care, technology assessment and drug approval issues.

Before coming to Aetna, as head of technology assessment at the American Medical Association, McGivney was in charge of developing the AMA position on the FDA's Treatment IND program, which applied primarily to AIDS drugs. In 1989, for his role in advocating the program, McGivney received the FDA Commissioner's medal of appreciation.

Soon after joining Aetna in 1991, McGivney developed the company's terminal illness program, which has since been recognized as a method for determining appropriateness of high-cost treatments, including bone marrow transplantation.

Aetna uses outside experts to review many such cases. Experts are selected by the Medical

THE CANCER LETTER

Founded 1974
Member, Newsletter Publishers Assoc.

Editors: **Kirsten Boyd Goldberg, Paul Goldberg**
Founder: **Jerry D. Boyd**

P.O. Box 9905, Washington, D.C. 20016
Tel. (202) 362-1809 Fax: (202) 362-1681
Editorial e-mail: kirsten@www.cancerletter.com
Subscriptions: subscrib@www.cancerletter.com
World Wide Web URL: http://www.cancerletter.com

Subscription $265 per year US, $285 elsewhere. ISSN 0096-3917. Published 48 times a year by The Cancer Letter Inc., also publisher of The Clinical Cancer Letter.

Ombudsman Program, a Bethesda, MD, based company. Case review is carried out by panels of three experts, and if one of the experts states that the patient has a reasonable chance of benefiting from the treatment, the insurer provides coverage.

The "ombudsman" concept was developed by Grace Powers Monaco, a lawyer and patient advocate. Monaco first applied the concept in volunteer programs of the Candlelighters Childhood Cancer Foundation, and, more recently, in the Chilhood Cancer Ombudsman Program of the Childhood Brain Tumor Foundation of Woodbridge, VA.

"Bill was familiar with the ombudsman program, and he specifically sought me out to suggest that I develop a commercial program with ombudsman features," Monaco said to **The Cancer Letter.** "I doubt that I would have thought to try out this application if it hadn't been for his urging."

Aetna became the ombudsman program's first client. Now, the program provides peer review panels selected on rotation by specialty for over 100 clients, typically insurers, employers and managed care programs. Altogether, 485 medical specialists, most of them academics, review the potentially contentious cases.

Monaco said the process facilitates patent access to appropriate care while reducing the employers' exposure to litigation. Monaco said she is aware of fewer than 20 of the 4,500 cases reviewed by MCOP going on to litigation.

"The same determination to provide appropriate care that carried Bill through the pioneering work he accomplished for Aetna will carry him through his new assignment," Monaco said. "I don't know of anyone more qualified to blend scientific integrity *with patient care concerns.*"

"Natural Alliance"

The ombudsman review process has become a model for managing terminal illness. Late last year, California passed a law that requires every health care service plan and insurer in California to establish the process of independent review.

The review process described in the Friedman-Knowles Experimental Treatment Act of 1996 mirrors that of Monaco's program. McGivney was among the witnesses who testified at legislative hearings that preceded the passage of the law.

"It's not rocket science," said McGivney about the review program. "It's simple, fair, and objective, and it's a model that took hold."

Two years ago, as he took part in a panel discussion at the American Society for Clinical Oncology, McGivney was asked what he thought of the emerging NCCN.

"I think it's an excellent idea," McGivney said at the time (**The Cancer Letter,** June 2, 1995). "We are doing a similar thing nationally with cardiac care."

Aetna's program, called "centers of excellence" ended up setting up a network of academic medical centers in cardiology and organ and bone marrow transplantation.

"I think there is a natural alliance [between managed care companies and academic cancer centers] because of our orientation on outcomes-based decision-making," McGivney said at the time.

McGivney said that while academic cancer centers are not the lowest cost providers, the care they provide is more likely to be appropriate, he said. "Our problem with patient selection criteria is not with the academic institutions; it's with the community cancer centers out there, which are not keeping up with the data in certain areas."

McGivney's move to NCCN coincides with Aetna's merger with US Healthcare.

Though the merger has altered the programs he oversees, McGivney said his decision to change jobs is based on the attractiveness of the NCCN job.

"I am interested in learning new things," he said to **The Cancer Letter.** "This is an opportunity to work with the premier institutions, to apply my knowledge of the inner working of managed care, contracting with major institutions, technology assessment, development of coverage policy, outcomes research, an development of public policy.

