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Leavitt Confirmed as HHS Secretary

On January 26, Michael O. Leavitt was sworn in as the 20th Secretary of the U.S. Department of Health and Human Services (HHS). As HHS Secretary, he will command an annual budget in excess of \$548 billion and will oversee more than 66,600 federal employees, including those of the National Institutes of Health (NIH) and National Cancer Institute (NCI).



Prior to his current service, Secretary Leavitt served as Administrator of the U.S. Environmental Protection Agency (EPA) and as Governor of Utah. He is widely recognized as a health care innovator and welfare

reformer. In 1994, the Utah legislature passed then-Governor Leavitt's "HealthPrint," a comprehensive, incremental approach to health care improvement in the state. A decade later, Utah has more than 400,000 additional people with health insurance, marked increases in the number of children with health care coverage,

and per capita cost of healthcare 25 percent below the national average.

Secretary Leavitt also has an accomplished record on cancer control and outreach. During his service as
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Director's Update

Pursuing the Promise of Biomarkers

In recent presentations about the great potential of cancer biomarkers and diagnostics, Nobel laureate Dr. Leland Hartwell has delivered a critical message. "I am optimistic that we have the knowledge, science, and technology to greatly improve outcomes for cancer in a relatively short timeframe," he said at last year's American Society of Clinical Oncology annual meeting. "But I am cautious because I don't know whether we have the ability to organize the effort."

We do, in fact, have the knowledge to make significant advances across the cancer care spectrum over the next decade, especially in the area of cancer

biomarkers. If we can strategically and systematically apply that knowledge, we can dramatically alter the cancer process, paving the way for early detection and the ability to predict a cancer's biologic virulence—both of which could significantly reduce morbidity and mortality from cancer.

This will be the central issue at a 3-day meeting that begins today in Houston convened by NCI and the Food and Drug Administration (FDA). Leaders in clinical oncology, proteomics, genomics, nanotechnology, imaging, bioinformatics, and other supporting areas will use this
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(Leavitt continued from page 1)

Governor of Utah, he joined with the Huntsman Cancer Institute to draw attention to the high incidence of skin cancer among Utahns through Skin Cancer Detection and Prevention Month. Also under his leadership, the state launched the Utah Cancer Action Network, a consortium of 70 agencies and individuals that were “champions” of cancer issues. Secretary Leavitt is also a former member of the Board of Directors of the American Legacy Foundation, an organization established in the 1998 settlement agreement between 46 state attorneys general and the tobacco industry to reduce tobacco usage in the United States.

Said President Bush upon nominating Leavitt to this post, “He is an ideal choice to lead one of the largest departments of the United States government. [HHS] touches the life of every person in this country. To meet [its] responsibilities, the Department needs...a leader who is able to act on many fronts all at once.”

NCI director Dr. Andrew C. von Eschenbach stated, “I look forward to working with Secretary Leavitt to reduce the burden of cancer on our society. Given his passion and record of leadership in the area of cancer control in Utah, as well as his leadership and interest in the area of health care technology, I believe there is a lot we in the cancer community can learn at this critical time in the fight.”

Secretary Leavitt’s commitment to using technology to improve the quality of care, reduce mistakes, and manage costs was evident in one of his first public appearances after his appointment as HHS Secretary. Just one day removed from his Senate confirmation, he joined President Bush in Cleveland to talk about the importance of adapting emerging technologies for computerizing

medical recordkeeping and electronic prescriptions.

Secretary Leavitt has a bachelor’s degree in economics and business from Southern Utah University. He succeeds former Secretary Tommy G. Thompson, who in a letter to HHS staff earlier this week praised HHS for its accomplishments during his tenure, stating that, “We’ve lived up to our reputation as the Department of Compassion by helping to spread hope and opportunity to those who need it most in America and around the world. This work truly is a noble calling, and I urge you to continue to pursue it with seriousness and great humility.” ♦

(Director’s Update continued from page 1)

meeting to discuss and develop strategies for integrating biomarkers into cancer clinical trials. Incorporating these critically important signals—found in serum, urine, or tissue—into clinical trials will help investigators more quickly determine which patients are likely to respond best to a given treatment and whether the treatments are working, as well as achieve the biologically relevant dose of new therapeutic agents.

