THE CANCER LETTER

Vol. 31 No. 20
May 20, 2005

Johnson To ASCO Members: Reconnect To Patients, Recommit To Profession

By Kirsten Boyd Goldberg

ORLANDO—Concluding his term as president of the American Society of Clinical Oncology, David Johnson urged his colleagues to "reconnect to our patients" and "recommit to our profession," emphasizing high-quality care.

"When the stakes are the lives of our patients, can we afford to be average?" asked Johnson, deputy director of the Vanderbilt-Ingram Cancer Center, in his presidential address May 15 at the society's annual meeting.

"Challenges imposed by reimbursement changes or regulatory burdens

(Continued to page 2)

In Brief:

ASCO Presents Awards At Annual Meeting; Ronald Beller, Deborah Whippen To Leave

ORLANDO—**AMERICAN SOCIETY for Clinical Oncology** presented awards for 2005 at its annual meeting here May 14-17. **Barbara Weber** received the American Cancer Society Award for her research in the field of breast cancer genetics. She created the Breast Cancer Program at the Abramson Cancer Center, University of Pennsylvania, in1995 and has been the director of the program since its inception. **Charles Sawyers,** of the University of California and the Howard Hughes Medical Institute, was presented with the David A. Karnofsky Memorial Award. He was honored for his research in leukemia and prostate cancers. He is director of the Prostate Cancer Program Area at the Jonsson Comprehensive Cancer Center at UCLA. **John Minna,** director of the Moncrief Center for Cancer Genetics and the Hamon Center for Therapeutic Oncology Research at the University of Texas Southwestern Medical Center in Dallas, received the Distinguished Service Award for Scientific Achievement. He was recognized for his work in lung cancer research and cancer genetics. **Sharon Murphy** was presented with the Distinguished Service Award for Scientific Leadership for developing national oncology organizations and research initiatives. A pediatric oncologist, Murphy is known for her research in pediatric lymphoma. **Carolyn Aldigé** received the Partners in Progress Award for promoting education in the areas of cancer prevention and adoption of early detection techniques. She is founder and president of the Cancer Research and Prevention foundation, a non-profit organization. **Richard O'Reilly,** chairman of the Pediatrics Department and chief of the Pediatric Bone Marrow Transplant Service at Sloan-Kettering Cancer Center, was honored with the Pediatric Oncology

(Continued to page 8)

Johnson: High-Quality Care Must Be ASCO's Core Issue

(Continued from page 1)

must retreat before our most fundamental charge, which is to put our patients first and to do all we can to treat their disease and to alleviate their suffering," Johnson said. "Our true treasures are our patients and our profession. We must be ever-mindful of that simple fact."

In his remarks, Johnson reviewed the major issues in oncology over the past year, including changes in Medicare, approval of new drugs, research ethics, and the flattening of the cancer research budget.

"During my presidential year, I have frequently felt the tug of competing agendas, but through it all, I have worked hard to keep the focus of the society where I believe it belongs—on our patients and on advancing the science of clinical oncology," said Johnson, a lung cancer expert.

The Medicare Modernization Act of 2003, which went into effect last January, had the potential to disrupt the delivery of cancer care in the U.S., Johnson said. ASCO worked with the Centers for Medicare & Medicaid Services to shape a "common-sense policy," softening the impact by establishing a demonstration project that pays physicians for the services they provide for patients, such as managing symptoms and side effects. The project should be continued, Johnson said.

"It is ASCO's firm position that evidence-based, high-quality cancer care is cost-effective care," Johnson said.

Over the past year, ASCO completed the National Initiative on Cancer Care Quality, and started the Quality Oncology Practice Initiative, to collect practice data to develop quality measures. More than 400 ASCO members are involved in QOPI.

"ASCO must embrace the concept of high-quality care as a core issue," Johnson said. He appointed a Quality Advisory Group to coordinate the quality initiatives.

The debate over drug safety over the past year has "cast a pall across the prospects for the rapid approval for all drugs currently in development," Johnson said. However, it provided the opportunity to examine how the risk-benefit ratio differs for cancer patients, he said. Under the newly established Office of Oncology Drug Products, directed by Richard Pazdur, "we are hopeful that the appropriate balance will be struck going forward," Johnson said.