"These are all things that NCCN has been involved in, but their activity and visibility in these areas need to be enhanced," he said.

The impact of NCCN could go beyond its 15 member institutions, McGivney said.

"I think cancer will be a model of how managed care companies eventually will deal with specialty care," he said. "It's a critical time in terms of establishing how these premier institutions are going to be utilized in our nation's new health system.

"It's important that their viability, productivity and their ability to provide care to patients be

enhanced .

"These premier institutions embody what this country needs in terms of cancer clinical research, and I think cancer will lead the way and will be the model on how patient care costs will be covered in other areas.

"This is an opportunity to do a lot of good," McGivney said. "That's the bottom line."

NCCN includes City of Hope National Medical Center, Dana Farber Cancer Center, Fred Hutchinson Cancer Research Center, Fox Chase Cancer Center, Johns Hopkins Oncology Center, M.D. Anderson Cancer Center, Memorial Sloan-Kettering Cancer Center, Northwestern University/Lurie Cancer Center, Roswell Park Cancer Institute, Ohio State University Comprehensive Cancer Center, Stanford University Medical Center, St. Jude Children's Research Hospital, University of Michigan Comprehensive Cancer Center, University of Nebraska Cancer Center, and the University of Alabama Cancer Center.

NCCN, based in Philadelphia, will hold its second conference on practice guidelines at Fort Lauderdale March 2-5. For additional information, contact PRR Inc. 516/4248900, ext. 813.

In Brief

North Carolina Honors Pagano; White House Selects Awardees

(Continued from page 1)

industry, academia and international organizations, and its director, **Francis Collins**, will have equal standing with other institute directors, NIH said in a statement. . . **JOSEPH PAGANO**, Lineberger Professor of Cancer Research and director, UNC Lineberger Comprehensive Cancer Center, received the 1996 North Carolina Award in Science, the state's highest civilian honor. The award was presented by **Gov. Jim Hunt**. . . . **TEN NIH GRANTEES** were selected by the White House Office of Science and Technology Policy to be among 60 individuals to receive the Presidential Early Career Award for Scientists and Engineers. The NIH nominees were selected from investigators receiving their first R29 or R01 grant. The NIH awardees are: **Ali Hemmati-Brivanlou**, Rockfeller Univ.; **Allison Jane Doupe**, Univ. of California, San Francisco; **Paul Khavari**, Stanford Univ.; **Aron Lukacher**, Emory Univ.; **Deirdre Meldrum**, Univ. of Washington; **Lee Niswander**, Sloan-Kettering Institute for Cancer Research; **David Self**, Yale Univ.; **Morgan Sheng**, Massachusetts General Hospital; **Mark Walter**, Univ. of Alabama at Birmingham; and **Keith Woerpel**, Univ. of California, Irvine. . . . **SUSAN BAIRD**, former director of nursing and patient care services, Fox Chase Cancer Center, was named vice president of publications for Meniscus Limited, of Bala Cynwyd, PA.

Funding Opportunities

ONS Fatigue Initiative Offers Instrumentation Grants

The Oncology Nursing Society's Fatigue Initiative Through Research and Education invites applications for targeted grants that will support the development of instruments to assess cancer-related fatigue in clinical settings.

Application deadline is June 1. A required letter of intent is due April 15. The letter must include names and institutional affiliations of members of the research team, including consultants, list of potential research sites, and tentative aims of the research project.

Three grants of $50,000 including 10% indirect costs are available. The funding period is from Oct. 1, 1997 to Sept. 30, 1998. The principal investigator must be a registered nurse actively involved in some aspect of cancer patient care, education or research.

To advance the clinical assessment of cancer-related fatigue, instrumentation studies are needed in many areas, including but not limited to: the development of new clinical assessment tools or the revision of existing tools; the adaptation of research-oriented instruments for use as clinical assessment tools; the development of clinical tools for use by non-English speaking populations; and the examination of the psychometric properties of new or revised instruments, including feasibility, compliance, reliability and validity, sensitivity and patient burden. Preference will be given to multi-institutional projects that include the use of diverse patient populations and settings and collaborative partnerships between nurse scientists and clinicians.

Inquiries: Oncology Nursing Society Research Dept., 501 Holiday Dr., Pittsburgh, PA 15220-2749, tel: 412/921-7373, fax: 412/921-6565, email: research@ons.org.