The Houston meeting is part of the ongoing development of a multi-pronged effort at NCI to leverage the cancer biomarkers’ promise, including a strong basic science portfolio, the Early Detection Research Network (EDRN), and a new program to harmonize and support rational biomarker discovery. This meeting will add the dimension of sound strategies to accelerate biomarkers’ integration into cancer clinical trials.

Progress in this area has been swift. Several biomarker tests under investigation for a variety of cancers have shown promise for early detection, and researchers across all sectors are extending these findings, using these biomarkers to identify new therapeutic targets.

EDRN has had remarkable success in its 4-year existence, including the launch last October of a 3-year study to validate an EDRN-created test that looks for biomarkers in urine that indicate bladder cancer recurrence. Biomarker validation and discovery continues to evolve through EDRN-funded laboratories, including approximately \$10 million in funding announced late last year for 17 biomarker developmental laboratories. In addition to EDRN, NCI also is funding the development of tools and infrastructure to support biomarker discovery, validation, and development.

Finally, through the Interagency Oncology Task Force (IOTF), NCI is working to streamline regulatory processes that could affect biomarkers’ use in clinical trials. An IOTF subgroup, for example, is developing plans for the development of biomarkers in coordination with the FDA’s Critical Path Initiative. A special focus of biomarker development for IOTF is the development and integration of imaging as biomarkers, and potentially surrogate endpoints—one of the most promising areas of biomarker research for cancer. And IOTF has formed a new subcommittee to examine the use of biomarkers to determine efficacy and long-term toxicity of agents in prevention trials.

Like Dr. Hartwell and many others, I believe in the promise of biomarker research. It is an important component of an integrated, multifaceted strategy NCI embarked upon 2 years ago to develop new interventions that disrupt or arrest the mechanisms responsible for cancer initiation and progression. We have made important progress in a short time, and I fully expect it to continue. ♦

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



Spotlight

New Study Brings Mouse Cancer Models Closer to Humans

Before a new drug, device, or surgical procedure can be tested in humans, each must first be tested in animals, the usual preclinical biosystem being mice. Genetic engineering has produced hundreds of strains of mice for this purpose, with cancers that look the same and develop in the same organs or tissues as tumors seen in people. But the question remains: How similar are these tumors in terms of their signaling pathways and gene transcription? How well do they mimic the human cancer biosystem?

“Before now, the criteria that have been used to select mouse models for cancer research were most often based on a single gene, one that is mutated or lost in a particular human cancer,” explained Dr. Snorri Thorgeirsson of NCI’s Center for Cancer Research (CCR). “But extrapolating findings from mouse models to the human situation is complicated because of the molecular heterogeneity seen in humans.”

To better match mouse cancer models to human cancers and take this heterogeneity into account, NCI scientists including Dr. Thorgeirsson and researchers from Northwestern University’s Feinberg School of Medicine in Chicago focused on a subset of genes in human hepatocellular carcinoma (liver cancer) that are associated with survival, and compared their expression patterns with those seen in mouse hepatocellular carcinoma—a process they aptly named “comparative functional genomics.”

Dr. Thorgeirsson and colleagues worked with seven different mouse models induced to develop liver cancer: two through the chemicals ciprofibrate and diethylnitrosamine; four through transgenic overexpression of the genes *Myc*, *E2f1*, and *Tgfa*; and one strain, a knockout, missing the *Acox1*^{-/-} gene. After collecting tissue samples from 68 mouse tumors, the researchers used microarray analysis and grouped the samples according to gene expression prevalence.

Gene expression profiles from these 68 tumor samples fell into three clusters: One included samples from mice that were exposed to diethylnitrosamine, a carcinogen, and those that overexpressed *Myc* and *Tgfa*; the second included mice that overexpressed *Myc* and *E2f1*; and the third included those exposed to ciprofibrate, a peroxisome proliferator, as well as those that overexpressed *Acox1*^{-/-}.