ASCO is working with FDA on endpoint panels for clinical trials, to permit more efficient assessment of efficacy, Johnson said. He noted that some recent large-scale clinical trials didn't take advantage of existing scientific knowledge. "I worry that the 'need for speed' in getting drugs to market may be outstripping our ability to apply good science to study design," he said. "These failed trials resulted in wasted time, money, and precious human resources."

Horning: Care, Research, Practice Management

Sandra Horning, of Stanford University Medical Center, became ASCO president on May 16 at the society's annual meeting. Horning said her goals for the year include increasing ASCO's emphasis on high-quality cancer care, clinical research, and clinical practice management.

"Rapid technologic advances, an explosion of scientific information, and requirements for cost containment in health care delivery have created many challenges for ASCO," Horning said in a statement. "The confluence of these forces presents significant opportunities for the Society to promote high-quality and readily available care for patients with cancer.

"Important issues before ASCO include how to better provide timely and relevant education to members, how to promote an environment for rigorous evaluation of new diagnostics and therapeutics, and how to advocate for a system that provides appropriate incentives for scientific discovery, clinical investigation, and the delivery of high-quality cancer care," she said.

THE CANCER LETTER

Member, Newsletter and Electronic Publishers Association

Editor & Publisher: Kirsten Boyd Goldberg
Editor: Paul Goldberg
Editorial Assistant: Shelley Whitmore Wolfe

Editorial: 202-362-1809 Fax: 202-318-4030
PO Box 9905, Washington DC 20016
Letters to the Editor may be sent to the above address.

Customer Service: 800-513-7042
PO Box 40724, Nashville TN 37204-0724
Customer service FAQ: www.cancerletter.com

Subscription $335 per year worldwide. ISSN 0096-3917. Published 46 times a year by The Cancer Letter Inc.
Founded Dec. 21, 1973, by Jerry D. Boyd.

"ASCO must continue to build a worldwide network that embraces all the components necessary for bringing the latest technologic advances from diverse fields of science, medicine, industry, and government to patients with cancer.

"ASCO must remain scientifically and politically relevant to individual constituents while striving to meet the needs of a diverse membership," Horning said. "The international and multispecialty composition of its membership makes the society uniquely positioned to address issues of importance to patients with cancer and oncology professionals worldwide."

Horning, an ASCO member for 22 years, is a professor of medicine in the Divisions of Medical Oncology and Blood and Bone Marrow Transplantation at Stanford. She also is chairman of the Lymphoma Committee of the Eastern Cooperative Oncology Group. She has served on the FDA Oncologic Drugs Advisory Committee, the NCI Leukemia, Lymphoma and Myeloma Progress Review Group, and the NIH Clinical Oncology Study Section.

Von Eschenbach: "Revolutionary Evolution"

"Revolutionary" progress in cancer research is dramatically changing the field of oncology, NCI Director Andrew von Eschenbach said in an address at the ASCO annual meeting May 14.

These changes pose enormous challenges and opportunities, and while change is necessary, "it's a process that's only really enjoyed by a six-month-old with a dirty diaper," von Eschenbach said.

"Change can be evolutionary or it can be revolutionary," the NCI director explained. "It can be a process that is natural and normal and somewhat gradual, or it can be a process that is quite, at times, cataclysmic, and, in fact, quite challenging."

Oncology is going through both forms of change simultaneously, von Eschenbach said. "Oncology is actually in the midst of a revolutionary, evolutionary change," he said. "We are in the midst of a process, a change process, that has been quite natural and has been quite gradual, but, in fact, at this particular moment in time, has the potential to also be quite traumatic."

Advances in the understanding of the biology of cancer have led "to a point where we can begin to envision conquering cancer, not eliminating cancer completely, but eliminating its outcome, the suffering and death that's due to cancer," he said.

Clinical oncologists "must be part of that change process," he said. "That means that we must change, and clinical oncology must change."

Von Eschenbach made the following predictions:

—"Clinical oncology will no longer be empiric in nature, so that our decisions are made not on statistical probabilities and expectations of success, but our decisions are made based on our understanding of mechanisms that we are targeting, and we are able to define, and we are able to predict with regard to outcomes and impact."

