THE CANCER LETTER

Vol. 31 No. 41
Nov. 11, 2005

Price $335 Per Year

European Regulators Plan More Rigorous Rules For Accelerated Approval In Cancer

By Paul Goldberg

The European drug approval agency is instituting stringent procedures for ensuring that pharmaceutical companies continue to study drugs that receive marketing approval based on surrogate endpoints.

The European version of the FDA "accelerated approval" mechanism, which will go into force next year, will require sponsors to reapply for marketing approval once a year. Companies that fail to study drugs with sufficient rigor would lose approval and may face financial penalties.

"There is a very clear emphasis on conditional marketing authorization that has to be reassessed and renewed every year and the possibility of imposing financial penalties in case of lack of compliance," said Francesco Pignatti, scientific administrator at the London-based European Agency for

(Continued to page 2)

In the Cancer Centers:

Pestell To Direct Kimmel Cancer Center, TJU To Expand Role Of Center Director

RICHARD PESTELL was named director of the Kimmel Cancer Center at Thomas Jefferson University, effective Dec. 1, said **Robert Barchi**, university president. Pestell is director of the Lombardi Comprehensive Cancer Center at Georgetown University. He plans to move a cadre of Georgetown researchers to TJU, according to a press release. He holds five NIH R01 grants totaling more than $20 million. With Pestell's appointment, the cancer programs at Jefferson are being restructured and the role of the cancer center director expanded. Pestell also will be appointed professor and chairman of the new Department of Cancer Biology, associate dean for cancer programs at Jefferson Medical College, and vice president for oncology services at TJU Hospital. Molecular biologist **Renato Baserga**, who has served as interim director of the cancer center, will step down and resume his research and teaching. Pestell said he plans to build on the center's strengths in basic cancer biology research, while expanding translational and clinical research, and clinical programs in diagnosis and treatment. Pestell's recruitment "is pivotal for the cancer program in realizing the goals set forth in Jefferson's strategic plan," Barchi said. **Thomas Lewis**, hospital president and CEO, said Pestell would be "a catalyst for enhanced collaboration between Jefferson's scientists and clinicians and renewed growth in our clinical cancer programs.". . . **ABRAMSON CANCER CENTER** of the University of Pennsylvania received a five-year, $39.7-million Cancer Center Support Grant

(Continued to page 7)

New Rules In Europe Require Sponsors To Reapply Annually

(Continued from page 1)

the Evaluation of Medicinal Products, which approves drugs for 25 European Union countries as well as Norway and Iceland.

Pignatti spoke at the Nov. 8 meeting of the FDA Oncologic Drugs Advisory Committee, as that group met to hear the sponsors' updates on six drugs approved under the US accelerated approval procedures.

Under FDA regulations, it is theoretically possible to order withdrawal of an accelerated approval drug, but such measures are impractical. The agency has, in effect, admitted that, barring unexpected toxicities, accelerated approval drugs wouldn't be pulled off the market.

To keep track of outstanding post-approval "phase IV" commitments, the agency periodically calls sponsors to face ODAC and provide updates on their data. Altogether, 29 indications of 25 drugs have been given accelerated approval, and 16 of those indications are yet to demonstrate clinical benefit and earn a regular approval.

The European agency is instituting a more rigorous system at a time when FDA finds itself under attack from conservative groups that assert that the agency's requirements constitute an unnecessary, costly impediment to drug development (The Cancer Letter, Aug. 5).

Moreover, FDA's current acting commissioner Andrew von Eschenbach, who also serves as NCI director, is openly sympathetic to "accelerating" progress in medicine in order to meet his goal of "elimination of suffering and death due to cancer" by the year 2015. (The Cancer Letter (Sept. 30, Oct. 7, Oct. 21). At NCI, von Eschenbach's top political operatives called for greater reliance on surrogate endpoints for cancer treatment as well as cancer prevention (The Cancer Letter, May 30, 2003).

Until now, the European agency, which reviews drugs for cancer, AIDS, diabetes, and neurodegenerative disorders, had two categories for drug approval: "normal" and "exceptional circumstances."

With the third category, "conditional marketing authorization," exceptional approvals would likely become less common, Pignatti said to ODAC. "The conditional marketing authorization is expected to detract from that provision that was excessively used in the past," he said.

