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NCI Pilot Project To Speed Phase III Trials Deemed Unsuccessful, Will Be Shut Down

An NCI pilot project designed to streamline the review of proposed phase III clinical trials is being shut down on the advice of Institute staff and external advisors, officials said.

The three-year pilot project enlisted external experts rather than Institute staff to review concepts for phase III trials for lung cancer and genitourinary cancers. Had these Concept Evaluation Panels been successful, NCI would have been likely to form similar panels for other major cancers.

The CEPs were one of three pilot projects developed after four
(Continued to page 2)

In Brief:

Roswell Park Hired 31 Faculty In 2002

In "Second Wave" Of Recruitment Push

ROSWELL PARK CANCER INSTITUTE has recruited 31 scientists and clinicians since early this year in a second wave of hiring in its effort to rebuild its stature as a major cancer research center, President and CEO **David Hohn** said. Last January, Hohn announced that the center had hired 42 faculty members since October 1999 in what he promised would be "only the first wave." By the end of this year, 26 of the 31 new hires will have arrived at the center. Recently, RPCI announced the recruitment of **James Marshall** as senior vice president for cancer prevention and population sciences. Marshall was associate director of cancer prevention and control at Arizona Cancer Center. "Roswell Park has been on a mission to rebuild its stature as one of the world's leading research facilities in the quest to cure cancer," Hohn said. "With our commitment to enacting change and recruiting top-tier clinicians and scientists, we believe that Roswell Park will continue to play an increasing leadership role in research and treatment advances." . . . **NATIONAL COALITION FOR CANCER SURVIVORSHIP** was awarded a grant from The Robert Wood Johnson Foundation that, in part, will support a town hall on integrating palliative care across the lifespan for people with cancer. NCCS also will use a portion of the grant to develop its website, www.canceradvocacy.org, adding a new patient education section on palliative care resources that help cancer survivors manage the symptoms of cancer and its treatment throughout their lives. The town hall forum is scheduled for April 25, in Cleveland. Inspired by the 2001 Institute of Medicine report, "Improving Palliative Cancer Care," NCCS said it hopes
(Continued to page 7)

Cancer Statistics:

NCI Outlines Plan
For Marin County
Breast Cancer Review
... Page 4

State Cancer Incidence
Report Published
By NCI, CDC
... Page 4

NCI Programs:

Half Of New Funds
Were Spent On Grants
In FY2002; NCI Funded
1,262 Competing Grants
... Page 5

Cancer Screening:

Frequency Of Screening
For Cervical Cancer
May Be Cut, ACS Says
... Page 6

NCI Intramural Program:

Scientists Glimpse
Cellular Machines
Inside Living Cells
... Page 6

Funding Opportunities:

RFA Available
... Page 7



Concept Evaluation Panels Weren't Faster Than CTEP

(Continued from page 1)

years of planning by NCI and two advisory committees. Altogether, the design of the review system and its trial run lasted seven years.

Other components of NCI's Clinical Trials Initiatives, which are continuing, include:

—A \$50-million, five-year contract for a Clinical Trials Support Unit to manage phase III trials.

—“State-of-the-Science” meetings on the major cancers, where NCI invites experts to discuss future directions for clinical research.

According to a review of the Concept Evaluation Panels presented to the NCI Board of Scientific Advisors last week, the panels were no faster than the traditional NCI concept review, and cost about \$180,000 more a year to run for the two diseases.

Also, the panels were no more rigorous in concept reviews than the NCI Cancer Therapy Evaluation Program, Institute officials said. CTEP and the panels approved about the same proportion of phase III trial protocols over the past three years.

“We were unable to show a significant difference between CEP and CTEP in approvals or disapprovals of protocols over the three-year pilot,” Jeffrey Abrams, senior investigator in CTEP, said to the NCI Board of Scientific Advisors at a Nov. 14 meeting.

Earlier this year, a survey of cooperative group

members conducted by Research Triangle Institute found no strong preference for either form of review.

Group chairmen earlier this year recommended against extending the panels to other diseases. “The CEP process is expensive, time consuming for the reviewers, and prone to conflicts of interest that are less likely to pervade the CTEP review process,” Richard Schilsky, chairman of Cancer and Leukemia Group B and chairman of the group chairs advisory committee, wrote in a letter to NCI.

