

January 17, 2006
Volume 3 | Number 3

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A Publication of the
National Cancer Institute
U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES
National Institutes of Health
NIH Publication No. 05-5498

<http://www.cancer.gov>

New FDA Guidance Aims to Speed Early Drug Development

Last week, the Food and Drug Administration (FDA) released two new guidance documents and a final rule intended to streamline the early clinical development of new drugs and biologics for cancer and other diseases. The documents represent strategic actions that are part of the agency's Critical Path Initiative. The Critical Path is a blueprint for updating the technologies and tools needed to optimize the process of discovery, development, and delivery of medical products. These specific guidances address major barriers in the early development of new interventions, including testing small quantities of new agents prior to undertaking

full-scale clinical trials and evaluating new investigational agents in humans before demonstrating their manufacturability.

The joint NCI-FDA Interagency Oncology Task Force (IOTF), which was established in 2003 to enhance and accelerate the overall process of developing new cancer interventions, has focused extensively on these issues as part of its work to improve the overall cancer drug development process.

Today, 9 out of 10 compounds developed in the laboratory fail in human studies. "One problem is that *(continued on page 2)*

Director's Update

NCI Advisors Explore Future Research Investment Strategies

Last week, NCI leadership held an important retreat with members of the institute's primary advisory panels. This was the 3rd annual NCI Joint Boards Retreat, and together we grappled with how NCI programs can continue their pioneering innovative trajectory, given the current fiscal limitations facing biomedical research.

As the discussion at the retreat illustrated, the ongoing budget constraints will require difficult but creative choices. The retreat also reinforced for me, however, the resolve of staff and the community to take the necessary steps to ensure continued progress against cancer by accelerat-

ing the pace of discovery, development, and delivery.

The President recently signed the appropriations bill that provides funding for the Department of Health and Human Services (HHS) for fiscal year 2006. The bill includes \$4.842 billion for NCI. However, after a government-wide 1 percent reduction, as well as adjustments made for rescissions, assessments, and mandatory increases, NCI starts FY 2006 with fewer dollars than FY 2005, an amount that was already lower than the previous year.

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(FDA continued from page 1)

researchers conducting very early studies were required to follow the same manufacturing procedures as those companies that mass-produce products for broad scale distribution,” said Dr. Janet Woodcock, FDA deputy commissioner for Operations.

In the first guidance document, *Exploratory IND Studies*, FDA offers recommendations about safety testing, manufacturing, and clinical approaches that can be used in very early studies, sometimes called exploratory, or phase 0, trials. This guidance will allow researchers to develop a better understanding of parameters such as drug distribution, pharmacokinetics, and target localization of new agents prior to undertaking large-scale trials. *INDs—Approaches to Complying with CGMP During Phase I*, and an accompanying rule, outlines an approach for compliance with good manufacturing practice (CGMP) requirements for the manufacture of small amounts of drug product for testing prior to undertaking large phase I studies. Requirements for full-scale phase I studies will not change.

“This new guidance will allow investigators to evaluate microdoses of investigational agents in small numbers of patients, which will provide the opportunity to apply new molecular technologies, and answer questions about pharmacokinetics and potential biomarkers of efficacy and toxicity,” said Dr. Anna Barker, NCI deputy director for Strategic Scientific Initiatives. “A microdose is less than 1/100th of a typical drug dose that would have a pharmacologic effect. However, it is sufficient for use in areas such as advanced imaging to assess effect at the molecular level, such as whether it is readily metabolized or is hitting its intended molecular target.”

Dr. Barker added that through its intramural program, NCI has set up a new unit to do these types of trials on promising candidate drugs with a goal of speeding up safer and more effective cancer interventions to patients.

“This guidance really makes it possible to do those kinds of studies very early on, so we can screen a wider variety of individual drugs in the pipeline to better understand those we should take forward,” said Dr. James Doroshow, director of NCI Division of Cancer Treatment and Diagnosis.