RFA Available

RFA CA-97-012

Title: **Improved Technologies For Production Of Full Length Human cDNA**

Letter of Intent Receipt Date: Feb. 15

Application Receipt Date: April 29

The NCI Technology Development Branch of the Cancer Diagnosis Program, Division of Cancer Diagnosis, Treatment, and Centers, invites applications for the development and application of innovative technologies for efficiently generating representational, full length cDNA libraries. Full length cDNAs are those clones that contain a copy of the entire mRNA sequence from which they were derived. Representational libraries are those libraries that contain at least one cDNA for every mRNA species present in the starting tissue.

Ultimately, this new technology must provide an efficient, cost-effective method for generating full length, representational cDNA libraries from tissue samples. These libraries will provide access to full length clones for those investigators who have previously identified important partial clones in other libraries. In addition the clones from these libraries will provide new gene sequences which will aid in gene discovery and gene function assessment. Therefore, investigators may propose to develop novel technologies initially on a small scale or they may propose to further develop existing efficient technologies into a high-throughput system. The most desirable technologies will be those that are easily exportable to the research community.

In order to encourage applications proposing innovative, high-risk projects, exploratory/ experimental research grant (R21s) will be used. A total of $2.5 million will be available to support approximately 10 awards. The total project period may not exceed three years. The anticipated award date is Sept. 1.

The rapid increase in our understanding of tumor biology coupled with the technology and data emerging from the human genome project offer the opportunity for a change in the way cancer research is done. It is becoming clear that cancer is not a single disease but many, and that cancers arise from the gradual accumulation of genetic changes in single cells. It is not clear which changes and how many changes are required to cause an invasive cancer. Defining which genes are involved in the initiation and progression of cancer remains a challenge.

An immediate benefit from the human genome project has been the large scale generation and sequencing of over 500,000 human expressed sequence tags (EST). EST are valuable in that they allow a rapid preliminary identification of a large number of expressed genes. They are limited in that the clones themselves often represent only partial genes. Often the partial clone is not adequate to assess the gene's biological function. In addition, few of the libraries currently being sequenced are from tumor or other cancer related tissues. Cost-effective, representational full length cDNA libraries are necessary to facilitate the identification of genes involved in cancer initiation and progression.

NCI has established the Cancer Genome Anatomy Project (CGAP) to capitalize on the technology and data emerging from the human genome project and refocus it in the direction of cancer research. CGAP has two main foci: first, the development of a complete index of genes expressed in tumors and second, the development of new technologies that will facilitate high throughput analysis of molecular alterations in cancer cells and dissemination of these technologies to basic and clinical researchers. The initial effort of CGAP is to generate and sequence cDNA libraries from four targeted tumor sites: breast, prostate, colon and lung. Though these libraries will be useful in identifying genes involved in cancer, they rely on current technology which does not guarantee complete representation or full length clones.

Current technology allows the production of representational libraries of partial genes or production of more limited libraries of full length clones, which are generally enriched for shorter genes. In addition, technology exists to create normalized (reduced redundancy) cDNA libraries. However, it is not currently possible to efficiently generate representational libraries of full length cDNAs. In order to derive the maximum benefit from libraries currently being developed and to find expressed genes not present in the initial libraries, new technologies for generating full length representational cDNA libraries are necessary.

This RFA is intended to support the development and/ or the implementation of technologies that generate representational libraries of full length cDNAs from tissues that will contribute to the understanding of cancer at the molecular level. Investigators may propose to create novel technologies or adapt existing technologies for the generation of representational libraries of full length cDNA clones. They may also propose feasibility studies designed to generate libraries from appropriate tissues using the developed technologies. Preferred technologies will be those that are efficient (including, but not limited to, normalization techniques), scalable for high-throughput and easily transferred to other cancer researchers.

A primary goal of CGAP is the compilation of a complete index of all genes expressed in tumors. In order to understand the significance of individual genes or gene expression levels, it will be necessary to have libraries from cancerous and nonneoplastic tissue from the same organs for comparison. Therefore, investigators may propose to generate individual libraries or to generate libraries that are enriched for genes differentially

expressed from appropriate tissues after successful completion of the technology development phase of the project. Appropriate tissues are those that will provide information about the initiation and/or progression of cancers, including but not limited to tumors of different stages, tumor vs. nonneoplastic tissue, etc. In all cases, approaches must be described for demonstrating that the clones in the libraries encode the entire sequence of the mRNA from which they were derived and contain a representative sample of the original mRNA population of the selected tissue.