The quality of the CEP review “is not clearly superior to the concept reviews provided by the traditional CTEP process,” wrote Schilsky, professor of medicine and associate dean for clinical research, University of Chicago Division of the Biological Sciences.

CTEP concurred with the group chairmen. Since the BSA had originally approved the Clinical Trials Initiatives in 1999, NCI asked for its opinion. The BSA voted unanimously to accept the recommendation.

The panels “will be shut down immediately,” Abrams said to **The Cancer Letter** earlier this week. “We have notified the members that we will not be holding a December meeting. We explained to them the outcome of the evaluations and the vote of the BSA and thanked them for helping us to conduct this pilot.”

Four Years Of Planning

NCI formed the CEPs for lung and GU cancer in October 1999, after an often contentious four-year process in which two advisory committees and the cooperative groups chairmen studied ways to improve the clinical trials system.

The process began in the spring of 1996 with the formation of the 29-member Clinical Trials Program Review Group, chaired by James Armitage, the Henry J. Lehnhoff Professor and chairman of the Department of Internal Medicine, University of Nebraska Medical Center.

The review group was one of several committees convened by former NCI Director Richard Klausner to study the Institute's major programs.

At the time, “reinvention” initiatives, inspired by then-Vice President Al Gore, swept through the federal government. Klausner, appointed NCI director in 1995, had described his mission as one that would infuse the Institute with a new “ethos” grounded in scientific rigor and guidance from experts outside the



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Institute (**The Cancer Letter**, Vol. 21 No. 30, July 28, 1995).

In the fall of 1997, after more than a year of study, the Armitage committee presented Klausner with a report that made a number of specific recommendations (**The Cancer Letter**, Vol. 23 No. 38, Oct. 3, 1997).

Primarily, the committee urged NCI to:

—Support the formation of an NIH study section solely for the peer review of patient-oriented cancer research grant applications.

—Increase funding to the cooperative groups to bring their budgets up to peer-review recommended levels.

—Provide more support for the training of clinical investigators.

—Reduce the administrative burdens on cooperative groups.

—Develop uniform standards for data collection and reporting.

The committee said that if more patients were enrolled in trials, the trials could be completed faster. “The level of funding [for the groups] will determine how many patients can be on clinical trials,” Armitage said in a Sept. 24, 1997, presentation to the National Cancer Advisory Board.

While the committee could not reach consensus on how the clinical trials program should be structured, it recommended that NCI form another committee to review the cooperative groups and recommend the optimal number of groups that should be funded.

“We don’t need to invent a new system, but we need to modify this one to let these clever folks we have out there do their job as efficiently as they possibly can,” Armitage said at the time. “We need to remove obstacles from their path.”

NCI then formed a 37-member Clinical Trials Implementation Committee, which deliberated from December 1997 to August 1998 on how to remove those obstacles. But, for the first several months, some committee members and cooperative group chairmen thought that NCI was developing further obstacles.

CTEP staff proposed projects that several group leaders interpreted as an attempt by the Institute to take over management of the clinical trials groups, centralizing power in Bethesda (**The Cancer Letter**, Vol. 24 No. 23, June 12, 1998).

The implementation committee presented its report to the BSA in September 1998. But the BSA

nearly revolted when the two-hour, 80-slide presentation entered its third hour. After a lunch break, and a summary by Robert Wittes, then deputy director for extramural science, the board voted to accept the plan for the three pilot projects.

At that meeting, NCI officials promised to double the funding for the cooperative groups over the next three to four years.

In FY 2002, funding for the cooperative groups for treatment studies alone was \$158 million, an increase of \$69.5 million from the FY 1997 allocation of \$88.5 million.

The funding for cooperative group treatment studies was \$93.9 million in FY 1998; \$126 million in FY 1999; \$145.5 million in FY 2000; and \$154.2 million in FY 2001. The groups experienced the largest increases in patient accrual during the years of the largest budget increases, sources said.

The \$50 million contract for the CTSU was awarded in 2000 to Westat Corp., of Rockville, Md. Westat subcontracts part of the project to the Coalition of National Cancer Cooperative Groups, based in Philadelphia, and to the Oracle Corp. Health Informatics Consulting Practice.

Earlier this year, NCI allowed oncologists not affiliated with cooperative groups to enter patients on phase III trials through the CTSU. As of this spring, the CTSU enrolled only 160 patients. “We had hoped to be in the thousands by now,” Abrams said at the time (**The Cancer Letter**, Vol. 28 No. 19, May 10, 2002).