The researchers then matched these clusters with the gene expression profiles from 91 human hepatocellular carcinoma samples that had been preclassified according to survival-correlated gene expression patterns. They found that cluster 1 mouse tumors matched profiles from humans who had poor survival rates (categorized earlier, in the September 2004 issue of *Hepatology*, as subclass A), the cluster 2 tumors matched up with those from humans who had better survival rates (categorized as subclass B), and cluster 3 had low correla-

tion with human liver cancers. Other aspects that were similar between the mouse and human tumors in each cluster included proliferation and apoptosis rates, as well as the degree of ubiquitination—a process of marking proteins for degradation—seen between the two.

In their article based on this research, published in the December 2004 issue of *Nature Genetics*, Dr. Thorgeirsson and colleagues wrote, “Taken together, these results support the notion that better- or best-fit mouse models for human studies can be identified by applying genome-scale comparison of gene expression patterns.” They also pointed out that the lack of correlation between human tumors and mouse tumors induced by ciprofibrate support previous studies that showed the human liver may be insensitive to peroxisome proliferators.

While the tissue in this study came from hepatocellular carcinomas, Dr. Thorgeirsson said that the findings hold promise for preclinical research on a wide range of human cancers.

In an editorial related to this research, published in the January 2005 issue of *Nature Genetics*, Drs. Thomas Graeber and Charles Sawyers of the UCLA School of Medicine commend the study’s findings, but note that this type of research could miss crucial events in cancer development that might not be reflected in gene expression. “Although we expect gene expression-guided mouse modeling to advance cancer biology,” they wrote, “we wonder whether the mouse modeling and computational biology communities should consider a more comprehensive approach.” Dr. Thorgeirsson agrees with their assessment and, to that end, says that his future research plans include complementing comparative functional genomics with both computational and proteomic approaches. ♦



Cancer Research Highlights

Obesity Could Skew Test for Prostate Cancer

Obese and overweight men have lower levels of the blood protein prostate-specific antigen (PSA) that “could mask biologically consequential prostate carcinoma” when those men are given PSA tests for prostate cancer, according to a population study that will be published in the March issue of *Cancer*, and appearing now in the “early view” section of the journal’s Web site (<http://www3.interscience.wiley.com/cgi-bin/jhome/28741>).

The study was conducted by Dr. Jacques Baillargeon and colleagues at the San Antonio Center of Biomarkers of Risk for Prostate Cancer, one of the NCI EDRN clinical and epidemiological centers.

Between 2001 and 2004, 2,779 men without prostate cancer were evaluated, comparing their blood serum PSA level with their body mass index (BMI), a standard measure for weight and obesity. PSA levels are already known to vary with an individual’s race/ethnicity and age, but once these factors were controlled for, researchers also found a strict inverse relationship between weight and PSA levels. Thinner and fitter men had higher PSA levels than individuals with higher BMI scores.

According to the researchers, PSA levels appear to be suppressed by about one-third in men whose BMI scores are greater than 40. This tendency could lessen the value of the PSA screening test for overweight

and obese men, producing false-negative results and delaying diagnosis of prostate cancer, the study concludes.

The PSA test is currently an FDA-approved, Medicare-reimbursed method of screening for prostate cancer among men over 50. Prostate cancer is the most common cancer in men, after skin cancer. Approximately 232,090 men in the United States will be diagnosed with the disease in 2005, and about 30,350 men will die from it.

Dramatic Rise in Esophageal Adenocarcinoma Appears to be Real

Between 1975 and 2001, the number of cases of esophageal adenocarcinoma rose faster than for any other major cancer type in the United States, increasing more than six-fold from 3.8 to 23.3 cases per million people in that time period. Researchers from the VA Outcomes Group and the Center for the Evaluative Clinical Sciences at Dartmouth Medical School set out to determine whether the cause could be traced to overdiagnosis or reclassification. Their results are published in the January 19 *Journal of the National Cancer Institute*.

