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Eliminating the Suffering and Death Due to Cancer

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Targeted Drug Shows Dramatic Results for Follicular Lymphoma

The targeted drug, iodine-131 tositumomab (Bexxar), which is easier to take and less toxic than standard chemotherapy, could one day be the treatment of choice for people with late-stage follicular lymphoma. That's the view of the researchers who originally developed Bexxar, based on results from a phase II clinical trial reported in the February 3 *New England Journal of Medicine*.

Bexxar is currently approved to treat follicular lymphoma after chemotherapy fails, but researchers at the University of Michigan believe it has potential as a first-line treatment.

The phase II trial included 76 patients with advanced-stage follicular lymphoma. Nearly all of the patients (95 percent) responded to treatment, and three out of four were free of the disease after a single course of treatment, the study found. Five years later, most of the patients were in remission, the researchers added.

"We're pleased that almost all the patients responded, but even more important is the number of patients who achieved complete remission," said Dr. Mark Kaminski, who led the trial.

"This regimen compares favorably to

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Director's Update

Looking Back on HHS-NCI Collaborations

When I came to the National Cancer Institute (NCI) in January 2002, I was privileged to join a consortium of agencies guided by the dynamic leadership of U.S. Department of Health and Human Services (HHS) Secretary Tommy G. Thompson. Secretary Thompson has supported NCI's strategic commitment to eliminate the suffering and death due to cancer and initiated steps that would enable us to accomplish this by 2015. Our shared vision also included the belief that the fruits of scientific progress must ultimately be spread beyond our nation's borders and benefit the entire world.

HHS Deputy Assistant Secretary for Health Dr. Howard Zucker, NIAID Director Dr. Anthony Fauci, HHS Secretary Tommy G. Thompson, and NCI Director Dr. Andrew C. von Eschenbach visit troops in Baghdad.

Over the past 3 years, I've had the pleasure of working with the Secretary on a number of critical initiatives, including international cancer programs, prevention initiatives, bioterrorism research and planning, advanced technology programs, HHS public health efforts, and interagency collaborations.

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(Targeted Drug continued from page 1)
even the most aggressive treatments, especially when you consider that it only takes 1 week to administer compared to several months for chemotherapy," Dr. Kaminski explained. However, he added that the only way to know how effective Bexxar is compared with standard chemotherapies is to conduct a randomized trial.

Such a comparative trial is warranted based on the new results, concurred Dr. Joseph Conners of the British Columbia Cancer Agency in an accompanying commentary. He noted, however, that the patient group in the study was overall slightly younger and perhaps healthier than patients in other trials. In addition, Bexxar was not tested on people with more than 25 percent of their bone marrow affected.

Dr. Wyndham Wilson of the Lymphoma Section of NCI's Experimental Transplantation and Immunology Branch cautioned, "These results are promising, but it's not at all clear that they're better than standard treatments." He also hoped the phase II study will "generate a random trial comparing treatments."

New treatments are needed. Current therapies can temporarily control follicular lymphoma, but there is no cure and most patients die of the disease or complications from treatment.

Bexxar was developed 15 years ago by Dr. Kaminski and Dr. Richard Wahl at the University of Michigan. They launched the current trial in 1996 based on preliminary evidence that treating relapsed patients sooner rather than later yielded better responses.

"We knew it worked well late in the disease and wanted to know what would happen if used earlier," said Dr. Wahl, now at the Johns Hopkins School of Medicine. "The idea was to take your best shot with the best agent early on. If something is working better than chemotherapy, why wait?"

Bexxar is a type of radioimmunotherapy that shrinks tumors through both radiation and an immune response. The drug consists of a radioactive atom (I-131) attached to an antibody on the surface of cells. In the bloodstream, the radioisotope is guided to lymphoma cells by the antibody, where it binds to protein, selectively delivering its radioactivity.