Also in the past two years, NCI developed a Central Institutional Review Board for phase III trials, designed to address the overwork and backlog being experienced by many local IRBs. An evaluation of that program is pending.

Benefit Of Trial Concept Review

While the CEP pilot failed to take off, the project provided independent validation of the benefit of review of phase III trial concepts, Abrams said at the BSA meeting last week.

From October 1999 to October 2002, 13 trials were disapproved by the CEPs. During the same period, 23 trials were disapproved by CTEP. Costs of the disapproved trials if conducted would have been more than \$41 million just for patient-reimbursement costs, Abrams said.

About 20 to 30 percent of concepts for phase III trials are disapproved, generally due to underpowering of the study, weak preliminary data,



or the existence of competing trials. Most disapproved concepts are modified to improve the design.

“If disapproved studies were conducted, this would cost NCI over \$1.6 million per trial on average,” Abrams said.

CTEP is working on ways to speed the development of protocols once trial concepts are approved, Abrams said. While the goal is 60 days from approval to protocol, CTEP’s median time from concept to provisional approval is 95 days, and median time from concept to protocol approval is 218 days.

Also, some of the cooperative groups are considering whether to use some form of Web-based concept review using software that NCI licensed for the CEPs. The software enabled the panels to have online meetings, saving travel time and expense.

The text of the Armitage report is available at: http://deainfo.nci.nih.gov/advisory/bsa/bsa_program/bsactprgmin.htm.

The Implementation Committee report is available at: <http://ctep.cancer.gov/resources/committee.html>.

CTSU Web site: www.ctsu.org.

NCI CTEP: <http://ctep.cancer.gov/index.html>.

Cancer Statistics: **NCI Outlines Review Of Marin Breast Cancer Rates, Risks**

NCI has outlined a plan for reviewing the high incidence rates of breast cancer in Marin County, Rep. Lynn Woolsey (D-Calif.) said this week.

Woolsey received on Nov. 21 a report she requested from NCI outlining a plan of action developed by a task force that includes representatives from NCI, the National Institute of Environmental Health Sciences, and the Centers for Disease Control and Prevention (**The Cancer Letter**, Vol. 28 No. 42, Nov. 15, 2002).

Under the plan, the agencies will:

- Determine actual breast cancer rates in Marin and other counties based on 2000 Census data.
- Define the role of known risk factors.
- Define the role of environmental factors.

As part of the plan presented by NCI, the task force will recalculate cancer rates in California so that Marin breast cancer rates can be compared to those of other counties, and facilitate the completion of epidemiologic studies in Marin County to help

determine new breast cancer diagnoses attributable to known risk factors, according to a statement released by Woolsey. Also, NCI will work with the CDC to explore opportunities and technologies for measuring environmental exposures in Marin County.

“We’ve just begun to get to the bottom of what is happening to women in Marin County,” said Woolsey in a statement. “Good work to find the cause of breast cancer in Marin County has been going on in many different places. Enhancing community efforts by coordinating with federal agencies that have the resources to scientifically research the incidence of breast cancer in the North Bay will go a long way to determining what is causing the high rate of the disease and help us figure out what we can do.”

Woolsey invited Larry Meredith, director of the Marin County Health and Human Services Department, to participate in the Nov. 21 meeting. Woolsey said she will have a follow up meeting with the NCI Director Andrew von Eschenbach early next year.

State Cancer Incidence Rates Published By NCI, CDC

HHS has released “U.S. Cancer Statistics: 1999 Incidence,” the most comprehensive federal data available to date on state-specific cancer incidence rates.

Produced jointly by NCI and the Centers for Disease Control and Prevention, in collaboration with the North American Association of Central Cancer Registries, the report provides state-specific and regional data for cancer cases diagnosed in 1999, the most recent year for which data are available.

The new data, compiled from cancer registries that have met criteria and standards of accuracy, completeness and timeliness, are from 37 states, six metropolitan areas, and the District of Columbia and represent about 78 percent of the U.S. population. Previous reports on cancer incidence used data from smaller samples of the U.S. population.

According to the report:

—The leading cancer in men, regardless of race, is prostate cancer, followed by lung/bronchus and colon/rectal. Prostate cancer rates are 1.5 times higher in black men than white men.