The agency gives exceptional circumstances approvals to when diseases were too rare to make a study feasible. Drugs approved under this mechanism include MabCampath (alemtuzumab), Foscan (temoporfin), Gleevec (imatinib), Onsenal (celecoxib), Taxotere (docetaxel), Trisenox (arsenic trioxide), Velcade (bortezomib), and Zevalin (ibritumomab tiuxetan).

The conditional approval law states that "following consultation with the applicant, an authorization may be granted subject to certain specific obligations, to be reviewed annually by the agency." The authorizations will be valid for one year "on a renewable basis."

The European system is based on risk-benefit analysis and seems to require randomization. Under the regulations, conditional approvals would be granted based on "presumed positive benefit-risk" ratio, and would be converted to normal approval once the risk-benefit ratio is verified, Pignatti said.

The U.S. accelerated approvals are granted based on a determination that a surrogate endpoint is reasonably likely to predict a clinical benefit, and full approvals are granted after clinical benefit has been demonstrated.

Claims of clinical benefit can be—and usually are—based on data from single-arm phase II trials. In fact, the U.S. accelerated approval law has given drug companies incentives to conduct large phase II studies that serve as registration trials.

Phase II trials can produce data on surrogate endpoints—such as tumor shrinkage or time to progression—which can be interpreted as a hint of benefit to patients. However, such trials are unlikely to measure the risk-benefit ratio, especially when treatment

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.

effects are small, which is often the case in oncology.

Indeed, Pignatti said single-arm trials are "problematic."

"We must be reminded about the fact that there is a very high risk of rejection [of the marketing applications] where there is a lack of randomized, controlled trials," Pignatti said. Reliance on subset analysis in otherwise negative or inconclusive studies to find groups of patients who appear to have benefited from therapy would also be "highly discouraged," he said.

Drugs could receive conditional approval based on interim analysis of data from randomized trials and converted to normal approval after final analysis of the trial is completed, Pignatti said. This development schema would require sponsors to receive advice from the regulatory authorities early in the drug development process, he said.

Sponsors would have to maintain a dialogue with the agency to keep their drugs alive.

If a sponsor fails to apply for annual renewal, authorization would be forfeited.

Conditionally approved drugs could be withdrawn if their safety or efficacy profiles start to look less advantageous. Also, according to a draft regulation, financial penalties could be imposed is sponsors fail to meet their obligations.

FDA and the European agency have been cooperating formally, under a confidentiality arrangement, and sharing approval materials over the past year.

"With the advent of conditional approval in the E.U., we consider a greater dialogue on our accelerated approval commitments with FDA to be warranted," Richard Pazdur, director of the FDA Office of Oncology Drug Products, said at the ODAC meeting. "Therefore, the Office of Oncology Drug Products will routinely forward to the EMEA meeting minutes with sponsors that involve accelerated approval, design issues and commitments.

"In turn, EMEA will provide similar records to FDA regarding discussions with sponsors on their conditional approval program. We feel that this interaction is important since many of our phase IV commitments have been performed either partially or fully outside the U.S., with significant accrual from E.U. countries. The adoption of an accelerated approval program by the E.U. may impact this future accrual."

Under the agreement that has been in force over the past year, the FDA office shares its "special protocol assessments" with EMEA.

Conversely, the European agency sends FDA copies of the "letters of scientific advice" sent to sponsors regarding protocols and drug development plans for oncology products

In other aspects of the collaboration:

—EMEA and FDA will share current thinking on guidance documents that provide advice on endpoints and other regulatory considerations. "Each agency has already received draft copies of each other's oncology drug endpoint guidances," Pazdur said at ODAC.

—The agencies hold monthly teleconferences to discuss pending regulatory decisions, bases for approval, clinical and non-clinical reviews.

—The agencies share and discuss any requests for early stopping of clinical trials or significant changes in statistical analysis plans previously determined with sponsors.

—Staff members of the two agencies attend each other's key regulatory meetings, including ODAC and EMEA scientific advice meetings.

—The two agencies will collaborate with oncology professional societies to develop educational programs that reflect current regulatory thinking.

At the one-day meeting, ODAC was updated on the progress of post-approval studies of:

—Doxil (doxorubicin HCL liposome injection) for AIDS-related Kaposi's sarcoma;

—Ontak (denileukin diftitox) for persistent or recurrent cutaneous T-cell lymphoma in patients whose malignant cells express the CD25 component of the IL-2 receptor;

—Mylotarg (gemtuzumab ozogomicin) for acute myelogenous leukemia in first-relapse patients over 60 who have no other treatment options;

—Depocyt, sustained release cytarabine for lymphomatous meningitis, Celebrex (celecoxib) for Familial Adenomatous Popyposis, and

—Campath (alemtuzumab) for chronic lymphocytic leukemia.

