NATIONAL CANCER INSTITUTE

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Eliminating the Suffering and Death Due to Cancer

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Funding for Strategic Initiatives Highlights Research Priorities

Final details about allocations under the Fiscal Year 2004 National Cancer Institute (NCI) budget have been completed, providing an important snapshot of some of the top research priorities for NCI and the cancer community over the next few years. Included among these details is how the five percent pool drawn from each NCI division's 2004 base budgets will be used. Speaking at last week's joint meeting of the NCI Board of Scientific Advisors and Board of Scientific Counselors, NCI Director Dr. Andrew C. von Eschenbach provided a breakdown of how that pool of funds would be redeployed.

As reported previously (*NCI Cancer Bulletin*, February 3), NCI received a slight increase in funding for the 2004 fiscal year. However, because of mandated federal salary increases, an increasing number of noncompeting grants, and assessments to support the NIH Roadmap Initiative and other centralized activities, NCI is effectively operating with $2.7 million less than the 2003 budget. As a result, NCI division directors were asked to reduce their base 2004 budgets by five percent to create a pool of dollars to fund new initiatives. Those funds yielded a pool of approximately $75 million.

Of that $75 million, Dr. von Eschenbach explained, approximately $54.5 million has been redeployed "to address the strategic initiatives that we as an entire institute—division heads, center directors, the deputies, the senior

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Director's Update

Cooperative Group Chairs Visit Bethesda

On March 17, the Clinical Trials Cooperative Group Chairs came to NCI to continue an ongoing dialogue about re-engineering the cancer clinical trials infrastructure to improve the publicly funded cancer clinical research system.

The cooperative groups have played an integral part in the many accomplishments of our cancer clinical trials infrastructure, but we all agree we must commit to a process of continuous improvement and must adapt to the challenge of the future of molecular oncology.

For almost a year, the Cooperative Group Chairs worked together under the aegis of the Coalition of National Cancer Cooperative Groups to develop recommendations to improve the nation's multicentered cancer clinical cooperative groups research system. Based on what the Chairs see as influencing the future of the system—unprecedented opportunities in cancer treatment and prevention; more complex clinical trials that incorporate molecular profiling, pharmacogenetics, and advanced imaging; regulatory challenges; and the existing clinical trial programs that could function more efficiently and effectively as an integrated, public

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leadership—had all agreed were the highest priorities for the year." These strategic initiatives and redeployed amounts are as follows:

- Integrative cancer biology: $11 million
- Bioinformatics: $15 million
- Scale-up of several programs, including the Rapid Access to Intervention Development (RAID) and Rapid Access to Prevention Intervention Development (RAPID) programs: $4 million
- Clinical trials program: $10 million
- Biomarkers: $7.5 million
- Imaging: $4 million
- Health disparities: $3 million

NCI is engaged in a number of important and worthy initiatives, Dr. von Eschenbach noted, all of which require resources. "[This is] a significant challenge for us," he said, but "not because the resources have shrunk. In fact, the opposite is true. There has never been as much money invested in biomedical and cancer research as there is today. The problem is that the opportunities are even greater."

The challenge in redeploying resources, he added, "is being as strategic about the things we say 'no' to as we are strategic about the things we say 'yes' to... So we want to be making good choices on both sides of that portfolio."

As for the remainder of the $75 million pool, $15 million was put into a reserve to "be used for unexpected issues that come up between now and the close of the fiscal year," Dr. von Eschenbach explained. The final $5.5 million was reallocated to operational units to cover a variety of areas, including the initiation or expansion of division-specific program activities or projects.

"We're trying to be good stewards of the precious resources that we have," Dr. von Eschenbach stressed. "We're doing everything we possibly can to support young investigators and new investigators coming into the field." ◆

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system—they outlined three main categories for discussion:

1. Reducing structural barriers. To remove structural barriers the Chairs proposed 1) harmonizing guidelines to allow trial participation regardless of institutional affiliation, 2) encouraging collaboration through modification of peer-review mechanisms, 3) providing opportunities for cancer centers and SPOREs to function as central laboratories for trials, 4) establishing an inventory of repositories and their capabilities, 5) developing an integrated informatics platform, and 6) rewarding leadership and finding incentives for collaboration.
2. Adjusting NCI pilot programs and oversight role. To accelerate the pace of cancer clinical research, the Group Chairs recommended establishing expedited study review and activation processes, eliminating redundancy in the review system, and strengthening the NCI programs that facilitate trials across centers and groups.
3. Encouraging public-private partnerships. The Group Chairs proposed increased support for public-private partnerships that encourage industry participation in clinical research by recognizing industry-sponsored trials in the peer-review process and by facilitating regulatory review of industry-sponsored trials.