—The leading cancer in women, regardless of race, is breast cancer, followed by lung/bronchus and colon/rectal in white women, and colon/rectal and lung/bronchus in black women. Breast cancer rates



are about 20 percent higher in white women than in black women.

—Melanomas of the skin and cancer of the testis are among the top 15 cancers for white men, but not black men.

—Melanomas of the skin and cancer of the brain/other nervous systems are among the top 15 cancers for white women, but not black women.

—Multiple myeloma (cancer that arises in plasma cells) and cancer of the stomach are among the top 15 cancers for black women, but not white women.

—Multiple myeloma and cancer of the liver are among the top 15 cancers for black men, but not white men.

The report also shows geographic variations in the occurrence of cancer. It does not include information about cancer deaths.

“Researchers will continue to examine the quality of data associated with race, ethnicity, completeness of reporting, and the effects of using census projections from 1990,” an HHS press release said. “Data collection procedures for identifying specific racial and ethnic populations vary widely from registry to registry; therefore, only data for blacks and whites are included in this report.”

Future reports will include data for other racial and ethnic populations, HHS said.

“Cancer rates usually have some uncertainty associated with them and are updated as more information becomes available from registries and as better estimates of state and regional populations become available from the U.S. Census Bureau,” HHS said. “The process of recalculating cancer rates is standard practice.”

The full report is available at www.cdc.gov/cancer/ and www.seer.cancer.gov/statistics.

NCI Programs: **Nearly Half NCI Budget Spent On Research Project Grants**

NCI spent nearly \$272 million, two-thirds of its \$423 million budget increase for fiscal 2002, on research grant initiatives, NCI Deputy Director Alan Rabson said.

For the fiscal year ended Sept. 30, NCI’s final obligations were \$4.177 billion, an 11 percent increase over FY2001, Rabson said to the NCI Board of Scientific Advisors at its Nov. 14 meeting.

Rabson provided the following budget highlights:

—**Research Grants:** About \$197 million of the increase funded research project grants. Of that, about \$123 million, or 62 percent, funded non-competing (type 5) grants.

Including the \$86 million SBIR/STTR program, the size of the research project grant pool grew to over \$1.9 billion—more than 45 percent of the Institute’s total budget.

NCI funded 1,262 competing research project grants, 419 more than last year. The FY2002 payline was at the 22nd percentile. One additional P01 grant was funded compared to last year, for a total of 36 competing awards in 2002. P01s represent only about 3 percent of the number of awards, yet are 17 percent of the funds, Rabson said.

Grants funded through Requests for Applications remained at about 6 percent, or \$25 million, of the competing pool.

—**Cancer Centers** and Specialized Programs of Research Excellence budget increased by about 14 percent. This includes funding one new cancer center, and 11 new SPORES in the following sites: head and neck (2); brain (2); lymphoma (2); prostate (3); and GI (2).

—**Training:** Funding for the careers program went up by \$3.7 million, a 7 percent increase. Cancer Education awards increased dramatically, by \$5 million, or 23 percent. -National Research Service Awards remained constant at about 1,600 trainees, but at a stipend level of about 10 percent higher.

—**NCI Intramural Program** remained at about 15 percent of the total NCI budget.

—**Cancer Control** expanded by more than 9 percent, or more than \$40 million in 2002. Cancer control represents about 12 percent of the NCI budget.

Planning Difficult Without FY2003 Budget

The NCI budget for FY2003 currently is held flat at the FY2002 level under a continuing resolution.

“We are modeling different [budget] scenarios based on our current CR level, as well as the President’s budget,” Rabson said. The Senate recommended an appropriation of \$4.642 billion for NCI, the same level as the President’s request.

“The House has not considered an appropriation bill and we are not sure when they will,” Rabson said.

Under the Senate proposal, NCI would transfer \$60 million in grants to the newly established National Institute of Biomedical Imaging and Bioengineering.



NCI transferred \$20 million to the new institute last year.

“Regardless of our final budget for 2003, we project a need to put about \$122 million of our increase, or a 10 percent increase, into non-competing RPGs,” Rabson said.

The number of grant applications submitted to NCI are continuing to rise, which affect the payline, or the chance of success. “From the first round, we are seeing an increase of 13 percent,” Rabson said. “Projecting for the full year, we think that the increase will be in the range of 8 to 10 percent. This obviously has many consequences on the payline we set for 2003.”

Currently, non-competing grants are being awarded at the level committed on the prior grant award statement.