National Academies:

Cancer Policy Board Urges Distinct Care, Follow-Up Plans For Cancer Survivors

Every cancer patient should receive an individually tailored "survivorship care plan" that would summarize information critical to the individual's long-term care, according to a report by the National Cancer Policy Board of the Institute of Medicine.

Such plans should include the cancer diagnosis, treatment, and potential consequences; the timing and

content of follow-up visits; tips on maintaining a healthy lifestyle and preventing recurrent or new cancers; legal rights affecting employment and insurance; and the availability of psychological and support services.

The report also called for new evidence-based clinical guidelines to assure the quality of care given to cancer survivors, as well as for better coordination between specialists and primary care providers.

"There is currently no organized system to link oncology care to primary care," said Sheldon Greenfield, professor of medicine and director of the Center for Health Policy Research, University of California, Irvine, and chairman of the board's Committee on Cancer Survivorship. "Successful cancer care doesn't end when patients walk out the door after completion of their initial treatments."

Advances in the detection and treatment of cancer, combined with an aging population, mean greater numbers of cancer survivors in the near future, the report said. Primary care physicians often are not extremely familiar with the consequences of cancer, and seldom receive explicit guidance from oncologists, the committee found. Also, the lack of clear evidence for what constitutes best practices in caring for patients with a history of cancer contributes to variation in care.

Besides being at risk for cancer recurrence and for developing other cancers, survivors also may face psychological distress, sexual dysfunction, infertility, impaired organ function, cosmetic changes, and limitations in mobility, communication, and cognition. Some of this is due to the fact that most cancer treatments can have long-term effects.

"Unfortunately, many critical aspects of cancer survivors' needs are lost somewhere between active treatment and long-term follow-up, which is why we call for every patient to be given a summary of their cancer treatment and a description of follow-up care needed," said committee vice chairman Ellen Stovall, president of the National Coalition for Cancer Survivorship.

Such plans should be written by oncology providers and thoroughly discussed with patients, and the cost should be covered by insurers. The concept of a cancer survivorship plan was previously suggested by the President's Cancer Panel.

For survivorship plans to be carried out successfully, an organized set of clinical practice guidelines based on the best available evidence is needed, the report said. Innovative models also should be developed to coordinate the care provided by oncologists, primary care doctors, nurses, social workers, psychologists, and others involved in addressing the myriad problems faced by cancer survivors. The Centers for Medicare and Medicaid Services is in the best position to test the merits of various models of care through pilot programs funded by Congress, the committee said. Both public and private support will be needed to develop new clinical guidelines and to monitor their impact.

Quality-of-care measures also are needed, the report said. Some measures—such as annual mammograms for breast cancer survivors—already exist, while others could be established based on available evidence. For example, patients treated with certain chemotherapies should be monitored for heart conditions, and some individuals treated with radiotherapy need to be checked for thyroid conditions. Quality assurance programs to monitor and improve cancer survivors' care should be set up as well.

The committee recommended that medical education and professional training curricula include more instruction about cancer survivors' particular care needs. Expanded research, including long-term population studies, also is needed to fill gaps in understanding of the effects experienced by cancer survivors later in life. Steps also should be taken to prevent discrimination against cancer survivors in the workplace and to ensure they have affordable health insurance and are reimbursed for evidence-based care. In addition, the committee called on health care providers and patient advocates to raise public awareness of the needs of cancer survivors and to establish cancer survivorship as a distinct phase of cancer care.

The study was sponsored by NCI, the Centers for Disease Control and Prevention, and the American Cancer Society.

Copies of the report, "From Cancer Patient to Cancer Survivor: Lost in Transition," are available from the National Academies Press, www.nap.edu.

Besides Greenfield and Stovall, members of the committee were: John Ayanian, Harvard Medical School; Regina Benjamin, Bayou La Batre Rural Health Clinic; Harris Berman, Tufts University; Sarah Donaldson, Stanford University; Craig Earle, Harvard Medical School; Betty Ferrell, City of Hope National Medical Center; Patricia Ganz, Jonsson Comprehensive Cancer Center; Frank Johnson, Saint Louis University; Mark Litwin, University of California, Los Angeles; Karen Pollitz, Georgetown University; Pamela Farley Short, Pennsylvania State University; Bonnie Teschendorf, American Cancer Society; Mary Vargo, Case Western Reserve University; Rodger Winn, National Quality Forum; and Steven Woolf, Virginia Commonwealth University.

