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Advisory Panel Weighs COX-2 Inhibitors' Fate

Advisors to the Food and Drug Administration (FDA) last week recommended that "black box" warnings be added to the label of the two COX-2 inhibitors currently for sale in the United States, and to a third that might be reintroduced (rofecoxib, or Vioxx). The warnings would alert physicians and patients to an increased risk of cardiovascular events associated with the drugs' use. The risk, the committee agreed, represents a so-called class effect of COX-2 agents like celecoxib (Celebrex), valdecoxib (Bextra), and rofecoxib that were developed to alleviate pain while limiting gastrointestinal effects by blocking the action of the COX-2 enzyme.

Dr. Robert Temple, of the FDA Center for Drug Evaluation and Research, told committee members that the agency was "committed to working as quickly as possible" in considering and implementing the recommendations.

Although COX-2 inhibitors' primary indication is to treat pain associated with osteoarthritis and rheumatoid arthritis, the committee's recommendation to leave the drugs on the market means that at least celecoxib,

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Director's Update

Guest Update by Dr. Robert Croyle

Health Information National Trends Survey Web Site Unveiled

At this time last year, we made public our dataset from the first-ever survey to collect nationally representative information on the American public's need for, access to, and use of cancer information. Since then, more than 100 researchers have delved into the National Cancer Institute (NCI) Health Information National Trends Survey (HINTS) to analyze how people use mass media, new media such as the Internet, and personal channels for health information purposes, and how the use of those communication channels may impact their knowledge and acceptance of healthy living guidelines.

Dr. Robert Croyle
Director, NCI Division of Cancer Control and Populations Sciences

Today, I am pleased to announce that a new HINTS Web site (http://hints.cancer.gov) expands access to HINTS data for multiple audiences, using tables, charts, population estimates, and technical history information on every question in the survey. The updated Web site reflects NCI's

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(Inhibitors' Fate continued from page 1)
which the committee almost unanimously agreed is the least likely to be associated with adverse cardiac events, can continue to be studied for use in the prevention and treatment of cancer. Both aspirin and COX-2 inhibitors have shown promise in preventing polyps that can lead to colon cancer.

The 3-day meeting was just one part of a flurry of activity surrounding the "coxib" drugs last week, including a decision by European drug regulators to limit the use of COX-2 drugs only to patients without cardiac problems and the publication of four studies in major medical journals indicating an increased risk of cardiac events and increased blood pressure among patients taking them.

Included among these studies were data on cardiovascular events seen in the APC trial, a randomized, placebo-controlled study jointly funded by NCI and Pfizer Inc., testing whether daily use of a high dose of celecoxib could prevent colon polyp recurrence. No data on polyp reduction from the trial, which was halted in December because of increased cardiac events among patients on celecoxib, are yet available. The data published in the February 16 *New England Journal of Medicine* (*NEJM*) revealed that patients taking celecoxib had significantly increased risk of cardiac-related death, nonfatal heart attack, stroke, and congestive heart failure (see *NCI Cancer Bulletin*, February 15). Also published in the same issue of *NEJM* were data from the APPROVe trial, which tested whether daily use of high doses of rofecoxib could prevent polyp formation in those at high risk. In that study, rofecoxib use increased cardiovascular event risk, but also reduced the incidence of colon polyps by 24 percent.

Dr. Ernie Hawk, director of the NCI Office of Centers, Training, and Resources, who presented the cardiovascular event data from the APC trial during the meeting, explained that NCI is investigating the use of celecoxib in prevention and treatment trials because both animal model and epidemiological studies have shown profound benefits of COX-2s in preventing colon cancer. More than 30 epidemiological studies, for example, have shown that COX-2s reduced adenoma incidence, cancer incidence, and cancer-associated mortality. Moreover, celecoxib has been shown to reduce the number of adenomas in individuals with familial adenomatous polyposis, a genetic condition strongly associated with colorectal cancer development.