—"We will see public health give rise to personal health. No longer will we be making broad prescriptions, but, rather, being able to make specific and individualized interventions, based not only on our understanding of the cancer process, but also on our ability to understand the patient and the individual."

—"We will see a system that will be highly dependent upon technology, both biotechnology as well as information technology. Those technologies will radically transform how we go about delivering the interventions that will be placed in our hands."

—"We will see a delivery system that is distributed, decentralized, and segmented, because, as we move to an understanding of diseases and subsets of cancer at the molecular level, no longer will we be clumping them according to organ site."

Clinical Trials Working Group

Clinical research also must change, von Eschenbach said. "The mechanisms that we use in clinical research, especially the processes and mechanisms of clinical trials, served us extraordinarily well in the past," he said. "But they are poorly equipped for the new reality."

It's not enough to "fine-tune" the clinical trials system, von Eschenbach said. What's required is to "look at the reality that we will create in the future based on discovery and development, and with that reality before our eyes, ask the question, 'What kind of a delivery system, what kind of a clinical research system, what kind of clinical trials system must we create to be adapted to that reality, that future?'"

To begin a process to change the system, von Eschenbach appointed a committee of NCI staff and external advisors. The Clinical Trials Working Group presented a preliminary report to the National Cancer Advisory Board last February (The Cancer Letter, Feb. 25). The group is scheduled to present an update to the board on June 7.

The report's major recommendations included reorganization of NCI's internal oversight of clinical trials, as well as the appointment of a permanent external oversight committee.

In a panel discussion at the ASCO meeting, James

Doroshow, director of the NCI Division of Cancer Treatment and Diagnosis, said the goals of the working group are to:

—Improve coordination and cooperation through comprehensive information exchange, increasing rewards for participation in an integrated clinical trials system, and regulatory coordination.

—Enhance scientific quality and prioritization so that the best trials are performed using the appropriate scientific tools.

—To increase operational efficiency so trials can be initiated and completed in a timely, cost-effective manner.

The goal of the working group is to "enhance the best of all the components of the NCI-supported clinical trials system to develop a cooperative enterprise built on a stronger scientific infrastructure," Doroshow said.

David Parkinson, vice president and head of the Clinical Oncology Therapeutic Area at Amgen, who served on the CTWG, said the group examined "how to get more deliverables out of the clinical trials system."

The group's recommendations included creating a comprehensive clinical trials database that would link information from all NCI-sponsored trials (through the Cancer Therapy Evaluation Program, Specialized Programs of Research Excellence, cancer center, P01, and R01 grants).

Also, NCI funding should be realigned to reward collaboration among clinical trials groups, and provide awards to key clinical trialists who might not be the principal investigator, but play important roles, the CTWG said. This may encourage "cultural change," Parkinson said.

Howard Fine, chief of the Neuro-Oncology Branch in the NCI Center for Cancer Research, said the group recommended establishing a "transparent prioritization system." This would involve two new groups: an Investigational Drug Steering Committee for strategic input on drug development planning for phase I and II trials for which NCI holds the IND; and, a scientific steering committee to prioritize phase III clinical trials conducted by the cooperative groups. Priority would be given to the best ideas from the groups, cancer centers, SPOREs, intramural investigators, and community oncologists.

Richard Schilsky, professor of medicine and associate dean for clinical research in the University of Chicago Division of the Biological Sciences, and chairman of Cancer and Leukemia Group B, outlined the CTWG recommendations to improve efficiency in the trials system. The group recommended revising the current funding model to provide incentives for faster patient accrual. High-performing sites should be rewarded with additional support, he said. Also, the per-case reimbursement should be modified to reflect the different levels of complexity of different trials.

"To accomplish these important goals is going to require boots on the ground," ASCO President David Johnson said. "ASCO was founded 41 years ago with the goal of advancing the science of oncology. Nothing has changed in that regard."

ASCO, in its role as a "conduit for information," could help NCI implement the CTWG recommendations, Johnson said. He suggested that ASCO could establish an accreditation program for investigators and clinical trial sites and training programs on regulatory issues. ASCO members could be involved in the NCI disease steering committees and the clinical trials oversight groups, he said.