The research team looked at data from the SEER 9 program, which collects information on newly diagnosed cancer in Connecticut, Hawaii, Iowa, New Mexico, and Utah, as well as the cities of Atlanta, Detroit, San Francisco, and Seattle—in all, representing about 10 percent of the U.S. population. They found that the

anatomic distribution of esophageal cancers has shifted over time toward the lower third of the esophagus, near the site of adenocarcinomas, while the incidence of adenocarcinoma in the upper portion of the stomach, near the opening of the esophagus, remained steady, thus refuting the possibility that disease reclassification is causing the trend.

They also identified a steep rise in the mortality from esophageal adenocarcinoma, while the proportion of disease diagnosed at early stage versus late stage has remained steady, thereby clearing overdiagnosis as a cause of the trend. “Our results strongly indicate...a true increase in disease burden,” the authors write. “To explain a rise of this magnitude, however, the prevalence of a strong risk factor must also rise dramatically...Such a risk factor has not yet been identified and defining it should be a priority.”

Online Gene Viewing Tool Available

Scientists at NCI’s Core Genotyping Facility (CGF) are making available a Web-based tool, Genewindow, to facilitate some of the primary genetic research tasks facing scientists. Genewindow is an interactive genome browser designed to view and catalog the millions of known single-nucleotide polymorphisms (SNPs) found in all known human genes. The tool integrates schematic maps of genes with publicly available annotations from researchers.

The browser (<http://genewindow.nci.nih.gov>) is available at no charge and may be useful to universities, cancer centers, biotechnology companies, and laboratories worldwide.

Genewindow was developed to help automate and manage CGF’s complicated work flow, which in 2004

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(Research Highlights continued from page 4) delivered over 4 million genotypes in response to requests by NCI researchers. Typically, a researcher requires a local “map” when looking for a gene that might be associated with a particular trait, condition, or disorder. Analyzing the regions on a gene entails finding and mapping a particular region on a chromosome, then looking for SNPs that might vary from one individual to another.

CGF scientists designed Genewindow to be an intuitive, user-friendly reference tool that even non-geneticists can use to conduct gene studies. Genewindow has become “the primary tool for pre- and post-genetic bioinformatics and analytical work at the CGE,” say the authors of an article published in the February issue of *Nature Genetics*. CGF plans other enhancements, and will release the source code so that other labs may use and adapt it to analyze their own data, even for species other than humans.

Localized Radiation Boosts Survival in Breast Cancer Patients

Patients with high-risk breast cancer who underwent a radical mastectomy and received adjuvant chemotherapy were more likely to survive if they also had localized radiation treatment, according to results of a 20-year follow-up study reported in the January 19 *Journal of the National Cancer Institute*.

The original trial in British Columbia, Canada included 318 premenopausal women with lymph node-positive breast cancer who had mastectomies and chemotherapy during the period of 1979–1986. They were randomly assigned to receive either no radiation treatment—the general standard of care—or locoregional radiation therapy (radiation to the lymph nodes and chest wall).

Dr. Joseph Ragaz and his colleagues from the McGill University Health Center first analyzed the patients’ data at the 15-year mark and found that radiation therapy was associated with improved breast cancer survival but not with overall survival improvement. However, at the second follow-up 5 years later, the researchers discovered a 32-percent reduction in breast cancer mortality and a 27-percent reduction in overall mortality compared with chemotherapy alone.

The researchers believe the radiation therapy improves survival because it destroys microscopic cancer cells that chemotherapy cannot eradicate. “Our results, and those from other groups, confirm that in situations where residual disease remains, adjuvant chemotherapy alone in high-risk breast cancer patients is suboptimal and that the addition of locoregional radiation therapy is important to achieve the highest cure rate,” they concluded.

Large International Study Confirms Dangers of Secondhand Smoke

A new study involving nonsmokers and former smokers in 10 European countries is the latest to warn that exposure to secondhand tobacco smoke is a risk factor for lung cancer and other respiratory diseases, particularly among ex-smokers.

At the start of the prospective study, which appeared February 1st on the *British Medical Journal* Web site, the researchers interviewed more than 120,000 nonsmokers and former smokers—men and women aged 35–74—about their lifetime exposures to cigarette smoke. Seven years later, 97 people had developed lung cancer, 20 had developed upper respiratory cancers, and 14 had died from chronic obstructive pulmonary disease or emphysema.