"These agents may very well have a unique set of contributions for patients living with cancer or at risk for cancer," Dr. Hawk said. "The data strongly support this and justify further investigation." ◆

(Director's Update continued from page 1)
commitment to public data sharing by making the science of cancer communication easily accessible to multiple audiences. The new tools within the site were developed with extensive input from federal and private partners in cancer communication research and practice.

With the new Web tools, it is now possible for a public health or communication practitioner to look up answers to individual survey questions to learn, for example, how concerned the American public might be about detecting colon cancer. They can also learn, for example, how much attention people say they pay to different health communication channels such as the Internet. The site will not only provide users with accurate, weighted population data directly from the survey to address those questions, but it also will provide users with charts and graphs for copying into reports and presentations. Cancer control scientists can use the site to check the accuracy of their own calculations and obtain information concerning the origin and development of each survey question.

In addition to the new Web tool, it is important to note that research using HINTS is still underway. Last month, we hosted our first HINTS data users conference to discuss findings and to set the stage for HINTS II, which will begin data collection next week. The first analysis using HINTS data was published in this month's issue of *Preventive Medicine*. Investigators examined survey responses to assess prevalence of self-reported prostate-specific antigen (PSA) use and its association with patients' information seeking and decision making. The authors looked at HINTS data from 927 males aged 50 and over who had no history of prostate cancer, with consideration of respondents' attention to health information, cancer-information seeking behavior, and perceptions of health care providers' communication styles. The study revealed that men aged 65-74 who have college degrees and who reported regularly seeking and paying attention to health information were more likely to report receiving a PSA screening recommendation from their physicians.

Dr. Bradford W. Hesse, acting chief of NCI's Health Communication and Informatics Research Branch, has led a great team of HINTS investigators within and outside NCI. His efforts are integral to the success of the project.

HINTS provides an invaluable snapshot of how adults use the many information resources around them to lead healthier lives. We look forward to continued collaboration with researchers and practitioners to use HINTS to inform our cancer communication strategies to accelerate progress in reducing the burden of cancer in America. ◆

Spotlight

Viruses Added to Federal List of Human Carcinogens

The Department of Health and Human Services has for the first time included viruses on the federal government's official list of agents that cause cancer in people.

The hepatitis B and C viruses, which cause cancer of the liver, and the human papillomavirus (HPV), which causes cervical and anal cancers, are listed along with 55 other "known" human carcinogens, including asbestos, tobacco smoke, and ultraviolet radiation.

The list was published January 31 in the National Toxicology Program's (NTP) *Report on Carcinogens*, now in its 11th edition. This biennial report for the National Institute of Environmental Health Sciences historically has focused on the toxins that people might encounter in their homes or workplaces. But the editors of the last two editions broadened the scope to include more than just harmful chemicals.

"The report was originally requested by Congress to provide a public document that informs people of the causes of cancer in their everyday lives," explained NTP Associate Director Dr. Christopher Portier. "Viruses are one such cause, and we felt it was important to include them in the report."

Although a number of viruses have been linked to cancer, the evidence is strongest for the three in the report. Their inclusion will likely surprise no one in the field.

Dr. Thomas O'Brien of NCI's Division of Cancer Epidemiology and Genetics welcomed the addition of viruses to the list. "Viruses are among the strongest carcinogens that are known," he said. "They cause a variety of cancers, such as liver cancer, which is one of the most prevalent worldwide."

More than 80 percent of the world's cases of liver cancer are attributable to infection by the hepatitis B and C viruses, and some 350 million people are chronically infected with one of the seven subtypes of the hepatitis B virus (HBV). Chronic infections and those that occurred during early childhood are particularly strong risk factors for the major form of liver cancer known as hepatocellular carcinoma, which is usually untreatable and fatal.

The good news about discovering links between viruses and cancer is that it becomes possible, at least in theory, to prevent cancers through vaccines and the surveillance of viruses. The HBV vaccine offers an example.