Dr. Steven Rosenberg, chief of NCI’s Surgery Branch, added, “This will have a major impact on the ability of scientists to evaluate whether their findings will be helpful to patients.” ♦

(Director’s Update continued from page 1)

The number of competing Research Project Grants (RPGs) awards for FY 2006 is expected to be approximately the same as last year, with an average cost equal to what it was in FY 2005. That said, paylines and grantee success rates will again decline.

We presented these tough fiscal realities at the retreat, which included the Board of Scientific Advisors, Board of Scientific Counselors, National Cancer Advisory Board, and the chairs of the President’s Cancer Panel and the Director’s Consumer Liaison Group. Acknowledging that declining budgets are likely for the near future, we sought the participants’ guidance on a number of critical questions, and asked for their long-term perspectives on some of the most difficult issues facing NCI and the cancer research community.

We also had the opportunity to model alternative budget scenarios

for FY 2007, assessing the inevitable trade-offs that occur at different target levels for RPGs, paylines, and individual program spending. We are being confronted with very difficult choices. So while many excellent initiatives will continue to be supported, others will have to be cut.

As expected, participants offered forthright suggestions for NCI to consider. For example, on the crucial issue of how to mitigate the impact of low RPG paylines, there was consensus on the need to protect and sustain new investigators applying for first-time R01 grants. They urged NCI to continue our practice of setting paylines for first-time grantees at levels above the average R01 grant.

One interesting idea is to require biomedical institutions to provide mentoring components as part of their new investigators’ grant applications.

Most importantly, the advisors agreed to aid in a more in-depth analysis of strategies to ensure continued innovation in research, including how to better promote partnerships with industry and other outside groups, support training, and find new mechanisms to measure progress and evaluate programs.

I want to express the institute’s deep thanks to these outstanding leaders for taking their valuable time to help ensure that NCI will continue to foster and advance the type of research that will improve and save lives. Because now more than ever, it is imperative that we continue to engage in careful planning, monitoring, and reporting of our efforts. Those relying on us to defeat this disease deserve no less. ♦

Dr. Andrew C. von Eschenbach
Director, National Cancer Institute



Spotlight

A Multipronged Attack on the Cancer Cell

The cancer cell differs from a normal cell in several ways. One big difference is that a cancer cell can survive, and in some cases thrive, under environmental assaults—such as the severe lack of oxygen in tumors or even the onslaught of cytotoxic chemotherapy agents—that would destroy a normal cell.

These remarkable survival skills are due in no small part to a family of proteins spurred to action by stress in the cellular environment. These so-called heat shock proteins (HSPs) serve as both molecular mechanics and bodyguards to other proteins. Stressed intracellular proteins that begin to misfold, for instance, are quickly repaired. Mutated proteins that otherwise would be shuttled away by the cell for degradation are somehow aided in carrying out their tasks as transcription factors, hormone receptors, and the like.

One HSP in particular, HSP90, has fascinated researchers because many of its “client” proteins—those that require HSP90’s chaperoning skills in both normal and stress-laden environments—also are members of the most-wanted list of proteins that spur cancer development and growth, including mutant p53, Bcr-Abl, HER-2, HIF-1, and many others.

Therein lies HSP90’s potentially immense therapeutic value, says Dr. Len Neckers, a senior principal investigator in NCI’s Urologic Oncology

Branch, who has been a leader in HSP90 research.

“By inhibiting HSP90, you avoid focusing on a specific step in cancer development, which, as we’re beginning to see, tends to allow cancers to evade molecularly targeted attacks,” he says. “By inhibiting HSP90, we’re simultaneously attacking multiple signaling nodes of a cancer cell’s survival network.”

In 1993, Dr. Neckers and his NCI colleagues discovered that a common, off-patent antibiotic, geldanamycin, could inhibit HSP90’s chaperoning function. It was the first such discovery, and it launched an onslaught of research at institutions across the country and the world to delve deeper into HSPs in terms of their functionality and anticancer potential.