The researchers found an association between exposure to environmental tobacco smoke and risk of lung cancer. The risk was higher among former smokers (who had stopped for at least 10 years) than among people who never smoked. The researchers suggest that former smokers may be more susceptible due to previously acquired genetic mutations.

The study also found that children who were exposed to environmental tobacco smoke at infancy were up to three times more likely to develop lung cancer as adults, compared with children who were not.

Although elevated risks for lung cancer among people exposed to secondhand smoke have been found before, this study’s strengths include its large size and the ability to rule out other risk factors.

Dr. Paolo Vineis, of Imperial College London, is first author of the study, which was directed by Dr. Elio Riboli, of the International Agency for Research on Cancer. The study was part of the large, multicenter cohort European Prospective Investigation into Cancer and Nutrition study. ♦

CCR Grand Rounds

February 15: Dr. Elias A. Zerhouni, Director, NIH; “The Future of Medical Imaging”

February 22: Dr. Andrew P. Feinberg, King Fahd Professor of Medicine, Molecular Biology & Genetics, and Oncology, Johns Hopkins University School of Medicine; “Epigenetic Mechanisms in Human Disease”

CCR Grand Rounds are held 8:30 to 9:30 a.m. at the NIH campus in Bethesda, Md., in the Clinical Center’s Lipsett Amphitheater. ♦

Funding Opportunities



Featured Clinical Trial

The following are newly-released NCI research funding opportunities:

Molecular Approaches to Diet and Pancreatic Cancer Prevention

PA-05-040

Application Receipt Dates: May 10, Sept. 10, 2005; Jan. 10, May 10, Sept. 10, 2006; Jan. 10, May 10, Sept. 10, 2007

This funding opportunity will use the NIH investigator-initiated research project grants (R01) award mechanism.

For more information, see http://cricri.nci.nih.gov/4abst.cfm?initiativeparfa_id=2520 or contact Dr. Sharon Ross at rosssha@mail.nih.gov.

Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) to Improve the Chemistry and Targeted Delivery of RNAi Molecules

PA-05-041

Application Receipt Dates: May 10, Sept. 10, 2005; Jan. 10, May 10, Sept. 10, 2006; Jan. 10, May 10, Sept. 10, 2007

This funding opportunity will use the STTR (R41/R42) and SBIR (R43/R44) grant mechanism(s).

For more information, see http://cricri.nci.nih.gov/4abst.cfm?initiativeparfa_id=2521 or contact Dr. Suresh K. Arya at aryas@exchange.nih.gov.

For comprehensive information about NCI funding priorities and opportunities, go to <http://www.cancer.gov/researchandfunding>.

The NIH Roadmap provides a framework of the priorities NIH must address to optimize its research portfolio. It identifies the most compelling opportunities in three main areas: new pathways to discovery, research teams of the future, and re-engineering the clinical research enterprise. For information on Roadmap funding opportunities, go to <http://nihroadmap.nih.gov>.

Chemoprevention Trial for Head and Neck Cancer

Name of the Trial

Phase II Chemoprevention Study of Pioglitazone in Patients with Hyperplastic or Dysplastic Oral Cavity or Oropharyngeal Leukoplakia (UMN-0109M07254). See the protocol summary at <http://cancer.gov/clinicaltrials/UMN-0109M07254>.

Principal Investigator

Dr. Frank Ondrey, University of Minnesota Cancer Center

Why Is This Trial Important?

Head and neck cancer affects over 38,000 Americans each year, resulting in 11,000 deaths. Head and neck cancer sites are divided into the oral cavity, the oropharynx, and the larynx (voice box) and related structures. The oral cavity includes the lips and most of the soft tissue inside the mouth (for example, the gums and the main part of the tongue). The oropharynx includes the soft palate at the back of the mouth, the tonsils, and the base of the tongue. The larynx includes the voice box area and the entry tissues into the esophagus.

Leukoplakia, an abnormal patch of white tissue that forms on mucous membranes inside the mouth and elsewhere in the body, may be a precursor to head and neck cancer.