CCOPs Ask About One-Year Renewals

In a question-and-answer session following the CTWG discussion, Thomas Saphner, of the St. Vincent's Regional Cancer Center Community Clinical Oncology Program, in Green Bay, Wisc., asked why NCI provided only one-year renewals to several CCOP grants this year, rather than the usual three- to five-year renewals.

The abrupt change "caused CCOP investigators to wonder" about NCI's future plans for the program, Saphner said.

"My own view is that CCOPs are important," NCI's Doroshow responded. "There's no question that CCOPs will continue." The reason for one-year funding was to allow NCI to "get a handle" on its organization and examine "how all the elements" of the trials programs will work together, he said.

"There is no way we can do this without you," Doroshow said.

Following the session, von Eschenbach spoke with several CCOP investigators. He explained that NCI would like to even out the funding for CCOPs. Currently, there are "two big humps" in funding, when CCOPs from CALGB and the Southwest Oncology Group come up for renewal. The one-year renewals are "extensions," he said.

Also, should it turn out that some changes are proposed in the CCOP guidelines in implementing the CTWG recommendations, "we don't want to do anything with one major part of the [CCOPs] that we couldn't do with the other," he said. "We were unwilling to put an RFA out and lock in for four years when we

don't have the [CCOP] guidelines."

The one-year funding is "just an extension," von Eschenbach said to the CCOP investigators. "You don't have to write a grant for a year. Your business continues as usual."

CCOP grants are usually around $400,000 to $500,000 a year and help community oncologists accrue patients to cooperative group trials, providing support for regulatory issues and data management. The oncologists don't earn anything from the program, and those who are involved do so because they believe that offering patients the opportunity to enroll in a clinical trial is "the right thing to do," a CCOP investigator said to The Cancer Letter.

Varmus: Change the Culture of Cancer Research

In his Science of Oncology Award lecture at the ASCO annual meeting, Harold Varmus, president of Memorial Sloan Kettering Cancer Center, 1989 Nobel Laureate, and former NIH director (1993-99), discussed the history of cancer research and outlined changes in the culture of research that he said are necessary for the field to reach its full potential.

"Thirty-five years ago, I became what I then called a cancer researcher, in 1970, and now, only now, is cancer research actually entering its most interesting phase," Varmus said.

"For most of the 20 years I spent at University of California, San Francisco, the world of molecular genetics of cancer, to which I belonged, and the world of clinical oncology seemed nearly entirely separate," Varmus said. "Different language, different culture, different tools for doing research, different people. You could almost imagine these as being as separate as the spheres of religion and science. Probably each sphere thought the other was religion.

"Another way to think about this is that one world was perceived as potentially irrational and the other as potentially irrelevant," he said.

In about 1990, these worlds began to overlap, Varmus said. This could be seen by the advent of DNA-based testing of residual CML cells in patients, the introduction of antibodies against oncogenic proteins, and the beginnings of risk assessment by looking for inherited mutations in tumor suppressor genes.

"Over the last six years, things have become much more interactive, with the appearance of gene expression profiling that has been widely employed in research in looking at indicators of diagnostic, prognostic, and therapeutic approaches--perhaps more invested than has actually become clinical practice, but, nevertheless, bringing these two worlds together," Varmus said. Also, the use of drug treatments that inhibit the products of mutant oncogenes has emerged.

"Still, we are not yet at the time when the two worlds are completely integrated and overlapping, when clinical oncology and molecular genetics of cancer allow us to carry out all the components of cancer care, from risk assessment, to diagnosis, to strategies to treat or prevent cancer, all based on the molecular damage that actually drives the carcinogenic process," Varmus said. "What is required to get us to that ideal state in which all of our actions are rational and based on a clear understanding of the basic biology of cancer?

"First, we need to understand and apply the many things we now know.

"Second, we need to move to a position in which we are defining the complete genotype of all cancers.

"Third, we will need new strategies for prevention and treatment.

"Finally, we need to change the culture of what we do, find better ways to disseminate new knowledge to all, and to change the basic culture by which we train people to practice the oncological sciences."

Three "big ideas" have emerged in cancer research over the past 35 years, Varmus said.