Jump ahead more than a decade, and five phase I trials testing a geldanamycin derivative, 17-AAG, developed at NCI in collaboration with the pharmaceutical company Kosan Biosciences, have now been completed in the United States and the United Kingdom. None, Dr. Neckers says, was a “home run,” but that’s typical for phase I trials, which are principally intended to establish safety measures, such as the maximum dose at which clinical and/or biological activity can be detected without causing life-threatening toxicities.

However, in a phase I trial of 17-AAG conducted in the United Kingdom

on patients with a variety of solid tumors, two patients with advanced melanoma had sustained periods of stable disease, one of which lasted for nearly 4 years, says the study’s leader, Dr. Ian Judson of the Institute of Cancer Research.

More than 20 phase II trials of 17-AAG—alone, or in combination with chemotherapy or targeted agents—are under way. The trials cover a broad range of indications, including advanced breast cancer, prostate cancer, and an assortment of leukemias.

Dr. Jeff Moley from the Siteman Cancer Center of the Washington University School of Medicine is leading a phase II trial of 17-AAG to treat two different kinds of thyroid cancer, including medullary thyroid cancer (MTC). RET, the protein that fuels MTC, is yet another HSP90 client, and Dr. Moley’s research has demonstrated that 17-AAG inhibits RET activity.

“There is no standard of care for MTC patients with distant metastases who are no longer taking up radioactive iodine,” Dr. Moley says. With 17-AAG, he adds, “We are plowing new ground.”

The drug is also being tested in patients with chronic myelogenous leukemia who have developed resistance to perhaps the most famous and effective targeted drug, imatinib (Gleevec).

As it turns out, says Dr. Luke Whitesell, a pediatric oncologist at the University of Arizona currently on leave at the Whitehead Institute for Biomedical Research in Massachusetts, imatinib-resistant leukemia cells “retain their sensitivity for geldanamycin and, if anything, become more sensitive to it.”

Dr. Whitesell, who was part of Dr. Neckers’ team that discovered

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Cancer Research Highlights

Quality of Postmastectomy Radiation Therapy Affects Survival

A new meta-analysis published in the January 4 *Journal of the National Cancer Institute (JNCI)* reports that radiation therapy after mastectomy for breast cancer, using appropriate radiation doses and treating appropriate areas of tissue, increases both 5-year and 10-year survival for women at high risk of recurrence. Radiation therapy using too little or too much radiation, or failing to treat all areas at risk of recurrence, does not increase survival.

The *JNCI* study, led by Val Gebski from the University of Sydney, Australia, divided 38 comparisons from 36 trials of radiation therapy into 3 categories: optimal radiation therapy, defined by modern treatment guidelines; inadequate or excessive radiation therapy; or incomplete tissue coverage.

Overall, the study found a statistically significant 2.9 percent absolute increase in 5-year survival for all patients receiving optimal radiation therapy. This increase in survival rose to 6.4 percent at 10 years after treatment. In contrast, no significant increase in survival was found in patients receiving inadequate or excessive radiation therapy, or incomplete tissue coverage.

An increase in non-breast cancer death was noticed in the groups receiving any category of radiation therapy, but for optimal therapy, this was overshadowed by the survival benefit. The investigators applied the data on survival after optimal radiation therapy

to hypothetical patients with different risks of recurrence and death. They determined that a high-risk patient receiving optimal radiation therapy has an 11 percent absolute reduction in risk of death from any cause.

“Consequently,” state the authors, “we recommend that postmastectomy radiation therapy be considered as part of standard care for all women at high risk.”

More Data on Prostate Cancer Screening, But No Answers

Two randomized clinical trials now under way in the United States and in Europe are investigating whether screening men for signs of prostate cancer saves lives. Many experts believe that only these large trials can answer the question of whether men should be screened, but the results are not expected until around 2009.

In the meantime, a study published last week found no evidence that screening reduced mortality among men in New England. The case-control study involved 1,002 men and looked at 2 commonly used screening methods, the prostate-specific antigen (PSA) test and a rectal examination. According to findings in the January 9 *Archives of Internal Medicine*, PSA testing, with or without rectal examinations, did not prevent deaths from prostate cancer among the men.