NCI recently established a Clinical Trials Working Group as a subcommittee of the National Cancer Advisory Board. The subcommittee, led by Drs. James Doroshow and Howard Fine, will develop an architectural blueprint of a national clinical trials system led by NCI. The discussions between NCI leadership and the Group Chairs covered many overlapping topics that addressed the efficient management of the clinical research enterprise. After NCI leadership and the Clinical Trials Working Group have an opportunity to examine the issues raised at the March 17 meeting in the context

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Clinical Trials Cooperative Group Chairs	
American College of Radiology Imaging Network	**Dr. Bruce Hillman**
American College of Surgeons Oncology Group	**Dr. Samuel A. Wells, Jr.**
Cancer and Leukemia Group B	**Dr. Richard L. Schilsky**
Children's Oncology Group	**Dr. Gregory Reaman**
Eastern Cooperative Oncology Group and Chair, Coalition of National Cancer Cooperative Groups	**Dr. Robert Comis**
Gynecologic Oncology Group	**Dr. Philip J. DiSaia**
National Surgical Adjuvant Breast and Bowel Project	**Dr. Norman Wolmark**
North Central Cancer Treatment Group	**Dr. Jan Buckner**
Radiation Therapy Oncology Group	**Dr. Walter J. Curran, Jr.**
Southwest Oncology Group	**Dr. Charles A. Coltman, Jr.**
Coalition of National Cancer Cooperative Groups Patient Advisory Board	**Ms. Deborah Collyar**

Cancer Research Highlights

Inherited Genetic Variation Influences Response to Nicotine-Dependence Treatment

Pharmacogenetics is starting to provide some new insights into the treatment of nicotine dependence, both on how genetic variation influences dependence and in finding potential targets for therapy, Dr. Caryn Lerman said last week during the Joseph W. Cullen Memorial Award lecture at the American Society of Preventive Oncology annual meeting.

Progress in this area is important, Dr. Lerman stressed. About one in four Americans still smoke, and although two drugs have been approved by the FDA for treatment, they are only effective in a fraction of people.

"Clearly there is a need to develop new models of treatment that can be translated to the clinical setting," she said. Pharmacogenetics offers one possible approach to changing how treatments are delivered in practice, including enhancing outcomes by tailoring the approach according to an individual's genetic makeup.

Dr. Lerman, the associate director for Cancer Control and Population Sciences at the Abramson Cancer Center of the University of Pennsylvania, has led two recent clinical trials that investigated how genetic variation influenced response to nicotine-dependence treatment. In a 600-subject, placebo-controlled clinical trial published in 2002, smokers seeking treatment were randomly assigned to bupropion (Zyban®) or placebo, plus group counseling, for eight weeks. The investigators focused on the CYP2B6 gene, which plays a role in bupropion and nicotine metabolism. Overall, patients on bupropion fared better than those on placebo, although those with a decreased-activity variant of CYP2B6 had lower abstinence rates and increased cravings at the end of the treatment phase. This was especially true in females.

When the investigators looked at craving data, they found that cravings after treatment were not as significant in individuals with the CYP2B6 mutation treated with bupropion compared to those with placebo, meaning that the drug may be reducing relapse in these patients by tempering the craving for nicotine.

In a similar trial that compared two different types of nicotine replacement therapy—nicotine nasal spray or nicotine patch—Dr. Lerman and her colleagues focused on the mu opioid receptor gene (OPRM1). Nicotine increases release of beta endorphin, and the less common Asp40 variant of this gene is associated with greater binding of beta endorphin to the mu opioid receptor (and perhaps the more pleasurable effects of nicotine). The data, currently in press, showed that individuals with the OPRM1 Asp40 variant were more likely to benefit from nicotine replacement therapy but that the effect appeared to be more pronounced during the higher dose phase of the treatment regimen. "This suggests a hypothesis that smokers with this variant may be candidates for extended high-dose patch treatment," Dr. Lerman said.