"First, the idea familiar to all of you, that cancers are built on multiple mutations, largely somatic. Those mutations affect principally three classes of genes: proto-oncogenes, resulting in gain in function mutations; tumor suppressor genes, resulting in loss of function mutations; and mutations that affect those genes that preserve DNA integrity, and, hence, if faulty, give rise to additional mutations.

"Secondly, we know a lot about the products of those genes, what they do physiologically in normal live before they are mutated, how mutations affect them, what the biochemical properties of many of those proteins are, including those proteins encoded by mutant oncogenes that have enzymatic properties such as protein tyrosine kinase activities that become the targets for drug treatment.

"Thirdly, we've learned that oncogenes, which were identified initially as initiators of oncogenic events, can also maintain the oncogenic state, and that's an important concept, because we now know that cancer cells may be exquisitely dependent upon—some refer to this as 'addicted' to—those oncogenic proteins for viability, not just oncogenesis, providing prime targets for interventions which will result in the death of cancer cells.

"How did we come to know these things?

It's important to reflect that there are at least five methodologies that underlie what we know: studying retroviruses and their oncogenes, and the mutant versions of their oncogenes; inherited mutations in patients that confer a high risk of cancer; the somatic mutations we find by cloning and sequencing DNA from human cancers; the use of transgenic mice, especially those with regulated oncogenes; and finally, the use of drugs in clinical practice to inhibit oncogenic functions in patients themselves, in mice, in cell cultures, and in biochemical assays."

Varmus said he supports a proposal submitted to NCI for a Human Cancer Genome Project, which would cost about $1.35 billion over 10 years and would characterize the molecular genotypes and phenotypes of about 250 tumors in 50 tumor types. The cost "would seem large at first, but when you compare that with the more than $300 billion that the NIH will receive over the next 10 years, not so much to be in the affordable range, especially when this information is so valuable in understanding one of our most dread diseases as a society," he said.

Even under the current "cottage industry" approach to identifying mutations, there are currently several approved drugs or drug candidates that target common mutations, he said.

New methods of training investigators will help merge the worlds of oncology and molecular genetics, Varmus said. MSKCC will admit its first class in July 2006 to the Louis V. Gerstner Jr. Graduate School of Biomedical Sciences. The program will lead to a PhD in cancer biology.

As an example of overlap in the worlds of research and oncology, Varmus described the work in his laboratory at MSKCC, a collaboration between basic researchers and clinicians who treat lung cancer patients. The project found the genetic basis that explains why some lung cancers with epidermal growth factor receptor mutations stop responding to treatment with the drugs erlotinib and gefitinib.

The study was published online on Feb. 22, in the open-access journal PloS Medicine, www.plos.org. Varmus is co-founder of the Public Library of Science, or PLoS, a nonprofit organization designed to provide free access to research results.

Greater public dissemination of knowledge is required as part of the culture change, Varmus said. However, efforts to move in that direction are being stymied by publishers of high-subscription fee journals, such as "the grossly for-profit entrepreneurs, like those at Elsevier," and scientific societies that publish journals, Varmus said.

"We need to face the question of whether we are going to behave like a community that believes in the public library or like monks who believe in squirreling away documents," he said. "Are we going to make the best use of the Internet and the powers of information technology?"

NIH has asked that investigators contribute their articles to the NIH library, PubMed Central, after peer review. "Why are scientific societies, even scientific societies that are disease-oriented and immensely interesting to the public, even cancer-oriented societies, obstructing this move, with letters to their members which discourage participation?" Varmus asked.

In a letter to its members, the American Association for Cancer Research wrote that, "The NIH policy is not a requirement. The society will not be able to assist you in depositing articles," Varmus said, quoting from the letter.

"What is gained by doing this? Who benefits from this?" Varmus said. "In my view, this is going to hurt everyone in the long run…. Do we need to rethink how some of our societies are behaving?"

Varmus concluded his remarks by showing a slide of the Oct. 16, 2004, issue of The Economist, which featured a cover article titled "Beating Cancer."

"Notwithstanding the enthusiasm of The Economist or the enthusiasm of Dr. von Eschenbach, we have a long way to go before we beat cancer," Varmus said. "We're not going to do so before 2015.