The researchers, led by Dr. John Concato of the Veteran Affairs Connecticut Healthcare System, acknowledge that more research is needed on the subject, and they urge

physicians to obtain informed verbal consent from patients who undergo screening.

“This is a well-done study, but it does not really answer the question” of whether screening saves lives, comments Dr. Howard Parnes of NCI’s Division of Cancer Prevention. “Until the results of the randomized trials are known, men should be encouraged to discuss the potential risks and benefits of screening with their physicians.”

An editorial accompanying the study agrees with this message and notes that the long-awaited results are “now not that far away.” The NCI-sponsored Prostate, Lung, Colorectal and Ovarian Screening Trial and the European Randomized Study of Screening for Prostate Cancer trial should be completed “after the next summer Olympics in Beijing,” says Dr. Michael Barry of Massachusetts General Hospital.

New Algorithm Proves Effective for Colorectal Cancer Screening

Screening for colorectal cancer can significantly reduce mortality, particularly because precancerous polyps and adenomas can lead to blood in the stool, which is normally detected by a guaiac fecal occult blood test (FOBT). A study published in the January 6 online edition of *Lancet Oncology* shows that a more discriminating, immunochemical version of FOBT can be used to better determine which patients should be examined further by colonoscopy.

During an observational screening study in Scotland for colorectal cancer in men and women aged 50 to 69, researchers used the immunochemical FOBT test to collect 2 samples from each of 795 patients, all of whom had previously tested positive
(Highlights continued on page 5)

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with guaiac FOBT. Patients then had clinical colonoscopies, and any disease detected was correlated with the results of the immunochemical FOBT tests. Patients who tested positive on both immunochemical FOBT tests were 7.57 times more likely to have an invasive cancer than were those who had either one or no positive tests. They were also 1.48 times more likely to have large adenomatous polyps and 3.11 times more likely to have more than three polyps of any size.

Dr. Callum G. Fraser, of the Ninewells Hospital and Medical School in Dundee, Scotland, and colleagues recommend that this “reflex” two-tier approach be used to distinguish between patients who would and would not benefit from colonoscopy. By eliminating guaiac FOBT-positive patients who are not double-positive on the immunochemical FOBT test, the need for colonoscopies would be reduced by about 30 percent. As reported, “The implications for national screening programs are important in terms of reducing costs, inconvenience, and associated morbidity, without compromising the effectiveness of screening.”

Meta-Analysis Suggests No Cancer Prevention Benefit from Statins

A new meta-analysis indicates that the cholesterol-lowering drugs known as statins have no effect on cancer risk. The analysis was published in the January 4 *Journal of the American Medical Association*.

To conduct the study, Dr. Krista M. Dale and colleagues from the University of Connecticut School of Pharmacy and Hartford Hospital identified 26 randomized clinical trials of statins for cardiovascular risk

reduction that met specific criteria, including the collection of information on cancer diagnosis or cancer death on more than 100 participants with follow-up of at least 1 year.

Statins have a “neutral effect on cancer and cancer death risk,” the authors concluded.

The study’s conclusion contradicts several recent retrospective, case-control studies, including a [study](#) published last May by researchers from Michigan and Israel, which found that people who took a statin for at least 5 years had a significantly lower risk of developing colorectal cancer than those not taking the drug.

The meta-analysis, although well-conducted, is not the final word on statins and cancer prevention, says Dr. Ernie Hawk, director of the NCI Office of Centers, Training, and Resources.

“The prior data from animal models treated with statins, the mechanistic data on possible ways they would fight cancer, and the observational studies suggesting reductions in cancer risk still make the question interesting,” he says. “We still lack data from well-conceived phase II clinical trials focused on cancer-related mechanisms. These trials would help either to support or refute statins’ potential use for cancer prevention.”

NCI is sponsoring two such trials—one in patients at risk for colorectal cancer and the other in patients at risk for melanoma. Both trials are expected to begin early this year.