In this study, researchers are investigating the ability of pioglitazone, a drug used to treat type II diabetes, to reverse leukoplakia and prevent it from developing into head and neck

cancer. Pioglitazone belongs to a new class of oral antidiabetic drugs called thiazolidinediones that have been shown to inhibit growth of some epithelial cancer cells.

“There is no current standard for screening or treatment of leukoplakia like there is for precancerous lesions of the colon, for example,” said Dr. Ondrey. “We know that over the course of 5 years about 5 percent of patients with oral leukoplakia will develop invasive cancer, so it is important that we develop an effective means of treating the condition and preventing it from progressing to cancer.”

Who Can Join This Trial?

Researchers seek to enroll up to 33 patients diagnosed with hyperplastic or dysplastic oral cavity or oropharyngeal leukoplakia. See the list of eligibility criteria at <http://cancer.gov/clinicaltrials/UMN-0109M07254>.

Where Is This Trial Taking Place?

This trial is being conducted at the University of Minnesota Cancer Center in Minneapolis.

Contact Information

For more information, call the University of Minnesota Cancer Center at 612-624-2620 or NCI's Cancer Information Service toll-free at 1-800-4-CANCER (1-800-422-6237). The call is completely confidential. ♦

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

Notes

Dr. Mary-Claire King Lectures on Breast Cancer Genetics

Dr. Mary-Claire King, credited with the first discovery of a hereditary breast cancer link, BRCA1, in 1990, spoke at the NIH Director's Wednesday Afternoon Lecture series on January 26. Her seminar covered the nuances in BRCA1 and 2 gene sequence that lend themselves to the disease, the New York Breast Cancer Study, and an approach her lab is using to identify new breast cancer genes. Dr. King's lecture focused, in part, on recent controversial data from her work showing that among the relatives of women who developed breast cancer due to BRCA1 mutations, those who also carry the mutation have as much as an 80 percent risk of developing the disease by the age of 80. Now she is looking for possible risk modifiers by working with families devoid of breast cancer, despite carrying the associated mutations. Her lecture is available on the NIH VideoCasting Web site at <http://videocast.nih.gov>.

Chang Discusses Tumor-Targeting Nanodelivery Systems

Dr. Esther Chang, professor of oncology and otolaryngology at the Lombardi Comprehensive Cancer Center, gave the inaugural talk in NCI's new Nanotechnology Seminar Series on January 27. Dr. Chang discussed the use of targeted nanoscale liposomes to deliver genes, siRNA, and imaging contrast agents to both primary and metastatic tumors.

Dr. Chang, who also serves on NCI's Board of Scientific Advisors, highlighted 10 years of preclinical work in which her laboratory successfully demonstrated that cationic liposomes smaller than 100 nanometers in diameter could safely and selectively deliver therapeutic genes, such as tumor suppressor genes, to tumor cells.

One such preparation, which uses transferrin to target tumor cells and the p53 gene, is slated to begin phase I clinical trials in head and neck cancer this spring.

Other work in Dr. Chang's laboratory is focusing on using cationic liposomes to deliver siRNA constructs capable of down-regulating various oncogenes that are overexpressed in prostate and pancreatic cancers.

Future presentations in the series are scheduled for February 24 and March 8. Visit http://nano.cancer.gov/events_nanotech_seminar_series.asp for more information.

"NCI Listens and Learns" on the Web

On January 26, NCI and the Director's Consumer Liaison Group (DCLG) launched a new pilot Web site—<http://ncilistsens.cancer.gov>—to enhance communication and collaboration between NCI and the cancer advocacy community. The site serves as an online forum for discussing issues related to NCI's strategic plans and initiatives. Advocacy groups can register at the site to participate in this online process; more than 90 groups have registered to date.

Through DCLG, NCI will pose monthly questions to the advocacy community and the public. Groups and individuals can post their comments on the Web site. Following the comment period, NCI will summarize comments made by the advocacy community and provide an official response. For more information on "NCI Listens and Learns," call 301-594-3194.

President's Cancer Panel Meets in New York

The President's Cancer Panel held its fourth and final meeting on translating research to reduce the burden of cancer at Memorial Sloan-Kettering

Cancer Center. A call was issued to make financing for all aspects of translational research—discovery, development, and delivery—a top national priority in order to reduce suffering and death due to cancer. It was emphasized that delivering current cancer information to the American people would have an immediate impact on cancer survival.