ImClone:

MSKCC Oncologist Settles Insider Trading Case With SEC, Pays Government $2.6 Million

By Paul Goldberg

The former chairman of the department of radiation oncology at Memorial Sloan-Kettering Cancer Center has settled the insider trading case stemming from the sale of stock of ImClone Systems Inc. in December 2001.

Zvi Fuks settled the case without admitting or denying civil charges filed against him by the Securities and Exchange Commission. Fuks and co-defendant Sabina Ben-Yehuda paid $2.8 million to settle the charges.

Fuks and Ben-Yehuda were arrested last March on criminal charges of insider trading.

According to attorneys for Fuks and Ben-Yehuda, the U.S. Attorney's office in August decided not to pursue criminal charges against them.

The government's case hinged on testimony of a convicted felon, former ImClone CEO Samuel Waksal, who testified against Fuks and Ben-Yehuda while serving a sentence in a federal prison (The Cancer Letter, March 11).

Fuks stepped down from his position as a department chairman at Memorial soon after his arrest, and his status at the cancer center remains unchanged. According to a spokesman, he is continuing with patient care and research.

SEC charged that Waksal had tipped off Ben-Yehuda, a business associate, that FDA was about to refuse to file the company's marketing application for Erbitux.

According to court documents, Ben-Yehuda then tipped off Fuks. As a result, on Dec. 27, 2001, Fuks sold over $5 million in ImClone stock, and Ben-Yehuda sold over $73,000 worth of stock, documents state.

SEC said that without admitting or denying the allegations, Fuks agreed to disgorge $1,214,239, the losses he avoided by the sales of ImClone stock, and paid the prejudgment interest of $230,615 and a civil penalty of $1,214,239.

Ben-Yehuda agreed to disgorge $50,958, the losses she avoided by selling ImClone stock, paid prejudgment interest of $9,678, plus a civil penalty of $50,958, the agency said.

Both were permanently enjoined from violations of securities laws.

NCI Programs:

NCI Funds Biorepository For Prostate Cancer SPOREs

By Kirsten Boyd Goldberg

NCI has funded a cancer biorepository pilot project designed to standardize biospecimen collection and management among investigators of the institute's 11 Specialized Programs of Research Excellence in prostate cancer.

To support the project, NCI awarded a contract to the American Type Culture Collection of Manassas, Va., a non-profit organization.

The institute did not release the dollar amount of the project, despite several requests from a reporter.

The project, called the Biorepository Coordination System, would create a common biorepository of clinically annotated biospecimens, including paraffin-embedded and frozen tissue, serum and/or plasma, according to an NCI press release.

The biorepository would support an Inter-Prostate SPORE Biomarkers Study, which would provide a specific scientific framework for testing the BCS model by conducting validation trials on five promising prostate cancer prognostic biomarkers.

Anna Barker, NCI deputy director for advanced technologies and strategic partnerships, who led NCI's effort with the nonprofit organization C-Change to develop a National Biospecimen Network, called the newly funded project "an important milestone."

"The NCI has engaged in a series of efforts over the past few years to determine best practices for biospecimen collection and management to support 21st century cancer research," Barker said in a press release. "With the launch of the BCS pilot project through the prostate cancer SPOREs, we will be able to test many of these concepts and the principles offered in a number of models such as the NBN blueprint."

* * *

NCI has appointed 60 individuals to the Translational Research Working Group to review the institute's intramural and extramural translational research portfolio.

The membership list is available at http://www.cancer.gov/trwg/members-list.html. Eighteen of the group members work for NCI.

Ernest Hawk, director of the NCI Office of Centers, Training and Resources, serves as chairman of the TRWG. Co-chairmen are Lynn Matrisian, Ingram Distinguished Professor and Chair of Cancer Biology at Vanderbilt University, and William Nelson, professor

of oncology, urology, pharmacology, medicine, and pathology at Johns Hopkins University.