New Databases Available for Calculating Racial/Ethnic Cancer Risks

[New databases](#) will soon be available from NCI that allow calculation of cancer risks among diverse racial/ethnic groups in the United States. Using these databases, with data centered on the

1990 decennial census, NCI researchers report that 48 percent of Japanese American men will develop cancer in their lifetime, the highest risk of the 10 groups studied. White men follow at 47 percent. Among men, American Indians are the least likely to develop cancer, at 24 percent lifetime risk.

Women in all groups, except for Native Alaskans, have a lower lifetime risk than their male counterparts, according to the research published in the December 30, 2005, online edition of *Cancer*. The authors calculated lifetime and age-conditional cancer risks of 10 racial and ethnic groups; previous estimates provided figures only for whites and blacks. More recent databases with racial/ethnic information are also available, but are limited to broader classifications because of the lack of detailed population estimates needed for the calculations.

The type of risk estimate reported by the authors measures the population burden of cancer because it integrates the chance of developing cancer with the chance of dying of other causes. For example, although black men have significantly higher age-adjusted prostate cancer incidence rates than whites, the lifetime risks of developing cancer in the two groups are more closely comparable because fewer blacks live to older ages when prostate cancer predominantly occurs. The authors conclude that this type of cancer burden estimate can complement routinely reported incidence and mortality statistics. ♦

Featured Meetings and Events

A calendar of scientific meetings and events sponsored by the National Institutes of Health (NIH) is available at <http://calendar.nih.gov/cgi-bin/calendar>. ♦



Featured Clinical Trial

Breast Cancer Treatment for Premenopausal Women

Name of the Trial

Phase III Randomized Study of Triptorelin and Exemestane Versus Triptorelin and Tamoxifen in Premenopausal Women with Endocrine-Responsive Breast Cancer (IBCSG-25-02). See the protocol summary at <http://cancer.gov/clinicaltrials/IBCSG-25-02>.

Principal Investigators

Drs. Barbara Walley, International Breast Cancer Study Group, and Olivia Pagani, Breast International Group

Why Is This Trial Important?

The benefits of antiestrogen therapy for breast cancer—in terms of reduced disease recurrence and improved survival—have been clearly established for postmenopausal women whose tumors can grow in response to the female sex hormone estrogen (endocrine-responsive breast cancer). Women who have not undergone menopause, however, may not benefit as much from antiestrogen therapy because their ovaries are still producing large amounts of estrogen.

In this trial, premenopausal women with endocrine-responsive breast cancer will receive the drug triptorelin to suppress the function of their ovaries (induction of menopause) and long-term antiestrogen therapy with either exemestane (an aromatase inhibitor), to inhibit the production of estrogen outside the ovaries, or tamoxifen, to block the growth-promoting effects of any estrogen that

might be produced. Researchers hope to determine which antiestrogen treatment will help premenopausal women, whose ovarian function is being suppressed, survive longer without a recurrence of their cancer.

“We hope to see the same degree of benefit in this younger population that we currently observe in older, postmenopausal women on aromatase inhibitors,” said Dr. Walley. “With this trial and others being conducted by breast cancer researchers, we hope also to determine the role of ovarian suppression in premenopausal women with early-stage breast cancer.”

Who Can Join This Trial?

Researchers seek to enroll 1,845 premenopausal women diagnosed with breast cancer who have had their tumors surgically removed. See the list of eligibility criteria at <http://www.cancer.gov/clinicaltrials/IBCSG-25-02>.

Where Is This Trial Taking Place?

Multiple study sites in the United States and elsewhere are recruiting patients for this trial. See the list of study sites at <http://www.cancer.gov/clinicaltrials/IBCSG-25-02>.

Contact Information

See the list of study contacts at <http://www.cancer.gov/clinicaltrials/IBCSG-25-02>, or call NCI's Cancer Information Service at 1-800-4-CANCER (1-800-422-6237). The call is toll free and completely confidential. ♦

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

Funding Opportunities

Improving Diet and Physical Activity Assessment

PAR-06-104

Letter of Intent Receipt Dates: May 1, 2006; Jan. 1 and Sept. 1, 2007; May 1, 2008; Jan. 1, 2009.