To help narrow the gap between discovery and delivery, it was recommended that geographic areas of excess mortality be targeted. "There are hundreds of 'silent tsunamis' across the United States at any given time, where people are dying at high rates," remarked one speaker. While funding for scientific discovery remains strong, additional financial support is needed to "commercialize" and move discoveries from the laboratories to physicians and patients. "Discoveries are rendered useless if they do not reach the people who need them," reflected panel member Dr. Margaret Kripke.

Strategies for improving our current system of translational research were discussed at length. Participants touched on many issues similar to those discussed at prior meetings, but with different emphases. The need for "team science," review of unintended consequences of current regulations (e.g., the Health Insurance Portability and Accountability Act), examination of intellectual property and patent barriers, and better integration of communities into research and dissemination efforts are some of the major themes that surfaced throughout this series of meetings and will be addressed by the panel in its final report to the President. ♦



Community Update

Distress Treatment Guidelines Address Void in Cancer Care

Cancer patients usually experience varying levels of distress about their disease, treatment, and prognosis. These negative but understandable feelings of anxiety and depression can frequently be severe enough to impair patients' daily lives and abilities to comply with treatment regimens. However, only about 5 percent of cancer patients receive any psychological help for these very real problems related to their primary disease condition.

To address this void in cancer care, the National Comprehensive Cancer Network (NCCN) and the American Cancer Society (ACS) announced the release of *Distress Treatment Guidelines for Patients*. The 32-page booklet—which is available free in English and Spanish at NCCN's Web site (http://www.nccn.org/patients/patient_gls/_english/_distress/contents.asp)—was developed by an NCCN panel of 23 cancer experts to enhance patients' lives, support patient-doctor communications, and increase the success of cancer therapies by increasing patient compliance with treatment plans.

The NCCN guidelines were initially developed to help clinicians respond to their patients' distress symptoms. However, "given the busy oncology offices today, there is often not enough time for doctors to ask about distress," noted Dr. Jimmie Holland, a psychiatrist at Memorial Sloan-Kettering Cancer Center, who chaired the NCCN panel. She has found that "most cancer patients are reluctant to bother the doctor and feel it would be a sign of weakness to mention their distress. These guidelines make it easy for patients to assess their level of distress and take positive steps to reduce it."

At the heart of the guidelines is a "Distress Thermometer," an easy-to-use screening tool to assess the level of patient distress (on a 0–10 scale). Patients are provided with a problem list to help pinpoint their reason(s) for distress. The list covers common problem areas such as: practical (housing or child care), family (dealing with children or partner), emotional (worry and sadness), spiritual or religious concerns (loss of faith), and physical (pain, diarrhea, or appetite).

The guidelines recommend that patients who score 5 or higher on the Distress Thermometer ask for referrals to mental health, social work, or pastoral services. The NCCN booklet also provides in-depth descriptions of psychosocial and practical problems that can occur during cancer treatment and resources that are available to help patients cope.

"We are very pleased to once again be collaborating with NCCN, this time on the *Distress Treatment Guidelines for Patients*," said Dr. Stephen Sener, president of ACS and vice chairman of the Department of Surgery at Evanston Northwestern Healthcare in Chicago. "By making these NCCN guidelines accessible, we are ensuring that patients and their caregivers will be on the same page when it comes to discussing the level of distress associated with cancer diagnosis and treatment."

These guidelines were developed in response to, and to attempt to help NCI meet, the recommendations in the Institute of Medicine's report on improving quality care in cancer and in the President's Cancer Panel report on cancer survivorship for improved access to psychological support for cancer patients/survivors and their families across the course of care. NCI continues to play a key role in the direction and support of research to establish the evidence base for interventions with potential to improve the emotional and social well-being of those diagnosed with and treated for cancer. ♦

Featured Meetings and Events

A comprehensive calendar of cancer-related scientific meetings and events sponsored by NCI and other scientific organizations is available at: <http://calendar.cancer.gov/> ♦

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.