When the vaccine was developed years ago, hepatocellular carcinoma became the first cancer that could largely be prevented through vaccinations and the screening of blood and blood products for viruses. Rates of cancer due to HBV infection have decreased in those countries that have large-scale vaccination programs, although the rates for liver cancer associated with the hepatitis C virus (HCV) in particular have risen in the United States.

Over the next 50 years, deaths from liver cancer can be reduced if universal HBV vaccination programs are implemented around the world, according to Dr. James Goedert of NCI's Viral Epidemiology Branch. In a commentary in the February 16 *Journal of the National Cancer Institute*, he stresses the need for programs that can reach infants in rural areas of Africa, Asia, and South America, where mortality from hepatocellular carcinoma is 20 times higher than in the United States.

In an interview, Dr. Goedert identified two other viruses he feels are worthy of inclusion in NTP's report: HTLV1, which causes adult T-cell leukemias, and human herpesvirus 8 (HHV8), which causes Kaposi's sarcoma and primary effusion lymphomas. HIV, the Epstein-Barr virus, and the bacterium *Helicobacter pylori* have also been linked to cancers.

"From a public health perspective, it's important to look at these viruses very closely because there's reason to believe they're responsible for a lot of cancers worldwide," said Dr. Eric Engels of NCI's Viral Epidemiology Branch, who has studied a range of viruses, including HIV and HHV8, both linked in some way to cancer.

Dr. Engels is also investigating HCV in tumors other than liver cancer, such as non-Hodgkin's lymphoma (NHL). HCV infection is twice as common in people with NHL compared with people from the general U.S. population, his team reported in the *International Journal of Cancer* in March 2004.

Experimental vaccines have been developed against forms of HPV that cause cervical cancer, one of the most common among women. The virus is found in most women treated for cervical cancer, though infection does not always lead to the disease.

As noted in the November 30, 2004 *NCI Cancer Bulletin*, NCI researchers have launched a phase III clinical trial in Costa Rica to test an HPV vaccine. ◆

Cancer Research Highlights

Measles Virus Retargeted at Cancer Cells in Mice

An international team of researchers has re-engineered a robust strain of the measles virus to find and attack only cancer cells in a proof-of-concept study in mice published in the February 2005 issue of *Nature Biotechnology*. While development of clinical therapies is still years away, the new Six-his[tidine] Tagging and Retargeting (STAR) system opens the door to a new class of "retargeted viruses from other virus families," reported study leader Dr. Stephen J. Russell of the Mayo Clinic.

Viruses survive by penetrating a cell and commandeering its ability to reproduce. About 5 years ago, scientists discovered that the common measles virus was "oncolytic," with the ability to preferentially attack cancer cells. They began to search for ways to neutralize the measles virus' indiscriminate assault on healthy cells while retaining its potency against cancer—an approach known as oncolytic virotherapy.

Dr. Russell and his colleagues created the STAR system by first disabling the measles virus from attacking normal cellular targets. They then re-engineered the virus to effectively fuse to receptors on the cell membranes of new targets: a trans-membrane molecule (CD38) and a receptor (EGFR) found at abnormally high levels on the surface of many cancer cells. Finally, they discovered a "molecular tag" that permits the new virus to be propagated in large quantities on universal substrate cells. The STAR system produces "very clean, very clear targeting," said Dr. Russell. "We can take our pick as to what new receptor we target and send the virus after it."

Managed Care Growth Doesn't Sap Fee-for-Service Care Quality

The quality of cancer care provided by the fee-for-service sector in a given region does not appear to be negatively affected by an increased managed care presence in the same area, a new NCI-funded study concludes. The authors note that the study provides some assurance that fee-for-service providers are not short-changing patients by offering less—or at least less expensive—care in an effort to contain costs and compete with managed care providers. Fears that such a "spillover effect" might be occurring, lead author Dr. Nancy L. Keating and colleagues from Harvard Medical School wrote, have grown as managed care has continued to be a formidable presence in many parts of the country.