The therapy is tailored to the patient on two levels, explained Dr. Wahl. The drug targets only certain cells in the body, and the dose is determined for each patient individually. Doctors inject the drug and use imaging tools to monitor the body's response. The therapeutic dose is delivered a few days later. ◆

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As Secretary Thompson embarks on a new career after his successful stewardship of HHS, I want to highlight a few of these initiatives and the crucial role that Secretary Thompson and the Department have played in their planning and implementation. On behalf of my colleagues at NCI, I also offer our deep gratitude and sincere best wishes to Secretary Thompson for the future.

The Secretary played an important role in supporting the President's initiatives promoting global health and its contribution to the economy and security of nations. He worked closely with NCI on several international programs, recognizing the growing global burden of cancer. He led delegations, which I was able to join, to Iraq, Jordan, and Russia.

The 2004 delegation to Iraq assessed infrastructure needs for health care. We saw first-hand the achievements of HHS agencies in the rebuilding of Iraq. I was also honored to lead a roundtable with the new Minister of Health of Iraq, the Honorable Dr. Ala'adin Al-Alwan.

Last February, Secretary Thompson and I joined officials from the King Hussein Cancer Center in Jordan, a regional cancer treatment facility that is now saving the lives of many cancer patients from around the Middle East. During our visit, we saw the launch of a state-of-the-art telemedicine system and met with Iraqi children with cancer who were doing well, receiving treatment that would not have been available only a few years ago.

On the home front, HHS has enlisted NCI's help in some national initiatives. When the Interagency Committee on Smoking and Health's Subcommittee on Cessation published its recommendations in February 2004, Secretary Thompson began to address the recommendations by tasking NCI and CDC with developing a national network of tobacco cessation quitlines. On November 10, 2004, the National Network of Tobacco Cessation Quitlines was launched. The toll-free phone number (1-800-QUIT NOW) puts callers in touch with programs that can help them give up tobacco.

Secretary Thompson was also involved with the CEO Cancer Gold Standard, which calls for corporations to actively reduce their employees' risk of cancer through workplace programs. NCI intends to continue these and other collaborations that Secretary Thompson has supported.

With this in mind, we are delighted to welcome another former governor as the new HHS Secretary. Mike Leavitt also comes to the Department after a distinguished career in which he demonstrated that he knows the importance of continuing to strengthen the health care system and to serve the well-being of the American people at all levels of our society and in all communities. ◆

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

Spotlight

NCI Radiation Oncology Program Tackles Cancer Disparities

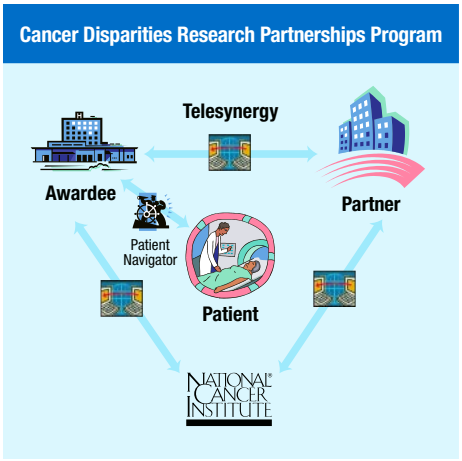
For many years, it has been known that certain U.S. populations experience a greater incidence, prevalence, mortality, and overall burden from cancer.

Such disparities are evident throughout the American health care system: People in underserved populations and communities have less awareness of cancer, which translates into less healthy behaviors, less screening, and patients presenting at later stages in the course of disease. In addition, institutions that provide the care for a disproportionate number of medically underserved people are not usually involved in NCI research—and clinicians who treat low-income, ethnic, and minority populations do not typically devise clinical trials.

One NCI response to those circumstances has been to fund six flagship studies in radiation oncology through grants from NCI's Cancer Disparities Research Partnership (CDRP) Program.

"We realized that trying to do cancer research on health disparities was a complex undertaking," says Dr. Frank Govern, deputy director of the Radiation Oncology Sciences Program. "The organizational models developed to conduct research in the mainstream population didn't fit here. We know, for example, that Hispanic males have much greater incidence and mortality of cancers of the stomach, gall bladder, and liver. Too few studies have explored why that may be so."