Application Receipt Dates: June 1, 2006; Feb. 1 and Oct. 1, 2007; June 1, 2008; Feb. 1, 2009.

This is a renewal of PAR-03-009. This funding opportunity will use the R01 award mechanism. For more information, see http://cri.nci.nih.gov/4abst.cfm?initiativeparfa_id=3318. Inquiries: Dr. Amy Subar—subara@mail.nih.gov; Dr. Richard Troiano—troianor@mail.nih.gov ♦

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geldanamycin's prowess for inhibiting HSP90, is focusing much of his research on HSP90's role in allowing cancer cells to evolve and develop resistance to a given treatment.

“Acquired resistance is a fundamental barrier to curing many cancers,” he says. “Within tumors, you've got a genetically unstable and heterogeneous population of cells with tremendous selective pressures placed on them. Evolution to more malignant, drug-resistant phenotypes over time is an inevitable, but poorly understood consequence.”

His theory is that HSP90 not only moderates the impact of potentially lethal mutations in cancer cells, but also can preserve those mutations that confer resistance.

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“If you could control cancer cells’ ability to evolve, it could make other treatments more effective,” he argues. In fact, cell line and animal model studies of cervical and lung cancer have shown that 17-AAG can enhance the effectiveness of what would otherwise be suboptimal radiation therapy.

Work is already under way at NCI and several small biotechnology companies to develop next-generation HSP90 inhibitors. 17-DMAG, an agent developed at NCI in collaboration with Kosan, is now in phase I trials. At least six other companies/laboratories are working on their own novel HSP90 inhibitors. ♦

By Carmen Phillips

Mr. Protein Head?

For most of its serious chaperoning, HSP90 functions as part of so-called super-chaperone complexes of HSPs. In fact, HSP90 actually directs their formation. “It’s like a Mr. Potato Head,” Dr. Neckers says. “It serves as an assembling point for other chaperone proteins.”

These HSP complexes lie at the center of 1 theory behind the fact that 17-AAG has at least 20 times more affinity for HSP90 in cancer cells than it does in normal cells. Nobody has proven why this occurs, but the theory holds that in a normal cell, HSP90 is relatively dormant because there is little stress for it to react to. But as Dr. Whitesell explains, “Cancer cells, unlike normal cells, are already at their margin in utilizing their full HSP90 capacity...so it’s highly activated and more sensitive to the drug.” ♦

Notes

NCI Holds Its 11th Annual Intramural Scientific Retreat

On January 11, NCI held its 11th Annual Intramural Scientific Retreat, bringing together investigators from across the NCI Intramural Research Program; SAIC-Frederick core scientists; the NCI Executive Committee; and members of the National Cancer Advisory Board, the Board of Scientific Advisors, and the Board of Scientific Counselors. The intramural retreat followed the 3rd annual NCI Joint Boards Retreat. Through poster sessions, the retreat provided an opportunity for communication and transdisciplinary interactions.

Highlights of the retreat included the invited award lectures for outstanding contributions in cancer research. Dr. Joan A. Steitz received the 5th annual NCI Rosalind E. Franklin Award for women scientists in cancer research for her seminal work on snRNPs, Dr. Elizabeth H. Blackburn received the 10th annual Alfred G. Knudson Award for her pioneering contributions in cancer genetics, and Dr. Steven A. Rosenberg received the 2nd annual Alan S. Rabson Award for excellence in NCI intramural research.

In addition, several scientists received the 2006 NCI Director’s Intramural Innovation Awards, which are designed to support the development of highly innovative approaches and technologies aimed at significant cancer-related problems.

Applications Now Being Accepted for the NCI DCLG

NCI is now accepting applications for five positions on the NCI Director’s Consumer Liaison Group (DCLG). All qualified members of the cancer advocacy community are encour-



Drs. Susan Gottesman, NCI; Joan Steitz, Yale University; and John Niederhuber, NCI, at the 11th Annual Intramural Scientific Retreat

aged to submit an application package postmarked by March 31, 2006. Terms for these positions will begin in July 2006. Directions for how to complete the application package are available at <http://deainfo.nci.nih.gov/advisory/dclg/applications/DCLGmemberApplication2006.pdf>. For more information on the DCLG, go to <http://la.cancer.gov/dclg.html>.