NCI recently outlined the group's "mission." First, the group will evaluate the current portfolio of NCI-funded translational activities and invite public comment. Second, the group will "devise an optimized translational research model and offer recommendations about how NCI could achieve that future vision for translational research." The recommendations will be made public and remain open for comment. Third, the group will finalize its model and recommendations, and will develop an implementation plan. The plan may include both short-term adjustments intended to better harmonize existing programs, as well as long-term initiatives that may transcend existing programs.

Funding Opportunities:

Program Announcements

PAR-06-039: Dissemination and Implementation Research in Health. Letters of Intent Receipt Dates: Dec. 26, Aug. 22, 2006; April 24, 2007; Dec. 26, 2008; Aug. 25, April 22, 2009. Application Receipt Dates: Jan 1, Sept. 22, 2006; May 24, 2007; Jan 24, 2008; Sept. 24, May 22, 2009

The PA invites R01 grant applications that will identify, develop, and refine methods, structures, and strategies that disseminate and implement research-tested health behavior change interventions and evidence-based prevention, early detection, diagnostic, treatment, and quality of life improvement services into public health and clinical practice settings. The PA encourages collaboration between trans-disciplinary teams of scientists and practice stakeholders to develop and/or test conceptual models of dissemination and implementation applicable across diverse practice settings, and design studies that will assess the outcomes of dissemination and implementation efforts. The PAR is available at http://grants.nih.gov/grants/guide/pa-files/PAR-06-039.html.

Inquiries: For NCI--Jon Kerner, 301-594-7294, kernerj@mail.nih.gov.

PA-06-042: Academic Research Enhancement Award. The NIH program would stimulate research in educational institutions that provide baccalaureate or advanced degrees, but that have not been major recipients of NIH support. AREA grants may support small-scale, new or renewal, projects in biomedical and behavioral research. The PA is available at http://grants.nih.gov/grants/guide/pa-files/PA-06-042.html.

Linda Stecklein, 301-402-7989, stecklel@od.nih.gov.

PA-06-045: Novel Technologies for In Vivo Imaging. Small Business Technology Transfer applications are invited from small business concerns for in vivo image acquisition or to enhance technologies and methods for biomedical imaging and image-guided interventions and therapy--applications may incorporate limited pilot or clinical feasibility evaluations using either pre-clinical models or clinical studies. The PA is available at http://grants.nih.gov/grants/guide/pa-files/PA-06-045.html.

Inquiries: For NCI--Guoying Liu, 301-496-9531, guoyingl@mail.nih.gov.

PA-06-046: Novel Technologies for In Vivo Imaging. The PA invites Small Business Innovation Research applications from small business concerns to develop and deliver in vivo image acquisition or enhancement technologies and methods for biomedical imaging and image-guided interventions and therapy. PA is available at http://grants.nih.gov/grants/guide/pa-files/PA-06-046.html.

PA-06-051: NCI Phase II Small Business Innovation Research Renewal Awards for Cancer Diagnosis, Prevention, and Treatment. Letter of Intent Receipt Dates: March 1, July 1, and Nov. 1. The PA solicits applications from small business concerns to fund the competing renewal of funded phase II SBIR grants that would require approval of a Federal regulatory agency and clinical evaluation up to proof-of-principle demonstration, only through a phase II trial. Products for development include, but are not limited to: drugs, vaccines, radioligands, biomarkers, medical implants or devices, imaging protocols proposed for clinical use, new software for instrument performance, and diagnostic or predictive assays applicable for cancer diagnosis, prevention, and treatment. The PA is available at http://grants.nih.gov/grants/guide/pa-files/PA-06-051.html.

Inquiries: For NCI—Rosemary Wong, 301-496-9360; rw26f@nih.gov.

PA-06-052: NCI Phase II Small Business Technology Transfer Renewal Awards for Cancer Diagnosis, Prevention, and Treatment. The PA solicits STTR grant applications from small business concerns and will use the phase II STTR R42 grant mechanism. The PA is available at http://grants.nih.gov/grants/guide/pa-files/PA-06-052.html.

Limited Competition

NOT-CA-06-001: Notice of Limited Competition for Competing Continuation Applications: Breast Cancer Family Registries. NCI is requesting competing renewal U01 cooperative agreement applications from awardees for the B-CFR initiative. The funding opportunity would support the maintenance and re-structuring of the research infrastructure to increase its use and exploitation by interdisciplinary teams of researchers, including investigators from the B-CFR participating institutions and scientists from the research community. The notice is available at http://grants.nih.gov/grants/guide/notice-files/NOT-CA-06-001.html.