In the early 2000s, Dr. Govern and Dr. C. Norman Coleman, associate director of the Radiation Research Program in the Division of Cancer Treatment and Diagnosis, hoped to reverse these trends by crafting a blueprint for the CDRP based on a new model. "Rather than hoping centers and physicians in disparities regions would be reached by the cancer centers and cooperative groups, we reversed the dynamics and brought the resources to the disparities regions and empowered them to reach out to the major centers and groups," explains Dr. Govern. Through creative funding approaches to nontraditional organizational models, "We sought to take the high-tech oncology research enterprise directly to the populations and institutions where the people who most need it are not getting its benefits."



The six hospitals serving the target populations use the TeleSynergy system to discuss clinical details with mentors at NCI and in traditional cancer centers; patient navigators help patients in the trials through the process.

Radiation oncology provides "fertile ground for conducting disparities research," Dr. Govern adds. "CDRP is a focused effort to leverage national resources and deliver them to smaller hospitals and treatment centers—and the minority populations they treat—who often don't have access to clinical trials." Several components have been incorporated into the CDRP grant structure: a relationship with a large comprehensive cancer center as a mentor in the conduct of those clinical trials; the use of NCI's TeleSynergy® system to enhance communications; and "patient navigators" to provide one-on-one assistance to patients in the trials.

Dr. Patrick Maguire, principal investigator for one of the six projects, is a radiation oncologist at the Zimmer Cancer Center, part of the New Hanover Regional Medical Center (NHRMC) in Wilmington, N.C. "We hope to establish a presence in our community to enhance cancer awareness for patients and clinicians alike," Dr. Maguire notes. His CDRP trial recruits primarily African Americans for a study of hyperfractionated intensity modulated radiotherapy on stage III and IV-A head and neck cancers.

The nine counties served by NHRMC typify the CDRP focus on underserved populations. The counties are 22.5 percent African American, compared with 12.3 percent for the United States as a whole. Overall, North Carolina's median per capita income of $13,548 is 37 percent lower than the national average. For African Americans in the nine counties, median income is generally even less, ranging from $9,624 to $14,083. These are not the

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Cancer Research Highlights

Initial Glioma Treatment Shows Wide Variation

Care patterns for patients newly diagnosed with the most common form of advanced brain tumors can vary dramatically, according to a study published in the February 2 *Journal of the American Medical Association* (*JAMA*). In some areas, the study authors reported, care patterns closely followed results from published literature, such as the heavy use of contrast-enhanced MRI at diagnosis (92 percent of patients) and postoperative radiation therapy (87 percent).

Other care patterns, however, contrasted sharply with published literature and the few practice guidelines available for treating patients with grade III or IV gliomas. Nearly 9 in 10 patients received antiepileptic drugs (AEDs), despite the fact that only 32 percent of patients presented with seizures—meaning that many patients received the antiepileptic drugs prophylactically. According to published guidelines on antiepileptic prophylaxis for patients with newly diagnosed tumors, lead author Dr. Susan M. Chang of the University of California, San Francisco noted that AEDs "have little value for seizure-free patients…and actually are associated with significant adverse effects."

The study, funded in part by NCI, was conducted by the Glioma Outcomes Project, a prospective, longitudinal database that tracks clinical practice patterns and outcomes among malignant glioma patients. The analysis published in *JAMA* included 565 patients.

Among other findings were the limited use of antidepressants, even among patients who reported depression symptoms, and the near universal use of corticosteroids to limit neurologic symptoms. Although corticosteroid use is supported by the published literature, the authors wrote, the drugs can have significant adverse effects, including immunosuppression and hypertension. These effects, they added, "may be ameliorated by lower doses," and consensus guidelines on corticosteroids may be needed "to optimize corticosteroid dosing."

False-Positives Cause Some Men to Skip Subsequent Prostate Cancer Screening

Researchers have found that, among men undergoing a baseline round of prostate cancer screening, African Americans, men who have a high school education or less, and men with a false-positive baseline screen are less likely to return for subsequent screening. These findings are published in the January issue of *Cancer Epidemiology Biomarkers & Prevention*, and are based on 2,290 Caucasian and African American patients enrolled at the Detroit site of the Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial.