Agricultural Health Study Examines Alachlor Link to Cancer

A possible association between alachlor application and the incidence of lymphohematopoietic cancers—particularly leukemia and multiple myeloma—is being investigated as part of the Agricultural Health Study (AHS). Developed in 1993 by NCI's Occupational and Environmental Epidemiology Branch (OEEB) in the Division of Cancer Epidemiology and Genetics (DCEG), AHS is a large-scale prospective cohort study of nearly 60,000 farmers and other professionals who apply pesticides to crops. Thirty thousand of their spouses are also included in the study, which is designed to evaluate the effects of environmental, occupational, genetic, and dietary factors on the health of farmers and their families in Iowa and North Carolina.

Alachlor, introduced in 1969 under the trade name Lasso, is an herbicide used mainly in the production of corn, soybeans, and peanuts. It is one of the most widely used herbicides in the United States, according to U.S. Environmental Protection Agency estimates.

The study's latest findings, published in the February 15 *American Journal of Epidemiology*, evaluated the exposure-response relationship between alachlor and cancer incidence, controlling for the effects of several potential confounding factors. Approximately 26,510 study participants reported use of alacholor. A total of 1,466 incident malignant neoplasms were diagnosed in study subjects during the 1993-2000 study period (805

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in the alachlor-exposed group and 661 in the nonexposed group). The investigators noted that these findings suggest a possible association between alachlor application and the incidence of leukemia and multiple myeloma in this population but that additional follow-up of the cohort will shed further light on the risks for these and other cancers.

"AHS is the capstone of a major area of research for DCEG," said Dr. Aaron Blair, chief of OEEB. "The prospective design, with detailed information on agricultural exposures and rural lifestyle factors and biologic specimens to assess gene-exposure interactions, will allow us to evaluate a number of potentially hazardous chemicals that may affect the health of farm families as well as the general population."

Radiation Therapy Early After Recurrent Prostate Cancer Effective, Review Shows

A retrospective review of 501 patients treated with radical prostatectomy who subsequently underwent salvage radiotherapy for recurrent prostate cancer has found that a significant subset of patients typically considered to be at the highest risk of progressive metastatic disease can achieve a durable response. The NCI-funded study may offer some important insights for clinical oncologists who have been reluctant to use radiotherapy in these patients, presuming that their rising prostate-specific antigen (PSA) levels indicate the disease had spread, meaning radiotherapy would likely prove futile.

In the study, published by Dr. Andrew J. Stephenson and colleagues in the March 17 *Journal of the American Medical Association*, the four-year

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Special Report

The Search for a New Method to Increase Screening for Colorectal Cancer

Even though it is estimated that over 90 percent of patients with colorectal cancer could be cured if the cancer were detected at an early stage, the disease remains the second leading cause of cancer death in the nation. This is believed to be due to the fact that the screening rate for the disease lags far behind that of other cancers, with only 30 to 40 percent of people over 50 years old actually being screened for colorectal cancer.

One highly publicized screening method for colorectal cancer is colonoscopy—a method that involves the insertion of a six-foot-long flexible endoscope into the colon of a sedated patient. Despite the probable effectiveness of colonoscopy and its highly accurate results, it has not been implemented on a large scale nationwide. Resistance to the test is partly due to its highly invasive nature and the fact that sedatives administered during the exam require recovery time and leave the patient groggy and unable to drive home alone. It is hoped that the development of a more convenient and noninvasive colorectal cancer screening test might increase compliance and ultimately reduce the mortality rates of the disease.

An endoscope is used to view the colon in optical colonoscopy.

Another commonly used screening tool, the fecal occult blood test (FOBT), is a noninvasive and relatively inexpensive colorectal cancer screening tool that looks for traces of blood in the stool. This test, however, is not highly sensitive or specific—that is, it fails to identify colorectal lesions (polyps or cancers) that do not produce blood in the stool, and it also generates false-positive results from blood being present in the stool due to other diseases or disorders.