ICRC Candidates Available for Interviews

NCI’s Introduction to Cancer Research Careers Program (ICRC) brings experienced science students from diverse and/or disadvantaged backgrounds to NCI for an overview of its scientific training programs and to interview for summer and/or postbaccalaureate internships. Twenty candidates for the 2006 program will be interviewing at NCI early in February. Students selected for an internship will be provided with summer housing and travel. Undergraduate and graduate science students interested in applying for the 2007 ICRC program can get information at <https://icrc.nci.nih.gov> or by calling 301-435-8524. The program will begin accepting applications in August 2006. ♦

OMH Conference Energizes Minority Health Leaders

One of the most overlooked aspects of Dr. Martin Luther King, Jr.'s, civil rights agenda was his call to action on health. He once said, "Of all forms of inequity, injustice in health is the most inhumane."

On January 9–11, to perpetuate Dr. King's legacy, HHS brought nearly 2,000 researchers; academicians; faith- and community-based health representatives; and state, local and federal government officials to the nation's capital for a national conference on eliminating health disparities. The 2006 National Leadership Summit on Eliminating Racial and Ethnic Disparities in Health marked the 20th anniversary of the Office of Minority Health (OMH), HHS's lead office on health disparities. NCI, which has identified addressing cancer health disparities as a priority, served as a cosponsor of the conference.

Attendees from around the country spent 3 days building and strengthening partnerships, exchanging ideas, sharing best practices, and advancing policies to improve the health of America's racial and ethnic minority communities.

The 2006 Summit also was an opportunity for broadening the health disparities agenda and discourse from the more traditional disease-focused approach to an issue-based approach.



The conference featured more than 96 workshops and special institutes on current and emerging health issues in the areas of health care access, utilization, and quality; health care and the public workforce;

research, data, and evaluation; health information technology; health disparities across the lifespan; and culture, language, and health literacy. Specific issues that were examined included the quality of care provided to racial and ethnic minorities, patient/provider interactions and relationships, developing health technologies in minority communities, and workforce diversity.

The deliberations on these health issues will undoubtedly have far-reaching implications for health policies and programs targeting the elimination of health disparities.

Several NCI staff served as moderators for workshop sessions, and NCI Deputy Director Dr. Mark Clanton presented one of the prestigious Minority Health Community Leadership Awards on January 10 to two-time cancer survivor and African

American businessman Robert Samuels, for his efforts to educate black men about prostate cancer as founder of the National Prostate Coalition. Mr. Samuels, who built a career in banking and finance, has survived both prostate and throat cancer.

Created by HHS in response to the landmark *1985 Report of the Secretary's Task Force on Black and Minority Health*, OMH works to improve the health of racial and ethnic minority populations by advising on and coordinating HHS minority health promotions, research, policies, and programs to address health disparities. Since its establishment, OMH has collaborated with many HHS divisions; national, local, tribal, and other partner organizations; and individuals in myriad settings across the country.

To view the conference webcast, go to http://www.kaisernetwork.org/health_cast/hcast_index.cfm?display=detail&hc=1616.

More information on OMH can be found at <http://www.omhrc.gov>. For information on NCI's efforts to reduce cancer health disparities, go to <http://crchd.nci.nih.gov>. ♦

*Dr. Garth Graham
Deputy Assistant Secretary for
Minority Health, U.S. Department of
Health and Human Services*

The *NCI Cancer Bulletin* is produced by the National Cancer Institute (NCI). NCI, which was established in 1937, leads the national effort to eliminate the suffering and death due to cancer. Through basic, clinical, and population-based biomedical research and training, NCI conducts and supports research that will lead to a future in which we can identify the environmental and genetic causes of cancer, 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://www.cancer.gov>.

NCI Cancer Bulletin staff can be reached at ncicancerbulletin@mail.nih.gov.