The researchers found that men who received false-positive test results at baseline were 1.9 times as likely not to return for subsequent screening appointments, compared with those who tested negative. African American men were 1.6 times as likely not to return for screening as Caucasians, and men with a high school education or less were 1.6 times as likely not to return as those with a post-high school education. A total of 184 patients did not return for their appointments, their reasons being refusal (61 percent), scheduling problems (29 percent), illness (4 percent), and travel out of the area (6 percent).

The authors concluded that when clinicians discuss prostate cancer screening with their patients, they should cover the likelihood of false-positives, the meaning of these results, the anxiety that may occur after receiving abnormal results, and the relationship between screening and mortality due to prostate cancer. "During the shared decision-making process, patients' attitudes and perceptions should be ascertained," they wrote. "This process could assist clinicians in ensuring that patients make informed choices about subsequent prostate cancer screening."

Researchers Synthesize Dendrimer Clusters for Targeted Therapy

Scientists at the University of Michigan have devised a method to easily create multipurpose molecules for use in targeted anticancer therapy. By attaching single-stranded DNA linkers to dendrimers—polymers that branch out like a tree—the researchers could bridge together individual dendrimer subunits with specific functions and create a multifunctional dendrimer cluster. This bridging technique, described in the January

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Chemistry and Biology, could potentially lead the way to developing customized therapies for individual patients.

Dendrimers are promising candidates for use as the base of anticancer drugs, to which functional molecules can be attached. Ideally, an anticancer therapeutic agent would have multiple functional groups; for example, a targeting molecule to bind a cell, a radioactive compound to kill the cell, and a fluorescent probe so the process can be imaged. However, there are problems synthesizing these compounds, and different drugs would have to be designed for each different tumor with this approach.

Dr. James Baker, Jr., and colleagues improved compound synthesis through a "building block" approach in this NCI-funded study. They created two single-function dendrimers; one with a molecule to bind folate receptors, and the other with a fluorescein molecule for imaging. They then added complimentary 34-base stretches of single-stranded DNA to each, and the two dendrimers conjugated through base pairing. Using fluorescence imaging, they observed that the dendrimer cluster specifically bound to a cancer cell line overexpressing the folate receptor. Compared with traditional chemistry, DNA-linked dendrimers could provide a more effective way to mix and match different therapeutic combinations to better treat individual patients.

Sunlight May Also Reduce Some Cancers

Two case-control population studies appearing in the February 2 *Journal of the National Cancer Institute* provide evidence that sunlight, a known cause of skin cancer, may actually reduce the risk of certain other cancers.

In a large study of Scandinavians, Dr. Karin Ekström Smedby and colleagues at the Karolinska Institutet in Stockholm looked for links between ultraviolet exposure from sunlight and several types of lymphomas, in part because the incidence of melanoma has been found to rise in parallel with the incidence of non-Hodgkin's lymphoma (NHL). Instead, the researchers found that increased sun exposure was associated with reduced risk for NHL, and also, though less clearly, with decreased risk for Hodgkin's lymphoma.

In a second, smaller study of 528 people living in Connecticut, Dr. Marianne Berwick's team from the University of New Mexico conducted a 5-year follow-up to her earlier trial looking at skin self-examination and melanoma mortality. Her results clearly show that increased sun exposure and heightened skin awareness reduce the risk of dying from melanoma.

Sunlight's salutary influence on some cancers has been discussed for several decades, according to an accompanying editorial. The editorial noted that breast, colon, and prostate cancer mortality all show "a striking latitudinal gradient," increasing from the southern to the northern United States. Dr. Berwick suggested that the greater exposure to sunlight could enhance DNA repair mechanisms, and/or leading to less fatal forms of melanoma. Vitamin D is synthesized when the skin is exposed to ultraviolet B light, which may also have a protective effect.

New Drug Shows Promise in Combating Imatinib-Resistant CML

Temple University researchers have developed a new drug, ON012380, that can override imatinib (Gleevec) resistance in chronic myelogenous leukemia (CML). Similar to imatinib and other CML drugs, ON012380 works by inactivating the key oncoprotein BCR-ABL, but targets a different site on the protein. The study, which appeared in *Proceedings of the National Academy of Sciences* online on January 27, showed that ON012380 was about 10 times more potent than imatinib and could induce apoptosis in all of the known imatinib-resistant leukemia cells.