In addition, NCI is interested in stimulating the development of innovative technologies that may be supported by limited preliminary data. In order to judge the feasibility of the proposed studies, it is necessary to establish criteria for scientific progress. Therefore, in their applications, investigators must propose specific, quantifiable milestones which can be used to measure the progress of the studies. Although the details are left to the investigator, the milestones proposed must consist of clear, well defined criteria for measuring progress. They must be appropriate for the proposed studies and as specific as possible. Investigators should also propose a clear time line for successfully completing the proposed milestones.

Due to the specialized nature of this program, it is strongly recommended that prospective applicants contact NCI staff to discuss research objectives.

Inquiries: Jennifer Couch, Division of Cancer Treatment, Diagnosis and Centers, NCI, 6130 Executive Blvd Rm 513-MSC 7388, Bethesda, MD 20892-7388, tel: 301-496-1591, fax: 301-402-1037, email: couchj@dcbdcep.nci.nih.gov.

NCI Cooperative Human Tissue Network Resources Available

NCI's Cooperative Human Tissue Network provides human tissue for biomedical research. The CHTN provides normal, benign, pre-cancer and cancer tissue. Trained personnel coordinate the retrieval, preservation and delivery of specimens from surgical resection and autopsy.

During nine years of operation, the CHTN has supplied more than 100,000 specimens to approximately 600 investigators. Human tissue provided by the CHTN has been utilized for a variety of research projects, such as studies of gene isolation, gene deletion, gene mutation, growth factors, isoenzymes, subcellular organelles, flow cytometry, DNA hybridization and the development of monoclonal antibodies and cell lines. Five member institutions coordinate the collection and distribution of tissues in the US and Canada. Collection, storage and distribution requirements vary with the research approach and tissue type.

Studies on M-RNA and labile proteins require snap-frozen surgical tissue stored at ultra-low temperatures. More stable biological molecules allow a wide range of studies on autopsy tissue, including establishing viable tissue cultures and cell lines. Investigators should discuss the tissue requirements for their research, to assure the largest number and range of research specimens. In order for the CHTN to collect and provide quality tissue specimens to meet specific user needs, each investigator is required to complete a detailed tissue request form. This includes information about the type and amount of tissue required, tissue preparation, storage, and shipment requirements (e.g., media, snap frozen, sterile). The CHTN makes every effort to tailor collection, storage and shipment to the needs of the investigator. Tissue is provided according to the following priority order:

1. Funded, peer-reviewed investigators, including those from Federal and National laboratories.
2. New investigators and academic investigators developing new research projects.
3. Other investigators.

A nominal processing fee of $20 per specimen is charged to cover some of the cost of collecting, preparing, and handling the tissue. In addition, the investigator is responsible for the cost of shipping specimens to his/her laboratory.

Application forms will soon be available from the CHTN Internet site at: http://wwwicic.nci.nih.gov/chtn/chtnmain/html. Applications are also available from the division that serves each geographical area:

Eastern Division—The northeast, the area bounded by the western border of Pennsylvania, and the southern border of Maryland and Alaska and Hawaii. University of Pennsylvania Medical Center, Philadelphia, PA 19104-4283, tel: 215-662-4570, fax: 215-614-6554, email: chtneast@mail.med.upenn.edu

Midwestern Division—From West Virginia and states west of Pennsylvania north to Minnesota and south through Missouri and Canada. The Ohio State University, Columbus, OH 43210, contact: Carolyn Cordial, tel: 614-293-5493, fax: 614-293-5851, email: cordial-1@medctr.osu.edu

Pediatric Division—Nationwide. Children's Hospital, Columbus, OH 43205, contact: Nancy Sachs, tel: 614-722-2890, fax: 614-722-2897, email: nsachs@chi.osu.edu

Southern Division—Kentucky, Virginia and all states south and west of the Carolinas to Texas. University of Alabama at Birmingham, Birmingham, AL 35294-0007, contact: Katherine Sexton, tel: 205-934-6071, fax: 205-934-0816, email: sexton@tp.path.uab.edu

Western Division—States north of Oklahoma and west of Texas. Case Western Reserve University, Cleveland, OH 44106, contact: Diane Zorkle, tel: 216-844-8538, fax: 216-844-8522, email: dmz2@po.cwru.edu