However, a new noninvasive method that is in the early stages of development may offer better sensitivity and

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specificity than an FOBT. The multitarget assay panel (MTAP) test looks specifically for mutations in DNA found in the stool that are indicative of colorectal cancer. In this test, the presence of any of 21 specific DNA mutations known to be present in colorectal cancer, as well as changes in DNA structure, are used to diagnose colorectal cancer. Benefits of this test include the fact that it requires neither a prior bowel-cleansing regimen (as in colonoscopy or virtual colonoscopy) nor the use of any sedatives.

In a study published last year, Dr. Kuldeep Tagore and colleagues used the MTAP test to attempt to distinguish between healthy patients and those with colorectal cancer. The researchers looked at 80 patients with verified colorectal cancer and 212 control subjects. The MTAP test correctly identified over 60 percent of the patients with colorectal cancer as having the disease, while only about four percent of control group patients were improperly diagnosed as having cancer. These numbers compare favorably to similar studies testing the effectiveness of FOBT that resulted in only about 35 percent of cancer patients being correctly diagnosed and about six percent of patients incorrectly identified as having cancer.

"Compared with historic FOBT results," says Tagore, "the detection of DNA abnormalities in stool appears to be substantially more sensitive [for colorectal cancer], with comparable specificity. The MTAP as a noninvasive screening option may be useful in bringing a larger segment of the population into screening and help... patients who can benefit most from colonoscopy." ◆

A Conversation with Dr. Ernest Hawk

Dr. Ernest Hawk is the Chief of NCI's Gastrointestinal and Other Cancers Research Group.

Dr. Ernest Hawk
Chief, NCI Gastrointestinal and Other Cancers Research Group

Who should be screened for colorectal cancer and how often?

Currently, the U.S. Preventive Services Task Force recommends that Americans aged 50 years and older be screened for colorectal cancer. Those at higher risk for cancer, as evidenced by a close relative with either adenomas or cancer, are advised to start at an earlier age. Colorectal cancer is largely a preventable illness but, unfortunately, in the United States only 30 to 40 percent of people who should be screened have been.

What is virtual colonoscopy (VC)?

VC is a new technique that uses x-rays delivered through a CT scanner to take cross-sectional views of the colon through the abdomen. Those views are then reconstructed using computer software. The result is a set of images that provides radiologists trained in this technique with essentially the same sort of view of the colon that a gastroenterologist would get using optical colonoscopy (OC), which acquires images through a tube inserted into the colon. VC is relatively quick, fairly sensitive, and only minimally invasive.

What are the benefits of VC over OC?

The speed, relatively low level of invasiveness, and potential for broad availability are major advantages of VC at the moment. VC only takes on the order of a few minutes to actually do the exam, and probably 15 to 30 minutes more to read the exam.

What are the disadvantages of VC compared to OC?

The biggest drawback is that VC is not widely available and still awaits definitive testing. Another limitation of VC relates to patients still needing to go through the same bowel preparatory regime. In addition, VC requires instrumentation to put air into the colon. These are the key issues holding VC back from being widely appreciated and implemented. ◆

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of the overall NCI clinical research program, I will strategically focus on each of the specific issues and work with the cooperative groups to fully assess opportunities for streamlining infrastructure. I will meet with the representatives of the Group Chairs in three months to update progress.

I am grateful to the Chairs for the thought and effort they put into their recommendations. I am also committed to working with them and other groups, including the Community Clinical Oncology Program, cancer centers, SPOREs, and the Intramural Research Program, to promote broader coordination and redefine the nation's cancer clinical research program to serve the needs of oncology in 2015. ◆

Dr. Andrew von Eschenbach
Director, National Cancer Institute

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progression-free probability was 45 percent. In addition, the authors stressed that "subsets of patients with high-grade disease and/or a rapid PSADT [PSA doubling time] who were thought to be incurable could still achieve a durable response to salvage radiotherapy when the treatment was administered early in the course of recurrent disease."

In a related editorial, Dr. Mitchell S. Anscher of Duke University Medical Center noted that the finding that salvage radiotherapy early after recurrence was beneficial in these patients "probably could have been anticipated." Nevertheless, he said, the study's findings "will provide useful guidance both for better selecting patients for salvage radiotherapy and for designing future clinical trials." ◆

Featured Clinical Trial

Combination Therapy for Head and Neck Cancer

Name of the Trial

Phase I Study of Bortezomib and Radiotherapy in Patients With Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck (NCI-01-C-0104). See the protocol summary at http://cancer.gov/clinicaltrials/NCI-01-C-0104.