"But, I contend, and I hope that you agree, that as our science increases in strength, and as our cultures--the culture of clinical oncology, the culture of molecular genetics--overlap, I feel, and hope you feel, that we can ultimately prevail."

Onward To 2010? NCI Pledges Faster Result For More Money

Can the 2015 goal be achieved five years earlier?

Yes, but it would cost more, said NCI Director Andrew von Eschenbach in testimony May 11 before the Senate Appropriations Subcommittee on Labor, HHS, and Education.

Von Eschenbach's formal, written response to questions from Sen. Arlen Specter (R-Pa.), subcommittee chairman, is going through NIH and HHS review, the Institute said.

According to the May 17 issue of the Institute's official publication, NCI Cancer Bulletin, it would cost

$600 million a year in new funding over the next five years to convert the 2015 plan into the 2010 plan.

The accelerated plan would include three components: funding the National Advanced Technologies Initiative for Cancer; increasing NCI's Comprehensive Cancer Centers network by adding 15 centers; and expanding and integrating the clinical research infrastructure.

So far, NIH and HHS have been silent on the NCI director's goal to "eliminate the suffering and death due to cancer by 2015."

Will they sign off on the 2010 plan?

NCI Awards $11 Million For EDRN Re-Competition

NCI has awarded $11 million for 13 grants over the next five years for the Early Detection Research Network.

EDRN seeks to translate biomarker information into clinical application and evaluation of early cancer testing and risk assessment. The grants are being awarded to three of the network's four components. Four grants are to institutions new to EDRN. Funding was awarded to eight Clinical Epidemiology and Validation Centers, which conduct the early phases of clinical and epidemiological research on the application of biomarkers; four Biomarker Reference Laboratories, which work to validate the biomarker tests; and one Data Management and Coordinating Center/Informatics Center, which provides logistical, informatics, and statistical development and support. The Informatics Center comes through an interagency agreement between NCI and the Jet Propulsion Laboratory. Funding for the fourth component of the network, the Biomarker Development Laboratories, was awarded late last year.

The clinical epidemiology and validation center principal investigators include Dean Brenner, University of Michigan; Daniel Cramer, Brigham and Women's Hospital; Paul Engstrom, Fox Chase Cancer Center; Henry Lynch, Creighton University; Alan Partin, Johns Hopkins University; William Rom, New York University School of Medicine; Martin Sanda, Beth Israel Deaconess Medical Center; Ian Thompson, University of Texas Health Science Center; Elizabeth Unger, Centers for Disease Control and Prevention.

Biomarkers reference laboratories principal investigators include Peter Barker, National Institute of Standards and Technology; Daniel Chan, Johns Hopkins University; David Chia, University of California, Los Angeles; William Grizzle, University of Alabama, Sanford Stass, University of Maryland.

Data management coordinating center and principal investigator is Ziding Feng, Fred Hutchinson Cancer Research Center. Informatics Centers principal investigator is Dan Crichton, NASA-California Institute of Technology.

Funding Opportunities:

Lustgarten Foundation Offers Research Opportunities

Letter of Intent Receipt Date: July 1.

Applications Receipt Date: Aug. 12

RFP: Lustgarten Foundation is making available one-year grants that will be awarded in amounts up to $100,000. The Foundation provides research funding into the biology, diagnosis, and prevention of adenocarcinoma of the pancreas, as well research into various treatment modalities. National and international applications will be considered. The complete RFP is available at www.lustgarten.org.

Inquiries: Lustgarten Foundation for Pancreatic Cancer Research, 1111 Stewart Ave., Bethpage, NY, 11714; phone 516-803-2304; fax 516-803-2303.

RFA: Lustgarten Foundation for Pancreatic Cancer Research. Letter of Intent/Application/Inquiries: Please see preceding RFP.

The foundation is taking applications for an RFA into the biology, diagnosis, and prevention of adenocarcinoma of the pancreas, as well research into various treatment modalities. Two-year or three-year grants will be awarded in amounts up to $250,000. per year.