In another development, NCI’s Bypass Budget for FY 2004 has gone to press and will be available online and in print soon, Rabson said.

Cancer Screening: **Cervical Cancer Screening Frequency May Be Reduced**

The American Cancer Society this week issued new guidelines on early detection tests for cervical cancer and precancer.

Under the new recommendations, most women would begin cervical cancer screening later, have an option to stop at a certain age (70 years) and be exempt from screening entirely if they have had a hysterectomy.

“The new guidelines will have a major impact on the number of women who are over-screened and over-treated,” said Mary Simmonds, ACS president. “Because most cervical precancers grow slowly, having a test every two to three years will find almost all cervical precancers and cancers while they can be removed or treated successfully.”

The new guidelines are:

—Cervical cancer screening should begin about three years after a woman begins having vaginal intercourse, but no later than 21 years of age.

—Cervical screening should be done every year with regular Pap tests or every two years using liquid-based Pap tests. At or after age 30, women who have had three normal test results in a row may get screened every two to three years. But a doctor may suggest getting the test more often if a woman has certain risk factors such as HIV or a weakened

immune system.

—Women 70 years of age and older who have had three or more normal Pap test results and no abnormal results in the last 10 years may choose to stop cervical cancer screening.

—Screening after a total hysterectomy (with removal of the cervix) is not necessary unless the surgery was done as a treatment for cervical cancer or precancer. Some other special conditions may require continued screening. Women who have had a hysterectomy without removal of the cervix should continue cervical cancer screening at least until age 70.

NCI Intramural Program: **Scientists Glimpse Cellular Machines Inside Living Cells**

Using advanced imaging technology and computational simulations, scientists have, for the first time, glimpsed the action of a cellular machine at work within living cells. The work puts forth a new concept of cellular machines as dynamic protein complexes that are continually building and rebuilding themselves within the cell, rather than the stable structures scientists have traditionally thought them to be.

The study was published in the Nov. 22 issue of *Science*.

Researchers from NCI, in collaboration with scientists from three other institutions, investigated a cellular machine known as RNA polymerase I, an enzyme that decodes a specific group of genes in the cell. The polymerase is composed of more than ten protein subunits. By analyzing the time it took the many subunits to arrive at a gene and assemble themselves into a functioning protein complex, researchers discovered that RNA polymerase I is constantly assembling and disassembling itself from a large pool of subunits within the cell.

“These findings challenge the current model of cellular machines,” said Tom Misteli, of NCI’s Cell Biology of Gene Expression Group, the lead investigator on the study. “No longer can we think of cellular machines as stable, static, and precisely-assembled complexes, akin to man-made machines.”

Instead, researchers found that polymerase subunits came together and formed a complex each time a gene was read, on average every 1.4 seconds. Computer simulations suggest that each formation resulted from random, chaotic interactions between protein subunits that eventually came together in the



proper configuration. Once a complete polymerase finished reading a gene, the subunits quickly disassembled and scattered throughout the cell. Researchers speculate that the dynamic nature of cellular machines allows components to assemble as needed in response to changing environmental conditions.

“The new method we used here allows us to study a whole new dimension in cellular processes – time,” said Miroslav Dundr, also of NCI’s Cell Biology of Gene Expression Group.

To visualize the polymerase at work within living cells, researchers marked many of the smaller subunits with a small jellyfish protein that emits fluorescent light that can be detected under a microscope. To track the assembly and disassembly of these subunits, the researchers applied a very short, intense laser pulse to the cell. While most of the tagged subunits throughout the cell continued to emit fluorescent light, the laser bleached the fluorescence out of a defined area within the cell. As tagged polymerase subunits began to move into the bleached area, their movement could then be tracked as an increase in fluorescence.

Using the data they had collected about the time it took the fluorescently tagged polymerase subunits to form a complete RNA polymerase I complex and then redisperse, researchers applied computer simulations to test various models of how the polymerase assembles and reads genes. Combining observations made in living cells with computational methods enabled researchers to measure fundamental biophysical properties in living cells. The approach is considered a first step toward complete computer models of living cells and organisms.

Funding Opportunities: **RFA Available**

RFA CA-03-018: Cooperative Planning Grant for Cancer Disparities Research Partnerships

CDRP provides resources for the cooperative planning, development and conduct of radiation oncology clinical research trials in institutions that care for a disproportionate number of medically underserved, low income, ethnic, and minority populations but have not been traditionally involved in NCI-sponsored research.