Published in the February 16 *Journal of the National Cancer Institute*, the study used data from NCI's Surveillance, Epidemiology, and End Results (SEER) program and Medicare on more than 89,000 patients who had been diagnosed with breast or colorectal cancer between 1993 and 1999. They focused their review on several indicators of quality care, including use of surveillance mammography after breast cancer diagnosis, use of radiation therapy after breast-conserving surgery, and use of adjuvant chemotherapy in patients with stage III colorectal cancer.

The only truly marked effect of expanded managed care penetration on fee-for-service providers was an increased rate of carcinoembryonic antigen testing for patients with colorectal cancer, which increased significantly as managed care market share grew.

"Performance on most indicators of quality was relatively poor overall," the authors wrote. "Our observed rates were consistent with those reported in other studies, suggesting that substantial improvements in quality remain possible."

Protein Test Could Detect Bladder Cancer Earlier

Researchers have found that testing for the nuclear mitotic apparatus protein (NMP22)—which is released into the urine during cell death and often elevated in the presence of malignancy—could become an important tool for diagnosing patients who are being screened for bladder cancer.

In a study published in the February 16 *Journal of the American Medical Association*, a team led by Dr. H. Barton Grossman from the University of Texas M.D. Anderson Cancer Center found that the NMP22 protein marker successfully detected tumors 3.5 times more effectively than did standard cytology tests.

The study enrolled 1,331 patients with bladder cancer risk factors or symptoms at 22 sites. Overall, 79 cases of bladder cancer were detected in the study group. Participants were screened for indications of bladder cancer using either the new NMP22 protein test or the current standard

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(Research Highlights continued from page 4)
cytology analysis. The cytology diagnostic tool has very high specificity but is "offset by low sensitivity, ambiguous test results, expense, and time lag to obtain reports," said the authors.

If further studies confirm the findings of the NMP22 assay, it could help diagnose bladder cancer earlier, before the disease has spread, the researchers concluded. NMP22 testing could become an important complement to cystoscopic imaging for detecting bladder cancer. Results of the noninvasive test are available during the same patient visit as the screening.

The NMP22 protein was detected by a device that is intended to be used at point-of-care in physicians' offices and clinics. The NMP22® BladderChek® Test device is made by Matritech, Inc., of Newton, Mass., which provided funding for the study.

Researchers Develop Nanoprobes to Visualize Tumors Inside the Body

Scientists at the University of Pennsylvania and the University of Minnesota have designed organic nanoprobes that enable them to use infrared light to visualize tumors deep below the skin surface of rats. Their findings, which demonstrate a novel optical imaging approach through "soft matter," appear in the February 22 edition of *Proceedings of the National Academy of Sciences*.

The probes were created using synthetic polymers that aggregate into spherical vesicles, or polymersomes, in the presence of water. The researchers then interspersed fluorescent molecules called porphyrins throughout the vesicle surface, creating tiny organic spheres that "light up" when struck by infrared light. Because infrared light has a longer wavelength than visible light, the researchers could see deeper into tissue.

They injected the vesicles into a glioma tumor 1 centimeter below the skin in a rat and saw a highly localized fluorescence. The polymersomes also proved to be stable; when placed in blood plasma heated to human body temperature, the vesicles maintained a constant fluorescence for a week.

The researchers believe polymersome vesicles may be well-suited for deep-tissue imaging. They can be made biodegradable, posing little risk of build-up in the bloodstream. Therapeutic agents can be dissolved in the aqueous center, allowing for drug delivery to the tumors while they are imaged. "Another feature that makes polymersomes useful is that they self-assemble," added author Daniel Hammer. "Simply mixing together all the component parts gives rise to these functional cell-like vesicles." ◆

Symposium on Cancer Screening and Mortality at AAAS

At the American Academy for the Advancement of Science (AAAS) annual meeting, held in Washington, D.C. February 17-21, a panel of experts from cancer research institutions around the country discussed the successes and shortcomings of cancer screening. Dr. Barnett Kramer, who heads NIH's Office of Disease Prevention and is editor-in-chief of the *Journal of the National Cancer Institute*, began the session on February 20 by pointing out that cancer screening often involves a "clash between science and intuition." Explaining the different ways that screening studies can incur bias and mislead people to believe that the results are significant when in fact they may not be, he presented data showing that screening has not reduced mortality in some cancers. "Unless we have a net benefit" in screening cancer patients, he said, "we could be in the position of incurring higher cost with net harm."