Imatinib treats CML by inhibiting BCR-ABL, a cancer-inducing protein created by a rearrangement of two chromosomes that bring the Bcr and Abl genes together. It blocks BCR-ABL's ability to bind ATP. While imatinib has been extremely effective, many patients eventually develop resistance to it because BCR-ABL can mutate and adapt. Currently, 17 clinically identified mutations in this ATP-binding region have been identified.

Dr. E. Premkumar Reddy and his team circumvented imatinib resistance by targeting a different, but equally critical, part of BCR-ABL: the substrate binding domain. They found that ON012380 was effective at inhibiting the growth of all 17 imatinib-resistant human cell lines, working at a 10-fold lower concentration than imatinib. In mice expressing T315I, the most common BCR-ABL mutant, ON012380 was able to induce a regression in the leukemia while being extremely well tolerated.

The 100-percent efficacy and low toxicity of ON012380 potentially make it an important new drug against imatinib-resistant CML, and Dr. Reddy is currently seeking Food and Drug Administration approval to proceed with clinical trials. ◆

(Spotlight continued from page 3)
people who typically find their way to government-funded clinical trials, explains Dr. Maguire, "but we do active outreach into the community, and we partner with physicians who refer their patients for our clinical trials."

The CDRP model recasts the major U.S. cancer centers in a mentoring, supportive role. Radiation oncologists from the University of North Carolina at Chapel Hill advise and consult with Dr. Maguire and other members of the NHRMC treatment staff. Such consultation revolves around clinical research using the TeleSynergy work stations installed at both sites. Physicians several hundreds of miles apart talk with patients and with one another over joint access to medical records, CT and MRI images, and pathology specimens.

The third piece of the partnership is the Patient Navigator program. At each CRDP trial site, NCI's Center to Reduce Cancer Health Disparities provides support for one or more counselors to work with each patient, guiding them through the process, helping to navigate the obstacles they encounter, and ensuring they don't give up or drop out of continuing care. This system is the key to success, according to Tufanna Bradley, the patient navigator for the NHRMC trial. "It's easier to provide individualized support because I can usually establish a bond with patients because I go to their church, or at least I know their neighborhood," she says.

Other CRDP partnerships support trials in Inglewood, Calif.; McKeesport, Pa.; Rapid City, S.D.; Laredo, Texas; and Pascagoula, Miss., reaching other underserved populations and communities, such as Hispanic/Latinos, Native Americans, and the poor in inner-city and rural environments. ◆

NIH Update

NIH Announces New Ethics Regulation

A new supplemental ethics regulation announced last week by the National Institutes of Health (NIH) will prohibit agency scientists from engaging in a number of outside activities, including consulting arrangements with "substantially affected organizations," which include all pharmaceutical and biotechnology companies and NIH-supported research institutions. Under the new regulation, NIH staff who are required to file specific financial disclosure reports will not be allowed to hold or acquire stock or other financial interests in biotechnology, pharmaceutical, medical device, and other companies involved in research or the development of many medical products.

"Nothing is more important to me than preserving the trust of the public in NIH," said NIH Director Dr. Elias A. Zerhouni. During a news conference on February 1, Dr. Zerhouni stressed that his goal with the new interim regulation was "to create a bright line that is so clear" there will be no "ambiguity in terms of interpreting where that line is."

The new regulation comes amid concerns raised by members of Congress over the past year about consulting or other business arrangements between some NIH scientists and industry that they alleged may have violated federal conflict-of-interest regulations or at least created the appearance of such conflicts.

Other provisions in the new regulation include a prohibition among senior NIH employees on the receipt of gifts or awards valued at more than $200 given because of their official position or from a prohibited source. The exception to the prohibition are awards that are considered among the most prestigious in the fields of medicine or scientific research, such as the Nobel Prize or Lasker Award, or those for which the employee simply receives a plaque or certificate and free attendance at the award event.