The grant will also support the development and maintenance of support/mentor partnerships between these institutions new to radiation oncology clinical

trials research and experienced institutions actively involved in NCI-sponsored cancer research. The total budget for CDRP is \$27.M over five years. The NCI made two awards in FY 2002 and anticipates making four additional awards in FY 2003.

The full text of the RFA is available at <http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-03-018.html>.

Inquiries: Dr. F. Govern, 301-496-6111, governfr@mail.nih.gov, Dr. N. Coleman, 301-495-5457, ccoleman@mail.nih.gov, or Dr. R. Wong, 301-496-9360, wongr@mail.nih.gov, of NCI's Radiation Research Program.

In Brief:

Hiatt To Leave NCI; Croyle Named Acting DCCPS Director

(Continued from page 1)

to encourage public dialogue about the need for cancer survivors to have access to both high-quality and coordinated palliative care that is integrated across the life span. NCCS will highlight Project Safe Conduct, a collaboration of Ireland Cancer Center at University Hospitals of Cleveland, which is an NCI-designated comprehensive cancer center, and the Hospice of Western Reserve. . . . **NCI STAFF CHANGES: Robert Hiatt**, deputy director of the NCI Division of Cancer Control and Population Sciences, will leave the Institute in February to accept appointments as director of population science at the University of California, San Francisco, Comprehensive Cancer Center, and professor of epidemiology at the UCSF School of Medicine. **Robert Croyle** was named acting director of the NCI Division of Cancer Control and Population Sciences, following the departure of Barbara Rimer. He has been associate director for behavioral research in DCCPS. **Jill Bartholomew** has been named acting director of the NCI Office of Communications. She has been deputy director of the office. **Frank Balis** was named acting clinical director for NCI and will be recruiting for clinical positions. Balis replaces **Gregory Curt**, who has left NCI for AstraZeneca. . . . **ROBERT BRESALIER** joined the University of Texas M.D. Anderson Cancer Center as professor and chairman of the Department of Gastrointestinal Medicine and Nutrition, in the Division of Internal Medicine. Bresalier was director of gastrointestinal oncology and the gastrointestinal cancer research laboratory at the Henry Ford Health



Sciences Center. He also held appointments at the University of Michigan School of Medicine, Josephine Ford Cancer Center, and the Karmanos Cancer Institute. . . . **LAWRENCE DELUCAS** will deliver the first Hugh R. K. Barber endowed lecture during the annual meeting on women's cancer, at the Society of Gynecologic Oncologists annual meeting Feb. 1 in New Orleans. The lectureship honors one of SGO's founding members and past president. DeLucas, professor of optometry and director of the Center for Biophysical Sciences and Engineering at the University of Alabama at Birmingham, was the first optometrist in space. He served as payload specialist for the Microgravity Laboratory Mission on the Space Shuttle Columbia in 1992. . . . **CARLO GIOVANNI TRAVERSO**, a research student in the Kimmel Cancer Center at Johns Hopkins University, is one of six winners of the Collegiate Inventors Competition by the National Inventors Hall of Fame. He was chosen for his work on the development of a non-invasive stool test for colon cancer screening. Traverso has been working on the test in the lab of Hopkins cancer researcher Bert Vogelstein. Vogelstein, Traverso and colleagues invented a technology they call Digital Protein Truncation to

divide extracted genetic code from stool samples into separate, smaller portions so that mutated copies of DNA stand out. Preliminary studies of the test were published in January 2002 in the New England Journal of Medicine. Traverso will receive a \$20,000 award and \$2,000 worth of computer equipment. . . . **TED KENNEDY JR.** was the keynote speaker at a Nov. 8 event in Washington, DC, marking the 20th anniversary of the founding of The Wellness Community, a non-profit organization that provides free emotional support for people with cancer. Kennedy, who lost one of his legs to bone cancer in 1973, is a member of the National Board of Directors of The Wellness Community and often lectures on behalf of the organization. In his remarks, he urged people with cancer to become active in their care by learning about their treatment options and seeking out emotional support services. . . . **HYAM LEVITSKY**, a Johns Hopkins University oncologist and scientist, received a \$1.5 million, three-year grant from the Multiple Myeloma Research Foundation for his research on multiple myeloma. Levitsky and colleagues will coordinate research projects on myeloma stem cells and various methods of cell-mediated immunotherapy.



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