Dr. Diane Solomon of NCI's Division of Cancer Prevention talked about cervical cancer screening, observing that it "is the poster child of what cancer screening can achieve." She discussed HPV infection, its incidence among younger and older women, and how this has influenced screening recommendations demographically. "Cervical cancer screening is a misnomer," she said. "We're not detecting cancers—when it's too late—we're detecting precancers."

Other speakers that morning included Dr. Ian Thompson of the University of Texas Health Science Center, Dr. Sandra Lee of the Dana-Farber Cancer Institute, Dr. Timothy Rebbeck of the University of Pennsylvania School of Medicine, and Beth Peshkin of Georgetown University. Abstracts of their talks can be accessed at: http://php.aaas.org/meetings/MPE_01.php. ◆

Funding Opportunities

The following is a newly released NCI research funding opportunity:

Specialized Programs of Research Excellence (SPOREs) in Human Cancer for Year 2005-2006

PAR-05-042
Letter of Intent Receipt Dates:
Lung and genitourinary (bladder, kidney, testicular, not prostate) cancer SPORE: Mar. 23, 2005; Skin and prostate cancer SPORE: July 23, 2005
Application Receipt Dates:
Lung and genitourinary (bladder, kidney, testicular, not prostate) cancer SPORE: May 23, 2005; Skin and prostate cancer SPORE: Sept. 23, 2005

This is a reissue of PAR-03-158, which was previously released Aug. 4, 2003. The Organ Systems Branch of the Office of Centers, Training, and Resources, NCI Office of the Director, invites grant applications for Specialized Programs of Research Excellence (SPOREs) in organ-specific cancers. A SPORE is supported through the specialized center (P50) grant mechanism.

For more information see http://cri.nci.nih.gov/4abst.cfm?initiativeparfa_id=2580. Inquiries: Dr. Jane Fountain—jf227t@nih.gov; Dr. Peter Ujhazy—pu5s@nih.gov; Dr. Andrew Hruszkewycz—ah5x@nih.gov

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

***The NIH Roadmap for Medical Research Funding** 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 additional Roadmap funding opportunities, go to http://nihroadmap.nih.gov.* ◆

Featured Clinical Trial

Improving Allogeneic Stem Cell Transplantation

Name of the Trial
Phase I Pilot Study of T-Cell-Depleted Allogeneic Stem Cell Transplantation after Immunoablative Induction Chemotherapy and Reduced-Intensity Transplantation Conditioning in Patients with Hematologic Malignancies (NCI-04-C-0116). See the protocol summary at http://cancer.gov/clinicaltrials/NCI-04-C-0116.

Principal Investigator
Dr. Michael R. Bishop, with Dr. Robert Dean (protocol chair), NCI Center for Cancer Research (CCR)

Dr. Michael Bishop
Principal Investigator

Why Is This Trial Important?
Some patients with hematologic malignancies (blood or bone-marrow cancers) can be cured with allogeneic stem cell transplantation (ASCT). After preparative chemotherapy, doctors introduce donor stem cells into the patient's bloodstream, where they migrate to bone marrow and help restore the immune system. White blood cells are critical immune-system components. Cytotoxic T cells can kill cells they recognize as foreign, including cancer cells. When this process occurs after ASCT, doctors call it the graft-versus-malignancy effect.

Stem cell donors are usually genetically similar (matched) siblings or unrelated volunteers, but over half of patients lack a matched donor. To address this problem, researchers have studied the use of partially matched (haploidentical) donors. However, ASCT from haploidentical donors often causes serious complications, including graft-versus-host-disease (GVHD), which occurs when donor T cells attack normal tissues.