"Clearly we do not want to impair scientific interchange that is justified and valid," Dr. Zerhouni noted during the news conference. As a result, activities such as teaching classes, editing and writing of textbooks, and providing continued medical education courses will continue to be allowed. "We do not want to isolate our scientists from the mainstream of science," he said.

The new regulation took effect on February 3, when it was published in the *Federal Register*, and will remain in effect unless changed by subsequent regulations. The ban on outside activities will allow NIH to put in place the systems needed to effectively manage scientists' outside activities, Dr. Zerhouni said. Over the next year, HHS will review some of the provisions in the regulation, including some of the new prohibitions, and invites comment from the public during the 60-day comment period. That review, Dr. Zerhouni said, will include an evaluation of the regulation's impact on staff recruitment and retention. ◆

Notes

Rimer Named Dean of UNC School of Public Health

Dr. Barbara Rimer, former director of NCI's Division of Cancer Control and Population Sciences (DCCPS), has been appointed dean of the School of Public Health at the University of North Carolina at Chapel Hill (UNC), effective June 1.

Dr. Rimer is currently an alumni distinguished professor in UNC's department of health behavior and health education and the deputy director for population sciences at the Lineberger Comprehensive Cancer Center. She served DCCPS from 1997 to 2002, introducing or providing leadership for a number of vanguard initiatives in cancer control, including behavioral research, quality of cancer care, health communications, genes and the environment, cancer survivorship, and tobacco control, among others.

Prior to her tenure with NCI, she held joint appointments at the UNC School of Public Health and Duke University Medical Center's community and family medicine department and its comprehensive cancer center. Dr. Rimer was the first woman and first behavioral scientist to lead NCI's National Cancer Advisory Board—a presidential appointment she held from 1994 to 1997.

Upcoming NCI Science Writer's Seminar

On February 23, NCI will host its 12th science writers' seminar on the topic of cancer genetics at the University of Southern California's (USC) Norris Comprehensive Cancer Center in Los Angeles. The seminar, "Can Genes Help Prevent Cancer—or Increase Your Risk?" will take place in a classroom setting and include presentations by a panel of experts in this field from NCI-designated comprehensive cancer centers. Panelists include Dr. Peter Laird of USC, who will discuss DNA-based detection of cancer; Dr. Steve Libutti of NCI, covering the latest in gene tests for thyroid cancer; Dr. Mark Pegram of the University of California, Los Angeles' (UCLA) Jonsson Cancer Center, highlighting molecularly targeted therapies; Dr. Dennis Deapen of USC, talking about genetics and the risk of cancer in ethnic populations; Dr. Joyce Seldon of UCLA, discussing hereditary cancers; and Dr. Jeffrey Weitzel of City of Hope, who will touch on the ethics of cancer genetics and counseling. The seminar will last from 11:00 a.m. to 1:15 p.m., and conclude with a question-and-answer session. Journalists who wish to attend should contact the NCI Press Office at (301) 496-6641 or send an e-mail to ncipressofficers@mail.nih.gov.

NIH Public Access Policy to be Activated in May

After months of discussion and a period of public comment, NIH has adopted a policy requesting the scientists whom it funds to submit an electronic version of their manuscripts—once they have been accepted for publication—to the National Library of Medicine (NLM), making their research results available to the public at no cost. The policy will go into effect on May 2, and gives authors the flexibility to designate a specific time frame for public release—ranging from immediate public availability after final publication to a 12-month delay—when they submit their manuscripts to NLM. Scientists will use a secure Web site to submit their manuscripts, which will then become available through the NLM PubMed Central online digital archive (http://www.pubmedcentral.nih.gov). To oversee the implementation of this policy, NIH will establish a Public Access Advisory Working Group under the NLM Board of Regents, including members from patient advocacy, scientific, library, and publishing communities. More information about the public access policy can be found at http://www.nih.gov/about/publicaccess/index.htm.