Inquiries: Daniela Seminara, 301-594-7347, seminard@mail.nih.gov.

In Brief:

Abramson Center Receives NCI Core Grant Renewal

(Continued from page 1)

from NCI. The grant represent a 37-percent increase in money awarded in 1999, the last time NCI reviewed the center, said **John Glick**, center director. The center also recently broke ground on the construction of the Center for Advanced Medicine, a $247 million ambulatory care facility that will house all outpatient care for cancer patients at Penn. The facility will include a new department of radiation oncology, as well as ambulatory surgery, diagnostic imaging, and cardiovascular services. This 350,000-square-foot building is scheduled to open in June 2008. . . . **UNIVERSITY OF MINNESOTA Cancer Center** received two program project grants from NCI totaling $20 million over five years for cancer research into stem cell and natural killer cells. Principal investigators are **Philip McGlave,** chief of the Division of Hematology, Oncology, and Transplant and co-leader of the Translational Research Program, and **Jeffrey Miller**, hematologist/oncologist and co-leader of the Transplant Biology and Therapy Program. . . . **FOX CHASE CANCER CENTER** received a $900,000 three-year grant from the Ovarian Cancer Research Fund, a philanthropic organization. **Andrew Godwin**, director of the Clinical Molecular Genetics Laboratory, will lead a group of researchers studying the tumor stroma in ovarian cancer. . . . **MEMORIAL SLOAN-KETTERING** Cancer Center announced two appointments: **Laura Liberman**, radiologist in the Breast Imaging Section of the Department of Radiology, was named program director of Women Faculty Affairs in the office of the president. **David Klimstra** was named chief of the Surgical Pathology Service in the Department of Pathology. . . . **JOHNS HOPKINS** Avon Foundation Breast Center, in the Johns Hopkins Outpatient Center on the East Baltimore Medical Campus, was dedicated Nov. 9. The 14,500-square-foot facility brings together experts and state-of-the-art imaging equipment and technology for full coordination of care. The center houses the only digital mammography equipment in Baltimore, said **Martin Abeloff**, director of the Johns Hopkins Kimmel Cancer Center. It is overseen by **Theodore Tsangaris**, director of breast surgery and associate professor of surgery. **Nagi Khouri** is director of breast imaging and associate professor of radiology. The center was constructed with funds from a $10 million gift from the Avon Foundation in 2003. The funds also support research and outreach to underserved women. Recently, the cancer center also received a Specialized Programs of Research Excellence grant from NCI for translational breast cancer research, as well as research funding from the Department of Defense. . . . **CALIFORNIA STATE UNIVERSITY** at Sacramento and **UC Davis Cancer Center** have signed an agreement to create the Partnership to Reduce Cancer Health Disparities Through Education, Research and Training. The collaboration would join the UC Davis Cancer Center Outreach Research and Education Program with departments in Sacramento State College of Health and Human Services, said **Ralph deVere White**, assistant dean for cancer programs at UC Davis and director of the UC Davis Cancer Center. Three projects are in development for the first year: co-development of an NIH grant to develop and test ways to improve symptom management and quality of life in elderly cancer patients; co-sponsorship of events centered on ovarian cancer; and creation of community networks focused on the Hispanic/Latino, African American and American Indian populations.

Awards & Appointments:

Three Young Researchers Share Paul Marks Prize

PAUL MARKS PRIZE for Cancer Research was awarded to three young researchers who will share a $150,000 award. The winners are **Tyler Jacks**, of the Massachusetts Institute of Technology and the Howard Hughes Medical Institute; **Scott Lowe**, of Cold Spring Harbor Laboratory and HHMI; and **Jeff Wrana**, of the University of Toronto and the Samuel Lunenfeld Research Institute. The prize, named after the MSKCC president emeritus, recognizes significant contributions to the basic understanding and treatment of cancer by scientists under age 45. Winners were selected by a committee led by **Jeffrey Friedman**, professor at Rockefeller University. . . . **HAROLD MAURER**, chancellor of the University of Nebraska Medical Center and pediatric oncologist known for his work in rhabdomyosarcoma, was named the 109th King of Ak-Sar-Ben during the annual Knights of Ak-Sar-Ben Coronation Ball in Omaha Oct. 15. Ak-Sar-Ben, which is Nebraska spelled backwards, is a civic organization. The traditional Nebraska event promotes volunteerism, philanthropy, and community pride, and has raised nearly $3 million in scholarship funds. For 26 years, Maurer served as principal investigator of NIH research grant awards and was chairman of the national Intergroup Rhabdomyosarcoma Study Group.