In this study, researchers are testing whether a modified transplantation regimen may reduce complications while preserving the benefits of haploidentical ASCT. The researchers will use reduced doses of transplant chemotherapy to decrease the risk of serious side effects. Then they will transplant stem cells purged of T cells to lessen GVHD risk. If transplantation is successful, the researchers can give patients donor T cells to enhance the graft-versus-malignancy effect.

Who Can Join This Trial?
The researchers will recruit 6-10 patients aged 18 to 55 diagnosed with hematologic malignancies or related conditions. See the complete list of eligibility criteria at http://cancer.gov/clinicaltrials/NCI-04-C-0116.

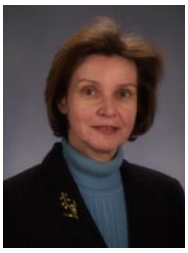
Where Is This Trial Taking Place?
The trial is taking place at the NIH Clinical Center in Bethesda, Md.

Contact Information
For more information, contact the NCI Clinical Studies Support Center toll free at 1-888-NCI-1937. The call is confidential. ◆

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

Notes

Gerhard Named OCG Director



Dr. Daniela S. Gerhard has been named director of NCI's Office of Cancer Genomics (OCG). She joined NCI in 2002 and has served as acting director of OCG since mid-2003.

Dr. Gerhard has spearheaded a number of OCG initiatives, including the Cancer Genome Anatomy Project, the human transcriptome program, and a pilot program to evaluate the technologies and process for an expanded human cancer genome project.

Dr. Gerhard received her undergraduate degree from Barnard College, earned her doctorate in genetics and molecular biology from Cornell University Graduate School of Medical Sciences, and performed postdoctoral work in human and cancer genetics at Massachusetts Institute of Technology. Prior to joining NCI, she was on the faculty of Washington University School of Medicine in St. Louis in the department of genetics.

Third Annual Cancer Survivorship Telephone Workshop Series

The third annual Telephone Education Workshop Series: *Cancer Survivorship: Living With, Through & Beyond Cancer* can assist cancer survivors and their loved ones by providing practical information to help them deal with concerns and issues that arise after treatment ends. The workshop series is designed primarily for cancer survivors who have recently completed their cancer treatment, though it also may be helpful for other cancer survivors and health care professionals.

The program is a collaborative effort between NCI, Cancer*Care*, the Lance Armstrong Foundation, the Intercultural Cancer Council, Living Beyond Breast Cancer, and the National Coalition for Cancer Survivorship.

The workshops are free; no telephone charges apply. To register, visit the Cancer*Care* Web site at: http://www.cancercare.org/Feedback/Feedback.cfm?r=21&ii=1&ip=0%20. All workshops will take place via telephone Tuesdays from 1:00 p.m. to 2:00 p.m. ET on the following dates:

Part I: *Care & Wellbeing After Treatment*, April 12, 2005

Part II: *Managing Long-term Lingering Side Effects*, May 24, 2005

Part III: *Health Promoting Behaviors: Things You Can Do*, June 14, 2005

NCAB Quarterly Meeting Held

On February 15-17, the National Cancer Advisory Board (NCAB) held its 133rd quarterly meeting in Bethesda, Md. One of the highlights of the meeting was the presentation of a report by a recently established working group on biomedical technology headed by Drs. Lee Hartwell and Eric Lander. The working group focused its report on four specific areas, including a recommendation that NCI and the National Human Genome Research Institute (NHGRI) collaborate on a project to identify the range of genomic alterations that underlie all major cancers. The recommendation was endorsed by NCI Director Dr. Andrew C. von Eschenbach and by NHGRI Director Dr. Francis S. Collins. NCI and NHGRI held a joint workshop to explore the parameters of this project in April 2004. The NCAB Subcommittee also recommended that NCI create a standing working group on cancer technology, expand research in cancer molecular diagnostics (especially in the areas of cancer imaging and biomarker discovery), and restructure clinical trials to accelerate the translation of advances in targeted therapies and diagnostics efficiently into standard treatments.