Investigators

Dr. Barbara A. Conley, principal investigator, NCI's Center for Cancer Research; Dr. Carter Van Waes, co-investigator, National Institute on Deafness and Other Communication Disorders; and Dr. David Gius, co-investigator, NCI's Radiation Oncology Branch

Why Is This Trial Important?

Head and neck cancers account for three percent of all cancers in the United States. Most of these cancers begin in squamous cells found in the lining of structures in the head and neck. Initial treatment options for most patients with head and neck cancer include surgery followed by radiation therapy or chemotherapy combined with radiation treatment. No standard therapy currently exists for head or neck cancer that recurs after treatment with radiation.

In the past, doctors have been reluctant to re-treat patients with radiation if their cancer recurred. However, some studies of "re-irradiation" have shown long-term survival rates of up to 20 percent. This study is the first test of whether the drug bortezomib (Velcade™) can increase the effectiveness of re-irradiation. Bortezomib, a proteasome inhibitor, is one of the new class of targeted cancer therapies. Proteasomes are clusters of proteins necessary for cancer cell growth.

"In preclinical studies conducted in the laboratories of Drs. Carter Van Waes and James Mitchell at NIH, bortezomib has been shown to inhibit growth of head and neck cancer cells, inhibit their blood supply, and enhance the effect of radiation," said Dr. Conley. "In this study we hope to see a similar effect in patients."

Another goal of this phase I study is to identify the most tolerable dose of bortezomib that can be given with radiation to the head and neck.

Who Can Join This Trial?

This trial seeks to enroll 51 patients aged 19 and older with squamous cell carcinoma of the head and neck that has recurred after initial treatment or metastasized to areas other than the brain. See the full list of eligibility criteria for this trial at http://cancer.gov/clinicaltrials/NCI-01-C-0104.

Where Is This Trial Taking Place?

This study is taking place at the National Institutes of Health Warren G. Magnuson Clinical Center in Bethesda, Md.

Who to Contact

For more information, call the study nurse, Christine Muir, at 301-594-6590, or call the NCI Clinical Studies Support Center (CSSC) at 1-888-NCI-1937. The CSSC provides information about cancer trials taking place on the NIH campus in Bethesda, Md. The call is toll free and confidential. ◆

An archive of "Featured Clinical Trial" columns is available at http://cancer.gov/clinicaltrials/ft-all-featured-trials.

Notes

Dr. Blauvelt Elected to American Society for Clinical Investigation

Dr. Andrew Blauvelt, an investigator in the NCI Center for Cancer Research's Dermatology Branch, was recently elected to the American Society for Clinical Investigation (ASCI). Established in 1908, ASCI is one of the nation's oldest and most respected medical honor societies. It comprises more than 2,700 physician-scientists from all medical specialties, who were elected to the society because of their outstanding records of scholarly achievement in biomedical research. ASCI represents active physician-scientists who practice at the bedside, research bench, and blackboard.

Dr. Blauvelt received his M.D. degree from Michigan State University. He then completed a year of internal medicine training at Henry Ford Hospital and three years of dermatology residency training at the University of Miami. He also performed three years of research training in the laboratory of Dr. Stephen I. Katz in NCI's Dermatology Branch and another year of research training at the National Institute of Allergy and Infectious Diseases in the laboratory of Dr. Kuan-Teh Jeang. Since 1996, Dr. Blauvelt has been an investigator in NCI's Dermatology Branch, studying pathogenesis of skin diseases associated with viral infections. He was tenured by the NIH in 2003.

NCI at AACR

Orlando, Fla. will host the 95th annual meeting of the American Association for Cancer Research (AACR), March 27-31. Researchers from NCI and its funded programs will be represented throughout the meeting. In addition to viewing scientific presentations of NCI-funded research, attendees can learn about training and funding opportunities at NCI or provide policy feedback at the "NCI Listens" session on March 30 at 2:00 p.m. NCI Director Dr. Andrew C. von Eschenbach will speak at the AACR public forum on March 27 at 10:00 a.m. and deliver the NCI director's address on March 29 at 9:00 a.m.