RFA Available

RFA-DP-05-071: Breast and Prostate Cancer Data Quality and Patterns of Care Study

Letters of Intent Receipt Date: May 27

Application Receipt Date: June 28

The RFA will support up to six registries to conduct enhanced surveillance and operations research utilizing population-based data from the National Program of Cancer Registries. The research will focus on improving the completeness, timeliness, quality, and use of first course of treatment and stage data, and on describing patterns of care for female breast cancer and prostate cancer. A long term goal is to strengthen the capacity of NPCR funded state cancer registries to use their data to improve aspects of cancer care. The funding opportunity will use the cooperative agreement funding mechanism CDC U01. The RFA is available at http://grants.nih.gov/grants/guide/WeeklyIndex.cfm?WeekEnding=05-13-2005.

Inquiries: Scientific/Research Contacts--Brenda Colley Gilbert, Centers for Disease Control and Prevention, Office of Extramural Research, phone 770-488-8390; e-mail BColleyGilbert@cdc.gov.

Program Announcement

NOT-CA-05-018: Addendum to PA-05-054: Functional Links Between the Immune System, Brain Function, and Behavior

NCI encourages applications to study basic biobehavioral processes related to immune-to-central nervous system interactions in cancer. Cancer and cancer treatments (e.g., radiotherapy and chemotherapy) often result in patients experiencing debilitating symptoms such as pain, gastrointestinal distress, wasting/cachexia, fatigue, cognitive impairments, anxiety, and depression. Growing evidence suggests these symptoms share common biological mechanisms.

Cytokines, readily produced in the tumor microenvironment and capable of immune-to-CNS communication, are recognized to be the central mediators of cancer-related sickness behaviors. However, further understanding of how cytokines and other neuroimmune molecules act on the CNS to influence the cancer experience is needed. The development of relevant animal models is encouraged.

The notice is available at http://grants.nih.gov/grants/guide/notice-files/NOT-CA-05-018.html.

Inquiries: Paige McDonald, Division of Cancer Control and Population Sciences, phone 301-435-8776; fax 301-435-7547; e-mail mcdonalp@mail.nih.gov.

In Brief:

ASCO Honors Clinical Trialists; Harold Moses To Lead Forum

(Continued from page 1)

Award and Lecture. He was recognized for his scientific contributions to pediatric oncology. **Joseph Bailes** was given the Public Service Award for his advocacy efforts to promote governmental commitment to high quality cancer care. He is a partner at Texas Oncology and is chairman of the ASCO Clinical Practice Committee. **Harold Varmus,** president of Sloan-Kettering Cancer Center and former co-recipient (with J. Michael Bishop) of the 1989 Nobel Prize in Physiology or Medicine, and former director of NIH, was honored with the Science of Oncology Award. He was recognized for his research on the genetic origins of cancer. The Special Recognition Award for individual efforts and accomplishment in oncology and oncology research was presented to two ASCO staff members: **Ronald Beller,** vice president and CEO of ASCO, and **Deborah Whippen,** senior director of the Publications Department and executive editor of the Journal of Clinical Oncology. Beller and Whippen said they will be retiring from ASCO this year. . . . **CLINICAL TRIALS** Participation Awards were presented by ASCO to the following practices and institutions: Barnes-Jewish Hospital, Mallinckrodt Institute of Radiology, Breast Imaging Section, St. Louis, Mo; Cedar Rapids Oncology Project, Cedar Rapids, IO; Evanston Northwestern Healthcare, Evanston, Ill.; Hotel Dieu Oncology Clinic, St. Catharine's, Ontario, Canada; Kansas City Cancer Centers, Overland Park, KS; Kinston Medical Specialists, Kinston, NC; Leo Jenkins Cancer Center, Greenville, NC; Medial Oncology Hematology Associates, Philadelphia; Mount Sinai CCOP, Miami Beach; Our Lady of Mercy Cancer Center, Bronx, NY; Presbyterian Hospital of Dallas; University of New Mexico Pediatric Oncology Program, Albuquerque. The awards are supported by a grant from the Coalition of National Cancer Cooperative Groups. . . . **HAROLD MOSES**, director emeritus of the Vanderbilt-Ingram Cancer Center, was named chairman of the National Cancer Policy Forum of the Institute of Medicine, established through a contract with NCI. The forum replaces the National Cancer Policy Board, which began in 1996, also under an NCI contract. The forum will provide a focus within the National Academies of Science on issues in science, clinical medicine, public health, and policy that are important to preventing and curing cancer, or mitigating its symptoms and effects. . . . **TIM BYERS** was named deputy director of the University of Colorado Cancer Center. Byers is professor of preventive medicine at the University of Colorado School of Medicine, and associate director for Cancer Prevention and Control at UCCC. He replaces **Tom Slaga** of the University of Texas Health Sciences Center. Byers will work with **Paul Bunn Jr**., director of UCCC, in selecting the scientific direction and research goals of the cancer center. The deputy director also assists with the operational management of the cancer center. Formerly chief of the Chronic Disease Prevention Branch of the Nutrition Division at the Centers for Disease Control and Prevention in Atlanta, Byers is known for his research in cancer prevention. . . . **DAVID SCHWARTZ** will join NIH on May 23 as director of National Institute of Environmental Health Sciences and National Toxicology Program. Schwartz is director of the Pulmonary, Allergy, and Critical Care Division and vice chairman of research in the Department of Medicine at Duke University. . . . **JACK GRIFFITH,** Kenan Distinguished Professor of Microbiology and Immunology at the University of North Carolina, Chapel Hill, School of Medicine and member of the Lineberger Comprehensive Cancer Center, was elected a fellow of the American Academy of Arts and Sciences. Griffith has been a member of the Chapel Hill faculty since 1977.