. . . **JANET WOODCOCK,** deputy commissioner for operations at FDA, is the first recipient of the Leadership in Personalized Medicine award from the Personalized Medicine Coalition, a non-profit group of academic, industrial, government, patient, and health care provider organizations. The group singled out two initiatives under her leadership: the Critical Path initiative to modernize methods for evaluating the safety and effectiveness of drugs; and the FDA Guidance on Pharmacogenomic Data Submissions, which established a framework for voluntary submission of data in evaluating new drug and biologic license applications. . . . **KENNETH BUETOW** was appointed associate director for bioinformatics and information technologies, a new position at NCI. He was director of the NCI Center for Bioinformatics. He is a member of the NCI Executive Committee. . . . **JULIE ROSS**, professor of pediatrics at the University of Minnesota Medical School and associate director for population sciences at the University of Minnesota Medical Center, was selected by CureSearch National Childhood Cancer Foundation to head the Childhood Cancer Research Network, a new North American childhood cancer research registry. CCRN will collect and maintain information on children and young adults at medical centers affiliated with CureSearch Children's Oncology Group. All COG sites, of which there are more than 200 hospitals, will be required to register pediatric cancer patients in the CCRN at the time of diagnosis.

Organizations:

Cancer Quality Alliance Formed By ASCO, NCCS

The American Society of Clinical Oncology and the National Coalition for Cancer Survivorship have formed the Cancer Quality Alliance, a forum for stakeholders in the cancer community whose mission is to improve the quality of care provided to people with cancer.

The Alliance met late last month in Washington, D.C. ASCO and NCCS members will co-chair the Alliance, which will work to foster collaboration among organizations committed to cancer care quality improvement.

"The goal of the Cancer Quality Alliance is to become a national voice for quality cancer care," said Patricia Ganz, a medical oncologist with the University of California, Los Angeles, Schools of Medicine and Public Health and co-chairman of the Alliance. "ASCO is committed to improving the quality of the cancer care delivery system, and through this new partnership, we can put the systems in place to ensure all people with cancer receive the best care possible."

"The Centers for Medicare & Medicaid Services has put a high priority on advancing initiatives for quality healthcare, so there is no better time than now to bring together strong organizations with creative ideas for quality improvement," said Ellen Stovall, NCCS president and co-chairman of the Alliance. "We look forward to working through the Cancer Quality Alliance to encourage quality monitoring and improvement mechanisms that will guarantee a high level of care for all people diagnosed with cancer."

* * *

NATIONAL BREAST CANCER COALITION FUND and former President **Bill Clinton** announced the formation of the Virginia Clinton Kelley Fund, during the organization's annual gala dinner in New York City on Nov. 3. Created as part of NBCCF, the new fund honors the President's mother, whose courage in the face of adversity inspired Clinton's commitment to public service. She died of breast cancer during his presidency.

"The Virginia Clinton Kelley Fund will make it possible for us to pose the toughest questions and take the kinds of risks we must to overcome clinical, political, and social barriers to real progress in breast cancer," said NBCC President Frances Visco.

"Tangible change on an issue as pervasive as breast cancer demands courage and commitment," Clinton said. "My mother was a strong and persistent woman, who firmly believed that anything can be done if you put your mind to it. Tonight I stand, as a former President but, even more so, as a proud son, committed to helping the National Breast Cancer Coalition in its ongoing efforts to eradicate this disease."

Revlon CEO **Jack Stahl** presided as chairman of the gala, which was sponsored by Revlon.

* * *

SOCIETY FOR NEURO-ONCOLOGY announced the election of officers: **Abhijit Guha**, president; **Mark Gilbert**, vice president; **Corey Raffel**, secretary/treasurer**.** The medical oncology representative is **Glenn Lesser**. **Timothy Cloughesy** is the neuro-oncology representative and Jonathan Finlay is the pediatric representative. The board of directors includes: **Erwin Van Meir** for basic science; **Frederick Lang** for neurosurgery; **David Louis** for pathology; **Minesh Mehta** for radiation oncology; and **Christina Meyers** for other specialties. **Michael Prados** is the past president.

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.