Prostate SPOREs Plan Launch of a Shared Biorepository Network

Last week, representatives from the Specialized Programs of Research Excellence (SPOREs) for prostate cancer met in Houston to plan the launch of a pilot biorepository coordination system and informatics infrastructure for prostate cancer research.

This project will assess the feasibility of establishing biorepositories to support post-genomic cancer research and evaluate standardized approaches for biospecimen collection, storage, and distribution through an inter-prostate SPORE biomarker validation study. The pilot is designed to enhance the quality and availability of biospecimens and associated data for the scientific community.

Prostate SPORE representatives discussed the interoperable informatics system needed to facilitate resource sharing. Participants demonstrated informatics tools, suggested approaches for managing inter-SPORE partnerships, outlined preliminary use cases, and brainstormed interfaces to the Cancer Biomedical Informatics Grid.

To support the development of the shared biorepository network, NCI issued a request for proposals to identify a contractor to help build the system. A synopsis is available at http://rcb.cancer.gov/rcb-internet/appl/rfp/published_rfps.jsp. NCI expects to hold a preproposal conference for potential applicants this spring. ◆

HHS News

Medicare Expands Coverage for Cancer Drugs

On January 28, the Centers for Medicare & Medicaid Services (CMS) issued two national coverage decisions that should improve care for cancer patients by expanding coverage for diagnostic tests and chemotherapy treatments for Medicare beneficiaries.

"We are working with NCI, the oncology community, and cancer patient advocates to ensure that patients get the care they need and to develop the evidence needed by doctors and patients to make informed decisions about their treatment," said CMS Administrator Dr. Mark B. McClellan. "NCI-sponsored clinical trials offer patients safeguards, ensuring appropriate evaluation, selection, and use of cancer chemotherapy."

The actions expand coverage for additional off-label uses in CMS-selected clinical studies for drugs that are already approved for treatment of colorectal cancer, including oxaliplatin (Eloxatin), irinotecan (Camptosar), bevacizumab (Avastin), and cetuximab (Erbitux). Positron emission tomography (PET) scans for certain uses in evaluating patients with brain, cervical, ovarian, pancreatic, testicular, and other cancers will also be covered.

The decisions reflect Medicare's emphasis on ensuring that patients receive high-quality, medically necessary care and on developing better evidence by linking coverage to clinical data collection. The new drug policy will ensure that all Medicare contractors pay for the four anticancer drugs in selected clinical trials sponsored in part by NCI.

"The CMS-NCI partnership will enhance clinical evaluation of new medications to improve decision making about drug approval," said NCI Director Dr. Andrew C. von Eschenbach. "Ultimately, our goal in working with CMS is to improve the quality of and access to care for cancer patients everywhere."

The CMS Council on Technology and Innovation is developing draft guidance on this policy. An open-door forum will be held on February 14 to get public input. Comments can also be submitted to http://www.cms.hhs.gov/providers/cti. More information on CMS coverage decisions is located at http://cms.hhs.gov/coverage. ◆

FY 2006 Budget News

On February 7, President Bush unveiled his fiscal year 2006 budget request. The President's budget authority request for NIH totaled $28.740 billion, or 0.5 percent more than the FY 2005 budget. The President requested a 0.3 percent increase for the National Cancer Institute. The total request for NCI is $4.842 billion or $16.5 million more than the enacted budget for FY 2005. Of this increase, $12.8 million will be directed to the NIH Roadmap, bringing the total NCI contribution to the NIH Roadmap to $43.3 million.

FY 2006 President's Budget Request for NCI	
FY 2005 Appropriation	$4,825.3*
FY 2006 President's Budget Request	$4,841.7
FY 2006 Increase	$16.5
Percent Change from FY 2005	+0.3%

* All dollars in millions

All NCI funding mechanisms are projected to remain flat in the proposed budget. However, Research Project Grants (RPGs) will receive a slight increase to support the same approximate number of competing awards as in 2005. No inflationary increases are provided for direct, recurring costs in noncompeting RPGs and the average cost of competing RPGs will remain the same as in FY 2005. However, stipends and health benefits for postdoctoral trainees will increase.

The President's Budget will be presented before both the House and Senate during appropriation hearings. ◆

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.

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