A Notch-Signaling Pathway Inhibitor in Patients with T-cell Acute Lymphoblastic Leukemia/Lymphoma (T-ALL)

An investigational study for children, adolescents and adults with relapsed and refractory T-cell acute lymphoblastic leukemia/lymphoma is now accruing patients at various centers around the country.

This study's goal is to evaluate the safety and tolerability of a Notch inhibitor as a rational molecular therapeutic target in T-ALL, potentially uncovering a novel treatment for these cancer patients.

Eligibility criteria and treatment schema for the study include:

Notch-Signaling Pathway Inhibitor in Patients with T-ALL	
Eligibility Criteria	Patient must be ≥ 12 months with a diagnosis of T-cell acute lymphoblastic leukemia/lymphoma AND must also have: • Relapsed T-ALL • T-ALL refractory to standard therapy • Not be a candidate for myelosuppressive chemotherapy due to age or comorbid disease ECOG performance status ≤2 for patients >16 years of age OR Lanksy performance level >50 for patients 12 months to ≤16 years of age Fully recovered from any chemotherapy and >2 weeks from radiotherapy, immunotherapy, or systemic steroid therapy with the exception of hydroxyurea or intrathecal therapy Patient must be >2 months following bone marrow or peripheral blood stem cell transplantation No treatment with any investigational therapy during the preceding 30 days No active or uncontrolled infection
Treatment Plan	Open label and non-randomized, this study is conducted in two parts. Part I is an accelerated dose escalation to determine the maximum tolerated dose (MTD), and Part II is a cohort expansion at or below the MTD. MK-0752 will be administered orally. Plasma concentrations will be measured at defined time intervals.

For information regarding centers currently open for enrollment, please contact 1-888-577-8839.

Copying Policy for The Cancer Letter Interactive

The software that comes with your issue allows you to make a printout, intended for your own personal use. Because we cannot control what you do with the printout, we would like to remind you that routine cover-to-cover photocopying of The Cancer Letter Interactive is theft of intellectual property and is a crime under U.S. and international law.

Here are guidelines we advise our subscribers to follow regarding photocopying or distribution of the copyrighted material in The Cancer Letter Inc. publications in compliance with the U.S. Copyright Act:

What you can do:

--Route the printout of the newsletter to anyone in your office.

--Copy, on an occasional basis, a single story or article and send it to colleagues.

--Consider purchasing multiple subscriptions. Contact us for information on multiple subscription discounts.

What you can't do without prior permission:

--Make copies of an entire issue of the newsletter. The law forbids cover-to-cover photocopying.

--Routinely copy and distribute portions of the newsletter.

--Republish or repackage the contents of the newsletter.

We can provide reprints for nominal fees. If you have any questions or comments regarding photocopying, please contact Publisher Kirsten Boyd Goldberg, phone: 202-362-1809.

We welcome the opportunity to speak to you regarding your information needs.