Check the NCI at AACR Web site for more information.

NCI Honored with Plain Language Awards

Thirty-nine NCI staff are winners of this year's NIH Plain Language Awards. A total of 58 awards were made to NIH institutes and centers; 15 awards went to NCI: four in the Outstanding category, five in the Excellent category, and six in the Honorable Mention category. The four items judged to be Outstanding were: the 9 A Day Campaign for African American Men brochure, the Radioactive Iodine (I-131) and Thyroid Cancer presentation aid, the Smokefree.gov Web site, and the Fellowship Handbook brochure.

The NIH Plain Language Awards program, which began in 1999, recognizes publications, Web sites, and other materials that effectively communicate agency materials to a variety of audiences. Entries are judged on how well they are organized, how readable they are, and how well they are targeted to their audiences.

A recognition ceremony will be held on April 20 at 2:00 p.m. in Lipsett Auditorium on the NIH campus. National Public Radio senior science correspondent Joe Palca will be the keynote speaker. ◆

Funding Opportunities

Research Partnerships for Improving Functional Outcomes

PAR-04-077
Application Receipt Dates: Oct. 13, 2004; Oct. 13, 2005; Oct. 13, 2006

The objective of this Program Announcement (PA) is to encourage basic, applied, and translational multidisciplinary research directed toward improving the health of individuals with acute or chronic diseases who may benefit from rehabilitation. This PA supports Research Partnerships for Improving Functional Outcomes.

In the context of this program, a "partnership" is a multidisciplinary research team that applies an integrative systems approach to develop knowledge and/or methods to improve functioning, promote health, and increase participation in community life.

The PA will use the NIH Research Project Grant (R01) award mechanism.

For more information see http://cri.nci.nih.gov/4abst.cfm?initiativeparfa_id=1940.

Inquiries: Dr. Noreen M. Aziz, na45f@nih.gov ◆

Missed an NCI Director's Lecture event? View past lectures, including FDA Commissioner Mark McClellan and Biotechnology Industry Organization President Carl B. Feldbaum, at: http://videocast.nih.gov/.

Featured Meetings

This is a list of selected scientific meetings sponsored by NCI and other organizations. For locations and times and a more complete list of scientific meetings, including NCI's weekly seminars and presentations open to the public, see the NCI Calendar of Scientific Meetings at http://calendar.cancer.gov.

NCI Advisory Committee Upcoming Meetings

Date	Advisory Committee
Jun 1-3	National Cancer Advisory Board
Jun 24-25	NCI Board of Scientific Advisors

Selected Upcoming Meetings of Interest

Date	Meeting	NCI Speakers
Mar 21-25	43rd Annual Meeting of the Society of Toxicology	Dr. J. Carl Barrett, Director, Center for Cancer Research
Mar 24-27	25th Anniversary Annual Meeting & Scientific Sessions of the Society of Behavioral Medicine	Dr. Robert T. Croyle, Director, Division of Cancer Control and Population Sciences
Mar 24-28	9th Biennial Symposium on Minorities, the Medically Underserved & Cancer	Dr. Andrew C. von Eschenbach, Director; Dr. Anna Barker, Deputy Director, Advanced Technologies and Strategic Partnerships; Dr. Harold P. Freeman, Director, Center to Reduce Cancer Health Disparities
Mar 27-31	95th Annual Meeting of the American Association for Cancer Research	Please refer to NCI at AACR, http://cancer.gov/aacr2004.
Mar 27-31	Annual Meeting of the Academy of Molecular Imaging	Dr. Andrew C. von Eschenbach, Director

NCI Exhibits

NCI Exhibits are presented at various professional and society meetings. Further information about the NCI Exhibits program can be found at http://exhibits.cancer.gov.

This *NCI Cancer Bulletin* is produced by the National Cancer Institute (NCI). NCI, which was established in 1937, leads a national effort to eliminate the suffering and death due to cancer. Through basic and clinical biomedical research and training, NCI conducts and supports research that will lead to a future in which we can prevent cancer before it starts, identify cancers that do develop at the earliest stage, eliminate cancers through innovative treatment interventions, and biologically control those cancers that we cannot eliminate so they become manageable, chronic diseases.

For more information on cancer, call 1-800-4-CANCER or visit http://cancer.gov.

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