NCAB also heard from Dr. Anna Barker, NCI deputy director for strategic scientific initiatives, and Dr. Arthur Caplan, chair of the department of medical ethics at the University of Pennsylvania, on ethical issues and concerns surrounding biospecimens and biorepositories for post-genomics research. Dr. Caplan detailed several important areas that must be considered in sample collection, access, privacy, and confidentiality to secure public trust and ensure the future sharing of resources across the cancer research community. Although several issues were discussed, the development of consensus on approaches to consent, data anonymization, and access were considered key to future planning for biospecimens and biorepositories. ◆

CCR Grand Rounds

March 1: Dr. Jeffrey S. Rubin, Senior Investigator, Laboratory of Cellular and Molecular Biology, CCR; "Keratinocyte Growth Factor: From Basic Research to Clinical Application"

March 8: Dr. Peter M. Blumberg, Chief, Molecular Mechanisms of Tumor Promotion Section, Laboratory of Cellular Carcinogenesis and Tumor Promotion, CCR; "From Roadside to Bedside: Natural Products Providing a Path to Therapeutic Targets"

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. ◆

Community Update

Cancer Research and Regulatory Fellowships Announced

NCI and FDA have announced the inception of the NCI-FDA Research and Regulatory Review Fellowship program. The program's objective is to train a cadre of scientists in cancer research and research-related regulatory review so that they can develop skills that bridge the two disciplines and cultures.

The program is one of the initiatives of the NCI-FDA Interagency Oncology Task Force (IOTF), created in 2003. IOTF's purpose is to efficiently move safe new oncology medical products from the laboratory to the clinic.

NCI-FDA fellows will learn to build awareness of regulatory requirements into the early stages of medical product development and will devise strategies to improve planning throughout the research and regulatory review phases. They will also learn how to use state-of-the art knowledge and technology in the design, conduct, and review of clinical trials.

"NCI and FDA share the common goal of bringing safe and effective products to cancer patients quickly and carefully," said NCI Director Dr. Andrew C. von Eschenbach. "This type of partnership between science and regulation is vital, especially given the rapidly advancing scientific environment."

Acting FDA Commissioner Dr. Lester M. Crawford added, "This cross-fertilization with NCI will be invaluable in helping FDA prepare for the next wave of promising cancer-fighting agents."

Dr. Jonathan Wiest, associate director for training and education in NCI's CCR, commenting on the importance of the new fellowship programs, said, "We believe that physicians and scientists who are trained in the regulatory process and also understand the inner workings of NCI and FDA will be able to facilitate and improve the development and approval process for drugs—especially for chemotherapy."

The NCI-FDA fellowships offer a unique career opportunity for participating researchers to become well-positioned to facilitate the new age of molecular medicine. New targeted therapies and diagnostic products will demand new skills and processes that must be incorporated into the research and regulatory system.

Program graduates will develop skills of value to academia, the pharmaceutical industry, and government agencies, noted Dr. Wiest. Through their training experiences, he continued, "the fellows will gain the knowledge and skills to fill a void in the cancer research enterprise and hasten the delivery of medical products to patients using 21st century science."

NCI-FDA fellowship programs are available in:

- Clinical Oncology Product Research/Review
- Clinical Oncology Product Research/Review for Board-Certified Oncologists
- Oncology Product Research/Review
- Cancer Prevention

The fellowships last for 1 to 4 years, based on the training program. Fellows will work closely with mentors representing senior-level medical and scientific staff at NCI and FDA.

Fellowship candidates must have an M.D. and/or Ph.D., or an equivalent degree. They must also be either a U.S. citizen or have permanent residency status.

Additional information about the program, including application deadlines, can be found at http://iotftraining.nci.nih.gov. ◆

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.